EXPERT OPINION

Professional Medical Liabitity, Lex Artis, Medical Malpractice, and Guidelines for the Clinical Practice. The importance of adhering to the current Clinical Guidelines in the daily practice

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Professional medical liability is the results of medical malpractice. It can be by negligence, inexperience or imprudence. The Lex Artis is the skill set and knowledge, which has been universally accepted by peers in the relevant medical speciality and must be diligently applied in the specific situation of a given patient. So, Lex Artis means guidelines for the clinical practice. Considering that in México the exercise of Medicine is an obligation of means, but not of results, therefore, by applying this principle, it is the most effective way to defend oneself, avoid complaint or lawsuits for a medical act, by adhering to the recommendations of the guidelines for the clinical practice.

Key words: **Guidelines for the Clinical Practice; Lawsuit; Lex Artis; Malpractice; Negligence; Professional Medical Liability.**

La responsabilidad médica professional es el resultado de malpraxis médica. Esta puede ser por negligencia, impericia o imprudencia. La Lex Artis es el conjunto de conocimientos y habilidades, los cuales deben ser diligentemente aplicados en la específica situación de un paciente dado y que han sido universalmente aceptadas por los pares. Entonces, Lex Artis es fundamentalmente todo lo contenido en las guías para la práctica clínica. Considerando que en México el ejercicio de la Medicina es una obligación de medios, más no de resultados. Por consiguiente, aplicando este principio, ésta es la manera más efectiva para defenderse, o aún evitar una queja o demanda legal por malpraxis, apegándose a las recomendaciones de las guías para la práctica clínica.

Palabras clave: **Guías para la Práctica Clínica; Demanda legal; Lex Artis; Malpraxis; Negligencia; Responsabilidad Médica Profesional.**

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Every medical act carries an implicit degree of Professional Responsibility. Depending on the circumstances in question, Professional Medical Liability as may arise, can be civil, criminal or administrative. However, for a medical act to be deemed as "liable", there must be illicit conduct, which in turn, may be willful or negligent.

In Mexico, the practice of Medicine is legislated by the Political Constitution of México (articles 4, 5, 13, 14, 16, 17, 20, 108-113), the Federal Penal (Criminal) Code, the Civil Federal Code (articles 1910, 1913, 1915), the General Health Law (articles 2, 32, 50, 51, 78, 79, 83), the Regulation of the General Health Law on provision of Health Care Services (articles 7, 9, 21, 29, 32, 79), Regulatory Law of the Constitutional Article 5, relative to the Exercise of Professions in the Distrito Federal (articles 2, 24, 29, 33), the Regulation of the General Health Law on Research for Health, the Regulation of the General Health Law on Sanitary Control of the Disposal of Tissue Organs and Corpses of Human Beings, las Normas Oficiales Mexicanas (NOM) of the Ministry of Health, the General Law of Professions, the Federal Law of Responsibilities of Public Servants, the Federal Law of Administrative Responsibilities of Public workers, the Federal Law of Administrative Procedure and the Federal Law of Administrative Procedure of the Distrito Federal. The aforementioned legislation indicates that medical practice is strongly bound to the legal and judicial system in Mexico.

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A medical act is considered to be any kind of medical treatment, surgical intervention or examinations for prophylactic, therapeutic or rehabilitative diagnostic or research purposes, carried out by a general practitioner or a specialist in any branch of medicine. The medical act is a sine qua non condition for any medical legal responsibility [1].

When we talk about professional medical liability, the vast majority of the time, if not always, the illicit act is not related to malicious intent. It is a wrongful fault case, with no intention to harm. That is, the medical doctor acts trying to help a patient, in the best way, and with the best intentions. In other words, he acts without intent to do wrong. However, in México, in accordance with Civil legislation, the Federal Civil Code, 1928, Art. 1910 establishes that "whoever acts illicitly or against decency causes damage to another, is obliged to repair it, unless he proves that the damage occurred as a result of the inexcusable fault or negligence of the victim". Whereas the Federal Civil Code, 1928, Art. 1915 which literally states "the reparation of the damage must consist, at the choice of the offended, in the reestablishment of the previous situation, when possible, or in the payment of damages" [2].

The basis of the professional liability in medicine is the guilt. No fault wrongful responsibility without "culposo" act [3]. As such, it entails three possible conditions: i) negligence, ii) inexperience, iii) imprudence [4,5]. Negligence means that the doctor, knowing what he should do, stops doing it, or does the opposite. Inexperience is when the doctor ignores or is not qualified to carry out the indicated therapy. Imprudence or recklessness is when the doctor overdoes his actions, acting rashly without measuring the consequences of the act. All three are classified equally under the heading of medical malpractice, and therefore, are subject to Professional Medical Liability. Depending on the case, and on the elements that surround and gave rise to the results contrary to those expected by the patient, and which are the ones that finally give rise to the complaint or demand, the doctor may be entitled to Civil, Criminal or Administrative Professional Liability [6].

