

Mandatory Vaccination Against COVID-19 in Europe: Public Health Versus ‘Saved by the Bell’ Individual Autonomy



Elena Ignovska 

Abstract The text aims to reconcile the bioethical principles (autonomy, beneficence, non-maleficence and justice) (Beauchamp TL, Childress JF in Principles of biomedical ethics, 6th edn. Oxford University Press, 2009) with the principles used by legal institutions (primarily, the European Court of Human Rights) to evaluate possible human rights infringements due to mandatory vaccination against Covid-19 (legality, necessity, proportionality and legitimate aim) (This is the so-called ‘structural approach’ that the ECtHR follows when considering interferences of the qualified right and is also stipulated in article 26 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo Convention).) by National Public Health policies of the Member States of the Council of Europe. (Even more, the idea is to bring closer the methodology of teaching/learning and researching via the HELP platform of the Council of Europe in the course on Bioethics to the law students.) The trigger is to test these principles using deductive reasoning in the pioneering Austrian case of mandatory vaccination, while inductive methodology is used to evaluate how recent similar cases (such as Vavříčka and Others v. Czech Republic) contributed to support the theory that next to human rights, there are also duties. Since circumstances with the pandemic are rather turbulent and constantly changing (even as this article is being written), the time factor significantly influences the conclusions drawn. Namely, the author holds the opinion that with a carefully chosen methodology and model, any severe disease that significantly threatens the individual and public health at particular time, period or might constantly be a reason to restrict individual autonomy with scientifically proven, safe and efficient vaccines. Nevertheless, regarding Covid-19, at the current time, even if the means of coercion do not include applying direct physical force (As in the case of Vavříčka or in the pioneering but suspended legislation for mandatory vaccination in Austria.), they are not proportionate to the possible infringement on

E. Ignovska (✉)

Department of Civil Law, Faculty of Law, University Ss. Cyril and Methodius, Skopje, Republic of North Macedonia

e-mail: e.ignovska@pf.ukim.edu.mk

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one's private life and individual consent for the sake of public health, or at least not anymore.

Keywords Mandatory vaccination · Covid-19 · Informed consent · Public health · Bioethics · Law

1 Introduction

The Covid-19 pandemic management emphasized the necessity for an international and interdisciplinary approach among a few disciplines such as, but not limited to, medicine, epidemiology, virology, bioethics and biolaw in order to create adequate public health policies. An isolated observation of such a complicated (yet not fully known)¹ and broad-scale (global) phenomenon fails to be satisfactory. The first mass vaccination program started in early December 2020 and since then different brands of vaccines such as prevention from infection have been available.² Societies worldwide initially faced dilemmas regarding: (1) the fast-track vaccine development in a public health emergency³ and (2) equality and equity in their distribution,⁴ whilst later on there was a shift towards: (3) their mandatory or voluntary application (related to the concept of informed consent) and (4) restrictions on human rights for the non-vaccinated (for instance, the right to free movement⁵ and the right to private life) or possible discrimination.⁶ The reasons why a person intentionally avoids vaccination differ (mostly related to trust towards the institutions or the health system that approves and applies them⁷ or fraudulent research findings).⁸ Regardless of the reasons, the mere fact that there is vaccine hesitancy and skepticism over immunization via vaccination is enough for the purposes of this text.

¹ For instance, we lacked for a long time the necessary medical and epidemiological expertise to assess whether vaccines as a mandatory public health measure are necessary and proportionate to the aim—protecting public health and the rights of others. Namely, developing herd immunity could count as a legitimate aim but we still do not fully know if the mandatory vaccination is the only or the best (there are no others/better alternatives) way to achieve that goal. Even more, with corona viruses, it is probable that vaccination cannot achieve herd immunity at all times, having in mind that we constantly need buster doses. Furthermore, we still do not fully know if vaccines are efficient for the newly detected variants.

² WHO (2022).

³ In Europe monitored by European Medicines Agency (EMA).

⁴ Committee on Bioethics (DH-BIO), Council of Europe (22 Jan. 2021).

⁵ Derived from art. 45 of the European Charter of Fundamental Rights as a right of EU citizens and legally resident third-country nationals to move and freely reside within the territory of the EU Member States.

⁶ Committee on Bioethics (DH-BIO), Council of Europe (4 May 2021).

⁷ Larson et al. (2018), p. 6.

⁸ Wakefield et al. (1998).

Austria was the first country in Europe that tried to make Covid-19 vaccines mandatory for all adults with the law in force since February 3, 2022 (soon after suspended). Other countries were considering similar possibilities (for instance, Greece, France, Germany, Italy, Hungary, the United Kingdom, Poland, Slovakia, Luxembourg etc.),⁹ while already having restrictions for the non-vaccinated on different grounds: (1) age (usually over 50 or 60), (2) profession (doctors, nurses, teachers etc.), (3) participation in public activities, entrance to particular restaurants, institutions etc.¹⁰

Inevitably, questions arise regarding the ethical and legal aspects of mandatory immunization.

2 How Both Bioethics and Biolaw Are Engaged in the Discussion over Mandatory Vaccination

The term bioethics was first introduced by Van Rensselaer Potter in 1970 who launched the beginning of a new scientific field critical towards life and new scientific challenges. Next to Potter, a very important contribution is held by Andre Hellegers. Even though they come from different professional background (biologist and physician), they managed to unite and standardize a new emerging discipline—bioethics.¹¹ In the very beginning of such conception, the American contribution is also indisputable, especially after the Conference on the birth of Bioethics organized by Albert R. Jonsen at the University of Washington in 1992.¹² According to him, the genesis of bioethics is deeply rooted in the American ethos and its three main characteristics: moralism—affinity to moralize human actions, meliorism—belief that the human condition could and should be improved and individualism as a reflection of the human's free will. Despite some controversies regarding the issue as to who holds the innovation rights of the new discipline—bioethics, Diego Gracia stands at the opinion that bioethics is a global phenomenon with global importance and implications that are more our future than our past. For him, one of the main reasons for the development of the new science is the emancipation of the human person in light of making decisions on his own about his own body (including the controversial decisions about his own life and death) by substituting the traditional principle of imposed preferred decisions with the principle of autonomy.¹³

⁹ Chadwick (2022). Also see: Reich (2021).

