

Utilization of Information and Communication Technology in IRBs as a countermeasure against the COVID-19 outbreak and future challenges

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Abstract

Background : The worldwide spread of the new coronavirus disease 2019 (COVID-19) had an immediate impact on accelerating the introduction of alternative methods of operation for Institutional Review Boards (IRBs).

Methods : An online survey of IRBs was carried out in Japan from May 20 to 31, 2020.

A self-administered questionnaire on IRB organization, the impact of the COVID-19 outbreak on IRB operation, and the status of using Information and Communication Technology management and digital communication systems was distributed by e-mail to 520 IRBs.

Responses were collected electronically via the online questionnaire survey.

Results : A total of 97 IRBs participated in the survey. The majority of these were local IRBs (87%). Eighty-seven percent of the IRBs held monthly review meetings. Despite half of the IRBs reporting no impact, scheduling/holding the review meeting was affected in all clinical trials, with a greater impact on “Ongoing” trials than “New” trials to be submitted. The most common countermeasure was the introduction of a digital communication system. Thirty-four of the 38 IRBs (89%) installed such a system after the outbreak. Satisfaction with digital communication systems appeared to be lower than for electronic document management systems. The primary concern regarding the use of a digital communication system was “Facility”, followed by “Operation of the system”, and “Document delivery for review”. In addition, general concerns, measures, and proposals for current IRB management were noted for future analysis.

Conclusions : In the emergency caused by the COVID-19 outbreak, the introduction of a digital communication system contributed significantly to maintaining IRB operations. Analysis of the concerns identified should benefit future preparation for clinical trials.

Key words

COVID-19, Institutional Review Boards (IRBs), Information and Communication Technology (ICT), digital communication system

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1. Introduction

The COVID-19 outbreak has had a significant impact on the conducting of clinical trials¹⁾.

The major regulatory authorities issued notifications^{2~5)} regarding the response to the outbreak, and clients and Contract Research Organizations (CROs) presented response policies^{6~9)}. IRBs were also notified by the authorities^{10,11)} and each IRB responded accordingly.

The rapid development of Information and Communication Technology (ICT) in recent years has significantly transformed clinical trials. Moreover, the worldwide spread of the new coronavirus disease 2019 (COVID-19) had an immediate impact on accelerating the introduction of ICT, such as an electronic documentation and a digital communication systems, including the web-based meeting and the TV conference system, etc., to the operation of Institutional Review Boards (IRBs). As IRBs in particular are responsible for protecting the rights and welfare of the human subjects in clinical trials, they are expected to take various efforts in accordance with national policies.

This study aimed to investigate the use of ICT (electronic document management and digital communication systems) at Japanese IRBs before and after the outbreak. The study also identified concerns regarding the use of ICT that should be considered in order to establish a more functional and efficient IRB operational model in the future.

2. Method

An online questionnaire (Table 1) was designed and distributed to 520 IRBs in Japan registered in the Massive Network for Clinical Trials (MNCT), a nationwide network of hospitals and clinics developed by the Japan Medical Association

Center for Clinical Trials (JMACCT), via e-mail from JMACCT on May 20, 2020. A reminder was sent five days after the survey began in an effort to improve the response rate.

The anonymous responses containing no personal information were collected electronically from the online questionnaire survey conducted during the period May 20-31, 2020.

3. Results

3.1 Characteristics of IRBs

A total of 97 out of the 520 IRBs registered with MNCT responded during the survey period from May 20, 2020 through May 31, 2020.

The response rate (19%) was similar to that observed in the previous survey conducted by MNCT from April 20 through 30, 2020, “Announcement of the current condition of clinical trials under the outbreak in Japan”¹²⁾ regarding the status of new/ongoing clinical trials, restrictions to site visits, IRB meetings, the acceptance of online operation by sponsors, and the restriction of remote monitoring.

In this survey, we defined as “local IRBs” those IRBs established by individual clinical trial sites to review their own clinical trials; as “central IRBs” those established by an external organization to collectively review trials conducted at multiple clinical trial sites; and as “cooperative IRBs” those established by affiliated sites to review their trials.

