

Cognitive and Field Testing of a New Set of Medication Adherence Self-report Items for HIV Care

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Background

- Understandable, reliable, and valid self-report measures of ART adherence are needed
- Wide variety of self-report items have been used
- Relatively few have undergone rigorous cognitive testing, field testing, or formal validation
- Previous work identified 3 items
- Next step: field testing to assess reliability, distributions



Background

- Regimen variation: 1 pill once a day, 2 or 3 pill regimens
- Additional question: do you have to ask about each individual ARV?



Methods: Study Design

Clinic-based, pencil
and paper survey
N=351

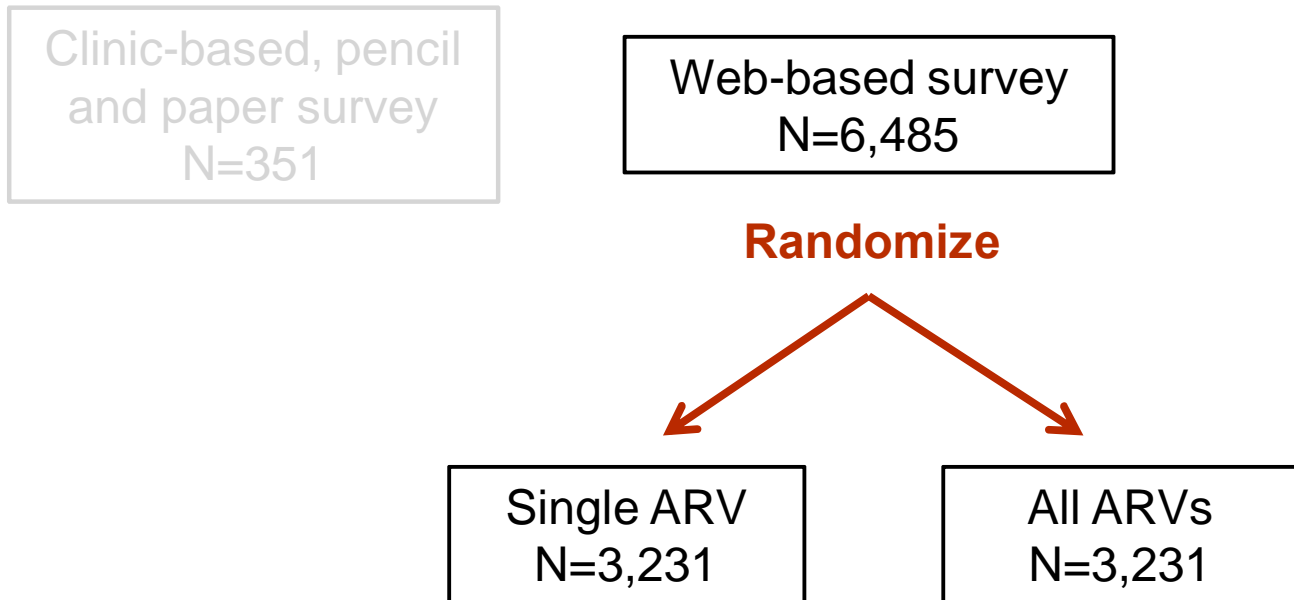
Web-based survey
N=6,485



1. Descriptive Statistics
2. Distributions
3. Reliability: Cronbach's



Methods: Study Design



ARV Adherence Items

In the last 30 days, on how many **days** did you miss at least one dose of any of your HIV medicines?

Write in number of days: _____ (0 - 30)

In the last 30 days, how good a job did you do at taking your HIV medicines in the way you were supposed to?

- Very poor
- Poor
- Fair
- Good
- Very good
- Excellent

In the last 30 days, how often did you take your HIV medicines in the way you were supposed to?

- Never
- Rarely
- Sometimes
- Usually
- Almost always
- Always



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Methods: Pencil and Paper Survey

- Two hospital-based HIV care practices
- Completed while in waiting room
- 3 ARV adherence items
- Additional items
 - Duration of ART
 - Gender
 - Age
 - Educational level
 - Ethnicity
 - Race



Methods: Web-based Survey

- Sample: cross-sectional, national sample of US members of social networking site for gay/bisexual men, Online-Buddies.com
- Randomization
 - Half randomized to a web version identical to the pencil and paper survey
 - Half randomized to a version in which they selected a specific ARV



About taking your HIV medicines

Please look at the medicine chart below. In the next question, you will be asked to choose from a drop-down list **one** of the HIV medicines that you are taking. You will be able to return to this page to review the chart again, if you need to.

