The prevalence of neurodegenerative diseases has been significantly increasing in the last decades, and it is expected to continue to grow. These health disorders can impair patients’ decision-making capacity in healthcare. The capacity to make healthcare decisions is a fundamental pillar of informed consent, therefore, it should be carefully assessed. Clinicians’ assessment, when not supported by a standardized tool, has revealed to be unreliable, so the recourse to an instrument of capacity assessment is crucial. The present paper aims to identify and summarize published instruments of healthcare decision-making capacity. To do so, a search of peer-reviewed articles in English, Portuguese and Spanish was conducted. A total of eighteen articles, detailing seventeen assessment instruments were selected. Instruments differ on format, structure, assessed abilities and psychometric properties. Likewise, instruments’ targeted population also varies, with a few being specifically developed for patients with dementia. Although a high number of instruments were found, there is still no gold standard for healthcare decision-making capacity assessment. The lack of a gold standard highlights the need for more research in this field, as well as an effort to develop guidelines and normative data, in order to improve clinical practices.
Decision-making Capacity in Healthcare: Instruments Review and Reflections about its Assessment in the Elderly with Cognitive Impairment and Dementia

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Abstract

The prevalence of neurodegenerative diseases has been significantly increasing in the last decades, and it is expected to continue to grow. These health disorders can impair patients’ decision-making capacity in healthcare. The capacity to make healthcare decisions is a fundamental pillar of informed consent, therefore, it should be carefully assessed. Clinicians’ assessment, when not supported by a standardized tool, has revealed to be unreliable, so the recourse to an instrument of capacity assessment is crucial. The present paper aims to identify and summarize published instruments of healthcare decision-making capacity. To do so, a search of peer-reviewed articles in English, Portuguese and Spanish was conducted. A total of eighteen articles, detailing seventeen assessment instruments were selected. Instruments differ on format, structure, assessed abilities and psychometric properties. Likewise, instruments’ targeted population also varies, with a few being specifically developed for patients with dementia. Although a high number of instruments were found, there is still no gold standard for healthcare decision-making capacity assessment. The lack of a gold standard highlights the need for more research in this field, as well as an effort to develop guidelines and normative data, in order to improve clinical practices.

Keywords: Capacity assessment; Healthcare decision-making; Dementia; Mild cognitive impairment.

1. Introduction

To provide medical care, physicians need to obtain informed consent form their patients. This presumption relies on the bioethical principle which stands for people’s right to decide what happens to their own body. However, in order to consider an informed consent as valid, three assumptions are required: disclosure of information, voluntariness and capacity [1, 2]. Capacity to make healthcare decisions has been generally understood accordingly to Grisso and Appelbaum’s [3] model of four abilities. This model describes four functional abilities implied in healthcare decision-making and is based on the legal standards of competence to consent [4]. The four abilities are understanding, appreciation, reasoning and expressing a choice [5]. Understanding regards the ability to understand the disclosed information about the disease, as well as the risks and benefits of each treatment option. As for appreciation, it stands for the ability to apply the disclosed information to one’s own problem. Reasoning describes the process of weighing the risks and benefits of each treatment option, which allows the
patient to reach a decision. Finally, expressing a choice refers to the ability of communicating a clear and consistent decision through speech, write, or other mean [5].

The assessment of capacity to consent to treatment is a routinely procedure in clinical practice [6]. Although, some situations require a more thorough assessment, specially cases of mild cognitive impairment, dementia or other health issues related to cognitive impairment.

Frequently, capacity assessments are performed by clinicians in a non-structured way. However, clinical assessment per se does not seem to be the most effective way to evaluate healthcare decision-making capacity, since various studies have pointed out low interrater reliability between clinicians [4]. These limitations highlight the need of a structured assessment of healthcare decision-making capacity, with recourse to a specific assessment tool. Several instruments have been developed. This article aims to review the existing instruments, summarize their content, administration procedures, psychometric properties, and reflect about their usefulness in people with cognitive impairment and dementia.

2. Method

We conducted searches for English, Portuguese and Spanish papers, published between 1980 and 2018, describing instruments of decision-making assessment in healthcare. The search terms used were “capacity to consent to treatment”, “competence to consent to treatment”, “healthcare decision-making” and “assessment tools” or “assessment instruments”. Searches were limited to peer-reviewed publications, and conducted in the following databases: Web of Science (Web of Science Core Collection, Current Content Connect MEDLINE and Scielo), EbscoHost (Psychology and Behavioral Sciences Collection, Cochrane database of Systematic Reviews, Cochrane Clinical Answers, MEDLINE complete), Scopus, Wiley Online Library, Taylor & Francis Online, Clinical Key, Proquest Psychology Journals, and PubMed.

