Navigating ethical and legal challenges in artificial nutrition and hydration: The role of guidelines and patient autonomy

Michele Ahmed Antonio Karaboue, Elisabetta Dimauro
Department of Clinical and Experimental Medicine, University of Foggia, Foggia, Italy

Abstract. This article examines the complex ethical, medical, and legal issues surrounding the use of Artificial Nutrition and Hydration in critically ill patients. It highlights the importance of guidelines in clinical decision-making, while also recognizing the limitations and variability of these guidelines across different organizations. The study emphasizes the necessity for healthcare professionals to critically assess and apply guidelines based on the specific circumstances of each case, considering the best interest of the patient and involving them in the decision-making process. Additionally, it discusses the legal framework in Italy, particularly the evolution from the 2012 Balduzzi law to the 2017 Gelli-Bianco law, which seeks to provide greater clarity and protection for medical practitioners adhering to validated guidelines. The article underscores the ethical imperative for physicians to exercise their professional judgment and autonomy, even when it means deviating from established guidelines, to ensure that patient care is personalized and aligned with the patient's values and conception of a dignified life. The ultimate decision on ANH should be made by the patient, based on a thorough evaluation of the risk-benefit ratio through interdisciplinary consultation.

Key words: artificial nutrition and hydration, bioethics, medical guidelines, nutritional ethic, defensive medicine

Introduction

In every culture, nutrition holds an essential role, not only physiologically but also socially and emotionally (1). It expresses profound sentiments, such as solidarity towards others. Although Artificial Nutrition and Hydration (ANH) is not a natural form of nourishment (2), it still constitutes a means of providing sustenance (3). For many, denying or discontinuing it represents a difficult decision to accept. Some argue that depriving a person, especially if ill, of artificial nutrition or hydration (4), means causing them to die agonizingly from hunger and thirst. Others, however, believe that in some cases, such as patients with advanced-stage diseases, artificial nutrition provides no benefit and instead prolongs suffering (5-6). These reasons raise numerous questions regarding the practice of artificial nutrition and hydration. Therefore, the decision to initiate or discontinue ANH (7) is not an easy one, particularly due to contradictory data (8), the uncertainty of prognosis, and differing ethical considerations (9).

Discussion

A primary issue in clinical practice concerns the indications for treatment (10) First, there is debate over the exact parameters or criteria for making an ethically (11) sustainable choice, as well as the technical-scientific documents that ensure the medical decision is ethically and legally legitimate (12-13). In this regard, one of the most useful tools for clinical governance and good practice is currently represented

by guidelines (14), systematically prepared documents based on the best available synthesis of scientific knowledge (15). However, these guidelines are not binding but serve as an aid to assist doctors (16) and patients (17) in making decisions about the appropriate management (18) of specific clinical conditions. The guidelines prepared by the Italian Society of Artificial Nutrition and Metabolism (19) highlight multiple clinical situations in which artificial nutrition should be administered (20). According to this documentation, artificial nutrition should be provided in cases of severe or moderate malnutrition (21) with anticipated or estimated insufficient hospital food intake for more than 5 days (22); when nutritional status is normal, but there is a clear risk of malnutrition or insufficient oral nutrition for at least 10 days, or there is severe or moderate hyper-catabolism with expected insufficient oral nutrition for more than 7 days; or there are severe and not rapidly reversible issues with absorption, intestinal transit, or digestion of food. Conversely, it is not recommended if the duration is less than 5 days or when a well-nourished patient has had insufficient food intake for less than 10 days. Additionally, other guidelines on artificial nutrition can be consulted (23-24). These include those by the European Society for Clinical Nutrition and Metabolism, adopted by the American Society for Parenteral and Enteral Nutrition, the Italian Association of Dietetics and Clinical Nutrition, the European Society for Paediatric Gastroenterology, Hepatology and Nutrition, the National Institute for Health and Care Excellence, and the World Gastroenterology Organisation. For our purposes, it is important to highlight that the guidelines of the European Society for Clinical Nutrition and Metabolism recommend the administration of enteral artificial nutrition to critically ill patients within 48 hours from the point at which oral food intake is no longer possible. If enteral nutrition is not feasible or is contraindicated, parenteral nutrition is advised within 3 to 7 days for critically ill patients, and immediately if they are severely malnourished. Conversely, the guidelines of the American Society for Parenteral and Enteral Nutrition suggest initiating early enteral nutrition within 24-48 hours for critically ill patients at high nutritional risk or those who are malnourished, provided that voluntary feeding is not possible. When enteral nutrition is contraindicated or impractical, parenteral nutrition is recommended after 7 days for patients at low nutritional risk, and immediately for those at high nutritional risk or who are malnourished. This prospective framework indicates that the guidelines provided are not always perfectly coincident, raising the question of which documents to follow. In other words, it brings into question the type of approach to take regarding scientific information. It is necessary to clarify that guidelines are recommendations for clinical behaviour, developed through a systematic review of literature and scientific opinions (25), aimed at assisting doctors and patients in making appropriate care decisions in specific clinical situations. The need for healthcare professionals to feel secure, guided by experts to navigate the complex labyrinth of symptoms and pathologies, has recently contributed to the development of methods that validly and swiftly inform the medical team about the effectiveness of medical interventions. However, doctors must not be misled by the presence of one or more documents capable of guiding care actions in terms of potential patient benefit (26). Healthcare professionals are required to exercise additional diligence, namely, to know the relevant guidelines, verify their authority and currency, and assess their appropriateness for the specific case. Consequently, a doctor can choose the recommendation that seems most appropriate in their opinion and has both the duty and the authority to deviate from the guidelines, if necessary, as the uniqueness of each clinical condition cannot always be reduced to the generality of reference guidelines. In particular, non-compliance with a guideline, provided it is adequately justified in a specific case, represents an expression of the doctor's critical and informed autonomy, who, while aware of the recommended practices based on current knowledge, decides differently in the best interest of the specific patient. Therefore, guidelines serve as a decision-making support tool for doctors (27), enabling them to adopt the most suitable alternative among several valid options for the specific case, offering the best balance between benefits and

