

Active ageing and health protection: new healthcare scenarios

SERENA CANCELLIERI

(PhD Student in Civil Law and Constitutional Legality of University of Camerino, serena.cancellieri@unicam.it.)

Abstract

La promozione dell'invecchiamento attivo, avente natura transfrontaliera, è da anni un obiettivo contenuto nell'agenda dell'Unione europea.

Da questo impulso, nel 2022, è stato rinnovato per ulteriori tre anni, l'accordo fra il Dipartimento per le politiche della famiglia e l'Istituto Nazionale Riposo e Cura per Anziani (INRCA).

Il lavoro in oggetto ha due obiettivi principali. Il primo è quello di comprendere gli strumenti che, inseriti in un contesto multidisciplinare, possono incentivare un invecchiamento in buona salute e quello di comprendere concretamente come questi si inseriscono in un sistema sanitario sostenibile al fine di garantire un equo accesso alle cure.

Oltre a ciò verranno considerati diversi scenari di decadimento cognitivo su pazienti affetti da Alzheimer per indagare come, nelle diverse fasi della malattia, questi riescano a prestare un libero ed effettivo consenso informato ai trattamenti sanitari.

Il lavoro porrà una particolare attenzione anche alle tecniche di potenziamento cognitivo applicato a diversi profili terapeutici realizzabili sia tramite l'assunzione di farmaci, che per mezzo di impianti neuronali capaci di stimolare l'attività celebrale.

Nello specifico verrà analizzato il tema dell'invecchiamento attivo nei pazienti affetti da demenze e il diritto di quest'ultimi all'autodeterminazione nelle scelte assistenziali o di cura alla luce di queste nuove tecnologie mediche.

In virtù delle novità introdotte dalla scienza, il quadro giuridico si presenta complesso in mancanza di fattispecie di consenso informato che considerino un paziente affetto da forme di demenza nelle varie fasi di decadimento.

Saranno infine analizzati sia l'impatto che queste tecniche hanno nei bilanci del sistema sanitario nazionale, sia come, dal punto di vista statistico, sono state accolte dalle famiglie come scelte assistenziali.

Promoting active ageing, which is cross-border in nature, has been a priority for the EU for years. From this desire, in 2022, the agreement between the Department for Family Policies (DIPOFAM) and the National Institute for Rest and Care for the Elderly (INRCA) was renewed for another three years. This paper aims at two main objectives. The first is to understand the tools that, in a multidisciplinary context, can encourage healthy ageing; the second is to understand particularly how they fit into a sustainable health system in order to ensure fair access to care.

In addition, different cognitive decay scenarios will be considered on Alzheimer's patients to investigate how, at different stages of the disease, they can give free and effective informed consent to health treatments.

The work will also pay specific attention to cognitive enhancement techniques applied to different therapeutic profiles achievable both through the intake of drugs, and by means of neuronal implants capable of stimulating brain activity. Precisely, the topic of active ageing in patients with dementia will be analyzed as the latter's right to self-determination in the choice of care in the light of these new medical technologies.

Due to the innovations introduced by science, the legal framework is complex in the absence of a case of informed consent that considers a patient suffering from dementia in the various stages of decay.

Finally, the impact that these techniques have on the national health system budgets will be analyzed, as well as how, from the statistical point of view, they have been accepted by families as welfare choices.

Summary: 1. Introduction 2. Human enhancement and dementia 3. Legal nature of cognitive enhancement 4. Analysis of the concept of capacity in Law 219 of 2017 and supranational sources 5. Arguments 6. Conclusion

1. Introduction

The Organization for Economic Cooperation and Development (OECD) projects that by 2030, the percentage of people aged over 65 in Europe will represent 27.1% of the population¹. Italy is set to become ‘the country’ with people aged over 65 years, one of the oldest countries in Europe, which is why promoting active ageing across borders has been a common objective among EU member states, also included in the Agenda 2030. This work addresses the issue of population ageing and the emergence of new scenarios resulting from it, such as the increase in dementia cases. In Europe, the prevalence of dementia is currently 1.94%, and it is expected to rise to 2% by 2025². Given the new therapeutic approaches to these conditions based on cognitive enhancement, the goal is to investigate whether these can be considered healthcare treatments. Furthermore, the protection of therapeutic self-determination for vulnerable individuals will be analyzed, including how a person with a neurodegenerative disease can freely express informed consent for healthcare treatments. Promoting active ageing means working multi disciplinarily to guide healthcare systems in creating governance capable of supporting an inevitable social change while protecting the most vulnerable individual situations. Building on this momentum, in 2022, the agreement between the Department for Family Policies and the National Institute of Health and Science on Aging (INRCA) was renewed for another three years³. The issue of “old age” is certainly not new, and the problems and consequences associated with it are not easily solvable. It has been discussed for years in doctrine

