New patient-reported outcome measure to assess perceived barriers to antiretroviral therapy adherence: the PEDIA scale

Uma nova medida de desfecho relatada pelo paciente para avaliar barreiras percebidas à adesão à terapia antirretroviral: a escala PEDIA

Una nueva medida de resultados apreciados por pacientes para evaluar los obstáculos percibidos en la adherencia a la terapia antirretroviral: la escala PEDIA

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Abstract

This study sought to develop and evaluate a new patient-reported outcome measure to assess perceived barriers to antiretroviral therapy (ART) adherence. The Perceived Barriers to Antiretroviral Therapy Adherence (PEDIA) scale was developed based on individual interviews with patients. After pilot testing and assessing the evidence based on content analysis, the scale's revisions resulted in a 40-item version. The PEDIA was applied to 415 HIV-infected adults receiving ART for a maximum of 180 days, recruited from three healthcare facilities of reference in the city of Belo Horizonte, Minas Gerais State, Brazil. The analyses included exploratory factor analysis, internal consistency, item response theory, temporal stability, and predictive test-criterion relationship. The scale's final version contains 18 items distributed in three dimensions, as follows: cognitive and routine problems (4 items); medication and health concerns (6 items); and patient's fears and feelings (8 items). The results of McDonald's omega and temporal stability demonstrate that the PEDIA is internally consistent and yields stable scores over time. The assessment of the information's functions suggested that the three dimensions were informative for assessing a broad range of latent traits. Evidence concerning the test-criterion relationship confirmed that the PEDIA was able to predict non-adherence three months later. Our findings suggest that the PEDIA is a psychometrically adequate tool for evaluating perceived barriers in adult patients initiating ART. It could be used in both research and clinical practice for the early detection of patients at risk of non-adherence and for the identification of potentially modifiable barriers.

Patient Reported Outcome Measures; Psychometrics; HIV Infections; Medication Adherence

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Introduction

HIV infection is a significant contributor to morbidity and health-related costs worldwide [1]. Brazil account for almost 50% of HIV infection cases in Latin America, registering 14,000 HIV-related deaths per year [2]. Antiretroviral therapy (ART) effectively improves immune reconstitution, prevents the emergence of drug resistance and decreases HIV transmission by more than 95% [3,4,5]. Although the advances in the ART regimens have significantly improved the patients' prognosis and quality of life, living with HIV still requires the use of lifelong daily medications, and a strict adherence is required to ensure the treatment's success.

Providers and researchers would welcome a simple, yet effective, screening tool to help them identify patients who may be at risk of suboptimal adherence. The identification of these cases and the application of interventions to improve adherence are especially important for patients at the beginning of treatment. Adherence in the beginning of treatment is an important predictor of future therapeutic success [6,7]. Perceived barriers are one of the strongest predictors of nonadherent behavior [8]. As a social cognitive construct often incorporated in health behavior theories such as the Health Believe Model and the Theory of Planned Behavior, perceived barriers refer to a patient's personal estimation of social, personal and environmental obstacles to achieve a goal, such as medication adherence [9]. The identification of perceived barriers among people living with HIV/AIDS (PLWHA) could support the development of strategies to overcome difficulties and improve adherence [10].

Patients provide a unique perspective on the outcome being measured and self-report questionnaires have the advantage of obtaining the patient's perception directly without interpretation by a third party [11]. Currently, patient-reported outcome measures (PROMs) are available for the individual assessment of behavioral constructs, such as regimen complexity, lack of social support and negative beliefs in relation to medication [12]. Although these instruments typically assess important factors believed to hinder the adherence to ART, they are not perceived barrier scales per se. In contrast, instruments developed specifically to assess barriers to ART adherence do not comprehensively describe the perceived barriers often reported in qualitative studies [13,14,15,16]. For instance, the *Structural Barriers to Medication-Taking* scale does not evaluate pill burden/fatigue, negative beliefs about medication, lack of motivation, disruption in daily routine, or factors related to the healthcare system [17]. Similarly, the *Self-reported Barriers to Adherence* does not evaluate substance abuse, complexity of therapy, or healthcare-related factors [18]. On the other hand, an instrument developed by Wohl et al. [19] (IRT-30) does a good job describing the perceived barriers construct, but is not a good predictor of non-adherence.

So far, no instrument has been developed to explore patient-specific barriers to ART adherence in Brazilians living with HIV. Thus, the purpose of this study was to develop and evaluate a new patient-reported outcome measure to evaluate perceived barriers among PLWHA at the beginning of antiretroviral treatment. We hypothesized that the measure may be able to predict non-adherence to ART. Predicting non-adherence can help stakeholders plan interventions before the treatment fails. Because certain perceived barriers have different degrees of relevance to different patients, this measure may also offer practical insights for behavioral interventions by adopting an individualized approach.