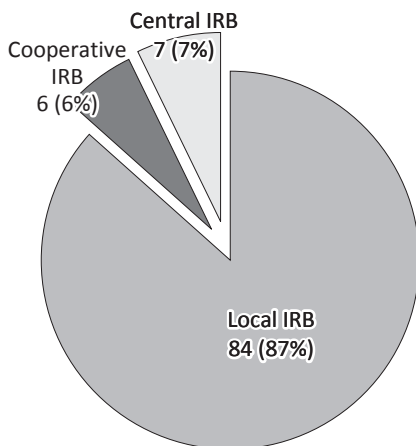
Based on this definition, 84 local IRBs, 7 central IRBs, and 6 cooperative IRBs participated in the survey (Fig. 1).

The most common frequency of review meetings was “monthly” (87%). Others (11%) met less than 9 times per year (bimonthly or every two months) (Fig. 2).

Table 1 Questionnaire format

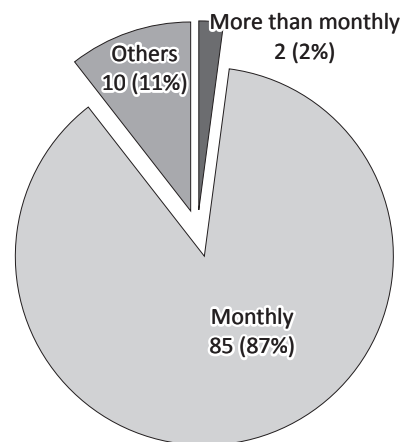
| Questionnaire format | |
|--|--|
| 1. Background | <ul style="list-style-type: none"> - Name of IRB - Type of IRB - Frequency of review meeting |
| 2. Impact of COVID-19 outbreak | <ul style="list-style-type: none"> - For "New" clinical trial to be submitted, which IRB procedure was affected by the Coronavirus disease (COVID-19) outbreak? - For "Ongoing" clinical trial to be submitted, which IRB procedure was affected by the COVID-19 outbreak? - What action(s) has/have been taken against the problems caused by the COVID-19 outbreak? |
| 3. Status of using an electronic document management system | <ul style="list-style-type: none"> - Did you use such a system for IRBs prior to the COVID-19 outbreak? - How satisfied are you with the system? - Do you have any concerns regarding the use of such a system for IRBs? |
| 4. Status of using a digital communication system | <ul style="list-style-type: none"> - Did you use such a system for IRBs prior to the COVID-19 outbreak? - How satisfied are you with the system? - Do you have any concern to use the system for IRB? - What written procedure have you defined to use the system? |
| 5. Comment: | <ul style="list-style-type: none"> - Current IRB management issues, measures to overcome these issues, and opinions for future responses (free text) |

Fig. 1 Types of IRBs



Types of IRBs (n=97)

Fig. 2 Frequency of IRB review meetings



Frequency of IRB review meeting (n=97)

3.2 IRB procedures affected by the COVID-19 outbreak

Fig. 3 shows the IRB procedures affected by the outbreak in “New” and “Ongoing” clinical trials that were reviewed by an IRB.

The outbreak was found to have affected similar procedures for both “New” and “Ongoing” clinical trials. However, “Scheduling/holding the review meeting” was impacted more in “Ongoing” clinical trials than in “New” clinical trials.