In Mexico, the complaint or demand can be filed through amicable conciliation and arbitration through CONAMED, or through jurisdictional channels through a Public Ministry. On June 03 of 1996, by Presidential decree CONAMED was born as a decentralized organization, dependent on the Secretary of Health. The purpose of CONAMED is to facilitate and expedite the complaint process through amicable means, conciliation or arbitration. One of the objectives of CONAMED has been to reduce the enormous workload that Public Ministries and Criminal and Civil Courts have faced with the progressive increase in the number of claims for medical malpractice in recent years. The procedure is free, more agile and less complicated than the traditional judicial process, which can sometimes consume several years and a considerable financial expense for the parties involved. In the absence of an amicable resolution, the case is arbitrated and a judgment (laudo) is issued [1]. For its execution as res judicata, this judgment must be enforced through the intervention of a judge. It is not always easy, and sometimes it takes years to accomplish. It is important to note that the purpose of the judgment (laudo) is to impose a pecuniary penalty or financial amount to be compensated. While this sentence or judgment (laudo) does have an impact as an administrative recommendation, it is important to emphasize that it does not have a criminal scope, which is the responsibility of the criminal judge.

Usually, the cases that are processed through the courts, are cases that seek to compensate the damage through a punishment or pecuniary amount, this being the objective of Civil Liability. In the case of Criminal Liability, the punishment imposed on the doctor is exemplary, not compensatory, even when one does not contravene the imposition of the other, and they can coexist in the same case. Unlike civil liability, which is fundamentally of a patrimonial nature, penal or criminal responsibility falls on the person of the offender, by means of custodial or restrictive sanctions of his freedom, in addition to the sentence to repair the damage [7]. This is regulated by the Federal Penal (Criminal) Code, Art 228: "…they will be suspended from one month to two years in the exercise of the profession or definitive in case of recidivism", Art 229: "The previous article will apply to doctors who, having granted responsibility to take charge of the care of an injured or sick person, abandon him in his treatment without just cause, and without giving immediate notice to the corresponding authority", Art 230: "Prison from three months to two years, up to one hundred days fines and suspension from three months to one year in the judgment of the judge, will be imposed on the directors, managers or administrators of any health center, when they incur in any of the following cases: i)prevent the departure of a patient, when he or his family members request it, adducing debts of any kind; ii) needlessly retain a newborn, for the reasons referred to in the final part of the previous section; iii) delay or deny for any reason the delivery of a body, except when an order from a competent authority is required. The same sanction shall be imposed on those in charge or administrators of funeral agencies who unduly delay or deny the delivery of a corpse, and also to those in charge, employees or dependents of a pharmacy, who, when filling a prescription, substitute the medicine, specifically prescribed by another. that causes harm or is obviously inappropriate to the condition for which it was prescribed".

As it can be seen, in México, the cases of Professional Medical Criminal (Penal) Liability are limited to a very peculiar circumstances, but which can occur in the field of daily medical practice.

In Mexico, from a legal perspective, the practice of Medicine is an obligation of means, but not of results. The Judicial Power of the Federation has established the difference between the obligation of means and of results as follows: The obligation of means supposes that the professional is not obliged to achieve a specific

result, but rather to the deployment of diligent conduct, the assessment of which is based on the Lex Artis ad hoc. The obligation of results, on the other hand, occurs in other cases in which the patient must only prove that this result was not obtained in accordance with the normal required technique [8]. The Supreme Court has also established that the responsibility of doctors and institutions is one of means and not results. The foregoing given that the people who provide these services are subject to carry out all the necessary behaviors to achieve their objective according to the experiences of the Lex Artis [9].

This means that the doctor cannot and should not guarantee results a priori. Results can be subject to myriad variables, some of which may be attributable to the fault of the patient. Many other instances, it is not in the hands of the doctor to control all the variables involved in a medical act. This is in line with what was mentioned above about the fact that, legally speaking, medicine is an obligation of means. This means that the doctor has the obligation to know the best universally recognized therapies to be applied to his patient. This is known as Lex Artis is defined as "the set of norms or evaluative criteria that the doctor, in possession of knowledge, abilities and skills, must diligently apply in the specific situation of a patient and that have been universally accepted by their peers" [10]. This, translated into the medical language of daily practice, is called guidelines for clinical practice (GCP). These documents are commonly endorsed by Scientific Societies and Organizations involved in a specific area of medicine. Theoretically, they contain all the useful information about a certain disease, which has been analyzed by a group of experts, who issue treatment recommendations. The recommendations can vary from those that are Class I (unobjectionable fact that must be applied to the letter), to Class III (which indicate that the recommendation is not recommended or even dangerous; that is, it should not be applied). When these recommendations are applied in the environment of a certain patient, and adapted to the reality of the case, it is called Lex Artis ad hoc [10].

