



## The Degree of Readiness among a Population of HIV Infected Patients in Sweden

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### Abstract

**Objective:** The objectives were to assess the degree of readiness for HIV infected patients currently on treatment and to evaluate factors potentially influencing readiness.

**Methods:** All HIV-treated patients, who attended a HIV clinic in Sweden, during 7 months, were asked to complete a questionnaire containing Willey's 2-item readiness assessment and questions about other factors potentially affecting readiness. The Willey's 2-item readiness assessment categorises patients into either of five stages of change. Patients categorized as in the action or maintenance stage were classified as 'ready to adhere to medicines'.

**Results:** In total 327 patients participated (response rate 87.4%). The proportion categorised as in the action and maintenance stage was 97%. Factors associated with readiness were lower mean CD4 count at start of treatment and lack of resistance. The proportion with viral loads below detection limit was very high (91%).

**Conclusion:** Although the initiation of ART is extremely important, to ensure good treatment results, follow-up and motivation throughout the treatment are also important. Continuous measurement of the patients' readiness to maintain treatment adherence needs to be further explored.

**Keywords:** Readiness; HIV; Transtheoretical model of change; Adherence; Sweden

### Introduction

Adherence in chronic diseases has been a research focus for several years [1], especially in the case of HIV [2,3]. The full benefits of ART (Antiretroviral Therapy) treatment requires early diagnosis, continuous retention in care, and uninterrupted access and adherence to ART [4].

The negative consequences of non-adherence not only affect the individual by development of resistance, treatment failure and limited future treatment options [5], as in most other chronic diseases, but also affect society, due to the spread of resistant viral strains [6,7].

When to start ART has continuously been debated. Previously it was rarely an urgent matter to initiate ART in asymptomatic patients [8]. Currently there is evidence that the lower the CD4 counts are when treatment is initiated the more increased risk of death [9] while if patients start treatment at the time of diagnosis they live longer [10,11]. This is also reflected in the current guidelines [4]. However, not all patients might be ready to adhere to treatment when they get diagnosed.

Consequently, whether a patient is ready to adhere to the treatment has been suggested to be an important factor for a successful treatment outcome [12,13]. For a detailed description of readiness and its measurement, see Nordquist et al. [14] and Grimes et al. [15].

Several different theories [13,16-18] have been used to explain how a patient becomes ready to adhere to treatment. The theory most commonly used is the Transtheoretical Model of Change (TTM) [16]. TTM consists of six "stages of change": precontemplation, contemplation, preparation, action, maintenance and the last stage is termination. In addition to this TTM also consists of ten processes of change, decisional balance (where the person considers the pros and cons of changing), self-efficacy and temptation.

During the stage of precontemplation the person is not aware of a problem and is hence not thinking about changing either. In the stage

of contemplation the person has started to realize the need for a change but still also sees reasons not to change. The change is planned within the next six months. During the preparation stage, change is intended within the next 30 days and the person is determined to initiate change. When the person actively changes their behaviour to obtain the desired behavioural change, the person is in the action stage. This stage might last as long as 6 months. The person also needs to maintain the change and actively work to prevent relapse to the previous undesired behaviour. This stage is called maintenance and may be as short as 6 months or last up to 5 years. Termination is the last step and when the patients have reached this state, they are no longer tempted to relapse to their former behaviours.

Readiness is a complex phenomenon and physicians have no better than a chance probability of correctly predicting whom of their patients will be adherent, before they initiate treatment [19,20]. It is hence important for clinicians to be able to systematically assess readiness, and to predict future adherence among HIV infected patients in a way that can be implemented in routine care [21]. Several instruments have been used to measure readiness in other conditions [22-26] but only four instruments have been used in HIV [27-29]. None have been used in routine care, [14,15] but Willey's 2-item readiness assessment, has been used in several research projects [28,30].

In an American convenience sample of HIV infected patients

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already prescribed HIV medication [28], 15% were not ready for treatment according to the Willey's 2-item readiness assessment but were still prescribed antiretroviral treatment. A further development of the original Willeys 2-item readiness assessment has also been tested in a prospective study [30]. The authors found that the readiness scores predicted 1 year viral load levels [30].

