Acta Bioethica 2023; 29(1): 9-16. DOI: http://dx.doi.org/10.4067/S1726-569X2023000100009

ENHANCING MEDICAL ETHICS EDUCATION FOR MEDICAL STUDENTS IN CLINICAL RESEARCH: CONSIDERATIONS AND STRATEGY ANALYSIS

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Abstract: In recent years, the vigorous development of clinical researches carried out by medical schools is inseparable from the effective participation of medical students. However, as the number and categories of clinical research projects that medical students participate in increase, medical ethics related issues gradually occur. This article sorts out the ethical issues that arose in clinical researches, in which medical students participated, analyzes the underlying causes, and proposes solutions for the above-mentioned ethical issues, aiming to provide reference for medical ethics education and research project management for medical schools.

Keywords: clinical research; continuing education; ethics education; research ethics; subject protection

Mejorando la educación ética médica para los estudiantes de medicina en la investigación clínica: consideraciones y análisis de estrategias

Resumen: La participación efectiva de los estudiantes de medicina ha contribuido en gran medida al desarrollo exitoso de la investigación clínica en las escuelas de medicina de China en los últimos años. Sin embargo, con el creciente número y tipos de proyectos de investigación clínica en los que participan estudiantes de medicina, las cuestiones éticas se exponen gradualmente. Este trabajo enumera las cuestiones éticas que han surgido en la participación de los estudiantes de medicina en la investigación clínica en los últimos años, analiza las causas subyacentes y propone soluciones a las cuestiones éticas mencionadas anteriormente, con el objetivo de proporcionar referencia para la enseñanza de la ética médica y la gestión de proyectos de investigación para las escuelas de medicina.

Palabras clave: investigación clínica; educación continua; educación ética; ética médica; protección de los sujetos

Melhorando a educação de ética médica para estudantes de medicina em pesquisa clínica: pensamentos e análise de estratégia

Resumo: A participação efetiva dos estudantes de medicina tem contribuído muito para o próspero desenvolvimento da pesquisa clínica nas escolas médicas da China nos últimos anos. No entanto, com o aumento do número e tipos de projetos de pesquisa clínica dos quais os estudantes de medicina participam, questões relacionadas à ética e à alfabetização são gradualmente expostas. Este artigo lista as questões éticas que surgiram na participação de estudantes de medicina em pesquisas clínicas nos últimos anos, analisa as causas subjacentes e propõe soluções para as questões éticas acima mencionadas, com o objetivo de fornecer referência para o ensino de ética médica e gestão de projetos de pesquisa para escolas médicas.

Palavras-chave: pesquisa clínica; educação superior; educação ética; ética médica; proteção dos sujeitos

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1. Introduction

In the past few years, with China's emphasis on and promotion of scientific research and innovation abilities of medical schools, a growing number of medical school faculty and students, especially graduate students, and undergraduates, have actively participated in scientific research and innovation projects, significantly contributing to the development of clinical research*(1)*. However, as the number and categories of clinical research projects increase, medical ethics related issues gradually occur. Moreover, due to the relatively short history of clinical research development in China, legislation is inadequate regarding ethical review. Therefore, it is urgent to further promote medical ethics education, to standardize medical ethics review procedures, and to enhance supervision of clinical research projects.

2. Ethical issues of medical students

In order to learn more details about ethical issues concerning medical students in execution of clinical research projects, we summarized and classified the ethical issues related to clinical research projects in our hospital from January 2020 to December 2021.These issues can mainly be divided into the following three categories.

2.1. Weak ethical awareness

According to "Global Minimum Essential Requirements in Medical Education (GMER)" defined by the Institute for International Medical Education (IIME): the requirement of "Medical professional attitudes, behaviors and ethics" is one of the seven most fundamental competencies that are necessary for medical students to be equipped with. Carrying out medical ethics education and practice for medical students is not only an essential requirement in medical education, but also indispensable in developing bio-psycho-social medical mode of modern medicine*(2-7)*. However, during the process of reviewing ethical applications for clinical research projects, it is found that ethical awareness, and the awareness of the necessity of ethical review, is commonly lacking in medical students, such as lack of initiative in ethical review application, untimely application for ethical review, inappropriateness of ethical review materials, failure to report safety accidents, and absence of follow-up review and final review, etc.

