PRACTICAL TIPS

Guidelines for Evaluating Clinical Research Training using Competency Assessments [version 2]

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Abstract
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Effective training programs in clinical and translational research (CTR) are critical to the development of the research workforce. The evolution of global CTR competencies frameworks motivates many CTR institutions to align their training offerings with these professional standards. Guidelines for integrating competency-based frameworks and assessments into rigorous program evaluations are needed in order to promote the quality and impact of these training programs. These guidelines provide practical suggestions for how to ensure that subjective and objective assessments of CTR knowledge and skill can be effectively integrated in the evaluations used to improve these essential training programs. The approach presented here necessarily involves the systematic and deliberate incorporation of these particular types of assessments into comprehensive evaluation plans. While these guidelines are broadly applicable to the work of those charged with developing, administering and evaluating CTR training programs, they have been specifically designed for use by program directors.

Keywords
clinical and translational research, workforce development, competency-based assessment, competency framework, program evaluation, program improvement, logic model
Introduction
Clinical and translational research in the United States is supported by numerous federal, industrial and academic organizations, and many other stakeholder groups (Callard, Rose and Wykes, 2012; Martinez et al., 2012; Trochim, Rubio and Thomas, 2013; Joosten et al., 2015). The NIH National Center for Advancing Clinical and Translational Science (NCATS) is a distinctive among them as it funds a broad network of research support centers, Clinical and Translational Science Awards (CTSA), embedded in over 50 research institutions located across the country (NCATS, 2018). A key strategic goal of these CTSA is to develop the clinical and translational workforce through dedicated research training programs (NCATS, 2017). Clinical Translational Research (CTR) training programs provide highly valued instruction on relevant research skills and demand rigorous evaluations that demonstrate their impact on the development of the research workforce (Bonham et al., 2012; Calvin-Naylor et al., 2017).

CTSA programs offer a variety of training options, typically in the form of short-term programs, short courses or one-time workshops. These training programs are often tailored to the need of professional degree students on a research track, postdoctoral fellows, residents, or early career faculty. These programs often provide education and training in a variety of core competencies, including study design, communication, teamwork, and research ethics, to name only a few areas of study.

Rigorous evaluations of CTR programs periodically require measurement of demonstration and application of research skills and acquired competencies (Misso et al., 2016). Medical education programs are often subject to quality control, quality management, and quality assurance by regulators. However, no analogous formal mechanism exists for evaluating CTR programs. Instead, the responsibility for evaluating CTR education and training programs often resides with small groups of investigators, research managers and administrators with little experience measuring research competencies per se. This work provides concrete steps they can take to integrate competency assessments into evaluation plans implemented by CTR training programs (Centers for Disease Control and Prevention, 1999; Trochim, Rubio and Thomas, 2013).

In this paper, we provide twelve guidelines for evaluating research education and training programs to better understand learner attainment of the skills and knowledge in clinical translational sciences. The guidelines discussed in this paper have been adapted to the role of the CTR training program directors. Therefore, to ensure the relevance of these guidelines to this role, the authors carefully considered the typical demographics, job duties, motivations, knowledge, skills and experiences of an administrator charged with guiding the evaluation and quality improvement of these education and training programs.

Guidelines for using competency assessments in program evaluation
Review team roles and expertise related to trainee’s professional development
The responsibility for evaluating CTR training programs is often carried out by personnel in a number of positions and roles. The collaborative review of these roles can be facilitated by creating personas, which are defined as archetypes with distinctive needs, goals, technical skills and professional characteristics (Adlin and Pruitt, 2010). Creating a persona that defines who will be conducting evaluations can help program teams and stakeholders discuss and negotiate changes to the ways this work is distributed and coordinated. Table 1 provides examples of personas of clinical research professionals who are likely to share responsibilities for administering a CTR training program. This process can be carried out by CTR program leads and administrators to help focus collaborative efforts on measuring the research knowledge and skills of researchers.