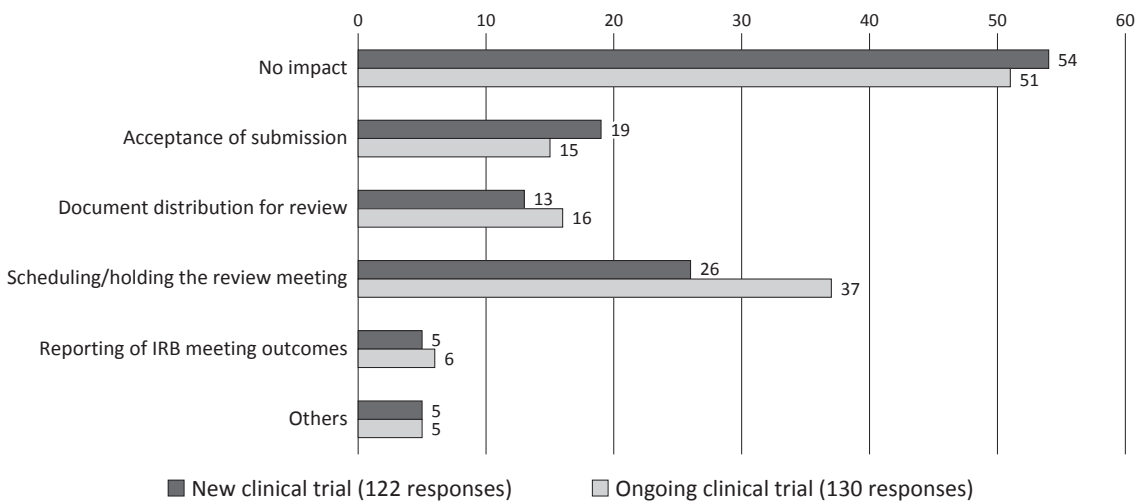
3.3 Use of electronic document management/digital communication system for IRB operation

Fig. 4-1 indicates the use of an electronic document management system (filing, reviewing, and storage) and digital communication system for IRB meetings at all 97 IRBs. In total 49% of the IRBs—9% introduced an electronic document management system only, 22% a digital communication system only, and 18% both systems—had either system. This also reflects the status of 84 local IRBs. In the case of central IRBs, 100% of

IRBs—29% an electronic document management system, 14% a digital communication system, and 57% both—had equipped either systems (Fig. 4-2). On the other hand, the introduction rate of ICT in cooperative IRBs was 67%, and all of them were a digital communication system at the time of the survey (Fig. 4-3).

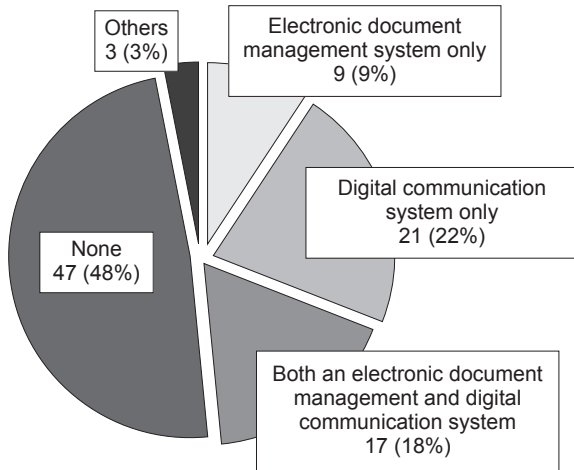
Fig. 5 shows whether the electronic document management and digital communication systems were introduced before or after the COVID-19 outbreak. Of the 26 IRBs using an electronic document management system, 24 (92%) installed the system before the outbreak. As regards digital communication systems, 34 (89%) out of 38 IRBs installed their system after the outbreak. All of 7 central IRBs were using an electronic document management system before the outbreak and introduced a digital communication system after the outbreak. In all 6 cooperative IRBs, which only used a digital communication system, one IRB introduced the system in advance, with the remaining 3 IRBs commencing use afterwards.

Fig. 3 IRB procedures affected by the COVID-19 outbreak (multiple responses permitted)



