Patient safety, quality of care and ethics of health organizations

Manuel Portela Romero[1], *Rosendo Bugarín González*[2], *María Sol Rodríguez Calvo*[3], *Alfonso Alonso Fachado*[4]

Abstract

The "To err is human: building a safer health system" report from the United States Institute of Medicine in 1999 concluded that skilled care activity was not infallible and was likely to cause adverse events. From the early years of the twenty-first century developed countries have focused their interest on citizens in order to reduce the damage of health care systems. All modernization strategies will aim to improve the quality of care. In this context, patient safety is a key component of quality of care. In 2003 the Hastings Center published the report "Promoting patient safety: an ethical basis for policy deliberation", which provides an ethical reflection on the moral obligations underlying the safety culture developed following the publication of the report *To err is human*.

Keywords: Patient safety. Quality management. Ethics professional.

Resumo

A segurança do paciente, qualidade do atendimento e ética dos sistemas de saúde

Em 1999, o relatório "Errar é humano: construir um sistema de saúde mais seguro" do Instituto de Medicina dos Estados Unidos concluiu que a atividade de atendimento especializado não era uma prática infalível e que havia maior probabilidade de causar eventos adversos. Para reduzir os danos dos sistemas de cuidados de saúde, os países desenvolvidos concentraram seu interesse nos cidadãos a partir dos primeiros anos do século XXI. Todas as estratégias de modernização terão como objetivo melhorar a qualidade do atendimento. Nesse contexto, a segurança do paciente é um componente-chave da qualidade assistencial. Em 2003, o Hastings Center publicou o relatório "Promover a segurança do paciente: uma base ética para a deliberação de políticas", que faz uma reflexão ética das obrigações morais subjacentes à cultura de segurança desenvolvida na sequência da publicação do relatório "Errar é humano".

Palavras-chave: Segurança do paciente. Gestão da qualidade. Ética profissional.

Resumen

Seguridad del paciente, calidad asistencial y ética profesional

En 1999, el informe "Errar es humano: construir un sistema de salud más seguro" del Instituto de Medicina de los Estados Unidos llegaba a la conclusión de que la especializada actividad asistencial no era una práctica infalible y había supuesto una mayor probabilidad de ocasionar eventos adversos. Para aminorar los daños derivados de la atención sanitaria, los sistemas sanitarios de los países desarrollados centrarán su interés en el ciudadano a partir de los primeros años del siglo XXI. Todas las estrategias de modernización tendrán como objetivo la mejora de la calidad asistencial. En ese contexto, un componente fundamental de la calidad lo constituye la seguridad del paciente. En 2003, el Hastings Center publicó el informe Promoviendo la "Seguridad del paciente: una base ética para la deliberación de políticas", que realiza una reflexión ética de las obligaciones morales que subyacen en la cultura de seguridad desarrollada tras la publicación del informe "Errar es humano".

Palabras clave: Seguridad del paciente. Gestión de la calidad. Ética profesional.

1. Doutor manuel.portela.romero@sergas.es – Servicio Gallego de Salud **2. Doutor** rosendo.bugarin.gonzalez@sergas.es – Agencia de Conocimiento en Salud (ACIS), Servicio Gallego de Salud **3. Doutora** msol.rodriguez@usc.es – Universidad de Santiago de Compostela, Santiago de Compostela **4. Doutor** alfonso.alonso.fachado@sergas.es – Servicio Gallego de Salud, Santiago de Compostela, España.

Correspondência
Manuel Portela Romero – Calle Eduardo Pondal, 33, 1ºC CP 15702. Santiago de Compostela, España.

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In 1998, the psychiatrist Arthur Barsky published an article in which it was pointed out that despite undoubted technical, diagnostic and therapeutic advances and improved health indicators, medical services users in developed countries were increasingly dissatisfied with the attention they were receiving [1] and also with their perceived health. Barsky pointed out that although the collective health of the population has improved significantly in the past 30 years, research has revealed a decrease in satisfaction with the perception of personal health over the same period.

