

## Workload and Work Importance of Clinical Research Nurse

Su A Kwon<sup>1</sup> and Nam Young Yang<sup>1+</sup>

Department of Nursing, College of Nursing, Konyang University, Daejeon,  
302-832, Korea

<sup>+</sup>Corresponding author, E-mail: [nyyang@konyang.ac.kr](mailto:nyyang@konyang.ac.kr)

### Abstract

*This study was conducted to investigate the workload and work importance of Clinical Research Nurses (CRNs). Subjects consisted of 152 CRNs. The mean scores were 4.79/7 points in workload; 5.75/7 points in work importance. Workload differed significantly according to their job-related characteristics, depending on the type of employment ( $p=.027$ ), the number of ongoing studies ( $p=.027$ ), while there was no statistically significant difference in their work importance according to their job-related characteristics. These findings indicated that, in order to increase CRN's job satisfaction, it is necessary to understand their job related characteristics, well and to prepare a work environment for effective job performance along with standardized job analysis.*

**Key words:** Workload, Work Importance, Clinical Research Nurse

### 1. Introduction

A Clinical Research Nurse (CRN) is one of Clinical Research Coordinators (CRCs) who support and operate clinical trials, and other than nurses, pharmacists, clinical pathologists or medical assistants with a medical knowledge may serve as CRCs, but typically, since CRCs should have knowledge about medicine, pharmacy and clinical trial, nurses are considered most suitable for that (KFDA & NiTR, 2005) [1]. The majority of CRCs in the United States are nurses (Bowen & Rice, 1998) [2], and the term, CRC is used mixed with CRN. Nurses who have knowledge and experience of specific diseases, the subjects of this study, play a very important role in managing clinical trial subjects effectively and safely and increasing the quality of materials and compliance according to clinical trial procedures (Spilsbury, *et al.*, 2008) [3]. Rebecca and Christine (2010) [4] said that nurses who have knowledge about disease processes can report medical changes in symptoms, increase subjects' registration, complete clinical trials timely and make great contributions to the enhancement of the quality of data and the improvement of the observation of clinical trial protocols. The scope of clinical trial-related tasks of which CRNs are in charge may differ depending on the degree and content of delegation of the person in charge of tests, and are classified into administration, providing direct practical works, monitoring, research, education and counseling, advocacy and coordination, clinical trial progress, subject management and self-development, *etc.* (Doh, Seon-Ju, 2010 [5]; Hwang, Yun-Seon, 2008 [6]; Hwang, Yun-Seon & Ko, Il-Seon, 2010 [7]), and the tasks mainly performed include screening, scheduling of clinical trial subjects, preparing the Case Report Form (CRF), acquisition of agreement, serious adverse events report, and description and education of clinical trial procedures (Kim, Tae-Eun, 2009) [8]. Also, in foreign countries, it is reported that CRNs' tasks include protocol review, preparation of documents for evaluation of qualifications in research institutions, budgeting and consultation, researchers meetings, attendance of the initiation meeting in research institutions, clinical trial subject screening, recruitment, enrollment, informed consent process based on a full explanation, evaluation and implementation of research components, data management, performing professional nursing role, clinical trial subject

visit management, supporting documents management and data collection, participation in monitoring and preparation of the completion of study visits (Elisa, 2010 [9]; Rebecca & Christine, 2010 [4]). However, currently, in South Korea, although CRNs play an important role, the security is low, and almost no eligibility criteria, wages and system status, roles and task regulations, training programs and meeting for mutual task exchange regarding CRNs have been established (Kim, Tae-Eun, 2009) [8], and CRNs' job satisfaction is at an ordinary level (Kwon, Su-a & Yang, Nam-yeong, 2015) [10].

Thus, this study attempts to understand the workload and task significance perceived by CRNs and propose basic data for preparing strategies to investigate the role identity as professional nurses.

## 2. Methods

This study was conducted to investigate the job satisfaction of 152 Clinical Research Nurses (CRNs). Also was accepted from IRB of Konyang University Hospital, Daejeon. Data were analyzed using t-test and ANOVA.

## 3. Results

As for the subjects' sex, all of them, 152 persons (100%) were female. As for their age, those in their 30s were 91 persons (59.9%), followed by those in their 20s, 41 persons (27.0%) and those in their 40s or older, 20 persons (13.2%). As for the level of their education, university graduates were 91 persons (59.9%), followed by college graduates, 45 persons (29.6%) and graduate students or higher, 16 persons (10.5%). As for their religion, 95 persons had one (62.5%), while 57 persons (37.5%) did not, and as for their marital status, 96 persons (63.2%) were unmarried, while 56 persons (36.8%) were married (Table 1).

