

Palliative care regulation and assisted death

José Ramón Cossío-Díaz¹, José Fernando Franco González-Salas¹, David Kershenobich-Stalnikowitz², Lorena Goslinga-Remírez³, Rodrigo Montes de Oca-Arboleya³, Laura Estela Torres-Morán³ and Mariana Calderón-Vidal⁴

¹Ministers of the Supreme Court of Justice of the Nation, México, D.F.; ²General Director, Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, México, D.F.; ³Colaborators in the proposal presented by Minister Cossío, México, D.F.; ⁴Anesthesiologist and consultant of Tómatelo a Pecho A.C., México, D.F.

Abstract

The present article aims to expose some reflections with regard to the way Mexican legal order regulates palliative care and its connection with the debate on assisted death. Herein, the authors analyze the contents of the General Health Statute –after a reform published in January 2009–, its Rules for the Provision of Healthcare Services and other regulations applicable to palliative care, with the purpose of promoting a public debate on the different forms of care available for people with a disease failing to respond to curative treatment. (Gac Med Mex. 2015;151:108-18)

Corresponding author: Suprema Corte de Justicia de la Nación, gacetasaludyderecho@gmail.com

KEY WORDS: Palliative care. Treatment of pain. Assisted death. Assisted suicide.

Introduction

This article presents some reflections with regard to the way Mexican legal system regulates palliative care and its connection with the debate on assisted death. The relevance of this theme becomes apparent if we review data of the National Institute of Statistic and Geography (INEGI - *Instituto Nacional de Estadística y Geografía*) with regard to the main causes of death in Mexico throughout the 20th Century and the period elapsed in the 21st. The figures, show clearly that a radical change has occurred. In table 1, the 10 main causes of death in 1920 and 2011 are presented, as well as life expectancy of men and women during these years¹.

Causes of death in the Mexican population over the last century have varied considerably: early in the 20th Century, infectious diseases were predominant and, currently, chronic-degenerative diseases are the most common. On the other hand, table 1 also shows that life expectancy has increased considerably. From these data, it is possible to infer that palliative care is becoming increasingly necessary, since people suffer from conditions that gradually reduce their quality of life more frequently. Infectious diseases, which prevailed as causes of death in the past, ended with people's lives in a short time because they have a reduced evolution period. In contrast, currently, chronic-degenerative conditions gradually deteriorate the health of patients, who, in many cases, live in pain and as it will be seen throughout this work, this situation must not to

Correspondence:

Suprema Corte de Justicia de la Nación
Pino Suárez, 2
Col. Centro, Del. Cuauhtémoc, C.P. 06065, México, D.F.
E-mail: gacetasaludyderecho@gmail.com

1. INEGI (1920-2011). Data obtained at the Instituto Nacional de Estadística y Geografía website: "Causas de Mortalidad". Available at: <http://www3.inegi.org.mx/sistemas/sisept/Default.aspx?t=mdemo107&s=est&c=23587>. [Downloaded: 13 December 2013].

Table 1. Ten main causes of death in 1920 and 2011 and life expectancy among men and women

1920	2011
Pneumonia and influenza	Heart diseases
Diarrhea	Diabetes mellitus
Fever and cachexia due to malaria	Malignancies
Whooping cough	Accidents
Smallpox	Liver diseases
Congenital malformations	Cerebrovascular conditions
Pulmonary tuberculosis	Assaults
Violent deaths (except suicide)	Chronic obstructive pulmonary disease (COPD)
Heart conditions	Influenza and pneumonia
Post-partum and delivery conditions	Perinatal conditions
Life expectancy:	Life expectancy:
– Men: 33 years	– Men: 73 years
– Women: 35 years	– Women: 78 years

be disregarded from the point of view of the human right to health protection.

The above described situation is what motivates us to write this article. We try to expose legal aspects that activate the public debate on the different forms of care available for people with a disease that fails to respond to curative treatment. In this work, the rights and obligations established by the General Health Statute and the regulations that establish the system to offer the care that those entail are analyzed in this paper. In concrete, the forms in which people can realize their rights are identified in the current legal framework, as well as the obligations and powers that healthcare providers have in order to protect the right to health.

To accomplish this objective, regulations on palliative care and assisted death will be examined from the perspective of the constitutional right to health protection. First, we have to start with a brief explanation of the elements of this right taking into account the contents of article 4 of the Mexican Constitution. This will allow us to identify, in broad terms, the obligations the State has to fulfill with regard to palliative care and comprehensive management of pain. Subsequently,

the contents of the General Health Statute, in its character of regulatory law of the referred constitutional precept, will be analyzed, as well as the recent additions to its Rules for the Provision of Healthcare Services.

From the above, we will try to answer two questions: what are the rights for people who suffer a disease that fails to respond to treatment? and is there a right to die under certain minimal conditions? The answers given to these questions will contribute to encourage public debate and will serve as a basis to question the forms established by the Mexican legal system for the exercise of those rights and whether it promotes their effective exercise or not.

