Launch of the 2021 WHO HIV clinical and service delivery recommendations

World Health Organization

Dr Meg Doherty
Director, Global HIV, Hepatitis, STI Programmes
World Health Organization
17 & 18 March 2021

Outline

Director's Welcome

[Department of Global HIV, Hepatitis and Sexually Transmitted Infection Programmes]

SESSION 1: The dapivirine vaginal ring for HIV prevention

SESSION 2: Diagnostic interventions and treatment monitoring

SESSION 3: ART initiation for TB/HIV management

SESSION 4: Starting and continuing ART and re-engaging in care

SESSION 5: Psychosocial interventions for adolescents and young people

SESSION 6: Linking and integrating services

SESSION 7: Implementation considerations on key populations, children, adolescents, pregnant and breastfeeding women

The ‘triple billion’ goal

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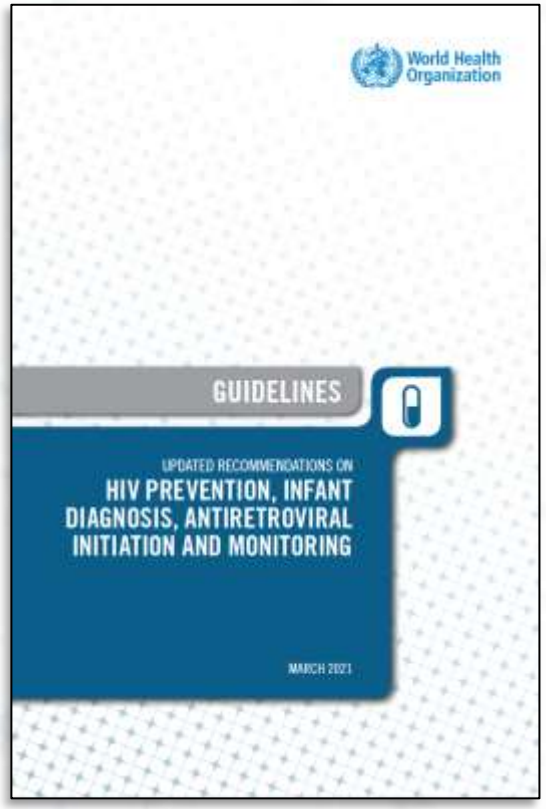
We must reach the “triple billion” in the next 5 years to be on track for delivery of the SDG targets by 2030.

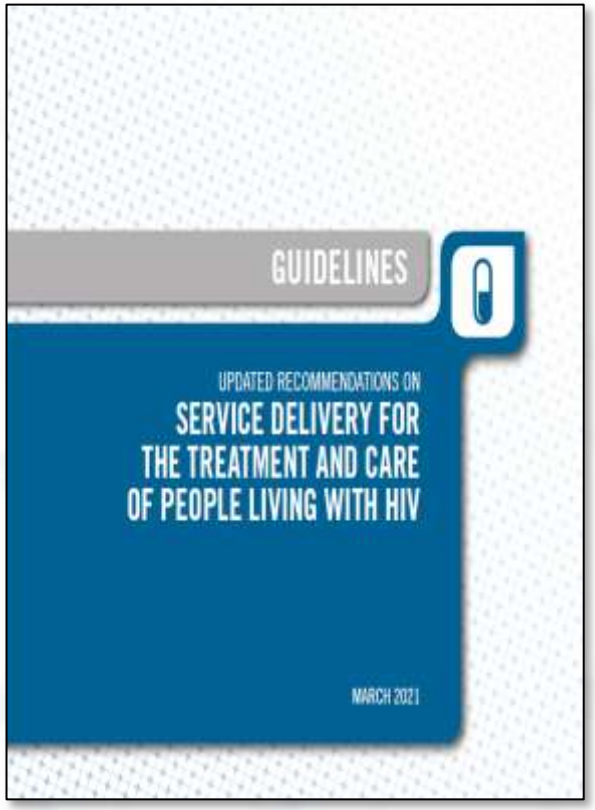
Vision, goals and targets

- The department is developing new targets, goals and strategies for 2022-2030
- Aligned with the UNAIDS and The Global Fund initiatives
- Progress report to be delivered at World Health Assembly 2021
- Focus on integration across HIV, Hepatitis and STIs

WHO HIV CLINICAL AND SERVICE DELIVERY RECOMMENDATIONS

Hub-and-spoke model for technical scoping conducted for the guidelines update





https://apps.who.int/iris/handle/10665/340190

Updating the Consolidated HIV Guidelines

Chapter 2 – Testing & diagnosis

- Point-of-care tests for diagnosing HIV infection among children younger than 18 months
  April 2020
- Consolidated guidelines on HIV testing services for a changing epidemic
  27 November 2019
- **New:** POC infant diagnosis

Chapter 3 – HIV Prevention

- A framework for voluntary medical male circumcision
  15 July 2016
- **New:** Dapivirine vaginal ring