According to TTM, readiness is a continuous process and has been described as a spiral where patients go from stage to stage until they reach the stage of termination but it is also common for the patients to have setbacks and return to earlier stages in the process. Patients hence continuously need to prevent relapse into the former behaviour (i.e. non-adherence), even though the patient has reached the action and maintenance stages. The degree of readiness, therefore, changes during ongoing treatment. In order to take timely measures to motivate the patient if the degree of readiness is declining, but before adherence is affected, repeated measurements of readiness throughout treatment would be helpful, if readiness has adherence predictive properties. The readiness assessments used so far have mainly been for research purposes so little is known about the degree of readiness in clinical practice as well as which factors are influencing readiness [14,15].

The objectives were to assess the degree of readiness for HIV infected patients currently on treatment and to evaluate factors potentially influencing readiness.

## Method

### Patients

All adult patients ( $\geq 18$  years of age) attending the HIV clinic at Karolinska University Hospital, Huddinge, in Stockholm, Sweden during 7 months were consecutively asked to participate in the study if they had been on treatment for over 4 months and considered able to read and write in Swedish. Patients were not asked to participate if their health care providers considered them unable to fill out the questionnaires due to illiteracy, severe mental illness or poor general health status. Three hundred and seventy-four patients visited the clinic within the time period. Of these, 87.4% (327 patients) fulfilled the inclusion criteria. Brief details were collected regarding the patients that did not fulfil inclusion criteria and those who declined to participate.

The questionnaires were handed out by health care personnel at the clinic and the patients were asked to fill out the questionnaire, preferably before their appointment with the doctor or nurse. Treatment results for the patients agreeing to participate were collected from the clinic's research database, where the entire clinic's patient population was registered. The study data on viral loads was based on blood samples drawn at the time when the questionnaire was filled out. Patient demographics were also obtained from the database as was history on treatment and resistance. The regional ethics committee in Stockholm gave approval for this study.

### Questionnaire

Demographic, adherence and readiness data were collected using a previously validated questionnaire [31,32]. Willey's 2-item readiness assessment [28] questions were used to assess the degree of readiness. These assessment questions categorize the patient into one of the first five stages of change (precontemplation, contemplation, preparation, action or maintenance). Patients in this study were considered 'ready to adhere to medicines' if they were categorized by the instrument as being in the action or maintenance phases.

### Statistical analysis

The statistical analysis was carried out using SPSS for Windows

version 12.0.1 (SPSS Inc, Chicago, 2003). The Chi Square statistic (or Fisher's exact test, if expected frequencies less than 5) was used to analyse categorical data. The Mann-Whitney test was used to compare means, as the measurements were not normally distributed, and to analyse ordered variables.

Logistic regression analysis was used to identify factors associated with readiness, while adjusting for covariates. Variables in the univariate analysis with a p-value less than 0.1 were included in the logistic regression model [33].

## Results

Three hundred and twenty patients completed the questionnaire, giving a response rate of 97.9% (Figure 1). Data on readiness were available for 305 patients.

### Demographic information

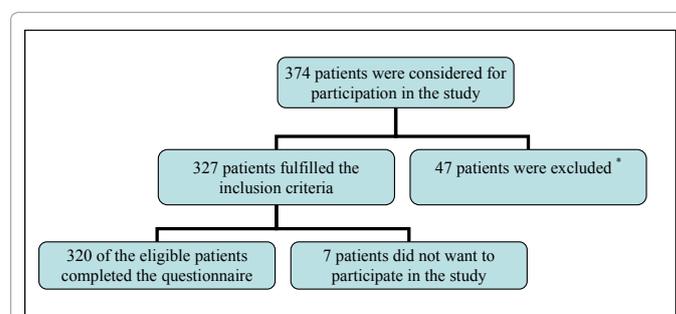
Demographic information is presented in Table 1 and is based on data from the research database at the clinic. The data on viral loads and CD4 was based on blood samples drawn at the time when the questionnaire was filled out. The majority of the respondents were male and in their mid-40s. Heterosexual transmission was the most common transmission route and over 90% of the respondents had viral loads below 20 copies/mL. The mean CD4 count at the start of treatment was roughly 220 and at the time of participating in this study were almost 500. The majority were CDC class A. The mean time on any treatment was almost 8 years and the mean time on the current treatment was almost 3 years. The majority were on a twice daily regimen. Slightly over a quarter of respondents had developed resistance and over 70% were of European origin.

