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Development of an Easy to Use Tool to Assess HIV Treatment Readiness in Adolescent Clinical Care Settings

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Abstract

Optimal management of HIV disease requires high levels of lifelong adherence once a patient initiates highly active antiretroviral therapy (HAART). Because suboptimal adherence to HAART is associated with adverse consequences, many providers are hesitant to prescribe HAART for patients whom they perceive as not being ready to initiate treatment. Accurately predicting HIV treatment readiness is challenging. Despite the importance of this construct, few reliable and valid instruments to assess HIV treatment readiness have been developed; none of these have been validated with adolescents and young adults, who comprise an increasing proportion of new HIV cases diagnosed. As a first step to achieve this goal, we developed the HIV Treatment Readiness Measure (HTRM) for administration via audio-computer-assisted self interview and conducted a study to examine its internal consistency, test-retest reliability, acceptability, and preliminary factor structure. We recruited 201 youth from 15 adolescent medicine clinics that were part of the Adolescent Trials Network for HIV Interventions. Youth completed the initial assessment and two weeks later the re-test assessment. The refined HTRM had high internal consistency ($\alpha = 0.84$). Test-retest reliability using both sum scores and mean scores were high. The HTRM was also highly acceptable and feasible to use in routine clinical practice. In exploratory factor analysis we found that a five-factor solution was the best fit; each of the subscales (*Disclosure, Psychosocial Issues, Connection with Care, HIV Medication Beliefs, Alcohol and Drugs*) had good to acceptable alphas and eigenvalues greater than 2.0. Our findings support conducting a future study to examine the tool's predictive validity.

INTRODUCTION

Unlike many other chronic conditions, optimal management of HIV disease requires high levels of lifelong adherence once a patient initiates highly active antiretroviral therapy (HAART) to achieve continuous viral suppression that results in improved outcomes (Bartlett et al. 2000; Hammer, Saag, Schechter, Montaner, Schooley, Jacobsen, et al. 2006). Suboptimal adherence (e.g., not taking any medications, taking less or more medication than prescribed, and not taking doses at the appropriate frequencies) continues to be a significant health concern and has implications for the long term management of HIV disease (Golin et al., 2002). Suboptimal adherence can decrease treatment benefits and has been linked to HIV drug resistance and treatment failures (Montaner et al., 1998; Paris et al., 1999;

Bangsberg et al., 2004). Studies have shown that virologic failure is more commonly due to suboptimal adherence than drug formulation or drug resistance (Descamps et al., 2000). In addition, HIV strains that mutate due to suboptimal adherence can then be passed on to newly infected individuals, making them resistant to many HAART regimens despite never having taken these regimens (Wainberg & Friedland, 1998). Given the potential for adverse consequences of failure to adhere, many providers are hesitant to prescribe HAART for patients whom they perceive as not being ready to initiate treatment.

A patient who is not ready or willing to begin HAART will likely not adhere to the treatment regimen, placing him or her at increased risk for drug resistance and treatment failure (Montaner et al., 1998; Paris et al., 1999; Bangsberg et al., 2004). For many of these patients, delayed readiness to initiate HAART after diagnosis has been associated with denial, hopelessness, anxiety, confusion, depression and suicidal ideation (Morgenstern et al., 2002), factors which can impact the individual's likelihood of adhering to HAART once he or she has begun treatment. Because medical management of HIV disease requires adherence to a continuous, non-ending treatment regimen, this seeming "unendingness" of treatment can hinder adherence (Safren et al., 1999) and requires a degree of psychological readiness to begin and sustain treatment. In addition, since many patients starting HAART are asymptomatic, the side-effects of the medication can make patients feel worse than when they were not taking medication, further impacting adherence (Reynolds & Neidig, 2002). Many patients (Morgenstern et al., 2002) do not initiate treatment immediately after HIV diagnosis even if they meet DHHS guidelines. Since the initial therapeutic regimen is usually the most appropriate and the one most likely to result in the best treatment outcomes (Nordqvist et al., 2006), a continued challenge for many HIV treatment providers is accurately predicting whether or not a patient is ready to initiate HAART therapy in order to balance clinical need with the individual's readiness to begin treatment (Fogarty et al., 2002; Bogart et al., 2001; Murri et al., 2002).

