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Healthcare compliance: pioneer experience in a public hospital

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INTRODUCTION

The judicialization of health is an irreversible reality not only for professionals, but also for public or private institutions, with an exponential increase in actions against public entities, hospitals, and professionals. Such actions can result in indemnification for alleged malpractice, accountability for various illegal acts, in addition to requiring the right to treatments, hospitalizations, and surgeries. The Brazilian National Council of Justice published a report showing a 130% increase in cases involving health-related aspects between 2008 and 2017, compared to a 50% increase in cases in general[1]. A detailed analysis identified that medications, orthotics, prostheses and auxiliary means, examinations, procedures, and hospitalization beds are the main causes related to the search for judicial guardianship. On the contrary, actions with allegations of medical error represented a higher number than the demands for transplants, for example.

Another very sensitive subject is hospital mortality related to the occurrence of preventable adverse events. In a survey by the Institute for Supplementary Health Studies, it was demonstrated that mortality from this cause could be prevented in almost 40% of cases. In addition, the prevention of serious adverse events could provide fence one million beds for hospitalizations for other causes every year[2]. In addition to the direct and indirect damages caused to patients and families, there is undeniable and enormous financial damage, with the consequent misuse of resources that could be used in the treatment of other patients.

Some of the possible causes of this situation may be the lack of hierarchical definitions, tolerance for individualistic measures and practices, poverty in available information, and fear of punishment. Adjunct to these aspects, conducts known to be unethical or even illegal can be taken in professional practice, which should not be seen as mere individual inappropriate conduct, but as systemic problems in hospital institutions[3].

In this scenario, it is evident that measures need to be adopted to try to prevent or reduce harm, such as the establishment of a non-punitive culture of care security, so that failures are seen as real opportunities for improvement, and the training of health professionals to know and use measures to prevent these failures. It is essential to make professionals aware of the consequences of harmful attitudes, even when they are routine and apparently harmless. As a result, it is urgent to implement a compliance culture in health practices.

COMPLIANCE IN THE HEALTH SECTOR

In the current reality, it is indispensable to apply compliance programs in the health area, even though this is one of the most complex areas to implement the program. This is due to the fact that there is a very high level of specialties, techniques, and procedures to be strictly followed, surrounded by several contradictions and dilemmas, mainly ethical[4]. Compliance in the health sector should be oriented toward the observation of administrative, ethical, and legal rules present in the various resolutions of regulatory agencies, codes of conduct (such as those of the National Accreditation Organization), codes of ethics of professional councils, and, ultimately, the legal system that regulates health practices. Without any doubt, the adequacy of conducts to national and international standards, the adoption of educational methods for the use of the best care protocols, and the improvement of patient safety are attitudes that can be improved with an active compliance program help[5].

"Defensive medicine" is a medical practice that prioritizes the adoption of diagnostic and/or therapeutic conducts with the primary objective of avoiding lawsuits, since the doctor can be triggered in the ethical courts, and most of these processes focus on actions in the judiciary, whether in civil justice or even criminal justice. An UK study showed that 63.8% of physicians adopted defensive practices such as unnecessarily referring patients to other

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doctors, performing unindicated control tests, and requesting unjustified complementary tests[6,7]. In the United States, in the 1990s, 17.6% of medical care investments were related to defensive medicine practices, with amount greater than $10 billion[8,9].

In Brazil, the daily reality of the practice of defensive medicine is not much different. In our country, in addition to the aspects already pointed out, this practice also occurs due to poor medical training, causing the professional to use diagnostic means of difficult public access (and expensive) instead of adequate communication with the patient and a detailed and enlightening clinical examination. Deficient professional training can be explained by the indiscriminate creation of medical schools, many without the minimum operating conditions, added to the fact that most of these trained physicians do not have access to medical residency or specialization courses[10].

The adequacy of the norms does not aim at a definition of a standard of conduct that can interfere with the autonomy of professionals. Its objective is to rule out possible frameworks and punishments, while enabling a rational use of scarce health resources[11]. In fact, what is sought are prevention mechanisms and not only compensation after the occurrence of the act performed in noncompliance with the rules and laws[12].

Two other important aspects that must be faced by health professionals and institutions and that go through the activities of these programs are (1) acts of corruption in hospitals, such as deviations from public resources or bribes to circumvent lines of care or receive priority care and (2) compliance with the recently approved General Data Protection Law[5].

In relation to corruption in the public health system, in addition to the damage caused by diverted financial values, such situations demonstrate that it is easy for professionals to find some ways to enrich themselves using the Public Health money, a fact that directly compromises the image and efficiency of public health. These situations may be a constant source of concern for the administrators of these institutions so that they can curb such practices. These should combat illicit attitudes in a systemic way, acting in the relationship between health providers and public authorities, as well as between these suppliers and various civil servants[13]. The relationships of these professionals with the industry, such as the rich distribution of free samples of medicines, sponsorship for event participation, donation of gifts and gifts, and hiring for lectures and studies, are situations that are in a border zone between morality and legality, which can generate dangerous conflicts of interest.

The General Data Protection Act (LGPD – from Portuguese) was created with the aim of protecting citizens' personal data, maintaining the privacy of these users, and protecting them from the collection and misuse of their personal data. Among the various impacts in the health area, the entry of this law will generate the need for users' consent, expand the concept of sensitive data, and decrease the possibility for other users to access the data.

There is no doubt that the implementation of the LGPD by health institutions, clinics, hospitals, health plan operators, laboratories, pharmacies, and other companies in the sector will be a major challenge since patients are the true owners of their personal data. All these institutions, whether public or private, in the implementation of this legal provision, must be based on what is recommended by the LGPD. Every process of collecting, storing, and transmitting patients' personal data must be carried out in systems, with encryption, and by software approved by institutions, such as the Brazilian Society of Health Informatics. Furthermore, the confidentiality between doctor and patient, a presupposition long provided for in the Code of Medical Ethics, must be guaranteed in digital medicine tools[14].