Methods

Scale's development

The *Perceived Barriers to Antiretroviral Therapy Adherence* – PEDIA scale – assesses the patients' perceptions of difficulties faced while managing ART. A list of 47 items was created based on the qualitative analysis of open-ended questions with 598 PLWHA from 17 health care centers across the five geopolitical regions of Brazil [20,21]. Each item was formulated as a statement, as close as possible to the patients' words. After pilot testing and assessing the evidence based on content analysis and cognitive processes, the scale's revisions resulted in a 40-item version [22]. Subsequently, we conducted face-to-face cognitive interviews with 27 patients. The participants answered the questionnaire and assessed

the items' clarity and comprehensibility, suggested rephrasing problematic items and made additional comments. The items were also modified in a consultation with a panel of three HIV treatment experts, including a physician, a pharmacist and a public health decision-maker. All three judges rated the items for the contents' relevance, dimensionality, and the appropriateness of the scale's format. Four dimensions were originally defined (Supplementary Material, Table S1: http://cadernos.ensp. fiocruz.br/site/public_site/arquivo/suppl-e00184218_1333.pdf): (1) emotional factors, representing the patient's feelings and beliefs; (2) social and economic factors, such as financial constraints and social support; (3) factors related to ART regimens, including side effects, physical characteristics of medicines, pill burden and routine disruptions; and (4) factors related to the healthcare facility and caregivers, representing the patient-caregiver relationship and the patient's perception of the care and services provided. These evaluations indicated the suitability of the scale's contents to the construct it intends to measure [22].

The respondents were asked to rate their level of agreement with the statements about what makes it difficult for them to adhere to ART. In the pilot version of the PEDIA, the items were rated in a five-point Likert-type scale ranging from 1 to 5, where 1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, and 5 = strongly agree.

Design and setting

As part of a larger cohort study evaluating the effectiveness of ART in patients beginning treatment (ECOART study) [23], patients from three healthcare facilities in the city of Belo Horizonte, Minas Gerais State, Brazil, were recruited between September 2015 and October 2017 and followed-up for a maximum of six months. The three services are a reference in HIV treatment and, together, they are responsible for the treatment of 80% of PLWHA in Belo Horizonte.

Participants

The patients were eligible if they were HIV-infected adults (> 18 years old) receiving ART for a minimum of seven and a maximum of 180 days from one of the three services considered. Their time on ART was measured according to the patients' self-report and confirmed by analyzing their medical charts. The exclusion criteria included previous use of ART for prophylaxis and being too ill to participate.

The sample size's estimation considered 10 individuals per item of the version of the scale being tested (40-item version) – the suggested ratio for conducting factor analysis [24,25] – and 20% loss (n = 500). The participants were consecutively approached by the researchers to ask about their interest in participating, assess the eligibility criteria and obtain their informed consent. Patients who did not go to the healthcare facility for medical appointments or ART refill during the data collection period were not considered for inclusion.

Procedures

Ethics approval was granted by all participating institutions and the Federal University of Minas Gerais. All interviews were conducted in Portuguese, in private rooms inside the healthcare facilities, and they were identified by number for anonymity purposes.

After obtaining the participants' consent, we conducted face-to-face interviews using a self-report questionnaire. Participants with a complete baseline assessment were invited to return for a second interview approximately three months later, where we re-administered the PEDIA for the test-retest analysis and assessed their non-adherence for prediction of the test-criterion relationship.

Measures

The self-reported questionnaire assessed sociodemographic (i.e., age, sex, marital status, race, education and employment status), clinical (i.e., HIV viral load and CD4 count) and treatment-related characteristics (i.e., time on ART, ART regimen and adherence to treatment).

The data on ART regimen, viral loads and CD4 count were extracted from two information systems of the Brazilian Ministry of Health, the Medication Logistics Control System (SICLOM) and the Laboratory Test Control System (SISCEL). Non-adherence to treatment was assessed at baseline and at the three-month follow-up by asking "Did you skip your HIV medication over the past 2 weeks?". Participants who answered "yes" were considered non-adherent.

Analyses

The descriptive statistics were computed in terms of number and frequency for categorical data and mean and standard deviation (SD) for continuous variables. We assessed differences in characteristics at the baseline between respondents and non-respondents of the follow-up interview using chi-squared and t-tests.

Skewness and kurtosis were used to judge the normality of each item's distribution. For psychometric purposes, skewness and kurtosis values between -2 to +2 were considered acceptable [26]. A stepwise item selection procedure was used to refine the scale. The selection process was recursive and considered the results of internal consistency, exploratory factor analysis (EFA) and the item response theory (IRT).

Internal consistency was evaluated based on the item-total correlation coefficient. An item-total correlation coefficient equal to 0.3 is the minimum recommended for items in a new scale [25]. Reliability was assessed using McDonald's omega (ω) [27]. This estimator is suitable even when items with different factor loadings are present in the representation of the construct [28]. A ω value equal to 0.75 or higher is suggested for a composite score to provide unique, reliable variance [29].

We performed an exploratory factor analysis of the selected items to analyze the PEDIA's internal structure. The Hull method was used to determine the number of factors in the instrument [30]. We used the polychoric correlation matrix and performed EFA with the unweighted least squares estimator and promax rotation [31,32]. Items with loadings greater than 0.3 in only one factor were retained [33]. Complex items, i.e., those with similar loadings in two or more factors, were excluded.

In the item response theory model, the items were evaluated using Samejima's graded response model (GRM) for each unidimensional set of items [34]. In this model, the items' responses were used to estimate the person's score in the latent trait, indicating how well the item discriminates (distinguishes) differences between individuals over the latent trait [35]. The items were selected based on their discrimination "a" (a > 0.65) and difficulty "b" (-3 < b < +3) [36]. To allow a visual evaluation, we plotted Test Information Functions (which indicate how well the scale estimates perceived barriers over the whole range of latent trait), Item Characteristic Curves (which allow us to visually evaluate each item's discrimination and difficulty) and Category Characteristic Curves (which display the probability of selecting each category of response at various levels of the latent trait).

