

Ethical evaluation of medical errors and the patient's safety

Valoración ética de los errores médicos y la seguridad del paciente

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Abstract

In the offer of health care services, errors may arise that are repeated, so when one has occurred, it is essential to reflect on the elements that could cause it and act on them; however, in general, there is a natural tendency to hide them, mainly due to fear of sanctions or lawsuits. The ethics of clinical safety finds it essential to reveal errors, including almost errors or those without significant consequences, betting on transparent management of them. No error should be filed, since its review in an honest and open manner is not only an ethical obligation, but it can also help to lessen its effects and improve the doctor-patient relationship. Achieving safe medical care requires continuous learning about how the different components of the system interact, this implies putting into practice the behaviors that have shown their effectiveness to reduce the probability of the appearance of faults and errors, increase their detection and reduce their consequences, as well as continuing to investigate the factors that contribute to improving patient safety and the quality of care. In this paper we analyze the incidents related to patient safety, through statistical information from the Comisión Nacional de Arbitraje Médico (CONAMED), referring to complaint files concluded by arbitral award in the 2012-2016 period.

Key words: Incidents related to patient safety. Medical errors. Ethics.

Resumen

En la prestación de servicios de atención médica pueden surgir errores que se repiten; por ello, cuando se ha producido uno es indispensable reflexionar sobre los elementos que pudieron ocasionarlo y actuar sobre ellos. Sin embargo, de manera general, existe una tendencia natural a ocultar los errores, principalmente por temor a sanciones o demandas. La ética de la seguridad clínica encuentra indispensable revelar los errores, incluso los casi errores o aquellos sin consecuencias significativas, apostando por una gestión transparente de los mismos. Ningún error debe ser archivado, pues su revisión de forma honesta y abierta no solo es una obligación ética, sino que puede contribuir a aminorar sus efectos y mejorar la relación médico-paciente. Lograr una atención médica segura requiere aprendizaje continuo sobre cómo interaccionan los diferentes componentes del sistema; ello implica poner en práctica las conductas que han mostrado su efectividad para reducir la probabilidad de aparición de fallas y errores, aumentar su detección y disminuir sus consecuencias, así como continuar investigando sobre los factores que contribuyen a mejorar la seguridad del paciente y la calidad de la atención. En este trabajo se analizan los incidentes relacionados con la seguridad del paciente, a través de información estadística de la Comisión Nacional de Arbitraje Médico (CONAMED) referente a expedientes de queja concluidos por laudo en el periodo 2012-2016.

Palabras clave: Incidentes relacionados con la seguridad del paciente. Errores médicos. Ética.

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Introduction

Health care interventions are carried out with the purpose to benefit patients, but they can also cause them harm, since although the complex combination of processes, technologies and human interactions that make up the modern healthcare service provision system can offer important benefits, it entails risks for the occurrence of adverse events as well¹.

Hospitals, clinics, and health centers mobilize the abilities and efforts of a wide variety of professional, technical and non-professional personnel in order to provide highly specialized services, and are therefore vulnerable to the occurrence of errors, and thus the complexity of their processes suggests the need for a systematic approach aimed at recognizing its risks and problems, considering additionally that in the literature on the subject the current trend is to recognize errors as part of the system in order to improve the quality of care and patient safety².

From the ethical point of view, the new paradigm of reporting about errors is recognized, since making mistakes is inherent to the human condition, particularly in areas where uncertainty of certain variables in decision-making and the idiosyncrasy of human biology preclude an accurate result³.

Medicine is not comprised within the so-called exact sciences, but within the scope of biological phenomena, and therefore its practice is subjected to a variability that not always can be controllable, which exposes health personnel to errors, which can lead or not to causing harm to the patient. Patient harm can also be the consequence of health personnel incorrect performance, by actions or omissions in their duties, which are regarded as malpractice, and give rise to professional liability⁴.

Since medicine is not an exact science, the service provider's duty is to act with the diligence and expertise that each patient's case warrants; i.e., showing the highest diligence in care and using all applicable knowledge and resources, according to patient characteristics and clinical presentation, with the purpose to improve or restore his/her health, as well as to anticipate possible complications, provide treatment continuity and inform the patient or his/her relatives about the diagnosis, prognosis, treatment, management alternatives, and benefits and risks, in terms of medical *lex artis*⁵.

The term *lex artis* (literally "law of the skill", "artisan law" or "rule of the action in question") is used to refer

to the assessment of whether the task performed by the professional is correct or not, if it adjusts or not to what should be done; i.e., the specific orders or rules that must be observed within the profession. For the National Commission of Medical Arbitration (CONAMED – *Comisión Nacional de Arbitraje Médico*), the scientific principles of medical practice (*lex artis*) refer to the "set of rules for medical practice contained in universally accepted literature, where the ordinary means for medical care and criteria for their use are established"⁶.

In this context, given the great variability and complexity surrounding a specific clinical situation, with some factors depending on the professional and others on patient particular conditions, on available resources or infrastructure, and ultimately, due to the circumstances that surround it, it is impossible to apply the same rule to all cases, and it must be adapted to each specific case. Therefore, it can be said that *ad hoc lex artis* is an indeterminate concept that should be established at each case where the doctor, through a deliberative process, prudently applies the measures to a specific clinical situation and considering concurrent conditions. In this sense, *ad hoc lex artis* has been defined as "that evaluative criterion of the correctness of a specific medical act executed by the medicine-science or medical art professional that takes into account the special characteristics of its author, of the profession, of patient complexity and vital importance and, where appropriate, of the influence on other endogenous factors –status and intervention of the patient, of his/her family members or of the health organization itself–, to qualify said act in accordance or not with the required normal technique"⁷.

