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Initial Education for CRCs With Different Background Knowledge: A Case Study of a Company Supporting Clinical Trials in Fukuoka, Japan

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ABSTRACT

The purpose of this paper is to examine the curriculum requirements for the development of clinical research coordinators (CRCs). In particular, the purpose of this paper is to examine and clarify what kind of effect their prior knowledge and skills had in acquiring the basic knowledge and skills of CRCs when they landed this profession. Clinical trials on human subjects are trials to test the efficacy and safety of drug candidates (hereafter referred to as investigational drugs). CRCs come from a variety of backgrounds, including licensed nurses, licensed laboratory technicians, and non-medically qualified personnel. Companies must provide initial and ongoing education to CRCs to ensure they become an asset in the company. However, there is no uniform training curriculum in the industry to date, as each company is providing its own training to CRCs. In this study, we conducted in-depth interviews with six CRCs at Company F in Fukuoka, Japan, including three new CRCs (one CRC a certified laboratory technician, one CRC a certified nurse and one CRC without a medical license). In addition, CRCs' work practices were conducted by participant observation to examine what kind of initial education is needed for CRCs with different backgrounds, in line with the qualitative data.

Keywords: Clinical research coordinators (CRCS), Initial education, Participant observation

INTRODUCTION

Drugs must be both effective and safe. Therefore, the final step in the development of a new drug is to conduct efficacy and safety studies in humans. These trials are called "clinical trials." Clinical trials are conducted by three parties: the pharmaceutical company, the medical institution, and the subjects. Because of the rigorous and complex procedures involved in conducting a clinical trial, it is essential to have an organization that supports the pharmaceutical company and the medical institution. Generally, CRC is outsourced because medical institutions are usually preoccupied with medical treatment and at the same time have to perform complex clinical trials. The role of CRC is not only to support clinical trials, but also to oversee the proper conduct of clinical trials in accordance with Good Clinical Practice (GCP). The CRC profession emerged since the establishment of Good Clinical Practice (Ebbe

and Kurt, 2003) in 1997, which tightened the conduct of clinical trials, and has enabled medical institutions to conduct clinical trials with efficiency and provide appropriate informed consent. Although CRCs are indispensable for conducting clinical trials with thorough knowledge of GCP (Jessica et al., 2020), there is no national qualification system in Japan. Furthermore, the history of the CRC as a profession is about 20 years old, much younger than nurses and other medical professions, hence the education system and career ladder has not yet been standardized throughout the industry.

Another characteristic of outsourced CRCs is that they are not allowed to perform medical procedures. According to data from Japan SMO Association (JASMO, 2023), in 2022, 28.3% of CRCs were not medically qualified.

In clinical trials, the collection of data on adverse events (all adverse health events) in subjects is a major part of safety assessment. CRCs are first to obtain information than anyone else as they need to conduct interviews with subjects and check test results. CRCs are not allowed to practice medicine or make medical judgments, but they are required to make judgments on matters that require medical urgency. Since certain medications cannot be used in combination, if a subject starts a new treatment, the CRC needs to make sure it is not a prohibited treatment, and no adverse events have occurred. Thus, CRCs must have basic knowledge of diseases, drugs, and laboratory values, as well as the skills to negotiate and coordinate with all departments within the institution to ensure that the trial is conducted according to protocol and in compliance with GCP. Most of the CRCs have experienced other professions such as a nurse or a pharmacist before landing their career in this profession. Some even have no professional medical qualifications. In the initial stage of their career, CRCs' basic job-related knowledge and skills vary depending on their backgrounds. Therefore, optimal training would be tailor-made to suit each individual albeit the issue of high cost. While there is much debate regarding the training of CRCs, there has been no qualitative studies which focus on the background knowledge of individual CRCs. This study aims to examine the background knowledge of CRCs. Being aware of the issue, we conducted an ethnographic study of CRCs at Company F and examined specific qualitative data to clarify what kind of abilities CRCs acquire and what kind of training programs are effective.

The questions pursued in this study should have implications on various types of in-house training for working professionals, in terms of which training considers the individual's background knowledge in the early stages of his or her professional career.

