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Risks and vulnerabilities of injectable administration in health promotion settings with the impact of lack of biosafety

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ABSTRACT

Biosafety is a set of measures aimed at preventing, minimizing or eliminating risks inherent to activities in occupational environments. Several problems have been reported regarding the lack of biosafety, especially in health care facilities that have sectors associated with the manipulation of injectables and other invasive procedures. Therefore, describing the performance of the pharmaceutical professional in relation to biosafety management directs a technical qualification seeking to identify, minimize and even eradicate risks and vulnerabilities associated with these invasive practices with the possible exposure of biological fluids to which they are exposed. Thus, the objectives of this study were to analyze and discuss the risks and vulnerabilities of injectable administration in health promotion environments, indicating the impact of the lack of biosafety. To this end, we conducted a small literature review, in addition to a field research among pharmacists in the Lakes Region, State of Rio de Janeiro, where an online questionnaire with 19 closed questions on the theme already explained above was applied. Our results found a wide variety of studies related to the theme, corresponding to the data found in the participation of 20 pharmacists who were technicians in charge, working in pharmacies with injectables or who had already worked in this practice. The results were impactful because they confirmed the fragility of many professionals who work with injectable injections. Lack of knowledge in current legislation, other disabled professionals performing these activities without proper preparation, among other difficulties. In view of the results obtained in the research, it is concluded that there is a need to broaden the discussion on occupational risks, work accidents and vulnerability in the practices of health professionals, with the objective of developing health policies for pharmaceutical professionals.

Keywords: Application of Injectables, Pharmacy, Biohazard and Biosafety.

1 INTRODUCTION

Biosafety is a set of measures aimed at preventing, minimizing or eliminating risks inherent to activities in occupational environments. The standards, in general, are for guidelines regarding care to keep both the patient and the professional free from contamination of microorganisms harmful to health, from hand washing, floor cleaning, choice of disinfectant for sterilization of materials and even how to dispose of chemical and biological waste (NUNES, 2018).

With the advent of RDC No. 44, of August 17, 2009, which established a series of standards and guidelines that authorized the characterization of injectable application rooms in health care environments such as drugstores and pharmacies, these criteria and guidelines were evidenced in order

to reduce possible accidental events against the health of the professional who works in these places. including pharmacists. (ANVISA, 2009).

Many risks and concerns came in line with this resolution, seeking a direct correlation with the sanitary difficulties and the economic and social precariousness of an underdeveloped country, that is, as well as in the maintenance that such standards are being complied with in health care environments, especially such as drugstores and pharmacies. (ANVISA, 2009).

Thus, this study brings a discussion about this specialized service based on an analysis of the professionals in these environments and the use of Personal Protective Equipment (PPE) and/or Collective Protective Equipment (CPE) indicated, as well as the acquisition of devices that guarantee the biosafety of these professionals as a result of exposure to waste generated and with the manipulation and/or exposure with biological fluids. (TOSMANN, 2019).

The biosafety of the pharmaceutical professional is extremely important, because it is not enough to be only the caregiver aiming only at the safety of the client. This professional also becomes the target of care and deserves to receive the proper support (PONTES, et al., 2018).

This study aims to discuss the problem of Biosafety issues of the pharmaceutical professional, either due to the unfavorable logistical conditions that do not meet the requirements already established by law, or due to the lack of dexterity or knowledge of the professional, due to the lack of training in a procedure that he is qualified and authorized to perform through a RDC that gives him autonomy.

Risks in professional environments, including health care environments, are present in the most varied environments, including health care environments, described as occupational safety hazards that affect the health and well-being of workers in various work activities. In the 1970s, Brazil was considered a world champion in occupational accidents, which led to the establishment of a policy aimed at the safety and health of workers in their work environment, aiming to reduce the incidence and prevalence of accidents and diseases at work (LIMA, et al., 2017).

The Ministry of Labor and Employment has been reinforcing actions to promote safety and prevent accidents and occupational diseases, especially in environments aimed at health promotion (BRASIL, 2005).

Biosafety comprises a set of actions aimed at preventing, controlling, mitigating or eliminating risks inherent to activities that may interfere with or compromise the quality of life, human health and the environment. Thus, biosafety is characterized as strategic and essential for research and sustainable development, being of fundamental importance to evaluate and prevent the possible adverse effects of new technologies on health (BRASIL, 2005).

Biosafety in health care environments begins with the adoption of Standard Precautions (PPs), such as: hand washing, use of personal protective equipment (PPE) and collective protection equipment (CPE), in addition to proper management of waste from health services and immunization,

always with the objective of protecting patients and health professionals, especially against exposure to biological fluids. Biosafety in Brazil is ensured by Regulatory Standard No. 32 (NR 32) directed and regulated by the Ministry of Health (Ministry of Health - Normative 32). It recommends, guides, among other regulations, preventive measures for each risk situation with the objective of promoting the safety of workers in health services, especially the use of PPE (CORRÊA, et al., 2017).

Another regulatory standard of extreme importance, with a view to ensuring the integrity and safety of health professionals, is regulatory standard 6 (NR6), which establishes standards, including the sizing and definition of PPE, as any device or product, for individual use used by the worker, intended to protect against risks that may threaten safety and health at work. such as: masks, goggles, gloves, disposable apron or gown, hat etc. In addition, this standard directs and establishes which professionals should use the specific PPE, always aiming at the prevention of diseases indicative of contact between professional and patient and the risks of other occupational accidents aiming at the preservation of their own health (BLEY, et al., 2005).

Personal Protective Equipment (PPE) and collective protective equipment (PPE) are essential in any industrial activity. It is no wonder that several Regulatory Standards (NR-4, NR-6, NR-10, NR-12 and NR-33) address its use and importance. Among the benefits is, first and foremost, the health and safety of the worker – through protection against the risks of accidents at work and/or occupational diseases. In addition, the correct use of equipment provides, as a consequence, a reduction in costs for the employer with personnel replacements, leaves of absence and indemnity processes (*TOSMANN, 2019).*

Many studies suggest that PPE has the function of reducing the incidence of accidents, protecting professionals against different diseases associated with the risks of each work environment and, consequently, promoting a reduction in the number of events caused to the health and especially to the physical integrity of professionals, including those that manifest themselves in the medium and long term (GONÇALVES, 2011; CISZ, 2015; SILVA 2014; SILVA, et al., 2018).