Medical care refers to the series of services that are provided to the person in order to protect, promote and restore his/her health, with its activities being preventive, curative, rehabilitating and palliative. Physicians' professional practice should be fairly appreciated, since it is one of the human activities with the highest risk, given that it directly affects people's health and lives. Similarly, it should be emphasized that it's not enough establishing what a correct action would be from the point of view of scientific knowledge, but it is also necessary taking into account the circumstances of the modality, time and place care is provided in.

Thus, in medical care, certain diligence obligations that the profession demands and that Health Law recognizes fundamentally in obligations related to

means, safety and results are assumed. Obligations in terms of means are inherent to the provision of the service and are defined by the execution of actions and medical procedures in accordance with the scientific and ethical principles that guide medical practice, according to the circumstances of the modality, time and place the service is provided in. Safety obligations correspond to actions and medical procedures aimed at reducing or avoiding health risks and harm. In turn, obligations in terms of results are determined by the doctor and the patient, and represent agreeing on a specific result prior to the provision of care (as it could be defined in cases of cosmetic surgery, stomatology, pathology and diagnostic aids), in compliance with the provisions of the Health Workers General Rights charter⁸.

Indeed, as a general rule, doctor's obligations are related to means, since they admit for the professional not to be constrained to the achievement of a specific result, but to the deployment of diligent behavior, committing to provide care not only with knowledge and the techniques that have been established for the case in question with adherence to medical science, but applying the techniques with the demandable care and precision, addressing the circumstances and risks inherent to each intervention, the assessment of which is based upon *ad hoc lex artis*. It is different when the obligation is related to results, where it is not enough for the professional to act diligently for their fulfillment, but he/she must obtain a particular effect or result in the patient.

Recognizing medical decisions uncertainty does not mean justifying mistakes, but explaining that, even in favorable circumstances, this uncertainty results from the large number of variables involved, many of which are beyond the control of health professionals⁸.

Moreover, the essential commitment of those who practice the medical profession is to act ethically, since their mission and social responsibility is precisely to preserve such invaluable assets as people's lives and health⁹.

In this context, medical care should be provided in accordance with the purposes established by law, in accordance with the rules of care provided by medical science and trying to comply with the ethical duties of the profession, given that doctors' commitment implies acting with the expertise and diligence each case deserves¹⁰.

Clinical safety ethics recognizes that people, in all their professional activities, have an error rate that can be minimized, but not completely eliminated. In this

sense, it considers three different perspectives: the teleological perspective, aimed at seeking the greatest possible good for the patient; the deontological perspective, which comprises principles and values; and accountability ethics, which advises that human beings should rationally justify their ends and their means, without establishing such absolute rules that leave no room for exceptions¹¹.

Thus, the purpose of clinical safety ethics is that each professional uses his/her competencies to create safe work habits and analyzes the risks inherent to his/her activity, trying to minimize them¹².

Given the nature of the profession, the ethical aspect fundamentally estimates the physician's vocational and moral conviction, based on the principles established by health professionals themselves and that refer to a set of patterns in the light of which medical behavior can be assessed on grounds of fairness, reasonableness and impartiality. However, morality is closely related to legal aspects, as it tends to preserve values, and thus the demand to comply with freely-acquired obligations related to the medical profession becomes a rule of coexistence, upon which legal order is based; i.e., in many areas, such as that related to medicine, the law embraces morality as a reference for its provisions, which is why the existence of standards of both moral and legal scope is possible¹³. In this subject, it is essential to refer to medical deontology, which precisely addresses the rights and obligations that are acquired by the fact of being a health professional. The word deontology comes from Greek *deontos* (duty) and *logos* (study, treatise); therefore, etymologically it means "study of the obligations and rights of doctors", with these being both ethical and legal. That is, deontology implies much higher responsibility than simple adherence to ethical or moral behavior, and hence its knowledge is essential for professionals, since they are self-regulation standards that should be observed above particular opinions and views¹⁴.

In Mexico, General Statute of Health Regulations ninth article regarding the Provision of Medical Care Services stipulates that "Medical care should be carried out in accordance with the scientific and ethical principles that guide medical practice". Under this approach, it should be mentioned that CONAMED considers medical practice ethical principles as "the set of universally accepted bioethical and deontological rules for medical care".

According to the glossary of terms applied to patient safety issued by the Federal Ministry of Health, patient

safety refers to those actions that are free of accidental injury, ensuring the establishment of operating systems and processes that minimize the possibility of error and maximize the probability of its avoidance.

Furthermore, “medical error” is considered to be a wrong clinical behavior in medical practice as a consequence of the decision to apply an incorrect criterion, and “adverse event”, an incident that causes mild or moderate harm to the patient as a consequence of the process of care.

The Harvard study on the incidence of adverse events and negligence carried out by Brennan et al.¹⁵, with a cohort of 30,000 patients hospitalized in the State of New York throughout 1984, among its results found that 4% of patients suffer some type of harm during hospitalization, that 70% of adverse events cause patient temporary disability, and that 14% of incidents are fatal¹⁵.