Chapter 4 – HIV treatment and monitoring

- Update of recommendations on first- and second-line antiretroviral regimens
  22 July 2019
- Transitioning to an optimal paediatric ARV formulary: implementation considerations
  19 July 2018
- **New:** POC viral load and treatment algorithm

Chapter 5 – Co-morbidities

- Guidelines for diagnosing and managing disseminated histoplasmosis among people living with HIV
  1 April 2020
- Guidelines for the diagnosis, prevention and management of cryptococcal disease in HIV-infected adults, adolescents and children
  1 March 2018
- **New:** TB HIV
- Cervical cancer prevention

Chapter 6 – Service Delivery

- Maintaining and improving quality of care within HIV clinical services
  22 July 2019
- **New:** Service delivery recommendations

Chapter 7 – Toxicity, HIVDR, M&E

- Consolidated guidelines on person-centred HIV patient monitoring and case surveillance
  20 June 2017
- Tackling HIV drug resistance: trends, guidelines and global action
  20 July 2017
- Consolidated HIV strategic information guidelines: Driving impact through programme monitoring and management
  April 2020

Updated Recommendations on First-line and second-line antiretroviral regimens and post-exposure prophylaxis and on early infant diagnosis of HIV
27 December 2018

Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations
1 July 2016 – **update End of 2021**

Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy
20 July 2017

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WHO HIV Apps and toolkits – Feedback requested

WHO HTS Info: new app

WHO guidance on HIV testing app

HIV Tx app

HIV treatment and care app

Oral PrEP Tool app

WHO PrEP Implementation Tool app.

WHO HTS Info app:

- App store: https://itunes.apple.com/us/app/who-hts-info/id1359010276
- Google Play: https://play.google.com/store/apps/details?id=com.whohtsinfo

WHO Tx app:

- App store: https://play.google.com/store/apps/details?id=uk.co.adappt.whoarv
- Google Play: https://apps.apple.com/us/app/who-hiv-tx/id1473013705?ls=1

WHO PrEP Implementation app:

- App store: https://itunes.apple.com/us/app/hiv-oral-prep/id1233271674?mt=8
- Google Play: https://play.google.com/store/apps/details?id=org.hivoralprep.app&hl=en

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WHO HIV Apps and toolkits – Feedback requested

https://www.who.int/tools/aids-free-toolkit

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Sessions on new WHO recommendations

Chaired by:
Dr. Ilesh Jani (Ministry of Health, Mozambique)
Dr. Aleny Couto (Ministry of Health, Mozambique)

Session 1: The dapivirine vaginal ring for HIV prevention

Michelle Rodolph, WHO HQ, Switzerland

Department of Global HIV, Hepatitis and Sexually Transmitted Infection Programmes

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Brief background

- **More than half of all new HIV infections are among women and girls**
  - Approximately 7,000 young women aged 15–24 years become infected with HIV each week.
- Continued HIV transmission **despite current prevention efforts**, including oral PrEP, and expanding treatment programmes suggests more is needed.
- The DPV-VR is a **female-initiated option** to reduce the risk of HIV infection.
- To use, the ring
  - must be worn inside the vagina for 28 days, after which it should be replaced by a new ring.
  - is made of silicone and is easy to bend and insert.
  - works by releasing the ARV drug, dapivirine, from the ring into the vagina slowly over 28 days.

Summary of the evidence

A review and analysis of DPV–VR trials demonstrated that the **ring is effective in reducing the risk of acquiring HIV infection**.

- Two RCTs reported that the DPV–VR was approximately **30% effective in reducing HIV infection** in intention-to-treat analysis.
- Two OLEs found **increased efficacy, increased adherence and increased retention** relative to the randomized controlled trials
  - The results from one of the OLEs indicated a **62% reduction in HIV transmission**, comparing study results to a simulated control
- **No difference** in the treatment and placebo arms **of Adverse Events** related to pregnancy, fetal outcomes and/or infant outcomes.
  - Number of pregnancies was small so ongoing trials are further assessing safety data during pregnancy and breastfeeding
- The dapivirine ring **acts locally, and systemic absorption is low**
- Research on **values and preferences** indicate ring use is considered **highly acceptable**

Recommendation

The dapivirine vaginal ring may be offered as an additional prevention choice for women at substantial risk* of HIV infection as part of combination prevention approaches.

(conditional recommendation; moderate-certainty of evidence)

* Substantial risk of HIV infection is defined as HIV incidence greater than 3 per 100 person–years in the absence of PrEP

Implementation considerations / Research gaps

- Addressing the provision of the DPV-VR as part of **comprehensive services**;
- Ensuring women are offered full information in order to make an **informed choice** about the benefits and potential risks when considering to use the ring;
- **Adolescent girls and young women** may need more support during initiation and for continuation;
- Acceptability among women from **key population groups;**
- Additional **adherence support** and **demand creation;**
- **Training and support for providers** to understand and be able to offer this new product;
- Further information on **safety in pregnancy and breastfeeding** and **cost-effectiveness.**

Community perspective

Imelda Mahaka

Pangaea Zimbabwe AIDS Trust

Session 2: WHO recommendations on key diagnostic clinical and service delivery considerations