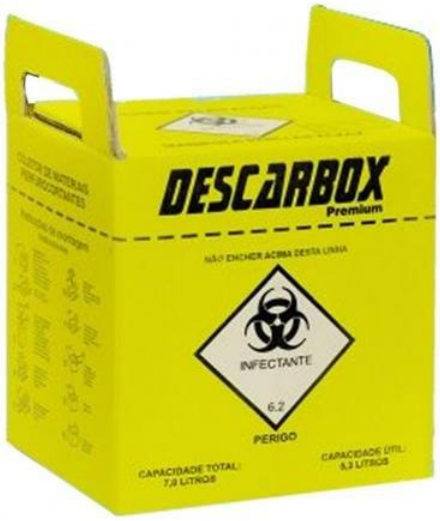
The document entitled "National Strategy for the Reduction of Occupational Accidents 2015-2016", published in 2015 by the Ministry of Labor and Employment, identified the occurrence of 2,797 fatal occupational accidents in Brazil, associated with a mortality rate of 6.53 individuals per 100,000 insured persons in the country. The report also suggests that the International Labor Organization (ILO) estimates that more than two million people die each year due to the occurrence of occupational accidents (BRASIL, 2015).

Many PPEs and EPCs are established in different instructional standards, always with the objective of reducing accidents in health care environments. Varying according to each professional specificity, they are important parts in the biosafety process.

Many places with manipulation of biological fluids have been worrying health teams, especially inspection and epidemiological support agencies. The need for essential devices and equipment to perform these services, combined with the reality of the population and the different economic and financial realities, varying from place to place, causes an alert in the surveillance teams with attention to non-compliance and lack of different devices indispensable for this type of specialized service.

A great example of essential devices for a site with handling biological fluids are sharps disposal boxes (**Figure 1**). In addition to these boxes, signage and material supports are extremely important in the development of this specialized service. There are many risks with the exposure of these residues (SILVA, et al., 2018).

Figure 1: Sharps puncture disposal box, a mandatory item in injectable rooms.



Source: Google.

Sanitary Surveillance is, by definition, "a set of actions capable of eliminating, reducing or preventing health risks and intervening in health problems arising from the environment, the production and circulation of goods and the provision of services of interest to health" – Organic Health Law – Law 8.080 of 09/19/1990, Art. 6, Item I. The objective of the development of Health Surveillance actions goes beyond ensuring that the products, as well as services provided, have a level of quality such as to eliminate or minimize the possibility of the occurrence of negative effects on health caused by the consumption of goods and the provision of improper services. It is necessary to understand Health Surveillance as an integral and primary part of the health area, being a set of specific actions to protect it, which ultimately contemplates the most diverse fields of action, from those specific to the health area to others, such as sanitation, education, security, among many others that contribute to the quality of life (BRASIL, 2010).

The actions developed by the Health Surveillance are educational (preventive), normative (regulatory), supervisory and, ultimately, punitive. They are developed at the federal, state and municipal levels and occur in a hierarchical manner in accordance with the provisions of the Organic Health Law – Law 8.080/90, in Ministerial Ordinance 1565/94 – GM/MS, which established the National Health Surveillance System, and in Federal Law 9.782, of January 26, 1999, which defines the National Health Surveillance System, creates the National Health Surveillance Agency, and makes other provisions (BRASIL, 2001).

Within the Brazilian history of pharmacy in Brazil, it is contemplated that from the beginning there was an environment of dispute between the pharmaceutical profession and other untrained professionals. This was due to the Healers, Healers where they had the trust of the population and even because it was a local culture of the colonies. Therefore, access for pharmacists was almost impossible, or we would say that it did not exist in these regions. In Brazilian cities, apothecaries began to have an important social contribution due to their determining commercial potential, directing the relationship of the professional who worked in the apothecary's shops, who provided a kind of link between pharmaceutical services and customers. With the beginning of the twenty-first century, apothecaries that made their medicines in an artisanal way began to lose their status when several therapeutic discoveries in the 1930s and 1940s boosted the scientific community for new methodologies, thus growing the drug industries (ANGONESI, SEVALHO, 2010).

From 1931 onwards, in Brazil, pharmacies played a form of establishment for the sale of medicines, and the pharmaceutical activity in pharmacies was regulated through Law No. 5,991, of December 17, 1973. Drugstores then became partners of the industries, making the distribution of their products generate a consumption of medicines, thus providing self-medication, since the pharmacy became a commerce aimed at financial profit (ANGONESI, SEVALHO, 2010).

The Consensus on Pharmaceutical Care in Brazil, after meetings of professional groups, proposed the insertion of the concept of Pharmaceutical Care as a model of practice directed to comprehensive Pharmaceutical Care, reaffirming its ethical values, behaviors and skills, in addition to involving commitment and responsibilities aimed at disease prevention, health promotion and recovery. Providing the interaction between the pharmacist and the user (BRAZILIAN CONSENSUS ON PHARMACEUTICAL CARE, 2002).

Pharmaceutical Care, nowadays, makes pharmacists encouraged to provide the client with their skills and knowledge as a trained health professional. A differentiated and essential professional to change reality, becoming an encouraging agent, promoting a new concept associated with care and assistance seeking the patient's recovery. Making Community Pharmacies an establishment for the recovery of health, leaving the paradigms of the past with the link of the pharmacist as a mere dispenser of medicines, which only praised the pharmaceutical industry and its profit motives.

With the advent of Law No. 13,021/2014, which provides for the exercise and supervision of pharmaceutical activities, different articles were described that determined the current concepts of pharmaceutical services, including the following:

> Art. 2. Pharmaceutical care is understood as the set of actions and services aimed at ensuring comprehensive therapeutic care, promotion, protection and recovery of health in public and private establishments that perform pharmaceutical activities, with medicine as an essential input and aiming at its access and rational use (BRASIL, 2014).

Inside the Law No. 13,021/14, published on August 11, 2014, denoted the concept of the word Pharmacy used in Brazil, emphasizing that Pharmacies and Drugstores cease to be mere commercial establishments to become a unit for the provision of pharmaceutical assistance, health care and individual and collective health guidance (BRASIL, 2014).

In the face of this new approach and the modified vision of the Community Pharmacy as an establishment that is made of health and not only aiming at the capitalist part of the pharmaceutical industry, there is a concern about the Biosafety of the pharmaceutical professional, as well as their training for such practice, which in this case is the procedure directed to the application of injectables. once it becomes exposed to biological hazards.

