

Patient safety and the principles of beneficence and non-maleficence

La seguridad del paciente y los principios de beneficencia y no maleficencia

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Abstract:

On one hand, patient safety actions represent a means to avoid unsafe practices during medical care, establishing rules to instruct health personnel not to be negligent or carry out behaviors that produce or increase the risks inherent to medical practice. On the other hand, bioethics constitutes a discipline to protect the dignity of the patient, against interventions in their entirety to recover, improve or preserve health. In particular, the principles of beneficence and non-maleficence of so-called principlalist bioethics are fulfilled with those actions that are aimed at avoiding harm to the patient, through the observance of rules closely related to said principles.

Keywords:

Bioethics. Patient safety. Beneficence and Non-maleficence

Resumen:

Las acciones para la seguridad del paciente representan un medio para evitar las prácticas inseguras durante la atención médica, estableciendo reglas para encausar al personal de salud a no ser omisos o realizar conductas que produzcan o incrementen los riesgos inherentes a la práctica médica. Por otra parte, la bioética constituye una disciplina para proteger la dignidad del paciente, frente a las intervenciones en su integridad para recuperar, mejorar o conservar la salud. En especial, los principios de beneficencia y no maleficencia de la llamada bioética principlalista, se ven cumplidos con esas acciones que están dirigidas a evitar el daño en el paciente, mediante la observancia de reglas íntimamente relacionadas con dichos principios.

Palabras Clave:

Seguridad del paciente. Beneficencia y no maleficencia. Legislación

INTRODUCTION

The evolution in the development of new biotechnologies of scientific investigation in the field of health disciplines, particularly in the medical practice, the complexity of new diseases, and the possibility of applying procedures to try to improve the quality of life and to keep death border requires a safer practice each time, intending to avoid or decreasing unsafe actions that patients could suffer.

Thus, international organizations and the authorities of different countries have implemented programs and actions for patient safety, from the identification of the most frequent risks that are presented during the provision of medical care.

Esos programas y acciones deben ser eficaces, por lo que les ha reconocido en diversas normas jurídicas, como parte de los principios científicos -con énfasis en la *lex artis*- que rigen la

práctica médica, dentro de las llamadas obligaciones de medios, imponiéndose su obligatoriedad.

These programs and actions must be efficient since they have been recognized in diverse legal standards as part of the scientific principles with emphasis on the *lex artis*- that rule the medical practice, within the called medical obligations, imposing its obligatory.

In the bioethical context, patient safety is connected with the principles of beneficence and non-maleficence, and whose exercise corresponds to the health personnel. Thus, it is a safe practice whose benefit is to the patient from evading and causing eventual damage.

The World Health Organization's statements with the World Alliance for Patient Safety, its International Goals, World Medical Association Declarations, and the Secretarial. The agreement will refer to Mexico declaring as imperative the

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compliance of eight essential actions to safeguard patients and the relationship within the bioethical principles mentioned.

WHAT IS PATIENT SAFETY?

According to the World Health Organization, the Patient Safety Action Plan 2021-2030 refers to a framework of activities organized to create cultures, processes, procedures, behaviors, technologies, and healthcare environments that decrease the risks constantly and sustainably reduce the occurrence of avoidable damages. As a result, they make mistakes less likely as well and they mitigate the impact on damages when they are produced. (Global Patient Safety Action Plan: towards the eradication of avoidable damages in health care, 2021).

The book *Patient Safety Within Everyone's Reach* mentions that safety can be comprehended as the set of actions oriented to the protection of the patient against unnecessary risks and damages during medical care (Pérez Castro & Vázquez, 2013).

Based on the previous concepts mentioned, patient safety is the actions done to avoid, or at least decrease the eventual risks that might cause unsafe practice.

Concerning biotechnological advancements, the extension of coverage of health services raises the demand for medical care, which requires more careful behavior from health personnel and ensures safer practice.

This has been a concern since worldwide organizations and governments of diverse countries have offered safer health services to face medical practice risks.

As stated by the World Health Organization, the patients' damages are a cause of an unsecured medical practice. Moreover, disability, sequel, or event death causes. (Global Patient Safety Action Plan 2021-2030 towards the removal of avoidable damages in health care, 2021). This is the importance of implementing necessary actions to guarantee the respect and protection of life, dignity, and personal integration as human rights of essential character.

Meanwhile, these actions not only represent a benefit for the patient but also to medical personnel, thus its actions are legitimized while attaching to the parameters of their profession.

It cannot be taken apart from the relation of the actions to provide patient safety with the Law, thus they precisely constitute a positive set of rules. In other words, the legal recognition to regulate the healthcare personnel's actions with the search for a safer medical practice.

Such is the case of legal significance diverse documents with normative character have been issued to make the compliance of these actions compulsory.

NORMATIVE DOCUMENTS

The World Health Organization (WHO) (World Health Organization, 2002) passed a resolution in 2002, the WHA55.18 Resolution "Quality of Care: Patient Safety", under adverse events that have to in danger the quality of care, and caused human beings to damage and suffering. Additionally, the financial losses and the opportunity costs from health institutions.

