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MEDICAL DECISION-MAKING AND CHILDREN[****]

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Pediatric medical decision making has been a matter of discussion for the last few decades. Generally, the currently prevailing viewpoints are that the children's wishes should be heard and that children should be allowed to participate in medical decision-making according to their development. Those discussions do not only touch on ethical, legal and political matters, but are also based on empirical research. There are no simple answers to those large issues, especially the age limit at which children can be considered capable of giving informed consent. In that context, a balance needs to be struck between the protection of children's interests and the respect for their "developing autonomy". The first part of this article outlines the principle of autonomy that informed consent is based on, whereas the second part focuses on two concepts: that of parental permission and of assent of the child, both of which are well-known in the contemporary medico-legal realm. The term "assent" is commonly used in cases when individuals are not legally allowed to give informed consent but are capable of taking part in the process of medical decision-making.

In the third part of the paper, three Croatian legal acts were analyzed in a context of the informed consent of the child: the Protection of Patient's Rights Act, the Family Act and the Civil Obligations Act. The fact that several legal regulations, in particular the Protection of Patient's Rights Act, the Family Act and the Civil Obligations Act, must be used in parallel when it comes to the issue of informed consent of a child, can be, legally speaking, quite confusing. Thus, such regulation may leave some doubts and difficulties in the immediate application, especially with regard to emergency medical interventions. In this regard, perhaps the fact of adopting a special law on the consent of children to medical procedures could be considered, or at least the provision within the Family Act or the Protection of Patient's Rights Act, which uniformly summarizes all the above regulations.

Key words: *autonomy, informed consent, child assent, parental permission, capacity*

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1. INTRODUCTION

Informed consent is one of the foundations of the ethical practice of medicine[1]. A concept that was unknown until just a few decades ago, it has profoundly affected modern medical practice and empowered patients to take a more active role in issues regarding their health[2]. Historically, informed consent came to be as a response to Nazi atrocities[3]. The Nuremberg Code, considered one of the most important documents in the history of the ethics of medical research, established ten guidelines for ethical research – the first guideline being the "voluntary consent" of the subject[4].

Ever since – especially backed by the ethical idea of personal autonomy[5] – the concept of informed consent developed even more, and thus became one of the key mechanisms by which research subjects and patients exercise their power [6]. Over the past seventy years, this term has been incorporated into numerous international treaties, national legal acts, and ethical guidelines as a mechanism to protect vulnerable individuals from exploitation and harm[7].

However, the concept of voluntary participation in pediatric treatments and research is not accompanied by abundant scientific analysis, as is the case with the informed consent of adult individuals. Today, one can find much more published literature on the topic of informed consent of adult individuals than on the topic of parental medical decision-making, i.e., the inclusion of children and adolescents in medical decision-making[8].

The first part of this article outlines the principle of autonomy that informed consent is based on, whereas the second part focuses on two concepts: that of parental permission and of assent of the child, both of which are well-known in the contemporary medico-legal realm. In the third part of the paper, three Croatian legal acts were analyzed in a context of the informed consent of the child: the Protection of Patient's Rights Act, the Family Act and the Civil Obligations Act.

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[1] Kodish E., *Informed Consent for Pediatric Research: is it really possible*?, The Journal of Pediatrics, vol.142, no. 2, 2003, p. 89.

[2] *Ibid.*

[3] Kodish E., *Pediatric Ethics and Early-Phase Childhood Cancer Research: Conflicted Goals and the Prospect of Benefit*, Accountability in Research, vol. 10, no. 1, 2003, p. 18.

[4] Shuster E., *Fifty years later: the significance of the Nuremberg Code*, The New England Journal of Medicine, vol. 337, no. 20, 1997, p. 1436.

[5] Katz A. L. and Webb S. A., *Informed Consent in Decision-Making in Pediatric Practice*, Pediatrics, vol. 138, no. 2, 2016, p. 2.

[6] Kodish, *op. cit.*, note 1, p. 89.

[7] Corrigan O., *Empty ethics: the problem with informed consent*, Sociology of Health & Illness, vol. 25, no. 3, 2003, pp. 768–792.

[8] Institute of Medicine (US) Committee on Clinical Research Involving Children, Field M. J., Behrman R.E. editors. Ethical Conduct of Clinical Research Involving Children, Washington (DC), National Academies Press (US), 2004, p. 159.

2. THE PRINCIPLE OF AUTONOMY

The principle of autonomy, as a fundamental ethical, legal and political concept in Western culture, is interpreted in various ways[9]. In clinical ethics, it is usually interpreted as the patient's right to make decisions according to his own principles and thus bear responsibility for the consequences arising from those decisions[10].

According to liberal theory, we are required to "always respect the humanity in all persons", that is, to "respect all persons equally as Ends-in-Themselves"[11]. According to Kant, "humanity is essentially the same as rational nature, i.e., the ability to be autonomous, self-legislating". It follows that the meaning of the formula treating an individual as "an End-in-Itself" actually means "treating him as an autonomous being, capable of self-legislation"[12].

Autonomy is in practice "exercised through informed consent or informed refusal"[13]. The goals of informed consent in clinical practice are to promote and protect the patient's health and to engage him in medical decision-making[14]. There are four necessary conditions for the legitimacy of this process: the patient must have decision-making capacity and there should be "adequate disclosure of information with its adequate understanding and voluntariness[15]."

The main issue with pediatric treatments and research is the autonomy-based model of informed consent[16]. According to Kant, children and adults differ in that children are heteronomous and adults are autonomous - "a child finds the rule (*nomos*) of his moral conduct in another (*eteron*) person whereas adults are able to find this same rule (*nomos*) in themselves (*auton*)"[17].

Adults are presumed competent to make decisions regarding their health, while children are not[18]. To put it in other words: children lack the legal capacity to provide informed consent[19]. It is obvious, both theoretically and practically, that children

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[9] Rus M. and Groselj U., *Ethics of Vaccination in Childhood-A Framework Based on the Four Principles of Biomedical Ethics*, Vaccines (Basel), vol. 9, 2021, p. 3. On the concept of autonomy see also Tucak I., *Cultural Differences and Informed Consent* in Steger, F. *et al.* (eds.), *Migration and Medicine*, Karl Alber, München, 2020, pp. 65-86; Tucak I. *Ograničenje autonomije u javnom zdravstvu: obavezno vakcinisanje dece*, Zbornik radova - Pravni fakultet u Novom Sadu, vol. 50, no. 2, 2016, pp. 621-645.

[10] *Ibid.*

[11] Van der Rijt, J., *The Importance of Assent: A Theory of Coercion and Dignity*, Springer Netherlands, 2012, p. 73.

[12] *Ibid*. p. 74.

[13] Rus *et al*., *op. cit*., note 9, p. 3.

[14] Katz, *op. cit*., note 5, p. 2.

[15] Rus *et al*., *op. cit*., note 9, p. 3.

[16] Kodish, *op. cit*., note 1, p. 89.