Increasingly, respondents reported more somatic symptoms and increased feelings of general malaise. Barsky proposed four factors that would trigger the discrepancy between subjective perception and objective health indicators. He noted, first, that advances in health care had reduced the mortality rate of acute infectious diseases, which would have led to the emergence of relevant health problems, such as chronic and degenerative disorders. Second, an increased public awareness of health matters would have led to greater self-control and an increased perception of symptoms and illnesses. Third, the widespread commodification of health and greater attention to health issues in the media has created a climate of insecurity and alarm about diseases. Finally the progressive medicalization of daily life would have created unrealistic expectations about the cure of diseases.

In 1999, one year after Barsky's article, the report "To err is human: building a safer health system" was published by the Institute of Medicine" (IOM) of the National Academy of Sciences in the USA. The report concluded that between 44,000 and 98,000 Americans died each year, victims of medical errors [2]. In other words, it was concluded that the complex and specialized care activity, with its combination of technological improvements with human process and interactions, was not an infallible practice and implied a greater probability of causing adverse events (AEs).

Since the end of the Second World War, and especially since the late 1970s, the American media regularly echoed the problem of patient safety, but it is the publication of the aforementioned report "To err is human: building safer health system" of the IOM, which caused the concern for patient safety and the implementation of a safety culture in health organizations, has, in just over a decade, gone from being a marginal and ignored matter to become an emerging element in health management, with the impulse of initiatives aimed at investigating, detecting and alleviating this problem. Although there is controversy about its magnitude, unwanted effects secondary to health care represent a cause of high morbidity and mortality in all developed health systems, as has been shown by several epidemiological studies carried out at an international level [3,4]. In 2016, a study was published that suggests that security problems in medical care may be the third leading cause of death in the United States [5].

In Spain and Latin America, the most important studies on safety in health care are those carried out by the Aranaz team. In 2005, these authors published the ENEAS study [14] on adverse events in Spanish hospitals. An incidence of AEs of 9.3% was found, with the rate of avoidable events of 42.6% and those related to the death of 3.5% of the total number of AEs. In 2007, this same team carried out the study on the safety of patients in primary care in Spain (APEAS) [7]. The prevalence of AEs was 11.18 ‰. 54.7% were considered mild, 38.0% moderate and 7.3% serious. The preventability of the AEs was related to their severity, in such a way that the mild AEs were avoidable in 65.3%, the moderate ones in 75.3% and the serious ones in 80%.

In 2011, the Aranaz team published the IBEAS Study [8] on the prevalence of adverse events in hospitals in Argentina, Colombia, Costa Rica, Mexico and Peru. The found prevalence of AEs was 10.5%, varying from 7.7% to 13.1% among the different countries. About 59% of the AEs were considered avoidable. 19.8% were considered serious, that is, they caused death or damage that remained at discharge or needed surgery for correction. Of the total number of AEs, 5.8% were related to the death of the patient.

In 2015, Montserrat-Capella et al. published the results of the AMBEAS study [9] (Study on the frequency of adverse events in ambulatory care in Mexico, Peru, Brazil and Colombia). The prevalence of AEs was 5.2%, and the cumulative incidence was 2.4%. It was considered that close to 50% were preventable.

It is important to point out that the personal consequences of these damages on the health of patients must also be added to the high economic and social impact of the same [10-12]. From the economic perspective, in 2013 Fernando Antoñanzas publishes the only study carried out in Spain on the amount of non-safety costs in the Sistema Nacional de Salud", SNS (National Health System), both in the field of primary and specialized care [13]. In this work it is indicated that

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these costs represent approximately 6% of the annual health expenditure of the SNS, amounting to 2,474 million euros in hospitalized patients and 960 million euros in non-hospitalized patients.

Patient safety and quality of care

Health systems in developed countries are devoting their interest to citizens since the early years of the 21st century in order to avoid or minimize health care damage and the increase of dissatisfaction with medical care. All development and modernization strategies will aim at improving the quality of care services. In this context, a key component of quality consists of trust and patient safety.

