



Who gets to decide for the older patient with a limited decision-making capacity: a review of surrogacy laws in the European Union

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Abstract

Family members of older incompetent patients are increasingly playing an essential role in the decision-making process relating to medical treatment. Furthermore, rights of patients and carers and the extent of their legal involvement vary widely across the European Union. Starting with an illustrative case within the Italian legal framework, this review focuses on statutory laws in the European Union to analyse the role and the rights of surrogates on behalf of older incompetent patients. The authors have identified two main essential areas of surrogate's law in Europe, in the absence of the advance directives: the role of family members automatically accepted as surrogates by law and a legal representative appointed by a court.

Keywords Decision making-capacity · Competence · Older patients · European Union · Surrogates · Informed consent

Background

A 94-year-old female patient was hospitalised in 2017 for management and investigation of anaemia and weight loss. The physicians providing her care reached a diagnosis of gastric cancer. The patient had no locally invasive or metastatic disease at the time of presentation and, thus, the oncologists proposed perioperative chemotherapy and a curative resection. The physician's attempts to explain the need for surgical intervention to the patient, at an appropriate cultural and emotional level, were not successful. She did not have

any advanced directives or legal representation in place at the time. Assessment of her decision-making capacity, via evaluation with neuropsychological testing, demonstrated that the patient had a significant cognitive impairment and was incapable of expressing her wishes, values, and preferences consistently. She required assistance with toileting and transferring. The patient's son was fully informed about the nature of the surgery, the expected benefits, material risks and adverse effects, alternative treatments and the consequences of not having the surgery. Based on the information provided, he declined surgical intervention; however, the primary physician explained that as he was not the legal representative of the patient he was unable to give or refuse consent on behalf of his relative.

Italian legislation

According to the Italian law effective at that time in such a case, it would be necessary to ask the tutelary judge—via the hospital's social service—to appoint a supporting administrator (Amministratore di Sostegno). The tutelary judge usually has the discretion to nominate one of the following persons: a spouse not legally separated; a cohabiting partner; a father, mother; son, brother or sister; a 4th-degree relative; or a caseworker (if the available surrogates suggested above are conflicted or unavailable). In this particular case,

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the patient's son reluctantly accepted the position, and the tutelary judge appointed him as a supporting administrator. He subsequently refused the proposed treatment. Article 1 of Law 6/2004 [1] defines the purpose of a supporting administrator: "to protect persons who are fully or partially lacking autonomy, with the least possible infringement on their capacity to act, in the execution of daily functions through temporary or permanent supportive intervention". Family members have no power to consent (or dissent) under Italian law, with the next of kin only allowed providing legal representation if designated by a court of law. The right of the patient to decide in full awareness and freedom if, who and how they receive treatment derives from Article 32 of the Italian Constitution. This article states that "no one may be obliged to undergo any health treatment except under the provisions of the law". Relatives can provide informed consent and dissent only in the cases of patients under 18 years of age (expressly delegated to the parent) or cases of an interdicted person (entrusted to the relative or other persons as legal guardians). Thus, in the Italian legal system, the persons that can sign and express the informed consent are the person concerned; the parent (for the children); the legal guardian in the case of interdiction procedure and the supporting administrator (Fig. 1). The power to take into account the patient's previously expressed wishes, in the absence of the advanced treatment provisions (recently adopted by Italian government), according to a ruling by a Supreme Italian court, is also given to the supporting administrator [2].

Introduction

Informed consent for clinical treatment has become a vital part of contemporary medical practice [3]. In everyday clinical practice, physicians are required by law to obtain informed consent and dissent in many different clinical

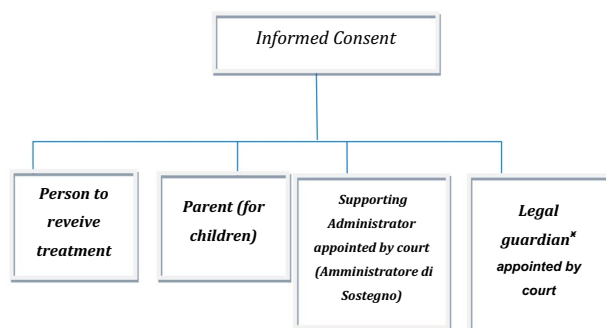


Fig. 1 Who gets decide according to the Italian laws. "Asterisk" For interdict persons who are permanently and completely deprived of the possibility of the decision-making process