### Readiness assessment

In Table 2 is a detailed description of the readiness results. Over 99% of the respondents were categorized as in the Action or Maintenance stage according to the Willey's 2-item readiness assessment. Almost 90% of the patients were categorized as being in the most optimal stage of readiness i.e. maintenance.

### Background characteristics associated with readiness

The univariate analysis is presented in Table 3. Patients categorized as ready to start treatment (i.e. in the action or maintenance phase) according to the Willey's 2-item readiness assessment had a higher mean CD4 count at the start of treatment (227 versus 85) and a higher mean present CD4 count (492 versus 439). The patients categorized as ready were also less likely to have developed resistance (26% versus 60%), were more likely to be of European origin (74% versus 20%) and white (75% versus 20%).



**Figure 1:** Distribution of the number of included and excluded respondents in the study.

Note: \* Exclusion due to: on treatment for less than 4 months (n=3); could not read (n=6); did not understand Swedish (n=33); were not mentally capable of participating (n=5).

Characteristics	Respondents
Male, %	69.1
Mean age ± SD	46.6 ± 9.3
Mode of exposure, %	
Heterosexual exposure	48.1
Homo or bisexual exposure	28.1
Intravenous exposure	22.5
Blood transfusion	0.9
Unknown	0.3
Viral load, %	
Below 20 copies	91.3
50 copies	1.9
Over 50 copies	6.9
CD4 lowest ± SD, cells/mm <sup>3</sup>	157.3 ± 99.8
CD4 at start of treatment ± SD, cells/mm <sup>3</sup>	224.3 ± 147.3
CD4 now ± SD, cells/mm <sup>3</sup>	492.1 ± 248.3
CDC class, %	
A	40.9
B	34.7
C	24.4
Mean years since start of any treatment ± SD	7.9 ± 4.3
Mean years since start of the current treatment ± SD	2.6 ± 1.7
Resistance, %	27.2
Number of daily doses of HIV drugs, %	
Once daily	32.2
Twice daily	67.5
Three times daily	0.3
European origin, %	73.8
Ethnicity, %	
White	71.3
Black	23.4
Latin	1.9
Oriental	2.2
Other	1.3

Table 1: Characteristics of the respondents (n=320).

Characteristics	Value (n)	Missing (n)
Willey's 2-item readiness assessment, %		15
Precontemplation	0.3 (1)	
Contemplation	0.7 (2)	
Preparation	2.3 (7)	
Action	7.9 (24)	
Maintenance	88.9 (271)	

Table 2: Readiness according to Willey's 2-item readiness assessment (n=320).

### Multivariate analysis

Data from the logistic regression analysis of factors associated with the action or maintenance phases of readiness, while adjusting for covariates, are presented in Table 4. The variables included in the analysis were gender, mode of transmission, lowest CD4 count ever, CD4 count at the start of treatment, present CD4 count, resistance, origin of the patient, ethnicity and perceived contacts with health care. Full data for the analysis were available for 298 respondents (93%). There were significant differences between respondents whose data were included or excluded from the logistic regression analysis. Excluded patients were more likely to be of non-European origin and less likely to have a stable housing situation. Of the factors included in the logistic regression model, CD4 count at start of treatment and resistance remained independently associated with readiness.

### Discussion and Conclusion

The objectives of this study were to assess the degree of readiness for treatment of HIV infected patients currently on antiretroviral treatment and to evaluate factors influencing that readiness. In this sample, 97% of the respondents were classified as being ready (i.e. being in the action or maintenance phase). Factors associated with readiness were lower mean CD4 count at start of treatment and no resistance development. The proportion of respondents with viral loads below detection limit (less than 20 copies/mL) was 91%. This is higher than previous published studies from other countries [34-36] but consistent with previous results from Sweden [32,37-39]. The response rate of almost 98% was exceptionally high and in accordance with previous findings from Sweden [32].

The proportion of patients currently on antiretroviral treatment and categorized as in the maintenance phase were in this study 89% while the corresponding proportion in an American convenience sample was 41% [28]. One reason for this discrepancy might be that the HIV clinic at Karolinska University Hospital, Huddinge, follow a treatment model with the aim to get the patients to become sufficiently motivated that they can take responsibility for their own treatment and thus avoid treatment interruptions and resistance. This treatment model has been described elsewhere [31], and it focuses on; information, motivation, instruction and availability. The idea is that the patients should have

their own nurse and doctor to promote continuity in care, the nurses are available for their patients during business hours through telephone and information material has been produced specifically for the patients at the clinic based on their needs.

