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Review Article

Practice and Reflection on the Ethical Review on Covid-19 Pandemic

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Abstract

Since December 2019, Wuhan City, Hubei Province, has reported a cluster of pneumonia patients cause by a novel coronavirus infection with a history of exposure to the South China Seafood Market. Later, the disease has been stipulated by the law of the people's republic of China on the prevention and treatment of infectious diseases as a B class infectious disease, and measures for the prevention and control of A-class infectious diseases have been taken [1]. The virus is airborne and spread through close contact. The main source of infection is the patients with the incubation period also highly infectious. The population is generally susceptible, and there are clusters of family aggregation [2]. During the epidemic, to protect the reviewers and researchers and reduce cross-infection, the principle of fewer meetings and avoiding gathering has been enforce and the traditional face-to-face on-site ethical review must be transformed to a contactless online review by remote online meetings. This study analyzes the background, review methods, review process, and review focus of our hospital's ethical review during the epidemic period, and aims to provide ideas for the hospital's ethical review for infectious disease during pandemic.

Keywords: *COVID-19, Epidemic period, Contactless ethical review*

Background of Ethical Review during the Epidemic Period

Ethical review is to standardize and review medical scientific research activities with the principle of ethics, thus to protect the interests and benefits of subjects, respect the rights and privacy of subjects and avoid damage to subjects [3,4]. With the increasing innovation of medical research, a growing number of researchers need to collect human specimens for research. The ethical and moral issues are more prominent during the research process, therefore more standardized and accurate ethical review works need to rely on legal regulations to protect the subjects as a premise [5]. Since December 2019, Wuhan City, Hubei Province has discovered a serial of new cases of coronavirus-infected pneumonia, and the epidemic has swept the country at an extremely rapid rate [6]. Human transmission situation of the COVID-19 is not optimistic, the number of new cases is growing every day, and has spread from large and medium-sized cities to third-tier cities and counties [1,7,8]. To control the epidemic situation, the General Office of the State Council issued documents to extend the Spring Festival holiday. Non-epidemic prevention and control related industries were recommended to work at home to avoid the occurrence of cluster infections. As a province with a large population base and a large number of infections, and various in basic conditions, Henan adopts traffic control in many districts prohibits the movement of people, and encourages people to wear masks, stay in-door, keep hygiene, and avoid massive gathering Thus to avoid cross-infection.

SARS-CoV-2 is a new virus, and there is no established clinical diagnosis and treatment method. The diagnosis and treatment of the diagnosed patients can only be carried out in accordance with the new coronavirus diagnosis and treatment guidelines issued by the National Health Construction Commission. During the outbreak of the epidemic, to support the clinical work of anti-epidemic, all regions urgently started the application of the COVID-19 related clinical research and encouraged researchers to actively declare COVID-19-related clinical research on the basis of ensuring the regular process of clinical diagnosis and treatment. These policies allow for the appropriate scientific evaluation of current interventions that are being explored or in progress, to provide corresponding countermeasures for clinical diagnosis and treatment. During the epidemic period, the number of applications for COVID-19-related projects has continued to increase. The novel coronaviruses are high-risk viruses. There are certain risks in conducting relevant clinical studies. All relevant clinical studies should be subject to ethical review and approval by the ethics committee. As the review and supervision department, the ethics committee should conduct the review openly and transparently based on protecting the rights and benefits of the subjects to ensure the quality and efficiency of the review.

Methods of Ethical Review during the Epidemic Period

The traditional ethical review method generally adopts face-to-face on-site review, that is, after the ethics committee secretary conducts the preliminary review of the research project, the meeting

time and venue are determined, then the ethics committee members are organized to arrive at the meeting site for the review according to the quorum. Studies have shown that there are already some guidance documents supporting the adoption of modern information technology such as telephone conferences and video conferences to meet the timeliness and effectiveness of the review meeting. When the members cannot assemble on the meeting site due to irresistible factors such as an epidemic, remote meeting mode can be used to conduct an ethical review on the premise of accord with meeting review procedures [8]. During the epidemic, to protect the reviewers and researchers and avoid cross-infection, it is not appropriate to hold a concentrated meeting. In addition, due to traffic control, individual members or independent consultants are in a state of isolation due to irresistible factors and not reach the quorum for the on-site meeting review. It is not realistic to participate in face-to-face on-site reviews. At the same time, it is not realistic for some to participate in face-to-face on-site reviews, as the majority of medical staffs are fighting on the front line, and some researchers need to work in isolation wards. To cope with this situation, the ethics committee of our hospital broke the pattern of traditional ethical face-to-face on-site review and adopted a new review method based on electronic review materials and contactless online video conferences. Online contactless video conference enables contactless video conferences to be carried out without commissioners and researchers at the conference site, reducing the cross-infection rate, ensuring ethical review at anytime and anywhere which is a good strategy for ethical review during the epidemic.