Integrate competency frameworks into evaluation planning
Ideally, evaluators should be involved in the process of developing training programs to identify learning outcomes. However, early involvement may not always be possible due to contextual constraints. Ideally evaluators should be involved in mapping any existing CTR training curriculum to competency-based education (CBE) frameworks (Dilmore, Moore and Bjork, 2013). It may be necessary to partner with subject matter experts who understand CBE during this mapping process. There are multiple evidence-based competency frameworks applicable to CTR education and training (NCATS, 2011; Calvin-Naylor et al., 2017; Sonstein et al., 2018). Table 2 shows training opportunities that have been mapped to one domain of an established CTR competency framework (Joint Task Force, 2018).

The outputs of this mapping process should be shared with programmatic stakeholders to facilitate the collection of their feedback about the breadth and depth of the existing or potential CTR training opportunities. Collecting stakeholder feedback about the content of CTR training programs is an essential first step in many guides to evaluating health research training programs, including the U.S. Center for Disease Control and Prevention’s (CDC) guide for the evaluation of public health programs (Centers for Disease Control and Prevention, 1999).
Engage stakeholders in identifying critical knowledge and skill outcomes

As soon work on an evaluation plan has begun, evaluators should engage program stakeholders to help identify the most important knowledge and skills taught to CTR trainees. In collaboration with various stakeholder groups, evaluators can partner with instructional designers and other stakeholder groups to develop relevant and measurable lists of competencies. When identifying which specific stakeholder groups to involve in this phase of the evaluation planning process it is important to ensure that those with divergent recommendations of which CTR skills are in greatest need of development and assessment are included (Callard, Rose and Wykes, 2012; Martinez et al., 2012; Trochim, Rubio and Thomas, 2013; Joosten et al., 2015).

Diverse stakeholder feedback can be systematically collected and synthesized using standard survey methods, interviews, focus groups and Delphi panels (Brandon, 1998; Geist, 2010). Evaluators should collect stakeholder opinions about short- and long-term outcomes, including those regarding participant learning and behaviors (Kirkpatrick and Kirkpatrick, 2006). The collection of data on all types of programmatic outcomes, but particularly including the knowledge and skills accrued through the program, is necessary for the development of rigorous program evaluations (Centers for Disease Control and Prevention, 1999; Trochim, Rubio and Thomas, 2013). Evaluators should take care to

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**Table 1. Professional roles involved with evaluating Clinical and Translational Research (CTR) training programs**

| Persona | CTR Investigator | CTR Training Program Director | CTR Training Program Administrator |
|---------|------------------|-------------------------------|-----------------------------------|
| **Associated professional responsibilities** | Junior investigators or senior research fellows | Research department supervisor or supervisor of training programs for research team members and junior investigators | Research and regulatory support or program manager |
| **Professional motivation** | Wants to provide rigorous training for research teams who are required to complete research training. | Wants to use assessments of clinical research skill to revamp educational programs. | Wants to provide consistent training and professional development experiences for research teams |
| **Understanding of best practices in evaluating learning** | Expertise in program evaluation, use of logic models and postsecondary teaching | Understanding of learning outcome assessment, CTR competency frameworks and postsecondary teaching | Understanding of survey administration, data management and use of observation checklists |
| **Responsibility for competency assessment administration, analysis and reporting.** | Identifying validated competency assessments and interpreting the results with stakeholders | Developing assessment forms and communicating with CTR trainees and developing results reports for stakeholders | Communicating instructions to CTR trainees and instructors, monitoring administration of assessment forms and management of resultant data. |

