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Challenges in the ethics review process of clinical scientific research projects in China

Zhu-Heng Wang, Guan-Hua Zhou, Li-Ping Sun and Jun Gang

Abstract

Purpose: Ethics review processes have become increasingly complex. The objective of this study was to explore the challenges currently faced in ethics reviews of clinical scientific research projects in China, with the goal of standardizing the structure of medical ethics committees and better protecting the rights and interests of research participants.

Methods: We reviewed and comprehensively analyzed the available literature discussing standardized ethics reviews of clinical scientific research projects.

Results: We identified the following problems: incomplete legislation, absence of supervision, vague review criteria, limitations of ethics committee competence, inadequate ethics consciousness, and poor tracking of reviews. In this paper, we suggest strategies for the development of future ethical reviews of clinical scientific research projects.

Conclusion: To standardize the ethics review process of clinical scientific research projects in China, it is necessary to establish relevant laws and regulations and implement supervisory responsibilities. Professional training of medical ethics committees is suggested as an effective way to improve the quality of ethics reviews.

Keywords

Ethics review, clinical scientific research, China, regulatory system, medical ethics committee, ethics education

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Introduction

Two genetically modified babies have been born successfully in China. However, the technique that was followed has not yet been carefully vetted by other scientists

Department of Critical Care Medicine, Daxing Teaching Hospital, Capital Medical University, Beijing, China

Corresponding author:
Zhu-Heng Wang, Department of Critical Care Medicine, Daxing Teaching Hospital, Capital Medical University, Address: No 26, Huangcun West Street, Daxing district, Beijing, 102600, China.
Email: 1147070617@qq.com

and many researchers have criticized the project. With the continuous development of medical technology, biomedical research projects involving human beings have become increasingly common, and ethics review processes have become more complex.[1]

From the perspective of the development of medical ethics, there have been two major systems used in the West: naturalism and religious ethics, which emphasize medical ethics. Traditional Chinese medical ethics is the organic union of medical ethics and medicine. Medical ethics founded on Chinese and Western traditional culture has its own advantages and limitations. Therefore, with deepening exchanges between the two, Chinese and Western medical ethics will inevitably demonstrate an increasingly obvious trend of complementarity and integration. Of course, this trend is not only an objective requirement in the development of medical ethics, it is also an inevitable trend in the development of different rational cultures in China and the West.

The current laws and regulations in China are based mainly on the Measures for Ethics Review of Human Biomedical Research (MERR), issued by the former State Health Planning Commission in 2016, as well as the Quality Management Standards for Drug Clinical Trials (Revised Draft), issued by the former State Food and Drug Administration in 2016. Many hospitals that integrate clinical medicine, teaching, and scientific research not only have heavy clinical medical tasks but also undertake a large number of clinical research projects at different levels.[2] Hospitals encourage doctors to innovate in science and technology by providing funding to support researchers who can independently design and complete medical research projects. Since World War II, human experimentation has created some challenging problems with the increasing use of patients as experimental subjects when it is apparent that most of these individuals would not likely have agreed to participation if they had been truly aware of the use that would be made of them. International requirements for the independent review of research were first established in the 1975 version of the Declaration of Helsinki. Whether researchers are seeking to conduct research projects or to publish research reports, they are required to obtain approval from an ethics review committee. This requirement has been confirmed in several authoritative documents and has achieved widespread international consensus.[3–5] However, the increasing number of clinical research projects raises challenges for ethics committees. We explored the main problems in ethics reviews of clinical scientific research projects in China and put forward relevant suggestions for improvement.

Results

To clarify the reasons for the lack of proper ethics reviews in China, we reviewed and comprehensively analyzed the available literature discussing standardized ethics reviews of clinical scientific research projects. As a result, we identified the following problems.

Incomplete legislation

Although "informed consent" and "legal liability" have been added to MERR, the ethics code itself may have some room for improvement. Increasingly, as technology promises to lengthen patients' lives, questions arise about the ethical line between extending life and delaying death. Ethical analyses often lag behind developments in medical technology, which has ethical implications that might not be immediately apparent. The existing provisions in China mainly focus on clinical drug testing whereas other clinical research projects involving human beings still lack specific operational

norms as well as effective and feasible mechanisms of supervision; most clauses only make provisions on principle and their operability still needs to be improved. At present, relevant laws and regulations for the supervision of clinical research projects are very weak.