The World Health Organization (WHO) and its associates have called for intensified research aimed at improving patient safety. In a conference for the establishment of a European program on the subject, they examined revealing data that harms caused by medical care entail a considerable burden of suffering and mortality in Europe and around the world, highlighting that¹⁶:

- Health care-associated infections affect 1.4 million people at all times. In developed countries, they affect 5-10% of patients, and in some developing countries they can reach one fourth of patients, with a marked increase in antimicrobial resistance in the world; therefore, it is critical for research to focus on antimicrobial resistance and on the spread of multidrug-resistant pathogens.
- As for adverse reactions to medications, 7-10% of patients cared for in acute care services have an adverse reaction to some medication, while 28-56% of these reactions are preventable.
- Data from developed countries indicate that adverse episodes occurring in operating rooms account for at least 50% of total adverse episodes. In developing countries, surgical care is hampered by deficient facilities, lack of trained personnel, inadequate technology and limited supply of drugs and materials; therefore, research on the reasons for the observed geographic differences in the incidence of surgical and anesthesiology errors is required.
- Data on dangerous injection practices show that, worldwide, up to 40% of injections are carried out with reused syringes and needles, without prior

sterilization, and, in some countries, that proportion amounts to up to 70%. Hazardous injection practices worldwide cause approximately 1.3 million deaths per year, a loss of 26 million years of life, and an economic burden of USD 535 million annually, in direct medical costs, and thus future research will need to focus on assessing the impact of this type of practices.

- Adverse reactions to medical devices also cause harm to patients. In the United States of America, more than one million of this type of adverse reactions are recorded annually. In some developing countries, up to half the medical equipment is unusable or only partially usable, which makes the establishment of effective surveillance programs necessary in order to detect the types, frequency and clinical settings of these reactions.
- Lack of patient safety is a global public health problem that affects countries at any level of development.

The World Alliance for Patient Safety was established with the purpose to promote efforts aimed at improving care safety in all WHO Member States. In Mexico, it has become an essential component of national health programs, in search of effective and quality care, accessible to the entire population.

The purpose of this document is to present an overview of errors’ ethics and patient safety, which is not limited only to physicians’ actions as commonly it is understood, but it is extensive to professionals, technicians and assistants from other disciplines, among which dentistry, psychology, nursing, chemistry, nutrition, biomedical engineering and social work stand out.

Statistics

Medical complaint is an overt expression of dissatisfaction of the patient or his/her relatives with the medical care received, and should be considered a right they have to disagree with the provision of a service that in their opinion is deficient, but it should also be appreciated as an opportunity for health personnel to identify the most common risks and problems in order to prevent and correct them. In this sense, the complaint serves as a trigger to seek better quality and more safety in the care process. Recognition of the concept of “medical care quality” is a starting point for determining the origin of errors, malpractice and professional liability, in order to solve and prevent them¹⁷.

CONAMED is a public governmental institution that, through the medical arbitration model, offers alternative extrajudicial mechanisms for the resolution of controversies between users and providers of public, social or private medical services, due to possible irregularities or refusal in the provision of services. In addition, it collaborates with law enforcement and administration authorities, and participates in research and in promoting medical care quality and patient safety¹⁸. Thus, without substituting ordinary law, CONAMED resolves disputes using a voluntary, free, impartial, confidential and specialized process, evaluating each case with an analysis methodology adjusted to the legal provisions applicable to the subject¹⁹.

The arbitration process essentially comprises three stages:

- The initial stage, which begins with the manifestation of disagreement by the user due to the care received from a medical services provider. This disagreement may result in guidance (informative means to guide user activities), specialized advice (medical-legal guidance provided to the user, to the service provider or their representatives), immediate arrangements (when the disagreement refers to medical services delay or denial, mainly in an emergency) or receipt of the complaint when it meets the requirements to be classified as such.
- Once the complaint is admitted, the second stage is carried out, which consists of a conciliatory procedure that seeks a compromise between parties.
- If an agreement is not reached, the procedure continues to the third stage (adjudicatory), in which CONAMED acts as arbitrator and issues a ruling (pronouncement by means of which CONAMED resolves, in strict law or in conscience, the issues submitted to its knowledge by the parties). It should be mentioned that in all cases medical care review is carried out in ad hoc *lex artis* terms, addressing the modality, time and place circumstances (a medical review that interprets medical care *lex artis* guarantor nature), and compliance with a normative vision (legal review, to verify due adherence to Health Law provisions).

Below, CONAMED statistical information regarding the complaint files concluded by arbitration resolution (ruling) in the 2012-2016-period is presented, which

illustrates the health care-related incidents detected in a study focused on the field of patient safety²⁰.

For its analysis, CONAMED estimated two concepts:

- Patient safety-related incident, understood as an “event or circumstance that occurs during clinical care and that, although it does not necessarily generate direct harm to patient health or person, it does affect the patient to the extent that, when failures occur in medical processes, the process of patient care and eventually his/her hospital stay is generally prolonged”.
- Adverse incident, defined as “an event or circumstance that is usually unforeseen and unfavorable, and that causes unnecessary harm to a patient or that might have caused it”. In the same sense, an adverse incident is considered to become an adverse event when it meets the criteria of patient harm, as a result of health care and caused without intention or malice.

In those terms, taking into account the type of source the information was obtained from, and considering that it is not always easy to identify or specify the scope incurred by adverse incidents, the concept of “incident” is employed, using it in all cases with the connotation of “occurrence of circumstances that caused some real or potential harm to the health of users”, and incidents are coded based on an abbreviated list prepared in accordance with the WHO International Classification for Patient Safety.

