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THE HISTORY OF THE DEVELOPMENT OF INFORMED CONSENT IN HUNGARY,

WITH A BRIEF DISCUSSION OF THE CHALLENGES INDUCED BY DIGITAL HEALTH TECHNOLOGIES

thesis booklet

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1. OBJECTIVES AND METHODOLOGY OF THE DOCTORAL DISSERTATION

1.1. Subject, aim and relevance of the research

Research into, and regulation of, issues relating to healing and, in this context, to the performance of the duties of those who carry it out – healers, and later physicians and other professionals – can be traced back to antiquity. Beyond the eponym of the Hippocratic Oath, which is still widely used and well known today, numerous sources, in some cases much earlier ones, attest that reflection on the actors involved in healing began very early. All this also became the basis for the gradually emerging regulations. In this historical process, the development of the doctor-patient relationship plays an important role.

For a long period in historical development, practically until the middle of the twentieth century, the doctor-patient relationship was defined by the so-called paternalistic approach. In this context, paternalism means that the patient is placed in a specific, subordinate role, so that the relationship, communication and all necessary decision-making arising from the illness are determined by the physician. In this system of relations, the patient is assigned the role of an obedient, compliant party, that is, the unconditional following of the doctor's instructions in the interest of recovery, while all responsibility and decisions concerning healing fall to the physician. In this historical phase of the doctor-patient relationship, the patient's consent to intervention is formal, and the purpose of information is to ensure the proper implementation of therapy rather than to support patient awareness or involvement in decisions.[1] This changes in the period following the Second World War with the explicit regulation of patients' rights and, in connection with this, the development of the doctrine of informed consent.

The doctrine of informed consent, and later its formulation as a legal requirement, is historically the result of American legislative initiatives following the Nuremberg trials and the related social discourses; this was then adopted by European countries and, over time, by Hungary as well. The result of the lengthy historical development in Hungary is the Act on Health adopted in 1997 and still in force today. The current phase of this historical development is the digitalization of healthcare, which may confront the already traditionally embedded concept of informed consent with new challenges.

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[1]It is important to emphasise here that, before the twentieth-century paradigm shift, the paternalistic approach was a phenomenon that fit naturally and organically into the framework of social coexistence in relation to the doctor-patient relationship. The expression itself gains meaning from a modern perspective. Accordingly, in the present dissertation, until the appearance of patient involvement in the modern sense as a legal-ethical requirement in care decisions, I evaluate the paternalistic character of medicine primarily in a descriptive manner, illustrating the situation of the given period and highlighting those of its elements that had an effect on later developments.

When examining the Hungarian trajectory, three regulations should be highlighted in connection with the twentieth-century development of informed consent. After the Second World War, separate regulations governed certain areas of the sector, and in this context Decree Law No. 8 of 1959 on medical doctors' regulation should be mentioned with regard to the doctor-patient relationship. Subsequently, Act II of 1972 on Health represented the first comprehensive statutory regulation of healthcare in Hungary. Following these antecedents, the adoption of Act CLIV of 1997 on Health brought about a substantial change in the provisions concerning patients, since it created the detailed, statutory, sector-specific regulation of patients' rights in the Hungarian legal system. Within this framework, the patients' rights reflecting the doctrine of informed consent also appears formally.

The subject of the research is informed consent and its Hungarian historical development as part of the doctor-patient relationship. In the modern sense, the doctrine of informed consent (consent based on information) can be summarised as a process through which the physician (or designated healthcare professional), by communicating with the patient (in one or more discussions), presents and discusses all information, alternatives and risks related to the intervention that are necessary for the patient to give consent to the performance of the intervention.[2] A long path led to the formulation of this complex set of expectations as a legal requirement and then to its incorporation into Act CLIV of 1997 on Health, and, because of nearly thirty years of experience in the application of the law since the adoption of the Act, the results of regulation and scholarship, and the new challenges created by digitalization, it is timely to examine the doctrine of informed consent.

The primary objective of the research is to review the history of the development of the doctrine of informed consent and of its incorporation into the Hungarian legal system. This also includes the examination of the international framework, which ultimately led to the formulation of Hungarian rules in Act CLIV of 1997 on Health, still in force today. A further aim is to analyse, from the perspective of the doctor-patient relationship, the actual process of obtaining consent to healthcare interventions from a historical perspective. Ultimately, a defining aspect of the inquiry is the developmental path followed by the history of involving patients in decisions related to their own care within a system of relations shaped by historical traditions and social changes, and the key regulatory steps through which this led to the emergence of patients' rights and, within them, the complex system of expectations of informed

[2] In the Hungarian legal system and language use, the expression of 'informed consent' (*'tájékozott beleegyezés'*) ultimately became established, although from the perspective of content and implementation 'consent based on information' (*'tájékoztatáson alapuló beleegyezés'*) would be a more fortunate translation of the original English term. Nevertheless, the latter designation is also appearing increasingly often in the literature, and therefore in my dissertation I ultimately decided to use it consistently, thereby also conveying the meaning carried by the doctrine.

consent. Finally, the research also aims to provide a brief discussion on certain major new challenges appearing in health care as a consequence of technological development, in this case the expansion of digital technologies, as the newest and dominant factor in this developmental arc.

