Metrics of Success: How to Measure Adherence to PrEP and Intermittent PrEP

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Objectives
Share brief overview of self-reported adherence
Decompose self-report
Reclaiming self-report as a useful measure
Misreporting of Product Adherence in the MTN-003/VOICE Trial for HIV Prevention in Africa: Participants' Explanations for Dishonesty.

Montgomery ET¹, Mensch B², Musara P³, Hartmann M⁴, Woeber K⁵, Efima J⁶, van der Straten A⁴,⁷

Self-reported Adherence

The science of being a study participant: FEM-PrEP participants' explanations for overreporting adherence to the study pills and for the whereabouts of unused pills.

Cornell AL¹, McKenna K, Perry B, Ahmed K, Agot K, Malamatscho F, Skhosana J, Odhiambo J, Van Damme L

- High rates of adherence reported in clinical trials
- Early work signals concern with over-reporting (68% PPV, 2011)
- Studies show that reports were off by 60% or more in some studies compared to drug level

Adherence

• ART adherence
  • Main measure of adherence at first
  • EDM data
    – Tends to correlate w SR
    – SR 5-15% over
  • Improvements in measures through cognitive testing
  • Still used as secondary outcome in many studies

PrEP adherence

• Adapts ART SR measures
• High rates of adherence reported in clinical trials
• Early work signals concern with over-reporting (68% PPV, 2011)
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• Series of studies show that reports were off by 60% or more in some studies compared to drug level
The “ASK”

Question (examples)
– How good of a job did you do…
– On how many days did you miss a dose…
– How often did you take…
– Dates of last 3 doses
– Rate how much/many/dosing days…
– Dosed on this and that day

Answers
– Open ended
– Number field
– Percentage or numeric scales
– VAS
– Never to Always
– Yes/No

Methods
– Interviewer
– Survey
– Computer
– Cell/SMS
– Website

Add-ons
– Permission statements
– Definitions
– Time frames
Reclaiming Self-report?

- Consider context
- Evaluate demands

Table 1: Assumptions underlying common measures of adherence

<table>
<thead>
<tr>
<th>Measure</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-report</td>
<td>Self-report participants can reasonably answer the questions (when doses were taken, how many, or provide general estimate). Cognitive deficits that impact memory/recall are not present. Immediate negative consequences (e.g., added procedures, reprimands, so on) of reporting non-adherence are absent. The scale used to measure adherence is reliable and valid. Social desirability bias is minimized or it is measured.</td>
</tr>
</tbody>
</table>

Table 1: Ten ways to improve the validity of self-report measures

1. Do not reinvent the wheel; choose a self-report adherence measure with validation data for your target population whenever possible.
2. Define the adherence construct of interest (i.e., extent of adherence vs. reasons for nonadherence) and select a measure containing items matched to that need.
3. Administer adherence measures through computer surveys rather than face-to-face data collection to reduce social desirability concerns and improve data quality.
4. In research contexts, staff members who collect adherence data should be separate from staff members who deliver adherence support or adherence interventions.
5. Introduce the self-report adherence measure with a statement which normalizes nonadherence to help address social desirability concerns.
6. Use a question response format that asks respondents to estimate their overall adherence behavior. Response items that characterize adherence in ordinal terms (e.g., anchored Likert ratings scale) or quantitative continua (e.g., estimated percent of doses taken) may help reduce ceiling effects.
7. Use a self-report adherence measure that specifies a recall period for adherence behavior. A recall period of the last 30 days may reduce ceiling effects relative to shorter intervals. Populations characterized by cognitive impairment may require other approaches (e.g., daily text message or interactive voice response surveys).
8. Consider dichotomization of self-report adherence measures at the 100% mark to recognize their tendency for over-reporting relative to other adherence measures.
9. Add a social desirability measure to complement analysis of self-report adherence data.
10. Research publications should include clear descriptions of any self-report adherence measure, its administration method, and descriptive data resulting from the measure (e.g., mean, median, standard deviation) to help further the science.

Table 1: Lessons learned from cognitive testing by item stem and response option

<table>
<thead>
<tr>
<th>Lesson</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item stem</td>
<td>No consistent understanding of “the last week” or “the last month”; better the last 7 or 30 days</td>
</tr>
<tr>
<td>Attention to reference period</td>
<td>Attention to the reference period was poor overall; patients estimate rather than count</td>
</tr>
<tr>
<td>Taking “as prescribed”</td>
<td>Understood inconsistently</td>
</tr>
<tr>
<td>Understanding of “dose”</td>
<td>Understood consistently</td>
</tr>
<tr>
<td>Response option</td>
<td>Both worked poorly</td>
</tr>
<tr>
<td>Visual analogue scales and points</td>
<td>Worked poorly</td>
</tr>
<tr>
<td>Use of the word “perfect”</td>
<td>Worked poorly</td>
</tr>
<tr>
<td>Options that express feelings</td>
<td>Subjects level of recall is more appropriate to verbal than numerical answers and subjects more comfortable with adjectives and adverbs than numbers as way of providing answers</td>
</tr>
</tbody>
</table>

Stirratt et al 2015
Amico et al 2013
Williams et al 2012
Thank you