Ensuring Representativeness in Competencies for Research Coordinators

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Ensuring Representativeness in Competencies for Research Coordinators

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Abstract

Providing educational programs designed to promote clinical research coordinators' (CRCs') implementation of competency skills is essential to workforce development; however, little is known about how programs address CRCs' needs. The purpose of this study was to assess CRCs' experiences in a six-month course. Using focus group methods, six participants revealed how the training assisted them in daily work.

The findings supported previous study results, and led to the identification of two competencies which are missing from the existing Joint Task Force for Clinical Trial Competency framework domains of "Communication and Teamwork" and "Leadership and Professionalism." The authors explain why these competencies are important for coordinators. The authors also discuss the instrumentality of qualitative research to ensure that competency domains reflect the needs of those for whom they are developed.

Introduction

The knowledge and skills of CRCs are fundamental to the success of those working in the profession and, in turn, the success of the research enterprise of institutions and investigators. The center of the CRCs' activities is human subjects research, with all its implications for ethics and participant safety.

CRCs undertake a variety of tasks, including requesting informed consent from participants, collecting and managing data or biological specimens, submitting regulatory documents to

committees or agencies, and overseeing budget issues.{1} The multifaceted and, at times, highly technical nature of these activities can be daunting because they span broad and diverse work environments and require a highly specialized work force.

However, CRCs are generally trained in an on-the-job fashion, rather than by completing more formal training prior to working in these roles.{2} Furthermore, evidence suggesting that completing an academic program in clinical research results in CRC competence is not available.{3} Consequently, expanding workforce skills requires competency-based, focused training and evaluation efforts—both for novice and experienced professionals—in order to operate in today's complex research arenas.

Frameworks have been developed to guide trainings that focus on the implementation and application of competency-based skills in research coordination and management. One of these, the Joint Task Force for Clinical Trial Competency (JTF) framework, is intended to be broad and applicable to individuals conducting, supporting, and managing research in varied professional capacities.{3} This evolving framework currently includes the domains of "Leadership and Professionalism" and "Communication and Teamwork" among its eight competency domains.

After reviewing other established professional leadership programs{4} offered through University of Florida Training and Organizational Development and relevant literature{5} on leadership education, the authors of this article developed and implemented a training program for experienced CRCs on topics relevant to the JTF competency domains. This program was developed concurrently with other training programs for CRCs in an effort to ensure robust training for our research workforce.{6–8}

In our literature search, we found a *Harvard Business Review* article that noted how "[m]embers of complex teams are less likely…to share knowledge freely, to learn from one another, to shift workloads…to help one another complete jobs and meet deadlines, and to share resources—in other words, to collaborate."{9} The article's authors explain a strong team leader is essential for success.

The purpose of the study outlined in the following sections was to assess CRCs' experiences in a six-month length course, and to describe if and how the training assisted them in daily work.

Methods

A single, 90-minute focus group was conducted with six experienced CRCs following completion of a six-month course. Topics addressed included navigating academia, vision and creativity, professional development, leadership, mentorship, and communication. The moderator (another researcher who was not a course instructor) explained the purpose of the study, and asked for consent to videotape the session using Zoom technology. The questions used during this semi-structured interview are shown in Appendix A.

A professional transcription service transcribed the audiotape. Questions were designed to ascertain how the training program addressed participants' professional needs, and to gain details on the following items pertaining to each individual participant:

- instructional preferences for in-class or online teaching and module content, and for a standardized coordinator curriculum

- essential skills or competencies

- whether their level of professionalization increased or decreased

- the ideal characteristics of a research coordinator

- how the coordinator training program influenced their role enactment

- if and how the training program influenced their sense of being/becoming an ideal CRC

All four authors of this article read the transcript independently, and each developed a list of emergent themes and sent it to the last author, who entered the collective themes into an Excel spreadsheet. The authors met and together developed a consensually agreed-upon list. Next, each author was assigned a subset of themes and was instructed to enter representative excerpts into the spreadsheet. After completing this task, another author checked the accuracy of the selected text passages.

Following data entry, the last author checked all areas of differences and sent a list to the primary analyst assigned to those areas where agreement was not reached. However, in all instances the primary and secondary analysts reached consensus. This process helped ensure the primary analyst stayed immersed in the data and enhanced their analytical acumen. The use of four analysts strengthened the credibility and dependability of the findings.

After conferring about the findings, the authors noted that some themes were similar to those found in previous studies.{6–8} However, two themes (elaborated upon in the Results section below) had not been identified in the JTF framework.

Results

As referred to above, this section presents two new competencies detected by the authors in this study that were not cited in the JTF framework.

