

Core Competencies of Clinical Research Coordinators

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Abstract

A standardized education program covering core competencies of clinical research coordinators (CRCs) is necessary to match the sophisticated and expanding role of CRCs. This study focused on identifying core competencies of CRCs in order to develop a standard education program. Data from presentations given by thirteen experts were first analyzed by the text mining approach. Categories extracted by software of text mining were then edited, summarized and identified based on the property of the data. The following twelve elements were extracted as core competencies of CRCs: rational problem-solving, management, communication, coordination, being knowledgeable, caring for research subjects, working as a team, consultation, ensuring the quality of clinical researches, behavior as a medical personnel, leadership, and information technology (IT) skill. Those core competencies are essential abilities of CRCs working in a clinical setting with research subjects. Management might be a central competency. Further research is needed to clarify the scopes of practice and performance level of CRCs in order to develop an education program that focuses on the core competencies of CRCs.

Keywords: *Clinical Research Coordinator, Core Competency, Education*

1. Introduction

Clinical research coordinators (CRCs) are professionals who work at a clinical research site with study subjects under the immediate direction of a principal investigator, whose research activities are conducted under Good Clinical Practice (GCP) guidelines [1]. There is a critical need for training CRCs. The reasons are: 1) protocols have become progressively more complex, and regulations intended to protect the safety of research subjects and study data integrity have continued to evolve; 2) as a result, the CRC's role has become more sophisticated and the CRC's responsibilities have expanded even though training programs do not cover these new responsibilities of CRCs; and 3) the additional responsibilities of CRCs place increasing burdens that could adversely affect their primary role of research subject management [2]. However, several articles suggested that only approximately half of CRCs had opportunities of training [2-3]. A warning letter by the US FDA also suggested inadequate training of CRCs [4]. The Clinical and Translational Science Award Research Coordinator Taskforce of the US National Institutes of Health recommended that institutions conduct a gap analysis of their training program focusing on the core competencies of CRCs [2].

Competency is more than just knowledge and skills; it involves the ability to meet complex demands by drawing on and mobilizing psychosocial resources (including skills and attitudes) in a particular context [5]. Core competencies specifically refer to a group of skills or procedures that an individual must be able to successfully and competently perform [6]. The importance of competency has been emphasized in many areas of health care [6].

However, there are no described core competencies of CRCs. The Oncology Nursing Society provides Clinical Trials Nurse Competencies [7] for nurses in the oncology field. Approximately 30-40% of CRCs have a nursing license [2], indicating that 60-70% of CRCs have a license in another field or no license. Therefore, it is necessary to describe the core competencies that apply to all CRCs regardless of licensure. The fourteen contents of the typical role of CRCs shown by the Association of Clinical Research Professionals (ACRP) [8] do not describe the essential abilities of CRCs to meet the complex demands of their role. Although the Joint Task Force (JTF) for Clinical Trial Competency showed that the core competencies consist of eight domains [9], that study focused on the competencies of clinical research professionals (CRPs) including not only CRCs but also clinical research associates (CRAs) such as data managers, project managers, monitors and auditing persons. Therefore, core competencies that focus on the abilities or skills required by CRCs who work at a clinical research site with study subjects have not been identified. Those core competencies of CRPs emphasized the actual activities included in each competency domain, and it is difficult to understand the essential characteristics of CRCs.

Revealing the core competencies of CRCs would provide helpful information to develop a standard education program that matches the sophisticated and expanding role of CRCs. This study focused on determining the core competencies of CRCs. In this study, core competencies of CRCs were defined as essential abilities that CRCs require including knowledge, skills and attitudes.

2. Methods

This was an exploratory study using the text mining approach.

2.1. Study Participants

The criteria for selecting participants were a person who has stated an opinion regarding the role expectation and education of CRCs and is acknowledged as an opinion leader in Japan by the investigators. The investigators used convenience sampling [10] to select study participants using networks in the research community in Japan.

