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Original Research Article

A retrospective pilot study comparing data from monitoring reports to identify staffing influence on protocol deviation rates

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ABSTRACT

Background: Clinical research sites are hiring more non-licensed personnel to coordinate clinical trials and to replace licensed nurse counterparts. Revised regulatory documents heavily emphasize research staff training and research activity delegation of authority. The Scope and Standards of Practice for Clinical Research Nursing, published by the American Nurses' Association and based on role delineation studies for nurses, is the guidance document for clinical research nurses participating in research activities. Policy making related to research activity delegation of authority would be informed by data that correlate protocol deviation rates with licensure and education of research staff. Protocol deviations can lead to invalid clinical trial results, adverse events, and ethical concerns related to participant risk exposure. Outcome data are lacking, which directly compare frequency of protocol deviations by licensed nurse study coordinators to deviation rates of non-licensed study coordinators.

Methods: This pilot study reviewed 45 monitoring reports for 3 clinical research studies and associated research sites staffed with licensed RN study coordinators and research sites staffed with non-licensed, non-RN study coordinators to compare deviation rates related to informed consent, protocol endpoints, participant eligibility and adverse events.

Results: We identified 101 deviations. Adverse event and endpoint deviations were the highest frequency. Differences were evident in overall deviation rates; however, specific deviation comparisons failed to show statistical significance due to low sample size.

Conclusions: This study illustrates a useful method for planning future studies using monitoring reports for deviation tracking and comparison across staffing levels.

Keywords: Clinical research nurse, Research nurse coordinator, Clinical research coordinator, Delegation of authority, Protocol deviations, Scope of practice, Protocol violations

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INTRODUCTION

Well conducted protocols within the clinical research enterprise follow a trajectory where bench discovery with preclinical testing ultimately leads to clinical trials in human participants. The progression from new discovery to marketing approval can take more than 10 years and cost more than \$2 billion dollars. Only those protocols supported by confirmatory, applicable research results generated from animal studies, assays, molecular pathways, and genetic links move into the early Phase 0 and Phase 1 clinical trials in humans.

Human participant data measuring the safety and efficacy of protocol endpoints are the heart of clinical trial results. Safety and efficacy endpoint data are submitted to the Food and Drug Administration (FDA) where decisions are made based on these data to either market the new product or not. Clear evidence of safety and efficacy of the new product to prevent, treat or cure health problems is required. When a study is well conducted, rigorous quality data ensure that those determinations are made accurately with high validity. Factors that may damage efficiency and quality include delays in study processes or issues in the transfer of data from patient visit to database. The enrollment of patients who do not meet eligibility criteria will confound study results. Lack of proper participant informed consent can render collected data useless. Issues in safety reporting can also threaten validity of a trial; for instance, undetected or unreported adverse events, adverse drug reactions or serious adverse events can cause a trial to continue longer than it should, exposing study participants to undue harm. Moreover, improper collection of endpoint data can fail to address key study hypotheses. Failure to follow the protocol rigorously, e.g., failure to collect data through physical assessments and laboratory testing for the purposes of safety and efficacy reporting are other key threats to study validity. These deviations from the protocol, incongruent with federal regulations and ICH GCP

(International Conference on Harmonisation Good Clinical Practice guidelines) are not uncommon. Deviations may also result in both bioethical concerns and potential legal and financial liabilities. The FDA has mandated human subject protection training to improve performance gaps; however, despite mandated training, FDA inspection results remain static and deviations related to informed consent, eligibility, adverse event reporting and endpoint collection continue to occur at higher than expected rates.^{2,3}

When a principal investigator (PI) accepts the responsibility to lead a clinical trial of an investigational drug or medical product, he or she agrees to adhere to federal regulations and ICH GCP. This includes rigorously following the protocol, ensuring IRB approval, obtaining informed consent, supervising study activities, and confirming that sufficient resources, including trained study staff, are in place at the clinical research site to carry out the investigational plan as approved by regulatory authorities.⁴ While PIs are ultimately responsible for the conduct of the study, delegation of specific research activities is often necessary.

