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Changes in workflow to a University Pharmacy to facilitate compounding and distribution of antiseptics for use against COVID-19

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ARTICLE INFO

Keywords: Coronavirus 
Gels antiseptics 
Actions against Covid-19 
Compounding pharmacy

ABSTRACT

This article is a report from an experience about a work developed by Farmácia Universitária at UFRJ (FU-UFRJ) during the nCoV-19 pandemic period. The aim of this work was to describe its contribution in the production of antiseptic supplies used to prevent contagion by the new coronavirus. The work routine at the pharmacy has been changed to allow the implementation of local workflow during the pandemic, and to adapt the protection rules to meet the safety measures. FU-UFRJ started to manipulate two antiseptic formulations: 70% ethyl alcohol and gel alcohol, which are included in the National Form, manufacturing around 100 L of these formulations, weekly, to donate to different health units. The experience enabled the adaptation to emergency health standards, planning and meaningful guidance to pharmacists and technicians to attend clinics at university hospitals, vaccination center and UFRJ city hall, in order to facilitate the access to adequate hand hygiene to the population.

Introduction

The COVID-19 pandemic is currently a major distress for public health worldwide. The new coronavirus agent (nCoV-2019) is a simple ribonucleic acid (RNA) genome virus, with a high transmissibility potential. Most symptomatic patients will develop mild symptoms. However, in some patients it can cause severe infection of the respiratory tract, causing pain and suffering, enabling progression to acute respiratory failure, respiratory distress syndrome, multiple organ dysfunction and death. There are no proven effective treatments against nCoV-2019 and the development of a safe vaccine is expected, therefore it is very important to prevent its spread by controlling contagion and transmission. nCoV-2019 was discovered on December 31, 2019, after cases registered in China, and the World Health Organization (WHO) declared, in March 2020, the pandemic situation for nCoV-2019. Now, on 09/20/2020, the COVID-19 dashboard displays 30,675,675 confirmed cases of COVID-19, including 954,417 deaths reported to WHO, and in Brazil, 4,495,183 million confirmed cases of COVID-19, with 135,793 deaths.

One of the greatest pandemic control dualities is due to the coronavirus route of transmission that can be direct or indirect (Fig. 1). The direct route involves contaminated droplets (Fig. 1A) or drops (Fig. 1B) that are airborne to the airways (nasal and oral mucosa) and eyes. The indirect route involves transmission by contact with hands (Fig. 1C) or contaminated inanimate surfaces (contamination occurs by deposition of drops containing the coronavirus) (Fig. 1D). Contaminated hands are the focus of transmission to inanimate surfaces or mucous membranes (nasal or buccal), in addition to the ocular (Fig. 1E).

Thus, the use of face masks can reduce the transmissibility of the coronavirus, and disinfectant agents, such as 70% ethyl alcohol, 0.1–0.5% sodium hypochlorite, 2% glutaraldehyde are effective in inactivating nCoV-19.

WHO recommends social isolation and personal hygiene care to reduce the transmissibility of nCoV-19. In Brazil, the Ministry of Health (MS) declared the community transmission of COVID-19 throughout the national territory. One of the containment measures is isolation for, at

https://doi.org/10.1016/j.sapharm.2020.09.016
Received 27 September 2020; Accepted 28 September 2020
Available online 1 October 2020
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least, 14 days for any patient with confirmed infection and mild symptoms, according to Resolution Nº 356.\textsuperscript{8} The biggest challenge of this pandemic situation is the lack of specific pharmacotherapies proven up to date. There is no specific vaccine or antiviral drug to prevent or treat COVID-19. Infected people should receive supportive care to relieve symptoms. People with serious illnesses must be hospitalized.\textsuperscript{9}

In this context, it is important to highlight the obstinate participation of health professionals in the fight against COVID-19. Since the discovery of the pandemic, the population has relied on the tireless work of doctors, nurses, physiotherapists, pharmacists and other health professionals who are on the front lines. Work routines were altered by additional activities related to the pandemic, to serve a much larger number of patients on the various fronts, health posts, emergencies and hospitals, in addition to pharmacies.\textsuperscript{10}