Nucleoside/Nucleotide Analogs (NRTIs)

Atripla (efavirenz/ emtricitabine/ tenofovir DF)	Combivir (zidovudine/ lamivudine)	Complera (rilpivirine/ emtricitabine/ tenofovir DF)	Emtriva (emtricitabine or FTC)	Epivir (lamivudine or 3TC)	Epzicom (abacavir/ lamivudine)	Retrovir (zidovudine ZDV or AZT)	Trizivir (abacavir/ lamivudine/ zidovudine)	Truvada (tenofovir DF/ emtricitabine)	Videx, Videx EC (didanosine or ddl)	Zerit (stavudine or d4T)	Ziagen (abacavir or ABC)	Viread (tenofovir DF or TDF)

Non-Nucleosides (NNRTIs)

Edurant (rilpivirine or RPV)	Intence (etravirine or ETV)	Rescriptor (delavirdine or DLV)	Sustiva (efavirenz or EFV)	Viramune (nevirapine or NVP)

Entry Inhibitors

Fuzeon (enfuvirtide or ENF)	Selzentry (maraviroc or MVC)

Integrase Inhibitor

Isentress (raltegravir or RAL)


Protease Inhibitors (PIs)

Aptivus (tipranavir or TPV)	Crixivan (indinavir or IDV)	Invirase (saquinavir or SQV)	Kaletra (lopinavir/ritonavir)	Lexiva (fosamprenavir or FPV)	Norvir (ritonavir or RTV)	Prezista (darunavir or DRV)	Reyataz (atazanavir or ATV)	Viracept (nelfinavir or NFV)



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Scale Summary		
Code	Label	Show-If
0	Aptivus	
1	Atripla	
2	Combivir	
3	Complera	
4	Crixivan	
5	Edurant	
6	Emtriva	
7	Epivir	
8	Epzicom	
9	Fuzeon	
10	Intelence	
11	Invirase	
12	Isentress	
13	Kaletra	
14	Lexiva	
15	Norvir	
16	Prezista	
17	Rescriptor	
18	Retrovir	
19	Reyataz	
20	Selzentry	
21	Sustiva	
22	Trizivir	
23	Truvada	
24	Videx	
25	Viracept	
26	Viramune	
27	Viread	
28	Zerit	
29	Ziagen	

From this list, choose one of the HIV medicines that you are taking. Click on  to return to the chart, if you need to.



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You have chosen Kaletra.

If this is not the medicine you wanted to choose, please click on [Previous](#) to return to the last question and then choose a different medicine.

Kaletra
(lopinavir/ritonavir)



In the last 30 days, how good a job did you do taking your Kaletra in the way that you were supposed to? (Very poor to excellent)



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About taking your HIV medicines

In the last 30 days, how good a job did you do at taking your -- **Select One** -- in the way that you were supposed to?

- Very poor
- Poor
- Fair
- Good
- Very good
- Excellent



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Results: Participant Characteristics

Characteristic	Web based		Paper
	One med (N=3231)	All meds (N=3254)	N=351
Age (mean years (SD))	46.7 (10.0)	47.2 (10.0)	49.4 (9.7)
Gender (% Male)	→ 99.3	99.4	75.1
Hispanic (%)	9.5	8.9	19.0
Race (%)			
White	89.5	89.1	57.0
African American	4.7	5.1	25.1
Asian	1.2	1.2	1.7
Pacific Islander	0.4	0.3	0.3
Native American	1.8	1.6	4
Other	4.4	5.0	14.5
Education			
8th grade or less	0.2	0.2	4.0
Some high school but did not graduate	1.3	1.3	11.5
High school graduate or GED	9.8	10.5	25.0
Some college or 2-year degree	34.6	34.9	33.0
4-year college graduate	24.6	25.4	13.5
More than 4-year college degree	29.5	27.7	12.9



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Results: Descriptive Statistics

Item (mean (SD))	Web based		Paper
	One med (N=3231*)	All meds (N=3254*)	N=351
How many days NOT missed...	95.8 (11.4)	95.1 (12.9)*	94.7 (14.1)
How good a job did you do...	87.8 (19.8)	86.8 (20.9)	84.2 (21.7)*
How often did you take...	89.7 (17.3)	88.8 (18.1)*	88.0 (19.9)
Mean of the 3 item scales	91.0 (14.6)	90.2 (15.8)*	88.8 (17.1)*
<u>Cronbach's alpha</u>	0.86	0.89**	0.89*

Using One med as a reference, scales were compared by t-test (Non parametric tests' results were the same) and Cronbach's alpha were compared by Fisher's z-transformation.