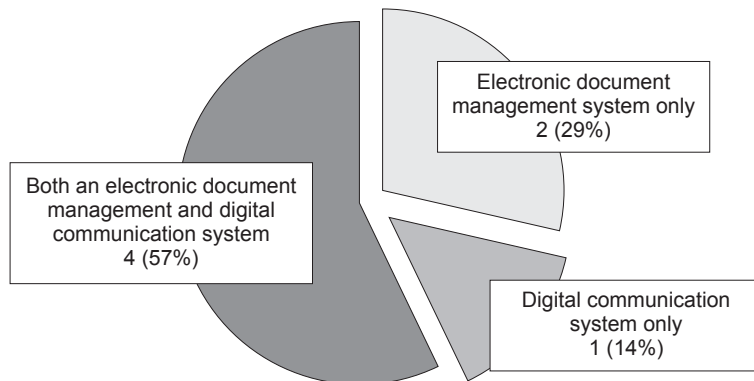
IRB procedure affected by the COVID-19 outbreak (n=97)

Fig. 4-1 Use of ICT by IRBs: Overall



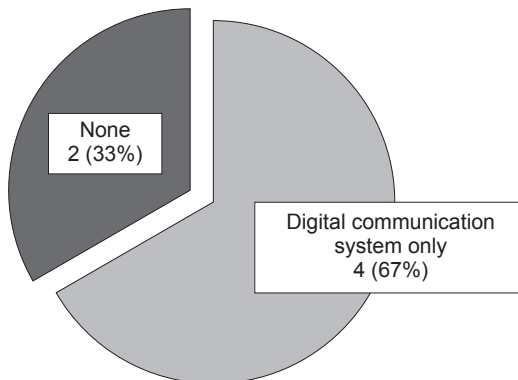
Use of ICT by IRBs: Overall (n=97)

Fig. 4-2 Use of ICT by IRBs: Central IRBs



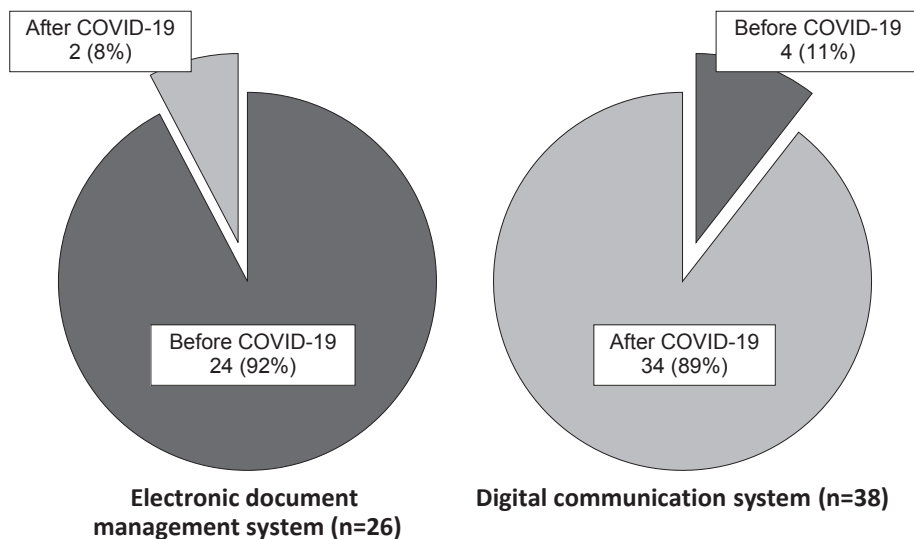
Use of ICT: Central IRB (n=7)

Fig. 4-3 Use of ICT by IRBs: Cooperative IRBs



Use of ICT: Cooperative IRB (n=6)

Fig. 5 Timing of the introduction of electronic document management/digital communication systems for IRBs



3.4 Satisfaction with the use of electronic document management/digital communication systems among IRBs

Fig. 6 shows the degree of satisfaction with the use of electronic document management and digital communication systems against the three categories of accessibility, usability, and speed/performance. For all categories, satisfaction with digital communication systems appeared to be lower than for electronic document management systems.

3.5 Actions taken against the COVID-19 outbreak for IRB continuity

The actions taken by IRBs against the outbreak, as described in the free column of the questionnaire, were summarized by category (Fig. 7). On the one hand, IRBs took various actions such as using a digital communication system (26), taking COVID-19 preventive action (22), including restricting site visits, the submission of materials for IRB review, and introducing written resolutions by e-mail/paper²⁾ (18). On the other hand, the postponement/cancellation of review meetings

was observed in 15 IRBs. Four local IRBs carried out the digitization of paper documents.

