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Original Research Article

Competency indices to assess the knowledge, skills and abilities of clinical research professionals

Carlton A. Hornung[1,2]*, Carolynn Thomas Jones[1,3], Nancy A. Calvin-Naylor[4], Jared Kerr[5], Stephen A. Sonstein[1,6], Terri Hinkley[7], Vicki L. Ellingrod[8]

[1]Consortium of Academic Programs in Clinical Research, [2]School of Medicine, University of Louisville, USA
[3]School of Nursing, Ohio State University, Ohio, USA
[4]Institute for Social Research, [8]College of Pharmacy, University of Michigan, Michigan, USA
[5]School of Nursing, University of North Carolina at Wilmington, North Carolina, USA
[6]School of Health Sciences, Eastern Michigan University, Michigan, USA
[7]Academy of Medical-Surgical Nurses, USA

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***Correspondence:**
Mr. Carlton A. Hornung,
E-mail: cahornung@louisville.edu

ABSTRACT

Background: Clinical research in the 21st century will require a well-trained workforce to ensure that research protocols yield valid and reliable results. Several organizations have developed lists of core competencies for clinical trial coordinators, administrators, monitors, data management/informaticians, regulatory affairs personnel and others.
Methods: We used data collected by the joint task force on the harmonization of core competencies from a survey of research professionals working in the US and Canada to create competency Indices for clinical research professionals. Respondents reported how competent they believed themselves to be on 51 clinical research core competencies.
Results: Factor analyzes identified 20 core competencies that defined a competency index for clinical research professionals—general (CICRP-General, i.e., GCPs) and four sub-indices that define specialized research functions: Medicines Development; Ethics and Participant Safety; Data Management; and Research Concepts.
Conclusions: These indices can be used to gage an individual's readiness to perform general as well as more advanced research functions; to assess the education and training needs of research workers; and to evaluate the impact of education and training programs on the competency of research coordinators, monitors and other clinical research team members.

Keywords: Core competence, Clinical research professional, Self-efficacy, Factor analysis, Competency index, Workforce development

INTRODUCTION

The 2013 revision of the Declaration of Helsinki stated that "*Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications*."[1] Considerable efforts to train principal investigators have been made through NIH funding mechanisms such as the Clinical Research Curriculum Awards to academic medical centers (K30 programs), as well as individual training awards such as the K08 or K23, and now the K99 mechanism.[2] At the same time, professional organizations such as the Association of Clinical Research Professionals (ACRP) and the Society for Clinical Research Administrators (SoCRA) provide educational opportunities for clinical research professionals as well as opportunities for certification as coordinators, monitors, etc. In addition, a number of for-profit companies offer

on-line and short courses for individuals in differing roles in the clinical research enterprise.

Insuring the continued integrity of clinical and translational research in the 21st century will require refining existing training programs and developing new education and training opportunities for the clinical research workforce; particularly for trial coordinators, monitors, regulatory affairs specialists, data managers/informaticians as well as for investigators and those that design clinical trials.[3] The era of precision medicine is beginning to replace the randomized, double blind, placebo controlled parallel group trial that utilizes two-tailed testing at the alpha.05 level in an intention-to-treat analysis, the bedrock of clinical trial design, with innovative designs that test equivalence or non-inferiority and by designs that increase trial efficiency by reducing costs and/or by shortening time to a decision).[4] For instance, adaptive designs, such as sequential multiple assignment randomized trials (SMART), involve individualized treatment regimens and decision rules that include group sequential statistical methods of analysis that control the type I error rate and guide alterations in the type or intensity of treatment depending upon patient outcomes. These trials present challenging and complicated problems for study coordinators, monitors and data managers who recruit participants, obtain their informed consent, manage data collection and conduct patient education and follow-up. Further, newer trials often include patient reported outcomes collected via various electronic monitoring devices and utilize web-based evaluation tools. Disease registry-based randomized trials and community-based epidemiologic studies are being used more frequently either as stand-alone research or in conjunction with practice-based pragmatic trials which, in contrast to explanatory trials, are designed to provide evidence for adopting or not adopting an intervention in "real world clinical practice."[5] These pragmatic trials create special regulatory and ethical issues, especially in terms of informed consent, that were the topics of a special issue of the Journal of Clinical Trials in 2015.[6] Similarly, trials that assess the comparative effectiveness of two or more interventions or therapies that are integrated into routine patient care can present additional challenges to data managers who may be required to integrate trial outcome data that is unique to the protocol but may be incongruent with their existing electronic medical record.[7]

Adding to problems posed by the increasing complexity of pragmatic and comparative effectiveness studies is the fact that they are done in the real world clinical environment often with non-clinical research staff and sub-investigators who may lack formal training in clinical research procedures. Economic pressures can further complicate real-world trials when untrained or minimally trained staffs are required to manage a clinical study in addition to their primary care duties.

