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The evaluation of capacity in dementia: ethical constraints and best practice. A systematic review

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Abstract

The progressive ageing of a population leads to an increase in the number of people suffering from cognitive deterioration. This requires particular attention in terms of the necessity to assess these people's cognitive functions and their capacity to make decisions. The present systematic review analyses the clinical and ethical aspects of any assessment of capacity, with a specific focus on the capacity of the individual to give informed consent for medical treatment and also with regard to their testamentary capacity. The results indicate that the concepts of capacity, competence and decision-making need to be better clarified, ad-hoc devised tools are required and a multidisciplinary, clinical and legal approach to assessments of capacity needs to be adopted. This is crucial to guarantee that the two ethical principles of capacity assessment are adhered to: respect for an individual's autonomy and the protection of fragile individuals.

Key words
- decision-making
- assessment of capacity
- ethical issues
- clinical competence
- testamentary ability

INTRODUCTION

According to Art. 2 of the Italian Civil Code (CC), the *Ability, or capacity, to act,* or natural capacity, refers to an individual's power to perform acts that are legally valid and effective. In Italy, this capacity is acquired at the age of eighteen, with some exceptions (e.g., sixteen for an employment contract). The term ability to act implies that the person is responsible for his/her acts and this differs from *Legal capacity* which is acquired at the time of birth and represents the condition of being a bearer of rights and duties (art. 1, Italian CC). Consequently, whereas legal capacity is guaranteed and recognised for every human being, the ability to act may be uncertain under some clinical conditions, such as mental deterioration.

The assessment of patients' ability to act and their degree of awareness regarding the consequences of decisions represents a challenge in both neuropsychological and legal fields and ethical dilemmas may arise.

Nowadays, this is a particularly relevant and urgent issue due to the introduction in the Italian legal system of some regulations that allow individuals to delegate specific areas of decision to a "proxy" – that is, a *Support Administrator* or a *Trustee.* The figure of the Support Administrator (AdS) has been introduced in Italy (Law 6/2004, artt. 404 onwards) [1] with the aim of changing the approach to the protection of vulnerable subjects. The person is appointed by a tutelary judge with the aim of helping and safeguarding individuals who are no longer autonomous in terms of decision-making. The introduction of this figure is innovative in that the areas covered (for example decisions about asset management, daily purchases or medical treatments) are not based on a medical diagnosis but on the effective deficits and abilities of each individual. The figure of the *Trustee* has been established as part of a recent legislation on informed consent and advance treatment directives (Law 19/2017) [2]; this proxy is directly appointed by the patients themselves, and represents them in dealings with doctors and healthcare facilities. Both these regulations represent useful opportunities for people who are unable to take decisions or are expected to have difficulties in the future due to the diagnosis of a pathology. For the Support Administrator, it becomes crucial to determine the areas in which the proxy needs to make decisions. For this reason, the judge may ask for a clinical assessment.

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In its clinical meaning, the ability to act indicates an individual's capacity to perform tasks of varying degrees of complexity. This capacity relies on cognitive functions such as, for example, decision-making abilities. However, the capacity to act also depends on the congruency between each individual's ability and the contingencies involved (i.e., the specific situation in which a decision is taken). This implies that a clinical assessment should pursue the maximum coincidence between these factors.

It is worth noting that, although a clinician's opinion may have a relevant weight in the final decision of a judge, the outcome of this assessment is rather a legal matter [3, 4].

The assessment and determination of capacity are particularly sensitive fields of investigation [5, 6]. On one hand, a judgment of incapacity may lead to a significant reduction in a person's rights, while on the other hand, not recognising a decrease in capacity can expose a patient with dementia, as well as other people, to various risks (domestic accidents, failure to plan both simple and complex actions, necessity to request assistance, etc.). For this reason, any reductions in a person's rights must necessarily be offset by an evaluation of what is in the "best interest" of that person and his/her family.

As a result, any assessment of capacity needs to take into account the reasons underlying the request for an evaluation, the patient's environment, his/her affective, social and financial resources and any potential benefits resulting from the adoption of support measures, such as the appointment of a legal proxy.

Since the prevalence of dementia increases dramatically with age, capacity assessments – previously a marginal aspect of clinical and legal practice – have become a common issue. There are many areas involving capacity that clinicians may be called to examine (for medical and/or legal purposes) including the individual's capacity to consent to treatment, to act as a witness, to make a will, to manage their finances, to vote, to drive, to carry out a profession, and so on. In particular, in addition to the assessment of the ability to express their informed consent (essential for a patient following a medical therapy or participating in a clinical trial), clinicians are more and more required to assess the ability of elderly people to make a valid will. Indeed, Italian law states that some patrimonial acts may not be valid if performed by a person who is deemed incapable to act, although not prohibited from doing so (art. 428, CC).

This study was prompted by a document published in Italy by the "Ethics" sub-group within the National Dementia Plan (www.regioni.it/newsletter/n-3900/del-10-08-2020/raccomandazioni-per-la-governance-e- la-clinica-nel-settore-delle-demenze-21590/) [7], which some of the authors of this paper take part in as experts. The search for scientific sources was further extended with the aim of raising awareness concerning the ethical debate on respect in clinical and legal fields for the autonomy of patients with dementia. Then, we focused on the assessment of two specific capacities that have become more and more important: clinical and testamentary capacities.

METHODOLOGY

A search of the literature on the subject was carried out using PubMed, PCM and Cochrane Library databases. It took into consideration English language publications from January 1990 to June 2020. Over this period, there is an enormous quantity of papers (7,098) on both the ethical and methodological aspects of assessing the capacities of patients suffering from dementia indicating the relevance of this topic in scientific research.

In order to narrow down the research, a further search was run which focused only on systematic and major reviews. The following keywords were entered: [dementia] AND [decision-making] or [competence evaluation] or [informed consent] or [ethics] or [testamentary capacity] or [Testamentary capacity evaluation] AND [review] or [systematic review].