Pharmacies, due to their capillarity and geographical distribution, present an important role in society.\textsuperscript{11} Compounding Pharmacies, for example, offer various medications, antipyretics, analgesics, anti-inflammatories, antimicrobials and bronchodilators in a personalized way. All of it, respecting patient’s profile, which are fundamental to manage the symptoms of the diseases, in addition to antiseptics, used in the prevention of transmission, such as 70% ethyl alcohol in solution or in gel form. These resources are considered highly effective for hand hygiene at this time.\textsuperscript{12,13}

Pharmacists are health professionals who work directly or indirectly to combat the pandemic supplying the demand for health services.\textsuperscript{14} The roles and activities of pharmacists during the COVID-19 pandemic involved: provides reliable information about disease and associated symptoms to reduce health risks, educational actions in relation to infection control and preventive measures to reduce transmission (hand hygiene, social distance, self-isolation), maintain continuity of pharmacy services, including essential drug supplies and other products (hand sanitizers, protective masks and ambient sanitizers), support local and national management teams to ensure a response coordinated health services and participate in multiprofessional study groups to enable the return of post-pandemic activities.\textsuperscript{14}

The Farmacia Universitária at the Universidade Federal do Rio de Janeiro (FU-UFRJ) is a public pharmacy, usually supporting 300 patients/day. It was created in 1986 as a project based on the need to offer curricular internship to students from the graduation courses from the Faculty of Pharmacy at UFRJ. Until 2019, it trained approximately 6,500 undergraduate students from the University and from external Higher Education Institutions (IES). Also acting in the training of qualified human resources at the postgraduate level. In 2008, the FU-UFRJ project was made official as an Extension Program (FU-UFRJ) supported by the Dean of Extension of UFRJ. Within the extension activities, its main goal is to promote the exchange of knowledge with the population using allopathic and homeopathic medicines manipulated at FU-UFRJ, as well as among high school and elementary school students, through the various extension projects developed by teachers and pharmacists. This program displays excellent results in relation to the professional insertion of alumni and enables the association between education, research and extension, especially at the FU-UFRJ, as a concrete reality. In addition, it plays an important role as a health establishment providing opportunities for exchange between social problems and education.\textsuperscript{15}

Due to the public health emergency and the norms established by the Health Surveillance Agency (ANVISA), FU-UFRJ started to produce alcohol gel and 70% ethyl alcohol, according to the National Form,\textsuperscript{16} aiming to meet the needs of some clinics at the University Hospital Clementino Fraga Filho of UFRJ, the Vaccination Center and the City Hall.

According to the literature, it is very important to determine the concentration of alcohol, since the mechanism of microbicidal action of 70% alcohol occurs due to the hydration degree of this presentation. In this dilution, the alcohol has an optimal concentration for the denaturation of microorganism proteins, since in the presence of water, the entry of alcohol into the bacteria is facilitated, and the volatilization of alcohol is delayed, allowing longer contact time. Thus, the destruction of the microorganism’s external cell membrane occurs by dehydration in the presence of alcohol, since the alcohol is hygroscopic and hydrophilic. Then the alcohol molecules penetrate the cytoplasm causing the precipitation of proteins by denaturation, also promoting the coagulation of enzymes responsible for essential cellular activities.\textsuperscript{17}

In this context, the production of alcohol gel at 70% and ethyl alcohol at 70% by FU-UFRJ complied with the protocols and contingency plans to cope with COVID-19. In February 2020, the National contingency plan for human infection was activated by nCovid-19, which established regulatory measures that included the aforementioned products. The use of antiseptic agents, such as 70% gel alcohol and 70% ethyl alcohol, considering their ability to inactive nCov-19, prevent its transmission between individuals and self-inoculation by hands has become a fundamental habit.\textsuperscript{18}

Thus, the objective of the present study was to describe the contribution of FU-UFRJ in the production of antiseptic inputs used to prevent the contagion of nCovid-19, considering the public health emergency and the standards established by ANVISA.

Methods

This is a report, since it describes a particular experience over a new approach to care at work that led to reflections on the role of the pharmacists in the pandemic. In this case, the focus is on the process adaptation to health standards for maintaining work at pandemic time. The executive time of FU-UFRJ is usually composed of seven professors, thirteen pharmacists, an economist, seven pharmacy technicians and four administrative employees. However, due to the COVID-19 pandemic, there was a reduction in the executive team, in the schedule and work regime, which started to operate in shorter periods, from 10 to 14 h, under a rotation scheme. Hence, the executive team became three professors, seven pharmacists, an economist, 4 pharmacy technicians, four administrative technicians and a graduate student. None of the professional were considered as part of the risk group.