The relevance of the research is primarily provided by technological changes permeating our everyday lives and by the impact of digital transformation, which increasingly determines the activities of every actor in the healthcare system, on patient involvement and the related regulations. Although at first sight this does not appear to be a legal-historical question, in reality we are at the beginning of, or perhaps already in the midst of, a paradigm shift in which fundamental regulatory questions may open up, and, in order to answer them adequately, the systematic examination of the developmental arc of informed consent as part of the doctor-patient relationship is of decisive importance. Along these lines, it is possible to evaluate not only the social and regulatory processes that led to the current regulation, but also the value choices that ultimately determined the legal framework and the practice of legal application at any given time. Knowledge of all this may be crucial for successfully answering our current regulatory questions and for developing future regulatory frameworks.

1.2. Methodological framework of the research

In order to achieve the objectives of the research, the use of a mixed methodology is justified. Within this framework, in addition to an interpretive presentation of the relevant scholarly context and the analysis of relevant documents and legislation, an empirical inquiry conducted through a questionnaire-based study also serves the comprehensive approach to the subject.

With regard to the regulatory framework and the experiences of application, an evaluative presentation in a broad sense is required. This includes a review of the relevant literature as well as the so-called grey literature and legislation. Part of the qualitative research process is the exploration, with the stakeholders, of experiences in shaping the regulation. This aim is made possible by processing interviews conducted with researchers and experts who participated in the legislative drafting committee during the preparation of Act CLIV of 1997.

As the quantitative part of the research, in order to map the effectiveness of nearly three decades of law-application practice since the adoption of Act CLIV of 1997 on Health, I examine, within the framework of a non-representative survey using my own questionnaire and an online anonymous questionnaire management system (EUsurvey), the knowledge of patients, physicians and patients' rights representatives concerning patients' rights and, in connection with this, their experiences regarding the realization of informed consent.

On the basis of the way in which the questionnaires were compiled, beyond processing the responses of the three respondent groups by statistical methods, it is also possible to carry out a comparative analysis of the groups' perspectives. In each group, sampling took place by means of an online questionnaire and on a voluntary basis. The involvement of respondents was achieved, in the case of patients, predominantly through social-media platforms and by contacting patient organisations; in the case of physicians, by inviting publicly and privately financed health-care providers; and in the case of patients' rights representatives, on the basis of consultation with the Integrated Legal Protection Service.

One part of the questionnaire prepared for patients almost entirely repeats the questions of Tibor Jakab's 2007 questionnaire survey, and its structure also follows the methodology of the sampling at that time in order to enable a cross-sectional analysis regarding patients data.[3] In addition, the second half of the questionnaire consists of questions developed by me. No such antecedent could be identified for the other two questionnaires, but the formulation of the questions was influenced by the aim of ensuring possibilities for comparative evaluation. In light of the research conditions, achieving statistical representativeness is not an expectation in any of the cases; the aim, however, is to make it possible to analyse orienting results through convenience sampling, and for the analysis to provide a basis for further research by developing questionnaires that also enable quantitative analysis in connection with the qualitative studies.

The present research naturally has limitations, the recording of which is indispensable in order to provide the interpretive framework. The focus of my dissertation is the legal and regulatory history of the development of informed consent. In Hungary, the adoption of Act CLIV of 1997, and in particular the chapter on patients' rights, is usually regarded as the fulfilment of this development. In view of this, the focus of my inquiry is ultimately an analysis reviewing the Hungarian and international regulatory antecedents of this Act, as well as the experiences of its application over nearly the past three decades, specifically from the perspective of the realization of the meaningful involvement of the patient. This makes it necessary, along several lines of connection, to delimit the subject matter of the research.

