#### **LETTER**



# Report on the Establishment of the Consortium for Hospital Ethics Committees in Japan and the First Collaboration Conference of Hospital Ethics Committees

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#### **Abstract**

Hospital ethics committees (HECs) are expected to play extremely broad and pivotal roles such as case consultation, education of staffs on healthcare ethics, and institutional policy formation. Despite the growing importance of HECs, there are no standards for setup and operation of HECs, and composition and activities of HECs at each institution are rarely disclosed in Japan. In addition, there is also a lack of information sharing and collaboration among HECs. Therefore, the authors established the Consortium of Hospital Ethics Committees (CHEC) in October 2020, which has been regularly hosting a couple of core activities. One is the Healthcare Ethics Forum, held monthly online for CHEC members to freely discuss HECs and healthcare ethics consultation. The other is the Collaboration Conference of Hospital Ethics Committees, intended to provide a place for HEC members and administrative officers from across Japan to exchange information of their HECs, learn from each other, and cooperate to operate HECs appropriately. In this paper, the authors introduced CHEC as well as reported the results of a questionnaire survey conducted at the first conference among participating facilities, suggesting the diverse structures and activities of HECs in Japan.

**Keywords** Hospital ethics committee · Healthcare ethics consultation · Consortium of Hospital Ethics Committees in Japan · Healthcare Ethics Forum · Collaboration Conference of Hospital Ethics Committees · Clinical ethics

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### Introduction

The first ethics committee in the field of medical research and healthcare in Japan was launched in 1982 at Tokushima University Faculty of Medicine to deliberate on the clinical application of in vitro fertilization (Sakai 1989), and ethics committees were established in all the Japanese medical schools by the early 1990s (Akabayashi and Slingsby 2003). Since the term 'ethics committee' has been used variously in Japan (Akabayashi et al. 2007), the authors define and categorize ethics committees in this paper based on what they deal with as follows. Research ethics committee (REC) is defined as "an institutional ethics committee which is in charge of reviewing research involving human subject and has responsibility for approving or disapproving proposals to conduct research" (Levine 2004). Hospital ethics committee (HEC) is defined as "an institutional ethics committee that is responsible for ethics support in healthcare and deals with issues and cases related to clinical or healthcare ethics in medical institutions." RECs and HECs are not always distinguished in each medical institutions, and some of them have an ethics committee that functions as both a REC and a HEC.

Regarding clinical trials to obtain regulatory approval of Ministry of Health, Labour, and Welfare of Japan (MHLW), research protocol review was become mandatory in 1989. In addition, administrative guidelines enacted by MHLW in 2002 and 2003 required that almost all medical research involving human subjects undergo research protocol review before it could be conducted. It is assumed that these regulations have led many medical institutions that conduct medical research on human subjects to possess an ethics committees functioning as a REC. In fact, according to the MHLW's Research Ethics Review Committee Reporting System (MHLW 2022), there are 2334 committees registered as of August 2022. In the context of healthcare, Japan Council for Quality Health Care (JCQHC) began to apply the list of items to be evaluated for accreditation Ver. 4.0 in July 2003, which required that "a functioning system for reviewing ethically problematic cases and issues (4.1.3.1)." This is believed to have triggered the spread of an ethics committee functioning as a HEC and healthcare ethics consultation services in many Japanese hospitals (Akabayashi et al. 2007; Dowa et al. 2022). There were 2041 hospitals having JCQHC accreditation as of July 2022 (JCQHC 2022).

As for RECs, their roles, responsibilities, composition of committee members, education for committee members, and requirements for the establishment of meetings are specified in detail in the law and administrative guidelines, and the committee rules, member list, and outline of minutes must be made public in Japan. In terms of information sharing and collaboration among medical schools, the Liaison Association of Medical Schools' Ethics Committees has played an important role since its establishment in 1989 (Hoshino 1992), especially in the area of research ethics. On the other hand, there are no standards set by the government or academic societies for the establishment and operation of HECs, although they are responsible for essential and important roles such as healthcare ethics consultation, staff education on healthcare ethics, and the preparation of institutional ethical guidelines. JCQHC also has not provided explicit criteria for HECs. Furthermore, the structure and activities of HECs at each facility are rarely disclosed, and information sharing and collaboration among HECs is not sufficient.



