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Development and Content Validation of Measures Assessing Adherence Barriers and Behaviors for Use in Clinical Care

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Abstract

Background: Providers are often unaware of poor adherence to prescribed medications for their patients with chronic diseases.

Objective: To develop brief, computer-administered patient-reported measures in English and Spanish assessing adherence behaviors and barriers.

Design, Participants, and Main Measures: Item pools were constructed from existing measures of medication adherence behaviors and barriers, which informed development of a patient concept elicitation interview guide to identify medication adherence behavior and barrier-related concepts. Two hundred six patients either living with HIV (PLWH) or without were interviewed. Interviews were coded, concepts matched to item pool content, and new items were developed for novel concepts. A provider/investigator team highlighted clinically relevant items. Cognitive interviews were conducted with patients on final candidate items (n=37). The instruments were administered to 2081 PLWH.

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Key results: Behavioral themes from concept elicitation interviews included routines incorporating time of day, placement, visual cues, and intentionality to miss or skip doses. Barrier themes included health-related (e.g. depressed mood, feeling ill), attitudes/beliefs (e.g., need for medication), access (e.g., cost /insurance problems), and circumstantial barriers (e.g., lack of privacy, disruption of daily routine). The final instruments included 6 behavior items, and 1 barrier item with up to 23 response options. PLWH endorsed a mean (SD) of 3.5 (1.1) behaviors. The 201 PLWH who missed ≥2 doses in the previous week endorsed a mean (SD) of 3.1 (2.5) barriers. The intraclass correlation coefficient (ICC) for the numbers of behaviors endorsed in 61 PLWH after 4-16 days was 0.54 and for the number of barriers for the 20 PLWH with ≥2 missed doses the ICC was 0.89, representing fair and excellent test-retest reliability.

Conclusion: Measures of medication adherence behaviors and barriers were developed for use with patients living with chronic diseases focusing on clinical relevance, brevity, and content validity for use in clinical care.

Keywords

medication adherence; patient-reported outcomes

Introduction

Poor adherence to prescribed medication for chronic conditions is widespread [1] at rates of 25 to 50% [2,3]. Poor adherence is estimated to cost over $100 billion yearly [1], and has a dramatic negative impact on long-term clinical outcomes [4-22] including increased mortality [5,8,9,14,23-25]. Since 1988, the proportion of patients taking three or more prescription drugs in the U.S. has increased across all age-sex groups [26].

For many chronic conditions, it may be difficult for health care providers to detect inadequate adherence until an adverse health outcome occurs; a few examples include cardiovascular disease [4-9], HIV [13-21], osteoporosis [11], hypertension [27], diabetes [28,29] and mental health conditions, such as schizophrenia [10]. Inadequate adherence is routinely under-diagnosed by providers [15,30-32]; as such, providers are unlikely to be aware of their patients' medication-taking routines and barriers to adherence.

One means of increasing provider awareness of medication-taking routines and adherence barriers is the use of patient reported outcomes (PROs), which are assessments of a patient's health, behaviors, and symptoms elicited directly from the patient in a structured and standardized format [33]. Self-administered, electronic PRO measures administered at point-of-care detect significantly more inadequate adherence than provider-patient interview alone [34]. However, no "gold standard" exists for measuring either patient-reported medication adherence, adherence-related routines, or barriers to adherence; in fact, such measures are highly heterogeneous across diseases and conditions, [35] each with varying length, content, and granularity [36]. The use of PROs in routine care requires selection of brief, clinically relevant, valid measures [37,38] and this is true for adherence measures in particular [39]. Given the increased number of patients prescribed medication for multiple chronic conditions, there is a need for feasible patient-reported measures of adherence-related routines and barriers that possesses these attributes and is administrable across disease categories. While

objective adherence measures exist, such as electronic drug monitoring, they have limitations as well, such as overestimating adherence if a patient opens a cap without taking the medication [40].

To help address this, electronic, touch-screen-administrable measures of medication adherence behaviors and barriers were developed for use in primary care across disease conditions. Its use was tested in a large cohort of patients living with HIV (PLWH), as it is a population with a high prevalence of multiple chronic conditions for which medication adherence is pertinent, and for whom adherence challenges are common. [15,41-45] The measures were developed using patients with multiple chronic conditions including HIV for which adherence is known to drive outcomes.