Quality, depending on the disciplinary structure, can be understood in different ways, using different terms, classifications, and models. Although there is a lack of consensus in the area of health care on how to define quality of care [14-19], one of the most accepted definitions is the one from the IOM, which defines the quality of health care service as the degree to which health services for individuals and the population increase the likelihood of achieving optimal health outcomes comparable to current professional knowledge [20]. Likewise, there is agreement in considering that the quality of care is the sum of

- provide health care according to current scientific medical knowledge;
- achieve adequate care for patients' needs;
- provide the most adequate health care that is possible ;
- offer a health care that satisfies the patient.

The dimensions that make up the service quality would be the following:

- professional competence or technical-scientific quality of care;
- efficacy
- efficiency;
- accessibility;
- satisfaction
- adequacy;
- equality
- patient safety

The World Health Organization (WHO) defines patient safety as *the absence of preventable harm to a patient and reduction of risk of unnecessary harm associated with health care to an acceptable minimum* [21]. In this definition, it is important to indicate that the concept *acceptable minimum* refers to *the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.*

Currently we can make the term "quality" synonymous with "excellence" and therefore we can say that the professional is excellent (he develops his work with quality) if he acts under three dimensions: technical, human and sustainable. That is to say, the health professional of the 21st century must be a good scientist, a good philosopher and a good economist.

Patient safety has been developed in several countries, such as the United Kingdom [22], Switzerland [23], Canada [24], Australia [25] and Spain [26], among others. At the global level, the World Health Assembly in 2002 urged Member States to pay special attention to the problem of patient safety. The World Health Organization launched ,in October 2004, the World Alliance for Patient Safety [27] in order to improve patient safety, with the motto "first do no harm" (which is the Hippocratic axiom *Primum non nocere*) and reduce accidents and risk of errors in health systems.

Currently, patient safety is an element that articulates the different dimensions of the quality of health services. Safety is the foundation upon which the other parts of the quality [28-30] dimensions are built on. Its absence would negatively affect the remaining dimensions and its improvement is one of the strategic lines of action in the health care area [31].

Human error theory and the second victim

At the end of the 20th century, cognitive psychologist James Reason described human error as the unintentional execution of an incorrect plan to achieve an objective or the inappropriate execution of a planned action. This means that the plan may be appropriate, but the actions associated with it do not occur as planned or the actions are carried out as planned, but the plan is not sufficient to achieve the desired result [32].

In order to understand how errors occur and how they compromise patient safety,

Reason proposes to study human error from two approaches:

1. Focused on people or personal model.
2. Focused on systems or systemic model.

The people-centered approach, whose premise is that people are the cause of errors, is the one that has traditionally been accepted and understands that errors are the cause of adverse effects. In short, the error is strictly individual. Errors are perceived as unsafe acts derived mainly from incorrect mental processes, such as lack of memory, lack of attention, lack of motivation, carelessness, abandonment and recklessness.

The strategy of action to prevent and treat the errors from a people-centered approach is to blame and punish (Name, Blame & Shame): Identify the culprits, point them out, train or retrain them and take disciplinary action [33].

Followers of this approach tend to treat errors as moral issues, assuming that "bad things happen to bad people". According to a 2016 survey conducted by the US Agency for Healthcare Research and Quality, 55% of hospital staff believe that their institutions respond to errors in a punitive manner [34].

Unlike the previous view, the systems-centered approach has the basic premise that human beings fail and errors are expected or predictable, even in the best organizations. The error is, therefore, in relation to the collective, to the system. The errors are shown as a consequence and not as a cause, which have their origin not in the perversity of human nature, but in latent failures in the healthcare environment and are a consequence of the processes and procedures that are applied. In the systemic approach, instead of seeking the guilt of those involved, the actions are aimed at preventing error, minimizing risks and designing security measures in the system [35]. In this perspective, it does not mean that individuals can be neglected. They are also expected to be more vigilant and responsible for their own actions. Reason believes that, although the human condition can not be changed, the conditions in which human beings work can be modified.

