Original Article
doi: https://doi.org/10.1590/1983-1447.2021.20200389

Routine workflow in a reference clinical research center in face of COVID-19

Fluxogramas de atendimento em um centro de referência em pesquisa clínica frente a Covid-19

Diagramas de atención en un centro de referencia en investigación clínica frente a Covid-19

Adriana Serdotte Freitas Cardoso[a]
Stella Marys Rigatti Silva[a]
Eneida Rejane Rabelo-Silva[b,c]
Daniel Umpierre[a,d]
Luciana da Rosa Zinn Sostizzo[e]
Isabel Cristina Echer[f]

How to cite this article:
Cardoso ASF, Silva SMR, Rabelo-Silva ER, Umpierre D, Sostizzo LR, Echer IC. Routine workflow in a reference clinical research center in face of COVID-19. Rev Gaúcha Enferm. 2021;42(spe):e20200389. doi: https://doi.org/10.1590/1983-1447.2021.20200389

ABSTRACT

Objective: To develop and validate the content of workflows for trial participants care in a clinical research center during the Covid-19 pandemic.

Method: development study by consensus of experts carried out from March to July 2020 in southern Brazil. The flowcharts were developed following literature and validated by specialists considering comprehensiveness, clarity and pertinence, obtaining a 100% agreement index on each item of the developed instruments. The study was approved by the Ethics Committee of the institution.

Results: two flowcharts of care were elaborated and validated: "Flow diagram to conduct protocols with research participant " and "Flow diagram in protocols with research participant with suspected or confirmed COVID-19 infection"; which describes activities to ensure continuity of care.

Final considerations: a routine workflow can promote the continuity and safety of clinical research protocols. It is expected that the adopted flowcharts in this study can guide other institutions with a similar research profile.

Keywords: Workflow. Coronavirus infections. Patient safety. Disease prevention.

RESUMO

Objetivo: Desenvolver e validar o conteúdo de fluxogramas de atendimento em Centro de Pesquisa Clínica durante a pandemia Covid-19.

Método: Estudo de desenvolvimento e validação por consenso de especialistas realizado de março a julho/2020 no sul do Brasil. Participaram do estudo 12 especialistas de diferentes áreas. Os fluxogramas foram desenvolvidos a partir da literatura e validados por especialistas considerando abrangência, clareza e pertinência, obtendo-se índice de concordância de 100%, sobre cada item dos instrumentos desenvolvidos. Estudo aprovado no Comitê de Ética da instituição.

Resultados: Construiu-se dois fluxogramas: "Atendimento geral ao participante de pesquisa (sem suspeita de Covid-19)" e "Atendimento ao participante de pesquisa com suspeita ou Covid-19 confirmado"; os quais descrevem atividades visando assegurar a continuidade do cuidado.

Considerações finais: os fluxogramas permitem que a continuidade e segurança dos protocolos de pesquisa sejam mantidos. Espera-se que os fluxos adotados possam nortear outras instituições com perfil semelhante de atendimento.

Palavras-chave: Fluxo de trabalho. Infecções por Coronavírus. Segurança do paciente. Prevenção de doenças.

RESUMEN

Objetivo: Desarrollar y validar el contenido de diagramas de flujo de atención en Centro de Investigación Clínica durante la pandemia de Covid-19.

Método: Estudio de desarrollo por consenso de expertos realizado de marzo a julio / 2020 en el sur de Brasil. En el estudio participaron doce expertos de diferentes áreas. Los diagramas de flujo fueron desarrollados a partir de la literatura y validados por especialistas considerando la amplitud, claridad y pertinencia, obteniendo un índice de concordancia de 100%, en cada ítem de los instrumentos desarrollados. El estudio fue aprobado por el comité de ética de la institución.

Resultados: Se elaboró y validó dos diagramas de atención: "Atención general al participante en la investigación (sin sospecha de Covid-19) y "Asistencia al participante en investigación con sospecha de COVID-19 o infección confirmada"; ellos describen actividades para asegurar la continuidad de la atención.