Absence of supervision

Registration for the testing of newly developed drugs and medical devices is under strict regulatory supervision and subject to audit mechanisms, but supervision of ethics reviews has not been strictly implemented, leaving a gap in management at operational level because drug and device registration and ethical reviews in China are carried out by two different agencies.[10] MERR stipulates that the State Food and Drug Administration and the Health and Family Planning Commission shall be responsible at all levels for the daily operations of ethics committees and shall also appoint experts to conduct project and site inspections or to reinspect clinical trial institutions within a certain period of time. In this way, the work of ethics committees is subject to a certain degree of supervision. However, these efforts toward verification are only aimed at registered trials of drugs and medical devices and usually do not involve clinical scientific research projects. Moreover, there is a lack of authoritative assessment of the ethics committees. Therefore, to a certain extent, clinical research projects have been out of control in China.[11]

Vague review criteria

In China, the ethics review standards of clinical research projects are still in the developmental stage, and at present, there are no specific and consolidated ethics review standards. Each ethics committee implements its own review criteria, so results from different ethics committees for the same clinical research project may differ or even contradict each other.[12] There is obvious heterogeneity in the quality of ethics reviews. Medical institutions attach less importance to ethics review of clinical research projects than to the review of clinical trials for drugs and medical devices.[13] Because the criteria are unclear, researchers often complain that review processes are vague and acceptance thresholds too high. Some researchers even try to evade ethics review altogether. Owing to the lack of proprietary criteria, ethics review has very few definitive rules to follow. Because the distribution of health resources involves various aspects of ethics, proprietary criteria should be emphasized in health decisions according to criteria of fairness and the correctly understanding and adoption of fundamental principles of ethics.[14] Although there is much literature on the concept of universal standards in the context of health resource disparities, and China has recently implemented many reform measures emphasizing the provision of health care services with equity as one of the main goals, because the level of development varies greatly across different regions of the country, national standards for China are still lacking.

Limitations of ethics committee competence

Most members of ethics committees are experts in medicine but lack ethics expertise and practical experience in analyzing issues of ethics. Training in ethics and professionalism is important, and a more standardized curriculum would be beneficial to ensure that trainees achieve competency. The goal of ethics education is to promote a discipline in which members of the ethics committee are willing and able to engage in ethical questions and in solving problems of ethics. Practicing professionals should be able to identify and critically evaluate

ethical dimensions in their field of expertise.[15] In addition, inconsistent professional standards can lead to arbitrary and subjective reviews, which is a challenge to the professionalism and authoritativeness of ethics reviews. Moreover, most ethics committee members have not had proper professional training. Because there are neither systematic training materials nor compulsory training requirements, it is difficult for ethics committee members to acquire knowledge of ethics to thereby fully understand academic trends.[16] This lack of knowledge and training has greatly compromised the judgment of ethics committee members and has seriously hampered the development of ethics committees in China.

Inadequate ethics consciousness

In China, most clinical researchers are clinicians who do not attach sufficient importance to ethics issues, and scientific research is usually a part-time occupation for these clinicians.[17] Some researchers feel no sense of responsibility to protect their research participants and do not understand basic concepts of clinical treatment and clinical research standards. After obtaining project approval documents, some researchers do not even submit materials required for review by the ethics committee. Some projects are not submitted to the ethics committee until just before the research report is to be published, and some researchers submit an application for approval to the ethics committee after their research has been completed.

Poor review tracking review

Studies have shown that Chinese ethics committees tend to focus only on the initial review and only pay attention to the scientific nature and feasibility of research protocols and whether informed consent meets ethical requirements.[18] Most ethics committees do not conduct timely follow-up reviews of revisions to research protocols, informed consent, and other documents; the occurrence of adverse events; violations of the protocol; and results after completion of the project. Because of a lack of external supervision, some ethics committees have not strictly required follow-up of research, such that the legitimate rights and interests of research participants are not effectively protected.[19] Such neglectful tracking of the review process is detrimental to the objective of ethics reviews and the protection of research participants becomes illusory.

Recommendations for ethical reviews

Strengthening supervision

Improvement in the capacities of ethics committees is complementary to external supervision.[20] In fact, relevant regulations and guidelines for ethics reviews of clinical research projects and regulatory measures at different levels are still in their infancy. To standardize the ethics review of clinical scientific research projects in medical institutions, it is necessary to strengthen relevant laws and regulations and implement supervisory responsibilities. Clarifying ethics reviews as a compulsory preliminary procedure for clinical research projects in the form of legislation is urgently needed.[21] Communication between scientific research management departments and ethics committees should be strengthened. Regulatory authorities can use administrative intervention to ensure the integrity of ethics reviews, to reduce risk to research participants and help to produce medical clinical research results that more scientifically sound and authoritative.

Unified procedures and standards

A unified work system and standard operating procedures are the strongest guarantees for the development of ethics review operational norms.[22] These elements directly determine the reliability and legitimacy of the findings of ethics reviews and determine whether the rights and interests of research participants can be effectively guaranteed. Competent governmental departments need to be created as soon as possible, to manage methods and standardize operating procedures for ethics reviews of clinical scientific research projects, refine the working procedures and review standards of medical ethics committees, and establish a series of operational review norms such that ethical review processes can be carried out according to laws and regulations.