* p-value <0.05. ** p-value<0.01



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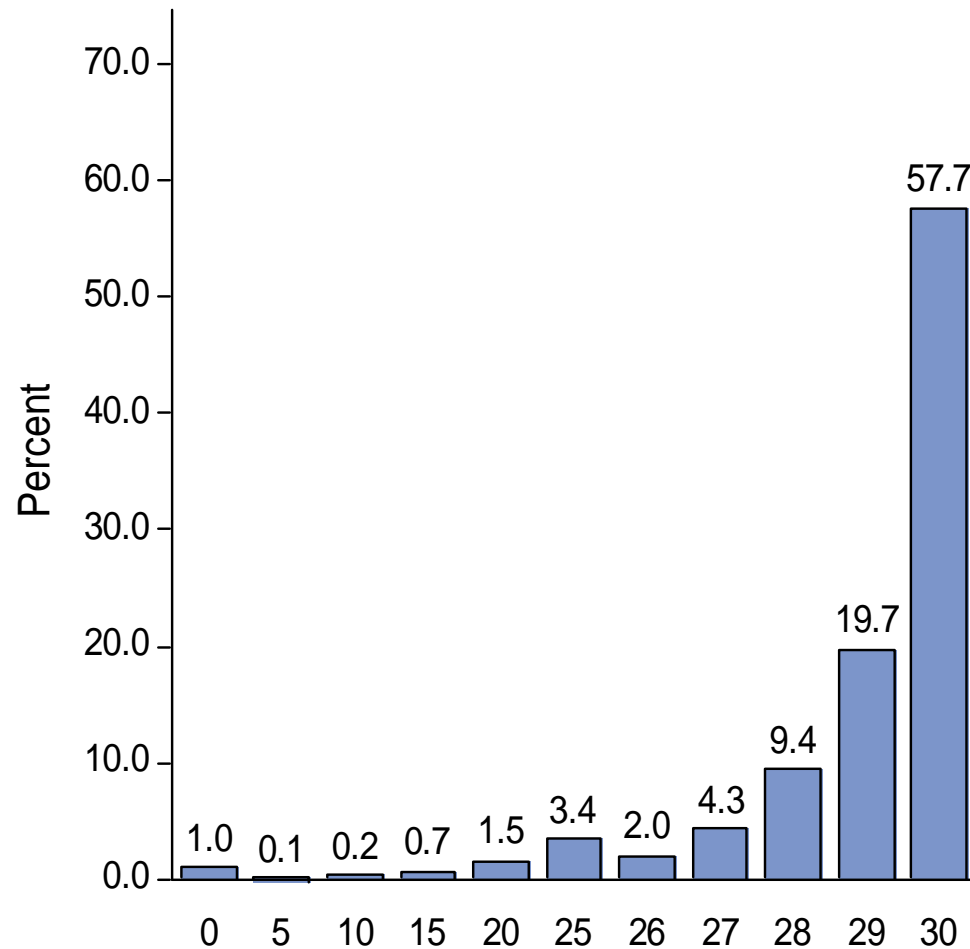
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Days NOT Missing a Dose ...