The analyzed files correspond to service providers who voluntarily agreed to resolve their dispute through arbitration, and where the medical complaint degree of complexity was such that it could not be solved by guidance, advice, immediate arrangements or conciliation, and had to reach the adjudicatory stage (arbitration trial), where, once procedural formalities were fulfilled and an exhaustive review of evidence was carried out by medical and legal advisers, the controversy was resolved by issuing a ruling. It should be noted that, since these are highly complex issues, the fact that the information cannot be interpreted as a pattern of what occurs in the National Health System versus usually provided medical services should be taken into consideration.

During the 2012-2016 period, 358 files corresponding to 362 cases were reported to have been concluded by means of a ruling, because in four of them medical attention was provided to two users, since they were mother-child binomials. Distribution within the period is shown in table 1.

Table 1. Annual distribution of files concluded by arbitration resolution at CONAMED²⁰

Year	Rulings	Cases
2012	91	94
2013	92	92
2014	55	56
2015	37	37
2016	83	83
Total	358	362

In most cases, the disagreement was raised in private sector medical services, with 229 of the 362 complaints (63.3%), which indicates that approximately two out of every three complaints concluded by a ruling originated in this sector, and the 133 remaining cases (36.7%) corresponded to the public sector, out of which 96 were from social security (26.5%) and 37 (10.2%) from establishments that provided care to unaffiliated population, as reported by CONAMED.

Regarding the type of establishment, in 94 cases, medical units corresponded to the Institute of Social Security and Services for State Workers, out of which 73 (77.7%) were hospitals and 21 (22.3%) were outpatient care units. The Ministry of Health and State Health Services provided the service in 37 cases, most of them (91.9%) in hospitals. In the private sector, the 229 cases occurred with a frequency of 60.3% in hospitals and 38.2% in outpatient care units. In support facilities, seven of the nine cases belonged to the private sector, as it can be appreciated in table 2.

As for the main department linked to the care that motivated the complaint, the trauma and orthopedics department was reported with the highest frequency, with 48 cases (13.3%) of a total of 362, followed by the emergency department, with 44 cases (12.2%), the general surgery department with 38 complaints (10.4%), obstetrics and gynecology with 33 cases (9.1%) and dentistry with 31 cases (8.6%). The remaining 67 cases (46.4%) corresponded to different departments, including neurosurgery, internal medicine, gastroenterology, psychiatry, urology, clinical laboratory, cardiology, pulmonology, dermatology, nephrology, physical medicine and rehabilitation, radiology, rheumatology, surgical oncology, thoracic surgery, intensive care and pathological anatomy. Table 3 illustrates the first ten departments involved.

The analysis of health care-related incidents to acquires higher relevance, since it showed that, in 199 of the 362 cases (55%), CONAMED determined malpractice, whereas in the remaining 163 there was no evidence of malpractice (45%).

Most malpractice cases corresponded to the private sector, with 120 cases (52.2%) of a total of 229. On the other hand, 59.4% of the 79 cases corresponded to the public sector, and the institutional analysis showed that, in this sector, State Health Services had a higher percentage of cases with evidence of malpractice (62.5%), with this being coupled with the fact that their number of complaints was reduced (five out of eight) (Table 4).

After the files were analyzed, 3,260 incidents were detected, which were classified by CONAMED in seven categories, as shown in table 5.

Considering the relevance of the subject, it is necessary pointing out that each one of the 3,260 incidents represents failures in patient safety, which turns into a valuable warning for establishing a culture focused on learning.

Management-related incidents

The number of incidents in this category was significant (579), with the most relevant aspects being anomalies in the integration of the medical record (193) associated with failure to comply with standards (33.3%): long waiting list, with 126 incidents (21.8%), as well as information mistakes and loss of documents, which together accounted for 134 cases (23.1%).

The aforementioned incidents represented 78% of total events in this area, which is a relevant issue, since the medical record is an essential instrument for the materialization of the right to health protection. It is the single set of information on a patient, where the various interventions of the staff and the description of patient health status are recorded at different times of the medical care process, in addition to including, where appropriate, data on patient physical, mental and social well-being, and, therefore, it is also essential for the provided care to be assessed, since it is a basic medical-legal document for care, teaching and research.

The criteria established in the Official Mexican Standard NOM-004-SSA3-, on the Medical Record, impact the quality of medical records, as well as of services and their results, since it requires health personnel committed participation²¹. This standard is of

Table 2. Institution involved with the medical complaint by type of establishment²⁰

Institution	Outpatient care unit	Hospitalization unit	Support establishment	Total	Percentage
SSA	2	26	1	29	8
ISSSTE	21	73	0	94	26
Pemex	0	1	0	1	0.3
SEDENA	0	0	1	1	0.3
State Services	0	8	0	8	2.2
Private Services	84	138	7	229	63.3
Total	107	246	9	362	100

ISSSTE (*Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado*): Institute of Social Security and Services for State Workers; SEDENA (*Secretaría de la Defensa Nacional*): Ministry of National Defense; SSA (*Secretaría de Salud*): Ministry of Health.

Table 3. Main departments involved in medical complaints²⁹

- Trauma and orthopedics
- Medical emergency
- General surgery
- Obstetrics and gynecology
- Dentistry
- Pediatrics
- Ophthalmology
- Outpatient services
- Plastic and reconstructive surgery
- Otorhinolaryngology

Table 5. Classification of health care-associated incidents²⁰

Adverse incidents	Total	Percentage	Incidence*
Management	579	17.8	159.9
Communication	420	12.9	116
Diagnosis	493	15.1	136.2
Procedure	856	26.3	236.5
Medication	470	14.4	129.8
Care	333	10.2	92
Healthcare-associated infections	109	3.3	30.1
Total	3260	100	901

*The incidence denominator corresponds to all 362 cases.