¹ ISTAT, *Previsioni della popolazione residente e delle famiglie | base 1/1/2020. Futuro della popolazione: meno residenti, più anziani, famiglie più piccole. Statistiche report*, in www.istat.it, 2021. (visited on date 3 May 2023); <https://www.oecd.org/> (visited on date 4 May 2023); I. R. E. S. PIEMONTE, IRPET, SRM., POLIS LOMBARDIA, IPRES., LIGURIA RICERCHE, AGENZIA UMBRIA RICERCHE 2021. *La finanza territoriale*, Soveria Mannelli, 2021, 1 ss.

² ALZHEIMER EUROPE, *Dementia in Europe Yearbook 2019 Estimating the prevalence of dementia in Europe. This Dementia in Europe Yearbook received funding under an operating grant from the European Union's Health Programme*, Luxembourg, 2019, 1 ss.

³ F. BARBARELLA, P. CHECCUCCI, M.L. AVERSA, G. SCARPETTI, R. FEFÈ, M. SOCCI, G. LAMURA, M. VILLA, *Le politiche per l'invecchiamento attivo in Italia. Rapporto Sullo Stato dell'arte*. in <https://famiglia.governo.it/it/>, 2020, 1 ss.

about its different facets⁴. On the one hand, an exclusively socio-sanitary dimension⁵, on the other, inspired by criteria and principles of social solidarity⁶. However, no clear answers seem to have been found⁷. Nonetheless, progress has been made in developing an approach to the challenges posed by new needs. It is important to be cautious about constructing a category of the elderly and exclusive legislation for the elderly as it may lead to new forms of marginalization⁸. Similarly, proposing the establishment of an elder's rights⁹ or an elderly statute seems futile. Instead, it is crucial to identify appropriate solutions for the protection and promotion of individuals in particularly vulnerable situations¹⁰, including those with disabilities. The demographic ageing of the population has brought to light legal issues which have remained unresolved.

The latter should be read in the light of the intense technological and medical development, in a methodological interpretation that holds firmly the principles of protection of the person contained in the Constitution and in supranational sources. Special attention will be given to the elderly in fragile conditions in correlation with the increasing cases of dementia. The complexity lies not only in the interpretation of the elderly status, which deserves further examination in another context, but in the issue of the freedom of choice for patients with dementia. The focus of this work will be to analyze healthcare self-determination and informed consent. These topics may have an "ancient" flavor, but given the social transformations, they require a re-evaluation that can make the legislative interpretation of Law 219 of 2017¹¹ a true instrument for protecting the most vulnerable individuals.

⁴ F. PARENTE, *La vita, il tempo e lo spazio: l'anzianità come categoria dell'adulità e del diritto*, in I. FLOREK, I. LAKI, K. SCHOTTNER (a cura di), *Human Right sas a guarantee of smart, sustainable and inclusive growth*, Budapest, 174-181; P. STANZIONE, *L'età dell'uomo e la tutela della persona: gli anziani*, in *Riv. dir.*, 1989, 1, 439 ss.

⁵ M. PEREZ, V. LUMIA, A. MAZZOTTI, *Aspetti di una politica sociale e sanitaria per gli anziani in prob. sicur.*, 1972, 4, 529- 664.

⁶ V. ZAMBRANO, *La tutela dell'anziano*, in *Rass. Dir. Civ.*, 1990, 1, 200-205.

⁷ C.M. Bianca, *Senectus ipsa morbus?* In *Rass. Dir. Civ.*, 1998, 2, 241-250.

⁸ P. Perlingieri, *Il diritto civile nella legalità costituzionale secondo il sistema italo europeo delle fonti*, Napoli, 2020, 22, cit.; P. PERLINGIERI, *Diritti della persona anziana, diritto civile e stato sociale*, in *Rass. Dir. Civ.*, 1990, 1, 81-99, cit.