The right to health protection as a reflection of an obligation of the State

The fourth paragraph of article 4 of our Constitution establishes that all persons living within the national territory have the right to health protection². The contents of this constitutional-hierarchy right are gradually shaped in the first place by legislative changes, interpretations by different public administration bodies and

2. The text of article 4 of the Mexican Constitution states: "Every person has the right to health protection. The law will define the bases and modalities for access to health services and will establish the concurrence of the Federation and the States on general public health, as disposed by Article 73, fraction XVI of this Constitution".

criteria issued by jurisdictional bodies to solve litigations posed by different stakeholders in the National Health System framework. This does not mean that the entire contents of the right to health protection depend on what the law and the other mentioned sources establish, but only that, in principle –and as long as legislative or administrative regulations are not challenged and declared unconstitutional or there is a more extensive interpretation by jurisdictional bodies– the “size” of the right itself will depend on what was foreseen in infraconstitutional sources.

Taking into account the above statement, we have to consider that article 3 of the General Health Statute establishes a list of general public health matters or subjects. The list includes concepts as diverse as: organization, control and surveillance of healthcare services provision and health facilities; mother-child care: visual, hearing and mental health; health education or human genetics, among others. It is worth mentioning that through the reform to the General Health Statute, published on January 5, 2009, comprehensive pain management was incorporated to the 3rd Article itself, in fraction XXVII bis. With this addition, it is apparently clear that the legislator’s intention was for this concept to be included within the right to health protection considered in article 4 of the Mexican Constitution.

Distribution of responsibilities in general public health matters

Once established that comprehensive care of pain –understood as care that goes beyond the mere palliation of pain– is part of the right to health protection, the first problem arising is to establish which authorities must fulfill this government obligation. In order to develop this subject, the second title, chapter II of the General Health Statute establishes a responsibility distribution mechanism. Especially, article 13, section A, defines what issues correspond to the federal authorities, whereas section B lists those that are the responsibility of the states. Fraction I of the latter establishes that state governments must organize, operate,

supervise and assess the provision of general public health services related to “comprehensive care of pain”, according to applicable regulations. Up to this point, it remains relatively clear which authorities must carry out actions to protect the human right to health with regard to comprehensive management of pain.

The rationale behind the distribution of responsibilities made by article 13 is not evident in this and many other cases. In other words, it is not easy understanding why some issues are assigned to federal authorities and others to the local ones. This situation can generate conflicts and hamper enforceability of rights since, in the absence of further reasoning behind assignment of responsibilities, it is not clear if each task was given to the most capable authority³.

Even if it is clear which issues are the responsibility of federal authorities and which to the states, it is very important to have elements to articulate the legal system in order to make it efficacious and not maintaining it as a set of dissociated regulations. First, a clear differentiation between regulatory orders is required and, second –based on the above–, regulations governing the relationship between the different subjects bound to comply with actions to ensure access to some palliative care for people who require it.

Other identified problem is the lack of correspondence between the expression “comprehensive pain treatment”, used in the general health matters listing, and the expression used in Title Eight Bis, “palliative care for terminally ill patients”. If we consider the legislative processes that gave way to the January 2009 reform, by means of which both concepts were added, it can be assumed that the referred title contains the development legislators tried to imprint on comprehensive pain treatment. This can be interpreted in two forms: first, it is possible to understand there is a legislative error because comprehensive pain management is only part of palliative care; and second, it is possible to consider that comprehensive pain management –as a general public health matter– should have had a further development in the law. This issue will be taken up again in the final reflections of this work once the current legal framework is discussed.

3. With regard to implications of responsibilities distribution, the Supreme Court of Justice of the Nation (Mexico) has pronounced itself in several cases. Especially, in plenary sessions held on April 25, 29 and 30 and May 2, 2013, the court resolved constitutional controversies 89/2009, 104/2009 and 6/2009. Broadly, in these issues, the way in which certain official standards issued by the Ministry of Health influenced on areas of responsibility of different municipalities was analyzed. See: Cossio Diaz JR, Lara Chagoyán R, Mejía Garza RM, Rojas Zamudio LP, Orozco y Villa LH. Constituciones locales, derecho a la vida, distribución de competencias y otros malentendidos. *Este País*. 2013;266:48-54. Available at: <http://estepais.com/site/?p=45353>. [Downloaded 27 November 2013]

Contents of legal regulation on comprehensive pain management and palliative care

As previously mentioned, due to the reform made in January 2009, the General Health Statute contains a section on palliative care for terminally ill patients. It contains four chapters: one on common rules, other dealing with the rights of terminally ill patients, one more dealing with the powers and duties of health institutions and, finally, one establishing the rights, powers and duties of physicians and healthcare personnel. Curiously, provisions developing the subject of comprehensive treatment of pain include exclusively individuals with a survival prognosis of less than 6 months and, hence, those who are not in this circumstance, but suffer from conditions involving pain, are completely unprotected.