According to this study, lower mean CD4 count at the start of treatment and no resistance development were factors associated with readiness. This result could imply that the patients categorized as ready in this sample have been less complicated and more motivated

	Not ready		Ready		Total	% ready
	n	%	n	%		
Male†	4	40	206	69.8	305	98.1
Mean age	41.4		46.9		304	
Mode of transmission†					305	
Homosexual	0	0	85	28.8		100
Heterosexual	9	90	136	46.1		93.8
Intravenous	1	10	70	23.7		98.6
Blood transfusion	0	0	3	1		100
Unknown	0	0	1	0.3		100
Viral load detection limit	9	90	270	91.5	305	96.8
Mean lowest CD4†	76.2		158.9		305	
Mean CD4 at start of treatment***†	85.1		227.3		300	
Mean present CD4***†	439.3		491.9		305	
CDC class					305	
A	2	20	119	40.3		98.3
B	3	30	106	35.9		97.2
C	5	50	70	23.7		93.3
Mean years since start of treatment	8.1 ± 3.6		7.8 ± 4.3			320
Mean years since start of current treatment	1.9 ± 0.7		2.6 ± 1.6			320
Resistance**†	6	60	76	25.8	305	92.7
Number of daily doses of HIV drugs					305	
Once daily	3	30	97	32.9		97
Twice daily	7	70	197	66.8		96.6
Three times daily	0	0	1	0.3		100
European origin**†	2	20	218	74.4	303	99.1
Ethnicity**†					305	
White	2	20	221	74.9		99.1
Black	7	70	61	20.7		89.7
Latin	0	0	4	1.4		100
Oriental	1	0	6	2		85.7
Other	0	0	3	1		100
Homeless	1	10	16	5.5	299	94.1
Trouble with drugs or alcohol	2	20	68	23.2	303	97.1
Contacts with psychiatric health care	1	10	85	29.4	299	98.8
Perceived contacts with health care†					303	
Very good	9	90	266	90.8		96.7
Good	0	0	26	8.9		100
Neutral	1	10	1	0.3		50
Bad	0	0	0	0		0
Very bad	0	0	0	0		0
Will treatment prevent getting sick					299	
Yes absolutely	3	30	113	39.1		97.4
Yes probably	4	40	108	37.4		96.4
Maybe	2	20	46	15.9		95.8
No, probably not	1	10	17	5.9		94.4
No, absolutely not 0	0	0	5	1.7		100
Friends or family to discuss the treatment with	8	80	217	74.6	301	96.4
Friends or family that remind the patient to take the drugs	6	60	136	47.2	298	95.8
Mean motivation	88		91.8		272	

**Table 3:** Univariate analysis of background factors with respect to readiness (i. e. categorized as in the action or maintenance phase) (n=320).

Note: \* P<0.05

\*\* P<0.01

\*\*\* P<0.001

†Included in multivariate analysis (p<0.1).

Variable <sup>a</sup>	Odds ratio	(95% CI)	P-value
Gender			
Male	1		
Female	1.00	0.17-5.99	1.000
Mode of transmission			
Homosexual	1		
Heterosexual	0.00		0.996
Intravenous	0.00		0.996
Blood transfusion	0.50		1.000
Unknown	0.04		1.000
Mean lowest CD4	0.98	0.96-1.01	0.238
Mean CD4 at start of treatment*	1.03	1.00-1.05	0.049
Mean present CD4	1.00	1.00-1.00	0.999
Resistance*			
Yes	1		
No	7.61	1.43-40.63 0.018	
European origin			
Yes	1		
No	0.75	0.01-83.51 0.906	
Ethnicity <sup>b</sup>			
White	1		
Black	0.13	0.00-15.86	0.402
Other	0.06	0.00-14.52	0.315
Perceived contacts with health care <sup>c</sup>			
Very good	1		
Other	0.61	0.04-8.49	0.716

**Note** <sup>a</sup>Including all variables with p<0.1 in the univariate analysis

<sup>b</sup>The variable was collapsed into the options; White, black and other (latin/oriental/other), due to few responses in the original categories.