⁹ M. DOGLIOTTI, *I diritti dell'anziano* in *Riv. Trim.*, 1989, 1, 711-720.

¹⁰ G. LISELLA, *Rilevanza della "condizione di anziano" nell'ordinamento giuridico*, in *Rass. Dir. Civ.*, 1989, 1, 794- 812.

¹¹ Legge 22 dicembre 2017, n. 219. Norme in materia di consenso informato e di disposizioni anticipate di trattamento.

2. Human enhancement and dementia

While it may be impossible to control the inevitable increase in dementia cases, it is necessary to find tools that can combine this aspect with improving the quality of life for individuals. In the context of neurodegenerative diseases, medicine, particularly neuroscience, has made significant diagnostic and therapeutic advancements in recent decades, including those based on human enhancement, such as cognitive stimulation often used in these cases¹². This can be achieved through therapeutic interventions involving medication or neural implants capable of stimulating cognitive and moral abilities. The use of neuro-technologies such as Brain-Computer Interfaces (BCIs) or Transcranial Magnetic Stimulation (TMS) has also shown significant results in the treatment and reduction of symptoms in patients with dementia¹³. The delicate and often experimental nature of these treatments raises questions, particularly regarding the legal nature of these therapeutic hypotheses and the protection of a patient's healthcare self-determination when faced with the opportunity to participate in such treatment for neurodegenerative disease.

3. Legal nature of cognitive enhancement

Cognitive enhancement treatments have been recognized under Article 76 of the Code of Medical Ethics¹⁴, titled "enhancement

¹² C. Casella, *Il potenziamento cognitivo tra etica, deontologia e diritti*, in *BioLaw Journal*, 2020, 2, 151- 167.

¹³ G. ARENDASH, C. CAO, H. ABULABAN, R. BARANOWSKI, G. WISNIEWSKI, L. BECERRA... & A. SMITH, *A clinical trial of transcranial electromagnetic treatment in Alzheimer's disease: Cognitive enhancement and associated changes in cerebrospinal fluid, blood, and brain imaging* in *Journal of Alzheimer's disease*, 2019, 1, 57-82.

¹⁴ Approved in Turin by the National Federation of the Orders of Surgeons and Dentists on May 18, 2014, then reformulated in 2017: "The physician, both in research activities and when required to carry out non-therapeutic activities but aimed at strengthening the individual's physical and cognitive physiological capacities, shall operate with respect for and safeguarding the dignity of the individual in all his or her individual and social reflections, identity and integrity of the person and his or her genetic characteristics, and the principles of proportionality and precaution. The physician shall acquire informed consent in writing taking care to verify, in particular, understanding of the risks of treatment. The physician has a duty to refuse any request deemed disproportionate and high risk also because of the invasiveness and potential irreversibility of the treatment in the face of non-therapeutic but potential benefits".

medicine,” which approves their practicability for experimental purposes while respecting and safeguarding the individual’s identity and integrity through written informed consent¹⁵. The question to be clarified is whether a patient with dementia could have the freedom to refuse any treatment that could significantly improve their quality of life and still provide valid informed consent. This issue is complex and does not lend itself to clear conclusions from a contemporary jurist’s perspective¹⁶. In this context, it is necessary to reflect on the available legal tools and how they can be improved inclusively, considering the hypothetical and future applications of these therapies within the national healthcare system. On one hand, there is the complexity of determining whether cognitive enhancement can be considered a healthcare treatment, given its experimental nature. On the other hand, there are challenges related to the capacity of the individual, as indicated in the application phase of Law 219 of 2017, particularly in cases of neurodegenerative diseases.

4. Analysis of the concept of capacity in Law 219 of 2017 and supranational sources

If cognitive enhancement treatments are considered healthcare treatments (under Article 76 of the Code of Medical Ethics), they would require informed consent from the patient. Through a comparative analysis of the data contained in Law 219 of 2017, the European Charter of Patients’ Rights¹⁷, and the Oviedo Convention¹⁸, a methodological approach based on constitutional personalism (Articles 2, 3, 13, 32 of the Italian Constitution) has been applied (Perlingieri, 2020). Informed consent is provided by an adult capable of understanding and deciding, or by a parent or guardian in the case of a minor, taking into account considering the individual’s will. However, according to the legislation, if an adult refuses or revokes informed consent for any diagnostic assessment or healthcare treatment, they must possess “legal capacity.” Additionally,

¹⁵ E. PULICE, *La deontologia medica come “motore” della Costituzione* in *BioLaw Journal*, 2019, 2, 323- 347.