We quickly selects 2-3 members to conduct a systematic and comprehensive review of the plan and informed consent and decides to agree, modify, or transfer to the meeting for review based on the final opinion. For projects that meet the rapid review, to avoid personnel contact, our hospital cancels the acceptance of paper-based materials and fully receives electronic versions of materials. Firstly, the secretary of the ethics committee conducts an initial review of the submitted electronic materials. After the initial review, the chairman of the committee will determine the 2-3 members for the rapid review, establish contact with the chief reviewer, and send all electronic materials to the members' email address. After the review by the chief reviewer, the voting slip with the signature and voting results was scanned and sent to the mailbox of the ethics committee. The contactless office was carried out throughout the process, saving the time of researchers and ethics committee members by speeding up the efficiency of the review. For projects that do not meet the standards of the rapid review and must be reviewed by the meeting, the chairman will approve and decide, and our hospital will conduct a contactless ethical review of online video conferences. The ethical principles followed in the online video conference review would not change due to changes in the review format. All the conditions for review and approval of the research implementation, the research plan and the informed consent review and the face-to-face on-site review should be consistent and comply with existing laws and regulations as well as compatible with the current rules and procedures of the hospital, has certain timeliness and effectiveness, and would not change due to changes in the review method.

Ethical Review Process during the Epidemic

For projects that must undergo a conference review, our hospital conducts the contactless ethical review of online video conferences. The review process is as follows:

1. The secretary of the ethics committee conducts an initial review of all items that need to be reviewed by the meeting and sorts them according to the list of materials submitted for review. If there is a need for amendment, the researcher will be notified in time to amend. After meeting the criteria for submission, the examination materials will be sent to the referee committee members for pre-examination. The relevant materials are only used for review and should comply with the confidentiality agreement.

2. The secretary of the ethics committee determines the time of the remote online video conference and the meeting review committee establishes the review committee ethics review WeChat working group, informs the committees of the meeting timetable by phone or WeChat and to ensure the meeting committees meet the quorum, withdraw any members who have conflicts with the research project and sent all the electronic materials passed by the review and voting papers to the email addresses of the members in advance. At the same time, the secretary of the ethics committee formed a researcher ethics report working for WeChat group and informed the researchers of the report schedule of the research project in advance in the group to prepare the PPT report.

3. The secretary of the ethics committee will notify all participating committee members and reporting researchers to download the remote network video conferencing software and reserve the meeting time in advance in the software. The remote network video conference standard is implemented regarding the face-to-face on-site ethical review conference, which will be chaired by the chairman of the committee. The secretary of the ethics committee will enable the remote network video conference function according to the schedule and ensure that all the participating members will join the group. Participants will ensure that both the mobile terminal and the computer terminal enable at the same time. The mobile terminal will connect to the remote network video connection to listen to the PPT report of the researchers. The computer terminal opened the electronic version of the research project materials and votes to vote. The secretary "invites" the investigators of the reports one by one on time according to the report schedule established in advance, and the members ask questions on the spot, the researchers answer the questions and exit after the report is completed. To ensure the impartiality and privacy of the review, ensure that no irrelevant personnel are present during the meeting.

4. After all the researchers have completed the reporting and Q&A sessions, the secretary ensures that the researchers, independent consultants and other unrelated personnel offline and the committee members will start full discussion and voting.

5. All participating members should complete the voting and voting during the meeting process. The secretary will conduct the on-site counting of votes and the announcement of the results, and promptly communicate the electronic version of the review decision. After the epidemic is lifted, the member's vote and the formal review decision will be signed.
6. According to the review decision of the meeting, the chairman will issue a written ethical review opinion/approval, the scanned electronic version will be distributed to the secretary of the ethics committee, then the secretary will distribute it to the researcher's ethics report working group for researchers to download.
7. Secretary organizes video materials after the meeting and guarantees the electronic version of conference documents and video materials for archival filing.

