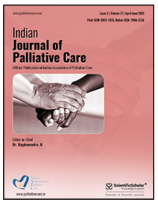
https://jpalliativecare.com/

Indian Journal of Palliative Care



Review Article

Protecting Incapacitated Patients' Rights and Best Interests

Ercan Avci[1]

[1]Grefenstette Center for Ethics, Duquesne University, Pittsburgh, Pennsylvania, United States.

ABSTRACT

Contemporary medical ethics requires providing healthcare services in accordance with the patient's values, preferences and interests based on the rights to self-determination and privacy. Incapacitated patients utilise these rights through substitute decision-makers in light of the substituted judgement and best interest standards. In this context, the article aims to briefly study informed consent and focus on protecting incapacitated patients' rights and best interests. The article underscores the importance of promoting the autonomy of every patient as much as possible. However, in the case of the lack of decisional capacity and advance directives, surrogates should decide for incapacitated patients based on patients' known/documented/expressed wishes/preferences and best interests. Nevertheless, due to the high possibility of the misinterpretation of patients' values, preferences and interests by surrogates as well as potential financial and social conflicts between patients and their surrogates, in the event of medical procedures with serious consequences, such as life-sustaining support, surrogates should be requested to provide convincing evidence proving that their decisions are in line with the patient's values, preferences and interests.

Keywords: Incapacitated patients, Informed consent, Substitute decision-making, Autonomy, Best interest

INTRODUCTION

Informed consent in medical ethics is a cornerstone of bioethics to fulfill the requirements of the principle of respect for autonomy.[1] Informed consent indicates a thorough dialogue and communication between the physician and patient in clinical practises to allow the patient to actualise his/her rights.[2] In the patient's complete or partial incapacity, expecting a satisfactory interaction between these two parties is difficult. Ethically, it is unquestionable that capacity-impairing conditions do not eliminate the patient's fundamental rights; they only preclude the patient from practising the rights by him/herself.[3] However, Buchanan and Brock claim that 'bioethics has tended to concentrate primarily on the rights of the competent patient' (p. 3).[4] Therefore, scholarly works should focus more on the status of incapable patients to protect their fundamental rights. Legal and ethical requirements demand the representation and safeguarding of incapacitated patients' rights through surrogate decision-makers. Nevertheless, studies reveal that approximately one in three surrogates incorrectly judge patients' end-of-life care desires.[5] Therefore, healthcare professionals and institutions should meticulously enquire into patients' wishes and best interests in incapacity. This article aims to briefly examine informed consent and elaborate on protecting incapacitated patients' autonomy and best interest. In this paper, the term incapacitated patient refers to any person who temporarily or permanently loses decision-making capacity due to physical or mental conditions.

INFORMED CONSENT

Informed consent is an essential concept and requirement, not only in clinical ethics but also in research. Indeed, the driving force behind the birth of informed consent is brutal research with human subjects, such as the Nazis' notorious experiments and the Tuskegee Syphilis Study.[6] According to some sources, the first appearance of informed consent goes back to the 19th century.[7] Walter Reed's written consent in his yellow fever research in Cuba is an early example of informed consent.[8] However, in parallel with the development of bioethics, informed consent has become an indispensable component of the therapeutic relationship through the emphasis on respect for autonomy and the right to self-determination.[9]

***Corresponding author:** Ercan Avci, Grefenstette Center for Ethics, Duquesne University, Pittsburgh, Pennsylvania, United States. avciercan@yahoo.com

Received: 18 July 2023 **Accepted:** 04 October 2023 **EPub Ahead of Print:** 03 November 2023 **Published:** 11 November 2023 **DOI:** 10.25259/IJPC_173_2022

