

White Paper: Best Practices for Measuring Medication Adherence for Behavioral Medicine Research

- Background: Idea emerged based on needs assessment of Science of Behavior Change (SOBC) scientists, chartered by the SOBC
- Goal would be to convene a panel of adherence experts (e.g., Ian, Corrine, Carolyn, Steiner others...) to draft a preliminary report, group should include representation from experts in psychometrics and adherence measurement
- Present findings at SOBC Meeting
- Incorporate SOBC feedback, publish findings Fall of 2017 with stamp of SOBC approval, including NIH Program Officers and SOBC scientists with interest in adherence measurement

Overview

Medication adherence is one of the most important health behaviors for improving outcomes in patients with chronic disease. Behavioral scientists seek a gold-standard measure of medication adherence that they can incorporate into their research into adherence interventions. Yet, adherence does not represent a single construct. Adherence is comprised of a set of behaviors (initiation, day-to-day adherence to taking medication and related behaviors such as with or without food, persistence with refilling medication). Each of these behaviors are influenced by overlapping but different types of barriers and facilitators. Thus, different measurement methods are needed to measure these different aspects of adherence behavior. For example, if one wanted to capture the extent to which a patient was initiating a treatment, one might use pharmacy fill data. However, to assess day-to-day pill taking behavior, one might use self-report or electronic drug monitoring.

The accuracy of self-report literature and the validity of using self-reported adherence as the primary adherence measure is often debated. Many self-report measures are validated against objective measures of adherence. But, many self-report measures mix extent of adherence questions with reasons for non-adherence items, and then seek to demonstrate validity by comparing to fill data or electronic adherence data which is problematic from a measurement perspective as the different measurement methods are measuring different behaviors, and thus, it is difficult to assess whether the lack of agreement between self-report and objective measures is due to unreliability/lack of validity or to the fact the different measurement approaches are measuring different aspects of adherence behavior.

Objective measures also have limitations, most notably, Hawthorne effects and uncertainties induced by whether measuring adherence to measurement approach (e.g., taking pills without using electronic pillcap, filling meds outside of electronic prescribing system) or true adherence to the medication. Objective measures make it challenging to know which aspect of adherence behavior was interrupted. For example, are there no pill cap openings because a patient did not fill a medication, because they filled it but missed taking it, or because they did not refill the medication.

The goal of this paper is to guide scientists in the selection of the most suitable measurement method relevant to their research question. Our assertion is that the optimal approach will involve mapping measurement methods to the specific adherence behavior, assessing the positives and negatives of each method. This approach will involve mapping specific adherence behaviors to measurement methods, and recognizing the positives and negatives associated with each method. This way, researchers can make more informed decision.

Considerations when choosing a measure:

- Different aspects of validity, reliability, other
- usability, convenience, (e.g., number of questions/time to complete, availability in Spanish, health literacy requirements)
- cost, copyright issues

Below, we describe in more detail the distinct adherence behaviors and provide examples of adherence measures that are and are not well-suited to measuring that particular adherence behavior.

Nonadherence Behavior	Self-report including daily diary (OPTIONS: Yes, indirectly, No)	Pill refill	Pill count	Pill bottle review	EDM	Drug levels (metabolites)	Biomarkers	Direct observation (attended visit at which medication taking observed)
Not obtaining the initial medication (first fill)	Y	Y, Best Measure (requires linkage between pharmacy and electronic prescribing records (e.g., at VA)	Indirectly	Y	Indirectly	Indirectly	Indirectly	N/A
Refilling the medication late or not at all	Y – though not sure if questionnaires assess this	Y, Best Measure	Indirectly	Y	Indirectly	Indirectly	Indirectly	N/A
Stockpiling medication (refilling when supply is already on hand)	Y – though not sure if questionnaires assess this	Y, ?Best measure	Indirectly	Y	Indirectly	Indirectly	Indirectly	N/A
Implementing the regimen incorrectly -Missing doses -Taking extra doses -Taking doses at the wrong time	Yes	Indirectly (PDC)	Indirectly	Indirectly	Y, Best Measure	Indirectly	Indirectly	Y, though it is designed to prevent this; a
Improperly administering medications leading to incorrect dose	Y with careful interview though patient may not	N	N	N	N	N	N	Y, Best Measure

Comment [IK1]: What about Proteus system?

(e.g., bad inhaler or injection technique, or taking synthroid with food) or increased risk for side effects (e.g., lying down after bisphosphonate)	realize it								
Discontinuing the medication prematurely	Y	Y, Best measure (though don't know if consistent with MD recommendations unless linked to medical records)	Y	Y	Indirectly	Indirectly, only have data on recent dosings	Indirectly, only indicates recent dosing	Y but not usually done, lost to follow-up, don't know for sure, depends if they have other way to access medication	

Reasons for not taking the medication as prescribed	Voils items BMQ Subset of Morisky items	N	N		N	N	N	N
SAVE FOR PAPER BUT NOT IN TABLE								

Comment [CIV2]: This seems broad..would include clinical characteristics, psychological measures, etc. do you mean to say how we can measure barriers to adherence? When I think of predictors, I think race, self-efficacy, etc.

Comment [IK3]: Ian here: Do we want to guide researchers on which covariates to include such as sex, ethnicity, age?

Comment [IK4]: Ian here: Separately, do we want to summarize measures of barriers to nonadherence like self-efficacy, BMQ, other?

Then do we need to even hash out the limitations of each type of measure (the columns), or is that already known? Feels like it's beaten to death. Maybe we should briefly summarize.

I also think we need to bring in the issue of time... some things should be measured over short periods of time (self-report of whether you took your medications in the past week---longer time periods are not really valid), whereas others should be measured over longer periods (e.g., prescription for 90 days cannot be assessed in less than 90 days)

CAN IDENTIFY NEEDS FOR SELF REPORT MEASURES

SO CAN GIVE GUIDANCE ON HOW TO SELECT MEASURES

CRITERIA TO THINK ABOUT

CAN REFERENCE OTHER PAPERS THAT GIVE CRITERIA FOR MEASURES

Recommendations on Adherence Measures

Comment [IK5]: Provide some expert recommendations on which tools to recommend, and why and for which conditions.