

# Adequate Chronic Pain Care in Italy

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Appropriate pain care should be regarded as a right and effectively guaranteed to people with chronic pain (CP). Additionally, the World Health Organization (WHO) has recognized the importance of addressing CP as a global public health concern and has recommended that pain management be integrated into primary healthcare systems. Many individuals with CP continue to experience barriers to accessing appropriate and effective pain care, including a lack of education and training among healthcare providers, limited availability of specialized pain clinics, and misconceptions about the use of opioid medications for pain management. Furthermore, CP patients often encounter social stigmatization and discrimination, which can further complicate their access to care. There is a need for ongoing efforts to improve the recognition, assessment, and management of chronic pain, and to ensure that individuals with CP have access to appropriate and effective pain care that addresses their physical, psychological, and social needs. Law 38, enacted in Italy in 2010, establishes the citizen's right not to suffer.

Keywords: chronic pain ; pain management ; pain therapy network

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## 1. Introduction

Regarded for a long time as a non-life-threatening condition and often overlooked, pain has historically been under-treated and the clinical sequelae of its poor control disregarded <sup>[1][2]</sup>. However, recent evidence highlighted a worrisome prevalence of pain worldwide with variability across countries ranging from 9.9% to 50.3% thus endorsing pain as a worldwide primary health issue <sup>[3]</sup>. Chronic pain (CP) inflicts the greatest loss of productivity than any disease condition <sup>[4]</sup> and contributes to significant healthcare costs <sup>[5][6]</sup>. Long-lasting untreated or inadequately controlled pain is a chronic condition that severely impacts patients' quality of life (QoL) through wide-ranging negative physical, psychological, and functional effects <sup>[7][8]</sup>. Therefore, access to adequate pain care should stand as a non-postponable right <sup>[9][10]</sup>, and the rights of people with CP must be championed <sup>[11]</sup>.

An important milestone in the European healthcare regulatory framework was represented by Law 38, enacted in Italy in 2010, which ratified the citizen's right not to suffer <sup>[12]</sup>. The law pioneered recommendations to develop dedicated health centers for palliative care and pain therapies and to provide both inpatient and outpatient care settings to ensure continuity in the diagnostic-therapeutic journey of patients with CP <sup>[12]</sup>. To date, alongside Italy, few European governments have recognized pain management as a legal obligation <sup>[13]</sup> and few national health organizations approved a charter of rights for people living with CP <sup>[14]</sup>.

Despite the regulatory framework defined by Law 38/2010, the provision of adequate CP care appears challenging in the country. It is currently missing a multidisciplinary pain management approach stemming from the observation that CP pathology has intricately related biological and psychosocial components. Therefore, the usual treatment delivered by a single department/specialist may not be sufficient for people with CP thus requiring multi-professional teams. Furthermore, there is limited awareness of the opportunities Law 38/2010 can offer to citizens with seven out of ten citizens knowing neither the Law nor the rights that it establishes to avoid the patient "unnecessary suffering" <sup>[15]</sup>. As a result, Italy is the third European country in terms of CP prevalence <sup>[16]</sup> with about one in four subjects suffering from it and one in three pain patients undiagnosed or referred late to pain therapy centers <sup>[17][18][19]</sup>. Overall, the missed or partial enforceability of the right not to suffer demands a call to action to mitigate the CP burden, and a greater awareness of rights can no longer be disregarded among the general population and within the medical community. In the last few years, several initiatives intended to both assess the degree of implementation of Law 38/2010 at a national level and bridge the clinical, organizational, and cultural gaps that hamper CP patients' access to the care they are eligible for were organized <sup>[20][21]</sup> <sup>[22]</sup>. Recently, a Social Manifesto against pain, spearheaded by the Italian Society of Anesthesia, Analgesia, Resuscitation, and Intensive Care (SIAARTI) and signed by seventeen scientific societies and patient associations, has been issued to foster awareness of the burdensome impact of CP at both individual and societal level <sup>[23]</sup>.

## **2. Current Gaps Hindering Appropriate Care for Patients with Chronic Pain**

With one in three undiagnosed pain patients and frequent late patient referral to pain therapy centers, access to pain care reveals burdensome shortcomings in Italy <sup>[17][18][24][25]</sup>. Now, more than ever, the translation of pain knowledge into practice, as advocated by the International Association for the Study of Pain (IASP) 2022 Global Year <sup>[26]</sup>, is imperative to maximize the opportunities that full implementation of Law 38/2010 could provide. Major diagnostic, therapeutic, and organizational gaps which currently hinder the full enforceability of the right not to suffer and appropriate multidisciplinary CP care are identified.

