

Palliative care as a Fundamental Human Right: where are we at in Italy?

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Abstract

The right to live with dignity during the final stages of existence, enshrined in national and supranational Charters of Rights, represents a significant step towards humanizing medicine and is integral to the right to health. Palliative Care, rooted in health, dignity, and therapeutic self-determination, has emerged as a fundamental human right and a moral imperative within health systems. It seeks to alleviate suffering, emphasizing the holistic well-being of patients with life-limiting illnesses. This paper provides an analysis of the current situation of Palliative Care in Italy and examines its critical aspects, also in relation to the issues found in other European and non-European countries. In Italy, although laws have been enacted to ensure the provision of Palliative Care, its availability remains inconsistent across different regions. Financial constraints and insufficient support hinder the comprehensive dissemination of these services. Recognizing the significance of Palliative Care, the Catholic Church also endorses its implementation as a response to human suffering and an approach to end-of-life care. Efforts to strengthen Palliative Care are critical to meeting the rising demand and ensuring access to compassionate and dignified care for all individuals in need. Through legislative advancements and adequate resources, Italy can make significant strides in advancing the provision of Palliative Care. *Clin Ter* 2024; 175 (4):252-258 doi: 10.7417/CT.2024.5072

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Introduction

The right to live with dignity in the final stages of existence is enshrined in the Charter of Rights of national and supranational rank. This right propels the humanization of medicine and is an integral aspect of the right to health. Health is no longer to be considered as the absence of disease or statistical averages. It now encompasses the overall psycho-physical well-being of individuals in their identity, reflecting the personalistic principle. This evolution addresses the imperative to provide moral and psycho-physical well-being to terminal patients (1). To date, the physician's

mission is to ensure respect for the dignity and therapeutic self-determination of the patient according to the principle of equity in access to care and the quality of care. This is in line with the recent shift in the cultural paradigm of the doctor-patient relationship, which increasingly places self-determination at its core. This applies both to the acceptance and refusal of proposed medical treatments. The innovations introduced by Law no. 38 of 2010 have generated in Italy an impetus in ethical reflections and an increase in scientific and jurisprudential production in the field of palliative care. The aim of this paper is to provide an overview of the state of the art of Palliative Care in Italy, retracing the historical and legislative process of their development and highlighting its limitations and potential, also in comparison to the criticalities faced by other European and non-European countries.

Material and methods

Law no. 38 of 2010 was examined and the historical jurisprudential process of palliative care development in Italy was analyzed, consulting the official gazette of the Italian state. The material was also extrapolated from jurisprudential rulings considered relevant to the subject matter, reports issued by international and national associations and from public and official statements. Finally, we carried out a computerized search of articles dating from 2005 to 2023 published on the PubMed database, which was refined using the following MeSH terms and text words: palliative care, palliative care need, palliative care criticalities, palliative care costs, palliative care problems, palliative care diffusion. Additional data were identified through the reference list and online research. Title and abstracts were first screened by F.C. and then by G.V. based on their relevance, and when considered potentially relevant, the article's full text was read by the same two authors. All the material has been used to describe the current situation and hypothesize possible interventions for an adequate diffusion of Palliative Care in Italy.

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What is Palliative Care

Health, dignity, and therapeutic self-determination are the pillars of modern Palliative Care, which have become a fundamental human right and a moral imperative of all health systems that consider relief from suffering an essential dimension of care (2). WHO defines Palliative Care as an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual, both in children and adults. This definition encompasses not only physical pain but also emotional, social, and spiritual dimension (3). This happens through the management of the needs of the entire patient/family nucleus by the multidisciplinary team, without anticipating or postponing death and excluding both abandonment and therapeutic obstinacy in the perspective of the revolutionary vision of “to care”. This approach, thanks to the pioneering contribution of Dr. Cicely Saunders and the establishment of the Hospice Movement in 1967 (a new method of clinical treatment for achieving relief of the incurable patient in “A Space for Dying”) aims at an accompaniment towards the inevitable end overcoming the traditional medicine which considered the dying bearer of medical disvalue and pain an instrument of expiation, inspired by the vision of “to cure”(4).