Lara Vojnov, WHO HQ, Swizerland

Department of Global HIV, Hepatitis and Sexually Transmitted Infection Programmes

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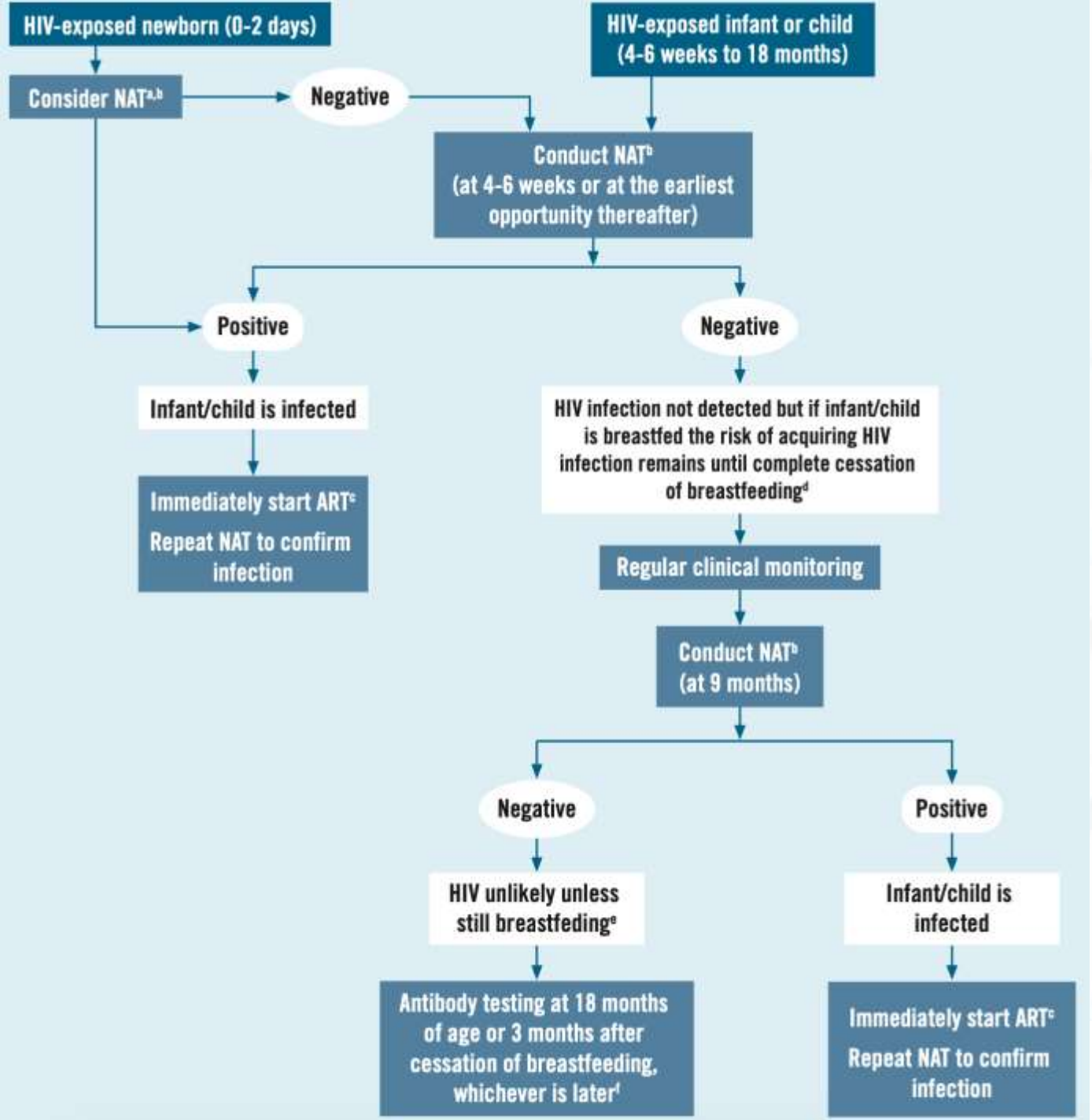
Key 2021 Guideline Questions

Clinical

- Point-of-care infant diagnosis
- Point-of-care viral load
- Treatment failure algorithm

Service Delivery

- Task-sharing of specimen collection and point-of-care testing
- Diagnostics integration



Infant testing algorithm: it's a process!