Table 4. Medical care assessment²⁰

Sector	No evidence of malpractice		Evidence of malpractice		Total	
	Cases	%	Cases	%	Cases	%
Private	109	47.6	120	52.4	229	100
Public	54	40.6	79	59.4	133	100
Institution	Cases	%	Cases	%	Cases	%
SSA	14	48.3	15	51.7	29	100
ISSSTE	36	38.3	58	61.7	94	100
SEDENA	0	0	1	100	1	100
PEMEX	1	100	0	0	1	100
State services	3	37.5	5	62.5	8	100
Total	163	45	199	55.0	362	100

ISSSTE (*Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado*): Institute of Social Security and Services for State Workers; SEDENA (*Secretaría de la Defensa Nacional*): Ministry of National Defense; SSA (*Secretaría de Salud*): Ministry of Health.

mandatory observance for health personnel and health care services providing establishments of the public, social and private sectors, including doctors' offices.

In addition to this, within the framework of the exercise of patient rights, it confirms the importance of guaranteeing the free expression of the patient's will to be cared for or not by means of clinical or surgical procedures, for which the doctor must obtain patient consent, after information and explanation of possible risks and expected benefits have been provided. Table 6 shows the distribution of reported incidents.

Communication-related incidents

Communication between health professionals helps the doctor in decision-making and facilitates actions related to the follow-up of care; in this sense, it is both critical and important the need to improve

communication between health personnel, patients and family members, as well as appreciating the benefits of delving into the informed consent, assuming that establishing specific measures aimed at preventing unnecessary risks for the patient is required. Four-hundred and twenty communication-related incidents occurred (12.9%), with difficulties in doctor-patient communication being reported in 7 out of every 10 incidents, and following in importance, communication between doctors (12.9% within the category), as well as nurse-patient and doctor-nurse communication problems (3.3% and 2.4%, respectively). The rest of cases (10%) included hostile relationships and lack of collaboration that resulted in the incident.

This shows failure to comply with the provisions established by article 29 of the General Statute of Health in Matters of Medical Care Services Provision Regulations, which states: "Every health professional will have the obligation to provide the user and, if applicable, his/her relatives, legal guardian or legal representative, full information on the corresponding diagnosis, prognosis and treatment"²².

In the doctor-patient relationship, the main goal is to improve or restore patient health status, and communication is therefore essential. However, the results showed that 299 incidents related to patient information occurred (71.2%), showing the highest incidence (82.6%). This important category also revealed communication issues between health personnel (Table 7).

Diagnosis-related incidents

The process related to patient diagnosis is determinant in the definition of activities that must be carried out in the phases subsequent to its integration. In this category, 493 incidents occurred, which were grouped in three components: 1) diagnostic delay (32.5%); 2) failure to comply with the necessary means to integrate the diagnosis (30.8%); and 3) diagnostic error (24.5%) due to medical knowledge failures, which generated errors or biases in criteria and interpretations.

Diagnosis is one doctors' fundamental tasks; it is not an end by itself, but an indispensable means to establish appropriate treatment at each case (Table 8).

Procedure-related incidents

In this category, 856 adverse incidents were detected, with four important areas in particular standing out:

Table 6. Administrative process-related incidents²⁰

Incidents	Total	Percentage	Incidence*
Long waiting list	126	21.8	34.8
Loss of documents	50	8.6	13.8
Healthcare information mistake	84	14.5	23.2
Patient identification error	35	6.0	9.7
Erroneous appointment	5	0.9	1.4
Incomplete medical record [†]	193	33.3	53.3
Reference and counter-reference	13	2.2	3.6
Failure to refer to specialties	10	1.7	2.8
Failure to present medical record	2	0.3	0.6
Failure to present informed consent	24	4.1	6.6
Contemplative attitude	9	1.16	2.5
Other [‡]	28	4.8	7.7
Total	579	100	159.9

*The incidence denominator corresponds to all 362 cases.

[†]Refers to non-compliance with clinical record standards that put patient health at risk.

[‡]Refers to adverse incidents related to accurate information on patient health status, untimely admission or distribution of tasks to untrained personnel.

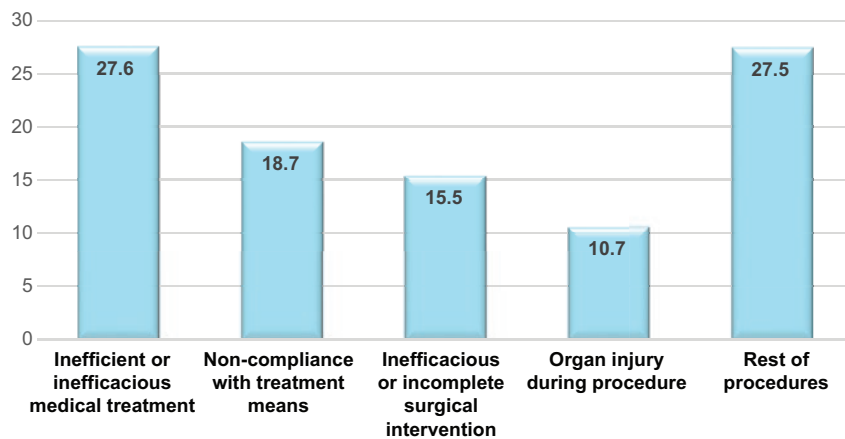
Table 7. Communication-related incidents²⁰

Adverse incidents	Total	Percentage	Incidence*
Doctor-patient communication	299	71.2	82.6
Nurse-patient communication	14	3.3	3.9
Doctor-nurse communication	10	2.4	2.8
Doctor-doctor communication	54	12.9	14.9
Idiomatic barrier	1	0.2	0.3
Other [†]	42	10.0	11.6
Total	420	100	116.0

*The incidence denominator corresponds to all 362 cases.