[17] Turoldo, F., *Relational Autonomy and Multiculturalism*, Cambridge Q. Healthcare Ethics, vol. 19, 2010, p. 543.

[18] Henkelman J. J. and Everall R. D., *Informed Consent with Children: Ethical and Pratical Implications*, Canadian Journal of Counselling, vol. 35, no. 2, 2001, p. 111.

[19] Field *et al.*, *op. cit.*, note 8, p. 196.

are a group that has to rely on others to protect their interests, they need protection and guidance[20].

Psychologists talk about "progressive and gradual growth towards autonomy"[21]. The capacity of children to be autonomous is gradually improving, "shifting from moral behavior based essentially on the authority of the adult to more mature moral behavior based on responsibility towards others and on objective moral rules"[22]. It is important to note that this process never ends, that is, that we never become completely autonomous[23].

It is also important to note here that the terms "capacity" and "competence" are often used vaguely or confusingly[24]. "Capacity is a clinical determination that addresses the integrity of mental abilities, and competence is a legal determination that addresses society's interest in restricting decision-making when capacity is in question"[25]. Whether children are competent or incompetent is a normative judgment[26]. Pediatricians need to determine whether children are "capable of making health care decisions", while it is up to the courts to "determine competence" to consent, refuse or dissent to medical treatment[27]. Even a legally incompetent individual can have "decision-making capacity"[28]. Capacity "is not an all-or-none phenomenon and is relatively task specific"[29]. It "depends on a context"[30]. In order to make a medical decision, patients need to have "a minimum level of capacity to receive information, understand it, make their choices and articulate them"[31]. Neither capacity nor competence is a permanent category and should be assessed regularly over the course of the disease[32].

Research on the difference between children and adults in terms of their competence to make medical decisions has shown that children have difficulty "to restrain impulsivity" and "to place a given decision in a larger temporal context" or that they have difficulty understanding the long-term consequences of their choices[33].

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[20] Salas H. S., Aziz Z., Villareale N. and Diekema D. S., *The Research and Family Liaison: Enhancing Informed Consent*, IRB, Ethics & Human Research, vol. 30, no. 4, 2008, pp. 1-8; Van der Rijt, *op. cit.*, note 11, p. 73.

[21] Turoldo, *op. cit.*, note 17, pp. 543-544.

[22] *Ibid.* p. 544.

[23] *Ibid.*

[24] Katz *et al., op. cit.*, note 5, p. 3.

[25] *Ibid.*

[26] Hein I. M., De Vries M. C., Troost P. W., Meynen G.,Van Goudoever, J. B and Lindauer, R. J. L., *Informed consent instead of assent is appropriate in children from the age of twelve: Policy implications of new findings on children's competence to consent to clinical research*, BMC Med Ethics, vol. 16, no. 1, 2015, p. 1.

[27] Katz *et al., op. cit.*, note 5, p. 3.

[28] *Ibid.,* pp. 3-4.

[29] *Ibid*. p. 4.

[30] Rus *et al., op. cit.*, note 9, p. 3.

[31] *Ibid.*

[32] Katz *et al., op. cit.*, note 5, p. 4.

[33] Hein *et al., op. cit*. note 2, p. 5.

3. PARENTAL PERMISSION AND CHILD'S ASSENT

In the context of pediatric treatment and research, it is common today to use the terms "parental permission" and "child's assent" instead of the term "informed consent". These terms were introduced by the American Academy of Pediatrics statements on informed consent in 1976[34] and 1995[35] and reaffirmed in 2016.[36] The Confederation of European Specialists in Pediatrics also confirmed that children should have the right to give their assent or dissent. In acute and life-threatening situations no parental permission (and therefore no child's assent) is required[37]. For example, according to the Confederation of European Specialists in Pediatrics, unlike adult individuals, children cannot refuse medical intervention that would save their lives or prevent serious harm[38].

Today, many other international documents include the term assent[39]. Among the most prominent are the WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, 2013 (hereinafter Declaration of Helsinki) and International Ethical Guidelines for Health-related Research Involving Humans, Council for International Organizations of Medical Sciences (hereinafter CIOMS International Ethical Guidelines) in collaboration with the World Health Organization (WHO), 2016. The Declaration of Helsinki states: "When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected" (Par. 29).

According to the CIOMS International Ethical Guidelines (Guideline 17):

"Before undertaking research involving children and adolescents, the researcher and the research ethics committee must ensure that a parent or a legally authorized representative of the child or adolescent has given permission; and that the agreement (assent) of the child or adolescent has been obtained in keeping with the child's or adolescent's capacity, after having been provided with adequate information about the research tailored to the child's or adolescent's level of maturity".

To summarize, on the one hand, according to these documents, before performing a medical intervention on a pediatric patient, it is necessary to obtain informed permission from his / her parents or legal guardians, and, on the other hand, they

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[34] American Academy of Pediatrics, Consent, Pediatrics, 1976, 57(3), pp. 414–416.

[35] American Academy of Pediatrics, Committee on Bioethics, Informed consent, parental permission, and assent in pediatric practice, Pediatrics, 1995, 95 (2), pp. 314–317.

[36] Katz *et al., op. cit*., note 5, p. 1; Grošelj U., *The concepts of assent and parental permission in pediatrics*, World J Pediatr, vol 10, no 1, 2014, p. 89; Rus *et al., op. cit.*, note 9, p. 3; American Academy of Pediatrics, *op. cit.*, note 35, pp. 314-317.

[37] de Vos M. A., Seeber A. A., Gevers S. K. M., Bos. A. P., Gevers F. and Willems D. L., *Parents who wish no further treatment for their child*, Journal of Medical Ethics, vol. 41, 2015, p. 197.

[38] Grošelj, *op. cit.*, note 36. p. 89.

[39] Krajnović D., Arsić J., *Etička pitanja u pedijatrijskim kliničkim studijama: izazovi i problemi kod pacijenata s rijetkim bolestima*, Jahr: Europski časopis za bioetiku, vol. 5, no. 2, 2014, pp. 277-289.

confirm that patients must participate in medical decisions according to their development - "they should provide assent to care whenever reasonable"[40].

Child assent means "affirmative agreement of a minor" who is participating in the informed consent procedure, and parental permission "means the agreement of parent(s) or guardian to the participation of their child or ward" in the informed consent procedure[41].

Informed consent, in regard to pediatric ethics, is thus considered "a combination of informed parental permission and (when appropriate) the assent of the child"[42]. Same standards apply to both informed parental permission and informed consent, but informed parental permission is ethically distinct from consent[43]. Some authors use the terms "consent by proxy" and "parental consent" to describe informed parental permission, but others consider those terms as wrong and an oxymoron[44]. Consent cannot be given for another person. Parents can give informed consent only for themselves because they are held competent by law to be autonomous decision-makers, while children (minors) are not[45].