Admitting fallibility is socially unacceptable and, in a profession with values of perfection, the error is practically forbidden. By extrapolating the data from the ENEAS and APEAS studies, it is concluded that each year 15% of healthcare professionals in Spain are involved in an adverse event with relatively serious consequences for patients. Given the situation we should ask ourselves in what situation are the health professionals involved in an error of care. Although it is evident that the AEs with serious consequences have their worst side in the suffering of the patients and their relatives and friends (first victim), they are not the only ones who suffer and are affected. Despite being in the background, professionals who are directly or indirectly involved in the AE and who suffer emotionally as a result are also victims.

In the year 2000, the term second victim appeared for the first time in the editorial article of the British Medical Journal about the impact of errors on the professionals involved [36]. The term second victim was introduced by Albert Wu to refer to the professional who participates in an unavoidable AE and who is traumatized by that experience or who is not able to deal emotionally with the situation. In 2009, Scott et al. expanded this definition by referring to any health professional participating in an AD, a medical error or an unexpected injury related to the patient and who becomes a victim in the sense that he/she is traumatized by the event [37]. This emotional impact, which affects considerably the personal life of the second victim, in addition to affecting the workplace, with the loss of professional reputation, distrust, loss of goodwill towards patients and separation, tends to be magnified and become chronic when the institutional strategy of action against mistakes is based on the people-centered approach and not on the systemic model. Most of the second victims report that the most valued support is that of their co-workers, but, paradoxically, this is the rarest one to be found.

Scott et al. described a trajectory of six stages in the general recovery of the second victims: 1) chaos and accident response, 2) intrusive reflections, 3) restoring personal integrity, 4) enduring the inquisition, 5) obtaining emotional first aid and 6) moving on.

Faced with this situation, Denham proposes the 5 most relevant rights [38] of a second victim, which he names with the acronym "TRUST":

1. Treatment that is just. One can not and should not presume negligence or assign 100% responsibility to professionals against failures in systems that can predispose to human error.
2. Respect. All members of the health care team are susceptible and vulnerable to error and its consequences. They should

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be treated with the same respect we would expect of them.

3. Understanding and compassion. The professional needs time and help to be able to go through the process, we must understand the pathophysiology of the psychological emergency that occurs when a patient is injured unintentionally.
4. Supportive Care. Professionals have the right to psychological services and support services. A systematic approach should be adopted to provide this type of care in a professional and organized the way it would be in the treatment of any other patient.
5. Transparency and the opportunity to contribute to learning. It is the basis of risk management: the prevention of errors is linked to learning from them. Learning from mistakes is only possible when they are communicated. Instead of a simple statement of the facts and a unilateral approach, it is necessary to share and talk about it. Otherwise, it is easy to abandon the professional.

Ethical considerations about defensive medicine and the culture of safety

Medicine has traditionally been conceived as an act of great trust between the patient and the physician. If this confidence disappears there is a risk that defensive medicine will be established, which is the practice of medicine based on mistrust [39]. Defensive medicine is understood as the substitution of good medical judgment for a healthcare practice that, in the evaluation of the tests or treatments that should be applied in a specific clinical process, takes more into account the risk of the professional being the subject of a claim by the patient or their relatives, than of the scientific evidence or therapeutic use [40]. The medical professional, under the influence of defensive medicine, develops a set of behaviors consisting of extreme diagnostic and therapeutic procedures, although these may be ineffective or unnecessary, thus causing excessive expenses in the care provided and subjecting the patient to unnecessary inconveniences and avoidable risks.

Historically, defensive medicine became relevant in the United States in the 1970s, when advances and specialization in medicine, together with the progressive modernization of applied technology, led to an unreal transformation in the life expectancy and healing of the patients. Patients and, as a consequence expected, the growing spiral of demands against doctors for unfulfilled expectations [41].