The professional role of clinical research coordinator (CRC) emerged from the growing clinical research enterprise and the need for PIs to delegate clinical research activities to ancillary staff.^{5,6} In the United States (US), clinical research coordinators were initially registered nurses (RNs). Clinical trials were primarily conducted in academic medical centers in federally funded clinical research units. As studies progressed to community medical settings, CRC positions expanded to include non-licensed personnel. At the same time, multiple roles in clinical research expanded into additional specializations, such as data management and regulatory affairs. This expansion produced a broad heterogeneity and poorly standardized clinical research job titles. A recent report from Duke University shows the role of "clinical research coordinator" to represent 82 job titles.⁷

Table 1: The rise of clinical trial complexity.

Complexity indicator	2000-03	2008-11	Change (%)
Median study treatment period	140 days	175 days	25
Median study "site work burden"	28.9 units	47.5 units	64
Number of eligibility criteria	31 criteria	46 criteria	58
Number of case report forms per protocol	55 pages	171 pages	227
Number of procedures per study protocol	105.9	166.6	57

Note: Adapted from: Getz, Campo & Kaitlin, Drug Information Journal, 2011;45:413-20.

As the "era of complexity" emerged, the scientific backdrop for new molecular discoveries including genomic, genetic, and immunologic criteria contributed to the stressors of study management.⁸ Protocols required more participants, complex visit operations, increasing numbers of study visits and long follow-up periods. Advances in clinical testing emerged to best characterize endpoints. Sicker patient populations with rare diseases

became targets for the regulatory strategy for new discoveries. A factor of 10 increase in numbers of protocol amendments correlated with protocol complexity. Additionally, new technological advances in data collection and electronic reporting, complex protocols and shrinking funding resulted in increased burden on clinical research site personnel, especially CRCs. Despite these complexities, CRC workload did not

decline but study budgets remained relatively stable. From 2001 to 2011 the average number of clinical trial protocols that a CRC was responsible for rose from 4.3 studies to 7.0 studies.⁸ Table 1 illustrates rise of complexity in clinical trials as published by Getz, Campo and Kaitin.⁹

With the increasing complexity and workload of clinical trials, institutional and federal policies related to scope of practice and delegation of authority have emerged to specify those study activities that require a licensed health care professional; however, such policies are not the norm. $^{10,\Pi 1}$ Yet, the numbers of CRCs lacking clinical licensure are increasing, including within academic medical center research sites. Administrators of clinical research sites argue that no performance differences exist between RN-CRCs and non-licensed CRCs. However, an exhaustive literature search revealed no published data supporting the Administrators' conclusion. economics of operating a clinical research site demand cost-cutting measures. The national average salary of an experienced RN-CRC in the United States is \$72,862, compared to non-licensed counterparts (\$47,100). 12-14 Hiring lower paid CRCs to replace RNs, coupled with increased workload therefore may become the preferred solution.

Several research publications highlight the role of the RN-CRC, and identify the unique contributions of nurses to the clinical research enterprise. The American Nurses Association (ANA) and the International Association of Clinical Research Nurses have copublished Scopes and Standards of Clinical Research Nurses.¹⁸ ANA formally recognized clinical research nursing as a professional nursing specialty. 19 Survey research comparing RN-CRC perceptions of activities being performed by non-licensed CRCs confirm a broad overlap in roles despite RN-CRC concerns that assessment of safety and efficacy parameters may be jeopardized and that there is potential for unlicensed personnel to function outside their scope of practice. 20,21 Comparative research that demonstrates the RN-CRC contributions (e.g., quality indicators) to informed consenting, eligibility, safety, and endpoint assessment is lacking.¹⁶ Moreover, as the complexity of patient populations, clinical research studies and assessments increase, the requirements for hiring RN-CRCs should be increasing, rather than decreasing. To bridge the gap in research, this pilot study compares quality and safety variables based on the frequency of protocol deviations by RN-CRCs to unlicensed CRCs. This study seeks to determine if there are differences in deviation rates in studies where the site has RN-CRCs assigned to the study rather than non-licensed CRCs. It will also demonstrate a potential future method of integrating these comparisons in future research.

