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Status survey on research ethics education for physicians: toward proper clinical research

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Objective: Physicians in hospitals and clinics were surveyed to clarify the status of research ethics education and learning motives, and any differences depending upon their affiliations.
Methods: This study was commissioned to a questionnaire survey company. We conducted an anonymous internet questionnaire survey among 200 randomly selected physicians from multiple locations throughout Japan. There were 100 physicians each who worked in a hospital or a clinic. The main survey items included degree of recognition of terminology related to clinical research, current opportunities for research ethics education. The status of clinical research at their workplaces and their reasons for receiving research ethics education as a physician were also asked to determine their learning motives.
Results: Regardless of affiliation, many respondents answered that they could explain the content of "Clinical research" in terms of their recognition of clinical research-related terms. On the other hand, with regard to the "Research ethics committee," significantly more physicians who work in hospitals answered that they could explain the contents. Regarding "Learning motives," a significant difference was found between the two groups for the extrinsic motivation "Adaptation" and "Remuneration."
Conclusion: To learn research ethics actively, not only intrinsic but also extrinsic motivation was found to be important.

Key words: research ethics education, learning motives, intrinsic motivation, extrinsic motivation

Introduction

To ensure the proper conduct of clinical research, in Japan, several laws and ethical guidelines have been established, including the "Ministerial Ordinance on Good Clinical Practice (Ordinance of the Ministry of Health and Welfare No. 28 of March 27, 1997)," "Clinical Trials Act (Act No. 16 of April 14, 2017)," and "Ethical Guidelines for Medical Research Involving Humans (Ministry of Education, Culture, Sports, Science and Technology and Ministry of Health, Labour and Welfare Notification No. 3 of 2014, revised in 2021)."

Background to this subject are multiple issues of clinical research misconduct discovered one after another from the 2000s to recent years. In particular, there is a relatively wide range of misconduct related to the reliability of clinical research such as falsification and fabrication, issues related to conflicts of interest, and issues related to the protection of human subjects due to inappropriate informed consent.[1]

After reflections on cases of misconduct in clinical research in the past, laws and ethical guidelines on clinical research now stipulate regulations concerning the education and training of researchers, and require those involved in clinical research to receive education on research ethics before starting research. The trend to implement research ethics education has also affected the education on that subject in medical schools. In medical schools in Japan, "Medical Research and Ethics" was established as a new subject in the Model Core Curriculum for Medical Education, and revised in 2016, requiring students to learn ethical standards in medical research in particular. Thus, the importance of research ethics education for researchers has been increasing year

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by year, and research institutions have been conducting in-house research ethics education in various ways.[2]

Preceeding that, in 2015, a system for core clinical research hospitals was established.[3] In that system, consultation on the implementation of clinical research, provision of necessary information, and so forth, to other hospitals or clinics, and support for clinical research conducted by other facilities, were required. Furthermore, since the 2000s, as clinical trials have become more active, the number of institutions that support the implementation of clinical research such as clinical research organizations and site management organizations has increased, and the scope of clinical research has widened, even in hospitals and clinics with relatively little clinical research experience. Physicians are often the principal investigators conducting clinical research, making continuous research ethics education for physicians important for the proper execution of their research.

Physicians working in hospitals and clinics throughout Japan were randomly surveyed to clarify the status of research ethics education and clinical research, and to determine if there were any significant differences depending upon their affiliations.

Methods

Survey methods and targets

This study was outsourced to a questionnaire survey company (Nextit Research Institute, Hyogo), and conducted among approximately 1,300 physicians from September 2018, who registered for market research purposes. The subjects for the present survey were complete when the number of respondents reached 100 physicians affiliated with hospitals and 100 physicians affiliated with clinics. For the purposes of the present study, we conducted an anonymous Internet questionnaire survey, from November 28 to December 12, 2018, of those physicians working in hospitals and clinics who composed the "H" and "C" groups, respectively.

Survey items

The main survey items were basic information (e.g., sex, age, workplace, etc.), degree of recognition of terminology related to clinical research (e.g., Clinical Research, Research Ethics Committee, and Ethical Guidelines for Medical and Health Research Involving Human Subjects), current opportunities and methods of research ethics education, and hopes and methods of future research ethics education. Qusetions on the status of clinical research at the respondents' workplaces and the reasons for their receiving research ethics education as a physician (i.e., learning motives) were also asked.

The "Learning motives" question was prepared referring to Arita et al.[4] in their awareness survey on research ethics education for pharmacists (Table 1). The answers were on a 5-point Likert scale, from 1 to 5, "Hardly applicable" to "Very applicable," respectively.

