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Informed Consent and Public Health: The Case of Childhood Vaccination

SUMMARY

Informed consent, which is primarily aimed at encouraging individual patients and subjects of scientific research to make autonomous decisions, and public health measures, such as compulsory vaccination against infectious diseases, the successfulness of which implies harmonized administration of vaccines to a broad population, seem to be irreconcilable opposites at first glance. This paper deals with investigating whether these opposites can reconcile or whether informed consent can be applied in the field of public health.

The first part of the paper provides a short overview of the main features of informed consent and its relevance in treating individual patients. The second part of the paper tackles the issue of immunization. If not provided with consent of their patients or having a legal obligation, physicians are believed to interfere with the bodily integrity of other people when conducting vaccination and their act can be deemed as an assault and entail non-pecuniary damage compensation. Herd immunity as a "public good" can only be achieved if all people are equally subject to public health measures. At this point, the key question is if informed consent and appertaining freedom of decision-making represent a threat to the accomplishment of this public health goal.

This question should truly be answered since vaccination may, though rarely, bring to medical complications, which may then lead to high treatment costs, loss of income and extremely rare, to death. The purpose of this paper is to demonstrate that disclosure of the risks and benefits of immunization within the framework of public health programmes could contribute to putting the fundamental bioethical postulates into practice: establishing and fostering mutual trust between physicians and their patients, which can, in the end, contribute to a higher immunization rate of a population.

Keywords: informed consent, compulsory vaccination, trust, public health policies, public good.

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1. Introduction

This paper investigates whether the informed consent of an individual patient can become a rule in childhood vaccination. Informed consent and vaccination against infectious diseases are elaborated in numerous scientific studies. Yet, although there is comprehensive literature about informed consent and the issue of compulsory vaccination, there are not so many papers tackling the issue of informed consent in the context of public health, which this paper revolves around (Rubinstein Reiss & Karako-Eyal, 2019, pp. 357–359).[1]

Making a decision on vaccination belongs equally to the private sphere and to the respective public health system (Rubinstein Reiss & Karako-Eyal, 2019, p. 382; Parmet, 2005, p. 109; Tucak, 2017a). Vaccination does not imply only benefits for an individual but also benefits for the public, such as herd immunity to infectious diseases, and hence, informed consent, which protects an individual's autonomy and self-determination when making medical decisions, is often regarded as an obstacle to the accomplishment of important goals related to public health (Kochuba, 2009, p. 771). In order to make public health policies sufficiently efficient, those policies have to be universal for an entire population (O'Neill, 2004, p. 4).

This paper is aimed at exploring whether the argument that informed consent is inconvenient when it comes to childhood vaccination dwindles in the light of the new development of medical law and bioethics (Schumacher, 1999, p. 116). It is divided into two main parts. The first one provides a brief overview of the doctrine of informed consent while the second one focuses on the possibility of its application in the sphere of compulsory vaccination.

2. Informed consent

The relevant literature explores the legal and ethical origins of informed consent (Farber Post et al., 1996, p. 351; Wilen Berg, 2012, p. 5).[2] It is beyond any doubt that case-law played the leading role in the emergence and development of informed consent (UNESCO, 2005, paragraph 63). Prior to the development of "judicial doctrine", informed consent had no or was of lesser importance in medical practice. Indeed, some other doctrines, such as "the doctrine of confidentiality", used to play

1 Little has been written about informed consent in the context of vaccination. In addition to the authors we deal with in more detail in this paper, we would like to mention: Berg (2012), Bradley (1999), Kochuba (2009), Malone & Hinman (2007), Peterson Woolley (1977), Schumacher (1999), Severyn (1995).

2 See Beauchamp & Childress (2019), Hurd (1996), Katz (1977, 1994), Manson & O'Neill (2007), Schaber & Müller (2018), Sreenivasan (2003, 2021), Gutmann Koch & Elster (2017), Wicks (2001).

major roles in the history of medicine (Wilen Berg, 2012, p. 5). In terms of informed consent, the American case-law bears particular relevance; the case of Schloendorff v. Society of New York Hospital. 211 NY 125 (1914), conferred to judge Benjamin Cardozzo, was the first to acknowledge a patient's right to self-determination whereas the case of Salgo v. Leland Stanford Jr. Univ. Bd. Trustees. 317 P. 2d 170 (1957) was the first one to mention informed consent (Beširović, 2008, p. 258; Selak, 2017, p. 172). The doctrine of informed consent was based on "the law of assault and battery holding that any unconsented-to touching constituted an unlawful act" (Farber Post et al., 1996, p. 351). Later the courts turned to the doctrine of negligence, enabling "a nuanced examination of whether the discussion reflected the risks and benefits that were material to this patient" (Farber Post et al., 1996, p. 351). Some stress that informed consent primarily arose as legal protection of physicians from "accusation, litigation and compensation claims" (O'Neill, 2003, p. 4).

The justification of informed consent mostly refers to an individual's autonomy. The emergence of various rights movements in the second half of the 20th century upgraded the principle of autonomy to "the major support for individual empowerment and self-determination" (Farber Post et al., 1996, p. 352). In all social layers, the power of decision-making was to be equally distributed among members of different races, classes and genders (Farber Post et al., 1996, p. 352). That also concerned healthcare where a balance between patients and their doctors was to be established, turning the former into a partner when making medical decisions. A patient became "an informed health care consumer" and his/her autonomy "the controlling principle" with respect to health care providers (Farber Post et al.,1996, p. 352).

