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Training Impact on Novice and Experienced Research Coordinators

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Abstract

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Introduction

Identifying and implementing competency-based training and professional development programs are critical to the future of the clinical research enterprise. According to the International Conference on Harmonization Good Clinical Practice (ICH) individuals who conduct trials should be qualified by education, training, and experience (U. S. Department of Health and Human Services Food and Drug Administration, 1996). The training and education of research staff is integral to the success of the team and the studies they work on. However, standardization of training across all research staff, and within specific roles of the team, is limited (Duane, Granda, Munz, & Cannon, 2007). Developing a skilled professional workforce coincides with the World Health Organization's initiative on transforming health professionals' development (World Medical Association, 2013).

The current model of non-standardized training, given via online modules, may not adequately meet ICH guidelines or ensure professional competence. Competency development by definition refers to an observed ability that develops from an integration of knowledge, skills, values, and attitudes (Dreyfus, 2004; Frank et al., 2010). In Medicine, professionalism is often equated with competency. Epstein and Hundert (2002) suggested "professional competence is the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and community being served" (p. 226). In the clinical research enterprise, each team member must acquire the necessary knowledge, training and experience so that they can successfully perform the responsibilities for conducting clinical research. However, the issue of ensuring competency is yet another matter.

A standardized training model based on common core competencies is instrumental to a professional workforce's ability to meet the demands of an evolving clinical research landscape. The Joint Task Force for Clinical Trial Competency (JTF) described eight domains and related cognitive competencies (Sonstein, Seltzer, Li, Silva, Jones, & Daemen, 2014). Subsequently, these competencies have been vetted by CTSA investigators on the Enhancing Clinical Research Professionals' Training and Qualifications (ECRPTQ) NCATS supplement study (Calvin-Naylor et al., 2017). Movement towards competency-based educational standards coincided with recommendations from a Clinical and Translational Science Award (CTSA) Research Coordinator Taskforce. They called for expanding the scope of clinical research coordinators roles. Moreover, the task force recommended that enhanced educational opportunities were crucial to the support of professional development (Speicher et al., 2012). Evidence shows there are insufficient numbers of adequately trained and educated professionals in the workforce to address the overall evolving demands in the clinical research enterprise (Dickler, Korn, & Gabbe, 2006; Drain, Robine, Holmes, & Bassett, 2014; Silva et al., 2013). Educational evaluation research belays the critical need.

The training course reported in this study consisted of a prerequisite on-line course, the CITI Program's Clinical Research Coordinator (CRC) online course to provide research staff with basic knowledge. Using lectures, case studies, and hands-on work with realistic research materials, the in-person training expanded and developed further online learning. This study was designed to implement and evaluate a standardized competency-based training process for clinical research personnel. The method used was grounded in a collaborative approach leading towards generating best practices across research universities. Recognizing the need to tailor learning to adults, there has been a decided shift towards the use of problem-based learning guided by experiential learning theory (Jones, Jester, & Fitz-Gerald, 2010; Sternberg & Zhang, 2014).

To simulate experiential learning, recently published results from SPRINT were used to develop interactive activities (SPRINT Research Group, 2015). Participants were instructed

to read both the edited SPRINT protocol and select study publications. The protocol and its informed consent were used throughout the training, during the presentations and case discussions. In addition, participants were required to read an overview of the core competency framework for the clinical research professional since those competencies were covered during the in-person course (Sonstein, Seltzer, Li, Silva, Jones, & Daemen, 2014)

Table 1. Two-day in person course curricula

Topic	CITI CRC Course tie-in	Competency Domain
Overview of Joint Task Force Recommendations		
Medicines Development Process		Medicines Development and Regulation
Types of Research and Research Design (bias, etc.)	CITI module Research Planning	Scientific Concepts and Research Design
Ethical Considerations in Human Subject Research		Ethical and Participant Safety Considerations
Case Studies: Ethical Considerations in Human Subject Research		
Regulatory Issues (History and current perspectives)		Medicines Development and Regulation
Roles & Responsibilities (PI, coordinator, sponsor)	CITI Research planning, PI, coordinator, sponsor	Clinical Trials Operations; Leadership and Professional Development; Communication and Teamwork
Institutional Review Boards & Case Studies	CITI Working with IRBs & Protocol Review & approvals	Ethical and Participant Safety Considerations
Informed Consent	CITI Informed Consent	Ethical and Participant Safety Considerations
Budget and Finance; Group Budget Creation	CITI Funding, financial management & budgeting, CRC Resources	Study and Site Management

Recruitment & Retention (include disparities info.)	CITI no specific comparable, CRC Resources	Clinical Trial Operations
Case Studies: Recruitment & Retention		
Informed Consent	CITI Informed Consent, CRC Resources	Ethical and Participant Safety Considerations; Clinical Trial Operations
Data Collection & Management	CITI no specific comparable, CRC Resources	Data Management and Informatics
Case Studies: Data Collection & Management		
Study Monitoring and Close-out		Medicines Development and Regulation; Clinical Trial Operations
Regulatory File Maintenance (including QA/QC)	CITI Funding, financial management & budgeting, CRC Resources	Study and Site Management
Case Studies: Regulatory File Maintenance & QA/QC		Study and Site Management
Adverse Events (AE) and Protocol Deviations		Ethical and Participant Safety Considerations; Clinical Trial Operations
Case Studies: AE & Protocol Deviations		

Participants were asked to send certificates of completion to the study team. The CITI Program's Clinical Research Coordinator (CRC) course focused on the operational and regulatory elements guiding the ethical conduct of clinical research. Course instructors and content experts evaluated the CITI CRC Course and identified the corresponding competency domain tie-ins for the in-person course (see Table 1). During the in-person course, participants were asked to role-play in groups of three during the Informed Consent break-out sessions. Each person took a five-minute turn acting as a patient, a recruiter/coordinator, and an observer. After each turn, five-minutes were spent providing feedback to the recruiter.

The purpose of this study was to describe participants' perspectives regarding the impact of the research coordinator online and classroom training sessions towards the development of a standardized competency training model. Understanding these perspectives is important for training and establishing a common core curriculum. However, the overall goal of training is to ensure that the translational science workforce has the skills and knowledge necessary to advance translational science.