[†]Refers to adverse incidents related to attitudes such as hostility, non-collaboration, disregard or physical aggression, both from health personnel and from patients or relatives.

1) inefficient or inefficacious medical treatment (with regard to treatment response), where 236 incidents occurred (27.6%); 2) not exhausting the treatment means, with 160 incidents (18.7%); 3) performance of an inefficacious surgical intervention with regard to patient diagnosis or performance of an incomplete surgery, which accounted for 133 incidents (15.5%); and 4)

Figure 1. Procedure-related incidents²⁰.Table 8. Diagnosis-related incidents²⁰

Adverse incidents	Total	Percentage	Incidence*
Diagnostic delay	160	32.5	44.2
Diagnostic error	121	24.5	33.4
Diagnostic means non-compliance	152	30.8	42.0
Contemplative attitude	18	3.7	5
Diagnostic omission	11	2.2	3
Other†	31	6.3	8.6
Total	493	100	136.2

*The incidence denominator corresponds to all 362 cases.

†Refers to adverse incidents in tests or analyses not performed, unprocessed samples or inadequately delivered results.

having affected an organ during the procedure or surgical intervention, with 92 incidents (10.7%) (Fig. 1).

In this category, in addition to concentrating the highest number of incidents, repercussions on patients had greater impact, since among the reported incidents there were hemorrhages and hematomas related to the procedure or surgical intervention, involvement of an organ during the performed procedure, uterine tears, pneumothorax, surgical wound dehiscence and textilomas.

It should be emphasized that CONAMED classified incidents with a focus on patient safety, using the concept of incident in all cases as “the occurrence of circumstances that caused some real or potential harm to users’ health”, with this being an entirely different context from their categorization based on the

professional liability that health personnel may incur due to malpractice.

Medication-related incidents

This section includes adverse incidents or events related to inappropriate medication prescription or administration, as well as the consequences of medication mishandling. The category as a whole included 470 incidents, accounting for 14% of total reported incidents. Medications are the most widely used therapeutic resource, and, consequently, medication errors are one of the most common causes of medical care-related adverse events (Table 9).

Care-related incidents

In this category, 333 incidents were identified, out of which 243 (73%) corresponded to patient evolution inappropriate follow-up, followed in importance by hasty discharge in 27 cases (8.1%), consequences of prolonged immobilization in eight cases (2.4%) and pressure ulcers in seven cases (2.1%) (Table 10).

Healthcare-associated infection-related incidents

Infections contracted in healthcare facilities are among the leading causes of death and increased morbidity in hospitalized patients. The importance of these incidents lies in the fact that, being of a preventable or avoidable nature, cause prolonged hospital stays, long-term disabilities, microorganisms increased resistance to antimicrobials, additional costs for health

Table 9. Medication-related incidents²⁰

Adverse incidents	Total	Percentage	Incidence*
Medication inadequate preparation	63	13.4	17.4
Nausea, vomiting or diarrhea secondary to medication	11	2.3	3
Renal function worsening	10	2.1	2.8
Heart failure and shock	7	1.5	1.9
Electrolyte imbalance	7	1.5	1.9
Adverse drug reactions	16	3.4	4.4
Medication errors	78	16.6	21.5
Medication incorrect dose	22	4.7	6.1
Dose or medication omission	8	1.7	2.2
Incorrect medication administration frequency	42	8.9	11.6
Medication preparation or manipulation error	54	11.5	14.9
Medication monitoring	75	16.0	20.7
Incorrect medication duration	31	6.6	8.6
Other†	46	9.8	12.7
Total	470	100	129.8

*The incidence denominator corresponds to all 362 cases.

†Adverse incidents related to blood products, nutrition, inappropriate supervision, as well as adverse reactions to anesthetic agents, medication administration to wrong patient, blood glucose poor control, or medication-associated upper gastrointestinal hemorrhage.

systems, patients and their families, as well as deaths. Table 11 shows the incidents found in the 362 reported cases.

Sentinel events

To modify the impact disease causes in the patient, clinical manifestations must be recognized, diagnosis should be appropriately integrated and therapeutic strategies should be used in a timely manner, in order to avoid complications to the extent possible.

According to the agreement made by the Ministry of Health/General Public Health Council, which declares the mandatory nature of implementation, for all members of the National Health System, of the document titled *Essential Actions for Patient Safety*, published in the Official Gazette of the Federation on September 8, 2017, a sentinel event is an unexpected event that involves death or serious physical or psychological harm, and that is not related to natural

Table 10. Care-related incidents²⁰

Adverse incidents	Total	Percentage	Incidence*
Patient evolution inappropriate follow-up	243	73	67.1
Hasty discharge	27	8.1	7.5
Prolonged immobilization consequences	8	2.4	2.2
Pressure ulcer	7	2.1	1.9
Acute lung edema and respiratory failure	7	2.1	1.9
Burns, erosions and contusions (including consequent fractures)	5	1.5	1.4
Other†	36	10.8	9.9
Total	333	100	90.1

*The incidence denominator corresponds to all 362 cases.