With regard to biological risk, it is known that the Regulatory Standard No. 32 of the Ministry of Labor and Employment aims to establish guidelines for the implementation of protective measures for the safety and health of workers, as well as the evaluation of the workplace, thus considering the organization and description of the sector in order to evaluate occupational exposure to biological agents (BRASIL, 2005).

Biosafety is an action aimed at preventing, minimizing or eliminating risks related to the work performed, as well as production, technological development activities, such as accident prevention in occupational environments, including, among many other measures: technical, educational, administrative, medical and psychological (PENNA, et al., 2010).

Therefore, it is understood that since this professional is exposed to biological risks, he needs all the support and adequate working conditions to carry out the practice; since there is a law that backs it up through pre-established regulations.

According to the Resolution of the Collegiate Board of Directors - RDC No. 44, of August 17, 2009, which provides for Good Pharmaceutical Practices for the sanitary control of the operation, dispensation and commercialization of products and the provision of pharmaceutical services in Pharmacies and Drugstores and provides other measures. It is addressed as follows:

> Art. 74. The administration of medicines in Pharmacies and Drugstores is allowed in the context of pharmacotherapeutic monitoring.
> Art. 75. Drugs for which a medical prescription is required must be administered upon presentation of a prescription and after its evaluation by the Pharmacist (ANVISA, 2009).

Considering that the reality in the injectable application rooms of these establishments is related to the most frequent routes, namely: Subcutaneous (CS), such as insulins and vaccines; intramuscular (IM), mostly focused on analgesics and contraceptives. Others, such as intravenous (IV) and intradermal (ID) are the least common, with the intravenous being more invasive and with more immediate risks of reaction because it reaches blood circulation more quickly. Many of them have characteristics of hospital exclusivity, according to Article 74, sole paragraph, of RDC 44, which says: "*The administration of medicines for exclusive hospital use is prohibited*" (ANVISA, 2009).

2 METHODOLOGY

2.1 FIRST EVALUATIVE TOOL - LITERATURE REVIEW

To support the discussion with the data obtained in the evaluative questionnaire, a literature review was carried out in the Google Academic, Pubmed and Scielo databases, in the period between 2010 and 2020. The keywords used were "injectable application" and "biosafety". Exclusion criteria were: articles published before 2010 and articles that did not have the essence of the theme.

2.2 SECOND EVALUATIVE TOOL - ONLINE EVALUATIVE QUESTIONNAIRE WITH PUBLIC OPINION WITHOUT IDENTIFICATION

The evaluative questionnaire is an important diagnostic tool that identifies and measures information and results on a subject/theme in order to collect data from different points of view (professionals) on a particular subject/demand or phenomenon in order to clarify and collect both quantitative and qualitative data.

The questionnaire was applied by the Google Forms platform due to social distancing, respecting all protocols and procedures universalized due to the Covid 19 Pandemic.

The questionnaire consisted of 19 closed questions, which were sent by messaging applications with the link to Google Forms, where information was analyzed that consolidated the hypotheses and results expected in this study in order to correlate through a broad discussion with the results obtained by a literature review and that pointed out real data to the research.

After the detection of the data, statistical analysis was performed and the results analyzed will be described and discussed.

3 RESULTS AND DISCUSSION

3.1 PROFILE OF THE PHARMACISTS INTERVIEWED

The results were obtained from the questionnaire answers. The questionnaire was answered by 20 people (n=20), predominantly female (65%) and (35%) male (Table 1). The average age of the participants was 34 years old, ranging from 31 to 35 years old (40%), with the participation of people

from 25 to 51 years old, constituting a young group of professionals working in the field of pharmacies and drugstores. Regarding academic background (25%), only have an undergraduate degree, demonstrating that a large part of the interviewees already have a postgraduate degree and most of them have a specialization in lato-sensu (70%). Another piece of information related to the profile was the parameter of the time since graduation, which was mostly between 5 and 10 years, totaling (40%). Regarding the time of practice and experience in the profession, it corresponds to the same time of training between 5 and 10 years (40%).

Table 1 - Sociodemographic characteristics of the informants according to age, gender, academic background, time of academic training and time working in the area

Sociodemographic Characteristics of the Informants						
Age:	**25 to 30 years**	**31 to 35 years old**	**36 to 40 years old**	**41 to 45 years old**	**46 or more**	**Total**
	25%	40%	10%	10%	15%	100%
Gender:	**Male**		**Female**			**Total**
	35%		65%			100%
Training:	**Graduation**	**Post-Graduation (Specialization)**		**Masters**		**Total**
	25%	70%		5%		100%
Training Time:	**Up to 1 year**	**1 to 3 years**	**3 to 5 years**	**5 to 10 years**	**10 or more**	**Total**
	0%	10%	20%	40%	30%	100%
How long have you been working in the field?	**Up to 1 year**	**1 to 3 years**	**3 to 5 years**	**5 to 10 years**	**10 or more**	**Total**
	5%	20%	5%	40%	30%	100%

Source: Author, 2021

By analyzing the data reported by the pharmacists, we have the first questions addressed in (**Figure 2 A, B, and C**). Initially, it was demonstrated in (**Figure 2 A**), the technical responsibility of the pharmacy or health promotion service. Obtaining the information that (70%) of the pharmacists participating in this research are the technicians responsible for pharmacies and health care environments, that is, most of them (30%) do not have this attribution.

The results indicated that (70%) of the pharmacists had already worked in an injectable application room and (30%) had not had this experience (**Figure 2 B**). In addition, the data showed that the majority of pharmacists have training and qualification in the area, totaling (80%), although some, even qualified, do not have the opportunity to work in the establishments where they work and

(20%) of pharmacists do not have training and technical skills for the development of the practice (**Figure 2 C**).