The history of patients' rights and, in this connection, of the involvement of patients in healthcare decisions, as well as the doctrine of informed consent itself, is a highly multifaceted subject with many connections spanning numerous disciplines and several fields of law within the legal discipline, and, accordingly, its research possibilities are also wide-ranging. Within

[3] Jakab Tibor: A felnőtt korú magyar lakosság betegjogi ismeretei – kérdőíves vizsgálat [Knowledge of patients' rights among the adult Hungarian population – questionnaire study]. Budapest, 2007. Betegjogi, Ellátottjogi és Gyermekjogi Közalapítvány, Szószóló Alapítvány, Studies.
https://globephoto.hu/szoszolo/06tanulmanyaink/280611betegjogi_ismeretek.pdf

this broad spectrum, I examine the issue primarily from a legal-historical approach, focusing on historical development. Within this, by specifically scrutinizing the substantive process of the patient's actual involvement and of becoming an active participant in care, I seek to reveal the long historical trajectory of Hungarian legal regulation, and specifically of the drafting of the laws considered emblematic in this developmental path. For all these reasons, I review the subject matter under examination primarily along healthcare regulations, that is, an analysis of the legal institution of informed consent from the perspective of every other discipline or branch of law – such as civil law, administrative law or even constitutional law – goes beyond the aims of the research, and in connection with these I address only what is fundamentally necessary for understanding the topic discussed and outlining further connections.

Following the line of reasoning set out above, my inquiry likewise does not include the detailed judicial practice relating to the subject matter. The omission, or only brief mention, of the analysis of judicial practice is also justified by the basic approach and aims of the present dissertation. In this context, judicial practice can provide an undoubtedly valuable picture only to a limited extent, specifically of how claims are enforced by legal means and of the issues examined in cases brought before courts that are accessible to those concerned (on the basis of the resources, knowledge, etc. available to them). The present dissertation, however, approaches the examination of the subject matter in a broader sense. It analyses the domestic realisation of the integration of patient involvement in care decisions, and of the doctrine of informed consent, into society's everyday practice of care, and especially through regulation, placing the question in a historical perspective.

It should also be noted that, because of the general approach to patient consent and authorization, the detailed examination of special cases (e.g. questions relating to organ transplantation, end-of-life decisions, abortion or psychiatric patients) is not the subject of my dissertation either. These are independent fields of research in their own right and appear only in the form of mention or reference, where their connection to the general rules so warrants. Likewise, I address only tangentially the independent regulatory issues of the participation of relatives, or of any other person on the basis of legal authorization, in decision-making.

To the extent necessary for revealing and understanding the Hungarian historical development and antecedents of the research topic, I also analyse the related international literature and regulatory history in order to review the emergence and historical change of the doctrine of informed consent. Nevertheless, in this respect as well, I reveal only the legal and theoretical framework, in the strict sense, of the possibilities for, or obstacles to the actual realization of information provision, insofar as they are substantially connected to the shaping of the Hungarian regulatory environment.

Finally, beyond what has been described here, in order to place the analysis in context and to keep within the assumed framework, I also indicate briefly in connection with individual chapters, for certain specific topics, when further analysis of a given question already goes beyond the aims of the present dissertation. It should be emphasized in this regard that, in Chapter 8, which processes the quantitative questionnaire-based research, I assess in a separate section the special limitations of the empirical study because of its methodological characteristics.

Overall, it is clear that in my dissertation, in light of the aims and methodology of the research – even with the limitations presented – I examine the Hungarian history of the regulation and realization of informed consent along a fairly broad arc of analysis. A necessary consequence of this is that the questions discussed in the individual chapters, or even certain aspects of them, could themselves form the subject of an independent dissertation. On the basis of the foregoing, the feasibility of my research required consciously boundary-setting analytical decisions and approaches, which are also intended to ensure, while maintaining the structural integrity of the dissertation, a substantive evaluative analysis of those aspects of the wide-ranging subject matter that are decisive from the perspective of my research.

1.3. Research questions

In my dissertation – in connection with the meaningful feasibility of ensuring patients' active participation in their care through appropriate information, along the relevant theoretical and legislative foundations – I examined the following questions:

Research question 1: What effect does the historical development of the doctor-patient relationship and its eighteenth- and nineteenth-century regulation in Hungary have on the domestic spread of the doctrine of consent in the modern sense?

Research question 2: What international theoretical and regulatory-historical background does Hungarian legislation have with regard to involving patients in healthcare decisions?

> Sub-question 2.a: How did the international emergence of the concept of informed consent and the related guidelines and regulations affect Hungarian legal rules?
>
> Sub-question 2.b: How does the interpretation of informed consent change in Hungarian regulation and practice after the Second World War compared with the developmental trajectory of Western-type societies?

Research question 3: What process resulted in the regulation of patients' rights in Act CLIV of 1997, and what are the experiences of the practical realization of decision-making based on patient involvement, also with regard to the challenges of digitalization?

Sub-question 3.a: What processes and changes led to the transformation of the traditionally paternalistic regulation with the adoption of Act CLIV of 1997 on Health?

Sub-question 3.b: In what way is the detailed, catalogue-like statutory regulation of patients' rights realized in everyday practice with regard to patient involvement?

