New HIV Diagnosis and ART Initiation in a Woman of Childbearing Age

Module 1 | Facilitator Guide

OVERVIEW

Goal

The goal of this session is to prepare learners to assess and manage a woman newly diagnosed with HIV using a team-based approach.

Objectives

By the end of the module, the learner will be able to:

1. Recognize the psychosocial effects of a new HIV diagnosis
2. Identify barriers to linkage to care for individuals newly diagnosed with HIV
3. Demonstrate how to support an individual newly diagnosed with HIV with the aim on improving linkage to care and rapid ART initiation for all patients
4. List risk factors related to increased risk of HIV transmission and understand that individuals who are virally suppressed cannot sexually transmit HIV (undetectable = untransmittable or U=U)
5. Discuss appropriate ART regimens for any adult
6. Describe contraception options for women living with HIV and at risk of acquiring HIV
7. Describe the appropriate interprofessional clinical management and follow-up for (a) a newly diagnosed patient and (b) a stable patient with undetectable VL

PEPFAR
HRSA Health Resources & Services Administration
UCSF Institute for Global Health Sciences
AFRE health African Forum for Research and Education in Health
Strengthening Interprofessional Education for HIV

Workshop Roadmap

Duration: 80 minutes

Duration	Activity	Content
5 min.	Introduction	
10 min.	1. Discussion	Psychosocial effects of diagnosis
10 min.	2. Discussion	Barriers to linkage to care
10 min.	3. Role-play	Facilitators for linkage to care
10 min. 10 min. (optional)	4. Discussion Group Work	Risk factors of HIV transmission and U=U
10 min.	5. Discussion	ART regimens
10 min. 15 min. (optional)	6. Group Work Group work and Discussion	Contraception options for women
15 min.	7. Discussion and teach back	Management and follow-up
5 min.	Conclusion	

Workshop Setup

How to tailor this module: All references to guidelines are based on WHO guidelines. Where country-specific recommendations on the provision are different from these, we encourage STRIPE partners to adapt to align with country guidelines. Facilitators are encouraged to prepare a tailored conclusion to summarize key takeaway messages most pertinent to the country's context.

Reminder to facilitators: Key learning points in the answers will be underlined. Please emphasize these learning points as you move through the module.

Additional learner materials

HEARTS-D Diagnosis and Management of Type 2 Diabetes: pages 13-15, 25

Osteoporosis Management Algorithm

Comprehensive Cervical Cancer Control (WHO): pages 170-173

Acronyms

ART	Zidovudine
CARG	Community ART refill group
CATS	Community Adolescent Treatment Supporters
CrAG	Cryptococcal antigen
DTG	Dolutegravir
EFV	Efavirenz
FTC	Emtricitabine
HBsAg	Hepatitis B virus surface antigen
HIV PrEP	HIV pre-exposure prophylaxis
IPE	Interprofessional Education
NVP	Nevirapine
PEP	Post-exposure prophylaxis
PMTCT	Prevention of mother-to-child transmission of HIV
PWH	People with HIV
QI	Quality improvement
RPR	Reactive plasma regain
SDG	Sustainable Development Goals
TDF	Tenofovir disoproxil fumarate
U=U	Undetectable = Untransmittable
VL	HIV RNA viral load
3TC	Lamivudine

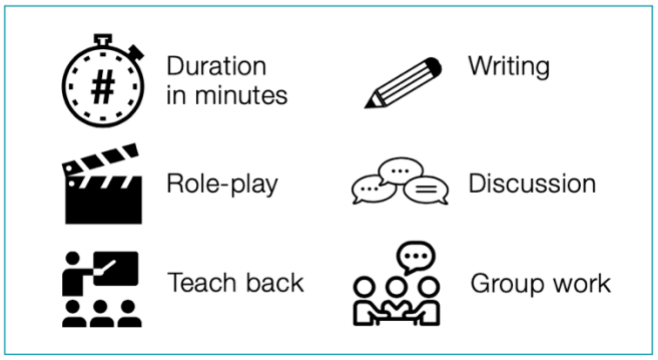
TEACHING CONTENT WITH OBJECTIVES & ANSWER KEY

Introduction

Facilitator: Read the case vignette aloud.

Case: Blessing is a 24-year-old woman who comes to the HIV clinic to receive HIV positive results and further management. She presents for post-test counselling. She has intentions to eventually start a family and cannot afford not to work.