Methods

Methodological overview

Figure 1 shows a methodological overview. Literature-review based item pools were created from adherence behavior and barrier measures, and the number of measures and items was winnowed down based on set criteria. Patients were interviewed regarding adherence behaviors and barriers, and interview content was matched to item pool content. Clinician review identified clinically relevant matched items. Cognitive interviews were performed with patients on candidate items, items were finalized, and validity testing was performed by administering the items to patients.

Selection of dimensions of adherence

A series of teleconference calls was convened with co-investigators, stakeholders, and key informants with expertise in the domain of medication adherence to identify and define dimensions of adherence specifically focusing on clinically relevant adherence behaviors beyond quantification of doses taken/missed, and barriers to adherence. **Medication adherence behavior** items and instruments were defined as those assessing how patients remember to take prescribed medications. Also included were items pertaining to interactions with medications and regimens themselves, such as pill-alteration, doubling up on doses, and intentional missed doses. **Medication adherence barrier** items and instruments were defined as those capturing any obstacle or circumstance that may hinder adherence. Measures were included containing items that identified barriers of any nature, including but not limited to cost or access; circumstantial factors, such as being ‘busy’ or separation from medication; social factors, including lack of family support or lack of privacy; physical or psychiatric symptoms; and attitudes/beliefs. Instruments and items were included that assessed either intentional or unintentional inadequate adherence.

Item pool creation

An extensive literature search of existing adherence behavior and barrier instruments and items was conducted to create a pool of items for consideration. Medline/PubMed and also additional databases such as PsychINFO, HaPI (Health and Psychosocial Instruments), CINAHL (Cumulative Index to Nursing and Allied Health Literature), and conference proceedings (e.g. International Conference on HIV Treatment and Prevention Adherence)

were included. Trained health sciences research librarians from the University of Washington Health Sciences Library were consulted to identify appropriate search terms, key words, MeSH terms, Boolean logic, limits, and vocabulary terms to ensure large and comprehensive initial item banks [46]. The resulting search criteria were:

1. "Patient Compliance"[MeSH] AND
2. Keywords ("self report*" and "patient report*" and "patient based*") OR "Questionnaire"[MeSH] AND
3. Disease specific terms [MeSH or keyword strategy depending on findings for each disease]
4. LIMIT to English

Then, several conditions and related medication classes were selected for which adherence may impact clinical outcomes such as survival or quality of life. These were: antiretroviral medications for HIV, transplant immunosuppressants, antidepressants, antipsychotics, mood stabilizers, anticonvulsants for epilepsy, cardiovascular medications, diabetes medications, antihypertensive medications, pulmonary medications, osteoporosis medications, and dyslipidemia medications. Team members with expertise in each specific condition performed an independent literature review for that particular condition using library informaticist-recommended search criteria.

Our literature review yielded 206 measures for potential inclusion.

Inclusion/exclusion criteria

Measures were included if they had been externally compared to an objective adherence measure such as pill counts, drug levels, viral load (for antiretroviral medication adherence), or against a patient reported adherence instrument that in turn had been previously externally compared to an objective adherence measure.

Instruments were excluded and items from the bank if they were:

- Reported by someone other than the patient (i.e., clinician report)
- Not assessing medication adherence behavior or barriers
- Quantifying measures of adherence, such as doses missed
- Formatted for collection of written or oral narratives rather than simple response options
- Adaptations of already included measures with only semantic changes (i.e., name of disease inserted into items without changing item meaning)
- Not available in English
- Not available in published form, online, or after multiple attempts to contact authors via email

Item pool categorization

A team of qualitative researchers categorized 351 candidate items gleaned from the 206 measures using a collaborative open-coding process. Two coders independently classified items using their own terms, and then, with a third reviewer with medication adherence expertise, reached agreement through group consensus discussions regarding the most salient categories for classification. For adherence behaviors, two thematic areas selected were behaviors that promote adherence, and patients' alterations to regimens or medications. Adherence barriers included eight thematic areas: health-related (e.g., side-effects), activity-related (e.g., disruption of daily routine), attitudes/beliefs (e.g., belief that the medication was not needed), access-related, regimen attributes (e.g., high frequency of administration making adherence difficult), disease-related stigma, forgetting, and reliance on others for reminding or administration. Inter-coder agreement in classifying items was 95%.