Temporal stability was assessed based on the test-retest correlation and invariance in scores over time [24]. The intraclass correlation coefficient (ICC) estimates and their 95% confident intervals (95%CI) were calculated according to a mean-rating (k = 2), absolute-agreement, 2-way mixed-effects model. ICC values lower than 0.5 are indicative of poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability, and values greater than 0.90 indicate excellent reliability [37]. Stability was further assessed by comparing the baseline and three months post-baseline mean PEDIA scores using paired-samples t-test. Comparisons not significant at the 5% level (p > 0.05) suggest the measure's stability.

To provide evidence that the instrument's scores predict the criterion's performance (i.e., non-adherence), we conducted binary logistic regressions with non-adherence at the three-month follow-up as the dependent variable and the PEDIA scores as the independent variables. The analysis was controlled by age, sex, marital status, race, education, employment status, viral load, CD4 count, time on ART, ART regimen and non-adherence at the baseline. The association was expressed in terms of adjusted odds ratios (aOR) with 95%CI.

Analyses of internal consistency, IRT, temporal stability and test-criterion relationship were conducted in Stata version 14 (https://www.stata.com). EFA was conducted using FACTOR 10.7 (http://psico.fcep.urv.es/utilitats/factor/Download.html) and reliability was estimated using OMEGA (http://edpsychassociates.com/Watkins3.html).

Results

Sample's characteristics

A total of 507 patients were approached to participate in the study. Most individuals were excluded due to their time on ART; 37 had been on it for less than seven days and 16 for more than 180 days. Five individuals were excluded due to previous use of ART. Of 449 eligible individuals, 33 declined participating for being "too busy" or not interested and one did not complete the interview, resulting in a total of 415 individuals included.

Table 1 displays the characteristics of the participants. The mean age was 34.6 (SD = 10.9), and 81% were male. Most participants were adherent to ART (84%) and the prevalence of detectable viral load (> 50 copies/mL) was high (94%). Most participants had been using the once-a-day single-tablet regimen of tenofovir disoproxil fumarate (TDF), lamivudine (3TC) and efavirenz (EFV), which was the first-line regimen adopted in Brazil between January 2015 and December 2016. As of January 2017, the first-line regimen changed to TDF + 3TC and dolutegravir (DTG), which was used by 31% of our sample.

Table 1 also presents the baseline characteristics of the subsample of participants who returned for the follow-up interview (n = 355), which took place approximately three months after the baseline visit. Of the 60 participants lost, 4 died, 12 withdrew their consent, 7 abandoned care, 6 were transferred to another healthcare facility and 31 did not return for the follow-up. There was no difference in the patients' baseline characteristics between respondents and non-respondents of the follow-up interview (Table 1).

PEDIA evaluation

Most participants were able to fill in the scale within 10 minutes. All participants answered at least 80% of the PEDIA's items and were therefore included in further analyses. The initial item analysis stage included examining the answer categories' frequency distribution. Most items showed little variability in their answer patterns. Also, the analysis of the Category Characteristic Curves confirmed that the participants had difficulty discriminating between answer categories. For each item, some categories

Table 1

Baseline characteristics of the total sample and the follow-up subsample.

Characteristic	Total sample (N = 415)	Follow-up subsample		
		Respondents (n = 355)	Non-respondents (n = 60)	p-value
Sociodemographic				
Age (mean ± SD)	34.64 ± 10.95	34.95 ± 10.99	32.90 ± 10.65	0.18
Sex (% male)	336 (81.16)	290 (81.92)	46 (76.67)	0.34
Marital status (% married)	86 (20.72)	76 (21.41)	10 (16.67)	0.40
Race (% white)	99 (23.86)	81 (22.82)	18 (30.00)	0.23
Education (% ≥ high school)	280 (67.63)	238 (67.23)	42 (70.00)	0.67
Employment status (% working)	254 (61.20)	211 (59.44)	43 (71.67)	0.07
Clinical				
Viral load (% > 50 copies/mL)	327 (94.24)	286 (95.02)	41 (89.13)	0.11
CD4 count (% < 200 cells/μL)	87 (26.77)	76 (26.76)	11 (26.83)	0.99
Treatment				
Time on ART (months; mean ± SD)	2.83 ± 1.94	2.79 ± 1.92	3.00 ± 2.08	0.43
ART regimen (% single-tablet)	253 (60.96)	216 (60.85)	37 (61.67)	0.90
Non-adherence (% yes)	66 (15.98)	53 (15.01)	13 (21.67)	0.19

ART: antiretroviral therapy; SD: standard deviation.

were never the most probable answer. When the range of available answer categories obscures rather than clarifies the intent of the respondent, one strategy is to collapse the data across categories [38,39]. Therefore, the answer categories were reduced from five to three [40]. The categories "totally disagree" and "partially disagree" were recoded into "disagree", "totally agree" and "partially agree" were recoded into "agree", and the category "neither agree nor disagree" remained as the original.

Table 2 displays all the 40 items and their characteristics. The agreement was higher in positively phrased items, such as item 15. Before further analyses, these items were reverse coded so that a higher mean score would indicate more perceived barriers. The two items with the higher mean scores (items 2 and 25) were both related to stigma. Given that the answer format is categorical, the item distributions were expected to demonstrate some degree of non-normality. High levels of skewness and kurtosis occurred in items 1, 5, 6, 14, 15, 16, 21, 23, 25, 26, 27, 31, 38 and 39 (Supplementary Material, Table S1: http://cadernos.ensp.fiocruz.br/site/public_site/arquivo/suppl-e00184218_1333.pdf). These items were considered for potential exclusion from the PEDIA, but the decision had to be made also considering the results of the item-total correlation and the EFA.

