

Research on the Influencing Factors of Medical Ethics Committees from the Perspective of Organizational Capability—A Crisp-Set Qualitative Comparative Analysis Based on 107 Cases

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Abstract

Background

Compared with international Institutional Review Board, China started late; however, in recent years, under the promotion of Chinese government departments, academic organizations, and experts and scholars at all levels, Chinese Institutional Review Board have made great achievements in the protection of rights and interests, systems, and procedures. Chinese Institutional Review Board are still weak in their organizational capacity building. The organizational capacity building of Institutional Review Board is a subject with complex causality, and it is difficult to offer a completely reasonable explanation for all aspects.

Method

In this article, we analyzed the influencing factors that affect the current status of the operation of Chinese Institutional Review Board, using literature analysis to refine the conditional variables and analyze the cases of 107 tertiary hospitals in China through crisp-set qualitative comparative analysis (csQCA) to explore the impact of medical ethics. Using the necessary conditions and combination of committee construction, combined with the “Yang Triangle” model of organizational capabilities, we designed a “Triangle force” model of the organizational capabilities of Institutional Review Board and proposed solutions from the perspective of organizational capabilities, reflecting on and analyzing the current management status of Chinese Institutional Review Board.

Results

We found that the protection of rights and interests was a necessary condition for a medical ethics committee. A lack of member ability, lack of review process, and lack of a supervision mechanism were sufficient conditions for a poor construction of a medical ethics committee.

Conclusions

We analyzed seven interpretation paths for this organization to operate well and they can be summarized into three typical paths: member ability-oriented, institutional process-oriented, and resource system-oriented, which are consistent with the “Triangle force” model hypothesis of the medical ethics committee’s organizational capabilities as constructed in this article. The driving factors and supporting forces of an ethics committee provide a theoretical basis and policy suggestions for the organization of Chinese Institutional Review Board.

Background

Compared with international Institutional Review Board, China started late; however, in recent years, under the promotion of Chinese government departments, academic organizations, and experts and scholars at all levels, Chinese Institutional Review Board have made great achievements in the protection of rights

and interests, systems, and procedures. The progress of the medical sciences has played an increasingly important role in ensuring the rights and safety of patients and medical human test subjects and has attracted great attention from society as well as medical circles.

Although great progress has been made in other areas, Chinese Institutional Review Board are still weak in their organizational capacity building. The organizational capacity building of Institutional Review Board is a subject with complex causality, and it is difficult to offer a completely reasonable explanation for all aspects.

Traditional quantitative research focuses on net effects and cannot explain complex causality. However, different from traditional analysis methods, qualitative comparative analysis (QCA) combines the advantages of both qualitative and quantitative research methods (Villanueva et al., 2017; Castellano Rioja et al., 2019; Crespo-Hervás et al., 2019; Giménez-Espert et al., 2019). Compared with case analysis, QCA is more objective and, compared with traditional linear regression, it can clearly reflect the complexity of causality, which makes case analysis more scientific and quantitative analysis closer to the facts. In layman's terms, its essence is a multi-case quantitative analysis method, and thus the number and nature of the selected cases in this study are more suitable for this method over other analysis methods.

Definition of Chinese Ethics Review Committee

Because the Ethic Committee (EC) is an imported product in China, China's understanding of it is also a dynamic process. It is to solve problems or problems related to ethics in the medical field. Scholars in different periods have different names and definitions. At present, the classifications that are generally accepted and applied in China are Hospital Ethics Committee (HEC), Institutional Review Board (IRB) and Medical Ethics Committee (MEC) set up in the national government and medical organizations. In specific applications, MEC It is established in the national administrative department and is mainly used for ethics consultation on major ethical problems, such as the "National Health and Health Commission Medical Ethics Expert Committee". However, the two types of medical ethics committees, HEC and IRB, are often confused and discussed. Here is a simple distinction. It can be considered that HEC belongs to the consultation mechanism of the hospital, and conducts ethical consultation on the ethical choices encountered by the hospital in clinical practice Mandatory. However, IRB refers to the ethical review of clinical trials and medical research projects involving human beings, and has the power to review and approve, and review projects cannot be implemented without their approval.

The object discussed in this article refers to the institution that conducts ethical review of clinical trials and medical research projects involving human beings, so it is called Institutional Review Board (IRB).

Literature Analysis and Model Construction

1.1.1 Literature Analysis

We used “Medical Ethics Committee”, “Ethics Committee”, or “Institutional Ethics Committee” as the subject headings, and searched according to topics or keywords in the CNKI (China national knowledge infrastructure) database, and selected the core journals and CSSCI (Chinese Social Science Citation Information) journals as the search source. A total of 20 documents were searched. Considering that China promulgated the “Measures for the Ethical Review of Biomedical Research Involving People” in December 2016, and it was officially put into operation, we set the time node for the selection of the literature from 2017 to the present. In the obtained documents, after removing duplicates and redundant and not highly relevant documents, we found that many documents put forward external suggestions for establishing regional ethics committees, strengthening external evaluation and certification, etc.

The focus of this article was on committee organization. The internal factors affected the capacity, and so only the variables mentioned in 11 documents concerning the construction of Institutional Review Board were analyzed. At the same time, we fully studied and considered the requirements of China’s relevant laws and regulations on ethics review. Under this premise, we analyzed and contrasted the forward-looking and superior evaluation content in the international evaluation standards (see Table 1), which affect the operation of the medical ethics committee. The internal influencing factors were refined and divided into six categories (see Table 2).

Table 1

The regulations and international guidelines on ethical review. Files from official website of the Chinese government and the US Office for Human Research Protections and World Medical Association.

