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Advancing the Practice of CRCs: Why Professional Development Matters

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Abstract

Clinical research coordinators (CRCs) assume critical responsibilities central to the success of the research team. The complexity of their role requires essential professional qualifications. One barrier to professionalization, however, has been the inconsistent, or absent, competency-based training. This study explored participants' perceptions of training experiences designed to prepare them for the national certification exam. Focus group methodology was used to document their experiences. The findings showed that sustainable mentoring relationships developed, participant confidence levels increased, and anxiety about performance capacity diminished. Cognitive reframing of the work environment and CRC roles was facilitated by training that fostered sharing and social reinforcement of professional and personal identities. Findings from this study suggest that access to meaningful training and quality instruction supports the professionalization of CRCs.

Keywords

clinical research coordinators, qualitative research, CRC certification, competency-based training

Background

The role of clinical research coordinators (CRCs) lies at the core of clinical research. They are responsible for communicating with principal investigators, study monitors, referral networks, institutional review boards (IRBs), patients and families, clinics and departments, other supervisors, and study staff.[1] CRCs frequently face numerous complex and challenging issues requiring deep and critical thinking. In addition, the CRC role entails assuming critical responsibilities central to the success of the research team, which calls for essential professional qualifications.

In 2012, a Clinical & Translational Science Awards Program (CTSA) taskforce reported on the expanding scope of the role of clinical research coordinators, highlighting current evidence suggesting there is inadequate support, training, and job satisfaction among CRCs at Clinical Translational Science Institute (CTSI) centers.[2] To ensure meaningful professional development of CRCs, an educational environment is required that values and supports the clinical research workforce and fosters the capacity for aspiring research professionals to gain competencies needed to pursue a clinical research career path. The need for a supportive educational environment reinforces the critical need reported by the Research Coordinator Taskforce and coincides with evidence that there are insufficient numbers of adequately trained and educated professionals in the workforce to address the evolving demands of the clinical research enterprise across the nation.[3-5]

A critical barrier to completion of effective, efficient, and rigorously conducted clinical trials is varying, or missing, competency-based training for study staff members involved in clinical trials.[6] Importantly, consistent requirements for providing and ensuring appropriate levels of qualification or professional standards remain nascent in development and application. However, the most recent version of the Declaration of Helsinki speaks to this deficiency by stating that "medical research must be conducted by individuals with appropriate training and qualifications in clinical research."[7] This guidance is further reflected in the CTSA strategic goals and subsequently manifested in the objectives of the National Center for Advancing Translational Sciences (NCATS) supplemental grant (3UL1TR000433-08S1) to the CTSA, Enhancing Clinical Research Professionals' Training and Qualifications (ECRPTQ), each expressing a key principal objective to provide a high-caliber workforce to execute large-scale, high-quality clinical trials.

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Moreover, this "critical need" aligns with NCATS national consensus to "develop and implement a competency-based education curriculum for study teams across the CTSA consortium that equips a highly-qualified workforce with the necessary competencies to effectively, efficiently, and safely execute clinical trials."[8] To that end, among the next steps the ECRPTQ project outlined were recommendations to conduct evaluations of existing training while expanding the catalog of available training. In addition, these evaluations are to include deeper explorations of training gaps to determine what new training is needed.

To address clinical research competency, various research industry organizations and universities formed a Joint Task Force for Clinical Trial Competency (JTF) in 2014 to develop, publish, and disseminate a Harmonized Core Competencies Framework for the Clinical Research Professional. This core competency framework is meant to guide the definition of professional competency across the clinical research field. The JTF deliberations described 8 domains, and within each domain, they identified expected cognitive competencies.[9]

These core competencies, currently being diffused nationally, have begun to affect the clinical research enterprise, as evidenced by the Proceedings From the Core Competencies in Clinical Research: Real World Applications, Convergence and Evolution of a Framework (2016) workshop hosted by Harvard University's Multi-Regional Clinical Trials program.[10] A core competency standard is now fundamentally established and globally accepted, clarifying the professional roles and competencies required for clinical research. Moreover, these core competencies have been vetted by the work of investigators on the CTSA Consortium's ECRPTQ and accepted by NCATS. The goal of ECRPTQ was to implement a standardized training process for personnel involved in CTSA clinical research and advocate for a collaborative approach leading to the development of consistent training and qualification strategies that serve as the foundation for generating additional best practices across research universities.[11]

