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Job Analysis of Clinical Research Coordinators Using the DACUM Process

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Purpose: This study was done to analyze the job of clinical research coordinators (CRCs). **Methods:** Through the "developing a curriculum (DACUM)" workshop, the definition of CRCs' role was described and CRCs' duties and tasks were identified. Finally, the developed duties and tasks were validated for importance, difficulty, and frequency. **Results:** A CRC is defined as the one who coordinates and performs tasks related to clinical research/trials among investigators, participants, and sponsors according to the Good Clinical Practice at institutions conducting clinical trials. Twelve duties and 78 tasks were identified on the DACUM chart which represented the importance, difficulty, and frequency of tasks represented as A, B, and C respectively. Based on determinant coefficient (DC) of the task, the highest ranked task was confirming the eligibility of participants for research (DC = 8.03) and the lowest was inventory management for clinical study materials (3.95). **Conclusion:** In this study, the job of a CRC was analyzed through the DACUM process and it was found that CRCs were doing various duties and tasks. Based on these results, it is suggested that it is necessary to develop CRC education programs considering the career ladder of CRCs.

Key words: Role; Job description; Analysis

INTRODUCTION

A clinical research coordinator (CRC) is a clinical research professional with various specialty backgrounds and is responsible for conducting and supporting clinical trials. Nurses occupying the majority of CRC are the rightful workforce as they have extensive understanding and accessibility of subjects and clinical research data along with basic knowledge of medicine, pharmacy, and clinical trials (Kang, Kim, Jeong, & Baik, 2004; Pelke & Easa, 1997). Thus, the term 'CRC' is often used interchangeably as 'research nurse'.

With the rapidly increasing trend of clinical trial cases performed in Korea lately, the number of CRC has also increased. It is rather difficult to obtain accurate statistical data of Clinical Research Coordinator in Korea as most of CRCs are contract-based employees; however, it was estimated that there were about 100 CRCs in 2003 which increased to about 2,000 CRCs at present (Kang, 2010). Despite such a sharply in-

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creasing number of CRCs, there is no established guideline for the educational background or performing roles of CRCs. This indicates the lack of systematic efforts to develop infrastructure, such as defining and clarifying responsibilities of CRCs (Kang, Kim, Jeong, Choung, & Shin, 2004). In foreign countries, CRCs play important roles such as taking care of subjects in clinical trials, enhancing their cooperation for research, maintaining the quality of research, and strengthening the connection between research and clinical practice (Poston & Buescher, 2010; Rico-Villademoros et al., 2004; Spilsbury et al., 2008). In fact, CRCs perform many different roles as educators, speakers, direct nursing practitioners, and clinical trial operators (Dawson, & Benson, 1997). Among them, patient care and research-related administrative works have been reported to blur the boundary of their research roles and increase their workload. For example, a study reported that CRCs perceived Good Clinical Practice (GCP) and ethics as important tasks but considered tasks like research fund management and data management as not so important (Hill & MacArthur, 2006). Like this, the boundary of CRCs' jobs and their responsibilities is somewhat ambiguous depending on the type and characteristic of research; for this, clearly defining job description of CRC is needed (Pelke & Easa, 1997; Rico-Villademoros et al.).

On the other hand, many of CRCs in Korea are sent out to the field without adequate and systematic training that has been an obstacle to the development of new drug as well as to active participation in multinational clinical trials (Park, 2010). Thus, in order to ensure the reliability of clinical trials and to protect subjects, it is very important to improve abilities of clinical research staffs through systematic education programs and certification systems for clinical research specialists. Accurate and specific information on definition and roles of CRCs is essential in the development of human resource programs, and job analysis should be conducted first to collect such information.

Therefore, in order to enhance people's understanding of research related jobs and reducing ambiguity of job boundaries, job analysis of CRC becomes very critical. Through job analysis of CRCs, establishment of systematic guideline that clarifies work scope and direct how to solve problems faced by CRCs are possible. However, just handful studies have been made on CRCs and studies on research nurses also lacks. The only previous study on job analysis is the analysis of research nurses in oncologic clinical trials (Hwang, 2008), and there are no studies on job analysis for CRCs. For those reasons, this study is to analyze CRCs' jobs to be used as ground materials for developing curriculums and certification systems and furthermore to contribute to efficient and convenient guidance that prevents confusion or conflicts in CRCs' roles.