In accordance with the contemporary development of law and medical ethics, a medical intervention in somebody's body without his/her "sufficiently informed and voluntary consent" would be deemed legally impermissible (Eyal, 2019). The doctrine of informed consent requires from doctors to provide their patients with adequate information on benefits and risks relating to a medical intervention, after which it will be up to the patients to make the final decision (Holland, 2012, p. 79). Similarly, drug manufacturers shall provide complete information on the risks of taking their products (Holland, 2012, p. 79). Even though the term of informed consent is widely used in relevant literature, some authors believe that the term of "informed choice" is more appropriate (Wilen Berg, 2012, p. 6). This term is appropriate in cases where the patient has the right to choose between different medical treatments. As Turković (2008, p. 159) points out, the right to refuse medical treatment is the other side of the right to give consent.

The Explanatory Report to the Convention for the Protection of Human Rights and the Dignity of Human Being with Regard to the Application of Biology and

Medicine (hereinafter Oviedo Convention) can help us determine more precisely what constitutes informed consent today. The report states that the patient's consent can be deemed free when given without any external pressure, and informed, when based on information provided by health professionals about the nature and possible consequences of medical intervention and its alternatives (The Explanatory Report to the Oviedo Convention, 1997, paragraph 35; Acosta Lopez, 2015). The term "intervention" is used in this Convention in a broad sense to cover all "medical acts", including those undertaken for the purpose of preventive care (The Explanatory Report to the Oviedo Convention, 1997, paragraph 34; Acosta Lopez, 2015).[3]

2.1. Theory of Informed Consent

Although the justification of informed consent nowadays mostly refers to autonomy, it is important to emphasize that there are different concepts of autonomy (Tucak, 2020, pp. 67-70; O'Neill, 2003, p. 5). Pursuant to O'Neill (2003, p. 5), contemporary approaches to autonomy have lost connection with their Kantian sources in which the link between autonomy and respect for a human person is well-substantiated. Most modern approaches reduce autonomy to some form of individual independence and identify it with "independent choosing", which is not a real reflection of its ethical significance (O'Neill, 2001, p. 691, note 2). Ethical theories propagating respect "for agency", "persons, autonomy and individuals" differentiate between treatments appropriate for agents and those appropriate for other beings (O'Neill, 2001, p. 691). Agents should be provided with "a distinctive sort of respect" and they must not be treated as objects.

> "The traditional rationale for this thought is that where consent is forthcoming, nobody's status as agent is overridden: in consenting to the ways in which others treat us, we authorise such action, so are not injured by it" (O'Neill, 2001, p. 691).

Therefore, holds O'Neill, it is no surprise that many authors put great efforts into elucidating informed consent and explaining hard cases in which individuals are not capable of providing informed consent due to their "impaired" or "underdeveloped" "cognitive and decision-making capacities" (O'Neill, 2001, p. 692). In standard cases, informed consent represents a sharp boundary between "legitimate medical" and other actions (O'Neill, 2001, p. 692).

O'Neill (2001, p. 691, note 2) highlights the importance of Kant's concept of autonomy, which is based not only on free but also on "reasoned choice". In O'Neill's opinion, Kant's approach to moral autonomy does not include the possibility

3 For an overview of international and domestic legal acts and guidelines governing the right to informed consent see Sorta-Bilajac Turina & Šupak Smolčić, 2019, pp. 497-507.

of freedom for an individual if he/she acts "without reference to all other moral agents" (Campbell, 1995, as cited in Stirrat & Gill, 2005, p. 127). O'Neill calls such an approach, which is contrary to the one that might be considered individual autonomy, "principled autonomy" (Stirrat & Gill, 2005, p. 127).

However, it should be noted that a new approach has been gaining importance lately. There is a growing number of authors who do not justify informed consent with individual autonomy but built it on trust. Eyal (2012, p. 1) sees informed consent "as a safeguard for trust in caretakers and medical institutions". This author proposes the ideal type which she calls "the trust-promotion argument for informed consent". In line with the ideal type of informed consent, the prerequisites for justification of informed consent are as follows (Eyal, 2012, pp. 1-2):

- existence of social trust is required and without it, people would neither ask advice from medical institutions nor adhere thereto;
- trust must not be jeopardized (at least in most cases);
- "coercion", "deception", "manipulation" and use of similar procedures for obtaining informed consent might seriously put such trust in danger.

Though, thinks Eyal (2012, p. 2), this argument is not necessarily utilitarian, it justifies informed consent as an instrument for achievement of a social good: "trust in caretakers and medical institutions and, more broadly, social trust". Trust is not only confined to "a clinical setting". Societies characterized by "mutual trust and trust in institutions" are more advanced in the economic and democratic sense than societies where there is no such trust. In this light, one should differentiate between "high-trust" and "low-trust" societies (Eyal, 2012, p. 2).

3. Informed consent and Public Health

Firstly, public health needs to be defined. The term of public health usually refers to "promoting and protecting the health of populations" (Faden & Shebaya, 2016). According to Faden and Shebaya (2016), there are four characteristics of public health: 1) it is regarded as a public or collective good; 2) it focuses on prevention; 3) it implies state-initiated action; 4) it includes "an intrinsic outcome-orientation". Public health concentrates on a population rather than on an individual. Many public health measures are coercive, so their justification is of utter importance (Faden & Shebaya, 2016).