The Focus of Ethical Review during the Epidemic

During the COVID-19 epidemic, researchers of the COVID-19 epidemic should conduct clinical research in the same way as the non-epidemic period. All participants in the research including researchers, institutions, ethics committees, and national regulatory agencies should strictly follow the following Principles: The risks should be reasonable relative to expectations; the choice of subjects should be fair and voluntary (it is necessary to ensure that informed consent is obtained as most patients with COVID-19 are mild); the rights and health of the subjects are fully guaranteed; the research should be fully reviewed by an independent process. As the review and supervision department, the ethics committee should be fair and standardized. During the epidemic period, and the ethics review work should be focused and planned, mainly following the following points:

The review should be time-critical. The traditional face-to-face on-site review requires the submission of paper-based materials, and the reporting must be conducted on-site. After the epidemic broke out, the majority of medical staff worked hard on the front line, the clinical work to treat patients was heavy and urgent. It was necessary to conduct clinical research on COVID-19 while ensuring normal clinical work. The ethics committee should establish and improve the supervision mechanism under the premise of providing substantial protection to the subjects, simplify the ethics review process, and speed up the ethics review. The ethics committee of our hospital pre-examined the general scheme of the COVID-19 related research, adopted electronic version of the receiving materials, and no longer required the researchers to provide paper-based materials, saving time for the frontline medical staff. The research plan review follows the principle of rigor. The SARS-CoV-2 is a high-risk virus, it is risky to carry out relevant clinical research. The ethics committee as a review and supervision agency should be fair and rigorous to ensure the safety of the subjects, and no sloppiness is allowed. The focus is on whether the research plan is rigorously designed, whether the sample size selection is statistically justified, whether the grouping settings are accurate, whether the inclusion criteria and exclusion criteria are accurately demarcated. It is strictly forbidden to have subjects who meet both the inclusion criteria and exclusion criteria at the same time and effectively guarantee the research data scientific validity and subject's acceptability of research methods. For the research involving the collection of SARS-CoV-2 specimens, focusing on examining whether the collection process is safe and whether the research is carried out in a qualified laboratory. It is not allowed to carry out experimental research on SARS-CoV-2 in unqualified and unconditional laboratories, to ensure laboratory biology safety and prevent laboratory contamination. Meanwhile, the research involving the collection and transportation of blood specimens should strictly follow the relevant national laws and regulations and be carried out after approval by the Human Genetic Resources Management Office of the Ministry of Science and Technology.

Informed consent review follows the principle of flexibility. Informed consent is the communication bridge between the researcher and the subject. It should be focused on whether the collection of the blood sample or biopsy sample ensures that the clinical routine diagnosis and treatment of the subject will be conducted normally and whether the right to be informed of the subject is guaranteed. The informed consent should indicate the collection method and quantity, clearly describe the rights of the subject, risks and discomfort. During the epidemic, the acquisition of informed consent should be flexible, and the forms of obtaining informed consent for different subjects can also be different. Most of the subjects involved in the clinical research of the novel coronavirus are confirmed or suspected patients of COVID-19. Many potential subjects who may be quarantined or have been quarantined are in isolation. For this group of subjects, they have the right to decide, and the signing of informed consent should adhere to the principle of self-signing. However, in the face of many severely ill subjects who are unconscious, cognitively impaired, or in critical condition, unable to comprehend the information, they should fully obtain the consent of their family member. For minor patients in quarantine, they should obtain the parent's consent. After signing the informed consent, take special measures to keep it sealed to prevent infection caused by exposure.

Discussion

Review of an exploratory research review follows the principles of study design and clinical risk minimization. Exploratory research is mostly groping research by researchers in clinical work. After the outbreak, many critically ill patients suffer a high mortality rate. In emergencies, some researchers provide exploratory research treatments beyond clinical trials for individual patients. In the review work, the ethics committee must grasp the strength of the exploratory research review, focusing on the feasibility of the design and clinical operation of the exploratory research, whether the benefits and rights of the subjects are placed first, and to guarantee the safety is maximized and the risk is minimized in the process of exploratory research. At the same time, it is important to review whether the operation process meets the following points: there is no effective treatment for clinical treatment; it is impossible to carry out clinical research immediately; obtain preliminary support data on the effectiveness and safety of the intervention from laboratory or animal studies; approved for use by

relevant national regulatory authorities; have sufficient resources to ensure that risks are minimized; fully obtain the informed consent of patients and their family members. Only when the above conditions are met can the real benefits and rights of the subjects be put in the first place, to ensure the safety of the subjects in the research process, and to avoid harm to the subjects.

Conclusion

In summary, the contactless ethical review of online video conferences during the epidemic period has effectively protected the safety of committee members and researchers and avoided cross-infection. As the review supervisory agency, the ethics committee ensures the safety of the subjects in the review process, the research protocol review follows the rigorous principle, the informed consent review follows the flexible principle, and the exploratory research review follows the study design and clinical operation risk minimization principles, to ensure that the ethical review work is completed with high efficiency and high quality.

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