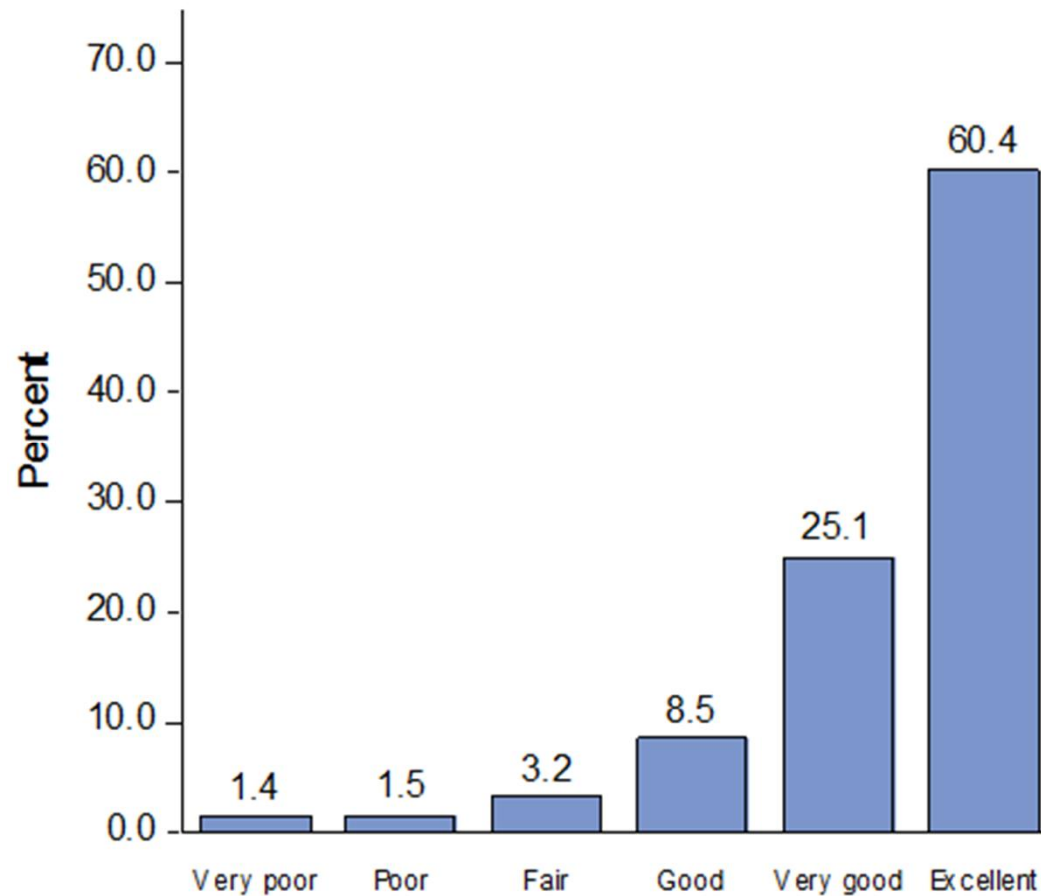
In the last 30 days, on how many days did you miss at least one dose of any of your HIV medicines?

Figure shows 30 minus the response, or days not missed.



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How Good a Job Did You Do ...

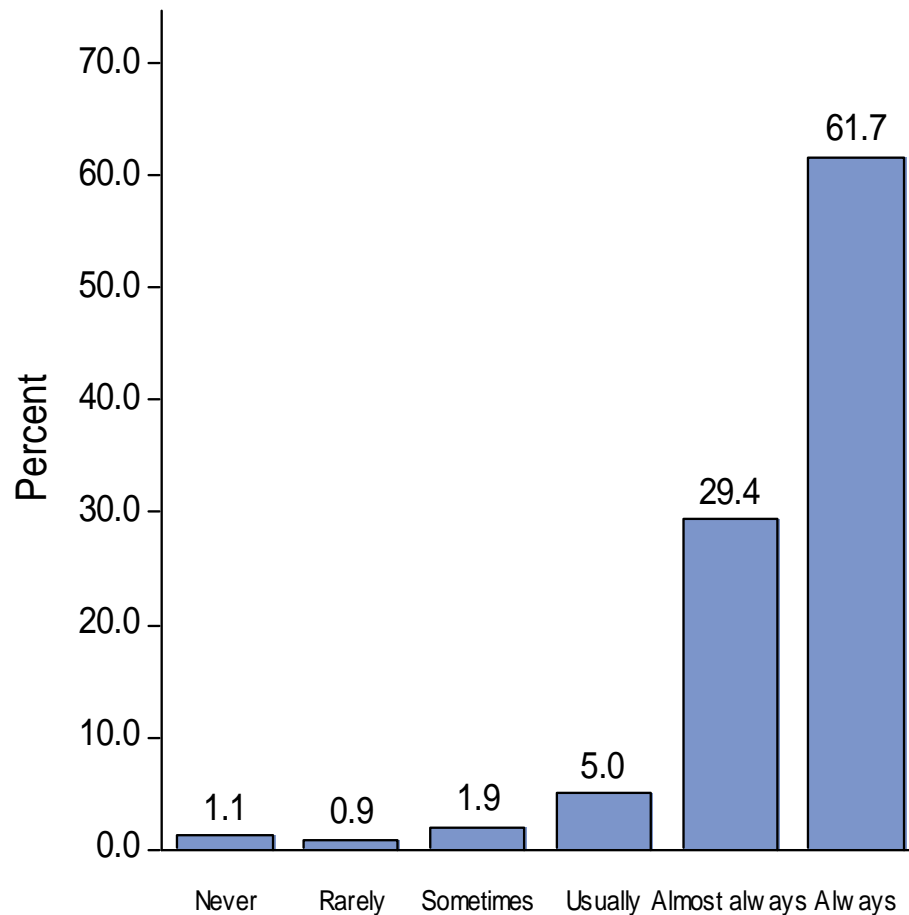


In the last 30 days, how good a job did you do at taking your HIV medicines in the way you were supposed to?