The ECRPTQ project responded to calls for improvement in the efficiency of clinical research via education in core clinical trial competencies by establishing one set of high-level standards to serve as a framework to define professional competency for the clinical research workforce. Drawing from the JTF framework, which identified 8 broad domains of competence and 51 competency statements, ECRPTQ investigators developed working groups and carefully reviewed each competency subsequently modifying and curating for clarity and focus, landing on a consensus of 48 ECRPTQ competency statements aligned to the roles of the principal investigator (PI) and CRC, respectively.[11-13]

Academic health centers are well positioned to provide an engaging educational environment to address the critical needs of research coordinators toward professional development. Moreover, moving in this direction is keeping in harmony with the World Health Organization's (2013) initiative on transforming health professionals' training and education, which states that "transformative scaling up of health professionals' education and training is defined as the sustainable expansion and reform of health professionals' education and training to increase the quantity, quality and relevance of health professionals, and in so doing strengthen the country health systems and improve population health outcomes."[7(p11)]

Few studies have identified best practices needed to develop training programs directed toward ensuring that CRCs acquire professional competencies. In this study, CRCs, or those performing research coordination activities, received foundational training that focused on the operational and regulatory elements necessary for the ethical conduct of clinical trials. Instructional activities were designed to certify that research coordinators had acquired baseline knowledge of core competencies and were prepared for a national professional certification exam. The purpose of this study was to explore participants' perceptions of their experiences.

Methods

CRC Certification Course Design

Participants were required to complete 21 discreet online modules: 9 for the Collaborative Institutional Training Initiative and 12 for the Association of Clinical Research Professionals (ACRP; see Table 1). Before progression to the next set of modules, the established cohort met in a classroom setting to debrief and demonstrate full integration of knowledge via discussion of cases, review of posttest, and presentation of a refection paper. One classroom meeting was scheduled every 5 to 6 weeks over a 7-month timeline for approximately 2 hours per class. A passing grade of 80% on all postmodule tests was required.

Participants

Fifty-six individuals enrolled in a CTSI-sponsored CRC certification course. Of those, half were invited by the course instructor to participate in a focus group interview following completion of the course.

Data Collection and Analysis

A single 90-minute focus group was conducted with all but one of the participants who had agreed (n = 10). The moderator, another researcher who was not involved in teaching the course, explained the purpose of the study and then asked for consent to videotape the session using Zoom technology. The questions used during this semistructured interview are shown in Appendix A. A professional transcription service transcribed the audiotape. The first author reviewed the transcript while viewing the video to ensure its accuracy. Questions were designed to ascertain how the training program addressed participants' professional needs: (1) their instructional preferences for in-class or online teaching and module content and for a standardized coordinator curriculum, (2) essential skills or competencies, (3) whether their level of professionalization increased or decreased, (4) the ideal characteristics of a research coordinator, (5) how the coordinator certificate training program influenced enactment of their role, and (6) if and

Table 1. CITI and ACRP Module Titles, Course Descriptions, and Platforms.