Consideraciones finales: Los diagramas de flujo pueden promover la continuidad y seguridad de los protocolos de investigación. Se espera que los flujos adoptados puedan guiar a otras instituciones con un perfil similar de atención.

Palabras clave: Flujo de trabajo. Infecciones por Coronavirus. Seguridad del paciente. Prevención de enfermedades.

[a] Hospital de Clínicas de Porto Alegre (HCPA), Centro de Pesquisa Clínica. Porto Alegre, Rio Grande do Sul, Brasil

[b] Universidade Federal do Rio Grande do Sul (UFRGS), Escola de Enfermagem. Porto Alegre, Rio Grande do Sul, Brasil

[c] Hospital de Clínicas de Porto Alegre (HCPA), Programa de Acesso Vascular. Porto Alegre, Rio Grande do Sul, Brasil

[d] Universidade Federal do Rio Grande do Sul (UFRGS), Escola de Enfermagem, Departamento de Saúde Coletiva. Porto Alegre, Rio Grande do Sul, Brasil.

[e] Hospital de Clínicas de Porto Alegre (HCPA), Serviço de Enfermagem Ambulatorial. Porto Alegre, Rio Grande do Sul, Brasil

[f] Universidade Federal do Rio Grande do Sul (UFRGS), Escola de Enfermagem, Departamento de Assistência e Orientação Profissional, Porto Alegre, Rio Grande do Sul, Brasil.

INTRODUCTION

Confronted with the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) pandemic, the Agência Nacional de Vigilância Sanitária (ANVISA) published the Technical Note 14/2020[1], advising sponsors, research centers and researchers in the country about the fact that the studies could be affected due to difficulties in transporting patients, the lack of source materials, the closing of centers, or other causes, and considering the possibility of deviations from protocol.

This notification recommended that research participants and designs such as clinical trials should have their safety reassured, and that studies should be continued respecting good clinical practices. The document points at the need to carry out triages and emphasizes that measures must be taken to protect participants, especially those who are part of the risk group for the new coronavirus[1]. Furthermore, the American Food and Drug Administration (FDA) addressed the continuity of clinical studies during the pandemic, reiterating the need to adopt good practices and recommending sponsors to keep the participants under protocols associated to the control of the disease and/or of its symptoms[2].

According to the publications about this subject[3–4], the profile of participants attended in the Clinical Research Center (CRC) of the institution being studied seems to be more vulnerable to infections caused by the new coronavirus 2019 (COVID-19). Although the CRC attends to participants from several specializations, most are research protocols of onco-hematologic studies. In this regard, Chinese studies[3–4] have suggested that cancer patients are under a greater risk and have a worse prognosis than patients without the disease, also showing a high death rate (28.8%) when infected by COVID-19. Furthermore, age, sex and the comorbidities that are predominant in trial participants show a profile of vulnerability to the infection by the coronavirus, as indicated by several studies[5–8].

Despite the risk of infection and the restrictions caused by the pandemic, it is necessary to provide a safe treatment using research protocols that control signs and symptoms and/or promote the quality of life of its participants, since this population is vulnerable to the infection. Therefore, the relevance of this study is focused on the possibility of using a customized routine workflow to continuing protocols for trial participants who come from several regions of the country. This alternative stands out as a strategy to carry out health care, since it allows to provide planning, organization, and support to continue attention and maintain the safety and integrity of participants, technical multiprofessional teams, and researchers. Participants often remain in studies because it is the only possibility they have to receive a therapy or to have access to medication that is not yet commercialized. Therefore, other centers may benefit from the use of the workflows created here to enable the continuity of the assistance provided.

In this context the objective of this study is to answer the following guiding question: "Considering the risk of SARS-CoV-2 infections, what should be included in workflows created to provide safe attention to participants and researchers?" Therefore, the objective of this article is to develop and validate the content of routine workflow in a CRC during the pandemic of COVID-19.