Before giving their informed parental permission, the parents should receive the same information and disclosures as if they were consenting for themselves[46]. Briefly said – all the criteria that make informed consent valid (disclosure, understanding, voluntariness, and competence) apply to informed parental permission as well[47].

In pediatric practice, it is important that children gradually become more engaged in decision-making in accordance with their "developmental maturation"[48]. Today, it is considered unquestionable that a patient should give his or her informed consent before undergoing a medical procedure, and when it comes to a medical procedure on a child, that parental permission should be obtained before the child undergoes the procedure. It is equally important to insist on obtaining a child's assent[49]. Assent serves as respect to the child's developing autonomy[50]. Physicians should provide information to children "in an age-appropriate and descriptive manner"[51]. The informed consent standards apply here as well, but they are a bit more nuanced, considering that children lack competence. Children should receive as much information about their health condition/treatment/research as possible for them to understand their alternatives, and then make an informed and voluntary

[40] Katz *et al., op. cit.*, note 5, p. 1.
[41] Hein *et al., op. cit.*, note 26, p. 4; Guidelines from the US - 45 CFR 46.
[42] Kodish, *op. cit.*, note 1, p. 90.
[43] Roth-Cline M. and Nelson R. M., *Parental Permission and Child Assent in Research on Children*, Yale Journal of Biology and Medicine, vol. 86, 2013, p. 293; Field *et al., op. cit.*, note 8, p. 148.
[44] Kodish, *op. cit.*, note 1, p. 90.
[45] Field *et al., op. cit.*, note 8, pp. 148-149.
[46] *Ibid*, p. 154.
[47] Kodish, *op. cit.*, note 1, pp. 89-90.
[48] Katz *et al., op. cit.*, note 5, p. 8.
[49] Grošelj, *op. cit.*, note 36, p. 89.
[50] Field *et al*., *op. cit.*, note 8, p. 148.
[51] Katz *et al*., *op. cit.*, note 5, p. 3.

choice[52]. More precisely, assent in paediatric decision-making should consists of the following elements: it should enable the patient to reach "appropriate awareness" of his condition in accordance with his development; explain the importance of test results and treatments; provide "a clinical assessment of the patient's understanding of the situation"; and seek "the patient's willingness to accept the proposed care"[53].

The relevant age when a child should be asked for its assent has not been universally agreed upon[54]. It can be said that there is a consensus that "the evolving abilities of children and adolescents are reflected by a gradual development of decision-making capacities"[55]. For example, the United States federal regulations prescribe that the institutional review boards in determining which children are capable of assent "shall take into account the ages, maturity, and psychological state of the children involved"[56]. Some point out that the seventh year of life represents a milestone. This claim is based on the "Rule of Sevens" which originated in the 14th century during the reign of Edward the Third[57]. In 1987, in its decision in the *Cardwell v. Bechtol* case, the Tennessee Supreme Court upheld the rule of sevens in regard to children's assent. The rule of sevens, an already very known rule in the common law at that point[58], states that children under the age of 7 have no capacity; that children aged from 7 to 14 are presumed to have a lack of capacity, but it may be proven otherwise; and finally that children over the age of 14 are presumed to have capacity, but it may be proven otherwise[59].

There is controversy over whether a fixed age limit should be set for assent or whether the system should be set up on a case-by-case basis[60]. Hein *et al.* find justification for "a fixed age limit" in the claim "that age is an efficient indicator of competence." This rule also has its practical advantages in the administrative and legal context, as it can be easily determined.

Nevertheless, its disadvantage is that it does not take into account the existing differences between individuals[61]. The child's assent should also be a unique process, since every child has a different level of competency[62]. For example – even

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[52] Pelčić G., Aberle N., Pelčić G., Vlašić-Cicvarić I., Kraguljac D., Benčić I., Gjuran Coha A. and Karačić S., *Croatian Children's Views towards Importance of Health Care Information*, Collegium Antropologicum, vol. 36, no. 2, 2012, p. 544.

[53] Katz *et al*., *op. cit.,* note 5, p. 8

[54] Hastings Y. D., Bradford N. K., Lockwood, L. R., Ware, R. S. and Young, J., *Parental perceptions of the informed consent process in pediatric oncology clinical trials*, Journal of Nursing Education and Practice, vol. 3, no. 11, 2013, p.73.

[55] Hein *et al*., *op. cit.*, note 26, p. 3.

[56] Department of Health and Human Services,11 45 CFR 46.608a; Wendler D. S., *Assent in paediatric research: theoretical and practical considerations*, J Med Ethics, vol. 32, no. 4, 2006, p. 229.

[57] *Ibid.*, p. 230.

[58] Cardwell v. Bechtol, 724 S.W.2d 739 (1987), Supreme Court of Tennessee, at Knoxville.

[59] Katz *et al., op. cit.*, note 5, p. 7.

[60] Hein *et al., op. cit*., note 26, p. 5.

[61] *Ibid.*, 3-4.

[62] Hastings *et al., op. cit.*, note 54, p. 73.

some very young children may have the capability of making decisions in certain situations, like simple interventions[63].

This means that when we firmly set the age limit for providing assent, some individuals who are competent to make decisions will be excluded because they are below the current age limit, and some who are above "that limit will unjustly be deemed competent"[64]. "A case-by-case assessment of decision-making competence" also has its advantages and disadvantages[65]. It consists in finding objective assessment methods instead of the intuitive ones that are dominant today. Such a way of assessing the competence of pediatric patients "would impose a heavy burden on patients, professionals, and the medical system". Therefore, the wide application "of a standardized competence assessment" is not recommended. It is more convenient to use it only in exceptional situations[66].

When we talk about competence to assent, we must also mention competence to refuse or dissent[67]. Assent has three major purposes: its first purpose is to provide information to the child, its second purpose is to create a shared decision-making process with the parents and the child, and its third purpose is to honour the child's dissent[68]. "When we indicate competence to consent, we also consider competence to refuse or dissent"[69].

It is important to note that the child's mere failure to object should not be considered as assent[70]. As for dealing with the child's dissent – the rules also vary greatly from country to country. Dissent should especially carry weight if the proposed intervention is not mandatory[71].

The rules for dealing with the child's dissent also vary greatly from country to country. We will focus here on some international guidelines. It is interesting to mention here the European Convention on Human Rights and Biomedicine of the Council of Europe[72]. Although this Convention does not explicitly mention child assent and stipulates that intervention on a minor may be carried out only with the authorization of a legal representative, it also stipulates that "the 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" (Article 6, par. 2). However, it also stipulates that the authorization of the intervention cannot be withdrawn at

[63] Leikin, S., *Minors' Assent, Consent, or Dissent to Medical Research*, IRB, Ethics & Human Research, vol. 15, no. 2, 2013, p. 4.

[64] Hein *et al., op. cit.,* note 26, p. 4.

[65] *Ibid.*

[66] *Ibid.* p. 5.

[67] *Ibid.* p. 2.

[68] Leikin, *op. cit.* note 63, p. 5.

[69] Hein *et al., op. cit.,* note 26, p. 2.