Course Title	Course Description	Platform
Planning Research	The purpose of this module is to provide the clinical research coordinator (CRC) with an understanding of the planning aspects of clinical trials, including an overview of the clinical trial process and the roles and responsibilities of key clinical research team members.	CITI
Funding, financial management, and budgeting	The purpose of this course is to assure that CRCs understand the steps involved in the process of clinical trial budgeting, funding, and financial management.	CITI
Working With the Institutional Review Board (IRB)	The purpose of this module is to provide the CRC with an understanding of the function of the IRB and the various forms of communication and information exchange that occurs between the CRC and the IRB throughout the course of a research study.	CITI
Protocol Review and Approvals	The purpose of this module is to provide an overview of the different committees involved in the review of clinical trials. This module covers ancillary reviews that may be required for most clinical studies.	CITI
Principal Investigator (PI) Responsibilities	This module covers feasibility assessment and other sponsor issues, training the study team and delegating study tasks, subject enrollment and informed consent, adverse event assessment and reporting, study documentation and data management, drug storage and sample processing, monitoring visits and federal audits, and authorship and publication.	CITI
CRC Responsibilities	This module focuses on the general skills involved with coordinating clinical research. Remember that regardless of who is conducting the clinical research, the protection of human research subjects (participants) is of the utmost importance.	CITI
Sponsor Responsibilities	This module focuses on early-career CRCs who are just beginning to coordinate clinical trials for sponsors who may be manufacturers or academic sponsor-investigators.	CITI
Informed Consent	This module is designed to help CRCs understand their roles and responsibilities in the consenting process.	CITI
Site Management, Quality Assurance, and Public Information	This module provides practical information about the management of both small and large research sites and introduces the concept of research integrity, provides examples of research misconduct in clinical trials, and reviews procedures for ensuring quality at the clinical research site.	CITI
Understanding Clinical Trial Protocols: Key Considerations for Effective Development and Feasibility Review	This eLearning course reviews what a protocol is, its components, and how these vary depending on research need.	ACRP
Theory to Practice: Operationalize Their Clinical Study Protocol	This course guides learners through a mock protocol review. This course ensures learners are exposed to statistical considerations for clinical trials so that learners are can operationalize their study protocol through comprehension of clinical trial development and design, data analysis, safety and tolerability evaluations, and reporting requirements.	ACRP
The Drug Development Process: Improving Trial Feasibility and Exploring Their Growth Potential	This course equips learners with easy-to-apply tools for evaluating a site's feasibility to conduct research in each trial phase, as well as protocol feasibility to meet drug development plan goals.	ACRP
Key Skills for Ensuring Quality Control Through Risk-Based Decision Making	This course helps learners make the right risk-based decision at the right time, ensuring no harm is done.	ACRP
Site Quality Management Tools: SOPs, Metrics, and Training	This course builds on a solid understanding of the key components related to quality management systems (root cause and corrective action preventive action [CAPA]) and risk-based decision making by providing the basic guidance and information needed to start setting up actual quality management systems for sites.	ACRP
Building Quality Management Systems for Sites and Sponsors: Root Cause and CAPA	This course enhances learner ability to contribute to the improved quality of their clinical trials by using tools such as "Corrective Action Preventive Action (CAPA)" and "Root Cause Analysis (RCA)," and by applying methodologies and key factors such as documentation best practices and risk management strategies that support and enhance the excellence of a quality management system.	ACRP
Mastering the Event Reporting Cycle: Understanding Their Impact on Patient Safety I	Course teaches learners how to more efficiently and readily identify and report safety events during the conduct of a clinical trial.	ACRP
Risk-Based Monitoring: The Essentials for CRCs	This course helps learners adapt and implement risk-based monitoring plans efficiently at their sites.	
Inspection Readiness: Best Practices for Managing Clinical Trial Inspections	This course focuses on regulatory inspection and includes reasons for inspections, inspection objectives, types of inspections, inspections frameworks, selection and preparation strategies, routine inspection key focus areas, inspection findings classifications, and guidance on providing acceptable responses to inspection findings	ACRP

(continued)

Table 1. (continued)

Course Title	Course Description	Platform
Form 1572: Get It Right the First Time	This interactive course helps participants become comfortable with document preparation, its completion and management, and understanding of who should be on this form.	ACRP
Ethics: Identifying Potential Pitfalls in Human Subject Protection	In-depth training on the importance of ethical conduct in clinical trials involving human subjects and how to put the rules into practice to ensure human subject safety and well-being is the major focus of this course.	ACRP
ICH Gap Analysis Tool	A game-based module designed to assess the participant's knowledge and skill levels related to ICH guidelines (E2a, E6, E8, and E9) and the Declaration of Helsinki.	ACRP

Abbreviations: ACRP, Association of Clinical Research Professionals; CITI, Collaborative Institutional Training Initiative; CRC, clinical research coordinator; SOP, standard operating procedure.

Table 2. Clinical Translational Science Institute Coordinator Certification Program Themes and Conceptual Definitions.

Theme	Conceptual Definition
1. Extolling course benefits	Recognizing tangible benefits
1a. Preparing for certification test	Acquiring practice
1b. Refreshing knowledge	Ensuring correctness of practice
1c. Expressing vitality of role	Appreciating the centrality of research coordinator in clinical studies
1d. Advocating mentoring	Recommending ways to encourage coworker growth
2. Creating a community of CRC practitioners	Describing research coordinators' role in context
2a. Informing coworkers about related job roles	Explaining to others what research coordinators do
2b. Addressing knowledge gaps	Recognizing information not yet attained
2c. Recognizing local context/support resources	Facilitating knowledge of institutional structure
3. Increasing confidence	Reporting enhanced abilities
4. Fostering institutional community and networking	Promoting worth of and research for research coordinator work
4a. Appreciating research coordination	Holding the roles of research coordinators in esteem
5. Suggesting program improvements	Suggesting changes to training

Abbreviation: CRC, clinical research coordinator.

how the training program influenced their sense of being/becoming an ideal research coordinator.