METHOD

This study is the development and validation of the content of a routine workflow in a CRC during the COVID-19 pandemic according to the consensus of specialists. This method makes it possible, after the analysis of a specific theme, to obtain the collective opinion of specialists, and has been used in the health field to determine better practice standards[9].

The study was carried out from March to July 2020, in the CRC of a large sized hospital in the South of Brazil. Its infrastructure is adequate for the development of all stages of clinical and epidemiological trials, in accordance with the public health needs of the country. It is formed by multi-user areas that provide support to researchers and research participants. The areas that are directly influenced by this study are the reception, the research offices, the rooms for interviews with the participants of the researches, the blood collection sector, and the nursing unit (nursing station and infusion room).

In the reception, located on the 1st floor of the building, the participants of researchers are welcomed, records are made, consultations are scheduled, and researchers are attended. The 2nd floor is the area for the infusion of the medications being studied, the observation of participants, and the collection of blood sample for pharmacokinetic purposes. It has a room with nine armchairs and another with six beds. The care team of this floor includes two nurses and two nursing technicians distributed in the morning and afternoon shifts, from Monday to Friday.

To create the flowchart, at first, a situational diagnosis was carried out, regarding the safety of participants and teams involved in the studies being carried out in the CRC. For this diagnosis, the team of the unit participated in a

virtual meeting with the Risk Management, the Programa de Gestão da Qualidade e da Informação em Saúde (QUALIS), and the Commission for the Control of Nosocomial Infections (CCNI). In these meetings, they attempted to discuss, based on the scarce literature already published on SARS-CoV-2, what measures should be adopted for the attention to continue to be provided with safety, even during the pandemic.

Later, in March, a search was carried out in the databases (MEDLINE/PubMed), using the terms: "Sars-CoV-2" AND "clinical features patients"; "Sars-CoV-2" AND "Vulnerable Populations"; "Sars-CoV-2" AND "clinical features patients vulnerable", to contextualize the clinical profile of the patients in research centers with a profile of risk for COVID-19, as described up to that moment. Later, from May to June, another research was carried out, in which the term "Workflow" was added. Due to the very limited COVID-19 time frame and to the respective procedures for the control of infections and the safety/quality of work processes, original articles (cross-sectional, cohort, clinical trials, or case reports) were consulted, as long as they were available in full and published from November 2019 to June 2020, in English, Spanish, or Portuguese. Bibliographic and integrative reviews were excluded, as were publications with no peer review (preprint). In addition to the research of the articles, the study also considered the most recent protocols and directives about the theme published by the World Health Organization (WHO), the Pan American Health Organization (PAHO), the Centers for Disease Control and Prevention (CDC), the FDA, and the Ministry of Health.

The development of the workflows was based on the scientific literature available, on official documents from these health organizations, on the experiences of the health workers involved, and on the recommendations from the risk management and the CCNI of the institution being studied. No exclusion criteria were predicted, due to the fact that the theme is new. However, all was done with support from documents and literature scientifically recognized.

To validate the routine workflow, 12 specialists from the multiprofessional team were selected, including one from the Risk Management of the institution, one from the QUALIS, and one from the CCNI, not to mention the team of the sector and its leaders. This group was formed by three registered nurses, two nursing technicians, and four faculty members (two nursing professors, one medical professor, one exercise sciences professor).

For the initial elaboration of the workflows, the technique of the nominal group[10] was used interactively, simultaneously, and in-person, searching for a consensus in the group. The validation process, despite adopting the same methodology, could not be done in-person, due to the isolation demanded by the pandemic.

Two virtual meetings were carried out between the specialists, after the document was sent to them digitally. The workflows were validated by specialists considering their scope, clarity, and pertinence for clinical practice. The validation process was guided by the following questions: does the workflow attend to sanitary and safety norms considering the particularities of the assistance provided to participants of researches and the multiprofessional team? Does it provide scientific-based clarifications about the theme? Can it be used as an assistance guideline? Do the language and schemes allow for an adequate understanding of the content?