Search results are presented in the flowchart below (fig.1). Articles describing assessment tools of healthcare decision-making capacity were included. For this purpose, assessment tools should have a standardized scoring procedure. Articles containing guidelines for clinical assessment of healthcare decision-making capacity were excluded. Instruments of decision-making capacity in activities of daily living, advance directives, consent to clinical research, and healthcare decision-making capacity in children were also excluded.
3. Results

Through online database research, 18 articles, describing 17 assessment instruments of healthcare decision-making capacity were included. Each instrument main features are presented in Table 1. More detailed descriptions can be found below.
### Table 1: Assessment tools of Decision-Making Capacity in Healthcare

| Instrument                        | Application Time | Format                      | Abilities included                        | Reliability                                      | Cut-off scores | Pilot study participants                                                                 |
|----------------------------------|------------------|-----------------------------|------------------------------------------|-------------------------------------------------|----------------|------------------------------------------------------------------------------------------|
| Two-Part Consent Form [7]        | No information available | Semi-structured interview. | Understanding.                          | Test-retest reliability, $r = .76$; Interrater reliability, $r = .96$; Agreement between judges, $0.5 \geq k \leq 0.83$. | No information available | Psychiatric patients referred to electroconvulsive treatment. |
| Direct Assessment of Decision-Making Capacity [8] | No information available | Structured interview with clinical vignettes. | Understanding and Reasoning. | No information available. | Bellow the lower 99.5% confidence limit of control group mean. | Elderly inpatients with acute ill, without neurologic or psychiatric history. |
| Competency Interview Schedule [9] | No information available | Structured interview. | Evidence a choice, Understanding, Appreciation and Evidence rational reasons for the choice. | Test-retest reliability, $r = .79$; Interrater reliability, ICC $= .95$; Inter-item correlation coefficients average $= .64$; Cronbach’s alpha $= .96$. | No information available. | Psychiatric inpatients with recommendation to electroconvulsive treatment. |
| Understanding Treatment Disclosure [10] | 25-30 minutes | Semi-structured interview | Understanding. | Interrater reliability for individual items $k \geq .60$ for 90% of the comparisons, and | No information available. | Hospitalized groups: Schizophrenia or Schizoaffective Disorder; |
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|----------------------------------------|
| **Perceptions of Disorder [10]** | 10-20 minutes | Semi-structured interview with clinical vignettes. | Appreciation. | ICC ≥ .84 for subtests scores; Test-retest reliability ranged from .50 to .80; Cronbach’s alpha ranged between .55 -.85. | Major Depressive Disorder; and Ischemic Heart Disease. Community groups. |
| **Thinking Rational About Treatment [10]** | 25-30 minutes | Semi-structured interview with clinical vignettes. | Reasoning and Expressing a Choice. | Interrater reliability, for individual items $k \geq .60$ for 76% of the comparisons, and ICC ≥ .88 for total scores; Test-retest reliability ranged from .66 to .68; Cronbach’s alpha between .39 -.74. | No information available. | Hospitalized groups: Schizophrenia or Schizoaffective Disorder; Major Depressive Disorder; and Ischemic Heart Disease. Community groups. |
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| MacArthur Competence Assessment Tool for Treatment [11] | 15-20 minutes | Semi-structured interview. | Understanding, Appreciation, Reasoning and Expressing a choice. | Interrater reliability, ICC = .99 for understanding, .87 for appreciation and .91 for reasoning. | No information available. | Hospitalized groups: Schizophrenia or Schizoaffective Disorder; Major Depressive Disorder; and Ischemic Heart Disease. Community groups. |
|---------------------------------------------------------|---------------|----------------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------|---------------------------------------------------------------------|
| Capacity to Consent to Treatment Instrument [12]       | 20-25 minutes | Structured interview with clinical vignettes. | Understanding, Appreciation, Reasoning, Expressing a choice and Making a reasonable choice. | Interrater reliability, $r = .83$ on interval scales and $96\%$ agreement on categorical scales. | Two standard deviations below the control group mean for four abilities. | Elderly with probable Alzheimer’s Disease and older control group. |
| SICIATRI [13]                                         | 20 minutes    | Structured interview.      | Awareness, Not waive the right to decide, Evidence a choice, Understanding, Wants to get better and Insight. | Interrater reliability, for individual items, $0.14 \geq k \leq 0.82$. | No information available. | Psychiatric and medical inpatients.                                   |
| Hopemont Capacity                                     | 30-60 minutes | Semi-structured interview with | Understanding, Appreciation and Reasoning. | Interrater reliability has consistently been of $0.90$ or more. | No information available. | No information available. However, the instrument was designed to assess decision- |
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| Assessment | Interview [14] | clinical vignettes. |  | making in nursing home residents. |
|------------|----------------|---------------------|-------------------------|----------------------------------|
| Aid to Capacity Evaluation [15] | 10-20 minutes | Semi-structured interview. | Understanding, Appreciation and Reasoning. | Overall impression of probably or definitely incapable according to ACE classification, associated with a score between 0-16 on Standardized Mini-Mental Examination. |
| Vignette method described by Schmand [16] | No information available. | Structured interview, with clinical vignettes. | Understanding, Appreciation, Reasoning and Expressing a choice. | Internal consistency of .74; Agreement between the vignette method and clinical judgment, $k = .36$. |
| Decision Assessment Measure [17] | No information available. | Semi-structured interview | Understanding and Retaining information, and Expressing a choice. | Interrater reliability, $k = .87$. No information available. |
|  |  |  |  |  |