¹⁰ The ECtHR already rejected three applications for interim measures during the pandemics against Greece and France, as well as against other countries where not all national remedies have been exhausted. In addition to it, other applications are ongoing in front of the courts of the member states of the European Union and of the Council of Europe. See more in Janis (2021).

¹¹ See more in Potter (1970, 1971).

¹² Jonsen (1997).

¹³ Gracia (1989).

Theoretically, there are two opposed standpoints regarding the role that the law may have in bioethical issues. According to the first, the role of the law should be minimalistic so that a private, individual approach and choice of the patient is allowed. The reason for such a diminutive attitude towards the law could be traced in the concepts of individual autonomy and social regulation but also in the internal ethical codex of medicine.¹⁴ According to the second, the role of the law is crucial because it has to regulate it all and not leave it up to individual discretion to differentiate what is right and what is wrong. The third, neutral approach stands for weak law—a law that imposes only some basic rights and obligations. Here, individuals are free to make their choices in between these basics but only in informed, predictable, unified and equally available ways.

Chronologically, the first and still the main source of regulating the intersection between Human rights and Bioethics is the European Convention on Human Rights (ECHR)—1950. The Convention itself does not mention Bioethics directly (since Bioethics as a scientific field emerged later on), but many articles such as art. 2 (right to life), art. 3 (prohibition of inhumane and degrading treatment) and art. 8 (right to private and family life) refer to it and are used by the European Court of Human Rights (ECtHR) when dealing with such issues in particular cases. The Court actually has to be very prudent and patient when deciding in such ethically sensitive issues, especially those related to the beginning of life, end of life and many bio-processes in between, due to the margin of appreciation mechanism, that in such cases is still considered to be flexible allowing national states (Member States of the Council of Europe) to decide themselves about issues they consider important for their public interest, therefore under their own national supremacy.^{15,16}

Second, yet a very important source of legal reasoning for the ECtHR in the intersection of bioethics and law is the Convention for the Protection of Human Rights and Dignity of the Human Being with regards to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (so called Oviedo

¹⁴ Nielsen (1998) and Garrison and Schneider (2002).

¹⁵ For more on how the mechanism operates see in Schokkenbroek (1998).

¹⁶ For instance, the application of art. 2 is controversial in cases regarding the beginning and the end of human life. In cases that deal with the beginning of the human life, the destiny of human embryos is still contested. The ECtHR has decided in many cases that regard the life of in vitro embryos (for instance, the cases *Evans v. the UK*, *Droon v. France*, *Maurice v. France* or *Costa and Pavan v. Italy*), or in vivo embryos that touch upon abortion (one of the most important to be *Vo v. France*) in which, in general, concluded that life of embryos is not covered by the protection offered in art. 2 (even though there were many dissenting opinions). In the cases that deal with the end of life, the Court has also been challenged to decide (for instance, in the case of *Pretty v. the UK*, concluding that the right to live does not include the right to die). In both cases (beginning and end of life), the general conclusion still is that these topics do not enjoy European consensus, therefore national states should enjoy more flexibility and supremacy to decide on their own. When it comes to the application of art. 8 (private and family life), in circumstances where surrogate arrangements are not a European consensus (in most European countries are forbidden due to prevention of women's bodies exploitation), the case of *Paradiso and Campanelli v. Italy* (reproductive tourism from a country that bans surrogacies to a country that allows them) followed a wide margin of appreciation towards the national authorities allowing them supremacy in regulating such ethically sensitive practices under the excuse—protection of public interest.

Convention).¹⁷ The Preamble of the Convention states its devotion to take measures that are necessary to safeguard human dignity and fundamental rights and freedoms of the individual with regard to the application of biology and medicine, legally regulated in advance and with consent of the concerned. The aim of the Convention is to protect human dignity, rights and freedoms through informed consent, protection of private life and ban on discrimination. In general, the Convention gives priority to individual over collective interests as a prevention of eventual experiments for the sake of certain group interests or ideologies, especially ones practiced in the past, with the goal being that they are never repeated again. The approach of the Convention is structural (art. 26)—the rights and freedoms could be restricted only under certain circumstances: (1) the restrictions are stipulated in the law (principle of legality), (2) the restriction is necessary in a democratic society (principle of proportionality), and the restriction is in public interest (protection of public health, rights and freedoms of others etc.) i.e. legitimate aim. This is in line with the legal methodology used by the ECtHR itself.¹⁸

The last, but not least important, European international document in the intersection of human rights and bioethics is the Charter of Fundamental Rights of the European Union (Charter). This Charter is in line with the ECHR and the Oviedo Convention and acknowledges the Member States of the European Union regarding their implementation of the EU law. The first three articles of the Charter represent the supreme values to be protected: human dignity (art. 1), right to life (art. 2) and the right to integrity of the person (art. 3) including both physical and mental.