Three reviewers with content area expertise independently winnowed candidate items into a smaller pool, selecting the best alternatives when items were similar in content, using the PROMIS Qualitative Item Review (QIR) process [47,48], which uses specific exclusion criteria (e.g., lack of clarity, too-population or disease-specific) for assessing item quality and has been effective in other domains.[49] Discordance was reconciled through a series of conference calls, resulting in a pool of 84 conceptually unique legacy candidate items (16 behavior and 68 barrier items).

Concept elicitation interviews

A semi-structured interview guide was developed with representation of item pool content areas for use with individual patients querying medication adherence behaviors and perceived barriers to adherence. Examples of behavioral questions included: "Do you use anything to help remind you to take your medication? If so, what?", and "Have you ever changed the way you took this medication without a doctor's advice? If so, what did you change?" Examples of barrier questions included "Do you have any challenges or problems with taking your medication as prescribed? If so, what are they?" Accompanying probes included mental/emotional states, environmental circumstances, and personal beliefs about the medication, disease, or health in general. Interviewers were comprised of a mix of study investigators and project staff with experience in conducting patient interviews for research purposes. Interviewers were trained by a PhD-level scientist with extensive qualitative research expertise, both prior to conducting interviews and during biweekly team conference calls. Spanish-speaking interviewers possessed lifelong Spanish fluency and interacted with Spanish-speaking patients on a daily basis within their clinic settings.

A mix of patients was selected living with and without HIV. PLWH were oversampled, as they are a group typically prescribed medication for multiple chronic conditions and for whom adherence challenges are known to be common; rich data was anticipated from discussion with these patients. PLWH were recruited both by phone and in-person from three HIV clinical care sites in the Centers for AIDS Research Network of Integrated Clinical Systems (CNICS): 1917 Clinic, University of Alabama, Birmingham, AL; Owen Clinic, University of California, San Diego, CA; Madison HIV Clinic, University of

Washington, Seattle, WA. All participating clinics offer comprehensive high quality HIV care services and are affiliated with local Center for AIDS Research sites.

Among PLWH, less-adherent patients were recruited for the behavior-plus-barrier interviews in advance based on self-reported responses in the past 3 months to a 7-day adherence recall item adapted from the Adult AIDS Clinical Trials Group (AACTG) Adherence Instruments [50], administered as part of routine clinical care. Patients without HIV were recruited from four general community health clinics including Chase Brexton Health Services (CBHS) clinics from both Baltimore and Columbia, MD; Fenway Community Health, Boston, MA; and Beaufort Jasper Hamilton Comprehensive Health Services (BJHCHS), Ridgeland, SC, ensuring a clinically diverse mix of patients with different chronic conditions, geographic regions and urban/suburban/rural areas. To be included, patients had to have been prescribed one or more of the following medication classes: antiretrovirals, antihypertensives, lipid-lowering medications, diabetes medications, anticonvulsants, antidepressants, mood stabilizers, antipsychotics, and/or osteoporosis medications. All patients were asked the behavior questions. Patients identifying routinely missed doses during the behavior interview were invited to answer questions about barriers to adherence. All HIV care clinics and Fenway Community Health received Institutional Review Board (IRB) approval through their respective institutions; the University of Washington IRB approved activity at BJHCHS and CBHS.

Interviews with the behavior group lasted up to 30 minutes; behavior-plus-barrier interviews lasted up to 45 minutes. Patients with known cognitive impairment were excluded. Both English and Spanish speakers were interviewed and women, African-Americans, and youth aged 18–25 were purposely over-sampled to ensure robust numbers of these groups. Patients received $25 for participating in interviews. Interviews were audio-recorded and transcribed using an external transcription service (Verbal Ink).

Item matching and development of new content

Patient interviews were transcribed and coded using the same codes used for classifying item bank content, via Dedoose, a web-based qualitative coding platform [51]. Team members fluent in Spanish coded the Spanish excerpts. In either language, a third team member reconciled coding differences when present. Interview excerpts were matched to individual items in the item pool using the behavior and barrier codes. Excerpts that did not match item pool content were evaluated by co-investigators and project team members for possible new item development to address potentially new content areas. When truly new content areas were identified, three team members with expertise in item development each independently developed one item per each new content area. Then, via conference call with principal and co-investigators, the drafted items were reviewed and a consensus was generated regarding the strongest items, by applying the same QIR standards to the new items that were used for the legacy item pool. Combining finalized new and legacy items, measures were drafted entirely based on patient-derived content containing all new and matched items for which the underlying concepts were endorsed by at least 5% of patients.