However, accurately predicting which patients are ready to initiate treatment and thus adhere to the prescribed regimen is difficult (Fogarty et al., 2002; Bogart et al., 2001; Murri et al., 2002). The challenges are even more pronounced when making treatment decisions for adolescents and young adults whose cognitive abilities and developmental stage may make it more difficult to achieve good adherence (Hosek, Harper & Domanico, 2005). Despite the importance of the construct, few reliable and valid instruments to assess HIV treatment readiness have been reported in the literature (Willey, Redding, Stafford, Garfield, Geletko, Flanigan, Melbourne, Mitty, & Caro 2000; Kennedy, 2000; Fleury, 1994; & Highstein, Willey, & Mundy. 2006; Balfour, Tasca, Kowal et al., 2007; Rathbun, Farmer, Stephens, 2007). None of these has specifically been validated for adolescents and young adults.

A number of factors have hampered the development of a clinically useful tool to assess treatment readiness. First, although treatment readiness has been demonstrated to be a distinct construct that can be assessed independently of adherence (Södergard et al., 2007), a widely accepted definition of the construct has yet to be developed. Two theories of motivation and change (Wellness Motivation Theory [WMT], Fleury, 1991; Transtheoretical Model of Change [TMC], Prochaska & Velicer, 1997; Nordqvist, 2006) have guided efforts to define the construct. WMT views readiness as a "separate step that precedes change" whose goal is to increase "empowering potential" as the individual moves/proceeds through three distinct stages in a stepwise manner. (Nordqvist, 2006, pp. 22-23) In contrast, TMC views readiness and change as a continuum that lasts almost throughout an individual's entire treatment (Prochaska & Velicer, 1997; Nordqvist, 2006). Consequently, these competing perspectives have resulted in differing conceptualizations and measurement approaches and lack of standardization (Nordqvist et al., 2006). Second, rather than focusing research attention on the construct of readiness *per se*, some researchers have examined

readiness as one of the factors determining the efficacy of adherence interventions (Balfour et al., 2006; Wagner, 2003; Wagner et al. 2002), while others have developed tailored interventions to improve readiness for treatment (Grimes & Grimes, 1995). Although some advances in identifying the key components of readiness have been made (Enriques et al. 2004; Södergard et al., 2007), few standardized and valid tools to assess the construct *per se* are currently available. Lastly, despite the growing number of adolescents and young adults living with HIV/AIDS, efforts to examine treatment readiness within this population are limited. In our literature review, we did not find a single tool to assess treatment readiness validated specifically in this population. There is a critical need for a reliable and valid tool to assess readiness for antiretroviral treatment among adolescents and young adults that could be easily integrated into routine care.

As a first step towards achieving this goal, a multidisciplinary team of experienced behavioral scientists and HIV adolescent medicine providers developed a conceptual definition of treatment readiness (a measure of an individual's likelihood of successfully initiating and adhering to his/her HIV treatment regimen that includes influences of psychological, social, and environmental factors as well as access to care issues) and developed the HIV Treatment Readiness Measure (HTRM) to assess the construct. We then conducted a study as part of the Adolescent Trials Network (ATN) for HIV interventions (*Protocol ATN 065: Development and Validation of the HIV Treatment Readiness Measure*) to examine the tool's psychometric properties among adolescents and young adults. In this paper, we report the internal consistency, test-retest reliability, acceptability, and preliminary factor structure of the HTRM and describe how we arrived at a more parsimonious version of the tool whose predictive validity we plan to examine in a future ATN protocol.