To analyze the CRC's role or job, we used "Developing a curriculum (DACUM)." DACUM has been used to analyze tasks conducted by specific jobs in order to develop competency-based curriculums. The DACUM methods are effective due to group interaction, group synergy, and group consensus via brain storming process; future orientation; cost-effectiveness because the DACUM workshop is completed in two days (Norton, 1997, 2008). Because of those strengths, DACUM method has been used in nursing and health care professions when a new job was developed and/or a new educational program is needed (Byun, Kim, Kim, Ha, & Jeon, 2003; Cooper, Aherne, & Pereira, 2010; DeOnna, 2002; Kim, Park, & Lim, 2008; Oh et al., 2006; Sherrill & Keels-Williams, 2005; Shin et al., 2012; Stevenson, Hornsby, Phillippe, Kelley, & McDonough, 2011). DACUM Process starts from conducting DACUM workshop to produce DACUM chart by identifying duties and tasks. Task verification by rating importance, difficulty, and frequency is followed.

1. Objectives

The objectives of this study are to identify CRCs' duties and tasks by analyzing CRCs' jobs and to provide materials for educating and assessing CRCs.

The specific goals of this study are as follows:

1) Define CRCs' jobs.

2) Develop a CRC task sheet ("developing a curriculum (DACUM)" Chart).

3) Identify CRCs' important duties and tasks based on determinant coefficient.

METHODS

1. Research design

This is a descriptive study for CRC job analysis that adopted a multidimensional research design using workshops and questionnaire surveys of experts for defining CRCs' jobs using the job analysis technique of DACUM classifying their duties and tasks, and confirming the validity (Kim, 2006). This study was approved by the institutional Review Board at the College of Nursing, Seoul National University (No. 2010-66).

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2. DACUM

DACUM is a systematic method for developing practical competency-oriented education programs (DeOnna, 2002; Norton, 2008), analyzes jobs on the assumption that those with rich field experiences can explain their job most accurately, that a job can be defined most effectively by those highly experienced in the job, and knowledge, behavior, and that skills are required in addition to tools or instruments in order for a task to be carried out adequately (Norton, 1997). DACUM is a process of developing curriculums by analyzing requirements through need assessment of a given job area. There are many other methods used for job analysis like the Vocational-Technical Education Consortium of States (V-TECS) (Oliver & Hill, 1974) and the Functional Job Analysis (FJA). FJA is a costly and time-intensive methodology performed using interviews and observations (Levine, Ash, Hall, & Sistrunk, 1983). V-TECS is not intensive as FJA, but very similar to DACUM in terms of producing task-based output and processes, but not used commonly these days. DACUM requires less time and cost while it is easily understandable to participants (DeOnna, 2002; Norton, 1997, 2008; Sherrill & Keels-Williams, 2005). Therefore, the DACUM technique was chosen for CRC job analysis in this study. Unlike the job analysis by expert opinion or filed survey only, DACUM process use both group interaction and consensus by committee and agreement via survey. That is the reason the results induced by DACUM process are more reliable and valid.

3. Research procedures and data collection

1) CRC job analysis using DACUM analyze method

(1) Selection of DACUM committee members

We asked 14 government-accredited clinical trial centers to recommend their most experienced CRCs who were good at communication and self-expression which are required characteristics for DACUM committee. To select committee members, gender, geographic representation, and years of experience are also considered. We considered geographic representation. At the time of selection, there was no male CRC. Therefore all of the committee members were female. The location where the CRCs were affiliated was Seoul, Gyeonggi, Chungcheong, and Kyungsang areas. The most experienced CRC was selected on the assumption that "the skilled workers are best able to describe the competencies needed to perform their work (Norton, 1997)." Finally eight CRCs coming from 8 out of 14 centers participated as DACUM committee.

(2) Derivation of CRCs' duties and tasks

DACUM job analysis was performed through a workshop for deriving CRCs' duties and tasks. For the workshop, we notified the 8 CRCs of the schedule, location, and programs of the workshop in advance so that none of them would be late on the day of workshop.