	Name	Issuer	Time
China	“Guidelines for the construction of clinical research ethics committees involving human subjects”	Office of Medical Ethics Expert Committee of China National Health Commission	2019 year
	“Measures for Ethical Review of Biomedical Research Involving Human Subjects”	China National Health and Family Planning Commission	2016 year
	“Drug Administration Law of the People’s Republic of China”	The Twelfth Meeting of the Standing Committee of the 13th National People’s Congress of China	2019 year
	“Guiding Principles for Ethical Review of Drug Clinical Trials”	China State Food and Drug Administration	2015 year
	“Administrative Measures for the Clinical Application of Medical Technology”	National Health Commission	2018 year
	“Administrative Measures for Drug Registration”	China State Administration for Market Regulation	2007 year
	“Measures for Ethical Review of Biomedical Research Involving Human Subjects (Trial)”	National Health and Family Planning Commission	2016 year
	“Guiding Principles for Clinical Trials of In Vitro Diagnostic Reagents”	State Food and Drug Administration	2014 year
	“Regulations on Clinical Trials of Medical Devices”	State Food and Drug Administration	2004 year
	“Pharmaceutical Clinical Trial Quality Management Standards”	State Food and Drug Administration	2003 year
“Regulations for the Implementation of the Drug Administration Law of the People’s Republic of China”	Order of the State Council of the People’s Republic of China	2016 year	
International	The Nuremberg Code	Nuremberg Military Court	1949 year
	The Belmont Report	Belmont Convention Center	1964 year
	The Declaration of Helsinki	World Medical Association	2013 year
	“International Ethical Guidelines for Human Biomedical Research” (CIOMS)	International Committee of Medical Scientific Organizations	2002 year

Table 2

Analysis of factors affecting Institutional Review Board. References from China national knowledge internet (CNKI).

Classification	Author and Time
Related to monitoring mechanism	(Xue, D., 2019), (Li et al., 2017), (Zhang et al., 2017), (RDPAC, 2018), (Wen et al., 2018), (Wang, J. and Xin, B. 2019), (Zhang et al., 2017), (Zhou et al., 2017)
Related to member structure	(Wen et al., 2018), (Fan et al, 2017), (RDPAC, 2018), (Wang, J. and Xin, B., 2019), (Zhang et al., 2017), (Zhou et al., 2017)
Related to office resources	(Yu et al, 2020), (Zhang et al., 2017)
Related to rights protection	(Li et al., 2017), (Jiang et al., 2017)
Related to the review process	(Wang, H. B. and Wang, Y. R., 2017), (Jiang et al., 2017), (Fan et al, 2017), (RDPAC, 2018), (Yu et al, 2020), (Wang, J. and Xin, B. 2019), (Zhang et al., 2017)
Related to rules and regulations	(Wen et al., 2018), (Zhou et al., 2017), (Zhang et al., 2017)

Through our literature review, we found that the existing related research had the following limitations: First, the existing research mainly revolved around the establishment of medical ethics committee systems and procedures, and the countermeasures for ethics committee organization construction were mostly through case analysis or theoretical norms. The analysis method was refined or summarized, and there was a lack of systematic comparison and analysis between cases. Second, the existing literature mostly explored the “net effect” of a single influencing factor, ignoring the “combined effect” of multiple factors or emphasizing the impact of a single variable on medical ethics. The impact of the committee either emphasized the comprehensive impact of multiple variables on the medical ethics committee at the same time or lacked analysis of the impact of different combinations of different variables on the capacity building of the medical ethics committee. The construction of Institutional Review Board is the result of multiple factors from different levels and different subjects.

Therefore, this study refers to the relevant Chinese foreign policies and regulations of the medical ethics committee and relevant authoritative documents, combined with the actual situation of the on-site interview data and case responses, and summarizes the relevant variables that affect the capacity building of the medical ethics committee in the member structure, office resources, and systems with six factors, including the review process, internal and external supervision, and rights protection. The capacity building of Institutional Review Board is the result of the combined effect of many factors, which is an ongoing problem.

However, how the membership structure, office resources, rules and regulations, review process, rights protection, supervision mechanisms, and other factors together affect the capacity building of Institutional Review Board is an open question. Based on this, this article attempts to explore the joint

effects of the above variables on the capacity building of Institutional Review Board and to explain the possible connections between different variables.

1.1.2 Model Construction

The term “organizational competence” is well known and commonly used by the general public, but what is its connotation? This is rather vague in the literature. Organizational ability refers not to an individual ability, but to the overall power of a team. It is the DNA of a team’s (or organization’s) competitiveness. It is the ability of a team to clearly surpass its opponents in certain aspects and create value for customers.

In this article, we regard the medical ethics committee as an organization and refer to the “triangular framework of organizational capabilities” proposed by Professor Yang Guoan, also known as the “Yang Triangle” model (Yang, G.A., 2010). Guoan proposed that organizational capabilities were inseparable from employee capabilities and employee thinking patterns and indicated that organizational capacity building could not be separated from the three pillars of employee mentality, employee ability, and employee governance (as shown in Fig. 1). To construct or transform the organizational ability, it should be adjusted in the following three aspects simultaneously:

1. Employee Mindset: This involves what the employee is willing to do, how to adjust their attitude, how to cultivate the culture of the enterprise, and so on.
2. Employee Competence: Employees may not have sufficient competence even if they are willing to cooperate. In such a case, an enterprise should start by providing training and improving the employee competence.
3. Employee Management: Even if employees are willing and able to step up to corporate goals, employee competence may be undermined and lost in the process along with the organizational structure of the enterprise.

