



Report:

A survey of five first-level hospital ethics committees in Urumqi, China*

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Abstract: This paper presents the results from a survey of first-level hospitals in Urumqi, China. The survey had two parts: the first part was aimed at understanding the operation of the ethics committees of first-level hospitals, including the process for electing members and the variety of members' backgrounds. Information was also gathered about the establishment of criteria, operational rules and regulations, and standard operational procedures. The aim of the second part was to investigate the level of understanding among technicians and doctors about the function of the ethics committees. This paper identifies and analyzes some deficiencies found in the operation of hospital ethics committees, offers some constructive suggestions for improvement, and promotes the role of the Xinjiang Uygur autonomous region hospital ethics committees.

Key words: First-level hospital, Ethics committee, Xinjiang Urumqi

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1 Introduction

1.1 Background to the introduction of hospital ethics committees

Along with the development of modern biomedical science and clinical technology, methods for clinical diagnosis are improving, but there are some issues relating to morality and law. In particular, the problem of how to protect the rights of human subjects involved in biomedical science trials (e.g., informed consent and respect for autonomy) is very important. Groups of informed people are needed to consider these moral issues and to make decisions for medical research. The first hospital ethics committee was set up in USA in 1975 (Sun *et al.*, 1996).

1.2 Types, significance, and functions of hospital ethics committees

Internationally there are three types of ethics committees, hospital ethics committees, institutional review boards, and medical ethics committees (Cao *et al.*, 2004). There are small differences in their functions. Some focus on biomedical research, others on clinical medicine. Their duties have four aims: (1) to give consultation and advice to hospitals, (2) to provide education and training within faculties in hospitals, (3) to consider ethical issues, and (4) to adjust the doctor-patient relationship (Chen and Qiu, 2003). In China, such committees in each hospital aim to provide all these services.

1.3 History of hospital ethics committees in China

The hospital ethics committee was set up as a branch of the Chinese Medical Association (CMA) in 1988. In Chengdu in 1991, at the sixth conference of

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medical ethics, "The Regulation of Hospital Ethical Committees in China" was introduced, which was revised by the CMA in 1995 (Hu *et al.*, 2005). The Ministry of Health of China (2007) published a review of "Methods Used in Biomedical Research Involving Humans".

Nowadays, a hospital ethics committee is set up in each medical institution or hospital in China. Respect for autonomy, beneficence, and justice are fundamental principles on which they are based. Every human subject or patient in medical trials has a right to make decisions, to be asked for their informed consent, and to consult with their doctors. This is in accordance with the Belmont Report's basic ethical principles: respect for persons, beneficence, and justice (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

Many first-level hospitals in central cities of China have set up hospital ethics committees. In August 2011, the Science and Education Department of the Ministry of Health held a meeting in Xinjiang Medical University to train members of ethics committees and doctors from around the whole country.

1.4 Status of health care and hospital ethics committees in Urumqi

Xinjiang Uygur Autonomous Region is situated in the northwest of China; Urumqi is the capital of Xinjiang, which is a developing area. The medical and health services in Xinjiang are developing to safeguard the people's health. There are many medical research and clinical services acting in the medical institutes and hospitals in this area. We wanted to investigate hospital ethics committees of first-level hospitals in Urumqi. The objectives of our research were to determine the status of ethics committees and to promote awareness of this knowledge to the faculties in these hospitals.

According to the "Urumqi Statistical Yearbook 2011" (Wang, 2011), there are 147 hospitals, 4 nursing homes, 191 community health care service stations, 29 township central clinics, 85 out-patient departments, 1 maternal and child health care center, 3 special disease hospitals, and 1 emergency centre in Urumqi. There are 10 first-level hospitals.

Five hospital ethics committees have been set up in the 10 first-level hospitals. They established regu-

lations and processes for their activities, but these differ among the committees. Because there has been a lack of research into ethics committees in China, we needed to determine if problems exist in their operation (Xiong *et al.*, 2003). Therefore, we surveyed factors that influence the operation of first-level hospital ethics committees and to study the status of the awareness of their activities among medical staff in first-level hospitals in Urumqi.