Analysis method

The χ^2 test was used to analyze the respondents' degree of recognition of clinical research-related terminology, the desire to receive research ethics education, and the situation regarding the field of clinical research and ethical problems. The *t* test was used to determine the difference in the mean values of "Learning motives." Values of $P < 0.05$ were concidered to indicate statistical significance. JMP 14.0.0 software was used for the analyses.

Ethical consideration

This study was conducted after an application was submitted to the research ethics committee of Kitasato University Kitasato Institute Hospital, and the decision was made that an ethics review was unnecessary (No. 18081), as the study was an anonymous and voluntary Internet questionnaire survey conducted through an independent research company (Nextit Research Institute, Hyogo), and no personal information from the respondents was collected, nor were the questions invasive.

Table 1. Learning motivation questions and labels

Questions	Items	Learning motives
1.	Fulfillment	Desire to learn something new
2.	Training	Desire to learn how to think in medical practice
3.	Practice	I want to use the knowledge I have learned to practice medicine.
4.	Adaptation	Everyone does it, so I think it's natural.
5.	Conformity	The doctors around me study a lot, so I'm obsessed with it.
6.	Self-respect	It's natural for doctors to train themselves.
7.	Remuneration	By getting training credits, you can become a certified or professional doctor.

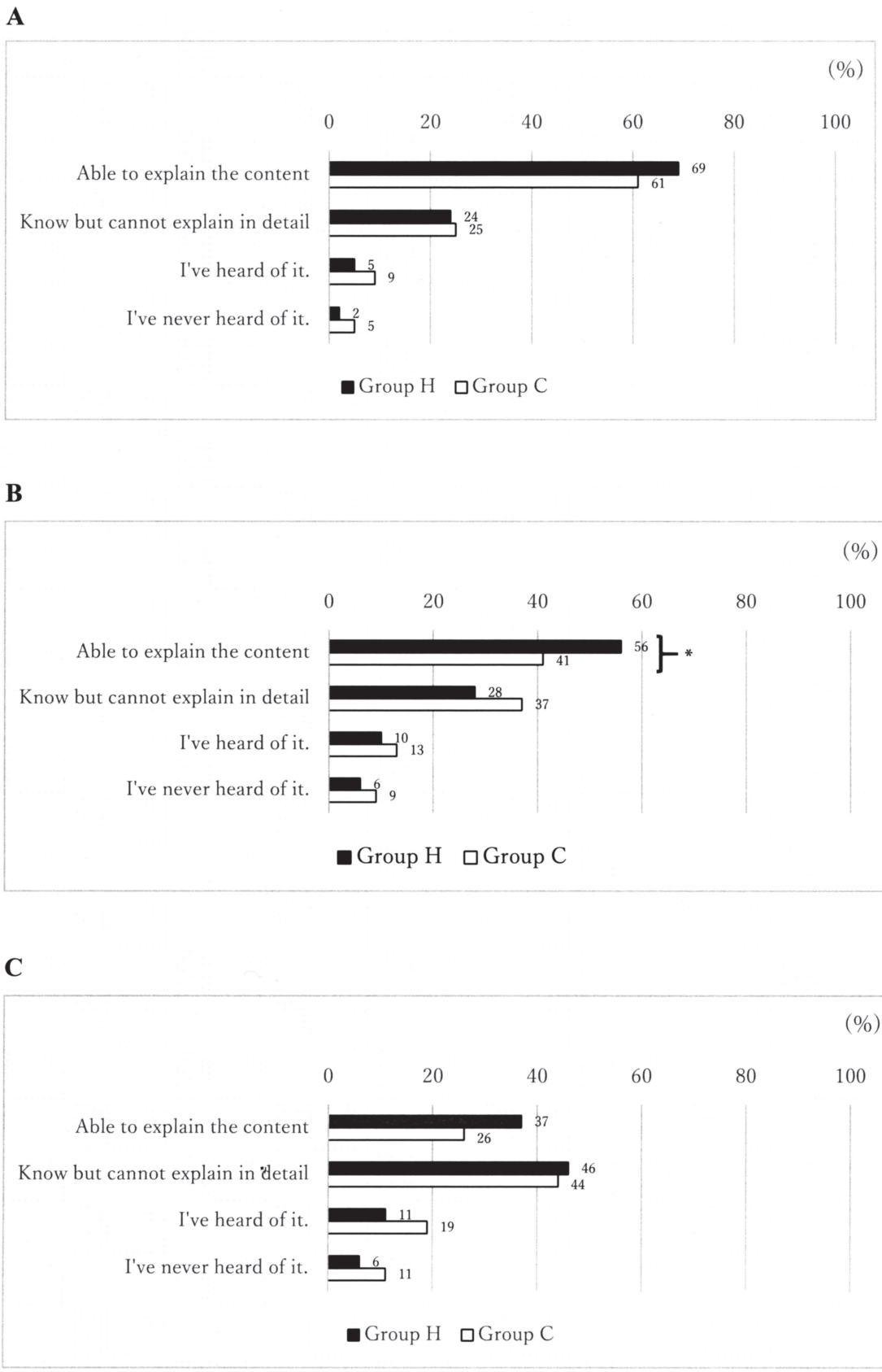

Figure 1. Awareness of clinical research terms (Group H, n = 100; Group C, n = 100)

A. Clinical Research
B. Research Ethics Committee
C. Ethical Guidelines for Medical and Health Research Involving Human Subjects
*P < 0.05, χ^2 test

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Results

The attributes of the 200 respondents are shown in Table 2.

Awareness of research ethics-related terms
