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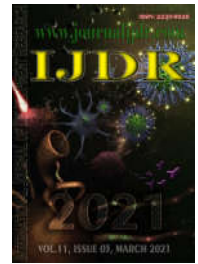
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EXPERIENCE OF THE BRAZILIAN HEALTH REGULATORY AGENCY IN COPING WITH THE COVID-19 PANDEMIC: PREVENTIVE ACTIONS OF INFECTION IN HEALTH SERVICES

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ABSTRACT

COVID-19 is a public health problem worldwide. The Brazilian Health Regulatory Agency (ANVISA) is responsible for preventing and controlling healthcare-associated infections (HAIs), in conjunction with state and municipal health surveillance centers (VISAs). Thus, the present study aimed to relate the experience of ANVISA in organizing, preventing and monitoring COVID-19 in the country's healthcare services. Given the emergency, ANVISA, VISAs and specialists developed sanitary strategies and actions to organize, prevent and monitor COVID-19, between December 2019 and March 2021, in order to establish national disease prevention measures, and collect HAI-COVID-19 data. A number of national regulations and recommendations were published, such as technical notes and risk alerts to prevent COVID-19, in addition to disseminating the measures adopted. The experience may contribute to organizing, preventing and monitoring COVID-19, provided the national measures established are adopted by healthcare services. The improvement in sanitary response processes to prevent COVID-19 in these services is essential to strengthening the Brazilian Health Regulatory System (SNVS) in the fight against the disease.

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INTRODUCTION

The Coronavirus Disease – 2019 (COVID-19) pandemic, caused by the coronavirus SARS-CoV-2, is a public health problem (Chen *et al.*, 2020; WHO, 2021c) with an enormous impact on health systems around the world (Stevens *et al.*, 2020). Despite the efforts of the Brazilian Ministry of Health (MoH) to prevent the spread of SARS-CoV-2 and promote a rapid response to the emerging threat (Szylovec *et al.*, 2020; Oliveira *et al.*, 2020), cases have increased over time, totaling 10,587,001 confirmed cases and 255,720 deaths as of March 1st, 2021 (Brasil, 2020c). The Brazilian Health Regulatory Agency (ANVISA) consists of the Brazilian Health Regulatory System (SNVS), whose mission is to protect and promote the health of the population through interventions in the risks caused by the production and use of products and services subject to health surveillance, using coordinated and integrated action with the National Health System (SUS) (Brasil, 1990).

This agency is responsible for national coordination of the prevention and control of healthcare-related infections (HAIs) and microbial resistance, in addition to other adverse events (AE) in healthcare services (Brasil, 1999). Although the role of the SNVS in mitigating risks is well-known by the Brazilian population (Brasil, 1999; Santana *et al.*, 2020), few studies highlight the sanitary measures developed by ANVISA in conjunction with state and municipal Health Surveillance Centers (VISAs), in order to impede the spread of SARS-CoV-2 in the country's healthcare services (Henriques, Vasconcelos, 2020; Carneiro *et al.*, 2021). As such, the present study is justified due to the ongoing public emergency and immediate need to prevent and control SARS-CoV-2 infection, and it is essential to understand the conduct of the Agency in this context. The aim of this study was to relate the experience of ANVISA in systematizing the organization, prevention and monitoring of COVID-19 in Brazilian healthcare services.

MATERIALS AND METHODS

This is a descriptive study, an experience report, that discusses the systematization of the working process and the development of sanitary strategies and measures implemented to organize, prevent and monitor COVID-19 in Brazilian healthcare services, between December 2019 and March 2021, devised by professionals that work at ANVISA headquarters in Brasília, at the Management of Health Services Surveillance and Monitoring (GVIMS), of the General Management of Health Services Technology (GGTES). The systematized work process to deal with COVID-19 consisted of the following stages: 1) establishing national organization, prevention and monitoring measures against COVID-19; 2) strengthening the role of VISAs in healthcare services and 3) dissemination of the sanitary initiatives to organize, prevent and monitor COVID-19. Not only did the VISAs and GVIMS/GGTES/ANVISA provide technical-sanitary support for prevention measures against COVID-19 at the state, Federal District (FD) and municipal health services, but also to the Brazilian Association of Professionals for the Control of Infection and Hospital Epidemiology (ABIH). This agency coordinated the Working Group (WG) entitled “Collaborative COVID-19 Brazil” (consisting of representatives of associations, professional societies, universities and the MoH) and established strategies and measures to prevent SARS-CoV-2 transmission (Carneiro *et al.*, 2021).