The purpose of the study was to analyze the results of research on the status of first-level hospital ethics committees in this area and to propose suggestions for their improvement.

2 Materials and methods

2.1 Objects of investigation

We investigated five first-level hospital ethics committees in Urumqi. We designed a questionnaire 'A' for the hospital ethics committees and a questionnaire 'B' for the faculties in their hospitals, to research the status of these ethics committees and the perceived level of knowledge of medical ethics among staff. We visited the five hospital committees to deliver our questionnaire, and received five returns from their secretaries, a 100% response rate. The five first-level hospitals included two integrity hospitals, one traditional Chinese medicine hospital, one military hospital, and one special hospital, referred to herein as A, B, C, D, and E, respectively. In addition, we distributed 300 B questionnaires to the faculties of 10 first-level hospitals in Urumqi from which we received 292 (97.33%) usable returns.

2.2 Investigation contents

1. The basic status of hospital ethics committees in Urumqi. We investigated the overall condition of the committees in the five first-level hospitals since their establishment, and the content of their procedures for ethical review.

2. The composition of ethics committees. We determined who was appointed to the committees and the backgrounds of the members. Other questions included: How were their committees established? Do they have a full-time secretary? What processes do they follow when they have a meeting?

3. The operating mechanisms of the ethics

committees. We investigated how they carry out their processes, e.g., informed consents and the examination of ethical aspects of their medical researches. We also asked: Do the ethical committees have an office and support for their operation, including facilities for storage of documents and materials? Do their members have relevant qualifications?

4. The level of awareness of the role of ethics committees within the faculties in these hospitals. We designed questionnaire B for the faculties in 10 first-level hospitals to determine how many doctors and others understand the functions of their hospital ethics committees.

2.3 Methods

The methods adopted in our investigation were questionnaire and interview. We invited the directors of the five hospital committees to fill in questionnaire A, and provided questionnaire B to the faculties of 10 first-level hospitals in Urumqi. Microsoft Excel was used for data entry and statistical analysis.

3 Results and discussion

3.1 Basic status of hospital ethics committees in Urumqi

Basic information on the ethics committees of the five hospitals is summarized in Table 1. The nature of ethical examinations in the committees varied, depending on the role of each hospital (Table 2).

Our investigation included five (50%) of the ethics committees in first-level hospitals in Urumqi. First-level hospitals have three functions: medical treatment, scientific research, and education. So they need an ethics committee to provide ethical reviews of their work. According to the "Methods Used in Biomedical Research Involving Humans" by the Ministry of Health of China (2007), every hospital must set up a committee, especially first-level hospitals. In Zhejiang Province, an economically developed area of China, there are 75 Grade A Class Three hospitals of which 39 (52%) have set up medical ethics committees. First-level hospitals account for 64% of all ethics committees in that province (Fan, 2008).

Table 1 Basic status of hospital ethics committees in Urumqi, China

Hospital	Date of establishment of ethics committee	n_m	n_b	n_s	n_{ss}		
					NSF	Local hospital funding	NNSF
A	July 2005	44	6	145	12	230	152
B	Jan. 2008	11	4	135	9	126	0
C	Jan. 2009	15	3	55	5	50	0
D	Aug. 2010	12	3	32	2	32	0
E	Dec. 2009	9	4	25	2	23	0

n_m : number of members; n_b : number of branches; n_s : number of submissions examined in 2011; n_{ss} : number of submissions examined by source of funding in 2011; NSF: the Natural Science Foundation Project of Xinjiang Uygur Autonomous Region, China; NNSF: the National Natural Science Foundation of China