The suggestions from the specialists were focused on how the CRC process would take place and, especially, on the personal protective equipment (PPEs) that should be used in each specific situation. There were exhaustive discussions, based on scientific literature, about what equipment could provide the greater protection to the teams of assistance. The suggestions were compiled in the material, until a consensus of 100% was reached by specialists about each item of the instruments developed in the final version.

The participations of the specialists was voluntary and they all accepted participation by signing a Free and Informed Consent Form. The project was approved by a Research Ethics Committee under the Certificate for Submission to Ethical Appreciation (CAAE) 95847518.1.0000.5327.

RESULTS

With the expertise of the 12 professionals from different fields in the institution and knowledge about the theme, two flow diagrams were elaborated and validated to standardize and enable the continuity of clinical research protocols during the pandemic.

The elaboration of the workflow was preceded by an in-depth review of literature[1–8], a discussion about the existent flows in the unit, and the characteristics of the participants. The search of articles allowed to trace the vulnerability profile of the individuals infected by Sars-CoV-2, as well as getting to know and understand forms of transmission. Therefore, it was possible to establish criteria to attend the research participants and adequate the work process to maintain the research project safe for the professionals, researchers, and participants. This review also subsidized the situational diagnosis, which made it possible to identify the needs of the sector (provide a continuous safe support), of the participants (guaranteeing the continuity of their treatment), and of the

professionals (providing safe assistance, minimizing as much as possible the risk of occupation exposure) involved, thus enabling the planning of health actions.

The initiatives proposed included the use of personal protective equipment (PPEs), and, as the pandemic developed, other items were recommended, such as the mandatory use of masks by participants and their companions, and by anyone else who entered the building. Finally, an electronic form about the presence of flu-like symptoms in the participants, companions, and close contacts was also incorporated. The process of validation of the workflow, with multidisciplinary participation, made it possible for the conducts to be widely discussed over theoretical bases, culminating in criteria for the attention to be continued.

Two flowchart were developed and validated. Workflow 1 was targeted at attending participants from researchers who were not suspected of being infected with COVID-19, while workflow 2 was targeted at those who were suspected or confirmed to be infected. These workflows prescribe that, before the consultation, the research team must contact the participant and verify their health state, and, in the day of the consultation, the participant must be evaluated again to guarantee that there are no flu-like symptoms. The same is required from any companions. The objective of this prescription is to provide fast and safe care for the health teams and other participants of the research, since, in the presence of respiratory symptoms, the participant and/or their companions will be referred to the routine attention or to the emergency, depending on the severity of the case.

The need for the research groups to fill in an online form, preferably 24 hours before the procedure, makes it possible to screen for COVID-19 symptoms in the participants who will visit the CRC and their companions (when there are any). The information in the spreadsheet is verified by the sector in the reception of the CRC every turn, at the moment the volunteers for the research arrive. When there are symptoms, the nursing team is notified, and the adequate referrals are made.

The training and guidance of the clinical researchers in regard to the changes in the workflow of the attention and in the filling of the online form were all carried out through internal institutional communication and virtual meetings. The participants and companions received individual guidance by the team responsible for them during the previous contact in the attention, and throughout the consultations.

Thus, Workflow 1 includes, in general, the attention to be provided to all research participants who come to the CRC for consultations or to accompany someone who will