2.2. Insufficient protection of the rights and interests of subjects

The fact that a significant part of medical students' time and energy during medical school are spent in classroom and laboratory research, limits their involvement in clinical practice, resulting in insufficient clinical experience and lack of medical ethical perception, as well as weak awareness and insufficient protection of the rights and interests of participant subjects in clinical practice. Common issues arising during clinical practice include confusing informed consent forms used in clinical treatment with those used in clinical research, inadequately disclosing informed consents to subjects*(8)*, obtaining some medical information without consent of subjects*(9)*, inadvertently disclosing subjects' privacy, the above of which all risk the rights, interests and even health of participating subjects.

2.3. Excessive participation of medical students

The rapid development of clinical research in China owes to adequate participation of medical students. However, in some clinical researches, from research design, data acquisition, and statistical analysis, to thesis writing, medical students undertake almost all research work, going beyond their responsibilities as participants. Whereas, as teaching faculty, the principal investigators do not play their roles of overseeing research, controlling implementation quality and providing guidance. The excessive participation of medical students and lack of guidance of principal investigators could risk the benefits and health of subjects.

3. Cause analysis

3.1. Insufficient education in fundamental medical ethics

Through communications with students and tea-

ching faculty, we obtained feedback from both sides that there is a deficiency in ethical education. Although "Medical Ethics" is listed as a compulsory course for undergraduates by most medical schools, it's offered only in one semester*(10)*, in which stage medical students usually prioritize on fundamental medical theories and lack clinical experience and clinical perception without contact with patients*(11)*. Thus, the study of medical ethics, regarded as a "useless compulsory course", is limited to memorizing theories, failing to achieve the initial purpose of medical ethics education*(12,13)*. The medical ethics education in developed countries "runs through the entire stage of medical education, has a certain interval, and is repeatedly carried out", in contrast, China's medical ethics education is prone to be centralized in one semester and separated from clinical practice, failing to have a long-term effect on medical students. Therefore, ethical thinking and ethical consciousness are difficult to be integrated into the clinical career of medical students. A survey of medical students and medical staff shows that 46.64% of those surveyed are well aware of the hospital medical ethics committee, while 53.32% are not well informed, indicating inadequate ethics education during fundamental and continuing education phases*(14)*.

3.2. Lack of effective guidance in clinical research

In September 2021, the National Health Commission of China issued the Administrative Measures for Clinical Research Initiated by Investigators in Medical and Health Institutions (trial implementation), requiring that "medical and health institutions and their investigators carrying out clinical researches shall obtain clinical qualifications required by laws and regulations and should have corresponding capabilities and necessary financial guarantees". According to this statute, medical students should not lead clinical research because they lack clinical experience, have not yet obtained physicians' licenses, have not accepted GCP training (Good Clinical Practice) and are unable to meet the requirements of principal investigator for clinical research. Medical students should receive and complete relevant training and authorization before participating in and performing auxiliary work under the guidance of principal investigator in clinical research.

The principal investigator of a clinical research generally assumes the role of a teaching advisor, who should not only pay attention to humanistic care and rights protection of subjects during research design, but also effectively guide students through standard implementation*(11)*. However, in practical research, many principal investigators focus on research design, experimental technology, and methods, while ignoring medical ethical issues and paying insufficient attention to medical ethics and protection of the rights and interests of subjects*(15)*. While in the face of academic pressure, some medical students are utilitarian and eager to achieve. Eventually, these thoughts might lead to results such as skipping the ethics application, conducting clinical research or obtaining medical information without consents of subjects.

3.3. Absence of stricter ethical supervision

Many teaching hospitals encourage development of various types of clinical researches, giving rise to a surge in the number of research projects. Taking the author's hospital as an example, common clinical research projects include new drugs/medical devices, new clinical technologies, R&Ds, and clinical research projects of provincial or ministerial level. The growing number of projects and the wide range of professional fields involved, indeed increase the difficulty of medical ethics supervision.

The clinical research projects participated by medical students usually involve multiple departments, including the Medical Ethics Committee, the Scientific Research Management Department, the Medical Affairs Department, and the Academic Affairs Department, etc. One reason giving rise to the lagging exposure of ethical issues is the lack of effective connection and efficient cooperation among these departments*(14)*. However, with the existence of academic barriers and differences in administrative system among different departments, the absence of effective and collaborative communication mechanism makes it difficult to effectively achieve consensuses in a timely manner, thus negatively affecting the efficiency and quality of ethical review and

resulting in issues such as improper application of management documents and random implementation processes*(16)*.

4. Strategies and solutions

4.1. Enhance education in fundamental medical ethics and improve continuing education

A single undergraduate course is insufficient to foster medical students' ethical awareness; it is necessary to carry out medical ethics education throughout the entire medical career, and strengthen ethics awareness repeatedly throughout continuous clinical practices and scientific researches*(16)*.