[70] Field *et al., op. cit.*, note 8, p. 205.

[71] Katz *et al., op. cit.*, note 5, p. 8.

[72] Stultiëns L., Goffin T., Borry. P, Dierickx K. and Nys H., *Minors and informed consent: a comparative approach*, Eur J Health Law, vol. 14, no. 1, 2007, p. 22.

any time, as is the case with adults, but can be withdrawn "at any time in the best interests of the person concerned" (Article 6, par. 5).

According to CIOMS International Ethical Guidelines (Commentary on Guideline 16, p. 62), "Any explicit objection by persons who are incapable to give informed consent must be respected even if the legally authorized representative has given permission. An explicit objection may be overruled if the incapacitated person needs treatment that is not available outside the context of research, prior research has demonstrated a significant benefit (…), and the treating physician and the legally authorized representative consider the research intervention to be the best available medical option for the person lacking capacity".

In some situations, minors can become emancipated and make decisions as if they were mature – including giving informed consent[73]. While those situations are differently defined in every country, the most usual examples are if the minor is in the military, if the minor is a parent or is pregnant, or the minor is declared emancipated by the court, etc.[74]. Also, some states give decision-making abilities to minors who are seeking treatment for drug and/or alcohol abuse[75]. The same goes for giving consent for health care needs regarding sexual activity (for example, the provision of contraceptive services or treatment for sexually transmitted diseases)[76]. In some states, minor parents are able to give legal permission for their child to undergo medical treatment but do not have the same right to do so for themselves[77].

The main problem with the idea of informed assent is that there are no simple answers to some major questions regarding assent, for example, the minimum age at which a child is capable of giving assent/consent, how to objectively assess whether children are competent to make different medical decisions, or how the disagreements between parents and children should be resolved[78].

Whether a child is competent or incompetent is a normative question, but that does not mean that it cannot be substantiated by objective data from empirical research[79]. Some authors argue that children's ability to make medical decisions can be properly assessed using instruments such as the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR)[80][81]. But the use of such

[73] Field *et al., op. cit.*, note 8, p. 157.

[74] American Academy of Pediatrics, *op. cit.*, note 35, p. 316.

[75] *Ibid.*

[76] Katz *et al., op. cit.*, note 5, p. 9.

[77] Field *et al., op. cit.*, note 8, pp. 157-158.

[78] Roth-Cline, *op. cit*., note 43, p. 296; Hein et al., *op. cit.*, note 26, p. 2.

[79] *Ibid.*

[80] "The MacCAT-CR is a semistructured interview format developed by Appelbaum and Grisso in 2001, which measures the four aspects of decision-making capacities that reflect the standards for competence in most jurisdictions (understanding the disclosed information about the nature and procedures of the research; reasoning in the process of deciding about participation; appreciation of the effects of research participation on the patient's own situation; and expressing a choice about participation)".

[81] Hein *et al., op. cit.,* note 26, p. 2.

instruments also has its critics. Thus, it is emphasized that MacCAT-assessment gives priority to "rational reasoning" over values and emotions[82].

3.1. The parents' responsibility to make medical decisions for their children

Parental responsibility to make a medical decision for their child in the treatment context is shared with physicians[83]. As already emphasized, parents must provide informed permission before a medical procedure that includes all elements of informed consent[84]. The only exceptions to this are emergency situations. It is emphasized that doctors and parents are "in the fiduciary relationship" with the child, which means that they must act in his best interests, subordinating their own interests[85]. In doing so, they must not only promote his health interests but also "the non-health-related interests"[86].

Informed permission must reflect the best interests of the child[87]. The best interest standard has been used with regard to incompetents and minors much earlier than the principles of autonomy and privacy[88]. Parents had a "responsibility to act in their children's best interests"[89].

The legal presumption is that parents regularly act in the best interests of their children. The state may intervene in this relationship only in exceptional cases where there is disagreement between the state and the parents regarding medical decisions that may have serious consequences for the child[90]. The parental responsibility is therefore not an absolute right[91]. According to the doctrine of *parens patriae*, the state "has a societal interest in protecting the child from harm" that may be caused by the exercise of parental authority[92]. Thus, "parental decision-making" should be seen primarily as their responsibility to support the best interests of the child and preserve family relationships[93]. Parental permission does not consist of "their rights to express their own autonomous choices"[94].

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[82] *Ibid.* p. 3.

[83] Grošelj, *op. cit.*, note 36, p. 89.

[84] *Ibid.*

[85] Katz *et al., op. cit.,* note 5, p. 2.

[86] *Ibid.*

[87] Grošelj, *op. cit.*, note 36. p. 89.

[88] Beauchamp, T. L., Childress, J. F., *Principles of biomedical ethics*, 5th ed, Oxford, Oxford University Press, 2001, p. 102.

[89] *Ibid.*

[90] *Ibid.*

[91] Katz *et al., op. cit.*, note 5, p. 5.

[92] *Ibid.*

[93] *Ibid.;* Nelson R. H., Moore B., and Blumenthal-Barby J., *Pediatric Authenticity: Hiding in Plain Sight*, Hastings Center Report 52, no. 1 (2022), pp. 42-43.

[94] Katz *et al., op. cit.*, note 5, p. 5.

The dominant position is that in case the patient does not have the capacity to provide informed consent, the decision to do so is assigned to a surrogate[95]. Surrogates, when making decisions, must first "apply the patient's known wishes, ideally expressed formally in advance care planning documentation"[96]. If these wishes are unknown or unclear, "the surrogate should make a substituted judgment" by asking himself what the patient's wishes were and what decision he would make if he had decision making capacity[97] [98]. This standard is appropriate for adult individuals who once had the capacity for medical decision making, but not for children and adolescents as most of them have not yet expressed their preferences that would reflect their values[99] [100].

For these patients who are not fully autonomous and whose preferences are unknown, surrogates are unable to make substituted judgments. Medical decisions relating to them must be made in accordance with the standard of best interest[101]. The decision maker must "determine the net benefit for the patient of each option, assigning different weights to the options to reflect the relative importance of the various interests they further or thwart, then subtracting costs of disbenefits"[102].

It is important to note that there are several approaches to the application of the best interest standards[103]. According to the narrow approach, parents should take into account the best medical interests of the child in complete isolation without taking into account other interests, for example, financial or the child's family. In a broader sense, parents should take into account the child's "emotional, social, and medical concerns along with the interests of the child's family" when making a medical decision[104].

Some authors for making medical decisions for pediatric patients mention another standard - authenticity[105]. It is considered particularly relevant in the context of children who are too young to be able to provide assent to treatment[106]. This approach, in contrast to the standard of best interest and substituted judgment, does not focus on the question of what is best for the pediatric patient or what he would decide, but focuses on the question of "what is most consistent with who this patient is"[107].