2.2. Data Collection

The primary investigator informed each participant about the purpose of the study and asked the participant to prepare an oral presentation of 15 minutes in length about what is expected of CRCs. Participants were invited to investigator's meetings for this study and freely presented his/her opinion about what is expected of CRCs from August 2013 to August 2014. We invited two participants to the first meeting to hear their opinions in August 2013. To collect other opinions after summarizing the data from the first meeting, we invited five participants to the second meeting in October 2013, and invited six participants to the third meeting in August 2014. The investigators heard the views of the participants regarding what is expected of CRCs. We concluded that data saturation was achieved after the third meeting; therefore, we did not add more participants.

The investigators had the opportunity to ask questions to the participants after their presentations. Although we did not prepare any guide for the questions, we asked them questions and had discussions with them until the meanings of each participant's opinion became clear. The meetings were audiotaped and transcribed verbatim.

2.3. Data Analysis

Data from the audiotaped meetings were analyzed using the text mining approach. Text mining seeks to extract useful information from data sources through the identification and exploration of interesting patterns [11]. We first mined text from verbatim records of the meetings by using the software of text mining, IBM® SPSS® Text Analytics for Surveys 4.0.1 including the Japanese language. We then edited categories extracted by that software, grouped them into large categories, and identified the core competencies of CRCs while not using that software. Table 1 shows the process of data analysis.

The detailed process of analysis was as follows. (1) Text mining: The resource template of that software read verbatim records on a one-sentence basis. By that reading, verbatim records on a one-sentence basis were separated to parts of speech: noun, verb, adjective and adverb (excluding personal names, geographical names, and organization names). The separated parts of speech were extracted from the records and categorized based on the linguistic approach of that software, and categories were developed. (2) Editing: We checked all parts of speech that were not extracted by that software. Parts of speech describing CRCs' core competencies were picked up according to the definition of core competency of CRCs and were included in existing categories or placed in new categories. Some names of categories that were automatically made by the text data mining software did not appropriately show the property of the parts of speech included in that category. Therefore, we checked all names of the categories and modified them if necessary. As a result, there were 62 categories. (3) Summarizing: The categories were manually grouped into large categories. Twelve large categories as candidates of core competencies of CRCs were extracted. (4) Identifying: The validities of the large categories were identified among the investigators. Finally, twelve core competencies of CRCs were revealed.

IK analyzed all processes, and AN confirmed their validity.

Table 1. Process of Data Analysis

Step	Extracted Description	Sample of Descriptions ^{*)**)}
1. Text Mining Separated parts of speech were extracted from the records Separated parts of speech categorized based on the linguistic approach of that software	Categories containing parts of speech included descriptions of both CRCs' core competencies and items that were not core competencies	Handling (34) • <i>Good if it can be handled (1)</i> • <i>Should be able to handle (2)</i> • <i>Handling capability (1)</i> • <i>Deal (2)</i> • <i>Must be handled (1)</i> • <i>Must be handled (1)</i> • <i>To handle (1)</i> • <i>Handle (22)</i> • <i>In case of handling (1)</i> • <i>Action (2)</i>
2. Editing Parts of speech describing CRCs' core competencies were picked up according to the definition of core competency of CRCs. Some names of the categories were modified based on the property of the categories if necessary.	Sixty-two categories regarding core competencies of CRCs	Handling (27) ***) • <i>Good if it can be handled (1)</i> • <i>Should be able to handle (2)</i> • <i>Handling capability (1)</i> • <i>Deal (2)</i> • <i>Must be handled (1)</i> • <i>Must be handled (1)</i> • <i>To handle (1)</i> • <i>Handle (15) ***)</i> • <i>In case of handling (1)</i> • <i>Action (2)</i>
3. Summarizing Categories were grouped into large categories on the basis of data property	Twelve large categories as candidates of core competencies of CRCs	Rational problem-solving • Handling • Implementing • Problem-solving • Speedy

			<ul style="list-style-type: none"> • Judging • Accuracy • Performing • Smoothing • Executing • Logical thinking • Observation • Establishing evidence
4.	Identifying Validities of the large categories were identified among the investigators	Twelve core competencies of CRCs	<ul style="list-style-type: none"> ▪ Rational problem-solving <ul style="list-style-type: none"> ▪ Management ▪ Communication ▪ Coordination ▪ Being knowledgeable ▪ Caring for research subjects <ul style="list-style-type: none"> ▪ Working as a team ▪ Consultation ▪ Ensuring the quality of clinical researches ▪ Behavior as a medical personnel <ul style="list-style-type: none"> ▪ Leadership ▪ Information technology (IT) skill

*Parts of speech are indicated in italic; large categories are indicated in bold

**The number in parentheses indicates the number of records.

***This number is smaller than that in Step1 because it is the number that was remaining after parts of speech describing CRCs' core competencies were picked out.

