READY4THERAPY

POCKET GUIDE

for Health Care Providers supporting people living with HIV as they make therapy decisions

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ABOUT THIS POCKET GUIDE

Combined antiretroviral therapy (ART) has drastically reduced HIV-related morbidity and mortality[1,2]. In clinical practice, successful ART requires the close collaboration of health care providers and patients over time. Optimally, the collaboration begins with a shared decision-making process about when and how to initiate ART. Once the decision to start has been made, patients need to implement the medication intake into daily life and medication safety has to be monitored. Since ART is a long-term treatment with no defined endpoint, adherence to ART must be maintained by patients over many years. To do this, patients need to keep up motivation and skills, and toxicities must to be monitored carefully [3,4].

International care and treatment guidelines provide instruction to health care providers as they support patients making decisions to initiate or change ART [5,6]. The guidelines reflect evidence-based criteria for assessing a patient's treatment need and treatment options. The guidelines also provide suggestions for monitoring of ART regimens in respect to safety and toxicities.

However, the treatment success of a chosen regimen depends on the readiness of an individual patient to initiate, implement and persist on ART over time [3,7,8]. One patient may struggle to find motivation to start ART, because of his health beliefs. Another patient has difficulties finding strategies for timely medication intake because of an irregular work schedule and fear of HIV-disclosure at the workplace. A patient, who had adhered to ART over years without problems, suddenly struggles with forgetfulness. As these examples illustrate, barriers to ART experienced by patients can be diverse and individualized, and skilled support by providers is needed [11,17].

This pocket guide was written to assist providers in clinical practice support their patients in preparation for ART. A main focus is on the first phase of therapy decision-making, yet strategies to support implementation and persistence are included as well. The guide presents strategies based on available research evidence and clinical expertise. It should be used by providers to obtain patient input and develop their own skills for supporting a patient's readiness to begin ART.

SUCCESSFUL ART INITIATION

The first step to effective long-term antiretroviral treatment is the successful start or restart of ART. Determining when to start ART is a two-step process. The first is determining the patient's need for ART based on guidelines.

The second is assessing and supporting the patient's readiness to initiate ART. These processes usually start with the first consultation and continue in follow-up meetings. Many patient and provider-related barriers can hamper both steps.

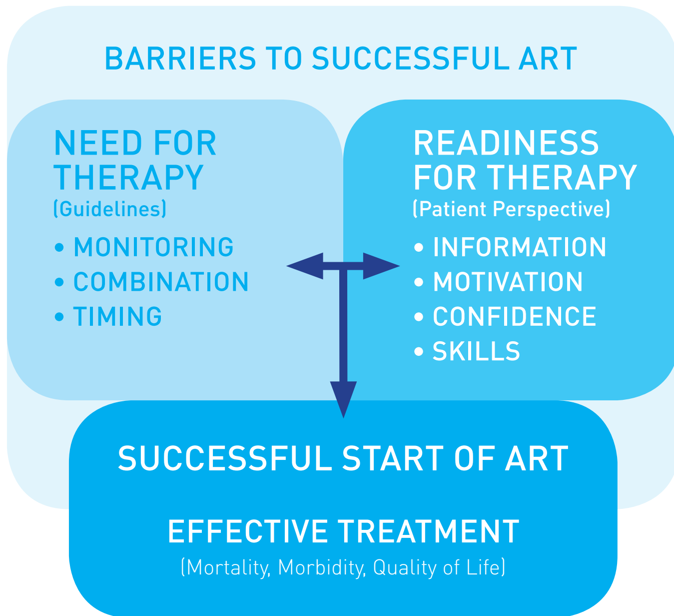

Figure 1: Process of successful ART Initiation

STAGES OF ART READINESS

Patients pass through the following stages while making their decision about starting ART (see also figure 2). Be aware that patients may stay in one stage for a long time or regress from advanced to earlier stages [9,10,12,13].

The description of stages is illustrated by the quotes of a 48-year-old gay man and a 38-year-old woman with a history of illicit drug use. Both talked about their ART decision-making experiences within a qualitative study [14].

1. PRECONTEMPLATION

The patient has no intention of engaging in an ART regimen and does not realize the potential health risks of going without medication.

– or –

The patient has thought about starting ART but prefers to avoid the issue and procrastinates as much as possible.

"I haven't really spent much time thinking about it, but I had the image in my mind of someone having to swallow huge amounts of pills — it made me want to push back the whole thing as far as possible."
(48-year-old male)

2. CONTEMPLATION

The patient is thinking about reaching a decision about ART at some point in the next few months. Aware of the pros and cons, he or she is emotionally torn about what decision to make.

