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LEGAL AND ETHICAL ISSUES

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Regulation of advance directives in Italy: a bad law in the making

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Abstract *Purpose:* The Advance Directives (ADs) have been adopted in many countries to defend patients' autonomy. In Italy, the role of ADs has recently been the subject of heated debate involving political parties and the Roman Catholic Church. In February 2009, the conservative government coalition presented a bill of law on this issue. It has been passed by the Low Chamber and is now being discussed in the Senate. The purpose of the article is to highlight any possible bill's contradiction with Italian Constitution, Italian Code of Medical Ethics (ICME), and Oviedo Convention contents, relevant for intensivists. *Methods:* Analysis of bill's content in the light of Italian Constitution, ICME, Oviedo Convention articles and in comparison with French legislation regarding end of life (Leonetti law). *Results:* In the Authors' point of view the bill's articles limit the moral and judicial importance of four main issues as informed consent, permanent incapacity, artificial nutrition/hydration, and withdraw/withhold treatments. *Conclusions:* In the Authors' opinion the ADs must represent informed preferences made freely by patients within the relationship with their physicians, as part of an advance care planning. When this relationship develops in accordance with the ICME rules, it contains all of the ethical/professional dimensions to legitimate right choices in each case. The law should draw inspiration from ICME principles, assigning them a juridical power, acknowledging their validity in legitimating end-of-life decisions, and defining a framework of juridical legitimacy for these decisions without infringing on patients' right to autonomy with prescriptions on the care.

Keywords Advance directives · Patient autonomy · End-of-life decisions

The high-tech care available in today's ICUs has progressively undermined our concept of death as the natural end of life, and there is growing awareness among healthcare professionals and citizens that advanced organ support can represent excessive, inappropriate treatment, particularly when administered without the patient's expressed consent [1]. Recent data, however, show that 95 % of European ICU patients are mentally incompetent when end-of-life decisions are required [2] and thus very likely to receive treatment they might refuse if they could [3]. To safeguard patient autonomy, various countries have passed laws acknowledging the validity of advance healthcare directives, ideally elaborated during advance care planning (a process in which competent patients faced with serious disease, aided by physicians and family, make informed decisions about the care they wish to receive in the future) [4, 5].

In February 2009, a bill on advance directives was presented to the Italian Senate by the center-right coalition headed by Prime Minister Silvio Berlusconi. It came on the heels of the highly publicized death of Eluana Englaro, a young woman in a persistent vegetative state since 1994. Her father and legal guardian had repeatedly sought authorization to stop the artificial nutrition/hydration that was keeping his daughter alive, against what he maintained were her previously expressed wishes. His request was finally granted by Italy's Supreme Court in late 2008. Staunchly supported by the Roman Catholic Church, the center-right coalition adamantly opposed Mr. Englaro's request with methods that included emergency legislative decrees and threats to terminate public funding of any facility that allowed withdrawal of Eluana's nasogastric tube. These efforts were ultimately unsuccessful [6], but the government was determined to prevent future cases like that of Ms. Englaro's death [7].

The Calabrò Bill[1] was approved by the Senate in February 2009, amended by the Chamber of Deputies and returned to the Senate for final examination in July 2011. Since then, the Berlusconi government has been replaced, and the Parliament's attention has been focused almost exclusively on the economic emergency in Europe, but at some point, the bill may well be signed into law. This paper examines some of the major inconsistencies in the current version of the bill [8].

For example, in keeping with the provisions of the Italian Constitution (article 32) and the Oviedo convention on human rights and biomedicine [9], article 38 of the Italian code of medical ethics (ICME) (Online Resource)[2] guarantees competent patients' rights to receive healthcare only after providing informed consent and to withdraw that consent at any time, and written, signed documentation of both acts are mandatory. The Calabrò Bill explicitly requires chart documentation of non consent (article 2, paragraph 5), whereas written documentation of informed consent is required only "when deemed necessary by the physician or requested by the patient" (article 2, paragraph 3).

As for incapacitated or disabled individuals, in the absence of an advance directive, article 2, paragraph 8 obliges physicians "to act with the exclusive aims of safeguarding the health and life of the patient." Advance directives "assume importance" only when the individual becomes "permanently incapable of understanding information regarding treatment and its consequences owing to the ascertained absence of integrative cerebral and cortical-subcortical activity" (article 3, paragraph 5). References to the physician's duty to relieve suffering or preserve patients' dignity are glaringly absent, as are citations of other clinical situations in which advance directives might be admitted as a guide to patient preferences.