METHODS

Ethnographic research (Ito, 2016) mainly based on participant observation and interviews, was conducted on six CRCs working with Company F. The study period was from April 2022 to January 2024. The work experience of the observers is shown in Table 1.

Table 1. Attributes of the CRCs.

CRC	History of CRC	Background (Previous Occupation)
L	13 years	Medical Qualification: laboratory technician Previous occupation: laboratory technician 2 years
PK	9 years	Medical Qualifications: laboratory technician Previous occupation: embryologist 3 years
E	2 years	Medical Qualifications: no medical qualifications Previous occupation: a design job Clinical trials administration: 1 year CRC assistant: 2 years
PD	4 years	Medical Qualification: laboratory technician Previous occupation: laboratory technician 1 year 9 months
O	2 years	Medical Qualification: laboratory technician Previous occupation: laboratory technician: 3 years, embryologist: 2 years
J	1.5 years	Medical Qualification: nurse Previous occupation: 1 year as a nurse

One of the authors (ES) worked as a nurse for 10 years before switching her career to CRC and is now the executive manager of Company F. She assumes the additional post as CRC and works with the CRCs in the study daily, so she was able to observe them in action.

In addition, casual reporting from each of the CRCs provided information on their work activities. Emails and checklists shared by the CRCs and medical institutions for dealing with subjects provided insights into how CRCs approached each stakeholder. At the kick-off meeting for medical institutions conducting clinical trials for the first time, senior CRC and new CRC had a meeting with the medical institution staff. This allowed us to grasp the extent to which the new CRCs had acquired knowledge about the clinical trial in detail.

RESULTS AND DISCUSSIONS

Table 2 below shows an example of the work and role of a CRC during a visit to a hospital. It describes a day of a CRC.

Table 2. An example of a CRC's activity in a day (visited two hospitals in one day).

	Item	Contents
Visit F-University Hospital	Check the process for handling subjects	Confirm type of assessment and order Confirm specimen kit contents, pick-up booking, etc.
	Handling subjects' visits	• Interviews: to check on medical adherence, to check for adverse events, to check concomitant medications, etc. • Assistance with medical examination: reporting the contents of the interview and confirming the safety assessment => confirm whether the clinical trial can continue, confirm the efficacy assessment of the regulations • Allocate investigational medicinal products by electromagnetic system and request for prescriptions from physicians

(Continued)

Table 2. Continued.

	Item	Contents
		• Laboratory assistance: check the number, volume and collection time of specimens • Investigational medicines: check that the correct investigational medicines have been given to the subject and explain how to use the investigational medicines • Explanation on the date of the next visit • Confirm accounting (will be different from normal medical fees)
	Subsequent processing	• Data entry into electronic reports • Prepare for the next subject visit • Prepare specimen kits and book for collection • (a few days later) Receipt of test results • ⇒Request a safety assessment to a doctor
Visit S-clinic	same as above	same as above

CRC is a highly specialized profession (Speicher et al., 2012) and requires a solid initial education, but the type and presence of medical qualifications complicate the education. For example, qualified nurses have basic knowledge of pathology and pharmacology prior to the start of basic CRC education but must learn new test processing methods and basic CRC knowledge. Those without medical qualifications need to acquire basic CRC knowledge in addition to pathology, pharmacology, and test processing methods. At company F, all newcomers undergo CRC introduction training including 35 items on basic knowledge (including pathology, pharmacology and test processing methods). However, it was anticipated that the understanding of an individual would differ depending on his or her background (Fig. 1).

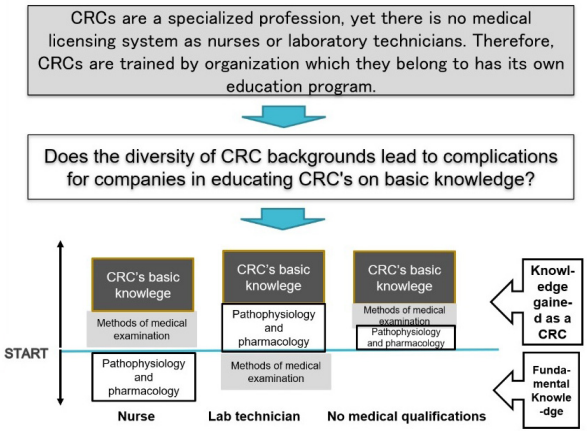

Figure 1: Image of basic education for those with different backgrounds.