The WG offered proposals at virtual meetings and in ANVISA publications on organizing, preventing and monitoring COVID-9, in addition to collaborating in preparing and revising the national guidelines established by GVIMS/GGTES/ANVISA. A “COVID-19” form was distributed for national diagnosis of the situation in field hospitals (FH) and other provisional facilities to be filled out by teams belonging to VISAs, VISA State Centers for Patient Safety (NSP VISA) and State, District and Municipal Coordination for the Control of Hospital Infection (CECIH/CDCIH/CMCIH)” (ANVISA, 2020b). The healthcare services also completed the form for AE and infectious outbreaks suspected by FH/provisional facilities - COVID-19 (ANVISA, 2020c). In addition, HAI COVID-19 forms were provided to collect infectious case data (ANVISA, 2020d).

RESULTS AND DISCUSSION

National measures for the organization, prevention and monitoring of COVID-19: Given the emergence of the new coronavirus in December 2019 as the reported cause of a respiratory disease outbreak in the city of Wuhan, China (Zhu *et al.*, 2019), ANVISA mobilized to protect Brazil’s borders from this biological threat. Joint measures were enacted to offer technical support to the SNVS and health services to face the imminent pandemic. In January 2020, ANVISA launched “Return to the Beloved Country Brazil” (“Retorno à Pátria Amada Brasil”), an interministerial initiative aimed at repatriating Brazilians from Wuhan, China (FAB, 2021; Henriques, Vasconcelos, 2020). This operation encompassed the transport, reception and safe welcoming of repatriated citizens at the Anápolis Air Base. ANVISA organized lodging, contributed to sanitary guidelines and established protocols, primarily related to preventing the dissemination of SARS-CoV-2 while transmission was still possible, in order to guarantee the safety of repatriated families, the professionals involved in the endeavor and all those at the Anápolis air base, in Goiás state (GO). Given that the National Coordination for the Prevention and Control of HAIs and other AE is the responsibility of GVIMS/GGTES/ANVISA, that knowledge of infectious diseases and the prompt implementation of these measures is crucial to save lives (WHO, 2021b), and that this decision is supported by specialists, efforts were made to establish evidence-based measures. Thus, in order for the states/FD to be able to systematically organize their health services, a survey was taken of the scarce world literature on COVID-19 and SARS-CoV-2. Despite the fact that the COVID-19 pandemic was declared by the World Health Organization (WHO) only on March 11, 2020 (WHO, 2020), Technical Note (NT) GVIMS/GGTES/ANVISA no. 04/2020 entitled

“Guidelines to health services: prevention and control measures that should be adopted while caring for suspected or confirmed cases of infection by the new coronavirus” (ANVISA, 2020e) was published on the agency’s website in January 2020 (ANVISA, 2021a). It is important to underscore that all ANVISA guidelines and recommendations aimed at supporting local health services initiatives, involving health administrators, healthcare professionals, patient safety centers (NSP) and the Hospital Infection Control Commissions (CCIH). Since new information on COVID-19 was emerging daily, GVIMS/GGTES/ANVISA sought the support of specialists to review the evidence and help make sound and safe national decisions regarding preventive measures (Carneiro *et al.*, 2021). In March 2020, TN GVIMS/GGTES/ANVISA no. 05/2020 – “Guidelines for the prevention and control of infections by the new coronavirus in long-stay institutions for the elderly (LSIE)” was published (ANVISA, 2020f). The latest version of the TN provides essential information for administrators, LSIE professionals, families and residents on how to prevent viral transmission between residents and professionals, and in case of infection, guidelines for effective isolation.