Medical inpatients.

Groups with mental illness: Dementia, learning disability and schizophrenia or schizoaffective disorder. Control group.

Community dwelling elderly with dementia syndromes (minimal, mild and moderate) and cognitively intact elderly.
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| Capacity Assessment Tool [18] | A few minutes, not specified. | Semi-structured interview. | Communication, Understanding choices, Comprehension of risks and benefits, Insight, Decision process and Judgment | Agreement between CAT and Psychiatrist’s evaluation, $0.77 \geq k \leq 1$. | No information available. | Elderly hospitalized in a Geriatric Unit or followed at the Unit’s consultation service. |
|--------------------------------|-------------------------------|---------------------------|---------------------------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------|
| **Assessment of Consent Capacity – Treatment [19]** | 45 minutes | Structured interview with clinical vignettes. | Understanding, Appreciation, Reasoning and Expressing a Choice. | Interrater agreement across the vignettes between 97% - 98%; Cronbach’s alpha between 0.82 and 0.88. | No information available. | Groups with mild and moderate mental retardation. Control group. |
| **Vignette Method by Vellinga [20]** | No information available. | Structured interview with clinical vignettes. | Understanding, Appreciation, Reasoning and Expressing a Choice. | Interrater reliability, $k = 0.64$. | Fifth centile of the control group. | Elderly with dementia (58.8%) and without (37.5%). |
| **Assessment of Capacity to Consent to Treatment [21]** | No information available. | Semi-structured interview with clinical vignettes. | Understanding, Appreciation, Reasoning and Expressing a Choice. | Interrater reliability, $r = 0.90$; Cronbach’s alpha of 0.96. | 2 standard deviations below the control group mean for understanding, | Elderly with dementia or schizophrenia. Control groups. |
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|                     | appreciation | and reasoning. |
|---------------------|--------------|----------------|

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3.1 Two-Part Consent Form

The Two-Part Consent Form was developed to assess capacity to consent electroconvulsive treatment in psychiatric patients [7]. The first part presents information about electroconvulsive therapy and it is followed by a questionnaire of fifteen items, which evaluate patients’ understanding of the disclosed information. Understanding is measured by recall tasks, language understanding and reasoning. Patients’ answers are scored between 0 and 2, with higher scores representing higher understanding. A total score can be obtained by summing all individual scores. The pilot study was performed with a sample of psychiatric patients, to whom electroconvulsive therapy had been recommended. The study included a total of fifty seven patients, forty four who had consent electroconvulsive treatment, and thirteen who had refused it [7].

3.2 Direct Assessment of Decision-Making Capacity

Fitten and Waite [8] proposed an assessment tool to evaluate treatment decision-making capacity in elderly patients with acute ill. This instrument presents three clinical vignettes of increased complexity, followed by a structured interview. After each vignette’s presentation participants are asked to make a decision about treatment. The vignettes describe problems of insomnia, pleural effusion and resuscitation in chronic illness. The Direct Assessment of Decision-Making Capacity assesses the ability to understand the medical problem, proposed treatments, its risks and benefits, and reasoning. Patients’ answers are scored as complete (2 points), partial (1 point) or no understanding of the question (0 points). Validation studies included twenty five inpatients over 60 years old, without history of neurologic or psychiatric problems and a control group with twenty five community-dwelling volunteers. Inpatient participants showed significantly lower scores on the clinical vignettes [8].