Despite the fact that all the rights that stream from the above mentioned international documents are binding (for the countries that ratified them), it remains that the intersection between human rights and bioethics is an evolving concept that is founded in principles. They are not only rooted in the formal documents but are also directions for the interpretation of rights in a particular context facilitating the role of institutions entitled to interpret them. The origin of the principles could be located in the Belmont Report and the activities of the American Commission for the Protection of Human Subjects of Biomedicine and Behavioral Research in between 1974 and 1978.¹⁹ Beauchamp and Childress are the authors of the Principles of Biomedical Ethics, which are still considered to be the alphabet of Bioethics. These principles are: (1) Principle of autonomy, (2) Principle of beneficence and its antipode, (3) Principle of non-maleficence and (4) Justice.²⁰ The first principle refers to the obligation of the institutions to enable free and informed consent for each therapy/intervention, as well as the possibility to withdraw it, right to gain information regarding one's own health condition, but also the antipode of that right—not receiving the information. The second and the third principle refer to the moral obligation to maximize potential wellbeing while minimizing potential harm or risk (as much as possible), and the last principle refers to the need for legal order and justice, certainty, equality,

¹⁷ Council of Europe, European Treaty Series, No. 164. 1997.

¹⁸ In line with footnote 2.

¹⁹ The Belmont Report (18.4.1979).

²⁰ *Op.cit.* Beauchamp and Childress (2009).

equity and nondiscrimination when it comes to health protection of human beings in general. Even though these principles should be guiding human actions in particular circumstances, when it comes to mandatory vaccination they are being interpreted differently: *contra*—presuming beneficence of individuals as a private choice each can make for themselves,²¹ and *pro*—presuming beneficence not to an isolated individual, but to the wider public.²² Therefore, the Covid-19 vaccines pose a serious paradox during times of crises: beneficence of individuals as part of the collective or of the collective in general and non-maleficence of individuals as part of the collective or of the collective in general? Even though beneficence and non-maleficence of individuals are meant to be uplifted by vaccination, they are simply not perceived like that by individuals who, for various reasons are opposed, yet remain steadfast in their quest—individual autonomy over their own body to be guaranteed.

3 Personal Autonomy (Informed Consent) as an Individual Right

Personal autonomy and the concept of free and informed consent followed the well-established and rooted practice of patriarchy in the relationship between the patient and the physician that was unquestionable until the second half of the twentieth century. The foundations could be found in the North-American jurisprudence, while the concept found relevance after the condemnation of the cruel research practices on humans conducted by the Nazi in the Nuremberg Code.²³ The dignity and the integrity of the human being associated with it are protected in many international documents (such as the Universal Declaration on Human Rights, International Covenant on Civil and Political Rights, International Covenant on Economic, Social and Cultural Rights etc.). In Europe (Member States of the Council of Europe), the ECHR covers the physical and mental integrity as part of the private life in art. 8, while in severe cases (in the domain of inhuman and degrading treatment) it is covered by art. 3. The Oviedo Convention covers it in more details in articles 5, 6, 8, 9, 16, 17, 20, while the Charter in its art. 3. Under the Oviedo Convention (art. 5) and the EU law, the modalities

²¹ Cheng (2022). This author holds the opinion that an individual protects oneself before protecting the community; and taking care of oneself during this pandemic is beneficial to society. In contrast, a compulsory shot ignores the fears of vaccines hesitant people and unreasonably pushes them to sacrifice their personal safety along physical and psychological dimensions that is tantamount to collective bullying, while forcing them in name of civic responsibility is moral bullying.

²² Here, a state justifies compulsory vaccination, as a way to prevent further harm to its population (duty of non-maleficence), by removing, treating, or curing the particular contagion before it (duty of beneficence). See more in Beazley (2020).

²³ Some parts from this section (3) and the following (4) are elaborated also in the text Ignovska E. Human Rights and Bioethics during the Covid-19 Pandemic, The International Legal Match Djokovic v. Australia, 2022 when explaining concepts since they were written simultaneously but for different purpose, in different context and with different conclusions. The relation with this text is also mentioned in a note in the above-mentioned text.

of informed consent (presumed—meaning that consent is implied if there is no objection, or explicit—explicitly stated) are left upon the decision on national states, while the concept is included in several Directives and Regulations (such as Reg. No. 536/2014 on Clinical Trials). Nowadays, the concept of free and informed consent is a leading principle in Bioethics (principle of autonomy) overtaken by national laws governing the intersection between bioethics and medicine. The concept presupposes the process of enabling a person to make individual choices based on information, understanding and clearly expressed wish on the choice, barring in mind all the other alternatives as well as the future prospects. Therefore, key elements of the concept are: (1) Information,²⁴ (2) Freedom of consent (voluntary in nature, lack of pressure or undue influence) and (3) Ability to make decisions.²⁵ The presumption of personal autonomy is not, however, absolute. In fact, it is the most often overridden like, for example, when urgent medical care is needed for a patient unable to provide the consent,²⁶ or in cases when the consent is presumed unless explicitly stated the opposite.²⁷

However, there are restrictions and limitations to its application as envisaged in art. 8(2) of the ECHR and art. 26 of the Oviedo Convention and they both include (1) Situations that are prescribed in the law so that persons are aware and can guide their actions (principle of legal certainty) and (2) Situations that are necessary in a democratic society (principle of legitimate aim). Such situations may be provoked by a pressing social need—public safety, prevention of crime, protection of public health or rights and freedoms of others. In such situations, the interference by the state towards the claimed right of an individual should be proportionate to the legitimate aim i.e. if a fair balance has been struck between the legitimate aim pursued and the requirements for protection of individual rights.

Elucidating informed consent and vaccination is the case *Solomakhin v. Ukraine*²⁸ where the ECtHR (par. 36) stated: ‘In the Court’s opinion the interference with the applicant’s physical integrity could be said to be justified by the public health considerations and necessity to control the spreading of infectious diseases in the region. Furthermore, according to the domestic court’s findings, the medical staff

²⁴ In the case of information regarding vaccines, one of the problems that appears is that there is an overload of information coming from different sources. The Governments that want to increase the level of vaccinated should inform their population accordingly. Nevertheless, people read different sources, experts’ opinions, even fake news on different media and form their opinion based on the different sources of information they consulted.