METHODS

The purpose of this pilot study is to compare deviation rates for nurse RN-CRCs to non- RN CRCs based on a

review of site monitoring reports between the dates of March 14, 2006 to May 8, 2013 for three specific clinical research studies (Study A, B, and C). The hypotheses for this pilot study was: "the frequency of deviations found at RN sites would be less than the frequency of deviations found at non-RN sites." We calculated frequencies and percentages for each of the four types of deviations and for the total number of deviations for comparison.

The availability of monitoring reports provided feasible access to study performance. The Director of clinical trials coordinating center located at a large academic medical center in the United States facilitated this study after initial approvals by study sponsors and the coordinating center's principal investigator. The study received an expedited review by the University of Alabama at Birmingham Institutional Review Board because this was secondary analysis of available data. To protect confidentiality, site and study protocol identifiers were coded alphabetically and numerically so that they would protect the identity of studies, sponsors, investigators and institutions. The code for study and site numbers were kept separately from final analyses. The analysis and study report included no personal identifiers.

Table 2: Categorization of study coordinators working at study sites from monitoring report review.

Protocol	Sites RN CRC Sites	Non-RN CRC Sites	Total
A	2	2	4
В	2	1 ^a	3
C	3	3	6
Total	7	6	13

Note: ^aPrior to review, the study team eliminated monitoring reports from one site due to lack of confirmation of study staff designation (RN or non-RN).

The coordinating center maintained a standard operating procedure (SOP) for reporting deviations; whereby deviations were reported by sites and reviewed and tracked by monitors. Site monitors were required to quantify deviations in their site visit reports and perform quality control checks against site reported deviations. A copy of all monitoring reports were maintained as PDFs in a file in the coordinating center and were reviewed for data collection. Three clinical research studies were targeted for this review. A table of study sites and site personnel job titles and degrees aided in sorting which sites had employed only RN-CRCs for the study; and which sites had employed only non-RN CRCs. Some sites conducting the three clinical research studies had a combination of RN and non-RN CRC staff; however, for the purpose of this study, none of the sites selected for review had a combination of RN and non-RN CRCs. Monitoring reports for the three studies and 14 participating sites were reviewed and analyzed. Staffing categories (RN CRCs and non-RN CRCs) at the sites were later confirmed by a review of monitoring reports

that described the study staff titles and responsibilities. One site in Study B lacked sufficient documentation to determine if the staff was RN or non-RN, so monitoring reports for that study and site were removed from analyses of deviations. Table 2 characterizes the staffing for each protocol included in this study.

RESULTS

A total of 45 monitoring reports were analyzed and coded for four types of deviations identified by monitors during specific monitoring visits:

- Informed consent deviations (ICD): incomplete signatures on informed consent; incorrect consent; non-documented consent;
- Endpoint deviations (EPD): failure to accurately assess and/or report endpoints; missing endpoint visits:
- 3. Eligibility deviations (ELD): enrollment of patients that do not meet the inclusion/exclusion criteria;
- Adverse event deviations (AED): failure to report or misclassification of adverse events and serious adverse events.

Table 3: Deviations for 45 monitoring reports.

Deviation type	Frequency N (%)
ICD	17 (17)
EPD	39 (38)
ELD	2 (2)
AED	44 (44)
Total	101 (100)

A total of 101 deviations were identified in the 45 monitoring reports. Of the 45 total monitoring reports, 25 (55.5%) were reports that were associated with sites that employed only RN CRCs to manage the study. The additional 20 (44.4%) monitoring reports were from sites that assigned only non-RN CRC sites. The frequency of deviations by type is summarized in Table 3. Deviations categorized as adverse event reporting (AER) deviations and endpoint reporting deviations (EPD) had the highest number of deviations found (44% and 38% respectively).

The frequency of deviations by CRC staff are shown in Table 4 below. The highest numbers of deviations for both groups was for adverse event reporting (AED) followed by end point deviations (EPD).

Table 4: Deviations from monitoring reports.