During the virtual meetings with the working group (WG), the need to provide national guidelines for surgical centers was raised, since considerable unofficial contradictory information had been published, creating concern and insecurity among surgical teams. Thus, in April 2020 TN GVIMS/GGTES/ANVISA no. 06/2020 – “Guidelines for the prevention and control of infections by the new coronavirus (SARS-CoV-2) in surgical procedures” (ANVISA, 2020g) was published. The official document, revised in May 2020, provides guidelines on pre-surgical organization, team training, necessary precautions before, during and after surgery, and the safe return to elective surgery during the pandemic. In light of the global concern about infections in health services, other official documents were provided to these entities. In May 2020, TN GVIMS/GGTES/ANVISA no. 07/2020 – “Guidelines for the prevention and epidemiological surveillance of infection by SARS-CoV-2 (COVID-19) in healthcare services” was published, recommending a series of measures to prevent HAIs caused by SARS-CoV-2, in addition to containing the epidemiological definition for hospital transmission of COVID-19 (ANVISA, 2020h). The analysis of 1343 cases of HAI-COVID-19 notified to the SNVS between August and December 2020, revealed an incidence density (ID) of 2.01 infections per one thousand patients/day in adult ICUs, while pediatric and neonatal ICUs exhibited an ID of 0.19 and 0.22 infections per one thousand patients/day, respectively (ANVISA, 2021b). Due to undernotification, the findings may not reflect the national reality, but rather the intra-hospital transmission rate of SARS-CoV-2 in the ICUs of the notifying health services. Cases of HAI - SARS-CoV-2 have been underestimated, and constitute significant problems, in both the medical-legal area and the field of public health (Cioffi, Rinaldi, 2020). The CECIH/CDCIH/CMCIH were informed of the need for health services to comply with the guidelines proposed by the National Program for the Prevention and Control of HAIs – PNPCIRAS (Brasil, 2016), in addition to the recommendations contained in the GGTES/ANVISA technical notes concerning COVID-19 (ANVISA, 2020a; ANVISA, 2020e; ANVISA, 2020g; ANVISA, 2020h).

The rapid increase in hospital bed occupancy prompted state, district and municipal health departments to provide FH/other provisional facilities to treat patients with COVID-19 (Brasil, 2020d). Official documents were published on the need to restructure FH/provisional facilities during the COVID-19 pandemic (ANVISA, 2020i; ANVISA, 2020j; ANVISA, 2020k). A national report on the registration of these services identified 283 reference hospitals enrolled in ANVISA (ANVISA, 2021a). In addition to this challenging context, the work performed in conjunction with NSP – VISA focused on monitoring the serious AE notified to the SNVS, an initiative containing regulatory frameworks such as the National Patient Safety Program (PNSP) (Brasil, 2013b) and RDC no. 36/2013 (Brasil, 2013a). Studies show that 10% of hospitalized patients suffer some type of AE in health services (WHO, 2021a), causing an increase in hospital stays and additional costs to an already

overloaded system (ANVISA, 2020i). In order to prevent AE, TN GVIMS/GGTES/ANVISA no. 08/2020 contains general guidelines for implementing patient safety measures in FH/other facilities (ANVISA, 2020i). It is known that the rising demands on health services imposed by COVID-19 can be addressed by adopting safety practices. Hospitalized patients with COVID-19 report having received few visits by health professionals (Wu *et al.*, 2020), which may have a negative impact on the quality of care provided. TN no. 08/2020 reinforces the need to notify serious AE, deaths caused by AE, and never events (events that should never occur in health services) (ANVISA, 2020i).

Analysis of serious AE notified to the SNVS by FH/provisional facilities showed that the most frequently notified were pressure injuries (PI) (ANVISA, 2021a). It is known that the use of basic safety protocols, such as those to prevent PI, is essential to prevent these events (Brasil, 2013c; ANVISA, 2017). The accidental loss of devices, such as probes, is the second most frequent AE in FH/provisional facilities (ANVISA, 2021a). Similarly, of the 22,613 healthcare-associated incidents reported to the SNVS (N=75,296) in 2017, and classified as "Others", one of the most frequent was "loss of probes" (n=4,890; 21.6%) (Brasil, 2018). In order to reinforce safety, TN GVIMS/GGTES/ANVISA no. 01 was published, alerting administrators, NSP, the CCIH and healthcare professionals to the need to reinforce prevention measures against AE and HAIs during the COVID-19 pandemic (ANVISA, 2020a). It is important to underscore the vital role of health service administrators, who should focus not only on bed occupancy, infrastructure, supplies and resource rationing, but also on appropriate resource management, in order to comply with good practices and team management to improve performance (Phua *et al.*, 2020). With respect to the CCIH and NSP, both entities are highly relevant to instituting a culture of safety (Brasil, 2013a; Brasil, 2013b) and encouraging healthcare teams to adopt evidence-based practices (Shekelle *et al.*, 2013). Given the challenges imposed by the pandemic, it is essential that health professionals comply with the patient safety and care quality protocols (Shekelle *et al.*, 2013; Brasil, 2015).