The construction of enterprise organization ability relies on the above three aspects to cooperate with each other. Being short of one aspect may make all efforts fail. The author for the organization, construction, or renovation of the medical ethics committee (organization), must balance the following three aspects:

1. The ethics committee thinking involves the ethics committee in the management of the professional ethical review work of force, such as the review process and whether there are strict processes, rules, and regulations in accordance with the stipulated relevant laws and regulations, and rights and interests protection centered and strict and orderly in the ethical review. The thinking mode of the entire organization should be in accordance with the specification for the job.
2. Competence of ethics committee members: Even if the committee members are willing to cooperate, they may not have sufficient competence. In this case, enterprises should start with providing

training and improving the competence.

3. Ethics committee organization support: Even if members have the ability, the organization's infrastructure, process, and organization structure may allow members to lose momentum in manifesting the medical ethics committee through a lack in office resources, supervision mechanisms, etc.

The study found that the insufficient main factors of medical ethics committee management are consistent with the three pillars of the "Yang Triangle force" in terms of management dimensions. Therefore, the author constructs the "three forces" hypothetical model of medical ethics committee organizational capabilities from the perspective of organizational capabilities. The "Triangle force" model is a reflection and exploration of the management method of Institutional Review Board. It is centered on the core value of the medical ethics committee (protection of rights and interests of the subjects), and builds the "triangle forces", namely the organizational support of the medical ethics committee (office resources and supervision mechanism), and the management expertise of the medical ethics committee (review process, rules and regulations), the ability of medical ethics committee members (member ability), the "three forces model" of medical ethics committee management constructed by the author.

Figure 2 shows the "three-force model" for the management of medical ethics committee as constructed by the author.

Methods

Sample Selection and Data Collection

To ensure the reliability and validity of the measurement tool, this study adopted a questionnaire that was developed by Chinese scholars and was empirically tested. After modification, based on the opinions of experts in the field, the research was established in the top hospitals in Zhejiang Province, China (The First Affiliated Hospital of Wenzhou Medical University, the Eye Optometry Hospital of Wenzhou Medical University, the Second Affiliated Hospital of Wenzhou Medical University, the First Affiliated Hospital of Zhejiang University etc.), and the questionnaire was conducted pre-investigation.

After interviewing the members and secretaries of the ethics committees, and fully understanding the internal structure of the ethics committees of the above-mentioned tertiary hospitals, some questions and options of the questionnaire were modified to form the questionnaire used in this investigation. The research team began a nationwide survey in China from July to September 2020, based on the distribution of tertiary hospitals and, at the same time, conducted research in key areas, military hospitals, China Boao Super Hospital, and other hospitals, and visited hospitals across the country.

Nearly 550 institutions were issued structured questionnaires, and 110 valid questionnaires were recovered. Interviews were conducted with highly cooperative hospitals during the survey period. The second-hand data was used to supplement and verify the interview and questionnaire data. The information verified the data, and with the help of second-hand data, individual values in the questionnaire with partial data ambiguities or missing values can be clarified or supplemented. We eliminated four missing hospitals; therefore, the effective sample size of this article was 107, and the effective questionnaire response rate was 98.1%.

Analysis Strategy: Qualitative Comparative Analysis (QCA)

This study is an exploratory attempt to introduce the QCA method into the field of health service management to analyze the current status of Institutional Review Board. This method has unique advantages. QCA uses Boolean algebra algorithms to formalize the logic process when people analyze problems. The main point is that QCA can reveal the specific combination of these conditions and their relationship with the results. In terms of specific technical analysis, we chose QCA mainly based on the following reasons:

First, different from single-case analysis, QCA is a cross-case research method. The general criteria for case selection is that the case population has sufficient homogeneity (that is, cases must have sufficient background or characteristics) and the maximum heterogeneity of the case population (that is, the degree of diversity of cases). The cases selected in this study are all tertiary and first-class public hospitals in various regions, all of which are under the background of relevant Chinese health management policies. The cases are representative and meet the requirements of sufficient homogeneity; this study selected the location, establishment time, number of people, and independence of the research objects as different, which meets the requirements of the QCA method for the maximum heterogeneity of the research objects. Therefore, the use of QCA can not only distinguish the heterogeneity of different cases but also observe the commonality of different cases.

Second, different from quantitative analysis, QCA usually requires 10 to 80 cases, which makes QCA more advantageous when analyzing small samples. (Ragin, 2008; Eng and Woodside, 2012). This study was of the ethics committees of the top hospitals in China, and the number was limited; therefore the study sample was a small sample, which met the requirements of the method.

The third reason is that QCA assumes that the causality that leads to a certain social phenomenon is complex, diverse, and non-linear, and the causality obtained by its operation is also presented in the form of a combination of causes, which is more conducive to explaining human psychological activities and the process of behavior selection. The complexity is higher (Seawright, 2005; Vis, 2012; Legewie, 2013). The capacity building of a medical ethics committee is affected by many factors. In addition to personal reasons, there are also organizational environmental factors.

This study focused on the organizational environment factors of the institution where the medical ethics committee was located, including the resources, culture, and education of the institution where the

medical ethics committee was located. In addition to the complexity of personal factors, if regression analysis focusing on the measurement of net effects is used, it is easy to cause multicollinearity and the consumption of degrees of freedom. Multiple linear regression was used; however, qualitative comparative analysis breaks through this net effect and combines various conditional factors. We used a combination to explain the result with the greatest strength.

Fourth, QCA focuses on the sufficient and necessary conditions to cause a certain result, which is beyond the reach of traditional regression analysis. There is an asymmetric relationship between the conditions and results; however, regression analysis follows the statistical method of a symmetric relationship, and cannot solve this problem. Using qualitative comparative analysis can make up for the related deficiencies of regression and better explain the impact on medical ethics committee capacity building.