From the common provisions chapter, different elements stand out. The first is that the goals of the section on palliative care are not set. These include: to safeguard terminally ill patients' dignity in order to ensure a "life of quality" for them through the required medical care and support for this purpose; to ensure for natural death to occur in dignified conditions; to establish and warrant their rights with regard to their treatment; to differentiate between curative and palliative care, as well as to establish the boundaries between defense of life and therapeutic obstinacy.

Additionally, the same chapter presents several definitions indicating the direction the interpretation of provisions contained this article and other lower-hierarchy regulations referring to palliative care must take. One definition that results highly relevant is that of the concept of "terminally ill patient". According to article 166, bis 1, it is that person with an incurable and irreversible disease with a survival prognosis of less than 6 months⁴. It seems reasonable stating that it

refers to individuals who have been diagnosed by a physician with a condition with a maximal likelihood of survival of 6 months, although this implies a high degree of uncertainty, since there are many factors that can influence the prognosis.

In addition to the definition of the subjects entitled to these rights, it is important to highlight that there is also a legal definition available on what is to be understood as "palliative care". This has been established to comprise "active and total care of those diseases failing to respond to curative treatment. Control of pain and other symptoms, as well as care of psychological, social and spiritual aspects". From this concept, two central elements to the care people with an end-stage disease are entitled can be deducted⁵. The first is that initial differentiation between curative and palliative treatment has to be established, which, as we will expose below, is better understood taking into account the contents of the General Health Statute Rules for the Provision of Healthcare Services. In article 138 bis 2, fraction V, it establishes that curative treatment includes "all measures supported by scientific evidence and ethical principles intended to offer possibilities to cure a disease".

The second relevant element deducted from the definition of "palliative care" is that pain control is just one of many aspects comprised by this concept⁶. We should bear in mind that in order for natural death under the most dignified conditions possible to be ensured, the patient must also receive psychological and spiritual assistance, as well as support within his/her social setting.

The definition of "palliative care" has shown an important evolution over the past few years. If we analyze the concept by the World Health Organization (WHO) we can notice that it has broadened from emphasizing on care for improving quality of life on final stages, to establish that care must be delivered since the earliest

4. Christakis NA, Lamont EB. Extent and determinants of error in physicians' prognoses in terminally ill patients. *West J Med.* 2000;172(5):310-3. Available at: <http://www.biomedcentral.com/1472-684X/1/1>. [Downloaded: 12 December 2013].

5. Article 166, bis 1, of the General Health Statute establishes: "For the purposes of this Article: I. End-stage disease will be understood as any recognized, irreversible, progressive and incurable condition at an advanced stage and with a survival prognosis for the patient of less than 6 months"

6. The term "palliative care" is very broad and its not restricted only to the management of pain, but to the management of essentially neurological symptoms such as anxiety, depression, anguish, dysesthesia, vertigo, etc., which commonly affect chronic and end-stage patients. In general terms, palliative care is designed only to mitigate suffering and does not relate to the treatment of disease etiology. Therefore, it is the physician's obligation to administer it to every patient in need. In general terms, these treatments are not controversial within the medical community and practically nobody rejects them.

7. Of note, the same Article 166 bis 1 of the General Health Statute, in fraction VIII, defines natural death as follows: "Natural death. The process of natural death of an end-stage patient, with physical, psychological and, if appropriate, spiritual assistance being available.

8. Sepúlveda C, Marlin A, Yoshida T, Ullrich A. Palliative care: the World Health Organization's Global Perspective. *Journal of Pain and Symptom Management*, U.S: Cancer Pain Relief Committee, Nueva York. 2002;24(2):92. Available at: <http://www.hpca.co.za/pdf/publications/Sepulveda.pdf>. [Downloaded 21 September 2013].

stages of disease⁸. The development of this concept has a close relationship with the type of diseases for which the WHO recommends it. Initially, it was associated almost exclusively with cancer; now, the situation is very different, since healthcare service providers have identified the need to offer it with regard to other conditions such as HIV/AIDS and chronic degenerative conditions including congestive heart failure, arthritis, multiple sclerosis, COPD, diabetes and kidney and or liver failure⁹.

In this context, among the concepts defined by the law, some others establishing limits to curative treatment also stand out. We refer to the concepts of "extraordinary means" or "extraordinary measures" and "therapeutic obstinacy"¹⁰. The first of them refers any treatment that the patient considers as "a load that is too heavy and the damage of which is larger than the benefits". This is a concept that addresses the patient's personal situation and privileges his/her wish to continue or not with a treatment intended to prolong his/her life.