²⁵ Council of Europe HELP Course: Key Human Rights Principles in Biomedicine - Bioethics, Module 2.

²⁶ *Op. cit.* Beazley (2020).

²⁷ This is the case for instance, in the Republic of North Macedonia for transplantation from deceased donors. The previous concept of informed consent was replaced by the concept of presumed consent (unless the person did not object explicitly and officially—with a written statement authorized by notary public during life: Закон за земање и пресадување на делови од човечкото тело заради лекување (2011, 2013) Such a flip in concepts was decided on referendum in Switzerland in May, 2022 for purposes of shifting the organ donation in the country. See more in *The Guardian* (2022).

²⁸ *Solomakhin v. Ukraine* (2012).

had checked his suitability for vaccination prior to carrying out the vaccination, which suggests that necessary precautions had been taken to ensure that the medical intervention would not be to the applicant's detriment to the extent that would upset the balance of interests between the applicant's personal integrity and the public interest of protection health of the population.'

Another similar case regarding restrictions to informed consent (this time due to mandatory X-rays to children from prevention of tuberculosis in Belgium) is the case of *Acmanne v. Belgium*²⁹ where the ECHR (the Commission) stated that there was no violation of art. 8 as it does not include an unlimited right to do with one's body as one pleases.

The Oviedo convention has specific rules to protect persons not able to consent. The general rule is that an intervention may be carried out only if it is in their direct benefit (art. 6(1)). When it comes to minors, an authorization by a legal representative/custodian is required or one of an individual assigned by law. In any case, an opinion of the minor should be taken into account depending of the level of maturity and possibility to understand the consequences. In some countries, it is explicitly regulated that a consent from the minor could be given if the minor is over 14 (Latvia), 15 (Slovenia), 16 (Spain), 15 (Denmark), 16 (UK).³⁰ When it comes to persons not able to consent authorization has to be given by the person's representative or an authority provided by law. An exception of this rule is possible in two cases: concerning medical research (art. 17) and removal of regenerative tissue (art. 20).

4 Public Health as a Collective Right

Public health is defined as "the science and art of preventing disease, prolonging life and promoting health through the organized efforts and informed choices of society, organizations, public and private, communities and individuals".³¹ The term public health includes 'public' in terms of a small or larger number of people that could spread (a disease) on a smaller or larger territory (this for instance, makes difference between epidemics and pandemics), and 'health' which is already defined very wide by the WHO including physical, psychological and social well-being.³²

²⁹ *Acmanne and Others v. Belgium* (1984).

³⁰ *Op. cit.* Council of Europe HELP Course: Key Human Rights Principles in Biomedicine - Bioethics, Module 2.

³¹ Gatseva and Argirova (2011), pp. 205–206.

³² The WHO Constitution (1946) envisages ... 'the highest attainable standard of health as a fundamental right of every human being'.

Public health may be invoked as a ground for limiting certain rights ‘in order to allow a state to take measures dealing with a serious threat to the health of the population or individual members of the population’.³³ The Siracusa Principles require that any measures taken which limit individual human rights be (1) provided for and carried out in accordance with law; (2) directed toward a legitimate objective of general interest; (3) strictly necessary in a democratic society to achieve the objective; (4) least intrusive and restrictive to achieve the objective; (5) be based on scientific evidence³⁴; (6) neither arbitrary nor discriminatory in application and of limited duration; (7) respectful of human dignity; and 8. subject to review. Nevertheless, these principles are part of a soft law mechanism, non-binding suggestions on how to solve conflicts between individual and collective rights and are dependent on the willingness of national states to uphold and exercise them.³⁵

The ECHR also has a specific provision authorizing to derogate unilaterally to conventional rights. Article 15, entitled ‘derogation in time of emergency’, permits states ‘in time of war or other public emergency threatening the life of the Nation [...] to take measures derogating from its obligations...’. In application of art. 15(3) of the ECHR, many countries such as, Latvia, Romania, Armenia, Estonia, Moldova, Georgia, Albania, North Macedonia, Serbia, and San Marino invoked this provision to face the ongoing pandemics.³⁶ According to Emilie Hafner-Burton et al. derogations are ‘suspensions of certain civil and political liberties – in response to crises’. They defined them as ‘a rational response to [the] uncertainty, enabling governments to buy time and legal breathing space from voters, courts, and interest groups to combat crises by temporarily restricting civil and political liberties’.³⁷

The central dilemma in public health law and ethics is that any legal intervention to safeguard population health will inevitably initiate a conflict between collective interests and individual rights to bodily integrity, privacy, freedom of association, freedom of movement, freedom of conscience, and other core liberties. Authors who approve mandatory vaccination use utilitarian arguments, mostly relying on collective herd immunity.³⁸ Contrary to them stand authors who consider that mandatory vaccination underestimates human autonomy, dignity, and individuality in the name of a presumed ‘greater good’, ‘communal need’, or ‘national interest’.³⁹ As a result, ethical and legal tensions between the individual and the collective good (or their definitions and scopes in particular circumstances) still do exist.

³³ Siracusa Principles on the Limitation and Derogation of Provisions in the International Covenant on Civil and Political Rights. American Association for the International Commission of Jurists (1985), par. 25.

³⁴ Apart of the fact that this measure provides further specification, proves to be tricky in light of the Covid-19 pandemics since scientific evidence varied over time, i.e. from the time the abstract for this text was sent until the time of writing it, the new variants of the virus showed that vaccines are becoming less effective or ineffective.