Methods

We used qualitative methods to analyze the text of the transcripts as this is the preferred approach when an understanding of participants experiences is the researcher's goal. Because there has been a dearth of research about the impact of research coordinator online and classroom training, we used a grounded theory approach with the hope that findings might guide the development of a standardized competency training model.

Participants

Both new and experienced research coordinators (n=31) from three institutions located in the Northeast and Southeast participated in a two-day pilot training course for this study. The program was evaluated using surveys and focus groups. Clinical research staff signed informed consent. Of these, 27 completed the course and a subset of participants agreed to take part in Focus Group (FG) interviews. FG participants included 13 females, four males, eight underrepresented minorities (URM) and 9 non-URMS. By institution, there were seven participants from the Southeastern private university, four from the Northeast private university, and six from the Southeastern university. Ten participants were designated as novice (0-up to 10 years); seven were experienced (more than 10 years) based on years employed as a research coordinator. The study was approved by the institutional review board (IRB201601579).

Data Collection

We conducted two one-hour focus groups one with novice and the other with experienced research coordinators. Participants in both groups were asked the same questions which sought to illicit their beliefs about: (a) preferences for online or classroom learning; (b) essential skills or competencies; (c) changes in confidence level; (d) characteristics of ideal research coordinators; (e) influence on enacting roles; and (f) program influence on becoming an ideal research coordinator.

Focus group (FG) methodology, a qualitative approach, relies on the use of a skilled interviewer (moderator) to collect narrative data related to the shared experiences among a group of participants or to develop an understanding regarding a phenomenon. This approach affords interactions between interviewer and participant and among all participants. FGs also allow for varied viewpoints to be shared, permits exploration and elaboration of what has been stated, and encourages the collection of a greater range of responses. The interactions among participants enhance data collection by implicitly providing checks and balances on one another, which tends to ferret out false or extreme viewpoints. The extent of shared views or the extent of diversity in viewpoints can be quickly assessed. FG dynamics may generate new thinking about a topic, which is likely to foster more in-depth discussion (Behar-Horenstein, Catalanotto, & Nascimento, 2015; Creswell, 2002; Estrada et al., 2016; Krueger, 1998; Treadwell, Catalanotto, Warren, Behar-Horenstein, & Blanks, 2016).

Data Analysis

The first, third, and last authors independently read the FG transcripts as separate datasets and formulated impressions of emergent themes. During a meeting, they shared individual impressions of the dataset. They reached consensus regarding emergent themes and related conceptual definitions and developed a codebook to guide subsequent phases of analysis. The authors used gerunds to maintain the actions implied by the participants

(Charmaz, 2014; Saldaña, 2015). Next, while reading line by line, one of three authors while acting as a primary analyst extracted selected text representative of the conceptual definition related to the theme. After the primary analyst extracted text, a second analyst audited the analysis to indicate agreement or disagreement with selected text or suggested moving data to better fitting codes as appropriate. This iterative process led to clarifying themes, locating quotations to support themes and illustrating the thematic similarities and differences among participant groups. 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. In all cases the primary and secondary analyst reached consensus. This process ensured that the primary analyst stayed immersed in the data and enhanced their analytical acumen. The use of two analysts strengthened the creditability and dependability of the findings.

Grounded Theory Approach

We visually describe the steps undertaken to explain how we used the grounded theory approach in this analysis. However, we acknowledge that we cannot fully explain the cognitive and intuitive leaps taken when drawing inferences related to sensitizing concepts (Glaser & Strauss, 1967). By way of offering the reader transparency, we carefully explicate our collective positionalities and describe how our roles, experiences and knowledge bases informed the analysis and interpretation (see Figure 1).
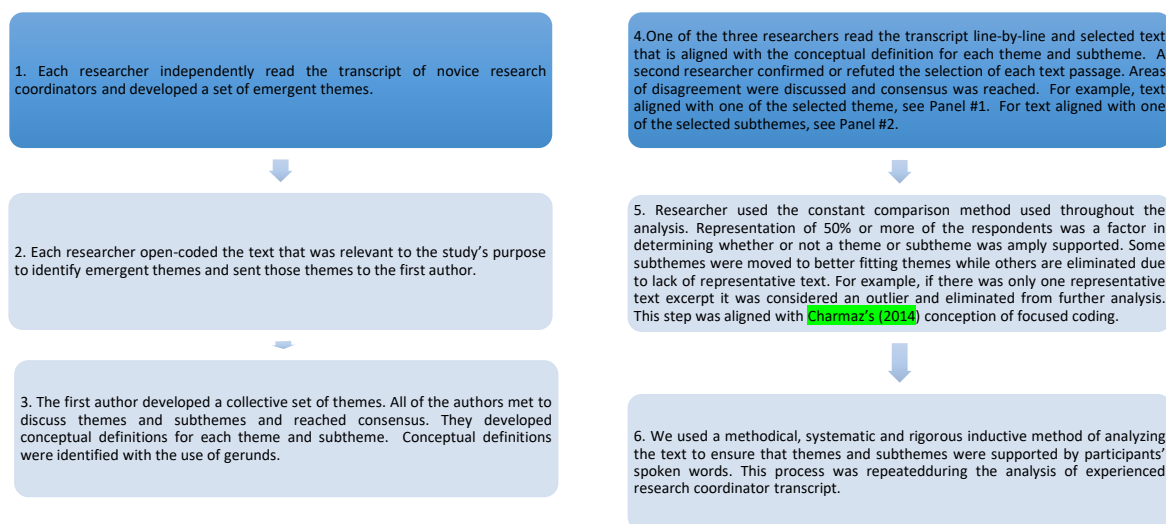
1. Each researcher independently read the transcript of novice research coordinators and developed a set of emergent themes.

2. Each researcher open-coded the text that was relevant to the study's purpose to identify emergent themes and sent those themes to the first author.

3. The first author developed a collective set of themes. All of the authors met to discuss themes and subthemes and reached consensus. They developed conceptual definitions for each theme and subtheme. Conceptual definitions were identified with the use of gerunds.

