Measuring Clinical TR Outcomes

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Topical Focus

- Measuring clinical efficacy is the heart of a unified data system to evaluate telerehabilitation outcomes.
- In our final session, we hope to:
  - discuss the challenges and need for a viable way to measure TR clinical outcomes,
  - offer some preliminary guidance around conducting such studies,
  - obtain a formal reaction to that guidance, and
  - ask for your input in defining and disseminating
Challenges and Need

• Weak TR evidence base so far
• Most of the positive evidence to date relates to specialized clinical applications and not necessarily routine clinical practice
• What works for telemedicine does not necessarily translate to TR; Nature of rehabilitation presents unique challenges (e.g., frequency and intensity of sessions, “in vivo” assessment and intervention)

Challenges and Need (cont’d)

• Diversity of disciplines under the purview of TR
• Diversity of populations served by TR
• Diversity of TR approaches/Technologies
• High costs to conduct rigorous studies
• Small sample sizes, thus, few RCTs
• Selection bias
Guidance: Conducting TR Clinical Outcome Studies

- **Purpose**: to compare clinical outcomes when services/interventions are delivered using TR versus a traditional face to face service delivery modality with as much uniformity and standardization as possible.

- **Audience**: any individual who might participate in conducting a clinical outcome study.
Conducting TR Clinical Outcome Studies (cont’d)

Who?
• Ensure that target population is accessible in adequate numbers (able to draw a sufficient sample size), and conduct power analyses to be sure sample size is appropriate.
• Use inclusion criteria that are practical, clear and operational and not too narrow to optimize generalizability (Kobb et al., 2008).

Conducting TR Clinical Outcome Studies (cont’d)
• Capture descriptive/demographic information on participants using common data elements.
• Take steps to minimize selection bias based on difference in motivation levels among participants, and Heckman’s statistical technique is a good tool for limiting bias in non-random samples (Kobb et al., 2008).
Conducting TR Clinical Outcome Studies (cont’d)

- Strive for homogeneity of case mix: there is comparability of diagnosis and severity of functional challenges in the study sample (treatment and control/comparison groups).

Conducting TR Clinical Outcome Studies (cont’d)

What?
- As a starting point, develop a cogent study rationale with the help of a framework like the PICOT (population, intervention, comparison, outcomes, and timeframe).
Conducting TR Clinical Outcome Studies (cont’d)

- Decide which design is feasible given practical considerations, e.g., ability to randomize, (RCT, prospective quasi-experimental [regression-discontinuity, interrupted time series, and delayed treatment designs], retrospective comparison [retrospective propensity score matched cohort design]) (Kobb et al., 2008), and remember that greater rigor is best for building evidence.

Conducting TR Clinical Outcome Studies (cont’d)

- Design the study with replication in mind.
- Identify extraneous factors that can account for variance in the outcome beyond the independent variable that can be controlled for, neutralized or accounted for in terms of their influence.
Conducting TR Clinical Outcome Studies (cont’d)

- Thoroughly describe the nature, type and scope of intervention/service delivered (i.e., face to face vs. TR) in terms of an operational definition, describe procedures and instrumentation involved (prefer standardized over “homegrown” instruments), and strive for standardization.

How Much?

- Ensure that the intervention/service has sufficient theoretical grounding to produce desired change.
- Ensure there is an adequate dose or exposure (i.e., sufficient threshold) to the intervention to expect to see a change: face to face and using TR.
Conducting TR Clinical Outcome Studies (cont’d)

- Dose considerations also include some measure of the intensity of service/intervention, which is frequency of contact divided by duration of the service/intervention.

Conducting TR Clinical Outcome Studies (cont’d)

- Include variables that speak to the quality of the service delivery (i.e., implementation/process measures) to be able to address concerns related to fidelity of intervention implementation.
- Measure the level of participation and/or degree of engagement of customers in the services being measured.
Conducting TR Clinical Outcome Studies (cont’d)

How Effective?
• Be clear on unit of analysis (i.e., client).
• The best outcomes will address both customer and provider perspectives.
• Improved access to services can be a viable TR outcome.

Conducting TR Clinical Outcome Studies (cont’d)
• Evaluate outcomes based on direction of change, percentage of change, the attributes of the outcome measurement continuum (i.e., post only, pre to post, pre to post post, longitudinal, etc.), and significance.
• Statistical significance cannot establish equality of approaches (service modalities), but can establish equivalence (Lesaffre, 2008).
Conducting TR Clinical Outcome Studies (cont’d)

- Statistical significance is different from clinical significance.
- Clinical significance is when treatment meets standards of efficacy set by stakeholders (customers, providers and researchers) (Wise, 2004).
- Use the reliable change index when possible to bolster the reliability of clinical significance, especially with self-report measures (Wise, 2004).