- Moving to a multi-HIV NAT algorithm
  - Birth (where of value)
  - 6 weeks
  - 9 months
  - Any time HIV exposed infants present sick
- Ensuring **confirmatory** testing of a positive NAT result is undertaken
- **Diagnosis is not completed without "final diagnosis" at the end of the period of risk for transmission**

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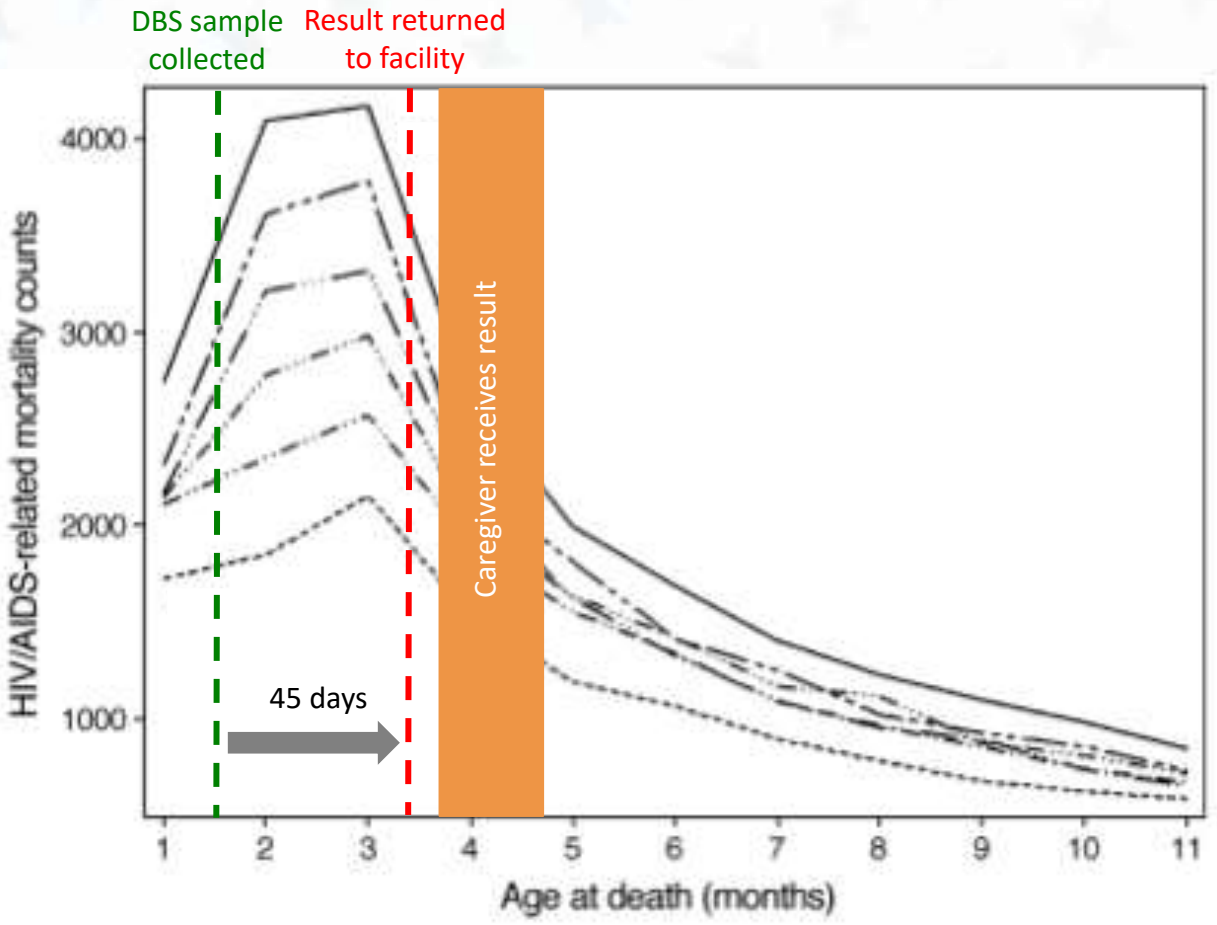
Systematic review of laboratory-based infant testing outcomes



- 77% of test results were received by caregivers
- The mean age at infant testing was 74 days
- The mean age at treatment initiation was 214 days (7 months)
- 15% of HIV-positive infants had died after infant testing but before ART initiation