THE MEANING AND GOALS OF INFORMED CONSENT

Despite the existence of specific challenges in the informed consent processes, including differences between the theory and practice, complexities resulting from advanced technologies, and sickness and maturity-based limitations, informed consent is still the most appropriate and practical method to allow people/patients to enjoy their right to self-determination and autonomy.[9,10] The literature demonstrates various approaches regarding the definition and perception of informed consent. For example, some studies accept it as an agreement between the physician and patient, while others deem it a shared decision-making process.[11] Berg *et al*. assess informed consent in light of three different concepts: 'autonomous authorisation,' 'legal and institutional rules and requirements' and 'shared decision making' and conclude by highlighting the importance of informing patients adequately and appropriately and the indispensability of patients' autonomous action.[1] Jonsen *et al*. describe informed consent 'as the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention, its risks and benefits and also its alternatives with their risks and benefits' (p. 53).[2] Beauchamp and Childress evaluate informed consent through two threshold elements (competence and voluntariness), three information elements (disclosure, recommendation, and understanding), and two consent elements (decision and authorisation).[3] As three primary elements, competence demands having decision-making capacity; voluntariness requires being free from internal or external influences and disclosure requests informing patients about the diagnosis, recommended treatment, risks of treatment, alternative treatments, and expected medical consequences of accepting or refusing the treatment according to the patient's insight and educational status. In this view, informed consent refers to a voluntary choice made by a person with the decision-making capacity to accept or refuse a recommended medical intervention after receiving sufficient information about the consequences of the intervention and its alternatives. Moreover, in accepting a recommended medical procedure, informed consent denotes authorisation given by the patient to caregivers to carry out the intervention.

Cassileth *et al*. interpret the goal of informed consent as 'to provide a mechanism for patients to participate in treatment decisions with the full understanding of the factors relevant to their proposed care' (p. 896).[12] Enabling patients to participate in treatment decisions actively is an overall goal of informed consent. However, it also has some more specific functions in clinical procedures. For instance, according to Berg *et al*. and Jefford and Moore, protecting patients or subjects from harm and promoting their autonomy are two primary purposes of informed consent.[1,8] Protection is an umbrella term covering any forms of manipulation, pressure, coercion, deception, and exploitation from social, economic, cultural, and religious factors. As Grady underscores, people 'in many cultures, rely on their families and sometimes on their communities for important decisions, and this may be the norm in cultures that stress the relationship of individuals to others and the embeddedness of individuals within society' (p. 855–856).[9] Furthermore, the culture, religion, or social structure may implicitly or explicitly force people to decide in line with the general cultural, religious, or social acceptance. However, in such situations, the critical point is to evaluate the person's voluntariness, not the cultural, religious, or social values. For example, in the event of Jehovah's Witnesses refusal of blood transfusions, we should focus on whether the patient makes an autonomous decision when rejecting the transfusion, not judge the belief system and its values; the person's decision can be irrational (refusing the blood transfusion during severe blood loss), but as long as the reason is rational (being a faithful follower of the belief and observing its rules), the decision should be respected and honoured.[13] In other words, protecting patients and promoting their autonomy necessitate supporting 'individuals to pursue their own good in their own way' (p. 24).[1]

Protecting healthcare professionals from unwarranted allegations and sharing the responsibility of recommended medical procedures and treatments with patients or surrogates are some other benefits of informed consent. The ultimate goal of informed consent is to allow patients to make autonomous decisions, which may author caregivers to conduct a medical procedure or reject a recommended medical intervention. In the case of both options, accepting or rejecting treatment, through the informed consent process, patients or surrogates bear potential outcomes of their decisions, including side and adverse effects, except for malpractice.[11]

DECISION-MAKING CAPACITY

Beauchamp and Childress utilise the terms competence and decision-making capacity interchangeably and consider competence a precondition of informed consent, meaning that informed consent does not apply to incompetent or incapable patients. Competence is the capacity to carry out a duty.[3] Nevertheless, clinical ethics does not require a person's full capacity for every action; the ability to conduct a specific task is sufficient. For example, a person paralysed from the waist down cannot walk, but he/she can make judicious decisions. However, competence and decision-making capacity refer to two distinct concepts. Even though both show the ability to do something, competence carries legal content, whereas decision-making capacity, also known as decisional capacity, encompasses a clinical text. In other words, the presence and absence of competence are decided by a court, whereas decision-making capacity is determined

by a physician. For this reason, at the clinical level, the pertinent term is decision-making capacity.[2]

