

LAW 38/2010: THE RIGHT NOT TO SUFFER A LAW TO KNOW AND TO APPLY

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Abstract:

This paper aims primarily at presenting an analysis of the legislation, guidelines, procedures developed to Italian legislation, as well as an analysis of the treatment of pain in European countries. Moreover, it is our intention to analyze the major progress made by pain medicine over the last decade. Another goal is verifying the criteria (qualitative and quantitative standards) regarding the size structure and process that characterize the network for Palliative Care and the state of the two networks development provided by the Law 38/2010 (one for palliative care, the other for the pain therapy) in Italy divided by individual Italian regions, by taking into account the fact that the organizational choices made are different from region to region. To answer the research questions, we will analyze official data published on corporate websites (e.g. Ministry of Health), reports and documents recently published. This paper outlines the consumption of drugs in relation to the total expenditure and consumption per capita, so as to enable an economic impact evaluation on federalism in Italian health. In the final part of the work, we aim at outlining strengths and opportunities of the legislative measure and its main problems. This paper tries to point out the legislative measure value from a cultural, organizational and welfare point of view by highlighting important critical aspects, such as the region's lack of educational interventions, the lack of attention to the necessary (and mandatory) specialized training of medical and paramedical staff and, in general, the citizens, as well as world worker's and health professional's lack of knowledge about such ratified right.

Keywords: palliative care, pain therapy, law, suffering

1. INTRODUCTION

Pain is the unpleasant sensation associated with actual or potential tissue damage or at least perceived as such. This is the definition of pain given by the *International Association for the Study of Pain* (IASP). Pain is a warning bell set in order to protect our body from attack. This is true but only for acute pain (which has a limited life and is an expression of a tissue injury), instead loses its function as a useful stimulus and becomes a real disease when endures over time and becomes chronic pain (a pain that persists beyond 3-6 months). Chronic pain is a condition rather widespread which affects 50% of Europeans over 65. In Italy there are about 15 million people suffering from chronic pain, of which only 10% in connection to cancer (Tribunal for Patients' Rights 2010).

The World Health Organization (WHO) coined the phrase "global pain" for this condition because it is not a simple extension time of acute pain but a real illness that involves the patient in a spiral of events of psychological and social nature that will fundamentally undermine the quality of life and ability to work, with strong social, economic and psychological impacts (Tribunal for Patients' Rights, Active Citizenship).

Yet pain is often regarded, both by patients and physicians, as an inescapable part of the disease that should be accepted. It is necessary that chronic pain be treated in an appropriate way in order to avoid additional health care costs related to the long-term morbidity.

2. THEORETICAL FRAMEWORK

2.1 The Law No. 38 of 15 March 2010

The year 2010 marks a turning point, at least at the legislative level, in the fight against pain in Italy.

On March 15, 2010 the House approves the Law No. 38 "Provisions for access to palliative care and pain therapy" published in the Official Gazette No. 65 of 19 March 2010 with 476 votes in favor and none against. The Law No. 38 has represented an important milestone in the Italian and European healthcare landscape, because it ratifies the citizen's right not to suffer.

This law is among the first in Europe to provide answers to the needs of the population in terms of palliative care and chronic pain: among the purposes of the Act referred to in Art. 1 it has highlighted the need to ensure respect for the dignity and autonomy of the human person, the need for health, equity in access to care, quality of care and their appropriateness with regard to the specific requirements.

Table 1: The articles of Law 38/2010 (Ministry of Health 2014)

Art. 1	Finality
Art. 2	Definitions
Art. 3	Ministry of Health and the Standing Conference for relations between state, regions, autonomous provinces of Trento and Bolzano
Art. 4	Information campaigns
Art. 5	National networks for palliative care, for the treatment of pain, for the pediatric
Art. 6	Hospital Project - Territory without pain
Art. 7	Obligation to report the detection of pain within the medical record
Art. 8	Training and refresher courses for medicine and health
Art. 9	Ministerial Monitoring for palliative care and pain therapy
Art. 10	Simplification of procedures for access to medicines used in the treatment of pain
Art. 11	Annual Report to Parliament
Art. 12	Financial coverage

3. REPORT TO PARLIAMENT ON THE IMPLEMENTATION OF LAW 38/2010: THE SALIENT ASPECTS

According to Art. 11 of Law 38/2010, the Minister of Health, by December 31 of each year, submits a report to Parliament regarding the implementation of this Act as well as information and data collected

by monitoring for treatment palliative and pain therapy, investigating specifically (Ministry of Health 2011, 2014):