situations, including individualised elderly care planning, rehabilitation planning, means of protection, surgical procedures, diagnostic tests and other invasive procedures and techniques. Informed consent is strongly related to the assessment of the patient's decision-making capacity (DMC) for treatment. There is a close relationship between the ability to make decisions and the patient's cognitive status. The prevalence of cognitive impairment without dementia steadily increases with age and affects a substantial proportion of the elderly population [4]. Furthermore, there are many causes frequently associated with cognitive impairment in hospitalised older patients, including the presence of delirium [5], acute illnesses [6] and dementia [7] that assess the degree of cognitive impairment present at a given time problematic. For older incapacitated patients, relatives often consider the appointment of a legal representative for their older loved one's healthcare management, an unsatisfactory practice for a number of reasons. Firstly, the relatives have often played central roles as primary caregivers for many years and thus have a good understanding of their relative's wishes and preferences. Secondly, relatives often prefer to trust the ethics and professional competence of physicians for some "routine" health care measures and only become involved in the consent process for more intensive procedures. Additionally, it is not uncommon for family members to prefer a course of treatment more focused on patient comfort than more radical treatment being suggested by medical teams [8]. Furthermore, it is our experience that physicians may struggle to understand the need to formally appoint a supporting administrator in cases where clinical decision making in the patient's best interests appears straightforward. Therefore, we hope to answer the following questions as part of this review of surrogacy laws in the European Union: (1) who determines the competence and decision-making capacity of patients, and how? (2) which factors limit a family member's ability to provide informed consent? (3) Is there a common approach to this issue across Europe? (4) Is the family members' role defined in law, and if so, how? (5) who gets to decide on behalf of incompetent patients in European member states where family members are not automatically recognised?

Who determines competence and decision-making capacity, and how?

The concept of competence is a multidimensional construct with significant clinical, legal, ethical, social, and political aspects. The terms capacity and competency occur frequently and are often used interchangeably in clinical practice. Competence is determined by a judge, and while a legal incompetence ruling does suggest a likely lack of decision-making capacity, it does not confirm it. Additionally,

patients may still retain legal “competence” regarding medical matters even if deemed incompetent regarding, for instance, financial decisions and a judicial declaration of incompetence may thus be either global or limited (e.g. to financial matters, personal care, or medical decisions) [9]. Competence refers to the mental ability and cognitive capabilities required to execute a legally recognised act rationally and may differ according to the action in question [10]. Competence in care and treatment setting refers specifically to DMC which, unlike competence, can vary over time. In practice, medically qualified personnel with overall clinical responsibility for the person lacking capacity will establish the goals of care for that patient. Any decisions made are, therefore, generally restricted to consenting to treatment or investigation decisions offered by expert clinical staff. The consent process involving the patient or the surrogate is directed at establishing reasonable expectations for a medically indicated treatment’s outcome. However, the DMC is a compound of abilities typically divided into four sub-capacities: understanding, appreciation, reasoning, and choice. To be able to understand information properly, individuals must have the general cognitive skills to understand information about the condition, treatment, and outcome. Recognition of one’s situation refers to the ability to realise and evaluate the consequences of different alternatives. Reasoning covers the ability to use and process information to reach a decision, including the ability to take different viewpoints and arguments into account in one’s decision making. The choice covers aspects of the selection itself, i.e. to be able to settle for a decision and communicate it [11]. For an older patient, the assessment of decision-making capacity should also take into account the patient’s ability to control their emotions, their activities of daily living and the ability to express their preferences and wishes consistently [12]. A thorough assessment of the ability would include most, if not all, of the following components: (1) a clinical and diagnostic interview; (2) neuropsychological testing; (3) functional ability assessment, and (4) review of legal standards [13]. Also, in the presence of depression and mild cognitive impairment or early dementia, psychiatric consultation should be considered, although these conditions do not preclude the patient’s ability to make a competent decision [14]. A number of different tools used for making assessments of a patient’s capacity have been developed and utilised in the past. The Mini-Mental Score Examination (MMSE) is a commonly used and widely recognised tool, although its accuracy in adult patients without severe mental illnesses is very limited. The Aid to Capacity Evaluation (ACE) score is considered one of the better available instruments to aid physicians in making assessments of medical decision-making capacity [15]. The ACE includes an evaluation of the medical condition, the proposed treatment, and therapeutic alternatives. It also consists of additional options regarding