Table 2 Nature of ethical examinations in the ethics committees

Hospital	N1	N2	N3	N4	N5	N6	N7	N8	N9
A	+	+	+	+	+	+	+	-	+
B	+	+	-	+	-	+	-	-	-
C	+	-	-	+	-	+	-	-	+
D	+	+	-	+	-	+	-	-	-
E	+	+	-	+	-	+	-	-	-
Yes	5	4	1	5	1	5	1	0	2
No	0	1	4	0	4	0	4	5	3

N1: biomedical research involving human subjects; N2: medication and medical appliances for clinical research; N3: assisted reproductive techniques; N4: organ transplantation; N5: examination of human specimens; N6: clinical research involving human subjects; N7: use of laboratory animals; N8: preventive medicine; N9: human stem cell research. + denotes 'yes'; - denotes 'no'

In the 1980s, the Association of Hospital Management of America required that every hospital had to set up an ethics committee (Li, 2007). Later, UK, Canada, Sweden, Spain, South Korea, India, Austria, and Belgium set up similar committees (Wang and Xiong, 2006). For example, bioethics has developed rapidly in New Zealand, and there are ethics committees in every area in New Zealand. It is in a leading position of the world (Nie and Anderson, 2003). Thus, China has fallen behind developed countries in this work. We need to promote this work in the other five first-level hospitals in Urumqi. Our survey of the nature of ethical examination in the committees of the five hospitals showed that they have developed ethical examination of biomedical research involving human subjects, organ transplantation, and clinical research involving human subjects. Hospital A has expanded the scope of its ethical examinations to include human specimens, laboratory animals, and stem cell research.

In 2006, hospital A in Urumqi set up an ethics committee according to the Institutional Animal Care and Use Committee (IACUC) regulations, and in 2009 received accreditation from the International

Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). It is their advantage in China (Lu *et al.*, 2009). However, none of the hospitals surveyed have covered the ethical examination of preventive medicine, perhaps because this type of work is not the main focus of research in first-level hospitals.

3.2 Composition of ethics committees

Hospital ethics committees ought to be composed of medical specialists and nonmedical experts or community representatives, and use medical principles to examine the ethical issues involved in the practice of medicine (Li, 2009). Normally, hospital ethics committees are made up of biomedical scientists, medical ethics scholars, lawyers, administrators, and community members. Through investigation and analysis, we determined the composition of five hospital ethics committees in Urumqi (Table 3).

The directors of the five hospital ethics committees are all senior medical specialists. While all the ethical committees have secretaries, only one is full-time (hospital A) (Table 4).

Table 3 Composition of five hospital ethics committees in Urumqi

Hospital	n_{total}	n_{senior}	n_{male}	n_{female}	n_{inside}	$n_{outside}$	$n_{biomedicine}$	$n_{administration}$	n_{ethics}	n_{law}	$n_{sociology}$	$n_{community}$
A	44	37	21	23	41	3	38	3	1	1	1	1
B	11	9	7	4	10	1	6	3	0	1	0	0
C	15	13	9	6	13	2	10	3	0	2	0	0
D	12	10	7	5	11	1	9	2	0	1	0	0
E	9	7	5	4	8	2	7	1	0	1	0	0

n_{total} : total number of directors; n_{senior} : number of senior medical specialists; n_{male} : number of males; n_{female} : number of females; n_{inside} : number of members inside the hospital; $n_{outside}$: number of members outside the hospital; $n_{biomedicine}$: number of biomedical scientists; $n_{administration}$: number of administrators; n_{ethics} : number of medical ethics scholars; n_{law} : number of lawyers; $n_{sociology}$: number of sociologists; $n_{community}$: number of community members

Table 4 Status of the directors and secretaries of five hospital ethics committees in Urumqi