The most frequent responses in terms of awareness of terms related to clinical research were: Able to explain the content" (130 respondents, 65%) for "Clinical research," "Able to explain the content" (97 respondents, 48.5%) for "Research ethics committee," and "Know but cannot explain in detail" (90 respondents, 45%) for "Ethical Guidelines for Medical and Health Research Involving Human Subjects."

By affiliation, the most common answer for "Clinical research" was "Able to explain the content," with 69 and 61 respondents from groups H and C, respectively. As for "Research ethics committee," the most common response was "Able to explain the content," with 56 and 41 from groups H and C, respectively (χ^2 test, $P < 0.05$). On the other hand, regarding the "Ethical Guidelines for Medical and Health Research Involving Human Subjects," "Know but canot explain in detail" was the most common response for 46 and 44 respondents from groups H and C, respectively (Figure 1).

Table 2. Respondent attributes

Variable	Group H (n = 100)	Group C (n = 100)
Age		
20s	2	2
30s	13	10
40s	35	18
50s	30	44
60s and older	20	26
Sex		
Male	88	84
Female	12	16
Education		
University graduate	60	70
Graduate	40	29
Other	0	1
Working as a doctor	23 years	25 years

Experience in research ethics education
Regarding their experience in research ethics education, 39 respondents (19.5%) reported that they had never studied research ethics. Regarding the time of receiving education and learning methods, among those who answered, "Have studied research ethics," the most common response was, "After employment in a medical institution" (77 respondents [38.5%]). Regarding learning methods, 120 respondents (60%) answered, "Lecture (classroom study only)," and 42 respondents (21%) answered, "E-learning" (multiple answers allowed).

By affiliation, "Have never studied research ethics" was the answer of 18 and 21 respondents from groups H and C, respectively. Regarding the period when group H respondents were educated, "After employment in a