RESULTS

The second search yielded 1,821 articles. Further screening was then carried out following the process outlined in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [8] statement for systematic reviews and the outcome of this is shown in *Figure 1*. Forty-four articles met the eligibility criteria: 12 systematic reviews, 21 reviews and 2 brief reviews, 2 integrative reviews, 2 narrative reviews, 2 clinical reviews, 1 critical review, 1 methodology review and 1 literature review; in addition, there were 46 referenced papers, 6 web resources and 5 books, giving a total of 101 references. Among the 44 reviews included in the study, 12 mainly addressed the decision-making process, 13 informed consent, 6 ethical issues, 5 assessments of capacity and there were also 8 concerning financial and testamentary capacity. It is worth noting that this classification was not rigid as in reality a number of these studies addressed multiple aspects. The studies selected are summarised in the *Supplementary Material available online.*

In the following sections, the results are outlined starting with a definition of the main constructs (that is, capacity, competence and decision-making) that form the basis of any assessment of capacity. Two specific capacities and the assessment of these are then discussed: the capacity to give informed consent and testamentary capacity.

Competence, capacity and decision-making: three concepts in one

A long-standing, heated debate concerns the disambiguation of the concepts of "competence" and "capacity", but some confusion in the clinical field remains. In many countries, both terms are often used interchangeably, although in the scientific and legal literature on the subject, subtle differences are sometimes reported *(Table 1)*.

Both in medical and legal terms, *capacity* is primarily considered to be established by means of a clinical assessment. It has been variously defined as: i) the ability to learn, process and make decisions based on available information [9]; ii) the individual's capacity to decide or to perform daily life activities, such as working, driving,

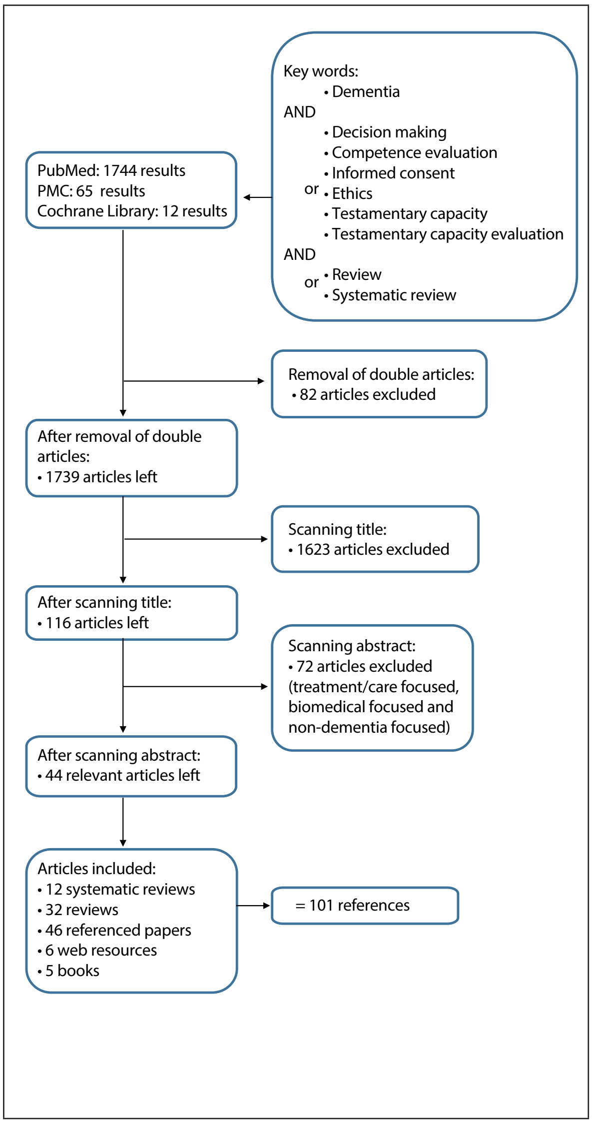

Figure 1

Flow chart of the systematic literature review process.

looking after relatives, making medical decisions, and entering into legal contracts [10] and iii) the functional determination of whether an individual has the ability to adequately make a context-specific decision [11].

In contrast, *competence* is generally considered to be established legally and is defined as: i) the legal determination of whether an impaired mental capacity limits a patient's ability to make legally relevant decisions or actions [12]; ii) a legal construct established and governed by the courts [10] and iii) a legal state, namely the degree of mental soundness necessary to make decisions about a specific issue or to carry out a specific act [13].

In Italy, capacity and competence are synonyms and are used interchangeably to indicate the ability of an individual to use personal, social and/or methodological skills in various different contexts [3].

For the purposes of the present study, and in an effort to overcome confusing terminology, we will refer to the term capacity as the equivalent of competence.

The notion of capacity is closely related to that of *decision-making*, namely, the process of selecting an appropriate action from a number of possible options. Decision-making involves many cognitive processes, including selecting one's goal and motivation, weighing the potential consequences of different options, and determining expected consequences [12]. The loss of decision-making capacities represents one of the most dramatic consequences of cognitive decline in patients with neurological or psychiatric disorders, and it progressively affects everyday life and medical and legal choices, thus potentially exposing patients to the risk of adverse events and financial abuse [17-19]. The prevalence of disorders in decision-making in patients suffering from cognitive decline is consistent, ranging from a percentage of 34% of hospitalised patients to 45% of psychiatric patients [20].

Multiple cognitive functions, in particular executive functions, contribute to the case of decision-making deficits in Alzheimer's disease (AD) [21-23]. Nevertheless, a recent systematic review [24] has shown that in people with dementia, factors other than cognitive impairment contribute to decision-making abilities, including varying degrees of freedom of choice and contextual factors (e.g. socio-economic and personal factors).

