Implementation of clinical research coordinator hospital certification course to spread understanding of clinical trials

Toshiko Miyamoto*[1], Akiyo Akaishi*[1], Tomoko Takagai*[2], Kikue Kida*[2], Masashi Akaike*[3] and Hiroaki Yanagawa[1]

*[1]Clinical Trial Center for Developmental Therapeutics, *[2]Division of Nursing, *[3]Center for Career and Professional Development, Tokushima University Hospital, Tokushima, Japan

Address for correspondence: YANAGAWA H, Clinical Trial Center for Developmental Therapeutics, Tokushima University Hospital, 2-50-1 Kuramoto-cho, Tokushima, 770-8503 Japan, Tel: 81-(0)88-633-9294, FAX: 81-(0)88-633-9295, Email: niseko@tokushima-u.ac.jp

Short title: clinical research coordinator certification

Keywords: clinical research coordinator, education, Japan

Abstract

Background and objectives: In Japan, the contribution of clinical research coordinators to trials for drug approval is now well recognized in investigators. In 2013, we initiated a clinical research coordinator hospital certification course at our facility. The purpose of the course is to pre-educate medical staff who are candidates for future roles of clinical research coordinator, and to spread recognition of clinical research.

Methods: To obtain information from course participants, we conducted a qualitative study in 2014, using a focus group interview in six participants who had completed the course in 2013. The initial topic was perceptions of the course before and after participation. Other topics were the present status and issues in clinical research coordinators.

Results: All participants agreed that the course was acceptable and effective in reexamining their own work and roles from the aspects of clinical research, and that the role of clinical research coordinator itself is not very familiar among staff in the facility. Some participants indicated that even their more senior coworkers have limited recognition about clinical research coordinators.

Conclusion: There are few reports that deal with awareness-spreading activities that targeted facility staff in positions other than those related to clinical research. This type of education could be considered to more quickly build support of clinical research.

Introduction

Clinical research and clinical trials are essential for medical progress. Clinical trials for drug approval (registration trials) are a key process for bringing new drugs from the bench to the bedside. In the Japanese setting, several plans were introduced by the Ministry of Health, Labor, and Welfare (MHLW) and the Ministry of Education, Culture, Sports, Science and Technology (MEXT) from 2003 to promote registration trials. These plans include a 3-year nation-wide clinical trials vitalization plan from 2003 (expanded by 1 year), a new 5-year clinical trials vitalization plan from 2007, and a 5-year clinical trials vitalization plan from 2012.[1)] Under the new 5-year clinical trials vitalization plan from 2007, Tokushima University Hospital, an academic hospital in a rural area of Japan, has played a role as a clinical trial core medical institution for five years. One role of the core hospital was to develop human resources to be involved in clinical research and clinical trials. Among these human resources, the role of the clinical research coordinator (CRC) is now held to be essential for clinical trials.[2)] CRC certifications offered by the Association of Clinical Research Professionals and by the Society of Clinical Research Professionals are internationally recognized, and the Japanese Society of Clinical Pharmacology and Therapeutics becoming

an accredited certifying body[3)] is considered to be a milestone for Japan. Under the vitalization plans, we have tried to increase the number of CRCs holding such certifications. Although the activities of our core medical institution came to an end in March 2012, we have continued to improve the study environment, including development of human recourses related to clinical trials.

In Japan, most registration trials conducted in clinics and hospitals are supported by the CRC of the site management organization, whereas those at key hospitals (academic, national center, and national hospital organization) are supported mainly by CRCs belonging to the institution.[3)] In these key hospitals, nurses of the nursing division and pharmacists of the division of pharmacy often rotate playing roles as CRC. This is the case at Tokushima University Hospital, and at present, six CRCs belong to the Clinical Trial Center for Developmental Therapeutics (CTCDT). In 2013, we began the CRC hospital certification course at Tokushima University Hospital. The purpose of the course is not only to pre-educate medical staff who are candidates for future CRC roles, but also to spread understanding of clinical research and clinical trials around the facility via their activity. In 2014, we conducted a qualitative study to explore the perception of the CRC hospital certification course and of CRCs among initial course participants,

and here we report the results.

Methods

Outline of the CRC hospital certification course at Tokushima University hospital

Tokushima University Hospital, Center for Career and Professional Development, has previously established a career support center to promote the continuing medical education of doctors, dentists, nurses, midwives, medical and technical staff, and administrative staff. In 2012, the nursing department obtained a grant for career support from the MEXT, and successfully implemented education courses in chemotherapy nursing, palliative care, diabetes, pressure ulcer management, risk management, intensive care, and human resource development. In 2012, the creation of a CRC hospital certification course was decided based on the activities of Center for Career and Professional Development and the Division of Nursing. During the preparatory period until the start of the course, CRC introduction leaflets were produced and provided at events such as seminars to the medical staff.