3.3 Competency Interview Schedule

Developed by Bean and collaborators [9], Competency Interview Schedule (CIS) aims to evaluate psychiatric patients capacity to consent to electroconvulsive therapy. CIS is a questionnaire of fifteen questions that assesses the ability to evidence a choice, to understand information related to treatment, to appreciate the nature of the situation and its consequences, and to evidence a rational reason for the choice made. Patients’ answers are rated in a Likert scale of seven points, where lower scores correspond to more adequate answers. Psychometric studies were performed with a sample of ninety six subjects admitted to a psychiatric hospital, who had been diagnosed with schizophrenia, schizoaffective, depression, mania, or other disorders [9].
3.4 MacArthur Treatment Competence Study Instruments

MacArthur Treatment Competence Study aimed to develop measures of competence to consent to treatment. During its course, three instruments were developed: Understanding Treatment Disclosure, Perceptions of Disorder, and Thinking Rational About Treatment. These instruments were designed based on the legal standards of capacity to consent to treatment: understanding, appreciation, reasoning and expressing a choice. The studies conducted included three clinical samples, named as hospitalized groups, and three community samples (non-hospitalized groups), with equivalent age, gender, ethnicity and socioeconomic status. The hospitalized groups included patients with schizophrenia or schizoaffective disorder (n=75), major depressive disorder (n=92) and ischemic heart disease (n=82) [22].

Understanding Treatment Disclosure (UTD) is a structured interview that assesses the ability to understand information about treatment. It starts with the presentation of a standardized vignette disclosing information for informed consent. Three clinical vignettes were developed for this instrument, related to the disorders of the hospitalized groups. In the assessment with UTD, each vignette is first presented in an “uninterrupted disclosure” format, without any questioning occurring. After the uninterrupted disclosure, ten standardized questions are made. Then, the vignette is presented again, in an “element disclosure” format, with each paragraph presented at a time. Each paragraph is followed by standardized questioning, which contain questions demanding information recall and recognition tasks. Each answer is classified in a three-point Likert scale (0-2). There are no instructions for a total score, but for three sub-ranking-scales scores, which represent the scores obtained after the uninterrupted disclosure and element disclosure (information recall and recognition questions) [10].

Perceptions of Disorder (POD) assesses the ability to appreciate the situation and its consequences to one’s own situation. Considering the three clinical groups, three forms of Perceptions of Disorder were developed. Each form is composed by three parts, but only two will be discussed, since research results of the third part have not been found during the research. The first part is Non-Acknowledgment of Disorder and the second Non-Acknowledgment of Treatment Potential. Each part presents a piece of information about the disorder and the treatment, respectively. After each part being presented, patients are asked to rate in a six-point scale how much they believe that the information applies to their own situation. Then, patients are asked to explain their reasons, which are rated between 0 and 2, with lower scores indicating greater non-acknowledgment [10, 23].

Thinking Rational About Treatment (TRAT) was also developed as a research instrument in MacArthur Treatment Competence Study. It measures the ability to reason or rational manipulate information, through the assessment of cognitive functions involved in decision-making processes. This instrument is composed by two parts: 1)
vignette presentation, followed by a series of questions that measure five cognitive functions; and 2) three tasks, unrelated to the vignette, which assess three more cognitive functions. Therefore, TRAT has a total of eight questions, that are scored between 0 and 2. A total TRAT score may be obtained by summing the scores of the eight questions. The authors also developed a TRAT-2 score, that includes only six of the eight tasks. This instrument also includes one item to assess the ability to express a choice, which can be rated between 0 and 2 [10, 22].

3.5 MacArthur Competence Assessment Tool for Treatment

MacArthur Competence Assessment Tool for Treatment (MacCAT-T) was based on Treatment Competence Study. It merges the three previous instruments into a structured interview, which allows the assessment of understanding, appreciation, reasoning and expressing a choice. The MacCAT-T does not include clinical vignettes, so decision-making capacity is assessed in real-life context. The scoring criteria allows to classify patients’ answers between 0 and 2, with higher scores representing more adequate responses. Based on the theoretical assumption that there are no universal levels of abilities which can distinguish between competence and incompetence, no cut-off scores are proposed. In the same way, as an impairment in a specific ability could compromise decision-making capacity, there are no instructions for calculating a total MacCAT-T score. The MacCAT-T study was developed with a clinical sample of hospitalized patients with schizophrenia (n=40) and a control group from community (n=40) [11].