Faced with the situation that modifies medical practice, we must ask the question of whether defensive medicine is ethical. In addition to deteriorating the doctor-patient relationship, it leads to the loss of trust between the two and, if a formal complaint or demand occurs, it causes loss of the doctor's confidence in himself [42] and favors later an increase in defensive behavior on his part [43]. Defensive medicine is contrary to the principle of justice or equitable distribution of resources because of its great impact on the cost and use of resources [44]. It also unnecessarily increases the risk to which the patient is subjected when implementing tests or treatments not indicated, so it endangers their safety, that is, it is a behavior also contrary to the principle of non-maleficence. If we consider that defensive medicine causes the physician to act on the premise of a self-protective attitude and not for the interests of the patient or in the pursuit of their good, then we can deduce that the principles of autonomy and beneficence are undermined.

Defensive medicine not only does not avoid errors and conflicts between the doctor and the patient but it also encourages them, increases health costs, and it is contrary to ethics, so it is mandatory to make proposals aimed not only to avoid defensive medicine, but also to avoid medical error, as far as possible. In this sense, a "safety culture" should be proposed that enables and promotes effective patient safety actions that reduce medical errors and that preserve, at the same time, the necessary physician-patient trust relationship.

In daily practice, the clinical relationship must move, within the framework of an equitable distribution of resources, between the respect for the preferences of the person and the duty not to abandon the patient, which implies, among other things, that the healthcare professional is the ultimate responsible for setting the indications (preventive, diagnostic and therapeutic), considering all the ethical principles that come into play, and the person is responsible for the choice between these various indications.

From the perspective of the principles of Bioethics, any action in the health field should be aimed at doing good to people, not only to desire it (principle of Beneficence) but promoting free choice among the different indications available through an

adequate informed consent. This means having the values and preferences of the person (principle of Autonomy). And all this avoiding harm to anyone, which implies avoiding what is contraindicated (principle of Non-maleficence), and treat everyone with the same consideration and respect, seeking an equitable distribution of goods and services, depending on the needs rather than demands, fighting against the law of reverse care and avoiding discrimination (principle of Justice).

Many authors consider that the Hippocratic maxim *primum non nocere*, first, do no harm, reflection of the universal ethical principle of Non-maleficence, is the most important premise to establish from the ethical perspective the necessary promotion of patient safety in health institutions.

In 2003, the Hastings Center published the report "Promoting patient safety: An ethical basis for policy deliberation", in which an ethical reflection [45] was made of the moral obligations that underlie the safety culture developed after the publication of the report. "To err is human: building a safer health system". For this institution, the ethical foundation of patient safety is not only based on the principle of Non-maleficence, but also implies the principles of Beneficence, Autonomy and Justice.

Favoring or at least not harming, are two different moral obligations. For Hippocratic physicians the imperative obligation was to favor (Beneficence). Not harming (Non-maleficence) was an obligation when favoring was not possible. From the seventeenth century these obligations are understood to the contrary. The primary obligation, the higher ethical imperative is not to harm (Non-maleficence). The first "first of all", as the motto of the WHO says, will now be, in the modern world, not to harm (First, do no harm).

From the perspective of patient safety, the principle of Beneficence corresponds to the positive obligation to eliminate or lessen the damage produced and to prevent a new one, while the principle of Non-maleficence would refer to the negative obligation to avoid causing harm. In this way, Beneficence would correspond to the obligation to avoid the omission of indicated acts, while the Non-maleficence would be identified with the obligation to avoid the commission of contraindicated acts.

The obligations related to patient safety also derive from the principle of Justice, since the error and the lack of security force the investment of extra resources with a high economic and social cost.

We must not forget that, from the perspective of the principle of Beneficence, the person has the right to be helped, but always respecting their autonomy. In this way, in the event that there is an injury derived from the welfare action, the person would have the right to have it repaired as far as possible and to be informed of what happened.

The obligation to prevent errors derives from professional obligations and health organizations emanating from the two principles that establish the universal level of correctness (non-maleficence and justice), known as minimum ethics, which precedes the establishment of the clinical relationship. This minimum ethics is many times regulated by laws and mandatory. Once an error has occurred and an injury has occurred, then the principles of Autonomy and Beneficence take the center of the stage: the patient has the right, on the one hand, to know what happened and, on the other hand, to claim and obtain support, help and repair of the damage caused.