In May 2013, various courses were opened, and following a common lecture for these courses (covering topics such as communication techniques), a specialized CRC training course started in October. Common lectures were mainly provided

by the faculty of the Graduate School of Biomedical Sciences, Tokushima University. Specialized lectures were provided by the members of CTCDT with help by physicians with specialty of oncology and diabetes mellitus. The course consisted of 34 hours of total time (lecture time: 26.5 hours; exercise: 4 hours; practical training: 3.5 hours), and each lecture was opened one by one in the evening to make it convenient to participate. Detailed descriptions of the course are shown in Table 1. As this volume is not satisfactory to obtain sufficient skills for CRC, basic knowledge of priority, mainly in registration trials, was included as well.

Seven applicants (one nurse, four pharmacists, one medical technologist, and one radiological technologist) participated in the initial 2013 course, with two other applicants (both nurses) participating partially. In March, 2014, a certificate of completion was awarded from the hospital director to the seven participants. One nurse among these participants became assigned at the Clinical Trial Center for Developmental Therapeutics, and begun serving as a CRC in April, 2014. The annual course has been continued to the present.

Focus group interview

To collect data from initial participants of the CRC hospital certification course of Tokushima University Hospital, we used a focus group interview, which has been reported to be superior to individual interviews.[4,5)] Written informed consent was obtained from all of the seven full 2013 course participants. The focus group interview was facilitated by the chief CRC of the CTCDT in December, 2014. Although informed consent was obtained from all course participants, one could not participate in the interview due to personal reasons. To avoid observer dependency and respect group dynamics, the observer only mentioned the following topics. The first topics were: “why did you decide to participate in the CRC Hospital Certification Course?” and “how do you feel about the course after participation?” After collecting general remarks, the participants were encouraged to express their own views on the course itself. Another topic that arose was the present status and issues of the CRC. After collecting their views, they discussed possible ways to spread awareness of the roles of CRC in the facility. Data are presented to include illustrative quotations and examples of dialogue between participants. This study was approved by the Ethics Committee of Tokushima University Hospital.

Results

“Why did you decide to participate in the CRC hospital certification course?”

Among the six participants, four had some relationship to registration trials. The detailed reasons for these four participants and for other two participants are shown in Table 2.

“How do you feel about the course after participation?”

All participants agreed that this course was acceptable and effective in encouraging them to reconfirm their own work and roles from the aspect of registration trials. Some participants realized that their respective present roles in registration trials were important steps in the many procedures related to registration trials, which made them feel motivated in their contribution.

One participant who started a CRC role in April, 2014, felt difficulty in understanding various aspects completely when she attended the course, but felt that pre-education is very valuable for performing daily work as a CRC.

As a suggestion to improve the course itself, one participant mentioned that inclusion of more issues related to investigator-initiated clinical research may

receive additional attention from staff.

Present status and issues in regarding CRCs

All participants agreed that the CRC role itself is not very familiar among staff in the facility. Some participants suggested that at least, the fact that CRCs consist of various backgrounds, such as nurses and pharmacists, should be shared among all staff, which would increase the acknowledgment of the CRC's work in the staff's daily practice.

One purpose of the course is to pre-educate medical staff who are candidates for future CRC, but some participants noted that most nurses are not aware that working as a CRC, at least temporarily for several years, is an option for all nurses. This makes it difficult for them to apply as a candidate for future CRC. One participant who started a CRC role in April, 2014, expressed that she is satisfied working as a CRC with regards to work-life balance, and feel unhappy recalling a previous occasion where she declined a facility without considering a position as a CRC. In addition, the participant indicated that training was effective in decreasing the gap between the reality of CRC's work and the misconception of

CRC work as a form of nursing work. Nevertheless, the participant felt a large gap existed even after completion of the present course.

Possible ways to spread awareness of the roles of CRC in the facility

Some participants indicated that even their senior coworkers have limited recognition about CRCs, and that it is important to spread awareness of the roles of CRC among these senior staff in addition to among the staff more generally. Some participants agreed that the CRC introduction leaflet that we provided as an initial activity before the beginning of the course was basically attractive and that distributing them to the senior staff could be the first attempt in spreading awareness to them.

This course deals with issues mainly related to registration trials. A participant suggested that inclusion of more issues related to investigator-initiated clinical research may receive more attention by staff.