In regression analysis, it is impossible to deal with endogenous problems; however, qualitative comparison methods can judge the adequacy and necessity of conditions and clarify the logical relationships between various variables. Sufficient conditions reflect the effect of independent variables on dependent variables. The necessary conditions reflect the reverse effect, and this two-way judgment can solve a certain degree of endogeneity problems (Ragin, 2008 [39]; Eng and Woodside, 2012; Boquera et al., 2016; Seawright, 2005; Vis, 2012).

Variable Measurement and Calibration

There are three main types of qualitative comparative analysis: crisp-set qualitative comparative analysis (csQCA), fuzzy set qualitative comparative analysis (fsQCA), and multi-value set qualitative comparative analysis (mvQCA). The condition variables of this study were the relevant variables within the organization that affected the operation of the medical ethics committee evaluated by whether the variable met the standards regulated by the industry during the operation of the medical ethics committee.

The result variable is whether the ethics committee's construction is effective or not. This is a typical categorical variable, combined with the characteristics and applicable requirements of different types of qualitative comparative analysis, as well as data characteristics and research goals. The crisp-set QCA (csQCA) method was adopted in this study for the cross-case analysis of the system (Rihoux, B. & Ragin, C.C., 2009).

We systematically conducted data collection and a literature search to understand which regulations and international guidelines the institution needs to follow regarding ethics review and the existing relevant content on the management and construction of ethics committees. This mainly referred to the relevant standards of the International Medical Ethics Committee's Strategic Action for the Development of Ethics Committee Review Capability (SIDCER) and the American Association for Human Research and Protection Project Certification (AAHRPP), combined with the "Clinical Trial Institutional Capability" issued by Professor Hong Minghuang in 2019, the "Ethics Committee Review Ability Evaluation" in the

Evaluation Series of Standards, and the 2015 Shanghai Municipal Bureau of Quality and Technical Supervision issued “Human Biomedical Research Ethical Review Norms”.

As China has no unified ethics committee evaluation standards so far, some ethics committees began to seek various international certifications. We propose that various ethical evaluation works should be viewed from an open perspective. Any scientific and logical evaluation method can be used as a reference method for ethics workers. Therefore, in accordance with the relevant regulations in the “Measures for the Ethical Review of Biomedical Research Involving Humans” promulgated in December 2016, this article determined whether the selected samples comply with the crisp-set two-point assignment of the 104 Institutional Review Board obtained.

After repeated calibrations and tests, 29 cases with good medical ethics committee construction were obtained, accounting for 25.2% of the total number of cases, and 78 cases with poor construction were obtained, accounting for 72.9% of the total number of cases. When assigning the result variable, this article counted each case that met a condition variable as “1 point”, and added “1 point” to those that passed the international assessment, for a total of two points (Boquera et al., 2016; Villanueva et al., 2017; Giménez-Espert et al., 2019; Ragin, 2008). There are many international evaluation standards, and the scientific and rigorous evaluation standards themselves are constantly developing and optimizing(see Table 3).

Any scientific evaluation work will not be complete after a certain evaluation. Continuous learning and reference in the process of practice is required to continuously improve the construction of ethics committees. However, international ethics evaluation standards are not necessarily fully applicable to the construction of Chinese ethics committees. Chinese ethics committees have passed certain international certification evaluations, which does not mean that ethics committees have reached international standards. All types of ethical assessments can be regarded as ways to build an ethics committee. Under the premise that China still lacks systematic evaluation standards for ethics committees, we should learn from international evaluation standards to make up for the deficiencies in the existing work.

In the qualitative comparative analysis, the simultaneous existence of “0” or “1” cases is a necessary condition for further analysis, but the number of the two has no substantial influence on the final calculation result and path combination. First, we conducted a univariate necessity test on the conditional variables to determine the necessary conditions that may exist; second, we calculated the sufficient path combination of the conditional variables to obtain a sufficient conditional combination path that affected the construction of the medical ethics committee; and finally, the combination was performed to model the induction and causal analysis.

Table 3
Condition variable assignment.

Condition Variable	Measurement Condition	Classification	Coding
Member ability	Reasonable structure, independent members, independent consultants, etc. meet the requirements	All meet	1
		Does not meet	0
Office resources	Office conditions, meeting rooms needed for review meetings; dedicated medical ethics committee management room; organizations provide necessary financial funds, etc.	All meet	1
		Does not meet	0
Rules and regulations	Does the charter, work system, and standard review process exist?	All meet	1
		Does not meet	0
Review process	The review methods and review records are all compliant and complete	All meet	1
		Does not meet	0
Monitoring mechanism	Internal: there is supervision within the organization, etc.	All meet	1
	External: information disclosure, acceptance of industry supervision, etc.	Does not meet	0
Protection	Protection of rights and interests of subjects; protection of rights and interests of experimenters.	All meet	1
		Does not meet	0
Outcome variable	Compliant with the six variables will be counted as 1 point, and 1 point will be added to those who pass domestic and foreign verification.	0–3	0
		4–7	1

Results

Necessity Analysis of Individual Conditions

The QCA-analysis followed a four-step approach supported by the software fsQCA (Ragin, 1987; Heikkila and Tanya, 2004; Schneider and Wagemann, 2010). Consistent with the mainstream QCA research, this article first examined whether a single condition (including its non-collection) constitutes a necessary condition for a complete merger. From the perspective of set theory, the necessity analysis of a single condition is to test whether the result set is a subset of a certain condition set. If condition X (a single condition or a combination of conditions) is a sufficient condition for Y, then the fuzzy set score of X should be less than or equal to the fuzzy set score of Y, and the consistency index should be greater than

0.8, and when the consistency level is greater than 0.9, the condition can be considered as a necessary condition for the result (Ragin, 2008; Schneider and Wagemann, 2012).

