This is therefore about aspiring to more humane and higher quality healthcare, basing ourselves on ethical questions too which guide the treatment process. While including biomedical questions, it will not forget personal values and wishes. It will cure–or try to cure–individuals, but will also care for them.

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Assessment of decision-making capacity for research participation: When, how and why to do it☆

Valoración de la capacidad de toma de decisiones en investigación: cuándo, cómo y por qué realizarla

Dear Editor,

Informed consent (IC) in research is the process by means of which an individual, in a free and informed manner, takes the decision whether or not to take part in a study. For the consent to be valid the subject must have the capacity to take the decision, receive sufficient information adapted to their level of comprehension and take the decision voluntarily. National and international law states that IC is a basic requisite and guarantee for the exercise of independence in personal decision-making and to protect vulnerable subjects who may require special guarantees to protect their rights.[1] There are no clear guidelines in Spain about who should evaluate the decision-making capacity of patients or how any such evaluation should take place. Spanish laws on IC for biomedical research cover decision-making capacity and indicate the situations in which this is limited, without specifying how it should be evaluated.[2] The law underlines the need to justify the inclusion of ''vulnerable populations'' in research studies, without clearly specifying who they are.[3] Although there are populations that could potentially be considered to be vulnerable because their decision-making capacity varies during the course of their disease, the difference between vulnerable populations and non-vulnerable ones is not clear. Most research has centred on individuals with mental or cognitive pathology without reaching conclusive results.[4] According to several studies up to 5%–10% of individuals without a psychiatric or cognitive disorder may have a restricted decision-making capacity, and within the population with a mental disorder there is a high level of heterogeneity in their levels of decision-making capacity.[5]

These questions should be weighed up to prevent the inappropriate recruitment of individuals in high risk clinical trials, when they do not properly understand the nature of the procedures they are consenting to. On the other hand, there is also a risk of assuming that the decision-making capacity of certain patients is always reduced due to their diagnosis. This may has major consequences in limiting research into their diseases and it would be a stereotyped way of considering their decision-making capacity.

Another point is that the growing importance of regulatory procedures, together with increasingly complex research techniques, has led to longer and longer IC documents which are often very technical and hard to understand. The available bibliography suggests that a percentage of possible participants in research lack a suitable level of decision-making capacity, and that even those who do have such capacity will not comprehend the information contained in an IC as well as would be desirable.[4]

These difficulties emphasize the need to individually evaluate individuals' decision-making capacity. Over the past 20 years and due to the interest in this subject, several instruments have been developed to evaluate capacity to take part in research.[6] There is broad agreement on

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the four dimensions that form the capacity construct: *comprehension* of the information described, *appreciation* of the effects of the same, logical *reasoning* in the process of deciding and *expressing a choice*.[7] The tool used the most often to evaluate this capacity and four dimensions is the semi-structured interview *MacArthur Competence Assessment Tool for Consent Research*, which was recently validated in Spanish.[8] The widespread use of this instrument would be a valuable accessory and guide in evaluating capacity for clinicians and researchers. This tool could help to reduce the vulnerability of individuals who take part in research, respecting their independent power to decide when they have the capacity to do so.[9] Additional protective measures may be proposed when their capacity is reduced.[10] Given that we sometimes come across individuals whose decision-making capacity varies, these measures may be highly useful. The evaluation of decision-making capacity must refer to a specific task and level of risk. The threshold to consider that a person is able to take a decision must vary according to the risks and benefits of the said decision. Due to all of the above considerations, we propose that decision-making capacity be evaluated routinely in those studies that involve more than a minimum risk in patients with any type of diagnosis (psychiatric or others), as there is no evidence to support always inferring absolute decision-making capacity or incapacity based on a specific diagnosis.

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