refusal of recommended treatment (including withholding or withdrawing proposed treatment) and evaluation of the consequences of accepting or declining a proposed treatment. The last part of this tool refers to the influence of depression and psychosis on the person’s decision [16]. The MacArthur Competence Assessment Tool for clinical research and treatment is another available method and has considerable empirical support [17, 18]. DMC, in all European member states, is usually assessed by a medical professional. In some cases, the court appointed an expert doctor to assess DCM. As part of that legal process, the court may consider expert testimony from a neuropsychologist, psychologist, or another qualified mental health professional who has conducted an assessment of the patient’s decisional capacity [19]. Other professionals, not physicians such as social workers, are involved in the assessment of DCM in their work with individuals and families. As part of the informed consent process, social workers continuously strive to ensure that individuals have all the information they need to make informed decisions, that they understand the information, and can appreciate the risks and benefits of their decisions [20]. Social workers, in hospitals, were more likely encountering patient and family conflict regarding treatment decisions, difficulty in communicating with the patient, family and medical professionals. Continued communication with all parties involved was key in resolving ethical problems [21]. In this their essential practice, social workers uphold each person’s right to self-determination, consistent with that person’s capacity and with the rights of others. Currently, the need for a consistent approach to DMCA is paramount, considering the ethical repercussion of autonomy versus protection. A recent study on physicians’ education on DCM assessment showed that participants noted that more education was required for DCM and that education and training should focus on person-centred care, a team-based approach, and available tools to guide the use of the DMCA model [22].

Which factors limit family member’s ability to provide informed consent?

Many different cultural, generational, and personality differences can influence the degree to which an individual wishes to have power over their decision making [23]. Older adult patients often enlist the help of family members during physician interactions, and some wish to defer decision making to them completely [24]. Via an ethical approach based on the family values model, family members tend to share similar values and it is likely that these values would be shared by their incompetent relatives [25]. According to this approach, family members have two options in the representation of an older patient: the substituted judgment,

and the choice in the best interests of the patient. The first requires that the arrangement makers use the patient's values to reach a decision. The second option demands that families use their values to make the best decision on the patient's behalf [26]. However, in general, the legal concept that one person can affect the substituted judgment's role for someone else requires that the surrogate should be authorised to assume that responsibility. It is necessary that there is acceptance of the duty by the proxy and an understanding by both parties that the surrogate will direct the activity. Indeed a surrogate should not just act as a spokesperson, but also as a representative empowered to use their judgment to make decisions on behalf of another person [27]. The surrogates' decision making may be more complex than standard ethical models, which are limited to the patient-centred principles of self-determination. The surrogates' interests may also play a role in decision making; being a next-of-kin could be viewed as an "accident of birth" and confers no guarantee of shared values with the incompetent. Next-of-kin may not even have each other's best interests at heart, and it is merely likely, in most cases, that the next-of-kin will share their relative's values [25]. The surrogates' consideration of how decisions may change their lifestyle as well as the impact of the outcome may exert influence on the decision-making process that is not entirely in the interests of the patient [28]. The unpleasant spectre of potential abuse of the elderly may impair the expectations of trust in institutions by family members, with this phenomenon significantly prevalent among European members' states, and may further impact on decision-making processes. The prevalence of psychological abuse in older people is cited at 19.4%, 2.7% for physical abuse, 0.7% for sexual abuse and 3.8% for financial abuse with the most common perpetrators of psychological (34.8%) and physical abuse (33.7%) being the spouse and adult-children. Abusers are more likely to be male and to have mental or physical health problems of their own. In the case of adult children, there is often a history of criminal activity, financial problems, mental health issues and past or current substance abuse [29, 30]. In recent years, the European strategy to combat and prevent elder abuse has led to the establishment of the (EUSTACEA) project. This project aims to create a lasting and growing partnership between organisations committed to improving the well-being and dignity of older people. The member states have also developed the "European Charter of the rights and responsibilities of older people in need of long-term care and assistance". This charter serves as a reference document detailing the fundamental principles and rights that are needed to ensure the well-being of all those who are dependent on others for support care due to age, illness or disability [31]. The importance and complexity of the relationships between elderly patients, physicians and family members may impact significantly on the ethical aspects of the decision-making