Conducting TR Clinical Outcome Studies (cont’d)

- Know the difference between superiority (one approach is shown to be better than another), equivalence (two approaches are shown to be “not too different” in terms of clinically defined criteria), and non-inferiority (a new approach is “not much worse” than an established or standard approach) (Lesaffre, 2008).
Conducting TR Clinical Outcome Studies (cont’d)

• Beware of the regression to the mean phenomenon for outlier values that can impersonate intervention-driven change (Kobb et al., 2008).
• As much as possible use both objective and subjective (e.g., satisfaction) outcomes.

Conducting TR Clinical Outcome Studies (cont’d)

• In addition to using outcomes based on reducing symptomatology, when possible include outcomes that reflect positive clinical change in moving from a point of dysfunction to a point of being functional in real world contexts, and this will require normative data on what constitutes dysfunction and
Conducting TR Clinical Outcome Studies (cont’d)

- Evaluate outcomes based on a clear delineation of the time horizon or immediacy aspect (initial or immediate outcomes versus mid-range or intermediate outcomes versus ultimate or long-term outcomes).

Conducting TR Clinical Outcome Studies (cont’d)

- When using “cut points” to designate levels of outcomes, consider using confidence interval bands to delineate the points (Wise, 2004).
- When possible look at economic outcomes (benefits versus costs).
Conducting TR Clinical Outcome Studies (cont’d)


Conducting Cross-Discipline Studies

- Develop taxonomies for core services (as possible) and outcomes that apply across disciplines.
- Develop a bank of common measures and instruments that can be used across disciplines (e.g., FIM scale, Beck Depression Inventory).
- Develop agreed upon criteria to select non-common measures/instruments.
Conducting Cross-Discipline Studies (cont’d)

- Agree to a common finite set of outcome domains for all TR studies across disciplines for a designated period of time (e.g., one or two years) to systematize TR evidence building in a coordinated and targeted manner across disciplines.

Conducting Cross-Discipline Studies (cont’d)

- The common finite set of outcome domains could be, for example, symptomatology, level of functioning, self-management, daily living, participation, satisfaction, quality of life, and benefit cost.
- These domains could be laid out on an agreed upon sequential continuum based on immediacy of outcome (see next slide).
Conducting Cross-Discipline Studies (cont’d)

<table>
<thead>
<tr>
<th>Short-term</th>
<th>Mid-range</th>
<th>Long-term</th>
<th>Ultimate</th>
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<tbody>
<tr>
<td>symptomatology</td>
<td>self management</td>
<td>participation</td>
<td>quality of life</td>
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<tr>
<td>level of functioning</td>
<td>daily living</td>
<td>satisfaction</td>
<td>benefit: cost</td>
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To the extent possible agree on common measures for these above outcome domains.

Conducting Cross-Discipline Studies (cont’d)

- Strive to develop generic “cut points” for outcomes such as the percentage of customers who ‘improved’, ‘exhibited no change’, or ‘became worse’ that can be agreed upon across disciplines.
- Adopt common meta-analysis and systematic review study conduct guidelines.
Conducting Cross-Discipline Studies (cont’d)

• For example, utilize a common template for evaluating TR studies such as the one developed by Hailey et al. (2004) that includes several key evaluative features (see next slide).

Conducting Cross-Discipline Studies (cont’d)

1. Study design (large vs. small RCT, prospective non-randomized and retrospective comparative)
2. Client selection methods
3. Description of intervention adequate
4. Specificity of analysis methods
5. Client disposal (handling of follow-up, dropouts and other compliance)
**Conducting Cross-Discipline Studies (cont’d)**

- Commit to conducting more studies that generate the highest levels of TR evidence (i.e., meta-analyses, systematic reviews, and RCTs).
- Utilize more comparative effectiveness research approaches since TR is uniquely positioned for such study designs, especially given current funding sources like PCORI.

**Cautions**

- Low statistical power
- Faulty or missing data
- Respondent bias
- Multicollinearity and unrecognized mediators and covariates/moderators
Cautions (cont’d)

- Imprecise variable measurements
- Differences in TR technologies and approaches
- Barriers (setting-based, regulatory, administrative or bureaucratic)

Your Input is Needed

- Content
- Level of detail
- Usable format to become a users’ guide
Next Steps

• We need your help.
• Please contact us (Allen Lewis: alelwis@pitt.edu), if you want to (1) be involved in the ICG, (2) want to submit TR data for us to use in our benefit: cost simulations/illustrations, or (3) want to help us take the content in this presentation and shape it into a formal guidance document.