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Competency-Based Self-Assessment Tools: A Mixed-Methods Retrospective Analysis of Need

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Abstract:

Evaluating the impact of Clinical and Translational Science Awards (CTSA) programs on the development of clinical research professionals is crucial. To this end, the value of competency-based metrics to assess the professional growth of CTSA awardees is unknown. A needs assessment was conducted to determine the present use and potential need for a competency-based self-assessment tool (CBST) as well as what professional competencies were valued. A mixed methods retrospective analysis was conducted using prior data from semi-structured interviews and online surveys. Overall, 29 unique CTSA hubs participated. Interview requests and surveys had a response rate of 21% (21 out of 102 contacted) and 33% (21 out of 63), respectively. Six institutions were doubly represented in both interviews and survey responses. Of interviewees, 33% reported existing use of a competency-based assessment tool, and 62%, inclusive of those already using a tool, indicated clear need for one. Interviewees highlighted that CBSTs should ideally be customizable, soft skill-focused, and complementary to other forms of assessment. Of the survey respondents, 67% reported already using a CBST. Both interview and survey results found that communication and teamwork were highly valued competencies in clinical research professionals. Among CTSA workforce development administrators, there is notable interest in CBSTs, particularly ones that are customizable and soft skill-focused.

Keywords: CTSA; NCATS; education; evaluation; translational science; core competency; clinical research professional; assessment tool; career development.

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INTRODUCTION

Quality research management is the cornerstone of clinical and translational science. In 2006, the NIH National Center for Advancing Translational Sciences (NCATS) created the Clinical and Translational Science Awards (CTSA) program to train new generations of clinical and translational researchers (Patel et al., 2019). While 60+ academic medical centers have created workforce development programs through CTSA funding, evaluating the use and comparative efficacy of competency-based assessment

tools to understand the effectiveness of these programs has remained unreported. Competency-based selfassessment tools (CBSTs) are question-based instruments to evaluate one's confidence in specific professional competencies with an implicit assumption that confidence may translate into competency (Robinson et al., 2013). CBSTs would allow programs to measure indirectly key professional development milestones of trainees. Currently, several CBSTs exist to assess individuals in specific clinical research roles, such as principal investigator, clinical research coordinator, and other ancillary research staff (Hornung, Ianni, Jones, Samuels, & Ellingrod, 2019; Hornung et al., 2018;

Mullikin, Bakken, & Betz, 2007), but little has been reported about the use or need for CBSTs within the CTSA community. Consequently, the New Jersey Alliance for Clinical and Translational Science (NJ ACTS) Workforce Development Core conducted a CTSA consortium-wide assessment to evaluate the present use and potential need for CBSTs in evaluating CTSA trainees. This work is a retrospective analysis of those materials, conducted to understand both the utility of CBSTs as an evaluation component to CTSA workforce development activities and which professional competencies are valued.

METHODS

A mixed methods retrospective analysis was performed using data from virtual interviews and asynchronous online surveys of CTSA hub administrators. Interview requests were sent to Workforce Development Core contacts at all 63 CTSA institutions, and all respondents were interviewed. Interviews were semi-structured but open-ended, per recommendations from NSF I-Corps™-provided resources (Constable & Rimalovski, 2014). Need was defined binarily by whether interviewees expressed any necessity for a CBST. Need was assessed and manually quantified by team members who independently analyzed interview recordings and transcripts, looking for common practices, themes, and challenges in the experiences of the interviewees. An online survey was also distributed to all CTSA hubs. The survey included questions related to the use of competency-based assessments and requested explanatory responses but did not explicitly ask respondents if they needed a CBST (Appendix). It also secondary endpoints, captured which were respondents' preferences for professional hard and soft skill competencies derived from the ITF Core Competency Framework ("Domains and Leveled Core Competencies - Joint Task Force for Clinical Trial Competency," n.d.)

RESULTS

A total of 29 unique institutions – 46% of all CTSA hubs – participated in the study, either as part of the qualitative interview, the survey, or both. Interview requests and surveys had a response rate of 21% (n = 21) and 33% (n = 21), respectively. Six institutions were doubly represented in both interviews and survey

responses. Interviewees included Workforce Development Core directors (n = 10), assistant or co-Core directors (n = 5), associate directors (n = 2), and program coordinators (n = 4). Respondents had a wide range of experience in their positions with the least experienced respondent having been in the role for six months.

Need and Current Assessment Practices

Of the 21 interviewees, 33% (n = 7) reported existing use of a competency-based assessment tool, and 62% (n = 13), inclusive of those already using a tool, indicated a clear need for one. Interviewees reported the following current methods to assess trainees: Individual Development Plans (IDPs) (Fuhrmann, Hobin, Lindstaedt, & Clifford, 2019) or adaptations of it, the Clinical Research Appraisal Inventory tool (Mullikin et al., 2007), formative writing assignments like research proposals, mentoring, K-Club workshops, and formal exams. Some interviewees used only one of the above methods, and others used more than one. The most common modalities were mentoring (n = 8) and IDPs (n = 7). Two interviewees stated that their institutions were developing their own assessment tools.

Of the survey respondents, 67% (n = 14) already use a competency-based assessment. Four of these 14 survey respondents were from institutions represented by interviewees as well.

Common Challenges

Interview participants described various challenges in meeting individual workforce development goals. Difficulties included the heterogeneity of both CTSA trainees and the field of clinical and translational science itself as well as assessing soft skills.

Heterogeneity

The most cited challenge was the heterogeneity of types of clinical research professionals involved in CTSA training and education, which can include graduate students, post- and pre- doctorate students, and early investigators entering the field with a variety of roles. Interviewees endorsed the view that the diversity in professional background and level of expertise made it a challenge to design and offer educational training programs that were both high quality and relevant to all participants. Two institutions expressed that the siloed nature of programs created barriers to standardized assessment activities.