The transcript was read by all 3 authors independently. Each author developed a list of emergent themes and sent it to the first author. 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 a Microsoft Excel spreadsheet. After completing this task, another author checked the accuracy of the selected text passages. Following data entry, the first author checked all areas of differences and sent a list to the primary analyst assigned to those areas where agreement was not reached. However, the primary and secondary analysts reached consensus. This process, undertaken to ensure that the primary analyst stayed immersed in the data, enhanced their analytical acumen. The use of 2 analysts also strengthened the credibility and dependability of the findings (see Table 2).

Results

Five themes and 10 subthemes emerged from the data. In this section, exemplars of the themes and subthemes are described. Their connectivity to the essential of roles of the CRC and the need for professional development are also explicated (see Table 1).

Extolling Course Benefits

Participants reported how the training program helped solidify their professional identity by providing test certification preparation, refreshing knowledge, fostering proactive behaviors, conveying the vitality of the CRCs' roles, and advocating mentoring.

Preparing for Certification Test

Amara appreciated the courses and described it as fulfilling a need "to be able to get certified, take the exam and get certified." Candice shared that she was "very happy to take this course to get prepared for certification so I can sit for it and finally get the scene behind the CRC." For June, certification had been a goal, which she was able to achieve upon training completion. However, although she had learned so much, she admitted that "I'm just scratching the surface now." Linda was glad to have extra modules and to be able to take special classes when she had time.

Refreshing Knowledge

The training assured participants that they were executing the CRC roles faithfully. "Because of the course," Amara began to understand the responsibilities of sponsors and FDA better. New knowledge translated into decreasing her frustration in

interactions with those professionals. Rachel found that the course advanced her knowledge about budgeting. Otherwise, the information she received was a refresher and helped her do her job better, particularly with regard to "steady startup and [asking if] this protocol feasible to do here." Lisa also felt that the course refreshed her memory on topics related to research, "especially how to submit serious adverse events (SAEs) and what's required."

Maria, who had been working in data management, had taken a leave of absence to care for her child. When she returned to the university, she had forgotten many work-related responsibilities. The course content helped reacquaint her with the job roles, and she felt as if she was becoming a more "professional-sounding person."

Delia oversaw coordinators in her department. She took the course to advance her awareness of job-related difficulties she experiences. The course forced her to understand the basics of clinical research and to identify ways she could help her coordinators enhance their work performance. Upon course completion, she understood the importance of data safety and integrity and had the legitimacy to discuss problems with research coordinators. Marion obtained a fuller picture of actions she needed to take in working with coordinators. She felt more prepared to do sponsor-initiated research, whereas she previously felt like she was "just winging [it, while] doing the best I can."

Amara's confidence increased after discovering she was on the right path in her work as a CRC. Like Marion, formerly, she relied on hope she was doing the right things. After completing the course, she learned that her own leadership was correct. For Katie, the most important take-aways were "ideas for project management for social science research studies." She learned about risk-based assessment, quality management, and quality control of the trial.

Advocating Mentoring

The course provided a critical instrumental role beyond enrollment. Rachel planned to use the course as a guide for mentoring novice coordinators in her office. Marion suggested anybody doing CRC work needed this course to have a better understanding of the role. Moreover, she argued that "even the PIs need to even take a brief course . . . so that [they could] realize that their actions have consequences."

Delia was inspired to return to her team, share what she had learned, and encourage them to take the course. She felt the course would advance the coordinators' confidence as their level of knowledge increased and they could use the information presented in their daily work. Moreover, she believed the course would result in CRCs having more efficient communication with PIs. Although people differ in their levels of confidence, she surmised some coordinators needed "that extra push." She was eager to promote the course as a way to provide that "push."

Maria complained that a lack of department structure resulted in extra work and high turnover. Becoming informed about the structure, she believed, would lead to better employee retention. She opined training would alleviate much of the need for extra work. She also reasoned that if others were better trained, there would be "less cost involved" in replacing those who were prone to leaving the position.

Creating a Community of CRC Practitioners

Forging a professional identity from a CRC perspective is in large part perceiving their work role as associated within a community of practice. This is the product of self-motivation and the evolving progression of competencies related to responsive work as they adopted a new identity, values, and knowledge base of a mutually defined role. It is as June reported: "I think that for me it's been really important to be part of a community and feel like we all have a common understanding in this community of how things need to happen." The strength of the training lied within the realm of communication as each participant became a resource to one another. Individuals who, as June continues, "have gone through and learned the same kind of map and orientation [and then they can say] okay, this is the procedure we follow."