Hospital	Gender		Seniority			Degree		Specialty		Administration		Secretary	
	Male	Female	Executive	Senior	Middle	Master	Doctor	Medicine	Ethics	Leadership	Director of section	Full-time	Part-time
A	-	+	+	-	-	-	+	+	-	-	+	+	-
B	+	-	+	-	-	-	+	+	-	+	-	-	+
C	+	-	+	-	-	-	+	+	-	-	+	-	+
D	+	-	+	-	-	+	-	+	-	-	+	-	+
E	+	-	+	-	-	+	-	+	-	-	+	-	+
Yes	4	1	5	0	0	2	3	5	0	1	4	1	4
No	1	4	0	5	5	3	2	0	5	4	1	4	1

+ denotes 'yes'; - denotes 'no'

The ethics committees were composed of medical experts but there were no medical specialty members. There were more medical experts than non-medical members. Only hospital A had a community member on its ethics committee, but all the hospitals retained lawyers on their ethical committees. The directors of ethics committees were all medical specialists with senior positions, such as director of a section of the hospital. All but one of the committee directors were males. Although the committee secretaries have a very important role with varied duties, only the secretary in hospital A was employed full-time. By including a range of specialists with different backgrounds, the hospitals aim to guarantee justice and the rights of human subjects involved in medical research trials. That is a requirement of “Methods Used in Biomedical Research Involving Humans” by the Ministry of Health of China (2007).

The “Operational Guidelines for Ethics Committees that Review Biomedical Research”, by the World Health Organization (WHO, 2000), states that ethics committees (ECs) “should be constituted to ensure the competent review and evaluation of all ethical aspects of the research projects they receive and to ensure that their tasks can be executed free from bias and influence that could affect their independence. ECs should be multidisciplinary and multi-sectoral in composition, including relevant scientific expertise, balanced age and gender distribution, and laypersons representing the interests and the concerns of the community. ECs should be established in accordance with the applicable laws and regulations of the country and in accordance with the values and principles of the communities they serve.”

The ethics committees in our survey were composed of medical experts and non-medical members, but there was a lack of medical specialists and community members.

The ethics committee of University of Otago in New Zealand, draws on undergraduate students as members to attend ethical examinations to safeguard the rights and interests of human subjects. To ensure informed consent, they appoint the chairman of the community group as the ethics committee director. However, multidisciplinary experts need to explain their submissions clearly, precisely, and in lay terms to the director and other members, to ensure that the human subjects involved are given respect for autonomy and a clear understanding during conversations with their doctors. The aim of their committee is “to ensure that all teaching and research within the university, or under the auspices of the university, which involves human participants or the use of personal information, is carried out in accordance with the university’s guidelines for ethics by: considering and, where appropriate, approving proposals...” (University of Otago, 2013). This approach may provide a reference for improving ethical reviews in China.

3.3 Operating mechanisms of ethics committees

3.3.1 Office facilities and operational procedures of the five hospital ethics committees

We surveyed and analyzed the office facilities and operational procedures of five hospital ethics committees (Table 5). These factors are important for their work, and reflect the attitude of each hospital.

Table 5 Office facilities and operational procedures of five hospital ethics committees

Hospital	Office	Funding	Subsidy	Informed consent	Operational procedure	Application of ethical examination	Source of funding for ethical committee		
							Subsidy	Administrative allocation	Self-financing
A	+	+	+	+	+	+	+	+	-
B	-	-	+	+	+	+	+	-	-
C	-	+	+	+	+	+	+	-	-
D	-	+	+	+	+	+	+	-	-
E	-	+	+	+	+	+	+	-	-
Yes	1	4	5	5	5	5	5	1	0
No	4	1	0	0	0	0	0	4	5

+ denotes ‘yes’; - denotes ‘no’

3.3.2 Conditions of attendance at hospital ethics committee meetings

The five hospital ethics committees hold non-scheduled meetings depending on the receipt of applications for ethical examination. However, a quorum of two-thirds of the members must be met for such meetings to proceed. They check for informed consent, examine the application, and confirm safeguards for the rights and interests of the human subjects involved. They then independently make the decision to approve, modify, or even reject the proposal.