In turn, therapeutic obstinacy is defined as "[the] adoption of disproportionate or useless measures in order to prolong life in a situation of agony". This concept is similar to that of "extraordinary means" because both presuppose the existence of a point where curative treatment is not only superfluous, but it becomes harmful because it prolongs the patient's suffering¹¹. In spite of the referred similarity, therapeutic obstinacy appears to have an objective nature, regardless of the treatment the patient is willing to receive. Both concepts indirectly settle what "curative treatment" is. It would have been convenient for the definition of the latter not to be reserved to regulatory provisions and to be established directly in the law, since this would make all these concepts clearer.

In addition to the definitions offered, the general provisions chapter also states that it is the duty of the

National Health System to ensure for end-stage patients to have full, free and informed exercise of the rights established by the law and other applicable regulations. In order to know how the National Health System is conformed we have to consider, the contents of article 5 of the General Health Statute, which states that all healthcare providers within the public –federal and of the states–, social and private sectors are part of it¹². Under these conditions, it remains clear that all persons, both natural and legal (corporations), that provide healthcare services are compelled to guarantee the different rights foreseen by the law for persons that face a disease with a survival prognosis of less than 6 months.

Once the definitions of the most relevant concepts have been noted and implicated subjects have been determined, we will proceed with a brief analysis on the way they relate to give way to a framework of rights and duties intended to ensure natural death in dignified conditions to patients in an end-stage situation.

In Chapter II of Title Eight Bis, the rights of terminally ill patients are determined, with the following standing out: the right to receive comprehensive medical care, to voluntarily leave the healthcare institution where they are hospitalized, to receive clear and timely information about their situation as well as their treatment options, to ask their doctor to give them medications to relief pain and to refuse receiving "any treatment they consider extraordinary"¹³. These and other more rights originate in the contents of article 166 bis and are developed in the rest of the referred chapter.

The list of prerogatives established by article 166 bis 3 contemplates the possibility for the patient to receive palliative care at his/her home. This situation is considered a significant challenge for healthcare providers, since it involves performing different activities outside of the premises they normally work at. Furthermore,

9. Kumar N. WHO Normative Guidelines on Pain Management: Report of a Delphi Study to determine the need for guidelines and to identify the number and topics of guidelines that should be developed by WHO. World Health Organization. Geneva. 2007. Available at: http://www.who.int/medicines/areas/quality_safety/delphi_study_pain_guidelines.pdf. [Downloaded 7 January 2014]

10. The definitions given by Article 166 bis 1 of the General Health Statute are the following: "For the purposes of this Title: (...) V. Therapeutic obstinacy will be understood as the adoption of disproportionated or useless measures in order to prolong life in a situation of agony; VI. Extraordinary means will be understood as those representing an excessively heavy load for the patient to bear, the damage of which is larger than its benefits; in which case, these means may be evaluated in comparison with the type of therapy, the degree of difficulty and risk they entail, the necessary expenses and application possibilities with regard to the results that can be expected from all of this; (...)".

11. This, regardless of medical and economic side-effects that can result from these behaviors.

12. The text of the referred article reads exactly: "Article 5. The National health System is constituted by Public Administration dependencies and entities, both federal and local, and natural or legal persons of the social and private sectors that provide healthcare services, as well as the mechanisms for actions coordination, and serves the purpose of enforcing the right to health protection".

13. To understand what this expression refers to, the general provisions chapter within title 8 bis establishes the following: "Article 166 bis1. For the purposes of this article: (...) VI. Extraordinary means will be understood as those representing an excessively heavy load for the patient to bear and the damage of which is larger than the benefits; in which case, these means may be evaluated in comparison with the type of therapy, the degree of difficulty and risk they entail, the necessary expenses and application possibilities with regard to the results that can be expected from all of this; (...)".

given that one of the main purposes of the statute on this subject is to ensure natural death in dignified conditions for people suffering from an end-stage disease, providing care at their homes is an important step.

Articles 166 bis 5 and 166 bis 6 foresee that competent legal adults in an end-stage situation have the right to discontinue the curative treatment they are receiving. In addition, they establish that the patient has the right to continue with strictly palliative treatment according to the contents of the law. The second of the referred subsections clarifies that voluntary discontinuation of curative treatment implies the cancelation of any procedure intended to counteract the disease, as well as the initiation of care intended to reduce pain or manage symptoms. This implies the statutory obligation for the physician specialist in the condition of the patient to interrupt, stop or not to initiate the administration of treatments intended to prolong life and allow for the disease to follow its natural course.

The law also establishes that patients who are only receiving palliative care because they decided to interrupt their curative treatment have the right to resume it. To exercise this prerogative, the decision must be conveyed in writing to the corresponding medical personnel. It is important to point out that all decisions taken by the patient with regard to his/her treatment must be respected by both his/her family and attending specialists in secondary and tertiary level institutions. It should be also pointed out that the law foresees that, in cases of emergency, when the patient is in no condition to express his/her consent and in the absence of family members a legal representative, legal guardian or trusted person, the decision to apply a surgical medical procedure or necessary treatment will be taken by the specialist and/or the Bioethics Committee of the institution where the patient is receiving treatment.