The paper does not elaborate the topic in details, but it should be noted that, when it comes to public health, there is no universal theory of the scope and limits of state power (Wilen Berg, 2012, p. 39). The most frequent justification of the exercise

of state power at the detriment of an individual can be found in social contract theory (Wilen Berg, 2012, p. 24). It is based on the perception that a society consists of individuals who have accepted certain obligations (Wilen Berg, 2012, p. 19). Explicit consent would surely justify state power, but it is provided very rarely (Wilen Berg, 2012, p. 25). Although a person has not given explicit consent to a particular intervention at a certain point in time, it may be assumed as if he/she had provided his/her "prior consent" thereto (Wilen Berg, 2012, p. 20).

As a possible alternative to justification of state power in the domain of public health, Wilen Berg (2012) mentions H. L. A. Hart's theory of fairness. In compliance with her interpretation of Hart's theory, it is not so important if an individual has tacitly submitted to a rule, but if he/she is willing to embrace both the benefits of living in a community and the accompanying burdens. In fact, carrying a burden and limitation of individual freedoms represent an inevitable result of living in a community (Wilen Berg, 2012, p. 24). Hart (1955, p. 185) proposes the term of "mutuality of restrictions", which differs from other ways of generating rights, such as consent and promising:

> "In its bare schematic outline it is this: when a number of persons conduct any joint enterprise according to rules and thus restrict their liberty, those who have submitted to these restrictions when required have a right to a similar submission from those who have benefited by their submission".

Public health ethics can be perceived as "the moral foundation of public health as social justice" (Faden & Shebaya, 2016; Powers & Faden, 2006, pp. 80-81). In that context, it is oriented towards providing all people with an appropriate level of healthcare and diminishing "unjust inequalities". It is connected with poverty-related issues and "systematic disadvantage" (Faden & Shebaya, 2016; Powers & Faden, 2006, pp. 80-81).

Rus and Grošelj (2021, p. 7) emphasize another aspect of justice in public health. According to these authors, justice means "ensuring subjects equal access to preventive measures and, in addition, equal contribution to control of communicable diseases (i.e., by vaccination)". In this context, it is important to focus on "just contribution to herd immunity" (Rus & Grošelj, 2021, p. 7). Herd immunity should be seen as a common good, since the protection of the population from infectious diseases is in the public interest and must be maintained by "external forces" (Rus & Grošelj, 2021, p. 7).

One of the most important problems in healthcare today is definitely how to strike a balance between individual and societal well-being (Sorta-Bilajac Turina, 2017, p. 11), how to find the right "framework for deliberation" on personal vs. common (Mićović et al., 2016, p. 81). The "commonal approach" has enabled the realization

of the greatest "medical gains" (Dickenson, 2013, as cited in Mićović et al., 2016, p. 84). Donna L. Dickenson (2013, as cited in Mićović et al., 2016., p. 83) in this context talks about the conflict of ME medicine with WE medicine. The focus of ME medicine is an individual as a user of the health system. Based on the principle of autonomy, he/she expresses his/her informed consent to a certain medical procedure (Mićović et al., 2016, p. 84). WE medicine is based on an individual as a member of the community, which can be wider or narrower, national, European, global (Mićović et al., 2016, p. 84). Public health is focused on removing structural and socio-economic inequalities (Callahan, 2000, 2002, as cited in Sorta-Bilajac Turina, 2017, p. 6). Thus, the focus of observation shifts from the principles of autonomy to the principles of justice and beneficence. Justice is defined as "social equity in front of the health care system" (Mićović et al., 2016, p. 84). And both of the mentioned bioethical principles are redefined in the public health approach within "the concept of social wellbeing" (Callahan, 2002, as cited in Mićović et al., 2016, p. 84).

3.1. Informed Consent and Vaccination

Until recently, medical ethics was primarily focused on treating individual patients. Providing medical services was considered "a (quasi-)consumer good", the distribution of which was related to "individual choices" (O'Neill, 2004, p. 1133). Vaccination itself is a preventive medical intervention, sometimes accompanied with adverse effects and it is performed on healthy individuals (children) for the purpose of prevention from nowadays extremely rare infectious diseases (Rubinstein Reiss & Karako-Eyal, 2019, p. 369). Therefore, it is no wonder that the informed consent of an individual or of children's parents or guardians is depicted as highly important (Rubinstein Reiss & Karako-Eyal, 2019, p. 363).

Beside the protection of a vaccinated individual, vaccination also has "a public health function" (Rubinstein Reiss & Karako-Eyal, 2019, p. 364). The fact that rejection of vaccination by an individual puts the whole public health system in jeopardy represents the reason why introduction of informed consent in immunization policy implementation raises public concern (Rubinstein Reiss & Karako-Eyal, 2019, p. 364). A failure to administer vaccines to children opens up the possibility of outbreak of diseases which have been almost eradicated. Providing individuals with the right to provide informed consent to vaccination may lead to "the tragedy of the commons" (Hodge & Gostin, 2001-2002, pp. 876-877; Gostin, 2005). For example, measles epidemic has hit the EU / EEA Member States recently. Between 1 January 2016 and 31 March 2019, 44,074 cases were recorded. Although according to the goals set by the World Health Organization (hereinafter WHO), the European region should

have been free from this disease by 2000. The experts put the blame on insufficient vaccination coverage (European Centre for Disease Prevention and Control, 2020).