2016 WHO recommendation

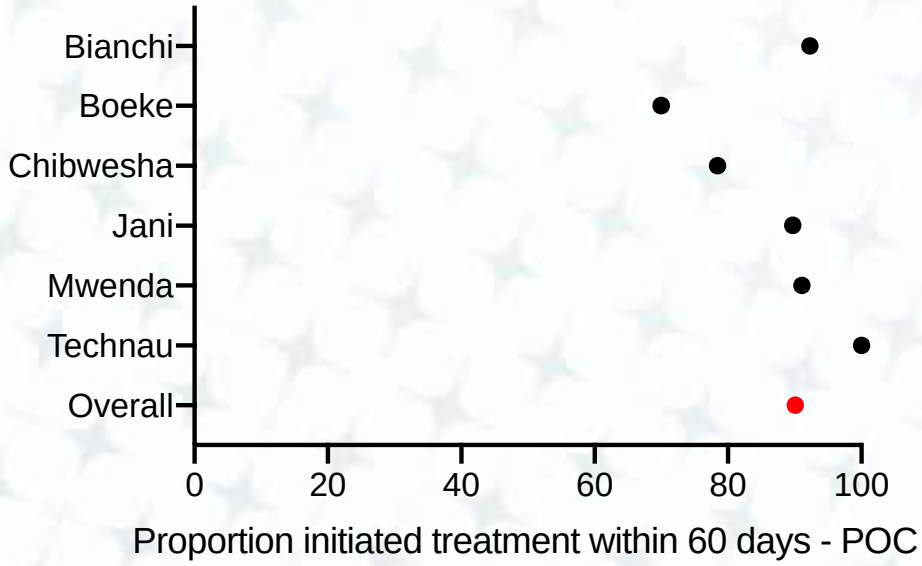
Recommendation

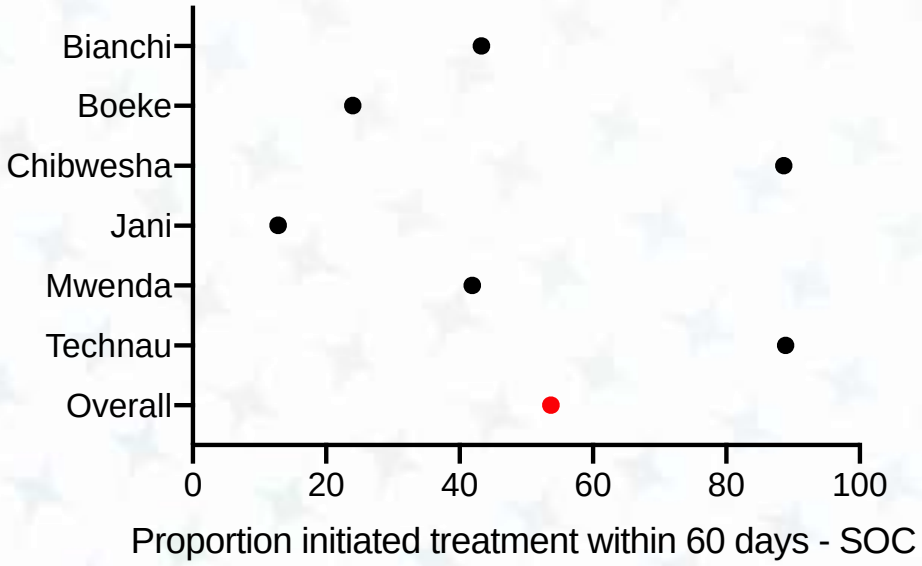
Nucleic acid testing (NAT) technologies that are developed and validated for use at or near to the point of care can be used for early infant HIV testing (conditional recommendation, low-quality evidence).

Point-of-care infant testing systematic review

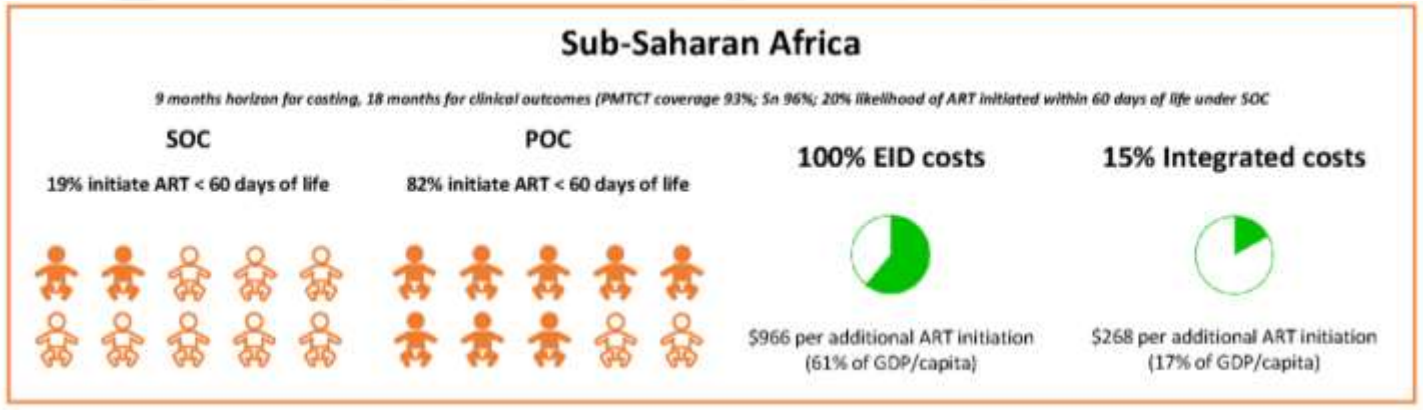
Infants 8 times more likely to start treatment within 60 days with POC testing compared to SOC testing