Sub-question 3.c: In what way does the spread of digital technologies in healthcare bring change to patients' participation in decision-making about their care and, as part of this, to the feasibility of informing them?

2. STRUCTURE OF THE DOCTORAL DISSERTATION

After the introductory part (Chapter 1), which clarifies the subject and aim of the research, the methodological framework, the research questions and finally the structural organization, I begin the processing of the topic with a general examination of the historical development of the doctor-patient relationship (Chapter 2). As part of this, in addition to presenting the general dominance for centuries of the paternalistic approach built on the traditions of the Hippocratic Oath, I describe the main nodes of Hungarian historical development and finally the decisive regulations of the eighteenth and nineteenth centuries, which also had an impact on the later period.[4]

As a significant element of the historical development of the doctor-patient relationship, I explore the basic theoretical connections of the concept of informed consent developed by legal practice after the Second World War (Chapter 3), which, together with a detailed analysis of the international legislative documents of the second half of the twentieth century, lay the foundation for a comprehensive evaluation of Hungarian regulation (Chapter 4).

Proceeding further along the theoretical foundations and the international regulatory context, I examine the Hungarian trajectory after 1945 through an evaluative analysis, embedded in a historical framework, of the relevant healthcare rules and their adoption process. The closing regulatory document of this is the detailed examination of the parliamentary debate and rules of Act II of 1972 (Chapter 5).

In a separate part, as the closing point of the Hungarian regulatory development, I first discuss, through analysis, questions relating to the circumstances and background of determining the rules of Act CLIV of 1997 on Health, the debates articulated during the parliamentary adoption of the Act, and the Act's subsequent life, as well as the new challenges arising from digitalization (Chapter 6). I then devote a further separate chapter to the analysis of the substantive statutory regulation of patients' rights connected to informed consent, with particular attention also to amendments to these rules (Chapter 7).

Finally, as the conclusion of the analytical arc of the dissertation, I discuss my empirical research and its results, conducted to analyse the knowledge of patients' rights that has

[4] In this analysis I follow the structural and substantive approach of the historical overview in the book written by Jay Katz, an internationally recognized authority on the subject, concerning the doctor-patient relationship, the involvement of patients in healthcare decisions and informed consent, and, connected to this, I process the evaluation of Hungarian historical antecedents. Cf.: Katz, Jay: *The Silent World of Doctor and Patient*. Baltimore and London, 2002. The Johns Hopkins University Press.

developed in the everyday practice of the actors in care and their opinions on the meaningful implementation of informed consent (a non-representative survey aimed at assessing the perceptions of patients, physicians and patients' rights representatives) (Chapter 8).

The dissertation closes with a section that, along the research questions, summarizes the results of the dissertation and sets out the conclusions formulated (Chapter 9).

3. RESULTS OF THE DOCTORAL DISSERTATION

In order to examine the meaningful feasibility of ensuring patients' active participation in their care through appropriate information, along the relevant theoretical and legislative foundations, I designed my research around several questions. Evaluating, along the long conceptual arc outlined by the interconnections among the topics analysed in the individual chapters, the theoretical and legislative background of the Hungarian history of the regulation of informed consent, my dissertation answers these questions step by step.

Research question 1 concerned the effect of the historical development of the doctor-patient relationship and its eighteenth- and nineteenth-century regulation in Hungary on the domestic spread of the doctrine of consent in the modern sense. This question is answered by the evaluative presentation developed **in Chapter 2**, which presents the legal and social history of the doctor-patient relationship.

The analysis begins with the history of the development of the doctor-patient relationship, which provides the theoretical framework for information provision and, at the same time, makes possible the form of its practical realization. In this context, it first addresses the fundamental importance of language use and the role of the Hippocratic Oath in establishing the traditionally paternalistic approach in Western-type societies.[5] This approach can be summarized, alongside the medical dominance of treatment, in the expectation of passive cooperation by the ill person, and, in this context, the idea of a prepared patient who actively participates in his or her own recovery is not part of the care process, and even if it were to arise, the patient would have neither the means nor the tools for meaningful contribution, while physicians are not prepared to receive it either.[6]

As illustrated by the section setting out the historical presentation that analyses the subject, the traditional Hippocratic approach, over many centuries and in fact until the middle