4. One of the three researchers read the transcript line-by-line and selected text that is aligned with the conceptual definition for each theme and subtheme. A second researcher confirmed or refuted the selection of each text passage. Areas of disagreement were discussed and consensus was reached. For example, text aligned with one of the selected theme, see Panel #1. For text aligned with one of the selected subthemes, see Panel #2.

5. Researcher used the constant comparison method used throughout the analysis. Representation of 50% or more of the respondents was a factor in determining whether or not a theme or subtheme was amply supported. Some subthemes were moved to better fitting themes while others are eliminated due to lack of representative text. For example, if there was only one representative text excerpt it was considered an outlier and eliminated from further analysis. This step was aligned with Charmaz's (2014) conception of focused coding.

6. We used a methodical, systematic and rigorous inductive method of analyzing the text to ensure that themes and subthemes were supported by participants' spoken words. This process was repeated during the analysis of experienced research coordinator transcript.

Figure 1. Illustration of Grounded Theory Steps in Taken in the Analysis

EXPERIENCED RESEARCH COORDINATOR THEMES	CONCEPTUAL DEFINITION FOR THEME		PRIMARY RESEARCH ANALYST	SECONDARY RESEARCH ANALYST
2. Promoting leadership and advocacy	Describing ways to increase understanding of research coordinator work within the institution and beyond	**Page 28 line 1248 -1266 Joan:** As an administrator, I'd like — I know that there are a couple of areas that we are not very strong in that impact resource utilization, and I definitely see a couple of areas that I can change both my practice, but also the practice of my coordinators so that we can move on and you know, make better choices earlier in our studies. Whether it's evaluating a study up front and identifying certain pieces that I don't find out about until the study's, you know, SIV, or whether it's, you know, our source documentation and being prepared for that first patient a little bit better, so that we don't end up with multiple queries for things that we really shouldn't be getting queried on.	HBK	BH
		Page 29 line 1328 - 1340 Joan: "– I tend not to get my study coordinators involved in the study until after the budget has been negotiated and we know that it's going to the IRB, because they're already busy. And since that, I wait, I don't think I'm going to wait anymore. I think I'm going to get them involved a little sooner than I have, so that they can begin to prepare a little sooner. "	HBK	BH
		Page 36 line 1650 -1669 Maria : Unfortunately we are the ones that need to communicate. Nobody else		

Panel 1. Linking text excerpts to a theme

NOVICE RESEARCH COORDINATOR THEMES	CONCEPTUAL SUBTHEME DEFINITION	PRIMARY RESEARCH ANALYST	SECONDARY RESEARCH ANALYST
2c. Impacting perceptions of ideal coordinator	Revising ideas of coordinator roles	945-953 Joan I think time management skills, especially if you're juggling at least over ten studies where most of us are entitled to meet deadlines and visit schedules and windows. It's very important to just map out and do like to-do lists, the things to check off daily, what you need to do to stay organized, of course.	Accept HRK
		962-971 Benita I feel detail oriented, and of course a people person; somebody who knows how to deal with people. I'm detail oriented because I feel like working with phase one, I feel like you miss one thing and there's like ten deviations, and you're sitting there filing that, and then putting all the things in in a day. So details in research.	Accept HRK

Panel 2. Linking text excerpts to a subtheme

Researcher Positionality

The first author is an experienced and published qualitative researcher. She has conducted multiple studies with heath care professionals. She participated in the conceptualization of the study. She urged the use of qualitative inquiry to develop an understanding of participants' experiences and preferences. The third author, a research assistant for the first author, has extensive experience in qualitative research. She was not affiliated with the study prior to data analysis. The last author is an Assistant Director of Clinical Research and Research Participant Advocate for the UF CTSI within the Regulatory Knowledge & Research Support services and Work Force Development Directorate. He develops coordinator directed training and programs geared towards professionalization of the clinical research workforce. He has more than 30 years of firsthand experience of being a Clinical Research Coordinator and Professional, working at all levels and in all phases of clinical research. In this context, along with a seasoned worked group that included the other authors and a community of engaged coordinators, he participated in and helped facilitate study design. His pre-conceptions and contextual relationships between the findings and his lived experience brought a particular level of insight.

Table 2. Themes and Conceptual Definitions for Experienced Coordinators

Themes/Subthemes	
IDENTIFYING PREFERENCES FOR INSTRUCTION	Describing kind of teaching liked
Naming favored modules	Identifying content liked best
Identifying topics not covered	Stating areas of research coordination not discussed
CHANGING SELF-PERCEPTIONS	Alterations in beliefs as a research coordinator
	Reporting enhanced abilities
Increasing confidence	Revising ideas of coordinator roles
Impacting perceptions of ideal Coordinator	
MAKING PROGRAMMATIC IMPROVEMENTS	Suggesting changes to training

Results
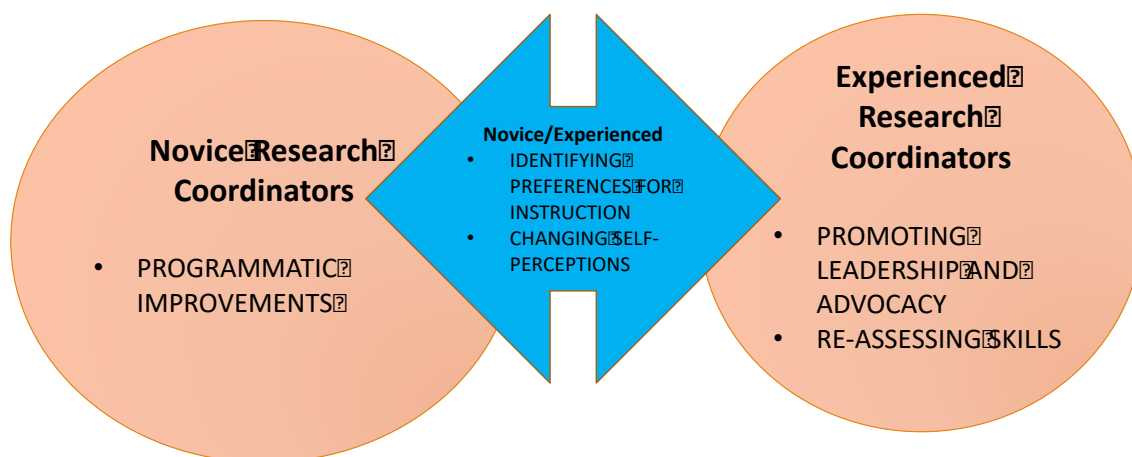
Figure 1. Grounded theory Novice and Experienced Research Coordinators' Training Preferences