Informing Coworkers About Related Job Roles

Within the context of an identified professional community, it becomes clear how the process was dependent on the skills of all involved. As participants developed a baseline of self-esteem and assurance in their professional role identity, they were encouraged and began to inform others. Supported with training and bolstered by mutual respect, Delia opined she now had "the legitimacy to go and tell my coordinators, hey guys, you need to pay attention to this topic." This was particularly salient when explaining the role to the Pis, who by general report were often too busy or simply did not want to be bothered. Marion shared, "I think as coordinators we need to make sure they know how important it [responsible conduct of research] really is when they take on one of these studies." She explained, knowing a CRC was grounded in values and professional identity facilitated better communication with PIs and allowed the CRCs to place more confidence in their knowledge.

Addressing Knowledge Gaps

Each of the participants reported having some gap in knowledge and experience associated with their conduct of clinical research. Budget, protocol, and study feasibility all seemed to rise as common areas identified as requiring extra attention prior to training. Amara was able to close the gaps on areas around "working with studies sponsors and their responsibilities," noting that the training "really fulfilled a need, a void that I had."

Others, like Rachel, who were already certified, participated because they had identified some gaps with budgeting and wanted to learn more. Rachel felt good to "repeatedly hear information to help me to do my job better." Overall, participants acknowledged that additional knowledge and education were necessary to meet the requirements of this

specialized field. Moreover, they reported using newly attained skills and knowledge.

Recognizing Local Context/Support Resources

Networking and support from others seemed to be key elements for CRCs in their professional growth. Part of this process was the identification and sharing of local resources and institutional structures for support. Programs such as the CTSI Work Force Development (WFD) CRC Certification filled a need across the span of experience, which Candice "recommend[ed] it for anybody who is in research, no matter how many years." CTSI WFD directorate sponsorship signified additional support for emerging structures to facilitate professional growth among CRCs.

As a result of the inherent socialization processes within the classroom, individuals began directing others to previously unknown resources. For example, Linda identified the CTSI as a resource to "supply the information and distribute it" without inefficient redundancies. Also, she described the concentric sphere of influence resulting from branching and networking and "learning from more than just the small little five or six people who were in your class." June discovered a larger research coordinator network and pointed out she was "learning about resources through people here" and realizing local networks were an implicit resource. Via these links, Delia became appreciative of knowing whom one could talk to about work-related issues by using key resources.

Rachel thought the "open discussion with other coordinators was very helpful" as she discovered she was not the only one "struggling with certain things." By opening up discussion and soliciting feedback from other coordinators, she "was able to apply that to [her] own personal interactions with people."

Increasing Confidence

Self-esteem and self-confidence are vital to developing the full potential of CRC professionalization. From her perspective, Katie believed a CRC needed to be proactive and become aware of "what kind of data you're collecting and how you can improve things." She also expressed an intent to monitor situations within her team's research projects and implement changes when necessary.

June shared that she gained confidence from the program. Prior to training completion, she admitted having "no idea what I was really doing." After the training was over, she started to feel "true confidence" when doing her work. Rachel agreed with June and explained that working on clinical trials, ensuring that patients remained safe, and making sure the trial was conducted with integrity increased her level of assertiveness. She felt more confident making certain the PI was compliant with "doing the protocol."

For others, such as Maria, the ability to handle the workflow efficiently enhanced her confidence. She felt less "behind the eight ball and I'm actually moving forward in front of the work and it's not just dragging me along." Her confidence increased, as indicated with the feeling she was current with her task and having a better focus. Lisa felt her sense of improved confidence directly translated to the PIs' placing greater trust in her. Signifying her sense of self-reliance and conscious decisions to pursue competency, Delia described her experience in the course as a way to understand the basics of clinical research. Both Marion and Amara mentioned gaining more confidence in understanding the language of clinical research, which helped them to speak with more authority. Rachel suggested that building confidence resulted in assertiveness and her ability to make sure the protocol was conducted correctly. She stated the program had "helped [her] build confidence as a coordinator" and to see herself at a professional level alongside the investigator.

It was passion and drive, combined with newly acquired knowledge, that converted training to professional confidence as participants offered each other empowerment while appreciating one another's insights. The quality of the shared experience of clinical research allowed the participant's innate personal power to be transformed toward becoming a professional.

Fostering Community and Networking

Participants described the value of community the course offered in augmenting their knowledge base regarding job roles and responsibilities, their professional worth, and how they believed others perceived them. June suggested this course provided CRCs with a sense of community, whereby common understandings "of how things need to happen" were fostered. She remarked that it was "a great resource" offering a common map, orientation, and procedural guidelines. Moreover, June pointed out how the course participant's group had become a resource in itself, as this group could continue to work together beyond the classroom structure and call upon one another if they were uncertain what procedure to follow.