The role of emotions and motivation also needs to be considered, as these can help a patient to understand various situations and take appropriate decisions despite a deficit in their decision-making abilities. Emotions represent a source of knowledge that provides crucial information about the internal states of an individual and the responses to external events; these are essential in order to reach decisions that are consistent with the individuals' value system. This refers to the concept of "authenticity", that indicates a congruency between an individual's values (i.e., their beliefs, relationships and commitments) and their decisions. In contrast to "autonomy" – which mainly refers to situations in which an individual exercises their right to express self-determination – "authenticity" does not require an intact capacity of self-determination, but only that the decision is consistent with the individual's values [25]. In people suffering from dementia, the relationship between autonomy and authenticity is complex as a patient may be lacking in self-determination but conserve ethically relevant skills such as communicating a preference, maintaining relationships and certain levels of decision-making [25, 26], including the ability to appoint a proxy for specific areas of decision [2]. It is therefore worth remembering that cognition and emotions are closely interconnected in all the decision-making processes, as cognition involves affective values when reaching a choice, and that inadequate levels of emotional activation – both reduced or in excess – may raise doubts on the appropriateness of the decision.

A recent review [27] recommends a more active role in the decisional process for patients with dementia, and shows that in mild to moderate stages, patients would like to be involved in day-to-day decision-making, especially with regard to health, financial and end-of-life issues. Things are different for geriatric patients

Table 1
Definitions of capacity and competence

Authors	**Capacity**	**Competence**
Ganzini *et al.*, 2005 [14]	A clinical assessment of a patient's ability to make specific healthcare decisions: evaluated by physicians specific, not comprehensive	A legal term used to describe a person's overall, comprehensive ability to make decisions: decided by a court/judge permanent unless overturned by a court/judge
Resnick and Sorrentino, 2005 [13]	An individual's ability to make an informed decision	The degree of mental soundness necessary to make decisions about a specific issue or to carry out a specific act
Moberg and Kniele, 2006 [8]	An individual's capacity to decide or to perform activities of daily living	a legal construct established and governed by courts
Willner, 2011 [15]	The ability to make decisions	The ability to perform actions needed to put decisions into effects
Moye, Marson, Edelstein, 2013 [11]	*Clinical capacity*: the functional determination of whether an individual has the ability to adequately make a context-specific decision *Legal capacity*: the specific ability or abilities which are sufficient to carry out a specific action according to law.	
Stracciari, Bianchi, Sartori, 2014 [3]	Legal capacity or "legal competence": ability to make a decision, regardless of its reasonableness Clinical capacity or "clinical competence": set of skills that allow individuals to perform more or less complex actions.	
Darby *et al.* 2017 [12]	The functional determination of whether a patient has the ability to adequately make a specific decision, such as financial decisions, or perform a specific task, such as driving	The legal determination of whether an impaired mental capacity limits a patient's ability to make a legally relevant decision or action
Sabatino, 2018 [16]	Clinical capacity is specific to a particular health care decision	Also called legal capacity, this is a legal status. It cannot be determined by health care practitioners
Gossman *et al.*, 2019 [9]	The ability to learn, process, and make decisions based on information given	A legal term, stating that a court of law has decided whether a person can make his/her own decisions. A legal declaration of incompetence may be global, or it may be limited

who can no longer make decisions for themselves. For them, family members in the role of surrogate decision makers are usually preferred since the family is the primary social unit involved in safeguarding the patient's welfare and wishes [28].

Experimental studies on the neuronal bases relating to decision-making have often focused on this interface between cognitive and emotional abilities. Overlaps have been found between cognitive and emotional abilities networks in the frontal, temporal and parietal areas, such as the dorsolateral prefrontal cortex, the medial prefrontal cortex, the medial temporal structures and the precuneus [29]. A lack of equilibrium between these networks has also been suggested as a cognitive marker of a deficit in decision-making, and as an empirical criterion for an impairment in cognitive abilities relating to informed consent [30]. The neural correlates of decision-making have also been assessed in relation to the neuroanatomical changes that occur in several neurodegenerative diseases [22], showing an elevated correlation between executive functions (planning, anticipation, judgment, reasoning) and decision-making. On the whole, although the anatomical model for decision-making is still being studied, there is a broad consensus with regard to the involvement of an extended neuronal network, including frontostriatal and limbic loops, the orbitofrontal and anterior cingulate cortices, the parietal cortex, the striatum, the amygdala and the basal ganglia [31].

Accordingly, decision-making can be considered to be a multidimensional construct rather than a single function, and it depends on the integrity of attention, orientation, memory and executive functions to ensure inferential processes [32], and is closely related to the appropriateness and intensity of emotions expressed [33].

The assessment of capacity

Evaluating whether or not a patient is able to make decisions in the real world is sometimes a challenge for clinicians. The necessity for this type of evaluation arises in particular when the clinician is faced with a patient with behavioural or cognitive symptoms which are suggestive of a decline in his/her abilities. Although a number of different tools have been developed, the absence of a "gold standard" persists making assessments difficult [34].

Freedman, Stuss and Gordon [32] proposed some guidelines for assessing capacities which focus on the evaluation of neurobehavioral deficits rather than on the neuropathology of disorders. The authors argue that the ability to make competent decisions depends on the nature and severity of the cognitive impairment, rather than on its cause. Sturman [35] shared a similar point of view and assumed that mental illness represents a risk factor for – but does not automatically define – a condition of incapacity. Similarly, Johnson and Karlawish [36] claimed that a diagnosis of AD in the mild to moderate stage did not coincide with an automatic judgment of incapacity: clinicians need to look at the severity of the general cognitive impairment of each individual patient and should specifically assess his/her decisional capacity.

The necessity for an extensive cognitive assessment may be decided after the administration of short screening measures, and, among these, there is a broad consensus that the use of MMSE is useful. The cut-off scores considered to indicate an individual's capacity range from <19 (i.e. it is probable that the patient's ability to give consent is reduced) to ≥23 (i.e. it is probable that the patient's ability to give consent is adequate), depending on the risk/benefit ratio; a cut-off of 25 has been suggested to discriminate competent and incompetent individuals, with a sensitivity between 91% and 100% [37-39]. Marson's model [6] provides a score ≥20 for capacity, that however needs to be supported by non-pathological results involving tests for verbal fluency, attentional/executive capacities and logical memory. Of course, given their inherent limitations, screening tests should not be used alone to assess capacity [40].

