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Informed consent in artificial nutrition and hydration: Ethical, legal, and clinical considerations

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Abstract. This article addresses the complex issue of informed consent in the context of Artificial Nutrition and Hydration (ANH). It explores how physicians should act when patients are unable to provide valid consent and whether explicit, legally prescribed consent is necessary or if presumed consent can be inferred from the patient's lifestyle, values, and beliefs. The necessity of detailed patient information and the evolution of the doctor-patient relationship from a paternalistic model to one recognizing patient autonomy are discussed. The article emphasizes that ANH should be administered based on informed consent, except in exceptional urgent cases where presumed consent is applicable. Ethical and legal responsibilities of physicians in ensuring clear and comprehensible information for informed decision-making are highlighted. The article concludes that adherence to guidelines should be carefully considered and contextualized, ensuring that therapeutic choices respect the patient's dignity and autonomy. This multidisciplinary approach, involving ethicists, legal experts, and family members, is essential for decisions made in the best interest of the patient.

Key words: artificial nutrition and hydration, bioethics, informed consent, nutritional ethic, patient autonomy

A controversial issue is that of informed consent. In this regard, there is the question of how a physician should act when the patient is unable to provide valid consent and artificial nutrition, and hydration (ANH) is deemed necessary (1). Specifically, there is debate over whether explicit consent (2), in the legally prescribed form, is necessary, or if presumed consent can be utilized, inferred from the patient's lifestyle (3), inclinations, reference values, and ethical, religious, and cultural beliefs (4-5-6). If it is accepted that the patient's will can be proven through means other than those provided by law, can the physician's conduct be justified (7) if they do not proceed with ANH or discontinue the ongoing treatment? To address this question, some preliminary clarifications are necessary (8-9). The essential prerequisite for respecting individual preferences (10) is to sufficiently inform the patient or their proxy (12), if the patient is unable to decide, about their clinical conditions (13), possible treatment (14) options, and the desirable therapeutic goals, so that they can provide their consent to the treatment (15). With the advancement of science and the spread of life-sustaining treatments, such (16) as ANH, individuals have increasingly been able to influence the course of their existence (17), extending and improving it both quantitatively and qualitatively. However, medical innovations (18) cannot be imposed on patients merely because they exist; their use must always represent the outcome of a precise discretionary choice. This understanding has been reached only relatively recently (19). Originally, the doctor-patient relationship was heavily skewed in favour of the doctor (20), who, by virtue of their knowledge, was considered a privileged (21) being with moral authority and legal impunity, making their choices difficult to challenge (22). Consequently, after an initial period during which cultural inertia tied to a paternalistic model led to the perception of the doctor as the sole decision-maker regarding medical treatments, a subsequent cultural (23) and legal evolution (24-25) identified the

patient as the real protagonist of decisions concerning their health (26). Given that the chances of success, alternatives, contraindications, side effects, and associated risks are informational variables that must be provided to make an informed decision, it cannot be denied that therapeutic choices also rely on a judgment of compatibility and coherence of the doctor's proposal with the patient's dignity (27) and self-image that they wish to leave behind (28). Thus, it seems reasonable to base the therapeutic choice (29) on the patient's will, provided they are sufficiently informed and are the intended recipient of the medical treatment (30). Therefore, ANH should be prescribed and ensured when treatment indications are present, requiring the patient's informed consent (31) as a guarantee of individual autonomy (32), which can also be refused if the person is capable of making and communicating decisions. In other words, once the attending physician has thoroughly informed the patient of the therapeutic options, it is within the patient's rights, even if terminally ill, to autonomously decide to undergo treatments (33), refuse them, or withdraw from them, thereby exercising the right not to be treated. For consent to be valid, it must be personally expressed by the interested party, be specific to each treatment, and be informed. However, in a situation of therapeutic urgency, known as a state of necessity, where the patient cannot provide valid consent, the attending physician is still required to ensure the essential care needed by the patient (35). Presumed consent can be invoked when it is reasonable to believe that a person in that situation would have consented to the treatment. In this context, the reference parameters are: the urgency and necessity of the intervention, meaning there must be an immediate danger to life (36) or psycho-physical integrity of the person, otherwise it is preferable that the physician waits for the likely recovery of consent capacity or the appointment of a legal representative; a danger that cannot be avoided otherwise; therapeutic utility, meaning the benefits of the treatment must outweigh the risks; and the absence of an expressed contrary will previously stated by the patient (37). From these considerations, it is inferred that ANH is typically administered only with informed consent, unless there are exceptional circumstances of necessity and urgency allowing for presumed consent. Consequently, only when the patient's condition is serious or life-threatening (38) can the physician intervene immediately. In other cases, the healthcare provider must always inform the patient about the possibility of using ANH to obtain their consent to the treatment. Another important aspect to consider is the ethical and legal responsibility of the physician to ensure that the patient or their proxy receives clear and comprehensible information to make a truly informed decision. This is particularly crucial when the patient cannot express their consent, as the decision must reflect the patient's values and preferences. The complexity of these cases requires a multidisciplinary approach, involving not only the attending physician but also ethicists (39), legal experts, and, if possible, the patient's legal representatives or family members, to ensure that all decisions are made in the best interest of the patient, while respecting their autonomy and dignity. In conclusion, adherence to guidelines for ANH should never be automatic but always carefully considered and contextualized, taking into account the specificities of each patient and clinical situation. Information and consent are fundamental pillars to ensure that therapeutic choices are ethically and legally sustainable, thereby protecting the patient's dignity and autonomy at every stage of treatment.

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