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[95] Nelson *et al, op. cit*. note 93, p. 43.
[96] *Ibid.*
[97] *Ibid.* p. 43.
[98] Katz *et al., op. cit*., note 5, p. 5.
[99] *Ibid.*
[100] Nelson *et al, op. cit*., note 93, p. 42.
[101] *Ibid.* p 43.
[102] *Ibid.*
[103] *Ibid.* p. 44.
[104] *Ibid.*
[105] Haupt L., *From the Editor, Authenticity and Clinical Decision-Making*, Hastings Centre Report, January-February 2022, p. 2.
[106] *Ibid.*
[107] Nelson *et al, op. cit.*, note 93, p. 42.

Authenticity, as a guiding principle for medical decision-making, is not a completely new approach as some authors have already suggested its use in "adult surrogate decision-making"[108]. Authenticity is "a normative ideal"[109]. According to Nelson, Moore, and Blumenthal-Barby, authenticity is an "a descriptive cluster concept" that encompasses a number of features important to a child's well-being – "a child's authentic self consists of that which makes her the individual she is, which may involve her likes and dislikes, disposition, plans, abilities, behaviors, relationships, and personality"[110]. Such a definition allows even young children to have "more- or less-well-established authentic selves" which may be relevant when making a medical decision for them[111]. The authors acknowledge that their understanding of authenticity is close to the American Psychological Association's definition of personality[112]. Authenticity, these authors point out, differs from assent in two respects. First, it can guide decision-making for patients who cannot provide assent, and second, in some cases, pediatric patients have the capacity to make medical decisions "but lack insight into which treatment options best align with who they are as an individual"[113].

4. PRIVATE (CIVIL) LAW FRAMEWORK OF INFORMED CONSENT OF A CHILD IN THE REPUBLIC OF CROATIA

4.1. Positive legal regulations – considerations and questions

In the context of consent, in the doctrine of civil law in general[114] [115] [116], as well as in Croatian positive civil law regulations[117] the Roman principle *qui tacet consentire videtur* was abandoned[118], stating that the will may be expressed "in words, usual signs or other conduct from which it can be concluded with certainty about its existence, content and identity of the declarant"[119]. In addition to the above general provisions contained in the Civil Obligations Act, the main sources that are regulating the concept of patient's consent to a medical procedure in the Republic

[108] *Ibid.* p. 43.
[109] *Ibid.* p. 46.
[110] *Ibid.*
[111] *Ibid.*
[112] *Ibid.* pp. 47-48.
[113] *Ibid.* p. 48.
[114] Vedriš, M., Klarić, P., *Građansko pravo*, Narodne novine, Zagreb, 2014, p. 130.
[115] Flume, W., *Allgemeiner Teil des Bürgerlichen Rechts*, Springer-Verlag Berlin Heidelberg GmbH, 1992, pp. 64-65.
[116] Bydlinski, F., *Bürgerliches Recht,* Band I. Algemainer Teil, Springer, Wien, New York, 2007, pp. 122-123.
[117] In the Civil Obligations Act, Official Gazette, No. 35/2005, 41/2008, 125/2011, 78/2015, 29/2018, 126/2021
[118] Two exceptions expressed in Art. 265, par 3 and 4 of the Civil Obligations Act
[119] Art. 249. par 1 of the Civil Obligations Act; Gavella, N., *Privatno pravo*, Narodne novine, Zagreb, 2019, pp. 235-236.

of Croatia are the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: the Convention on Human Rights and Biomedicine[120], the Protection of Patient's Rights Act[121] and the Protection of Persons with Mental Disorders Act[122].

Due to Article 5 of the Convention on Human Rights and Biomedicine "an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as its consequences and risks. The person concerned may freely withdraw consent at any time." The Convention does not give an unambiguous answer to the question of whether a child is capable of giving consent to a medical procedure, but leaves it to national legislation to regulate the issue of a child's consent to a medical procedure[123]. Nevertheless, the great value has the rule contained in the Convention under which "the opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity (article 6, par. 2)[124]." The incorporation of that provision could be seen in the Family Act[125] in article 86. where "parents and other persons caring for a child are required to respect the child's opinion in accordance with his age and maturity (par. 1)." Also, "in all proceedings in which is being decided about a child's right or interest, the child has the right to find out the important circumstances of the case in a convenient way, to obtain advice and to express his / her opinion and to be informed of the possible consequences of his / her opinion. The child's opinion is taken into account in accordance with his age and maturity (par. 2)." That is a sustainable and important base of informed consent of a child that will be elaborated on further. We also have to mention the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) as an important source of EU legislation.

There is no special legal act that regulates the issues of the child's consent to medical procedures, which, further analysis will show, proves to be a possibly confusing solution in the direct application of specific legal rules. In addition to the already mentioned legal sources governing the issue of patient's informed consent, legal sources that are regulating the matter of informed consent of a child in the Republic of Croatia are also the Family Act and the Convention on the rights of

[120] The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: the Convention on Human Rights and Biomedicine, Official Gazette, International Treaties, No. 13/03.

[121] The Protection of Patient's Rights Act , Official Gazette, No. 169/04, 37/08.

[122] The Protection of Persons with Mental Disorders Act, Official Gazette, No. 76/14; Čulo A., *Pravo djeteta pacijenta na informirani pristanak*, pp. 139-154, in Rešetar, B. (ed.), *Dijete i pravo*, Pravni fakultet u Osijeku. Osijek, 2009, p. 144.

[123] *Ibid.* p. 145.

[124] *Ibid.*

[125] The Family Act, Official Gazette, No., 103/15, 98/19.

the child[126]. In the following, we will focus on the analysis of those acts that have the greatest applicability in the context of a child's consent to medical procedures, namely the Family Act, the Law on the Protection of Patients' Rights, and the Civil Obligations Act.

According to Article 88, as the main provision of informed consent of a child, of the Family Act for a preventive, diagnostic, or therapeutic procedure on a child who has reached the age of sixteen, only consent of that child is needed, not the consent of a child and the consent of the parent or legal guardian cumulatively[127]. The consent of a child and the consent of the parent or legal guardian cumulatively is needed only if according to a medical doctor's judgment, medical treatment is related to the risk of serious consequences to the physical or mental health of the patient child[128]. In the case of a dispute, the court shall issue a final decision on the proposal of the child or parent[129]. Paragraph 4 is referred to situations of emergency medical intervention, where, in exception of paragraphs 1, 2 and 3, "the provisions of a special regulation governing the protection of patient's rights shall apply"[130].