### **2.1. Poor Disease Awareness and Late Diagnosis**

Pain is still regarded by the patients as an inevitable component of the disease thus favoring a frequent “wait and see” attitude on the part of the patients who may first attempt to control the pain by self-medication or simply by underestimating the problem <sup>[19]</sup>. Patients seek doctor consultations and/or pain center visit months or years after pain occurrence; nonetheless, a high percentage of patients who wait before contacting a pain therapy center are often unaware of its existence. In line with this, a recent cross-sectional study conducted on over 1000 patients with CP reported that one in two patients had suffered from CP for over four years <sup>[24]</sup>. To this end, it has been suggested that the acknowledgment of chronic and recurrent pain within the recent ICD-11 classification could be a premise for promoting greater consciousness as well as enhanced engagement of both healthcare providers and patients <sup>[27]</sup>. Advances in pain knowledge have laid the foundation for the ICD-11 classification and supported the notion that CP should be regarded as a disease, rather than a symptom, which carries both meaningful distress and functional impairment <sup>[1][28]</sup>. It has been suggested that the new ICD-11 CP classification could make CP more “visible” and better inform clinical practice and resource allocation <sup>[29]</sup>. Overall, coding CP with the ICD-11 may be of help primarily in terms of obtaining a timely diagnosis; therefore, a wider implementation of ICD-11 classification may thus shorten the time to diagnosis. Considering that ICD-9 is the version of ICD currently envisaged in country by the legislation for the coding of diseases and related problems <sup>[30]</sup>, it is paramount to promote the transition from ICD-9 to the ICD-11 that has come into force on 1 January 2022.

Mounting evidence suggests that most physicians may feel not be adequately prepared to manage patients with CP <sup>[31][32]</sup> <sup>[33]</sup>. The over-burdened primary care providers, while being at the forefront of pain care delivery pathways, often lack the time and resources to effectively assess and manage CP thus very often choosing to refer patients to specialized pain centers. Accordingly, 75% of patients visiting the Italian pain therapy network are referred by GPs <sup>[21]</sup>, after an unsuccessful trial of pharmacological and non-pharmacological options. Overall, after providing the first level of pain care, GPs should promptly refer CP patients to specialized centers where specialists can offer integrated, expert assessment and management of pain within the context of a multidisciplinary team.

### **2.2. Inadequate Management**

CP demands individualized management <sup>[34][35]</sup>. Therefore, the evaluation of analgesic treatment needs to reflect at a minimum improvement in pain degree of severity and pain-related distress, as well as lower interference with daily life. Currently, clinicians are still not fully aware that pain therapy success should go beyond reducing pain intensity thus not easily shifting toward an emphasis on patient functions. In line with this, it has been reported that although clinicians acknowledge a restoration of functionality as relevant as a significantly lower pain degree, they report limited use of multidimensional questionnaires <sup>[21]</sup>. Difficulties can be encountered in choosing the most promising therapeutic strategy. A recent survey among Italian GPs and specialists reported that only 1 in 2 physicians report the presence of treatment protocols and management patterns addressing patient pain according to pain type <sup>[25]</sup>.

CP should be addressed by combining both pharmacological and nonpharmacological approaches taking into consideration multiple aspects including its intensity and duration, pathophysiology, symptoms' complexity, and the coexistence of comorbidities <sup>[36][37][38]</sup>. Therefore, combining analgesics with different mechanisms of action or pharmacological approaches with invasive techniques may all serve as promising approaches to attain multimodal CP management with the final aim of improving function, and quality of life and facilitating and enabling the return to work <sup>[39]</sup>. Of note, multimodal pain management has become a fundamental part of perioperative care and may prevent the development of chronic postoperative pain <sup>[40][41]</sup>. Similarly, optimal treatment of CP (including rheumatic <sup>[42]</sup>, low back pain <sup>[43]</sup>, and osteoarthritis <sup>[44][45]</sup>) can be achieved by taking advantage of a multimodal approach encompassing structured interdisciplinary programs aimed at providing a multidisciplinary treatment plan. To this end, multimodal CP management should include medications, physical and occupational therapy, rehabilitation, behavioral therapy, mini-invasive and invasive procedures, and so on as illustrated in the analgesic trolley model for pain management proposed by Cuomo et al. <sup>[38]</sup>.