The activities started to be carried out internally, prioritizing the production of alcohol gel and 70% ethyl alcohol, according to the Brazilian Pharmacopeia National Form.\textsuperscript{19} The 70% ethyl alcohol used in the preparation of both liquid forms and gel formulations was subjected to process control such as organoleptic characteristics and pH, both for gel alcohol and 70% ethyl alcohol. The alcoholic level of the system was measured with the aid of a Gay-Lussac alcoholometer (Incoterm), at 20 °C.

Fig. 1. Direct transmission routes vectored by airborne drops (diameter < 5 μm: airborne ‘< 1 m’ (A) or by airborne drops (diameter ‘≥ 5 μm: airborne > 1 m”) (B). Indirect transmission routes by direct contact with contaminated hand (C) or by indirect contact with contaminated inanimate surfaces (D). Indirect transmission route that involves contaminated hands and inanimate surfaces (E).\textsuperscript{6}
Another action to confront COVID-19 was the development of an alcohol formulation alternative to the one found in the Brazilian Pharmacopoeia National Form, using ingredients with the same pharmaco-technological function, as determined by Resolution No. 347. In addition, controls on the manipulated formulations were also performed, as determined by the Resolution No. 67 published by National Health Surveillance Agency (ANVISA), such as: description of the formulations developed, aspect, organoleptic characteristics, pH (Bante Instrument - model 9220), viscosity (Brookfield viscometer, model DV-III), and recorded in the manipulation order. All the manipulation work took place in an environment that obeys Good Handling Practices (GHP), as determined by Resolution No. 67 (ANVISA, 2007). In addition, efficacy and safety tests of the alternative formulation and traditional formulation of 70% alcohol gel were executed. The effectiveness of the two formulations was tested according to the protocol of the National Institute for Quality Control in Health (INCQS) 653210, 019, with a few modifications. Ten sterile stainless steel cylinders were dipped for 15 min at room temperature, in a pool of microorganisms (Staphylococcus aureus, Salmonella choleraesuis and Pseudomonas aerugi-

nosa) grown in Casoy broth for 48 h at 32.5 ± 2.5 °C. Each cylinder was carefully removed with the aid of a sterile hook, placed on filter paper and in an oven for 40 min. After that time, every 1 min, a cylinder was placed in a tube containing 10 ml of each alcohol gel formulation. After placing the 10th cylinder, totaling 10 min, the first cylinder was removed and placed in a tube containing 10 ml of Casoy broth, successively repeating the procedure every 1 min for the other cylinders. The ten tubes containing the cylinders were incubated in a bacteriological oven at 32.5 ± 2.5 °C for 48 h.

As for safety tests, the formulations were analyzed in accordance with Resolution No. 481 (1999) which establishes Microbiological Control Parameters for Personal Hygiene Products, Cosmetics and Perfumes. According to the Resolution No. 481, for Total Count of Aerobic Microorganisms, 10 g of sample was transferred to a flask containing 90 ml (1:10) of Casoy broth under agitation until complete dissolution of the sample. Counting was carried out using 1 ml aliquots of the 1:10 dilution in four Petri dishes. Two plates had about 20 ml of casein-soy agar (TSA-medium for bacterial count) and for the other two, about 20 ml of potato dextrose agar (PDA-medium for mold and yeast count), in addition to 0.3 ml of 10% w/v tartaric acid. After homogenization, the plates were incubated in a bacteriological oven at 32.5 ± 2.5 °C, for 24–48 h, for the TSA plates; and 22.5 ± 2.5 °C, for 5–7 days for PDA plates. After the incubation period, the plates were examined for microbial development.

