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Patient Safety in pandemic times: A reflection based on the care quality attributes

Segurança do paciente em tempos de pandemia: reflexão a partir dos atributos de qualidade do cuidado

Seguridad del paciente en tiempos de pandemia: reflexión basada en los atributos de la calidad de la atención

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Abstract

Objective: to discuss patient safety based on a theoretical approach and on the health quality attributes in the context of the new coronavirus pandemic. **Method:** a reflection developed based on the structural, particular and singular dimensions contained in the Theory of Practical Intervention of Collective Health Nursing and in the Donabedian health quality attributes, as well as on the Program for Performance Evaluation of Health Services. **Results:** the drastic and sudden changes in the health care scenario caused by the pandemic constitute an additional risk to the provision of safe care. This can be evidenced through non-compliance with the adequacy, safety, access/opportunity, equality and effectiveness attributes. **Conclusion and implications for the practice:** the current pandemic context represented a serious threat to care quality and patient safety. The challenge is for us to rethink the consolidation of good health practices, based on investment in safe organizations, considering the health care quality attributes/domains. As well as to contribute to the reflection on responsible management of the health services based on scientific knowledge, and on the importance of persisting in strengthening the SUS, as a strategy for implementing the care quality attributes.

Keywords: COVID-19; Pandemics. Patient Safety; Health Care Quality; Safety Management.

Resumo

Objetivo: discutir a segurança do paciente sob um enfoque teórico e nos atributos de qualidade em saúde, no contexto da pandemia pelo novo coronavírus. **Método:** reflexão desenvolvida com base nas dimensões estrutural, particular e singular, contidas na Teoria da Intervenção Práxica da Enfermagem em Saúde Coletiva e nos atributos da qualidade em saúde de Donabedian, e no Programa de Avaliação de Desempenho dos Serviços de Saúde. **Resultados:** as mudanças drásticas e repentinas no cenário de assistência à saúde, ocasionadas pela pandemia, constituíram-se em risco adicional à oferta de uma assistência segura. Isto pode ser evidenciado por meio da ruptura dos atributos adequação, segurança, acesso/oportunidade, equidade e efetividade. **Conclusão e implicações para a prática:** o contexto pandêmico atual representou uma séria ameaça à qualidade do cuidado e à segurança do paciente. O desafio é repensarmos a consolidação de boas práticas de saúde, a partir do investimento em organizações seguras, considerando os atributos/domínios da qualidade do cuidado em saúde. Contribui para a reflexão sobre a gestão responsável dos serviços de saúde fundamentada em conhecimentos científicos, e sobre a importância de persistir no fortalecimento do SUS, enquanto estratégia de efetivação dos atributos de qualidade do cuidado.

Palavras-chave: COVID-19; Gestão da Segurança; Pandemias; Qualidade da Assistência à Saúde; Segurança do Paciente.

Resumen

Objetivo: debatir la seguridad del paciente desde un enfoque teórico y sobre la base los atributos de la calidad en salud, en el contexto de la pandemia provocada por el nuevo coronavirus. **Método:** reflexión desarrollada a partir de las dimensiones estructural, particular y singular contenidas en la Teoría de la Intervención Práctica de Enfermería en Salud Pública y en los atributos de calidad en salud de Donabedian, al igual que en el Programa de Evaluación del Desempeño de los Servicios de Salud. **Resultados:** los cambios drásticos y repentinos en el escenario de atención en salud provocados por la pandemia constituyen un riesgo adicional para la prestación de una atención segura. Esto puede evidenciarse a través de la ruptura de los atributos de adecuación, seguridad, acceso/oportunidad, equidad y eficacia. **Conclusión e implicaciones para la práctica:** el actual contexto de la pandemia representó una grave amenaza para la calidad de la atención y la seguridad del paciente. El desafío es que podamos repensar la consolidación de buenas prácticas en salud, a partir de inversiones en organizaciones seguras, considerando los atributos/dominios de la calidad de la atención en salud. Al igual que contribuir a la reflexión sobre una gestión responsable de los servicios de salud basada en el conocimiento científico, al igual que sobre la importancia de persistir en el fortalecimiento del SUS, como estrategia para implementar los atributos de calidad de la atención.