"At that time I realized I would have to go for it in the next few years. When I got the lab results before the summer holidays last year — that was when I really started to think about it."
(48-year-old male)

PATIENT BARRIERS TO ART

"You're always weighing things, inside you're torn about what to do about it. What is more important from a personal point of view? That's hard to communicate to the doctor. And then there are the side effects to consider, though you're also hoping for an improvement."
(38-year-old female)

3. PREPARATION
The patient has decided to start ART.
– or –
The patient has made an informed decision to decline ART.

"A clear image of the regimen only appeared to me the moment I came to my decision. That's when I confronted the issues about what it all meant. Now I have to take these pills at 7 o'clock in the morning and again at 7 o'clock at night. Until then, I somehow didn't want to visualize it."
(48-year-old male)

4. ACTION
The patient starts an ART regimen and integrates medication intake into her/his daily routine.

"I realized that I could get drugs that suited me. I found the fact that there are drugs that allow me to lead a normal life somehow reassuring."
(38-year-old female)

5. MAINTENANCE
The patient persists on treatment over time despite challenges e.g. difficult life events or medically initiated treatment changes.

Research shows that patients on ART make ongoing decisions in respect to medication intake and continuation e.g. dose and timing adaptions, drug holidays. Established patterns of taking medication can change over time[4].
In this respect, therapy decisions are ongoing.

Many barriers along the treatment continuum influence a patient's ART decision-making negatively[11,15,16,17].
In this pocket guide, we present a few selected barriers that can be screened with structured assessment tools. It is important for health care providers to recognize these barriers because they may have a negative influence a patient's ART readiness and adherence.

Here are questions, to be used in the clinical consultation, to screen patients for depression and harmful alcohol and recreational drug use (for details see references below).

DEPRESSION: PHQ-2 or PHQ-9[18]
Meta-analysis shows a consistent relationship between depression and ART non-adherence that is not limited to those with clinical depression. Therefore assessment and intervention aimed at reducing depressive symptom severity, even at subclinical levels is important[19].
Ask: "Over the last two weeks, how often have you been bothered by any of the following problems? 1. Little interest or pleasure in doing things; 2. Feeling down, depressed or hopeless."
Answers: Not at all (0) / Several days (1) / More than half the days (2) / Nearly every day (3). If the patient scores 2 or more, complete the following continuing questions:
"3. Trouble falling or staying asleep, or sleeping too much; 4. Feeling tired or having little energy; 5. Poor appetite or overeating; 6. Feeling bad about yourself — or that you are a failure or have let yourself or family down; 7. Trouble concentrating on things, such as reading the newspaper or watching television; 8. Moving or speaking so slowly that other people could have noticed. Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual; 9. Thoughts that you would be better off dead, or of hurting yourself."
Evaluation: Sensitivity and specificity of the PHQ-2 were 86% and 78% with a score of 2 and higher for major depression. For the PHQ-9 they were 74% and 91% with a score of 10 and higher. Interpretations of scores for PHQ-9 are: 1-4 minimal depression / 5-9 mild depression / 10-14 moderate depression / 15-19 moderately severe depression / 20-27 severe depression[18].

HARMFUL ALCOHOL USE: FAST[20,21]
Alcohol use: Meta-analysis supports a significant and reliable association of alcohol use and ART non adherence.

However several variables moderate this association, e.g. the alcohol-adherence association was significantly stronger in the context of lower intravenous drug use [22].
Ask MEN: "How often do you have eight or more drinks on one occasion?"
Ask WOMEN: "How often do you have six or more drinks on one occasion?"
Answers: Never / Less than monthly / Monthly / Weekly / Daily or almost daily
Ask: "How often during the last year have you been unable to remember what happened the night before because you had been drinking?"
Answers: Never / Less than monthly / Monthly / Weekly / Daily or almost daily
Ask: "In the last year has a relative or friend, or doctor or other health care worker been concerned about your drinking or suggested you cut down?"
Answers: No / Yes, on one occasion / Yes on more than one occasion.
Evaluation: Sensitivity 93%, Specificity 88%. If the response to question 1 is "never" then the patient is not misusing alcohol, so stop here. Otherwise continue and score questions 1,2,3 as follows: Never =0 / Less than monthly=1 / monthly=2 / Weekly =3 / Daily or almost daily=4. Score question 4 as follows: No=0 / Yes, on one occasion=2 / Yes, on more than one occasion=4.