The GVIMS/GGTES/ANVISA collaborated with other institutions in creating educational materials to cope with this unprecedented situation in the country. These included "Dental Care Guidelines in the Context of COVID-19" (Brasil, 2020g); "Managing bodies in the context of the disease caused by Coronavirus SARS-CoV-2 – Covid-19" (Brasil, 2020f); and "Recommended Practices – Washing hands and disinfecting surfaces" (ABNT, 2020). This situation requires behavioral changes in the community aimed at preventing COVID-19. Thus, guidelines for the general population were revised, since citizens empowered with more knowledge can actively participate in preventing disease, as well as in the treatment at health services (Brasil, 2017; ABNT, 2020). With respect to participation of the team in meetings coordinated by groups outside ANVISA, we underscore those held at the Center for Emergency Public Health Operations of the MoH (COE-COVID-19) (Brasil, 2020e). In addition, the GVIMS/GGTES/ANVISA collaborated with the Center for the Coordination of Crisis Committee Operations of COVID-19 (CCOP). Internally, the team worked with different ANVISA departments involved in combatting the COVID-19 pandemic, especially at meetings coordinated by the Office of the Director-President of the Agency (GADIP). In regard to technical regulations, the team supported the creation of RDC no. 356/2020 (Brasil, 2020b), amended by RDC 379/2020 (Brasil, 2020a), which temporarily relaxed the rules for the manufacture, importation and acquisition of priority medical devices for use in health services.

Strengthening the ability of VISAs in health services to combat COVID-19: In order to promote the combined actions of VISA administrators in the states/FD, responsible for inspecting health services and developing joint measures aimed at preventing and controlling COVID-19, weekly online meetings were held to discuss actions with the VISAs, in addition to bi-monthly meetings with CECIH/CDCIH/CDCIH and NSP VISA. Instructions for the pandemic, the registration of FH and provisional facilities

implemented to treat patients infected by SARS-CoV-2, in addition to the notification and monitoring of AE and infectious outbreaks, were the issues that motivated discussions at these encounters. The efforts expended in these institutions have contributed to a systemic set of sanitary measures to prevent COVID-19, and the lessons learned can be attributed to the improved collaboration between ANVISA and these entities, through the exchange of experiences at different levels. The present study shows that listening to the actors responsible for managing patient safety in the states, FD and municipalities (Brasil, 2015), in addition to jointly implementing adequate and timely sanitary measures, have been essential in helping ANVISA and the VISAs address the COVID-19 pandemic.

Dissemination of the sanitary initiatives of organization, prevention and monitoring of COVID-19: All the educational materials developed were published on the ANVISA website (ANVISA, 2021) and disseminated on the Agency's social media platforms, as well as at the GVIMS/GGTES/ANVISA virtual seminars aimed at hospitals, primary care facilities and the general population (FIOCRUZ, 2020; ANVISA, 2020i). It is important to underscore that the measures contained in the official documents are not definitive, given that new research and evidence on COVID-19 have been published throughout the pandemic period.

CONCLUSION

The partnership between the different institutions involved may contribute to the organization, prevention and monitoring of COVID-19, provided that the national measures established are adopted by the country's healthcare services. However, actions aimed at continuous training and technical-scientific updating of professionals that work at these facilities are essential to ensure the quality of the care provided to patients. The sanitary initiatives described may have promoted the evidence-based recommendations applicable to healthcare services, VISA and the general population. Although an arduous task, the work resulting from the joint efforts reported in this study to ensure sanitary safety remains ongoing, since national measures on organizing, preventing, controlling and monitoring infections such as COVID-19 involve continuous monitoring and assessment. Improving the sanitary response may culminate in strengthening the capacity of the SNVS to combat COVID-19, prevent the disease and treat suspected or confirmed cases at healthcare services, thereby mitigating the impact of the pandemic on the country. It is hoped that this will pave the way to qualifying the measures implemented by ANVISA in conjunction with the VISAs in order to stem the dissemination of SARS-CoV-2, reflecting in the health areas responsible for management, policies and patient safety processes, thereby overcoming the challenges and saving more lives.

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