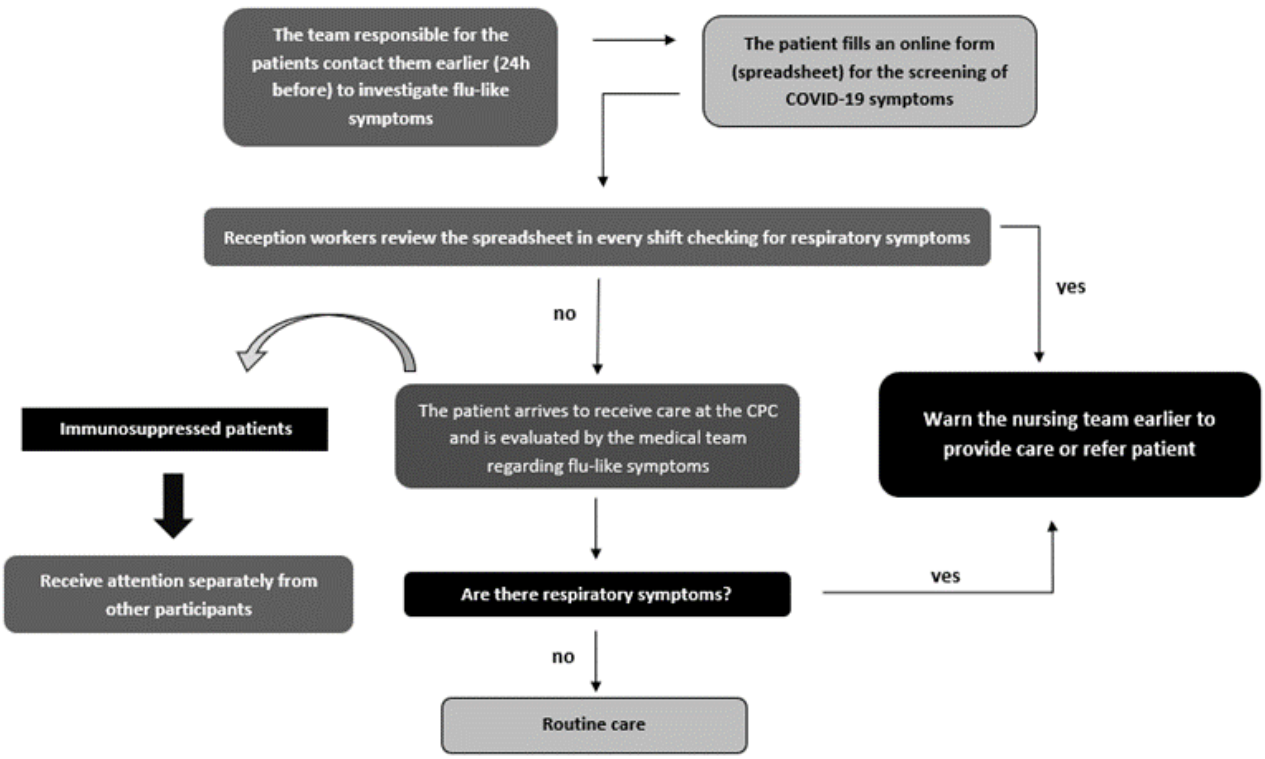

Figure 1 – Flow diagram to conduct protocols with research participant
Source: Research data, 2020.

be consulted. It also addresses the infusions related to the clinical protocols of these participants. The colors were used by presenting, in darker tones, warning information, such as "patient is suspected for COVID", while lighter colors showed other pertinent and complementary information, or information that is not in a specific order in the workflow (Figure 1).

The participants who were free from respiratory symptoms were referred for CRC attention, respecting order criteria and expecting some time waiting in an environment that could be used by other people, but whose number of people was controlled. As a protective measure, immunosuppressed individuals were attended separately from the others.

To carry out the attention, the team of assistance used the standard precaution that must be used for all participants. It includes hand washing, the use of procedure gloves and aprons in cases where there could be bleeding or contact with secretions or excretions, among others.

The workflow 2 was developed and validated for cases when there were participants with suspected or confirmed COVID-19 infections, since, in some cases, the infusion, even in these cases, can bring more benefits than harm to the patient (Figure 2).

In this case, the nursing team will, at first, communicate with the security, reception, and hygiene teams about the attention that will be provided. A member of the research team will receive the participant (and at most one companion) wearing a surgical mask and provide them with surgical masks. The participant will use the mask throughout the entire procedure and will be attended separately or after the other infusions were carried out. They will enter by the side entrance of the building, through which they will be able to directly access the 2nd floor of the CRC, and the patient will be conducted directly to the room where the attention will be provided. The elevator, after use, will be unavailable until it is sanitized. The health care team will wait for the participant wearing the adequate protective clothing, a N95 or PFF2 mask in cases where the procedure can generate aerosols or surgical masks in case it cannot, a face shield, a disposable apron or an impermeable one (in cases where there is abundant secretions or the risk of excretion), gloves and caps (optional in procedures where aerosols are not generated), as per CCNI recommendations.