Team and clinician review

A draft of the measures was presented to a panel of primary care and specialty care providers with adherence expertise to advise on the clinical relevance of each proposed item. "Clinical relevance" was defined as information that was likely to initiate or change a provider's clinical response to a patient. Using these criteria, a 6-item behavior measure was created for cognitive interview testing as well as a single-item barrier measure listing 22 or 23 response options for patients to potentially endorse as barriers. The Spanish-language version contained a barrier response option that the English-language version did not ("no one reminded me" [to take my medication]); this is because the concept was present in the Spanish-language but entirely absent from the English-language interviews; given this absence, this item was excluded from the latter.

Cognitive interview testing

Cognitive interviews were performed with patients testing the items for comprehensibility, applying the same recruitment criteria and methods used for concept elicitation interviews. Interviews were up to 45 minutes in length. Patients were compensated $25. A certified translation service performed translation of items from English to universal Spanish, using two simultaneous forward translations by native Spanish speakers, followed by a third reconciliatory translation, and a back-translation of the reconciled version by a native English speaker fluent in Spanish. Our 3-person Spanish content validity team then performed a back-translation review, modifying the Spanish items to further simplify and ensure proper grammar, readability, and relevance to our clinic population.

Validity testing

Validity of the measures was assessed by incorporating them into the CNICS patient-reported outcomes (PRO) assessment. PLWH at CNICS sites complete the electronic, web-based assessment on-site, using touch-screen computer tablets, as part of routine clinical care visits every ~6 months [38]. The PRO platform allows automated integration of instruments based on item responses. PLWH completed this instrument, following standard quantitative adherence measures including the Self-Rating Scale, a 7-day missed dose item, a visual analog scale for percent of doses taken in the last month, and AACTG adherence items (e.g., last missed dose) [50,52,53]. The instrument was presented in English or Spanish to patients who endorsed missing ≥2 doses of antiretroviral medication in the past 7 days, as well as patients who reported fewer than two missed doses, for comparison purposes. To assess longitudinal stability, the measures were administered in the PROs long enough to ensure that some patients received the measures more than once.

Test-retest reliability of the measures was assessed by inviting English and Spanish-speaking patients who had completed the measures as part of their routine PRO assessment prior to their medical care appointment to return in 6–14 days and complete the adherence measures again, using the same PRO platform. Patients were paid $30 for returning to clinic and completing the additional assessment.

The Intraclass Correlation Coefficient (ICC) was computed to assess the reliability of the total number of items endorsed; kappa coefficients were used for individual items.

Results

Concept elicitation and item matching

A diverse participant group (see Table 1) was recruited with roughly equal numbers across all sites. Two hundred and six patients participated in the adherence behavior interviews. Of these, ninety-one patients with self-reported inadequate adherence participated in the barrier interviews. Tables 2 and 3 show the number of patients who endorsed each behavioral or barrier-related concept, and highlight new concepts, defined as concepts not found in our item pool.

Cognitive interview testing

Cognitive interviews were performed with 27 English and 10 Spanish-speaking participants. Participants comprehended all items; no major revisions were necessary. Figure 2 shows the final measures used for quantitative validity testing.

Clinic sample administration for quantitative validity testing

• **Items endorsed—**The finalized 6 behavior items and single barrier item with 22 response options in English (23 in Spanish) were administered to 2081 PLWH in a clinical setting, where a mean (SD) of 3.5 (1.1) behaviors were endorsed. Among the 201 patients reporting missing 2 or more doses of medicine in the previous seven days, a mean of 3.1 (2.5) barriers were endorsed.

• **Retest reliability—**Sixty-one patients were administered the test twice, with a mean interval of 9 days (range 4–16). When asked to assess whether they thought they had missed fewer, more, or the same number of doses compared to “about a week ago”, 79% reported missing fewer; 15% reported missing about the same amount of doses, and 7% reported missing more. Despite this, patients endorsed similar numbers of adherence behaviors at both assessments - a mean (standard deviation) of 3.2 (1.2) at the initial administration and 3.4 (1.1) at retest (Wilcoxon paired sign rank p=0.35), though the ICC was only fair[54] at 0.54. Agreement on specific behavior items was not as strong (kappa range 0.25–0.50; poor to fair agreement beyond chance). Twenty of these patients also received the barrier items, and again numbers were similar, with a mean of 4.0 (2.6) at the first visit and 3.9 (3.2) at the second (Wilcoxon paired sign rank p=0.58), and an ICC of 0.89, which is considered excellent agreement [54].