Palabras clave: Administración de la Seguridad; Calidad de la Atención de Salud; COVID-19; Seguridad del paciente; Pandemias.

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INTRODUCTION

Patient safety is the provision of quality, efficient and, mainly, harm-free care; defined as the reduction, to an acceptable minimum, of the risk of unnecessary harm associated with health care.[1] Health care quality is conceptualized based on the quality attributes/domains. The following attributes will be emphasized in this article: Adequacy, Safety, Access/Opportunity, Equality and Effectiveness, according to the PROADESS and Donabedian conceptualization.

In addition to the theoretical framework of the quality attributes, the Theory of Practical Intervention in Public Health Nursing (*Teoria da Intervenção Práxica da Enfermagem em Saúde Coletiva*, TIPESC) will be used, for considering it as the basis for a broad understanding of reality, beyond the phenomena themselves. It allows looking at its determinants: the political-economic-ideological situation, contained in the totality (structural dimension), which permeates organization of the health services (particular dimension), and the care processes used by health workers (singular dimension).[2]

More than 20 years ago, from the report called "To Err is Human", the understanding was disseminated that health services, paradoxically, with their mission of caring, rehabilitating and/or curing, can be sources of risks to the very health of the people who need them. It was concluded that errors or failures called incidents can cause harms to people's health. Harms are conceptualized as adverse events, which can cause temporary or permanent lesions, and even death.[3]

For health services to be safer places, they have been the focus of both international recommendations made by the World Health Organization (WHO) and national ones by the National Patient Safety Program (*Programa Nacional de Segurança do Paciente*, PNSP). The WHO and the PNSP point out the need to adopt a safe organizational structure consisting of, among others, a strong safety culture, organizational management, structure and ambiance adaptations, training of workers and adaptation of work processes pertinent to the patient safety goals established in the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, ANVISA) protocols.

Adoption of such recommendations is encouraged and examined once a year through the process called National Evaluation of Safe Patient Practices, conducted by ANVISA. The results of such assessments show that only 68% of the Brazilian hospitals adhered to participating in the self-evaluation, in the year 2021. Among the participants, with regard to the process indicators, which verify the health services' adherence level to the safety recommendations, this adherence still presents significant variance, ranging from 48.1% to 89.2%,[4] which shows that it is still necessary to go a long way in the organizations' achievements towards a strengthened safety culture.

Given the concern for patient safety during the pandemic, the American Agency for Research and Quality in Health (ARQH) has described errors and harms that can potentially occur during this period, such as delays or errors in diagnoses, errors related to human factors and failures in infection prevention and control. For the agency, the errors related to diagnosis can include missed or late diagnoses in patients with respiratory problems, as well as delay or absence of diagnosis for a non-COVID-19 condition.[5] The pandemic was also attributed as a reason for delays in preventive exams, as well as in the diagnosis and treatment of cancer and other chronic diseases. Delays or postponements in care exerted negative impacts on the patients, potentially worsening the long-term results.[6]

Also in this sense, it is valid to understand that the interactions between human beings and their work systems can be useful to identify the causes of the errors that result from human conditions. A review of cases reported to the Pennsylvania Patient Safety Reporting System to identify patient safety events related to COVID-19 discovered that many of them were associated with human factors such as health workers' stress and exhaustion.[7]

The ARQH also noted that infection prevention and control practices were critical components of the strategy to contain COVID-19 spread in health units and reduce the risk of infection among health professionals. Failures in adherence to the guidelines and PPE shortage limited the workers' ability to develop their activities, mainly during the peaks in the number of patients requiring care.

In this direction, a reflection study on the actions related to patient safety in the face of the new coronavirus, used and suggested by regulatory bodies and health institutions, reinforced the importance of rescuing actions and strategies for safe and quality care.[8] Thus, the relevance is highlighted in terms of reflecting, based on a theoretical framework, about the impacts of the pandemic on patient safety. Given the above, the objective of this article was to discuss patient safety from the perspective of the Theory of Practical Intervention of Collective Health Nursing and the Donabedian and PROADESS quality attributes, in the context of the pandemic caused by the new coronavirus.