METHODS

Development of the HIV Treatment Readiness Measure

We conducted a thorough literature review to identify factors associated with the construct of readiness, as well as those related to treatment adherence and examined the few instruments designed to assess readiness available in the published literature (Willey, et al., 2000; Kennedy, 2000; Fleury, 1994; & Highstein, et al., 2006; Balfour, et al., 2007; Rathbun, et al. 2007). From these efforts, we identified key components and created items to assess each of them. These key components are: 1) attitudes toward HIV medication; 2) provider characteristics; 3) support system; 4) control of life; 5) intentions to adhere to medication; 6) psychosocial issues; 7) disclosure; and 8) use of alcohol and drugs. As described in the measures section below, the HTRM consisted of 49 items, the majority of which were scored on a 5 point Likert-type scale (strongly disagree [1] to strongly agree [5]). To guard against response bias, we ensured that approximately 50% of the items required reverse coding prior to analysis. Because our intention was to develop a tool that could easily be incorporated into routine care, we designed the tool for administration via audio computer-assisted self interview (ACASI) a format which is easier to use in clinical settings than paper and pencil questionnaires, and one which will support programming of a scoring algorithm during routine clinical use.

Participants

From May 2008 to February 2009, we enrolled 201 adolescents and young adults living with HIV from 15 adolescent medicine clinics in the United States affiliated with the ATN. To be eligible, youth had to be: 1) living with HIV or AIDS; 2) 14 to 24 years of age, 3) not having taken HAART for at least 30 days prior to enrollment (includes both HAART naïve and experienced patients) and medically indicated to initiate HAART within the next 2 months;

4) enrolled in care at one of the ATN sites; and 5) able to speak and understand English. Almost 90% of youth completed both the initial as well as the retest assessment.

The sample characteristics are summarized in Table 1. The mean age was 20.5 years ($SD=2.5$) and the majority (88%) were born in the U.S. Two-thirds of the sample was male; 48% of the sample identified as gay and 15% as bisexual. Forty percent of the females had been pregnant at least once in their lives. Seventeen percent of participants were perinatally infected while 74% had acquired HIV sexually. Two-thirds of the sample was treatment naïve and the remainder was treatment experienced.

Measures

The assessment battery consisted of demographic questions, the HTRM, and 7 questions designed to assess the tool's acceptability.

Demographic Factors—Youth reported their age, gender, race, education, and sexual orientation. Demographic information was collected at the initial assessment only.

Previous Experience with HAART—Youth reported whether or not they had ever been prescribed HAART prior to the current prescription. The subset of youth who had been prescribed HAART in the past, also reported the circumstances surrounding their prescriptions (e.g., took HAART during a pregnancy, etc.) and whether or not they actually took their prescribed HAART regimens.

HIV Treatment Readiness Measure—The HTRM consisted of 49 items designed to assess the main domains (attitudes toward HIV medication; provider characteristics; support system; control of life; intentions to adhere to medication; psychosocial issues; disclosure; and use of alcohol and drugs) that have been associated with treatment readiness and adherence. With the exception of the section on alcohol and drugs, which require frequency responses, all items are rated on a 5 point Likert-type scale ranging from “strongly disagree” (1) to “strongly agree” (5).

Acceptability Questionnaire—Youth completed 7 items rated on a 5 point Likert-type scale ranging from “strongly disagree” (1) to “strongly agree” (5) regarding the understandability and relevance of the items, as well as their experiences taking the HTRM.

Procedures

Recruitment and Screening—In consultation with clinical providers, study coordinators at each of the participating ATN sites identified HIV positive youth not currently taking HAART. Research staff approached potential participants to describe the study during their regularly scheduled clinical care appointment. If the youth was interested, staff obtained verbal consent to administer a brief screener to determine eligibility. All youth who were eligible were invited to participate. Written informed consent was obtained from the participant, if appropriate. Participant assent with written parental/guardian permission was obtained as determined by local Institutional Review Boards (where required) before any study related procedures were performed. The protocol was approved by the Institutional Review Boards at each of the participating ATN sites and those of all protocol team members.