process. The cultural differences influence family dynamics at various levels in the case of a vital healthcare-related decision. They impact on communications, interactions with physicians and nurses, healthcare outcomes and the illness experience itself. Furthermore, factors such as the emotional distance, the geographic proximity, the frequency of meetings, and contact of telephone have an essential role on the functional relationship in family members [32]. In general, although each family has its unique ideology about the background, values, communication, roles and responsibility, the nuclear family model (more frequent in northern European countries) and the extended family model (more frequent in Southern Europe) may influence the family dynamics differently. In the extended family model, there is a collectivistic involvement of family members. Individuals rely heavily on an extended network of reciprocal relationships with parents, siblings, grandparents, aunts and uncles, cousins, and many others. Many of these people are involved in significant health care decisions, including some who are unrelated to the patient through blood or marriage [33].

Is there a common approach to this issue across Europe?

The Convention for the Protection of Human Rights and Dignity of the Human Being about the Application of Biology and Medicine [34] is the most critical and prominent legislative basis for all European member states to guarantee the protection of human rights in the biomedical field [35]. It was opened for signature on 4 April 1997 in Oviedo, Spain and is thus otherwise known as the Oviedo Convention. This convention is a unique legal instrument with the power to hold responsible the ratifying states about the minimum level of protection conferred to human rights regarding biology, medicine, and healthcare. The Convention recommended that "where an adult cannot consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided by law". This treaty specifies that "the previously expressed wishes relating to a medical intervention in a state to express his or her wishes shall be taken into account". Currently, the following member states have completed the ratification process: Bosnia—Herzegovina, Bulgaria, Croatia, Cyprus, The Czech Republic, Denmark, Estonia, Finland, France, Georgia, Greece, Hungary, Iceland, Latvia, Lithuania, Montenegro, Norway, Portugal, Republic of Moldova, Serbia, Romania, Slovak Republic, Spain, Switzerland and Turkey [36]. The European surrogates' role and rights laws are State specific. Many special laws, civil contracts on rights of the patients and various civil acts, different pieces of laws, ethics and medical codes

include these rights. However, in Europe, there are two main key areas of European surrogate's law in case of incompetent patients: the role of family members automatically accepted by law; and a legal representative appointed by a court. Beyond these two key areas, the healthcare and the decision-making process may provide some particular rules such as the "necessity treatment" approach, the binding consultation of the proxy relatives and the charter of the patient's rights. These rules are referred to in the "miscellaneous rules" section of this review. We include in this analysis many European countries that although not yet member states of the EU have ratified the Oviedo Convention as an essential legislative approach to human rights. The research conducted by Alzheimer Europe is notable in the field of the rights of the incapacitated older adult individuals and arguably leads the field in comparative health law research on competence and legally incapacitated adults [37]. The Alzheimer Europe society is a non-governmental organisation (NGO) aiming to make dementia a European priority. This organisation highlighted the differences between European countries on advance directives, social support, home care and practice for patients with dementia. The role of this organisation in promoting culture for the management of patients with Alzheimer disease is very significant.

Is the family members' role defined in law and, if so, how? (Table 1)

Many states have adopted a hierarchical structure for surrogate consent laws. A priority list of potential surrogates includes the members of the patient's family, and there is

a hierarchical scheme in place in the case of patients with limited DCM. In six member states (Belgium, Hungary, Latvia Lithuania, The Netherlands and Slovenia), several persons are designated to serve as surrogates in descending order of relevance. This order provides the priority list of the following persons: the person who is authorised through a legal document to act on patient's behalf; the spouse or the partner; a parent; an adult child; an adult sibling. Some hierarchies also include class designations for other adult relatives including grandchildren, grandparents and foster parents—the Hungary Health Care Act [38], for instance, contains grandparents and grandchildren in its structure. In the Belgium Law on Patient's Right [39], the surrogate's role is subordinated to the absence of the "mandatory". This person, appointed by the patient with capacity, can exercise rights under the law on that patient's behalf in the event of his/her subsequent incapacity. In the absence of such a mandatory, the spouse and the legal, cohabiting or "de facto" partner, have the priority as surrogates. In four states (Austria, Denmark, Finland and Spain), the specific laws accept the family members automatically as surrogates without recourse to a hierarchy scheme. In Austria, the recent changes in guardianship law allow for two other possibilities, namely consent by a next of kin who has been granted agent's authority or consent by a person (i.e. a trustee) who has a durable power of attorney [40]. Spanish law allows broader inclusion of person as a surrogate on patient's rights that enacted the expression "a relative or someone tied to him/her for "de facto reasons" granted the consent [41]. The term "de facto reasons" describes practices that exist in reality, even if not legally authorised. Two states (Netherlands and Lithuania) have a nominate contract, which is a specific