Near the end of the procedure, the member of the research group must contact the driver responsible for the

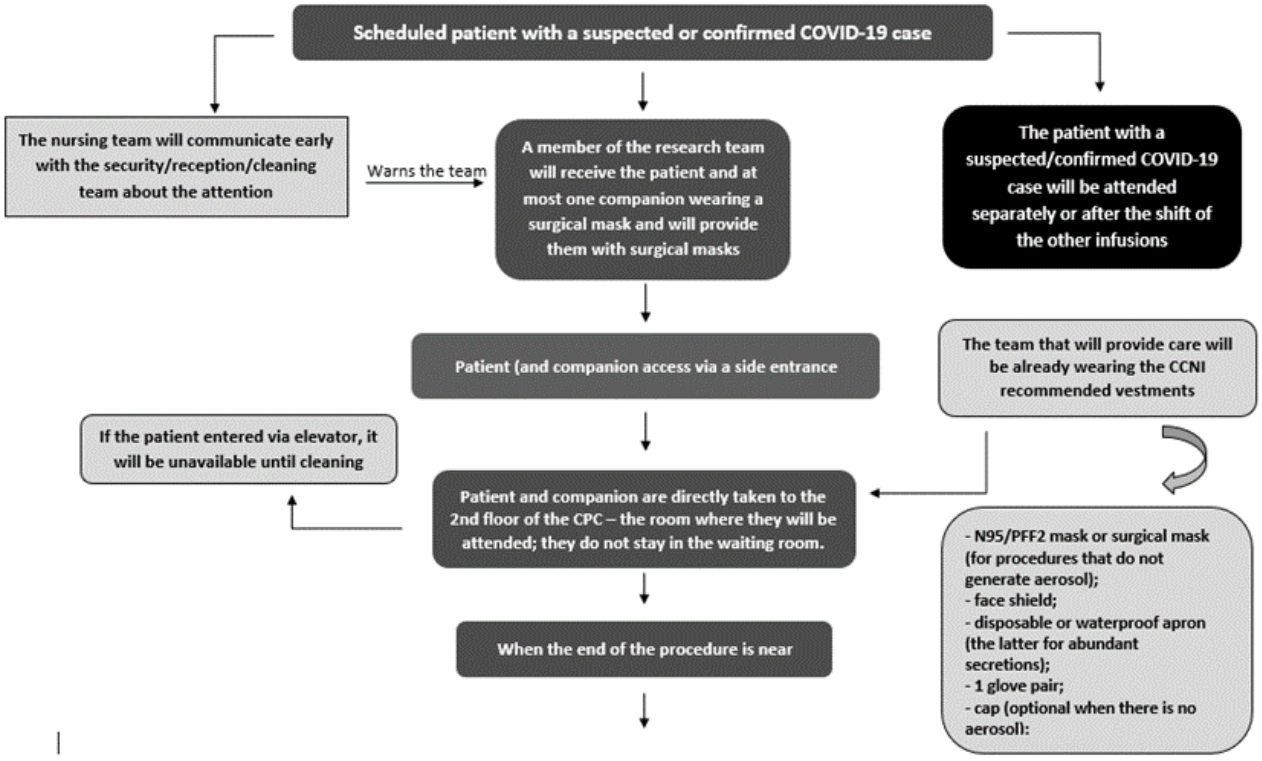

Figure 2 – Flow diagram in protocols with research participant with suspected or confirmed COVID-19 infection.
Source: Research data, 2020.

transport of the participant to request them to wait within the vehicle for the arrival of the participant. After the participant leaves, the elevator, once again, will be unavailable until sanitized. In the room where the patients were attended, the nursing technician, adequately dressed, cleans and disinfects all surfaces using a quaternary ammonium compound. After attention, the cleaning service sanitizes the other areas.