Activity Components



ACTIVITY 1

Recognize the psychosocial effects of a new HIV diagnosis.

Has anyone told somebody they have been diagnosed with HIV or observed how someone has processed a diagnosis of HIV? If so, would you be willing to share how what this experience was like for you or the patient? Irrespective of your own experiences, what are the psychosocial effects of receiving a new HIV diagnosis?

Answer: Note that there is no right answer to this question and no right way to feel about receiving an HIV diagnosis. Allow groups to share 1-2 effects they identified with the larger group.

Every individual has a unique, personal response to receiving a new HIV diagnosis and how you counsel an individual will depend on his/her personal response. Their reaction may be affected by whether they anticipated the positive result, what they know about HIV, if they know someone living with HIV, and many, many other factors.

Many individuals will pass through a grieving process, which often includes stages of denial, anger, sadness or depression, fear and anxiety, and stress. Allow patients to express their feelings and voice their concerns. There is no right way to feel, and feelings may come and go.

A new diagnosis may affect someone's life in many ways, including:

- Stigma and discrimination from friends, family, or the community
- Fear of being seen as abnormal
- Confronting an uncertain future
- Absenteeism from work, family, or community events due to illness
- Economic impact
- Depression, anxiety, or stress disorders
- Intimate partner violence: This can take many forms and can include physical or emotional abuse, isolation, minimization, denial, blame, or the use of children, male privilege, or economic situation to intimidate.

ACTIVITY 2

Identify barriers to linkage to care for individuals newly diagnosed with HIV.

Before we discuss Blessing's case in further detail, what is the HIV care continuum or care cascade? What are the 95-95-95 goals?

Answer: The continuum of care for any disease describes the delivery of health care over a period of time. In patients with chronic disease, this covers all phases of illness from diagnosis to the end of life. For HIV, the care continuum is the series of steps a person must pass through from the time they receive their diagnosis of HIV to becoming virally suppressed. The key steps in the HIV care continuum include HIV diagnosis, linkage to care, treatment with ART, retention in care, and viral suppression.

The HIV care cascade is a tool related to the HIV care continuum that is used to measure key HIV care and treatment outcomes on a programmatic level. The HIV care cascade consists of diagnosis, treatment, and viral suppression. We are all trying to achieve (and surpass!) the UNAIDS "95-95-95" goals by 2030 to have:

- 95% of all people living with HIV know their HIV status
- 95% of all people diagnosed with HIV are receiving sustained antiretroviral therapy
- 95% of all people on ART are virally suppressed

Now look at the graph of the 2019 worldwide HIV care cascade, which depicts progress towards the 2030 targets of 95-95-95. What do you think of the results? What are some barriers to achieving the testing, treatment, and viral suppression targets?

Answer: Advance to slide 2 to show the graph of the global HIV testing and treatment cascade from 2019. Country-specific graphs such as these may also be available in the "Miles to Go" campaign; if so we recommend using those as well.

Allow the learners 3-5 minutes to discuss their impressions of the care cascade and to discuss potential barriers to each 95% target. There is no right answer. Groups may conclude that we have come a long way in HIV diagnosis and treatment OR that we have a long way to go. Emphasize that we must strive for 95-95-95 to halt HIV transmission and end the epidemic.

Advance to slide 3. There are many barriers to achieving the 95-95-95 goals, some of which include:

- 95% of all people living with HIV know their HIV status
    - Limited access to HIV testing and counseling, especially for key populations
    - Avoidance of HIV testing or care engagement
    - HIV stigma
- 95% of all people diagnosed with HIV receiving sustained antiretroviral therapy
    - Limited access to ART
    - Cost
    - Stock-outs
    - Gaps in procurement systems
    - Alcohol and substance use among PWH
    - Delayed scale up of "Treat All" (ART for all PWH, regardless of CD4+)

- 95% of all people on ART virally suppressed
    - Healthcare worker shortages
    - Long distances to clinic
    - Limited viral load testing availability
        - VL testing not available
        - Delays in test results
    - Limited resources for patient tracking, engagement, additional support

Now that we have described some of the emotional responses to a diagnosis of HIV and the importance of improving linkage and retentiont are, let's discuss how care teams (nurses, doctors, pharmacists, peer-educators, etc.) can best support Blessing to (1) link her to care, (2) start ART, and (3) continue an ART treatment. What are the important features of post-test counseling?