- data on the prescription and use of drugs in the treatment of pain, and in particular drug opioid analgesics;
- the development of the two networks, with emphasis on the observance of the indicators and national criteria provided by law;
- the progress of the two networks, even with reference to the level of integration of the structures that are part of it;
- the benefits paid and the results, including the qualitative and quantitative analysis of the structures of the two networks;
- training activities at national and regional level;
- information campaigns at national and regional level;
- research activities;
- the economic aspects related to the creation and development of the two networks.

The report to Parliament on the implementation of Law No. 38 of 15 March 2010 “arrangement to ensure access to palliative care and pain therapy” of the Ministry of Health, 2014, has highlighted the following aspects:

Article 1 - Purpose

The Law 38/2010 incorporates and formalizes the provisions of the Charter of Rights on unnecessary pain brought by the Tribunal for Patients' Rights, in 2005:

- Right not to suffer unnecessarily: every individual has the right to alleviate their suffering in the most effective and timely way possible;
- Right to the recognition of pain: all individuals have the right to be heard and believed when they report their pain;
- Right of access to pain therapy;
- Right to expert's assistance;
- Right to continuous support;
- The right to a free and informed choice: every person has the right to actively participate in decisions on the management of their pain;
- Right of the child, the elderly and persons who have no voice;
- Right not to feel pain during any kinds of examinations.

Indeed, the Act aims at consolidating the right to health ratified in the Article 32 of the Constitution not only as individual protection but also as a commitment to the realization of a system marked by solidarity with all citizens in general and vulnerable people in particular.

This right is “regional fulfillment for access to additional financing of the National Health Service by the State” (Essential Levels of Care).

Article 3 paragraph 2 - Regional Coordination for the network of palliative care and the network of pain therapy for adult and pediatric patients

The Standing Conference agreement for relations between the State of the Regions and the autonomous provinces of Trento and Bolzano of 16 December 2010 establishes “the institution with appropriate measures, regional and business structure specifically dedicated to coordination of the Network” for both the development of palliative care and the treatment of pain.

The Ministry of Health has identified, with the decree of 23 September 2010, a facility dedicated to the national coordination of care networks and monitoring of the implementation.

Article 4 - Information campaigns (Ministry of Health 2014)

The communication campaign on the pain created in 2013 by the Directorate General Communication and Institutional Relations of the Ministry, shared with the Regions and Autonomous Provinces, have made the activation of four lines of outdoor activities possible (Ministry of Health, 2013).

These include:

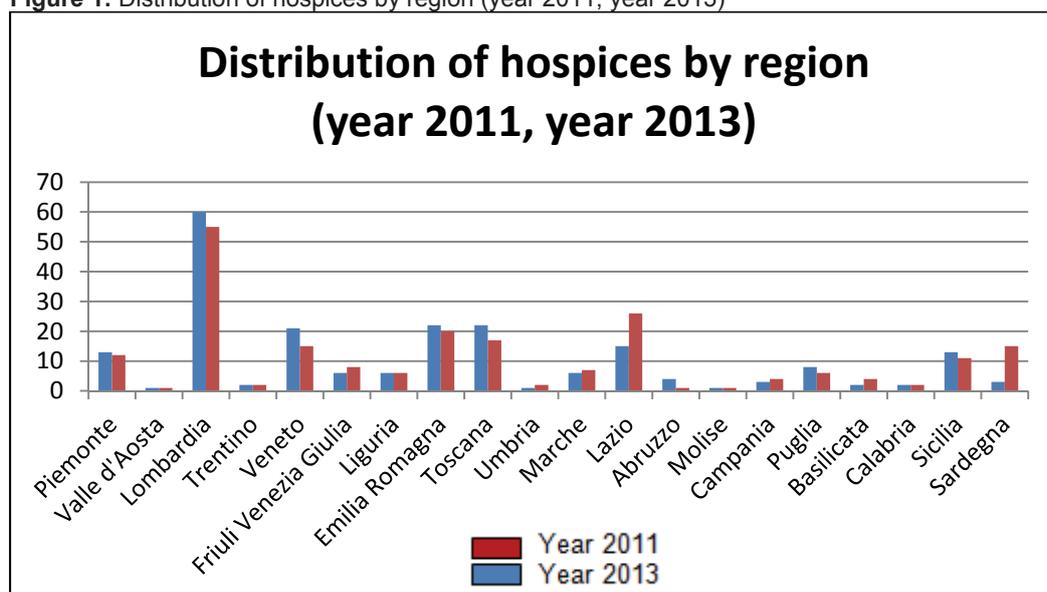
- Publication on the portal of the Ministry of all cards collected in relation to the 568 nursing facilities surveyed, reporting data, information regarding the names of those responsible and all contacts for the citizens;
- The review of the thematic pages of the portal of the Ministry dedicated to palliative care and pain therapy (600 pages) carried out by the Office XI of the Directorate General of Health Planning;
- Activation, for six months (June – December 2013) of the dedicated phone number 06.59945959 (billed to Rai UnoMattina May 31, 2013) and an e-mail senzadolore@sanita.it to ask for information and report problems;
- Publication on the portal of the Ministry of a brochure and a poster on pain that can be downloaded in a professional format by those who have interest in spreading them.