The work of Cox and McDonald shows us that typology adds a new dimension to the literature in this area and has important implications for researchers seeking more human research participant-centered approaches to participant recruitment and retention, as well as for research ethics boards seeking to better anticipate the perspectives of prospective participants.[23] Medical institutions should establish, implement, and improve a working system for ethics committees as soon as possible, with requirements for the structure and responsibilities of ethics committees and rules for review committee meetings. These practical steps will substantially improve the formulation and standardization of operating procedures for ethics reviews of clinical scientific research projects.

Improved training

Continuing education and training in medical ethics is an effective way to improve the quality of ethics reviews, strengthen the ability of members to properly perform a review, and enhance ethical awareness.[24] When researchers are faced with the dilemma of interpreting international ethics guidelines and the reality of their daily life and practice, the challenge then becomes answering questions of how familiar are ethics committee members in these local settings with these guidelines and how can their interpretation and use in the local context ensure respect for people and communities. This requires that the research be designed in collaboration with relevant communities, with services negotiated to ensure that the existing health service infrastructure is improved, and that protection of participants' well-being is recognized as paramount.[25] Even in developed countries such as the United Kingdom where the regulation of biomedical research is well established, challenges also exist with respect to on-site monitoring of research; this may be related to members agreeing to join ethics review committees voluntarily, as in China. Basic ethics knowledge can be promoted via multifaceted training through multiple channels. In Nigeria, the importance of community collaboration and establishing a centralized pool of national monitors have been highlighted as essential components in reinvigorating research monitoring capacities.[26] The efficacy of training to improve the capacity to address ethical issues in resource-limited settings should be highlighted in China. It is necessary to broaden international academic exchanges so as to keep abreast of critical new knowledge.

Advances in modern medical ethical standards should be combined with training content that includes current laws and regulations, ethics review procedures, research participant protections, and the key points of informed consent, so as to improve the ability of committee members to make proper determinations regarding ethical issues.[13] In addition, committee members' ability to make independent decisions should be regularly assessed and their judgments should be subject to regular review.

The results of such assessment should be recorded in annual reports. Government departments, medical institutions, and ethics committees should use the Internet and other media to create an ethics work exchange platform for resource sharing, publication of ethics review judgments, introduction of new laws and regulations, and to publish real-time information on education and training.

Improving the ethical consciousness of researchers

The advancement of clinical medicine cannot be separated from scientific research; however, clinical practice should not be an obstacle to ethical awareness.[24] Management departments and medical ethics committees should hold regular lectures on medical ethics to help researchers develop correct scientific research ethics values, consciously abide by ethical principles in the design and implementation of scientific research projects, and protect the health and rights of their research participants. In addition, medical colleges and universities should broaden education in medical ethics to instill these ideas in the thinking of all researchers.

Discussion

The importance of the ethics review process

The ethics review committee is responsible for investigating the scientific and ethical nature of clinical research to ensure that the dignity and rights of research participants are not violated. The ethics review process is an important means to protect the rights and interests of patients and study participants and to standardize clinical research. This process can help the ethics committee to understand and evaluate the procedures of the research.[6] Under the guidance of ethical principles, researchers can strengthen their ethics awareness and assure that their clinical research is conducted in an ethical manner.[7] Through the ethics review and supervision, anything that could violate ethical principles can be discovered and corrected, so as to enhance the ethical execution and compliance of research programs and ensure protection of the rights and interests of participants in the research.

Challenges in China

In China, clinical scientific research is governed under the 2016 MERR regulation, which describes the methods and procedures for ethics reviews.[8] According to this regulation, completing an ethics review before the start of clinical medical research is obligatory. However, clinical research projects in many medical institutions are begun without having completed this review.[9] At present, irregular ethics reviews are widespread in China, although the situation is improving. The present analysis clarified the reasons for the lack of proper review.

Conclusions

The responsibility of ethics review committees is to assess the scientific and ethical nature of clinical research, to ensure that the dignity and rights of participants in research are not violated. With the advancement of clinical research in China, and increasingly frequent participation in international research projects, the ethics review process plays an ever larger role in ensuring the quality of clinical research, protecting the rights and interests of research participants, and promoting the development of medical research. However, ethics reviews of clinical research projects still face serious challenges. Fortunately, the ethics review process for clinical research projects has

been receiving greater attention from researchers and research management departments. It is crucial to strengthen relevant laws and regulations and to implement supervisory responsibilities in China. Continuing education and training in medical ethics are recommended as effective ways to improve the quality of ethics reviews and enhance ethical awareness.

Authors' contributions

ZHW and GHZ participated in the design of this study and drafted the manuscript. JG participated in the design of the study. All authors edited the manuscript and read and approved the final manuscript.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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ORCID iD

Zhu-Heng Wang https://orcid.org/0000-0002-5638-3050

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