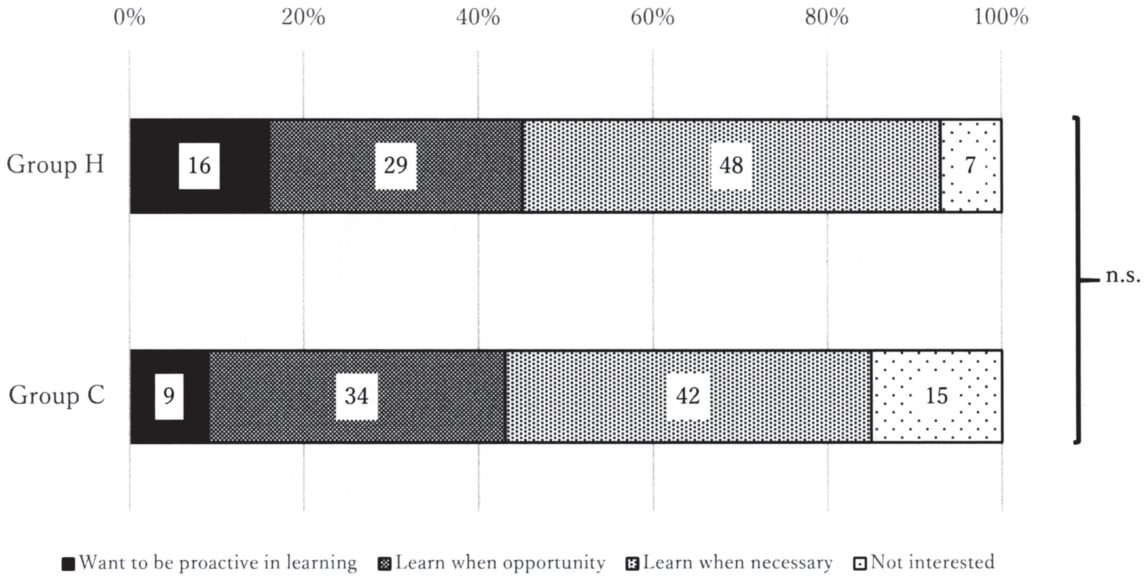

Figure 2. Motivation to study research ethics education (Group H, n = 100; Group C, n = 100)
ns: not significant, χ^2 test

medical institution" was the most common response (43 respondents), followed by "College student" (27 respondents) and "Graduate student" (18 respondents). Regarding the learning methods, "Lecture (classroom study only)" was the most common answer (62 respondents), followed by "E-learning" (24 respondents) and "Participatory (group discussion, etc.)" (17 respondents). Among group C physicians, there were 34 who answered, "After employment in a medical institution," 32 who answered "College student," and 18, "Graduate student." Regarding learning methods, "Lecture (classroom study only)" was the most common with 58 physicians, 18 for "E-learning," and 13 for, "Participatory (group discussion)."

Future research ethics education

When asked about their willingness to study research ethics in the future, 90 persons (45%) reported "Learn when necessary," followed by 63 persons (31.5%) who wanted to "Learn if given the opportunity." By affiliation, "Learn when necessary" was the most common, with 48 and 42 respondents from groups H and C, respectively, followed by "Learn if given the opportunity," with 29 and 34 respondents from groups H and C, respectively (Figure 2). We found no significant difference between the groups.

When asked about their preferred learning method based on multiple answers, 113 respondents chose "Lecture (classroom study only)," 85 chose "E-learning," and 31 chose "Participatory (group discussion)." By affiliation, "Lecture (classroom study only)" was the most common, with 58 and 55 respondents from groups H and C, respectively, followed by "E-learning," with 44 and 41 respondents from groups H and C, respectively, and "Participatory (group discussion)," with 22 and 9 respondents from groups H and C, respectively. As for the desired learning frequency, most physicians answered, "Several times a year," with 45 and 43 respondents from groups H and C, respectively, followed by "One time only," with 40 and 35 respondents from groups H and C,

Table 3. Situations regarding clinical research and ethics

Question	Answer	Group H (n = 100)	Group C (n = 100)	χ^2 test
Promotion of clinical research	Yes	38	15	0.0002
	No	62	85	
Opportunities to examine ethical issues	Yes	59	22	<0.0001
	No	41	78	

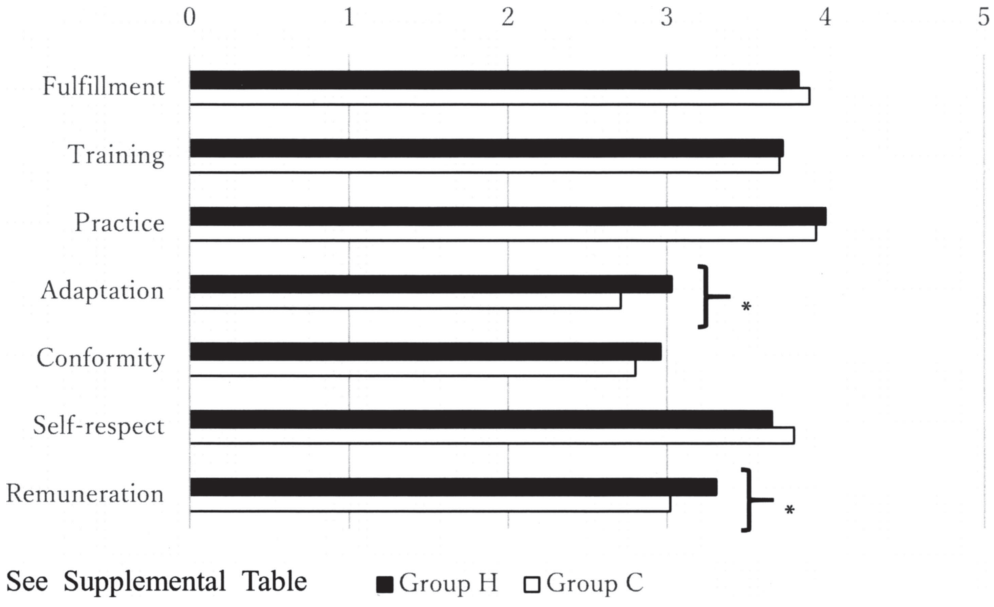

Figure 3. Average score of "Learning Motives" (Group H, n = 100; Group C, n = 100)
*P < 0.05, *t* test
See Supplemental Table

respectively. In addition, "Series (12 times a year)" had 8 and 7 respondents from groups H and C, respectively.