³⁵ *Op. cit.* Beazley (2020), pp. 6 and 7.

³⁶ *Ibid.*, p. 3.

³⁷ Hafner-Burton et al. (2011).

³⁸ Zaid et al. (2022) and Lefri (2021), pp. 30 and 31.

³⁹ Thomson and Ip (2020), p. 3.

5 Council of Europe—Statements During the Covid-19 Pandemics

At the forefront of the pandemic was the Council of Europe's Committee on Bioethics which highlighted some of the human rights principles laid down in the Oviedo Convention via its Statements on: Human Rights Considerations relevant to the Covid-19 Pandemics,⁴⁰ Vaccines⁴¹ and Vaccines Passes and Similar Documents.⁴²

The most relevant rights that are noted are: the right to life and the right to protection of health, the right of equitable access to health care, even in context of scarce resources, protection against discrimination, the right of privacy and data protection in respect of democracy, rule of law and respect for human rights.⁴³ However, these rights can be restricted as an exception for purposes of protection of public interest, including public health if interpreted in the light of the criteria established by the ECtHR (especially, necessity and proportionality) These principles are in line and moreover, complement the Oviedo Convention in order to stress the link between human rights, solidarity and responsibility urging for a greater unity between Member States. Therefore, an international cooperation for safeguarding rights and responsibilities of all members of society is encouraged. We live in a globalized world and this pandemic made it even more obvious, yet, as discussed above, the way societies dealt with the pandemic was mostly left upon their own assessments of good v. bad, right v. wrong, individual rights v. collective rights, i.e. their national supremacy.

Regarding vaccines, the Statement on Vaccines suggested that the application of the rights and principles should ensure that everyone, without discrimination, is offered a fair opportunity to receive a safe and effective vaccine. Vaccination is meant to be encouraged in a transparent, informed and communicated way in order to reach everyone, including those who may have low literacy levels or special communication needs. Vaccination outcomes are meant to be monitored for the purposes of reporting adverse effects, which was an obligation of the national competent authorities. Nevertheless, the Statement asks for insurance that persons who either temporarily or permanently could not be vaccinated, be otherwise protected.

The Statement does not discriminate between persons with different 'immune status' if a range of other options remain available. That would mean that for those who for either medical or other reasons cannot be vaccinated, there have to be other alternatives that allow them to enjoy their human rights.

The focus of all these documents is on different issues depending on the actual pressing need at the specific moment in the timeline of the Covid-19 pandemic. If anything, the pandemic showed that timing for particular measures is very important in the way societies deal with such events. For instance, the quarantine that was

⁴⁰ Committee on Bioethics (DH-BIO) (14 April, 2020).

⁴¹ Committee on Bioethics (DH-BIO) (22 January, 2021).

⁴² Committee on Bioethics (DH-BIO) (4 May, 2021).

⁴³ Committee on Convention 1081 and the Data Protection 1 Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (CETS No. 108) 3 Commissioner of the Council of Europe.

present almost in every society in 2020 became totally unnecessary (even unjustified) in 2022. In contrast, most public health policies allowed the spread of the virus in spontaneous ways to achieve collective immunity. Moreover, mandatory vaccination became less important topic, while other ways of personal protection remained in place (depending on individual choices) such as: voluntary vaccination (including booster doses), wearing masks, proper hygiene, physical distancing etc.

6 European Court of Human Rights' Case-Law Regarding Mandatory Vaccination in General and in Relation to Covid-19

Mandatory vaccination is in fact restriction of the right to freely decide about one's own body and physical integrity in terms of medical treatment and, therefore, an interference with the right to respect for private life.⁴⁴ Even though it may be considered as a way to overcome certain human rights restrictions (such as the freedom to move or assembly), it is at the same time a threat towards those very same rights. Furthermore, the right to effective legal protection (art. 13 ECHR) would presuppose certain responsibilities of the society if the mandatory vaccination triggers unwanted side effects, such as compensation of non-material damage etc.⁴⁵ For these reasons, the ECtHR is very cautious when dealing with such conflicting rights. Nevertheless, the case law inclines towards positive attitude regarding national authorities' efforts to combat contagious diseases via vaccination if certain requirements are fulfilled.

The case *Boffa and Others v. San Marino*,⁴⁶ developed the theory that if there is a lack of proof that vaccines could endanger human lives, then mandatory vaccination is not an infringement to the right to life as in art. 2. This means that the burden of proof lies on those who claim that vaccines are endangering human lives or health. In the case *Solomakhin v. Ukraine*,⁴⁷ the ECtHR found that the right to private life as stipulated in art. 8 is not infringed by mandatory vaccination if: (1) Vaccines are meant to protect the life of the individual as well as the collective health in an utilitarian way where the expected good effects by far outweigh the negative outcomes, (2) They are administered during extra-ordinary circumstances (i.e. epidemics), and (3) There are available mechanisms to examine eventual concerns regarding vaccines' quality and its side effects. In the case of *Jehovah's Witnesses*

⁴⁴ *Infra* *Solomakhin v. Ukraine*, par. 33, reaffirmed also in *infra* *Vavříčka and Others v. the Czech Republic*.

⁴⁵ Ognjanoska (2021). The World Health Organization (WHO) and Chubb Limited (NYSE: CB), through ESIS Inc., a Chubb company, signed an agreement on behalf of the COVAX Facility on 17 February 2021 for the administration of a no-fault compensation programme: <https://www.who.int/news/item/22-02-2021-no-fault-compensation-programme-for-covid-19-vaccines-is-a-world-first>.

⁴⁶ *Boffa and Others v. San Marino*, ECtHR (1998).