Table 1 EU member states with legislation conferring family members automatic right of formal involvement

Member states	Special laws, acts, binding codes	Provision of hierarchy of relatives or not	Oviedo convention/ratification or not	Advance directives or not
1. Austria	General Civil Law; Hospital Establishment Law of 1957; 55th Federal Act on Living Will	No	No	No
2. Belgium	Law of 22 August 2002 on Patients' Rights	Yes	No	Yes
3. Denmark	Health Act No. 1202 of 14/11/2014	No	Yes	Yes
4. Finland	Act on the Status and Rights of Patients, No. 785 of 17 August 1992	No	Yes	Yes
5. Greece	The Article 11 of the Greece Code of Medical Ethics	No	Yes	Yes ^a
6. Hungary	Cliv. Act of 1997 on the Hungary Health Care Act	Yes	Yes	Yes
7. Latvia	Medical Treatment Law of 1997	Yes	Yes	Yes
8. Lithuania	Law on the Rights of Patients and Compensation of the Damage to their Health of 1996	Yes	Yes	No
9. Netherlands	Medical Treatment Agreement Act, 1997 (Wet geneeskundige behandelingsovereenkomst—WGBO)	Yes	No	Yes
10. Slovenia	Act on Patients' Rights of 2008	Yes	Yes	Yes
11. Spain	Basic law 41/2002 Oviedo convention ratification	No	Yes	Yes

^aThe advanced directives are not legally binding for the doctor or for the patient's relatives or his Guardian

regulation of the treatment contract between doctor, patients and the surrogates in the civil code. In general, it governs the relationship between patients, providers, and nurse. According to The Netherland Medical Contracts Act, the physicians need prior consent for any act emanating from a medical services contract. For patients who are not competent, the law assigns this authority to others. The agreement states that if an adult patient cannot be considered capable of a reasonable assessment of his essential interests and he has not been placed under guardianship or had a mentor appointed for his benefit, the person authorised in writing by the patient to act on his behalf shall represent him. If no attorney has been elected or if he does not serve, the physician has to consider the spouse or another partner of the patients as a proxy decision maker. If there is no partner, a parent, child, brother or sister becomes the proxy decision maker [42]. In Lithuania, the law on the rights of the patient and compensation of the damage to their health of 1996 highlights explicitly the rights of the patients who lack the capacity to consent in the absence of a curator or guardian. This law provides the hierarchy of people authorised to approve on the person's behalf [43]. All the member states that automatically accepted the family members as decision makers have a (single) special law on patient's rights. One member state enacts the healthcare and decision-making process in a Code of Medical Ethics binding code. The Greece Code of Medical Ethics [44] states that if a patient is not competent, the legal representative gives the consent to medical treatment. In the absence of an authorised representative, the relatives of the patient approve. Between the member states (Austria, Belgium, and the Netherlands) that have not yet ratified the Oviedo convention, their internal laws cover the provision of advance directives as well as the principles of the Convention laws. Although widespread and widely accepted into legal practice, one of the most critical limitations of the hierarchy scheme model for the patient's family members is the extent to which the priority order of surrogates accurately reflects today's family and cultural diversity. This element is central to the success of the hierarchical structure as social and family differences, religious traditions, ethnic and racial backgrounds may significantly influence the decision-making process [45].