Two DACUM facilitators and two DACUM coordinators who would assist analysis conducted the DACUM job analysis workshop for 7 hours excluding orientation, icebreaking, and break time. Total time of workshop was 10 hours. Two day-workshop is desirable, but the workshop was done in a day because of special circumstances of this study. Due to the characteristics of tasks, employment type, and geographic location, the CRCs selected in the committee could not have two days off in a row at the job. The facilitators have the certificates of DACUM analysis and had experience on job analysis using DACUM. They analyzed seven special areas of nursing previously and published several articles based on the results. It is not mandatory for a DACUM coordinator, but the coordinators in this study have the Systematic Curriculum and Instructional Development (SCID) certificates. According to the procedure of DACUM, a DACUM facilitator provided the CRCs with an orientation on DACUM job analysis and obtained written consents from the participants. Led by the DACUM facilitator, the participants were made clear of the job definition of CRCs, analyzed and named their duties and tasks, revised and supplemented the analyzed tasks through crosschecking with duties, and determining the ranking the duties and tasks. The role of coordinators were assisting facilitators by recording duties and tasks or making the DACUM chart. In this process, we complied following principles. First, the participants should be treated equally despite position and age in order to feel free to participate. Second, the workshop was held in a comfort atmosphere. Third, the DACUM committee members should not use references. Fourth, the duties and tasks should be recorded and organized only after the members agreed through discussions. Through the DACUM job analysis workshop, 12 duties and 74 tasks were obtained.

2) Validating the results of DACUM job analysis

(1) 1st validation

Job definitions, duties and tasks of CRCs derived through the DACUM job analysis workshop were reviewed in another workshop of advisory committee members for adequacy, redundancy and mutual exclusiveness of each item, and a questionnaire was prepared based on the results. We asked 14 government-accredited clinical trial centers

again to recommend experienced CRCs other than those who participated as DACUM workshop committee. The selection criteria for the second committee members were same as those for the first committee except years of experience. Their years of experience were from 3 to 10 years because we need to have opinions from CRCs with various points of views. Ten CRCs agreed to participate in this validation process. We sent the questionnaire, and they assessed each item on a 4-point Likert scale (highly valid, valid, not valid, or not valid at all). Based on the results of the survey, we revised and supplemented items of which the descriptions are ambiguous, and then revised into 12 duties and 83 tasks as CRCs' jobs.

(2) 2nd validation

The 12 duties and 83 tasks obtained in the 1st validation were validated again with 21 CRCs, 5 researchers, and 2 clinical research associates (CRAs). Then we finally referred the duties and tasks to an officer of the Korea Food and Drug Administration (KFDA) to check whether there is any legal issue on duties and tasks of CRC. As a result, 12 duties and 78 tasks were deducted.

3) Preparing CRC task sheet (DACUM chart)

(1) Research instrument

We prepared a self-reporting questionnaire to check the importance, difficulty and frequency of the 12 duties and 78 tasks obtained through the 2nd validation on a 3-point scale (A–3 point, B–2 point, and C–1 point).

(2) Subjects and data collection

The target population was all CRCs in Korea, and 300 of them were selected through convenient sampling in consideration of representativeness. Calculated sample size was 239 based on the population size of 2,000; the confidence level was 95%; and the margin of error was 5% (Bartlett, Kotrlik, & Higgins, 2001). To consider missing rate, the final sample size was decided to be 300. The questionnaire was sent to the subjects by mail. Of the subject CRCs, 98.6% were female, 45.7% were in their 20s, and 57.0% were college graduates. In addition, 55% of the CRCs were working at clinical trial centers, 25.4% at clinical departments, and 16.7% at research centers. As for their experience as a CRCs, 62.9% of them had 1-5 year experience. As to employment status, 11.7% were permanent staff and 88.3% were contract-based staff.

(3) Data analysis

Collected data were analyzed with SPSS-Win 18. Excluding those answered inadequately, we analyzed a total of 282 questionnaires. Means and standard deviations were calculated for the importance, difficulty and frequency of duties and tasks. In addition, a DACUM chart that shows CRCs' job definition, duties and tasks was prepared. The DACUM chart presented tasks for each duty, and for each task, the mean values of importance, difficulty and frequency were marked as A (high), B (average) or C (low). Lastly, in order to identify important tasks, we obtained the determinant coefficient by multiplying the means of importance and difficulty. A possible range of determinant coefficient is 1 to 9. The higher the number, the more important and difficult the task is.