**Table 2. Sample Training Offerings for Scientific Concepts and Research Design**

| Developing Research Questions | Choosing an Appropriate Study Design | Selecting Valid Instruments | Determining an Adequate Number of Study Participants |
|------------------------------|-------------------------------------|----------------------------|-----------------------------------|
| Developing and Writing Research Questions, Aims & Hypotheses Formulating Research Questions, Hypotheses and Objectives The use of hypothesis testing in the social sciences | Experimental & Observational Study Designs Introduction to Clinical and Translational Research: Study Population and Study Design The Qualitative Research Process: Study Designs for Health Services Research | Finding Tests & Measurement Instruments: Library Research Guide Measuring assessment validity and reliability Community engaged approaches to measuring study team dynamics | Hypothesis Testing: Significance level, power, and basic sample size calculation Introduction to Power in Significance Tests Best practices in participant recruitment |
consider all program characteristics relevant to key outcomes, most particularly those affecting the learning environment in which learners and their instructors are expected to work.

**Develop models depicting the links between program operations and outcomes**

Logic models should be created in order to enrich and advance conversations with stakeholders and other administrators about the operation and impact of a CTR training program. Logic models are figures that typically depict the relationship between key programmatic A) inputs, B) activities, C) outputs and D) outcomes, often using itemized lists arranged into columns under each of these headers (McLaughlin and Jordan GB, 1999). Some also include references to relevant important contextual or environmental factors affecting key programmatic goals. The choice of which elements to represent in the model should be informed by the need to visualize links between programmatic operations and skills development that would be of greatest interest to key stakeholders. Many funders ask that logic models be included in program proposals, and the production of these figures are standard practice in the evaluation of training programs in the health sciences (Centers for Disease Control and Prevention, 1999; 2018).

Whenever possible, logic models for CTR training programs should include the identification of short-, intermediate-, and long-term goals. The acquisition of critical research knowledge and skills are often represented as outputs or short-term outcomes of these training programs in logic models. In contrast, distant impacts, such as the production of research grants, peer-reviewed publications and career advancement are often represented as intermediate- or long-term outcomes. To enhance the efficiency of the model-making process, utilize competency domains, each of which cover sets of related competencies, as outcomes rather than numerous specific competencies in these figures. Exemplars of logic models that include lists of CTR competency domains have been published and can be used inform development of logic models for similar programs (Rubio et al., 2010). Figure 1 shows a logic model that can be used a basic template for enabling the planning, implementation and evaluation of a CTR training program.

**Distinguish programmatic outcomes used for formative and summative evaluation**

The choice of when to measure outcomes should be informed by the intent to use the results for formative or summative evaluations (Newman et al., 1995; Yudkowsky, Park and Downing, 2019). Formative evaluation is typically conducted during the development or improvement of a program or course, whereas summative evaluation involves making judgments about the efficacy of a program or course at its conclusion. The results of formative evaluations are often used to improve programs and projects during their implementation. Outcomes chosen for the purpose of formative evaluation

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**Figure 1. Sample Logic Model for an Evaluation of a CTR Training Program**

| Inputs | Activities | Outputs | Outcomes |
|--------|------------|---------|----------|
| CTR Investigators | Didactic training | CTR Trainees | Short-Term |
| Scientific Mentors | Communications & Training Resources | Individualized Development Plans (IDP) | Number of Applications Received |
| Application Review Committee | Recruitment & Advertising | CTR Training Experience | Satisfaction with CTR Training Experience |
| Trainers (Guests/experts) | Application Review | Acceptance, Enrollment & Completion Rates | Implementation & Refinement of IDP |
| CTR Training Program Administrators | Mentor Meetings | Number of Mentor Meetings | Number of CTR Study Team Memberships |
| Advisory Committee | Pre & Post-Program Competency Assessments | Professional Network | Growth in Competency Assessment Scores |
| | Participant tracking & data collection | Competency Assessment Scores | Recommendation of CTR Training to Colleagues |

1) Metric Specification: The average score by competency domain as measured by a validated competency assessment for clinical and translational research trainees.

2) Metric Specification: Evidence of a research career as operationalized by NCAT’s Research Careers Common Metric.

