Analysis of the Status Quo and Factors Influencing Nurses' Perceived Professional Value in Drug Clinical Trials

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Abstract: Objective: We aimed to explore the status quo of clinical research nurses' (CRNs) perceived professional value and analyze its influencing factors. Methods: We selected a total of 230 CRNs from eight Tertiary hospital in China that met the inclusion and exclusion criteria using convenience sampling from February 2021 to February 2022. The investigation was conducted using a self-developed general information questionnaire and the perceived professional value scale. We used the independent sample *t*-test, single factor analysis of variance, and multiple linear regression analysis to process the data. Results: A total of 219 eligible questionnaires were collected from 230 CRNs involved in drug clinical research. Of these, 87.21% (191/219) were women. Most CRNs (69.41%, 152/219) had a bachelor's degree in nursing (78.54%, 172/219) and had worked for 3–10 years (66.21%, 145/219). Among CRNs, 57.08% (125/219) were engaged in drug clinical research less than 1 year. The mean score of perceived professional value among CRNs was 4.33±0.03. The score for social support was the highest (4.38±0.33), and the score of matched degree of occupation and ability was the lowest (3.42±0.20). The score of perceived professional value for matching professional and personal advancement and number of GCP trainings showed statistically significant differences among drug CRNs ($P<0.05$). Multiple linear regression analysis showed that sex, length of service in clinical research, and the number of clinical trial projects in which CRNs participated were the main factors influencing perceived professional value ($P<0.05$). Conclusion: Perceived professional value among CRNs in China is at a high level. The department, number of GCP training, and management of operations-related work affect CRNs' perceived professional value. Therefore, targeted interventions can be developed according to our findings to improve the perceived professional value of CRNs involved in drug clinical research.

Keywords: Clinical Research Nurse; Perceived Professional Value; Influencing Factors; Clinical Trial

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1 Introduction

Perceived professional value refers to self-judgment regarding the value of one's occupation, including personal identity, strengthening self-worth, personal growth and achievement, and interpersonal communication. Perceived professional value plays an important role in guiding an individual's professional identity, sense of belonging, and work enthusiasm [1, 2]. Clinical research nurses (CRNs) are closely involved in

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clinical trial research, and their screening and evaluation is more stringent than that of general nursing staff [3, 4]. Though CRNs as a member of the trial management group has a positive demonstrable impact on overall trial success [5, 6], the latest survey showed that 40% of respondents either misunderstood or had no idea of the role of the CRN, with 60% having limited or basic understanding [7]. Insufficient understanding concerning the perception of the CRN role and their contribution to the clinical trials exists. At present, the development of medical technology in China is accelerating, the number of related clinical trials is increasing, and the management of drug clinical trials is gradually becoming standardized. CRNs mainly provide care for trial participants and act as the executor, safety guarantor and doctor-patient communication liaison on the clinical research team, which makes their work complex [8]. However, there is no professional and unified CRN training and management system in China, which can lead to disorganized nursing practice as well as a heavy work burden and psychological pressure for CRNs, which affects their perceived professional value.

In this study, we aimed to investigate the status quo of perceived professional value of CRNs and analyze its influencing factors to provide evidence for relevant management departments to formulate strategies for improving the work efficiency of clinical research teams and improving the psychological status of CRNs.

2 Materials and Methods

2.1 Data Collection and Questionnaire

Data collection was carried out from February 2021 to February 2022. CRNs from eight Tertiary hospital in Jiangsu Province were selected using a convenience sampling method. CRNs were selected only when they met the inclusion criteria: (1) registered nurse; (2) obtained the Good Clinical Practice (GCP) training certification at or above the provincial level; and (3) voluntary cooperation with the investigation. CRNs were not selected if they were retired returning nurses, non-nursing personnel, or personnel transferred from another nursing post or who resigned during the study period.

With reference to previous studies [9], we designed a basic data questionnaire to record information of CRNs, including sex, length of service, major, educational background, professional title, department, length of service in clinical research, number of GCP trainings, number of trials clinical trial projects in which the CRN participated, and expected form of GCP training.