Lo underscores the importance of scrutinising patients' decision-making capacity before informing them about the recommended treatments.[11] According to Lo, decision-making capacity necessitates five specific abilities. First, the patient needs to have the ability to make a choice and communicate it, which means that the patient must be aware of his/her decisional power and eager to pick a course of care among different options and be able to communicate it.[11] However, communicating a choice does not require a conversation but any way or method to help the patient express his/her wish. Second, the patient must comprehend all the information pertinent to his/her medical condition and treatment procedure and appreciate the information and the consequences of his/her decision. Third, the patient's choice should be consistent with his/her values and goals. For instance, picking do-not-resuscitate would conflict with the goals of a patient who desires to live as long as possible regardless of the quality of his/her life. Fourth, the patient's decision must be built on facts and correct deductions, not delusions; the patient's inaccurate reasoning and interpretations may signify the deficiency of the decisional capacity. Finally, the patient should utilise reasoning to evaluate all the available alternatives accurately; the chosen option may be unusual or irrational, but the reasoning behind the decision should be rational.[11]

Another substantial issue regarding decision-making capacity is whether to apply an all-or-nothing approach. Veterans Health Administration's ten myths suggest not implementing a standard capacity assessment for all decisions. It states that 'because healthcare decisions vary in their risks, benefits, and complexities, patients may be able to make some decisions but not others' (p. 264).[14] This approach is called the sliding scale strategy, which refers to greater decision-making capacity for highly risky interventions and lower capacity for less risky medical interventions. Jonsen *et al*. consider this a valuable strategy for physicians to appraise patients' refusals.[2] Similarly, Buchanan and Brock recognise the appropriateness of applying different standards of decision-making capacity (looking for a minimal level of capacity when consenting to a life-saving course of treatment with a low level of risks but calling for the highest level of capacity in the event of refusing that treatment) based on the benefits and risks of the patient's choice.[4] However, Beauchamp and Childress find this approach 'conceptually and morally perilous' and emphasise that 'no basis exists for believing that risky decisions require more ability at decision making than less risky decisions' (p. 120).[3] Even though these arguments show the lack of a consensus on the applicability of the sliding scale strategy, it carries the high potential to provide physicians with a flexible assessment of the decisional capacity in daily medical practises.

SURROGATE DECISION-MAKING

When the patient does not have the decisional capacity, the physicians should determine whether the patient has an advance directive. If so, the physician should act in accordance with the instructions of the advance directive (either living will or power of attorney). However, in some countries such as India and Turkey, it is not possible to frequently encounter an advance directive.[15,16] Furthermore, even when a patient has an advance directive, it may not sufficiently address the patient's medical condition.[17] For this reason, in the event of a lack of decisional capacity and advance directives, healthcare institutions need to ask surrogate decision-makers to decide on behalf of patients.

INCAPACITATED PATIENTS

The lack of decision-making capacity may result from various medical conditions, including unconsciousness, unresponsiveness, and mental illnesses or distortions. These situations might result from permanent or temporary and reversible or irreversible medical problems. The shortage of at least one or more elements of capacity-determining abilities (understanding the provided information, appreciating the effects of available options, and making a decision by communicating with the caregivers) proves the patient's incapability. Nevertheless, in comparison with unconscious patients, the appraisal of the decisional capacity of patients suffering from psychological and mental disorders, such as depression, dementia, and schizophrenia, contains more difficulties because such patients are entirely or to some extent responsive and communicative, but these patients' mental abilities are questionable.[2,11]

Every mental illness or impairment does not make the patient incapable *per se*. Nevertheless, studies indicate that some psychiatric disorders, such as schizophrenia and depression, substantially reduce the patients' abilities to understand and appreciate the pertinent matters concerning their medical care.[14] However, each medical condition requires a clinical evaluation to conclude whether the patient has the decisional capacity. Rather than immediately regarding a patient as incapable, healthcare professionals who care for the patient should observe and assess the patient's decision-making abilities meticulously. It is not an obligation to be a psychologist or psychiatrist to appraise the patient's capability. All physicians in charge of the patient's treatment can do that. Nonetheless, in the case of ambiguous mental impairments or uncertainties, seeking a consultation from a psychologist or psychiatrist would help determine the patient's decisional capacity.