⁴⁷ *Solomakhin v. Ukraine*, ECtHR (2012).

of *Moscow and Others v. Russia*,⁴⁸ the Court elaborated on the concept of mandatory vaccination through the prism of health protection of others (third parties) that extended beyond the individual's determination to vaccinate or not. Most important is the most recent case of *Vavříčka and Others v. the Czech Republic* regarding mandatory vaccination for well-known diseases in medical science for kids.⁴⁹ The applicants alleged that the various consequences for them of non-compliance with the statutory duty of vaccination had been incompatible with their right to respect for their private life under art. 8 of the Convention. Due to its importance, the case was allocated to the Grand Chamber. Namely, in the Czech Republic (as well as in many other countries, including North Macedonia) there is a general legal duty to vaccinate children against nine diseases that are well known to medical science. Parents who fail to comply, without good reason, can be fined (not forced to vaccinate), whilst non-vaccinated children are not accepted in nursery schools (an exception is made for those who cannot be vaccinated due to health reasons). The Court recognized that the Czech policy pursued legitimate aims of protecting health as well as the rights of the others, noting that vaccination protects both those who receive it and those who cannot be vaccinated for medical reasons and are therefore reliant on herd immunity for protection against serious contagious diseases. It further considered that a wide 'margin of appreciation' was appropriate for the respondent State in this context. It noted that in the Czech Republic, the vaccination duty was strongly supported by the relevant medical authorities and therefore represented the national authorities' answer to the pressing social need to protect individual and public health against the diseases in question. The Czech health policy was considered to be consistent with the best interests of the children who were its focus since it protected every child against serious diseases (through vaccination or by virtue of herd immunity). The Court also observed that the vaccination duty concerned nine diseases against which vaccination was considered effective and safe by the scientific community, as was the tenth vaccination, which was given to children with particular health indications.⁵⁰

It furthermore noted that the fine imposed on Mr Vavříčka had not been excessive. Although the non-admission to preschool for the other applicants' children had meant loss of an important opportunity to develop their personalities, it was a preventative rather than a punitive measure, and had been limited in time wherein when they reached the age of mandatory school attendance their admission to primary school would not have been affected by their vaccination status. The Court also declared, that the complaints under art. 9 (freedom of thought and conscience) of the Convention are inadmissible and that there was no need to examine the case separately under art. 2 of Protocol No. 1 (right to education) to the Convention. It remains questionable

⁴⁸ *Jehovah's Witnesses of Moscow and Others v. Russia*, ECtHR (2010).

⁴⁹ *Vavříčka and Others v. the Czech Republic* (2021).

⁵⁰ European Court of Human Rights 116, Press release on Court's First Judgment on Compulsory Childhood Vaccination on Violation of the Convention, 8.4.2021.

if the decision of the Court would have been the same if it regarded compulsory vaccination for mandatory school attendance.⁵¹

The Court noted that 'there was a general consensus that vaccination was one of the most successful and cost-effective health interventions and that each State should aim to achieve the highest possible level of vaccination among its population. However, there was no consensus amongst the Contracting Parties to the Convention over a single model. Rather, there existed a spectrum of policies concerning the vaccination of children. Even though there is no European consensus about mandatory vaccination, the Court reiterated that, in matters of health-care policy, it was the national authorities who were best placed to assess priorities, the use of resources and the needs of society. All of these aspects were relevant in the present context, and they came within the wide margin of appreciation that the Court should accord to the respondent State. Even more, there was an obligation on States to place the best interests of the child, and those of children as a group, at the center of all decisions affecting their health and development. With regard to immunization, the objective had to be to protect every child against serious diseases only achievable by children receiving the full schedule of vaccinations during their early years.'⁵²

Consequently, the ECtHR in the case against the Czech Republic decided that there was a proportionality of the mandatory vaccination to the legitimate aims pursued (to protect against diseases, which could pose a serious risk to health) through the vaccination duty.⁵³ However, the weight of this consideration was lessened by the fact that vaccinations were not administered against the will of the applicants. Instead, they were either fined or not accepted in nursery that is not compulsory (meaning they had a choice while the measure was limited in time). This was interpreted as a measure of preventative rather than punitive nature. The Court considered the fact that the vaccines were considered efficient and safe by medical science. Moreover, the Czech law allowed exceptions due to medical reasons. Therefore, the interference was both legitimate and necessary in a democratic society.

The medical reasoning that was uplifted in the case of *Vavříčka* makes the analogy with the case of mandatory vaccination against Covid-19 trickier (at least where population confidence is concerned) since obtaining accurate medical data takes time to investigate and to reinvestigate initial assumptions. For instance, the mandatory vaccines in *Vavříčka* case were already proven to be safe, efficient and in line

⁵¹ As it is in the Republic of North Macedonia, where the Constitutional Court decided in 2014 that this too does not represent a Constitutional breach, especially when in line with art. 39(2) and art. 40(3) that stipulate that the a citizen has a right and a duty to protect not only its own but also the health of others while parents are responsible to do the same in behalf of their children (Решение на Уставниот суд на Република Северна Македонија - 2014). Parts of this decision were quoted in the comparative material in the *Vavříčka* case (par. 103): 'In order to safeguard the health of the child and the child's right to health, which was subject to a special level of protection, it was justified to deny the parents' freedom to refuse vaccination, since the right of the child to health prevailed over the parents' right to choose.'

⁵² European Court of Human Rights 116, Press release 8.4.2021.