O'Neill categorically rejects the possibility of asking informed consent in public health. This author regards public health as a public good that can only be achieved if it is equal for all (O'Neill, 2004, p. 1133). In the event of required informed consent, accomplishment of public health goals would be impossible. Fulfilment of such commitments is impossible and thus they are null and void ("ought implies can") (O'Neill, 2004, p. 1135).

It is considered legitimate to restrain an individual's autonomy when making decisions on his/her own health in the event of a threat to public health (Rubinstein Reiss & Karako-Eyal, 2019, p. 358; Tucak, 2016). Restriction of the informed consent of an individual is also set forth in the UNESCO Universal Declaration on Bioethics and Human Rights (IBC, 2008, pp. 24-26). In accordance with the 2008 Report of the International Bioethics Committee of UNESCO (hereinafter IBC) on consent, such restrictions shall be precisely regulated pursuant to Article 27 of the Declaration, referring to "Limitations on the application of the principles". In its Report, the IBC established that epidemic threats may empower governments to vaccine entire populations or some of their segments, e.g. public health providers. During an epidemic, the state can suspend the right of an individual to freely choose a doctor or hospital in which he/she will undergo a medical intervention. Patients may be directed to a place where they will receive a treatment according to a predefined plan. The Oviedo Convention also provides for restrictions on the exercise of the rights contained therein (Article 26).

If it is assumed that the informed consent of parents can be used in childhood vaccination, how should it be defined to protect the parents' autonomy, wellbeing of the child and health of the whole community in the best possible way (Rubinstein Reiss & Karako-Eyal, 2019, p. 358)?

3.2. Vaccination Hesitance

At the very beginning of this chapter, it is important to point out one terminological confusion. Namely, in discussions about compulsory vaccination, terms such as "anti-vaxxers", "vaccine refusal", "vaccine reluctancy" are used quite inconsistently. For this reason, we decided to focus here on a group that can be called "vaccine-hesitant parents" (Rus & Grošelj, 2021, p. 1-2). Members of this group "do not refuse vaccination in principle but" are concerned about its safety/efficiency or maybe just prefer alternative vaccination schedules" (Rus & Grošelj, 2021, pp. 1-2). This group does not represent extreme, vaccine refusing parents, but parents who have a

wide range of different perceptions of vaccination (Rus & Grošelj, 2021, pp. 1-2). The latter group, according to the World Health Organization Strategic Advisory Group of Experts on Immunization, is much more numerous than the former (Rus & Grošelj, 2021, pp. 1-2).

It is an indisputable fact that a large number of modern states is facing a fall in the childhood vaccination rate due to parents' vaccination hesitance. At this point, it should be answered why parents hesitate to have their children vaccinated. This is important to determine the effect of introduction of informed consent in childhood vaccination on immunization coverage. Vaccination hesitance has become a global problem. Among countries with poor childhood vaccination coverage (WHO, 2019 data), one needs to single out the USA and 34 countries belonging to the WHO European Region (Ratzan et al., 2019). The principal advisory group to WHO for vaccines and immunization has detected the main reasons why people refuse to have their children vaccined: satisfaction with the current situation, "inconvenience in accessing vaccines" and a lack of reliability in the data on vaccines (WHO, 2019). The Salzburg Statement on Vaccination Acceptance, adopted within the framework of the newly established International Working Group on Vaccination and Public Health Solutions, accentuates the need for new approaches to overcoming what its creators see as a major erosion of the trust of the public in scientific and state efforts in the protection of public health (Ratzan et al., 2019).

One can often hear the claim that introduction of parents to childhood vaccination risks may avert them from vaccination and that the procedure for obtaining informed consent prior to vaccine administration could itself take too much time and thus prevent the doctors from providing other medical services (Rubinstein Reiss & Karako-Eyal, 2019, p. 364). At the beginning of the 1990s, the American Academy of Pediatrics required reduction of information that appear in Vaccine Information Statements and that is provided to parents before the vaccination of their children for these very reasons (Holland, 2012, pp. 79-80).

Conducted research demonstrates that parents make decisions on the vaccination of their children in a broader socio-cultural context. They are guided by a number of socio-demographic factors: the way they perceive health, healthcare system, their personal experience, lifestyle and cultural and religious beliefs The main reasons definitely involve misinformation and insecurity regarding the benefits and risks of vaccination (Rubinstein Reiss & Karako-Eyal, 2019, 365). Parents also worry about vaccine safety and they fear that their children are unnecessarily exposed to numerous vaccines which may imply severe adverse effects on their children's immune system. Vaccines are thus connected, among other things, with "autism, multiple sclerosis,

sudden infant death syndrome, immune dysfunction, diabetes, and neurologic disorders" (Rubinstein Reiss & Karako-Eyal, 2019, p. 366).

The results of the above studies suggest that reliable, complete and clear information from reliable sources represent an indispensable precondition for successful childhood vaccination (Rubinstein Reiss & Karako-Eyal, 2019, p. 367). A failure to provide parents with full information on the vaccination of their children and all possible consequences thereof in order not to discourage them to have their children vaccinated can have only short-term benefits. In the long run, providing all necessary information should enhance the trust in health care providers (Rubinstein Reiss & Karako-Eyal, 2019, p. 368).