Medical humanities education, theoretical or practical, should be integrated into professional medical education, running through undergraduate, graduate, residents' training, and continuing education. Medical ethics education during undergraduate study aims to equip medical students with concepts of medical ethics, humanistic care, privacy protection, doctor-patient communication, genetic sample management, and bioinformatics security. As medical students are increasingly involved in clinical practice during graduate and postgraduate study, medical ethics education transits from theoretical study to practical application. At this stage, practical ethical problems are suggested to be discussed with real cases analysis, situational teaching, role-playing, etc.*(11)*. During residents' training or continuing education, the focus of ethics educations shifts to strengthen the interaction among ethical and medical values, thinking characteristics, and behavior modes.

4.2. Construct a team of designated faculty

Medical ethics education, especially during undergraduate study, are generally carried out by social science professors and teaching physicians independently or by either of them individually*(17-21)*. Social science professors, delivering ethics courses through such areas as social relations, psychology, economics, and legal ethics, focus more on ethical theories and values*(22)*, while teaching physicians deliver the course with a perspective of clinical practitioner by comparing the advantage and disadvantage of different treatment methods, emphasizing on clinical practice. Instruction only by social science professor or teaching physician, fails to foster the integration of medical ethics, humanistic care, and medical benefits, whereas independent instruction by social science professor or teaching physician also lead to unsystematic understanding and possession of ethics*(23)*. Therefore, the lack of designated faculty also leads to results of students lack of interest and knowledge in medical ethics.

As medical ethics is fundamental both in clinical practice and in clinical research, medical ethics faculty should have background in both clinical medicine and ethics. Taking the instruction of ethics at University of Chicago as an example*(24)*, the faculty delivering medical ethics courses are mainly composed of teaching physicians and ethics experts, some of whom possess both medical and philosophical doctorates. Setting a threshold for the recruitment of teaching faculty is suggested, such as completion of relevant courses or training or continuing education*(25)*. In addition, as medical ethics is an in-depth interdisciplinary subject, the Office of Ethical Education and Research should encourage communication among teaching faculty and synchronization of social science and clinical medicine, through such means as the inclusion of medical cases and current medical events in medical humanistic curriculum, the integration of legal provisions and moral norms into clinical medicine curriculum, the co-teaching mode of social science faculty and teaching physicians, and joint modification of teaching plan, in order to guarantee the quality of ethics courses and the effectiveness of education results*(26-29)*.

4.3. Strengthen professional training of teaching advisors

As ethical review is a key part of clinical research, the standardized application process, complete application materials, and detailed defense of ethical review lay a solid foundation for ethical standardization in subsequent clinical operations. However, the absence of teaching advisors in ethics education has led to issues in abovementioned procedures and implementations. Strengthening ethics education of teaching ad-

visors is also essential in current ethics training system*(17)*. The advisors' hands-on application of medical ethics facilitates the formation of ethical thinking and medical humanistic thinking among students*(25)*.

Conducting ethics education at orientation for newly employed medical school faculty and hospital staff is one way to infill them with the necessity of ethical review at the beginning of their professional careers*(30,31)*. Further, ethics training is suggested to be included in the annual training program for them, in which ethics applications are summarized, issues found in ethics review are presented, questions regarding ethics application are answered. Finally, the construction of a system regarding the ethical responsibilities of teaching advisors should be implemented. According to relevant laws and regulations, the principal investigator shall assume corresponding responsibilities, if the project is found to be illegal and suspended. Teaching advisors appointed for medical student in research projects are expected for comprehensive guidance on ethics, which can be strengthened by introducing ethical responsibility system. In addition, the responsibility system is also an effective feedback channel for ethical review application and process management, organically combining ethical guidance, implementation, and feedback.