⁵³ This is probably, the key point of the case—stressing out duties and responsibilities prior to rights (as opposed to how usually is in front of the ECtHR) when a person co-exists in a society.

with the objective—achieving herd immunity over time, unlike in the case of Covid-vaccines. Namely, these relatively new vaccines (which are also considered safe and efficient but only on a level to lessen the disease or not to cause lethal outcomes) were supposed to deliver immunity in the beginning, while this proved to be tricky over time (since booster doses are constantly needed while new variants of the virus are resistant to vaccines). In this sense, Janis makes an observation that when human rights experts,⁵⁴ suggest that the court should also support compulsory vaccination in the case of COVID-19,⁵⁵ without considering medical issues and scientific publications, the conclusions may be decisive. Therefore, not just primary, but also auxiliary sources of reasoning have to be consulted prior to making final judgments.⁵⁶ Consequently, in order to assess whether mandatory Covid-19 vaccination has legitimate aim (collective benefit), one needs to prove that they will eventually cause herd immunity. In the lack of such medical evidence, the measure—imposing compulsory vaccination against Covid-19 is not proportionate to the legitimate aim (achieving immunity, even less herd) in a democratic society.⁵⁷

Apart from the methodology of legitimacy, proportionality and necessity to evaluate certain applications, mandatory vaccination asks for other prerequisites to be fulfilled such as: informed consent, effective legal protection and remuneration of damage in case of unwanted side-effects.⁵⁸ When it comes to informed consent, it should be underlined that in such cases, the concept is suspended instead of falsely preserved. This is for instance when in mandatory vaccination there is an informed consent form that people should sign.⁵⁹ If there are negative consequences for not vaccinated, then that is indirectly forced, not voluntary vaccination, even less valid signed informed consent sheet. Along these lines, Anja Kresser, defines ‘every consequence as a result of refusing to carry out a vaccination as ‘compulsory vaccination’ ... as these consequences can (and are intended to) influence one’s decision to get vaccinated.’⁶⁰ Therefore, it is a ‘bitter choice’ to make ‘forced-voluntary’ (oxymoron per se) informed consent criteria satisfied in mandatory vaccination against Covid-19. Nevertheless, this ‘bitter choice’ could be a ‘better choice’ from the available

⁵⁴ Katsoni (2021).

⁵⁵ Vinceti (2021).

⁵⁶ Schabas (2015).

⁵⁷ Other authors go much further considering compulsory vaccination illegal due to lack of medical assurance, insufficient knowledge of the effects of the vaccine and its interactions with various medical conditions as well as no established treatments for its side effects and abnormalities caused by it. See for instance Niroshan (2022), p. 267.

⁵⁸ *Op. cit.* Ognjanoska (2021).

⁵⁹ Even those who are indirectly ‘forced’ to be vaccinated because of particular benefits that come along with the vaccination status (such as entrance to nursery school etc.) have to sign an ‘informed consent’ sheet prior to vaccination. However, informed consent in such cases or when there is a legal obligation to vaccinate (in mandatory vaccination) cannot be voluntary—which is one of its necessary premises and therefore—valid. Instead, it is ‘coerced informed consent’ which is an oxymoron per se. See for instance in Anna et al. (2018).

⁶⁰ Krasser (2021).

difficult options, having in mind all the negative consequences of the pandemics, especially during its initial peaks.⁶¹

The number of cases that tackle different aspects of the Covid-19 crisis management in its aftermath brought to ECtHR is raising.⁶² Especially relevant regarding mandatory vaccination for specific occupations is the case *Pasquinely and Others v. San Marino* (No. 24622/22) that raises concerns regarding art. 8 (right to respect for private life) of the Convention and is still pending. The Court also received requests for interim measures concerning vaccination schemes (lodged by workers in specific occupations, who challenged the compulsory vaccination) or certificates granting pass to public places. These requests were rejected for being out of scope of application of Rule 39.⁶³

7 Time as a Factor to ‘Change the Game’ and Ease the Conflict Between Individual Autonomy and Public Health

Austria was the first country to introduce mandatory vaccines with a law dating from 16 February 2022 but it promised not to enforce it for a month. In the meantime, and prior to its enforcement, Austria suspended its law because the circumstances changed—the next—Omicron variant showed to be less dangerous and the Government assessed that the measure would then be disproportional to the threat, while the infringement of individual rights may not be justified.⁶⁴ Therefore, the mandatory vaccination in Austria could not test both—bioethical and legal principles in practice.

Unavoidably, the essence of the debate regarding mandatory vaccination against Covid-19 is the way we perceive individualism v. collectivism, i.e. the prevalence of the individual right to bodily autonomy or the collective duty to preserve collective

⁶¹ See for instance: Gibelli et al. (2022).

⁶² In the case *Zambrano v. France*, the ECtHR (41994/21) an university lecturer complained about national laws which introduced and imposed health pass which, in his opinion, was essentially intended to compel individuals to consent to vaccination that allegedly caused a discriminatory interference with the right to respect for private life. The Court in the Decision from 21.9.21 declared the application inadmissible for several reasons, mainly due to the failure to exhaust the domestic remedies and the fact that it amounted to an abuse of the right of individual application. Another decision of the Court that declared inadmissibility due to failure to exhaust domestic remedies is in the case of *Thevenon v. France* (46061/21). This case is more closely related to mandatory vaccination since it concerned a firefighter’s refusal to comply with the Covid-19 vaccination requirement imposed on workers in certain occupations as part of the public management of the health crisis. After the refusal without claiming a medical exemption under the statute, he was suspended from both his professional and volunteer duties. For more cases regarding other aspects of the management of the Covid-10 health crises, see the Factsheet Covid-19 Health Crises, ECtHR, Press Unit, Jan. 2023.

⁶³ *Ibid.* Factsheet Covid-19 Health Crises, p. 12.

⁶⁴ BBC News (9 March, 2022).

health. They are both important, and only in specific particular circumstances could one make the difference and decide which one should prevail.