Rus and Grošelj (2021, p. 4) also point out that "lack of information, misunderstanding or false information" are the main reasons why parents are reluctant to vaccinate their children. Distrust of information provided by doctors is the primary reason why parents choose to search for information online. Therefore, as these authors (Rus & Grošelj, 2021, p. 4) point out, public health authorities and individual physicians have a responsibility to provide "adequate, reliable and understandable information about vaccination" to the parents. "Listening carefully to parent's concerns and provision of clear information about risks and benefits of vaccination can help hesitant parents to understand principles of vaccination and, with their consent, to obviate ethical dilemmas of vaccine refusal" (Rus & Grošelj, 2021, p. 4). Due to the lack of time for doctors to respond to all parental concerns about the vaccine, a systematic approach to this problem through organized education or social media is needed (Rus & Grošelj, 2021, p. 4).

Ivana Katarinčić (2019, p. 80) finds similar dilemmas with Croatian parents, who, as the author emphasizes in her article, even point out that when they ask for information about vaccinations from doctors, they "encounter threats, intimidation and conditioning".

3.3. Parents' Autonomy

The definitions of autonomy, which describe it as a form of "self–governance" or "self–direction" (Rubinstein Reiss & Karako-Eyal, 2019, p. 380; Sawicki, 2017, p. 41; Tucak, 2016, pp. 626-629) do not entail abstention from any form of persuasion of parents to subject their children to vaccination. For example, by means of an appropriate conversation ("telling real-life stories") about the consequences of the infectious diseases concerned (Rubinstein Reiss & Karako-Eyal, 2019, p. 381).

However, parents' free will could be jeopardized by providing them with information in a way that they are shown frightening pictures and data on the consequences

of failing to have their children vaccinated against particular infectious diseases, blaming them for being bad parents, free-riders; for being irresponsible, for causing epidemics, threatening them with medical treatment refusal and legal sanctions. All the aforementioned options imply the risk of depriving the parents from an alternative and thus forcing them to subject their children to vaccination (Rubinstein Reiss & Karako-Eyal, 2019, p. 381). Public health providers must be introduced to the fact that empirical research of "controlling interventions" indicates that beside jeopardizing the autonomy of parents, such interventions are not compliant with public health interests. "Judgmental and adversarial discourse" turns parents away from the vaccination of their children (Rubinstein Reiss & Karako-Eyal, 2019, p. 381). Severe punishments might undermine public health policies. If parents are fined or even sent to prison or faced with tort litigation, it might come to public discontent (Gostin, 2015, p. 2).

The ideal situation would enable parents to receive adequate information on the risks and benefits of the vaccine to be administered to their children and to give their explicit consent thereto (Zagaja et al., 2018, p. 8507). Nevertheless, many states prescribe compulsory vaccination and envisage legal sanctions for those who oppose it. For example, in the USA, non-vaccinated children cannot attend schools whereas in Poland, being fined does not release the parents from the vaccination obligation which can be repeatedly imposed (Zagaja et al., 2018, p. 8508). Australia withholds child benefits in case the child is not vaccinated ("No Jab, No Pay") (Savulescu, 2021, p. 81).

The Republic of Croatia also stipulates compulsory vaccination and foresees a pecuniary penalty if failing to comply with the respective regulation (Act on the Protection of the Population against Communicable Diseases, 2007-2021). In these states, it would make no sense to require from parents to give informed consent prior to the vaccination of their children (Zagaja et al., 2018, p. 8506). This would be contrary to one of the fundamental assumptions of informed consent – its voluntariness (Zagaja et al., 2018, p. 8508).

It is clear that there are good reasons why, from both perspectives - parents' autonomy and public health, parents should be provided with accurate and comprehensive information on the vaccination of their children: promoting trust, which will encourage parents to cooperate with medical health providers (Rubinstein Reiss & Karako-Eyal, 2019, p. 415).

At this point, it is important to emphasize that, although many vaccines are given to children before they are competent to make decisions, "(t)he opinion of the minor shall be taken into account as an increasingly determining factor in proportion to his or her age and degree of maturity" (Oviedo Convention, 1997, Article 6 § 2;

Wilkinson & McBride, 2022). Child Assent is a term that "refers to the agreement of a child or young person who is not legally able to give informed consent" (Wilkinson & McBride, 2022). It entered our dictionary in 1976 with the publication of the American Academy of Pediatrics (AAP) statement on informed consent (Katz & Webb, 2016, p. 1).

3.4. Public Health form of Informed Consent

Although providing informed consent to vaccination has not awaken great scholarly interest yet, here are some relevant papers in which the authors tried to develop an appropriate model of informed consent in this context. Parmet (2005) stresses that we need a public health-oriented form of informed consent which would revolve around the main objectives of any kind of informed consent: providing adequate information and the thing that define the subsidiary goals of informed consent: possible compensation for damage arisen from vaccination, prevention of unwanted harm and building of trust. A public health variant of informed consent should, believes Parmet (2005), remove the burden of legal liability from doctors and drug manufactures and put it on public health authorities. Provided information should include both the risks and benefits of vaccination for a whole population (Parmet, 2005, p. 107). Parents should be given the real reasons why the public health authorities want them to have their children vaccinated (Parmet, 2005, p. 109). In such a case, parents would understand that the state does not interfere with their seemingly private decisions. An emphasis on the public aspects of vaccination may diminish vaccination hesitance (Parmet, 2005, p. 109).