Critical issues in accessing palliative care

With the recognition of the protection of the dignity of the person as a cardinal principle of the right not to suffer, the fundamental nucleus on which Palliative Care is based, this prototype for the protection of the “process of dying”, thanks to the contribution of personality as Prof. Vittorio Ventafridda has been taken up worldwide. That happened first in Europe, with the birth of the European Association for Palliative Care in 1988. International organizations followed, with the definition proposed in the “Technical Report” by WHO in 1990, aiming at promoting the use of these treatments turned out to be one of the most efficient models for the changes of recent decades. (5,6).

The ongoing rise of Palliative Care is not only due to a growing need caused by the progressive aging of countries with high economic development and the increase in the incidence of chronic and evolutionary diseases for which there is no possibility of cure. Recent research, especially the one conducted by the World Health Organization -Worldwide Palliative Care Alliance estimates in Europe an annual need of 560 adult patients per 100,000 inhabitants: of these, 60% are affected by non-oncological diseases, overturning the idea that palliative care was born in oncology to accompany the terminally ill in their last days – to date only 40% (7,8). Also, the integration of active oncological treatment with the delivery of Palliative Care is one of the most effective responses for the psycho-physical well-being of a patient with advanced cancer. Research shows that with the same oncological treatment, patients who had consented to early

palliative treatment, according to the paradigm of simultaneous care, in line with the results of an early and shared planning of care - a decisive tool for aligning contemporary medicine with patient/family choices - enjoy better quality and increased life expectancy by presenting lower rates of depressive symptoms assessed through multidimensional assessment of needs (9).

Unfortunately, however, on the occasion of World Palliative Care Day (9 October 2021) the new Report (standard indicators to be used to assess and monitor the provision of Palliative Care in countries around the world) and the Technical Report (practical approaches and resources to support policy, strategy and practice in the field of Palliative Care) released by the WHO stated that despite the fact that there are over 56.8 million people in need of this care (of which 25.7 million in the last year of life) worldwide, only 1 in 10 people are receiving them, estimating a doubling of this need globally by 2060 (10).

Recently, the WHO report– “Left behind in pain” highlighted that, globally, there are significant disparities in access to opioid drugs for cancer care. In particular, 90% of the distribution of opioid drugs equivalent to morphine is the prerogative of the richest 10% of developed countries. The reasons for this disparity are to be found in the availability of resources (technological and economic) together with legislative and political choices that are most often restrictive in the developing countries.

The spread of palliative care worldwide is also related to various factors, among them their necessity, especially in relation to the incidence of incurable oncological diseases. The lack of financial and material resources is often the most significant barrier to the spread of palliative care worldwide. Economic developed country as United States and United Kingdom allocate a great part of their health-care expenditure in the end-of-life care, thus resulting in a wider availability of palliative care team (11,12).

At the contrary, as stated by a survey conducted by Lynch et al. on Palliative Care development in Central and Eastern Europe, the financial burden, as well as regulatory frameworks for opioid prescriptions are a great barrier to Palliative Care integration in many countries’ health systems (13). Sometimes the lack of economic material can be due to unstable politic situation, as happened in Tajikistan or Croatia. In other cases, such as in Montenegro, Palliative care was a low priority in politics’ attention due to more pressing social problems. Also, the lack of palliative care training and education at medical schools is often reported as a barrier to palliative care dissemination.

The same author well illustrates that, as previously suggested, a strong association globally exists between palliative care provisions and human development (14).

Finally, it can’t be forgotten how in armed crisis, such as the 2014-ongoing crisis in Ukraine, the role of Palliative Care and pain-relief appears to be crucial (15). The Lancet Commission on the Value of Death has emphasized that there is still much work to be done in reducing inequities in access to palliative care. The authors highlight that, especially considering recent conflicts, more attention should be given to specific categories of patients who stand to benefit from palliative care. Consider, for example, patients with particular kinds of neoplastic or degenerative diseases

that have been understudied due to their low incidence or the nature of their symptoms. Additionally, certain less affluent population groups are adversely affected by their status and should be considered when we aim to reduce the inequities in the access of Palliative Care. In the current socioeconomic and healthcare context, logistical challenges are compounded by the destruction of healthcare facilities due to bombings, as for example recently occurred in the city of Kherson and the increased necessity for opioid drugs due to war-related injuries.

