

Hospital Bioethics Committees Comités Hospitalarios de Bioética

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Abstract:

Hospital bioethics committees are collegiate bodies that represent a space for analysis, discussion, and support in bioethical dilemmas that arise in medical practice and teaching in the area of health. In Mexico, they are mandatory for health care establishments, according to their complexity and level of resolution. Its legal regulation is found in the norms of health law and the criteria that they issue in their opinions and recommendations are guiding criteria for those who make decisions in the clinical field and are a source of law.

Keywords:

Bioethics. Hospital Bioethics Committees. Legislation.

Resumen:

Los comités hospitalarios de bioética son cuerpos colegiados que representan un espacio para el análisis, discusión y apoyo en los dilemas bioéticos que surjan en la práctica médica y en la docencia que se imparte en el área de la salud. En México tienen carácter obligatorio para los establecimientos de atención médica, de acuerdo a su complejidad y nivel de resolución. Su regulación jurídica se encuentra en las normas de derecho sanitario y los criterios que emiten en sus opiniones y recomendaciones son criterios orientadores para quien toma decisiones en el ámbito clínico y son fuente del bioderecho.

Palabras Clave:

Bioética. Comités Hospitalarios de Bioética. Legislación.

INTRODUCTION

In medical practice, dilemmas eventually arise in decision making in light of the prevailing bioethical principles in the relationship between the staff and the user of health services, especially medical care.

Because of this, analysis, discussion and support are required to address them and to be able to issue a recommendation addressed to those who have the power or duty to make decisions.

This task is entrusted to the so-called hospital bioethics committees. These committees are often confused with research ethics committees, medical ethics committees, or committees in charge of hearing cases of medical malpractice.

An important precedent in the emergence of these committees was the case of Karen Ann Quinlan, who at 21 years of age, after ingesting alcohol and tranquilizer drugs, lost consciousness and was admitted to Newton Memorial Hospital in New Jersey in a coma. After several months, her parents requested the suspension of mechanical ventilation and life-sustaining care. The petition went all the way to the New Jersey Supreme Court, where Justice Richard Hughes ordered that an ethics committee be consulted to assist in the decision. This has been considered the germ of hospital bioethics committees.

This article will review the concept of the hospital bioethics committee, its legal regime, integration, functions, and competence, to identify its obligatory nature and usefulness in the provision of health services.

WHAT IS A HOSPITAL BIOETHICS COMMITTEE?

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There are several concepts and definitions of a hospital bioethics committee, both from doctrine and legislation.

On one hand, Article 41 Bis of the General Health Law stipulates that hospital bioethics committees will be responsible for the analysis, discussion and support in decision-making regarding bioethical problems that arise in clinical practice or in teaching in the health area, as well as for promoting the preparation of institutional ethical guidelines and guides for medical care and teaching.

On the other hand, Feito Grando (2005) states that these committees are interdisciplinary, plural, and open groups, whose mission is to make decisions in situations of conflict and whose validity is mainly based on the idea that dialogue between all those involved is essential for decision-making.

For its part, the National Bioethics Commission (2015) points out that hospital bioethics committees are bodies that represent a collegiate body, with professional competence, high scientific and technical soundness, objectivity, impartiality, and honesty in their actions.

LEGAL FRAMEWORK

As mentioned above, Article 41 Bis of the General Health Law mandates that, according to their complexity and level of resolution, medical care facilities will have a Hospital Bioethics Committee that will be subject to the legislation and criteria established by the National Bioethics Commission.

To that effect, in compliance with the Decree reforming various provisions of the diverse one creating the deconcentrated body called the National Bioethics Commission, published on September 7, 2005, reforms published in the Official Gazette of the Federation of February 16, 2017, that Commission has issued the National Guide for the integration and operation of the Hospital Bioethics Committees. Furthermore, the Ministry of Health of the Federal Government issued the Agreement by which the General Provisions for the Integration and Operation of Hospital Bioethics Committees are issued and the hospital units that must have them are established, under the criteria established by the National Bioethics Commission, published in the Official Gazette of the Federation on October 31, 2012, and which was amended employing a different one published in the same Gazette on June 6, 2018.