This resolution appeals to the state members of the WHO to pay more attention to the problem of patient safety and to construct and consolidate systems with a scientific basis to confront it. In particular, the monitoring of the medications, medical team, and technology. Furthermore, the General Direction is asked to elaborate standards and worldwide guidelines about the quality of care and patient safety to identify the adverse events produced, or that might be produced.

In 2004, the 57th World Health Assembly prompted the creation of an international alliance to facilitate the formulation of politics and practices of patient safety among the States' members. In the same year, works with the International Alliance began to safeguard patients as a collaborative work among the World Health Organization, external experts, and professional organizations with the support of the United Kingdom Government to assign funds. (World Health Organization, 2021).

In addition, the 72nd World Health Assembly expedited the Word Action in favor of patient safety to engage the members of the State to be familiar with patient safety as a health priority in the politics and programs of the health sector to achieve universal coverage in the provision of services (World Health Organization, 2019). Result Assembly asked for the General Direction of the World Health Organization to formulate a global plan for patient safety through a consensus with the members of the States and with the organizations that were interested in that.

The 74th World Health Assembly from 2021 to 2030, approved the Global Action Plan to safeguard the patient. It focuses on the elimination of avoidable damages in health care. In addition, it has an objective to fulfill the worldwide reduction in the possible avoidable damages due to unsafe health care.

The vision of this Plan is to accomplish having a world without anyone being harmed in terms of medical care, also each patient would receive safer and more respectful attention at any moment and everywhere. Its mission is to promote the politics,

strategies, and actions based on science, patients' experience, design of systems, and associations, whose purpose is the disposal of all the sources of avoidable risk and damage for the patients and the health workers (World Health Organization,2021).

It established the preceding seven guiding principles to have a fundamental set of values to orientate the elaboration, and application of propelled actions by the Global Plan (World Health Organization,2021):

1) Providing patients and families safe care.

The participation of the users, relatives, and community is unavoidable when receiving medical care which requires getting the information to allow them free consent to decision-making about their health.

2) Achieving results through cooperative work.

Not only will the instruments and orientations of the World Health Organization provide to the members of the countries, but also are the contributions these do according to the possible implementations and innovations fulfilled, in other words, it is about collaboration, not one-way intervention.

3) Analyzing and sharing data to generate knowledge.

It is unavoidable to have information about adverse events, incidents, cases of malpractice, medical audits, medicals, and revision of medical records to notice the possible causes and implement actions to prevent them, so the quality of the services will be improved.

4) Transforming the evidence into a feasible and measurable improvement.

There is a discrepancy between the theory and the practice, which impedes taking efficient ways to help avoid unsafe practices. Thus, it requires collaborative work among the different people involved in medical care to accelerate the implementation of these ways.

5) Basing the politics and ways into characteristics of the medical care environment.

It must be considered the availability of the resources and the social and cultural environment of the diverse health systems to develop actions for patient safety, taking advantage of the reciprocal experience to enrich the works.

6) Using both scientific resources and patient's experience to meliorate safety.

The implementation of the actions of patient safety not only considers scientific and technical knowledge but also requires the help of the patients and community. Thus experiences and their experience in providing healthcare services allow joint work with an expectancy of better results.

- 7) I.Fostering a culture of safety in the design and the provision of medical care.

Patient safety will materialize with the actions taken by the authorities and the health institutions; however, there needs to be strength in generating an authentic culture of patient safety that permeates all the health service providers, so with the actions, we will observe their performances.

Furthermore, it states the following guiding principles in the Plan (World Health Organization,2021):

- 1) Eluding zero avoidable damage with a mental attitude and a standard of intervention in the planning and provision of medical care everywhere.
- 2) Establishing high-reliability systems and health organizations that protect patients from damage every day.
- 3) Ensuring the safety of each clinical process.
- 4) Involving and empowering patients and relatives to support and facilitate safer health care.
- 5) Inspiring, educating, training, and protecting the health personnel to contribute to the design and provision of systems of safer attention.
- 6) Ensuring that there is a constant flow of information and knowledge to encourage the mitigation of risks, the level reduction of avoidable damages, and the improvement of safety in care.
- 7) Promover y mantener la sinergia, las asociaciones y la solidaridad multisectoriales con objeto de mejorar la seguridad del paciente y la calidad de la asistencia.Promoting and keeping synergy, the associations, and the multisectoral solidarity, whose objective is amending patient safety and the quality of care.

With the objectives mentioned, look for having a referential framework to formulate the public policies that channel the members of the countries to act together with them.

PATIENT SAFETY IN MEXICO

Based on the international dispositions about patient safety which insist on the members of the States of the World Health Organization, the General Health Council¹ has declared

executive functions; its provisions will be general, and mandatory nature in the country.

¹ Following Article 1 of its Internal Regulations, the General Health Council is a collegiate body that reports directly to the President of the Republic and has the status of the health authority, with normative, consultative, and

obligatory the implementation to all the authorities of the National Health System, from the document called Essential Actions for the Patient Safety through Agreements published on September 8, 2017, and June 16, 2023, in the Official Gazette of the Federation.