The appropriateness of care is a priority when managing prevalent diseases which need long-term treatment, such as CP [46]. To this end, Law 38/2010 aimed at simplifying the procedures to access pain drugs by modifying the Unique Text of Law regarding the use of narcotic and psychotropic substances, thus allowing general practitioners (GPs) to prescribe non-injectable opioids upon adequate training on their use. Although in the country the average per capita year of morphine equivalent dose is much lower than that reported in Northern Europe and the USA, avoiding misuse while guaranteeing all patients with a pain treatment has been regarded as a primary health matter [47]. In Italy, it has been recently reported both a lower consumption of weak opioids and marked heterogeneity in strong opioid consumption across regions [48]. Such findings highlight the achievements and pitfalls of Law 38/2010: The former is greater appropriateness of the use of such drugs for CP patients, as suggested by the tight surveillance of opioid use achieved in the country [49] and the latter is the need for harmonizing the access to pain care according to the equality principles of the law. Nevertheless, standardized protocols for opioid titration as well as for the management of opioid abuse are not currently available in many pain centers [20].

Finally, despite Law 38/2010, the possibility to ensure, via the national healthcare system, multidisciplinary care of people with CP is still challenging. To date, the essential levels of assistance (LEA), i.e., the services and benefits that the national health service is required to provide to all citizens, currently exclude chronic pain care from both psychological and rehabilitation settings.

### 2.3. Inhomogeneous Pain Care Delivery

The main objective of Law 38 was to ensure continued patterns of care for patients established through the hospital-primary medicine network. However, only 32.6% of the pain facilities guaranteed a homogeneous care continuity within the network via the use of the electronic medical record (EMR) of patients [20]. In addition, a comprehensive mapping of the Italian pain therapy centers unveiled significant organizational issues that might have contributed to the inhomogeneity of care delivery across regions. Nonetheless, it has been reported that inadequate pain assessment may stem from the limited time physicians have to devote to pain patients' consultation, the absence of streamlining available tools as well as the scarce proportion of physicians who devote their clinical activity to pain medicine [21].

It has been suggested that clinical care pathways could serve as useful tools to improve the quality of healthcare by facilitating the translation of evidence into practice [50]. Therefore, great efforts have been put in place by multiple scientific bodies and societies to develop best practice recommendations and propose pain care pathways. Despite the presence of multiple scientific bodies involved in pain care including the Italian Society of Emergency Medicine (SIMEU), Italian Resuscitation Council (IRC), Italian Society of Anesthesia, Resuscitation, Emergency and Pain (SIARED), Italian Society 118 System (SIS 118) and Italian Association for the Study of Pain (AISD), there is limited evidence of intersociety recommendations on pain management [51] thus hindering an integrated multidisciplinary pain care delivery. It has been suggested that multiple factors may contribute to the limited adoption of shared clinical pathways including skepticism, difficulty in portraying patients' clinical picture within a set pathway, and lack of support in obtaining knowledge [52]. In addition, there is limited evidence of shared clinical pathways as most clinicians would perceive them as a limitation (or even loss) to their autonomy in clinical decision-making. As a result, integrated care pathways for pain management in the country are difficult to implement and, if they exist, are limited to very local realities. To this end, it would be desirable to engage the representatives of the main healthcare professional categories daily involved in pain care (not only anesthesiologists but also and above all surgeons, psychologists, physiatrists, general practitioners, neurologists, nurses, physical and occupational therapists, and so on) to collectively design a shared pain care pathway within which the decision making and the organization of care processes are effectively coordinated by the multi-professional team that builds the care pathway.

From a regulatory standpoint, the absence of indices to quantify and monitor the activities related to pain therapy hampered a clear appreciation of the relevance and the burden of CP within the multiple care services delivered in the context of national health service. The introduction of coding 96 in 2018 [53], which identifies the activities related to pain therapy, is another milestone in the long process toward greater recognition of pain therapy within the national healthcare system. This coding has been waited for a long time by pain specialists and ensures clear documentation of all the activities related to pain therapy at the hospital level. Recognizing a pain code requires healthcare structures monitoring, through an electronic platform, how many hospital units can be devoted to pain therapy, how many beds are available and how many times such coding appears in the discharge letter. Importantly, the availability of such coding may allow specialized pain centers to be accredited for coding 96 thus standing as a reference center for managing CP patients and guiding primary care physicians during patients' referrals. However, the current implementation of coding 96 is not homogeneous at the national level and no integration among medical disciplines has been attained so far. As a result, patients with CP do not currently benefit from the innovative premises and goals of such coding.

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