Therefore, the ethical obligations surrounding the prevention of medical errors and the promotion of patient safety are shaped by the four principles of bioethics. In addition, these obligations are not personal obligations of the professionals only, but also obligations of health institutions as a whole. Thus, they set up a scheme to analyze the ethics of the organization responsible and its obligations with respect to the security of the people they serve.

Health workers, management teams of organizations, quality committees or ethics committees will be the appropriate bodies to conduct moral deliberation around the safety of patients, each in their own sphere of responsibility. This deliberation, within the framework of what is known as ethics of responsibility, must include a prior and mandatory analysis of the weighted application of the four principles of bioethics, which are the frame of reference used to consider arguments about the economic, legal or public policy aspects of patient safety, which would establish the most appropriate course of action, depending on the circumstances, within the ethically correct limits.

In addition, the deontological principles of responsibility, transparency, relevance and universal protection can contribute, in the culture of respect for patient safety, to behavioral norms at the personal level by each of the professionals involved and at the institutional level.

Studies indicate that most of the errors occur more due to problems arising from the operating

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processes of the organizations than because of individual failures of the workers. However, with regard to the errors produced by the lack of competence in the area of clinical knowledge, the importance of the individual responsibility in the acquisition and updating of competences is unquestionable. Despite the institutional duty to promote continuous training of the professionals of a health organization.

The challenge is to promote a safety culture within the organization in a way that will allow to avoid errors as much as possible. If preventive measures fail and an error occurs, then the question that must be asked is to look for what has failed considering individual, collective and institutional responsibilities, avoiding the risk of dilution of professional responsibility. One of the most important ethical challenges is that in order to improve the security of the person, the individual commitment of the professionals and of the institutions is necessary. The obligations arising from the four principles of bioethics affect both professionals at the individual level and the organizations of which they are part. The deontological principle of responsibility. The first reaction to an error must be one of serenity, of analyzing the facts, showing support to the professionals, correcting the error in the best possible way, making who has more institutional responsibility and involvement appear, and repairing the damage if the There will be, at the same time that organizational measures are taken so that it does not happen again.

All these actors must assume their responsibilities, which can be both retrospective and forward-looking. The health professional should know that he or she has an ethical obligation to protect the patient from harm by maintaining and updating the quality of professional practice. This means that the health professional must be responsible for acquiring and maintaining high standards of scientific and technical quality, giving special attention to competence in clinical reasoning. They must make appropriate use of the resources that the organization places at their disposal for the development of their assistance tasks, whilst maintaining a high degree of efficiency and being actively involved in the internal processes of the organization that seek to generate a "safety culture". In this way, by reinforcing their obligations regarding Non-maleficence and justice, the health professionals are taking responsibility to avoid, personally and prospectively, any harm to the patient.

If one starts from an individual blaming perspective, with the premise that the competent professional can not make mistakes, there will be a tendency to proceed by penalizing the one who is wrong with the belief that, as a result of this exemplary action, fewer mistakes will be made. As previously mentioned, in this way, the professional is abandoned by colleagues and by the institution, facing the problem alone, thus becoming the second victim. It is not uncommon and it is understandable that this form of action derives in secrecy, shame, concealment and defensive practices.

We can not fail to mention that a culture without fault does not mean without responsibility. Denying individual responsibility and attributing it solely to the institution supposes admitting a false moral immunity of the professionals.

For the professional, the prospective responsibility supposes the obligation of a care carried out through a quality healthcare practice, which guarantees the protection of the people it serves. If damage occurs, the professional is also responsible for informing the institution so that it contributes to repair the damage and put measures in place to prevent it from happening again. In retrospect, the professional is obliged to report the damage to the affected person, by virtue of respect for their right to know what happened. One must assume one's share of responsibility in the occurrence of this damage and repair it not only from the physical point of view but also from the moral point of view.