The summary score for hazardous drinking is 3 or more.

COGNITIVE DYSFUNCTION [24]

The prevalence of HIV-associated cognitive disorders is high and can influence a patient's decision making and ART adherence [23]. We recommend screening for cognitive dysfunctions. The following questions can be used. However, their evaluation is not yet well developed.
Ask: "Do you experience frequent memory loss e.g., do you forget the occurrence of special events, even more recent ones, appointments etc.? Do you feel that you are slower when reasoning, planning activities, or solving problems? Do you have difficulties paying attention e.g., to a conversation, a book, or a movie?"
Answers: never / hardly ever / yes definitely
Evaluation: With a positive answer ("yes definitely") further assessment is recommended.

Additional prevalent barriers that should be recognized and minimized, are:

PATIENT BARRIERS TO ART

STIGMA-RELATED BARRIERS

Fear of stigmatization and experiences of social discrimination influence ART adherence and levels of social support negatively [25]. It is important to note, that the presence of at least one close and informed support person is clearly beneficial to the patient's health [26,27]. Thoughtful disclosure management can be supported [28].

SYSTEM- AND PROVIDER- RELATED BARRIERS

Studies have found patients encountering system-related barriers such as inadequate health insurance and limited drug supply, or provider-related barriers such as guidelines that reduce the chance of intravenous drug users receiving ART [17,29]. It is important to note that evidence from meta-analysis fails to support withholding ART for IDUs because of the increased risk of ART resistance [30].

ASSESSING ART READINESS

Even the most experienced health care providers can be unaware of a patient's innermost thoughts and feelings. And, studies have repeatedly found that providers are not very good at predicting a patient's ART initiation or ability to adhere to the treatment program [11,31]. Given that providers are expected to adjust a treatment strategy to a patient's individual behaviour, these are serious shortcomings. However, adopting a patient-centered communication style can help providers identify a patient's thoughts and feelings about starting, implementing and maintaining ART. This understanding will help providers to decide which stage of readiness the patient is in and offer a stage-based support.

CONDUCTING A PATIENT-CENTERED INTERVIEW

Use the following techniques while conducting a patient-centered interview for assessing a patient's readiness for ART and for choosing the appropriate intervention [32].

SETTING THE AGENDA [32]

Set time limits, list the issues to be discussed, and obtain the patient's agreement before beginning the interview. Here is an example of ART initiation:
Provider: "We have about 30 minutes to talk today. If we need more time, we'll arrange for another meeting. Today, I would like to discuss the medication used to treat an HIV infection. Is there anything you want to talk about?"
Patient: "No."

If "yes" (plus a patient item), the provider responds: "OK, that's two topics for today. Let's get started!" Or: "Would you mind if we discuss this topic in our next meeting? Otherwise we might not be able to work through what we need to talk about today. "

ASKING OPEN-ENDED QUESTIONS

Sometimes, the patient's reaction to an item when setting the agenda offers a hint to his or her stage of readiness. Open-ended questions can be used to widen the scope of issues around initiation of therapy.

Example: "Today, I would like to talk about HIV medication." PAUSE to allow the patient to demonstrate how he or she feels about this topic. A moment of hesitance or frank rejection could reveal that a patient has not yet thought about starting ART or is reluctant to do so (PRECONTEMPLATION). In this case, the provider has to establish reasons for the patient's opinion. If the patient responds positively, he/she has probably already reached the CONTEMPLATION or even the PREPARATION stage.

Having elicited spontaneous responses from the patient during the process of setting the agenda, the provider can introduce focused, open-ended questions to fill in any gaps, such as:

- "What have you heard or read about drugs used to treat HIV?"
- "What do you think about these drugs?"
- "How would you feel about taking these drugs?"
- "Not long ago we talked about antiretroviral therapy — what are your thoughts and feelings about that now?"

After asking open-ended questions during the interview the following strategies may encourage narrative answers [32]:
Waiting: After the patient has said something, maintain eye contact while letting several seconds pass (> 3 sec).
Echoing: Patient: " ... the pills won't do me any good anyway!" Provider: "not any good ... ?" (PAUSE) Patient: "No, because I ... ."
Mirroring: "You seem rather disappointed ... ?"
Summarizing: "Let me summarize what you've been telling me. You've had bad experiences with drugs in the past ... ."