In all, 25 out of 40 items fulfilled the minimum item-total correlation coefficient value of 0.3 (Table 2). The other 15 items did not meet the selection criteria and were thus removed (items 1, 9, 10, 15, 16, 19, 21, 22, 24, 27, 31, 32, 33, 38 and 39). The Kaiser-Meyer-Olkin index (KMO = 0.77) and significance in Bartlett's test of sphericity ($p < 0.001$) indicated that the correlation matrix of the 25 items retained was adequate for the EFA. The Hull method suggested the extraction of three factors, which together explained 31.2% of the total variance. Notably, five items did not load strongly on any of the three factors, and two items loaded onto two factors with similar factor loading values (Table 2). These seven items were thus removed (items 11, 20, 26, 28, 34, 35 and 37), resulting in a final 18-item version.

All factors were well-defined by the items. The first factor reflects "cognitive and routine problems", and it included four items representing the patients' cognition problems to remember taking the pills and fit the treatment into their daily routines. The second factor had six items about side effects (real or anticipated), physical characteristics of the drugs and functionality, and was labeled "medication and health concerns". The third factor was named "patient's fears and feelings", and it included eight items related mainly to stigma, such as fear of disclosure, but also to pill fatigue and future concerns about treatment. The inter-factor correlation varied from 0.35 to 0.44, suggesting that each factor represented a distinct dimension and that there was low redundancy between dimensions.

McDonald's ω for the final scale was 0.97 and demonstrated good reliability. For the first dimension (cognitive and routine problems), ω was 0.92. For the second (medication and health concerns) and third (patient's fears and feelings) dimensions, ω was 0.94.

Regarding the item response theory, all 18 items satisfied the condition of $a > 0.65$ and $3 < b < +3$ (Table 2). They offered great discrimination potential, with parameters ranging from 0.73 to 2.13. In the dimension of cognitive and routine problems, the highest discriminating item was item 13. In terms of item difficulty, "b" values ranged from 0.72 to 1.72, reflecting moderate levels of difficulty. In the medication and health concerns dimension, the highest discriminating item was item 5. Items 6 and 14, both positively phrased items, were associated with higher levels of difficulty. Consistently, less than 10% of the respondents answered "disagree" in each of these items. Similarly, their observed means were also lower than those of the other items (Table 2). In the patient's fear and feelings dimension, the highest discriminating item was item 36. In terms of item difficulty, "b" values ranged from -2.50 to 0.78, reflecting low to moderate levels of severity.

The Test Information Functions are shown in Figure 1. For the dimension of cognitive and routine problems, information was good for scores between 0 and 2.5 (between the mean and two and a half standard deviations above the mean). The dimension of medication and health concerns was more informative in assessing the respondents whose scores in the theta continuum ranged approximately between 0 and 3. The patient's fears and feelings dimension was more informative in assessing the respondents whose scores ranged approximately between -2 and +2 (between two standard deviations below the mean and two standard deviations above the mean).

The three-month test-retest reliability method yielded an ICC equal to 0.52 (95%CI: 0.41, 0.61). There was no significant difference between the participants' total scores at the baseline (M0 = 30.81 ± 6.01) and three months later (M3 = 30.27 ± 6.00), (p = 0.27). The same occurred for each of the

Table 2

Descriptive statistics and parameters of items of the PEDIA scale (N = 415).

Item	Observed response frequencies (%) *			Classic item statistics **			Factor loading ***			Item parameter estimates #		
	1	2	3	M	SD	r	F1	F2	F3	a	b1	b2
1. Sometimes I do not take my HIV meds if I use alcohol or any illicit substance	92.49	1.55	5.96	1.13	0.41	0.10	-	-	-	-	-	-
2. The main problem of living with HIV is the stigma around it	15.90	6.75	77.35	2.61	0.61	0.31	0.11	-0.13	0.43	0.73	-2.50	-1.85
3. I am afraid to be identified as HIV positive when I go to the healthcare facility to get my HIV meds refill	37.11	8.19	54.70	2.18	1.02	0.42	0.06	-0.18	0.58	1.29	-0.53	-0.18
4. It frustrates me to think that I need to take the HIV meds in order to be alive	52.90	12.08	35.02	1.82	0.81	0.43	0.18	0.06	0.32	0.95	0.16	0.79
5. Sometimes I skip taking my HIV meds because I want to avoid side effects	93.45	1.70	4.85	1.11	0.41	0.33	0.02	0.57	-0.14	2.13	1.96	2.17
6. Despite my HIV status, I live a normal life	9.40	5.06	85.54	1.24	0.61	0.30	-0.07	0.40	-0.12	1.11	1.94	2.44
7. It is difficult to take my HIV meds at home	83.37	2.89	13.73	1.30	0.61	0.31	0.54	0.01	0.02	1.43	1.52	1.72
8. I do not like to take my HIV meds around others	56.50	9.50	34.00	1.78	1.02	0.50	0.24	0.00	0.37	1.08	0.30	0.76
9. Family or friends make sure I am taking the HIV meds correctly	66.67	4.20	29.14	2.38	0.81	0.12	-	-	-	-	-	-
10. The use of electronic devices, such as alarm clocks, reminds me to take my HIV meds consistently	53.10	3.97	42.93	2.10	1.02	0.13	-	-	-	-	-	-
11. I am worried about the reactions between my HIV meds and the medications I take for other diseases	58.64	6.02	35.34	1.77	1.02	0.40	0.00	0.14	0.24	-	-	-
12. Sometimes I forget to take my HIV meds because I get distracted	68.12	3.14	28.74	1.61	0.81	0.36	0.61	-0.04	-0.01	1.50	0.72	0.85
13. It is difficult to take my HIV meds at work	77.54	5.88	16.58	1.39	0.81	0.41	0.49	0.02	0.14	2.06	1.01	1.30
14. I believe that my HIV meds make me healthy	5.30	9.40	85.30	1.20	0.41	0.37	0.14	0.43	-0.07	1.20	1.81	2.88
15. I appreciate the fact that the HIV meds are provided free of charge	0.48	0.72	98.79	1.02	0.20	0.14	-	-	-	-	-	-
16. I appreciate when I get the chance to talk longer with my doctor during the appointment	2.17	3.62	94.20	1.08	0.41	0.03	-	-	-	-	-	-
17. It is tiresome to take my HIV meds everyday	53.49	6.75	39.76	1.86	1.02	0.54	0.10	0.23	0.36	1.41	0.14	0.41
18. I find it difficult to swallow the pills	79.47	5.07	15.46	1.36	0.81	0.32	-0.05	0.48	-0.10	1.04	1.56	1.95
19. I make a link between my HIV meds and some activity in my routine so I can remember to take them on time	30.12	5.06	64.82	1.65	0.81	0.12	-	-	-	-	-	-
20. There is not enough money for adequate food	64.25	8.21	27.54	1.63	0.81	0.32	0.17	0.19	-0.02	-	-	-
21. The staff at the healthcare facility treats me well	2.41	2.89	94.70	1.08	0.41	0.15	-	-	-	-	-	-