Since the majority of the IRBs participating in this survey were local IRBs, the actions they took were similar to those shown for Overall IRBs. No Standard Operation Procedure (SOP)-related actions by cooperative IRBs or postpone/cancellation by central IRBs were observed.

3.6 Written procedures for digital communication systems

Of the 38 IRBs that introduced a digital communication system, 13 (34%) created some procedural documentation for online IRB meetings. The specified documents confirmed by multiple response question were as follows: “Choice of operating system for online meetings” (7 IRBs), “Distribution method of documents for review” (5 IRBs), “Meeting facilitation method (e.g., the role of assistants, remarks, votes, etc.)” (4 IRBs), “User training for online meetings” (2 IRBs), and “Choice of device for each member (e.g., PC, tablet etc.) for online meetings” (1 IRB), followed by “Others”, including a user manual for online meetings.

Fig. 6 Satisfaction with electronic document management/digital communication systems

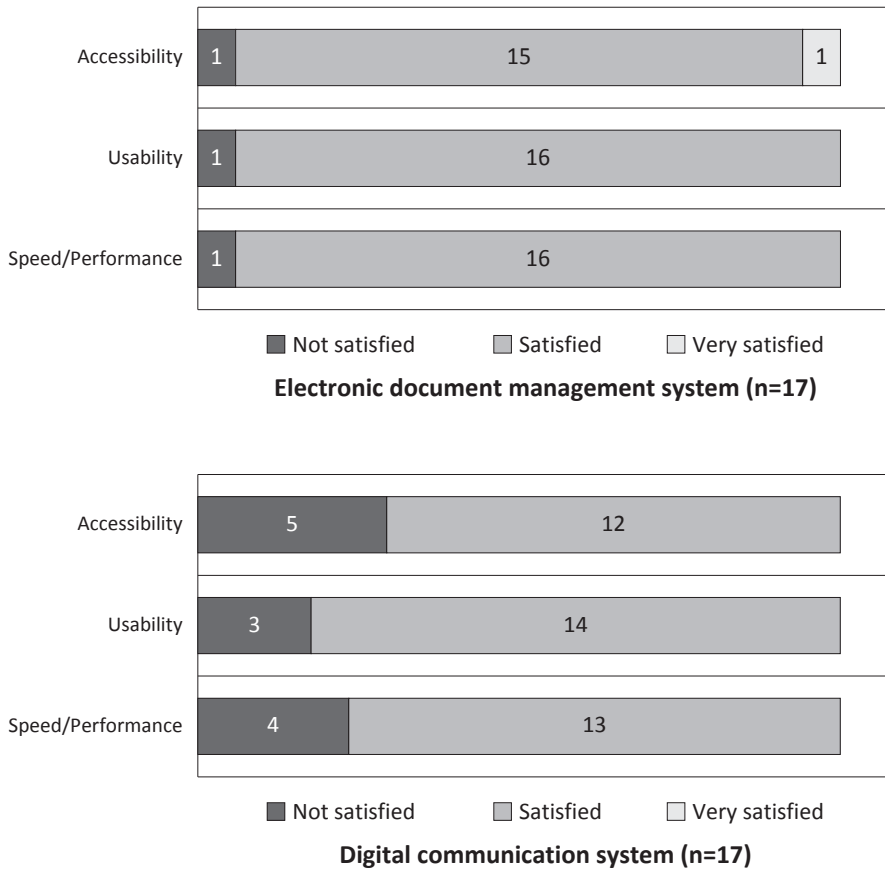
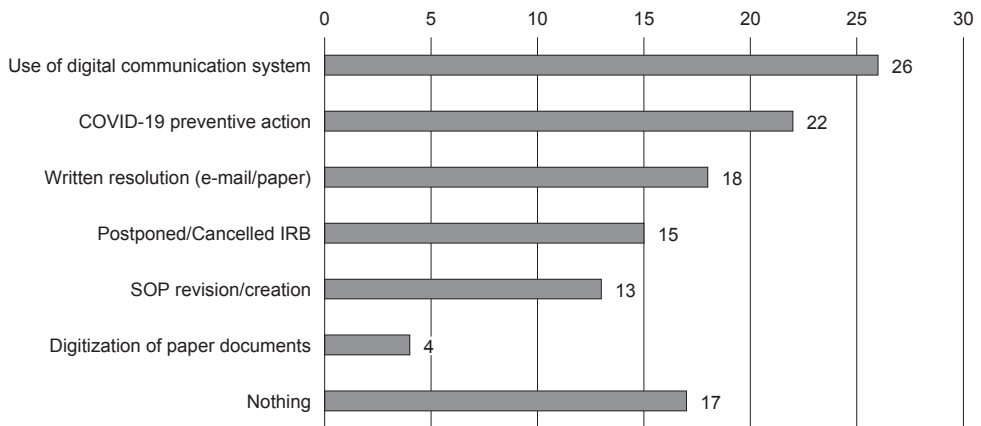


