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Readiness: The State of the Science (or the Lack Thereof)

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Abstract

HIV treatment guidelines state that patients' readiness should be assessed before initiating highly active antiretroviral therapy (HAART) to assure adherence. None of the guidelines provide a way to measure readiness. Therefore, this article sought to review the literature on readiness to determine if there was a viable predictor of adherence. Twenty-seven articles were reviewed. Nine described studies that examined the relationship between a measure of readiness and HAART adherence. No readiness measure demonstrated clinical utility as a predictor of adherence. Study flaws included small sample sizes (only one study >100 patients), short follow-up periods (all ≤ 1 year and six were ≤ 5 months, four ≤ 1 month), measures of readiness that related poorly to adherence, and inconsistent adherence measures (eight different measures were used by the researchers). Neither the guidelines nor the literature will help clinicians judge who should initiate HAART and who should delay treatment.

Keywords

Readiness; Antiretroviral therapy; Adherence; HIV; AIDS

Introduction

A number of guidelines suggest how antiretroviral treatment should be administered to HIV-infected persons. The guidelines differ in when to start highly active antiretroviral therapy (HAART) and which drugs are preferred. They agree, however, that HAART should not be started until a patient is "ready." The British HIV guidelines state that patients with CD4 counts between 200 and 350 cells per mm^3 should only start therapy if they are ready. This expert panel recommends that if the CD4 count is below 200, therapy should be started without any apparent regard for readiness [1]. The US Department of Health and Human Services guidelines emphasize in several places that therapy should be started after an assessment of readiness [2]. The International AIDS Society–USA Panel also recommends assessing readiness before initiating therapy [3]. However, none of these expert groups offer guidance on how to assess readiness. The European AIDS Clinical Society's guidelines stress the importance of assessing readiness and offer a list of items that are to be considered in assessing readiness with an explanation of their use. The guidelines do not explain how to measure the items nor do they

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suggest what weight should be given to the items in the list [4]. The World Health Organization's guide provides a list of questions that might be asked in order to ascertain the levels of readiness. Again, there is no measurement tool nor is there any advice on how to establish a cutoff point for those who should or should not receive care [5]. So, while the latter two groups' lists could assist the clinician in examining for readiness, the lack of a metric for judging ready versus unready greatly limits their clinical utility.

Guidelines writers are concerned with readiness because it is essential that medication be taken as prescribed. Failure to take medication as directed (being unready) leads to the development of drug-resistant virus, increasing numbers of circulating virus and speeding up of disease progression [6]. Greater than 95% adherence to prescribed medications has been demonstrated to be necessary to control the virus [7,8] Such a high level of adherence is very difficult to achieve because missing more than 20 doses in a year for a once-daily regimen puts the patient below the 95% level of adherence. So, making certain that patients are ready to take all of their medications is crucial.

While the guidelines recognize the importance of readiness, they do not address the concept in a way that would be useful to a practicing clinician who must make decisions about who should start therapy and who should wait. No one would advise clinicians to do laboratory tests before prescribing HAART without designating which assays should be done or how to interpret the test values. So, it seems prudent to have some agreed-upon approaches to defining and/or measuring readiness. The authors of this article conducted a systematic review of the published literature to identify measures of readiness and whether these measures have been found to predict future adherence to HAART.

Methods

The authors searched Medline, PubMed, and PsycINFO using the terms 1) ready or readiness, 2) HIV or AIDS, and 3) HAART or antiretroviral therapy for publications since 1996. This date was chosen because it is when HAART became more available. An additional source for articles on readiness was an excellent readiness review by Nordqvist et al. [9••]. All articles that Nordqvist et al. had referenced were reviewed and another search was done to identify any articles that had referenced articles in the Nordqvist et al. bibliography. These articles were examined to determine if they referred to readiness to initiate or reinstate HAART, or readiness to enter care. While there is extensive literature dealing with readiness in behavior change areas such as weight loss, substance abuse, smoking cessation, and other lifestyle changes, these were not included for review. Readiness articles dealing with other diseases were excluded because HAART is unique in that it requires lifelong commitment to taking multiple medications. Only those articles that contained either a definition and/or measures of readiness (or implied readiness) to HIV treatment and/or care were included. Conceptual articles were included if they provide good illustrations of a theoretical construct of readiness. Additionally, the references of included articles were searched for additional papers of interest. Although our search was comprehensive and systematic it was not exhaustive in that we only accessed the published literature. All articles were reviewed by both authors of this review.