RESULTS

1. CRCs' job definition, duties and tasks

The job definition of a CRC derived from DACUM job analysis was 'one who coordinates and performs tasks related to clinical research/trials among investigator, participants and sponsors according to the Good Clinical Practice at institutions conducting clinical trials,' and 12 duties and 78 tasks were deduced. Three tasks including direct nursing care in the duty of pariticipants management, complying standard operational procedures (SOP) and GCP in the duty of management of SOP, and mentoring new CRC member in the duty of self-improvement were removed by second validation from 21 CRCs, 5 researchers, and 2 CRAs. Two tasks such as identifying adverse reactions via history taking and physical assessment in the duty of subject management and constituting the persons in charge according to task assignment in the duty of plans for clinical trial were eliminated based on the view of legal perspectives from the officer in the KFDA.

2. Preparing CRCs' task sheet (DACUM chart)

CRCs' task sheet (DACUM chart) is a table showing the job definition, duties and tasks decided from DACUM job analysis (Figure 1). Each task is marked as A, B or C according to the mean values of importance, difficulty and frequency.

Among the tasks, 13 were A's in importance, difficulty, and frequency. These were 'Explaining informed consent,' 'Confirming the participant's eligibility for the research,' 'Performing the planned study procedures

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Definition	One who coordinates and performs tasks related to clinical research/trials among investigator, participants and sponsors according to the good clinical practice at institutions conducting clinical trials.

Duty	Task							
Participants management	Recruiting participants (BAA)	Explaining informed consent: Clinical study process only (AAA)	Confirming the participant's eligibility for the research (screening; criteria for inclusion/ exclusion) (AAA)	Enrolling the participants to the sponsor/ KFDA (BBB)	Scheduling the date of hospital visits (ACA)	Performing the planned clinical study procedures according to participant's visiting schedule (AAA)	Administrating investigational product to the participants (AAA)	Identifying participant protocol compliance (procedure, medication...) (ABA)
	Paying clinical study-related compensation to participants (CCB)	Following-up the participants according to clinical study schedule: Except medical observation (CCB)						
Participants education	Educating guidance for complying with protocol (forbidden drug, writing the participant's diary, precautions pre/post test, test method...) (AAA)	Explaining methods of drug administration for clinical study (ABA)	Educating for the targeted research disease (disease, diet, exercise, medication...) (BBA)	Educating on adverse events (AAA)	Educating/ counseling the participants & their families (CBB)	Educating the instruction of clinical study-related device (e.g.: PFT, self IVRS call ect.) (CBB)	Explaining the participants how to fill-out the questionnaire except in psychiatric studies (CCB)	
Plans for clinical trial	Reviewing the clinical study protocol (AAA)	Developing the work sheet for data collection (BAB)	Reviewing the research contract (BBC)	Participating in meetings on the clinical study initiation (BCB)	Completing the pre-study related training (IVRS, e-CRF) (BBB)	Educating the involved personnel in other departments for the clinical study (CCC)		
Management of standard operational procedure	Developing the standard operational procedures (BAC)	Reviewing and revising the SOPs (BAC)	Educating the on SOPs (CBC)	Distributing and discarding the SOPs to the involved departments (CCC)	Keeping all of the original SOPs (CCC)	Identifying any deviation from the SOPs (CCC)		
Research management	Discussing with the investigator (AAA)	Calculating and distributing workload for the clinical study (BBB)	Cooperating the work with other departments involved (BAB)	Cooperating with the sponsor (AAA)	Connecting with the participants with supporting resources (CBC)			
Data management	Discussing and agreement on the source document (ABA)	Collecting the source data (questionnaire, diary) (ABA)	Completing the case report form (CRF) (AAA)	Ensuring accuracy of the clinical study data (AAA)	Resolving data queries (AAA)	Inputting the clinical study data on CRF database (ABA)	Analyzing the study data (statistics) (CAC)	Organizing data for the clinical study report (BAC)

A (high), B (moderate), and C (low) indicate the degree of importance, difficulty, and frequency.
KFDA=Korea Food & Drug Administration; PFT=Pulmonary function test; IVRS = Interative voice response system;
e-CRF=Electronic case report form; CRF=Case report form; SOPs=Standard operating procedures;
EKG=Elctrocardiogram; IRB=Institutional review board; SAE=Serious adverse event.

Figure 1. Clinical research coordinators' work performance table.

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according to participant's visiting schedule,' 'Administrating the investigational product to the participants,' 'Educating guidance on complying with protocol,' 'Educating on adverse events,' 'Reviewing the study protocol,' 'Discussing with the investigator,' 'Cooperating with the sponsor,' 'Completing the case report forms,' 'Ensuring accuracy of the clinical study data,' 'Resolving data queries,' and 'Cooperating to report adverse events.'