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[5] Blasszauer, Béla. Az orvosi eskü [The Medical Oath]. *Lege Artis Medicinae*, 2008. 18(5), 358. p; Laki, Beáta, Szolcsányi, Tibor, Tiringer, István. Jelentős változások a hippokratészi eskü, illetve a nemzetközi orvosi fogadalom szövegében [Significant changes in the text of the Hippocratic Oath and the international physicians' pledge]. *Orvosi Hetilap*, 2022. 163(23), 926–928. p. https://doi.org/10.1556/650.2022.HO2706; Sándor, Judit: A betegek jogainak kodifikálásáról [On the codification of patients' rights]. *Fundamentum*, 1997. 1, 87–100. p. https://ojs.elte.hu/fundamentum/article/view/9570 (Sándor 1997a) 89. p; Rózsa, Erzsébet: Deficitek az orvos-beteg/páciens kapcsolatban – esélyek és lehetőségek bioetikai és egészségszociológiai vizsgálatok metszéspontjain [Deficits in the doctor-patient relationship – chances and possibilities at the intersection of bioethical and health-sociological studies]. *Metszetek – Társadalomtudományi folyóirat*, 2017. (6)2, 203–227. p. https://www.ceeol.com/search/article-detail?id=575731 205–206. p, 222–224. p.

[6] Kovács, József: Az orvosi beavatkozásokba való „tájékozott beleegyezés" elve a modern orvosetikában [The principle of 'informed consent' to medical interventions in modern medical ethics, Part I.] *Lege Artis Medicinae*, 1993. 3(6), 590–597. p. (Kovács 1993a) 590. p; Kovács, József: Az orvosi beavatkozásokba való „tájékozott beleegyezés" elve a modern orvosi etikában II. rész [The principle of 'informed consent' to medical interventions in modern medical ethics, Part II.] *Lege Artis Medicinae*, 1993. 3(7) 688–696. p. (Kovács 1993b.) 691–692. p; Katz 2002.

of the twentieth century, determines doctor-patient communication in the healing process, which therefore cannot meaningfully include the patient's real involvement in healthcare decisions.[7] This is also visible from the first related norms of systemic domestic healthcare regulation, including the analysis of the connections of the royal decree issued by Maria Theresa in 1770, *the Generale Normativum in Re Sanitatis* (GNRS), and Act XIV of 1876 on the regulation of public health.[8] This is not substantially changed in the period by the emergence of medical societies and medical journals, the development of healthcare education and medical language use, or the appearance of a professional demand for the health education of broad layers of society (and a need arising from the general state of public health).[9] Mentioning these is nevertheless important, because, following the organization of the medical profession, the emergence of health education and dissemination of knowledge is an indispensable prerequisite for a doctor-patient relationship involving a conscious patient capable of understanding his or her own condition. These efforts are significant despite the fact that their full development ultimately failed to occur because of the political events and wars of the first half of the twentieth century.

Research question 2 concerns what international theoretical and regulatory-historical background Hungarian legislation has with regard to involving patients in healthcare decisions. Two **sub-questions, 2.a and 2.b**, are connected to this question: they concern the international emergence of the concept of informed consent and the effect of the related guidelines and regulations on Hungarian legal rules, and also the way in which the interpretation of informed consent changes in Hungarian regulation and practice after the Second World War compared with the developmental trajectory of Western-type societies. These questions are answered by **Chapter 3**, which discusses the theoretical history of the development of the doctrine of informed consent, by **Chapter 4**, which analyses the main milestones in the development of

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[7] Katz 2002.; Kovács 1993a.

[8] Cf.: Balázs, Péter: *Mária Terézia 1770-es egészségügyi alaprendelete (1–2. kötet) [Maria Theresa's 1770 General Health Regulation (Volumes 1–2)]*. Magyar Tudománytörténeti Intézet Semmelweis Orvostörténeti Múzeum, Könyvtár és Levéltár, Piliscsaba-Budapest. 2007. https://real.mtak.hu/30273/1/balazs_kozegeszsegugy_1-2kotet.pdf; Feith, Helga Judit, Gradvohlm Edina, Balázs, Péter: Betegjogok a régmúltban? Normativitás az orvosi munkában a XIX. századig, különös tekintettel az első átfogó magyar egészségügyi uralkodói rendeletre [Patients' rights in the distant past? Normativity in medical work until the nineteenth century, with particular regard to the first comprehensive Hungarian royal decree on healthcare]. *Orvosi Hetilap*, 2014. 155(34), 1361–1366. p. https://doi.org/10.1556/oh.2014.ho2499; Kapronczay, Károly: A hazai egészségügyi felvilágosítás vázlata [An outline of health education in Hungary]. *Valóság*, 2001. (5), 31–41. p.; Pálvölgyi, Balázs: *A magyar közegészségügyi közigazgatás intézményrendszere (1867–1914) kiépülésének és működésének vizsgálata a himlő, a trachoma és a tbc elleni küzdelem fejlődésének tükrében [Examination of the development and functioning of the institutional system of Hungarian public health administration (1867–1914) in light of the development of the fight against smallpox, trachoma and tuberculosis]*. Budapest, 2011. ELTE Eötvös Kiadó.