DISCUSSION

The implementation of attention workflows is widely used in many fields of health[11–12], with the main objective of standardizing and directing assistance conduct. With the start of the COVID-19 pandemic in Brazil, the Ministry of Health developed several attention protocols, including workflows with guidance for the different levels of complexity of the health system[13–15], since they make it possible to standardize and facilitate attention, providing safe and effective care for participants and professionals.

The workflows developed aim to classify the attention to the research participants with no suspected/confirmed SARS-CoV-2 infections and the attention to those present some respiratory symptom or may be infected by COVID-19. To do so, it is necessary to have a previous knowledge about the result of the evaluations carried out by the medical teams, as a way to organize earlier the attention to be provided.

To this end, during the COVID-19 pandemic, it was necessary to establish routine workflow both for participants who were not contaminated and to those who showed respiratory signs and symptoms, to protect them and the health workers involved in their care. Due to the measures implemented, it became possible to provide a safe maintenance of the attention to participants without interrupting the treatment made available by research protocols.

At first, the researchers contacted the participants (24h before being attended in person, by phone, or via video conference), to evaluate the presence of respiratory signs and symptoms, filling in the online form. According to each case, they recommend or not in-person care, according to a risk-benefit ratio evaluation. This understanding is based on Decree No.467, from March 20, 2020[16], which authorizes tele-medicine activities that, as in the case mentioned, can include pre-clinical attention, health care support, consultations, monitoring, and diagnosis.

According to the guidance from the general routine workflow, the immunosuppressed patients are attended in separate rooms due to the increased risk of being infected with COVID-19, and to the fact that this population has been reported to have a worse prognosis[3]. Still, since the implementation of the process of triage at the entrance of the CRC, the procedures of the team to welcome and guide participants and the provision of protective masks are carried out since the participant enters the institution.

The Ministry of Health recommends that suspected cases must be recognized and identified early, and, in the presence of respiratory symptoms, these individuals must receive surgical masks and be referred to a separate flow of attention to avoid crossed-infections, in an attempt to provide a more rational use of resources and professionals[15]. Another important recommendation is that there must be only one companion[15–17], since, considering the current setting, it is necessary to reduce the transit of people in health services and keep adequate ventilation in the waiting room, while also observing whether the companion shows respiratory symptoms. These recommendations were adopted to guarantee the protection to participants and their relatives and to professionals.

One type of prevention that is paramount in both suspected and confirmed cases is the use of PPEs and their adequate vesting and removing, aimed at guaranteeing the safety of the health professionals[15,17]. In the workflows addressed by this study, the professionals use several PPEs, to guarantee their safety as they provide care to the participants who are suspected or confirmed to have COVID-19. Also, many training sessions were held in the institution, to train professionals to put and remove PPEs.

As the attention is over, the place where the participant was attended must be disinfected, and other environments, such as the waiting rooms and elevators used, must also be sanitized. These procedures, when the environment is adequately cleaned, are considered to be efficient and sufficiently safe to avoid contamination[17–18]. Therefore, to attend to these recommendations, the cleaning and disinfection process is also carried out and was described in the attention workflow.

FINAL CONSIDERATIONS

In this study, two workflows were elaborated. They are called "Flow diagram to conduct protocols with research participant " and "Flow diagram in protocols with research participant with suspected or confirmed COVID-19 infection". The content of these workflows was validated via the consensus of experts.

The routine workflow was elaborated and validated based on current scientific knowledge and were supported by the multidisciplinary specialist teams of the institution. Therefore, it should be highlighted that it can be changed at any moment, as new scientific evidences emerge.

The development, validation, and implementation of the showed the need to constantly reevaluate, with the teams and groups, the stages, the established conduct, and the

promotion of spaces to listen and embrace the demands from researchers and other workers from the center.