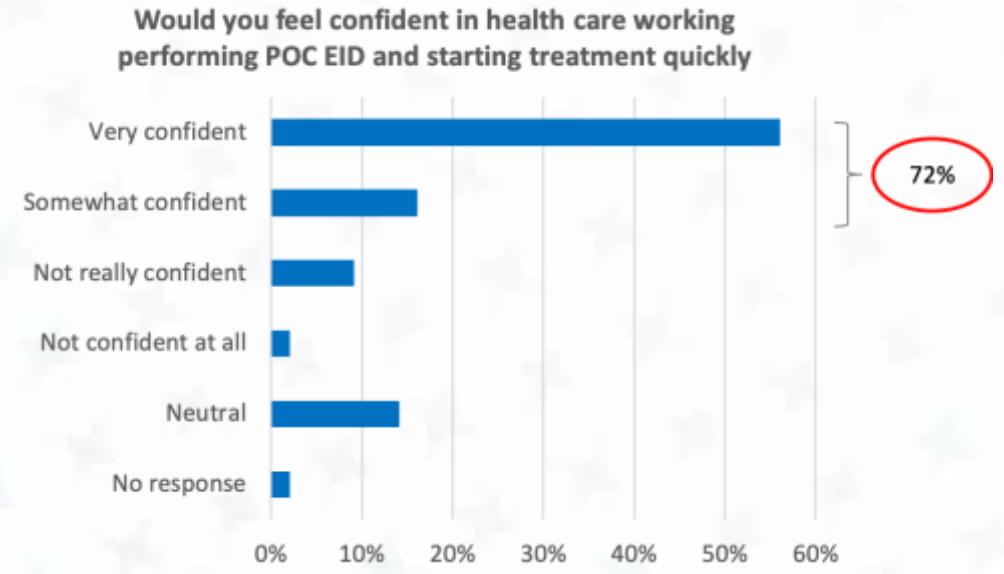
- OR 7.9 (95% CI 5.4-11.5, p<.001)
- 92.8% start within 60 days with POC, 50.5% with SOC
- Time to ART initiation: *0 days (95% CI 0-1 days) for POC vs 39.5 days (95% CI 34-43 days) for SOC*
- Same day treatment initiation 51% with POC, 0% with SOC



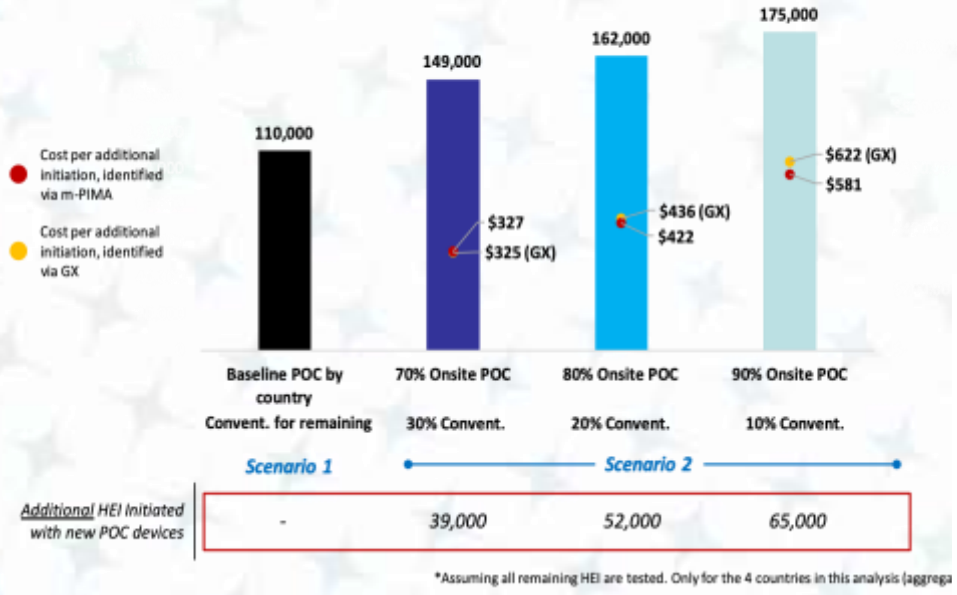


Cost-effectiveness, acceptability, and feasibility

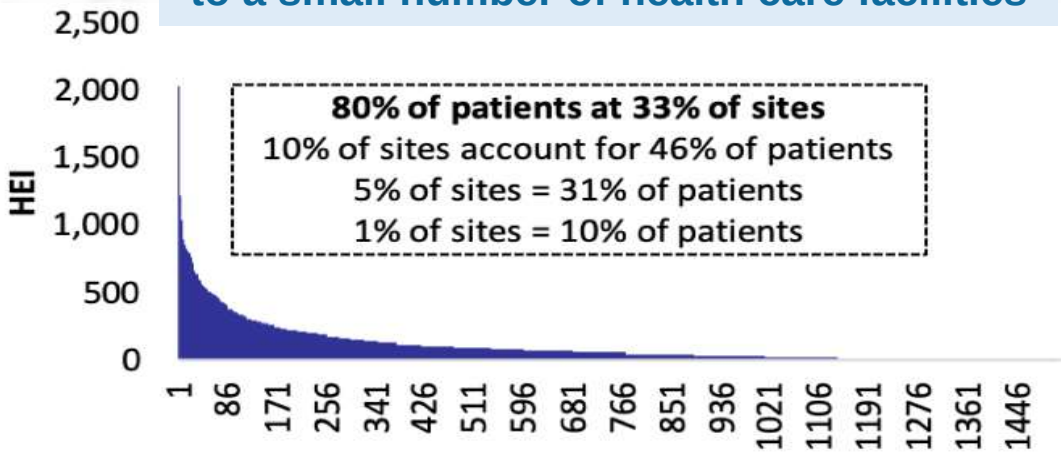




Although more expensive, rollout of additional *onsite* POC devices expected to result in significantly higher number of ART initiations