From the modified Agreement published in 2021, it was established eight essential actions. Firstly, the naming of the actions to align them with the International Goals to safeguard the patient. Considering the description of each one of them, the document of the mentioned Agreement will be as follows:

- 1) Action 1/ International Goal 1:Correct Identification of the patients.
- 2) Action 2/International Goal 2:Effective Communication.

Communication in terms of medical care could be affected by diverse factors, for instance, verbal or telephone orders. In comparison with the ones stated in the document or are sent electronically. As a result, the verbal orders must be clearly defined in a document to avoid mistakes in interpreting the indications.

- 3) Action 3/International Goal 3:Safety in the process of medication.

The medication process considers the design, implementation, and improvement process from the acquisition until the medication is administered.

- 4) Action 4 /International Goal: Safety in the procedures.

If well, the surgical procedures are an opportunity to save lives, implementing unsafe practices which have led to complications until the patient's death. As a consequence, a verification list is used to help reduce adverse events, and watchmen due to surgical mistakes.

- 5) Action 5/International Goal 5:Reduction of risks of infections associated with medical care(IAAS).

Patient care in healthcare facilities has been threatened with infections that could be acquired because of diverse factors. Nevertheless, most of them are preventable, so in 2005. The World Health Organization launched the campaign "A Clean Care is Safer Care", fostering handwashing among health personnel.

- 6) Essential Action 6/International Goal 6:Reduction of the risk of damage to the patient caused by falls.

The cited document affirms that falls are the second cause of death, occasioned by brain encephalic traumatism worldwide. Consequently, measures must be increased. For example,

education, training, and safer environments among others to decrease the risks.

- 7) Essential Action 7/International Goal 7: Prevention, notification, registration, and analysis of adverse events.

At the 59th World Health Assembly, the WHO exhorted the members of the countries to invoke the systems of notification and learning about patient safety. The identification of the adverse events and their causes will lead to learning and decision-making to evade them.

- 8) Essential action 8/ International Goal 8: Culture of patient safety to improve the quality of care.

The Agreement was previously stated in the published report in 2002 by the National Quality Forum of The United States, within the "Set of Safe Practices to Improve Health Care" referring to the implementation and enhancement of the culture because of patient safety to foster safe practices in medical care.

Implementing these actions in a regulatory document (the General Health Council Agreement), allows them to be compulsory compliance. Therefore, they are demandable to the health personnel, fulfilling them to ensure their effectiveness.

PATIENT SAFETY AND THE PRINCIPLES OF BENEFICENCE AND NONMALEFICENCE.

The bioethical principle is a contribution of philosopher Tom. L. Beauchamp & James F. Childress mentioned in their book *Biomedical Ethics Principles* that they refer to autonomy, nonmaleficence, beneficence, and justice (From Medina, Arellano, Jesus, 2019):

- A) Respect to autonomy: It consists of giving value to people's opinions and elections, and also refraining to obstruct their actions, at least why produce clear damage to others (Roche, w/d).
- B) Nonmaleficence: it is the obligation that human beings have to not cause danger intentionally to anyone, considering the exercise of a profession or with the dairy actions (From Medina, Arellano, Jesus, 2019).
- C) Beneficence: it is considered to benefit the patient (Roche, w/d).
- D) It gives each one what he needs, which consists of a resource distribution or provides adequate medical care to each patient according to his circumstances (Ferro, M., Molina Rodríguez, L., & Rodríguez, W. A. 2009).

It is evident that the relationship between the essential actions for patient safety and the beneficence and non-maleficence

principles. Once they match, unsafe practices elude in terms of the medical care process. Without any doubt, non-maleficence looks for impeding damage to the patient. Notwithstanding, careful acting to the intervention of health personnel represents an authentic benefit to the patient.

On one side, if the principle of non-maleficence forbids intentional damage, it is also true that unsafe practices are not necessarily caused by deliberate behavior to affect the patient. On the contrary, because of negligent conduct. In other words, neglect or excessive trust. In consequence, the demand of non-maleficence must be expanded not disregarding it with the proper care to elude a harmful result to the patient.

On the other side, beneficence obligates conduct “of doing “, which means directing actions focused on achieving a benefit for the patient. Then doing the diverse essential actions guarantees a safe practice which represents a benefit to medical care.

It cannot be stopped to give reference to Article 9 of the Regulations of the General Health Law in terms of provision of health care services which lead to the compliance of ethical principles orientating medical practice. As they are included in a legal norm, they become mandatory legal rules for health care providers.

CONCLUSIONS

To conclude, we can affirm that essential actions taken for patient safety must constitute an efficient way to fulfill the principles of beneficence and non-maleficence, in compliance with diverse regulatory provisions that ensure the patient’s right to quality care and dignified and respectful treatment.

This study emphasizes the importance of following actions to reach a double effect both respecting patients’ rights and legitimizing the performance of the health personnel.

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