Personnel category	ICD (n=17) (%)	EPD (n=38) (%)	ELD (n=2) (%)	AED (n=44) (%)	Total (n=101) (%)
RN Only Site	5 (29.4)	3 (7.89)	0 (0)	17 (38.6)	25 (24.75)
Non-RN Only Site	12 (70.5)	35 (92.1)	2 (100)	27 (61.4)	76 (75.24)

Table 5: Deviations by site and personnel category.

Site	ICD		EPD		ELD		AED		Total	
Site	RN	non-RN	RN	non-RN	RN	non-RN	RN	non-RN	RN	non-RN
1	0	0	0	0	0	0	0	0	0	0
2	1	4	0	0	0	0	3	3	4	7
3	0	0	0	33	0	0	0	20	0	53
4	0	2	3	0	0	1	14	3	17	6
5	0	1	0	0	0	0	0	1	0	2
6	1	5	0	2	0	1	0	0	1	8
7	3		0		0		0		3	
Subtotal	5	12	3	35	0	2	17	27	25	76
Total	17		38		2		44		101	

Table 6: Comparing 0 and >1 deviations at sites.

# PDs	ICD		EPD		ELD		AED		Total	
# PDS	RN	non-RN	RN	non-RN	RN	non-RN	RN	non-RN	RN	non-RN
0	4	2	6	4	7	4	5	2	3	1
>1	3	4	1	2	0	2	2	4	4	5
P value	p=0.6	p=0.56		P=0.19		p=0.29		p=0.56		

At first glance, these consolidated data appear to support our hypothesis that RNs are responsible for less deviations than their non-RN counterparts; however, when the data were put into a table that maps out deviations by type and site, it reveals interesting site level deviation issues. For instance, in Table 5, one site appears to have the majority of the endpoint deviations (EPD), suggesting that non-RNs perform more EPD; however, this may be an issue for that single site. This site also had a higher incidence of adverse event deviations (AED).

Because there were only six sites per category, low sample size and a lack of available information about the personnel at the site made it difficult to draw conclusions that compare RN to non-RN.

Table 7: Comparing 0, 1, 2 and >3 deviations at sites.

# PDs	ICD		EPD		ELD		AED		Total	
# PDS	RN	non-RN	RN	non-RN	RN	non-RN	RN	non-RN	RN	non-RN
0	4	2	6	4	7	4	5	2	3	1
1	2	1	0	0	0	2	0	1	1	0
2	0	1	0	1	0	0			0	1
>3	1	1	1	1	0	0	2	3	2	4
P value	p=0.84		p=0.7		p=0.19		p=0.39		p=0.3	7

We then sought to compare sites based on the number of protocol deviations dividing the sites groups as (a) no deviations, or (b) one or more deviations. Comparisons using Fisher's exact test did not reveal statistically significant differences (Table 6).

A second test compared the proportion of sites who had 0, 1, 2 and 3 or more deviations between sites to determine if we had too broad an approach for comparing rates. Fisher's exact test was used to measure significance. Those analyses also failed to prove statistically significant differences (Table 7).

DISCUSSION

This study is an initial attempt to compare clinical research quality indicators (deviation rates) based on staffing with clinical research coordinators that are RNs versus those who are not RNs and lack clinical licensure. Quality in clinical research has been defined by FDA as "the ability to effectively and efficiently answer the intended question about the benefits and risks of a medical product while ensuring protection of human subjects."²²

No existing studies have been conducted heretofore for nurse quality indicators for the clinical research protocol performance. Studies of nurse-sensitive outcomes in hospital settings have been published over the past 3 decades. Most studies connecting staffing patterns with outcomes have been conducted in hospital settings. Those studies provide insightful background for the important work of defending the importance of nursing in patient care across settings; however, in the clinical trial setting, especially outside of the inpatient setting, a different research approach would be necessary.

While there are increasing studies that explore nursing perceptions of scopes of practice and begin to address activities that are being shared by both nurses and nonnurses in the clinical research setting;^{20,21} no study has directly compared study quality outcomes in the form of protocol deviation rates between nurse and non-nurse CRC counterparts. Olsen, et al addressed issues

associated with nurse vs non-nurse staffing by evaluating delegation of duties using an external consultant, staff input and institutional and study site managers. ¹¹ The Olsen study resulted in new institutional policies that differentiated clinical research staffing based on scope of practice.

