Core Competencies for Clinical Research Professionals

Stephen Sonstein, Eastern Michigan University and MRCT Center

Dr. Stephen Sonstein explained that the Joint Task Force (JTF) for Clinical Trial Competency was established in 2013 since there were few standards or educational requirements for clinical research professionals. Subsequently, the JTF compiled and harmonized competency statements available from various professional organizations and created a harmonized core competency framework for the clinical research professional, first published in 2014.

In October 2016, individuals from organizations around the world who had utilized the framework convened at Harvard to present case studies and to make suggestions for the revision of the framework. Since that time, many suggestions have been addressed, namely: (1) a website has been created (Clinicaltrialcompetency.org) which enables the clinical research community to review JTF activities, provide input into future iterations of the Framework and post how their own organizations have utilized the JTF contributions to enhance workforce development efforts, (2) the framework has been revised based on suggestions received and Version 2.0 has been released, (3) a workgroup is currently expressing the competency statements within the Framework to reflect entry level, mid-level and advanced level knowledge, skills and attitudes.

Workgroup members gave examples of how they have used or intend to utilize the competency framework:

Rebecca Brouwer, Duke University

Ms. Rebecca Brouwer has been involved in site-based research and utilized the core competency framework to facilitate professional development. Her team revised the organization's clinical research role descriptions and reduced the number from 81 to 10, based on the core competency framework. Competencies for professional development were levelled in tiers for the majority of their research professionals: Fundamental (needs coaching), skilled (works independently), advanced (is the go-to expert, provides training). These "tiered positions" are used as a basis for advancing staff in job categories, e.g., coordinators, regulatory coordinators, program leaders. Based on objective assessment of applied knowledge--preferably through direct observation, but also self-report, case studies, knowledge assessments, review of documents--individuals move to higher levels of competency if they reach the requirements defined for the next tier of the levelled competency. About 10% of their workforce is currently going through assessment. Version 2 will be streamlined since assessment is laborious, especially for experienced positions who have to be tested on all competencies. More information can be found on the Duke CRPWG website (https://medschool.duke.edu/research/clinical-and-

translational-research/duke-office-clinical-research/about-clinical-research-and-navigating-research-duke/staffing-clinical-research).

H. Robert Kolb, University of Florida

Mr. Robert Kolb is using levelled competencies for the training of clinical research coordinators. He emphasized that having a competent workforce is important for safer clinical trials, protecting people in studies, and for better data integrity. He has collaborated in a study, published this week in *The Qualitative Report*[1] about a 2-day standardized training based on the competencies for a group of novice and experienced coordinators, showing that" one size of training does not fit all." The authors found that there is a need to target training – not just for novice and experienced coordinators, but according to the requirements of the specific study. While the concept of targeting training is important, the levelled competencies create tools to target content for professional development.

William Gluck, Durham Technical Community College

Dr. William Gluck has utilized levelled competencies in collaboration with pharmaceutical companies and clinical research organizations (CROs). They assessed that there were over 14,000 different role descriptions for clinical research professionals and that a large number were very similar but used different names. In the absence of understanding the specific demands of the job, unnecessary time and effort is expended to find appropriately qualified individuals. Dr. Gluck recommends that candidates for the job be evaluated by competencies not expertise. In addition, he suggested candidates be encouraged to become professionally certified and that the certification process be based on the core competencies.

Carolynn Thomas-Jones, The Ohio State University

Dr. Thomas-Jones is using competencies to have students create professional portfolios in her work as a trainer and academic educator. When utilizing objective assessment of competencies to create portfolios students can demonstrate their skills and show what they have achieved in their academic course work. Initially, Dr. Thomas-Jones used portfolios in low-resource countries in South America when teaching clinical research in order to give students a means to share via PowerPoint presentations of what they learned. Then, *WordPress* became available for e-portfolios in academic courses; however, this software lacked connectivity and had other issues. The current system that Dr. Thomas-Jones is using is called *Portfolium,* a digital portfolio that allows students to upload materials (e.g. data management plan, case report forms, consent forms.) Students manage portfolios according to core competency domains. Some students have

[1] Behar-Horenstein LS, Potter JE, Prikhidko A, Swords S, Sonstein S, Kolb HR. Training Impact on Novice and Experienced Research Coordinators. The Qualitative Report. 2017 Dec 1;22(12):3118-38.

appended the portfolio URL for job applications as one means of assessment for core competencies.

Panel Discussion

The profession of clinical research is evolving. What are efforts to standardize the evolving profession?

Dr. Sonstein acknowledged that the profession of clinical research became an academic discipline about 20 years ago. While about 100 academic programs exist that educate clinical research professionals, each evolved independently and similar content is taught in entry and advanced degree programs. Utilizing the levelled core competencies will enable the process of academic program standardization. Dr. Sonstein is chairing a committee on accreditation which functions under CAAHEP (Commission on Accreditation of Allied Health Education Programs) that offers the first academic program accreditation process for the clinical research profession. The next step is to follow the standard health professional model and link academic education, hands-on experience (internship, preceptorship) and professional certification.

We see an increasing demand for patients as study participants. How can patients be integrated into the core competency framework?

People from across the community participate in a community engagement board at the University of Florida to advise on development of protocols. This is an example of bringing participants in as team members. Additional efforts should be made.

How should one deal with a profession in which the Principal Investigator may not meet the entry level competencies?

Since there is virtually no clinical research related content in the medical school curriculum, mentoring has been the standard method whereby investigators learn about delegated responsibilities and to "know what you don't know." In many cases study coordinators are responsible for caring for clinical trial participants. It is time to raise the issue of core professional responsibilities, professional development, delegation of authority, and collaboration for clinical investigators.

How to give more credibility to observational studies?

While interventional clinical trials are the ones most often utilized for the approval of new medicines, a very large number of investigator initiated studies are observational in nature.

They should also be functioning within the competency framework. As concerns the competencies, there should be very little distinction between interventional and observational studies.