undesirable effects, and sharing it, where possible, with the patient or caregivers. In this regard, it is crucial to note that when applying guidelines, healthcare professionals must consider the patient's preferences and expressed opinions (28), their tolerance for suffering, and their personal risk assessment to ensure that the chosen option meets the patient's needs and values. Similarly, jurisprudence has defined guidelines as a condensation of scientific (29), technological, and methodological acquisitions concerning individual operational areas, considered such after careful selection and distillation of various contributions (30), without any claim to immobility and without suitability to reach the level of binding rules. From a legal perspective, guidelines gained normative recognition starting with the decree-law of September 13, 2012, no. 158, also known as the Balduzzi decree, later converted into the Law of November 8, 2012, no. 189, to counteract the practice of so-called defensive medicine and respond to the concerns and needs expressed by the medical profession. Article 3, paragraph 1, of the examined law stated that healthcare professionals who adhered to guidelines and good practices accredited by the scientific community would not be held criminally liable for minor negligence. Avoiding, in this context, delving into all aspects of the debate that the interpretation of the aforementioned rule has sparked (31), it is noted that one of the major concerns was that the law did not offer solid grounds for evaluating the quality of the guidelines. Indeed, given that the same clinical issue can be addressed by different guidelines developed by various authors (32), Law no. 189/2012 did not specify the requirements that these recommendations should meet, such as the quality of the cited scientific evidence, the qualifications of the authors, or the absence of conflicts of interest in their development and drafting. Furthermore, the practical results of the 2012 reform soon proved to be unsatisfactory. For these reasons, five years later, the legislator intervened again with Law no. 24 of March 8, 2017, also known as the Gelli-Bianco law, aiming to further enhance the role of guidelines by establishing a national validation system managed by the Ministry of Health. This reform introduced the new Article 590-sexies of the Penal Code, which seems to introduce a specific cause of non-punishability, contingent on adherence to guidelines that are appropriate to the specific case at hand (33). Indeed, the peculiarity of the specific case could lead the doctor to act differently from what is suggested, thus deviating from the guidelines (34). In fact, their strict observance, without a specific evaluation of the concrete case, not only does not exempt the healthcare professional from potential liability charges but also risks suppressing the independence, autonomy (35), and discretion of the professional, potentially leading to defensive medicine practices if the recommendations are followed solely to avoid future medico-legal repercussions.

Conclusion

Therefore, from this comprehensive framework (36), it can be inferred that, in the context of artificial nutrition, the adherence to guidelines should never be automatic for the physician. Instead, the physician, in the presence of multiple guidelines (37), should conduct a careful analysis of the content and scientific reliability of the information contained in the recommendations and choose the one most suitable to the specific case based on the best interest of the patient, involving the patient in the decision as much as possible (38). The physician is also required to deviate from these guidelines if deemed necessary, always in the interest of the specific patient. In any case, it is essential to emphasize that, despite these indications, the final decision on whether or not to resort to artificial nutrition should ultimately be made by the patient, according to their own conception of a dignified and liveable life (39), evaluating the risk-benefit ratio that emerges from the interdisciplinary consultation.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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Correspondence:
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Michele Ahmed Antonio Karaboue
Department of Clinical and Experimental Medicine, University of Foggia, Foggia, Italy
E-mail: michelekaraboue@gmail.com
ORCID: 0000-0002-3307-3922