The results obtained are:

- Over 1,000 telephone inquiries escaped;
- 600 new thematic pages published on the website of the Ministry;
- 24,000 user sessions;
- 68,000 visualizations;
- 101,000 pages visited on the Internet;
- 338 spot on the TV channel RAI

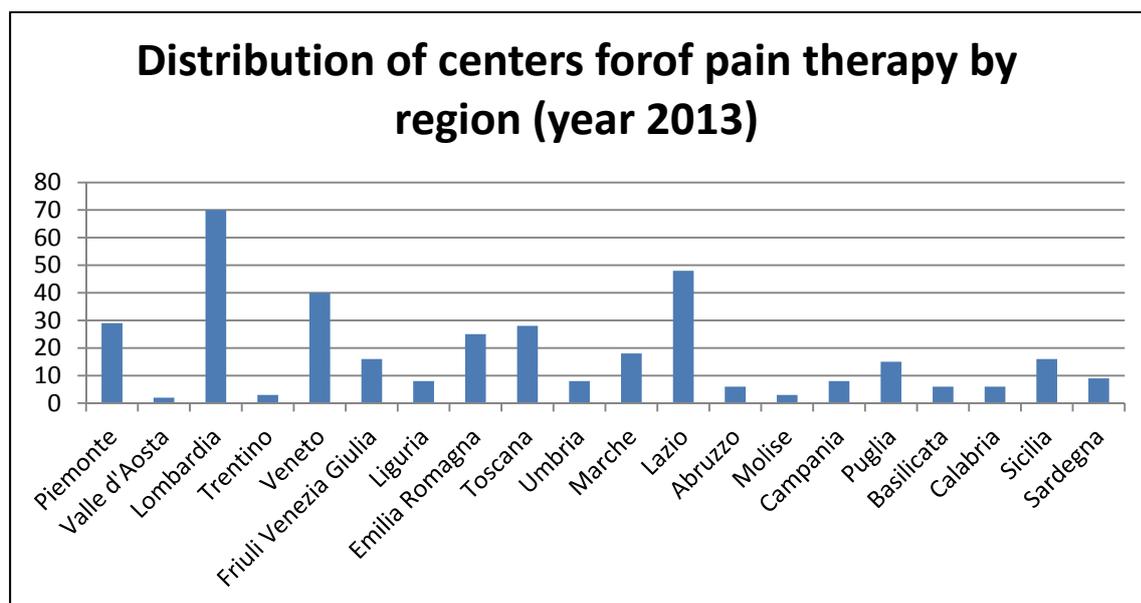
The Campaign in 2013, shared with regions and autonomous provinces, began with the mapping of all national networks and hospice pain therapy centers divided by Region and North - central and southern areas and islands.

Figure 1: Distribution of hospices by region (year 2011, year 2013)



Source: Data processed by the author.

Figure 2: Distribution of centers for pain therapy by region (year 2013)



Source: Data processed by the author.

The presence of structures is greater in the north than in the center and south, although the number is constantly increasing. The region with the highest number of structures is Lombardy (Ferrante, T.,2008).