METHODOLOGY

A descriptive study based on a literature review and with a qualitative approach, in addition to the authors' perception regarding the subject matter addressed. Data collection was carried out through scientific articles available in the Virtual Health Library (*Biblioteca Virtual em Saúde*, BVS), MEDLINE (PubMed) and entities of interest to discuss the problem, such as the National Health Surveillance Agency, the World Health Organization and the Brazilian Medical Association. The inclusion criterion adopted corresponded to all those that included the topics of patient safety, quality, safety management and COVID-19.

Patient Safety in pandemic times from the perspective of the care quality attributes defined by Donabedian and PROADESS

Since advent of the pandemic due to the new coronavirus in December 2019, scientists and scholars from all over the world dedicated themselves to trying to understand the etiological agent of COVID-19. Its dissemination routes and control measures; as well as the biosafety measures and mechanisms to protect people's health at the global level, in addition to that of health workers. There were many contributions and the advances were significant. Based on this diverse knowledge produced, governments and societies alike adopted important measures to

control virus spread, with social distancing, adoption of hygiene measures and use of Personal Protection Equipment in the health services among them. Those actions contributed to global health safety management.[9]

However, even with the advances of science and the global efforts to face the pandemic, its emergence installed a new health context, permeated by instabilities, uncertainties and new requirements, which were added to the already existing risks for patient safety. Anchored in the Theory of Practical Intervention of Collective Health Nursing, it is understood that the threats to patient safety in this pandemic context can arise from three types of sources: structural, from the global organization or disorganization in facing it, called external threats; particular, from *in loco* assistance in the health services, and singular, concerning the care processes and health workers. We shall call the last two "internal threats", or *in loco*, although it is understood that these three dimensions are interconnected and are part of a whole.[2] Donabedian describes the health care quality and assesses the dimensions (structure and process) necessary to measure care quality and proposes seven attributes, which he called the Pillars of quality: efficacy, effectiveness, efficiency, optimization, acceptability, legitimacy and equality.[10] In Brazil, the Health Systems Performance Evaluation Project (*Projeto de Avaliação de Desempenho de Sistemas de Saúde*, PROADESS), created after publication of the "World Health Report", identifies eight dimensions for the evaluation of the health system performance: effectiveness; access; efficiency; respect for people's rights; acceptability; continuity; adequacy and safety.[11] Of these attributes, five are of special interest for this reflection: Adequacy, Safety, Access/Opportunity, Equality and Effectiveness.

The coronavirus pandemic and patient safety: the peril from outside

In this dimension, identified as structural for including the health system response to a problem, anchored in its political framework, the drug therapy adoption logistics stands out. It is extremely valuable for patient safety, as it is the locus with the highest occurrence of cases.[12] And in this regard, there was stir around the case of chloroquine, adopted for drug treatment by many physicians and supported by the misguided national policy to fight against COVID-19 in Brazil, under auspices of doubts and conflicting studies.[13] Its use was based more on a concern for doing something than on scientific evidence. And such situation is considered the first major peril of the pandemic context for patient safety.

The evidence-based practice (EBP) emerged nearly 30 years ago, was conceptualized as *"ability to assess the validity and importance of the evidence before applying it to everyday clinical problems"*[14] and has been understood and adopted on a global scale as a necessary element in the provision of safe care. Neglecting it hurts the patient safety "**Adequacy**" attribute, conceptualized as *"degree to which the care provided to people is based on technical-scientific knowledge"*[11].

Consequently, making decisions and grounding actions without resorting to EBP is synonymous to striking a blow at patient safety. Health care is based on this is evidence of a strengthened safety culture.[15] At the beginning of the pandemic, chloroquine use might have found some justification in the absence of studies on its ineffectiveness. However, as the pandemic progressed, scientific studies also advanced and showed its ineffectiveness in the treatment of COVID-19;[16] on the contrary, they corroborated the risks related to its use. Therefore, persistence in its indication and use is configured as an attitude of denialism, a movement that threatens us all since the 19th century, period since which we started to live with major epidemics,[17] and which undoubtedly weakens patient safety.

In addition to that, we still have a more serious problem to discuss when therapeutic decisions are no longer the prerogative of people with training and competence to do so, and becomes the object of political decision.[18] Let alone the formulation of anti-COVID-19 kits, with chloroquine as one of its items, which is known to have the potential to produce side effects.[13] If its use, indicated and monitored by physicians, already raises doubts given the consolidation of diverse scientific evidence against its indication, in the second situation, based on political decision, this confidence becomes more nebulous.