Table 4 shows the test results of the necessary conditions for the establishment of better Institutional Review Board using fsQCA3.0 software analysis. The consistency of the rights protection exceeded 0.9. It can be seen that rights protection is a necessary condition for the results (the consistency is 0.93), followed by the review process, and office resources (consistency is 0.72). In view of the causal asymmetry of the QCA method, Table 5 shows the results of the analysis of the necessary conditions for the poor construction of Institutional Review Board. The lack of member ability, the lack of review procedures, and the lack of supervision mechanisms are sufficient conditions for poor Institutional Review Board. The consistency of rights protection was 0.78, indicating that the construction of Institutional Review Board is relatively good and poor, and the Institutional Review Board in terms of rights protection are relatively standardized.

Table 4
Necessity test for better construction of medical ethics committee.

Condition Variable	Consistency	Coverage
Member ability	0.620690	0.666667
~Member Ability	0.379310	0.137500
Office resources	0.724138	0.320000
~Office Resources	0.275862	0.256098
Rules and regulations	0.724138	0.396226
~Regulations	0.275862	0.148148
Review process	0.724138	0.636364
~Review process	0.275862	0.108108
Monitoring mechanism	0.620690	0.545455
~Supervision Mechanism	0.379310	0.148649
Protection	0.931035	0.306818
~Protection of rights	0.068966	0.105263
Note: "~" means that a factor does not appear or is "not".		

Table 5
Necessity test of poor construction of medical ethics committee.

Condition Variable	Consistency	Coverage
Member ability	0.115385	0.333333
~Member Ability	0.884615	0.862500
Office resources	0.217949	0.680000
~Office Resources	0.782051	0.743902
Rules and regulations	0.410256	0.603774
~Regulations	0.589744	0.851852
Review process	0.153846	0.363636
~Review process	0.846154	0.891892
Monitoring mechanism	0.192308	0.454545
~Supervision Mechanism	0.807692	0.851351
Protection	0.782051	0.693182
~Protection of rights	0.217949	0.894737
Note: “~” means that a factor does not appear or is “not”.		

Adequacy Analysis of Conditional Configuration

Different from the above-mentioned necessary condition analysis, the configuration analysis attempts to reveal the sufficiency analysis of the results caused by different configurations composed of multiple conditions. From the perspective of set theory, we explored whether the set represented by the configuration composed of multiple conditions is a subset of the result set. Conditional combination analysis uses a combination method to analyze the influence of different combinations on the outcome variable when a single variable does not meet the necessary conditions. In this paper, fsQCA3.0 software was used for the calculations. Based on existing research, this paper set the consistency threshold to 0.8 and the case frequency threshold to 1, and calculated the complex solution, simple solution, and intermediate solution of the location selection result. We combined the intermediate solution and a simple solution to explain the obtained conditional configuration (see Table 6).

Table 6
A good intermediate solution for medical ethics committee construction.

Path	Condition Combination	Original Coverage	Unique Coverage	Consistency
P1	Member ability*rules and regulations*review process*rights protection	0.344828	0.137931	1
P2	Office resources*rules and regulations*review process*~supervision mechanism*rights protection	0.103448	0.0689656	1
P3	Member ability*~office resources*rules and regulations*supervision mechanism*rights protection	0.206897	0.0344828	1
P4	Member ability*~office resources*review process*supervision mechanism*rights protection	0.275862	0.103448	1
P5	~Office resources*Rules and regulations*Review process*Supervision mechanism*Rights protection	0.310345	0.137931	1
P6	~Member Ability*Office Resources*~Regulations*~Review Process*Supervision Mechanism*~Rights Protection	0.0344828	0.0344828	1
P7	Member ability*office resources*~rules and regulations*~review process*supervision mechanism*rights protection	0.0689655	0.0689656	1
Note: Solution coverage: 0.793103 solution consistency: 1. "~" means logical "not", "*" means logical "and".				

The original coverage rate indicates the proportion of cases that can be explained by the condition combination in the total cases; the net coverage rate indicates the proportion of cases that can only be explained by the condition combination in the total cases; and the consistency indicates the path (condition or condition combination) reliability or suitability (Eng and Woodside, 2012).

By operating the truth table, the coverage of the solution is 1, and the conditional combination can explain all cases (see Table 5). There are seven paths to promote "good construction of Institutional Review Board", including member capabilities*rules and regulations*review process*rights protection; office resources*rules and regulations*review process*~supervision mechanism*rights protection; member capabilities*~office resources*Regulations and Regulations*Supervision Mechanism*Protection of Rights and Interests; Member Ability*~Office Resources*Examination Process*Supervision Mechanism*Protection of Rights and Interests; ~Office Resources*Rules and Regulations*Examination Process*Supervision Mechanism*Protection of Rights and Interests; ~Member Ability*Office Resources*~Rules and regulations*~review process*supervision mechanism*~rights protection; and

member ability*office resources*~rules and regulations*~review process*supervision mechanism*rights protection.

Among the seven combined paths, the unique coverage of P1, P4, and P5 is about 0.10, 0.13, and 0.13, respectively. The unique coverage of P2 and P7 also reached about 0.068. These four paths can explain about 49.6% of cases and have a strong explanatory power for the causal mechanism of Institutional Review Board. To improve the explanatory power of the final path combination, based on the basic principles of Boolean operations, this study transformed Table 6 into Table 7 with a more concise condition similarity in the path combination, and modeled and summarized the seven well-established paths of the medical ethics committee.