Several clinical research organizations have produced lists of knowledge, attitudes and skills they propose to be the core competencies for clinical research for members of their organizations. The Consortium of Academic Programs in Clinical Research (CoAPCR), formed in 2003 by directors of academic clinical research degree granting programs, consolidated the core competencies from these groups to create curricula to best prepare the next generation of clinical research professionals.[8] Efforts to further define core competencies for clinical research professionals progressed when representatives from professional organizations, academic institutions, contract research organizations, and the pharmaceutical industry met at the Multi-Regional Clinical Trial Center (MRCT) at Harvard University in 2013. A result of this meeting was the formation of the Joint Task Force (JTF) for Clinical Trial Competency.

The JTF set out to harmonize the core competency statements offered by the different organizations. The content analysis done by the JTF of the core competencies offered by the different organizations identified 8 theoretical competency domains containing 51 core competencies. The eight domains were: 1) Scientific Concepts and Research Design; 2) Ethical and Participant Safety Considerations; 3) Medicines Development and Regulation; 4) Clinical Trials Operations (GCPs); 5) Study and Site Management; (6) Data Management and Informatics; 7) Leadership and Professionalism; and 8) Communication and Teamwork.[9] The JTF then conducted an international survey of clinical research professionals to assess their perceptions of competence and relevance of the JTF competencies to their clinical research roles.[10]

The need for a competent clinical research workforce also led to the enhancing clinical research professionals training and qualifications (ECRPTQ) project lead by Thomas Shanley, MD and funded by the National Center for Advancing Translational Science (UL1TR000433-08S1). Shanley and colleagues, with the participation of several organizations representing clinical research professionals (e.g., ACRP, ACI Clinical, & CoAPCR), led this Clinical and Translational Science Awards (CTSAs) consortium-wide effort to develop recommendations for training the clinical research workforce including physician investigators. Representative from 63 CTSA hubs provided input to identify a comprehensive set of role-based competencies within the domain framework suggested by the JTF.[11]

Identifying the core competencies for clinical research professionals is only the first step in ensuring a qualified workforce. It is also necessary to assess the readiness of research coordinators, monitors, and other professionals to perform their designated roles. And, as Speicher and colleagues note, it is important to assess the not only the preparation of entry level workers but also the career development opportunities and continuing education requirements of more experienced professionals.[12]

In 2007, Mullikin, Bakken & Betz developed an assessment tool that sought to measure clinical research self-efficacy amongst physicians training for clinical research careers.[13] They developed the Clinical Research Assessment Inventory (CRAI) using 92 items from 10 competency domains that assessed the self-confidence of respondents in performing common tasks in clinical research. A total of 210 participants completed the online inventory. After factor analyses, the tool was reduced to 88 items. This tool provided insights for curriculum development for training K-30 awardees. Subsequent studies sought to develop and test shorter versions of the CRAI that were less cumbersome to complete. For example, a study at Washington University sought to evaluate Clinical Research Training Programs using a 76-item CRAI which, after factor analysis, resulted in a small reduction to 69 items. This study demonstrated significant improvements in self-efficacy as a result of participation in training.[14] Later, a group led by Robinson from the University of Pittsburgh Institute for Clinical Research Education factor analyzed 92 core competency items that produced six factors with the 2 highest loading items on each factor used to create a shortened version—the CRAI-12.[15] The short-form CRAI was used to measure perceived self-efficacy of undergraduate and first year graduate nursing students and to assess eight cohorts of medical students' perceptions and interest in clinical research careers.[16,17] One of us (JK) has been testing the use of a CRAI-SF (44 items, six domains) in undergraduate and graduate students enrolled in a clinical research curriculum.

CRAI and the shorter form CRAI-12 is based upon self-efficacy theory that argues that if individuals feel confident that they can complete a task and perform a role successfully, then they are more likely to actually do so and on social cognitive career theory that being able to do something successfully is associated with an increased likelihood of pursuing a role involving those activities.[18] While CRAI and its shortened form assess physician scientist's self-efficacy in the role of clinical investigator and translational scientist, no comparable index or instrument currently exists to assess the self-efficacy of clinical research professionals who perform roles in implementing and managing clinical research studies. Using data from the survey conducted by the JTF, we sought to develop such an index.[9]

METHODS

The JTF conducted an on-line survey from December 12, 2014 to July 1, 2015 in the United States (US), Canada, Latin American, Europe, Asia/Pacific, Middle East and Africa. The survey instrument was reviewed and approved by the University of Eastern Michigan IRB. Respondents were asked how competent they feel they were with carrying out each of the 51 JTF core competencies. Respondents were also asked how 'significant' they felt each core competency was in the performance of their role in the clinical research enterprise and whether they thought they could benefit from additional training in each core competency.