As for the department to which the research subjects belonged, 68 persons (44.7%) were individual professors, followed by members of a clinical trial center, 55 persons (36.2%), those in an individual medical department, 24 persons (15.8%) and other, 5 persons (3.3%). As for the official title of the research nurses, 81 persons (53.3%) were Clinical Research Nurses, while 71 persons (46.7%) were Clinical Research Coordinators. As for the type of employment, most of them were full-time workers at a work without holding four insurance policies, 98 persons (64.5%), followed by contract workers at a work covered by four insurance policies, 30 persons (19.7%); regular workers, 13 persons (8.6%); and part-time workers, 11 persons (7.2%). As for their income, 85 persons (55.9%) earned 1.5 million to 2 million won a month, followed by 35 persons with an income between 2 million and 2.5 million won, 35 persons (23.0%), 19 persons (12.5%) with an income over 2.5 million won and 13 persons (8.6%) with an income less than 1.5 million won. Regarding their working conditions, when duplicated responses were allowed, 148 persons (97.4%) were provided with a personal computer; 144 persons (94.7%) were given a personal space, (94.7%); 133 persons (87.5%) were provided with an opportunity to attend education; 132 persons (86.8%) were provided with a break; and 35 persons (23.0%) were provided with four insurance policies. As for their motive for application, most of them applied for full-time employment, 60 persons (39.5%), followed by participation in research, 39 persons (25.7%); having time, 24 persons (15.7%); a challenge to a new field, 17 persons (11.2%); and working and studying, 12 persons (7.9%). As for their previous place of work, 133 persons (87.5%) were clinical nurses, while 19 persons (12.5%) were non-clinical nurses, and as for the period of their service as a nurse, more than 5 years in 53 persons (34.9%); between 1 year and 3 years, 47 persons (30.9%); between 3 years and 5 years, 29 persons (19.1%); and less than 1 year, 23 persons (15.1%). As for the period of work as a CRN, between 1 year and 3 years in 56 persons (36.8%); between 3 years and 5 years, 33 persons (21.7%); more than 5 years, 34 persons (22.4%), less than 1 year, 29 persons (19.1%). As for the number of their

research in progress, 3 to 5 studies in 63 persons (41.4%); 6 to 10, 41 persons (27.0%), more than 11, 31 persons (20.4%); and 1 to 2, 17 persons (11.2%). As for the stage of research of which they were in charge when duplicated responses were allowed, 125 persons (82.2%) were in a three-phase clinical trial, followed by a four-phase clinical trial, 99 persons (65.1%); a two-phase clinical trial, 83 persons (54.6%); one-phase clinical trial, 46 persons (30.3%); and other, 25 persons (13.3%). As for their completion of training for clinical trials, 40 persons (26.3%) completed, while 112 persons (73.7%) did not, and as for the suitable affiliation as a CRN, 107 persons (70.3%) responded that it would be a clinical trial center, followed by a medical department, 21 persons (13.8%); other, 13 persons (8.6%); the hospital nursing department, 8 persons (5.3%); and an individual professor, 3 persons (2.0%). As for the Appropriate service period of CRNs, 97 persons (63.8%) responded that 1 to 3 years would be appropriate, followed by 3 to 5 years, 31 persons (20.4%); less than 1 year, 15 persons (9.9%); not necessary, 6 persons (3.9%); and more than 5 years, 3 persons (2.0%). As for their qualifications, 70 persons (46.1%) responded that graduation from a university would be necessary, followed by the graduation from three-year college, 44 persons (28.9%); the completion of a curriculum for research nurses, regardless of the level of education, 35 persons (23.0%); higher than a master's course, 3 persons (2.0%). 134 persons (88.2%) responded that they had a possibility of development, while 18 persons (11.8%) responded that they did not. As for the factors necessary for development, when plural responses were allowed, 114 persons (75.0%) picked the establishment of organizations in the hospital as a factor; 116 persons (76.3%), a switch to a regular position; 62 persons (40.8%), inclusion as a professional nurse; and 50 persons (32.9%), the implementation of a qualifying examination (Table 2).