Assessment Procedures—Data were collected at two time points using ACASI. In this mode of data collection, the respondent listens to a recorded human voice and responds to the questions using a computer keyboard or mouse. Not only does it elicit more frequent reporting of socially sensitive behaviors than face-to-face interviews, but it also eliminate

interviewer bias, standardizes administration and reduces skip pattern errors (Newman, Des, Turner, Gribble, Coley, & Pone (2002) . The majority of participants completed the first assessment shortly after providing informed consent. The second assessment was completed two weeks (± 2 days) from the date of the initial assessment (a standard retest window when assessing test-retest reliability of a fluid construct). At each participating ATN site, ACASI stations dedicated to the current study were set up in safe and private places to heighten participants' comfort level and protect their confidentiality. Research staff escorted participants to the ACASI station, entered a study ID, and provided instructions on completing the assessment. Participants were encouraged to seek assistance, if needed, as they completed the assessment. Upon completion of the initial assessment, youth were given an appointment for the second assessment. The assessment took approximately 15 minutes. Youth received a token compensation (determined by the local IRB) after each assessment for their time and effort.

Analyses

To examine the internal consistency of the scale, we computed Cronbach's alpha using the 201 participants who completed the initial assessment and trimmed items as necessary to improve internal consistency. Then we used Pearson's product-moment correlations to determine test-retest reliability of the refined instrument. Test-retest analyses were based on the 179 participants who completed both assessments. In addition to examining the item by item correlations, we used two separate scoring methods (sum score and mean score) to examine test-retest reliability of the instrument as a whole. For both the initial and the re-test assessments, we scored the instrument in these two ways and then calculated the correlation coefficients for each scoring strategy. To examine acceptability, we calculated the proportion of participants who positively endorsed (agreed or strongly agreed) each of the acceptability items and examined process indicators, such as patterns of skipped questions and number of youth who prematurely discontinued the questionnaire. To determine potential factors to guide scoring of the instrument and its predictive validity (both to be investigated in a future study), we conducted a confirmatory factor analysis using the theoretical factor structure that had guided development of the tool; however, the subscales that had been created *a priori* performed poorly in the analyses. As a result, we conducted an exploratory factor analysis utilizing a varimax rotation. We selected a varimax rotation to best differentiate the highest-loading factor for each item (thus enhancing interpretability). The factors generated were not correlated, thus upholding the necessary orthogonality assumptions of a varimax rotation. *Post-hoc* analyses utilizing other rotation methods produced similar factor structures. We examined scree plots and eigenvalues for 2 to 11 factor solutions to determine the best fitting, most parsimonious factor structure.

RESULTS

Factor Structure and Internal Consistency

In keeping with the goal of developing an instrument that could be easily interpreted and thus incorporated into routine clinical care, we determined that the 5 factor solution was best. The factors were: (1) Disclosure; 2) Psychosocial Issues; 3) Connection with Care; 4) HIV Medication Beliefs; and 5) Alcohol and Drug Use (See Table 2). Each of the five factors had eigenvalues at or above 2.0, and the five-factor solution accounted for 47% of the variance. We then examined the set of items composing each of the 5 factors from both an internal consistency and theoretical perspective and assigned items that loaded strongly on multiple factors to the factor which made the strongest conceptual and theoretical sense. Items with poor reliability, as well as items deemed redundant with other items were trimmed. In addition, we excluded items with binary outcomes from the factor analysis, but not the overall scale, because binary outcomes are unsuitable for factor analyses. These

efforts yielded a more parsimonious instrument composed of 38 items, an acceptable number of cases per item ($n=5.3$) to conduct the item level factor analyses on the reduced scale.

The refined HTRM had high internal consistency (0.84), well above the 0.70 traditional threshold (Nunnally, 1978). In addition, the internal consistency of three of the five subscales (Disclosure, Psychosocial Issues and HIV Medication Beliefs) was also high; alpha coefficients ranged from 0.78 to 0.83. The alpha coefficients for the other two subscales (Connection with Care and Alcohol and Drug Use) were 0.63 and 0.62, respectively. Given the high internal consistency of the total scale, these two marginal values provide evidence of moderate internal consistency of these subscales.

Test-Retest Reliability

Most items were significantly correlated at the $p < 0.05$ level for the two administrations. Two items with low correlation (<0.3) were retained because of their theoretical contribution to the scale and positive contribution to the internal consistency of the overall instrument and the factors. Test-retest reliability for both methods of scoring was high. The sum scores for the initial and retest assessments were highly correlated, with a correlation coefficient of 0.857 ($p < 0.001$). The mean scores for the initial and retest assessments were also highly correlated, with a correlation coefficient of 0.865 ($p < 0.001$).