We conducted a secondary analysis that focused on the competency questions (University of Michigan IRB review and designation as 'not regulated'). Responses: "Competent—Able to interpret or discuss concepts and use knowledge to solve simple problems based on application concepts" and "Mastery—Able to apply knowledge to complex problems, integrate information, and create solutions" were combined to indicate that the respondent felt "Competent" to perform the specific clinical research function (i.e., the core competency). In contrast, the responses "Never been exposed to this content" (i.e., core competency), "Aware of the content, but never needed to become further informed" and "Exposed and sufficiently aware of content that I can look up what might be necessary for my role" were combined to indicate that the respondent lacked sufficient mastery of the material to claim to be competent.[8]

Our factor analyses of the competency questions utilized only the data from participants in the US and Canada who reported their role in the clinical research process was coordinator, monitor, regulatory affairs, data manager or research administrator (Table 1). We deleted from the analysis respondents from outside the US and Canada to minimize possible confusion over role definitions as well as language differences. We also eliminated respondents who said they were principle investigators or physician or pharmaceutical scientists. Finally, we deleted two competencies items from the JTF scientific concepts and research design domain: (item 1 "Demonstrate knowledge of pathophysiology, pharmacology and toxicology as they relate to medicines discovery and development" and item 2 "Identify clinically important questions that are potentially testable clinical research hypothesis through review of the professional literature"). These items were deleted from the analysis because we felt they were not competencies expected of trial administrators, coordinators or monitors who constitute the clinical trial workforce of interest here.

Table 1: JTF study participants' role in the US and Canada Clinical Research Enterprise.

Role	N	%
Clinical research coordinator	83	34.9
Clinical research monitor	26	34.9
Data management	23	9.7
Regulatory affairs	23	9.7
Research administration	83	34.9
Total	238	100

We performed an identical exploratory factor analysis of the 49 remaining items to that done by Robinson, et al to create a hypothesized "Competency Index for Clinical Research Professionals" (CICRP) that would be equivalent to the CRAI for physicians aspiring to be

clinician scientists.[15] All statistical analysis was performed using SPSS-Version 22.

RESULTS

The 49 core competencies yielded nine principal components with eigenvalues greater than one. These principal components closely paralleled the theoretical competency domains described by Sonstein et al for the JTF as well as those described by the Enhancing Clinical Research Professionals' Training and Qualifications group.[10,12] We scanned the structure matrix (Promax rotation; Kappa=5) to identify the most important competencies defining each component that would enable us to reduce the number of items necessary to create a shorter, more easily administered survey instrument. We identified the two highest loading items on each of the nine factors and included two additional items from the Medicines Development factor that had loadings of 0.797 and 0.792 respectively yielding a total of 20 core competencies.

We performed a second-order factor analysis of these 20 items (Promax rotation, Kappa=5) that created five second-order factors or empirical domains (in contrast to the theoretical domains derived by the JTF content analysis). The structure matrix showed that ten core competencies pertaining to the "General Operation and Management of Clinical Trials" clearly defined the first empirical domain. This is a general domain consisting of knowledge, skills and behaviors (e.g., GCPs) that all professionals, including entry level employees, working in the clinical trial enterprise could/should be expected to be competent to perform. In contrast to this general domain, the remaining four factors or domains pertain to more advanced knowledge and skills related to specialized aspects of clinical and translational research activities. Specifically, the second empirical domain is defined by five core competencies that reference the rules and processes governing "Medicines Development". The third domain relates specifically to "Clinical Trial Ethics and Participant Safety" (five items) while the fourth domain is defined by five items that pertain to "Data Collection and Management". The fifth and final domain is defined by five items pertaining to "Research Concepts" (i.e., Epidemiology and Biostatistics) that guide the design of scientifically sound and valid clinical trial protocols. Many of the core competencies are expressed in two or more of these empirical domains as shown in Table 2.

Table 2: Competencies by empirical domain.