Who gets to decide on behalf of incompetent patients in European member states where family members are not automatically recognised? (Table 2)

Many patients with intellectual or psychosocial disabilities may be deprived of their legal capacity and put under some form of guardianship. Two main guardianship models are commonly used: partial and plenary guardianship. Persons

under partial guardianship keep the main bulk of their civil rights, but specific capacities are transferred to a legal representative, most commonly the power to manage financial affairs. Those under full or plenary guardianship, on the other hand, lose all or almost all of their civil rights [46]. Furthermore, in many European member states, the philosophy of the Acts and Laws is to safeguard the person's autonomy to the most significant extent possible, stressing the importance of the person's 'will and preferences'. In some States such as Ireland, Italy and Bulgaria the court may appoint a relative as a guardian. The Irish special law "assisted decision-making capacity" provides a gradation of guardianship measures [47]. This Act addresses three broad categories of people with reduced capacity: people with disabilities, particularly intellectual disabilities; older people with degenerative cognitive conditions; and people with mental health issues who may have a fluctuating capacity. The assisted decision-making model may be applied to persons whose decision making is somewhat impaired but who, with the necessary information and explanation, could exercise decision-making capacity. In this case, the persons themselves will appoint their decision-making assistant supervised by the newly established Office of the Public Guardian (OPG). The co-decision making model, often used as a second option, relates to people who require a higher degree of support but can still participate in decision making. It allows a person to appoint a trusted family member or friend as a co-decision maker. The third option is the appointment of a legal decision-making representative, which is exercised when the first two options are not possible. This gradation in the guardianship procedure is also present in the Italian legal System. Before the approval of Law 6/2004 that instituted the supporting administrator, the only possible legal representative for an incompetent adult was the legal guardian. Following the interdiction procedure, the guardian replaced the interdicted person in fulfilling all routine and non-routine acts of administration. The interdicted person is thereby completely and permanently deprived of the possibility to act. Another legal option is disqualification applied to the following situations: a condition insufficiently severe for interdiction; the exposure of oneself or one's family members to a severe economic burden due to extravagant wastefulness or the frequent use of alcoholic drinks or drugs; and blindness or deaf-muteness from birth in subjects lacking an adequate education. The appointed guardian assists the disqualified subject in non-routine acts of administration [48]. Interdiction and disqualification are nonetheless often excessive and disproportionate measures. For this reason, the Law. 6 on 9 January 2004 established the possibility of a supporting administrator. This law is a new protective measure that can be modelled by specific and unexpected situations and requirements. The Luxembourg Law provided a gradation in the protective regime. The Law established three kinds of different legal protection:

Table 2 EU member states with legislation requiring engagement of a legal representative or the court system

Member states	Type of law	Who gets to decide	Ratification of Oviedo Convention	Advance directives or not
1. Bulgaria	Law of Health of 1 January 2005 (last amended 02.06.2009); Civil Code; Procedure Family Code of 1 Oct 2009	Legal guardian A person from the relatives appointed by the court A representative of the municipal health service	Yes	No
2. Croatia	Law on protection of persons with mental disorders NN 76/14	Guardianship	Yes	Yes ^a
3. Cyprus	Art. 21 Law n 1 (I) 2005 Safeguarding and Protection of the Patient's Rights Law	Initiated by Social Service in special occasion Legal representative	Yes	No ^b
4. Czech Republic	Health Care Act No 20, 1966, Regulation no 385/2006 Article 26 Civil Code	A guardian appointed by a court	Yes	Yes
5. Germany	Professional rules for German doctors 1997; § 1904 Civil Code Book 4 Civil Code §§ 1901 a + b (Family Law, Legal Guardianship	Guardianship appointed by guardianship court	No	Yes
6. Ireland	Special law—Assisted Decision Making capacity Act 2005	Decision making assistant supervised by the office of public guardian; a trusted family member or friend as co-decision making confirmed by circuit court. A decision-making representative appointed by circuit court	No	Yes
7. Italy	Article 32 and 13 Italian Constitution. Italian Code of Medical Ethics of 2014; Article 408 of Civil Code. Law January 9, 2004, no 6; Supreme Court (Cass. Civ.), sez. VI, judgment 20 dicembre 2012 no. 23707	Legal guardian; Amministratore di sostegno appointed by guardianship judge.	Yes	Yes (DAT)
8. Luxembourg	Article 8 of the Code of Medical Ethics Law of 16 March 2009 palliative care	Doctors obliged as far as possible to respect the patient's wishes; Relatives contacted and informed	No	Yes
9. Poland	Physician's Profession Act of 5 December 1996; The Ministry of Health Charter of Patients Rights, December 1998; The Act of 30 August 1991 on Health Care Institutions; Article 68.1 of the Polish Constitution;	Guardianship (legal protection, curatorship, tutorship) Guardianship	No	No
10. Portugal	Basic Health Law 48/90 of 24-August; The Penal Code; Oviedo Convention	Legal representative	Yes	Yes
11. Romania	Romanian Family Code Law 448 of 18 December 2006	Guardianships trusteeship Legal assistance	Yes	No
12. Slovakia	Act no. 576/2004 Coll of 21 October 2004	Legal representative	Yes	No
13. Sweden	Health and Medical Services Act 1982	Custodian/trustee	No	No