Therefore, the authors started the Consortium of Hospital Ethics Committees in Japan (CHEC) with the aim of contributing to the improvement of the quality of healthcare in Japan through collaboration among HECs throughout Japan, working together toward the ideal HEC. This paper introduces CHEC and reports the results of a questionnaire survey of the participating facilities conducted at the first Collaboration Conference of Hospital Ethics Committees.

# **Consortium of Hospital Ethics Committees**

CHEC is a voluntary organization founded in October 2020 by the authors. As of August 2022, CHEC has 30 members and regularly hosts a couple of core activities. One is the Healthcare Ethics Forum, which is held monthly online for CHEC members to freely discuss HECs and healthcare ethics consultation. The other is the Collaboration Conference of Hospital Ethics Committees, which is intended to provide a place for HEC members and administrative officers from across Japan to exchange information, learn from each other, and cooperate to manage HECs appropriately.

# **Collaboration Conferences of Hospital Ethics Committees**

The first Collaboration Conference of Hospital Ethics Committees was held online on February 23, 2021 (Table 1). The invitation letters were sent to the HEC chairpersons of 151 university hospitals and 7 advanced treatment hospitals other than university hospital, and 53 facilities participated the conference. At the time of the conference, Dr. Yoshiyuki Takimoto from the University of Tokyo explained the purpose of establishing the CHEC after reviewing the history of HECs and healthcare ethics consultation in Japan. Dr. Hiroyuki Kaneda from Kansai Medical University Medical Center gave a lecture on "Challenges and Prospects for Healthcare Ethics Committees" based on his institution's experience with the HEC and healthcare ethics consultation. In addition, an online questionnaire survey was administered to participating facilities to share the current status of HECs and ethics consultation, and the results are presented on the spot.

The 2nd conference was held online on September 16, 2021, and participated by 56 facilities (Table 1). Dr. Yoshiyuki Kizawa from Kobe University Hospital and Dr. Kazuhiko Kabe from Saitama Medical Center, Saitama Medical University, gave lectures on what to expect from HECs from the standpoint of palliative care and neonatal medicine, respectively. A panel discussion followed between the speakers and participants.

The 3rd conference was held online on February 17, 2022, and participated by 39 facilities (Table 1). Dr. Yasuhiko Miura from The Jikei University Kashiwa Hospital reported on the HEC and practice of healthcare ethics consultation at his institution. In addition, Dr. Yumiko Matsumura from Kyoto University Hospital gave a lecture on patient safety and healthcare ethics, and a panel discussion was held between the speakers and participants.



	Date	Number of participating hospitals	Agenda
1st	February 23, 2021	53	Review of HEC in Japan and Establishment of CHEC (Dr. Yoshiyuki Takimoto, The Tokyo University Hospital) Challenges and Prospects for Healthcare Ethics Committees (Dr. Hiroyuki Knaeda, Kansai Medical University Medical Center) Questionnaire Survey and Sharing of the Results
2nd	September 16,2021	56	What to Expect from HEC (Dr. Yoshiyuki Kiazawa, Kobe University Hospital, and Dr. Kazuhiko Kabe, Saitama Medical Center, Saitama Medical University) Panel Discussion
3rd	February 17, 2022	39	HEC and Healthcare Ethics Consultation (Dr. Yasuhiko Miura, The Jikei University Kashiwa Hospital) Patient Safety and Healthcare Ethics (Dr. Yumiko Matsumura, Kyoto University Hospital) Panel Discussion

Table 1 Collaboration Conferences of Hospital Ethics Committees

At the time when the manuscript is being prepared, the 4th conference is scheduled for September 15, 2022. The conference will feature small group discussions on the topics of the issues and difficulties surrounding HECs and healthcare ethics consultation.

# Questionnaire Survey on Hospital Ethics Committees for the Participants of the First Conference

As noted above, an online questionnaire survey was conducted at the first Collaboration Conference of Hospital Ethics Committees on the structures and activities of HECs at each facility for the purpose of sharing information among participating facilities, and the results were shared online during the conference. Forty-seven of the participating facilities responded to the questionnaire survey.