The Grounded Theory

We present an overview of the grounded theory first before describing the findings unique to the novice and experienced research coordinators. We use the grounded theory as mechanism to (a) highlight the different insights among the experienced participants compared to the novice participants and (b) to point out the relationships between characteristic variables, such as the participant level of experience and qualitative data analysis results. The grounded theory (see Figure 1) highlights the distinctively different and similar foci among the two participating groups. For example, the novice research coordinators, perhaps owing to their

lesser number years on the job, focused considerably on how training could be improved as evident in their theme of Making Programmatic Improvements. In contrast, the experienced research coordinators discussed ways to address infrastructure and cultural issues, and how to advance the field of research coordination via the theme Promoting leadership and advocacy. They focused more deeply on personal change and strengthening their expertise via the theme, Re-assessing their skills. Both participant groups shared in a discussion of the theme, identifying preferences for instruction, and how the training seminar catalyzed changes in perceptions of their roles, via the theme, Changing Self-Perceptions.

Novice Participants

Three themes (Identifying preferences for instruction, Changing self-perceptions, and Making programmatic improvements) and four subthemes (Naming favored modules, Identifying topics not covered, Increasing confidence, and Impacting perceptions of ideal coordinator) emerged from the analysis of the novice participants' focus group (see Table 2).

Identifying Preferences for Instruction: Participants described which approach to instruction they liked best. They favored either the classroom instruction or a hybrid approach -- the combination of online learning and classroom instruction. Jeff remarked that classroom format "addressed my needs better." He found that peer interactions, opportunities to ask questions and engage in extended discussion deepened his learning. Jane agreed. She opined that interactions with the presenter were especially helpful for addressing particular questions. Moreover, she observed that classroom learning activities could be more easily tailored to individual learner needs. Ana agreed with Jeff and Jane. She pointed out that the classroom format permitted participants an "opportunity to ask, to share, and experience with other coordinators." Susan also enjoyed the classroom. As a new coordinator, she found that listening to others' experiences and asking questions provided insight into "something I might not think to ask."

Rosabel also found the classroom venue more valuable. She stated that was it "more adaptable" and allowed for elaboration especially in instances where "you either felt confused about [or] deficient" in particular content. She appreciated several classroom environment characteristics including (a) the chance to ask questions, (b) use of varied methods of learning, and (c) exposure to real life scenarios. Barbara also found the in-class model better. She pointed out that the experts, the discussions, and peer interactions were a better approach to learning. Ana liked the opportunity to observe processes and discover what was correct or incorrect. Dale described how examples of budgeting allowed participants to observe an expert's thought processes in real time. "Instead of seeing it done perfectly, we were able to see how someone who has done that many times would correct her mistake..... [We could] see how she justifies the prices …on the budget form, instead of just being given figures." Ernesto felt that the classroom interactions allowed participants to concentrate. He proffered that real time interactions caused him to ponder, "this is happening to me and how can we apply this?" Overall, the in-class setting fostered interactions that were impossible in the online venue, which ultimately contextualized the reality of day to day work tasks.

Ana suggested that "the combination of both [approaches] is more valuable." She recommended that requiring online first, followed by putting new knowledge into practice within a face to face classroom environment was optimal. Jeff agreed and suggested "a hybrid of both online and in-person" was best. However, he also pointed out the unique benefits of online learning whereby material could be presented at "a much significantly lower expense than having people together." Benita concurred with Ana and Jeff that completing some coursework and viewing the material before engaging in classroom learning was valuable. Benita pointed out the classroom part was refreshing especially following the tedium of sitting

through CITI online training. In particular, she appreciated engaging in role play and asking questions. Ernesto also liked the combination of classroom and online platforms. Ana explained the benefits of having online learning in statistics prior to classroom training. She described onsite training in statistics as overwhelming. However, she suggested that having an introduction to terminology beforehand would have increased her knowledge base and allowed her practice in class to be more efficient.

Naming favored modules: Most participants identified at least one module that they found to be particularly valuable across the 2-day training. Susan, appreciated the session on consenting. She liked the interactive teaching approach and asserted that it provided her with a better understanding of why mirroring a patient is important. Stressing the interactivity of the instructor's approach, Jeff concurred. He liked the communications portion of training. While acknowledging a lack of prior exposure, Jane favored learning about data management. She reported the importance of quality assurance and quality control and "making sure that you are tracking everything you do, correctly." Dale received a new perspective from a monitor outside the academic setting. This session helped him appreciate the organization and structure of the Case Report Form (CRF). Although at times contrary to his sense of logic, he acquired a better understanding of regulatory processes. Barbara stated that the regulatory information, in particular, such as doing her own budget was most beneficial. She also reported that the talks on ethics and informed consent were "really good."

Identifying topics not covered: Four participants stated that there was one particular content area that the training did not address. Jeff mentioned that good clinical practice and training and human subjects' protection were covered quite sparsely. However, both were covered in the online training prior to the face-to-face course. Rosabel wished trainers had provided more information about study team participant interaction after receiving patient consent. Ana was interested in learning more about study results so that while reading an article she would understand "how the results are presented." Ana wondered how coordinators should respond to patients who were reluctant to participate in a research study. She posed salient questions with implications for recruitment. "How do you approach them again? Do you respect [when they tell you no] the first time?" She wanted to know if it was appropriate for the research coordinator to approach the patient again. Jane, suggested that offering coordinators an opportunity to learn how studies were conceived "would be a valuable course" although she was cognizant that this activity did not apply to everyone.