<sup>c</sup>The variable was collapsed into the options; very good contacts with health care and other (good/neutral/bad/very bad), due to few responses in the latter categories.

\*P<0.05

\*\*P<0.01.

**Table 4:** Logistic regression analysis of factors associated with readiness (categorized as in the action and maintenance phase).

patients throughout their treatment history. A patient categorized as ready should be more adherent and as a result have undetectable viral loads [30] and will not as likely develop treatment resistance [5]. To our knowledge, no data has been published regarding factors associated with readiness during ongoing treatment, as defined by any of the existing theoretical frameworks.

The factors influencing the time from diagnosis to treatment initiation, i.e. readiness for treatment initiation, have, however, been evaluated. Morgenstern et al. [40] have investigated the factors influencing readiness for treatment initiation by evaluating the timeframe from when the patient found out about the HIV status to when the patient felt ready to start therapy. In their univariate analysis, some of the emotional responses (anger, hopelessness, denial, anxiety and confusion) following the diagnosis, and their severity, were found to significantly affect readiness for treatment initiation [40].

In a qualitative study [41] factors influencing refusal to start ART treatment were analyzed. The most common reason for refusing treatment was due to not feeling ready for adherence and a fear of side effects. Side effects were the most common reason for refusing to start treatment in a quantitative study [42]. In another study Raveis et al. [43] females who have delayed seeking care over 3 months were interviewed. The barriers most commonly mentioned were psychological responses

to the diagnosis. The responses included denial of status, fear of having the disease and trying to cope with the emotional responses by using illicit drugs.

## Limitations

We could not find an association between viral load and readiness in this sample. In a prospective study, the readiness scores at baseline predicted 1-year viral load levels [30]. The group of patients that have viral loads below detection limit in our sample is extremely high, hence the proportion of patients with viral load over 50 copies/mL was only 7%, resulting in difficulties detecting a significant difference.

The proportion of non-responders was small in this sample (2.1%) thus selection bias is likely to be limited. The proportion of eligible patients was also high. The internal attrition due to unanswered questions in the questionnaire or in the database were low since full data was available for 93% of the patients and hence included in the logistic regression analysis. There were however differences between included and excluded respondents in the logistic regression analysis. It is also important to remember that no temporal relationship between background factors and readiness can be established in a cross-sectional survey. Social desirability cannot be ruled out when it comes to patient reported outcomes and can have affected the results in this study. Another limitation of the study was that there was a small number of patients considered not ready according to the scale used. This could have an impact on the logistic regression analysis.

There are several readiness assessments available [14] and we chose Willey's 2-item readiness assessment [28] for this study. The reason for this was that the instrument is short, easy to understand even for patients with limited education and has previously been used in a study with patients on antiretroviral treatment [14]. A further development of that instrument has been tested by Highstein et al. [30] but was not available at the time of the planning of this study.

The other instrument that has been used to measure readiness in patients on antiretroviral treatment is the Kennedy's 26 item scale [29]. This consists of 26 items but has not been fully evaluated. The index of readiness [27] has so far not been used for patients on treatment and the instrument was also considered too long and complicated for the patients at Huddinge due to the high proportion of patients with limited education and language difficulties. The HIV medication readiness scale, was another scale not available at the start of this study [44].

## Future Research

The area of readiness has so far received limited attention [14,15]. Longitudinal studies are needed to further understand the factors associated with readiness and the fluctuations of readiness over time. An optimal way of measuring readiness among HIV infected persons has not yet been identified. The instrument should be able to measure readiness prior to treatment initiation as well as be able to capture changes in readiness during on-going treatment. The instrument should not only be of value in the research setting but also be useful in routine clinical practice.

## Conclusion

Swedish sample of HIV infected patients currently on antiretroviral treatment. Factors associated with readiness were lower mean CD4 count at start of treatment and lack of resistance development. The proportion of respondents with viral loads below detection limit (less than 20 copies/mL) was very high in this sample with 91% of the patients. This implies that although the initiation of ART is extremely important, to ensure good treatment results, follow-up and motivation of the patients

throughout the treatment are also important. Continuous measurement of the patients' readiness to maintain treatment adherence, to identify when interventions are required, need to be further explored.

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