The Protection of Patient's Rights Act is a special act that regulates the matter of protection of patient's rights, as the Family Act requires, but the same act does not say anything about situations where the child itself could give his/her consent willingly without their legal representatives or guardians. Furthermore, for a minor patient, except for an emergency medical intervention, the (general) informed consent of Article 16 paragraph 2 of the same Act[131], shall be signed by the legal representative or guardian of the patient[132]. So, the informed consent of a child is not mentioned at all. By legal interpretation, if we take these two Acts altogether, it could be said and observed that these provisions of the Protection of Patient's Rights Act do not exactly refer to a minor child, but to a minor child that is younger than the age of 16. The Family Act in this situation is a special and the only act

[126] The Convention on the rights of the child, Official Gazette, International Treaties, No. 12/93; In this regard, it is necessary to emphasize that according to Art. 3. the Convention on the Rights of the Child all actions must be taken in the best interests of the child, as further explained in General Comment No. 14 (2013) on the right of the child to have his or her best interests taken as a primary consideration (see in particular points 77 and 78). The right to the health of the child is regulated by Art. 24 of the Convention, and further explained in General comment no. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health.

[127] The Family Act, Official Gazette, No., 103/15, 98/19, Article 88, par. 1: "a child who has reached the age of sixteen and who, due to doctor's opinion, disposes with the information required to form his / her own opinion on a specific matter and, according to doctor's assessment, is sufficiently mature to make a decision on a preventive, diagnostic or therapeutic procedure related to his or her health or treatment, may give consent to an examination, search or medical procedure (informed consent)."

[128] The Family Act, par. 2: "if according to a medical doctor's judgment, medical treatment is related to the risk of serious consequences to the physical or mental health of the patient child, with the consent of the child referred to in paragraph 1, the consent of the child's parents or other legal representative is also required."

[129] The Family Act, Article 88, par. 3.

[130] The Family Act, Article 88, par. 4.

[131] The Protection of Patient's Rights Act, Official Gazette, No. 169/04, 37/08, Article 16, par. 2: „The patient expresses accepting a particular diagnostic or therapeutic procedure by signing the approval."

[132] The Protection of Patient's Rights Act, Article 17, par. 1.

that regulates the matter of informed consent of a child, so these two Acts must be observed altogether as a whole. But, it is important for every act to be precise and certain as much as possible, so the provisions of the Protection of Patient's Rights Act should include the fact to whom this provision should be applied, but also the age limit. However, only looking at the legal text it could be said that there is a legal inconsistency between these two Acts in this matter and one of the main reasons could be that the Protection of Patient's Rights Act (2008) was passed before the Family Act (2015).

Legal representative or guardian of the patient may withdraw its consent at any time by signing a declaration of refusal of a particular diagnostic or therapeutic procedure if the interest of the patient so requires[133]. If the interests of patients and their legal representatives or guardians are contradicted, the healthcare worker shall immediately notify the competent social welfare center[134].

Article 18 is referred to emergency situations where the consent of the legal representative or guardian cannot be obtained. So, if, due to an emergency situation, the consent of the legal representative or guardian cannot be obtained, the patient will be subjected to a diagnostic or therapeutic procedure only in the event that his life would have been directly threatened or threatened with the serious and direct danger of severe damage to his health. It is further stated that the procedure can be carried out without the consent of the legal representative or guardian of the patient until the said danger is maintained[135].

So, only in emergency situations, the Family Act addresses article 18 of the Protection of Patient's Rights Act, which is a special act governing the protection of patient's rights, but not the matter of informed consent of a child in the first place. The same act does not say anything explicitly about the informed consent of a child who has reached the age of 16 and who can independently consent to a medical procedure like any other act in the Republic of Croatia except the Family Act and the Protection of Persons with Mental Disorders Act. According to the latter law, the opinion of the children with mental disorders will be taken into account according to their age and maturity[136].

Also, we could say that the Family Act and the Protection of Patient's Rights Act are not really harmonized in this matter and the reason is that one act regulates the informed consent of a 16 years old child (article 88), and the other regulates the informed consent in general. So it is a little bit confusing that the Family Act addresses the Protection of Patient's Rights Act, because article 88 of the Family Act refers to the informed consent of a child, while articles 17 and 18 of the Protection of Patient's Rights Act refer to informed consent in general, not mentioning a child who has reached the age of 16 and who can independently consent to a medical

[133] The Protection of Patient's Rights Act, Article 17, par. 2.

[134] The Protection of Patient's Rights Act, Article 17, par. 3.

[135] The Protection of Patient's Rights Act, Article 18.

[136] The Protection of Persons with Mental Disorders Act, Official Gazette, No. 76/14, Article 10, par. 1.

procedure. That kind of confusion can be also noticed exactly in article 18 of the Protection of Patient's Rights Act. The same article regulates not all emergency situations, but the emergency situation where the consent of the legal representative or guardian cannot be obtained. So paragraph 4 of article 88 of the Family Act, the same provision that regulates the informed consent of a child, addresses to article 18 of the Protection of Patient's Rights Act, the provision that regulates the informed consent in general. So it could not be said that is clear what to do in emergency situations, because the Protection of Patient's Rights Act does not say anything about how to handle the emergency situation where the consent of the legal representative or guardian is not even necessary, and when a child that is 16 years old, due to the Family Act, has the right to give his informed consent. The regulated situation refers not to all emergency situations, but only to emergency situations where the consent of the legal representative or guardian cannot be obtained.

4.2. Consent to medical procedure and matter of child's age

Although the Acts are really clear about at what age the child can give his consent, the good question is it the age limit of 16 years too high and also why Croatian legislator really prescribe the age of 16 for the informed consent of a child? In following cases, the guiding thought must be the child's ability to reason about acts and things[137]. Also, the guiding thought of the child's ability to reason acts and things could make us consider other things in Croatian private law[138]. Therefore, according to the Civil Obligations Act, "natural person acquires its legal capacity with the age of majority and legal capacity with the date of its birth unless otherwise is provided by law[139]." Also, "a person who is not of major age can only create legal effects determined by a law"[140] and "instead of a person who does not have a legal capacity, legal representative or guardian will demonstrate his or her will[141]".

[137] Klarić, P., *Odštetno pravo*, Narodne novine, Zagreb, 2003, p. 404. For example, according to the Protection of Persons with Mental Disorders Act. the opinion of the children mental disorders will be taken into account according to their age and maturity (the Protection of Persons with Mental Disorders Act, art. 10, par. 1).

[138] Although in some researches there are two main components: understanding and reasoning.

"Several studies have been performed to learn how children and adolescents understand and reason about certain aspects of health care and biomedical and psychologic research. In these reports, it is sometimes difficult to distinguish between the mental processes of understanding and reasoning." – see more in Leikin, 1993; But according to U.S. Committee on Bioethics "pediatricians should not necessarily treat children as rational, autonomous decision makers, but they should give serious consideration to each patient's developing capacities for participating in decision- making, including nationality and autonomy. If physicians recognize the importance of assent, they empower children to the extent of their capacity." "Even in situations in which one should not and does not solicit the agreement or opinion of patients, involving them in discussions about their health care may foster trust and a better physician-patient relationship, and perhaps improve long-term health outcomes" – see more in Committee on Bioethics (1995).

[139] The Civil Obligations Act, Official Gazette No. 35/05, 41/08, 125/11, 78/15, 29/18, Article 18, par. 2.

[140] The Civil Obligations Act, Article 18, par. 3.