3.6 Capacity to Consent to Treatment Instrument

Capacity to Consent to Treatment Instrument (CCTI) is a structured interview developed to assess capacity to consent to treatment, especially in people with dementia. It contains two clinical vignettes, presenting a neoplasm and a cardiac problem, where symptoms and two possible treatments are described. After each vignette being presented (orally and in writing), patients are asked fourteen standardized questions. CCTI assesses the ability to express a treatment choice, make a reasonable choice, appreciate emotional and cognitive consequences of treatment, reasoning and understanding the medical condition and treatment choices. Patients’ answers are scored according to two scoring systems: Quantitative and Qualitative scoring. The first scoring system rates patients’ answers between 0 and 2 points. In the pilot study, scores of each ability were considered separately. A cut-off score of 2 standard deviations below the control group mean for the abilities express a treatment choice, appreciate consequences, reasoning and understanding was considered as an indicative of lack of competency.
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The Qualitative scoring system identifies sixteen types of errors, due to language dysfunction, executive dysfunction, affective dysfunction or compensatory responses [12]. A recent study proposes an experimental total score of CCTI. Age-independent and age-adjusted normative data for each ability and total CCTI score were also published, with a sample of three hundred eight community-dwelling adults, without cognitive impairment, between 19 and 86 years [24].

3.7 Structured Interview for Competency and Incompetency Assessment Testing and Ranking Inventory

The Structured Interview for Competency and Incompetency Assessment Testing and Ranking Inventory (SICIATRI) is a structured interview developed by Kitamura and Kitamura [13] for the assessment of competency in psychiatric patients [13]. SICIATRI is composed by twelve items that measure patient capacity to give informed consent for hospital admission or medication. The items assess the patients’ awareness of being informed, do not waive the right to decide, evidence a choice, understanding the right to decide, understanding risks and benefits associated to treatment, alternative treatment or absence of treatment, wanting to get better, the absence of pathological determinants and insight. Answers are rated between 1 and 3, with lower scores representing worst performances. According to the score obtained, patients’ performance is rated in one of the five levels of Ranking Inventory for Competency, which ranges from completely incompetent to completely competent. Validation studies included a sample of twenty five psychiatric and twenty three medical hospitalized patients between 21 and 80 years [13].

3.8 Hopemont Capacity Assessment Interview

Hopemont Capacity Assessment Interview (HCAI) is an interview in a semi-structured format, with two sections. The first section assesses the capacity to make healthcare decisions, and the second measures financial capacity. Only the first section will be considered in the present paper. Being so, HCAI assesses three core abilities: understanding, appreciation and reasoning. The interview starts by presenting the definitions of risk, benefit and having a choice, and next the patients are asked to explain the same definitions in their own words. After that, the interview proceeds with the presentation of two clinical vignettes (eye infection and advance directive), each followed by nine questions. HCAI may be scored by counting the number of correct answers, or assigning scores (0, 1 or 2) to each answer, with higher scores representing more adequate responses. Procedures to calculate total scores are not recommended, since the questions have different weights regarding decision-making capacity [14].
3.9 Aid to Capacity Evaluation

Aid to Capacity Evaluation (ACE) is a semi-structured interview that assesses capacity to make healthcare decisions, based in patients’ real health problem, not a standardized vignette. It evaluates the abilities: to understand information regarding the medical problem, proposed treatment, its alternatives, and the option of refusing treatment; reason about the consequences of refusing or accepting the treatment; and appreciation, which is conceptualized as the ability to make decisions not based on hallucinations, delusions or depression. Each question is scored as yes, if the patient gives an appropriate answer, as no, if the patient gives an inappropriate answer, or as unsure, when close-ended questions are necessary. After scoring ACE, the clinician should rate the patient as definitely capable, probably capable, probably incapable or definitely incapable [15].

3.10 Vignette method described by Schmand

Schmand and collaborators [16] studied the usefulness of a vignette method to evaluate capacity to consent to treatment and research in people with dementia. The pilot study included a sample of 240 subjects, distributed in control group (n=176), minimal dementia (n=14), mild dementia (n=43) and moderate dementia (n=7). The vignette method consists on the presentation of two clinical vignettes, describing a clinical trial and a hip fracture. After each vignette being integrally presented, a series of questions are asked. A total of sixteen questions evaluate understanding, appreciation, reasoning and expressing a choice. After rating patients’ answers, competency scores of each vignette and a combined score may be calculated, by summing the number of correct answers. The authors [16] established cut-off scores of 95% of the control group mean, which indicate lack of capacity to consent to treatment and research.