(continues)

Table 2 (continued)

Item	Observed response frequencies (%) *			Classic item statistics **			Factor loading ***			Item parameter estimates #		
	1	2	3	M	SD	r	F1	F2	F3	a	b1	b2
22. Talking with others about HIV helps me to keep taking the meds	30.37	12.10	57.53	1.73	0.81	0.11	-	-	-	-	-	-
23. When I feel depressed I do not want to take my HIV meds	90.27	1.95	7.79	1.18	0.61	0.44	0.26	0.48	-0.08	1.95	1.74	1.91
24. I enjoy sharing experiences with others living with HIV	38.76	16.54	44.70	1.94	1.02	0.16	-	-	-	-	-	-
25. It is difficult to tell people that I am HIV positive	11.57	4.34	84.10	2.72	0.61	0.32	-0.02	-0.19	0.49	1.19	-2.11	-1.74
26. I feel that the healthcare facility personnel have stigmatizing attitudes towards patients	83.78	4.60	11.62	1.28	0.61	0.31	0.12	0.20	0.04	-	-	-
27. My doctor encourages me to take my HIV medications	2.17	1.45	96.39	1.06	0.41	0.12	-	-	-	-	-	--
28. The HIV meds bring out bad feelings because they remind me I am HIV positive	46.02	10.84	43.13	1.97	1.02	0.54	-0.10	0.40	0.40	-	-	-
29. I am worried about the HIV meds stopping to work in the future	30.36	10.36	59.28	2.29	0.81	0.36	-0.06	0.07	0.31	0.76	-1.21	-0.54
30. It is hard to get used to the side effects	54.77	9.29	35.94	1.81	1.02	0.38	0.01	0.48	-0.03	1.51	0.19	0.54
31. I take my HIV medication because I want to live	0.96	2.41	96.63	1.04	0.20	0.12	-	-	-	-	-	-
32. I have a hard time getting a new job because of my HIV status	76.72	12.70	10.58	1.34	0.61	0.23	-	-	-	-	-	-
33. There is no proposal of support groups at the healthcare facility	50.39	22.86	26.75	1.76	0.81	0.24	-	-	-	-	-	-
34. There is not enough money for the transport to the healthcare facility	72.22	5.80	21.98	1.50	0.81	0.30	0.27	0.23	-0.19	-	-	-
35. It is hard to schedule medical appointments and laboratory tests at the healthcare facility	68.67	6.99	24.34	1.56	0.81	0.35	0.14	0.20	0.00	-	-	-
36. It bothers me that I have to get my HIV meds refill in the healthcare facility's pharmacy	49.88	8.43	41.69	1.92	1.02	0.47	0.05	-0.05	0.53	1.80	0.00	0.29
37. I have accepted the diagnosis of HIV	32.45	14.04	53.51	1.79	0.81	0.45	-0.24	0.32	0.38	-	-	-
38. I take my HIV medication as prescribed so I will not feel ill	0.72	1.45	97.83	1.03	0.20	0.16	-	-	-	-	-	-
39. I believe that the HIV meds can reduce the amount of HIV virus in my blood	0.73	7.04	92.23	1.08	0.20	0.26	-	-	-	-	-	-
40. It is harder to keep track of my HIV meds on weekends	73.73	6.27	20.00	1.46	0.81	0.42	0.31	0.05	0.15	1.04	1.23	1.63

M: mean; r: item-total correlation; SD: standard deviation.

Notes: b1 and b2 = item severity parameter estimates.