Katie relayed her astonishment the institution neglected to enhance the growth of the clinical research coordinator workforce. She opined this mission did not carry the same level of support as its commitment to building its capacity for preeminent scholarship. Moreover, Katie suggested the institution needed to commit to making this activity an important, integral, and supportive part of its daily employment activities. The rationale for ensuring a basic level of training, according to Katie, served to protect the institution and to ensure other newer CRCs' standards were "equal to ours." Katie found it "unnerving" individuals were placed in positions of such responsibility and oversight with little to no training.

Delia advocated other CRCs take the certification course and "use that information in their day-to-day life" because she believed that it would improve communication with PIs. Although she felt some of the coordinators had more confidence, she also observed others lacked it. To her way of thinking, learning what was presented in this course would solidify their knowledge and equip them to stand their ground when it came to pointing out deviations or issues that had the potential to result in adverse events. Rachel, too, agreed the course

"would be a very, very good program for our CRC coordinators [and she] recommended that it become] a part of orientation, because there is no standardized training."

Maria pointed out how the lack of training was deleterious to employee retention. She cited an example of 2 offices suffering from continuous turnover. More frequently, newly hired CRCs were coming from outside the institution as well as the field of clinical research. As a result, newer CRCs typically floundered for the first 2 years. She reasoned that by taking the certification course, the institution would have better trained CRCs more quickly and with less cost involved into hiring and rehiring and lessen the potential for deviations.

Others described the kind of support for their position they wished they had. Maria recommended a version of something used in her office. "We have a version of a Clinical Research Coordinator page that everybody could go to." Maria believed 1 or more generic versions of this resource would assist CRCs because "everybody would know this is where you go first for your questions." Subsequently, if this toolkit was insufficient, CRCs could then be directed to other individuals at the institution.

Fostering Institutional Recognition

All of the participants emphasized the need for the institution to hold greater respect for research coordination to take their communication with research groups seriously. Overall, the participants wanted the institution to consider their job role more seriously and demonstrate regard by receptivity and actions to address CRC communications. Coordinators felt obligated to point out deviations and the potential for adverse events to their PIs, as required by their role. Yet they hoped to fulfill this capacity without condescension or fear of reprisal. Lisa suggested the credibility of and regard for the CRC role could be advanced by the CRC's own behavior and their ability to demonstrate a palpable level of confidence. Lisa opined, "if you let them know that you're confident they put more trust in you and they'll be able to trust anything you do." From Delia's perspective, the certificate course was instrumental in promoting respect for coordinator work.

Marion stressed that clear communication with the PI is vital to "making sure that they know everything." From her experience, she recognized that many PIs who were doctors, with considerable patient loads, did not want to be distracted. However, and not surprisingly, CRCs felt it crucial to discuss important research issues and make sure they were aware of the research process. Marion believed coordinators needed to "make sure they [PIs] knew how important it really is when they take on one of these studies, that they're in charge of it." Although CRCs would take care of the project, ultimately the responsibility rested with the PIs.[14]

Rachel shared how one PI's disrespect toward research coordinators evoked her frustration. This situation occurred in her department where she thought all the professionals were respected. She explained the PI did not want to hear, "no, you can't do that." However, this underlying meaning was not discussed openly, and the doctor continued to denigrate the research coordinator. Rachel held onto hope that PIs would respect the CRC's role in the research process and diminish the frequency of condescending remarks.

Appreciating Research Coordination

Participants came to the table with variable and incomplete ideas of what defines the professional role of a CRC. After the training, CRCs participating in this study largely came to understand their work better. As Marion noted, "this [course] imprinted on me how serious this [clinical research] really is." In the interchange of group discussions, participants came to see themselves transitioning into this newly defined role positively. The opportunities afforded to explore personal development offered an unexpected self-esteem boost associated with active acknowledgment by respected peers. It is as June said: "I think that for me it's been really important to be part of a community and feel like we all have a common understanding in this community of how things need to happen."

All of the participants expressed their commitment to ethical and responsible conduct of research. They realized they were all working together toward common ends. This recognition and the training course increased their sense of safety and fostered increased self-esteem. Participants came to value new aspects of work in their career and work environment not previously seen. As Katie offered, "this has been really eye opening for me in so many ways . . . I learned an awful lot generally about, you know, the ins and outs of pharmaceutical research."