These Committees are also considered in other regulations, which are mentioned further on, such as the Regulations of the General Health Law on the Provision of Health Care Services and Transplants, as well as the Mexican Official Standard NOM-011-SSA3-2014, Criteria for the care of terminally ill patients through palliative care.

Given the processing of personal data by these committees, the general rules that have been enacted in the Mexican legal system regarding their protection are applicable, such as the General Law for the Protection of Personal Data in Possession of Obligated Parties -with its correlative local laws- and the Federal Law for the Protection of Personal Data in Possession of Private Parties, with their respective regulatory provisions.

At the international level, the United Nations Educational, Scientific and Cultural Organization (UNESCO) Guide Number 2 "Functioning of Bioethics Committees: Procedures and Policies" (2006) classifies ethics committees into four types: regulatory and/or advisory committee, health professional association committee, health care/hospital ethics committee, and research ethics committee. The purpose of the first is to advise public officials on the generation of national scientific and health policies. Health Professional Association Committees deal with bioethical issues raised by health professionals. Health Care/Hospital Ethics Committees discuss issues centered on patient care in medical practice. Finally, research ethics committees review clinical trials involving human subjects. These Committees are also considered in other regulations, which are mentioned further on, such as the Regulations of the General Health Law on the Provision of Health Care Services and Transplants, as well as the Mexican Official Standard NOM-011-SSA3-2014, Criteria for the care of terminally ill patients through palliative care.

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The same Guide mentions that sometimes problems are discussed jointly between the health professional association committees and the health care/hospital ethics committees, which can lead to confusion about the role of each of them.

For the sake of clarity, it is advisable to cite the objectives set for each committee in the Guide (2006):

- Regulatory and/or advisory committees: To establish appropriate scientific and health policies for the citizens of the Member States, in matters of public health, welfare, and rights.
- Health professional association committees: to establish appropriate professional practices for patient care by doctors, nurses, pharmacists, and allied professionals.
- Health care ethics committees: to improve patient-centered care in hospitals, outpatient clinics, long-term care facilities, and hospices.
- Research Ethics Committees: to protect participants in human research studies while acquiring generalizable biological/biomedical, behavioral, and epidemiological knowledge about pharmaceuticals, vaccines, and instruments.

From the aforementioned, it can be seen that the committees of health professional associations and health care ethics committees have objectives in which bioethical dilemmas can be addressed.

FUNCTIONS OF THE HOSPITAL BIOETHICS COMMITTEE.

In terms of the Agreement by which the General Provisions for the Integration and Functioning of the Hospital Bioethics Committees are issued and the hospital units that must have them are established, per the criteria established by the National Bioethics Commission, the Committees will have the following functions:

- To issue Resolution regarding the Bioethical Dilemmas that are placed under their consideration, based on a systematic analysis, propitiating prudent, reasoned, and substantiated decision making, thus contributing to safeguarding the dignity, rights, safety, and welfare of all current or potential participants in the provision of health care services and teaching that is imparted in the health area.
- Act in the interest of the participants in the provision of hospital services and the communities involved, taking into consideration national and international bioethical documents, laws, and national and facility regulations.
- Ensure that access to health services and resources is contemplated in institutional care protocols.
- Develop actions to contribute to preventing possible conflicts of interest that may arise in medical care, through guiding protocols for action, considering the socio-economic and cultural context and congruence

with the historical moment and the current legal framework.

- To develop a set of activities that help the members of the Committee and the health personnel of the Facility to incorporate information, knowledge, and behaviors for the identification and possible resolution of bioethical dilemmas and thus promote the permanent bioethical education of its members and the personnel of the facility.
- Submit an annual report of activities to the head or director of the facility within the first thirty calendar days of the year.