^aPerson of confidence authorised by notary—written advance directives^bAny previously expressed wishes of the patient concerning healthcare shall be taken into consideration

the legal protection (*sauvegarde de justice*), the curatorship (*curatelle*) and tutorship (*tutelle*). The first is generally a temporary protective measure waiting for curatorship or tutorship measures. The curatorship is provided when a person is in need of advice or assistance in carrying out daily acts. The main diseases that may require legal protection are dementia, psychosis, disability, etc. [49]. In Croatia, the Law on the protection of persons with mental disturbances established that the guardian has the role in signing an agreement. A close relative is generally appointed as the guardian of a person with intellectual disabilities, except where a conflict of interest is shown, or if the prospective guardian is found unfit to take on the responsibility. In some cases, a social worker or another unrelated person may be appointed as guardian. If the court procedure was not initiated, in some cases, the social workers are appointed as guardians when a family member is not appointed [50]. In case of disabled persons, regardless of their age, who are incapable, according to Romanian Law, they shall benefit from legal protection in the form of trusteeship or guardianship or legal assistance [51]. In Slovakia, the civil code established that if a person is incapable, the court appoints a legal representative or a curator [52]. According to the Bulgarian Law of health, the court shall appoint a representative from the relatives of the patient who is to express informed consent for the treatment. Should there be a conflict of interests or lack of suitable relatives, the court shall appoint a representative of the municipal health service or a person defined by the mayor of the municipality at the headquarters of the medical establishment [53]. A particular form of guardianship is the adoption of “the custodian” as a legal representative. In Sweden, relatives may be consulted regarding treatment options, but do not have a specific right to consent to treatment on behalf of an incapacitated person, with a nominated custodian responsible for providing consent. This custodian, and not a relative of the patient, is thus responsible for ensuring that their ward receives the care that he/she needs [54]. According to The Professional Rules for German Doctors [55], should a person undergoing treatment be unable to provide consent, a legal representative may be able to decide in certain circumstances. The guardian may consent to health examinations, medical treatment or surgery for the patient but must obtain authorisation from the Guardianship Court if there is a reasonable risk that the ward could die as a result of the measure or might suffer from severe and more prolonged damage to health. In this area, all the member states have not a single special law. Various laws, acts and binding codes are embedded in the patient’s rights. The court management model, therefore, provides a degree of protection for incapacitated patients. One limit of this model is the possible lack of a therapeutic alliance between the family members and doctors, although adoption of advance directives may help to attenuate this to some extent. The instructional directive refers to the wishes and preferences relating

to treatment decisions. Advance care planning is a more extensive health care concept whereby a patient, in consultation with healthcare providers, family members, and other involved parties, makes decisions about his or her future health care, should he or she become incapable of participating in medical treatment decisions [56]. Many studies have shown that the impact of advance care planning improves end of life care in elderly patients, including a reduction in hospital deaths and increased use of hospice services. It also leads to improved patient and family satisfaction and may reduce stress, anxiety, and depression in surviving relatives [57, 58]. However, the more widespread application of this otherwise positive model is currently limited for some reasons. Firstly, many European member states have not yet adopted into their law the advance directive model. Secondly, in other states where the law provide this model the majority of patients with chronic illnesses do not have advance directives in place on admission to hospital [59].

Miscellaneous frameworks of the Oviedo convention

In the United Kingdom (England and Wales), patients unable to make decisions relating to their care due to a lack of capacity are protected by the Mental Capacity Act (MCA) of 2005 [60, 61]. This act prevents patients lacking capacity from having decisions made for them that are not in their best interests. Should a Physician wish to treat a patient under the MCA, they must first contact the patient’s family (or close friends or care workers if there is no family) to attempt to establish what the patient would usually want in the circumstances. The court protection oversees everything to do with capacity. If the patient is competent, they may choose Lasting Power of attorney or may make an “advanced decision”. After all these steps if the patient cannot decide about the treatment, the MCA gives doctors and nurses the power to give the patient a physical treatment against his or her will if it is felt to be in their best interests (Table 3).