[9] Cf.: Kapronczay 2001.; Kapronczay, Károly & Szemkeő, Endre: A magyar orvostársaságok kialakulása és fejlődése a 19-20. században [The emergence and development of Hungarian medical societies in the nineteenth and twentieth centuries]. *Orvostörténeti közlemények*, 1979. 87–88(25,1–2), 141–155. p.

the related international regulation, and, building on these, by **Chapter 5**, which analyses the twentieth-century Hungarian statutory regulations and direct antecedents before Act CLIV of 1997.

As the starting point for evaluating in its proper context the twentieth-century Hungarian development of norms concerning patients' rights, and especially the regulation of informed consent, I chose the changes that occurred in international legislative efforts after the Second World War. This is the point at which Hungarian legal development – while accepting certain international norms and incorporating them into the legal system – separates from this new process, retaining a paternalistic model of medicine that excludes doctor-patient communication meaningful from the perspective of patient consent.[10] In order to make interpretable the precise effects of this turn, that is, the two radically different directions in the assessment of the patient's position in care, I continue the discussion of the topic with a systematic analysis of the new theories and regulatory and legislative efforts seeking respect for the patient's autonomy in healthcare decisions and the limits of that autonomy.[11] Thus, by presenting the history of the doctrine of informed consent and the legal development of the related bioethical theoretical approaches and standards, the organic construction becomes clear through which this complex concept reaches the substantive requirements known today and regulated in Hungarian law as well.

The analytical presentation of regulatory foundational documents closely connected to theoretical development, such as the Nuremberg Code or the Declaration of Helsinki, contributes to a complete overview of Hungarian processes just as much as the examination, as general guidance, of the historical significance of the International Code of Medical Ethics, the Declaration of Lisbon and the Declaration on the Promotion of Patients' Rights in Europe (Amsterdam), and, as binding norms, the Convention on Human Rights and Biomedicine (Oviedo Convention) and the Charter of Fundamental Rights of the European Union. From all these, in addition to the more important stages of the theoretical and regulatory development of the doctrine of informed consent, the sources of the Hungarian regulatory content and its links to the international environment are also clearly visible.

Until the end of the Second World War, the approach of Hungarian healthcare did not differ from that characteristic of Western-type countries, thus the doctor-patient relationship

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[10] Cf.: Katz 2002.; Kovács 1997a.; Kovács 1997b.

[11] Cf.: Beauchamp, Tom L. & Childress, James F.: *Principles of biomedical ethics*. New York, 2013. Oxford University Press 7th Ed.; Faden, Ruth R, Beauchamp, Tom L, King, Nancy M. P. *A history and theory of informed consent*. New York, 1986. Oxford University Press; Appelbaum, Paul S., Lidz, Charles W., Maiser, Alan: *Informed Consent – Legal Theory and Clinical Practice*. New York, 1987. Oxford University Press. 49–64. p. https://archive.org/details/informedconsent0000unse/page/n19/mode/2up

was predominantly dominated by a paternalistic and physician-centred approach, and the idea of informed consent essentially did not arise. As the analyses also show, the concept itself (informed consent) did not exist until the middle of the twentieth century.[12] The war and its legal consequences, however, brought a fundamental change in this respect. Hungary, however, in the absence of the necessary social and political changes – despite the creation of the necessary foundations at the end of the nineteenth and the beginning of the twentieth century – ultimately did not join this paradigm shift. A textual analysis of two emblematic statutory regulations of the period illustrates this clearly. Decree Law No. 8 of 1959 on medical doctors' regulation, as its title also indicates, regulated the question of healing in a one-sided approach with regard to the doctor-patient relationship, namely, the legislator determined the framework of healthcare in light of the physician's duties. Act II of 1972 on Health already contained rules on informing patients and on consent to interventions in a sectoral structure, but still with a clearly paternalistic approach. Nevertheless, it is true that on the basis of the right to human dignity declared by the Constitution and the personality rights regulated in the Civil Code, certain patients' rights could already be enforced at that time.[13] Overall, alongside the regulation of certain requirements of information provision and judicial practice that remains decisive to this day through its law-developing effect, the paternalistic approach of both the regulation and its everyday application in care remained dominant.