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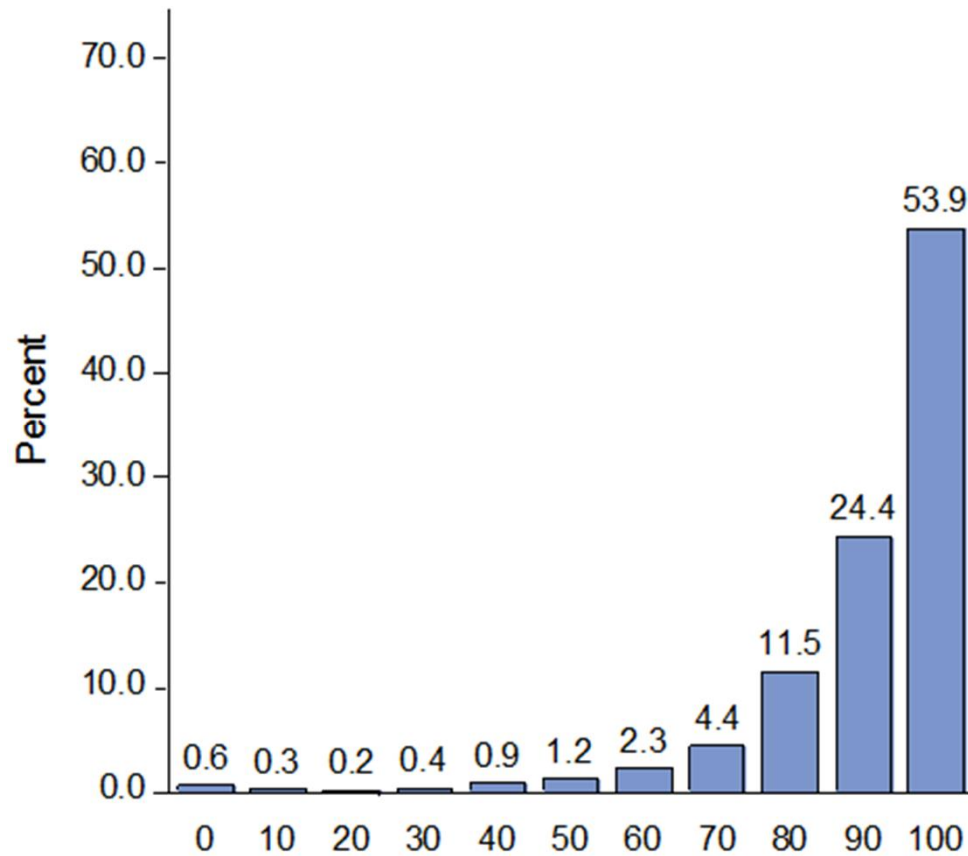
How Often Did You Take ...



In the last 30 days, how often did you take your HIV medicines in the way you were supposed to?



Summary Scale (3 items)



Distribution of 3 item
scale scores (0-100)



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Summary

- Pencil and paper and web-based versions yielded similar responses
- Asking about %your HIV medicines+and individual ARVs yielded similar responses
- 54% of respondents scored at the ceiling of the 3-item scale
- Internal reliability consistency (Cronbach's alpha) of the 3-item scale was very good



Limitations

- Generalizability to non-English speaking populations is unknown
- Field testing provides evidence about score distributions and internal consistency reliability, not validity



Discussion: Descriptive Measures

- Items and scale showed relatively good distribution and very good internal consistency reliability
- Similarity between clinic and web-based samples striking and suggests that the items perform similarly in diverse respondents
- Ceiling effects and socially desirable over-reporting



Discussion: Single vs. All ARVs

- Cognitive studies suggested that patients don't distinguish single and all ARVs
- Empiric data support use of items that ask about all ARVs
- Small literature on differential adherence
 - Relatively uncommon
 - When it occurs may be consequential (Gardner et al, AIDS, 2008)
- Measurement question vs. clinical question
- Our data address the measurement question, and suggest no clinically important differences



Conclusions

- 3-item self-report scale had reasonably good distribution and very good internal consistency reliability
- These data provide support for using an approach that asks about all ARVs
- Validity testing needed



Discussion: Descriptive Measures

- Items and scale showed relatively good distribution and very good internal consistency reliability
- Similarity between clinic and web-based samples striking and suggests that the items perform similarly in diverse respondents
- Ceiling effects: measurement error?
 - Beer et al., Open AIDS J, 2012 (Medical Monitoring Project, national sample): 62% report suppressed VL
 - Ohl et al., AIDS Behav, 2012 (VACS cohort, national sample): 25-40% high+adherence using pharmacy records