On the other hand, 13 tasks were C's in importance, difficulty and frequency. These were 'Educating involved personnel in other departments for the study,' 'Distributing and discarding SOPs to the involved departments,' 'Keeping all of the original SOPs,' 'Identifying any deviation from SOPs,' 'Discussing/confirming the period of study document preservation,' 'requesting archive of clinical study documents,' 'Making document registers,' 'Requesting the copy of radiological imaging,' 'Requesting the transfer of radiological imaging,' 'Confirming the adequacy of research facilities,' 'Confirming whether to control the preciseness of data collection equipment and instruments,' 'Inventory management of study materials,' and 'Purchasing and managing emergency instruments/kits.'

3. Important duties and tasks of CRCs according to determinant coefficient

Among the duties, the determinant coefficient was the highest in 'Administrative work for research review/supervision organization,' which was followed by 'Participnats management,' 'Data management,' and 'Self-improvement.' In addition, the determinant coefficient was the lowest in 'Management of research facilities and materials,' which was followed by 'Document management,' and 'Management of research-related specimens and tests' (Table 1). As to difference between the highest and lowest determinant coefficients of tasks within each duty, the difference was largest in 'participant management' and smallest in 'research budget management' (Table 1).

Most of the 10 tasks highest in terms of determinant coefficient were related to duties 'Participant management' and 'Administrative work for study review/supervision organization.' The task with the highest determinant coefficient was 'Confirming the Participant's eligibility for the research' in duty 'Participant management,' which was followed by 'Explaining the informed consent: clinical study process only' in duty 'Participant management' (Table 2).

On the contrary, the 10 tasks lowest in terms of determinant coefficient belonged to duties 'Management of research facilities and materials,' 'Participant management,' 'Management of research-related specimens and tests,' 'Document management,' and 'Management of Standard operational procedure.' Among them, 'Inventory management for clinical study materials' had the lowest determinant coefficient, which was followed by 'Paying clinical study-related compensation to participants,' 'Requesting the transfer of radiological imaging,' 'Requesting clinical study materials,' and 'Requesting the copy of radiological imaging' (Table 3).

DISCUSSION

In general, a CRC is defined as one who supports and operates clinical trials and works with responsibilities for the coordination and performance of clinical research/trials according to the principles of GCP under the supervision of senior researchers (Spilsbury et al., 2008). In the results of this study, a CRC was defined as 'one who coordinates and performs tasks related to clinical research/trials among investigator, participnats and sponsors according to the principles of GCP at institutions conducting clinical trials.' Through this study, we defined the basic roles of CRCs clearly, which are supporting the adequate performance of clinical trials and the acquisition of high-quality data by observing the principles of GCP (Rico-Villademoros et al., 2004). Moreover, our definition reflected those related to CRCs' roles such as researchers, participants and sponsors, so it is considered to include the specificity of relations. In addition, suggested CRCs' roles are largely divided into educator, mediator/resource, researcher, and clinical specialist (Dawson, & Benson, 1997), but this study clarified and described CRCs' roles as a coordinator.

This study concluded 12 duties as well as 78 tasks under the duties through systematic classification. In contrast, Kang, Kim, Jeong and Baik (2004) suggested 19 jobs of research nurses, which were filling case report forms (CRFs), contacting researchers/sponsors, screening participants, preparing research-related supplies, observing and reporting adverse events, holding and attending preliminary research meetings, educating participants and obtaining informed consents, collecting research data, managing contact information and schedules for participants, reviewing research plans and CRFs, scheduling research, etc. Moreover, Hwang (2008) suggested a total of 61 detailed tasks in 6 areas of jobs (administrative job, practical job, monitoring job, research-related job, education and counseling job, and advocating and coordination job) performed by research nurses working for oncologic clinical trials. These