Since this questionnaire survey was conducted during the conference, in which participating facilities were asked to respond in a short period of time, the information may not necessarily be accurate. Moreover, it is not considered universally applicable to all hospitals in Japan because only university hospitals and advanced treatment hospitals were allowed to participate the conference. However, it provides information on the current status and activities of HECs at these types of hospitals, and is considered to be of great value as a resource when considering HECs in Japan.

### Positioning of the Hospital Ethics Committee within the Hospital

The largest number of respondents (32 facilities) indicated that the HEC is an organization directly under the hospital director or an advisory board to the hospital



director (Table 2). Other facilities indicated that the HEC is subordinate to the highest decision-making body of the hospital, or belongs to the committee or department for patient safety. Of the hospitals having HECs separate from RECs, more than half of the responding hospitals indicated that their HEC and REC became a separate committee in 2016 or later, and only one hospital had had the separate HEC and REC before 2000. More than half of the hospitals responded that the reason for having separate HECs and RECs was to address JCQHC accreditation. Other reasons included requests from staff and occurrence of cases requiring HECs. Two hospitals cited busy workload of RECs as the reason.

As the method of reporting to the hospital director, most facilities indicated circulation of minutes or report submission, while two facilities indicated that there is no report to the hospital director (Table 2). Eight facilities responded that the hospital director attends the meeting and share information.

Table 2 Positioning of the Hospital Ethics Committee within the hospital

1. Positioning (Multiple answers allowed)	n = 47
Directly under the hospital director or an advisory board to the hospital director	32
Subordinate to the highest decision-making body of hospital administration	9
Belonging to a committee or department in charge of patient safety	6
Same committee as REC	3
Subordinate to REC	1
Others	5
2. When it became a separate committee from REC	
∽1989	0
1990~1999	1
2000~2005	1
2006~2010	6
2011~2015	11
2016∽	20
3. The reason for separate HEC from REC (Multiple answers allowed)	
To address JCQHC certification	23
Compliance to guidelines	5
Requests from staff	10
Occurrence of cases requiring HEC	14
Overload of REC	2
Unknown	8
Others	3
4. Report to hospital director (Multiple answers allowed)	n = 44
Circulation of minutes	27
Report submission	17
Attendance of hospital director	8
No report to hospital director	2



# Table 3 Configuration of Hospital Ethics Committees

1. Number of HEC members	n = 43
<b>∽</b> 5	1
6~10	15
11~15	18
16~20	6
21∽	3
2. Attributes of chair persons	n = 44
Hospital director	7
Vice director in charge of patient safety	11
Vice director in charge of something other than patient safety	7
Physician of patient safety department	6
Healthcare ethics expert (medical professional)	5
Healthcare ethics expert (non-medical professional)	2
Nurse	0
Others	6
3. Attributes of HEC members (multiple answers allowed)	n = 44
Hospital director	6
Vice director (physician)	29
Physician of patient safety department	31
Physician other than above	34
Director of nursing	27
Nurse	25
Pharmacist	32
Medical professional other than physician, nurse, and pharmacist	17
Social worker	17
Hospital administrative staff	31
Ethics expert	15
In-house attorney	2
Legal councel	10
Attorney other than in-house attorney and legal councel	10
Specialist in humanities and social sciences other than ethics	4
Representative for general public	9
Other	4
4. Number of external HEC members	n = 43
3~	5
2	5
1	10
0	10
0 (but a legal council is a member of HEC)	10
Others	3



# **Configuration of Hospital Ethics Committees**

The largest number of facilities (18) reported that a HEC consists of 11 to 15 members, followed by 6 to 10 members (Table 3). Three facilities reported their HECs have 21 or more members, and 1 facility has 5 or fewer members. HECs are chaired most frequently by a vice director in charge of patient safety (11 facilities), followed by a hospital director and a vice director in charge of something other than patient safety (7 facilities). Seven facilities have a medical or non-medical professional with expertise in healthcare ethics serving as chairperson of the HEC. None of the facilities indicated that a chairperson is a nurse. When asked about the attributes of HEC members in multiple responses, the most common responses were physicians including vice directors, physicians of patient safety department, followed by pharmacists, hospital administrative staff, directors of nursing, and nurses. Fifteen facilities reported that HEC members include ethics experts. There were facilities that reported to have attorneys serving on HECs; two facilities have in-house attorneys, 10 have legal counsel, and 10 have attorneys who are neither in-house nor legal counsel. Four facilities have experts of humanities and social science other than ethics on HECs. There were 9 facilities with HEC members representing the general public. Twenty facilities had external members.