A perceived professional value scale for CRN was developed by Zhao and Liang in 2020 [10]. The scale includes six items regarding CRNs, five items addressing the degree of matching between career and personal advancement, eight items regarding standards of the department reward and punishment system, five items involving support from colleagues, four items querying cooperation between nurses and patients, five items addressing social support, and four items querying the degree of matching between career and ability. The total score was 185 points, with higher scores indicating greater perceived professional value among CRNs. Cronbach's α for the scale was 0.961, the split-half reliability was 0.865, test–retest reliability was 0.951, and content reliability was 0.868; thus, the scale showed good reliability and validity. The data were collected in the form of questionnaires. The investigators were trained for 1–3 months and distributed the questionnaires in cooperation with the clinical trial management department.

2.2 Data Analysis

IBM SPSS 22.0 statistical software was used to analyze the data (IBM Corp., Armonk, NY, USA). Continuous variables are reported as mean±standard deviation (SD) and range and discrete variables as percentage. Comparisons between groups was conducted using the *t*-test or analysis of variance, and a multivariate linear regression model was used for multivariate analysis. The significance level was $\alpha=0.05$, with $P<0.05$ considered statistically significant.

3 Results

3.1 General Information of CRNs

According to 219 questionnaires that were effectively collected, most CRNs were women (87.21%), and most 3–10 years of service (66.21%); most CRNs were nursing majors (69.41%); From the distributions of educational background and professional titles, CRNs mainly had undergraduate degrees (78.54%) and junior professional titles (55.71%). In terms of GCP-related information, most CRNs were engaged in drug clinical research for

less than 1 year (57.08%). More than half (66.21%) had completed GCP training fewer than three times, and most CRNs had not participated in clinical trials (60.27%); From the perspective of the expected form of GCP training and teaching, both in-hospital and out-of-hospital as well as video instruction were preferred by most CRNs (89.04%) (Table 1).

Table 1 General information of CRNs

Characteristic		No.	%
Sex	Male	28	12.79
	Female	191	87.21
Length of service (years)	1–2	21	9.59
	3–5	71	32.42
	6–10	74	33.79
	11–20	48	21.92
	>20	5	2.28
Profession	Nursing	152	69.41
	Pharmacy	37	16.89
	Clinical medicine	15	6.85
	Other	15	6.85
Education	Technical secondary	3	1.37
	Junior college	25	11.42
	Undergraduate	172	78.54
	Postgraduate	19	8.68
Department	Clinical Department	101	46.12
	Medical Technology	63	28.77
	Clinical Trial Facility	3	1.37
	SMO	1	0.46
	Other	51	23.29
Professional title	No	20	9.13
	primary	122	55.71
	Senior	64	29.22
	Vice professor	10	4.57
	Professor	3	1.37
Length of service in clinical research (years)	0	125	57.08
	1–2	63	28.77
	3–5	14	6.39
	6–10	11	5.02
	>10	6	2.74
Number of GCP trainings (times)	0	63	28.77
	1–2	82	37.44

3.2 Perceived Professional Value Scale Scores

Among 219 CRNs, the average score for the perceived professional value scale was 4.33±0.03. The average score for each item is shown in Table 2. The average score for social support was the highest, and that for matched career and ability was the lowest.

Table 2 Perceived professional value scale scores

Characteristic	Item	Score					Mean (±SD)
		1	2	3	4	5	
Occupational cognition	6	80	26	148	242	818	4.29±0.03
Matched degree of career and personal promotion	5	72	19	115	263	626	4.23±0.03
Department reward and punishment system specification	8	99	10	176	433	1034	4.31±0.03
Colleague support	5	62	5	85	254	689	4.37±0.03
Nurse–patient cooperation	4	51	4	78	193	550	4.36±0.04
Social support	5	63	6	91	222	713	4.38±0.03
Match between occupation and ability	4	51	4	67	184	570	3.42±0.20