Changing Self-Perceptions: As a result of the training, participants began to change their beliefs as clinical research coordinators in several ways such as (a) increasing professional confidence; (b) understanding the qualities of the professional research coordinator and, (c) discussing how beliefs were linked with their ideas about images of an ideal coordinator. Ernesto suggested that newly acquired knowledge enhanced his understanding of the work that people were doing, and suggested alternate ways to do the work. Seeing that *"this is really how to do it"* increased his self-confidence about the value of the work. He reasoned that, "[Since] I'm doing something … important I need to take time doing it.*"* Barbara described herself as a mentor, who could translate the information she received. Previously she has been a preceptor. She saw the training as a way to broaden her mentoring role, and become *"a mini mentor or preceptor for new coordinators."* She felt armed with useful information and looked forward to bringing the information into her department. Although Barbara already felt confident in her work, she stated that the course stressed "the importance of training for research coordinators, and emphasize[d] the importance for administrators to appreciate the [significance]of it." She believed that these actions would enhance her role as a mentor.

Increasing confidence: Participants reported that coordinator abilities improved, and self-confidence increased due to their participation in training. Jeff said that getting in a group and talking about the commonalities among their job roles and experiences made him realize,

"well, that's really what I was doing, so now I feel good that I've gotten there." While he was developing a broader and contextualized appreciation of his work responsibilities, he gained confidence in seeing how professional development opportunities could assist his growth. Jeff believed that he would be able to see the fallacies more readily and use the training to enhance his performance in data management. Barbara agreed with Jeff. She reported that she felt validated. Despite "not having a formal training [I realize] that I'm pretty much on the right track." As she discovered that she was mentoring correctly, her confidence in this arena increased.

Rosabel had mixed feelings about changes in her self-confidence. She felt terrible thinking about possible knowledge gaps, "but the flipside of that was okay, I get it." She came to realize that she "could do this." Susan described feelings of loneliness as a novice coordinator. However, she found that the group sharing enhanced her self-confidence. Ernesto agreed that communication among colleagues enriched his self-confidence. Joan also reported improved self-confidence, while pointing out that training information, like the "epidemiology lecture" … reiterated things" that she knew.

Impacting perceptions of ideal coordinator: Participants identified the attributes that characterized an ideal coordinator. They also discussed how their ideas of coordinator roles changed as result of training. Joan suggested that time management skills were pivotal to juggling multiple studies and for meeting deadlines. She also reported that skills related to mapping out, making to-do lists, and ensuring that things were checked off daily were necessary to staying organized. Dale mentioned that being organized was a top priority, as well as being able "to troubleshoot just on the fly." For Dale, organization began at the point of consenting. He explored potential actions in situations, when "your transportation might not show up and you've got a participant that you don't want [to] drop out." This circumstance highlighted the importance of a quick and appropriate response to ensure the flow of the research project.

Benita stated that being detail-oriented was an essential quality. If "you miss one thing and there's like ten deviations" and then, the coordinator would be spending considerable time filing all related forms rather than doing other work. She also stressed that an ideal research coordinator had to be "a people person" and know how to work with others. Barbara identified communication skills and the ability to be comfortable as essential. She viewed a research coordinator as the center of the project. "The moment something could go wrong," everyone turns to the coordinator. Jane concurred and added that communication skills shaped the relationships among the people involved in the research. Ana felt that the coordinator was an ambassador of change. She recommended taking new information back to your office to "share [it] with the rest of the team." She perceived an ideal coordinator as well-organized and having interpersonal communication skills. Ana also perceived the coordinator to be a conduit to providing new knowledge to the entire clinical research team.

Making Programmatic Improvements: This theme referred to participants' suggestions for how training could be improved. Jane offered two suggestions. First, she recommended leaving extra time for breakout sessions and developing guidelines to organize discussions. Second, she proffered that discussion forums might encourage participants from "different institutions and experience levels to talk to one another." Rosabel reiterated the need for leaving more time for participant interactions and sharing. Jeff felt rushed by the amount of content covered in two days. He wanted the schedule to slow down so that participants would have more time to interact with others. He also suggested breakout sessions to "fill out some of the gaps" while emphasizing that some of the content deserved much more time. He also suggested hosting a week-long program or stretching it out over time as discreet segments in a series of half days to give each module more attention. Providing flexible scheduling over time with multiple sessions, in his opinion, would have offered more options.

Barbara opined that more time was needed for both online and in class platforms to increase opportunities to ask questions. She felt that the two-day schedule lacked enough time. Jane agreed and said that having half day training sessions offered greater flexibility in scheduling. She recommended grouping topics more closely together. Barbara advocated for keeping courses in close proximity to preserve context. However, unlike Barbara, Jane she stressed the need to avoid the program from becoming piecemeal by stretching it out over time. This was a particularly crucial consideration for new coordinators. Barbara echoed others' sentiments that, "having a real-life context" was pivotal to learning. Her feeling was this training might have been too soon for new coordinators.

Jeff talked about splitting up the training. He suggested offering a basic training early, allowing time in the field with an assignment to generate questions, and then bringing participants back to the classroom for debriefing and further training. Dale liked this idea too, but recommended offering it a few months after the starting date of new coordinators and then adjusting the date to coincide with participants' needs. He stressed that participants needed time to assimilate new knowledge. Ana suggested presenting material prior to class allowed an opportunity for participants to read, prepare questions and understand what needed more clarification. She liked the concept of pairing the less experienced and more experienced coordinator together to foster implicit mentoring relationships. Jeff recommended delivering material online and adding pre-tests to ensure that participants actually interacted with the material. Susan thought that initially new coordinators should be provided with a context to give them a better idea of what was expected and why.

Table 3. Themes and Conceptual Definitions for Experienced Coordinators

IDENTIFYING PREFERENCES FOR INSTRUCTION	Describing kind of teaching liked
Recognizing most important training content	Identifying essential topics
Identifying topics not covered	Describing topics not taught
Recommending training platform	Suggesting best type of professional development opportunities
Advocating for timing of training	Suggesting when coordinators should have professional development opportunities
PROMOTING LEADERSHIP AND ADVOCACY	Describing ways to increase understanding of and respect for research coordinator work within the institution and beyond
Dealing with conflict	Responding to others' reluctance

CHANGING SELF-PERCEPTIONS	Alterations in beliefs as a research coordinator
Increasing confidence	Reporting enhanced abilities
Articulating images of a research Coordinator	Revising ideas of coordinator roles
RE-ASSESSING SKILLS	Evaluating personal abilities as a research coordinator

Experienced Participants

Four themes (Identifying preferences for instruction, Promoting leadership and advocacy, Changing self-perceptions, and Re-assessing skills) and seven subthemes (Recognizing most important training content, Identifying topics not covered, Recommending training platform, Advocating for timing of training, Dealing with conflict, Increasing confidence, and Articulating images of a research coordinator) emerged from the analysis of the experienced participants' focus group (see Table 3).