Answer: Post-test counseling should do 3 key things:

1. Be patient-centered. In other words, should not follow a script and instead should be responsive to the individual and consider his/her unique needs and concerns.
2. Convey key information (see below).
3. Instill a sense of hope and optimism, which is key to successful engagement in HIV care after a new diagnosis. It is important to remind patients that although we do not have a cure for HIV, we have many excellent treatments that can allow them to live long and healthy lives.

After small groups have discussed for 5 minutes and shared their answers with the group, advance to slide 4.

Key information to include in new diagnosis counseling:

- Explain the test results and diagnosis
- Allow time for the patient to process the news
- Discussion of immediate concerns and identification of a support network
- Clear information on ART: benefits to health, reduction in transmission, and where and how to obtain it. Ideally, patients should receive test-and-treat, i.e., same-day linkage and initiation of ART
- A referral appointment with time and date for HIV care services (ideally same day)
- Discussion of anticipated barriers to linkage to care and services
- Information on preventing transmission to a sexual partner
- Discussion of risks and benefits of disclosure
- Offer testing for sexual partners, children, and family
- Assess risk of intimate partner violence
- Assess the mental health status of the patient and any risk for suicide
- Referrals to additional services if needs are identified
- Time for questions and answers

ACTIVITY 3

10

Demonstrate how to support an individual newly diagnosed with HIV, with the aim of improving linkage to care and rapid ART initiation for all patients.

Facilitator: Continue to project slide 4 during the activity for reference. Have learners form pairs. Distribute the Role-play handout. Explain that one learner should play a patient with a newly positive HIV test result (he/she may focus on an emotional response to the diagnosis, such as sadness, anger, denial, fear, or stress or have a particular concern about the diagnosis). The other learner should play the role of a member of the patient's care team from their own health profession (e.g., a nurse or nursing student should play a nurse).

- For learners whose scope of practice may involve informing a patient of their positive test result, they should roleplay disclosing the new HIV diagnosis and post-test counseling.
- For learners whose scope of practice may not involve disclosing a positive HIV test result, they should roleplay how to support a patient's ability to link to care and start ART (in this scenario, the learner would be evaluating the patient immediately after she has been informed of her HIV diagnosis).

ACTIVITY 4

10

List risk factors related to increased risk of HIV transmission and understand that individuals who are virally suppressed cannot sexually transmit HIV (undetectable = untransmittable).

Blessing is curious how she might have contracted HIV. **How is HIV transmitted? What risk factors increase the risk of HIV transmission?**

Answer: After the learners discuss for 5 minutes, debrief and discuss as a group. HIV can be transmitted through unprotected sexual intercourse, exposure to infected blood or specific body fluids, or perinatally from mother to child. A higher HIV viral load in the source individual is associated with a greater risk of transmission. An HIV-positive person who is virally suppressed cannot sexually transmit HIV: Undetectable = Untransmittable (U=U)! It is incredibly important that patients and providers understand U=U as it is a powerful strategy to prevent onward transmission of HIV, and it can empower patients to stay on treatment.

Risk factors that increase HIV transmission risk include:

- High HIV viral load of the source individual
- Unprotected sex, especially if it results in mucosal disruption and/or bleeding
- Sex under the influence of drugs or alcohol
- Lack of circumcision (increases risk of acquisition in HIV-negative men who have sex with women)
- Having a sexually transmitted infection (STI)

OPTIONAL ACTIVITY

Which types of exposures have the highest risk of transmitting HIV? Using the cards on your table with types of HIV transmission listed, arrange them from highest risk to lowest risk of HIV transmission after a single exposure from a patient who is not virally suppressed on ART.

Facilitator: Cut out the cards/paper from the page provided and leave one set per table. This should be completed before the module.

Rank the order of risk of HIV infection with exposure to:

- **Percutaneous needle stick**
- **Receptive penile-vaginal intercourse**
- **Insertive anal intercourse**
- **Biting, spitting, throwing body fluids (including semen and saliva)**
- **Insertive penile-vaginal intercourse**
- **Mucous membrane exposure to blood (eg, splash to eye)**
- **Mother-to-child**
- **Receptive anal intercourse**
- **Needle-sharing injection drug use**
- **Blood transfusion**
- **Receptive or insertive penile-oral intercourse**

Answer: Allow 5 minutes for learners to rank the cards. After 5 minutes, advance to slide 5 to show the answer/table adapted from Patel et al. to the right.