Research question 3 seeks to examine what process resulted in the regulation of patients' rights in Act CLIV of 1997, and what the experiences are of the practical realization of decision-making based on patient involvement, also taking into account the challenges of digitalization. The **three sub-questions, 3.a-3.c**, connected to this question concern the processes and changes that led to the transformation of the traditionally paternalistic regulation with the adoption of Act CLIV of 1997 on Health, then, in connection with this, the manner in which the detailed, catalogue-like statutory regulation of patients' rights is realized in everyday practice with regard to patient involvement, and, finally how the spread of digital technologies in healthcare changes patients' participation in decision-making about their care and, as part of this, the feasibility of informing them. These questions are answered by **Chapter 6**, which examines the legislative antecedents and adoption process of the Act, and, with a brief discussion of digitalization, the application challenges of recent decades, as well as by **Chapter 7**, which analyses the

[12] Faden 1986. 86–87. p.

[13] Dósa, Ágnes: *Az orvos kártérítési felelőssége [The civil liability of physicians]*. Budapest, 2010. HVG–ORAC. 188–189. p, 237–241. p, 243–244. p; Sándor, Judit: Hogyan érvényesülhet a hozzájárulás elve a magyar egészségügyi rendszerben? [How can the principle of consent prevail in the Hungarian healthcare system?] *Lege Artis Medicinae*, 1994. 4(1) 84–87. p. 84. p, Sándor, Judit: Gyógyítás és ítélkezés – orvosi „műhiba-perek" Magyarországon [Healing and adjudication – medical 'malpractice cases' in Hungary]. Budapest, 1997. Medicina Könyvkiadó. (Sándor 1997b) 181–184. p, 203–210. p.

substantive rules of the Act. The questionnaire-based research set out in **Chapter 8**, which examines the perceptions of patients, physicians and patients' rights representatives based on their knowledge and experiences, adds further nuance and confirms the findings of the earlier chapters along several aspects.

In the second half of the twentieth century, the period of what might be called the flourishing of patients' rights in the 1980s and 1990s was reached in such a way that the above-mentioned international development and the corresponding new legislative tendencies of European countries formally had no, or more precisely only marginal, effect on the Hungarian regulatory system. In practice, this predominantly meant the uninterrupted survival of paternalistic medicine. Nevertheless, during this period, new efforts also appeared to promote the treatment of patients' rights in accordance with the new paradigm. This was grounded mainly in the scholarly work and knowledge-disseminating activity of experts dealing with the subject – the legal and bioethical issues of the doctor-patient relationship and patients' rights – who already had international experience acquired in countries undergoing the paradigm shift, such as Ida Matkó[14], Judit Sándor[15] or József Kovács[16]. But the think-tanks (e.g. the Szószóló Foundation[17] or the LAM Club[18]) and journals (e.g. Lege Artis Medicinae) established at that time also played a decisive role in developing the new approach in Hungary, by providing forums for Hungarian scientific and social thought on this issue.

The 'incorporation' or adaptation of Act CLIV of 1997 in the Hungarian legal system is on the one hand, rootless in the absence of the underlying social development and movements, while, on the other hand, it is organically connected to the international tendencies of the time through the active contribution of the experts and professional communities dealing with the field in the 1980s and 1990s. Ultimately, the latter leads to Hungary's regulatory accession to

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[14] Chief anesthesiologist, former head of the intensive care units of several hospitals, a well-known advocate of patients' rights for decades and the former founding head of the Szószóló Foundation for Patients' Rights (Szószóló Foundation). See also Köbli, Anikó: *Aszklépiosztól a betegjogokig [From Asclepius to patients' rights]*. Budapest, 2009. Szépíró Műhely. 9–15. p.

[15] Lawyer and bioethicist, currently professor at Central European University (CEU) in Vienna, active contributor and leader in numerous research projects and organizations connected to bioethical and biomedical regulation, and a former founding member of the Szószóló Foundation.

[16] Physician, bioethicist and psychotherapist, currently professor at the Institute of Behavioural Sciences of Semmelweis University in Budapest, and a former founding member of the Szószóló Foundation. See also Köbli 2009. 91. p.

[17] The Szószóló Foundation was established in 1994 as the first organization in Hungary to undertake the protection of patients' rights. As part of this, in addition to carrying out rights-protection and educational activities, preparing publications and studies, and creating a kind of think-tank for experts dealing with the subject, the Szószóló Foundation is associated with the development and operation of a hospital ombudsman model (1997–2000), supported by a grant applied for and received from the Soros Foundation in 1996 to assess the situation regarding the enforcement of patients' rights.