Table 1. Determinant Coefficient Scores for Duties and Tasks

Duty (DC)	Task (DC)
Participants management (6.29)	Recruiting the participants (6.26) Explaining informed consent: clinical study process only (7.49) Confirming the participant's eligibility for the research (screening; criteria for inclusion/exclusion) (8.03) Enrolling the participants to the sponsor/KFDA (5.66) Scheduling the date of hospital visits (5.68) Performing the planned clinical study procedures according to participant's visiting schedule (6.66) Administrating investigational product to the participants (6.85) Identifying subject's protocol compliance (procedure, medication, etc.) (6.32) Paying clinical study-related compensation to participants (3.97) Following-up the participants according to clinical study schedule: except medical observation (5.08)
Participants education (5.87)	Educating guidance on complying with protocol (forbidden drug, writing the participant's diary, precautions pre/post test, test method, etc.)(6.81) Explaining methods of drug administration for clinical study (6.40) Educating for the targeted research disease (disease, diet, exercise, medication, etc.) (6.01) Education on adverse events (6.67) Educating/counseling participants & their families (5.65) Educating instruction on clinical study-related devices (e.g.: PFT, self IVRS call, etc.) (5.27) Explaining to participants how to fill-out the questionnaire except in psychiatric studies (4.70)
Plans for clinical trial (5.69)	Reviewing the clinical study protocol (7.27) Developing the work sheet for data collection (5.95) Reviewing the research contract (5.87) Participating in meetings on the clinical study initiation (4.94) Completing the pre-study related training (IVRS, e-CRF) (5.72) Educating involved personnel in other departments for the clinical study (4.92)
Management of standard operational procedure (5.28)	Developing standard operational procedures (SOPs) (6.29) Reviewing and revising the SOPs (5.83) Education on the SOPs (5.61) Distributing and discarding the SOPs to the involved departments (4.33) Keeping all of the original SOPs (4.36) Identifying any deviation from the SOPs (5.24)
Research management (5.99)	Discussion with the investigator (6.58) Calculating and distributing workload for the clinical study (5.91) Coordinating the work with other departments involved (6.21) Cooperating with the sponsor (6.17) Connecting the participants with supporting resources (5.08)
Data management (6.25)	Discussing and agreement on the source documents (6.11) Collecting the source data (questionnaire, diary) (6.06) Completing the case report form (CRF)(6.84) Ensuring accuracy of the clinical study data (6.64) Resolving data queries (6.71) Inputting the clinical study data on CRF database (5.88) Analyzing the clinical study data (statistics) (5.76) Organizing data for the clinical study report (6.07)
Document management (4.81)	Discussing/confirming the period of clinical study document preservation (4.62) Keeping the ongoing clinical study documents (source document, CRF) (5.31) Organizing the investigator's file (5.62) Requesting archives of clinical study document (4.28) Making document registers (4.23)
Management of research-related specimen and test (4.85)	Reserving the specific test (4.96) Performing the test using the clinical study-specified equipment (EKG ect.) (5.14) Performing the test using the clinical study-specified instruments (rating etc.) (5.03) Collecting the specimen (5.30) Handling the specimen (5.15) Requesting the transfer of specimen (frozen or ambient sample packing, etc.) (5.00) Requesting the copy of radiological imaging (4.20) Requesting the transfer of radiological imaging (4.03)

DC=Determinant coefficient; KFDA=Korea Food & Drug Administration; PFT=Pulmonary function test; IVRS=Interative voice response system; e-CRF=Electronic case report form; CRF=Case report form; SOPs=Standard operating procedures.

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Table 1. Determinant Coefficient Scores for Duties and Tasks (Continued)

Duty (DC)	Task (DC)
Management of research facilities and materials (4.52)	Confirming the adequacy of research facilities (5.18) Confirming whether to control the preciseness of data collection equipment and instruments (5.16) Requesting clinical study materials (4.07) Inventory management of clinical study material (3.95) Purchasing and managing the emergency instrument/kit (4.23)
Administrative work for research review/supervision organization (6.54)	Preparing the requested materials for review (IRB/KFDA) (6.52) Preparing documents for the requisition form (6.05) Confirming the review results (5.44) Preparing the interim/annual report (5.67) Cooperating to report adverse events (including SAE) (7.40) Cooperating to report any deviation or violation from the protocol (6.66) Receiving the monitoring (6.33) Cooperating to receive the audit (7.36) Cooperating to receive the inspection from KFDA (7.44)
Research budget management (5.91)	Budgeting for the clinical study (medical cost, personal expenses, indirect cost, etc.) (6.32) Executing clinical study cost (5.75) Calculating clinical study cost (5.68)
Self-improvement (6.05)	Completing the education for Good Clinical Practice (GCP) for medicine and medical instruments (6.42) Collecting recent information related clinical trials (5.90) Completing continuing education related to clinical trials (5.72) Improving communication ability (5.97) Improving foreign language ability (6.49) Improving ability in computer use (5.79)

EKG = Elctrocardiogram; IRB = Institutional review board; KFDA = Korea Food & Drug Administration; SAE = Serious adverse event.