[141] *Ibid.*

According to art. 234, par. 2 of the Family Act a person cannot be completely deprived of legal capacity. So, legal capacity is acquired at the age of 18, or earlier (with the age of 16) if the minor enters into marriage[142], offense capacity occurs at the age of 14 with presumed mental health[143], while a minor between the ages of 7 and 14 does not have offence capacity, unless it is exceptionally proven that he or she was capable of reasoning[144], and also persons younger than 7 years have no offence capacity at all[145] [146]. If a child with the age of 14 is liable for his or her delictual omissions and can be held liable with regard to the general rules on liability for torts, is it unlikely for the child to be capable of understanding all the consequences of consenting to medical procedure[147].

Furthermore, according to the Labor Act[148], there is no possibility of employment a person under the age of 15 or a person aged 15 and older than 15, but younger than 18 years, that is attending compulsory primary education[149]. Also, according to the Family Act, a child who has reached the age of fifteen and who earns money, can independently conclude and take legal actions, and take over obligations in the amount of money he earns and dispose of his income provided in the way that he does not endanger his or her maintenance[150]. So if a child is able to reason act of making the labor contract and all consequences that it brings, then the question is- isn't he/she able to understand and to make a decision on his/her preventive, diagnostic or therapeutic medical procedure[151]. The above question should be further elaborated.

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[142] The Family Act, Official Gazette, No., 103/15, 98/19, 126/21, Article 25, par. 2.

[143] The Civil Obligations Act, Article 1051, par. 3.

[144] The Civil Obligations Act, Article 1051, par. 2.

[145] The Civil Obligations Act, Article 1051, par. 1.

[146] Klasiček D., Pichler D., *O poslovnoj, deliktnoj i oporučnoj sposobnosti djeteta*, In Rešetar, B. (ed), *Dijete i pravo*. Pravni fakultet u Osijeku, Osijek, 2009, pp. 117-139.

[147] Crnić, I., *Odgovornost liječnika za* štetu, Organizator, Zagreb, 2009, p. 30. The criterion of child's reasoning is quite similar in criminal law. In the Republic of Croatia minor person is criminally liable with the age of 14 (The Act on Juvenile Courts, Official Gazette No. 84/11, 143/12, 148/13, 56/15, Article 2). The situation is the same in Austria (The (Austrian) Youth Courts Act, *Jugendgerichtsgesetz* (JGG) 1988), Section 1) and Germany (The (German) Youth Courts Act, *Jugendgerichtsgesetz* (JGG), Section 1) where person who is under the age of 14 is excluded from criminal prosecution. In accordance with that fact, in Austria and Germany, a person who has reached the age of 14 is capable of giving his informed consent (Turković, K.; Roksandić Vidlička, S.; Brozović, J.; *Informirani pristanak djece u hrvatskom zakonodavstvu*, In Turković, K., Roksandić Vidlička, S.; Maršavelski A. (eds.), *Hrestomatija hrvatskoga medicinskoga prava*, Pravni fakultet Sveučilišta u Zagrebu, Zagreb, 2016, pp. 572-584). If we take in concern our guiding thought, the logic is clear- if the child is able to reason his act of doing criminal offence then the child is able to understand and to make a decision on his/her preventive, diagnostic or therapeutic medical procedure. But of course that this fact cannot be unambiguously considered, so in Austrian and German law this is only presumption (Latin, *praesumptio iuris*) and in the case of doubt the final decision is made by the court (Turković, Roksandić Vidlička, Brozović, *Informirani pristanak djece u hrvatskom zakonodavstvu,* 2016). It is because not all children are the same and not all of them can understand the consequences of their acts in the same way.

[148] The Labor Act, Official Gazette No. 93/14, 127/17, 98/19.

[149] The Labor Act, Article 19.

[150] The Family Act, Article 85.

[151] Crnić, *op. cit.*, note 147, p. 29.

On the one hand, according to some civil law authors, consent to medical intervention, of its nature, is not a classical legal act of property-rights nature because it is not directed at the property-free disposal[152]. In that case, it would be a matter of exercising the right to personality, ie the right to life and bodily integrity that leads to the conclusion that patient's consent could be valid and when general preconditions for the validity of a legal act were not fulfilled[153]. So the main criterion is the child's ability of reasoning, precise - natural ability to understand things and ability of making decisions (*German. Natürliche Einsichts- und Entschlussfähigkeit*)[154] [155]. Since in the Republic of Croatia minor person is able to reason (sanity), offence capable and criminally liable with the age of fourteen, this kind of approach of informed consent of a child could be acceptable in Croatian legal system.

Due to principle *volenti non fit iniuria* ("to a willing person, injury is not done")[156], it is not unlawful to encroach on one's personal right what has been done with that person's valid consent[157] [158]. In that view and on the other hand, according to other authors, consent is a typical legal act, placed in the category of contracts, that is, the mutual agreement that arise from the encounter of two wills[159] [160]. In the context of the above, it may be a special contract on medical treatment between the patient and the hospital, which is not specifically regulated by Croatian legislation in relation to the German one (*der Behandlungsvertrag* § 630a BGB)[161]. It means that all general preconditions about the validity of legal acts must be fulfilled[162]. If informed consent is a contract, then, at first, we could say that there is really questionable is it a form of informed consent of a child legally right in Croatian legal system. If we take into consideration that contract may conclude only legally capable person, then we may conclude at first that it may be that informed consent of a child cannot stand alone in Croatian legal system. It means that prior to informed consent of a child we must have the informed consent of legal representative or guardian. But, that is not the case in Croatian legal system. Moreover, there is explicit provision in the Civil Obligations Act that states that "a person who is not of major age can only create legal effects determined by law[163]" and that legal effect in this case is determined

[152] Klarić, P., *Povreda prava na tjelesni integritet*, in Klarić, P. (ed.), *Odgovornost za neimovinsku* štetu *zbog povrede prava osobnosti*, Narodne novine, Zagreb, 2006, pp. 184-204.

[153] *Ibid.*; Deutsch, E., Spickhoff, A., *Medizinrecht : Arztrecht, Arzneimittelrecht, Medizinprodukterecht und Transfusionsrecht*, Springer, Berlin, New York, 2003, p. 135; Čulo, *op. cit.*, note 122, p. 144.

[154] Klarić, *op. cit.*, note 152, p. 193.

[155] Laufs, A., Uhlenbruck, W., *Handbuch des Arztrechts*, Verlag C. H. Beck München, 1999, p. 488.

[156] Compare the consideration of when in the context of private autonomy and personality rights *et volenti fit iniuria* applies in Bydlinski, *op. cit.,* note 116, p. 160.

[157] Nikšić, S., *Građanskopravna odgovornost za liječenje bez pristanka*, In Barbić, J. (ed.), *Građanskopravna odgovornost u medicini*, Hrvatska akademija znanosti i umjetnosti, 2008, pp. 83-110.

[158] Gavella, N., *Osobna prava*, I. dio. Zagreb, 2000, p. 58.