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are often represented as short- or intermediate-term outcomes in logic models. The results of summative evaluations are used to produce valid and objective measures of programmatic impact at the end of the implementation process. Footnotes can be added to logic models to differentiate the use of certain metrics for these two distinct purposes, as shown in the template above (Figure 1).

Measures of knowledge and skill can be used for both the formative and summative evaluation of CTR training programs. The results of relevant pre-program assessment tools, and of assessments conducted during the course of a program, enable formative evaluation when they are used to improve the experience of the currently participating trainees. For example, the results of subjective or objective skill assessment tools can be shared with respondents to inform development of individualized training plans or used to inform modifications to training curricula to address perceived or objectively-measured gaps in knowledge and skill. The results of post-program skill assessment tools enable summative evaluation when compared to relevant benchmarks, including the results of pre-program skill assessment tools or measures of skill acquisition produced by similar training programs (Newman et al., 1995; Centers for Disease Control and Prevention, 1999).

Select validated assessment tools to measure critical knowledge or skills
The validation of knowledge or skill assessment tools requires that evidence be marshalled to advance the claim that an assessment tool actually measures what it was designed to measure (Kane, 1992). Peer-reviewed publications that demonstrate the validity of a competency-based assessment will include the results of tests suggesting that the assessment tool provides reliable and accurate measures of knowledge or understanding among the level of learners targeted by the training program. The use of validated competency-based assessment tools for program evaluation lends credibility to the work and typically requires fewer resources than does the development of locally-developed assessments.

Several validated tools of CTR skills for investigators and research professionals have been published in recent years (Bakken, Sheridan and Carnes, 2003; Streetman et al., 2006; Bates et al., 2007; Ellis et al., 2007; Mullikin, Bakken and Betz, 2007; Lowe et al., 2008; Cruser et al., 2009; Cruser et al., 2010; Lipira et al., 2010; Murphy et al., 2010; Poloyac SM et al., 2011; Robinson et al., 2013; Ameredes et al., 2015; Awaisu et al., 2015; Robinson et al., 2015; Sonstein et al., 2016; Jeffe et al., 2017; Patel et al., 2018; Hornung et al., 2019). When choosing between validated assessment tools, it is critical to select ones which are most closely aligned with the competency framework chosen for a given CTR program and which have been validated using learners with similar credentials and research experience to those participating in that program. Be sure to obtain all the necessary permissions from the creators of any validated assessment tools before using the instruments for evaluation purposes.

Subjective vs. Objective assessment tools
The design and purpose of a CTR training program may require the use of subjective and objective assessment tools. Subjective assessment tools, through which participants rate their own knowledge or skills, can provide valid measures of self-confidence in one’s abilities, but have not been shown to correlate with the results of objective measures (Hodges, Regehr and Martin, 2001; Davis et al., 2006). Subjective and objective assessments of CTR knowledge and skill can be used simultaneously, but only the results of the latter type should be used to make justify claims about the actual knowledge and skills currently possessed by CTR participants.

Clinical and translational research training programs that confer any level of certification which are formally recognized by professional institutions or organizations may require that objective assessment tools be used to verify the actual research capabilities of the graduates. In these cases, the specific assessment tools that should be used by CTR training programs may have already been identified by these associated professional groups. When multiple or conflicting assessment tools are required by these groups conversations with programmatic stakeholders will be needed before any final determination about the use of any competency-based assessment tools can be made.

Estimate the time and effort required for implementing an evaluation plan
Evaluation plans take many different forms, but all plans detail how evaluation data will be collected, analyzed, reported and used (Trochim, Rubio and Thomas, 2013). The costs of implementing rigorous evaluation plans can be substantial, so it is essential that they are accurately estimated and budgeted for. Some evaluation activities, such as the administration of publicly-available skill assessment tools using free online platforms, have comparatively low costs. The costs of other evaluations, such as those involving focus groups, can be considerably higher.