Table 2. Determinant Coefficient Scores for the Most Important Tasks

Order	Duty	Task	DC
1	Participants management	Confirming the participants's eligibility for the research (screening: criteria for inclusion/exclusion)	8.03
2	Participants management	Explaining informed consent: clinical study process only	7.49
3	Administrative work for study review/supervision organization	Cooperating to receive the inspection from KFDA	7.44
4	Administrative work for study review/supervision organization	Cooperating to report adverse events (including SAE)	7.40
5	Administrative work for study review/supervision organization	Cooperating to receive the audit	7.36
6	Plans for clinical trial	Reviewing the clinical study protocol	7.27
7	Participants management	Administrating investigational product to participants	6.85
8	Data management	Completing the case report form (CRF)	6.84
9	Participants education	Educating guidance for complying with protocol (forbidden drug, writing the participant's diary, precautions pre/post test, test method, etc.)	6.81
10	Data management	Resolving data queries	6.71

DC = Determinant coefficient; KFDA = Korea Food & Drug Administration; SAE = Serious adverse event.

results of previous studies are different from the job classification criteria and structure suggested in this study. The reasons for the difference may be found in several factors including the purpose of job analysis, analysis method, and the researcher's idea. While previous studies surveyed research nurses using questionnaires prepared by the researchers based on literature on CRC jobs (Hwang, 2008; Kang, Kim, Jeong, & Baik, 2004), this study developed the questionnaire from experienced field CRCs with representativeness using the DACUM job analysis method on the assumption that those with rich practical experiences would be most familiar with their job. Accordingly, the results of this study are believed to suggest more comprehensive and specific CRC roles than the previous studies mentioned above. The consequent duties and tasks were validated twice as an effort to suggest the most valid CRC jobs in Korea.

In the results of this study, the duty with the highest determinant coefficient was 'administrative work for research review/supervision organization,' and the task with the highest determinant coefficient was

Table 3. Determinant Coefficient Scores for the Least Important Tasks

Order	Duty	Task	DC
1	Management of research facilities and materials	Inventory management for clinical study material	3.95
2	Participants management	Paying the clinical study-related compensation to participants	3.97
3	Management of research-related specimen and test	Requesting the transfer of radiological imaging	4.03
4	Management of research facilities and materials	Requesting clinical study materials	4.07
5	Management of research-related specimen and test	Requesting the copy of radiological imaging	4.20
6	Document management	Making document register	4.23
6	Management of research facilities and materials	Purchasing and managing the emergency instrument/kit	4.23
8	Document management	Requesting archives of clinical study document	4.28
9	Management of standard operational procedure (SOP)	Distributing and discarding the SOPs to the involved departments	4.33
10	Management of standard operational procedure (SOP)	Keeping all of the original SOPs	4.36

DC = Determinant coefficient; SOPs = Standard operating procedures.

'Confirming the participant's eligibility for research.' Tasks included in 'administrative work for study review/supervision organization' were about review/supervision related to the adequate performance of research by higher administrative authorizes. These results confirm that the job that CRC regards as most important and difficult is being reviewed and supervised by supervisory authorizes.

In case of research nurses in foreign countries, the importance of GCP and ethics was highest, which was followed by connection to and support from other research nurses, informed consent, research method, and practical skills, and on the contrary, the importance of research and development was lowest, which was followed by research fund management, data management, patient advocating, side effects, data protection, etc. (Hill & MacArthur, 2006). In contrast, jobs considered important by Korean research nurses were filling CRFs (87.0%), contacting researchers/sponsors (84.4%), screening participants (81.8%), preparing research-related supplies (79.2%), and observing and reporting adverse events (79.2%) in order of importance (Kang, Kim, Jeong, & Baik, 2004). In our study, the most important and difficult tasks were confirming the particinpat's eligibility and explaining the informed consent, and this result was consistent with the report of Kang, Kim, Jeong, and Baik (2004) that subject screening was the most important and difficult. The research of Hwang (2008) on research nurses working for oncologic clinical trials reported similar results, confirming the importance of participant management. In this study, on the other hand, inventory management for clinical study materials was the tasks showing the lowest determinant coefficient. This is probably because this task is supportive to clinical research and can be done by other personnel authorized by CRCs. In the research of Hwang as well, administrative work was least important among 6 areas, supporting our results.