The workload of the subjects of this study was  $4.79 \pm 0.95$  on average out of 7. Of the sub-domains, subject management task was highest at  $5.20 \pm 1.08$ , followed by administrative task at  $5.07 \pm 0.91$ , coordination/advocacy task at  $4.81 \pm 1.18$  and Self-improvement at  $4.09 \pm 1.33$ . The Work importance of the subjects of the study was  $5.75 \pm 0.81$  on average out of 7. Of the sub-domains, subject management task was highest at  $6.04 \pm 0.81$ , followed by administrative task at  $5.82 \pm 0.82$ , coordination/advocacy task at  $5.70 \pm 0.95$  and Self-improvement at  $5.41 \pm 1.05$  (Table 3).

The workload of the subjects of the study did not show statistically significant differences depending on general characteristics: age ( $F=0.37$ ,  $p=0.688$ ), educational background ( $F=2.14$ ,  $p=0.121$ ), religion ( $t=0.17$ ,  $p=0.858$ ) and marital state ( $t=0.51$ ,  $p=0.610$ ). The Work importance of the subjects of the study did not demonstrate statistically significant differences depending on general characteristics: age ( $F=2.12$ ,  $p=0.123$ ), educational background ( $F=2.72$ ,  $p=0.069$ ), religion ( $t=1.63$ ,  $p=0.105$ ) and marital state ( $t=1.25$ ,  $p=0.213$ ) (Table 4).

Workload according to job-related characteristics of the subjects of this study showed statistically significant differences depending on employment status ( $F=2.99$ ,  $p=0.033$ ), the number of studies in progress ( $F=3.15$ ,  $p=0.027$ ). In the results of a post-test, contract workers perceived a higher workload as compared to regular workers, and when there were over 11 studies in progress, the respondents perceived higher workload than when 1 study or 2 studies were in progress. In the meantime, there were no statistically significant differences depending on the department ( $F=0.16$ ,  $p=0.922$ ), income ( $F=0.57$ ,  $p=0.635$ ), reason for application ( $F=0.30$ ,  $p=0.876$ ), previous place of work ( $t=0.08$ ,  $p=0.935$ ), nurse years of service ( $F=0.90$ ,  $p=0.409$ ), CRN's employment period ( $F=0.60$ ,  $p=0.615$ ), completion state of education ( $t=1.69$ ,  $p=0.093$ ) and development possibility ( $t=-0.36$ ,  $p=0.712$ ). Work importance according to job-related characteristics of the subjects of this study did not show statistically significant differences depending on the department ( $F=0.12$ ,  $p=0.943$ ), employment status ( $F=1.18$ ,  $p=0.316$ ), income ( $F=0.07$ ,  $p=0.974$ ), reason for application ( $F=0.54$ ,  $p=0.705$ ), previous place of work ( $F=0.90$ ,  $p=0.368$ ), nurse years of service ( $F=0.57$ ,  $p=0.635$ ), research nurse employment period ( $F=0.26$ ,  $p=0.849$ ), the number of studies in progress ( $F=1.26$ ,  $p=0.289$ ), completion state of education ( $t=0.32$ ,  $p=0.743$ ) and

development possibility ( $t=.76, p=.447$ ) (Table 5).

**Table 1. General Characteristics of CRNs** (N=152)

Characteristic	Classification	n	%
Sex	female	152	100.0
	20s <sup>a</sup>	41	27.0
Age	30s <sup>b</sup>	91	59.8
	40s and over <sup>c</sup>	20	13.2
	College graduate	45	29.6
Education	Four-year university graduate	91	59.9
	Graduate student or higher	16	10.5
Religion	Yes	95	62.5
	No	57	37.5
Marital Status	Not married	96	63.2
	Married	56	36.8

**Table 2. Job-related Characteristics of CRNs** (N=152)

Characteristic	Classification	n	%
Affiliation	Individual Professor	68	44.7
	Clinical Trial Center	55	36.2
	Treatment Department	24	15.8
	Other	5	3.3
official title	Clinical Research Nurse	81	53.3
	Clinical Research Coordinator	71	46.7
Type of employment	Regular	13	8.6
	Contracted	30	19.7
	Full time	98	64.5
Income	Part time	11	7.2
	Less than 1.5 million won	13	8.6
	1.5-2 million won	85	55.9
	2-2.5 million won	35	23.0
working conditions*	2.5 million and over	19	12.5
	personal space	144	94.7
	personal computer	148	97.4
	vacation	132	86.8
Motive for application	Provide insurance	35	23.0
	Provide education	133	87.5
	Research participation	39	25.7
	Regular work	60	39.5
	Studying and working	12	7.9
Previous place of work	Having time	24	15.7
	Challenge in a new field	17	11.2
	Clinical	133	87.5
Period of	Non-clinical	19	12.5
	Less than 1 year	23	15.1