• **Longitudinal stability—**The behavior items were administered twice to 178 PLWH, with a mean interval of 108 days (range 77–162). The number of behaviors reported remained fairly stable across administrations, with a mean of 3.4 (1.2) at the first time and 3.6 (1.1) at the second (Wilcoxon paired sign rank p=0.09). However, endorsement of individual behavior items was not consistent (kappa range 0.27 – 0.40).

Discussion

Clinically relevant measures of medication adherence-related behaviors and barriers were developed for use in routine care with English or Spanish-speaking patients prescribed

medication for one or more chronic conditions. The final measures were well-understood by patients in both languages, and the behavior and barrier items performed with fair and excellent retest reliability, respectively. Patient interviews yielded a narrow thematic spectrum concerning adherence-related behaviors, and a much broader spectrum concerning adherence-related barriers. Both interviews and quantitative testing revealed the multifactorial nature of adherence barriers and behaviors, highlighting the potential complexity of remaining adherent to medication regimens for some patients.

Key behavioral themes for promoting medication adherence were the use of time of day, medication location, visual cues, and automated reminders. Alterations to medications, such as cutting/grinding up medication, or deliberate lengthy dose spacing to conserve medication, were uncommon. In contrast, barrier-related themes varied considerably, and included a mix of health-related barriers (e.g., side effects, depressed mood), attitudes/beliefs (e.g., not believing medication needed), access-related barriers (e.g., cost/insurance problems), and logistic/circumstantial barriers (e.g., lack of privacy, disruption of daily routine). The range of barriers revealed varying degrees of patient intentionality to skip taking medications, from completely unintentional (“just forgot”, “fell asleep”) to fully intentional, such as missed doses due to “wanting a break”, a desire to avoid mixing medications with drugs or alcohol, or a desire to avoid side effects. For some barriers, such as “did not have the medications with me”, intentionality was less clear; for this reason, it was found to be important to include a behavioral item querying intentionality.

Upon test-retest, a high percentage of patients believed themselves to be missing fewer doses; this increased adherence is a common phenomenon after routine visits when adherence or reported adherence has been found to improve in the period immediately following an appointment[40]. The relatively low ICC for adherence behaviors was unexpected, highlighting the potential variability in behaviors over short time periods and possibly also indicating a need for a different and perhaps more detailed approach to querying behaviors. Use of statements of agreement with binary yes/no response options did not yield consistent results for the behavior items at retest; whether this was due to variations in behavior or whether alternate question formats are needed is not clear. A single-item measure with more detailed response options may merit exploration given its excellent ICC agreement in the barrier measure. However, it is notable that these behaviors varied over short time periods, making it more difficult for providers to use these identified behaviors as the basis for interventions to have long-term impacts on adherence.

While our findings suggest more research is needed regarding the most useful formatting and approach to measure behavioral items to enable interventions in clinical care, the adherence barrier measure may prove useful to providers given its performance in validity testing. Without a systematic assessment of adherence barriers, adherence conversations between patients and providers may miss the breadth of barrier types found within the item. Given the consistency of these barriers over time, interventions that impact these specific barriers may be more likely to impact longer-term adherence. In the context of a time-constrained appointment, our adherence barrier measure may allow providers and patients to focus their time to address personally relevant adherence barriers.

Adherence measures have often been disease-specific with little uniformity across diseases[36]. This creates a great deal of complexity in the current era of clinical care where visits are time-constrained and where many patients often have multiple chronic conditions. Cross-disease or more generic measures that can address adherence across a range of diseases may be useful with advantages both for research with standardized data collection and ability to make comparisons across diseases and populations, and for clinical purposes with greater feasibility in time-limited visits. While there may be diseases where additional context is needed, such as diabetes and information on insulin, brief generic measures may be an excellent initial step to improving adherence assessment and intervention. Given the combination of public health need for better adherence management, evidence of acceptability of PROs among patients and providers [55-60] and the ability of PROs to help providers identify problems [60] for potential intervention, including inadequate adherence [34], focusing on individually relevant behaviors and barriers may prove to be an important tool toward improving inadequate adherence.