Furthermore, instead of immediately considering a patient incapable, waiting for a specific time to give the patient to make his/her own decision is ethically a proper approach because the lack of capacity may last for a short while during temporary and reversible medical conditions, such as in the event of general

anaesthesia and intubation-related physical situations, as well as delirium, confusion, and depression-based psychological conditions.[14] Therefore, postponing substantial decisions and implementing the full-code status until the patient regains his/her decisional capacity would be appropriate under the circumstances of transitory incapability. However, in such a case, the patient's healthcare representative/s should not be ignored; even a temporary decision should be made through the representative's active involvement. If no representative is available, caregivers should act based on the emergency privilege until reaching a representative.

SUBSTITUTED JUDGEMENT AND BEST INTEREST STANDARDS

Promoting the patient's autonomy, accurately evaluating the patient's decision-making capacity, and allowing the patient to make his/her own decisions are ethically indispensable requirements. Nevertheless, despite every effort, patients lacking capacity need a surrogate to represent them in medical decisions due to their medical or mental conditions. The patient can freely assign anyone as a surrogate decision-maker (healthcare agent) through a durable power of attorney for healthcare before becoming incapacitated. If the patient did not appoint anyone as the surrogate, in light of legal regulations and ethical standards, the patient's relatives (the next of kin) would serve as surrogate decision-makers (healthcare representatives). As the healthcare agent or healthcare representative, the surrogate is not as free as the patient to decide regarding the course of the medical procedure. A patient with decisional capacity can voluntarily consent or refuse a recommended treatment regardless of the expected consequences of the decision. However, a surrogate is restricted to two standards when deciding on an incapacitated patient: substituted judgement and best interest.[2] As Rid and Wendler underline, surrogate decision-making is not ideal because of the uncertainty over patients' preferences and interests.[18] This position causes surrogates to encounter specific 'emotional, cognitive and moral barriers' while deciding for patients (p. 480).[17] Even though some studies suggest shared decision-making between surrogates and clinicians as an ethically applicable method to mitigate the burden on surrogates when making a substitute decision, the collaboration between these two parties cannot guarantee the fulfilment of patients' values and preferences.[18] Nevertheless, the appropriate implication of the substituted judgement and best interest standards may give a chance to form a primary ground for guiding this sensitive and important area.

The substituted judgement standard demands the surrogate to act according to the patient's preferences, which the patient explicitly or implicitly expressed before becoming incapacitated. The surrogate must be sure of the patient's wishes concerning the current situation, either by hearing from the patient in the past or reaching a conclusion based on the patient's prior actions. If the surrogate is not convinced about the patient's wishes and preferences, the surrogate must decide based on the best interest standard.[2] According to Lo, 'the best interest must be determined for the particular patient in a specific situation in light of the available options,' and 'a patient's best interests are the best available option under the circumstances (p. 97).[11] This approach reveals that surrogates should directly take patients' values, interests, and preferences when deciding on a recommended treatment. Furthermore, it is essential to emphasise that the question directed to a surrogate is not 'What do you want us to do?' but 'What the patient would have wanted us to do if he/she was capable of deciding?' because we do not enquire into the surrogate's personal opinion, wishes or values; we need to figure out the patient's preferences, wishes or values to fulfill the patient's autonomy and best interest.

However, some studies demonstrate that more than 30% of surrogates, both healthcare agents (patient-designated) and healthcare representatives (next to kin), cannot correctly predict incapacitated patients' preferences concerning crucial medical interventions, including cardiopulmonary resuscitation, intubation, amputation, and surgery.[5] In addition, the conflict of interests and values between patients and surrogates are other serious challenges in substitute decision-making. For this reason, it is a crucial concern whether patients' rights and best interests are achieved through substitute decision-making due to distinct interpretations regarding the quality of life, cultural and religious matters-related perceptions, and financial and social factors between patients and their surrogates.[1]

In this context, healthcare professionals and institutions should sufficiently pay attention to the requirements of the substituted judgement and best interest standards to protect incapacitated patients from the risks of substitute decision-making. First, the surrogate should be informed thoroughly and correctly about the benefits and risks of the recommended medical intervention and alternatives with their potential consequences. Second, the surrogate should consider the provided information, evaluate it with the patient's known/documented/expressed wishes/preferences and values, and make a decision in light of that assessment. Third, in the case of critical medical interventions, such as surgery, amputation, and life-sustaining support, the surrogate should be asked to provide convincing evidence that the surrogate's decision adheres to the patient's known/documented/expressed wishes/preferences and values. The Supreme Court ruling in the Nancy Cruzan case in the United States requested such a requirement for forgoing life-sustaining treatments.[2] Finally, as the surrogate fails to present convincing evidence, the surrogate's decisions should be appraised with the medical team's/physician's recommendation to preserve the patient's best interest.