Some authors [41, 42] have suggested that capacity assessments should be divided into at least three steps: a) a general cognitive level, b) specific cognitive abilities and c) an ecological survey. Sullivan [43] emphasised the fact that capacity is "decision specific" and suggested the necessity of planning assessments using this key concept as a base; her two-stage approach recommends an assessment of basic cognitive skills (e.g. orientation, reasoning/judgment, general knowledge and memory), followed by the administration of tasks focusing on specific skills. These skills would be assessed by means of *ad-hoc* devised tests or structured interviews.

In their extensive review, Moberg and Kniele [10] also recommend the use of multiple approaches for an ethical evaluation of capacity. They advise that since there is no single tool capable of evaluating ability, clinicians must integrate various approaches and standardised measures in order to adequately cover the various skills and attitudes pertaining to everyday life. Observation of a patient in the context of his/her day-to-day life would be the best approach, but this is often impossible for practical reasons. Thus, considering the absence of specific, standardised tools and the difficulties associated with directly observing an individual's abilities in their daily life, the authors recommended following a number of steps: i) a detailed interview with both the patient and caregiver(s); ii) a neuropsychological examination carried out by means of validated tools; iii) an evaluation of functional skills and iv) a check of the legal reference standards.

Furthermore, whenever possible, the examiner should identify and advise the adoption of supportive strategies (e.g. a prosthetic environment) to improve the patient's abilities. In fact, the principle of showing respect for each single individual is, according to them, fundamental in an ethical approach of capacity assessment that needs to be shaped and tailored to each patient.

In Italy, Stracciari, Bianchi and Sartori [3] proposed an all-inclusive three-stage approach to the evaluation of capacity. The first step, called "Evaluation", involves the administration of interviews to the patient and his/her family members, an examination of the patient's cognitive functions and an analysis of their functional skills in a daily life context. The second step involves the "Interpretation" of the data collected in the light of legal standards and requirements, taking into account the potential consequences of the patient's decisions. A final step entitled "Rehabilitation" involves the planning of interventions aimed at cognitive reactivation and support (that is, a prosthetic environment). A recent document published in Italy as part of the National Dementia Plan [7] also recommended an accurate neurocognitive assessment and provided a two-level evaluation algorithm depending on the severity of the disease, as well as a list of useful tests.

The picture that emerges from the literature shows that there is a need to follow a complex procedure when assessing capacity, one that requires multiple professional competences and a multidimensional approach. Two main principles would guide this procedure: i) a balance between demonstrating respect for the patient's autonomy (i.e. self-determination and the freedom of choice) and patient safety and ii) taking into account not only the patient's disabilities but also any residual abilities (for example, coping strategies).

Informed consent

The term *Informed consent* refers to clinical capacity, that is, an individual's free and voluntary choice to participate in a course of treatment or a research project. This, therefore, represents a central requirement of ethical research involving human participants [44]. The importance of an individual's expression of will came to be seen as fundamental after the Second World War and originated as part of the Nuremberg Code (1946) that established that participation in research needs to be voluntary, with the freedom for any person to choose participation after adequate understanding of the experimental procedures involved. This means that the person involved in a course of treatment should have the legal capacity to give consent and that whenever a clinical condition induces doubts, the patient's ability to give consent needs to be assessed.

Informed consent has been extensively studied with reference to many pathologies and deficits in this capacity have been reported in learning disabilities, as well as in psychiatric and neurological disorders [45]. In the mild stage of dementia, patients with a good insight into their condition are often sufficiently competent to make decisions regarding their treatment and wish to be involved to the extent that their abilities allow [36]. However, capacity to consent may fluctuate over time, depending on various factors, both medical (e.g. drug therapy) and clinical (hydration status, pain, etc.), which mean that the risk of misunderstandings may arise [46].

Over the last few decades, the issue of informed consent has played a major role in the debate concerning bioethics. There is a need to guarantee the individual's right to self-determination, even in presence of reduced cognitive capacity. The Mental Capacity Act was brought into force in England and Wales in 2005 with the aim of empowering and protecting people who may not be able to make some decisions for themselves [47], and established that patients must be adequately supported in expressing any residual decision-making skills. These skills rely on certain functional abilities, as summarised by four functions: Understanding, Evaluation, Reasoning, and Expression of a choice [48].

The concept of informed consent therefore stems from the legal concern that patients should have adequate information to make informed decisions regarding medical treatments. However, information alone is not enough for an informed choice: the individual's freedom of choice needs to be guaranteed and his/her ability to use this information to make a rational choice preserved [44]. All of the ethical and legal issues concerning the assessment of this capacity stem from this latter point. Any assessment should therefore reflect the best balance between two extremes: on the one hand, the principle of protecting the patient from choices which may be potentially dangerous for his/her health, and on the other hand, the principle of inviolability of individual choice. This dilemma represents a point which is crucial to the debate on bioethics, as emphasised by some authors who have suggested that not adhering to a principle which safeguards patients with a reduced capacity to act may lead to the risk of "abandoning patients to their rights" [49].

The guidelines and standard procedures relating to obtaining informed consent have long been based on the simple assumption that consent is presumed if a patient does not provide explicit dissent. However, this assumption represents a meagre protection for patients who lack competence [36]. Indeed, this first principle has evolved over time into the current concepts of self-determination and autonomy as well as of a kind of therapeutic alliance involving mutual respect. However, despite this change in perspective, these principles still suffer from a lack of standardisation and adequacy with regard to the instruments available [50]. To date, informed consent has often been considered merely a formality, that is, a document to be signed by the patient to protect institutions and clinicians (rather than the patients themselves) in case there are accidents during the medical procedures. Furthermore, the consent form itself is invariably too complex, and is often incomprehensible (not only to those with a lower standard of education) [50] as language that is unfamiliar to the patient is used. Adopting clear, non-technical language and short consent forms which are appropriate to the patient's language skills is thus to be recommended [51]. A recent study in Italy [52] shows that the use of simplified texts considerably increases the possibility of patients with AD understanding the contents of the documents and thus being able to more easily express their preferences.