Discussion

Attempts to spread awareness of clinical research to a broad range of the general public are important for promotion of clinical research. Spreading public awareness to the general public including patients more generally is listed in the 5-year clinical trials vitalization plan (March 30, 2012) set forth by the Japanese ministries; one specific method given is to hold forums and public lectures for citizens and patients. We ourselves have held public lectures by taking advantage of conferences such as diabetes forums and the Tokushima health fair, and intend to continue these activities. However, spreading awareness of clinical research and trials among medical staff mainly engaged in clinical practice should be localized to the facility in question. Nevertheless, our previous investigation concerning nurse awareness of clinical research revealed that the awareness is not as high as expected.[6)] Enhancing opportunities to enlighten the significance of clinical research is an important strategy to foster a climate of ethical and scientific performance at the facility and thereby promote clinical research at a facility.

With regard to training opportunities in clinical research for the staff of Tokushima University Hospital, we have a local registration rule for clinical research

investigators. Attendance at clinical trial seminars, which includes basic issues affecting registration trials and clinical research, is mandatory if investigators ask the ethics committee to review their clinical research. Although these seminars are held monthly, the rule applies to medical staff only when working as investigators. Other opportunities include staff training at the time of employment, training sessions carried out in each department, and the start-up and kick-off meetings of each registration trials.[7)] The foundation of the present certification course is based on these previous activities and is intended to translate recognition of clinical research from those mainly engaged in research (such as researchers and CRC) to those mainly engaged in clinical practice. For the hospital itself to hold the certification course is an opportunity to spread awareness of the significance of clinical research and clinical trials through a facility.

Among the six participants of the present study, two had already had a relationship to clinical research, one had the desire to work as a CRC, and another had been appointed to work as a CRC. It seems natural that they applied for the course, and it could be thought that the remaining two participants had roles in registration trials in their own divisions. After the completion of the course,

some participants realized that their present roles in registration trials were important steps in many procedures related to registration trials, which increased their motivation in their contribution. Because staff in the division of laboratory medicine and the division of pharmacy deal with samples and drugs related to clinical trials, this course may add confidence in their daily work, and these staff could be potential future course participants. This might also apply to clinical nurses, since our previous study revealed that about 30% of clinical nurses have experience nursing patients who were participating in registration trials and/or clinical research.[6)]

One participant indicated that training was effective in decreasing the gap between the reality of CRC work and the misconception of CRC work as a form of nursing work. Nevertheless, the participant felt a large gap existed even after completion of the present course. Unlike nurses' clinical work in outpatient clinics and wards, CRCs tend to be in contact with only the study participants, and are a minority within the hospital, which causes many CRCs to feel isolated.[8,9)] Increasing the number of nurses who have experience participating in the certification course may lead to enhanced motivation among the CRCs themselves.

Although the name of the present course is “CRC hospital certification course”, only basic knowledge of priority, mainly in registration trials, was included, and the volume of training is not adequate to obtain sufficient skills for CRC. Nevertheless, this course may be effective as preliminary education for CRC candidates, as mentioned by one participant who began their role as a CRC after completion of the course. As one participant suggested, inclusion of more issues related to investigator-initiated clinical research may receive additional attention from staff. Dan et al.[10] proposed a new evaluation system for clinical trial team members based on the concept of crew resource management.[11,12] In the study, they evaluated eight abilities or skills: the ability to recognize the real situation, the communication skills, the ability to solve problems, the ability to maintain teamwork, the ability to accomplish tasks, the ability to manage stress, the ability to study questions, and the ability to educate and train the team members and to manage the team. Since the present course was established from practice and was not based on such theory, the quality and quantity of the courses provided should be improved year by year, and the body of literature on educational studies such as this[13,14] could be a valuable resource.

Conclusion

It is a considerable strategy, when promoting clinical research in facilities, to translate recognition of from those mainly engaged in research (such as researchers and CRC) to those mainly engaged in clinical practice. Nevertheless, there are still few reports that deal with awareness-spreading activities that targeted facility staff in positions other than those related to clinical research. Although here we reported an attempt with only a small number of participants, this type of education could be considered to more quickly build support surrounding clinical research. Further study is warranted to spread awareness of the significance of clinical research in facilities.

Conflict of interest

The authors declare that they have no conflict of interest related to this article.

Acknowledgements

We would like to thank Hiroko Kume, Division of Nursing, Tokushima University Hospital, for kind support in clinical research coordinator hospital certification course.

References

1. Yanagawa H. Current regulatory systems for clinical trials in Japan: Still room for improvement. *Clin Res Regul Aff*. 2014; **31**: 25-28.

2. Yanagawa H, Akaishi A, Miyamoto T, Takai S, Nakanishi R, Irahara M. Role of clinical research coordinators in promoting clinical trials of drugs for surgical patients. *Int Arch Med.* 2008; **1**: 26.