[18] In the 1990s, the LAM Club was a professional-public forum connected to the medical journal Lege Artis Medicinae. While the journal served the scholarly examination of individual topics, the associated club evenings and events played a prominent role in laying the foundations of modern Hungarian bioethics and patients' rights.

the new paradigm based on patient involvement and to the statutory regulation of the doctrine of informed consent, as is clearly visible from the preparation of Act CLIV of 1997 and, later, from the detailed analysis of the statutory text.[19] Examining the subsequent life of the norm, the analysis of the literature outlines that regulatory transplantation cannot by itself translate the new approach to care into everyday practice, and this is further complicated by the acceleration of healthcare digitalization over the past decade.[20] The new technologies appearing through digitalization (especially artificial-intelligence-based tools) pose further challenges to doctor-patient communication, presumably as part of another paradigm shift of global impact that is currently difficult to foresee.[21]

The questionnaire-based research presented as the closing chapter of the dissertation also confirmed the problems described with regard to the three decades of application of Act CLIV of 1997. Alongside the importance of regulating patients' rights, including informed consent, the frequent perceived lack of preparedness and intention necessary for patients' active and meaningful participation also becomes apparent. The uninterrupted persistence of the paternalistic approach throughout society is likewise decisive on the basis of how participants in care view themselves and each other, despite the fact that there is already a strong demand among all stakeholders for the patient's real involvement, as well as openness to acquiring the knowledge necessary for this (including with the help of solutions made possible by digitalization).

As the above shows, the historical examination of the legal regulation and practical realization of informed consent offers numerous lessons. The legal regulation of any subject matter, including the involvement of patients in healthcare decisions, as the ordering of social coexistence, is always a major challenge, even in terms of scale, for every community, country or supranational legislator. As a result of the long process leading to the elaboration and acceptance of social consensus, it is also necessary to reckon with the embeddedness arising from the circumstances of the time and with customary practices becoming fixed as traditions.

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[19] Sándor 1997a.; Kovács, József: A betegjogok helyzete a bioetika szemszögéből [The situation of patients' rights from the perspective of bioethics]. In Borza Beáta (ed.): „Beteg vagy egészségügy" A betegjogok helyzete egy átalakuló rendszerben, avagy kinek fontos a beteg? ['Patient or healthcare system' The situation of patients' rights in a transforming system, or who cares about the patient?] Budapest, 2012. Alapvető Jogok Biztosának Hivatala. (conference publication) 69–94. p; Dósa 2010. 190–192. p.

[20] Sándor 1997a. 89. p; Kovács 2012. 73. p.; See also Borza, Beáta (ed.): „Beteg vagy egészségügy" A betegjogok helyzete egy átalakuló rendszerben, avagy kinek fontos a beteg? ['Patient or healthcare system' The situation of patients' rights in a transforming system, or who cares about the patient?] Budapest, 2012. Alapvető Jogok Biztosának Hivatala. (conference publication) https://www.ajbh.hu/documents/10180/125038/%E2%80%9EBeteg+vagy+eg%C3%A9szs%C3%A9g%C3%BCgy%E2%80%9D%20%20A+betegjogok+helyzete+egy+%C3%A1talakul%C3%B3%20rendszerben,%20avagy+kinek+fontos+a+beteg/f32d6456-5977-4b03-a026-e8f0501896d5?version=1.5

[21] Kovács, József: *A modern orvosi etika alapjai. Bevezetés a bioetikába [The foundations of modern medical ethics. Introduction to bioethics]*. Budapest, 2025. Medicina Könyvkiadó, 1106–1108. p.

Changes in already strengthened social practices repeated over generations, whether attributable to various causes or, in a given case, to a system of causes, lead from time to time to drastic transformation. Such a paradigm shift determines the history of the emergence and continuous development of the doctor-patient relationship and, connected to it, of the doctrine of informed consent, which characterizes the active involvement of the patient in connection with the doctor-patient relationship. Ultimately, it is the shift from a paternalistic approach toward shared decision-making that makes its examination interesting, and from which it is worth learning. So much so that, with the seemingly unstoppable spread of digital tools over the past decade, we have probably reached the threshold of yet another paradigm shift. The history of this latter process has only just begun, nevertheless, incorporating it into a legal-historical examination – similarly to the analysis of the realization of the rules of the nearly thirty-year-old Health Act, accepting the compromise of involvement arising from incompleteness and limited perspective – highlights the importance of such research. Examining informed consent from this perspective may help us understand how many new questions and connections can be opened up, through a historical lens, by legal and regulatory problems that have already been regarded as clarified or, in some cases, closed. This, in turn, may lead to new shared thinking and to more "informed" answers over time, to which my dissertation will, hopefully, also serve as a useful contribution. In closing, I invoke a thought worth considering by Ágnes Losonczi, who, quoting György Lukács citing Hegel, closes her book with the following lines: *'When change is needed, something is changed', [...] the only question is what changes and who makes the changes*.[22]

[22] Losonczi, Ágnes: *A kiszolgáltatottság anatómiája az egészségügyben [The anatomy of vulnerability in healthcare]*. Budapest, 1986. Magvető Kiadó. 217–218. p.

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