Below are the results of research conducted with three new CRCs (one CRC a certified nurse, one CRC a certified clinical laboratory technician, and one CRC without a medical certification).

Observations and Interviews With Ms. J, Who Has Experience as a Nurse

During our observations in the medical institution, Ms. J always observed the nurses very closely. She also timed her requests to the busy nurses to examine the subjects. She said, "Right now, Nurse H is explaining the test to another patient, and it will take a while, so I will ask the subject to wait in the waiting room for about five minutes." "Now that there are so many patients in the clinic, I will talk to Nurse H and change the order for testing the subject." In the scattered circumstances, she suggested optimizing the entire outpatient flow so that the response to subjects could be completed efficiently.

She stated the following in an interview: "Although I'm not as good as a pharmacist, I do know what drugs the subjects are using (and I know what effect they have)." "On the other hand, back in college (University of Nursing), I only studied laboratory tests briefly, so I don't know how to process blood specimens. Even when I was a nurse, when I took blood samples, I immediately sent it to the clinical laboratory... So, after I became a CRC, I learned how to process and practiced it" (Interview with J, November 27, 2023).

Observation and Interview With Mr. O, A Licensed Laboratory Technician

Ms. O is a licensed laboratory technician, so she is familiar with specimen processing. She stated the following in the interview: "I am a laboratory technician, so I am familiar with laboratory data. Even if there is an abnormal blood test result, laboratory technicians have the advantage to tell immediately whether it is an adverse event or within the range of physiological fluctuations. On the other hand, as a laboratory technician, I only dealt with numerical values and had no opportunity to communicate with patients, so in the beginning, I had difficulty extracting important information, such as signs of adverse events, from conversations with subjects. However, as I gained experienced at work, I gradually became proficient in eliciting important information" (Interview with Ms. O, January 12, 2024).

Observations and Interviews With E, Who Is Not Medically Qualified

Ms. E originally worked in a design-related field. Although she was not medically qualified, she had some knowledge of CRC work, having worked in a clinical trial office for one year and as a CRC assistant for two years before becoming a CRC, and she understood what kind of medical knowledge was needed for a CRC and how to interact with senior CRC staff to gain knowledge.

Even though, Ms. was not medically qualified, she always kept a test textbook (she described it as the Bible) with her and went through each test procedure one by one. For example, when she asked a nurse to perform an EKG on a subject, she would refer to the textbook and explain the procedure to the nurse, in case the nurse made a mistake. "I somehow manage to explain the procedure to the nurses by referring to the textbook" she said. But

I cannot diagnose if the EKG waveform is normal or abnormal" (Interview with Ms. E, November 29, 2023).

CONCLUSION

In this paper, the authors focused on how to supplement the CRC's initial education. Both Mr. O, a qualified nurse, and Ms. J, a qualified laboratory technician, were aware of the strengths and weaknesses of their backgrounds and made efforts to compensate for their own areas of weakness.

Ms. E, who has no medical qualifications, did not talk to the author about her weakness as much in response to the author's interview. In fact, from her narrative, "I somehow manage to explain by referring to the textbook," it was discernible that she felt anxious about her work. Incidentally, Company F has a mentor-mentee system (Kram, 1983) and practices "visualization" of what they can do and what they cannot do. As Ms. E was a CRC assistant, she did not take part in this system. This may be part of the reason why her concerns have not been addressed and resolved.

Because of their different background knowledge, the CRCs have their own strengths and weaknesses. One way to improve initial education would be to make the backgrounds of CRCs "visible" to each other so that they can complement each other, such as the mentor-mentee program that F Corp. is attempting. We will discuss this point in more detail in another paper.

Furthermore, we believe that the initial training discussed in this paper will have implications not only for the CRC sector, but for other industries as well.

Limitations of This Study and Implications for Future Research

It is difficult to say that one of the authors who employed CRCs in this study had not had any effect on the interviews with the CRC subjects. In the interviews, it was found that they felt reluctant in explaining their weaknesses. This is a limitation of the research data in this study. In the future, we plan to conduct further observation and interviews with CRCs from other companies for comparison.

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