3.3 Analysis of Factors Influencing Perceived Professional Value

Among 219 CRNs, there was no significant difference in scores for different characteristics of perceived professional value. Scores differed according to sex, length of service, educational background, length of service in clinical research, and clinical trial items (P>0.05). From the perspective of the personnel department, Scores regarding site management organization (SMO) were highest for occupational cognition, nurse patient cooperation, and matched occupation and ability and lowest for matched occupation and individual promotion and in the department reward and punishment system. Scores for matched occupation and individual promotion were significantly lower than scores for clinical departments and medical technology departments (P<0.05). Perceived professional value scores of CRNs who had received three or more GCP trainings were significantly higher than those of CRNs who had only received 1–2 GCP trainings (P<0.05) (Table 3).

Table 3 Analysis of factors influencing perceived professional value

Characteristic		code	N	Occupational cognition (score)	Matched degree of career and personal promotion	Department reward and punishment system (score)	Colleague support (score)	Nurse–patient cooperation (score)	Social support (score)	Match between occupation and ability (score)
Sex	Male	1	28	24.29±7.79	20.18±6.45	33.75±9.40	20.86±5.96	16.50±5.06	20.93±6.13	16.75±5.13
	Female	2	191	25.94±5.96	21.32±5.23	34.58±8.11	22.01±5.00	17.55±4.07	22.07±5.05	17.68±4.01
	t			1.313	1.045	0.493	1.110	1.240	1.083	1.103
	P			0.191	0.297	0.623	0.268	0.216	0.280	0.217
Length of service (years)	1−2	1	21	27.14±4.07	22.76±3.12	36.52±5.07	23.1±2.98	18.52±2.56	23.19±3.01	18.48±2.44
	3−5	2	71	26.08±6.12	22.08±5.09	35.17±8.34	22.18±5.19	17.68±4.21	22.15±5.27	17.82±4.13
	6−10	3	74	24.97±6.77	20.42±5.65	33.93±8.61	21.34±5.42	16.73±4.43	21.36±5.46	17.04±4.43
	11−20	4	48	25.56±6.52	20.58±5.64	33.27±8.84	21.42±5.51	17.44±4.52	21.77±5.63	17.44±4.53
	>20	5	5	27.40±2.40	18.4±8.47	35.4±7.05	24.2±1.78	19.20±1.78	23.00±2.73	19.00±2.236
	F			0.696	1.823	0.794	0.913	1.151	0.619	0.764
	P			0.595	0.126	0.530	0.457	0.334	0.649	0.550
Profession	Nursing	1	152	26.67±5.35	22.06±4.52	35.68±7.21	22.61±4.44	18.11±3.54	22.74±4.45	18.24±3.51
	Pharmacy	2	37	22.95±7.77[a]	18.86±6.71[a]	30.32±10.62[a]	19.19±6.75[a]	15.08±5.44[a]	19.27±6.87[a]	15.30±5.44
	Clinical Medicine	3	15	26.13±5.64	19.93±6.43	33.67±7.99	21.8±4.78	17.47±3.88	21.6±4.83	17.33±3.88
	Other	4	15	22.60±8.16[a]	19.13±6.87[a]	33.27±9.30	20.93±5.58	16.13±5.22	20.53±5.86	16.53±5.13
	F			5.192	4.843	4.544	4.826	6.034	5.095	5.618
	P			0.002	0.003	0.004	0.003	0.001	0.002	0.001