Although many researches in Brazil or abroad have been making efforts to stop the advance of COVID-19, the knowledge about the disease is still incomplete. There are doubts about how transmission takes place, there is no consensus about the correct pharmacological treatment, and there is no prophylaxis, reiterating the importance of adopting strategies to contain the dissemination of the virus, as proposed by the workflows presented.

Thus, developing a routine workflow that involves pathology about which knowledge is still being created and is still quite incomplete, is one of the limitations of this study. What has been learned in a short period of time may be refuted and contested as new hypotheses are confirmed, since the world's entire scientific community has been allocating most of its efforts to this theme.

Still, the absence of specific literature about the theme, especially regarding the construction of workflows created for people who participate in research centers, is a factor that limits the discussion of the results found. Another limitation is the fact that there was no pre-test for the workflows due to the urgent character of their implementation. However, it should be noted that the workflows were improved as they were applied to clinical practice.

Disseminating these workflows can be a contribution for nursing, as it adds to the discussion about strategies for the protection of the users and health professionals, thus making it possible to carry out research protocols safely, guaranteeing that the continuity of the processes can be done while promoting the safety of all those involved. Furthermore, the workflows used are expected to serve as guidance to other institutions with a similar profile of attention. Later studies are needed to evaluate the reproducibility of these workflows, as well as their actual capacity of protecting the workers, researchers, and research participants of similar services during the pandemic.

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Authorship contribution:

Concept: Adriana Serdotte Freitas Cardoso; Stella Marys Rigatti Silva, Eneida Rejane Rabelo-Silva, Daniel Umpierre, Luciana Da Rosa Zinn Sostizzo, Isabel Cristina Echer.
Data selection: Adriana Serdotte Freitas Cardoso; Stella Marys Rigatti Silva; Luciana Da Rosa Zinn Sostizzo.
Formal analysis: Adriana Serdotte Freitas Cardoso; Stella Marys Rigatti Silva; Luciana Da Rosa Zinn Sostizzo.
Investigation: Adriana Serdotte Freitas Cardoso; Isabel Cristina Echer.
Methodology: Adriana Serdotte Freitas Cardoso; Stella Marys Rigatti Silva; Eneida Rejane Rabelo-Silva; Isabel Cristina Echer.
Project management: Adriana Serdotte Freitas Cardoso; Stella Marys Rigatti Silva, Eneida Rejane Rabelo-Silva, Daniel Umpierre, Luciana Da Rosa Zinn Sostizzo, Isabel Cristina Echer.
Supervision: Adriana Serdotte Freitas Cardoso; Isabel Cristina Echer.
Validation: Adriana Serdotte Freitas Cardoso; Stella Marys Rigatti Silva, Eneida Rejane Rabelo-Silva, Daniel Umpierre, Luciana Da Rosa Zinn Sostizzo, Isabel Cristina Echer.
Visualization: Adriana Serdotte Freitas Cardoso; Stella Marys Rigatti Silva, Eneida Rejane Rabelo-Silva, Daniel Umpierre, Luciana Da Rosa Zinn Sostizzo, Isabel Cristina Echer.
Writing - original draft: Adriana Serdotte Freitas Cardoso; Stella Marys Rigatti Silva, Eneida Rejane Rabelo-Silva, Daniel Umpierre, Luciana Da Rosa Zinn Sostizzo, Isabel Cristina Echer.
Writing - revision and editin: Adriana Serdotte Freitas Cardoso; Stella Marys Rigatti Silva, Eneida Rejane Rabelo-Silva, Daniel Umpierre, Luciana Da Rosa Zinn Sostizzo, Isabel Cristina Echer.

The authors declare that there is no conflict of interest.

Corresponding author:

Adriana Serdotte Freitas Cardoso
E-mail: aserdotte@hcpa.edu.br

Received: 20.10.2020
Approved: 19.04.2021

Associate editor:
Dagmar Elaine Kaiser

Editor-in-chief:
Maria da Graça Oliveira Crossetti