We refined the shared conditions or combination of conditions, and built a more explanatory model. In the end, three modes are summarized: the member ability-oriented (M1), institutional process-oriented mode (M2), and resource system-oriented mode (M3). The combination of these three models can explain all cases, and the unique coverage reached approximately 0.59 in total. Each model has strong explanatory power, as follows:

1. The first interpretation model is the member capability model (M1), which includes path 1, path 3, and path 4. The basic expression after Boolean simplification is $M1 = \text{member ability} * \text{rights protection} * [\text{rules and regulations} * \text{review process} + \sim \text{office resources} * \text{supervision mechanism} * (\text{regulations} + * \text{review process})]$. M1 covers 24 cases. In the sample case, the basic condition (combination) is the member's ability and rights protection. That is, under the premise of the protection of member capabilities and rights and interests, there is the existence of rules and regulations and review processes or a lack of office resources, but the existence of a supervisory mechanism and the coexistence of rules and regulations and review processes, and the capacity building of Institutional Review Board are also good.
2. The second interpretation model is the system process-oriented model (M2), which includes Path 5 and Path 2. The basic expression after Boolean simplification is $M2 = \text{rules and regulations} * \text{review process} * \text{rights protection} (\text{office Resources} * \sim \text{Supervision Mechanism} + \sim \text{Office Resources} * \text{Supervision Mechanism})$. M2 covers 12 sample cases, and the basic conditions (combination) are review process, rules and systems, and rights protection. That is, regardless of the ability of the members, only one type of office resources and supervision mechanism are qualified. When there are rules and regulations, review procedures, and rights protection, the capacity building of the medical ethics committee is also relatively good.
3. The third interpretation model is the resource system-oriented model (M3), which includes path 6 and path 7. The basic expression after Boolean simplification is $M3 = \text{office resources} * \text{supervision mechanism} * \sim \text{rules and systems} * \sim \text{Review process} (\sim \text{member ability} * \sim \text{rights protection} + \text{member ability} * \text{rights protection})$. M3 covers three cases. The basic condition (combination) is office resources, lack of supervision mechanism, rules and regulations, and lack of review process. That is, when the rules and regulations and review process are missing, regardless of the ability of members

and the protection of rights and interests, the existence of office resources, and supervision mechanisms, the capacity building of the medical ethics committee is also better.

Table 7
Good condition configuration for medical ethics committee construction.

	Resource System-Oriented Model (M3) Institutional			Member Capability-Oriented Model (M1)		Process-Oriented Model (M2)	
	P6	P7	P1	P3	P4	P5	P2
Monitoring mechanism	●	●	–	●	●	●	×
Office resources	●	●	–	×	×	×	●
Member ability	×	●	●	●	●	–	–
Rules and regulations	×	×	●	●	–	●	●
Review process	×	×	●	–	●	●	●
Protection	×	•	•	•	•	•	•
Unique coverage	0.1034484			0.2758618		0.2068966	
Note: “•” means “general conditions”, “●” means “core conditions”, “×” means “conditions do not appear”, and “–” means “corresponding conditions with paths do not matter”. Simple solution and intermediate solution. The condition that appears at the same time is the “core condition”, and the condition that only appears in the intermediate solution is the “general condition”, using the format of Fiss (2011).							

Robustness Test

This article references Fiss and Zhang Ming’s method to increase the consistency level from 0.8 to 0.85 for robustness testing. After adjusting the consistency level threshold from 0.8 to 0.85 in fsQCA, the case frequency was still 1, and the overall solution was consistent after analysis. The level of performance was 1, which still has a good explanation strength. The coverage of the overall solution is the same as before. The configuration after adjusting the consistency threshold is consistent with the configuration before the adjustment. Therefore, after increasing the adjustment consistency threshold, the result is still robust. fsQCA (Version 2.5, ©Raging and David, 1999–2008; Claude, 2013; Claude and Christopher, 2014) was used to perform the QCA analysis.

Conclusions

We first extracted the conditional variables that affect the construction of Institutional Review Board through the combination of policies and regulations and literature analysis, and constructed the “Triangle

force” hypothetical model of medical ethics committee’s organizational capabilities from the perspective of organizational capability. The “Triangle force” model is a reflection and exploration of the management method of a medical ethics committee, which is centered on the core value of a medical ethics committee (protecting the rights and interests of subjects and experimenters) to create the “Triangle force”, that is, the organizational support of the medical ethics committee (office resources and supervision mechanism), medical ethics committee management expertise (review process and rules and regulations), and medical ethics committee member ability.

Through the crisp-set qualitative comparative analysis (csQCA) method, 107 Institutional Review Board were empirically analyzed, and we found single condition variables and condition configurations that affected the differences in the construction of Institutional Review Board, from the perspective of single condition variables.

The variable of “protection of rights and interests” is a single necessary condition that leads to a better construction of Institutional Review Board, while the variable of “lack of member ability, lack of review process, and lack of supervision mechanism” is a single sufficient condition that leads to poor construction of Institutional Review Board. From the perspective of state analysis, three interpretation modes are summarized: the member ability-oriented (M1), system process-oriented mode (M2), and resource system-oriented mode (M3), and the organizational capabilities of the medical ethics committee are constructed in this article. The hypothesis of the “Triangle force” model is consistent. The “Triangle force model” of the medical ethics committee’s organizational capacity provides a reference for the organization of Institutional Review Board and provides a reference for the management of Institutional Review Board. Therefore, the following revelations are drawn:

Focus on the Shaping of Member Capabilities

The working ability of the ethics committee members is the basic ability of the hospital ethics committee to perform its functions; however, the abilities of the ethics committees of each hospital are not the same. In the actual operation of the hospital, the review standards of the ethics committee of each hospital are often different. In the same report, it is not uncommon for a hospital to pass the review without modification but not pass the review in other hospitals. This shows that the review capabilities of the ethics committees of each hospital are different.