Results

Description of the Published Literature

Twenty-seven articles published between 1998 and 2010 were included in this review (see Tables 1 and 2). Six of the articles reported qualitative interviews describing the experiences of patients and their readiness or non-readiness for care or treatment, while two articles were essays on readiness. Nineteen studies had a quantitative design. The number of participants in the quantitative and qualitative studies ranged from 12 to 997 HIV-infected persons. These

persons were recruited from outpatient clinics in major cities in the United States, Canada, the United Kingdom, Switzerland, Sweden, Germany, Australia, and Ethiopia. Nine quantitative studies analyzed the relationship between a measure of readiness and a measure of adherence to HAART (Table 2).

Conceptualization and Measurement of Readiness

These articles defined and/or measured readiness using six different conceptualizations. Four authors applied the trans-theoretical model (TTM) of Prochaska and DiClemente [10]. They conceptualized readiness as being one or more of the five TTM stages of change from pre-contemplation, contemplation, preparation, action, and maintenance [11–13,14•]. All four studies measured readiness with a two-item questionnaire to ascertain where the patients were in their decisions about HAART (to differentiate the first three stages of TTM) and how long they have been taking their medications as prescribed (to differentiate the last two stages) at the time they completed the questionnaire.

Others [15•,16•,17–21] have based their conceptualization on motivation or on Fleury's wellness motivation theory (WMT) [22]. Enriquez was the first to apply WMT in HIV/AIDS care and described readiness as including three steps in the model: evaluation of behavior with desire to change; identification of barriers and strategies to overcome the barriers; and valuing the new behavior enough to accept responsibility for change [17,18]. Three researchers who used the WMT [15•,16•,18] measured readiness with Fleury's 30-item index of readiness scale. Two other studies claimed to be based on the WMT and measured readiness with five questions to ascertain beliefs regarding treatment and care providers [20,21]. Although Sodergard et al. [19] described the information, motivation, and behavioral skills model, they measured motivation by asking two questions: 1) How motivated are you to use current treatment (0–100 on a visual analog scale)?; and 2) How sure are you that the medication will have a positive effect on your health?

Some authors theorized that readiness is a knowledge-based concept that sorts the ready from the unready based on their knowledge that HAART is good and that taking it as directed is beneficial [23–25]. Two of these authors measured knowledge readiness by testing the knowledge of participants [24,25].

Those authors who conceptualized readiness as decision-making measured readiness by whether participants had declined or accepted treatment [26–29], by the length of time to accepting care [30], or by qualitative information on why participants declined/accepted treatment [31].

Two papers describe readiness as a general psychological variable. Grimes and Grimes [32••] conceptualized readiness as a personal judgment and measured it by asking patients to indicate their level of readiness by two methods: 1) as a point on a visual analog scale ranging from “not ready at all” to “completely ready”; and 2) on a Likert-type scale. Balfour et al. [33] measured readiness for treatment with a 10-item medication readiness scale with values on each of 10 questions ranging from 0 = “not at all ready” to 4 = “completely ready.”

Others equated readiness with adherence to treatment or care [34–36•,37•,38]. For example, Wagner and colleagues [36•,37•] measured readiness by which participants achieved >90% adherence as measured by an electronic monitoring device in a placebo trial.

Relating Readiness to Adherence

Nine studies (Table 2) examined whether a measure of readiness predicted adherence to antiretroviral therapy. All were prospective studies with follow-up times ranging from 4 weeks to 1 year. The number of subjects in these trials ranged from 19 to 142.

Adherence was measured by four different methods in the nine studies, and some of the studies used more than one method. Three studies measured adherence by viral suppression [11,15•, 18]. Four studies employed electronic monitoring devices that were placed on medication bottles and that recorded when the bottles were opened [12,13,36•,37•]. Five different self-report scales were used in four different studies [11,13,16•,37•]. One study employed pharmacy refill records to calculate the percent of the prescribed drugs that patients had available to them during the time period [32••].

Not only does the research vary on measures of adherence but the studies vary widely on measures of readiness. The nine studies utilized six different measures of readiness: the 10-item medication readiness scale; the 30-item index of readiness; a stages of change questionnaire; a two-item stage of readiness instrument; a two-question self-assessment of readiness; and a measure of readiness based on adherence during a placebo trial.