	Exposure route	Risk per 10,000 expo- sures to an infected source (risk)	Order of risk
Blood- borne exposure	Blood transfusion	9250 (9/10)	#1
	Needle-sharing injection drug use	63 (1/150)	#4
	Percutaneous needle stick	23 (1/435)	#5
	Mucous membrane exposure to blood (e.g., splash to eye)	10 (1/1,000)	#7
Sexual exposure	Receptive anal intercourse	138 (1/72)	#3
	Insertive anal intercourse	11 (1/900)	#6
	Receptive penile-vaginal intercourse	8 (1/1250)	#8
	Insertive penile-vaginal intercourse	4 (1/2500)	#9
	Receptive or insertive penile-oral intercourse	0-4	#10
Perinatal	Mother-to-child	2260	#2
Other	Biting, spitting, throwing body fluids (including semen and saliva)	Negligible	#11

Discuss appropriate ART regimens for any adult

ACTIVITY 5

What does "Treat All" mean?

In 2015, the WHO officially recommended "Treat All," which is to initiate ART in all PWH regardless of CD4 cell count, WHO clinical stage, or age.

You want to start Blessing on ART. What are ART options for most adults?

Decoding ART

3CT	lamivudine
ABC	abacavir
AZT	zidovudine
TDF	tenofovir
FTC	emtricitabine
DTG	dolutegravir
EFV	efavirenz
NVP	nevirapine
DRV	darunavir
LPV	lopinavir
r	ritonavir

Answer: Note that some learners may not be familiar with HIV medications. If appropriate, pause to review the names of many of the commonly prescribed medications and emphasize that almost all patients with HIV should be taking 3 separate HIV medications (although sometimes these different medications are combined into one pill). The WHO recommended first-line regimen for people living with HIV and initiating ART is TDF + 3TC (or FTC) + DTG.

If DTG is not yet available where you practice, the alternative first-line regimen is TDF + 3TC (or FTC) + EFV.

Alternative first-line regimens for adults include: AZT + 3TC+EFV(or NVP) and TDF+3TC(or FTC)+NVP.

Does Blessing's age have bearing on what ART she is prescribed?

Answer: Blessing is 24 years old and of childbearing potential. She has told you she has intentions to eventually start a family. If she is interested in starting a family now or does not have reliable, consistent contraception, she should be given TDF + 3TC (or FTC) with either EFV or DTG. The WHO recommends that prescription of DTG, however, must involve a shared decision-making approach based on the risks and benefits of DTG in women who may become pregnant or who are in the first trimester of

pregnancy. Refer to the Clinician's Corner at the end of the module for additional information on the use of DTG in women of childbearing age.

ACTIVITY 6

Discuss contraception options for women living with HIV and at risk for acquiring HIV.

Blessing is worried that her contraception may have put her at risk for HIV infection. She asks you if her Depo Provera (DMPA-IM) may have increased her risk for contracting HIV.

The Evidence for Contraceptive Options and HIV Outcomes study—commonly called the ECHO study—recently looked at whether or not HIV infection risk and different contraceptive methods were linked. Spend 5 minutes reading the official statement from the WHO, UNAIDS, and UNFPA about the ECHO study results, included in Additional Learner Materials, followed by discussion.

Discuss in your small group the following questions:

1. **What are the main findings of this study?**
2. **What are the implications of this study?**
3. **When and how will you discuss contraception with your HIV-negative female patients?**

Answer: The ECHO study included 7,829 HIV-negative, sexually active women in Eswatini, South Africa, Zambia, and Kenya who were placed on 1 of 3 contraceptives: Depo-Provera injection (DMPA-IM, given every 3 months), a levonorgestrel implant (placed under the skin, effective up to 5 years), or a copper IUD (intrauterine device, effective up to 10-12 years). The purpose of the study was to determine if there was a difference in the risk of HIV infection between types of contraception. The main finding was that there was no significant difference in risk of HIV infection among women by type of contraception.

A secondary finding was that HIV infection rates were as high as 3.8% per year. The risk was especially high among women under age 25 years.