Strengths

A comprehensive standardized approach was used to identify themes within existing measures to develop our concept elicitation interview guide. This process likely ensured capture of the most salient concepts concerning adherence behaviors and barriers. The geographic and demographic diversity of our participant group, as well as representation across many chronic diseases, strengthens our confidence in the relevance of these concepts across the U.S. population of adults living with chronic disease.

Limitations

Interviews were not conducted with HIV-uninfected Spanish-speakers. Thus, our findings may be less generalizable to this population. Quantitative testing was conducted solely among PLWH; although many of them had a range of other chronic conditions, our quantitative findings may be less generalizable to HIV-uninfected people.

Despite this, measures may have sufficient generalizability to be considered for use in other chronic diseases, as our clinic population has high rates of other common co-morbidities included in this study. Finally, given the lack of a clear gold standard for patient-reported adherence behavior/barrier measures, validity testing against independent measures of adherence behaviors or barriers was not conducted.

Conclusion

Measures of medication adherence behaviors and barriers were developed for use with patients with chronic diseases focusing on clinical relevance, brevity for use in clinical care, and content validity. Providers should explore patient adherence behaviors with the understanding that these may be transient; more research is needed to develop a patient-reported measure of adherence behavior patterns that are clinically actionable. In contrast, the stability of adherence barriers over time suggests efforts to work with patients to come

up with strategies to address barriers may prove to be a more efficient use of time resulting in greater downstream benefits for adherence.

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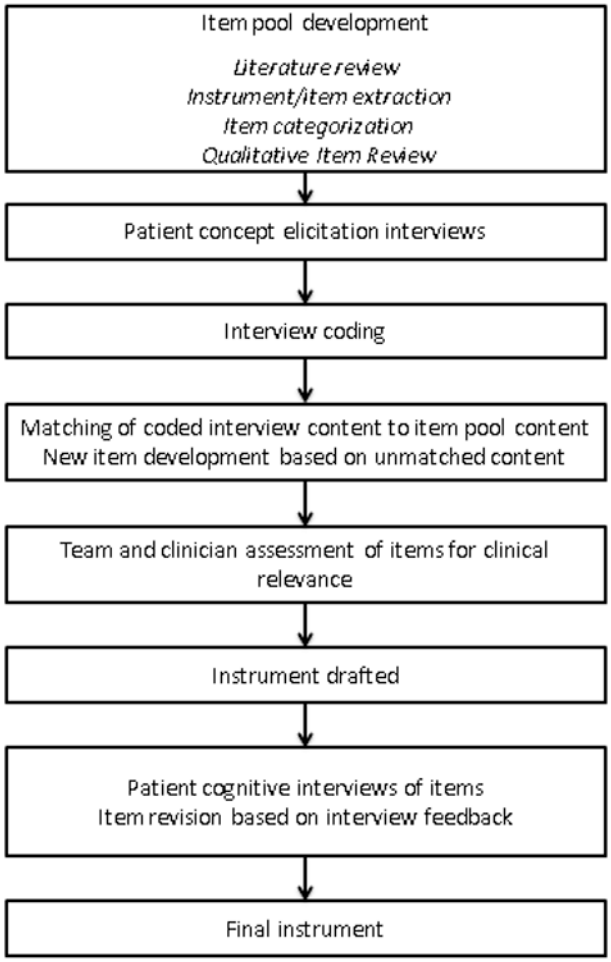
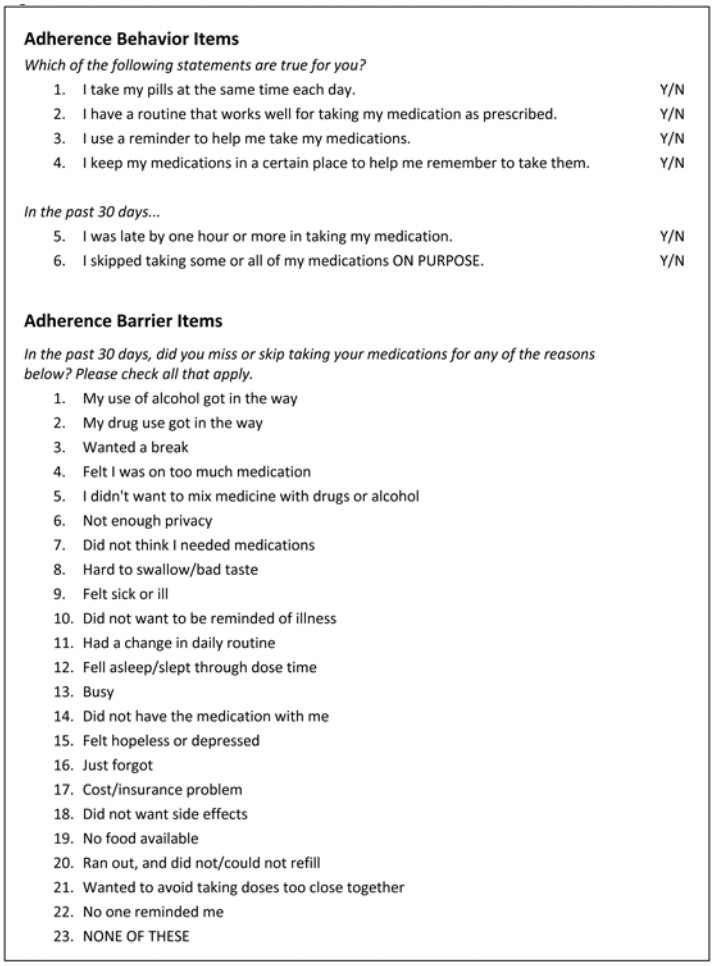