Suggesting Program Improvements

Several participants suggested changing the structure and format of the course as it unfolded in this study. Lisa recommended having a team buddy to improve the participant's ability to complete the assignments better. She pointed out it would also avert her experience of having "to take one test at least four times." She believed working in pairs would help participants balance the demands of the course and their jobs.

Linda wanted to stretch the class over a longer period of time; she preferred having a year-long course to enhance understanding of the material. She also felt a course project would solidify participant application. June concurred and explained that doing a project would help her see the relevance of what she was acquiring. She aptly pointed out the difference between simply reading about it versus "actually integrating what I'm learning." June needed a stronger experiential component in the course to help her see the linkages between abstract ideas and vocabulary. She exclaimed the course was not without experiential activities, it was just that she had a greater need for it than was provided.

Katie urged the institution to implement training into the daily work life of CRCs rather than beyond working hours. She pointed out that many of the CRCs were also mothers with myriad responsibilities. She believed the institution needed to make training an important, integral, and supportive part of

employment. Also, Rachel wanted the course to be stretched out or scheduled every other week. She also urged cutting down the number of ACRP modules because they were so time-consuming, while Linda and Rachel recommend decreasing the number of modules from 5 to 2.

Others suggested changes to course content. Maria mentioned course content could include a review of real, live scenarios that had occurred at the university or an overview of how those issues had been addressed. Along the same line, Amara recommended the group could review interactive videos. She provided an example of one activity in which they viewed scenarios "where the coordinator had a PI" who was uncooperative. Together, they discussed what they had observed and completed questions and quizzes. Amara remarked "that [this] was really helpful to kind of get people's perspectives on things." Katie was "struck by the lack of discussion at all about how to do that" or how to retain people in studies.

June wanted to enhance her understanding of study design itself, as well as details about enrolling patients into the study. She pointed out that patient recruitment was inextricably connected with study outcomes. June stressed a need to ensure all stakeholders had a solid understanding of the study design, its importance, the criteria and exclusion factors for patient recruitment, and how having the right kind of patients ultimately affects the study findings.

Linda suggested scheduling monthly research coordinator meetings and promoted networking with other CRCs across campus. She also recommended creating a regularly scheduled newsletter or email repository whereby questions could be posted and invite responses. Questions such as, "Who has done this? How do I respond to IRB? I have this issue. How did you resolve it?" Or this is how to submit a serious adverse event (SAE) would be an excellent resource for seeking and posting information at a central site for CRCs.

Delia and Maria wanted to have a detailed list of resources related to typical CRC issues in which questions often arose. Rachel advised that this resource include ethics or research tips. Marion had asked the course instructors to develop a roster of coordinators, their location, and level of expertise, so they could be accessed electronically.

Linda wished to have monthly seminars led by CRC coordinators from different offices to present "common mistakes that we see" and to show the participants "how to navigate" those issues. She believed this process would reduce the number of calls they received on a daily basis to point out errors in the IRB submission. Rachel advocated for developing a series of YouTube videos to capture SAEs and adverse events occurring in every division. This resource could provide guidance with "how to capture adverse events." Having a videotaped library could assist CRCs in more effectively recognizing and developing a plan to address them.

Conclusion

This study assessed participant satisfaction with and perceptions of the program content. As shown by the findings and the grounded theory in Figure 1, the sharing and social reinforcement of professional and personal identities facilitated a cognitive reframing of both the work environment and their roles. The tangible connections developed in a classroom network and the peer-to-peer championing of each to the other fostered the development of sustainable mentoring relationships. The findings showed that participants' confidence levels were enhanced. As shown in this study, many CRCs began training from a place of feeling inundated. They voiced as a sense of insecurity and a desire for stability and dependability in the work setting. Anxiety prior to training decreased after learning they were performing their jobs in an appropriate fashion and actually knew what they were doing. Growing confidence led to being proactive in planning future steps and their ability to recognize knowledge gaps.

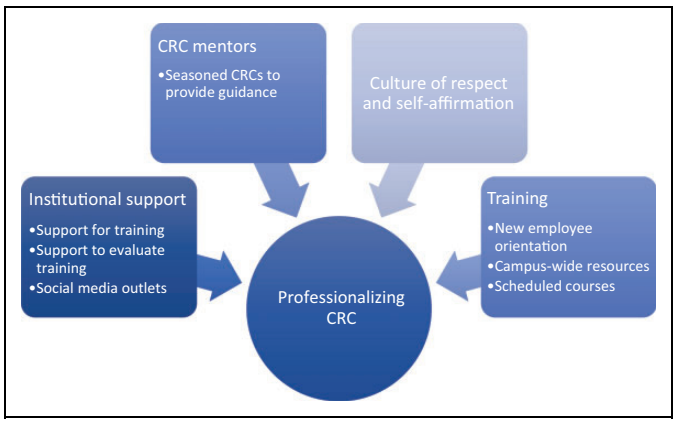

Figure 1. Grounded theory to professionalizing clinical research coordinators.