The researchers who based their research on the TTM used a two-item questionnaire to determine where patients were on the stages of change continuum. Willey et al. [13], who developed the scale, used it on 161 patients and found a good relationship between the instrument and adherence for 30 days as measured both by an electronic monitoring device attached to the patients' medication bottles and by patient self-report. A follow-up study using this scale on 103 women related it to suppression of viral load to undetectable levels. While a relationship was found, the small number of patients studied rendered the scale not sufficiently predictive to be used in determining who should start therapy [11]. Rathbun et al. [12] used this instrument in 31 patients who were starting therapy and found it to be a poor predictor of adherence at both 4 and 16 weeks as measured by an electronic monitoring device.

Other researchers based their studies of readiness and adherence on the wellness motivation theory. Enriquez and colleagues [18] conducted two studies in patients who had previously failed HAART regimens, using undetectable viral loads as the measure of adherence. One study with 19 patients who were beginning a new regimen used a 30-item questionnaire that consisted of three subscales. After 6 months on therapy, those who had a viral load of <400 copies were compared with those with detectable loads. The subscale that measured the patient's ability to identify barriers was related to adherence. The second study used the 30-item scale on 28 patients. There was a marginally significant relationship ($P=0.06$) between the readiness score and viral loads at 3 months [15•].

Of those who used the psychological approach, Balfour et al. [16•] conducted a study that looked at readiness as a psychological state as measured by a 10-item scale and adherence as measured by a composite of two different self-reported adherence scales at 4 weeks after starting therapy. This was found to be a reasonable predictor of adherence but the time frame was far too short to judge the scale's utility. Grimes and Grimes [32••] asked 39 patients to judge their own readiness and linked it to prescription renewals over a 5-month period. They used both a Likert scale and a visual analog scale as the measures of readiness. They found that patients' beliefs about their readiness on either scale did not predict their adherence.

Wagner and colleagues [36•] had patients take placebos for a period of time and monitored them with an electronic measuring device. Those who were not able to achieve >90% adherence in the practice trial were counseled and then were given another placebo trial. This was repeated up to five rounds before patients were allowed to start HAART. So, readiness was defined as having shown readiness in a placebo trial. Of the 15 patients who achieved "readiness," 87% achieved >90% adherence, as measured by the electronic measuring device during the first month of therapy. However, this approach was much less successful in a larger trial in substance-abusing patients that was conducted for a longer period of time [37•].

Conclusions

The results of this review did not find a consistent definition of readiness, nor a relationship between various concepts of readiness and actual adherence behavior. A patient characteristic deemed vital by clinical experts from around the world has not been consistently conceptualized nor is it measured in a way for clinicians to determine who should start therapy and who should wait. The multiple conceptualizations of readiness are based on several behavioral models/theories. Each is logical but all seem incomplete. The concept is viewed by both researchers and guideline writers as one-time concept dealing with initiating therapy or relating it to adherence at some point in the patient's course of taking HAART. The reality of antiretroviral therapy is that readiness is an "over-and-over" state of mind. Each day or multiple times per day, HIV-infected persons must be "ready" to take their pills. Patients must be "ready" to initiate therapy every time their prescriptions run out. They must be "ready" to call and order prescriptions or to attend clinic to obtain renewals and be "ready" to go to a pharmacy to pick them up. Life circumstances change and barriers and facilitators to readiness will disappear and reappear over the course of the patient's life. Believing that a readiness measure that makes a valid prediction for a person starting HAART in 2010 will be able to predict the patient's adherence behavior in 2012 or 2020 seems like a demand for a crystal ball rather than a psychometric instrument.

The studies that have measured readiness in an attempt to predict future adherence are of little use to a practicing clinician. The studies have been conducted on small numbers of patients in a handful of locales and the patients have been followed for very short periods of time—often as little as a month. It would seem that, if any of them were applied to a clinic population and if the results were used to prescribe or not prescribe HAART, they would be more likely to be wrong than right in predicting future adherence. Many of the other studies are qualitative in nature and are hypotheses-generating studies rather than hypotheses-testing.

Another difficulty with studying readiness and its relationship with adherence is that there is no agreed upon measure of adherence. Researchers of readiness have used electronic recording devices, several different kinds of self-report instruments, undetectable viral loads, and pharmacy renewals to measure adherence. Adherence researchers in other settings have also used pill counts. However, there is little evidence that these measures of adherence are measuring the same behavior. Two different studies that have used multiple measures of adherence on the same individuals for the same time have shown that the measures do not correlate with each other at a very high level [39,40]. It is possible that there have been good measures of readiness that were done with poor measures of adherence. Additionally, it has been shown that instituting an adherence measure can, by itself, improve adherence [41]. Any improvements that were shown by assessing readiness might only be showing that keeping track of patient adherence maybe responsible for the improvement and that the readiness assessment was not actually predicting future adherence.