When counseling HIV-negative women, it is important to allow women and girls to make informed decisions and to use a shared decision-making approach to contraceptive use. Counseling should be free of stigma, coercion, and discrimination. All women and girls should have access to effective contraception and methods to prevent HIV. During a counseling visit:

- Assess if a woman has a desire for contraception.
- Present her with contraceptive options: DepoProvera, levonorgestrel implant, IUD, or consistent condom use.
- Discuss the frequency of dosing, effectiveness of each method, reversibility and risks and benefits.
- Work together to choose the contraceptive method that best fits her life and needs.
- Remember: women and girls who fear or experience violence or coercion may not be able to practice safe sex or make their own decisions about reproduction. Access to contraceptive options in clinics gives them back some of this power.
- Counsel on HIV prevention methods: condoms, and, if available, PrEP.

OPTIONAL ACTIVITY

Blessing thanks you for the information. She tells you that she does not want to become pregnant right now. She would like to continue with a contraception method, but is worried about how a new medicine might interact with the ART. She asks for your advice on her options. **Use one of the following resources on drug interactions with HIV medicines to determine what advice you would give.**

- Drug interaction table from the AIDSInfo Guide- lines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV (relevant information is included in your learner materials; tables and complete guidelines can be accessed from https://aidsinfo.nih.gov/guidelines)
- Drug interaction tool from the University of Liverpool (available from: https://www.hiv-druginteractions.org/checker)

Answer: PWH should be counseled to consistently use condoms during sex and to adhere to an ART regimen that maintains viral suppression. The combination of strategies is crucial to prevent transmission of HIV and to prevent STIs. Condoms are the only contraceptive method that prevents the spread of HIV. When combining hormonal contraceptives and ART, some drug-drug interactions may make birth control less effective:

- Combined oral contraceptives:
    - Levels may be decreased by EFV and several PIs
    - Levels not changed by DTG and NVP
- Injectable contraceptives (e.g., DepoProvera):
    - Levels not changed by EFV, NFP, LPV/r or NRTIs. No data on INSTIs
- Levonorgestrel implant
    - Levels may be decreased by EFV; several studies have shown increased risk of contraceptive failure
    - Levels not changed by NVP, LPV/r
- The efficacy of barrier methods and IUDs are not affected by ART use.

OPTIONAL ACTIVITY

Blessing is also nervous about telling her partner. **How would you counsel her on discussing the diagnosis with her partner?**

Answer: Studies have shown that most HIV-positive people disclose their HIV diagnosis to their significant other—their spouse or partner, within a few days of learning their status. It's important to have someone to listen to your concerns and offer support. At first, many partners feel anxiety about their HIV status and may also feel angry or upset if the HIV infection occurred sexually outside the relationship. Disclosing the HIV status can strain the relationship, so it's important to counsel Blessing on when and how to disclose. Depending on the nature of her relationship, you might want to recommend that Blessing bring her partner to be tested at the clinic and how to use that as an opportunity to discuss her new diagnosis. This may help minimize the threat of GBV if this is of concern (which is a very real concern for some women).

ACTIVITY 7

15

Describe the appropriate interprofessional clinical management and follow-up for (a) a newly diagnosed patient and (b) a stable patient with undetectable VL.

Consider the range of health professionals participating in this training. How should a clinician screen a patient with HIV for referral to other members of a multidisciplinary team? To determine the need for referral, what clinical information should be obtained and what questions should be asked of the patient?

Facilitator: Give members of each health profession present the opportunity to share tips for appropriate referral with the group. Stress the importance of taking a full medical history and providing a comprehensive person-centered evaluation.

Determine how to arrange follow-up care.

Facilitator: Based on the number of small groups, divide the following three questions among the groups and have each group report their answers to the entire group.

You are nearing the end of the clinic visit. When should Blessing come back for follow-up?

Answer: Follow-up for newly diagnosed patients may depend on how advanced their HIV is. For an asymptomatic, otherwise healthy patient, such as Blessing, follow-up after ART initiation at enrollment should typically be done at week 2 and week 4 and then monthly until viral suppression is confirmed. Patients with more advanced disease at enrollment are more likely to have opportunistic infections, need consultation or referral, and/or develop immune reconstitution inflammatory syndrome. These patients may need earlier and/or more frequent follow-up.