The fundamental reason lies in the ethics of the ethics committee members. There is a gap between quality and ethical review ability. Insufficient ethics knowledge training and education come from different professional hospital ethics committee members with special skills. The necessary knowledge of medical ethics, the ability to understand and execute ethical principles and related laws and regulations, and the degree of understanding and mastery of new medical technologies may be different. However, as a member of the ethics committee, the imperfection of ethical knowledge will seriously affect the effective use of the ethical review role of the hospital ethics committee.

The role of the ethics committee members is not balanced. The members of the committee have different professional backgrounds and understandings of ethical principles and laws. The grasp of laws and regulations, the understanding and grasp of experimental schemes are different, and there are huge differences in the angle and authority of review. The members of the ethics committee perform the functions of the ethics committee and are closely related to their own interests and even have conflicts. Most of the members of the hospital ethics committee are employees of the hospital. The interest and emotional relevance of the unit may affect the objectivity and fairness of the ethics review (Liu, 2018).

Stakeholders of hospital ethics committee members participate in ethical review, which will lead to conflicts between their obligations to perform their duties and their pursuit of their own professional development and other self-interests. The urgent need for the construction of hospital ethics committees at this stage is prominently reflected in the hospital ethics committee's skill building. This is the fundamental requirement for improving the efficiency and level of the hospital ethics committee and giving full support to the role and function of the hospital ethics committee.

Optimize the Improvement of the System Process

The establishment of a sound system process can better ensure the independence of ethical organizations and also truly reflects the connotation of independence. Independence not only includes the requirements of independent places and supporting facilities, but more importantly, the rules and regulations of ethical organizations, and particularly the standards of ethical organizations. In the implementation of procedures, the institutional process-oriented model (M2) in the above-mentioned research and any medical ethics organization must standardize its operation, where the primary task is to continuously improve the construction of a series of rules and regulations with the goal of standardization, institutionalization, and proceduralization.

The rules and regulations of medical ethics organizations mainly include related systems in the construction and operation of hospital ethics organizations, which include: an ethics office management system, ethics organization work charter, member generation and replacement system, education and training system, conflict of interest declaration and avoidance system, financial management system, ethics committee year-end summary system, etc.

Relevant systems in ethics organization consulting review include a meeting review and emergency meeting review system, rapid review system; follow-up review management system after ethics review; management system for ethics consulting, review, and complaint acceptance; standard operating procedures; and a meeting management system. The file management system includes file creation, preservation, inspection and copying, etc. Hospital ethics organizations must strictly abide by various rules and regulations. For ethics organizations and their persons in charge who do not strictly abide by the rules, necessary punishments and the disqualification of evaluation qualifications must be carried out to ensure the standard operation of ethics organizations.

Attention Regarding the Construction of Resource Systems

The prerequisite for the medical ethics committee to have full power in its role is that it has sufficient organizational support—that is, the resource system-oriented model (M3) in the above-mentioned research. The current system of medical ethics committee management in China is mainly reflected in the unclear organizational structure, and they are often affiliated with unused departments, insufficient authorization of Institutional Review Board, a lack of internal self-monitoring and supporting information platforms, etc.

The reason is that the lack of resources (facilities, funds, technology, etc.) of the medical ethics committee is mainly reflected in the institution's lack of in-depth understanding regarding Institutional Review Board, a lack of scientific planning, and because it is not an independent department, a difficulty in obtaining organizational resources. Therefore, it is indispensable to match the necessary resources related to the work and to enhance the organizational support of the medical ethics committee. Organizational funding is one of the basic conditions for maintaining the normal operation of ethics organizations.

The 2016 “Measures for the Ethical Review of Biomedical Research Involving People” also mentioned that the department or institution that establishes the institutional ethics committee should be granted based on the work of the ethics committee members. Appropriate remuneration and training requires funding. However, a considerable number of ethics organizations in China still lack the basic funds to maintain their normal operations. In most cases, in the hospitals where they are allocated certain funds or project review fees, there are potential risks that affect the independence, objectivity, and fairness of the review results.

The reason is that the interests and reputation of medical institutions may exceed the safety of patients or subjects. The state can establish a reasonable funding mechanism, and provide appropriate special projects based on scientific budgets and funding management systems formulated by various ethical organizations, including funds to support the construction and operation of hospital ethics organizations and the scientific research related to them. The appropriate administrative intervention of the organization's organization is conducive to improving the construction of Institutional Review Board.

Therefore, it is advisable for the administrative department to be responsible for the supervision of the ethical organization's work; however, for the supervisory body, its specific responsibilities should be further clarified and specific. This should be mainly from two aspects: internal and external. Regarding the internal need for institutional ethics committee self-management, the institution should have special departments and personnel for internal quality supervision; regular self-assessment, and the development of quality improvement plans. Ethics committees should have improvement measures for problems found in self-examination, and should evaluate, train, and assess the chairman, committee members, office director, secretary, and staff. External supervision needs to be disclosed to the public through the official website, including the contact information of the committee, the list of members, occupations, affiliated units, articles of association and guidelines, etc., and they should accept industry supervision in accordance with the industry's regulatory requirements of the institution.