The need for training and ongoing quality improvement is stressed in the revised International Council on Harmonization, E6 (R2).²⁴ A clinical trial without deviations is rare. Often deviations are unintended, though some can be intentional variations from the study protocol. Critical deviations and major deviations are categories that have direct impact on patient safety.²⁵ Falling in these two distinct categories, those deviations most impacting bioethical and patient safety in the clinical research setting can be correlated with deviations from informed consenting; study eligibility violations; adverse event reporting and accurate collection of endpoint data. Moreover, these deviations from the protocol have potential implications to the generalizable population should study validity be jeopardized. In a setting where there is an increasing trend in non-nurse study positions; it is important for nursing to advocate for both study participants and the study protocol by exploring a means for comparing outcomes based on staffing and defining nurse-sensitive indicators.¹⁵

This is a small pilot study; therefore, several limitations are inherent in this study and results should be carefully interpreted. One factor that could lead to a misinterpretation of the data was the heterogeneity present among several aspects of the data. Our sample size was limited and the design of the three studies utilized also varied. Having a homogeneous type of study design would have been optimal (e.g., all Phase I, Phase II, or Phase III clinical trials; excluding registry or observational studies). Moreover, the type of study intervention should be similar; for example, in the case of virology studies, treatment trials for a given infection is one type of trial that should not be compared to a vaccine prevention trial. Populations under study should also be similar; e.g., adults or pediatrics; underlying disease processes. Therefore, we acknowledge that our results are not generalizable to all clinical research coordinators (nurse and non- nurse) across the research enterprise.

In general, the availability of demographic data describing the study coordinators (our study subjects) were limited. As a retrospective study, we only had access to existing information about staffing experience. Specific desirable CRC demographics would have included 1) how long the individual had worked in clinical research 2) the number and types of studies each had worked on in the past (depth of experience, 3) the types of academic degrees each had earned and 4) the number of years the nurse coordinators had worked as only clinic or hospital nurses (not in research). These additional demographic data would improve a future study.

A wide variation was noted in subject enrollment across the investigational sites. Some sites only had one subject who prematurely terminated participation or only had one study visit while other sites enrolled large numbers of subjects who completed all study visits. Wide variations were also noted in the types of studies, (adult versus pediatric; natural history versus drug), in the number of study visits, and in the number of monitoring visits. All of these factors could have contributed to the frequency of deviations a study coordinator (nurse or non-nurse) experienced at a given site; thus confounding results.

Additionally, the monitor plans and source of monitoring (different monitoring organizations) were variable across studies. This could have confounded the results. It would also have been interesting to have identified if RN-CRCs or non-nurse CRCs were more likely to identify their own deviations. It is also possible that the number of deviations were limited to only those identified by a monitor. A good, thorough coordinator would have identified his/her own deviations before the monitor's arrival. Comparing reporting rates and how those agree with monitoring reports may be revealing.

Further research is warranted to look at nurse versus nonnurse coordinators (including their experience and education) in a single, large research study to provide more homogeneity and to produce results more generalizable to a larger population of study coordinators. Gaining access to monitoring reports and deviation records for larger multi-center clinical trials that staff exclusively with RNs or non-RN CRCs would be an ideal place to start.

CONCLUSION

This is the first known study that compared rates of deviations for RN CRCs versus non-RN CRCs. Using monitoring reports is one way to compare quality performance of clinical research staff (RN and non-RN) by looking at the frequency of protocol deviations. This pilot study indicates differences in overall deviation rates; however, due to low sample size, it fails to suggest statistically significant differences by specific deviation comparisons. Notwithstanding, this study illustrates a useful mechanism to evaluate deviation metrics. Furthermore, it provides guidance for the planning of future studies that use monitoring reports for deviation tracking and comparison. While most clinical research sites employ a combination of RN and non-RN sites to maximize a team approach to clinical trial management, it is important to understand the rising complexity of clinical research protocol demands and the current staffing issues that require appropriate delegation of activities in clinical research studies based on licensure and scope of practice. Additional studies are needed to evaluate the unique value of RN CRCs to the clinical enterprise.

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