In fact, informed consent is not a one-time event but an interactive process, in particular for patients suffering from mental deterioration. The above-mentioned document in the Italian National Dementia Plan [7] states that information need not be fully transmitted at the beginning of the therapeutic relationship, but gradually provided as the clinical sessions progress in a way that is consistent with the progression of the individual's situation with regard to their medical condition, thereby integrating new information and advice. In this way, any request for informed consent regarding specific procedures becomes the result of a relationship built on trust based on the principles of protection and auto-determination.

As previously reported, four key elements in the consent procedure relating to treatment for medical (or research) purposes are recognised in the most widespread models of clinical competence [48, 53]: a) *Understanding*: the ability to understand information and the potential risks/benefits of a course of treatment (or of the lack of treatment); (b) *Appreciation*: the ability to apply the information received to one's own condition; (c) *Reasoning*: ensuring that the patient's decision reflects a consequential and comparative process, indicating a rational reasoning process based on the information; and (d) *Choice*: referring to an individual's ability to communicate a decision.

People suffering from dementia may be competent to make decisions regarding simple courses of treatment but incompetent when a choice requires them to weigh and balance the risks and benefits, or when the outcome is uncertain. Thus, thresholds for capacity vary according to the complexity and uncertainty of the decision in question: the higher the risk and uncertainty, the higher the threshold [54]. Some legal standards have been proposed based on the fact that there are various degrees of capacity that patients may reveal when faced with a specific decision. These standards can be easily applied to other competencies to consent, and to decision-making capacities in general *(Table 2)* [55, 56]

An additional ability [LS2] – *making a reasonable*

Table 2

Legal Standards [LS] for capacity, according to the complexity and uncertainty of the decision: the higher the risk and uncertainty, the higher the threshold. [LS2] is not accepted for judging the capacity since the reference to "what is a reasonable choice" is arbitrary

Legal standard	
LS1 (advanced stage)	*Evidencing a treatment choice*: this standard focuses on the presence or absence of a decision alone
LS3 (moderate stage)	*Appreciating consequences of treatment choice*: this standard emphasises the patient's awareness about the emotional impact and future consequences of their decision regarding treatment
LS4 (mild to moderate stage)	*Providing rational reasons for treatment choice*: capacity to use logical processes to compare the benefits and risks of various options
LS5 (mild stage)	*Understanding treatments, situation, and choice*: this standard requires memory for sequences of information about the treatment and their comprehension

choice regarding treatment when the alternative is unreasonable – is not accepted as a legal standard for judging the capacity to consent since the reference to "what is a reasonable choice" is arbitrary [57].

The assessment of an individual's capacity with regard to informed consent

Any assessment of capacity to consent to a course of treatment is challenging in cognitively impaired patients, but also crucial in order to respect the two principles of protection and auto-determination. Variable competence rates in elderly people are reported [58], with 54% of full competence among AD patients, 44% in nursing home residents and 68% in patients with learning disorders; however, the same study indicates that clinical judgment alone is reliable in only 42% of cases, with a prevalence of false negative over false positive results.

To date, the assessment tools available fall into two categories: traditional psychometric tests and *ad hoc* structured interviews/questionnaires. Both of these methods have advantages and limitations, so a combination of the two used in tandem is a good solution. Furthermore, it is important to investigate the role of emotions in the decision-making process, through both structured tools and in-depth psychological observations in clinical settings.

Several reviews on cognitive tools have been published over the last decade, but only a few of these have been systematic *(see Supplementary Material available online)*. A possible reason for the scarcity of contributions in this area is exemplified by the fact that a study by Hein and colleagues was initially (2014) published on the Cochrane Library website but was later withdrawn with the reason given that: "there is currently no clear diagnostic gold standard to compare the reviewed diagnostic tests making it impossible to assess the sensitivity and specificity of measures" (Cochrane Database of Systematic Reviews, 2015).

In effect, we found only two systematic reviews on this topic: the first [34] concerns assessments of capacity according to legal requirements in the UK, and the second [59] focuses on various different instruments that measure decision-making capacities in a medical setting. Both studies focused on two critical features: i) the fact that despite a wide range of instruments, there is no gold standard for the assessment of capacity, and this hampers any evaluation of the various different approaches and ii) none of the instruments available provides a clinical cut-off score that physicians can use to determine whether a patient has sufficient decision-making capabilities. However, even though this last factor may be considered to be a limitation, it is worth nothing that not having a pre-defined cut-off is very much in line with the idea that decision-making is not an all-or-nothing process. An integration between the opinion of a healthcare professional and the results of a structured assessment process would therefore constitute the most robust approach [34].

The association between informed consent and various specific cognitive domains has been widely studied over the last twenty years [60-62]. Extensive intra-individual variability in performance has proven to be predictive of a higher risk of deficits in decision-making capacities [63]. More specifically, studies assessing people's ability to give their consent to treatment have suggested that measures related to executive functions are the main predictive factors [64]. However, to date, there has not been a clear pattern of association between specific cognitive skills and decision-making, and the lack of a gold standard hampers the validation of specific instruments [65]. In an attempt to define the predictors of a person's ability to consent, Marson [6] examined the correlational studies between the Capacity to Consent to Treatment Instrument (CCTI) and Legal Standards (LS). Deficits in semantic memory, conceptualisation and verbal recall appear to be associated with reduced Understanding and Choice in mild to moderate stages of Alzheimer's disease (LS5). Deficits in executive functions are associated with reduced capacity for Appreciation and Reasoning in mild to moderate stages of dementia (LS4) and the identification of the consequences of the choice made in moderate stages (LS3). Finally, deficits in receptive language and semantic memory (naming) are associated with a reduced ability to communicate a simple choice in advanced stages of dementia (LS1).