Depending on viral load testing availability, 6 months is generally a reasonable time to confirm viral sup-suppression. The reason for frequent visits in the first 6 months of treatment is to support the patient, monitor for side effects, and address barriers to adherence. If viral suppression is confirmed at 6 months, follow-up can be every 1-3 months based on patient preference and clinician judgment.

What lab monitoring is necessary at the time of HIV diagnosis?

Answer: At enrollment, labs should include: CD4 cell count, CrAg if CD4 cell count < 100 cells/mm3, hemoglobin, pregnancy status, urinalysis, creatinine, glucose, lipid profile, HBsAg, and RPR. Viral load should be drawn at 6 months on ART.

What is the appropriate follow-up and laboratory monitoring for a stable patient with undetectable HIV RNA? Should follow-up be the same for all patients?

Answer: After the first year on ART, patients can be classified as "stable" or "unstable." In some settings, stable patients may be able to opt for returning to clinic less frequently or participating in community adherence groups that might enable her to visit the clinic less often. A stable patient is someone who:

- has been on ART for ≥ 12 months
- is virally suppressed on most recent VL test (< 1000 copies/mL)
- has no active OIs

- attends their clinic appointments
- is not pregnant or breastfeeding
- ≥ 20 years of age
- The healthcare team does not have concerns about spacing intervals between appointments

A year later, as a stable patient, and after discussion with the clinic nurse, Blessing decides to come for HIV clinic appointments up to every 6 months instead of every month. ART refills can be distributed for up to 3 months, and she should be offered an option for "fast-track" medication pick-up. Viral load should be checked annually.

In short, no follow-up should be the same for every patient! A one-size-fits-all model does not work for 37 million people! This kind of approach is often referred to as differentiated care. Differentiated care is a client-centered approach that aims to better serve individual needs, reduce unnecessary burdens on the health system, and adapt to the individual patient to give him or her the best care possible. It is recommended by UNAIDS, the WHO, CDC, MSF, and many ministries of health. More information about differentiated care is available at http://www.differentiatedcare.org.

Conclusion 

Advance to slide 6 and review the learning objectives as a group. Ask learners to briefly summarize what they learned for each objective with a focus on any particularly challenging areas of the training.

CLINICIAN'S & PHARMACIST'S CORNER

Evidence for Treat All

The evidence for Treat All comes from 2 large pro- spective, randomized clinical trials:

1. START trial: This multi-country trial randomized 4,685 treatment-naïve individuals with CD4 cell count > 500 cells/mm3 to either immediate ART or delayed ART when CD4 cell count <=350 cells/ mm3. After 3 years, they found that early ART reduced the combination of AIDS-related events, serious non-AIDS events, and death significantly (1.8% vs 4.1% in the delayed ART arm). The results of this trial were so strong that they had to stop the trial early because it would be unethical to continue giving patients delayed ART based on these results.

2. TEMPRANO trial: This Cote d'Ivoire trial randomized 849 individuals with CD4+ counts >500 cells/ mm3 to either immediate ART or delayed ART per WHO criteria at the time. They found that those who received early ART were almost half as likely to have an AIDS or non-AIDS related event compared to those on delayed ART.

Dolutegravir Safety in Women of Childbearing Age

It has been controversial whether DTG is safe in women of childbearing age. Recent studies in Botswana had highlighted a possible link between DTG and neural tube defects (birth defects of the brain and spinal cord that cause conditions such as spina bifida) in infants born to women using the drug at the time of conception. This potential safety concern was reported in May 2018 from a study in Botswana that found 4 cases of neural tube defects out of 426 women who became pregnant while taking DTG. Based on these preliminary findings, many countries advised pregnant women and women of childbearing potential to take efavirenz (EFV) instead.

However, data from two large clinical trials comparing the efficacy and safety of DTG and EFV in Africa have now expanded the evidence base. The risks of neural tube defects are significantly lower than what the initial studies suggested. The most recent data reports a rate of neural tube defects of 3/1000 pregnancies for women on DTG at the time of conception vs 1/1000 pregnancies for women on other ART at the time of conception.[16]

DTG is a drug that is more effective, easier to take and has fewer side effects than alternative drugs that are currently used. DTG also has a high genetic barrier to developing drug resistance, which is important given the rising trend of resistance to EFV and nevirapine-based regimens. In 2019, 12 out of 18 countries surveyed by WHO reported pre-treatment drug resistance levels exceeding the recommended threshold of 10%.

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