For the domain of "Communication and Teamwork," Table 1 deals with a new competency that refers to collaborating with coworkers within and outside the CRC role.

Collaborating with coworkers within and outside the CRC role was described as a bi-directional process, whereby coordinators acquired and implemented rules and norms of professional conduct in their work. Research coordinators described mechanisms of learning these processes in the social environment. Specifically, they focused on developing managerial skills, recognizing variety and variability of research processes and the autonomy of other social actors in the complex research studies they were coordinating. In

particular, they expressed the value of listening to and learning from others, as elaborated on in the following:

- Aileen extolled the importance of learning about "the decisions I make or how I communicate with the group" and reported that it was helpful.

- As a result of training, Harriet mentioned she now really "listen[s] more…[than] previously."

- Participants spoke about how learning from and about others assisted them in thinking about alternative ways to manage data or organize tasks.

- Joanne found it "helpful to get more information about organizing our studies… how people manage…their studies and what they do to be organized."

- Participants also described learning about software and began to recognize the variety and variability in research processes.

These comments indicate that the novice coordinator initially works toward understanding the importance of being attentive to tasks. This practice is demonstrated when the CRC is observed working in isolation from colleagues. The experienced coordinator who appreciates frequent collegial interactions often performs better (as noted in Table 1).

The focus group results also led to the identification of a new competency within the JTF framework domain of "Leadership and Professionalism" that refers to advocating for the professionalization of the CRC role (see Table 2).

The theme of the competency related to professionalizing CRC roles embraces professional identity development. It focuses on strong and assertive professional self-worth and establishes the need for recognition of the CRC as its own, distinctive profession.

Furthermore, professional identity is established through enculturation, as reflected in the following focus group comments:

- Harriet recommended that CRCs engage in group discussions to promote the "role of the coordinator…within the university." She found the training helped her "identify various resources" she could utilize, and remarked that participant interactions around training activities propelled research coordination toward a professional level. She emphasized it was necessary to "be assertive and … step up and fight for what you're worth." Through this course, she reported learning she did not have to settle for "okay, this is just the way it is," and reasoned that research coordinators could promote change.

- Helena noted that, despite the large role coordinators play in research, they "are not [well] represented" or regarded as professionals. She asserted they "deserved" greater recognition of their roles, since the effectiveness of study implementation often rests with their expertise and attention to detail.

- Lydia pointed out the necessity for assertive communication with principal investigators who may lack an understanding of the connection between their research goals and regulations requiring adherence.

These results lead to the development of a levelling rubric for the competency of advocating for the professionalization of the CRC role. This rubric describes characteristic behaviors that might be observed along the continuum from a novice research coordinator to an experienced one (as noted in Table 2).

Activities that typify the novice CRC role should help the individual begin to understand the importance of participating in institutional training activities. This competency may be marked by annual participation in CRC training activities. With increasing experience, CRCs come to value the importance of seeking advanced training and leadership opportunities, as exemplified by their willingness to mentor or train less experienced research coordinators.

Discussion

The Association for Clinical Research Professionals (ACRP) is "working…to standardize [practice] in the clinical trial workforce."{10} Thus, it becomes increasingly imperative that the respective competency domains for CRCs are comprehensive.

While evaluating the findings of this project, it became evident to the authors that the JTF framework (see Table 3), as well as an independent analysis of the JTF framework,{11} omitted two important competencies from the "Leadership and Professionalism" and "Communication and Teamwork" domains that are essential for the success of research professionals.

For "Leadership and Professionalism," we have identified a competency denoted as advocating for the professionalization of the CRC role, which is consistent with themes from earlier studies.{6–8} This competency reflects a desire to move toward creating a unique identity for CRC practice.

To reach professionalization, CRCs must be defined by practice and educational standards that support their role's recognition in developing and maintaining a professional identity. Absent these conventions, CRCs are left working in a discipline that is ill-defined, not well understood, and largely unappreciated. For CRCs who are committed to a career in clinical research, the experience of advocating for one's self and for others enables them to build a sense of personal power and self-identification.

Through the competency of advocating for the professionalization of the CRC role, learning and professional opportunities stimulate the intrinsic worth of CRC roles. This quality of faithfully representing oneself as a competent professional establishes dependability and credibility. By gaining self-esteem, the milieu of clinical research begins to look different, as synergy develops between self-perception and how others view CRCs.

Further, professional competence elicits confidence and engenders trust. To facilitate trustworthiness requires legitimate knowledge that has a structure and support which is transferable and replicable. This in turn strengthens and confirms the transformative transition to a professional identity. In this light, advocating for the professionalization of the CRC role becomes an essential competency.