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Results and discussion

Alcohol gel and 70% ethyl alcohol are antiseptic agents, used by the population in order to mitigate the expansion and spread of nCov-19 as hand sanitizer and surface sanitizer. Therefore, it is very important to ensure the safety and effectiveness of these products. The action carried out by FU-UFRJ was relevant in the health context, as all formulations were manipulated, according to the GHP, with the supervision of the handling process by a pharmacist, registered with the Regional Pharmacy Council of the State of Rio de Janeiro. The raw materials were from qualified suppliers and analyzed by the quality control of FU-UFRJ. The purified water was produced on the same day of the products handling at the pharmacy, in addition to physical-chemical and microbiological tests performed at the FU-UFRJ laboratories, that belong to the Brazilian Network of Analytical Health Laboratories (REBLAS); the handling process followed previously defined Standard Operating Procedures (SOP). The products label presented all the information required by the legislations issued by regulatory bodies. In the face of the pandemic, there was an increase in the consumption of gel alcohol and 70% ethyl alcohol, by society, as a preventive measure against the transmission of nCov-19. This high demand caused the lack of these products in the market at first, in addition to the abusive price increase. Another negative fact was the encouragement of homemade alcohol gel production, in addition to product counterfeiting, without considering the risk of accidents, as they were not subjected to quality controls to guarantee their efficacy and safety, contrary to the Brazilian legislation.

Selling of liquid alcohol in concentrations above 54° GL (Gay-Lussac) has been forbidden by ANVISA, since 2013, according to Resolution No. 46 (2002), which considered the risks offered to public health resulting from accidents, as fires, high-grade burns and skin and mucous membranes irritation. For solutions with a degree above 54° GL, the standard gel form is allowed.

According to Empresa Brasil de Comunicação (EBC), Agência Brasil published that the Civil Police arrested a Central scheme that produced counterfeit alcohol gel. This led ANVISA to publish an orientation for the purchase of alcohol gel® and a technical note on the requirements that must be met for the donation of 70% ethyl alcohol® to minimize these risks.

Thus, ANVISA has advised to always purchase these products from establishments that guarantee compliance with the minimum standards of BHP, with a professional responsible for the technical supervision of the activity, with raw materials that meet the technical requirements of quality and safety of the official comendiums. Besides, the labels/packages must include Company’s Name, CNPJ, address, telephone number of the establishment, validity, alcohol concentration, indication of use, complete formulation and warnings. Due to the scenario, given the exponential infection growth, the FU-UFRJ adopted agile and effective actions to enable quick and large-scale access to antiseptic products that could be used to combat the pandemic.

As of March 16, 2020, the FU-UFRJ with its reduced staff, started to operate according to the document prepared by the Federal Pharmacy Council (FPC), which describes that compounding pharmacies must implement emergency plans and local workflow during the nCov-19 pandemic.

Therefore, to meet safety measures, FU-UFRJ provided personal protective equipment (PPE), such as a face mask, disposable cap, glasses, latex gloves, disposable apron, for the whole team. In addition, recommended 2 m distance between people, talking as little as possible. The constant use of hand sanitizer was mandatory along with the attention to the initial symptoms of the infection (fever, cough, body pain, indisposition) also guided the employees when they got home on how to put on all the clothes to wash, how to quarantine shoes, wash hands correctly and finally how to take a shower. After the emergency plan and work flow were implemented, FU-UFRJ started to manufacture 50 L of alcohol gel and 55 L 70% ethyl alcohol weekly, according to the Brazilian Pharmacopoeia National Form, aiming the needs of some clinics at Clementino Fraga Filho University Hospital (HU-UFRJ), the Vaccination Center and the City Hall. The City Hall that began the distribution of antiseptics to the ambulance and bus drivers that continued to circulate around UFRJ campus compliant to the rules established by ANVISA for the public health emergence.
In addition, it was necessary to develop an alternative formulation for alcohol gel, due to the various ingredients’ stock out on the market. This was a measure recommended by Resolution No. 347 (ANVISA, 2020). Table 1 shows the formulations: alcohol gel described in the Brazilian Pharmacopoeia National Form and alcohol gel developed by the FU-UFRJ team.

The substitution of acrylic derivatives, such as Carbopol®, with other thickening agents, was a way of circumventing the lack of it in the market, considering its performance in forming gel in the presence of high concentrations of alcohol, when compared to other hydrogels. However, the copolymer of sulfonic acid acryloyldimethyltaurate and vinylpyrrolidone, also known as Aristoflex® AVC, belongs to a modern group of viscosity modifiers, conferring good spreadability and sensory characteristics to the formulation, in a concentration of use similar to Carbopol®, without the need of neutralization. Table 2 shows the physical-chemical results of the formulations manufactured by FU-UFRJ.