> "If, however, the government explains to the parent why the decision is not private, and how it affects other people, especially sick and vulnerable children in the child's community, perhaps the parent will have a different attitude. Unless we provide parents with the full story, we should not assume their lack of interest in their neighbor" (Parmet, 2005, pp. 109-110).

Rubinstein Reiss and Karako Eyal (2019, p. 374) also hold that the information provided to parents prior to the vaccination of their children should contain "the social nature of vaccination" and the benefits for the whole community arising therefrom. These authors studied how the process of providing consent to vaccination should look like. The ideal model enable parents to receive useful information on the nature of the vaccination of their children, direct benefits for vaccinated children and indirect benefits for a broader community as a result of developing herd immunity, and on the risks of vaccination. Since trust is a factor that affects parents' willingness to have their children vaccinated, transparency is of key importance; parents should not be informed only about the current knowledge of vaccines but also on the

unknown. In the short run, it will probably divert some people from vaccination, but the long-term effects should involve building of trust and satisfactory childhood vaccination coverage (Rubinstein Reiss & Karako-Eyal, 2019, p. 373). Physicians should respond appropriately to the parents' concern about the vaccination of their children and tackle their delusions (Rubinstein Reiss & Karako-Eyal, 2019, pp. 357; 415).

The above suggestions refer to the content of the public version of informed consent. As far as the form of informed consent to vaccination is concerned, the provided information should be readable, clearly formulated and conveyed "in an accessible language". It is important that parents have a chance to ask questions and that the provided information is adapted to the receiver. Written information might not be enough (Rubinstein Reiss & Karako-Eyal, 2019, p. 415).

Sawicki (2017, p. 41) argues that the model of providing informed consent to vaccination can be shaped by placing patients in the position of "societal stewards". Special attention should be paid to the fear that the debate over the social effects of vaccination will disrupt the doctor-patient relationship of trust. Physicians should primarily be faithful to their patient's interests. Does it mean that the ethical obligations of a physician must change (Sawicki, 2017, p. 41)? This new model necessarily aligns the obligation of physicians to act in the best interests of their patients and respect their autonomy with the obligation to act pursuant to the principle of justice (Sawicki, 2017, p. 41).

This is in line with the aforementioned Salzburg Declaration on Vaccination Acceptance, which instructs governments, policymakers, advocacy groups and educators to emphasize "community protection" of the public health law. Vaccination should be promoted as equivalent to "other essential public services like law enforcement, firefighting and sanitation" (Ratzan et al., 2019).

At this point, it should be examined if vaccination successfulness depends, among other things, on informed consent. Edward Jenner found the vaccine against small pox, which has saved countless lives so far, but in the key experiment, he tested the vaccine on a boy who was not capable of giving consent thereto. The positive correlation between the research subjects' consent and research usefulness is very dubious (Wellman, 1997, p. 85). It means that *(act) utilitarianism* cannot explain the importance of informed consent. Moreover, even if not accompanied with research subjects' consent, utilitarianism would justify all studies due to their ultimate benefits. This theory considers the risk borne by research subjects as irrelevant (Wellman, 1997, p. 86). Wellman emphasizes that research subjects' consent might increase the usefulness of the respective research if the research subjects are expected to actively cooperate with respect to providing answers to questions and taking

medications on a regular basis (Wellman, 1997, p. 85). Yet, this does not refer to the situation in which drugs are administered to a passive patient. Does this correspond to the situation in which a vaccine is injected into a passive patient? Parmet (2005) mentions an example from the American case-law, which indicates the importance of providing relevant information on vaccines before their administration. In the case of Kemp v. New Jersey (1997, 2002), the plaintiff was a high school girl who received the vaccine against rubella during the pregnancy and consequently, delivered a baby with "congenital rubella syndrome". An appropriate individualized approach to vaccination risk assessment should prevent the emergence of such injuries (Parmet, 2005, p. 96).

3.5. How are Parents Provided with Vaccine Information Today?

The 1986 National Childhood Vaccine Injury Act (hereinafter NCVIA) significantly changed the context of vaccination in the United States. This primarily refers to cases which revolve around harmful consequences for an individual after vaccination. The injured parties shall first go through a special administrative no-fault program: National Vaccine Injury Compensation Program; only if their application is not accepted, they can initiate a tort claim (Rubinstein Reiss & Karako-Eyal, 2019, p. 390; Tucak, 2017b, pp. 149-152).

With respect to the topic of this paper – informed consent, there have been some novelties as well. The Secretary of the Department of Health and Human Services shall prepare "information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table" (Rubinstein Reiss & Karako-Eyal, 2019, p. 391). The NCVIA requires from health care providers to deliver a copy of those materials to the person who is supposed to undergo vaccination or his/her legal representative (in most cases, it is a Vaccination Information Statement) prior to administration of each vaccine dose (Centre for Disease Control and Prevention, 2020a; Rubinstein Reiss & Karako-Eyal, 2019, p. 391). Centres for Disease Control and Prevention (hereinafter CDC) (2020b) produce Vaccination Information Statements (hereinafter VISs) and distribute them to competent state and local authorities and individual providers. Although serving to satisfy the need for information set out in the NCVIA, VISs do not represent an informed consent form. Yet, they resemble it since they provide information on the advantages and risks of vaccination (CDC, 2020c). Neither the law nor the relevant case-law could provide an answer to the question whether a VIS should be preceded by an oral discussion and when the parents should receive it (Rubinstein Reiss & Karako-Eyal, 2019, p. 393).