Environment related to research implementation

The results of the survey on the status of "Promotion of clinical research" and "Opportunities to examine ethical issues" are shown in Table 3. Regarding "Promotion of clinical research," 38 and 15 respondents from groups H and C, respectively, answered "Yes," showing a significant difference between the groups (χ^2 test, P = 0.0002). Regarding "Opportunities to examine ethical issues," 59 and 22 respondents from groups H and C, respectively, answered "Yes," showing a significant difference between the groups (χ^2 test, P < 0.0001).

Physicians' motivation to learn

The mean scores for "Learning motives" in each group are shown in Figure 3. With regard to "Learning motives," in group H, the mean value of "Practice" was the highest at 4.00 ± 0.82, followed by "Fulfillment," "Training," and "Conformity" at 2.96 ± 0.94. On the other hand, in group C, "Practice" had the highest value at 3.94 ± 0.76, followed by "Fulfillment," "Self-respect," and "Adaptation," which had the lowest value at 2.71 ± 0.98. A significant difference was found between the two groups for "Adaptation" and "Remuneration" (*t* test, P < 0.05).

Discussion

The statuses of research ethics education and clinical research were clarified for the medical profession with a high possibility of being elected as the research director in the implementation of clinical research. Regardless of affiliation, many respondents answered that they could explain the contents of "Clinical research" with clinical research-related terms. On the other hand, regarding the "Research ethics committee," significantly more physicians in group H answered that they could explain the contents. Considering the establishment criteria, e.g., the committee composition of research ethics committees are specified in the ethics guidelines, it is likely that many clinics do not have research ethics committees. Therefore, the recognition of the "Research ethics committee" was low in group C.

Regarding the "Ethical Guidelines for Medical and Health Research Involving Human Subjects," which is the basic ethical guideline for clinical research, the most common answer was, "Know but cannot explain in detail," in both groups, revealing the current situation where the progress of understanding the ethical guidelines is insufficient. Concerning clinical trials for the new drug application (NDA), an administrative notice was issued in accordance with Notification No. 874 of the Pharmaceutical Affairs Bureau issued by the Pharmaceutical Affairs Bureau of Japan on October 2, 1989, to ensure that clinical trials are conducted scientifically and properly on the basis of ethical considerations. Thereafter, in 1997, the "Ministerial Ordinance on Good Clinical Practice (Ordinance of the Ministry of Health and Welfare No. 28 of March 27, 1997)" based on the ICH-GCP (International Council for Harmonisation-Good Clinical Practice) was issued. Presently, strict implementation is required under the law. Regarding clinical research other than clinical trials with an NDA, the Ethics Guidelines for Clinical Research was issued in 2003, and the latest version of the ethics guidelines was also issued in June 2021 with several revisions.

In 2018, some clinical research was required to comply with other laws, not including the ethics guidelines. As the regulations on clinical research have been rapidly updated in recent years, many respondents could not keep up with the latest information and answered that they "Know but cannot explain in detail" the "Ethical Guidelines for Medical and Health Research Involving Human Subjects." The ethical guidelines for clinical research have been frequently revised because of the occurrence of irregularities in clinical research. Irregularities in clinical research have been frequently publicized since the early 2000s. According to published reports,[5-7] one of the reasons is that awareness of research ethics and ethical guidelines is low, even in recent years. Awareness of the "Ethical Guidelines for Medical and Health Research Involving Human Subjects," which is an administrative guideline rather than a legal regulation, such as clinical trials for the NDA, is low. Therefore, we suggest the importance of and necessity for research ethics education.