Among structured interviews and/or questionnaires which assess clinical competence, Dunn, *et al.* [66] indicated the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) and for Clinical Research (MacCAT-CR) as the best choices for measuring capacity to consent to treatment and research, due to their comprehensiveness and supporting psychometric data. Sessums, *et al* [58], however, reported the Aid to Capacity Evaluation (ACE) as being the best instrument to assist physicians in the assessment of medical decision-making capacities. This tool is available on the University of Toronto website and should always be associated with an MMSE lower than 24. However, this combination is not sufficient to determine capacity in patients with focal neurological disorders, and a comprehensive cognitive evaluation is always required [67].

The CCTI is similar to the ACE but has mainly been validated with AD patients. It shows a good correlation with several neuropsychological tasks [4], including phonemic and semantic fluency tests. In their model, Marson, *et al* [4] concluded that the integrity of frontal functions is a critical aspect in the assessment of decisional capacity, whereas memory defects are considered to be an "operational" deficit which may be compensated for by reminders [68].

While the standardisation of materials and procedures is quite simple for the cognitive tests that are used in clinical practice, any adaptation of interviews structured in order to cover specific situations may compromise the internal consistency of the test. In fact, standardisation is a key attribute for all psychometric tools, and any changes in content can potentially lead to a bias on inter-rater and test-retest reliability [69]. In principle, interviews may be useful in terms of guiding the assessment and supporting an experienced clinical judgment, but they cannot replace this latter [60, 70]. For example, the MacCAT-T takes into account the interactive and contextual nature of capacity and thus intentionally does not provide cut-off scores and relies on the collection of additional information such as interviews with family members, behavioural and ecological observations and an evaluation of the patient's value system.

In conclusion, despite the fact that there are many instruments and tools, a comprehensive assessment of capacity is often difficult and requires time. Moreover, the majority of instruments require further testing [70]. The MacCAT-T and the CCTI are currently the most widely used interviews and the latter seems nowadays to be the only one with normative values [4]. However, research on this topic is still ongoing, as confirmed by a number of reports of new tools, such as, for example, the University of California Brief Assessment of Capacity to Consent (UBACC). This is considered to be particularly promising as a result of both its simplicity and its applicability in clinical practice [45], but it is currently only applied to patients with psychiatric disorders.

Unfortunately, none of the above-mentioned instruments are available in Italian.

An emerging area of clinical and legal interest: testamentary capacity

In western societies, requests for assessments of testamentary capacity have been increasing since many populations are progressively ageing and illnesses related to dementia are more prevalent. In addition, relationships have become more and more complex in terms of financial aspects and family structures now often characterised by divorce, second marriages, de facto unions with the individuals within a family often living at great geographical distances from one another. All of this makes it difficult to resolve conflicts that arise regarding wills and inheritance and thus there is a greater necessity to ascertain the testamentary capacities of the individual concerned.

Testamentary capacity (TC) may be defined as the ability of a person (testator/testatrix) to make his or her own will in a clear and valid way [71, 72]. While from a legal point of view TC is subject to variations from country to country in accordance with the relative civic codes, from a neuropsychological perspective it is based on two general functions, an individual's capacity to understand relevant facts and to appreciate the reasonably foreseeable consequence of a decision.

As with other capacities, TC is considered to be present until proven otherwise, and a diagnosis of illness does not *per se* mean a deficit in TC [73, 74]. It is important to note that TC does not necessarily imply the ability to comprehend or manage complex financial transactions for instance [73, 75], but rather refers to a minimum level of the mental capacity required to make a will [75]. However, some cognitive abilities are in effect needed in order to create a will: individuals should be aware that they are making a plan to dispose of their estate after their death, to recognise the natural beneficiaries and to know the nature and extent of their estate. When there are doubts about whether these abilities are compromised, additional information is necessary and an assessment to establish the presence of capacity needs to be carried out. This is particularly important in those situations where cognitive abilities are apparently preserved, and deficits are hidden by adequate social interactions.

A seminal contribution to the doctrine regarding TC was given by the Banks *versus* Goodfellow sentence, the criteria of which have been recently revised by Shulman and colleagues [76, 77]. According to their interpretation, the authors suggest that the testator must be able to understand not only the act of making a will but also its potential effects. He/she needs to know the nature and extent of his/her property and to be able to clearly communicate the distribution of this property (particularly if the current wishes are different from those previously expressed). In addition, the testator must be capable of evaluating the claims of those who might be expected to benefit from the estate and express the rationale behind his/her choices. Finally, the testator needs to be free of mental disorders. However, any such symptoms will only invalidate the will when they clearly influence the disposition of the estate [73].

In any situation where these abilities are in doubt, a specific assessment is required. As TC is a function relating to both legal and medical fields, a collaborative approach is necessary to carry out an evaluation. Currently, any request for an assessment is usually advanced by a judge or a solicitor, often because there are disputes among the people involved in the inheritance or because there is the potential for a controversy in the future. However, when assisting a patient with dementia and his/her family, we must take into account that the patient's clinician may understand when and if it is appropriate to discuss making a will with the patient.

Unfortunately, to date there are no standardised tools for the clinical assessment of TC [77] and studies focusing on instruments which have been specially designed for the investigation of TC in elderly people or people with dementia are meagre. As a consequence, clinicians are required to achieve a general picture of an individual's capacity by means of integrating psychometric measures and other complex information relating to the testator's daily life and social relationships.

In general, assessments may be based on Retrospective or Contemporary evaluations.

Retrospective evaluations are requested when the testator is deceased and his/her mental state at the moment of drafting the will is being questioned. This process has been described as a sort of neuropsychological "autopsy", that is, an evaluation of the testamentary capacity of a person who has deceased and thus for whom an objective assessment is not available [78]. In this case, only collateral information and pre-mortem documentation are available in order for an opinion on the testator's capacity to be formed. Useful information comes from the results of prior medical and nursing home records (with lists of the individual's medications) and neuropsychological assessments, in addition to copies of other wills (when present), academic records, work performance records and financial transactions [72]. Medical reports should be collected in a systematic way following a "chronological" approach which makes it possible to track the progress of the testator's cognitive abilities. The date of the will is used as a reference point [79]. Another relevant source of information is the testator's personal correspondence and anything they have written, both of which may reveal the quality of the testator's interpersonal relationships and their intentions. Any other relevant legal documents can also be requested from people who were closely associated with the person in question, such as family members, close friends and medical staff (for details, see [79]).