Furthermore, the National Bioethics Commission, in the National Guide for the Integration and Operation of Hospital Bioethics Committees (2015), has classified the functions entrusted to these groups into three types:

The consultative function is developed at the request of healthcare personnel, the patient, family members, or legal representatives, so that, utilizing expert opinion, they will analyze the case for the formulation of recommendations. That is to say, from the request for the intervention of the Committee, it will study the case of the dilemma in the light of the bioethical principles and will issue the suggestion to the interested party in the decision making.

It is important to emphasize that the Committee's pronouncement does not constitute a sentence that imposes a duty on those involved in the dilemma.

The guiding function makes it possible to anticipate bioethical conflicts since it will establish useful criteria for the eventualities that may arise due to the circumstances surrounding each case.

By way of example, the intervention could take place in the case of decision-making procedures involving conflicts of value, such as the refusal of treatment and the lack of capacity to give consent. Through this function, the Committee will foster an appropriate relationship between the healthcare personnel and the patient, making them aware of the implications of their own or third party's decision making.

The educational function refers to the promotion of bioethical knowledge through training and continuous updating of health personnel -conferences, workshops, seminars, etc.-, and dissemination among users of health services and their families to sensitize them to the importance of bioethical debates. The dilemmas that arise in health care are dynamic, so a permanent teaching-learning process is unavoidable.

These Committees are linked to bioethical dilemmas, so they will not replace the individual in decision making and will act to the extent that the request for intervention allows. Neither do they analyze medical malpractice, labor, administrative or legal

problems, nor will they be considered activist groups. The review of research protocols on human beings is outside their functions since research ethics committees exist for that purpose. According to the Regulations of the General Health Law on Transplants, a representative of the Hospital Bioethics Committee will participate in the Internal Donation Coordination Committees and the Internal Transplant Committees.

Nonetheless, in its own opinion, Article 166 Bis 11 of the General Health Law and section 9. 4 of the Mexican Official Standard NOM-011-SSA3-2014, Criteria for the care of terminally ill patients through palliative care, unduly grants the Hospital Bioethics Committee the function of deciding to apply a treatment or surgical procedure, if a terminally ill patient presents a medical emergency and there is the incapacity to express informed consent and there is no family member, legal representative, guardian or person of his trust who can decide in substitution.

In such a case, the so-called presumed consent is given and it corresponds, in the exercise of the principle of beneficence, to the doctors authorized by the establishment to decide, with the agreement of at least two of them and recording this situation in the clinical record, in terms of Articles 51 Bis 2 of the General Health Law and 81 of the Regulations of the General Health Law on the Provision of Health Care Services.

INTEGRATION AND OPERATION

Given the multidisciplinary nature of Bioethics, Article 41 Bis, section II, of the General Health Law provides that Hospital Bioethics Committees will be made up of medical personnel from different specialties and professionals in psychology, nursing, social work, sociology, anthropology, philosophy or law who have training in bioethics.

In this regard, the National Guide for the Integration and Functioning of Hospital Bioethics Committees (2015) states that its integration should be multidisciplinary and plural, with health professionals, bioethics experts, professionals from non-medical areas, lawyers with knowledge in health matters, and representatives of the affected nucleus.

To guarantee their autonomy in the issuance of their pronouncements, the management of the facility should not be part of these Committees. By way of example, the Guide points out the intention of multidisciplinary integration: medical professionals clarify the clinical data of the case; the bioethics expert leads the reflection of the principles in conflict; the lawyer will analyze the legal scope of decision making, and the representatives of society contribute their opinion as users of

health services -in some committees, the so-called citizen endorsements are invited.

The requirements to be part of these Committees set in the Guide of the National Bioethics Commission (2015) are:

- Have a track record that demonstrates honesty and commitment (references from peers, jobs, community, and/or the organization to which he/she belongs).
- Document professional experience.
- Have some education or training in clinical bioethics, preferably.
- Be committed to continuous training in bioethical knowledge, from a secular and scientific perspective.
- Possess an interest and be willing to develop the ability to listen respectfully, **and argue rationally and reasonably.**
- Be tolerant, reflective, prudent, and honest.
- Represent the interests of the community using health care services.
- Maintain the commitment to remain for the period established by the Committee itself and perform its tasks.
- Admit and disclose conflicts of interest, if any.
- Be committed to the care of health care participants.
- Shall not belong to the hospital's governing body.