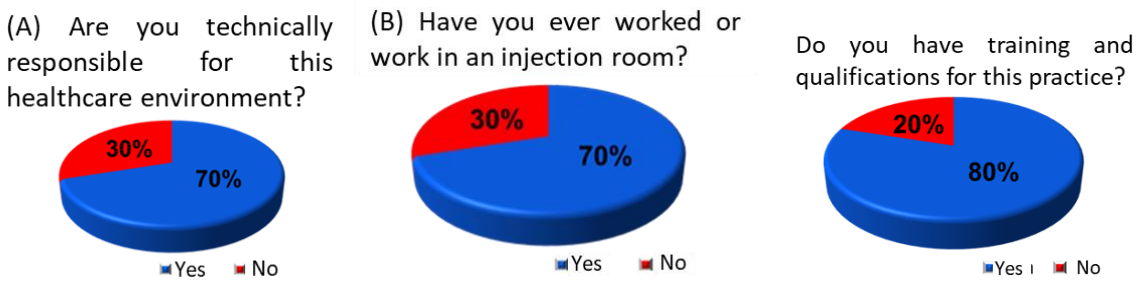
The results presented (**Figure 2 A**) corroborate the article by Oliveira, et al., (2017), which also presents a targeted context with an increase in the number of pharmacists working in drugstores in Brazil. In this study, 383 pharmacists (n=383) voluntarily participated, where (80%) of these pharmacists stated that they worked as technical managers (RT) in these commercial establishments. The authors reported that the responsibility for performing, supervising and coordinating all technical-scientific services of the company and establishment, such as pharmacy and health promotion environments, are the attributions of the pharmacist in charge of the technician (RT), who is responsible for the jurisdiction of the Federal Council of Pharmacy (CFF) and Health Surveillance bodies (OLIVEIRA, et al., 2017).

Similarly, Lucchetta and Mastroianni (2010) address in their study 85 health promotion units in a municipality in the central region of São Paulo with 200 thousand inhabitants, such as: public hospital, basic health unit, emergency care, private and public diagnostic center, in addition to 34 pharmacies and 52 drugstores. Among the 52 pharmaceutical RTs distributed among these AAS, 45 (86.5%) participated in the survey of the research in terms of knowledge. The RTs were questioned about their legal attributions, knowledge about the definitions of medications, such as the permission of injectable medications. (LUCCHETTA and MASTROIANNI, 2010).

Other current studies provide information that approximates the reasoning to the results we found and that were indicated in (**Figure 2 B and C**). Silva et al. (2015) demonstrate that 90 workers, including pharmacists and clerks, who worked in drugstores in a municipality in the interior of Minas Gerais and applied injectable medications, regardless of whether they had been trained and/or qualified for such a procedure, as it was verified that only the pharmacists in charge of the technicians were qualified for the activity of injecting drugs. This training is acquired through lectures and theoretical courses (SILVA, et al., 2015).

Indicating that there is a similar reality among the states, the percentage found in our studies did\ not show major differences, both in terms of technical accountability, which was also the majority, and in terms of the performance, training and qualification of pharmacists with regard to the practice of injecting drugs.

Figure 2



Legend: Representation of the questions applied in the evaluative questionnaire, being A- question 1, B- question 2, C- question 3.

Source: Author, 2021

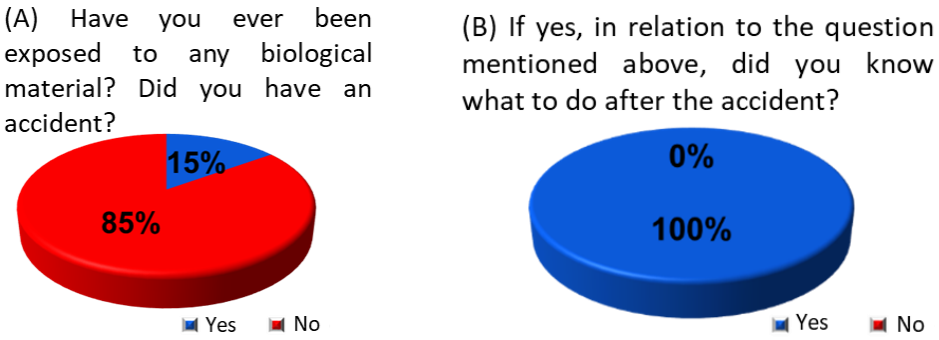
In the results that presented data associated with biological exposure accidentally through the acquired responses, they were illustrated in (**Figure 3 A and B**). It was demonstrated that most of the professionals had never been exposed to any biological risk (80%) and those who were exposed (15%) in their totality knew how to proceed in the face of the event, according to (**Figure 3 B**).

Similarly, Pontes et al. (2018) also presented data that indicated few reports regarding exposure to biological risks. Five students reported having suffered this accident, however only one notified the responsible sector and received outpatient follow-up, but they were aware of the risks, although they did not know how to proceed (PONTES, et al., 2018).

In 2015, another study showed that (100%) of the professionals who were exposed to biological risk sought immediate medical attention. Where (50%) sought care at the referral unit of a specialized service for acquired immunodeficiency syndrome (AIDS) and sexually transmitted infections (STIs), a unit indicated by the pharmacy and drugstore itself. Finally, (50%), on their own initiative, they turned to the private health care network (SILVA, et al., 2015).

Due to all the complexity of the subject, it was possible to discuss, through the research carried out, that most of the professionals are aware of the need to proceed after an accident with biological material for immediate care, in order to minimize the risks of contamination to which they were exposed, although there is still a need to improve the informative and educational means to further reduce these events.

Figure 3



Legend: Representation of the questions applied in the evaluative questionnaire, being A- question 4, B- question 5.
Source: Author, 2021

Many pharmaceutical professionals (95%) are aware of the biological risks to which they are exposed daily in the injectable room (**Figure 4 A**), however, (5%) claimed to be unaware of these risks.

The data shown in (**Figure 4 B**) indicated that (65%) of the investigated affirmed that the unit in which they work has protocols, such as: manuals of good practices and protocols displayed in the injectable drug application room. On the other hand, (35%) of those who responded stated that they did not have such informative documents on the use of sharps. The data presented warn of a worrying practice, given that studies published in 2015 indicated that sharps-related accidents are responsible for 80 to 90% of infectious disease transmissions among health workers (NOVACK, KARPIUC, et al., 2015).

Damasceno et al. also indicated, through a study with the participation of 382 health professionals in Goiânia, that many professionals do not have the necessary attention in relation to their own health care, ignoring or neglecting the risks related to accidents involving biological material with piercing and cutting agents (DAMASCENO, et al., 2006).

According to Santos et al. in 2012, their line of research showed that the rates of occupational accidents reported among physicians, pharmacists and nurses were lower in the literature analyzed, however, among the factors associated with the occurrence of occupational accidents, the inadequate use or resistance to use personal protective equipment (PPE) stands out, in addition to self-confidence, lack of continuous training, ineffective prevention measures and, finally, the inadequacy of disposal boxes for sharps (SANTOS, et al., 2012).