3. Japanese Society of Clinical Pharmacology and Therapeutics. System of certified clinical research coordinator by the Japanese Society of Clinical Pharmacology and Therapeutics. (in Japanese) [http://www.jscpt.jp/seido/crc/ (accessed 2017-9-11)].

4. Basch CE. Focus group interview: an under-utilized research technique for improving theory and practice in health education. *Health Educ Q.* 1987; **14**: 411-48.

5. Morse JM. Determining Sample Size. *Qual Health Res.* 2000; **10**: 3-5.

6. Yanagawa H, Takai S, Yoshimaru M, Miyamoto T, Katashima R, Kida K. Nurse awareness of clinical research: a survey in a Japanese University Hospital. *BMC Med Res Methodol.* 2014; **14**: 85.

7. Miyamoto T. Tokushimadaigakubyouinn no tikenn-niokeru start-up meeting jino kufuuto jireisyoukai (Case Studies and ingenuity of the start-up meeting at the time of trial in Tokushima University Hospital). *PHARM STAGE*. 2004; **4**: 18-25. (in Japanese).

8. Yanagawa H, Irahara M, Houchi H, Kakehi Y, Moritoyo T, Nomoto M, Miyamura M, Shuin T; Shikoku Collaborative Group for Promotion of Clinical Trials. View and present status of personnel involved in clinical trials: a survey of participants from the First Symposium of the Shikoku Collaborative Group for Promotion of Clinical Trials. *J Med Invest.* 2011; **58**: 81-5.

9. Raja-Jones H. Role boundaries - research nurse or clinical nurse specialist? A literature review. *J Clin Nurs.* 2002; **11**: 415-20.

10. Dan K, Noguchi T, Nakano S. Proposal of the evaluation system on the education for the team to work in the field of pharmaceutical medicine. *Jpn Pharmacol Ther.* 2009; **37**: 297-304. (in Japanese with English abstract)

11. Sundar E, Sundar S, Pawlowski J, Blum R, Feinstein D, Pratt S. Crew resource management and team training. *Anesthesiol Clin*. 2007; **25**: 283-300.

12. Maynard MT, Marshall D, Dean MD. Crew resource management and teamwork training in health care: a review of the literature and recommendations

for how to leverage such interventions to enhance patient safety. *Adv Health Care Manag*. 2012; **13**: 59-91.

13. Laidlaw A, Aiton J, Struthers J, Guild S. Developing research skills in medical students: AMEE Guide No. 69. *Med Teach*. 2012; **34**: 754-71.

14. Riley SC, Morton J, Ray DC, Swann DG, Davidson DJ. An integrated model for developing research skills in an undergraduate medical curriculum: appraisal of an approach using student selected components. *Perspect Med Educ.* 2013 ;**2**: 230-47.

Table 1 Detailed descriptions of clinical research coordinator hospital certification course

	Style	Time (hrs)
Common lectures for education courses		
Overview of education courses	Lecture	0.5
Team medical care	Lecture	1
Communication techniques	Lecture	6
Medical ethics	Lecture	1
	Exercise	1
Basic knowledge of registration trial and clinical research		
Clinical trial and clinical research coordinator	Lecture	1
Administrative office of clinical trial	Lecture	1
Role and practical issues of clinical research coordinator		
Basic knowledge	Lecture	1
Institutional Review Board	Exercise	1
Start-up meeting of registration trial	Exercise	1
Kick-off meeting of registration trial	Exercise	1
Informed consent	Lecture	0.5
	Practical Training	0.5
Data management and documents	Lecture	1
Case report form and electronic data capture	Lecture	1
Monitoring and audit	Lecture	1
Discussion with monitors	Practical Training	0.5
Detailed exposition of registration trial and clinical research		
Insurance system and reward for participants	Lecture	1
Adverse events and compensation	Lecture	1
Corporation with hospital departments	Practical Training	1.5
Cancer and its treatment	Lecture	1
Diabetes mellitus and its treatment	Lecture	1.5
Clinical trial seminar (in-hospital seminar for investigators)	Lecture	1
Carrier pass of clinical research coordinator	Lecture	1.5
Research ethics	Lecture	3
Advanced medicine	Lecture	1.5
Role of clinical research coordinator	Practical Training	1
Total		34

Table 2 Reasons for participation in the CRC hospital certification course

Reasons for participation in the CRC hospital certification course	No. of participants
Some relationship to registration trials	
Roles in registration trials in own divisions	2
Desire to work as a CRC	1
Appointment to work as a CRC	1
Desire to learn more about registration trials based on the experience to be in touch with registration trial participants	1
Roles in supporting investigator-initiated clinical trials in a department and encouragement by department superior to participate in the course.	1