3. Results

We recruited 13 opinion leaders who consisted of a patient advocate, principal investigators, clinical research professionals and education professionals in health care. Table 2 shows the background of the participants.

Table 2. Background of the Participants (N=13)

Background	N
Clinical research associate who had experience as a clinical research coordinator	1
Manager of clinical research organization	1
Manager of pharmaceutical company	1
Manager of the Academic Research Organization (ARO) who had experience as a clinical research coordinator	1
Manager who provides a learning program of clinical research funded by the Ministry of Health, Labor and Welfare	1
Medical journalist	1
Patient advocate	1
President of university who was involved in the initiative of clinical research coordinators training program	1
Clinical research coordinator who had experience as a trainer	2
Physician / Principal Investigator	3

After analyzing the audiotaped meetings, the total number of records was 517. Sixty-two categories were extracted from 426 records (82.4%). The 62 categories were placed in 12 large categories as core competencies of CRCs (Table 3). The 12 large categories of core competencies of CRCs were as follows.

The first large category was "Rational problem-solving", which had 12 categories such as handling, implementing, problem-solving and others from 85 records (16.4%). The second large category was "Management", which had 9 categories such as management,

project management, risk management and so on from 66 records (12.8%). The third large category was “Communication”, which had 9 categories such as communication, negotiation, explainable and so on from 54 records (10.4%). The fourth large category was “Coordination”, which had 5 categories such as navigation, coordination, flexibility and so on from 53 records (10.2%). The fifth large category was “Being knowledgeable”, which had 3 categories of knowledge, understanding and well-understanding from 34 records (6.6%). The sixth large category was “Caring for research subjects”, which had 6 categories such as understanding patients, care, ethical action and so on from 32 records (6.2%). The seventh large category was “Working as a team”, which had 6 categories such as working with others, being independent, asking and so on from 26 records (5.0%).

The eighth large category was “Consultation”, which had 3 categories of supporting, advising, and easy to consult from 25 records (4.8%). The ninth large category was “Ensuring the quality of clinical researches”, which had 4 categories of ensuring quality, protocol compliance, monitoring and auditing from 23 records (4.4%). The tenth large category was “Behavior as medical personnel”, which had two categories of medical personnel and fairness from 13 records (2.5%). The eleventh large category was “Leadership”, which had 2 categories of leadership and activating from 12 records (2.3%). The twelfth large category was “Information Technology (IT) skill”, which had 1 category from 3 records (0.6%).

Table 3. Core Competencies of CRCs Identified in this Study Number of all Records= 517

Large Categories	Categories	Number of records(%)	Including parts of speech
Rational problem-solving	Handling	27(5.2)	Good if it can be handled, should be able to handle, handling capability, deal, must be handled, must be handled, to handle, handle, in case of handling, action
	Implementing	13(2.5)	Feasibility, implementation, implementing
	Problem-solving	9(1.7)	Problem, solution, solving, problem-solving skill, ability to solve problems, problem solving
	Speedy	8(1.5)	Speed, speedy, input speed
	Judging	8(1.5)	To judge, judgment, ability to judge information
	Accuracy	5(1.0)	Accuracy, conscientious, information processing ability, person who are particular about the details, attention to details, meticulous person
	Performing	5(1.0)	To accomplish, to complete, completing, ability to perform jobs
	Smoothing	3(0.6)	Smooth, smoothness
	Executing	2(0.4)	Ability to execute, practical skills
	Logical thinking	2(0.4)	Logical, ability to think
	Observation	1(0.2)	Observation skill
	Establishing evidence	2(0.4)	Evidence, establishing evidence
Management	Management	17(3.3)	Management, managing person, management ability, resource, self-check, ability to manage, management, shared management, research and development management, under management
	Project management	13(2.5)	Project management, project, project manager
	Risk management	12(2.3)	Risk-based, risk evaluation, brake, risk-based monitoring, repeating, danger, risk, risk assessment
	Data management	8(1.5)	Input, managing data, electronic data capture, case report form, data management