These studies demonstrate the existence of awareness among professionals about the exposed biological risk, but there is low adherence to protection measures. In other words, they are aware of the importance of the use of PPE, but due to the speed of care or even the lack of habit in using certain equipment, haste in performing a procedure, either due to work overload or the demand for care, safety is not properly prioritized (SANTOS, et al., 2012).

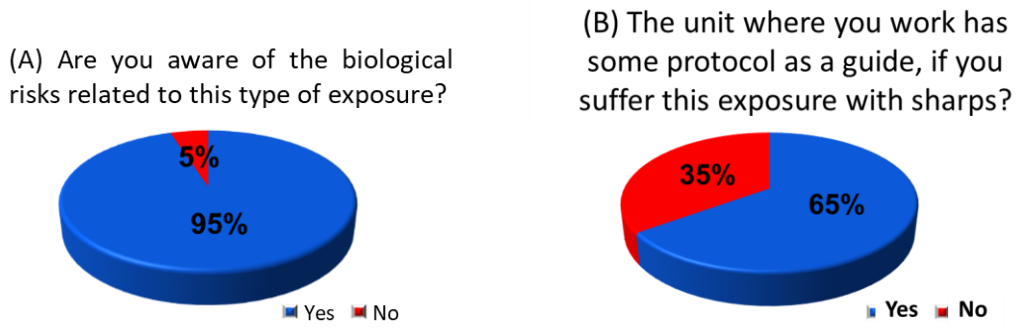
Finally, about RDC No. 44, of August 17, 2009, which provides for Good Pharmaceutical Practices for the sanitary control of the operation, dispensation and commercialization of products and the provision of pharmaceutical services in pharmacies and drugstores, and provides other measures, as already mentioned in the textual body of this research, it covers in its:

> Art. 27 – In training, employees must be instructed on procedures to be adopted in the event of accidents and episodes involving risks to the health of employees or users of pharmacies and drugstores (ANVISA, 2009).

In the current research, it is understood, correlating with the literature under analysis, that most pharmacists are aware of biological risks and their harmful consequences to health, as well as having knowledge of the protocols and all the existing apparatuses for their own safety. However, it is still perceived that (5%) are deprived of this information. This lack of education is directly related to the lack of continuing education. The lack of knowledge of the current legislation presents a small but worrying percentage regarding the prevention and exposure to biological risks, since, in view of the risks and vulnerability associated with this practice of injectable application, the pharmaceutical professional should have the primary commitment to know all these possible risk factors. Because he, in addition to being the possessor of scientific knowledge, has the technical support to carry out such practice and that no other professional, such as clerks and managers, even under his supervision, will not be able to perform them.

Another relevant finding for the research was the establishment in (**Figure 4 B).** More than one-third of respondents (35%) stated that they do not have standard operating procedures (SOPs) in AAS that have injectables, indicating the possibility of increased risks related to accidents.

Figure 4



Legend: Representation of the questions applied in the evaluative questionnaire, being A- question 6, B- question 7.
Source: Author, 2021

In the approach of (**Figure 5 A**) shows that (60%) of the pharmacists reported that no other professional working in the AAS practices the application of injectables, being a manager, owner or clerk. While (40%) answered yes, they know that other professionals work or have worked in this

practice. To the extent of this issue, the data presented to (**Figure 5 B)** point out that (35%) of these professionals have training and professional skills for this procedure, however, (15%) stated that these professionals do not have the training and qualification to perform this very important practice. In addition, (50%) of the interviewees did not know how to inform the other professionals who perform this function about this training.

All these data reinforce great concern, because, according to the Federal Council of Pharmacy, the administration of injectable drugs could only be administered by the pharmacist or by a qualified professional with the express authorization of the technical responsible in its Article 80. (CFF, 2001).

The National Council of Quality of the Order of Pharmacists defines specific rules on the administration of medicines, which, in the context of community pharmacy, is an activity to be carried out exclusively by pharmacists (ORDEM DOS FARMACÊUTICOS, 2009).

Following the above-mentioned publication regarding the administration of injectable drugs, which includes several requirements for administration of this drug. Subsequently, the National Authority for Medicines and Health Products, I.P. (indicated by Inframed) brings in its deliberation No. 139/CD/2010, of November 4, the establishment of the conditions that proceed to the administration of vaccines in pharmacies where they now have the following report:

> The administration of vaccines in pharmacies is the responsibility of the pharmacist, technical director of the pharmacy and must be carried out by pharmacists with appropriate training, recognized by the Order of Pharmacists, or by nurses specifically and exclusively hired for this purpose. (Resolution No. 145/CD/2010).

It is understood that although these deliberations refer to the administration of vaccines not included in the PNV (National Vaccine Program) or PNI (National Immunization Program), due to the links and similarities, it is to be considered that these procedures extend to the administration of injectables.

Focused on this context, the National Directorate of the Order of Pharmacists approved minimum requirements for the recognition of training in the administration of vaccines and injectable medicines, as well as the recognition of training and updating in this practice. According to these standards, pharmacists will need to obtain certification for registration and confirmation of their aptitude and competence. For the purposes of recertification, the technical director of the pharmacy must issue a statement in order to prove the practice of administering injectable medications, in which this pharmacist will perform this function later in the health care establishment that is the pharmacy (SANTOS, AZOIA, GUERREIRO, 2014).

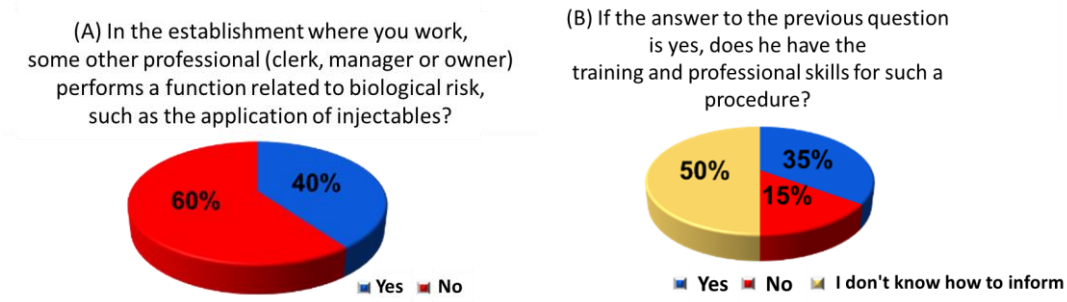
Within the context presented, studies in a city in the interior of São Paulo, thirty-four (n=34) pharmacy clerks who participated in the study, regarding their level of education, the predominance of high school was established. Therefore, the problem was presented, as it was confirmed that the clerks

did not have technical, scientific and legal knowledge to direct the use of medication, regardless of the route administered (GIR, et al, 2003).