3.11 Decision Assessment Measure

Decision Assessment Measure (DAM) is a semi-structured interview designed to evaluate decision-making capacity in patients with mental disabilities. Target participants were patients who had been advised by their physicians to have a blood test. The interview begins by asking the patients to say what they know about blood tests. Then an information sheet about blood tests is presented. After information disclosure, patients are asked a series of questions that aim to assess their ability to understand and retain information, and to communicate a choice. When revealing lack of capacity in the first series of questions, each element of the information sheet is presented at a time and it is followed by questioning and recognition tasks. After the questioning procedure, patients are asked to perform a non-verbal demonstration, simulating a blood test with medical items. These must
be chosen by the patient from a set of tools that include distracting items. Answers are rated according to a three-point system (0-2), where greater scores indicate a better performance. Scores should be used to support clinicians’ judgment. For study purposes, three clinical samples were considered: group with schizophrenia or schizoaffective disorder (n=21), learning disability group (n=20), and dementia group (n=21) [17].

3.12 Capacity Assessment Tool

Capacity Assessment Tool (CAT) was developed to allow a regular and time effective assessment of healthcare decision-making capacity. It enables the assessment of decision-making capacity in real-life situations, so it does not contain clinical vignettes. CAT’s score is based on six components, namely, communication, understanding choices, comprehension of risks and benefits, insight, decision process and judgment. Interviewees’ answers are scored between 0-3, or 0 and 1. It is not recommended to calculate a total score, so each of the six components must be individually considered. Pilot studies included a sample of twenty patients from a Geriatric Inpatient Unit or Consultation Service [18].

3.13. Assessment of Consent Capacity – Treatment

Assessment of Consent Capacity – Treatment (ACC-T) is a structured interview developed to evaluate capacity to consent to treatment in adults with mental retardation. It contains three hypothetical vignettes regarding psychopharmacological treatment, placement of an orthodontic brace and administration of injections to prevent allergic reactions. The vignettes are presented a paragraph at a time, with each being followed by questions that compose a thirteen-item questionnaire. The questionnaire measures the four decisional abilities, and each answer is scored accordingly to a three-point scale (between 0 and 2). There are no indications for calculating a total score, so each ability should be considered individually. Pilot study included a sample of ninety participants distributed in three groups: mild mental retardation, moderate mental retardation and no mental retardation [19].

3.14 Vignette method described by Vellinga

Vellinga and collaborators [20] compared three judgments of competency: a vignette method, family members’ judgment and physician’s judgment. A total of eighty elderly, of whom 37,5% had dementia, their physicians, and eighty family members were included. The vignette method consists on presenting two clinical vignettes (anemia and surgery for colon cancer), followed by a structured interview. The interview assesses understanding, evidencing a choice, reasoning and appreciation. Patients’ answers are scored between 0 and 2, with higher scores
representing better performance. A total score can be dichotomized into competent or incompetent performance, by a cut-off score of 95% of the sample without cognitive impairment [20].

3.15 Assessment of Capacity to Consent to Treatment

The Assessment of Capacity to Consent to Treatment (ACCT) is a semi-structured interview developed to assess consent capacity in patients with neurocognitive or neuropsychiatric diseases. It evaluates the four abilities of decision-making, namely understanding, appreciation, reasoning and communicating a choice, as well as values and preferences relevant to clinical decisions. The ACCT contains three clinical vignettes, the first reporting a case of rheumatoid arthritis, the second eliciting an advanced directive, and the third describing a leg ulcer. For clinical use, either the hypothetical vignettes or the patients’ real medical problem can be used. In this sense, the ACCT has the advantage of containing vignettes and also allowing the interview to adapt to real-life situations. Pilot studies included a control group (n=19) and two clinical groups, one with dementia (n=20) and other with schizophrenia (n=20). For statistical purposes, Moye et al. (2007) calculated a summary dichotomous score, which classifies the patient has has capacity or lacks capacity. To do so, cut-off scores of 2.0 standard deviations from the control group mean were established for understanding, appreciation and reasoning. Participants who had scores below the cut-off on any of these abilities had a summary dichotomous score of lacks capacity [21].

4. Discussion

Through this narrative review, seventeen measures of healthcare decision-making capacity were identified. Although the instruments intended to measure the same construct, they differ on what concerns the competencies assessed and the methods employed.