Contemporary evaluation is, however, recommended where possible for obvious reasons. Unlike retrospective evaluations, in this type of assessment, it is possible for the examiner to garner a cognitive picture of the individual at the moment when the will was drafted. Furthermore, contemporary assessments represent a means of avoiding any subsequent inquiry into the requisite decisional capacity of the person after their death thus preventing potential litigation, expense, and any negative impact on family relationships [77].

As in the case of clinical competence, the tools employed for the assessment of TC include cognitive tests, interviews or questionnaires, and a variety of instruments for functional assessment. General tests of cognitive ability are recommended [80, 81] since these furnish indications regarding an individual's cognitive profile which will assist the examiner in the identification of strengths and weakness and in terms of deciding which cognitive functions need to be assessed in depth. In general, executive functions are assessed in order to have data regarding the testator's capacity for the planning and reasoning required for the distribution of his/her estate. Ability to calculate, working memory and cognitive estimation are tested with the aim of ascertaining the testator's awareness of the current values of any assets he/she wishes to bequeath. Tests relating to semantic and autobiographical memory allow the examiner to not only establish whether the testator understands the nature and extent of any properties to be disposed of, but also whether he/she recalls the nature of his/her relationships and is able to evaluate any potential claims from people who might expect to benefit from the estate. Finally, language competence is tested in order to ascertain whether the individual is capable of understanding the text of a will and of communicating his/her personal wishes in a clear and rational way [82, 76, 77, 74, 79].

In the literature on the subject, there are some semi-structured interviews that investigate financial capacities (e.g., Hopemont Capacity Assessment Interview (HCAI); the Financial Capacity Instrument (FCI) [83, 53], but these are not specific to TC. The Testamentary Capacity Instrument (TCI) [82] is more specific and involves a list of questions to be administered orally or in writing. The questions focus on the four legal criteria introduced by Banks *versus* Goodfellow (1870): "he ought to be capable of making his Will with (i) an understanding of the nature of the business in which he is engaged, (ii) a recollection of the property he means to dispose of, and (iii) of the persons who are the object of his bounty, and (iv) the manner in which it is to be distributed between them". Finally, any functional assessment should comprise an evaluation of the daily activities the person engages in including those which are associated with the management of finances and properties.

Whatever instruments are chosen for an assessment, it is crucial that the examination follows a systematic approach which provides evidence both of any individual weakness and any residual abilities and competencies. Furthermore, certain ethical aspects should be considered.

First of all, the testator needs to be informed about the specific, legal nature of the assessment and he/she must be informed that personal questions may be addressed to him/her that may be related to private issues. Whenever possible, assent for a cognitive evaluation should be requested, even if this could result in an impasse (i.e. when the patients themselves are asked for their consent to be assessed on their abilities to make a will). The person carrying out the evaluation should also clearly understand the main questions to be asked depending on whether, for example, there is a doubt regarding the testator's ability to estimate his/her property or comprehend financial issues or he/she has difficulty recognising his/her relatives.

Another aspect that is of value from an ethical point of view relates to the context of the assessment. In particular, this should be conducted in the absence of anyone who might benefit from the will [73, 84]. This in some way guarantees a reduction of any external influences on the testator's wishes. The risk of undue influence is particularly high in the case of vulnerable people or in cases where the testator's wishes have changed over time. In these cases, it may be useful to identify the timeline of these changes and to understand the circumstances in which these happened in the context of the testator's relationships. For example, a manipulator may be identified in a person who acts in order to isolate the client from their usual support networks, encourage mistrust in others whilst winning over the client with gifts and acts of kindness, thus placing the individual in a position where they feel they are obliged to change their financial arrangements in favour of the potential manipulator [74].

Last but not least, TC assessment requires sufficient time. An ethical approach to evaluation may involve the necessity of collecting information from various different sources and in various different contexts (e.g. not only in a clinical setting but also at the testator's home). This may take more time and multiple sessions of assessment may be necessary. Understanding the current capacities of an individual can often be a complex task and every effort must be made to realistically investigate any remaining capacity.

DISCUSSION

The purpose of the present review was to collect and synthesise current knowledge concerning two domains of capacity which are of particular interest for clinical purposes: the capacity to give informed consent and testamentary capacity. A multidisciplinary perspective that integrates ethical, medical-legal issues and clinical assessment was adopted. The aim was also to provide clinicians with a theoretical and empirical overview that might be useful in their clinical practice. Some considerations emerged from our revision of the scientific literature on the subject covering the last 30 years.

Firstly, to date there have been no tests designed to measure capacity: all of the tools available have been adapted from those used for clinical diagnostics, and they investigate specific functions rather than abilities, with the result that the scores do not provide any relevant information concerning any compensatory, adaptive strategies implemented by the patient to face the demands of daily life [3]. Similarly, there are no standards for assessing capacity, probably due to the fact that patients vary greatly from one to another even though the diagnoses and levels of medical care are similar [65]. There is also the question of the specificity of the various different contexts relative to each individual (e.g. the risk/benefit ratio). This means that a case-by-case tailor made approach is required.

An issue in Italy regards the lack of translations and validation for structured interviews (e.g., informed consent, driving skills, testamentary skills, etc), that are widespread in English-speaking countries where these have been developed and validated. Although interviews should not be considered as indicators of ability but integrated into a neuropsychological examination, the absence of translations and validations constitutes a serious limitation for the Italian health system [7].

Secondly, the lack of a gold standard is now the greatest challenge since the complexity of assessments of capacity cannot be reduced to simple scores for cognitive tests or questionnaires but is a complex endeavour involving cross-disciplinary knowledge involving, for instance, ethics, law, neuropsychology and neuroscience [59]. Cognitive and emotional abilities, personal values and experiences are also important factors that influence decision-making. None of the instruments currently available are sufficiently flexible or broad in scope for individual and contextual factors to be taken into consideration, and thus in-depth investigations and consideration of every patient's narratives are essential.