¹⁶ P. PERLINGIERI, *Note sul potenziamento cognitivo* in *Tecnologie e diritto*, 2021, 2, 209-216.

¹⁷ European Charter of Patients’ Rights, Brussels, November 15, 2002.

¹⁸ Convention for the Protection of Human Rights and Dignity of the Human Being with Respect to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine signed in Oviedo on April 4, 1997.

Article 5 of the same law does not explicitly indicate the capacity required for shared care planning or acting as a healthcare proxy but suggests applying analogously what is established for advanced healthcare directives. Similarly, according to Articles 3, 4, and 5 of the European Charter of Patients' Rights, the individual must be capable of understanding and deciding freely to provide informed consent for healthcare treatments, without reference to legal capacity, which is clearly expressed in the text of Law 219 of 2017. The Oviedo Convention also refers to the individual's "capacity" to give consent in Articles 5 and 6, without mentioning legal capacity. Another critical aspect of the legislation is the lack of specific criteria for determining and certifying the nature and degree of a person's natural capacity with respect to informed consent, living wills, and shared care planning. The essential point that emerges from the data is not so much the terminological use of legal capacity in cases of refusal, but the essentiality of the consensual element concerning the fundamental right to therapeutic self-determination. This goes beyond lexical considerations and must be evaluated in each individual case, especially given the degenerative nature of cognitive states in certain diseases such as Alzheimer's¹⁹. The requirement of capacity, particularly with respect to revocation or refusal of consent, raises critical issues in interpreting the law in light of constitutional and supranational principles, as compared to the requirement of capacity for insight and decision-making.²⁰ The legislation under review emphasizes the role of free and informed consent, as well as patient will, and emphasizes the "therapeutic alliance" between physician and patient²¹.

5. Arguments

In the context of dementia, the problem lies in the progressive decline of cognitive abilities, which makes it increasingly challenging for healthcare professionals to establish effective relationships

¹⁹ P. PERLINGIERI, *Il diritto civile nella legalità costituzionale secondo il sistema italo europeo delle fonti*, Napoli, 2020, IMMETTI PAGINE; V. ROTONDO, *Responsabilità medica e autodeterminazione della persona*, Napoli, 2020, PAGINE; A. FERRERO, 2020. *Autodeterminazione dei minorenni. I minori come soggetti capaci in ambito sanitario* in *Diritto di Famiglia e delle Persone*, 2020, 1, 1792-1810.

²⁰ Artt. 2,13,32, comma 2, Cost.

²¹ E. BATTELLI, *I soggetti vulnerabili: prospettive di tutela della persona* in *Diritto di Famiglia e delle Persone*, 2020, 1, 283-297.

both in terms of communication and obtaining informed consent to make clinical decisions²². Protecting the patient's autonomy in therapeutic choices is the result of a reasonable balance between opposing needs²³. On one hand, the medical team is required to respect the patient's will, whether they accept or refuse treatment²⁴; on the other hand, the individual must always have the opportunity to be heard, even in cases where there are limitations to their natural capacity. The absence of specific criteria for determining the degree of natural capacity poses challenges, especially for diseases involving a gradual loss of cognitive abilities. This critical aspect affects the identification of individuals responsible for assessing capacity. How can individuals be effectively heard if the legal tools for evaluating their cognitive state are lacking? The risk of compromising the benefits introduced by the law becomes very high in practical terms, particularly for individuals in specific clinical conditions where capacity assessment is crucial for determining their will. Mental illnesses encompass a wide range of pathological conditions that vary greatly from person to person and progress at different rates, as is the case with dementia. The crucial point is that there is not necessarily a direct correlation between degenerative mental illnesses and the inability to make decisions about one's health. There are "grey areas"²⁵ that present a heterogeneous range of cases, which healthcare professionals must consider in light of the fundamental right to individual self-determination. The strict binary notion of a person having or lacking legal capacity does not align well with the process of understanding a patient's will, as emphasized by the Nuffield Council on Bioethics (UK)²⁶ in its report on ethical issues related to dementia. The practical implications pose uncertainties

²² M.C. DAVOLIO, *La tutela del paziente affetto da demenza ad esordio precoce (EOD): nuovo protocollo di accertamento della disabilità* in *Rivista Italiana di Medicina Legale (e del Diritto in campo sanitario)*, 2021, 4, 1001-1015.