Identifying Preferences for Instruction: Experienced participants preferred the classroom experience over the online module. Janie said the in-class provided a forum for asking questions and seeking clarification. For Janie, the face to face classroom setting *"often inspire[d] conversation and sharing."* Imparting experiences introduced new ideas and reinforced knowledge. This practice was not restricted to the classroom because it had the potential to extend outside of classroom. Marcy concurred with Janie that the classroom encouraged participant interactions and reinforced what she already knew. This observation was aligned with others who perceived classroom learning as a refresher of knowledge. Marcy also enjoyed the classroom interactions and concurred with Maria's expressed preference for face to face teaching because it provided an opportunity "to ask questions and get direct answers right away." A preference for the classroom contrasted with the on-line learning, which while valued, was not preferred. Of online, Janie pointed out that, "often they completed the modules because they were required to do so. However, she reported that, "I'm not sure that we're really paying as much attention to the details and the key facts." Marcy was glad she repeated the entire course again online after having completed it in the distant past. Janie also like the interactive nature of practicing consenting with her novice staff. It allowed them to see how skilled they were and noted that, "It was just a great way to reinforce our working relationship."

Recognizing most important training content: Several experienced participants found value in the training although they considered some topics to be more essential than others. Amy thought the section on Communication was one of the most important. Communication, presented in the context of conducting informed consent, revealed a ubiquitous procedure in a new light. After listening to the discussions across topic areas, she realized that communication concepts applied across other areas, like working with sponsors and source documentation. Herminie also remarked about the Communication content. While interacting with and discussing the protocol, she explained that that the coordinator should be expected to examine and interpret protocol components to ensure compliance with directions. Janie pointed out that the one best practice she learned during training was to create a protocol checklist to guide communication and direct the project.

Identifying topics not covered: The absence of discussion around Investigational Medical Devices was apparent to a several participants. Herminie and Maria mentioned there were no discussions of regulations or references to these devices and emphasized its importance

as a separate skill set. Amy also remarked on the absence of coverage on devices. She also observed that there was nothing covered related to writing informed consents. She added that there was a lack of review on documentation and grading of Adverse Events. Roberto noticed inadequate coverage in the informed consent material on pediatric and special populations. Janie added that the concepts of compliance with relation to "understanding what is [a] standard of care, what is not [a] standard of care" also were not covered.

Recommending training platform: There was a unanimous consensus, despite a majority preference for the classroom experience, that a combination of online and classroom was advisable. Amy suggested a combination so that she could go back and reference the information. She stressed the importance of completing online trainings beforehand because it provided a foundation.

Herminie also recommended the online and in person training while pointing out that the classroom format offered "a different perspective [where you] can interact with others and learn, or listen [to] their experience." Janie agreed that a combination of different approaches which addressed different learning styles was best. She pointed out classroom learning offered an "opportunity for confirmation of what you've learned" while seeking the wisdom of an instructor and peers.

Advocating for timing of training: Marcy encouraged that online training to be completed as close as possible to the classroom component. Amy recommended developing a basic foundation of knowledge online first and engaging in classroom learning to acquire more in-depth. She recommended breaking the classroom course up into two discreet courses to minimize overload. Janie felt new coordinators would not benefit much from early interaction due to a lack of experience and recommended *"phasing it in over time."* Amy valued obtaining baseline information early to inform subsequent experience. Marcy recommended sponsoring a novice coordinator at the training. She suggested that only after a significant period of gaining experience would the novice be able to assimilate some of the training offered in the two-day intensive. Beth had taken much of mandatory training, but "felt like a lot of the live interactive training was much more beneficial to her as a coordinator at 14 months than it might've been last year."

Promoting Leadership and Advocacy: This group of participants, by nature of their experience, were involved in leadership and advocacy to varying degrees. During the training, Janie, an administrator, realized that her unit was weak in areas that had ramifications for how resources were utilized. She recognized areas where she could change her coordinators' practice. In particular, she felt that engaging her staff earlier in the development process would help them "begin to prepare a little sooner." Maria linked leadership and advocacy to communication. She observed that it was incumbent upon individual coordinators to communicate the value of research coordinator work within the institution and beyond. For Maria, this process entailed finding a common cause and communicating the intrinsic value of the research coordinator role to overcome a "very deep resentment" in the clinical areas that interfaced with research.

Dealing with conflict: Maria explained that sometimes nurses and therapists who seemingly cared about the patients thought that research coordinators were experimenting with the patients. As a result, coordinators were compelled to take the time to explain why translational research was being conducted. Unfortunately, co-worker ignorance was an impediment to patient recruitment. As Maria opined "just a simple comment to the parent" from co-workers caused potential recruits to take a very negative view of the research study. Perhaps more conversation and team meetings were needed to clarify the role of research coordinators. Such meetings might reaffirm that all health employees work for a common purpose. Unclear from this portion of the group was what co-workers Maria referring to such as staff, nurses, or other healthcare workers.

Herminie identified another topic of concern -- how to address the undervaluing of the coordinator's role and professional stature. She pointed out that participants come for trainings, being edified and raised up in self-esteem, but then return to a work setting only to find that leadership does not understand their re-envisioned role. She suggested that there had to be a change in "the mentality" of the leadership. Roberto agreed and recommended that a "better culture of understanding why" research procedures are often very rigid in their execution were needed. He cited timed blood draws as an example and stated that cultural grounding "on why we're doing this that way" would alleviate angst and confusion.

One of the training goals was to enhance participants' willingness to speak up. The majority of research coordinators who took part in this FG achieved this goal. Maria explained that she could now express herself better. Additionally, she specified a need to change her communication with the sponsors of studies she coordinated. After training, she felt empowered and stated, "I believe now that coordinators have more power than I thought before." The training caused participants to see the purposefulness of their roles in a new light. They discussed ways to improve their own and fellow study coordinators' skills. Improved practice held the potential for impact on resource utilization, to foster better organization with greater attention to project details and to avert extra work.