Acceptability

As seen in Table 3, the HTRM was highly acceptable. The majority of participants indicated that the questionnaire was easy to take, that the questions made sense, that the answer choices were good, and that the questions focused on issues that were real to young people. Furthermore, the majority (87%) felt safe answering the questions. Only 4% indicated that the questions were hard to understand. In examining process measures, we discovered that the items related to alcohol and drug use were most frequently skipped (item 5 and 31); 8% of participants refused to answer these questions. While not all questions were answered by each participant, no one started the questionnaire without finishing, suggesting a high degree of acceptability.

DISCUSSION

As the number of adolescents and young adults living with HIV/AIDS continues to grow, an increasing number of clinicians are faced with deciding whether or not to initiate HAART therapy with their younger patients. Because suboptimal adherence to these therapies can compromise a patient's long term health outcomes, an important consideration in making treatment decisions is determining a patient's readiness to initiate HAART. However, a reliable and valid assessment tool that could help guide decision-making in routine clinical care is not currently available for adolescents and young adults. The goal of this study was to take the initial step in measurement development by creating such an instrument, determining its reliability, and examining its factor structure. In a future study we plan to further investigate scoring options and examine its predictive validity.

The results of our study suggest that the refined HIV Treatment Readiness Measure we developed has sound psychometric properties and good test-retest reliability. Although our theoretically derived factor structure was not supported by the confirmatory factor analysis, the exploratory factor analysis yielded a factor structure that was empirically and theoretically sound. More importantly, the five factor solution yielded a more parsimonious tool with greater utility for routine use in clinical care. Notwithstanding, further discussion of the process through which we arrived at a five factor solution is warranted.

One of the most important considerations in designing this study was the necessity of developing a tool that was feasible for use in clinical settings and acceptable to the youth to whom it was administered. Of note, 87% of youth felt safe answering the questions because they knew that no one could see their answers, highlighting the idea that youth may not feel comfortable honestly conveying their readiness for treatment to their providers. Furthermore, although most clinicians incorporate their perceptions of patients' readiness to initiate treatment when determining their patients' medication regimens, research demonstrates that clinical judgment alone correctly predicts a patient's adherence only 50% of the time (Tsasis, 2001). Thus, developing a readiness tool that can be administered using ACASI and programmed to automatically compute a readiness score not only increases the feasibility of the tool in busy clinical settings, but increases the likelihood that patients will honestly report their concerns and identify barriers to starting HIV treatment.

The version of the HTRM that emerged following these analyses appears to satisfy initial characteristics required of an effective instrument to assess treatment readiness (acceptability, internal consistency, and test-retest reliability). However, given the lower alpha levels for the Connection to Care and Alcohol and Drug Use subscales, we will conduct further developmental work to improve internal consistency before moving to the next stage of instrument development. Once this is completed, we will develop a scoring structure and test the predictive validity of the HTRM. By investigating the preliminary factors that emerged in these analyses in light of actual adherence of participants, we will be able to establish a scoring system that incorporates the overall importance of each item as well as each factor in predicting how ready an individual is to begin treatment. A reliable and valid treatment readiness measure can provide guidance to physicians in deciding the optimal time to start HAART and identify patients in need of intervention services to increase their readiness to initiate. Social workers and health educators may use the tool to help identify patients with a need to increase their readiness to initiate treatment and to reduce barriers they might have with adhering to their treatment regimens.

The HTRM appears to be a reliable, theoretically-sound, and developmentally-appropriate tool that is feasible to use in clinical settings and acceptable to youth living with HIV. While these results are encouraging, the predictive validity of the HTRM has yet to be tested and future studies are still urgently needed.