²³ P. PERLINGIERI, *Il diritto*, 33.

²⁴ U. VERONESI, *Il diritto di non soffrire. Cure palliative, testamento biologico, eutanasia*, Milano, 2011; C. CASONATO, *Introduzione: la legge 219 fra conferme e novità*, in *BioLaw Journal*, 2018, 1, 13-14.

²⁵ E.M. TURLA, C. PORTERI, *Capacità e diritto all'autodeterminazione terapeutica nella legge n. 219/2017. Il caso delle persone con disturbo psichiatrico e cognitivo* in *Rivista di psichiatria*, 58, 134-142.

²⁶ J.H. HUGES, *'Dementia: ethical issues' over ten years on. Report* in *Nuffield Council on Bioethics, web site*. <https://www.nuffieldbioethics.org/blog/dementia-ethical-issues-over-ten-years-on>, 2020. (visited on date 10 June 2023).

for both legal and healthcare professionals, which impact the psychological and physical health of the individual and their family. Especially in psychogeriatric contexts, it is often not easy to determine whether the subject is capable of understanding and willing in the existential choices that concern him. Encouraging continuous interaction between the legal and healthcare domains brings benefits to the patient's quality of life, improving their psychological and physical health, as well as the family and caregiving environment and reducing stress that often leads to social isolation and psychological and physical illnesses for the caregiver.

6. Conclusions

Based on these considerations, it is evident that such a variety of situations requires adequate legal protection based on a case-by-case analysis²⁷. Addressing the consequences resulting from the rigid legal dichotomy between capacity and incapacity of the individual necessitates a proactive and multidisciplinary approach, guided by constitutional and supranational principles. This approach involves constant interaction between the healthcare and legal fields to create synergistic collaborations that benefit vulnerable individuals. The adoption of good clinical practices that actively consider the various facets of individual capacity is desirable. From a legal perspective, legal professionals should adopt an interpretative flexibility that considers the uniqueness of each person and the relevance of diverse situations. Every development in technology and medicine presents epistemological and philosophical challenges, and only innovation that guarantees the well-being of humans can lead to a harmonious future and avoid “mechanical fundamentalism”²⁸. Therefore, the question arises: to what extent should we listen to a patient with dementia and allow them to provide free and informed consent based on their choices, and when is it necessary to involve a healthcare proxy to assist them? Answering this question is not easy, and concerns in this regard are significant, but they should not lead to a rejection of neuroscientific advancements that have many positive applications in healthcare and therapy. Understanding the point at which an individual is no longer cognitively capable of making decisions and where they still retain the ability to make therapeutic

²⁷ F. CARIMINI, *Ars medica e tutela del paziente*, Napoli, 2019, 139-140.

²⁸ P. PERLINGIERI, *Note*, PAGINA, 212, cit.

choices is perhaps one of the most challenging missions for both healthcare professionals and jurists. Jurists often bear the difficult responsibility of appointing a healthcare proxy to support the patient in their decision-making. A recent ruling by the ECHR²⁹ confirms the importance and necessity of understanding the nuances of a vulnerable individual's will and applying them to protect their dignity and freedom respecting private life. Therefore, the problem not only concerns the right to health but also encompasses the holistic psychophysical well-being of the individual. To meaningfully protect a patient's free and informed consent and ensure sustainable access to care, an interpretive approach based on individual cases and the continuous scientific evolution is necessary. Protecting individuals' self-determination in therapeutic choices requires a multidisciplinary approach that integrates science, law, ethics, and philosophy in a synergistic harmonization of the legal system with the needs of individuals, especially the most vulnerable among them³⁰.

²⁹ Corte e.d.u. 6 luglio 2023, Calvi e C.G. c. Italia.

³⁰ G. PERLINGIERI, G. ZARRA, *Ordine pubblico interno e internazionale tra caso concreto e sistema ordinamentale*, Napoli, 2019.