4.1 Assessed abilities

Regarding the competencies assessed, most instruments are based on the four abilities model. However, only eight instruments assess all the four abilities. Understanding is the only ability measured by all instruments, except for two which aim to measure specific abilities (POD and TRAT). Understanding is commonly assessed by asking the patients to paraphrase information disclosed in a hypothetical vignette or regarding their own medical problem. Appreciation is measured in ten of the seventeen instruments. Nonetheless, there are major differences in how this ability is assessed. On one hand, CIS, Perceptions of Disorder, MacCAT-T, HCAI and ACE operationalized appreciation as the acknowledgement of the significance of the information to one’s own circumstance,
recognition of the medical problem and potential benefits from the treatment [25]. In this way, appreciation is understood as insight towards the medical problem and potential benefits of the treatment. On the other hand, CCTI, Vignette Method by Schman, ACC-T and Vignette Method by Vellinga defined appreciation as the ability to anticipate emotional and cognitive consequences from the treatment. By that, appreciation is conceptualized as a foresight capacity, in which the individual should be able to predict changes in his life due to the treatment [26, 27]. These inconsistencies are serious and result in statistical fragilities [21]. To overcome this divergence, the ACCT assesses appreciation employing two subscales: The Distrust subscale and the Foresight subscale, in an attempt to consider both of the previous interpretations. In fact, recent definitions of appreciation propose that this ability implies both the acknowledgment of the medical problem and potential benefits of treatment, and the anticipation of consequences related to the treatment [26, 28]. Although these recent definitions allow to overcome the previous challenges on appreciation’s conceptualization, they bring another conceptual challenge, discussed below.

Reasoning assessment is included in eleven instruments, in which the participants are asked to enumerate the risks and benefits they would have in mind when making a decision, and also to generate consequences of what might change in their daily lives due to the treatment. When asking patients to generate consequences, reasoning is being assessed as a foresight ability. However, as discussed before, appreciation as also been defined as the ability to foresee possible treatment consequences [26]. In this sense, there seems to be a risk of overlapping between appreciation and reasoning, which should be avoided.

Finally, expressing a choice is contemplated in ten of the seventeen instruments. This ability has been uniformly measured by asking the participant to choose an option.

A fifth ability, making a reasonable choice, is included in CCTI [12]. The first publications concerning the legal standards of competence to consent to treatment included this competence [29]. Making a reasonable choice consisted on the ability to choose the option that a reasonable person would choose. However, this ability has disappeared from the clinical setting, due to the arbitrariness of what may be considered reasonable. In fact, Gerstenecker and collaborators [24], instead of making a reasonable choice, designates this ability of the CCTI as making choice, which reveals the discontinuity of this ability in capacity assessments.

4.2 Result interpretations

Apart from the differences on the assessed abilities, the instruments also differ on scoring procedures and interpretations. In this respect, most of the instruments do not provide instructions for total scores nor cut-off
scores. However, in Two-Part Consent Form, the authors [7] computed total scores by summing all item scores. Also, the authors of the Vignette method by Schmand [16] and the Vignette method by Vellinga [20] calculated total scores and established cut-off scores for lack of capacity to consent to treatment. Some authors disagree with this approach, since it assumes that low scores in an ability can be compensated by higher scores in another [30]. The CCTI [12] and the ACCT [21] propose cut-off scores for each ability, stating that the abilities should be individually considered. According to the four abilities model, in order to have decision-making capacity the patient must have preserved the four abilities, which may compromise the clinical usefulness of a total score [5].

4.3 Information disclosure

Another difference between the previous instruments regards the information disclosure, which may consist on the presentation of a hypothetical situation or the patient’s real health problem. On the hypothetical situation, a clinical vignette describing a fictitious medical problem and treatment options is presented. Conversely, in the realistic situation patients receive information about their own health problem and treatment options [31]. Both approaches have advantages and disadvantages. On one hand, standardized clinical vignettes enable the development of normative data, which are useful in clinical settings and also allow group comparison in research field [21]. On the other hand, some authors state that decision-making capacity should be evaluated in the context of the decision at hand, because patients’ performance could be different in hypothetical and realistic situations [30].

Few studies addressed this issue. Grisso and Appelbaum [32] studied the differences between hypothetical and realistic situations regarding the ability to understand. They found that psychiatric samples showed better understanding of information related to their own situation. However, non-psychiatric samples performed similarly in both hypothetical and realistic situations [32]. More recently, Vellinga and collaborators [33] found no significant differences in mean scores of understanding, appreciation, reasoning and expressing a choice, nor total mean score, between hypothetical and realistic situations. When comparing groups of impaired and non-impaired cognitive functioning, cognitive impaired patients performed better on appreciating their own medical problem and had a significant higher mean on total score. However, no significant differences were found on understanding, reasoning and expressing a choice [33]. Also, participants with cognitive impairment in the realistic group received the clinical information twice, which could had contributed to a better performance. These conclusions stand out the need for more investigation in this field. However, research shows that clinical vignettes
can approximate real-life situations [12], and they provide valid information about patients’ decision-making capacity [34], which stands for their usefulness in both research and clinical settings.