†Refers to adverse incidents related to formative, training factors or inadequate skills, patient status complexity or inadequate support networks.

Table 11. Healthcare-associated infection-related incidents²⁰

Adverse incidents	Total	Percentage	Incidence*
Surgical wound infection	44	40.3	12.2
Nosocomial pneumonia	16	14.7	4.4
Sepsis and septic shock	15	13.8	4.1
Urinary tract infection (nosocomial)	12	11	3.3
Nosocomial infection, not otherwise specified	11	10.1	3
Device-associated bacteremia	6	5.5	1.7
Other†	5	4.6	1.4
Total	109	100	30.1

*The incidence denominator corresponds to all 362 cases.

†Refers to adverse incidents related to preexisting comorbidity, factors such as lack of knowledge and appropriate skills.

evolution of the disease. Furthermore, surgery in the wrong anatomical site, with the wrong procedure, or on the wrong patient; maternal death; transmission of a chronic disease or condition as a result of blood or blood components transfusion, or organ or tissue transplantation; patient escape; suicide; misidentification or exchange of a newborn, and theft of an infant; rape, mistreatment and homicide of any patient; misidentification and exchange of a corpse, are all considered sentinel events.

Events are called “sentinel” because their occurrence alerts that something is failing, and that

something might be explained by numerous causes. It is important to note that the term “sentinel event” is not synonymous with error or mistake, and neither does it suggest legal liability in particular.

In this area, CONAMED reported 37 events where the patient died; out of these cases, 21 were males (56.8%) and 16 were females (43.2%). Analysis of the ratio between the number of deaths (37) and analyzed cases (362), globally provided the indicator of 10 deaths for every 100 cases, with different behavior of mortality depending on gender: 14 males and 8 females for every 100 cases.

As regards age group, in absolute terms, the highest frequency in the 65-year and older group stands out, with 16 deaths (43% of those reported), followed in importance by deaths occurring in children younger than 1 year (five), which accounted for 13% of total deaths, an identical figure to that corresponding to the 45- to 64-year age group.

The mortality ratio with the highest value was observed in the group of children younger than 1 year (42 deaths for every 100 analyzed cases), followed by the group from 10 to 14 years with a ratio of 33 deaths for every 100 analyzed cases, and then by the elderly, with 28 deaths for every 100 attended cases. The lowest value corresponded to the population group of between 35 and 44 years of age, which with 69 cases only had two deaths, with mortality ratio being three deaths for every 100 resolved cases (Table 12).

It should be noted that the mortality ratio does not refer to a high mortality rate as a result of medical care, since to arrive to that analytical criterion it would be necessary to specifically review each case and determine those where there was a direct causal relationship between medical care and patient death.

The same happens regarding the determination of the type of harm, since it is not specified if there was a direct relationship between medical care and patient harm, and thus it can only be regarded as an unwanted effect on the patient. In this area, CONAMED estimated that, in 52% of cases, the patient experienced permanent harm (in 144 analyzed cases), with more than half being females (80), and reported that there was temporary harm in 35% of cases (96 of both genders), the distribution of which shows a much higher relative frequency in females, since two out of every three cases belong to this gender and only one third are males.

The result of medical care assessment at different departments or specialties linked to the analysis of complaints is relevant, which is shown in table 13.

Table 12. Harm severity²⁰

Severity	Gender				Total	Percentage
	Male		Female			
	Cases	%	Cases	%		
Permanent harm	64	53.8	80	50.6	144	52
Temporary harm	34	28.6	62	39.2	96	34.7
Death	21	17.6	16	10.1	37	13.4
Total	119	100	158	100	277	100

Finally, it should be noted that complaints are not only filed when malpractice and professional liability requirements are met; it is enough for the patient or his/her family to be dissatisfied with the care received, either from a medical-technical point of view, due to an inadequate doctor-patient relationship, or due to a lack of respect for current ethical principles, among others.

Reflections

To the benefit of the patient, medical ethics encourages good practice aimed at protecting his/her life, health and dignity.

The World Alliance for Patient Safety motto “First do no harm” (which is the Hippocratic axiom *Primum non nocere*) articulates clinical safety ethics, since the principles of non-maleficence and beneficence compel to avoid any harm to the patient, as well as to use all the necessary knowledge and means available to comply with the duty of care, which means reducing risks in medical care and avoiding adverse events. In turn, the principle of justice is based on the fact that error and lack of safety implicitly entail lack of opportunity, which in the hospital setting means that all patients should have equal opportunities by trying to attain the best care²³. Similarly, also relevant is the principle of autonomy, which emphasizes the doctor-patient relationship, with the patient having to participate in decision-making on his/her care (choose what should or should not be done to his/her person), once having been informed. This decision-making is a right that, to be exercised, previously requires appropriate information; i.e., the patient, or where appropriate, his/her legal guardian or representative, have the right to freely, personally, and without any form of pressure, decide to accept or reject any diagnostic or therapeutic procedure that is offered, as well as the use of extraordinary