	Time management	7(1.4)	Time, time management
	Schedule management	4(0.8)	Being able to manage a schedule, schedule management, schedule
	Original source management	3(0.6)	Original source, medical chart
	Document management	1(0.2)	Required documentation
	Making systems	1(0.2)	Being organized
Communication	Communication	17(3.3)	Ability to communicate, communication ability, communication, communication skills, two-way communication
	Negotiation	6(1.2)	Negotiation, ability to negotiate
	Explainable	5(1.0)	Providing information, a person able to explain, explanation
	Asserting own opinion	4(0.8)	Opinion, express an opinion
	Partnership	3(0.6)	Partner each other, equal partners, parallel
	Creating relationships	4(0.8)	Trust, trusting relationship, relationship
	Business manner	3(0.6)	Business manner
	English proficiency	9(1.7)	English language ability, letter in English, English
	Medical writing	3(0.6)	Person able to support SAE report creation, medical writing
Large Categories	Categories	Number of records(%)	Including parts of speech
Coordination	Navigation	17(3.3)	Person able to guide, to navigate, guidance, navigate, navigator
	Coordination	15(2.9)	Ability to coordinate, coordination, concerning the department, receptor, coordination ability, coordinate, relevant parties, would like to have coordinated, ability to coordinate
	Flexibility	9(1.7)	Flexible, flexibility, pliant, withdrawal, suiting to the occasion
	Sharing information	7(1.4)	To share, information, sharing
	Sense of balance	5(1.0)	Sense of balance, balanced, balance
Being Knowledgeable	Knowledge	17(3.3)	Basic knowledge, knowledgeable, technical knowledge, being knowledgeable, knowledge
	Understanding	15(2.9)	To understand, able to understand
	Well understanding	2(0.4)	Person able to understand, essence
Caring for research subjects	Understanding patients	12(2.3)	Things understood, was able to understand, not having knowledge, understanding better comparatively, was not able to understand, to not understanding
	Care	6(1.2)	Relevant person, person who was gave care, confrontation, consideration, care, kind, to accompany, making arrangements
	Ethical action	5(1.0)	Ethical, would like to be treated with honesty, sense of ethics
	Making patients a priority	4(0.8)	Patient-centered
	Respecting participant	3(0.6)	For the sake of participants, protection of participants
	Advocate for a patient	2(0.4)	Advocate for a patient

Working as a team	Working with others	10(1.9)	Cooperation, collaboration, being team work, cooperating
	Being Independent	6(1.2)	Oneself, independent person
	Asking	4(0.8)	Asking
	Contacting/Informing	2(0.4)	Contacting, informing
	Responsibility	2(0.4)	Sense of responsibility, responsibility
	Cooperative	2(0.4)	Cooperativeness, cooperative
Consultation	Supporting	14(2.7)	Support, clinical research professionals, will support, virtually supporting, support
	Advising	7(1.4)	Educational, continuing to communicate, advice, instruction, supervise, continuing to educate
	Easy to consult	4(0.8)	Would like to consult, place for consultation, consultation service
Ensuring the quality of clinical researches	Ensuring quality	9(1.7)	Guarantee, based upon GCP, quality, compliance, condition, scientific evidence
	Protocol compliance	9(1.7)	Deviation, conforming to protocol, protocol management, conforming to protocol, without deviation
	Monitoring	3(0.6)	Able to monitor
	Auditing	2(0.4)	Audit, person able to audit
Behavior as a medical personnel	Medical personnel	9(1.7)	Medical profession, in order to become a medical practitioner, medical personnel
	Fairness	4(0.8)	conflict of interest, fairness
Large Categories	Categories	Number of records(%)	Including parts of speech
Leadership	Leadership	8(1.5)	Leadership, to lead
	Activating	4(0.8)	Activate, system promoting research, for research activities, activating
Information Technology (IT) skill	IT skill	3(0.6)	PC skills

4. Discussion

The responsibilities of CRCs, role of CRCs and content of training programs for CRCs have already been reported [2, 8]. However, previous studies did not show the core competencies that CRCs need. The present study clarifies core competencies of CRCs that had been extracted from oral presentations from 13 opinion leaders.