Urgent action and political support are needed to increase access to these essential services that have become indispensable also due to the recent COVID-19 pandemic with the need for adequate training for all healthcare workers as the demand for palliative services exceeds that provided by specialist teams alone (16,17).

Where are we at in Italy?

Even in Italy we are still far from a widespread diffusion of Palliative Care despite the existence of a dedicated law (Law no.38/2010) that guarantees the right to right to the best possible treatment of suffering. This law is one of the first in Europe to establish comprehensive support in the palliative field through adequate health and social assistance support for the patient and his family, covers care in hospitals, at home, and in hospices.

Law no. 38 of 2010 consists of 12 articles that other than Palliative Care cover for pain therapy and that can be summarized as follows:

Article 1: The law establishes palliative care as an integral part of healthcare in Italy. It defines palliative care and includes it in the Essential Level of Assistance (LEA).

Article 2: It establishes that palliative care must be accessible to all Italian citizens and anyone within the national territory.

Article 3: Provides for the training of healthcare personnel in palliative care.

Article 4: Creates a fund for the promotion and dissemination of palliative care.

Article 5: Establishes a data collection system for palliative care to monitor its progress and quality.

Article 6: Specifies the requirements for defining pediatric palliative care.

Article 7: Addresses pain management, emphasizing the importance of providing appropriate therapies for pain control.

Article 8: Discusses the importance of communication between the patient, family, and medical staff in palliative care.

Article 9: Provides for the promotion and dissemination of palliative care through informational campaigns.

Article 10: Regulates home care in palliative care.

Article 11: Establishes periodic assessment of palliative care to ensure its quality.

Article 12: Deals with administrative procedures and oversight of the law.

Professionals and non-profit organizations such as SICP (1987), FCP (1999), and Cittadinanzattiva (2005) have

shown public support for this law, which was initially limited to home-based care (1979) (18). This Law is the point of arrival of a revolutionary process that began with Law no. 39/1999 launching the national program for home palliative care and the implementation of Hospices and continued with a series of Agreements in the State-Regions Conference that have made the field of Palliative Care one of the most defined and shared among all those of territorial assistance at national level (19,20). Following the promotion of the right to self-determination of the subject supported both by recent jurisprudence and modern medicine, Law no. 219/2017 takes up the concept that, through informed consent, the Palliative Care is an institution to be promoted in care relationships as well as to be ensured even in the event of refusal or revocation of health treatment both in advanced treatment directives (DAT) and in shared care planning (PCC) and for which continuous and adequate training of healthcare personnel is necessary (21).

Despite achieving undeniable legislative milestones (such as the establishment of hospices: 55 beds in 1999, 1888 beds across 165 hospices in 2005, 2592 beds across 229 hospices in 2010, 2600 beds across 230 hospices in 2014, 2963 beds across 2277 hospices in 2020, and 3326 beds across 307 hospices in 2022, with a greater concentration in Northern Italy compared to the South Regions, along with recent updates to the “essential levels of assistance”, there still exist challenges in achieving consistent implementation at the regional level. This includes extending the provision of palliative care to early stages of incurable diseases within the framework of “Individual Care Plans” (PAI), incorporating “multidimensional assessment of needs” (VMD). Jurisprudence has also evolved to hold physicians responsible for the undue suffering of terminally ill patients due to the lack of necessary palliative care, representing a specification of the right to health. Although efforts have been made to establish structures, create “National networks of palliative care for continuity of care that include adult palliative care, pain therapy, and palliative care for the pediatric population, and carry out “Information campaigns for citizens” disparities in legislative application at the regional level are evident (17, 22-26). That is due to the lack of resources following cuts in health funds (Decree of the Ministry of Health no. 70/2015) to deal with the international financial crisis of 2007 and the sovereign debt crisis of 2011 (27). Current data show that, thirteen years later, seven out of ten citizens still do not know Law 38/2010 (of these: 38% have pathology that causes pain, 80% with chronic pain) and only one person out of four among those who would be entitled to it receives palliative care (regional coverage rate: Lombardy: 33%; Emilia-Romagna: 26%; Lazio and Valle-d’Aosta: 25%; Basilicata, Sardinia, Friuli-Venezia Giulia: 24%; Veneto: 23%; Autonomous provinces of Bolzano and Trento: 29% and 27%) compared to 543,500 adults in need/per year (regional need: Lombardy 83,176; Lazio 50,221; Campania 47,082 potential patients) and a total offer of only 124,063 units (79,648 patients assisted at home; 42,572 in hospice; 1,843 in day hospital) (28,29). To these must be added 35,000 needy minors of which only 5% can access it (Regions with greater shortages: Campania, Marche and Liguria) (30).