When an error occurs, honesty is expected as an ethical and deontological ideal of the medical profession. Nevertheless, the way to approach the error in medicine often consists of concealment, disinterest, lack of information to the patients and, sometimes, the punishment of the supposed responsible person [46].

The Code of Medical Deontology of Spain, approved in July 2011, states, in its Article 17.1 that "the physician shall assume the negative consequences of his actions and errors, offering a clear, honest, constructive and adequate explanation" [47]. That is, if a damage occurs, the professional must be able to personally assume the obligations derived retrospectively from it. The first, more difficult and conflicting one is to assume that respect for the principle of autonomy of the patient requires informing him of what happened and to assume his subjective responsibility before the patient, although it may trigger a legal process against the physician. It must be remembered that personal responsibility does not end with information: the principle of Beneficence leads

to providing some kind of reparation, both for the physical damage - usually assumed by the organization - and the moral one. In addition, if the damage to the patient's health occurs as a consequence of the care activity, there is also an ethical obligation of the professional/professionals involved with the health organization to which they belong. It is a duty to report what happened so that the institution and the ones responsible for it can adopt the necessary measures, aimed at repairing what happened and preventing it from happening again. With this way of proceeding, it would positively feedback and reinforce the ethical frame of reference based on respect for the principles of Non-maleficence and Justice.

It is necessary to facilitate the communication of professional errors among professionals and with patients. Once the errors are recognized, it is necessary to work on them since the multiplicity of mechanisms and causes means that there is no single, simple and universal way to reduce the error in medicine. The communication of error leads to a new care culture characterized by greater transparency of the medical act and a return of reliable information that allows us to know the dysfunctions that cause the error, correct them and thus achieve greater patient safety [48].

Different authors indicate that in order to facilitate the communication of errors it is necessary to implement specific communication and apology programs that have the institutional support [49, 50]. If this is not done in this way and professionals are encouraged to communicate and excuse the errors without adequate advice, it can help to magnify the concept of second victims through increased anxiety, emotional dissatisfaction and depression.

Institutions, prospectively, have the obligation to make an adequate investment of resources in the creation of a safety culture, fundamentally in human resources that would assure a correct development of the assistance processes, not forgetting the investments in the improvement of structures and facilities. In retrospect, if damage occurs, the safety culture assumes a correct and good handling of information for the institutions. This will be transparent and standardized. It will be used not only to repair the damage to the person, but also to provide moral support to the professionals. And, of course, it will be used for the launching of spaces and deliberative processes where risk is analyzed and safer proposals are made, with the participation of all the people involved.

We know that risks can not be eradicated, but we can and should reduce them, learn from them and improve the way we handle and treat them, thus reinforcing the relationship of trust with the people we serve in our health institutions.

Final considerations

Despite the expectation that physicians must have a diagnostic and therapeutic reliability of 100%, the truth is that the human condition is linked to error in any activity and the practical exercise of medicine is not the exception, since, by nature, it is an imperfect science, and the expectation of perfection is neither realistic nor possible. This does not mean that nothing can be done to decrease the frequency and mitigate the consequences of medical errors, so we must learn from them and improve the way we handle and treat them, thus reinforcing the relationship of trust with the person we serve in our health institutions.

As mentioned earlier, the ethical obligations surrounding the prevention of medical errors and the promotion of patient safety are shaped by the four principles of bioethics. These obligations are not only personal duties of each of the professionals, but also of the health institutions as a whole.

The traditional punitive approach to errors in health services does not lead to their prevention and has negative consequences, such as concealment and defensive medicine. It is necessary to change the paradigm, focusing its approach within a systemic model that enables a care culture characterized by greater transparency of the medical act that allows knowing the causes that lead to error, acting on them and achieving greater patient safety.

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Participation of the authors

Manuel Portela Romero was responsible for the conception, bibliographical revision and writing of the manuscript. Rosendo Bugarín González, Marísol Rodríguez Calvo and Alfonso Alonso Fachado were responsible for the conceptual supervision and critical revision of the text. Alfonso Alonso Fachado translated the abstract into Portuguese. All authors approved the final version of the manuscript.

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