In sum, additional research is needed to characterize readiness and understand how it predicts future adherence. Any such research should be long term and regularly assess readiness in recognition of the fact that readiness is not a onetime behavior. It maybe equally important to understand why patients who were ready to start therapy suddenly become unready to continue therapy. The bottom line is that the current science on readiness and adherence is not developed sufficiently to warrant using readiness as a criterion to decide who is an acceptable candidate for treatment.

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Table 1

Articles on readiness for HIV treatment or care that did not study adherence to HAART

Study	Focus	Design	Population	Theoretical framework/definition of readiness	Measure of readiness
Alfonso et al. [34], 2006	Experiences of patients on MDRT and the providers	Qualitative interviews	12 male patients, >19 years old, in Canada	None/defined from data as time to prepare to start treatment	Semistructured interviews on the challenges of being on MDRT, adhering, etc.
Balfour et al. [33], 2006	Evaluate an intervention for increasing medication adherence skills	Quantitative	63 HIV+ patients attending an HIV clinic in Canada	Multiple behavioral theories/psychological variable	10-item medication readiness scale (HMRS)
Balfour et al. [25], 2007	Develop and validate a scale to measure HIV treatment knowledge	Quantitative	130 HIV+, 22 Hep C/HIV co-infected, 78 Hep C only, in Canada	None	21-item treatment knowledge scale
Cooper et al. [26], 2002	Explore perceptions of HAART in a cohort who had declined treatment	Qualitative	26 gay men in the UK who were eligible for, but declined, treatment	Personal beliefs about one's condition and treatment/implicit that readiness is decision-making	Decision to decline HAART
Enriquez et al. [38], 2004	Decision-making of persons adhering to ART after prior failures	Qualitative	13 HIV+ who had failed ≥2 treatment regimens, in the United States	Implicit that it is adherence	Asked about why they changed from nonadherent to adherent
Fowler [17], 1998	Analyze the concept of readiness, using a modified version of Wilson method	Essay	Used case study approach of patient with HIV	WMT, SOC, readiness theory, and reversal theory/personal determination to change a behavior	Nursing assessment would include assessing the patient characteristics in the definition
Fehr et al. [29], 2005	Patients' readiness to start or change ART	Quantitative	75 HIV+ starting or changing ART in Europe	Llewellyn-Thomas' decision-making frame-work	Making a final treatment decision
Gardner et al. [14*], 2007	Predictors of attending an HIV medical care provider among persons recently diagnosed with HIV	Quantitative	273 (86%) of 316 HIV+ persons recruited for the ARTAS study in the United States	TTM stages of change/readiness to enter care based on stages of change	Based on responses to 2 items to indicate stage in the TTM
Gebrekristos et al. [23], 2005	-	Essay	-	Levels of health literacy (knowledge) before starting and after starting that is necessary to start or maintain ART	-
Gellatry et al. [27], 2005	Patients' satisfaction with information they have received about ART	Quantitative	115 HIV+ men in the UK, eligible to start ART	-	Decision to initiate or decline ART
Gold and Ridge [28], 2001	Understand the reasons patients who are eligible for therapy decline it	Qualitative interviews	20 HIV+ declining treatment in 1998 in Australia	None/decision-making	Decision to decline HAART

Study	Focus	Design	Population	Theoretical framework/definition of readiness	Measure of readiness
Kremer et al. [31], 2006	Reasons HIV+ persons decide to take or not to take ART	Qualitative	79 HIV+ persons eligible for treatment in 2003 in the United States	None/decision-making	Questions on decisions to take ART during the past year and why they made those decisions
Morgenstern et al. [30], 2002	Factors that influence the decision of an HIV + to initiate care and/or ART	Quantitative	83 HIV-infected patients on ART in the United States	None/decision to seek care and initiate ART	Time from learning HIV status to when they initiated medical care and ART
Sidat et al. [35], 2007	Patients' perspectives and experiences leading to 100% adherence to ART	Qualitative	10 patients with 100% adherence to ART for 6 mo in Australia	-	Interviews re: starting ART, managing daily use of ART, side effects coping, etc.
Sodergard et al. [19], 2006	Relationship between adherence and motivation	Quantitative	HIV-infected patients on ART in 1998 (<i>n</i> =60) and 2002 (<i>n</i> = 53) in Sweden	The information, motivation, and behavioral skills model of ART adherence/no definition of readiness	2-item motivation assessment re: 1) motivation to use one's current ART; and 2) certainty ART will positively affect health
Sodergard et al. [20], 2007	Test and compare a model with readiness and adherence, with a model without readiness	Quantitative	828 HIV patients >18 years and on ART in Sweden	Theory of trigger events; five components (following Enriquez 5 stages) must be present for a patient to be ready for treatment	5 questions re: treatment beliefs, experiences with providers, support system, medication-taking reminders, and goals
Tessema et al. [21], 2010	Assess determinants of nonadherence and non-readiness to HAART	Qualitative	504 HIV+ ART for ≥3 months in Ethiopia	Although not explicitly stated, the researchers used the WMT	5 questions re: treatment beliefs, medical staff, support system, reminders for taking medications, and goals
Weiss et al. [24], 2003	Analyze the association between HIV-related knowledge and adherence	Quantitative	997 participants in New York Treatment Adherence Project	Not explicit; concept is knowledge	5-item true-false test of knowledge about ART