Education	Technology secondary	1	3	29.00±1.00	24.00±1.00	39.67±0.57	23±2.646	19.33±0.57	23.67±1.15	19.33±0.57
	Junior college	2	25	27.28±5.19	22.8±4.45	36.52±7.13	23.12±4.32	18.48±3.58	23.32±4.30	18.64±3.45
	Undergraduate	3	172	25.49±6.48	21.05±5.49	34.22±8.57	21.72±5.35	17.26±4.38	21.76±5.42	17.44±4.34
	Postgraduate	4	19	25.32±5.31	19.74±5.70	33.21±7.02	21.37±4.29	17.16±3.48	21.32±4.36	16.95±3.53
	F			0.906	1.523	1.108	0.651	0.839	0.857	0.921
	P			0.439	0.210	0.347	0.583	0.474	0.464	0.431
Department	Clinical department	1	101	26.34±5.79	21.97±4.79	35.80±7.59	22.68±4.69	18.03±3.80	22.8±4.73	18.22±3.77
	Medical technology	2	63	26.92±4.31	22.24±3.71	35.76±6.09	22.63±3.71	18.33±2.87	22.86±3.60	18.25±2.88
	Clinical trial facility	3	3	30.00±0.00	21.67±5.77	34.67±9.23	21.67±5.77	17.33±4.61	21.67±5.77	17.33±4.61
	SMO	4	1	30.00±0.00	5.00±0.00[ab]	24.00±0.00	21.00±0.00	20.00±0.00	20.00±0.00	20.00±0.00
	Other	5	51	22.71±8.09	18.57±6.90	30.43±10.43	19.31±6.61	15.04±5.43	19.08±6.68	15.37±5.45
	F			4.576	7.100	4.793	4.409	5.936	5.496	5.002
	P			0.001	<0.001	0.001	0.002	<0.001	<0.001	0.001
Professional title	no	1	20	28.00±2.84	23.35±2.20	36.85±4.71	23.1±2.65	18.70±2.17	23.10±2.63	18.70±1.83
	Primary	2	122	25.56±6.19	21.36±5.19	34.63±8.40	21.81±5.25	17.32±4.24	21.91±5.26	17.52±4.17
	Senior	3	64	25.20±7.14	20.41±6.10[a]	33.53±9.00	21.55±5.65	17.19±4.73	21.66±5.85	17.34±4.76
	Vice professor	4	10	26.50±4.83	21.30±4.62	35.30±6.70	22.50±4.24	17.60±3.37	22.00±4.21	17.30±3.59
	Professor	5	3	26.00±6.92	15.00±10.00[ab]	29.33±9.23	20.33±5.03	17.33±4.619	20.00±5.00	17.33±4.61
	F			0.840	2.204	0.945	0.454	0.529	0.397	0.427
	P			0.501	0.070	0.439	0.769	0.715	0.711	0.789
Length of service in clinical research (years)	0	1	125	25.13±6.62	20.88±5.59	33.98±8.95	21.5±5.60	17.07±4.55	21.66±5.68	17.27±4.52
	1−2	2	63	26.76±5.47	22.05±4.72	35.25±7.76	22.37±4.71	18.08±3.78	22.52±4.68	18.05±3.70
	3−5	3	14	26.86±4.14	22.64±3.12	35.50±5.20	22.29±3.51	17.93±2.67	22.5±3.25	18.21±2.54
	6−10	4	11	25.55±6.87	19.64±6.13	36.27±3.43	23.45±1.91	17.36±3.47	21.73±3.58	17.73±3.66
	>10	5	6	25.00±7.97	17.50±8.80[b]	30.67±10.63	20.17±6.33	16.67±5.31	20.00±6.32	16.67±5.31
	F			0.860	1.705	0.748	0.751	0.696	0.535	0.519
	P			0.489	0.150	0.560	0.558	0.596	0.710	0.722
Number of GCP trainings (times)	0	1	63	25.08±6.59	20.92±5.62	34.54±8.39	21.83±5.22	17.22±4.46	21.90±5.33	17.43±4.35
	1−2	2	82	24.00±7.43	19.85±6.18	32.02±9.91	20.35±6.23	16.16±5.01	20.49±6.34	16.43±5.05
	3−5	3	35	28.63±2.17[ab]	23.66±2.52[ab]	38.37±3.09[ab]	24.09±1.88[ab]	19.23±1.49[ab]	23.89±2.41[b]	19.23±1.68[b]
	>5	4	39	27.79±3.18[ab]	22.13±4.20[b]	36.00±5.46[b]	23.10±3.11[b]	18.77±2.27[b]	23.21±2.86[b]	18.67±2.29[b]