This study identified more essential abilities of CRCs working in a clinical setting with research subjects than those found in a previous study on the competencies of CRPs [9]. Caring for research subjects, ensuring the quality of clinical researches, and behavior as a medical personnel are competencies reflecting the practical responsibilities of CRCs in clinical settings. CRCs serve a pivotal role in human subject protection [2], which is described as the competency of caring for research subjects. Protocol compliance, monitoring, and auditing are included in the large category “Ensuring the quality of clinical researches” in our results. CRCs are expected to be the leading person in clinical settings to ensure compliance with GCP guidelines and contribute to the reliability of the research study. Behavior as a medical personnel is a prerequisite competency for CRCs to perform those roles. The roles of CRCs are different from those of CRAs who don't provide direct care for research subjects and directly don't handle the data source. It is significant that our study revealed the core competencies of CRCs separately from those of CRPs including CRAs [9].

Other core competencies identified in this study warrant further discussion. Management, one of the core competencies of CRCs, might be a central competency

because Management as a large category in this study included a wide range of abilities as shown by its categories. Fourteen content areas of the typical clinical research role provided by the ACRP included 9 management-related areas: management of essential documents, investigative site management, clinical trial management, test article accountability and management, project management, data management, business management skills, and personal/professional management [8]. Project management, data management, original source management and document management, which were categories in the present study, are similar to several content areas described by the ACRP. Although other categories are not similar to the names of other content areas established by the ACRP, management is a comprehensive competency including managing research subjects, research-related personnel, material, time and financial resources. Communication, working as a team, behavior as a medical personnel and IT skill may be basic competencies. The first edition of the Oncology Clinical Trials Nurse Competencies in 2010 [12] mentioned strong verbal and written communication skills, ability to work in teams, oncology nursing experience, and ability to utilize computers and basic computer programs as initial requirements of clinical trial nurses. However, it is not clear whether or not there are differences in the level of competency required for each of the 12 core competencies extracted in this study. Competency of behavior as a medical personnel might be controversial. In our discussion, this competency does not mean that the CRC must have a medical license. However, this result suggests that CRCs need the ability to carry out basic responsibilities as medical personnel such as respecting patients, handling personal medical information, and understanding the contents of medical records. The lack of clear regulations and policies that guide delegation of clinical research activities creates risks to research participants and the quality of clinical research [13]. Further research is needed to clarify the scopes of practice of CRCs who do not have a medical license.

A standard training program for CRCs should consider covering the core competencies of CRCs revealed in this study. However, a well-structured education program for professionals needs to include not only core competencies but also the scope of practice and appropriate performance level as shown by the published report entitled "An Advanced Pharmacy Practice Framework for Australia" [14]. The scope of practice of CRCs was not revealed in the present study, and there are no descriptions in previous studies. Although several core competencies such as rational problem-solving, being knowledgeable, consultation and leadership extracted in this study are similar to the competencies or roles of advanced practice nurses (APNs) [15], the appropriate performance level is not clear from only the elements of core competencies revealed in this study. Further research regarding the scopes of practice of CRCs and performance level from general to advanced practice of CRCs is needed.

This study has several limitations. We extracted core competencies from the presentations given by opinion leaders about what is expected of CRCs. This means that we gathered a wide range of opinions from study participants about what they expected to be the role of CRCs. Therefore, the results of this study might be loose compared to interviews focusing just on core competencies of CRCs, but the validity of these results cannot be denied because we confirmed data saturation.

Regarding the process of data analysis using text mining, the relevancies of the large categories were not analyzed in this study. Other elements or influencing factors might be deduced if the relevancies of the core competencies are analyzed.

In conclusion, this study identified 12 core competencies that CRCs require, which were rational problem-solving, management, coordination, communication, being knowledgeable, caring for research subjects, consultation, ensuring the quality of clinical researches, working as a team, leadership, behavior as a medical personnel and IT skill. This finding suggests that those core competencies are essential abilities of CRCs working in a clinical setting with research subjects. Further research on clarifying the

scopes of practice and performance level of CRCs is needed in order to develop an education program that focuses on the core competencies of CRCs.

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