A total of 39 respondents aswered, "I've never studied research ethics." In addition, even among those who answered, "I have studied research ethics" most of the time, such education was received after employment. As for the learning method, "Lecture (classroom study only)" and "E-learning" were most common. In terms of future research ethics education, the most common response was to "Learn when necessary," and a few physicians wanted to learn by participating in role plays and other activities. The results suggest that physicians are more likely to learn research ethics when necessary and in a passive way. Students learning in passive learning settings such as classroom and e-learning are less likely

Supplemental Table

Item	Group	Average	±SD
Fulfillment	H	3.83	0.85
	C	3.90	0.72
Training	H	3.73	0.80
	C	3.71	0.81
Practice	H	4.00	0.82
	C	3.94	0.76
Adaptation	H	3.03	0.94
	C	2.71	0.98
Conformity	H	2.96	0.94
	C	2.80	1.02
Self-respect	H	3.66	1.02
	C	3.80	0.72
Remuneration	H	3.31	3.02
	C	1.02	1.02

to retain that acquired knowledge than those who learn in workshops in which the students can participate in discussions with the teacher and other students,[8] so that a participatory education program should be provided in combination with e-learning.

In this study, we also investigated physicians' motivations to learn. As for the physicians' reasons to study, high scores were given for: "Practice," "I want to use the knowledge I have learned to practice medicine," "Fulfillment," and "Desire to learn something new". These are so-called intrinsic motivations, and the acquisition of new knowledge and the utilization of this knowledge in the work would motivate physicians to study. Intrinsic motivational behavior is long-lasting[9] and, from a long-term perspective, more important than extrinsic motivation.[10,11] These results are consistent with the results of the survey of pharmacists in pharmacies[4] that suggested that this is an important feature in

Survey summary

1. Sex
   A) Male
   B) Female

2. Age
   A) 20s
   B) 30s
   C) 40s
   D) 50s
   E) 60s and older

3. Education
   A) University graduate
   B) Graduate
   C) Other

4. Term of medical practice (years, months)

5. Select the "Clinical research" that apply.
   A) Able to explain the content
   B) Know but cannot explain in detail
   C) I've heard of it.
   D) I've never heard of it.

6. Selection of items applicable to "Research ethics committee"
   A) Able to explain the content
   B) Know but cannot explain in detail
   C) I've heard of it.
   D) I've never heard of it.

7. Select items that apply to "Ethical Guidelines for Medical and Health Research Involving Human Subjects."*1
   A) Able to explain the content
   B) Know but cannot explain in detail
   C) I've heard of it.
   D) I've never heard of it.

8. Period of study of research ethics
   A) College student days
   B) Graduate student days
   C) After employment in a medical institution
   D) Other
   E) I've never studied research ethics.

9. To the respondents who selected (A) College student days to (D) Other in 6, the method at that time was:
   A) Lecture (classroom study only)
   B) Participatory (group discussion, etc.)
   C) E-learning
   D) Other

10. Do you want to learn about research ethics in the future?
   A) Want to be proactive in learning
   B) Want to learn if given the opportunity
   C) Want to learn when necessary
   D) Not interested

11. Frequency of desired education in 8 above
   A) One time only
   B) Several times a year
   C) Series (12 times a year, etc.)
   D) Others

12. The preferred method of education in 8 above
   A) Lecture (classroom study only)
   B) Participatory (group discussion, etc.)
   C) E-learning
   D) Other

13. Does your current employer promote clinical research?
   A) Yes
   B) No

14. Does your current employer present the opportunity and have a place to review ethical issues?
   A) Yes
   B) No

motivating medical professionals to learn.

Comparison by affiliations revealed that group H, compared with group C, attached more importance to external motivation such as the influence from surroundings, e.g., "Adaptation," "Everyone does it, so I think it's natural," "Remuneration," and "By getting training credits, you can become a certified or professional doctor." The results (Table 3) of this study also clarified that physicians in group H had significantly more opportunities to examine clinical research promotions and ethical problems. We speculated that physicians who work in hospitals might receive research ethics education in their work environment and by other external means, even if their individual learning volition toward the subject is negative. On the other hand, it is necessary for physicians working at clinics to increase their motivation to learn; therefore, creating an environment in which multiple medical institutions jointly create learning opportunities may also prove to be desirable.

The present study somewhat clarifies the current status of research ethics education for physicians working in hospitals and clinics. To learn research ethics actively, not only intrinsic but also extrinsic motivation was found to be important. A limitation may be that the respondents in this study were physcians who voluntarily registered with an Internet research source, so they may be an atypically motivated cohort. In addition, because the data on the size of the medical institution where the respondents work and the respondent's own previous clinical research experience was not collected, discussing the possible effects of the study was difficult. To properly conduct clinical research, continuous research ethics education is essential. We plan to conduct further detailed surveys in the near future.

Acknowledgments

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Conflicts of Interest: None

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