Characteristic		code	N	Occupational cognition (score)	Matched degree of career and personal promotion	Department reward and punishment system (score)	Colleague support (score)	Nurse–patient cooperation (score)	Social support (score)	Match between occupation and ability (score)
	F			6.802	4.797	5.792	5.644	6.438	4.766	5.093
	P			<0.001	0.003	0.001	0.001	<0.001	0.003	0.002
Clinical trial projects (number in which CRN participated)	0	1	132	25.14±6.49	20.85±5.46	34.11±8.46	21.55±5.27	17.02±4.37	21.62±5.37	17.29±4.33
	1−2	2	32	25.06±7.40	21.28±6.22	34.19±9.96	21.66±6.27	17.38±5.04	21.69±6.28	17.31±5.01
	3−5	3	29	27.72±5.03[a]	22.62±4.73	36.86±6.83	23.31±4.26	18.48±3.40	22.93±4.53	18.45±3.48
	6−10	4	17	27.59±3.24	22.12±3.31	35.06±5.57	22.88±3.05	18.82±2.35	23.41±2.91	18.76±2.33
	11−20	5	5	26.00±2.82	21.60±2.30	35.20±4.38	22.00±2.73	17.6.00±2.19	22.00±2.73	17.60±2.19
	>20	6	4	27.50±5.00	16.00±8.40[cd]	28.00±8.00[c]	19.00±4.89	17.00±3.83	20.00±4.08	17.00±3.83
	F			1.280	1.372	1.060	0.954	0.993	0.703	0.691
	P			0.274	0.236	0.384	0.447	0.423	0.622	0.631

SMO, site management organization.
[a] compared with group 1, P<0.05; [b] compared with group 2, P<0.05; [c] compared with group 3; P<0.05; [d] compared with group 4, P<0.05.

3.4 Logistic Regression Analysis of Influencing Factors of Perceived Professional Value

We established a logistic regression model with the mean score of perceived professional value as the variable. Sex, length of service in clinical research, and number of clinical trials in which CRNs participated were significant influencing factors of perceived professional value among CRNs (P<0.05) (Table 4).

Table 4 Logistic regression analysis of influencing factors of perceived professional value

Variable	Denormalization coefficient		Normalization coefficient	*t*	P	95% CI	
	B	*SD*	*B*			Lower limit	Upper limit
Sex	29.133	3.051		9.549	<0.001	23.118	35.147
Length of service	−0.346	1.104	−0.022	−0.314	0.754	−2.523	1.831
Profession	−0.810	0.491	−0.149	−1.652	0.100	−1.778	0.157
Education	−0.025	0.505	−0.004	−0.049	0.961	−1.021	0.972
Professional title	−1.302	0.805	−0.123	−1.617	0.107	−2.889	0.285
Department	−0.040	0.694	−0.006	−0.057	0.954	−1.408	1.328
Length of service in clinical research	−0.953	0.263	−0.285	−3.624	<0.001	−1.472	−0.435
Number of GCP trainings	0.468	0.429	0.087	1.091	0.277	−0.378	1.314
Clinical trial projects (participation)	0.831	0.431	0.165	1.931	0.045	−0.017	1.680

4 Discussion

CRNs begin their careers in university-affiliated hospitals, large public hospitals, and research institutes. After being authorized and trained by the principal investigators, CRNs assist researchers in affairs involving non-medical judgment during clinical trials, including obtaining informed consent, data collection and (or) assisting in trial management. Therefore, CRNs play important roles in ensuring the ethical soundness, scientific character, and credibility of the data in clinical trials. Thus, their degree of professional development is greater than that of general nurses [11, 12]. However, at present, CRNs usually comprise clinical nurses or part-time nurses, whose professional background is complicated, and their identification with and professional value of clinical drug trial work as well as their professional training, work experience, and practical skills differ from those of other nurses. Perceived professional value refers to self-judgment of the value of one's present and future career, estimation of possible achievement, and degree of satisfaction with social returns. Today, one's occupation is not only a means of making a living but also an expression of individual identity that is tied with life value, which is of great importance in the pursuit of a career, work completion, and occupational identity [13] Therefore, to better understand the CRN profession, it is helpful to analyze factors influencing perceived professional value to provide insight regarding how to

improve career value among CRNs.