Furthermore, there is the possibility that healthcare practitioners may give treatment without the consent of a patient or their legal representative. The justification for doing this is that the procedure is “necessary”. The concept of “necessity” does not only apply in emergency situations but can justify routine treatment and even simple care, although delivering treatment deemed necessary by the medical profession under MCA without consent is a drastic step that must not be undertaken lightly. A similar condition is provided in the Estonian Law [62]. In the case of an unconscious patient or incapable of exercising his or her will for any other reason and if he or she does not have a legal representative, or his or her legal representative cannot be reached, the provision of healthcare services is permitted

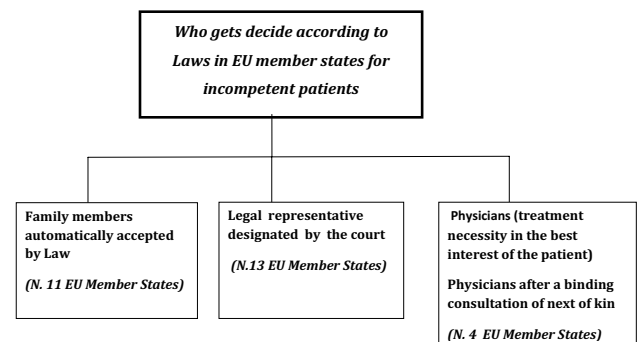
Table 3 Miscellaneous Rules' section of the Oviedo convention

Member states	Acts, binding codes, charter	Who gets decide	Convention bio-medicine ratified or not	Advance directives or not
1. United Kingdom	Mental capacity act	Treatment necessity concept Lasting power of attorney	No	Yes
2. France	Article L 1111-4 in the Public Health Code, article 16-3 in the civil code; article L. 1111-11 of the Public Health Code	If no legal representative, no action or investigation can be carried out without consulting a healthcare proxy, family member or friend	Yes	Yes
3. Malta	The Patients' charter of rights and responsibilities issued by Hospital Management Committee	Information to the relative or legal representative	No	No
4. Estonia	Paragraph 759 of the Law of Obligations Act of 26 September 2001	Legal representative Treatment necessity if there is no legal representative according to previously expressed wishes	Yes	Yes

without the consent of the patient. This action is possible only in the interests of the patient and corresponds to the intentions expressed by him or her earlier or to his or her presumed intentions. The consent is not necessary even if failure to provide health care services promptly would put the life of the patient at risk or significantly damage his or her health. In the Scotland Adults with incapacity Act 2000, a medical practitioner must issue a certificate to the effect that an assessment of capacity has been carried out, following consultation with the nearest relative and primary care. This certificate provides the right to safeguard or promote the physical or mental health of the patient. In the presence of several medical conditions, the doctor can draw up a medical treatment plan [63]. In France if the person is unable to express his or her wishes but does not have a legal guardian, no action or investigation can be carried out without consulting a health care proxy, family members or friend (article 1111-4 in the Public health Code and 16-3 in the civil code) [64]. Sometimes the patient's rights are embedded in non-legally binding documents such as patient charters and non-mandatory codes of medical deontology. The Malta "Patients' Charter of Rights and Responsibilities", for example, states that decisions on behalf of the incompetent patient can be made following the full involvement of family members. If a Court sentence declares a person incapacitated, the tutor appointed is the person in charge of giving consent on his/her behalf [65].

Concluding remarks

In European countries, albeit with different legislative approaches, the legal role and the rights of family members' consent of patient with a limited DMC are hugely varied. The role of decision maker for an elderly adult

**Fig. 2** Who gets decide according to the laws in EU member states

incompetent patient, however, is generally delegated to one of the three representatives, namely family members, legal representatives and Physicians (Fig. 2). In the case described at the beginning of this chapter, the patient's son, who was automatically accepted as a surrogate under the legal model of family members, would have a role as a decision maker. On the other hand, the necessity of a legal representative as in Italian legal system is a common position in many European member states. The possibility that the physicians could decide without the informed consent of the patient's son is possible in the United Kingdom and Estonia if it is in the best interest or corresponds to his/her previously expressed intentions.

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Compliance with ethical standards

Conflict of interest The authors declare that they have not conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent For this type of study formal consent is not required.

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