Fig. 7 Actions taken by IRBs against the impact of the COVID-19 outbreak: Overall (multiple responses permitted)



Actions taken by IRBs against the COVID-19 outbreak: Overall (n=97)

3.7 Concerns regarding digital communication systems

Fig. 8 shows the specific concerns regarding digital communication systems, grouped into 6 categories based on free text responses. “Facility” (30) was cited as the most common concern, which includes technical infrastructure, internet connection, choice of system/application, security, and system cost. Other concerns were “Operation of the system” (17), “Document delivery for review” (14), “SOP/Manual” (13), “Meeting quality” (12), including managing review meetings, facilitation, and “Staff resourcing” (4).

3.8 General concerns, measures, and proposals regarding current IRB management

Table 2 shows the summary of the descriptions of the general concerns, measures, and proposals regarding current IRB management from free text responses. Multiple responses of similar descriptions are summarized as representative description.

Seven categories of concerns—Facility (13) from 26 IRBs, SOP/Manual (5) from 15 IRBs, Digitization of paper documents (5) from 8 IRBs, Meeting quality (6) from 7 IRBs, Operation of the

system (2) from 3 IRBs, Staff resourcing (1) from 1 IRB, and Others (4) from 4 IRBs—were raised by 60 (62%) out of 97 IRBs.

As regards measures, seven comments were shown in three categories (Training, Meeting management, and Others). In addition, two proposals regarding legislation were provided.

4. Discussion

4.1 Characteristics of IRB centralization

Each local IRB operates IRB meetings differently, often with limited budgets and human resources, which may have made it difficult to adopt ICT. The centralization of IRBs such as central IRBs and cooperative IRBs, as the reviewing organizations for clinical trials, has been encouraged both within and outside Japan, in order to improve their efficiency^{13~16}. In Japan, the local IRB is dominant, as observed in this survey. Although the GCP in Japan stipulating the establishment of an IRB for each clinical trial site was revised in 2006^{17, 18}, their practice has not been changed, and it seems that many studies are still reviewed by local IRBs¹⁹.

Fig. 8 Concerns regarding digital communication systems (multiple responses permitted)