That can find an explanation in the historical socio-economical north-south gradient and in the organization

model of the Italian National Health System (SSN) which allows regional autonomy implying the co-existence of 20 different health systems, each of one have different financial allocation and incomes that exacerbates the differences in access to care across regions at every level. The regions in the north, historically benefiting from better infrastructure and greater economic resources, represent a greater “therapeutic attraction” than the regions in southern Italy and the islands. (31,32).

That implies that the so-called ‘medical tourism’ has now become common, which involves the movement of patients from one region to another for reasons related to the availability and quality of medical treatments in various fields. This is true both internationally and at the national level, especially in areas such as medically assisted reproduction, voluntary termination of pregnancy, and medically assisted suicide (33,34). However, this hypothesis is not feasible for palliative care. Patients in need of palliative care are often unable and unwilling to leave their place of residence, and their relocation would entail significant logistical challenges for both family members and caregivers.

Therefore, to date, it is necessary to strengthen the Palliative Care system, adopting a framework of implementing measures consistent with the principles and regulatory provisions by mapping the organizational models in order to fill the inhomogeneities and make the nodes of the welfare network dialogue in an optimal way, also because the current gaps are one of the reasons that can induce the terminally ill to choose the most extreme route of medically assisted suicide to end his suffering (35-37).

The motivations behind such a significant gap between the current state of palliative care in Italy and what still needs to be done could be various. Regarding the dissemination of the law among the population, considering that this is not such an infrequent event, especially when regulations address bioethical issues, various reflections can be made (38). Indeed, considering the political instability that has characterized Italy in the last decade, it is possible to hypothesize that political attention may have been more significantly focused on issues that citizens perceive as closer and more “practical,” perhaps to gain immediate consensus. Similar considerations can be made regarding the economic needs that the Palliative Care system requires. In Italy, the economic crisis of the last decades has led to a consistent cut in healthcare costs. A reduced availability of economic resources obviously affects the allocation to the Palliative Care network (39). Finally, it is also essential to consider the significant impact that the recent COVID-19 pandemic has had on the management of healthcare and economic resources and on the priority of public and political attention (40).

As far as Italy is concerned, we must refer to those leading cases -Piergiorgio Welby, Eluana Englaro, “Dj Fabo”, Davide Trentini and many others, that, in recent years, have cracked the idea that Palliative Care or continuous deep palliative sedation can always be considered modalities conforming to one’s personal dignity of a dying person who (only in cases where he is: capable, with irreversible pathology source of intolerable psychic and / or physical suffering and dependent on a life-sustaining therapeutic intervention) could prefer his right to obtain death thanks to a lethal drug

(despite the most recent obstructionism and illicit delays in the procedure for ascertaining the requirements) (41,42). In further proof of the increased sensitivity on end-of-life issues and the dignity of the dying, it was indeed only one year after the death of Eluana Englaro that Law No. 38 of 2010 was enacted and a strong impetus involved jurisprudential production in Italy. In these cases the Palliative Care play a fundamental role as both the mechanism of the “Double Pronunciation” of the Constitutional Court (triggered by the Cappato/Antoniani case following the inertia of the Legislator) and the bill on the “Provisions on voluntary medically assisted death” (approved by the Chamber of Deputies on 10 March 2022 but not by the Senate due to the change of Legislature) considered them the pre-requisite of the subsequent choice to resort to pharmacological death (to refuse or interrupt, to proceed with this request) in order to avoid that health facilities prematurely renounce to guarantee therapies aimed at eliminating the suffering of the patient becoming a sort of balance to that basic incompatibility with the practice of euthanasia. In fact, the countries that legalize euthanasia discourage the use of CP - only 10% - as are usually considered alternative practices, axiologically incompatible) (43-45).