Based on this literature, the present research reveals an aggravating factor to the detriment of illegal functions within health promotion establishments in the Lakes Region/RJ. Not only does this lead to a legal process due to all the documentary content mentioned in the body of the text above, but it also puts his own pharmaceutical activity at risk with regard to his professional registration, since he is the technical responsible for this health care unit and is aware of the exclusivity of his attributions. in addition to having a whole team under your care.

Professionals who work in pharmacies and drugstores and who perform procedures with biological risk should be periodically trained in the existing occupational prevention and post-exposure measures, considering that the vast majority of clerks have not taken specific technical or higher education courses in the health area. It is confirmed that these workers do not have scientific knowledge of the microbiological contaminants involved in the technique, that is, the procedure ends up being performed because it has become something habitual. It is up to the pharmacist to assume his posture as a qualified and trained professional to prevent possible errors and malpractice in the applied procedure.

Figure 5



Legend: Representation of the questions applied in the evaluative questionnaire, being A- question 9, B- question 10.
Source: Author, 2021

Information on the knowledge of the pharmaceutical professional in relation to NR 32 (Regulatory Standard), which aims to establish the basic guidelines for the implementation of measures to protect the safety and health of health service workers, as well as others who carry out health promotion and care activities in general, were presented in (**Figure 6 A, B, C, and D**). Such results establish safety parameters in all the logistics of an injectable drug delivery room **(Figure 6 A**). These results show that (75%) of the interviewees stated that they were aware of this regulation. In the same way, **(Figure 6 B),** it establishes the importance of the utensils in the injectable room, if these equipment are in compliance with the standards to favor the correct application procedure within the correct logistics. More than 2 thirds of the interviewees (85%) stated that they have appropriate

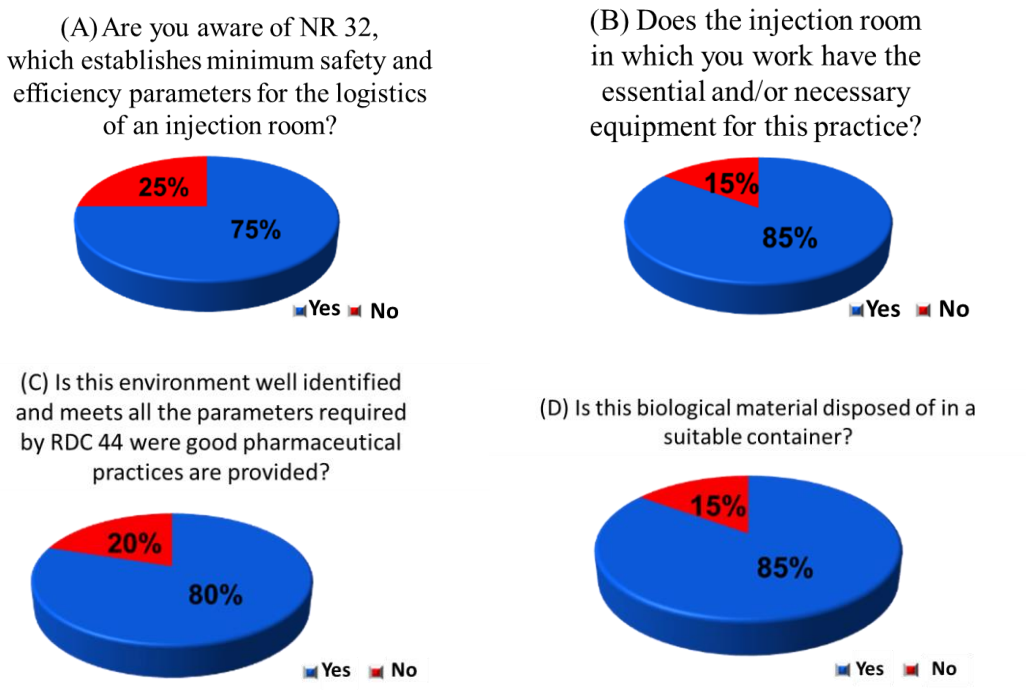
logistics for the performance of actions aimed at injectable applications. Even though those who responded that they did not have these essential materials expressed a small percentage of 15% compared to the statement of opposition, the data represent a very worrying statistic when looking at the degree of importance of this material. On the other hand, (**Figure C**) shows data inherent to the correct identification according to RDC 44, which governs good pharmaceutical practices. The vast majority (80%) say that the places where they work have signs in accordance with legal requirements. And finally, not most importantly, but presenting a considerable weight for this theme (**Figure 6 D)** are representative data on the correct disposal of biological material. Only 15% said they did not know and did not have the appropriate container. Reaffirming the importance of the provision of *Descarpack* recommended in the legislation in force in the AAS.

The results inherent to the information on knowledge about NR 32 and the safety parameters for the injectable room, as well as whether the room has elements for practice, and whether it complies with the parameters of RDC 44, correctly disposing of biological materials, were presented in (**Figure 6**). They indicate that most of the professionals participating in the research are aware of NR 32, as well as the presence and need for adequate disposal parameters to minimize the risk of accidents, being well identified by RDC 44.

The study by Silva and Campos in 2018 presented results where they described some pharmacies in Goiás, which had deficiencies in several stages in relation to the disposal of biological material. These studies confirm that establishments need to act correctly throughout the flow, from management to final disposal of waste. In contrast, in the study by Damasceno et al. in 2006, they demonstrated that many professionals are still resistant to adopting recommended preventive measures and the use of PPE (DAMASCENO, et al, 2006).

In the present research, it is observed that there is still a deficiency on the part of pharmacists, although in their minority, but becoming a relevant percentage in terms of safety and health knowledge of the professionals involved in the practice of injecting in the face of biological contaminants, as well as related to the standards and resolutions that guide all logistics and good practices. Since 15% of the patient received a negative answer regarding the correct disposal of sharps, it is understood that these professionals allow themselves to be exposed to this condition. With a negative response (25%) to the knowledge of NR32, it reaffirms that biosafety is a set of actions, equipment, methodologies, procedures and techniques appropriate to extinguish or minimize accidental, ergonomic, physical, chemical and biological risks related to work activities. Being devoid of this understanding, it is easy to fall into a wrong environment structurally and legally, as they will not be able to position themselves and have the autonomy to make the necessary changes due to the lack of this essential information.