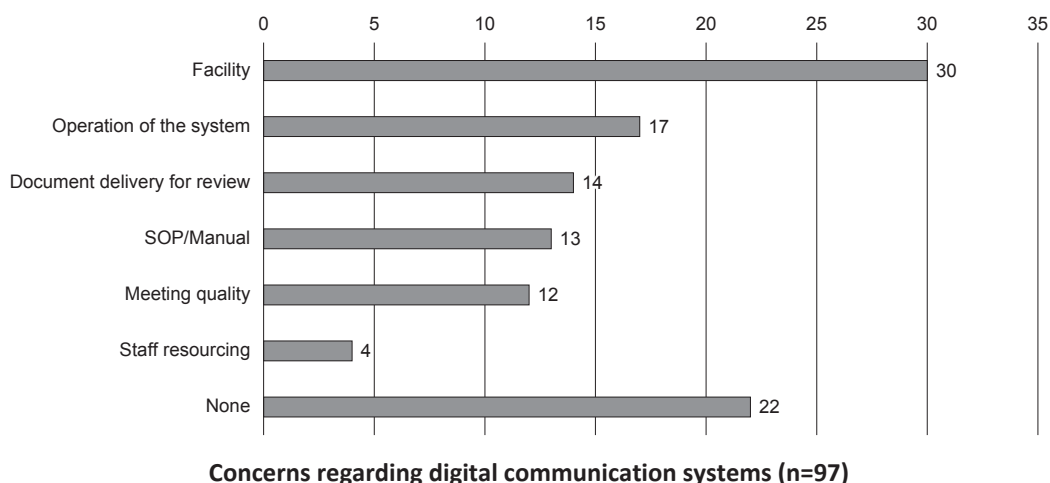


Table 2 General concerns, measures, and proposals regarding current IRB management*

| Concern (number of responded IRBs) | Description [number of comments] |
|--|---|
| Facility (26) | Introduction/Fulfillment of online meeting system [12] Preparation of equipment (Tablet etc.) [2] Personal environment of internet connection [2] Data security [1] Choice of online meeting system [1] Data capacity [1] Increase in workload (time and cost) [1] Back-up system against system trouble [1] Use of non-corporate account [1] Protection of information [1] Function of online meeting system [1] Inferior to a face-to-face meeting [1] Document archiving [1] |
| SOP/Manual (15) | Development of SOP for an online meeting (preparation, implementation, and reporting) [7] Revision of SOP [2] Level of SOP and other preparation [1] Choice of meeting method (face-to-face/online) [2] Contingency plan [3] |
| Digitization of paper documents (8) | Computerization of documents [4] Electronic archive of documents [1] Delivery of documents [1] Viewing documents on a PC display [1] Difficulty of document computerization due to seal impression requirement [1] |
| Meeting quality (7) | Meeting quality equivalent to a face-to-face meeting [2] TV conference inferior in number of remarks compared to a face-to-face meeting [1] Efficiency of meeting, especially dealing with safety information [1] Activation of discussion involving all IRB members [1] Method of annual review [1] Quality of review meeting [1] |
| Operation of the system (3) | Training for IRB members [2] Difference in the system operation skills of IRB members [1] |
| Staff resourcing (1) | Limitation in securing the number of staff (2 at most) to support an online meeting [1] |
| Others (4) | Deepen understanding of GCP [1] Measures in the event of prolongation of the COVID-19 outbreak [1] Restrictions on implementation of remote work associated with organizational structure [1] Difficulty in confirming the review status at Central IRBs [1] |
| Measure (number of responded IRBs) | Description [number of comments] |
| Training (2) | Giving small lectures on basic knowledge for clinical trials, including regulatory requirements, disease, and current topics, with a quiz by the IRB secretariat office [1] Provision of an explanation of the disease targeted in the clinical trial by the principal investigator [1] |
| Meeting management (2) | Considering consistency in the quality and ease of confirmation of documents for review [1] Sharing questions prior to the IRB meeting [1] |
| Others (4) | Preventive action for COVID-19 at face-to-face IRB meetings [2] Outsourcing of the IRB secretariat [1] No measure. Just hope COVID-19 ends[1] |
| Proposal (number of responded IRBs) | Description [number of comments] |
| Legislation (2) | Enactment of the law of written resolution and emergency and disaster response systems [1] Approval of certified and trusted systems for digital communication system by the government [1] |

* : Including responses from 4 IRBs in multiple categories

4.2 IRB procedures affected by the COVID-19 outbreak

Half of the IRBs stated that they had seen no impact to their activities as a result of the outbreak, suggesting they were able to maintain routine IRB activities by introducing alternative methods such as a digital communication system, regardless of the form of the IRB. Our survey results indicate a slightly greater impact on “Acceptance of submission” of “New” clinical trials compared with “Ongoing” clinical trials. This would be due to the complexity of the review process required for “New” clinical trials. In addition, this may have been caused by sponsor’s decisions to temporarily postpone the initiation of new clinical trials in response to COVID-19 outbreak^{6,7)}. On the other hand, in the “Ongoing” clinical trials, submission control was more difficult than in the “New” clinical trials, and as a result, the procedures for “Document distribution for review” and “Scheduling/holding the review meeting” may have been affected.