In total, 87.21% of the 219 CRNs in this study were women (191/219), among which 69.41% (152/219) were nursing majors and 46.12% (101/219) worked in clinical departments. CRNs are largely derived from nursing staff, and our findings may be related to the fact that the nursing profession today is dominated by women. Our results may also be influenced by the greater proportion of nursing staff in hospitals and research institutions who are women [14]. In addition, from the viewpoint of professional value, scores for nursing professional cognition, professional and personal promotion, department reward and punishment system, colleague support, nurse–patient cooperation, and social support were significantly higher than those among pharmacy professionals; however, there was no significant difference between the two groups in scores for the degree of matching between career and ability. CRNs are mainly responsible for assisting in clinical trial work, including data collection, trial management, and external communication, but CRNs can also participate in the drug research process, thereby gaining diverse work experience and a sense of accomplishment during the testing and project development process. Therefore, although the degree of matching between occupation and ability is low among CRNs, their overall occupational sense of well-being and value is high.

In terms of education and work background, a large majority of the CRNs in our study had undergraduate degrees (78.54%, 172/219), and most had worked for 3–10 years (66.21%, 145/219) and had junior professional titles (55.71%, 122/219). Nurses with relevant experience have certain occupational and communication skills and are more likely to be approved by the experimental research department. Morzinski found that when organizational and career goals tend to coincide, workers can achieve greater growth and career impact [15]. The findings of this study suggest that nurses with a junior title or no title have a more urgent desire to update their knowledge and use related practice to accumulate work experience so as to further enhance their overall skills and work title. Scores on the perceived professional value scale among CRNs without a professional title were higher than those of CRNs with a professional title. Further research into this aspect of perceived professional value among CRNs is warranted to allocate more time to non-clinical research-related work among some CRNs.

According to the information regarding GCP, 57.08% (125/219) of CRNs had been engaged in drug-related clinical research for less than 1 year, 66.21% (145/219) had not received GCP training more than twice, and 60.27% (164/219) of CRNs had not participated in any clinical trial projects. From this point of view, the current professional training level among CRNs in China is low and their actual practice and management experience is insufficient [16]. In our survey, perceived professional value scores among CRNs who had received three or more GCP trainings was higher than that of CRNs who had only complete 1–2 training. SMO showed the highest scores on the items of professional cognition, nurse–patient cooperation, and matching between occupation and ability and the lowest scores for professional and individual promotion and department reward and punishment system. Scores for matching of career and personal promotion were significantly lower than those for nursing department and clinical department. This indicates that relevant GCP training can seriously affect the sense of professional value among CRNs, and it is easier to achieve a high level of professional of self-worth through practice and management, which will improve nurse–patient communication efficiency and occupational skills. Finally, regarding the expected form of GCP training and teaching, both in-hospital and out-of-hospital as well as video instructions and courses were preferred by most CRNs (89.04%), which indicated that most CRNs have high expectation for GCP training and do not prefer only online or offline training modes. Thus, hospitals and institutions should choose their most convenient form of GCP training teaching form, according to their actual situation.

5 Conclusion

In conclusion, our findings revealed that most CRNs in China are women and the department, GCP training, and actual management and practice affect CRNs sense of professional value. Intervention measures can be developed to improve the perceived professional value of CRNs. At present, the biomedical industry in China is developing rapidly, and medical institutions are encouraged to actively participate in innovation activities. This sector will need highly skilled high-level personnel, which includes CRNs who have higher professional requirements. The development of CRNs in China is limited to some extent, which is related to the lack of knowledge, understanding, and management of CRNs in some hospitals. By analyzing the current perceived

professional value among CRNs, our study findings can help to deepen understanding of this occupation and lay a foundation for the stable and sustainable development of CRNs on clinical research teams.

Disclosure

The authors have no conflicts of interest to disclose.

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