service as a nurse	1-3 years	47	30.9
	3-5 years	29	19.1
	More than 5 years	53	34.9
Period of work as a CRN	Less than 1 year	29	19.1
	1-3 years	56	36.8
	3-5 years	33	21.7
	More than 5 years	34	22.4
No. of research in progress*	1-2	17	11.2
	3-5	63	41.4
	6-10	41	27.0
	11 and over	31	20.4
Stage of research in charge	Phase 1	46	30.3
	Phase 2	83	54.6
	Phase 3	125	82.2
	Phase 4	99	65.1
	other	25	13.3
Completion of training	Yes	40	26.3
	No	112	73.7
suitable affiliation of CRNs	Hospital nursing department	8	5.3
	Individual Professor	3	2.0
	Clinical Trial Center	107	70.3
	Medical department	21	13.8
	other	13	8.6
Appropriate service period of CRNs	Not necessary	6	3.9
	Less than 1 year	15	9.9
	1-3 years	97	63.8
	3-5 years	31	20.4
Qualifications of CRNs	More than 5 years	3	2.0
	College graduate	44	28.9
	Four-year university graduate	70	46.1
	Higher than a master's course	3	2.0
	Completion of a curriculum regardless education	35	23.0
Possibility of development of CRNs	Yes	134	88.2
	No	18	11.8
the factors necessary for development of CRNs*	Qualifying examination	50	32.9
	Inclusion as a professional nurse	62	40.8
	Establishment of organizations in the hospital	114	75.0
	Switch to a regular position	116	76.3

\* Duplicated responses allowed. Percentage of each item is the proportion to the total number of 152 persons.

**Table 3. Workload, Work Importance of CRNs** (N=152)

Variable	Sub-domain	M±SD
Workload	Administration task	5.07±0.91
	Subject management task	5.20±1.08
	Coordination/Advocacy task	4.81±1.18
	Self-improvement	4.09±1.33
	Sum total	4.79±0.95
Work importance	Administration task	5.82±0.82
	Subject management task	6.04±0.81
	Coordination/Advocacy task	5.70±0.95
	Self-improvement	5.41±1.05
	Sum total	5.75±0.81

**Table 4. Differences in Workload, Work Importance according to General Characteristics of CRNs** (N=152)

Characteristic	Classification	Workload		Work importance	
		M±SD	t/F (p)	M±SD	t/F (p)
Age	20s <sup>a</sup>	4.76±0.92	.37 (.688)	5.94±0.80	2.12 (.123)
	30s <sup>b</sup>	4.83±0.93		5.64±0.75	
	40s and over <sup>c</sup>	4.64±1.13		5.82±1.00	
Education	College graduate	4.82±0.93	2.14 (.121)	5.63±0.80	2.72 (.069)
	Four-year university graduate	4.86±0.93		5.86±0.75	
	Graduate student or higher	4.33±1.02		5.42±1.03	
Religion	Yes	4.80±0.93	.17 (.858)	5.83±0.75	1.63 (.105)
	No	4.77±0.99		5.61±0.88	
Marital Status	Not married	4.82±0.94	.51 (.610)	5.80±0.80	1.25 (.213)
	Married	4.74±0.97		5.64±0.81	

**Table 5. Differences in Workload, Work Importance according to Job-Related Characteristics of CRNs** (N=152)

Characteristic	Classification	Workload		Work importance	
		M±SD	t/F (p)	M±SD	t/F (p)
Affiliation	Individual Professor	4.78±0.94	.16 (.922)	5.72±0.79	.12 (.943)
	Clinical Trial Center	4.85±0.96		5.78±0.81	
	Treatment Department	4.72±0.88		5.77±0.76	
	Other	4.64±1.44		5.60±1.39	
Type of	Regular <sup>a</sup>	4.21±0.85	2.99	5.37±0.96	1.18