* Response score categories contain: 1 = "disagree", 2 = "neither agree nor disagree", 3 = "agree";

** The scores of positively phrased items were reversed so that higher scores denote higher perceived barriers;

*** F1 = cognitive and routine problems, F2 = medication and health concerns, F3 = patients' fears and feelings;

a = item discrimination parameter estimates.

Figure 1

Test information functions for each PEDIA dimension and PEDIA's overall score.
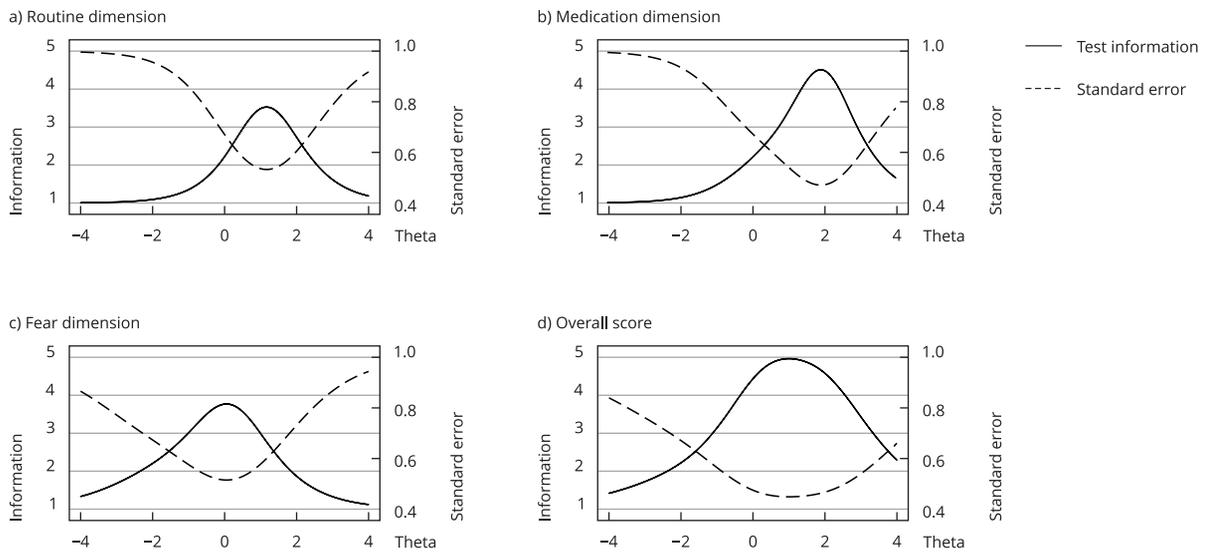
three dimensions: cognitive and routine problems (M0 = 5.74 *vs.* M3 = 5.76; p = 0.88); medication and health concerns (M0 = 7.87 *vs.* M3 = 7.61; p = 0.12); and patient's fears and feelings (M0 = 17.26 *vs.* M3 = 17.16; p = 0.75).

The evidence concerning the test-criterion relationship confirmed that the PEDIA was able to predict non-adherence. Independently of the other participants' characteristics, the odds of being non-adherent after three months was significantly higher for participants who scored 1 point more in the total scale (aOR = 1.12; 95%CI: 1.05, 1.21) and in each dimension: cognitive and routine problems (aOR = 1.23; 95%CI: 1.01, 1.49); medication and health concerns (aOR = 1.25; 95%CI: 1.08, 1.45); and patient's fears and feelings (aOR = 1.13; 95%CI: 1.01, 1.26).

The final version of the PEDIA (in Portuguese), together with instructions on how to compute the scale's scores, is available in the Supplementary Material (http://cadernos.ensp.fiocruz.br/site/public_site/arquivo/suppl-e00184218_1333.pdf).

Discussion

This study presents the development of a new patient-reported outcome measure to evaluate perceived barriers in patients on ART, the PEDIA scale. The 18-item PEDIA is a brief and simple tool that can help caregivers identify patients with poor adherence and develop individualized strategies to meet these patients' needs.

An important specificity of the PEDIA is that the perceived barriers are measured from the "what makes it difficult to take your medication" perspective, rather than assessing quantity or frequency, i.e., "how often or how much a given barrier has prevented you from taking your medication", as in other tools for evaluation of barriers to adherence [17,18]. This perspective gives PEDIA the advantage of measuring circumstances that could hinder adherence to therapy in the future (non-adherence has not necessarily occurred), rather than measuring reasons for skipping the medication (non-adherence has already occurred).

Findings suggest that, rather than reflecting a single unified construct, the perceived barriers encompass multiple dimensions, which corroborates theoretical concepts about medication-taking behaviors [9,41]. Although the PEDIA's pilot identified four dimensions (Supplementary Material, Table S1: http://cadernos.ensp.fiocruz.br/site/public_site/arquivo/suppl-e00184218_1333.pdf), only three were supported by the EFA. Other studies on the development and validation of scales also observed that the dimensions designed originally were not the same as the final dimensions [42,43]. Each of the three dimensions is conceptually equivalent to one of the original four dimensions or a combination of two. The dimension of cognitive and routine problems and the dimension of medication and health concerns are equivalent to the original dimension of factors related to ART regimens. On the other hand, the patient's fears and feelings dimension is equivalent to the original dimensions of emotional and social factors.

The items initially assigned to the dimensions representing economic and healthcare-related factors were not included in the PEDIA's final version. A possible reason for this finding is that, in Brazil, a national healthcare system provides universal medical care and medications to HIV-infected people. In these circumstances, patients may be grateful for the free service provided and may not perceive financial aspects or healthcare-related factors as potential barriers to their adherence to treatment. Further research is needed to explore this hypothesis.