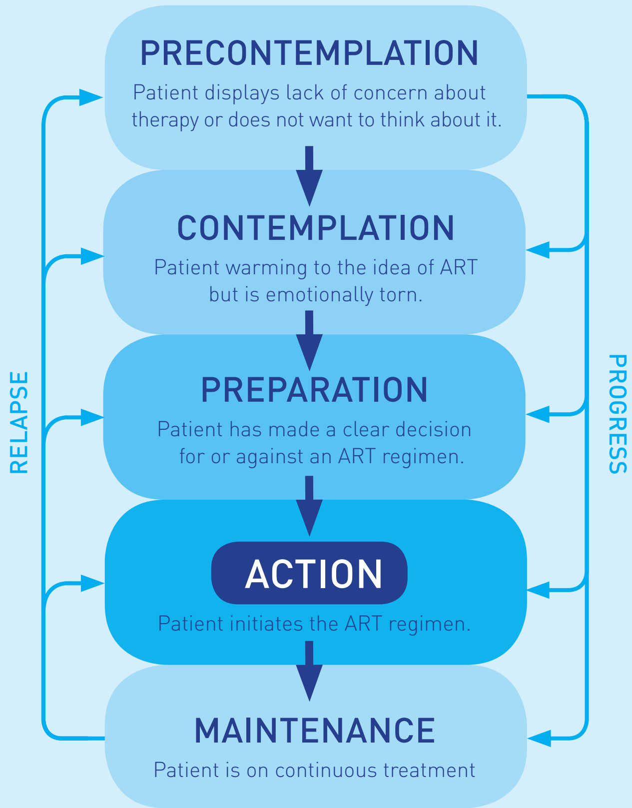

Figure 2: Changes in stages of readiness

MAKING A HYPOTHESIS ON THE STAGE OF READINESS

At the end of the interview, the health care provider should have an understanding of the patient's thoughts and feelings about starting ART and adhering to the regimen. Based on this understanding, the provider can make an informed decision on the patient's stage of readiness. This will help the provider to plan and conduct stage specific interventions. For patients not responding well to interventions, carefully re-evaluate the stage of readiness. The hypothesis concerning his/her stage might have been inadequate from the beginning, or the patient may have made progress to the next stage or regressed to an earlier stage of readiness as illustrated in graph 2.

STAGE-SPECIFIC INTERVENTIONS

Stage-specific interventions enable patients to progress to the next stages. Use the interventions listed below according to which stage a patient has reached. Choose the strategies best suited to a patient's circumstances from the stage-specific interventions. Carefully evaluate the effect of each intervention and continuously reassess a patient's stage of readiness. Making progress from stage to stage takes time and continuous support. A patient's regression to an earlier stage should not be a reason to quit stage-specific interventions.

1. PRECONTEMPLATION

- Identify how the patient feels about living with HIV, assess illness beliefs.
- Identify how the patient feels about ART, assess therapy beliefs.
- Based on the patient's illness and therapy beliefs, briefly explain what it means to live with HIV and why an ART regimen could be helpful. The goal is to empower, not to threaten or

STAGE-SPECIFIC INTERVENTIONS

frighten the patient.

- Establish a trusting relationship with the patient to encourage further discussion at a later appointment.

EXAMPLE (individualised information based on therapy beliefs)
Patient: "Medication is not an option for me. I've watched friends suffering from side effects. I'd rather have a good life and die when it is my time."
Provider: "My concern is that your plan might not work out the way you'd like." PAUSE "Would it be OK to tell you why?"
Patient: "Yes."
Provider:" I'm afraid your immune system will become weaker without therapy. And, with a weakened immune system, there's an excellent chance you'll develop health problems that won't kill you immediately, but that will make you suffer. Something else to consider is that the new drugs have fewer side effects and they're easier to tolerate. Many of my patients say they're leading active lives without HIV-related problems. It's much different from how it was just 10 years ago." (PAUSE)

2. CONTEMPLATION

- Ask the patient for thoughts on the pros and cons of ART using knowledge of their personal circumstances and emotions/feelings to obtain more detailed responses.
- Acknowledge that any ambivalence — a "yes, but..." answer — is a normal part of the process and allows the patient time to think things through.
- Offer information such as leaflets on the pros and cons of ART or support the patient in his/her quest for other information.
- Ask the patient to imagine what it would be like to follow an ART regimen. Explore different scenarios and what they might mean to the patient.
- Encourage the patient to feel that he/she can integrate an ART regimen into his/her life by telling stories of other patients who have succeeded with ART regimens.