Disobedience to the LGPD causes high fines to establishments that do not comply with the standards, which makes the dissemination of the culture of proper data processing, from the high-dome manager to the receptionist, fundamental. Thus, the implementation and application of LGPD terms in public health facilities is another challenge for compliance programs.

EXPERIENCE OF A COMPLIANCE PROGRAM IN A BRAZILIAN PUBLIC HOSPITAL

The complex structure of private hospitals in Brazil and competition in the sector caused them to start looking at their management with a strategic vision, with the implementation of a system that integrated the main management processes and generated speed in the quality of services provided for the benefit of patients. Especially after the validity of law 12.846/13 (Anti-corruption Law), there was a need for private hospitals to protect themselves from the danger of illicit acts that could be committed by employees, which would cause economic and image damage to public opinion. Thus, there was a need for these institutions to give more attention to the compliance area. The same did not occur in hospitals and public sector institutions.

The Hospital of Clinics of the Faculty of Medicine of the University of São Paulo (HCFMUSP) is the largest hospital complex in Latin America, which is considered one of the most important Brazilian centers for dissemination of technical and scientific information, serving as a center of excellence and reference in the fields of teaching, research, and care, as well as a pioneer in several medical, technical, scientific, and administrative activities in Brazil and Latin America. In March 2018, HCFMUSP became the first

Brazilian public hospital to establish a compliance program aimed at guiding the actions and professional conduct of approximately 23,000 employees of this hospital complex.

Its board guides the conduct of those who work at HCFMUSP to minimize the risks arising from actions taken in noncompliance with regulations and legislation. This is in line with the concept of Fair Culture, which is defined by the governance model that has as one of its principles that not all errors or violations of conduct are the result of bad intentions, according to which punishment is not effective, since the problem is not found in the individual itself, but in the institution[15,16].

Hospital of Clinics of the Faculty of Medicine of the University of São Paulo (HCFMUSP's) pioneering compliance program focuses on the role of guiding the ethical and legal conduct to be adopted, seeking to change the organizational culture and make clear the expected conducts and those that are restricted to employees, focusing mainly on situations of conflicts of interest – the great doors of access to improper practices. Examples of pillars of the guidelines include sponsorship of education activities, donations, sponsorships, events, and clinical research; the adequacy of prescriptions; patient enrollment; the correct relationship with suppliers; confidentiality obligations; the use of social media; and respect in the handling of privileged information. The seals are clear, grounded, and justified to employees, bearing in mind that the practice of unreasonable and unexplained prohibitions can generate an attitude of weariness and a lack of commitment to the rules.

The dissemination of the guidelines occurs through periodic training for the teams, as well as the dissemination of matters of interest and clarification summaries in official internal publications, maintenance of online portal, and direct communication channel, with the possibility of clarifying doubts, receiving complaints and providing guidance[17]. The HCFMUSP Complex' booklet of the Compliance Board, launched in 2018 and later updated, is distributed to employees (in its printed version) and maintained in the electronic portal of the institution, with ample access to employees and also to all users of the worldwide computer network[18].

Another aspect of the way this compliance board operates is its proximity and synergy with other hospital complex boards, such as the medical and health boards of all institutes, internal communication, information technology, the law center, and, more importantly, the clinical and executive boards of the hospital. Thus, there is no conflict or invasion of competencies, generating a harmonic and aligned discourse, which generates security for all employees and allows greater compliance from all those involved in the policy and principles of compliance.

At present, there is no doubt that this is a successful model. The results speak for themselves: in the 3 years since its installation, there have been hundreds of e-mails and requests for guidance, participation in more than a hundred corporate and board meetings, publication of more than 120 articles, referrals of complaints, and appointments to indictment committees to investigate possible administrative infractions, with clear indicators that show the growth of employees' compliance policies and acceptance of their guidelines year after year.

On the contrary, the support of the various areas of management is also evident, with the expansion of the sector, the ratification of its decisions, and the insertion of its board members in other institutional committees, such as the Bioethics Committee, among others[17].

CONCLUSION

The health sector, in its various segments and institutions, presents great vulnerability and enormous potential for illegal misconduct to occur. It is noted that self-regulation is already consolidated in private institutions, with the establishment of policies and a culture of fraud and damage control, either through guidance, investigation, or even punishment of the various parties involved in its production chain.

On the contrary, this philosophy and these practices are slow in the public sector, especially due to the lack of resources, managerial culture, and the presence of bureaucratic controls that are often archaic and harmful to new regulatory policies.

The experience of the largest hospital complex in Latin America, a public entity, demonstrates the feasibility of implementing tools for the institution of structural and cultural changes, with the use of accessible resources, through the collaboration of administrative bodies and their employees; the focus of this action, based on the culture of education and orientations, without the punitive aspect, undoubtedly contributed to the adhesion of all those involved.

This scenario demonstrates that models of self-control and pipeline restructuring, such as those adopted by HCFMUSP, can and should be replicated in other public hospitals in order to obtain the real confidence of the population and, gradually, and reduce deviations of funds and purposes, resulting in an improvement in healthcare for the entire population, which is one of the constitutional purposes of the Unified Health System.

AUTHORS' CONTRIBUTIONS

FRC: Conceptualization, Formal Analysis, Project administration, Supervision, Validation, Writing – review & editing. **MAO:** Visualization, Writing – original draft. MLG: Conceptualization, Project administration, Supervision, Validation.

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