It is important to note that the refinement of the measure was a dynamic process, involving both quantitative and qualitative approaches. Before being excluded, items with item-total correlation < 0.30 were subjected to a detailed analysis, which took in consideration the item's theoretical relevance. Items 9, 10, 19, 22 and 24, however, showed poor discrimination and low acceptance by the respondents, as observed using the Item and Category Characteristic Curves, and were therefore removed. The other items were added in the factor analysis and several attempts were made. The factorial solution with 18 items was the most robust and provided the greatest explanation of the variance.

The results of the IRT analysis suggested that some barriers are stronger discrimination indicators than others. For instance, items 5 ("Sometimes I skip taking my HIV meds because I want to avoid side effects"), 13 ("It is difficult to take my HIV meds at work") and 23 ("When I feel depressed I do not want to take my HIV meds") were found to have higher discriminating power. Caregivers may need to pay special attention to these barriers seeing as they are particularly useful to differentiate varied levels of the latent trait. The performance of the Test Information Functions suggested that the patient's fears and feelings dimension was informative in assessing a broad range of the latent trait. The other two dimensions offered great potential for assessing the higher level of the latent trait, and can thus be particularly useful for screening high-risk individuals with elevated latent trait levels.

In the logistic regression analyses, the odds of being non-adherent in the future were shown to increase as the PEDIA scores increased. Regardless of other important factors, such as adherence at the baseline, education and time on ART, the construct measured by the PEDIA scale had an impact on future adherence. The ability to predict non-adherence is a cornerstone of the treatment's success, seeing as non-adherence to ART is a central factor leading to incomplete viral suppression [44]. Furthermore, our results suggest that different types of barriers may show different behaviors in relation to non-adherence. The odds ratio for the dimensions of medication and health concerns and cognitive and routine problems were higher than the odds for the patient's fears and feelings dimension. Although the patient's fears and feelings dimension had the weakest association with non-adherence, concerns with stigma revealed to be prominent barriers to adherence in our sample.

The results of McDonald's ω and temporal stability demonstrate that the PEDIA is internally consistent and yields stable scores over time. Regarding the test-retest correlation, ICC indicated moderate reliability. As perceived barriers are expected to vary over time, we would expect only moderate levels of test-retest correlation. Shorter test-retest time intervals should produce somewhat higher correlations than longer intervals.

Gerend et al. [8] argue that ignoring the multidimensionality of perceived barriers by operationalizing them as a single composite unit may obscure critical information about the differential salience of specific barriers. Indeed, our logistic regression analysis showed that each dimension had a different impact on non-adherence. Therefore, we highlight the importance of evaluating each dimension separately rather than considering the overall score only.

This study had some limitations. Firstly, the confirmatory factor analysis was not conducted. Thus, the factor analysis results presented here should be considered exploratory and additional work is needed to confirm these assessments. Secondly, from the 15 items excluded due to low item-total correlation, 12 were positively-phrased items representing facilitators of treatment adherence. This result suggests that the facilitators are not necessarily mirroring the lack of barriers, as we initially thought. Thirdly, although the PEDIA was designed based on reports of both individuals with experience with ART and those initiating the therapy, evidence associated with its internal structure was evaluated using data from patients at the beginning of treatment only. This occurred because the validation process was part of a larger cohort study, which included patients initiating ART to obtain a homogeneous sample and detect the first event of treatment failure. The PEDIA was then administered to this population to evaluate its ability to predict non-adherence before treatment failure occurs. However, the PEDIA's items represent perceived barriers in all phases of treatment and, therefore, it could be administered to individuals at any point of their treatment. It is important to note that a first indication of the instrument's validity has been obtained with the present study. A measure's validation process is dynamic, and evidence accumulates over time for different groups. Therefore, further verification of the PEDIA's reliability and evidence of its validity will be necessary when using it in populations with experience with ART. Fourthly, we used self-reported non-adherence as variable, and there might be objective measures which are more suitable. However, the self-reported questionnaire was chosen because it is strongly correlated with detectable viral load measured six months later (data not shown).

A major strength of the PEDIA is that its items reflect multiple varied barriers identified by PLWHA with different backgrounds and characteristics in Brazil. Besides the fact that its list of items was developed using a national study, the sociodemographic and clinical characteristics as well as the prevalence of non-adherence to ART in our sample were similar to those of other studies in the Brazilian population using ART [45,46,47]. Another strength of our study is that the subsample size of 355 participants demonstrated enough power (> 80%) to identify significant differences (5% level) in the mean PEDIA scores between adherent and non-adherent participants.

The construct "perceived barriers" is particularly pertinent because it is potentially modifiable. The PEDIA's structure allows the evaluation and use of perceived barriers in three different ways: (1) general perceived barriers, by using the PEDIA's overall score. It could be used in the monitoring procedures for early identification of patients at risk of non-adherence; (2) three specific types of barriers, corresponding to the scores of each dimension. It may be used in the promotion of individualized care for identifying the specific barriers a patient needs to overcome; and (3) analysis of each item, corresponding to specific features within each dimension. It can be the basis for the development of behavior change interventions.

As a research tool, it may provide a valuable outcome variable, in addition to being used to compare the number and types of perceived barriers deemed as most relevant between adherent and non-adherent individuals. Finally, it can be used to assess the effectiveness of behavior change interventions. Using appropriate adaptation and translation procedures, the PEDIA may be adapted to evaluate the perceived barriers in other languages and cultures.