In addition to the rights of persons whose survival prognosis is less than 6 months, chapter II also foresees that every person, regardless of his/her health status, has the right to express his/her willingness to receive or not any treatment, in case he/she came to suffer from an end-stage condition and is not able to express his/her will. In addition to establishing this right, the General Health Statute states that the

person must be a competent legal and has to express his/her will in writing in the presence of two witnesses¹⁴.

On the other hand, chapter III of the same Title Eight Bis, concretely article 166 bis, develops the powers and duties of the National Health System institutions, that must offer services for the proper care of terminally ill patients since the moment the diagnosis is established. In order to fulfill their legal obligations, they must foster the creation of areas specialized on palliative care and ensure training and constant updating of their personnel. It should be noted that these institutions not only are compelled to provide care to patients, but also to offer guidance, counselling and follow-up to their family members or trusted persons when palliative care is provided at home.

In addition to the referred obligations and powers of institutions belonging to the National Health System, it is possible to identify other type of subjects on whom the legislation on palliative care is applicable: physicians and healthcare personnel. The respective regulation is found in chapter IV of Title Eight Bis, which establishes that specialist physicians at secondary and tertiary level institutions have the following obligations, among others: to maintain the patient informed on his/her situation, his/her treatment options –both curative and palliative– and the side-effects involved; ask the patient for informed consent to apply any treatment and to respect his/her decisions taken by the him/her. Additionally, consistent with the obligation of institutions that form part of the National Health System of maintaining their human resources duly trained, article 166 bis 14 establishes that attending physicians and all the members of their healthcare staff must be “humanly and technically” trained by authorized institutions.

The statutory obligations for attending physicians treating physicians include supplying “palliative drugs” to terminally ill patients, even if they cause a loss of consciousness or even shorten the patient’s life, provided it is done with the sole purpose of alleviating pain. This is established by article 166 bis 6, which also establishes that every action must be backed by the patient’s consent. The way in which it has to be granted should adhere both to the contents of the

14. To exemplify, the case of the Distrito Federal will be taken. In January 7 2008, the law of Advanced Directive for the Distrito Federal was published, as approved by the Legislative Assembly. This regulation establishes the requirements for the expression of the desire not to be subjected to treatments intended to unnecessarily prolong life to be valid. The advanced directive document must be personally subscribed before a public notary, but this can be done before healthcare staff and two witnesses if the grantor is an end-stage patient unable to appear before a notary. This shows that the Distrito Federal has a regulation that does not impose excessive requirements to people wanting to obtain this document.

General Health Statute itself –which in article 166 bis 15, fraction II specifies that consent must be written and before two witnesses– and to other applicable provisions.

The same article (166 bis 16) states that opioid analgesics can be used, reemphasizing that they will not be prescribed with the purpose of shortening the patient's life and it refers to applicable criminal law. Following the same logic, article 166 bis 21 states the following: "The practice of euthanasia, understood as mercy killing, as well as assisted suicide, is forbidden, as stated by the Federal Penal Code, under the provisions of this statute. Given the case, it shall be ruled by applicable penal provisions".

Given the contents of the law, it is clear that any means to cause or speed up the death of a terminally ill patient are forbidden; then, it is evident that any action that shortens life is not included within the concept of "palliative care". Furthermore, the article refers to the applicable penal legislation is made, a situation that not necessarily must be understood as mandatory for the state's legislative bodies, but that –within the logic of the categorical prohibition in the General Health Statute– clearly indicates it constitutes a behavior deserving criminal punishment. For example, the Penal Code for the Federal District (Mexico City, the national capital, is located within the Federal District) establishes a penalty of 1 to 5 years prison to any individual who helps another to commit suicide and, if the individual himself executes the killing, the punishment rises from 4 to 10 years.

In addition to the prohibition for medical personnel to administer drugs to shorten or end with the patients' life, the General Health Statute also forbids the implementation of extraordinary measures or treatments that fall under the concept of "therapeutic obstinacy" by attending physicians. As previously mentioned in the brief analysis of the definitions, both involve the administration of treatments that prolong the agony of the patient or that harm the patient's health more in comparison to the benefits they might provide. This circumstance is consistent with the rights of patients to receive information on their situation and to decide when to abandon a curative treatment and, given the case, to resume it.

Moreover, articles 166 bis 19 and 166 bis 20 establish that the medical personnel is compelled to provide

terminally ill patients with basic care and supportive measures¹⁵ and should not stop giving treatment by own decision, without the patient's consent, or in case the patient is disabled to express his/her wishes, that of his/her family or trusted person. The described legal framework shows that physicians are obligated to provide certain minimal care to the patient with a survival prognosis of less than 6 months. Nevertheless, the attending physician is compelled to recognize when a curative treatment prolongs agony or harms, rather than benefit, the patient. Consequently, knowing his/her situation, the patient is duly empowered to decide if he/she wants to continue with curative treatment or not, and the physician must obey that decision ensuring that the patient receives the necessary care to achieve a natural death in dignified conditions.