4.4. Promote cross-departmental collaboration and management

Considering that clinical research management involves collaboration among multiple administrative departments and clinical departments, an effective network of medical ethics supervision with minimal barriers should be built among the departments involved, in order to protect the rights and interests of subjects, and to effectively supervise the participation of medical students in clinical research*(14,32,33)*. Benefiting from enhanced communication and timely feedback, the network could guarantee a comprehensive process management on clinical research. First, it should be made clear that the scientific review, ethical review, research project establishment, funding, and allocation of personnel responsibilities have been completed before the implementation of a clinical research project. Second, during the process of implementation, multiple key procedures should be considered, including implementation in accordance with the established plan, fulfillment of informed notification of participant subjects, management of biological samples and reporting of serious adverse events timely. Finally, at the conclusion of a project, it is important to properly preserve the research materials, compose summary report and apply for ethics conclusion. Comprehensive process management helps to clearly define responsibilities of departments and participants involved in a research project, such as the Scientific Research Management Department is responsible for project initiation and conclusion, the Medical Ethics Committee reviews the ethical feasibility, the Academic Affairs Department verifies whether the division and authorization items of the project team members are appropriate, the Medical Affairs Department supervises the process of project implementation. Thus, these relevant departments form a closed-loop management from project initiation to conclusion, and provide effective contingency plans for possible regulatory loopholes or ethical risks.

5. Discussion

Clinical research is an integral part of medical progress*(34)*. The development of modern medical science and technology also poses challenges for medical ethics. Scientific research, clinical practice, and medical ethics are interactively related*(35)*. On one hand, the existing fundamental medical theories and clinical guidelines oversee daily clinical work, ensuring that every patient receive reasonable and effective treatment; on the other hand, the medical ethics issues found in clinical practice, if transformed into theoretical achievements with practical application through scientific research, can contribute to improve clinical guidelines and further promote individualized and precise treatments for individual patients. Thus, scientific research, clinical practice, and medical ethics constitute a virtuous cycle of modern medical practice, with the patients (subjects) being the center of the cycle. Therefore, whether under the current trend of continuous refinement of clinical guidelines or under the background of inclusion of "individual cases" in the process of scientific research, actively promoting more comfortable, economical, and human-friendly

treatment reflects respect and humanistic care for patients in biological-psychological-social mode of modern medicine.

At present, medical students constitute the majority of the implementers of clinical research all over the world. Medical students' attitudes towards research can even directly influence the quality of research. The purpose of ethical review is to better protect the rights and interests of subjects, simultaneously, supervise the implementation of projects to ensure the quality of researches. However, there were few articles discussing the problems of medical students' participation in clinical research so far.

Through our research, we found that although medical students have received ethical education in undergraduate stage, they could not practice with ethical principles accurately in clinical research, which is worsened by the absence of superior teachers and supervision departments. This paper is significant to a certain extent in providing guidance for medical students, principal investigators, young researchers, ethical committees and relevant administrative departments, especially for medical students who would receive ethical educations throughout their career so as to shape correct moral values*(36)*. Strengthening modern medical humanities education is not only an inevitable transition in shaping doctors' professional spirits, but also an important reference and approach in solving problems in medical practice, as well as a key role in providently resolving the conflicts between researchers and subjects.

We elaborated and analyzed the ethical issues encountered by medical students in research projects then put forward corresponding suggestions for reference. It remains to be seen whether these suggestions on ethical education for medical students will be successfully implemented and effective. We will continue to follow up on it in the next 3 ~ 5 years. So far, the Office of Ethical Education and Research has held many seminars to discuss the course, and the ethical course has become compulsory for graduate students since this year. And accordingly, the Human Resources Department of our hospital has also taken it as a project in teacher induction training and annual assessment. We will sort out ethical problems encountered by medical students every year, evaluate the effects of ethical education according to the results, and even further identify the most fundamental relevant factors and the most effective measures.

China still has a long way to go in building a complete educational system of medical ethics. Therefore, we will redouble our efforts in such aspects as designing the teaching purposes, enriching the teaching dimensions, optimizing and innovating the teaching models, and integrating the faculty resources. Since teachers are subjects and students are objects in teaching activities, we also need to reconsider which way is better suitable for students to understand ethics and guiding practice in both research and clinical activities. Next, we will also consider developing various forms of teaching models. We will improve the teaching quality by collecting students' feedbacks after class and expand them to other medical schools as effective cases.

6. Conclusion

Medical ethics education is not insignificant and should be integrated with other medical courses. A sound medical ethics management system is expected to run through the entire process of medical teaching, medical practice, and medical research. A comprehensive system of "source-process-result" is suggested as a method to protect the participant subjects: medical ethics education by medical schools, and strict ethical supervision by ethics committees, as well as quality control of medical practice by hospitals.

Declaration of Conflicting Interests

The authors declare no conflict of interests.

Funding

This study is supported by Grants from University-Industry Collaborative Education Program of Ministry of Education (202102543001), The Exploration and R&D Project of West China Hospital of Stomatology, Sichuan University (RD-01-202105).

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Received: July 22, 2022
Accepted: August 1, 2022