Evaluation Practices for Cultural Adaptation and Operationalization of Translational Research

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Agenda

• PRCTRC Overview
• Formulating Evaluation Questions
• Evaluation
  • Practices
  • Methodology
  • Findings
• Limitations and Challenges
• Conclusions
• Next Steps
PRCTRC Overview

NIMHD
• Lead scientific research to improve minority health and eliminate health disparities.

Program Announcement
• Support the development of infrastructure required for the conduct of clinical and translational research to develop approaches for the prevention, diagnosis and/or treatment of diseases to improve health and reduce health disparities.

Puerto Rico Clinical and Translational Research Consortium (PRCTRC)
PRCTRC Overview

Enhance & integrate existing infrastructure for clinical & translational research across Puerto Rico to support and expand Clinical & Translational Research in health disparities.

Encourage collaborations among basic, clinical, & social scientists and community networks and health programs.

Enhance & support existing training and mentoring programs to increase the number of new minority investigators in Clinical and Translational Research.

Facilitate the translation of knowledge from the bench into the community by establishing a centralized program.
<table>
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<tr>
<th>Question</th>
<th>Answer</th>
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<td>What is translational research?</td>
<td>There is not agreed upon definition of translational research. Translational research is part of a unidirectional continuum in which research findings are moved from bench to the population health (NIH, 2015).</td>
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<td>Can translational research be applied to our cultural context?</td>
<td>Translational research means different things to different people, but it seems important to almost everyone (Khoury et.al., 2010).</td>
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<td>What are the best practices to evaluate translational research?</td>
<td>Design models and establish measures are essential to understand the translational research and its implication on population health (Trochim et. al., 2011).</td>
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Evaluation Practices

Objective

• Cultural adaptation and operationalization of PRCTRC translational research, and to assess the translational stage of PRCTRC’s supported research
Evaluation Methodology

1. Conducted a Literature Review

**Translational Research Models**
- Harvard Clinical and Translational Sciences Center
- University of Texas Southwestern Medical Center
- Tufts University Clinical and Translational Sciences Institute
- National Center for Advancing Translational Sciences

**Identified translational research models and definitions used in other programs at national settings.**
2. **Initial Expert Panel Meeting**

Multidisciplinary Panel (n=6)
- Basic (n=2)
- Clinicians (n=3)
- Social (n=1)

Cultural adapted the PRCTRC’s translational research and operational definitions.
- T1: Translation to Human
- T2: Translation to Patients
- T3: Translation to Practice
- T4: Translation to Population Health
Evaluation Methodology

3. **Identify Data Sources**

Document Review
- PRCTRC Application Form
- PRCTRC Study Progress Report
- Study Protocol
- NIH RePORT

Develop a tracking system that includes:
- Study PI name
- Study title
- Study abstract
- Research area
- Translational research stage
- Experts id
Evaluation Methodology

4. **Conduct a Pilot Study**

Follow up expert panel meeting
- Five studies per expert
- Each study was assigned to two experts.
- The evaluators examined if there was consensus or disagreement in each study classification.

A total of 15 studies were classified.
- Inter-rater reliability score was 0.70.
- Review the PRCTRC translational research model and operational definitions.
- New: Not Translational Research Category
PRCTRC Translational Research Model

T1 Translation to Humans
With T1 translational research, findings from basic research are tested for clinical effect and/or applicability. T1 research yields knowledge about human physiology and the potential for intervention.

Operationalization
- Preclinical and Animal Studies
- Human Physiology (study must be related with a human disease)
- First in Humans (FHI) [healthy volunteers]
- Proof of Concept (POC)
- Phase 1 Clinical Trials [dose and toxicolgy]
- First time evaluation of a biomarkers [antibodies, none treatment involved]

T2 Translation to Patients
With T2 translational research, investigators test new interventions under controlled environments to form the basis for clinical application and evidence-based guidelines. T2 research yields knowledge about the efficacy of the interventions in optimal settings.

Operationalization
- Phase 2 Clinical Trials- biomedical or behavioral interventions with more than 100s patients
- Phase 3 Clinical Trials- compare and evaluate two interventions (news vs. controls) including pharmacotherapy trials and behavioral interventions.
- Behavioral intervention studies with a small patient’s sample.
- New intervention

T3 Translation to Practice
With T3 translational research, investigators explore ways of applying recommendations or guidelines in general practice. T3 research yields knowledge about how interventions work in real-world settings.

Operationalization
- Phase 4 Clinical Trials- side effect studies
- “post marketing surveillance trials”
- Health Services Research (Dissemination, Communication, and Implementation)
- Community Research
- Clinical Outcomes Research
- Know effective clinical intervention
- Focus on clinical practices

T4 Translation to Population Health
With T4 translational research, investigators study factors and interventions that influence the health of populations. T4 research ultimately results in improved global health.

Operationalization
- Population-level Outcome Studies
- Outcome Studies of Mass Screenings
- Social Determinants of Health

Not Translational (NT) – During the classification process the expert panel members identified that the T1 to T4 stages categories did not apply to certain studies. These studies were later categorized as Not Translational studies. The NT studies included non-intervention studies, comparative analysis, instrument validation, database development and prevalence/incidence studies.
5. **Assess Translational Research of PRCTRC Research Supported**

Each expert received 10 to 20 studies, via email, randomly assigned.
- Each study was assigned to two experts.
- The evaluators examined if there was consensus or disagreement in each study classification.

A total of 412 studies were classified.
- Inter-rater reliability score was 0.81, increasing 0.11 from the pilot study.
Evaluation Findings

- Cultural adaptation and operationalization of PRCTRC translational research
  - T1 to T4
  - Not Translational Research
  - Mixed Translational Research
Evaluation Findings

- Assess Translational Stage of PRCTRC Research Supported

**Graph 1. PRCTRC Studies Supported by Translational Research**
Evaluation Findings

- Assess Translational Stage of PRCTRC Research Supported

Graph 2. PRCTRC Translational Studies Supported by Research Area (n=339)
Limitations & Challenges

Limitations

• Study Abstract Format
  • Lack of quality and structured information (i.e., aims, objectives, methodology, clinical trial phase)

• Limited T3 & T4 Experts Panel
  • Only one expert in the area of community was part of the expert panel.

Challenges

• Time Consuming
  • Due to the lack of standardized procedures and multiple data sources.

• Lack of Gold Standard
  • Literature about best practices to evaluate translational research is scarce.
Conclusions

• Exemplary evaluation practices for translational research should validate and operationalize metrics that present the diversity and cultural context of their research environments.
  • Our evaluation practices illustrates the utility and relevance of mixed methods approach and multidisciplinary efforts in strengthening and assessing translational research.

• These evaluation practices have been vital in providing critical data for PRCTRC research supported along the translational continuum.
Conclusions

- As part of the data driven decision, the PRCTRC leadership has been implementing initiatives to increase T3 and T4 research by supporting:
  - Pilot Projects Awardees
  - Expanding collaborations with community members
  - Identify key researchers to design and implement T3 and T4 studies
Next Steps

- Further evaluation efforts will be focused on the evolution of PRCTRC translational research to understand
  - the movement of translational research
  - the movement of investigators by translational research
  - which factors could facilitate or limit the translational research movement

- Submit a Peer-reviewed Manuscript
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Questions and Answer
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