Changing Self-Perceptions: Participants reported how beliefs about the work of a research coordinator changed as a result of the training. Charisse and Maria reported feeling happier about their jobs. Maria discovered that her job was more important than she previously thought. Charisse now appreciated that her work was something very good and planned to "implement whatever I learned here" when she returned to her campus. Maria also felt more confident and was satisfied just by knowing she was" not doing anything wrong."

During training, Janie and Maria learned that there were aspects of their job that they needed to do better. Janie confessed that her group lacked strength in some areas that impacted resource utilization. She opined that she could improve as an administrator and that there were areas where she could influence improvement in her coordinators' practices. By doing so, she suggested that the research coordinators could make enhanced choices earlier in their studies. Maria recognized that she needed to improve communication with the research sponsor. She explained that her institution's studies needed to adhere to certain conditions but that physicians did not always comply. She surmised that by discussing this issue with physicians earlier rather than waiting that they could increase patient enrollment. Janie explained the importance of drilling down on the type of information needed for source documentation. To minimize queries, she decided to meet with her team prior to budget negotiation and help ensure that everyone was capturing the appropriate data.

Maria's sense of belonging to a career was enhanced as a result of the classroom training. She also felt more empowered. No longer was she going to simply accept others' resistance or lack of knowledge about research coordinator work. She felt that she had the prerogative to communicate with others especially staff and principal investigators, about the importance of strictly following a protocol.

Janie pointed out that one of the best practices she garnered from the classroom was a checklist that helped coordinators use protocols so that they could locate the necessary data that would be used to generate reports. She was grateful for the opportunity to learn from others. She also appreciated acquiring new practices that she could implement at her institution. As she surmised, "there's no price that you can put on that opportunity."

Increasing confidence: Discussions about self-confidence revolved around exploring enhanced abilities. Participants described ways in which their abilities to perform as a research coordinator were enhanced. Maria shared her feelings about her job, saying that she found her job being more important than she previously believed and said, "I am happier… I was kind of getting depressed before, but not anymore." She also gained insight that solidified that she

fulfilled her job responsibilities. Charisse also reported gaining more confidence and stated that she was doing something good, and had become a happier person. She planned to implement new knowledge in her work. Janie stated that her previous knowledge was reaffirmed. She described how training helped her develop a rationale for administrative decisions. Amy also saw the training as a "good refresher." Although her confidence remained unchanged, she enjoyed hearing different perspectives from other participants.

Marcy described feeling reinforced about the budget and that she was able to "tackle these things one at a time." Roberto expressed similar perspectives. He broadened his view and understanding of the budgeting processes and obtained concrete behavioral strategies to guide his actions "in situations where you don't necessarily know how." Amy summed up the reflections of her colleagues by saying, "I think it's always nice to get that confirmation that…, you're on the right track, because it can get very overwhelming with all the little details that you have to know." Overall, participants received validation and confirmation of the right-doing. Along with gaining new knowledge about their job, they felt that their confidence was bolstered and that their abilities were reinforced.

Articulating images of a research coordinator: During the course of the classroom training participants realized the vitality of their role in the research enterprise. Despite Maria's recognition of some very deep resentment within the clinical enterprise, she and others discovered that in many ways this circumstance was directly related to the quality of their work. They came to understand that they could become advocates of professionalizing research coordination and could teach others why their role was essential. Janie felt that the class setting encouraged participants to ask questions about things where they had doubts. She also stated that it inspired conversation and sharing experiences where they could promote change in their institutions about how others viewed their role. Janie also thought that classroom sharing allowed participants to acquire a portfolio of best practices to take back to their home institutions. Participants began to appreciate that they were the nexus of the research enterprise. Roberto wished that there was a better culture of understanding about the nature of clinical research. However, like the others, he began to recognize their responsibility in changing the institutional culture and researchers' perceptions. Charisse stated the classroom sessions helped her realize that she was doing some regulatory aspects of her job incorrectly. Now that she had new information she planned to go back and adjust everything that needed correction.

Re-Assessing Skills: During the FG, participants reflected upon their own skills as a research coordinator. Owing to the new knowledge acquired, participants were positioned to anticipate some things differently than they did prior to the training. Marcy confessed that there were some administrative processes that she had been hesitant to implement. She described how the trainer's logical framework helped her acquire new tools and skills for working on the budget. Following the training, she felt that she could more easily "tackle these things one at a time."

Janie described several areas where she ascribed her own weaknesses and was looking forward to changing her practice and the practice of her coordinators such as (a) evaluating studies upfront, (b) identifying certain aspects of the study, and (c) being prepared for the first patient. These actions could help her, and her team, avoid multiple queries. She began to question her particular group's practices related to data entry. Janie asked, "Why weren't we capturing that data in the way that they wanted?" She found that there was a discrepancy between what the coordinators were asked to do while recording standing blood pressure versus a sitting blood pressure, or when the blood pressure had to be taken five minutes before the patient was given the drug. Failure to follow the standard practice, meant that her team had ignored important protocol details. As a result, they had to do additional work to resolve these problems.

Roberto explained that because of new understanding about budget negotiation he had a better idea of where to put certain elements into the budget. He also described how the classroom sessions reinforced daily activities that research coordinators do. He felt that he was able to do a better job developing new protocols.

Discussion

Overall, the participants indicated a clear preference for a combination of onsite classroom instruction in real time along with online learning. However, this preference was qualified by the nature of the taught material, timing of training and level of expertise. Participants suggested that they be required to complete online learning prior to onsite classroom training for certain content, such as statistics. Providing participants with a primer of essential statistical terms prior to the face-to-face class might have aided their understanding. However, since the statistical competency required for coordinators is rudimentary, taking a semester-length online course in statistics is unnecessary. For other content such as developing a budget and learning how to obtain informed consent, they advised that their first exposure should be onsite classroom instruction. They pointed out that training opportunities, whether online or onsite classroom be tailored according to the longevity, or length of time as a research coordinator. These findings highlight that not all learning environments meet the needs of all learners.