Figure 6



Legend: Representation of the questions applied in the evaluative questionnaire, being A- question 11, B- question 12, C- question 13, D- question 14.

Source: Author, 2021

The results expressed in (**Figure 7)** present the relationship on the processing of contaminated waste generated. Where they were asked about the existence of a third-party company responsible for carrying out this collection and, consequently, the proper disposal (**Figure 7 A)**. The majority of professionals (85%) answered that the company they work for has a company responsible for the collection of biological waste, as well as in the studies by Silva and Campos, they highlighted that they temporarily stored the garbage with biological material in a cabinet in the injectable room and then delivered it to the company that performs the incineration service (SILVA and CAMPOS, 2018). In addition, in (**Figure 7 B)**, was referenced about the certification and authorization issued by the city hall, attesting to whether the injectable application room of the pharmacy or health promotion environment meets the sanitary standards established by the municipality for its operation, in this scenario the majority of professionals (90%) said that the companies they work for have the necessary documentation. Consonant, in (**Figure 7 C)**, data were related to the possible visit and inspection of injectable treatment rooms by inspection agencies. More than half of the professionals (60%) stated that they are inspected in their work environments and presenting a very expressive percentage portraying this absence, (40%) expressed that there is no regular inspection, since the author Oliveira, et al., (2020) described in their literature review that materials for disposal have become something very common not being found in different AAS, a management plan for these contaminated wastes, causing damage not only to human health but also to the environment, also pointed out that there is a deficit in relation to sanitary inspections for the control of this waste (OLIVEIRA, et al., 2020).

RDC No. 222 of March 28, 2018, addresses the RSS (Health Service Waste) of Group E in its Art. 86 describes that: "Sharps must be disposed of in labeled, rigid containers with lids, resistant to puncture, rupture and leakage."

> Art. 87 Group E RSS packaging containers must be replaced according to demand or when the filling level reaches 3/4 (three quarters) of the capacity or according to the manufacturer's instructions, and manual emptying and reuse are prohibited.

As far as the Health Surveillance is concerned, an investigation was carried out *On-site* in all community pharmacies (public, philanthropic and private) in a given municipality in the interior of Rio de Janeiro in order to see the adequacy of these places in relation to the legal frameworks along with their regulation. It was observed that both the work process and its physical structure did not meet the recommendations of the legislation, which points to failures for pharmaceutical and drug care due to the lack of legal and technical competence (VIEIRA, COSTA, SOLER, 2016).

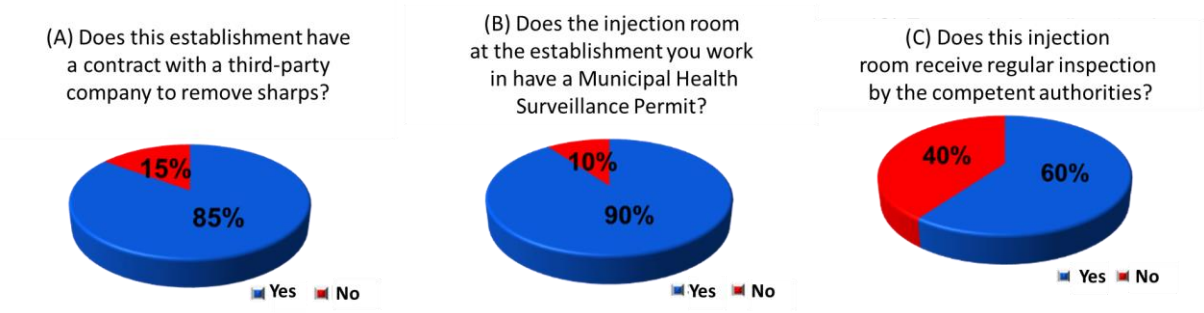
According to Silva and Vieira, based on 175 drugstores in the interior of São Paulo, 100 pharmacists Technical managers (RT) were interviewed to evaluate the legal aspects that govern the operation of drugstores and the profession, where they detected a deficit (50%) in the knowledge about the legal requirements of the permanence of pharmacists in the drugstores in the full-time operation of the establishment and about the regulation of the profession. An important fact that corroborates this current research is that only (15%) of the interviewees (99%) referred to an attribution of the pharmacist to the application of injectables (SILVA and VIEIRA, 2004).

The author verified the existence of a "myth" among them (pharmacists) regarding the prohibition for the procedure of injecting the application of injectables. (23%) made a mistake or did not know how to give an answer regarding "the pharmacist is prohibited by law from administering injectables", meaning the existence of a pharmaceutical professional who believes that he is prohibited by law from exercising such practice (SILVA and VIEIRA, 2004).

In view of all the subject explained above, it is understood through the current theme that pharmaceutical professionals with their institution located in the Lakes Region/RJ have the science and concern with the proper disposal of contaminating materials, such as biological and even chemical waste in the case of medicines, having outsourced companies to dispose of them in appropriate places, such as landfill or incineration process.

However, there are still few policies aimed at promoting the correct disposal of medicines and microbiological materials, in addition to the lack of supervision by competent health entities, as shown by the percentage of this survey where (40%) answers that there is no regular inspection, which contributes to an often inadequate disposal of waste from health services. as well as the maintenance of incorrect logistics to carry out the procedures that require care regarding exposure to biological risks.

Figure 7



Legend: Representation of the questions applied in the evaluation questionnaire, being A- question 15, B- question 16, C- question 17.

Source: Author, 2021

Finally, (**Figure 8 A)** presented data on the continuing education of pharmaceutical professionals regarding training for the application of injectables, interestingly, only 55% answered that they have been updated and only 15% of the professionals stated that they are not up to date with their vaccination schedule against Hepatitis B and Tetanus vaccines. This result provides further concern regarding the study carried out, since these professionals may be exposed to biological risks (**Figure 8 B).**

Regarding vaccines, the study by Pontes et al. 2018 observed that only 50% of students reported being up to date with their vaccination, of these, 56% against hepatitis B and 78% against tetanus. This study also points out that if it is necessary to continue training future professionals in biosafety training and monitoring vaccination coverage, it needs to be effective, since safe and conscious practice minimizes the risks of contamination in the environments where this future professional will work.