Development of the contents of the General Health Statute in the Rules for the Provision of Healthcare Services

Once a general overview of the rights and obligations foreseen by the General Health Statute for the care of terminally ill patients has been presented, we consider it necessary to analyze their development at the regulatory level. On November 1 2013, a reform of the General Health Statute's Rules for the Provision of Healthcare Services was published in the Federal Official Gazette, by means of which a chapter specifically dedicated to palliative care was added.

Firstly, with the addition to the rules, new objectives were established, the most relevant being the prevention of possible actions and behaviors resulting in neglect or therapeutic obstinacy, as well as application of extraordinary measures; establishment of treatment protocols for terminally ill patients and to provide support to the patient's family or trusted person to be able to cope with the disease and, given the case, with mourning.

Another important aspect of this addition is the fact that it incorporated definitions that help to interpretate the contents of the legislation. As previously mentioned, one of the most important concepts foreseen in the rules' new chapter is that of "palliative care". This is vitally important, since it helps to understand the scope of provisions referring to palliative care that don't include measures intended to cure the patient's disease.

15. "Article 166 bis 1. For the purposes of this section: (...) II. Basic care will be understood as hygiene, nutrition and hydration and, if required, patent airway management; (...)".

Although we consider that this concept should have been foreseen by the law since the beginning, it is quite convenient that it was defined in regulatory provisions.

Additionally, the previous rules establish that pain should be understood as “the sensory experience of physical and emotional suffering, variable in intensity, which can occur with real or potential damage to the tissues of the patient”. This definition motivates the following comments: first, it does not match the definition given by the International Association for the Study of Pain, which conceives it as an unpleasant sensory and emotional experience associated with real or potential tissue damage¹⁶; and second, this definition of pain does not necessarily refer to the diseases that threaten the life of those who suffer from them, a situation that reinforces the idea with regard to the lack of provisions to articulate the comprehensive treatment of pain for persons that don't have an end-stage disease.

Other concepts introduced by the rules and that are considered important to the implementation of provisions in matters of palliative care are those of “treating physician” and “palliative care plan”. These maintain a close relationship, since the first is understood as the responsible party for the care and following the plan, which is defined as the “set of actions indicated, programmed and organized by the “trating” or attending physician, complemented and supervised by the multidisciplinary team, which must be provided according to the specific condition of the patient, offering the possibility to control the symptoms associated with his/her condition. It can include the participation of family members or voluntary personnel”. This concept appears to be an important step in the provision of palliative care since, in spite of the uncertainty that may arise with regard to how the patient's disease may evolve, the regulation sets the standard in order for the different forms of treatment to occur in an ordered manner and according to the adequate protocol for the needs of each individual.

It should be noted that at the Rules foresee, the collaboration of a multidisciplinary team comprised by different persons for the development of the Palliative Care Plan. According to article 138 bis 19, the team must be comprised, at least, by: the attending physician, a nurse, a physiotherapist, a social worker or equivalent, a psychologist, an algologist or anesthetist,

a nutriologist and other professionals, technicians and assistants required by each particular case. Participation of all these stakeholders implies a huge challenge, since it requires availability of trained personnel in the whole country. It can be assumed that in urban areas this requirement could be fulfilled more easily than in rural areas, which is why authorities in charge of implementing the provisions under analysis must emphasize on generating the required conditions and sufficient human resources to ensure that all patients in need of palliative care have a plan designed by a multidisciplinary team, as stipulated by the regulation.

A third issue worth mentioning is that article 138 bis 3 of the reformed rules states that the Ministry of Health will issue the Official Mexican Standard (NOM) that foresees the criteria for the care of terminally ill patients by means of palliative care in institutions belonging to the National Healthcare System. With this regard, it should be noted that this standard has not been issued, although we were able to find a project that will be described later. In addition, regulatory provisions foresee that the Ministry itself should provide counseling and technical support to institutions and facilities of the public, social and private sectors that provide palliative care services.

On the other hand, with regard to the rights of patients suffering from a terminal disease, the rules establish the conditions to ensure they are provided with the necessary information to know their situation and decide on their curative and palliative treatment. In addition, it is stipulated that patients can ask for additional information and, in case they consider it necessary, for a second opinion.

As previously mentioned, regulatory provisions introduce the Palliative Care Plan as the guiding principle of the care terminally ill patients must receive. According to article 138 bis 10 of the rules, care can not be provided if this plan is not available. With regard to the training and updating that healthcare professionals, technicians and assistants must receive, the rules establish that National Healthcare System institutions must promote for it to occur at least once yearly. Furthermore, the same article stipulates that the creation of specialized areas referred by the law must adhere to the contents of the NOM on the subject, taking into account the resources available at the institution.