The purpose of these requirements is to ensure that the members of the Committee have the competencies, interests, and moral solvency for bioethical analysis. If someone does not have experience in bioethics, he/she may assume the commitment to receive training during the six months following his/her integration.

The Hospital Bioethics Committees will be integrated by:

- The president;
- A Vocal Secretary;
- Members, and
- External Consultants.

The President is essentially responsible for convening and chairing the sessions, promoting bioethics training, and notifying applicants of the Committee's recommendations. The Vocal Secretary will receive the requests for intervention, prepare the minutes of the sessions, keep the file updated and integrate the annual program of activities. The Vocal Members shall participate in the analysis and deliberation of the cases presented and collaborate with the training activities. The External Consultants will advise the Committee in the evaluation of bioethical dilemmas, basing their opinions on the discipline that motivated their invitation.

All members are obliged to guarantee the confidentiality of the information to which, due to their participation, they have access.

The Hospital Bioethics Committees will meet in ordinary sessions at least 6 times a year and in extraordinary sessions in those cases that require a quick response to the cases presented. For the sessions to be valid, the President and at least half plus one of the total number of members must be present.

The recommendations shall be delivered in writing to the applicant, and shall include, as a minimum:

- Problem presented to the Committee.
- Documents reviewed.
- Name of the applicant.
- Date and place of the recommendation issued.
- Name and registration code of the Committee that issued the recommendation.
- Statement of the recommendation(s) issued.
- Date and signature of the chair or secretary of the Hospital Bioethics Committee.

For each of the sessions, the corresponding minutes must be prepared.

The Hospital Bioethics Committees must request their registration before the National Bioethics Commission by the provisions issued for such purpose.

IMPORTANCE OF HOSPITAL BIOETHICS COMMITTEES.

As mentioned previously, Hospital Bioethics Committees constitute a space for analysis, reflection, and deliberation of the bioethical dilemmas that will eventually arise in medical practice.

Given their multidisciplinary nature, it will be possible to have different points of view that are more objective and very useful for the recommendations issued.

It is important to emphasize that the Hospital Bioethics Committees will act whenever there is a request for their intervention since it is up to the person to express if he/she considers that there is a conflict between the principles that protect his/her rights and govern his/her actions.

The recommendations and opinions issued by these multidisciplinary groups are part of the sources of law, particularly bio law and health law since they are criteria issued in light of the prevailing bioethical principles in medical practice.

Therefore, the Committee's file must be kept orderly and up to date for consultations required in the analysis of subsequent cases with similar characteristics.

The difference that exists with the Research Ethics Committees has been exposed so that the hospital Bioethics Committees are not allowed to approve research protocols on human beings.

In the deliberation of the cases presented to the Committees, respect for the plurality of thought and freedom of expression must be guaranteed.

CONCLUSIONS

To conclude, the hospital bioethics committees have as an antecedent the judicial decision in North American law to consult a group of experts to have the technical and ethical elements that will support the authorization or non-authorization of life support for a patient who had remained unconscious for a considerable time.

Its obligatory nature is based, particularly, on article 41 bis of the general health law.

They should not be confused with committees in charge of reviewing research protocols on human beings or those that review cases of medical malpractice.

Their recommendations are not binding but are guiding criteria for decision-makers in medical care.

In its integration, the management of the facility will not participate, to ensure autonomy in its pronouncements.

The criteria it issues are very useful for the legal regulation entrusted to bio law and health law.

In Mexico, the legal norms, in the opinion of this author, have come to grant them excessive permission to grant in substitution the informed consent of terminally ill patients, when it is not possible to obtain it from him or her or someone legitimized by kinship or legal representation.

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