Soft Skill Focus

The lack of focus on soft skills in evaluation tools was highlighted as well. Interviewees described soft skills as an asset to clinical and translational researchers but acknowledged considerable difficulty in their assessment. A wide range of soft skills was endorsed during interviews, with the most common being team science (n = 5), communication (n = 4), leadership (n = 2), and negotiation (n = 2). These findings dovetailed with survey results showing teamwork (n = 18) and oral and written communication (n = 17) as the top two most valued soft skills in trainees.

Some Insights into Tool Features

Several interviewees expressed sentiments that CBSTs could be a tool not only to longitudinally evaluate awardees based on competencies, but also to provide individualized advice, which would help address the challenge of trainee heterogeneity. A CBST could be used by CTSA administrators to recommend trainees toward specific courses, or trainees could use the tool to explore different educational pathways based on their current competencies. Interviewees also noted that institutional mentors would be crucial for providing direction and insight into the appropriateness of courses.

Also, because evaluation of soft as well as hard skills appeared to be a significant area of interest for CTSA workforce development administrators, a tool capable of assessing one's ability to work well in teams or communicate scientific research would likely be valuable. Potential assessable soft and hard skills endorsed by survey respondents are highlighted in **Table 1**.

DISCUSSION

This study suggests there is current use and notable interest amongst CTSA administrators in competency-based self-assessment tools, particularly ones that are customizable and soft skill-focused. Of note, because self-assessments are susceptible to personal biases and tend to measure confidence over true competency, CBSTs likely will need

implementation in tandem with more objective measurements of competency. While study insights are limited by low response rates and selection bias, our findings still shed light on the challenges in effectively evaluating clinical research professionals and offer direction into how an ideal CBST might be designed. As remote partnerships grow in prevalence, soft skills like collaboration, leadership, and effective communication are pushed to the forefront of necessary competencies for research professionals, and tools to help assess these competencies would benefit the entire clinical and translational research enterprise. Further research is necessary to clarify additional factors, such as limitations of existing tools, that could influence the design and implementation of a CBST within the CTSA consortium and beyond.

Table 1. Survey Respondents' Preferred Hardand Soft Skills for CTSA Awardees

Hard Skills	% of Respondents Endorsed
Scientific Concepts Research Design	85%
Data Management Informatics	75%
Communications Teamwork	70%
Clinical Study Operations	60%
Ethical Participant Safety	
Considerations	60%
Leadership Professionalism	60%
Study Site Management	35%
Investigational Product Development	
& Regulations	30%
Soft Skills	% of Respondents
Soft Skills	Endorsed
Teamwork	90%
Oral & Written Communication	85%
Leadership	70%
Time Management	70%
Ethics	65%
Planning Project Management	55%
Writing	45%
Diligence & Attention to Detail	40%
Accepting of Criticism	35%
Adaptability	35%
Coachability	35%
Enthusiasm	35%
Presentation	30%
Honesty	25%
Conflict Management	20%
Staying Calm Under Pressure	20%
Authenticity	15%
Conscientiousness	10%
Patience	10%

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Conflict of Interest

Peter Trinh, Barbara Tafuto, Yasheca Ebanks, Zahra Zunaed, and Doreen W. Lechner have no conflicts of interest to disclose.

REFERENCES

- Constable, G., & Rimalovski, F. (2014). Talking to humans: success starts with understanding your customers (First).
- Domains and Leveled Core Competencies Joint Task Force for Clinical Trial Competency. (n.d.). Retrieved January 7, 2021, from https://mrctcenter.org/clinical-trialcompetency/framework/domains/#domain8
- Fuhrmann, C. N., Hobin, J. A., Lindstaedt, B., & Clifford, P. S. (2019). myIDP. Retrieved December 9, 2020, from http://myidp.sciencecareers.org/
- Hornung, C. A., Ianni, P. A., Jones, C. T., Samuels, E. M., & Ellingrod, V. L. (2019). Indices of clinical research coordinators' competence. Journal of Clinical and Translational Science, 3(2–3), 75–81. https://doi.org/10.1017/cts.2019.381
- Hornung, C. A., Jones, C. T., Calvin-Naylor, N. A., Kerr, J., Sonstein, S. A., Hinkley, T., & Ellingrod, V. L. (2018). Competency indices to assess the knowledge, skills and abilities of clinical research professionals. International Journal of Clinical Trials, 5(1), 46. https://doi.org/10.18203/2349-3259.ijct20180130
- Mullikin, E. A., Bakken, L. L., & Betz, N. E. (2007). Assessing Research Self-Efficacy in Physician-Scientists: The Clinical Research APPraisal Inventory. Journal of Career Assessment, 15(3), 367–387. https://doi.org/10.1177/1069072707301232
- Patel, T., Rainwater, J., Trochim, W. M., Elworth, J. T., Scholl, L., & Dave, G. (2019). Opportunities for strengthening CTSA evaluation. Journal of Clinical and Translational Science, 3(2–3), 59–64. https://doi.org/10.1017/cts.2019.387
- Robinson, D. G. F. W. B., Switzer, D. G. E., Cohen, M. E. D., Primack, D. B. A., Kapoor, D. W. N., Seltzer, M. D. L., ... Rubio, D. D. M. (2013). A Shortened Version of the Clinical Research Appraisal Inventory: CRAI-12. Academic Medicine : Journal of the Association of American Medical Colleges, 88(9), 1340. https://doi.org/10.1097/ACM.0B013E31829E75E5