Empirical domain	Competencies
I. General operation and management of clinical trials	1. Describe the role and process for monitoring a study. 2. Identify the legal responsibilities, issues liabilities and accountability that are involved in the conduct of a clinical trial. 3. Describe the significance of data quality assurance systems and how SOPs are used to guide these processes. 4. Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials. 5. Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct. 6. Compare and contrast clinical care and clinical management of research participants. 7. Define the concepts of "clinical equipoise" and "therapeutic misconception" as they relate to the conduct of a clinical trial. 8. Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study. 9. Identify and apply the professional guidelines and codes of ethics which apply to the conduct of clinical research. 10. Describe the impact of cultural diversity and the need for cultural competency in the design and conduct of clinical research.
II. Medicines development	1. Describe the roles and responsibilities of the various institutions participating in the medicines development process. 2. Explain the medicines development process and the activities which integrate commercial realities into the life cycle management of medical products. 3. Summarize the legislative and regulatory framework which supports the development and registration of medicines, devices and biologicals and esures their safety, efficacy and quality. 4. Describe the specific processes and phases which must be followed in order for the regulatory authority to approve the marketing authorization for a medical product. 5. Differentiate the types of adverse events which occur during clinical trials, understand the identification process for AEs and describe the reporting requirements to IRBs/IECs, sponsors and regulatory authorities.

Empirical domain	Competencies
III. Ethics and participant safety	1. Compare and contrast clinical care and clinical management of research participants. 2. Compare the requirements for human subject protection and privacy under different national and international regulations and ensures their implementation throughout all phases of a clinical study. 3. Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards. 4. Differentiate the types of adverse events which occur during clinical trials, understand the identification process for AEs and describe the reporting requirements to IRBs/IECs, sponsors and regulatory authorities. 5. Describe the role and process for monitoring of the study.
IV. Data collection and management	1. Summarize the process of electronic data capture (EDC) and the importance of information technology in data collection, capture and management. 2. Describe the significance of data quality assurance systems and how SOPs are used to guide these processes. 3. Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct. 4. Identify and apply the professional guidelines and codes of ethics which apply to the conduct of clinical research. 5. Describe the impact of cultural diversity and the need for cultural competency in the design and conduct of clinical research.
V. Scientific concepts in clinical research	1. Explain the elements (statistical, epidemiological and operational) of clinical and translational study design. 2. Critically analyze study results with an understanding of therapeutic and comparative effectiveness Compare and contrast clinical care and clinical management of research participants. 3. Compare and contrast clinical care and clinical management of research participants. 4. Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials. 5. Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct.

Table 3: Correlations, reliability and distributional characteristics of indices.

	General	Medicines development	Ethics and participant safety	Data management	Research concepts
General	1				
Medicines development	0.63	1			
Ethics and participant safety	0.76	0.63	1		
Data management	0.87	0.50	0.57	1	
Research concepts	0.81	0.56	0.64	0.69	1
Cronbach's α	0.79	0.84	0.80	0.78	0.70
RFactor, Index**	0.98	0.98	0.97	0.89	0.85
Mean	5.44	2.58	3.87	3.06	1.96
Std. deviation	3.15	1.84	1.51	1.71	1.68

* Correlation between the factor score (20 core competencies; mean of zero, unit variance) and the summated competency index (0 to 10 general index; or 0 to 5 sub indices).

Table 4: Mean differences in competency by role in the clinical research enterprise.

Category N	General Comp.	Med. Dev.	Ethics and safety	Data Mngt.	Research concepts
CRC 83	5.65	2.51	4.22	3.17	2.02
CRA 26	6.00	3.27	4.56	3.42	2.50
Data Mngr. 23	3.52	1.70	2.48	2.79	1.34
Reg. Affairs. 23	5.04	3.21	4.00	2.43	1.78
Res. Adm. 83	5.70	2.50	3.63	3.10	1.95
P Value	0.029	0.016	0.000	0.267	0.191

Note: General Comp. = General clinical trials operation and management; Med. Dev't = Medicines development; Ethics & Safety = Ethics and participant safety; Data Mgt.= Data collection and management; Research concepts = Scientific concepts in clinical research.

We summed the "Competent" responses for the items shown in Table 2 to create shorter and thereby easier to administer measure of competency for each of these domains. The summated Competency Index for Clinical Research Professionals (CICRP-General) from the first domain involving ten competencies is an index of competence in performing the general operations and management of clinical trials that sponsors and investigators might expect or require for entry level workers. Summing the responses for the five competencies defining domain two yields CICRP-Medicines Development. Similarly summing the responses for the competencies defining domains three, four and five yields: CICRP-Ethics and Participant Safety; CICRP-Data Management; and CICRP-Research Concepts respectively. Each of these five-item indices assess competence in specialized clinical research core competencies that may be expected of more highly trained or experienced workers.