Significant proportions of infants present to a small number of health care facilities



2021 Point-of-care infant diagnosis recommendation

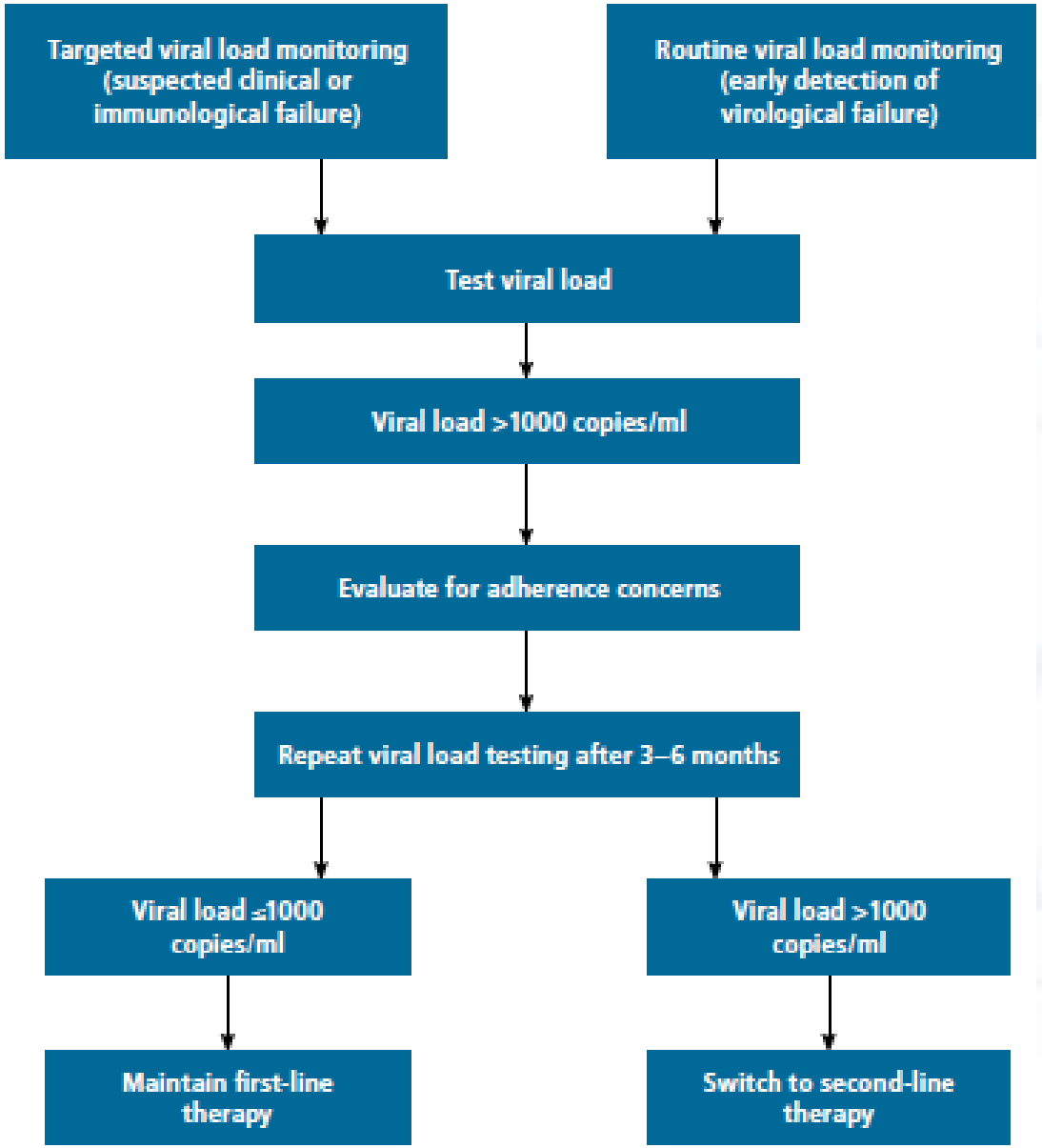
Recommendation

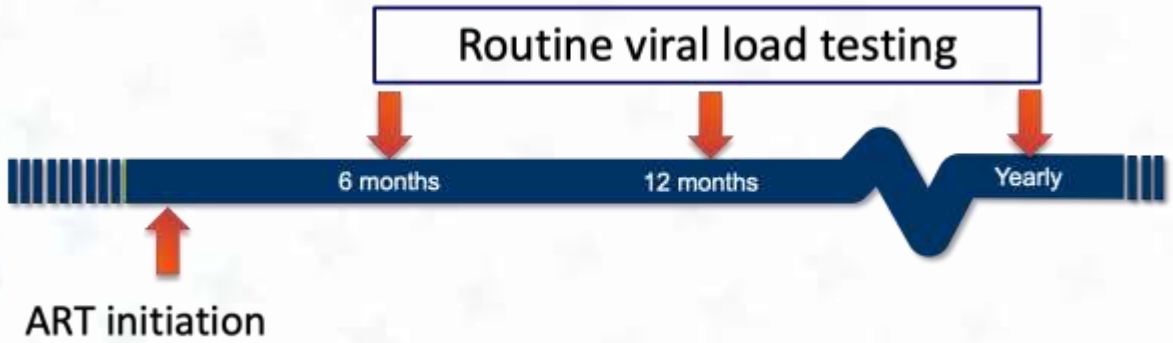
Point-of-care nucleic acid testing should be used to diagnose HIV among infants and children younger than 18 months of age.

(strong recommendation; high-certainty evidence)

- **Decentralization of ART** or strengthening of referral systems for ART initiation remain of critical importance to ensure impact on infant outcomes.
- Point-of-care infant diagnosis technologies should be considered and used within the current infant diagnosis algorithm at any point when a NAT is required.
- Access to high-quality diagnostic testing should be continually expanded across HIV and other molecular testing needs.
- Ensure adequate human resources, training, service and maintenance and quality assurance.

2016 WHO Recommendations for treatment monitoring





Scale-up of laboratory capacity and sample collection networks have facilitated increased access to diagnostics. However, **challenges** remain with:

- **inadequate access,**
- **infrastructural barriers,**
- **human resource shortages,**
- **long test turnaround times, and**
- **clinical utilization of results.**

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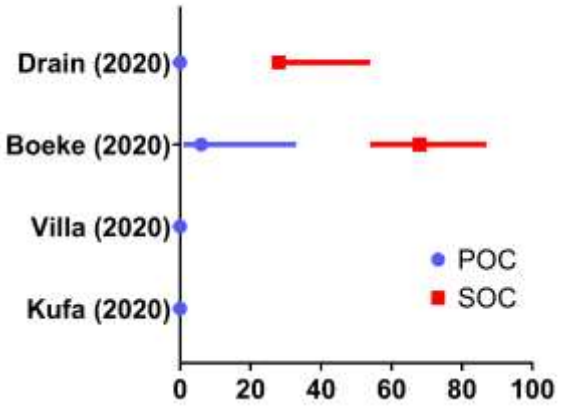