In light of this, the following ethical recommendations for the neuropsychological evaluation of capacity are particularly important [3, 11, 85]:

i) the use of several tools and various different approaches to the evaluation of the patient's daily life functioning skills;

ii) respect for his/her residual autonomy to whatever degree it is present and

iii) a tailored approach to his/her emotional, functional and cognitive responses, as well as to clinical and socio-demographic conditions.

Thirdly, an issue which we consider needs to be addressed emerged from the present review. This concerns the lack of emphasis on the concept of awareness within any assessment of capacity. Anosognosia (i.e., a lack of awareness) is a multifaceted syndrome that may affect patients with dementia. Awareness has been defined as "a reasonable or realistic perception or appraisal of a given aspect of one's situation, functioning, performance, or of the resulting implications, which may be expressed explicitly or implicitly" [86]. In cases of mental deterioration, anosognosia may involve some cognitive functions and not others, and often concerns impairments in daily activities [87, 88]. Although not directly correlated with capacity, in AD awareness needs to be specifically investigated [89-91]. In fact, an inability to recognise one own's symptoms may lead patients to make inadequate decisions [92].

It is noteworthy that awareness shares some brain networks with decision-making. Recent studies indicate a role of the medial structures in anosognosia, in particular the right temporal medial cortex, including the hippocampus [93] There are also disconnections within medial subsystems of the default mode network, subserving autobiographic memory and emotional states [94, 95]. We thus consider that an evaluation of capacity in a patient with dementia should not ignore tests regarding the awareness of self and of one's own symptoms and disease.

Lastly, it is worth considering two ethical issues. The first arises from a reflection on the subject of autonomy proposed by Reichlin in *Ethics and neuroscience* (p. 112) [96]: "autonomy (in dementia) cannot be conceived of as being based on the full decision-making freedom to make decisions, by a rational individual, who is fully informed and capable of pursuing a proper life plan. This representation, which is disproportionate in any individual made weak and vulnerable by a disease, appears to be altogether inapplicable to patients suffering from dementia".

If this is the case, autonomy cannot be the only value involved in the physician-patient relationship. It must also be accompanied by the concept of "best interest", which includes not only respect for the individual's previous wishes, but should also take into account the care required for his/her current well-being and quality of life. The second issue relates to the impact of ethical principles on clinical practice [97]. The care of dementia is deeply intertwined with ethical aspects, in all clinical and personal interactions, and general ethical principles such as "respect for patient autonomy" and "beneficence" should be at the basis of all medical decisions at every step (e.g. the communication of the diagnosis, information about the clinical course of the disease, drug therapy, etc.).

In conclusion, we consider that our findings will be useful for both clinicians and law practitioners when an analysis of protective measures and the patient's need for guardianship is being carried out. Limiting the role of guardianship to complex decisions may be enough to protect the majority of patients suffering from mild forms of AD. Less restrictive legal options, such as supporting in decision-making, might be applied for simpler decisions.

Limits

Our paper is structured as a systematic review. It focuses on reviews rather than on original articles, a choice which was necessitated by the multidisciplinary approach adopted and the long-time window considered (30 years). Unfortunately, quantitative findings on this topic are few. The field of systematic reviews on ethical issues lacks broadly consented standards, such as those available for systematic reviews on clinical research [98].

Moreover, the study does not consider the symptomatic predementia phase – that is, mild cognitive impairment (MCI). Along with the ascertaining of capacity in patients with dementia, some studies have focused on MCI, showing that some of these patients exhibit problems with making competent decisions, in particular regarding treatments and research protocols [40]. However, the diagnostic criteria for MCI state that cognitive changes should be sufficiently mild as not to compromise social and occupational functioning [99]. Furthermore, a reversion to normality has been described as a common outcome in this condition [100]. Addressing the issue of competence in MCI thus deserves a specific investigation and is beyond the scope of this study, which originated from the National Dementia Plan [7].

The main limitation of our study is probably due to the "cultural" bias present in the review of the literature. Indeed, the studies reported refer to various cultural contexts and legislative contexts and this makes it difficult to make comparisons. On the other hand, all of these studies came from Europe and North America and thus we cannot exclude the possibility that a rethink of the constructs of capacity and competence might be necessary when investing different cultural contexts.

Another limitation is that it was extremely difficult to find a solution to the issue regarding the confusion in terminology involving the various different shades of meaning that the authors give to the concepts of autonomy in competence and self-determination. We consider that only thorough integration between the many different professionals (e.g., legislators, judges, clinicians and neuropsychologists) will overcome this problem.

Finally, the interaction between cognitive and emotional dimensions in relation to the definition of capacity was not specifically discussed in this review as the literature on the subject is meagre. Further studies are necessary to investigate this relationship since it is fundamental in order to respect individuals in their uniqueness.

CONCLUSIONS

The evaluation of capacity in patients with dementia has several crucial aspects. On the one hand, these are linked to the patient's fragility which requires special care from people who are in contact with him/her (e.g., judges, caregivers and clinicians). Unfortunately, the urge to exclude the patient from the decisional process is common in real life, but his/her participation should instead be enhanced and validated. On the other hand, capacity is not a dichotomous condition to be merely defined as "present/absent". It always refers to a specific decision, in a given context and at a given time [101].

This involves an all-encompassing tailored approach to the assessment of capacity, and a continuous effort to help the patient to express his/her opinion when applying standardised procedures in a clinical setting. Clinicians should therefore be well trained in order to develop such skills, and to bear constantly in mind the importance of demonstrating respect for the autonomy and dignity of the patient.

The implementation of a series of tools to aid assessments of capacity and the validation of *ad hoc* questionnaires are strongly recommended in order for the current limitations in clinical practice to be overcome.

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The Authors certify that neither financial nor non-financial involvements that might represent a conflict of interest affect their work.

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