From the foregoing, it follows the understanding that Lex Artis ad hoc is the antithesis of medical malpractice. Consequently, the most effective way to defend oneself, even avoid a complaint or lawsuit for a medical act, is to adhere to the current GCP [11,12].

It has certainly been said that GCP do not constitute a legal document in themselves, and that the doctor is not legally obliged to follow them. However, there are some facts to the contrary. Firstly, the doctor is obliged to know these GCP as part of his constant five-year renewal of his certification of knowledge through organizations such as CONACEM and the Specialty Councils. Secondly, according to the General Health Law, there are the Official Mexican Standards or Normas Oficiales Mexicanas (NOM), which are mandatory. They are renewed every 5 years, and come into force once they are published in the weekly newspaper of the Official Journal of the Federation. It is important to note that there are no NOMs for all pathological entities. Diabetes and high blood pressure are the exception to the rule. But even so, when the NOMs are followed, upon reaching the specific treatment section, these NOMs refer us to consult the most appropriate treatment in question through the GCP. Therefore, it is concluded that it is the duty of the doctor to know and apply the recommendations of the CPG. Thirdly, adherence to the GCP is practically guaranteeing that the medicine is being applied following the precept of obligation of means, but not of results. By following the recommendations of the GCP, the doctor is applying the means described by the experts (Lex Artis), and adapting them to his environment (Lex Artis ad hoc). All of the above practically guarantees, or significantly minimizes, the possibility of having any Professional Medical Liability due to medical malpractice.

In addition to all the above, there is another situation in which the CPG play a fundamental role. In a judicial process, the judge can request an expert opinion. This is the specific case of cardiac surgery. Being an entity that is not in the public domain, even for the doctors in forensic medicine, the opinion of a judiciary expert is quite mandatory. In turn, the expert in the area will base part of his report considering the Lex Artis, that is, the GCP. In such a way, that if the defendant doctor has adhered to the GCP under the obligation of means, but not of results, it is very likely that the resolution will be in his favor, regardless of the result of the medical act as such.

We can summarize all the content above by saying that every medical act implies a risk, every medical attention carries an intrinsic medico-legal risk and consequently, the medical act must comply with the Lex Artis to reduce the risk for liability. The purpose of the medical act must be of help to the patient and must be based on following universally accepted scientific standards, that is, clinical guidelines. Even the doctor can justify certain errors that will not be reprehensible if he has treated the patient with the appropriate means, with current knowledge and following the rules imposed by their duty [2]. The doctor will be free of charges in turn if in the process of a lawsuit by malpractice he shows that he acted with due diligence and care for the case (Lex Artis ad hoc) [3]. That is, Lex Artis ad hoc, which can be translated into scientific-academic parlance, as GCP.

Nonetheless, there is a very specific situation in which the doctor can choose to adhere or not to the GCP. When an official Statement has been published, it has the same specific weigth than the GCP. Thus, the doctors can follow the GCP or the Statement. In this regard, when some Societies, Associations or Organizations are at odds or partially against what the GCP say or recommend, they have all the right to make clear a very precise situation or position by means of any Statement. This Statement becomes an official document when endorsed by these involved Societies or Organizations. This above has been the case of the Latin American Association of Cardiac and Endovascular Sur-

gery Statement against the 2020 ACC/ACC guidelines for valvular heart disease [13] regarding some very specific issues. This Statement has been universally accepted all across the globe and published in several Journals at the same time [14-19]. Hence, the doctor working in these geographical areas has the choice to follow and adhere to this Statement as an official document endorsed and supported by the involved Societies. Legally speaking, the official Statement has the same specific weight than the GCP.

The Mexican Society of Cardiac Surgery and the Mexican College of Cardiovascular and Thoracic Surgery have been aware of this extremely important and delicate situation. In this framework, both aforementioned Organizations have worked togehter in producing the Mexican Official Statement against the 2020 ACC/ACC guidelines for valvular heart disease [20], which is published in this issue, and also can be consulted in the corresponding official websites.

In this way, it is clear the importance of GCP as a non-legal document, closer to the official, as well as the legal importance of adhering to the recommendations of these GCP. In addition to a good doctor-patient-family relationship, adhering to the recommendations of the GCP is the surest way to avoid any Professional Medical Liability.

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