3.3.3 Number of proposals examined by the five hospital ethics committees in 2011

The number of proposals checked by the ethics committees of the five hospitals in 2011 are shown in Fig. 1.

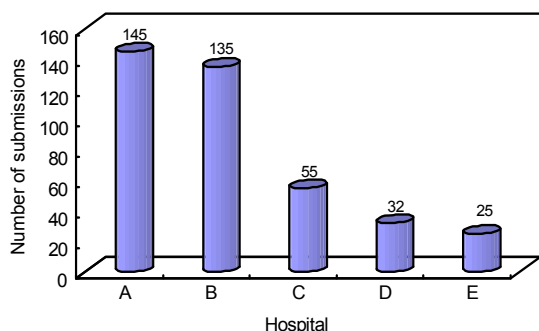


Fig. 1 Number of submissions examined by the ethics committees of five hospitals in Urumqi in 2011

3.3.4 Regulation and procedure of the five hospital ethics committees

To ensure integrity, the hospital ethics committees have established procedures and regulations. The five committees constituted their procedures for ethical inquiry and a confidential log of each meeting is kept in the archives. They also carry out educational activities in medical ethics for their faculties. Hospital A received a national qualification to train members of ethics committees in the Xinjiang area. About 360 members obtained such education in 2010 and 2011.

The five hospital ethics committees constituted their regulations and operational procedures for ethical examinations. Informed consent following ethical examination of research involving human subjects and the application of ethical examination

are the important aspects of ethical review. A quorum of two-thirds of members was set for committee meetings. They examine ethical issues and vote independently, in accordance with the principles of justice and autonomy. In 2011, we analyzed submissions examined by the five hospital ethics committees. Hospital A had received 145 proposals, hospital B 135, hospital C 55, hospital D 32, and hospital E 25. The variation in the number of submissions may reflect differences in the types and functions of the hospitals, but most of the submissions were related to medical research proposals and did not involve ethical issues about doctor-patient relationships. Adjusting the doctor-patient relationship is a very important function and duty of hospital ethics committees.

According to the “Operational Guidelines for Ethics Committees that Review Biomedical Research” by the WHO (2000), the operations of ethics committees include submission and application, review, decision-making, communicating a decision, follow-up, and documentation and archiving. These six aspects complete the process of ethical examination. We need to establish comprehensive procedures for ethical review to prevent oversights.

3.4 Level of understanding of the ethical committee’s role in the faculties of the five hospitals

The level of understanding of the role of ethics committees by medical staff of 10 first-level hospitals was the first of two parts in our investigation. Four aspects were considered.

3.4.1 Approach of medical staff to learning about the role of hospital ethics committees

We asked medical staff how they learned about the role of hospital ethics committees. The results showed that most medical staff (42%) were informed by special education, 28% by news media, 25% by professional journals, and 20% through professional networks (Fig. 2). Thus, it is important to continue the education of medical staff about the work of the committees and to promote publicity about the ethics committees and medical ethics.

3.4.2 Level of understanding of the regulation of ethical inquiry in hospital ethics committees

With regard to the level of understanding about the regulation of ethical inquiry by hospital ethics

committees, it appeared that 48% of faculty staff knew about “standardizing the quality management of drug clinical trials”, 22% knew about the “Declaration of Helsinki”, 16% knew about the “review methods in biomedical research involving humans”, and 14% knew about the “Nuremberg code” (Table 6).