16. International Association for the Study of Pain (IASP). Pain terms. Pain. 2012. Available at: http://www.iasp-pain.org/AM/Template.cfm?Section=Pain_Definitions#Pain [Downloaded 20 January 2013]

Moreover, regulatory provisions refer to specific drugs and consumable goods for the management of pain in terminally ill patients, the supply of which must be sufficient in institutions and facilities that provide palliative care. On this regard, it should be mentioned that the 12th Edition of the Basic Drug List and Formulary¹⁷, approved by the Council of General Public Health, includes a variety of opioid drugs considered by the WHO as essential to the treatment of pain as a part of palliative care¹⁸. From the above, it is possible to conclude that the administrative provision that determines which drugs are considered to be essential is consistent with international standards. This does not mean the actual supply of the drugs required to provide palliative care is adequate, but since they are considered as basic supplies, this makes it easier for healthcare providers to comply with the obligation of having sufficient supplies for those in need of palliative care.

Importance of the Mexican Official Standard on the subject

Finally, some brief observations with regard to the previously mentioned project of a NOM establishing the criteria for the care of terminally ill patients through palliative care¹⁹. First, it is important to mention that the project was published before the reforms that incorporated the right to receive palliative care to the General Health Statute were issued. In spite of this fact, both in current legislation and in the referred project the primary objective is, improvement of the quality of life of persons with an end-stage disease. In addition, it is relevant that the NOM project offers guidelines for home, outpatient and inpatient care, as well as for the treatment of emergencies, a situation that should be taken care of in any future project.

Final reflections

Going back to the questions stated at the beginning of this paper, we can establish that people with a disease that fails to respond to curative treatment and whose survival prognosis is less than 6 months have several rights. Conversely, people suffering from a

chronic degenerative condition without a survival prognosis of less than 6 months are unprotected since, although comprehensive treatment of pain is an element of the human right to health protection within the Mexican legal system, its implications are not developed in the General Health Statute.

From the legislative discussion processes that lead to the reform published in January 2009, it can be observed that the legislator tried to incorporate a series of statutory provisions that would generate a system for the care of end-stage patients. This is considered a great step forward. However, what happens with people who have their quality of life reduced by pain or other symptoms caused by a condition with a prognosis greater than 6 months or non life-threatening? Certainly, a combined interpretation of articles 3 and 13 of the General Health Statute would suggest that a right to comprehensive treatment of pain exists along with the obligation of local authorities to provide all the means to make it real. However, it is difficult to establish under which conditions comprehensive treatment of pain would have to be given to someone who doesn't have an end-stage disease but is in severe pain.

Regardless of the above, it would be desirable for the legislator to develop a series of provisions intended to regulate comprehensive treatment of pain and other forms of palliative care that could benefit people that suffer from non-life threatening conditions or that have a prognosis of more than 6 months of life. Furthermore, it would be convenient to eliminate the lack of consistency between the expressions used in the listing of general public health matters and those developed as titles in the General Health Statute. Should this suggestion be accepted, the distribution of responsibilities would be easier to understand.

In addition, it can be claimed that, within the Mexican legal system, all persons have the right to die in a context of respect to human dignity. From the analysis of the rights and obligations established within the Mexican legal system, we can conclude that patients with a survival prognosis of less than 6 months are entitled to receive special care that improves their physical status –by mitigating pain– and that prepares them to cope with the reality of death from the psychological and spiritual points of view.

17. Published in the Federal Official Gazette on May 21st 2013.

18. World Health Organization. WHO Model List of Essential Medicines. 18th ed. 2013;6. Available at: <http://www.who.int/medicines/publications/essentialmedicines/en/index.html>. [Downloaded 7 January 2014].

19. Published in the Federal Official Gazette on December 22nd, 2008.

Other conclusion that can be reached after analysing the different provisions that regulate palliative care is that the family members of a terminally ill patient have as well as their persons of trust also have the right to receive support to cope with the disease and, if necessary, with mourning. Furthermore, people comprising the familial setting of the patient, according to the legal framework, must collaborate with healthcare providers, especially if the patient decides to be taken care of at home. This poses interesting challenges for those in charge of regulating and overseeing medical care, the same that have to be taken on if it is intended for terminally ill patients to close their life cycle in a setting that is familiar to them, which contributes to preserve their dignity.

Additionally, within the Mexican legal framework the right of any person to refuse to receive any treatment stands out. This entitlement is especially important for people with an end-stage diagnosis, since it allows for them to decide how to live the final stage of their life, regardless of the opinions their physicians and relatives, since they are compelled to respect the decisions taken by the patient. Thus, the Mexican legal system not only allows the patient to refuse care, but conceives this right as a way to preserve human dignity. This conclusion is reinforced if we take into account the prohibition to physicians with regard to applying extraordinary measures or incurring in behaviors considered within the concept of “therapeutic obstinacy” or the acknowledgement of the wish of the patient to stop receiving a curative treatment, even when this leads to his/her death.