employment	Contracted <sup>b</sup>	5.12±0.83	(.033)	5.78±0.70	(.316)
	Full time <sup>c</sup>	4.79±0.95	a<b	5.80±0.80	
	Part time <sup>d</sup>	4.64±1.11		5.62±0.98	
Income	Less than 1.5 million won <sup>a</sup>	4.61±1.06	.57 (.635)	5.74±0.95	.07 (.974)
	1.5-2 million won <sup>b</sup>	4.75±0.97		5.72±0.84	
	2-2.5 million won <sup>c</sup>	4.96±0.73		5.80±0.60	
	2.5 million and over <sup>d</sup>	4.80±1.16		5.76±0.92	
	Research participation	4.91±0.88	.30 (.876)	5.70±0.90	.54 (.705)
Motive for application	Regular work	4.70±0.92		5.70±0.83	
	Studying and working	4.80±1.17		5.95±0.55	
	Having time	4.77±.88		5.70±0.72	
	Challenge in a new field	4.87±1.20		5.94±0.81	
Previous place of work	Clinical	4.80±0.92	.08 (.935)	5.72±0.80	-.90 (.368)
	Non-clinical	4.78±1.18		5.90±0.87	
Years of work as a nurse	Less than 1 year	4.57±1.20	.90 (.409)	5.58±0.95	.57 (.635)
	1-3 years	4.74±1.05		5.83±0.81	
	3-5 years	4.77±0.85		5.79±0.69	
	More than 5 years	4.95±0.77		5.71±0.81	
Period of work as a CRN	Less than 1 year	4.96±0.99	.60 (.615)	5.86±0.80	.26 (.849)
	1-3 years	4.68±0.97		5.74±0.79	
	3-5 years	4.77±0.95		5.70±0.93	
	More than 5 years	4.85±0.89		5.70±0.74	
No. of research in progress	1-2 <sup>a</sup>	4.49±1.02	3.15 (.027)	5.75±0.80	1.26 (.289)
	3-5 <sup>b</sup>	4.75±0.98	a<d	5.79±0.81	
	6-10 <sup>c</sup>	4.65±0.93		5.55±0.88	
	11 and over <sup>d</sup>	5.22±0.77		5.90±0.69	
Completion of training	Yes	5.00±1.06	1.69 (.093)	5.78±0.84	.32 (.743)
	No	4.71±0.90		5.73±0.80	
Possibility of development	Yes	4.78±0.96	-.36 (.712)	5.76±0.81	.76 (.447)
	No	4.87±0.91		5.61±0.81	

#### 4. Discussion

In the results of the above research, CRNs' workload was perceived differently depending on their job-related characteristics, but task significance was not perceived

differently depending on job-related characteristics. Thus, it is found that the perception of task significance does not differ depending on working conditions or task as well as CRNs' individual characteristics. Therefore, in order to establish CRNs' role identity, along with standardized job analysis, it is strategically necessary to create a working environment for effective job performance.

## References

- [1] KFDA and NiTR, Editor, Basic education for CRC. Seoul, (2005).
- [2] K. E. Bowen and L. S. Rice, "Who is clinical research nurse?", *Research Nurse*, vol. 4, no. 4, (1998), pp. 1-4.
- [3] K. Spilsbury, E. Petherick, N., Cullum, A. Nelson, J. Nixon and S. Mason, "The role and potential contribution of clinical research nurses to clinical trials", *Journal of Clinical Nursing*, vol. 17, (2008), pp. 549-557.
- [4] D. Rebecca and R. Christine, "The Essential Role of the Clinical Research Nurse(CRN)", *Urologic Nursing*, vol. 30, no. 1, (2010), pp. 55-63.
- [5] S. J. Do, "The Role of clinical research nurses at regional clinical trial centers", *Korean Academy Nursing Administration*, vol. 16, no. 3, (2010), pp. 348-359.
- [6] Y. S. Hwang, "Job analysis of clinical research nurse in oncology department", Unpublished master's thesis, Yonsei University. Seoul, (2008).
- [7] Y. S. Hwang and I. S. Ko, "Role Performance and Related Factors of the Clinical Research Coordinator", *Korean Academy Nursing Administration*, vol. 17, no. 4, (2011), pp. 524-537.
- [8] T. E. Kim, "Job related characteristics and job satisfaction among clinical research coordinator", Unpublished master's thesis, Chosun University, Gwangju, (2009).
- [9] B. Elisa, "Defining the role of the clinical research nurse", *Oncology Nursing Forum*, (2010), pp. 12-13.
- [10] S. A. Kwon and N. Y. Yang, "Job Satisfaction of Clinical Research Nurse", *Proceedings of International Workshop Healthcare and Nursing 2015, Jeju Island, Korea*, (2015) April 15-18.