4.4 Healthcare decision-making capacity assessment in cognitive impairment and dementia

Among the reviewed instruments, three of them were designed to assess consent capacity in the older population, and five of them to evaluate consent capacity in patients with dementia. When assessing dementia patients’ capacity to consent, it is important to use an instrument that has been specifically developed to assess capacity in these populations. Mild cognitive impairment and dementia symptoms affect cognitive functions relevant to decision-making, such as memory, attention and executive functions [35]. Due to this, capacity assessment tools should include strategies that allow to decrease the demand on such functions. For example, the ACCT, The Vignette Method by Schman and The Vignette Method by Vellinga include visual aids to reduce memory demands.

There are other factors which can impact capacity assessments, like the way by which information is presented [1]. Specifically, framing and phrasing of information can influence the decision-making process. Because of this, instruments’ disclosure of information through clinical vignettes or description of patients’ real problems should be designed in a way that facilitates their understanding of information and maximizes their capacity.

Healthcare values, beliefs and experience are also described as relevant to decision-making [36]. Regarding capacity assessments, coherence between patients expressed values and their treatment decisions can be an indication of capacity, and research has shown that people with dementia appear to express their values as consistently as elderly without cognitive impairment [37]. However, only ACCT includes values assessment.

When comparing assessment instruments’ targeting older adults or patients with dementia, it is possible to identify discrepancies among the assessed abilities. Furthermore, research has identified significant differences in capacity assessment results between different assessment tools. In this respect, Moye and collaborators [27] compared the results of CCTI, MacCAT-T and HCAI in a sample of elders with mild to moderate dementia and matched control groups. Study results showed differences on appreciation and reasoning assessments. Specifically, participants with dementia performed worse than control groups on appreciation when measured by CCTI, but according to MacCAT-T and HCAI. Similarly, participants with dementia performed worse than control group participants on reasoning, when measured by MacCAT-T and CCTI, but not when assessed by HCAI [27]. These inconsistencies reveal the need for more study in this area, in order to improve assessment tools’ reliability.
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Another relevant improvement to healthcare decision-making capacity assessment would be the development of normative data. According to the research conducted, only CCTI developed normative data [24]. Nevertheless, undertaking more normative studies could be a valuable contribution to increase capacity assessments precision. Normative data provide a point of reference from which patients’ performance can be compared to. Knowing what level of performance is expected for an adult within a specific age range or education level can give additional information about the patients’ capacity impairment, and therefore improve assessments accuracy.

5. Conclusion

Concerns about healthcare decision-making capacity will continue to grow world widely, since the prevalence of dementia and other diseases related to cognitive impairment keeps increasing. One of the most relevant topics in this field relates to the way capacity should be conceptualized. On one hand, clinical approaches conceptualize healthcare capacity as a gradual model, according to which the patient can vary among levels of competence. In this model, a person may retain capacity to consent to routine procedures, but lack competence to make decision about risky treatments. On the other hand, in legal settings healthcare capacity is predominantly considered a threshold competence, this is, either the person is considered to have or not have capacity to make healthcare decisions [28]. A gradual model is undoubtedly more congruent with how capacity varies in real life situations, where competence does not appear as a dichotomous construct [34]. However, it can be challenging to apply this approach in legal settings, where a specific judgment is required.

This review shows that a considerable number of instruments to assess decision-making capacity have been developed in the last decades. However, decision-making capacity in healthcare still lacks a gold standard [38]. In consequence, clinical judgment is still considered as the closest to a gold standard of capacity assessment [1]. Nonetheless, clinical judgment, without the recourse of a standardized assessment tool, has been proved to overestimate patients’ capacity to make healthcare decisions [39]. Alternatively, the Mac-CAT has been pointed out has a gold standard in decision-making capacity assessment [40]. Although Mac-CAT is one of the most widely used instruments, some restraints must be considered, as the lack of normative data.

Assessment of healthcare decision-making capacity raises a few unanswered challenges. A further develop of standardized tools, with normative data, and more widespread education and training in capacity assessment among psychologists and other mental health professionals are needed to achieve more accurate assessments.

Standardized tools development should be based on a thoroughly review of relevant literature and previous
assessment tools. Likewise, instruments development should consider experts experiences and practices, as well as gather professionals’ perspectives on how to assess healthcare decision-making capacity.

Furthermore, it is considered that in order to improve healthcare decision-making capacity assessments’ reliability, clear legal frameworks and guidelines regarding capacity assessments are necessary. To our view, assessments of healthcare decision-making capacity should follow specific legal procedures or guidelines that define assessment protocols, including a valid standardized capacity assessment tool with normative data, as well as a broader neuropsychologic assessment. The definition of guidelines seems to be a necessary condition to protect patients’ rights of autonomy and protection.

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