Given the delays for this kind of treatments, the choice adopted by Italy could make feasible a path that, if not imposed compulsorily, may not find concrete application, urging, again, to strengthen the offer: in fact, in this line of thought are resumed the principles contained in Law no. 38 of 2010.

One step in that direction is the recent news of the Italian legal system: since 23 September 2021, the SICP has been accredited in the List of Scientific Societies and Technical-Scientific Associations of Health Professions, at the Ministry of Health - Directorate General of Health Professions and Human Resources of the National Health Service. In addition, in the autumn of 2022 the first “Specialization Schools in Medicine and Palliative Care” started for graduates in Medicine and Surgery, defining the need of a specific training on the subject, which defines its value, allowing the National Health System to better respond to the needs of patients and their families (46). Until now, despite the progress within the University (establishing the need for specific credits) the graduate could become a palliative physician only through specializations identified as equivalent (Anesthesia and Resuscitation, Hematology, Geriatrics, Infectious Diseases, Internal Medicine, Neurology, Oncology, Pediatrics, Radiotherapy) together with the frequency of specific training and updating courses. Furthermore, it is hoped that a specific rule on the end of life will be approved as soon as possible and outline a clear legislative procedure, in line with the dictates of jurisprudence, which always respects the (essential) condition of personal dignity (to date, unfortunately, still too often disregarded).

Palliative Care, the Vatican’s view

Spirituality and religion have a readily discernible role for individuals afflicted by worsening diseases with poor prognosis and unresponsiveness to any type of treatment. These can indeed serve as a way to cope with the illness,

alleviate suffering, or hope for healing through therapy (47). Catholic Church historically had great influence in politics and public health matter in Italy (48-50). This is due to both the deeply Catholic roots of Italians and the geographical presence of the Vatican within Italian territory. Since the protection of life is one of the prerequisites of Palliative Care, the Catholic Church also favors their provision considering them the only tool that can be used in the perspective of the end of life. Since the timid openings of the Catholic Church with John Paul II's Encyclical "Evangelium Vitae", which recognized the role of Palliative Care for the dependent and terminally ill, several steps forward have been made. Even the Pontifical Academy for Life, The Vatican state entity whose purpose is the defense and promotion of the value of human life and the dignity of the person, highlights how Law no. 38 of 2010 is still little known and applied today, while "it would be a concrete response to the suffering of many people, for true help and accompaniment" (51-53). The support of the Pontifical Academy for Life has been made public through a position paper, the launch of the 'Pal-LIFE: An Advisory Working Group on Diffusion and Development of Palliative Care in the World' project, as well as the publication of books and articles on the importance of palliative care (54). This appears to be of extreme importance at the end of the dissemination and implementation of the law and, therefore, of palliative care in Italy, especially considering the strongly opposed stance to practices such as assisted suicide and euthanasia.

Conclusion

Therefore, it can be concluded that, to date, in a vision shared both worldwide and nationally Palliative Care are the indispensable approach in order to heal, at least, the "wounds of the soul of captive bodies", being able to rely to the Catholic Church support as well (55). Therefore, to increase them is necessary to guarantee, to all applicants, the administration. Several interventions are therefore necessary. First of all, a greater dissemination of the Law must be ensured among the population and healthcare professionals. Furthermore, adequate training for healthcare professionals must be ensured. Financial interventions also appear necessary, given the significant constraint that the lack of economic resources represents at the Italian and global levels. This is also to fill the gaps at the national level and the existing and highlighted differences between regions. For this to happen, considering the magnitude of the issue and considering experiences in other countries around the world, it is essential for policy attention to be directed toward addressing the problem of access to Palliative Care. Finally, the dissemination and growing awareness of Law No. 38 of 2010 in Italy must necessarily involve a cultural reform, as can be necessary in other countries to facilitate access to Palliative Care worldwide.

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