Shortcoming And Prospects

Finally, although many new discoveries and understandings were formed in this research, the current research on this issue is mostly qualitative analysis or single-case study, and there is a lack of systematic research on multi-case quantitative methods. This article used quantitative methods to study this problem for the first time. This was a tentative exploration, and it is inevitable that there are deficiencies. Judging from the existing literature, on the one hand, this work was limited by the literature and method framework, and there is still room for optimization of the conditional variables. Although the case selection of this study strictly followed scientific steps, limitations are unavoidable.

The influence of subjective factors may have strong subjectivity. Future research should increase the diversity of the influencing factors of the medical ethics committee and select multiple factors from different perspectives to further enhance the explanatory power. In addition, with the continuous increase of public information and the continuous deepening of research in related fields, the author will continue to work hard to solve the problems that still exist in this research, and further enhance the scientificity and effectiveness of this research.

Generally speaking, the Chinese medical ethics committee started late, has just finished the rapid development stage, and now in the transitional period of focusing on quality. In fact, the Chinese medical ethics committee has fully learned from the experience of other countries in its development process. And now, we try to summarize the findings of the survey in China into the experience that can be used by other countries.

Abbreviations

IRB

Institutional Review Board

csQCA

crisp-set qualitative comparative analysis

QCA

qualitative comparative analysis

EC

Ethic Committee

HEC

Hospital Ethics Committee

MEC

Medical Ethics Committee

CNKI

China national knowledge infrastructure

CSSCI

Chinese Social Science Citation Information

CIOMS

International Committee of Medical Scientific Organizations

fsQCA

fuzzy set qualitative comparative analysis

mvQCA

multi-value set qualitative comparative analysis

SIDCER

Strategic Action for the Development of Ethics Committee Review Capability

AAHRPP

American Association for Human Research and Protection Project Certification

Declarations

Ethics approval and consent to participate

Ethics Committee of Wenzhou Medical University, No. 2020-130

Consent for publication

Not applicable

Availability of data and materials

The data that support this study are available from the corresponding author (CV) on reasonable request, subject to privacy and confidentiality commitments.

Competing interests

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Author Contributions

All authors contributed equally to this paper. L.L. and S.S. described and developed the review and the hypothesis. B.L. and X.L. was involved in the data collection process. L.L. and S.S. performed the analysis,

interpretation of the results and formulated the main conclusions. B.L.and C.L. formulated the study limitations and future directions for research. All the authors help editing and formatting the paper.

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Figures

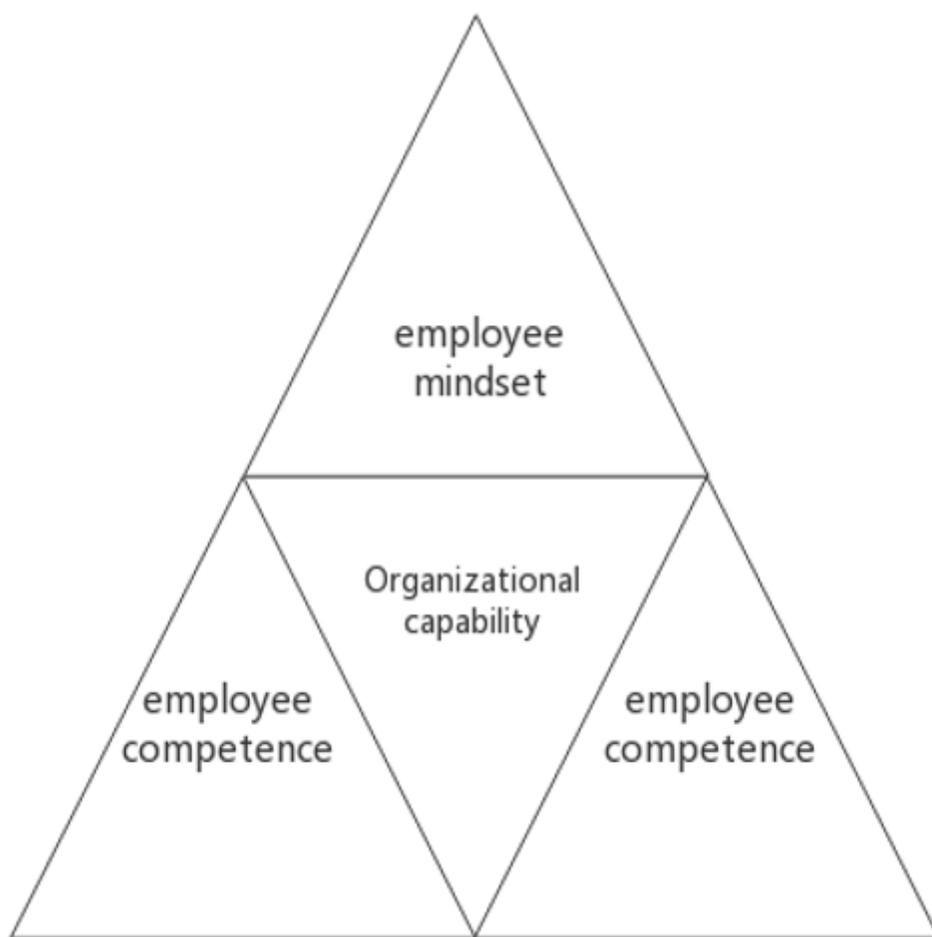


Figure 1 Triangular framework of organizational capabilities

Figure 1

Triangular framework of the organizational capabilities. It was proposed by Professor Yang Guoan.



Figure 2 The "Three Forces Model" of the Medical Ethics Committee

Figure 2

The "Three Forces Model" of a medical ethics committee.