Article 5 paragraph 3 - Standing Conference between state, regions, autonomous provinces of Trento and Bolzano

According to the agreement signed on July 25, 2012 health facilities that provide palliative care and pain management ensure an individual and personalized care program which, by recognizing the dignity and autonomy of the patient, provides assistance that must respect standards quality and appropriateness, highlighting the different specificities of palliative care and pain therapy. In order to satisfy this need, two national specifications have been established with the aim of "ensuring the continuity of care of the patient from the hospital to his home. Both of them are composed by hospitals and territorial facilities, as well as by professionals, and diagnostic and therapeutic interventions".

The agreement has been adopted by 12 regions: Calabria, Campania, Emilia Romagna, Lazio, Liguria, Lombardy, Marche, Piedmont, Sicily, Sardinia, Tuscany and Umbria.

Article 6 - Project "Hospital - Territory without pain"

The Project "Hospital - Territory without pain" provides funding for the development and implementation of the service network of pain therapy.

In the course of 2013 the regions Umbria, Lazio, Basilicata and Friuli Venezia Giulia have submitted projects in order to establish and/or develop models of care for pain treatment in the regional area and, at the present time, projects in Molise and Abruzzo are being evaluated.

Article 10 - Procedures simplification for access to medicines used in the pain treatment

The consumption of drugs used in the pain treatment (opioid analgesics) recorded sales of pharmacies in the two years from 2012 to 2013, shows a significant average increase (approximately + 50%). Analysis of expenditure at regional level has registered an increase in spending in all those regions with the highest values such as Campania (73%), Puglia (69%), Lazio (68%), Abruzzo and Sardinia (40%), Basilicata (39%), the lowest percentage of increase in the Tuscany region (30%) (Ministry of Health 2014).

4. THE THERAPEUTIC APPROPRIATENESS: THE TABOO OF OPIOIDS

The appropriateness of care is a crucial issue in the therapeutic management for important implications not only clinical but also ethical and socio-economic Casale, G., Alvieri, A. (2014).

It is a theme that becomes even more important in diseases which have a high prevalence and need a long-term treatment, such as chronic pain. According to the definition of “appropriateness”, better recognized by the scientific community and by WHO (World Health Organization), a treatment is defined appropriately when the benefits of therapy sufficiently outweigh the side effects of the same.

In this context to be interpreted the review of the most recent international guidelines that propose greater use of opioids and a lower use of NSAIDs and weak opioids (Smith, K., Hopp, M., Mundin, G., Leyendecker, P., *et al.*, 2008).

In fact the use of Paracetamol for short periods of time and the accumulation of evidence on the risks related to these drugs is recommended. The questionable safety profile and the lack of studies demonstrating the effectiveness of the latter in chronic pain require careful reflection on the appropriateness of such drugs in the treatment of pain. The effectiveness of opioids is, however, widely demonstrated.

5. THE TREATMENT OF PAIN IN EUROPEAN COUNTRIES

Prof. Hans Kress, President of EFIC (European Federation Pain) has outlined the situation in Europe in relation to pain and its management (Barham L., 2012).

The EFIC is a multidisciplinary professional organization in the field of pain medicine, founded in 1993. It has its headquarters in Brussels and gathers 36 national societies on the study of pain in Europe and 20,000 scientists, physicians, nurses, physiotherapists, psychologists, and other healthcare professionals across Europe. The main objectives are: to develop a pain medicine and research in this area; give the maximum availability of best practice pain management; provide adequate training in pain medicine at the university and postgraduate levels.

As Kress stressed: "pain is a problem underestimated and undertreated while being the main cause of suffering and reduced quality of life, especially in the case of cancer, aging, traumatic injuries, nerve damage, surgery and insufficient treatment of acute pain. Chronic pain is an epidemic and recognized as such".

Prof. Kress showed that in a survey of 46,394 respondents older than 18 years, chronic pain (moderate to severe) was present in 19% of adult Europeans, seriously compromising the quality of their social life and work: 19% have lost their jobs; 13% have changed jobs because of their pain; 60% visited their doctor from 2 to 9 times in the last six months for this issue and only 2% were today treated by a pain specialist. Also, another European survey revealed that over 40% of patients with chronic pain receive inadequate pain management. Regarding the social costs of chronic pain, these are absolutely not negligible; indeed they are comparable to those for cancer and cardiovascular diseases (Breivik, H. Collett, B., Ventafridda, V., Cohen, R., Gallacher, D., 2006).