Several authors have already discussed this (in more recent papers), suggesting methods on how to favor one method over others, offering arguments and counter-arguments.^{65,66} Savulescu suggests four conditions for mandatory vaccination: first, if the disease is a stern threat to public health; second, if vaccines are safe and effective; third, if mandatory vaccination proves to be a convincing cost–benefit profile compared with other alternatives; and lastly, if the level of coercion is proportionate. Other experts propose seven principles to make rational and transparent decisions, including three basic medical ethics (justice, autonomy and harm avoidance), public trust, solidarity and reciprocity, population health maximization, and protection of the vulnerable.⁶⁷ Having these elements as the basis to start from, Cheng offers arguments why Covid-19 vaccines should not be compulsory. Firstly, there are alternatives to vaccination methods to stop the spread of the disease, such as public mask usage, personal hygiene behavior, physical distancing and social distancing (limiting gatherings). Secondly, the booster dose that was recommended by experts, especially for vulnerable groups suggests that the vaccines we have at disposal are not capable of achieving herd immunity. In fact, it was recommended that even vaccinated people should continue with precautionary measures (including all of the above that were used even prior to vaccines). Thirdly, vaccination did not prove to prevent the spread of disease since even the vaccinated were capable of doing so.⁶⁸ Having all these concerns in mind (at the very least), mandatory vaccination is neither necessary nor sufficient, therefore proportionate.

Janis is on the similar page. He explores the compulsory vaccination against Covid-19 within the scope of article 2 and 8 of the ECHR.⁶⁹ In the framework of the right to life, he suggests that better public health response to the pandemic would be adequate preventative and therapeutic treatment for COVID-19.⁷⁰ In the framework of the right to private life, he rejects the existence of immunity as a reason to prioritize public good against private choices of the individual since the Covid-19 vaccines do not stop the transmission of the virus. Moreover, when the rate of transmission of infection for vaccinated individuals is equivalent to that of unvaccinated individuals,⁷¹ those vaccinated are deluded into believing they are safe for themselves and for others they come into contact with.

Even though ethical and legal methodology of reasoning regarding mandatory vaccination against Covid-19 differ, sometimes they achieve similar conclusions. Professor Stavroula Tsinorema during her lecture for master students of bioethics

⁶⁵ Savulescu (2021).

⁶⁶ Cheng (2022).

⁶⁷ Maeckelberghe and Schroder-Back (2020), pp. 852–853.

⁶⁸ *Op.cit.* Cheng (2022).

⁶⁹ Kjumel (2021).

⁷⁰ Therapeutics and COVID-19: living guideline.

⁷¹ Singanayagam and Hakki (2022), pp. 183–185.

criticized normative reasoning that tends to measure one right over another.⁷² Her criticism of the proportionality principle suggests that individual autonomy and common good should be harmonized and not measured. Similar conclusion (even though using precisely the opposite methodology—measuring) is reached by Cheng. He believes that voluntary participation can ease tensions between public interests and individual freedom because in this case individualism does not act against collectivism, in that it involves the interdependent self with shared interests. The individual self is an essential component of the collective self, and these are not necessarily mutually exclusive. The individual's membership in a group presupposes that individual interests are taken into account and the individual accepts his role as a group member and accordingly the aggregate interests.⁷³

If the role of the official authorities is understood on a level of informing, educating, recommending and providing incentives for vaccination,⁷⁴ then the individual health and public health could complement each other, at least in this period of the development of the Covid-19 pandemic.^{75,76}

8 Conclusion

The tension between the individual consent as a self-determination agency and the public health requirements that tend to limit it does exist. Accordingly, there is no European consensus about mandatory vaccinations and States enjoy wide margin of appreciation. The conflict was resolved by holistic approach (including medical science, epidemiology, virology etc.) added to the normative reasoning by the ECtHR in the case of *Vavříčka and Others v. the Czech Republic*. In many aspects, this case seemed relevant to Covid-19 and an analogy could be drawn especially when vaccines were first introduced while the state of the situation was still severe. However, the case of mandatory vaccination against known diseases to science for children in nursery currently differs from the case of mandatory vaccination against Covid-19 for everyone. Firstly, the threat of the virus becomes less serious in nature to both individuals and public health over time (the measure is not necessary, at least not anymore). Secondly, time has shown that prevention from Covid-19 cannot be achieved only and solely with mandatory vaccination because vaccination itself does not provide herd immunity and it does not stopcurb the spread. In that regard, there are other alternatives that can achieve that aim, such as voluntary vaccination, wearing masks, proper hygiene, amongst others, rendering the legitimate aim of vaccination unaccomplished. Lastly, time has also shown that even if the level of coercion does

⁷² Tsinorema (2022).

⁷³ Bishop (2014).

⁷⁴ D'Errico et al. (2021).

⁷⁵ *Op.cit.* Cheng (2022).

⁷⁶ Note: Prior to publishing this work, the author published another text that relates to the concepts elaborated here (Ignovska 2022).

not include direct force (instead, it includes fines or other restrictions, such as in the case of Vavříčka or in the pioneering but suspended legislation for mandatory vaccination in Austria), this is not proportionate to the possible infringements on private life and individual consent. It can therefore, be concluded that mandatory vaccination would currently be tantamount to infringement on human rights and liberties. It means that time has shown to be the factor that ‘changed the game’. However, if it had not been for (voluntary) vaccination that timing could have been extended and the number of deceased higher. As such, if the situation deteriorates, the bitter choice between appreciating consent or imposing one, will once more challenge bioethicists, lawyers, academics and citizens in general. The evaluation should therefore focus on two main elements: whether the measure is effective and whether the sole (or the best) methodology for prevention is scientifically proven and uncontested in regard to its efficiency as well as possible side effects.

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Решение на Уставниот суд на Република Северна Македонија, бр. 30/2014-0-0 од 8.10.2014 г.)

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