Figure 1.
Methodological overview



Adherence Behavior Items

Which of the following statements are true for you?

1. I take my pills at the same time each day. Y/N
2. I have a routine that works well for taking my medication as prescribed. Y/N
3. I use a reminder to help me take my medications. Y/N
4. I keep my medications in a certain place to help me remember to take them. Y/N

In the past 30 days...

5. I was late by one hour or more in taking my medication. Y/N
6. I skipped taking some or all of my medications ON PURPOSE. Y/N

Adherence Barrier Items

In the past 30 days, did you miss or skip taking your medications for any of the reasons below? Please check all that apply.

1. My use of alcohol got in the way
2. My drug use got in the way
3. Wanted a break
4. Felt I was on too much medication
5. I didn't want to mix medicine with drugs or alcohol
6. Not enough privacy
7. Did not think I needed medications
8. Hard to swallow/bad taste
9. Felt sick or ill
10. Did not want to be reminded of illness
11. Had a change in daily routine
12. Fell asleep/slept through dose time
13. Busy
14. Did not have the medication with me
15. Felt hopeless or depressed
16. Just forgot
17. Cost/insurance problem
18. Did not want side effects
19. No food available
20. Ran out, and did not/could not refill
21. Wanted to avoid taking doses too close together
22. No one reminded me
23. NONE OF THESE

Figure 2.
Adherence Behavior and Barrier Measures

TABLE 1.

DEMOGRAPHIC CHARACTERISTICS BY ACTIVITY TYPE

	Concept Elicitation Behaviors	Concept Elicitation Barriers	Congnitive Interviews	Clinic Sample	Longitudinal Stability	Retest Reliability
Total	206	91	37	2081	178	61
HIV serostatus						
HIV+	112 (54%)	52 (57%)	32 (86%)	2081	178	61
HIV−	94 (46%)	39 (43%)	5 (14%)	--	--	--
Present sex						
Male	129 (63%)	59 (65%)	23 (62%)	1772 (85%)	145 (81%)	48 (79%)
Female	74 (36%)	31 (34%)	13 (35%)	292 (14%)	33 (19%)	13 (21%)
Transgender	3 (1%)	1 (1%)	1 (3%)	17 (1%)	0	0
Race						
African-American	77 (37%)	37 (41%)	13 (35%)	669 (32%)	61 (34%)	37 (61%)
White	76 (37%)	32 (35%)	9 (24%)	1294 (62%)	106 (60%)	19 (31%)
Asian-American, Hawaiian, Pa	3 (1%)	2 (2%)	0 (0%)	44 (2%)	7 (4%)	2 (3%)
Native American	1 (0%)	0 (0%)	1 (3%)	10 (0%)	1 (1%)	2 (3%)
More than once race	2 (1%)	1 (1%)	0 (0%)	15 (1%)	1 (1%)	1 (2%)
Not Reported or other	0	0	0	49 (2%)	2 (1%)	0
Latino/Hispanic, any race	47 (23%)	19 (21%)	16 (43%)	361 (17%)	30 (17%)	10 (16%)
Age						
<30	38 (18%)	22 (24%)	2 (5%)	168 (8%)	10 (6%)	18 (30%)
30-39	30 (15%)	18 (20%)	4 (11%)	399 (19%)	28 (16%)	12 (20%)
40-49	47 (23%)	16 (18%)	6 (16%)	591 (28%)	55 (31%)	21 (34%)
50+	91 (44%)	35 (38%)	25 (68%)	923 (44%)	85 (48%)	10 (16%)
HIV+ONLY						
Time since initial HIV diagnosis of treatment *						
0-5 years	36 (32%)	22 (24%)	7 (19%)	989 (48%)	97 (54%)	30 (49%)
6-10 years	23 (21%)	12 (13%)	5 (14%)	532 (26%)	37 (21%)	16 (26%)
>10 years	53 (47%)	18 (20%)	20 (54%)	560 (27%)	44 (25%)	15 (25%)
Route of transmission						
MSM	59 (53%)	21 (23%)	20 (54%)	1342 (64%)	108 (61%)	35 (57%)