On the other hand, given the prohibition of euthanasia and assisted suicide by the General Health Statute, it can be claimed that terminally ill patients are not entitled to ask for help to accelerate their dying process. On the contrary, anyone who induces or takes part in any process that could be considered euthanasia is criminally punished. Although from the medical point of view euthanasia is completely excluded from the theme of palliative care, from the legal point of view, there is a relationship between these two subjects because of the way they were treated in the General Health Statute. Title Eight Bis, clarifies that means that deliberately shorten the patient’s life should not be used, and establishes the legally accepted actions with regard to terminally ill patients.

If penal codes, both federal and for different states and the Federal District are reviewed, it is possible to observe that there is uniform regulation with regard to behaviors considered criminally relevant, although variations exist with respect to the punishments they

establish. In general terms, there is a construct that could be described as follows: a patient facing a terminal illness is not entitled to ask for help to terminate his/her life, either by the administration of a substance that causes his/her death or by being provided with the means to do it. This possibility, which in the Mexican legal system is denied, remains open in other countries under very specific conditions. This is the case of the U.S.A. (in the states of Oregon, Washington and Montana), Belgium, the Netherlands, Switzerland and Argentina.

In this context, from the point of view of the terminally ill patient, a very interesting question arises, which could be phrased as follows: is the prohibition of euthanasia constitutionally valid? Even when this work does not pretend to give an answer to this question, it is possible to suggest that the prohibition established by article 166 bis 21 of the General Health Statute is debatable, especially if we considered that the 1st article of the Constitution proscribes every form of discrimination motivated, among other causes, by health conditions or any other that threatens human dignity. With this in mind, we wonder what would happen if a person with a terminal disease wants to be administered a substance that causes his/her death because he/she considers to be leading a life in conditions he/she finds highly undignified? In this situation, a collision would occur between the right to health protection –which basically aims to prolong life in dignified conditions– and the right to live free of discrimination due to health-related reasons or any other that threatens human dignity. The courts would have to resolve by relating the contents of constitutional articles 1 and 4 in order to determine if the prohibition established by the referred article 166 bis 21 is constitutionally valid.

In addition to what the legislation foresees, we should point out that regulatory dispositions constantly refer to the NOM, which has not been issued by the Ministry of Health in order to establish the standards to be followed for the care of terminally ill patients through palliative care. The fact that this standards have not been issued is an obstacle to standardization of services, since there are no parameters to know what kind resources –human and material– must a unit specialized in palliative care have.

Also noticeable is the central role played by the specialist physician in secondary and tertiary level institutions as a liable party with regard to the provision of palliative care. As previously established, the General Health Statute’s Rules for the Provision of Healthcare Services foresee that a multidisciplinary team

comprised by different persons should take part in the development of the palliative care plan, which includes, at least, "a nurse". It should be noted that international trends lean towards giving a larger role to male nurses who, according to Mexican legal framework, are able to participate in the plan since, with adequate training, they could assume a more active role in services involved with palliative care such as, for example, the prescription of drugs.

Additionally, the legal framework applicable to palliative care shows that the idea that palliative care should only be given in secondary and tertiary care institutions still prevails. This situation is deemed as not being the most favorable to open access to services, since the patient has to travel to the institutions and these are usually found only in the main cities. In this setting, it would be convenient to consider the possibility for the legal framework to incentivate the participation of primary level institutions through their personnel. This way, palliative care would be accessible to more people, and those skilled to provide to provide follow-up attention more easily.

The analysis presented in this paper reveals that the legal framework seeks for the patient to be able to receive the services in the most convenient way, and it even opens the possibility to do it at home. Therefore, it would be ideal for care to be offered mainly in primary level institutions or for clinics specialized in symptom management to be installed. This would also result in a benefit for institutions and personnel that

provide the care, since it would be easier to have control on the patient's situation and the resources he/she requires. Especially, let's think of the case of drugs, which, as previously mentioned, are controlled substances and are highly controlled on the side of prescription but, once supplied to the patient, no legal control is observed to prevent their abuse.

In conclusion, the study of the legal framework suggests that it would be desirable for different authorities involved to presented in this paper complete the regulatory system on the subject (law, rules NOM and other administrative provisions), in order for regulatory changes to start reflecting on practice and conditions to be in place so that patients who require palliative care are able to fulfill their rights. This is why the legislator must embark on the task of issuing the required provisions in order for people suffering considerable pains, although not caused by a life-threatening condition, to have access to adequate treatment. In addition, health authorities must develop the necessary regulatory and administrative provisions to ensure that all persons requiring such care have access to services that make their right to health protection effective.

Acknowledgements

The authors are grateful to doctors Julio Sotelo Morales and Juan Wolfgang Zinser Sierra for their comments for the preparation of this document.