The other crucial competency highlighted here, collaborating with coworkers in and outside the CRC role, falls within "Communication and Teamwork" and precipitates out of previous work.{6–8} Developing this competency would demonstrate that CRCs are better prepared to adapt to changing and complex environments which mirror current workforce practice.

This is particularly relevant to working within interdisciplinary groups, while trying to resolve conflicts. The psychosocial and communication facets of collaborative competencies transcend basic communication with sponsors on regulatory understandings, which is the primary focus of the JTF framework.

Instead, a true collaborative competence is a social experience which deepens appreciation of group norms, characteristics, values, and ideals and fosters integration of these qualities into one's professional self as individuals make sense of personal and group behavior in socially constructed interactions.{12} In effect, collaborative competency requires a CRC to understand his or her immersion into a culture of research, which requires enacting culturally competent communication and understanding what communicating means in this context.

Conclusion

Collaborative engagements with a professional community potentiate active network building and sharing of resources. This process facilitates self-discovery, innovation, and empowerment to create a sense of forward career equilibrium, which in turn resonates with advocating for the professionalization of the CRC role. The JTF's "Communications and Teamwork" and "Leadership and Professionalism" domains form a foundational matrix for the development of true competence.

Neglecting the importance of the intertwined competencies described in this article is a serious limitation if absent from any framework. Most coordinators have yet to understand competency training in terms of encountering a professional identity, or that there was even such a consideration. These additional competencies strengthen the intention of the professional competency movement as articulated by JTF and embraced by ACRP.

Acknowledgments

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Appendix A

Focus Group Questions for Evaluating the CTSI Research Coordinator Leadership Development Program

1. In what way has the UF CTSI leadership training program addressed your professional needs?

2. In your opinion what are the ideal characteristics of a research coordinator leader?

3. How has the UF CTSI leadership training program influenced how you perform your role as a research coordinator?

4. How will you use the information and skills learned in the UF CTSI research coordinator leadership program?

5. Has your confidence in your level of professionalization increased or decreased as a result of this UF CTSI coordinator leadership training program?

6. What aspects of the UF CTSI coordinator leadership training program influenced your own sense of being/becoming an ideal research coordinator?

7. Were the program co-facilitators (Bob Kolb and Lauren Solberg) effective? In what ways? How might they improve upon their role?

8. What is your opinion of the guest speakers who lectured?

9. Did you appreciate having speakers who are/were research coordinators, or would you have preferred someone without coordinator experience?

10. What were the most and least helpful out-of-class assignments?

11. What were the most and least helpful in-class activities?

12. Was the networking aspect of this program helpful for meeting your goals?

13. Would you recommend this program to a colleague?

14. What skills or competencies do you consider essential for coordinator leadership and professionalization that were not addressed in the UF CTSI coordinator leadership training program?

15. What else might you change about this program for future cohorts of research coordinators?

Table 1

Rubric for the Domain of "Communication and Teamwork" Competency—Collaborating with Coworkers Within and Outside the CRC Role

Novice Level	Advanced Beginner Level	Experienced Level
Understands the importance of being attentive to tasks.	Understands the importance of seeking collegial input.	Understands that frequent collegial interactions often lead to better performance.
Example	**Example**	**Example**
Generally works in isolation from colleagues.	Intermittently seeks input or feedback from colleagues about work-related issues.	Frequently and while using one's own initiative, incorporates input or feedback from colleagues into work when input or feedback is provided.

Table 2

Rubric for the Domain of "Leadership and Professionalism" Competency—Advocating for the Professionalization of the CRC Role

Novice Level	Advanced Beginner Level	Experienced Level
Understands the importance of participating in institutional training activities.	Understands the importance of participating in governance activities beyond the institution.	Values the importance of seeking advanced training and leadership opportunities.
Example	**Example**	**Example**
Participates annually in training activities for CRCs.	Seeks membership in local, regional, or national CRC professional organization(s) or local networking group(s) for CRCs	Mentors or trains less experienced research coordinators.

Table 3

JTF Domains 7 and 8{3}

Domain 7: Leadership and Professionalism
Describe and apply the principles and practices of leadership, management, and mentorship in clinical research.
Identify ethical and professional conflicts associated with the conduct of clinical studies and implement procedures for their prevention or management.
Identify and apply the professional guidelines and codes of ethics that apply to the conduct of clinical research.
Describe the impact of regional diversity and demonstrate cultural competency in clinical study design and conduct.
Domain 8: Communication and Teamwork
Discuss the relationship and appropriate communication between sponsor, contract research organization, and clinical research site.
Describe the components of a traditional scientific publication.
Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups, and the non-scientist community.
Describe the importance of team science and methods necessary to work effectively with multidisciplinary and inter-professional research teams.