In contrast, the bill explicitly delegitimizes advance directives requesting the withholding/withdrawal of artificial nutrition/hydration—a major issue in the Englaro case. The ICME (article 53), current scientific literature [10, 11], and the views of over 60 % of a large sample of Italian physicians surveyed in 2011 [12] support the definition of artificial nutrition/hydration (as distinguished from offers of food and water) as a medical/nursing intervention requiring patient consent. In the Calabrò Bill (article 3, paragraph 4) "nutrition and hydration in all forms offered by science and technology" becomes basic care that must be maintained as long as the patient is alive.

The bill also proscribes directives "aimed at bringing about the patient's death" (article 7, paragraph 3) and specifies that "the principle of the inviolability of human life and the preservation of health and life" must be applied when assessing directive admissibility. The prohibition of directives requesting euthanasia or assisted suicide is the rule in Europe [7], consistent with the ICME, and widely supported by physicians in Italy [12]. But there are other, far-grayer areas of end-of-life care that the bill makes no attempt to clarify, despite specific requests to do so by the Italian College of Physicians [13]. Shortly after Eluana Englaro's death, the team that withdrew her artificial nutrition/hydration was notified publically that it was being investigated for voluntary manslaughter by the prosecutor's office in Udine (where Ms. Englaro died). The investigation ended in January 2010 with full exoneration of all of the "suspects" [14]. However, the episode (and others like it) raised legitimate concern among Italian physicians regarding the withdrawal of life-sustaining treatments judged to be futile (e.g., mechanical ventilation) and the drugs employed to control any symptoms associated with such withdrawal. While narcotics are given to relieve pain, discomfort, and/or dyspnea, and major sedation may be used for symptoms like delirium that can only be alleviated by inducing unconsciousness, both interventions may also hasten the patient's death. The moral and legal permissibility of these interventions is widely based on the principle of "double effect", which distinguishes between the intended and unintended effects of such interventions, but the bill makes no attempt to explore the moral or legal complexities of this issue. Instead, its reiterative emphasis on the preservation of life as the sole scope of healthcare and its reticence on physicians' time-honored duty to relieve suffering or their more recently established obligations to respect patients' rights to autonomy, peace, and dignity at the end of life leave a void in which any attempt to limit treatment borders on what Pope Benedict XVI has referred to as euthanasia "masked with the veil of human compassion" [15].

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[1] From the name of the Senator who presented it (Sen. Raffaele Calabrò).

[2] Unofficial English translations are provided for selected articles of all three documents and of the Calabrò Bill.

In Germany, delivery of treatment described as unwanted in an advance directive is regarded as a physical assault on the patient [16]. In France, advance directives are not legally binding, but the Leonetti Law passed in 2005 clearly allows French physicians to withhold/withdraw life-prolonging treatment even when patients are unable to express their preferences, provided such decisions are made collegially and preceded by consultation of the patient's family and of any advance directives written by the patient himself. Furthermore, a recent revision of the French Code of Medical Ethics, which—unlike its Italian counterpart—has the force of law, requires that any additional suffering caused by such withdrawal be completely eliminated by palliative care, including major sedation that can potentially shorten life. Although the French code establishes legal and ethical limits to avoid the misuse of palliative sedation as a veiled form of euthanasia, it clearly acknowledges patients' role in end-of-life decision making and their right to be protected against needless suffering and makes avoidance of futile treatment an explicit legal and moral duty of physicians [17].

End-of-life care in the ICU will never be easy, with or without the aid of advance directives. Current data on efficacy of these documents are by no means concordant [18, 19], but directives elaborated during advance care planning can improve the quality of end-of-life care [20, 21] and reduce the incidence of post-traumatic stress syndrome among persons close to the deceased [22, 23]. Therefore, when such directives are available, at the very least they must be placed on the scales, and their use needs to be accommodated and encouraged by any law aimed at regulating end-of-life care.

Although the Calabrò Bill initially seems to authorize the use of these tools, its main effect is to restrict their scope and admissibility. Apart from prohibiting directives rejecting artificial nutrition/hydration, the bill does little to clarify the boundaries of acceptable end-of-life care. Although Italy's National Committee on Bioethics supports the definition of artificial nutrition/hydration as basic rather than medical care, its vice president has described the bill as "badly written and confusing" [24]. It is also in clear conflict with the ICME, the fundamental values of modern bioethics, and the rules of evidence-based medicine. Laws aimed at regulating complex, ethically sensitive issues like modern end-of-life decision making must not be hastily drafted in the heat of political and ideological clashes or in the wake of dramatic cases like that of Eluana Englaro. The Leonetti Law in France was a government initiative prompted by spontaneous public concern over end-of-life choices and informed by a 9-month inquiry by a panel of politicians, jurists, ethicists, clergymen, ministers, physicians, and caregivers involved in intensive care and palliative care, and representatives of civil society [17]. Italy—indeed, all countries—deserves a law with equally sound and broadly recognized foundations.

Conflicts of interest None.

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