After adoption of the NCVIA, it did not come to explosion of case-law relating to providing informed consent to vaccination while the special administrative program governing claims resulting from an injury or death as a consequence of vaccination requires "showing causation and damages but does not require showing fault, which prevents discussion of informed consent questions in the cases". Moreover, Rubinstein Reiss and Karako-Eyal (2019, p. 398) could not find any case relating to informed consent, which suggests that individuals who have experienced vaccine injuries do not require compensation before national courts.

Mary Holland (2012, p. 79) claims that since the adoption of the NCVIA, the standards pertaining to the process of providing informed consent to the vaccination against hepatitis B in the United States have been "substantially relaxed".

> "The NCVIA does not require doctors or vaccine manufacturers to give complete warnings directly to the person or guardian of the child being vaccinated. It requires that doctors give government-produced information and requires that manufacturers provide proper warnings to doctors only, who are considered to be "learned intermediaries"."

As demonstrated above, initially the NCVIA prescribed that parents should be provided with more information on vaccination than they are provided now:

> "The initial versions were twelve pages long and required parental signature (...) Instead of ten information items, statements for parents now contained four: the benefits of the vaccine, the risks, one sentence about the VICP, and a reference to the CDC for further information. Parents' signatures were also eliminated" (Holland, 2012, pp. 79-80).

In Holland's opinion, applicable VISs mostly assure parents of vaccine safety. It is laid down that vaccination, like any other drug, implies "a very remote chance of … causing a severe allergic reaction, other serious injury, or death" (CDC, 2020d). Holland (2012, p. 80) concludes that pursuant to the former vaccine laws which had been in force until 1986, current Vaccine Information Statements would not even meet the "minimum requirements for duty to warn". The hepatitis B vaccine package lists a number of adverse effects: "A partial list of adverse events reported (…) include anaphylaxis, encephalitis, encephalopathy, paralysis, optic neuritis, multiple sclerosis and vasculitis" (Holland, 2012, p. 80).

Shapiro (2012) challenges Marry Holland's objections to the impairment of the process of providing informed consent considering the drug manufacturer's information on the risks of using their products and points out that any law stipulating prohibition of providing relevant "efficacy and safety information" on vaccines would be unconstitutional, which is not the case, however, with the provisions of the NCVIA. Though, thinks Shapiro (2012, p. 163), the legislator has

really "lowered the standard", but no legal system requires disclosure of every possible risk of vaccination.

As far as the Republic of Croatia is concerned, the issue of providing informed consent to vaccination has already been handled by the Constitutional Court. The Croatian Constitutional Court rejected, on 30 January 2014, the proposals for assessment of the constitutionality of particular provisions of the Act on the Protection of the Population against Communicable Diseases (2007-2009) and the Ordinance on the Manner of Carrying out Immunization, Seroprophylaxis and Chemoprophylaxis against Communicable Diseases, and on the Persons Subject to this Obligation (2004-2007). A lack of informed consent was one of the reasons why the applicants challenged the constitutionality of those regulations (Constitutional Court of the Republic of Croatia, U-I-5418/2008, U-I-4386/2011, U-I-4631/2011, U-II-4387/2011 U-II-4632/2011 of 30 January 2014).

According to the applicants' viewpoint, the Act and Ordinance did not foresee free choice when it comes to refusal of immunization. Pursuant to Article 10 of the Ordinance, the only legitimate exemption from vaccination concerns persons who are proved to be affected by medical contraindications. The applicants based their case on Article 21 paragraph 1 item 8 of the Healthcare Act (2003, 2005, 2006), which foresaw the right of a person to decline to be the subject of scientific research without her/his prior consent (paragraph 6. 1). The Croatian Constitutional Court regarded the application filed in this light as ill-founded. In its ruling (2008, 2014, paragraph 6.5), it highlighted that the Healthcare Act cannot be compared to the Act on the Protection of the Population against Communicable Diseases in the context of the protection of the population from infectious diseases:

> "In fact, vaccination is an obligation of providing and accepting a medical service of standardized quality and with identical content with respect to all people who shall submit thereto based on and in the sense of applicable provisions of the Act on the Protection of the Population against Communicable Diseases".

In its ruling, the Croatian Constitutional Court did not emphasize the importance of providing adequate information to the patient prior to vaccination in a manner tailored to his individual needs and circumstances. In this context, a good example can be found at the Hungarian Constitutional Court which in its decision on compulsory vaccination emphasized the importance of the right to health information provided to a competent individual on the basis of the constitutional right to dignity and self-determination, and in case of persons who do not have "discretionary capacity", the importance of their right to information in accordance with their age and condition on the ground of the right to personal integrity. The right to information exists even in the event of vaccination as a mandatory epidemiological measure which,

according to Hungarian legislation, does not require consent. In addition, the Hungarian Constitutional Court (2007, paragraph 6.1.; Tucak 2017a, pp. 159-160) noted that "the provision of information is a precondition for the effectiveness and success of medical treatment because an appropriately informed person shows more trust regarding the professionals involved in the treatment and is better at complying with the doctors' instructions".