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Table 1

Sample Characteristics

Characteristic	
Age ^I	20.5 (2.5)
Percent less than 18 years old	11%
Gender	
Male	67%
Female	31%
Transgender	2%
US-born	88%
Currently in school	45%
Employed	42%
Household size ^I	4.6 (3.0)
Number times moved in past 12 months ^I	1.4 (1.0)
Ever been pregnant (females only)	40%
Have children	14%
Sexual orientation	
Straight	37%
Gay	48%
Bisexual	15%
Method of HIV infection	
Perinatal	17%
Sexual contact	74%
Drug use	0.5%
Transfusion	1%
Other (unspecified)	7.5%
Treatment experienced	34%

^I Mean and standard deviation

Table 2**Factor Structure and Internal Consistency Estimates of the Revised HTRM (N=201)**

Factor One: Disclosure ($\alpha = 0.779$; $\lambda = 7.4$; rotated variance accounted: 10.7%)

- Most of the people I live with know my HIV status.
- Most of my family and friends know my HIV status.
- I feel supported by my family and friends when times are tough.
- My family and friends who know I have HIV would help me remember to take my medications.
- I shouldn't tell the people I live with that I have HIV. (R)
- How many people you live with have you told your HIV status?

Factor Two: Psychosocial Issues ($\alpha = 0.826$; $\lambda = 3.8$; rotated variance accounted: 10.0%)

- I feel like I have a stable place to live.
- Sometimes a homeless shelter is the only place I have to sleep. (R)
- I feel confused about what to do about my HIV. (R)

In the past month, how often have you

- Felt lonely or sad. (R)
- Been told you seem sad or depressed. (R)
- Felt isolated or lonely, even when around other people. (R)
- Felt that things were going your way.
- Felt confident in your ability to handle your personal problems.
- Felt you could not cope with all the things you had to do. (R)

Factor Three: Connection with Care ($\alpha = 0.633$; $\lambda = 2.7$; rotated variance accounted: 9.8%)

- I would know how to contact my pharmacist or medical provider if I had problems or questions about HIV medications.
- If I don't take HIV medications exactly as instructed, the HIV in my body will become resistant to the medications.
- I have a strong, trusting relationship with my medical provider.
- I would know who and when to call for refills for HIV medications.
- Even when it may be difficult, I will be able to let my medical provider know if I miss doses of HIV medications.
- I regularly go to the clinic and meet with my medical provider.

Factor Four: HIV Medication Beliefs ($\alpha = 0.793$; $\lambda = 2.1$; rotated variance accounted: 9.1%)

- I am ready to start taking HIV medications.
- I believe taking HIV medications can keep me healthy.
- Taking HIV medications would give me bad side effects. (R)
- Taking HIV medication would not really help me. (R)
- HIV medications would be poison to my body. (R)
- I want to start taking HIV medications.
- Despite having HIV, I can move forward with my life.
- My household members who know I have HIV would help me remember to take my medication.
- Taking HIV medications as prescribed would keep me from getting sick.
- I would take HIV medications even if they made me sick at first because the side effects would go away.
- I know that I will be able to take all of my medication correctly.
- It would be important to me to take HIV medication correctly and on time every day.

Factor Five: Alcohol and Drug Use ($\alpha = 0.623$; $\lambda = 2.0$; rotated variance accounted: 7.4%)

In the past 3 months, I found myself wishing I hadn't used street drugs so often. (R)

In the past 3 months, I found myself wishing I hadn't drunk alcohol so often. (R)

In the past 3 months, I have been drunk. (R)

In the past 3 months, I have used marijuana. (R)

In the past 3 months, I have used drugs such as crack, meth, or cocaine. (R)

Total Scale: $\alpha = 0.842$; rotated variance accounted: 47.1%

α : Cronbach's alpha

λ : eigenvalue

(R): reverse-coded items

Table 3

Acceptability Ratings

	Strongly Agree/Agree
The questionnaire was easy to take	95%
Most of the questions were hard to understand	4%
I knew what to answer for the questions	90%
I felt as though the questions made sense	94%
I did not feel like the answer choices were good on the questionnaire	6%
Many of the questions focused on issues that were real to young people like me	89%
I felt safe answering the questions because I knew that no one in the clinic can see my answers	87%