	Concept Elicitation Behaviors	Concept Elicitation Barriers	Congnitive Interviews	Clinic Sample	Longitudinal Stability	Retest Reliability
MSM/IV drug use	14 (13%)	13 (14%)	0 (0%)	50 (2%)	4 (2%)	2 (3%)
IV drug use (non MSM)	7 (6%)	4 (4%)	1 (3%)	166 (8%)	19 (11%)	4 (7%)
Heterosexual	28 (25%)	10 (11%)	8 (22%)	453 (22%)	40 (22%)	18 (30%)
Other/unknown	4 (4%)	4 (4%)	3 (8%)	70 (3%)	7 (4%)	2 (3%)
Most recent CD4						
0-199	11 (10%)	6 (7%)	4 (11%)	147 (7%)	17 (10%)	12 (20%)
200-349	19 (17%)	6 (7%)	7 (19%)	296 (14%)	30 (17%)	11 (18%)
>349	82 (73%)	40 (44%)	21 (57%)	1632 (78%)	130 (73%)	38 (62%)
Unknown	0	0	0	6 (0%)	1 (1%)	0

*Initial diagnosis is for concept initiation and congnitive inteviews. Initiation of treatment for longitudinal stability and test-restest reliability analyses.

TABLE 2.

ADHERENCE BEHAVIOR CONCEPT PREVALENCE

Concept	Unique Patients (n = 206)	Percentage
Takes medications at the same time every day	80	39%
Keeps medications in a certain place to remember to take them	65	32%
Uses pillbox or another object to help take medications as prescribed	62	30%
Uses reminder to help take medications as prescribed	38	18%
Late by one hour or more in taking medication	34	17%
Intentionally skips some or all medications *	10	5%
Has a routine that works well for taking medication as prescribed *	6	3%
Takes more of medication than prescribed	5	2%
Has "back up" plan in case forgets to take medication *	5	2%
When medications running out, spreads out the time between doses	4	2%
Cuts or grinds up pills without a doctor's knowledge	3	1%
Delays or does not fill prescription	2	1%
When medication running out, takes less medication at each time	2	1%
Can tell whether took does of own medication	2	1%

* concept not represented in finalized item pool

TABLE 3.

ADHERENCE BARRIER CONCEPT PREVALENCE

Concept	Freq by Unique Pt (n = 91)	Percentage
Did not want side effects	46	51%
Just forgot	27	30%
Busy	26	28%
Felt hopeless or depressed	21	23%
Did not have the medications with me	21	23%
Did not think I needed medications	16	18%
Fell asleep/slept through dose time	16	18%
Not enough privacy	16	18%
Had a change in daily routine	15	16%
Hard to swallow/bad taste	15	16%
Felt I was on too much medication	14	15%
Did not want to be reminded of illness	13	14%
Felt sick or ill	13	14%
Ran out, and did not/could not refill	12	13%
Cost/insurance problem	12	13%
No food available	11	12%
I did not want to mix medicine with drugs or alcohol	9	10%
Was not reminded by anyone *	6	7%
Wanted a break *	6	7%
My drug use got in the way *	5	5%
My use of alcohol got in the way	5	5%
I wanted to avoid taking doses too close together *	5	5%
Felt medications would cause me harm	4	4%
Did not care	4	4%
I just did not want to deal with taking my medication	4	4%
Under too much stress *	4	4%
I did not have a routine for taking my medications	2	2%
I was confused or uncertain about how to take the pills	1	1%

* new concept (not found in item pool)