CONCLUSION

Informed consent is a pivotal matter in clinical ethics, deriving from the principle of respect for autonomy. Autonomy does not refer to certain rights available merely for competent and capable patients but also particular rights for incapacitated patients, who are entitled to receive healthcare in accordance with their preferences and values. The informed consent process and its elements should also be applied to surrogate decision-making to sufficiently inform the surrogate about the patient's conditions and treatment options with their benefits and risks. The surrogate should assess the given information with the patient's known/documented/expressed wishes/preferences and decide according to the patient's preferences and values. The patient's best interests should also be considered during the surrogate decision-making process. In addition, in the case of medical procedures with serious consequences, such as life-sustaining support, the surrogate should provide convincing evidence showing that the decision is consistent with the patient's preferences and values to eschew any potential conflict of interests and values between the patient and the surrogate.

Declaration of patient consent

Patient consent is not required as there are no patients in this study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The author confirms that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

REFERENCES

1. Berg JW, Appelbaum PS, Parker LS, Lidz CW. Informed Consent: Legal Theory and Clinical Practice. New York: Oxford University Press; 2001.
2. Jonsen AR, Siegler M, Winslade W. Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine. New York: McGraw Hill Medical; 2010.
3. Beauchamp TL, Childress JF. Principles of Biomedical Ethics. New York: Oxford University Press; 2013.
4. Buchanan AE, Brock DW. Deciding for Others: The Ethics of Surrogate Decision Making. Cambridge: Cambridge University Press; 1990.
5. Shalowitz DI, Garrett-Mayer E, Wendler D. The Accuracy of Surrogate Decision Makers: A Systematic Review. Arch Intern Med 2006;166:493-7.
6. Bhutta ZA. Beyond Informed Consent. Bull World Health Organ 2004;82:771-7.
7. Ilgili Ö. A Key for Informed Consent in Biomedical Research Involving Human Subjects. Turk Klin J Med Ethics Law Hist Spec Top 2018;4:31-40.
8. Jefford M, Moore R. Improvement of Informed Consent and the Quality of Consent Documents. Lancet Oncol 2008;9:485-93.
9. Grady C. Enduring and Emerging Challenges of Informed Consent. N Engl J Med 2015;372:855-62.
10. O'Neill O. Some Limits of Informed Consent. J Med Ethics 2003;29:4-7.
11. Lo B. Resolving Ethical Dilemmas: A Guide for Clinicians. Hong Kong: Lippincott Williams and Wilkins; 2009.
12. Cassileth BR, Zupkis RV, Sutton-Smith K, March V. Informed Consent -- why are its Goals Imperfectly Realized? N Engl J Med 1980;302:896-900.
13. Chell B. Competency: What it is, What it isn't, and Why it Matters. In: Monagle JF, Thomasma DC, editors. Medical Ethics a Guide for Health Professionals. Rockville: Aspen Publishers; 1988. p. 99-110.
14. Ganzini L, Volicer L, Nelson WA, Fox E, Derse AR. Ten Myths about Decision-Making Capacity. J Am Med Dir Assoc 2004;5:263-7.
15. Ghooi RB, Dhru K, Jaywant S. The Urgent Need for Advance Directives in India. Indian J Med Ethics 2016;1:242-9.
16. Guven T, Sert G. Advance Directives in Turkey's Cultural Context: Examining the Potential Benefits for the Implementation of Patient Rights. Bioethics 2010;24:127-33.
17. Scheunemann LP, Arnold RM, White DB. The Facilitated Values History: Helping Surrogates Make Authentic Decisions for Incapacitated Patients with Advanced Illness. Am J Respir Crit Care Med 2012;186:480-6.
18. Rid A, Wendler D. Can we Improve Treatment Decision-making for Incapacitated Patients? Hastings Cent Rep 2010;40:36-45.

How to cite this article: Avci E. Protecting Incapacitated Patients' Rights and Best Interests. Indian J Palliat Care 2023;29:343-7.