

Interdisciplinary Research on Consent of Alzheimer's Patients to Medical Procedures

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Abstract

Nowadays, research goes well beyond conventional academic boundaries, and bringing scientists from a variety of different backgrounds together is seen as a crucial part of addressing the main challenges facing the global society. Life sciences and social sciences, medical and legal sciences in particular, provide a great area for such interdisciplinary cooperation. The "International research network: Scientific research and development work for solving legal and medical problems of human health", composed of the University of Cambridge, University of Białystok, Medical University of Białystok and Medical University of Silesia provides a great example of a formal framework for conducting joint research within the field of medicine and law.

This paper addresses the most recent interdisciplinary research devoted to consent to medical procedures of patients with neurodegenerative diseases, with particular focus on Alzheimer's disease, and especially legal regulations thereon, results of which were published in the Journal of Alzheimer's Disease.

As Alzheimer's patients, especially in the final stages of the disease, are not always able to express their consent to medical procedures, or even to understand information provided by physicians, these matters are of huge importance, from both medical and legal perspectives. The research covered a comparative analysis of legal regulations of selected European countries (Poland, Germany, England and Wales) and the United States, representing 3 different types of legal orders, on the AD patients' consent to medical procedures. The conducted research indicated that although informed consent was required by all legal systems, laws of respective countries differed in many aspects. So far there have been neither international law acts, nor uniform guidelines on informed consent of AD patients.

Keywords: Interdisciplinary research; Alzheimer's disease; Neurodegenerative diseases; Consent to treatment

Mini Review

The high-priority issues of today and pressing research questions require insights from multiple disciplines. In order to address the main challenges facing the global society, scientists of various fields have to combine their efforts and must work together. Nowadays, research goes well beyond conventional academic boundaries, whereas bringing scientists from a variety of different backgrounds together is seen as a crucial part of fixing the world's problems. Research disciplines interpenetrate, providing a great area for cooperation. Life sciences and social sciences, and medical and legal sciences in particular, are a great example of such a combination.

Formal framework for conducting joint research within the field of medicine and law may be provided by joint research projects, conducted under different agreements, consortia, etc. The "International research network: Scientific research and development work for solving legal and medical problems of human health" (LMPHH), composed of the University of Cambridge, University of Białystok and two, high-ranked, Polish medical universities-Medical University of Białystok and Medical University of Silesia is a great example of such interdisciplinary structure.

The LMPHH was established in the Memorandum of Understanding signed on November 8, 2014. The purpose there was to formally record the mutual interest of these Universities in promoting and furthering academic links there between. Research cooperation within the LMPHH encompasses foremost broadly defined disciplines of legal sciences (in particular criminal law, criminology and criminalistics, healthcare law, civil law), as well as medical and health sciences. The Network serves integration and activation of local communities in

order to solve legal and medical problems of human health, including improvement of the quality of healthcare services provided in Poland. The activity thereof aims at integration of academic communities, experience exchange, as well as implementation of concrete actions. The LMPHH was established inter alia to: consolidate and strengthen the research potential of the research units for conducting joint research and development works complementary to the tasks performed within the statutory activity thereof; promote and coordinate research projects with the use of Network Members' experience; undertake joint projects and help Network Members use the funds for research, development and implementation, as well as assistance in undertaking international research programs; mutually inform of and exchange the research results; to exchange research and implementation services, as well as to use the infrastructure and the equipment within the joint projects; produce and disseminate information on the activity of the LMPHH; formulate de lege lata and de lege ferenda proposals; formulate proposals referring to the rules of conduct in healthcare, etc. The Network achieves its objectives through active participation in preparing and implementing joint research projects, in particular by: preparation of highly qualified

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research staff; joint research and development works; academic and personal exchange, training and internship; support for transfer and commercialization of new technologies; organization of regular both national and international academic conferences within the activity thereof. Although initially established for a period of three years, in the Annex of April 10, 2017, the Parties agreed to extend the MoU for a period of three years, or until April 2020.

So far, the LMPHH has undertaken a number of initiatives, including projects conducted within the Scientific Forum "Legal and medical aspects of human health", covering research on legal, criminological and medical aspects of: pediatric gynaecology; social exclusion; doping; as well as designer drugs. The most recent field of the joint activity has been neurodegenerative diseases (NDs). The conducted comparative research focused on consent to medical procedures of patients with neurodegenerative diseases, in particular legal regulations thereon, and its results were published in the *Journal of Alzheimer's Disease* [1].

According to the data of the statistical office of the European Union, Eurostat, the total EU population in 28 Member States amounted to 508.5 million in the beginning of 2015. In the EU, people age 65 and older amounted to 18.9%, meaning that every fifth person was of senior age [2]. And, according to the European Commission, the most common cause of dementia in the EU is AD, reaching about 50%-70% of cases. The U.S. population age 65 and older continues to increase [3] and is projected to nearly double from 48 million to 88 million by 2050 [4]. According to the *Demographic Yearbook of 2017*, prepared by the Central Statistical Office, at the end of 2016 there were 38.43 million people in Poland, of whom 6.30 million were 65 or older, reaching 16.4% of the total population and meaning that every sixth person in Poland is 65 or older [5]. According to the Eurostat projections, nearly one third of EU citizens will be at least 65 in 2060. Whereas, in Poland, people of that age are to amount to 34.5% [6].