The effort required for each step of the evaluation plan can be estimated in a basic table (Table 3). When reviewing an evaluation plan, carefully consider the risks and benefits of proposed assessment tools and choose those that are feasible to administer given the available financial and human resources. Collaborate with stakeholders to ensure that key
Train evaluation team members to collect assessment data in reliable ways
Once an evaluation plan has been developed, and a formal evaluation team has been assembled, it is important that team members understand the steps required for reliable data collection using competency-based assessments. For example, use of a CTR assessment of regulatory compliance may require that all persons administering the assessment tool be consistent in their use of the instrument as well as their subsequent scoring of individual’s performance. Even objective scoring systems include risks related to subjective interpretations (Van der Vleuten et al., 2010). Research has shown that individuals in apparent positions of power may influence or dissuade respondents from giving honest responses on tests of their knowledge or skills (Taut and Brauns, 2003; Van der Vleuten et al., 2010). Therefore, it is essential that the appropriate team members receive and demonstrate their understanding of validity, reliability, evaluation ethics, conflicts of interest, possible hegemonic practices or biasing and reporting procedures.

Use technology platforms that best facilitate data collection, analysis and reporting
Because no single technology platform specifically designed for CTR evaluation currently exists, evaluators must make use of existing platforms that are not tailored to CTR. To maintain consistency, accuracy and accessibility of the assessment results, CTR evaluators should use one platform to administer, analyze and report survey results whenever possible. For example, the same platforms used by clinical and translational researchers to collect research study data, such as REDCap™ (Harris et al., 2009), Qualtrics®, and SurveyMonkey®, can also be used to conduct evaluations of CTR skills. If necessary, the resultant data can also be extracted from these platforms so that further analyses can be performed.

Many statistical analysis programs familiar to clinical and translational researchers, such as STATA, SAS and R, can also be used for rigorous validity tests. These software programs have the ability to conduct exploratory and confirmatory factor analysis (Levine, 2005; Osborne and Costello, 2005), which are commonly used to identify and to validate the accuracy of the competency domains that structure many competency-based assessments. While there are many valuable validity tests (Kane, 1992), these are the ones most commonly used to validate skill assessments. Software programs for qualitative analysis, such as Dedoose® or NVivo®, can be used to conduct qualitative evaluations of CTR programs (Comeau et al., 2017).

Table 3. Example evaluation activities and time required for an evaluation of CTR training

| Evaluation Activities                                      | Hours |
|-----------------------------------------------------------|-------|
| **Evaluation Planning**                                   |       |
| Develop competency crosswalk for program components       | 4     |
| Draft logic model with short, intermediate & long-term outcomes | 4     |
| Draft and submit IRB application                          | 8     |
| **Data Collection**                                       |       |
| Institutional records of participant affiliations         | 2     |
| Competency assessment administration                     | 4     |
| Focus group administration                               | 8     |
| Focus group transcription                                | 16    |
| **Data Analysis**                                         |       |
| Cleaning and management of all quantitative data          | 4     |
| Quantitative analysis of competency assessment data       | 8     |
| Qualitative coding of focus group data                    | 16    |
| Qualitative coding of participant research projects       | 2     |
| **Reporting**                                             |       |
| Draft Stakeholder Reports                                 | 40    |
| **Total:**                                                | 116 hrs. (~3 weeks) |
Consult with subject matter experts to interpret assessment results

The results of competency-based assessment of CTR skill may not be readily interpretable, particularly when no established criteria or rubric is associated with the assessment tool. In fact, many validated assessment tools do not prescribe how the resultant scores should be interpreted by respondents to better understand their own training needs or by training program administrators to enable programmatic improvements. In these cases it is important to consult with subject matter experts in clinical and translational research, psychometrics and statistical analysis while conducting analyses of the assessment results.