What are the barriers to improving the management of pain? Prof. Kress said: "The deficit concerns more the lack of knowledge of the professionals on the mechanisms and management of pain. Chronic pain is stigmatized and national policies do not consider it as a real health problem. Research and patient education is lacking and also access to medicines and pain management is restricted." Seven strategic goals for improving the treatment of pain in Europe were determined:

1. Acknowledging pain as a limiting factor in the quality of life and as a priority for national health systems.
2. Information and access to adequate pain medicine.
3. Awareness of the social individual and overall pain.
4. Importance of training on the prevention, diagnosis and management of pain among health professionals.
5. Importance of pain research that needs to become a priority at national and EU level.
6. Building an EU platform for comparison of best practices and their impact on society.

7. Building an EU platform to monitor the news in pain management, services and results and to harmonize pain management in Europe.

These goals have not yet been achieved, there are some European countries that noted progress and countries that have remained fairly backward.

The national health systems of the various European nations are, in fact, very different and, therefore, the approach to pain management is different.

Prof. Kress then outlined how some European nations including Italy are activated nowadays.

Portugal → pain management is an integral part of the national health system: in 1999, the national day against pain was launched; in 2001, the national plan against pain was created; in 2003, pain has been recognized as the fifth vital sign; in 2004, the management of pain has been regarded as a specialist medical expertise; in 2008, the national plan for the control of pain was approved; in 2010, the national observatory on pain was activated; finally, in 2011, an electronic system for prescription of opioids was installed.

Germany → German society for the study of pain has decreed that the pain medicine is a mandatory part of the national curriculum of medical students and subject to examination. Since 1996 there is also a medical subspecialty on pain medicine with a specific Board of Control.

Austria → there is no such medical subspecialty; a course in pain medicine was set up at three universities, but is not recognized by the medical committee and by the medical association. However, there is an official diploma in pain medicine established by ÖGARI (Austrian Society of Anesthesiologists) from ÖGN (Austrian Society of Neurology) in collaboration with the ÖSG (Austrian Pain Society) with a final exam and two weeks of practice. At government level there is a monitoring body and not a dedicated observatory.

Ireland → the College of Anesthetists of Ireland has created the Faculty of Pain Medicine with a national diploma on pain management. The treatment of pain is, therefore, a medical specialty with a specific audit committee. In Turkey, the Turkish company on pain and pain on Israeli society has established a subspecialty "Algology" for an interdisciplinary specialization.

Prof. Kress said that looking to 2020 several steps to improve pain management need to be taken. These include: more education and training in pain medicine; medical and postgraduate education in academic institutions; support for research in pain medicine; communication with physicians and other professionals; maintaining contact with the community, patient groups, government and government agencies groups; above all, recognition for the subspecialty of Pain Medicine.

6. CONCLUSIONS AND CRITICAL ISSUES

As pointed out several times during the course of treatment, chronic pain affects not only those living with the disease and their families but also the health expenditure with costs reaching 2% of the GDP of the European countries.

The main cause of chronic pain is represented by diseases of the muscular – skeletal system, particularly those affecting the spine and lower limbs while only a small percentage of cases are due to an oncological disease. This explains why GPs are the main players in the first-line treatment of patients with this disease.

The chronic noncancerous pain is an important issue for public health and a difficult challenge for many general practitioners. The Law 38/2010, which is taken as an example in many countries, in Italy is still far from the citizens: it is absolutely necessary to bridge the knowledge gap of the majority of doctors and organizations, by intervening on their training with specific pre and post graduate courses. The current clinical practice on the pain treatment in Italy is substantially inadequate.

In general, at the central level a lot of steps forward have been made, but the problem emerges at the regional level.

It is clear that the concept of the network can be realized entirely, not only geographically but also among the many parties involved only with the synergistic contribution of the institutions, professionals working in care networks and the third sector, each with their own skills to ensure what is established by Law 38/2010.

Clear guidelines that include a guide to prescribing opioids are urgently needed. It is the only way to optimize the treatment in the context of primary health care and to avoid inappropriate use of opiates. It will reveal the cultural reform pending application of Law 38/2010 for the advancement of our health and for the protection of public health.

Finally, the UN calls for adoption of the Italian Law 38/2010 on pediatric palliative care as "model law" for the world legislation on the subject. The legislation will be drawn up on the basis of Italian law will be valid for all countries of the United Nations, starting from Africa and the Third World countries.

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