## Frequency of Hospital Ethics Committee Meetings

The largest number of facilities (16) had rules stipulating that a HEC meeting be held monthly (Table 4). As for the number of HEC meetings actually held from January to December 2020, 13 facilities held 12 or more meetings, while 3 facilities reported that they did not hold any meetings.

**Table 4** Frequency of Hospital Ethics Committee meetings

1. Frequency stipulated in the committee rule	
Monthly (11 meetings/year)	16
6 meetings/year	5
Less than 6 meetings/year	5
Regular meetings are not stipulated and are only held when necessary	16
Others	2
2. Actual number of meetings held in 2020	n = 44
12 and more	13
6~11	10
3~5	11
1~2	7
0	3



# **Matters subjected to Hospital Ethics Committees**

Thirty-eight facilities indicated that HECs provide case consultation (Table 5). Other reported common agenda were development of policies for healthcare ethics and codes of ethics, high-risk medical practices, education on healthcare ethics, organ transplantation, as well as assisted reproductive technology. In another

 Table 5
 Matters subjected to Hospital Ethics Committees

Matters subjected to HECs (multiple answers allowed)	n = 44
Case consultation	38
High-risk medical practice	24
Healthcare not covered by health insurance	12
Usage of unapproved drugs and devices	12
Highly difficult novel medical technology	9
Off-label use of drugs and devices	15
Organ transplantation	19
Assisted reproductive technology	18
Development of policy for healthcare ethics	33
Development of staff code of ethics	12
Unprofessional staff	2
Education on healthcare ethics	20
Others	2
2. Entity implementing healthcare consultation	n = 44
Not implemented	5
HEC	15
Subcommittee of HEC	16
Separate organization from HEC	8
Patient safety department	5
Ethics support department	3
3. Ethics guidelines developed since 2018 (free-text data)	n = 14
Advance care planning	2
End-of-life care	4
Do-not-resuscitation orders	1
Refusal of blood transfusion for religious reasons	1
Informed Consent	2
Forgoing of dialysis	1
Others	6
4. Ethics guidelines developed in association with COVID-19 pandemic (multiple answers allowed)	n = 41
Allocation of medical resources such as ICU, mechanical ventilators, and ECMO	7
Advance care planning	3
Code of ethics	1
Forgoing of life sustaining treatment	1
Others	1
None	33



question, 39 of the 44 respondents indicated that their hospitals provide healthcare ethics consultation, 15 by a HEC itself, 16 by a subcommittee of a HEC, and 8 by a separate department from a HEC. The departments in charge of healthcare ethics consultation, apart from the HEC, are patient safety departments in 5 facilities and departments for ethical support in 3 facilities.

The development of institutional ethics policies and codes of ethics is one of important missions of HECs. Fourteen facilities reported HECs developed ethics policies since 2018, which included those on end-of-life care, informed consent, advance care planning, and refusal of blood transfusion for religious reasons (Table 5). For the question about institutional policies in relation to the coronavirus disease 2019 (COVID-19) pandemic, 8 of the 44 facilities responded that their HECs had developed some type of policies, including that on allocation of medical resources such as intensive care units, mechanical ventilators, and Extracorporeal Membrane Oxygenation (ECMO).

# **Perspective of the Consortium of Hospital Ethics Committees**

CHEC is an organization open to a wide range of medical and non-medical professionals involved in HECs and healthcare ethics consultation at medical institutions. Although the Collaboration Conference of Hospital Ethics Committees have so far accepted university hospitals and advanced treatment hospitals, the authors intend to invite many more medical institutions to join the conference in the near future. Through the activities, the authors plan to explore the ideal form of HECs and healthcare ethics consultation at medical institutions in Japan, as well as to disseminate information and skills on healthcare ethics.

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#### **Declarations**

**Ethics Approval** The research ethics approval for secondary use of the data was obtained from the Institutional Review Board for Clinical Research of Tokai University School of Medicine (21R095).

Consent to Participate and Consent to Publish Before conducting the survey, it was explained that participation was voluntary and that the obtained data might be published at academic communities. Prior to the use of the data for research, the research plan was publicized on the Consortium's website.

**Conflict of Interest** The authors declare no competing interests.

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