The need to consult with these types of subject matter experts is particularly acute with subjective and objective assessment tools. Subjective tests of knowledge and skill have been shown to be poorly correlated with objective measures (Hodges, Regehr and Martin, 2001; Davis et al., 2006). There is evidence suggesting that while subjective measures of CTR knowledge and skill often increase between pre- and post-program tests the scores obtained through such objective tests do not increase at a similar rate (Ellis et al., 2007; Crusser et al., 2010). Measurement and educational experts can help ensure that assessment results are interpreted in ways that are justified by the design and administration of the assessment instrument.

Collect stakeholder feedback about options for programmatic improvement

An essential step of program evaluation involves sharing of evaluation results with stakeholder groups in order to facilitate collection of feedback about programmatic improvement (Wandersman et al., 2000). For example, in the four overlapping and iterative phases of the Plan, Do, Check, and Act (PDCA) quality improvement cycle, the third stage typically involves studying the outcomes of a given initiative in ways that enable the articulation of what was learned through the implementation process (Juran and DeFeo, 2010; Kleppinger and Ball, 2010). The involvement of stakeholders in this step of the process is critical to the rigorous evaluation of any CTR training program (Trochim, Rubio and Thomas, 2013).

Reports of evaluation results should be customized to speak to stakeholder subgroups whenever it is not possible or productive to share the same report with all of them. For example, stakeholders with distinctive interests in the scientific content or pedagogical approach of a CTR training program may be most interested in reports showing how the results of competency-based assessment tools are being used to help participants identify and address their personal research learning challenges (Chatterji, 2003). In contrast, stakeholders who value training programs as an institutional resource enabling the CTR enterprise may be more interested in the research careers or achievements of participants (Frechtling and Sharp, 2002). Whenever possible thoroughly document stakeholder feedback so that it can be used to inform future discussions about programmatic improvement and impact.

Conclusion

The guidelines presented here are intended to support the work of all clinical research professionals who are charged with the administration and evaluation of CTR training programs. In particular, this work fulfills a need for guidelines that clinical research investigators and administrators can follow to integrate competency assessment tools into their evaluation plans. Doing so will better enable research centers to collaborate with programmatic stakeholders efficiently and effectively in order to measure and improve the quality and impact of CTR training using the results of competency-based assessments of research knowledge and skill.

Take Home Messages

- Effective training programs in clinical and translational research are critical to the development of the research workforce.

- Guidelines for integrating competency-based frameworks and assessments into program evaluations are needed to promote the quality and impact of research training programs.

- The stakeholders of clinical and translational research training programs should be routinely consulted throughout evaluation processes that involve competency frameworks and assessments.

- The systematic incorporation of competency-based approaches into evaluation plans facilitates the work of those developing, administering and evaluating research training programs.

- The use of validated competency assessments for programmatic evaluation is essential to the collection of reliable and relevant performance metrics.
Notes On Contributors
All of the Co-authors contributed to the development of the guidelines presented in this work, informed the conclusions it advances and participated in all rounds of revisions required for submission.

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Declarations
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Ethics Statement
This work does not constitute human subjects research and so no IRB review was required. The work contains only the opinions and individual work of the authors.

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Migrated Content

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David Bruce

None

This review has been migrated. The reviewer awarded 4 stars out of 5

The authors are to be congratulated for tackling the complex issue of how to incorporate professional standards into clinical and translational research programmes. I think they have provided a logical set of steps for those charged with management and delivery of these programmes to consider and tailor to their own specific programmes. As a non-specialist reader I thought the paper provided sufficient background information about current CTR programmes to understand the need for the competency-based framework and assessment programmes that they were proposing. I particularly liked the flow of their 12 guidelines which dealt with in turn; the faculty and stakeholders involved and their roles, the development of models, the creation of an assessment programme and the support for faculty to deliver this, the use of experts in helping interpretation and finally seeking stakeholder feedback. I wonder if this paper could be produced as a short pamphlet / guideline for those teaching and managing other CTR programmes. I would have liked to hear more about which assessments were considered and whether they were assessments of learning or assessment for learning. However – I appreciate this would lengthen the paper and may need to be described in a future paper. This paper will be of great interest to all involved in the research community.