Elderly people are especially exposed to NDs, the most common of which is Alzheimer's disease (AD). The age range of greatest risk of AD is 65 and beyond. Worldwide, nearly 44 million people suffer from AD or a related dementia [7]. In the EU, there were 10.5 million people with dementia in 2015, and the number is predicted to increase to 13.4 million by 2030 and to 18.7 million by 2050 [8]. It is estimated that 5.5 million Americans of all ages are living with AD, including 5.3 million people age 65 and older [3]. In the U.S one in ten people age 65 and older has AD, and it is estimated that, by 2050, the number of people age 65 and older with AD may nearly triple, to projected 13.8 million [9]. In 2010, there were an estimated 454 thousand new cases of AD in the U.S; by 2030, that number is projected to reach 615 thousand and by 2050, 959 thousand, thus increase of 35% and 110% respectively. AD is the sixth-leading cause of death in the United States [10], and the fifth-leading cause of death for people age 65 and older [11]. In Poland, around 350 thousand people suffer from AD, and the number is projected to reach over million in 2050, so three times more than today.

As AD patients, especially in the final stages of the disease, are not always able to express their consent to medical procedures, or even to understand information provided by physicians, these matters are of huge importance, from both medical and legal perspectives. Due to their growing significance, there have been conducted studies devoted thereto [12-14]. Since ancient times, there has been a problem of *salus aegroti suprema lex* (the well-being of the patient shall be the most important law) or *voluntas aegroti suprema lex* (there's a supreme agreement to voluntarily accept treatment for illness). Nowadays autonomy of a patient and his will are of a great importance, and consent to medical procedures is a prerequisite for the legality of conducting

thereof.

Therefore, the research covered a comparative analysis of legal regulations of selected European countries (Poland, Germany, England and Wales) and the United States on the subject issue. These countries were chosen, because they represent 3 different types of legal orders, existing in the world, namely civil law (Poland and Germany), common law (England and Wales) and case law (the United States), differentiated by the sources thereof.

In Poland, regulation of a patient's consent to a medical procedure is provided for in the Act of December 5, 1996 on professions of doctor and dentist [15], setting out the principles and conditions of pursuing the profession of doctor and dentist, and in particular in Chapter 5 thereof, containing the rules for pursuing the profession of doctor. Additionally, Article 162 of the Penal Code of 1997 [16] obliges every person to provide assistance to a person in need, if providing such assistance is possible "without exposing himself or another person to the risk of death or severe health disorders", whereas anyone who does not provide such assistance is liable to imprisonment for up to three years.

In the Federal Republic of Germany, also belonging to the civil law legal system according to the sources of law, provisions on consent of patients to medical procedures can be found in the Civil Code of 1986 [17], as well as in the Penal Code of 1871 [18]. Additionally, a medical procedure has to satisfy specific premises excluding its criminality, so that behavior of a physician does not fulfil attributes of offences set forth in Chapter 17 of the German Penal Code.

In England and Wales, the issue of making decisions on treatment by patients, incapable of making decisions for themselves, including patients in the third phase of AD, is regulated by the Mental Capacity Act of 2005 [19]. This act sets out the rules of making such decisions, as well as introduces five principles that shall apply for the purposes thereof. Additionally, it provides for a number of solutions to be applied, when a patient is unable to make informed decisions on his treatment.

Finally, in the United States, the National Alzheimer's Project Act was signed into law on January 4, 2011 [20], establishing *inter alia* the Advisory Council on Alzheimer's Research, Care and Services. The Alzheimer's Association, the leading voluntary health organization in Alzheimer's care, support and research [21], encourages persons suffering from AD to plan for the future, with particular consideration given to legal plans [22]. Several important requirements for informed consent are stipulated in the 1987 federal Nursing Home Reform Law, providing for a numerous nursing home residents rights [23]. In 2012, the Improving Dementia Care Treatment in Older American Act [24] was introduced, providing for specific protocols for physicians and health care providers to follow for obtaining informed consent; it did not pass in the 112th Congress however. Additionally, a lot of attention is paid to an AD patient's consent to research. Legal framework is provided by *inter alia* regulations of the U.S. Department of Health and Human Services, at 45 C.F.R. parts 46 for the protection of human subjects in research [25]. Whereas state laws on informed consent differ in many aspects, all states have legislation that requires some level of informed consent.

Conclusion

The conducted research indicated that informed consent was required by all legal systems, regardless of their type. As patients with AD, especially in the last phases thereof, are unable to express valid consent, the so-called substitute consent is provided for, expressed on

behalf of the patient by persons authorized, i.e. close persons defined in the respective regulation. There are possibilities for the family and a guardianship court to intervene. Still, the informed consent and physicians' liability are regulated by different legal instruments, right for the respective system of the law. So far there have been neither international law acts, nor uniform guidelines on informed consent of AD patients. Such international standards or uniform guidelines would be welcomed by medical, legal and ethical communities around the world.

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