Table 3 shows high correlations between the CICRP-General and each of the CICRP specialty indices (an outcome of promax rotation). More importantly, there are high correlations between each CICRP specialty index with its parent factor score (i.e., involving all 20 competency items) which indicates that each of the indices has a high degree of content and face validity which is confirmed by Cronbach's Alpha (Table 3).

In Table 4 are the mean scores on each index according to the respondent's role in the clinical research enterprise. There are statistically notable differences across roles in CICRP-General, CICRP-Medicines Development and especially in competency involving CICRP-Ethics and Participant Safety. Respondents who report their role as clinical research monitor report the highest competency to perform functions related to Ethics and Participant Safety (mean=4.56) while respondents involved in data management score poorly on this index (mean=2.48). It is noteworthy that even those respondents who report their research roles involve data management and those who say their role is in regulatory affairs have low scores on the CICRP-Data Management index and on the CICRP-Research Concepts index meaning that few respondents in these roles feel competent to perform these research functions.

DISCUSSION

These results reveal notable differences in self-reported competency to perform different clinical research functions across self-declared roles in the existing clinical research enterprise. The ad hoc nature of clinical research often engenders role confusion among those involved in practice.[19] Job titles and roles vary across research sites and especially between real world clinical sites and academic institutions. Considerable work is needed to standardize job titles and their associated role expectations.[20,21] Clarifying job titles and performance expectations across the clinical research enterprise is a necessary first step to develop the education and training programs necessary to prepare the clinical research workforce for 21st century clinical trials.

Regardless of current role ambiguity, scores on the CICRP-General and CICRP special indices can be used by sponsors and investigators to select individuals for defined roles in a clinical trial with the belief that an individual who is confident that she/he can competently carry out a role will be more likely to succeed at that role than an individual who lacks self-confidence in their ability. At the same time the directors of education and training programs can use these competency indices to assess educational needs of novice as well as more experienced workers. Educators and trainers can use pre- and post-test evaluation measures to gage the impact of their curricula, training and mentoring activities on the self-confidence of students. Such data can be of considerable value in guiding competency-based curriculum and training reforms—a must have to insure the quality of 21st century clinical research.

Professional organizations providing clinical research certification currently require a minimum of two-years of experience to qualify for certification exams. Those organizations and individuals could use these indices to assess the readiness of candidates to sit for these examinations. These indices could also be used by institutions offering certified educational programs in clinical research to justify to these certification agencies that formal education can and should be substituted for some fraction of time currently required in on-the-job-training. This would shorten the time from entry into the workforce and certification in a clinical research profession that could help alleviate existing workforce shortages.

We recognize important limitations of these data. First, the JTF data were collected via self- selection methods (i.e., Survey Monkey) and therefore respondents do not constitute a random sample of the clinical research workforce. Second, respondents self-identified their role in the workforce and there is ambiguity in the definition of clinical research roles. The potential for even greater role ambiguity between countries with varying regulatory systems is why we limited the analysis to respondents working in the US and Canada. Nevertheless, the variable role in the workforce remains subject to a degree of misclassification bias. Third, a number of respondents did not answer each of the three survey questions (i.e., competence to perform; significance for role; and need for further training) about each of the 51 core competencies. The lack of complete response, more than likely a result of 'survey fatigue', resulted in case loss due to missing data for which there is no justification to assume 'missing completely at random'. To assess how problematic missing data is, we analyzed 'missing' as a function of the respondent's role in the workfore, their years of experience in the CR enterprise and their level of education. The differences in non-response by CR role

were statistically significant (χ^2=13.76, p=0.0174). Similarly, non-response rates differed by level of education (χ^2=29.28; p<0.001). However, there were no statistically or meaningful differences in non response by years of experience in the CR enterprise. Accordingly, the analytical file under-represents those at the extremes of education and may over represent those in the CR worksforce with a masters degree. It must be noted, however, that we really do not know the proportion of workers in various roles, their years of experience or the educational levels of the CR workforce in the US or in Canada. Consequently, estimating the extent of bias in the analytical data file would be speculative at best. What we can say with some degree of confidence is that these data are the most comprehensive data available about how competent those employed in clinical research in the USA and Canada perceive themselves to be in their ability to perform their functions in the clinical research enterprise.

CONCLUSION

This analysis has created a psychometrically valid general Competency Index for Clinical Research Professionals" and competency indices for specialized functions in the research enterprise. The CICRP-General as well as the four 5 item subscales of competency in specialized activities in clinical research can be a valuable tool for sponsors, investigators, organizations involved in the education and training or workers who support principal investigators by implementing clinical trial protocols. Further studies that relate self-proclaimed competence in performing clinical research activities as measured by the CICRP indices with data that assesses observable performance and the relationships between competency, education and experience in the workforce are needed.

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