It was observed that the physical-chemical characteristics obtained were similar between the formulations for alcohol gel. On the other hand, the pH resulting from the addition of Aristoflex® AVC showed greater compatibility with the skin, considering its slightly acidic characteristics (4.8–5.5). The pH for 70% ethyl alcohol is in line with skin pH.

In the microbiological test, all formulations inhibited the growth of Staphylococcus aureus, Salmonella choleraesuis and Pseudomonas aeruginosa. Therefore, no bacterial growth was evidence in any of the 10 tubes containing the contaminated cylinders and treated with both alcohol gel formulations. Such results proved the safety of the formulations developed, both for the growth of non-specific microorganisms, and for Staphylococcus aureus, Pseudomonas aeruginosa and Escherichia coli. Thus, it was possible to develop an alcohol formulation in gel alternative to the National Form, with similar characteristics of efficacy and safety.

Thus, for the protection of the population against nCov-19, everyone should practice social isolation, wear a mask appropriately and wash their hands with soap and water. When hand washing is not feasible, for example, inside the market during shopping, inside pharmacies where medicines are dispensed, inside buses during transport to work, there is the possibility of cleaning hands with 70% alcohol gel, which is able to kill 99.9% of microorganisms pathogenic, 62%–71% ethanol can reduce coronavirus viability on inanimate surfaces with 1 min exposure time.

All the work developed by the FU-UFRJ was publicized and recognized by society, as shown by the radio interview from the Federal University of Rio de Janeiro (UFRJ). Moreover, the work was publicized in the UFRJ bulletin, no. 13, of April 1, 2020, which established the contingency plan for coping with the pandemic caused by the new coronavirus within UFRJ; being the article published on the UFRJ extension office.

### Table 1

| Ingredients                  | Alcohol gel National Form | Alcohol gel developed by the FU-UFRJ |
|------------------------------|---------------------------|--------------------------------------|
| Carbopol®                    | 0.5 g                     | –                                    |
| Aristoflex® AVC              | –                         | 0.7 g                                |
| Aminomethylpropanol 95%      | 0.06 g                    | –                                    |
| Glycerin                     | 1 g                       | 1 g                                  |
| Phenoxethanol/parabens       | 0.5 g                     | 0.5 g                                |
| Alcohol 96% GL              | 75.73 g                   | 75.73 g                              |
| Distilled water q.s          | 100 g                     | 100 g                                |

### Table 2

Results of the physical-chemical analyzes of the formulations manufactured by FU-UFRJ.

| Test(s)                  | Result(s) | Specifications* |
|--------------------------|-----------|----------------|
| Standard Plate Count     | <10 CFU/mL| Maximum limit 5 x 10⁶ CFU/mL |
| Yeasts and Moulds        | <10 CFU/mL| Maximum limit 5 x 10⁶ CFU/mL |
| Staphylococcus aureus    |Absent     |Absent          |
| Pseudomonas aeruginosa   |Absent     |Absent          |
| Escherichia coli         |Absent     |Absent          |

### Table 3

Safety results of formulations developed according to the specifications contained in the Brazilian Pharmacopoeia.

### Conclusion

FU-UFRJ, with its reduced team, managed the production of two feasible antiseptic formulations, 70% ethyl alcohol and 70% gel alcohol. Both were applied in the prevention of nCov-19, considering the emergency in public health and the rules established by ANVISA, and donated to Clinics of University Hospitals, Vaccination Center and to City Hall of the University, in order to facilitate the access of vulnerable population to hand sanitizer products. In addition, safety and efficacy of these products was guaranteed through physical-chemical and microbiological tests performed by the university as well as the handling to GHP. FU-UFRJ has also developed an alternative formulation of alcohol gel that is comparatively safe and effective to the formulation described by the National Form. FU-UFRJ has been carrying out all its activities during the nCov-19 pandemic, according to the document prepared by the Federal Pharmacy Council (FPC), employing emergency plans, modified local workflow, and meeting all security measures to protect the work team.

### Funding

None.

### Declaration of competing interest

None.

### Author statement

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Acknowledgements

The authors would like to thank FU-UFRJ for support in the development of the work.

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