Both situations, professional behaviors that exclude scientific evidence and therapeutic decisions of a political nature, anticipate threats for patient safety. The first one characterizes neglect towards the evidence-based practice; and, in addition to that, involvement of the political actions in the direct decisions regarding people's health care is seen in the second. It is important to remember that the basic premise of a health service is not to harm its patients ("*primum non nocere*") and, therefore, we cannot use procedures or therapies with known collateral risk and weak evidence regarding the benefits.

However, the threat of denialism to patient safety was not a Brazilian privilege. Similar cases emerged all over the world. In the United States of America (USA), the scientific recommendation of measures to interrupt the contagion chain, such as mass testing and isolation, was neglected, to the detriment of investment in more ventilators; the country's president even used the phrase "USA, king of ventilators" and, in addition to that, conspiracy beliefs about origin of the virus were disseminated.[19] In Mexico, despite presenting one of the worst death rates in the world, there was feasible resistance to the restrictions on circulation and mass testing.[20] In Nicaragua, denialist extremism reached the point of denying existence of the disease in the country and its community transmission.[21] In India, Prime Minister Narendra Modi reprimanded the press warning about the importance of fighting against the dissemination of pessimism, negativity and rumors about COVID-19.[22]

When reflecting about the State direct intervention in the therapeutic-care decisions, it becomes necessary to remember that the State is the health policy organizer. In the Brazilian case, such organizer is the Unified Health System, not a drug prescriber. Is that not obvious? The State trains the prescribers, with good quality, especially by means of public universities. It does not prescribe or indicate any therapy. The State organizes the policies to cope with health crises, or in better terms, organizes the health care network.[23] Going beyond these limits weakens patient safety and, consequently, increases the list of possible health-related adverse events against which we have so arduously fought.

The coronavirus pandemic and patient safety: the peril inside

We shall now reflect on the risks of the pandemic for patient safety by looking at ourselves as health care producers. Here, based on the TIPESC, we identify the particular dimension, organization of the health institutions to face the pandemic, and the singular dimension, health workers' response, through their work processes, as a smaller totality.[2] Based on the current understanding of patient safety, it would not be possible to lead to a reflection looking for culprits but, on the contrary, seeking to look at health organizations as a whole, beyond their actors, individualized health professionals.

The scope of safe care includes a wide range of elements, which move between people (health workers, patients, managers), work processes (protocols), equipment, supplies, medications, technologies, ambiance and relationships, among many others. Therefore, it is intertwined in a complex network of connections, with no possibility of dissociate any given element from the importance of offering safe care.

As already mentioned, the new coronavirus came along with a series of requirements to cope with it. It is possible to cite adaptation needs regarding ambiance and ventilation;[24] sufficient number of beds to care for the outbreaks that were gradually emerging in all regions of the world;[25] technological devices such as mechanical ventilators, respiratory filters and respiratory masks;[26] restaffing of health workers, especially nurses, to account for the number of patients affected by COVID-19, who queued up in health services;[27] capable professionals; and updated knowledge about a new health condition and still incipient research about it. All these elements lead to reflect on the place that patient safety occupies in this context, mainly when considering the incipient safety culture in Brazil.

The first major challenge was the health services' installed structure and capacity. It its more than 30 years, the SUS made important progress for Brazilian health; however, striking a balance between service offer and demand is still one of the challenges. Especially after 2016, the advance of the neoliberal practice has been seen as a threat to the consolidation of health as a right for all.[28] As can be verified through the media and factually in health institutions, regarding workers in many Brazilian health services, the places to meet the demands arising from the pandemic were improvised.

Large institutions such as traumatology hospitals, for example, have reverted their beds to care for people with COVID-19; small-size institutions had to resort to flattening beds, reducing vacancies in medical and surgical clinics and canceling elective surgeries to allow opening of isolation beds.[29]

One of the concerning elements of this improvisation is related to suitable ambiance conditions. Most of our hospital institutions present limited infrastructures.[30] In addition, they were not designed or thought to respond to pandemics. Consequently, they lacked the necessary structure to allow safe care flows,[31] segregating, for example, clinically and laboratory confirmed COVID-19 patients from suspected cases. Consequently, it is very likely that adequate isolation of patients was one of the first criteria harmed in patient safety during COVID-19 times. And thus, the **Safety** attribute defined as "Ability of the health system to identify, avoid or minimize the potential risks of health interventions…"[11], was threatened, given the possibility that people not infected by COVID-19 run risks of contamination in contact with contaminated people, in the health service itself.