EXAMPLE (pros and cons discussion)
Provider: "You tell me you're hesitant to start because you're uncomfortable taking medication in public and you worry about side effects. AND you've said you think that ART would help you feel less fatigued and stay healthy. It sounds like you're torn about what to do?"
Patient: "Yes, somehow yes."
Provider: "Would it be helpful if we spent some time assessing these pros and cons?"

3. PREPARATION

When the patient has decided in favour of an ART regimen:

- Discuss individualized therapy options including the simplest possible regimen.
- Discuss the regimen's effects and potential side effects.
- Explain the importance of adhering to the regimen in order to prevent resistant mutations.
- With the patient, make a detailed plan of how to integrate the regimen into his/her daily life.
- Discuss available social resources and how the patient can involve close support persons in medication management.
- Identify resources as well as potential barriers to adherence, and, if necessary, implement appropriate interventions.
- Offer and discuss tools such as pillboxes, reminder devices and communication technologies
- Offer training in the use of medication with electronic pill boxes and provide feedback on outcomes to the patient in a constructive, non-threatening manner.
- Assess the patient's medication-taking self-efficacy belief (a patient's own judgment of his/her ability to manage medication in daily life as discussed with the health care provider) using a 10-point Likert scale (not confident 1 to totally confident 10) [33].

EXAMPLE (assessment self-efficacy belief)[33]
Provider: "We're now talking about the regimen and how to take the medications. On a scale of 1 to 10, how confident are you of managing ART once you start, from 1 being not confident to 10 totally confident?"
Patient: "Five."
For numbers below seven, improve the patient's confidence by asking:
Provider:"Why are you at five instead of four?" or "What would it take for you to move up to six?"

Where the patient has decided against an ART regimen:

- Acknowledge the decision.
- Point out that changes in circumstances, either personal or clinical in nature, will require a re-evaluation of the situation and ART may need to be discussed again.

STAGE-SPECIFIC INTERVENTIONS

4. ACTION

- Schedule regular appointments to check that set goals are being met and to establish new goals.
- Discuss various situations such as holidays, fear of disclosure, side effects, or forgetfulness that might affect a patient's adherence to ART.
- Determine if the patient might benefit from a more structured administration of medicines, e.g., daily observed therapy (DOT), or modified daily observed therapy (mDOT), including educational support.
- Provide information and support for the management of potential side effects.
- Offer positive, empowering feedback. Offer continued use of electronic pill boxes and feedback on adherence. Assess adherence regularly, and if the patient is having problems, discuss them without judgment or accusations.

EXAMPLE (Use of structured adherence monitoring tools for early adherence problem solving)
Once started, adherence to ART should be monitored on a regular base. A patient's adherence patterns can change over time and problems should be best assessed before nonadherence becomes evident in laboratory markers[34]. These two questions from the Swiss HIV Cohort Study Adherence Questionnaire have worked well in clinical practice[34,35]:
Ask: "Taking medications regularly can be difficult. In the past four weeks, how often have you missed a dose of your HIV medication?"
Answers: Every day, more than once a week, once a week, once every two weeks, once a month, never
Ask: "Have you missed more than one dose in a row?"
Answers: Yes / No
Evaluation: Any problems should be further assessed. For the combination of the two questions (taking adherence: percentage of doses taken compared to total doses prescribed / drug holiday: no medication for 24h) sensitivity and specificity were 87.5% respectively 78.8%, after electronic event monitoring[35].

5. MAINTENANCE

At periodic intervals and/or in the context of significant life events e.g. pregnancy, divorce; death of close ones, severe illness, new relationship:

- Repeat exploration of motivation, successful strategies and difficulties with a patient centered interview.
- Continue to use structured adherence assessment tools.

For a patient with sufficient adherence: Show respect and explore successful strategies to learn for other patients.
For a patient with problems in motivation or already insufficient implementation of adherence

- Demonstrate understanding and explore potential barriers with patient centered interview.
- Plan and evaluate supportive strategies together with the patient (e.g. support in symptom management including mental health problems, intensification of social support, support in disclosure management, use or reuse of devices, reminder- and feedback- systems, discussion of motivational problems, consideration of ART regimen adaptions, support in stabilization of living conditions)[36].

In sum, successful antiretroviral treatment is determined by the collaboration of motivated, skilled patients and skilled healthcare providers. For health care providers, the empowerment of their patients includes skills that can be learned and continuously developed. For training programs that support skill development of health care providers or health care teams see: www.ready4therapy.ch/team

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