Reporting procedures of IRB was found to be the area that saw the least impact, probably since these are undertaken as a manageable internal operation unrelated to the stage of clinical trials.

Notifications issued by PMDA, as the regulatory authority in Japan, encouraging alternative communication such as “e-mail exchange for written resolution” could have promoted the changes. In addition, recent advances in ICT may have been effective in encouraging the rapid introduction of digital communication systems, as observed in our survey.

4.3 Use of online systems by type of IRB

More than half of the IRBs were already using an online system in their operation, either an electronic document management or digital communication system.

Among the IRBs using an electronic document management system, 92% introduced it before the

outbreak, while among those using a digital communication system, it was available before the outbreak in only 11% of IRBs. While cooperative IRBs had a digital communication system only, central IRBs were better equipped with regard to taking proactive actions to efficiently conduct diverse reviews. Local IRBs may have found electronic document management systems to be particularly favorable since most of their documentation and handling tends to be paper-based.

4.4 Satisfaction with electronic document management/digital communication system

In general, satisfaction with digital communication systems was lower than that for document management systems. This difference in satisfaction may reflect the fact that most of the document management systems in question were introduced before the outbreak, thus providing IRBs with sufficient time to spend on their introduction, while many of the digital communication systems were introduced as an emergency response, with little time to adjust.

This also explains why fewer than 40% of the IRBs that had installed a digital communication system had also completed specific written procedures for online meetings. The procedures prepared were largely limited to administrative matters such as for “Choice of operating system for online meetings” and “Distribution method of documents for review”. If digital communication systems are to remain as the primary method by which IRB review meetings are conducted from now on, a series of procedures will need to be developed, including the training of system users.

4.5 Concerns, measures, and proposals for current IRB management

The greatest concern among IRBs centered on the introduction and maintenance of the operating

condition, such as internet connectivity and data security, in addition to the system (application) itself. Their second-biggest concern was for “Operations using the system”, which may reflect the characteristics of the system. Unlike in the case of an electronic document management system, users are required to operate digital communication systems by themselves. Thus, the problem revolves around how to train users who are unfamiliar with the system, enabling them to operate it independently.

While there were concerns about the deterioration of the quality of meetings due to changes in the environment of the review meeting, it was also confirmed that effective meeting management was achieved through measures such as devising hand-outs and prior sharing of questions. Fortunately, the IRBs were eager to carry out their reviews in accordance with their roles and responsibilities and the active use of an available online system is expected to contribute to the sustainable management structure of clinical trials in the future²⁰.

5. Conclusion

The COVID-19 outbreak has had a significant impact on the conducting of clinical trials; however, it has also introduced the possibility of a major paradigm shift toward a new model for clinical trials in the post-COVID-19 era.

This study has identified the impacts of the outbreak on the operation of IRBs and explored both the actions taken and their concerns, as investigated through a nationwide questionnaire survey. Although the outbreak has had a significant impact on IRB operations, we found that most of the IRBs we surveyed had acted quickly to meet their obligations.

While the majority of issues were related to digital communication systems, others were found to fundamentally be about improving the functionality and

efficiency of IRB meetings, which as an issue had already been discussed before the outbreak. In this sense, the outbreak may have provided them with the opportunity to realize an ideal IRB operation.

It is important that the changes and perceptions effected by the outbreak do not become merely temporary responses. Rather, they should be linked to continuous improvements in IRB function and its efficiency for the future.

Conflict of Interest

The authors have no conflicts of interest directly relevant to the content of this article.

Acknowledgments

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