Competing Interests: No conflicts of interest were disclosed.

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Trevor Gibbs
AMEE

This review has been migrated. The reviewer awarded 5 stars out of 5

I congratulate the authors on their re-working of their paper. I found it easier to read this time and appreciate the improved clarity. I would recommend this paper to all those involved in curriculum planning and competency development.

**Competing Interests:** No conflicts of interest were disclosed.

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**Version 1**

Reviewer Report 16 March 2020

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Trevor Gibbs
AMEE

This review has been migrated. The reviewer awarded 3 stars out of 5

An interesting although rather difficult paper to read. I personally found it difficult due to the interchange of the words evaluations and assessments, which to me have very distinct meanings. I would agree with all of my co-reviewer's comments and would add that I feel the main message(s) from this paper, i.e. the list of tips is lost in the complexity and lack of flow in the paper. This paper does cover an important area and one that has not been satisfactorily addressed, so I do congratulate the authors in attempting to apply logic to the question of how competency-based assessments used in Clinical and Translational Research (CTR) training can help inform the overall evaluation of a CTR programme. I would wonder how much importance one should place on the product outcomes as an evaluation measure of the programme. I do believe that this is a paper to recommend to those involved in evaluating research-training programmes, despite the reservations.

**Competing Interests:** No conflicts of interest were disclosed.

Reviewer Report 30 November 2019

https://doi.org/10.21956/mep.18998.r27248
David Bruce
None

This review has been migrated. The reviewer awarded 3 stars out of 5

I thought that this was a complex and interesting paper where the authors consider how competency-based assessments used in Clinical and Translational Research (CTR) training can help inform the overall evaluation of a CTR programme. Guidelines for the evaluation of CTR programmes have been developed and propose that the professional development and training within the programmes for all staff and their level of knowledge and skills should be considered when such programmes are evaluated. The authors propose 12 guidelines to help administrators and training programme directors used competency-based assessment in their evaluations. The background to CRT programmes in the United States and funding across 50 research institutions is outlined and the need for guidelines to help administrators and programme directors incorporate and make sense of competency based tests is proposed. At this stage in the paper I felt as a reader that some definitions and more clarity about CTR training programmes and who the CRT trainees are likely to be would have been helpful. As an example of what I mean about definitions, medical education programmes in the UK (undergraduate and postgraduate) are subject to quality control (by the providers) and quality management and quality assurance by regulators. This ensures that the standards for training are being met. I was unclear how this differed from the evaluations that this paper discusses. In respect of the training programmes within the CTR centres – I would like to have known the staff members in the training programmes and indeed if different training programmes were in place for different staff members. I assume some will be clinicians and some will be scientists. Are all in the one training programme / are the programmes clearly defined (learning outcomes defined and teaching and assessment programmes in place)? All this may be obvious to those involved in CTR programmes – but not clear to non-specialist readers. The paper then discusses each of the proposed guidelines. I counted 11 guidelines and not 12 as stated. Some of the guidelines proposed were general in nature - mapping of roles, data collection and use of IT platform - which matched previous guidelines for overall programme evaluation. A number of specific guidelines looked at competency based assessments. I felt that this part of the paper was less clear and more explanation was needed. The task for the administrators and training programme directors appeared to be considering what outcomes the programmes should deliver and the selection of validated competency assessment instruments. It now appeared to me as a reader that perhaps ad hoc training might be happening within the programmes and the evaluators were fitting competency assessments into this process. This may not be the case – but more explanation of the actual training programmes would be required to help explain these guidelines. I was also aware that the other factors normally considered when looking at the quality of an educational programme – such as the learning environment and how learners and their trainers are supported, did not seem to feature in these guidelines. This paper will be of interest to those working in CTR centres and those involved in CTR education and training. I think that for the general reader the
authors need to provide more background and explanation of their proposals.

**Competing Interests:** No conflicts of interest were disclosed.