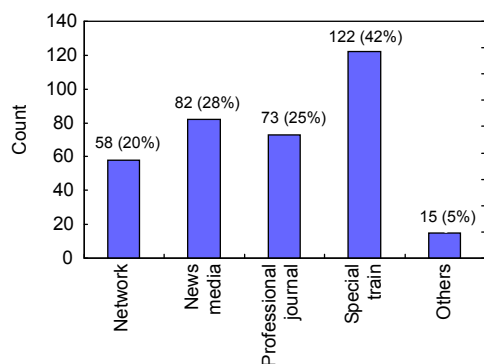


Fig. 2 Approach of medical staff to learning about the role of hospital ethics committees

Table 6 Level of understanding of the regulation of ethical inquiry in hospital ethics committees in Urumqi

Education degree	n_{R1}	n_{R2}	n_{R3}	n_{R4}
Secondary education	0	2	6	0
Junior college	1	5	8	1
Bachelor	20	33	102	30
Master upwards	21	23	23	17
Total	42	63	139	48
	(14%)	(22%)	(48%)	(16%)

n: number; R1: Nuremberg code; R2: Declaration of Helsinki; R3: standardizing the quality management of drug clinical trials; R4: review methods in biomedical research involving human

3.4.3 Level of understanding of the function of hospital ethics committees

With regard to the level of understanding about the function of the hospital ethics committees, 100% of staff knew about the function of ethical consultation, 80.1% about the relationship between doctor and patient, and 63.4% about education (Fig. 3).

3.4.4 Nature of consents for checking by hospital ethics committees

According to the analysis of our questionnaires, the content of submissions to the hospital ethics committees was related to biomedical research involving human subjects (82; 28.08%), medication and medical appliances for clinical research (278;

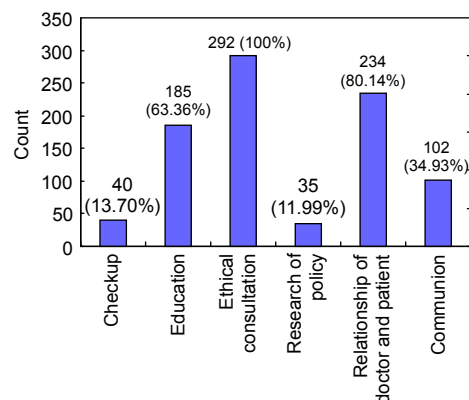


Fig. 3 Level of understanding of the function of hospital ethics committees

95.22%), assisted reproduction techniques (188; 64.38%), organ transplantation (192; 65.75%), clinical research involving human subjects (95; 32.53%), human stem cell research (5; 1.71%), and the relationship between doctor and patient (35; 11.99%).

The awareness of the ethical review process was not high among medical staff in Urumqi. The survey indicated the importance of education of the relevant staff in first-level hospitals in Urumqi to improve awareness of the role of the ethics review committees, e.g., ethical norms, the function of review and surveillance, and the fact that first-level hospital ethics committees are required for relevant ethical review. Another factor affecting the level of understanding of medical ethics was that the medical faculty lacked specialized knowledge, such as that contained in “Methods Used in Biomedical Research Involving Humans” by the Ministry of Health of China (2007). So we need to strengthen the education of hospital ethics committees.

4 Conclusions

Through a survey of first-level hospitals, we determined the status of five ethics committees in Urumqi. Although this survey and analysis revealed some operational deficiencies of the ethics committees, we put forward some constructive opinions and the suggestions for promoting reviews by the Xinjiang Uygur Autonomous Region hospital medical ethics committees. Firstly, ethical committees are needed in other hospitals, particularly, in other first-level hospitals in Xinjiang, and should become

permanent institutions in hospitals. Secondly, we need to make use of the full range of functions of ethics committees, especially in providing ethical reviews of moral issues relating to the doctor-patient relationship. Furthermore, we must pay close attention to the need for informed consent in the patient's mother tongue, especially in the Xinjiang minority area.

Medical laws and regulations are needed which will enhance the development and operation of hospital ethics committees. Finally, we need to align the operation of our ethics committees with international criteria in this field, opening the way for interaction with organizations in other countries, particularly the WHO. By understanding the current status of our ethical committees, we are confident that we can make improvements in the future.

Compliance with ethics guidelines

Jian LIU, Jie SHEN, and Pei-zhen LIU declare that they have no conflict of interest.

This article does not contain any studies with human or animal subjects performed by any of the authors.

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