As clinical research leadership searches for the penultimate solution directed at ensuring that all coordinators are trained, the study findings provide some guidance. Curriculum developers need to be mindful of the audience for whom instruction is intended. Perhaps they will need to create a different menu of options for audiences, rather than assume that a single set of modules or types of training platforms can satisfy learners' needs. Participants recommended specific ideas relative to when training is offered such as (a) offering training over time, (b) providing baseline information at the onset of employment, and (c) offering training modules only after a significant period of work experience. These suggestions highlight the importance of planning training alongside the skills obtained during the early years (up to ten) of being a research coordinator and later (over ten) when a coordinator was likely more skilled. Attention to who is providing the training will also need to be considered. The authors acknowledge that an enthusiastic presenter who used interactive learning activities is more likely to entice most participants compared to a presenter who simply delivers a lecture about the content.

In considering the findings, identifying preferences for instruction and the kinds of teaching preferred there may be a situational bias. The FGs were convened immediately after two days of classroom experience while the comparative online experience was received at variable intervals up to one month prior. Participants expressed a clear preference for what might be characterized as a "socially mediated experience," represented as in-class and live-interactive or more directly, person-to-person training. This "in-the-presence-of" instructors, teachers and other students, allowed participants to ask questions and promote conversation. The value placed on sharing experiences points to a social phenomenological relation between experience and experience, or rather what as RD Laing coined, a field of "*inter*-experience" (Laing, 1968, p. 2). As shown in this study, inter-experience fostered the ability to socially engage with others, to form meaningful, positive mentoring and to build networks in ways that transcended the implicit limitations of online training with its sociotechnical context of resting in one's *intra*-experience.

On-line learning was often characterized as a chore. Although participants took online modules, they did not necessarily pay attention to either the details or the facts. At times, they simply went through the motions of completing modules. The live training emphasized a

degree of social reinforcement that was not available online, especially given the non-interactivity that characterizes the CITI program.

Clinical Research Coordination is a complicated social activity. How individuals make sense of personal and group behavior is socially constructed in ways that Erikson (1974) would describe as integration of group norms, characteristics, values, and ideals into one's self. Reinforcement in observing was demonstrated in particular by participant's characterization of their visceral response to the role play activities that ensued during the informed consent. Social reinforcement plays a crucial role in conveying the values essential to the responsible conduct of research. The group process may also have solidified emergent bonds among individuals across institutions.

The use of qualitative methods and a grounded theory approach in particular revealed participants' multilayered experiences and responses to two very different learning platforms. The use of a codebook offers researchers another method that can be reliably implemented when care is taken by the research team to corroborate findings at each step of the analytical process. Qualitative inquiry illustrated the nuanced responses and explication of participant experiences that otherwise remain unknown. The online platform dedicated to knowledge acquisition occurred in an environment that lacked opportunity for bi-directional interactions. It offered dissemination of information in a one-way transmission from program to learner. The in-class, on-site learning, offered interactions, contextualized by the give and take between instructors and peers. This learning environment permitted asking questions, sharing experiences and role-playing, while allowing confirmation of professional roles and identities. This approach also fostered an application of theory to practice with real time clarification and opportunities to see how concepts and thinking were modelled by instructors. Clearly, this level of insight would have been unavailable from an analysis of survey results. The novelty of FGs offers a deepened appreciation of participant experiences that pointed out that training preference is not a binary. The FG experience fostered an assimilation of learning among the group, while accelerating self-realization and promoting new meaning among individuals. The situational, contextual and learner centric phenomena revealed in this study might provide guidance in the development of future training. Program developers, however, are advised to carefully consider learners' needs in relationship to type of skill, level of experiences, timing of training, and multiple pathways for achieving those desired outcomes.

The training played a significant role in changing participants' self-perceptions by validating their experiences. Research coordinators obtained an education-based framework for the variety of work related actions they were performing. The anticipation anxiety they have felt prior to the training decreased, while they became more confident after learning that they were performing their jobs in an appropriate fashion. This growing confidence led to being proactive in planning future steps in their professional development and the ability to recognize knowledge gaps. The training had an impact on coordinators' leadership abilities. While discussing the ideal research coordinator, they vocalized their zone of proximal development in the leadership realm.

One additional area of interest holds implications for future study. During discussion about feeling undermined by co-workers it was difficult to discern if the referent group was nurses or other healthcare workers. However, in Jones et al., they point out the need for further research and policy statements on the delegation and supervision of clinical research activities from the PIs to clinical research nurses and other clinical research staff (Jones, Hastings, & Wilson, 2015). In particular, they recommend clarifying the scope of practice among RNs and non-nurse research personnel. Titles including, Clinical Research Associate (CRA) or Clinical Research Coordinator (CRC), applied to nurses in clinical research are also used for non-nurses who coordinate or support clinical research (Association of Clinical Research Professionals, 2017a, 2017b; Hastings, Fisher, & McCabe, 2012). Certification for these titles do not require

registered nurse licensure. Since researchers pointed out long-standing role conflict between nurse and non-nurses who coordinate or support clinical research, this area might warrant further inquiry.

Limitations of the study were the use of one FG per experiential level. The overall findings are not generalizable. They are contextualized by the individuals who participated and are situated at a particular point in time. The questions asked are necessarily restricted by available response time, to permit individual participants an opportunity to answer each question. The methodological rigor of this study rests with verifiability, creditability, dependability, and transferability of findings, processes that are synonymous with validity, reliability, internal validity, and generalizability. Missing from this study is an assessment of the actual learning that occurred during the workshop. A pretest and a posttest based upon the actual content of the workshop would enable a quantitative comparison to the qualitative expressions in the paper.

Conclusions

Focus groups with novice and experienced research coordinators revealed their preference for a combination of onsite classroom instruction in real time along with online learning. This preference was qualified by the nature of the taught material, timing of training and level of expertise. Study findings highlight that not all learning environments meet participants' learning needs. Clinical Research Coordination is a complicated social activity. How individuals make sense of personal and group behavior is socially constructed. Qualitative inquiry illustrated the nuanced responses and explication of participant experiences that otherwise remain unknown. The findings advise that optimal training be tailored to participants' needs while considering their work experience, how technology can aid learning and offering content that is most urgently needed.

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