Access to meaningful training and quality instruction accentuated the integral role of the coordinator in research and supports the professionalization of CRCs. The experience of sharing direct knowledge elicited a capacity to transform and build a sense of personal power and self-identification as a clinical research professional. Through an introduction to learning and professional opportunities formerly not anticipated, a social journey of personal growth and confidence began.

This journey was propelled by stimulating the intrinsic worth of research coordinator work as embedded in the trustworthiness of competence. This quality of faithfully representing oneself as a competent professional establishes dependability and credibility. By gaining self-esteem, the institutional milieu begins to look different as synergy between self-perception and how others view you converge. Professional competence elicits confidence engendering trust. To facilitate trustworthiness requires a legitimate knowledge that has a structure and support that is transferable and replicable.

Online content is the coin of the realm for providers of professional clinical research development and training. Clearly, the use of online learning platforms can provide a solid introduction to the clinical research environment and regulations. However, in and of itself, the online platform is likely

insufficient to nurture the felt sense of professionalization that began to emerge in this study. This study's findings provided insight into self-assessment whereby intricate problem solving was facilitated through the natural interpersonal interchange of experience, above and beyond the mere collection of cognitive competencies. Group processes solidified emergent bonds among individuals while accelerating self-realization and promoting new meaning among individuals. This in turn strengthened and confirmed the transformative transition to a professional identity. At first knowing how much there was to know can challenge one's confidence. However, as participants became oriented to the map of knowledge, they felt more grounded in knowing what they knew.

There was, as seen in our previous studies,[15,16] a preference for combination of onsite classroom instruction in real time along with online learning. With the inherent socialization processes of a classroom, individuals directed others to previously unknown resources as the group became a resource of its own available beyond the classroom. Thus, it is not sufficient to simply point to online training. The absence of presence in online training limits opportunities of social integration of values so vital to the coordinator's role.[17,18]

The central theme for the study findings focused on moving toward professionalization of the field and creating a unique identity for the practice of research coordination. As the forgoing shows, to reach professionalization, CRC must be defined by practice and educational standards and structures that support its recognition in development and maintenance of a professional identity. In the absence of these conventions, CRCs are left working in a discipline that is ill-defined, not well understood, and largely underappreciated by the larger enterprise and for CRCs who are committed to a career in clinical research.

The findings in this study concur with previous investigations. For example, a previous study showed that both novice and experienced CRCs felt more confident about their skills following training.[15,16] Feeling grounded in a solid knowledge base, they realized an enhanced sense of empowerment and felt legitimized to bring issues to the attention of PIs. They also yearned for greater recognition and respect from coworkers.[15,16] In another study, participants demonstrated increased confidence following training. Participants expressed a sense of vulnerability to the PIs and the institution they served and concern about reporting serious deviations.[15,16] Both studies along with the present one suggest that training was instrumental in CRCs' professional development.

Study limitations include a single site and one-time focus group. Future studies should seek to explore changes in participant experiences before and after training or across institutions, to discern if the findings were unique to this setting. Finally, the findings could be used to develop a survey that might be disseminated across other CTSIs.

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Appendix A. Interview protocol for evaluating a novel model for training clinical research staff

1. In what way has the UF CTSI coordinator certificate training program addressed your professional needs? Compare and contrast the training program components.
   a. Which method, in-class or online, addressed training needs and professionalization?
   b. Which section or module was the most important? Why?
   c. If you were asked to recommend an instructional platform for a standardized research coordinator curriculum, what would you suggest: (1) online only, (2) in-class only, or (3) a combination of online and in-class instruction and why?
2. What skills or competencies that you consider essential for coordinator training and professionalization were not addressed in the UF CTSI coordinator certificate training program?
3. Has your confidence in your level of professionalization increased or decreased as a result of this UF CTSI coordinator certificate training program? Explain why.
4. In your opinion, what are the ideal characteristics of a research coordinator?
5. How has the UF CTSI coordinator certificate training program influenced how you enact your role as a research coordinator?
6. What aspects of the UF CTSI coordinator certificate training program influenced your own sense of being/becoming an ideal research coordinator?

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