At the end of this section of the paper, it is important to mention the first judgment of the European Court of Human Rights on compulsory vaccination of children, Vavřička and Others v. The Czech Republic of April 2021. The Court ruled that the Czech Republic did not violate the Convention on Human Rights and Fundamental Freedoms by imposing compulsory vaccination of children and noted the existence of a "positive obligation" of states under Article 2 (right to life) and Article 8 (right to respect for private and family life) of the Convention to take appropriate measures to protect the lives of their population (paragraph 282). It therefore concluded that the measures introduced by the Czech Republic were "in a reasonable relationship of proportionality to the legitimate aims pursued by the respondent State through the vaccination duty" (paragraph 309).

4. Conclusion

Informed consent is highly valuable both for medical practice and law (Gostin, 2015, p. 2). It represents a guarantee of the protection of the integrity and personal safety of its holder (Shapiro, 2012, pp. 162-164). Nevertheless, the possibility of its use in the area of public health is still vague (Wilen Berg, 2012, p. 2). Much work remains to be done in exploring this topic. Individual decisions on vaccination affect the health of other people (Sawicki, 2017, p. 42). It can often be heard that the successfulness of public health measures depends on their uniform implementation, which disqualifies the use of informed consent in this context. Individual consent, as asserted by O'Neill, does not support a coherent and acceptable approach to providing services in the sphere of public health (O'Neill, 2004, p. 1136).

This paper demonstrates that informed consent can play an important role in the implementation of public health policies. The assumption that comprehensive information on vaccines will scare the parents away from the vaccination of their children does not sound persuasive any more. This mostly results from the contemporary development of law and bioethics.

A proper version of informed consent, formulated for childhood vaccination purposes, may largely contribute to enhancing the parents' and public trust in health care providers, which should ultimately result in a higher immunization rate. Health

care providers should adequately inform parents on all known and unknown risks of the vaccination of their children and appertaining discomfort, and should always be willing to answer parents' questions. The parents' concern for the vaccination of their children should be seriously considered and all received misinformation should be dealt with (Rubinstein Reiss & Karako-Eyal, 2019, p. 370). Empirical research has confirmed the relevance of the information on vaccination, given by health care providers, as an incentive to the parents to have their children vaccinated (Rubinstein Reiss & Karako-Eyal, 2019, p. 367). Furthermore, parents ought to be introduced to the social consequences of their decisions; they should be provided with information assuring them that the vaccination of their children will protect the members of their community with no adequate immunity and hence minimise the possibility of disease outbreak and decrease the mortality; this will as well bring to reduction of healthcare costs and thus contribute to the economic development of a society (Rubinstein Reiss & Karako-Eyal, 2019, p. 374). As Sawicki (2017, p. 41) argues, informed consent to vaccination should be designed in a way that patients assume the role of "societal stewards". This new model necessarily aligns the obligation of physicians to act in the best interests of their patients and respect their autonomy with the obligation to act pursuant to the principle of social justice (Sawicki, 2017, p. 41).

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Informirani pristanak i javno zdravlje: slučaj cijepljenja djece

SAŽETAK

Informirani pristanak, koji prvenstveno ima za cilj potaknuti pojedine pacijente i subjekte znanstvenog istraživanja na donošenje autonomnih odluka, i javnozdravstvene mjere poput obveznog cijepljenja protiv zaraznih bolesti, čija uspješnost podrazumijeva usklađenu distribuciju cjepiva široj populaciji, čine se na prvi pogled kao nepomirljive suprotnosti. Rad istražuje mogu li se te suprotnosti pomiriti, tj. može li se informirani pristanak primijeniti u području javnog zdravstva.

U prvom dijelu rada daje se kratak pregled glavnih značajki informiranog pristanka i njegove važnosti u liječenju pacijenata. Drugi dio rada bavi se pitanjem imunizacije. Ako nemaju pristanak pacijenata i ne postoji zakonska obveza cijepljenja, smatra se da liječnici prilikom cijepljenja zadiru u tjelesni integritet drugih osoba te se njihov čin može smatrati napadom i povlačiti naknadu nematerijalne štete. Imunitet krda kao "javno dobro" može se postići samo ako svi ljudi podjednako podliježu javnozdravstvenim mjerama. U ovom trenutku, ključno je pitanje predstavljaju li informirani pristanak i pripadajuća sloboda odlučivanja prijetnju ostvarivanju ovog javnozdravstvenog cilja.

Na ovo pitanje doista treba odgovoriti jer cijepljenje može, iako rijetko, dovesti do medicinskih komplikacija, koje potom mogu dovesti do visokih troškova liječenja, gubitka prihoda i, iznimno rijetko, do smrti. Svrha ovog rada je pokazati da bi otkrivanje rizika i dobrobiti imunizacije u okviru javnozdravstvenih programa moglo pridonijeti provođenju temeljnih bioetičkih postulata u praksi: uspostavljanju i njegovanju međusobnog povjerenja između liječnika i pacijenata, što sve može pridonijeti višoj stopi procijepljenosti stanovništva.

Ključne riječi: informirani pristanak, obvezno cijepljenje, povjerenje, javnozdravstvene politike, javno dobro.