Along with the ambiance-related problem, patient safety was also strongly affected by the collapse of the health services. We saw on television media reports of families who went on a pilgrimage with their loved ones, especially older adults, among various health institutions and were unable to find a vacancy. There are even reports of patients who died in their homes, without any health care.[32] In this situation, the "**Access/Opportunity**" attribute is not respected, defined as "Ability of the health system to provide the necessary care and services at the right time and in the right place"[11].

It is also worth reflecting on the **Access/Opportunity** attribute, remembering that the people most affected by the pandemic, individuals with comorbidities, black-skinned and poor people, are the ones with the highest social and health vulnerabilities. Groups that already suffer from restricted access to health-related goods and services. And in the Brazilian case, this situation was exacerbated by the ongoing fiscal austerity policies, social security and labor reforms, and underfunding of the SUS.[33] Therefore, the pandemic constituted a fertile ground for disruption of this patient safety attribute.

On the other hand, the low availability of technological devices, especially related to ventilatory support, together with the scarcity of personal protective equipment, caused days of anguish for health workers. The resources to cope with the pandemic fail to arrive at the health services at the same speed as the disease. They became more expensive and scarce than usual on the market and sparked a real gold rush. Between the provision of health services with technological resources and the capitalist disputes that were created around them, patient safety was also threatened. Health professionals had to choose who was going to die and who was going to survive based on the availability of mechanical ventilators, for example. And we do not know how many people were extubated on time, aspirated or ventilated due to lack of some of these devices. This situation characterized impairment of the **safety**, **equality** and **effectiveness** attributes, with "equality" defined as fair and reasonable care distribution and "effectiveness", as the degree to which the care provided achieved the expected results.[10,11]

We also mentioned as disruptions of the **effectiveness** attribute the wrong choice of the model to face the pandemic, disdain or rejection towards the epidemiological control measures to the detriment of harm mitigation. The first measures have been scientifically recognized for centuries regarding their effectiveness to control highly contagious respiratory diseases. In turn, the mitigation strategy, which tried to suppress the infection from the ICU beds, proved to be a total failure.[33]

Alongside the lack or scarcity of resources and technological devices, patient safety during the COVID-19 pandemic has been severely threatened by the scarcity of the most important health care element, the human one. Undoubtedly, it is impossible to develop good health practices with inadequate staffing. As recognized by the World Health Organization (WHO), "At the heart of every health system, the workforce is central to advancing health[34]". In 2007, the WHO had already identified a threshold for the health workforce density and assessed that it was far below the numbers required to meet the health demands and

goals in the millennium. Furthermore, Nursing staffing stands out because the health workforce is comprised by more than 50% of workers from this area.[35]

Due to worsening of the shortage of health workers during the pandemic, both public and private managers, especially from the SUS, where massive confrontation of the pandemic took place,[36] needed to hire people on an urgent basis, and it was not possible to choose rigid quality criteria for this purpose; and, on the other hand, not being possible to select workers with previous experience.

Therefore, an important percentage of the workforce in the front line against the pandemic consisted in young workers with still limited experience in health care. This situation certainly contributed and still greatly contributes to health care quality and safety during the pandemic, considering that there was not enough time for training and acquisition of experiences by these new workers. In a brief period of time they had to assume job positions in coping with COVID-19 and undergo training after entering the services. And, as a matter of fact, complex intensive care unit (ICU) services, as severe forms of COVID-19 require ICU hospitalization.

It is important to reflect that instability in health workers' qualification to cope with the pandemic is not exclusive to newly hired or inexperienced ones. The pandemic context also challenged experienced workers who were already active in health services before the pandemic. This is because it gave rise to a new work context, requiring new attitudes and behaviors from health workers, in addition to new knowledge and the need to face the unknown and a lethal etiological agent. In an experience report, the authors state that "Adaptation of the care professionals in the face of drastic changes in their scope of work can be seen as one of the main challenges presented in the face of this pandemic"[37].