In the study addressed by Lucchetta and Mastroianni (2010), it was observed in their results that the level of conduct was more satisfactory than the level of knowledge on the part of RT pharmacists in their attributions, which can be explained by their time of training favoring greater practice. As for knowledge, the level has become low due to the lack of updating rather than the training itself. The study points out that these evidences are due to the lack of habit in seeking continuing education and participation in congresses, where often these congresses are attended mostly by academics and not pharmaceutical professionals already active, so the study suggests strategies to encourage the habit of updating. (LUCCHETA and MASTROIANNI, 2010).

In relation to the authors' study, it is necessary to identify the causes of accidents and for this, continuing education can be used as a strategy to minimize risks and, thus, investment in continuing education is necessary, and for any educational program to be successful, it must be linked to the participation and recognition by the workers and support of the institution (NOVACK, KARPIUCK, 2015).

The current study brings a relevant point when it comes to continuing education, it is noticed that (45%) of the professionals do not update themselves, it is not known if it is due to the lack of

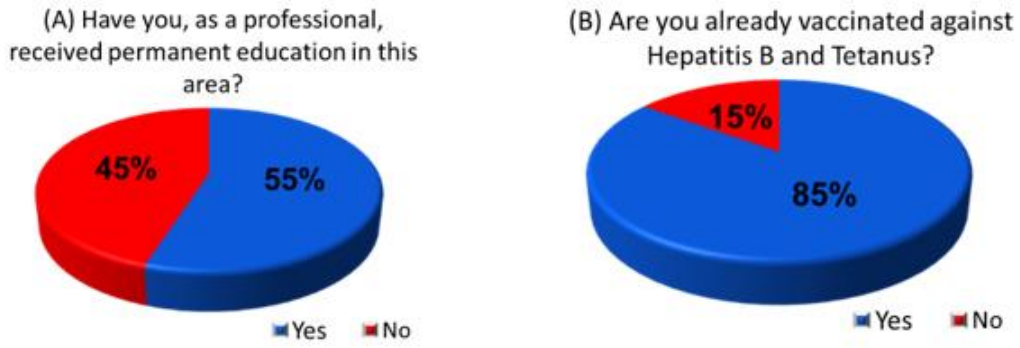
seeking to be trained, due to the lack of time since the workload is overloaded or even by the institution that does not provide the incentive, but according to the National Council of Quality of the Order of Pharmacists it says that it is the competence of the Pharmacist to continue training where it should include the attendance of scientific and technical training courses, such as participation in symposia, congresses and other scientific initiation projects, as well as reading publications with the aim of professional updating and strengthening of their skills.

RDC 44, of August 17, 2009, in its section III, speaks of the training of employees in its Articles 24, 26 and 27:

> Art. 24. All employees must be trained in complying with current health legislation applicable to pharmacies and drugstores, as well as the establishment's Standard Operating Procedures (SOPs).
> Art. 26. Initial and continuous training on the use and disposal of PPE should be provided, in accordance with the Health Services Waste Management Plan - PGRSS, according to specific legislation.
> Art. 27. During training, employees should be instructed on procedures to be adopted in the event of accidents and episodes involving health risks to employees or users of pharmacies and drugstores.

This is the legal support that the professional has regarding continuing education. On the other hand, the relevant point, even if in a total of 15%, refers to the concern about the vaccination schedule of these working professionals, because in view of the practice developed, which is the application of injectable drugs, it becomes extremely important to require vaccination coverage for all professionals involved.

Figure 8



Legend: Representation of the questions applied in the evaluative questionnaire, being A- question 18, B- question 19.
Source: Author, 2021

Concerning **Question 8 (eight)** From this evaluative questionnaire, which is described in text form, (65%) of the participating pharmaceutical professionals believe that they will be welcomed by the institution in the event of an accident with biological material and the others (35%) believe that they will not be supported.

The author Azevedo, et al., used a quantitative, descriptive, and retrospective method in the database of a given hospital pharmacy. A total of 529 cases of accidents involving exposure to biological material were reported, 496 (93.8%) required post-accident prophylaxis and (43.3%) did not obtain information from the source. The author points out in his study that exposure to biological material causes not only physical but also emotional damage and extends to the victim's social and family environment (AZEVEDO, et al., 2019).

It is understood that all professionals who suffer this type of exposure deserve all the support, both from the health team and from the institution through which they provide their services and care. In the present study, a percentage of (65%) of confirmation by the professionals regarding this embracement was observed. This becomes important for the professional in terms of trust and credibility. This also leads us to review some positions and conducts on the part of the institutions when a percentage of (35%) who do not believe that they will be welcomed is verified. An issue to be analyzed, because it brings to light some indications, do you not accept because you neglect the fact or because you do not know how to conduct? That is a question to be evaluated.

4 CONCLUSION

In view of the above, it is concluded that most of the pharmaceutical professionals involved in the practice of injecting drugs in health promotion services such as pharmacies and drugstores, among other AAS, are the technicians responsible for the establishment. They demonstrated to have scientific knowledge, training and qualification to perform the procedure, as well as the understanding of health safety protocols, regulatory standards of good practices and biological risks inherent to the practice, but within this group there is still a portion devoid of this understanding, which becomes worrying since he is the main responsible for carrying out this attribution supported by law.

The fact that this small portion is unaware of these standards, which guide all part of the structural logistics of an injectable application room, makes these professionals much more susceptible to risks with microbiological contaminating materials. Another aggravating point, that within this study, the lack of knowledge on the part of pharmacists regarding the training of clerks to practice the application of injectables was presented, it is understood that once they are not able to practice, they are more vulnerable to errors, malpractice and consequently exposed to risks. In view of this result obtained in the research, the need to broaden the discussion on occupational risks, occupational accidents and reinforce the need to have permanent education, as well as the elaboration of health policies for the pharmaceutical professional, is emphasized.

It also reinforces the need for regular sanitary inspection, which will also help to minimize accidents, since they will detect non-conformities, whether of physical structure, and even of actions developed such as the improper disposal of sharps and biological waste. Now when the pharmacy

becomes a health promotion establishment and develops activities of exposure of the professional himself, the role of the pharmacist is not limited only to facilitating the patient's access to the proposed treatment, he also becomes the target of care and due support when his health is exposed to both operational and biological risks.

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