As presented above, the determinant coefficient of a duty did not match exactly with the determinant coefficients of tasks under the duty but was correlated to the sum of the determinant coefficients of tasks. Therefore, it is meaningful to examine tasks for which importance, difficulty and frequency were rated grade A, B or C. Among the tasks, 13 were A in importance, difficulty and frequency, 8 were B, and 13 were C. Many of the A-grade tasks belonged to the category of participant management, including tasks explaining the informed consent, confirming the participant's eligibility, performing the planned clinical study procedures according to participant's visiting schedule, and administrating investigational product. This suggests that participant management is the core of clinical research. Because nurses have the most desirable background to be a CRC, many nurses are working as CRCs, and in this situation, it has been reported that there is a high redundancy between nurses' jobs and CRCs' roles (Raja-Jones, 2002). However, it is more valid to think that only nurses can properly carry out CRCs' job, which demands a lot of time to be spent with participants. In addition, duties such as standard operational procedure management, document management, and the management of research-related specimens and tests were considered relatively less important, less difficult and frequent. This may reflect the current situation that although standard operational procedure management and document management are high-level CRCs' jobs, most of CRCs are too busy to cover such jobs.

The duties and roles of CRC are not solidly established yet in Korea and the contents and time of CRC education program are various depending on the institutions which provide the program. To improve the quality of CRCs, it is necessary to introduce systematic curriculum and

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certification system. To do this, it is essential to perform job analysis. The significance of this job analysis study is to identify duties of CRC and prepare the evidence to develop a standardized curriculum. In addition, the importance, difficulty, and frequency identified through this study can be utilized to separate the contents for the advanced course. For example, the contents for the basic course can include the tasks with low degree of difficulty and high degree of frequency such as scheduling as date of hospital visits, educating for the targeted research disease, collecting the source data, organizing an investigator's file, collecting specimen, etc. The tasks with high degree of difficulty and low degree of frequency such as budgeting for clinical study, developing SOPs, reviewing and revising the SOPs, and organizing data for the clinical study report should be included in the advanced course. These phased education programs can help CRCs prepare their duties and assign duties to CRCs according to their preparation. This can be also decrease new CRCs' frustration and increase experienced CRCs' self-esteem. To get recognition of CRC's role and ladder system externally as well as internally, national certification system, especially graded certification system, is necessary. The job analysis from our study can be evidential basis to help to develop evaluation standards.

In this study, we found very trivial tasks that CRCs perform which can reduce CRC's self-esteem. As CRCs perceived management of research-related specimens and tests to be a miscellaneous job, it can be adjust by delegating the job such as using assistants for those works and assigning CRCs only for duties purely related to research. That is, we need to clarify the boundary of CRCs' roles and ease their burden through finding methods to transfer tasks rated C in all of importance, difficulty and frequency to other personnel or departments.

To prevent CRCs from feeling conflicted and burdened in carrying out their roles, we need to develop and operate systematic education programs and establish systematic CRC employment conditions through the introduction of a certification system. To do this, the government, universities and industries should make joint efforts to reflect and apply the contents of KGCP in the field. Furthermore, future research needs to derive CRC roles through agreement between CRCs and clinical research associates and senior researchers whose jobs are closely connected to CRCs' roles.

CONCLUSION

In this study, the roles of CRCs were defined using the DCUM job analysis method. After CRCs' job was defined and their duties and tasks were derived through DACUM job analysis, the duties and tasks were validated twice and finally, 12 duties and 78 tasks were obtained. For CRCs, the most important, difficult and frequent duties were participant management and research review/supervision organization administrative work, and the least important, difficult and frequent one was the management of research facilities and materials.

This study suggests that it be required the phased education programs considering frequency, difficulty, and importance. In addition, graded certification system through national examination may be needed. The results of this study also suggest that CRCs are experiencing strains from various duties and tasks. Thus, it is necessary to adjust their roles, focusing on those that CRCs consider most important. In addition, research assistants may be utilized or inessential jobs should be transferred to other departments so that CRCs are able to concentrate on essential jobs for clinical research. Based on the results of this study, furthermore, we need to inform researchers and sponsors on CRCs' roles so that they share the same understanding of CRCs' roles.

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