All these elements, synthesized in the Chart 1, lead to reflect on the place patient safety occupies in pandemic contexts. It can be understood that it is a place characterized by weakness, especially in realities such as the Brazilian one, where the patient safety culture has not yet been satisfactorily established.[38] And as if that were not enough, patient safety in Brazil was threatened twice, on the one hand by the pandemic and on the other by a political crisis that disrupted important sectors of the government, among which we can mention the Ministry of Health. Evidence of this crisis is in the post-pandemic health minister changes. Between January 1st, 2019, and March 15th, 2021, Brazil had four Health Ministers.

We appreciate the idea that it is necessary to move forward in strengthening the patient safety culture today and always in order

Chart 1. Synthesis of the disruptions in patient safety attributes during the COVID-19 pandemic.

PATIENT SAFETY ATTRIBUTES AND DISRUPTIONS IN THE PANDEMIC CONTEXT			
Attribute	Concept	Disruption	Specific situation
Adequacy	Degree to which the care provided to people is based on technical-scientific knowledge	-Adoption of behaviors not grounded on scientific evidence	-Use of chloroquine and hydroxychloroquine in COVID-19 treatment
		-Refusal to adopt proven effective recommendations to control the pandemic	-Incentive by political leaders to not adhere to the proven recommendations to control the disease
		-Definition of the therapy based on political prerogatives	-Interference by presidents and ministers to use chloroquine and hydroxychloroquine
Safety	Ability to avoid injuries and harms resulting from health care	-Doubtful ability of the health services to prevent cross-infections	-Incipient structure in health institutions
			-Shortage of protective supplies
Access/ Opportunity	Ability of the health system to promote care and the necessary services at the right time and place	-Collapse of the health service	-Bed waiting lists
			-Reports of deaths due to unsuccessful hospitalization attempts
Equality	Fair and reasonable care distribution	-Unequal distribution of the technological resources required for the pandemic	-Health professionals' reports about the need to choose who was going to survive and who was going to die
Effectiveness	Degree to which the care provided achieved the expected results	-Rejection of the epidemiological model to cope with the pandemic	-Investments in more ICU beds to the detriment of controlling and interrupting transmission
			-More than 600,000 deaths

to be ready for everyday health problems as well as emerging ones. And in the Brazilian case, it is necessary to persist in the struggle espoused by the Brazilian Health Reform Movement, for a universal, equitable and egalitarian health system.

The limitations of this research are related to the scarcity of scientific literature discussing patient safety in pandemic contexts.

FINAL CONSIDERATIONS AND IMPLICATIONS FOR THE PRACTICE

The SARS-CoV-2 pandemic context represented and still represents a series threat to patient safety. This evidenced nudity and weakness through important health quality attributes; with Adequacy, Safety, Access/Opportunity and Effectiveness standing out among them. The pandemic also left the challenge of rethinking the consolidation of good health practices, based on investment in safe organizations, responsible management and consideration of the health care quality attributes/domains.

This investment presupposes availability of the necessary technological apparatus for health care, adequate staffing of workers and their permanent training; as well as work processes based on care protocols and recognized scientific evidence. Such conditions are crucial for the promotion of patient safety in any health context, be it pandemic or non-pandemic. This is a commitment that must be assumed by all: governments, society and health organizations. Neglecting this responsibility strongly impairs the important principle of health care: "first, do no harm".

It is believed that this reflection is important to be proposed to managers, health workers and the civil society, so as to persist in strengthening the SUS and in the patient safety culture, under a more accurate look at the elements required for the construction of safer health organizations. Furthermore, the study draws the attention to the necessary refusal of denialism and to the perennial adoption of practice based on acceptable scientific evidence.

AUTHOR'S CONTRIBUTIONS

Design of the reflection study. Rhanna Emanuela Fontenele Lima de Carvalho. Shérida Karanini Paz de Oliveira. Jaira Gonçalves Trigueiro.

Theoretical-Reflective analysis. Rhanna Emanuela Fontenele Lima de Carvalho. Saiwori de Jesus Silva Bezerra dos Anjos. Shérida Karanini Paz de Oliveira. Jaira Gonçalves Trigueiro.

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