Conclusions

We have developed an 18-item patient-reported outcome measure with three dimensions, namely: cognitive and routine problems; medication and health concerns; and patient's fears and feelings. Our results suggest that the PEDIA is a psychometrically adequate tool for evaluating perceived barriers in adult patients initiating antiretroviral therapy in Brazil. In addition, it was suggested that the PEDIA may be useful for predicting non-adherence to ART. Future research will confirm the findings of this study with a wider population of patients in different contexts. The PEDIA could be used both in research and clinical practice for early detection of patients at risk of non-adherence and for identification of potentially modifiable barriers to medication adherence. The PEDIA has the potential to narrow the gap between the caregivers' and the patients' realities and support the implementation of individualized interventions to improve adherence.

Contributors

C. C. Almeida-Brasil contributed to the work's conception and design, participated in data collection, performed the analysis of the data and interpretation of the findings and was responsible for drafting the paper and approved the manuscript's final version. E. Nascimento contributed to the study's design, participated in data analyses, in the article's writing and in the interpretation of the findings and approved the manuscript's final version. M. R. Silveira and P. F. Bonolo contributed to the study's design, critically reviewed the work and approved its final version. M. G. B. Ceccato contributed to the study's design and conception, participated in the drafting of the article and interpretation of the findings, and approved the manuscript's final version.

Additional informations

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Resumo

Este estudo teve por objetivo o desenvolvimento e avaliação de uma nova medida de desfecho relatada pelo paciente para avaliar barreiras percebidas à adesão à terapia antirretroviral (TARV). A escala Percepção de Dificuldades com o Tratamento Antirretroviral *(PEDIA) foi desenvolvida com base em entrevistas com pacientes. Após teste piloto e avaliação de evidências com base no conteúdo do teste, revisões da escala resultaram em uma versão com 40 itens. A PEDIA foi aplicada em 415 adultos soropositivos para HIV que receberam TARV por um máximo de 180 dias, recrutados de três unidades de saúde de referência na cidade de Belo Horizonte, Minas Gerais, Brasil. As análises incluíram análise fatorial exploratória, consistência interna, teoria da resposta ao item, estabilidade temporal, e relação preditiva teste-critério. A versão final da escala contém 18 itens distribuídos em três dimensões, no caso: problemas cognitivos e de rotina (4 itens); preocupações com medicamentos e saúde (6 itens); e medos e sentimentos do paciente (8 itens). Resultados do ômega de McDonald e estabilidade temporal demonstram que a PEDIA é internamente consistente e produz escores estáveis ao longo do tempo. As funções de informação do teste sugerem que as três dimensões foram informativas na avaliação de uma ampla gama do traço latente. Evidências relacionadas à relação teste-critério confirmaram que a PEDIA foi capaz de prever não-adesão três meses depois. Nossos resultados sugerem que a PEDIA é uma ferramenta robusta do ponto de vista psicométrico para a avaliação das barreiras percebidas por pacientes adultos que iniciam TARV. Ela pode ser usada em contextos clínicos e de pesquisa para a detecção precoce de pacientes em risco de não-adesão e para a identificação de barreiras potencialmente modificáveis.*

Medidas de Resultados Relatados pelo Paciente; Psicometria; Infecções por HIV; Adesão à Medicação

Resumen

Este estudio se propone desarrollar y evaluar una nueva medida de resultados informados por los pacientes para evaluar los obstáculos percibidos en la adherencia a la terapia antirretroviral (ARV). Las barreras percibidas para la adherencia a la terapia antirretroviral según la escala Percepción de Dificultades con el Tratamiento Antirretroviral *(PEDIA) se desarrollaron basándose en entrevistas a pacientes individuales. Tras unas pruebas piloto, y evaluando evidencias basadas en el contenido de las pruebas, las revisiones de la escala resultaron en una versión de 40 ítems. PEDIA se administró a 415 adultos infectados de VIH que recibían ARV durante un máximo de 180 días, captados en tres centros de salud de referencia en la ciudad de Belo Horizonte, Minas Gerais, Brasil. Los análisis incluyeron el análisis exploratorio factorial, la consistencia interna, la teoría de respuesta al ítem, estabilidad temporal, y validez de criterio en las pruebas predictivas. La versión final de la escala final cuenta con 18 ítems distribuidos en las siguientes tres dimensiones: problemas cognitivos y rutinarios (4 ítems); medicación y problemas de salud (6 ítems); además de miedos y sentimientos del paciente (8 ítems). Los resultados del omega McDonald y la estabilidad temporal demuestran que PEDIA es internamente consistente y obtiene puntuaciones estables en marcadores con el paso de los años. Las pruebas de información sugirieron que las tres dimensiones fueron informativas, evaluando un amplio abanico de características latentes. Las evidencias respecto a la relación entre las pruebas y los criterios confirmaron que PEDIA era capaz de predecir la no-adherencia tres meses después. Nuestros resultados sugieren que PEDIA es una herramienta psicométrica para evaluar los obstáculos percibidos en pacientes adultos que comienzan una ARV. Se puede utilizar tanto en el entorno de investigación, como en el de la práctica clínica para una detección temprana de pacientes con riesgo de no adherencia y la identificación de obstáculos potencialmente modificables.*

Medición de Resultados Informados por el Paciente; Psicometría; Infecciones por VIH; Cumplimiento de la Medicación