Table 13. Medical care assessment by department²⁰

Medical department	Total cases	No evidence of malpractice	Evidence of malpractice	Percentage without evidence of malpractice	Percentage with evidence of malpractice
Trauma and orthopedics	49	21	28	42.9	57.1
Medical emergency	44	16	28	36.4	63.6
General surgery	37	14	23	37.8	62.2
Obstetrics and gynecology	34	15	19	44.1	55.9
Dentistry	31	5	26	16.1	83.9
Ophthalmology	26	14	12	53.8	46.2
Pediatric specialties	26	11	15	42.3	57.7
Outpatient services	21	11	10	52.4	47.6
Plastic and reconstructive surgery	17	12	5	70.8	29.4
Otorhinolaryngology	9	5	4	55.6	44.4
Other	77	39	29	50.6	37.6
Total	362	163	199	45.0	55.0

measures for survival in terminally ill patients. Similarly, in the assumptions stipulated by regulations, the patient has the right to express his/her consent, always in writing, when he/she agrees to undergo procedures for diagnostic or therapeutic purposes that involve risk, for which he/she should be informed in a broad and comprehensive manner on what the risks consist of, the expected benefits and alternatives, as well as the complications or negative events that might occur as a consequence of medical care²⁴.

Errors are repeated and, therefore, when one has occurred, it is essential to reflect on the factors that might have caused it and act on them; however, in general, there is a natural tendency of health professionals, technicians and auxiliaries towards concealment, mainly out of fear of sanctions or lawsuits.

Excessive caution to avoid claims and lawsuits can lead to defensive medicine, which is more expensive and contrary to medical ethics²⁵. In defensive medicine, medical decisions are not based on scientific knowledge, or arise from it, but turn out being unnecessary, even risky, since they do not constitute a requirement for proper patient management. This way of acting should be considered malpractice, since whether consciously or unconsciously, it is an ethically unacceptable professional practice, which adds enormous costs without justification or benefits for patients, and that in many cases turns out being detrimental²⁶.

Defensive practices can be avoided to the benefit of the patient when the physician is aware of his/her failures and of risks, and seeks to correct them²⁷.

In our country, there are different types of professional liability (civil, criminal, administrative, labor) that health personnel can be involved with; in this sense, there will be adverse events that may be a cause of liability, but others will not, if they are the consequence of fortuitous or force majeure circumstances that exclude liability.

Examining why adverse events occur is essential in order to establish strategies aimed at reducing their incidence. Factors that contribute to their occurrence include human fallibility, the complexity of processes, deficiencies in systems and vulnerability of preventive barriers²⁸.

Clinical safety ethics finds it essential to reveal errors, even near-errors and those without significant consequences, aiming at a transparent management of these events that allows improving the safety and quality of care. No error should be shelved, since its honest and open analysis is not only an ethical obligation, but it can help reduce its consequences and improve doctor-patient relationship²⁹.

The imperative of disclosing errors has been addressed at the international level. In Mexico, the Ministry of Health, since several years ago, has been carrying out actions to address this problem; among them, the establishment of discussion tables between

the General Public Health Council and the General Directorate of Quality and Health Education technical areas stands out, which have the purpose to identify cardinal aspects of patient safety that health care establishments should follow in order to reduce the occurrence of adverse events and that resulted in the issuance of an agreement declaring the mandatory implementation, for all members of the National Health System, of the *Essential Actions for Patient Safety* document³⁰.

Following international recommendations for patient safety, the following should be regarded as necessary:

- Establishment of a solid and permanent approach to attain leadership, research and instruments that allow potentiating knowledge on patient safety.
- Identification of safety problems and learning from them through registration and reporting systems, either of voluntary or mandatory nature.
- Risk assessment activities and the adverse event registration and reporting system should form the basis of the quality and patient safety plan at each facility dedicated to the provision of medical care services.
- Formulation of standards for improving safety by professionals and scientific societies.
- Implementation of safe practices at different levels of care.
- Promotion of training in patient safety in health disciplines undergraduate and postgraduate plans.
- Implementation of mandatory medical supervision by those responsible for each one of the areas and departments in order to find processes that can be improved, and periodically measuring the execution of activities to validate the standards that guarantee the quality of services and comply with patient expectations.
- Periodically carrying out evaluations of patient care clinical processes, through the formation of multidisciplinary groups (medical audit), with feedback, implementation of actions for improvement and the corresponding monitoring.
- Presentation of illustrative clinical cases to new generations, which serve to support decision-making and reinforce the use of clinical practice guidelines.
- Constructing a safety culture based on shared values, aimed at minimizing the harms patients might suffer as a result of care processes.
- Dissemination of patient safety policies among patients, their families and the general population.

Conclusions

Achieving safe medical care requires continuous learning on how the different components of the system interact, which implies putting into practice behaviors that have been shown to be effective in reducing the probability of failures and errors occurrence, increase their detection and attenuate their consequences, as well as to continue investigating the factors that contribute to improving patient safety and medical care quality.

It is essential for a safety culture to be developed at all levels of the health system, including users, as well as the training of leaders, who should work to promote it and achieve its impact on each health organization's critical processes and systems, which requires collaboration, commitment and a systemic and multidisciplinary approach.

Patient rights will be protected to the extent health professionals conduct themselves under the scientific and ethical principles of their profession.

Health organizations' managers must ensure the best possible conditions that allow quality of care improvement and risk reduction, and maximum benefit for the patient to be achieved.

The relevance, viability and future projection of health organizations in highly changing settings demand well-committed leaders with an efficiency-oriented vision, who transform them into proactive, highly accountable, patient-centered entities.

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