[159] *Ibid.*

[160] Čulo, *op. cit*., note 122, p. 144.

[161] Radolović A., *Pravni poslovi prava osobnosti*, Zbornik Pravnog fakulteta Sveučilišta u Rijeci. vol. 35, no. 1, 2014, pp. 95-118.

[162] Gavella, *op. cit*., note 158, p. 58.

[163] The Civil Obligations Act, Article 18, par. 3.

by the Family Act. So, in conclusion, according to the Civil Obligations Act and the Family Act together, this kind of approach to informed consent is harmonized and acceptable.

It may be vaguely why Croatian legislator prescribed that only a person who turned the age of 16 is able to make a decision (informed consent) on his/her preventive, diagnostic, or therapeutic medical procedure when other elaborated acts and provisions are prescribing different age limit for establishing other important and vital legal acts. In favor of the age determination contained in family law, there are probably those situations that have nevertheless led the legislature to prescribe an age limit of 16 years, for example, marriage under special provisions from the age of 16[164], also paternity that may be recognized by a minor who has reached or younger the age of 16, under other legal conditions[165], etc. So, that age barrier is not something that is new or strange in the same Act. In that view, there is a precise explanation why Croatian legislator really prescribed that only a person who turned the age of 16 is able to make a decision (informed consent) on his/her preventive, diagnostic, or therapeutic medical procedure. The Government's Proposal (Bill) of the Family Act[166] states that such a legal solution where only a person, according to the Protection of Patient's Rights Act, who turned the age of eighteen is able to make a decision (informed consent) on his/her preventive, diagnostic or therapeutic medical procedure- "leads to an absurd possibility in which a juvenile older than 16 who became a parent and a legally capable person by the court decision will not be able to decide on diagnostic and therapeutic procedures on his body even though he will be able to undertake any legal business as a legally capable person"[167]. Likewise, "a juvenile who has become a parent and a legally capable person, will be able to decide as a legal representative of his child about medical treatment on his child's body, while someone else will have to do the same thing for him and his body[168] ." According to the same Proposal, that provision is based on the Convention on the Rights of the Child, the Convention on Human Rights and Biomedicine and comparative legal systems of Austria, Germany, the Netherlands, Spain and Slovenia[169]. Notwithstanding all that has been said in this passage, remains the fact that in this age matter Croatian legislation from the view of different private legal branches is not harmonized.

[164] The Family Act, Article 25, par. 2.
[165] The Family Act, Article 63, par. 1.
[166] The Government's Proposal (Bill) of the Family Act (2015), p. 199.
[167] *Ibid.*
[168] *Ibid.*
[169] *Ibid.*

5. CONCLUSION

The issue of informed consent, as shown in the article, has its roots in ethical theory and law, but it is primarily based on the concept of autonomy which presupposes that an autonomous agent makes his decisions based on his own reason[170]. Informed consent can only be given by patients with "appropriate decisional capacity"[171]. In cases of children without such capacity, parents give "informed permission" for a medical procedure, whereas children give informed assent[172]. Child's assent grows in importance as the child ages, until the child eventually reaches the full capability to give informed consent[173]. Thus, it is important to include minors in medical decision-making. The child receiving the information should receive it in a way appropriate to its emotional and cognitive maturity[174]. One of the greatest issues that needs to be resolved here is determining the age at which the child reaches its decision-making capacity[175].

In the Republic of Croatia, there are numerous sources of domestic and international law in the context of a child's consent to medical procedures. In this paper, three legal acts were analyzed in a common context: the Protection of Patient's Rights Act, the Family Act and the Civil Obligations Act. The fact that several legal regulations, in particular the Protection of Patient's Rights Act, the Family Act and the Civil Obligations Act, must be used in parallel when it comes to the issue of informed consent of a child, can be, legally speaking, quite confusing. Thus, such regulation may leave some doubts and difficulties in the immediate application, especially with regard to emergency medical interventions. In this regard, perhaps the fact of adopting a special law on the consent of children to medical procedures could be considered, or at least the provision within the Family Act or the Protection of Patient's Rights Act, which uniformly summarizes all the above regulations. Also, the interesting question is whether the statutory provision of 16 years is still a little too high, convenient, but also a bit non - unified considering all the above legal age restrictions within Croatian private law.

[170] Katz*, op. cit*., note 5, p. 2.
[171] Grošelj, *op. cit.*, note 36, p. 89.
[172] *Ibid.*
[173] Rus *et al., op. cit.*, note 9, p. 3.
[174] Field *et al., op. cit.*, note 8, p. 206.
[175] Hein *et al., op. cit*. note 26, pp. 1-7.

DJECA I DONOŠENJE MEDICINSKIH ODLUKA

Posljednjih nekoliko desetljeća vode se opsežne rasprave o problematici donošenja medicinskih odluka koja se tiču djece. Općenito, trenutno prevladava gledište da se djetetove želje treba poslušati i da se djeci treba omogućiti sudjelovanje u donošenju medicinskih odluka u skladu s njihovim razvojem. Te rasprave ne dotiču se samo etičkih, pravnih i političkih pitanja, već se temelje i na empirijskim istraživanjima. Nema jednostavnih odgovora na ta bitna pitanja, osobito na ona koja se tiču dobne granice u kojoj se djeca mogu smatrati sposobnima dati informirani pristanak. U tom kontekstu potrebno je uspostaviti ravnotežu između zaštite interesa djece i poštivanja njihove "autonomije u razvoju". Prvi dio ovog članka prikazuje načelo autonomije na kojem se temelji informirani pristanak, dok se drugi dio usredotočuje na dva koncepta: roditeljsko dopuštenje i pristanak djeteta, koja su oba dobro poznata u suvremenoj medicinskoj praksi. Izraz „pristanak" (*assent*) obično se koristi u slučajevima kada pojedincima nije zakonski dopušteno davanje informiranog pristanka, ali se smatraju sposobnima sudjelovati u procesu donošenja medicinskih odluka.

U trećem dijelu rada analizirana su tri hrvatska pravna akta u kontekstu informiranog pristanka djeteta: Zakon o zaštiti prava pacijenata, Obiteljski zakon i Zakon o obveznim odnosima. Činjenica da se nekoliko zakonskih propisa, a posebno Zakon o zaštiti prava pacijenata, Obiteljski zakon i Zakon o obveznim odnosima, moraju koristiti paralelno kada je u pitanju pristanak djeteta, može biti, pravno gledano, prilično zbunjujuće. Stoga takva regulativa može ostaviti određene nedoumice i poteškoće u neposrednoj primjeni, posebno u pogledu hitnih medicinskih intervencija. S tim u vezi, mogla bi se razmotriti mogućnost donošenja posebnog zakona o pristanku djece na medicinske zahvate koji bi ujednačeno sažimao sve navedene propise.

Ključne riječi*: autonomija, informirani pristanak, pristanak djeteta, roditeljsko dopuštenje, sposobnost*