HAART highly active antiretroviral therapy; Hep hepatitis; MDRT multidrug rescue therapy; SOC stages of change theory; TTM trans-theoretical model; WMT well motivation theory

Table 2
Studies that analyzed the relationship between a measure of readiness and adherence to HAART

Study	Design/follow-up	Population	Theory: measure of readiness	Measure of adherence	Analysis/findings
Balfour et al. [16], 2007	Quasi-experimental/4 week	142 HIV+ patients from an outpatient clinic in Canada	Wellness motivation theory; 10-item medication readiness scale (HMRS)	2 self-reports: ACTG adherence scale and general treatment scale	HMRS increased following the intervention and demonstrated predictive validity for adherence after 4 weeks
Enriquez et al. [18], 2004	Prospective, pre-post test/6 months	19 HIV+ males who had failed prior treatment, in the United States	Wellness motivation theory; Fleury's 30-item index of readiness (IR) scale	Sustained viral suppression (HIV PCR <400)	Readiness scores of those who attained viral suppression (9) were compared with those who did not (10); no differences on total score
Enriquez et al. [15], 2009	Pre-post test study; with follow-up at 3 and 12 mo	28 HIV+ adults on failing regimens and starting new ones	Wellness motivation theory; 30-item index of readiness	Viral load <50 copies considered to be adherence	Not statistically significant inverse relationship between viral load at baseline and 3 mo
Grimes and Grimes [32], 2009	Prospective, observational/5 months	39 HIV+ patients: 24 new to HAART; 15 restarting after >6 mo break, in the United States	Self-assessment of readiness using a visual analog scale and Likert-type scale	Percentage of needed drugs that patients had available; data from pharmacy records	Neither readiness measure predicted adherence for naive or for experienced patients
Highstein et al. [11], 2006	Prospective, cohort study/1 y	103 HIV+ women on HAART or eligible for it by CD4 count, in the United States	Trans-theoretical model stage of change; 2-item stage of readiness scale	1) Sustained viral suppression (HIV PCR <400); 2) self-reported adherence	For the 63 patients starting ART an association was found between initial scale and HIV suppression
Rathbun et al. [12], 2007	Prospective study of a larger intervention to improve adherence/16 wk	31 indigent patients; 26 of 31 were evaluated at week 16, in the United States	Trans-theoretical model; 2-item stage of change (SOC) instrument	% of doses taken; measured by electronic monitoring of the pill bottle	The SOC at start of ART did not predict adherence at 4 or 16 weeks
Wagner et al. [36], 2002	Pilot intervention study/5-9 weeks	20 HIV+ men, of whom 17 completed the program, in the United States	Equated with adherence: achieving >90% adherence in placebo trial	Proportion of doses taken; electronic monitoring for 4 wk after starting ART	Of 15 patients achieving >90% adherence in the placebo trials and starting therapy, 13 achieved >90% adherence at 4 wk
Wagner [37], 2003	Prospective intervention; 1-2 wk on placebo followed by 1 mo on HAART	HIV+ with a history of drug dependency in the United States, 83 started HAART	Equated with adherence: achieving >90% adherence in a 2-wk placebo trial	% of doses taken; measured electronic monitoring; plus self-report over 3 days	83 (45%) of the participants who completed phase 1 started HAART; 39% of these achieved >90% adherence
Willey et al. [13], 2000	Observational/1 mo	161 HIV+ patients in the United States	Trans-theoretical model; 2-item stage of change scale	Electronic monitoring of 85 patients; 4-item self-report medication adherence scale	Significant association between scale and electronic monitoring of adherence for 30 days

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HAART highly active antiretroviral therapy