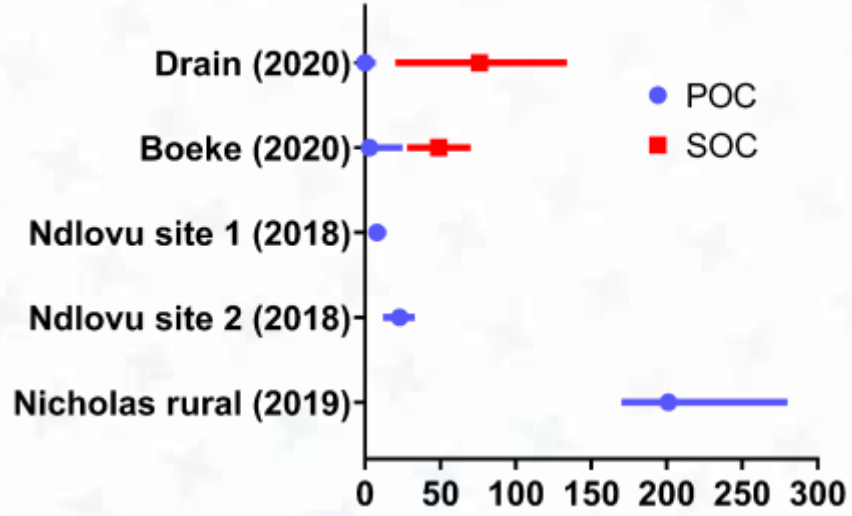
Point-of-care viral load systematic review

POC improves TAT-R to patients

HR 17.7 (13.0-24.2)



- Improves turnaround time of results to clinician (HR 11.7)
- Increases probability of same-day results to patients
- Increases probability of and reduces time to differentiated care (RR 2.2 and HR 3.5, respectively)
- Increases retention in care and viral suppression at 18 months (RR 1.2)



POC reduces time to clinical action for elevated VL

HR 10.9 (2.1-57.5)

2021 Point-of-care viral load recommendations

Recommendation

Point-of-care viral load may be used to monitor treatment among people living with HIV receiving ART.

(conditional recommendation; moderate-certainty evidence)

Box 2. Priorities for point-of-care viral load testing

Point-of-care viral load testing should be given priority for the following populations:

- Pregnant and breastfeeding women
- Infants, children and adolescents
- People requiring a repeat viral load after a first elevated viral load
- People for whom treatment failure is suspected
- People presenting sick, living with advanced HIV disease or having a known opportunistic infection (TB, cryptococcal infection, etc.)
- First scheduled viral load test for people re-entering care

Considerations for updated treatment failure algorithm

Four key questions to consider for revision:

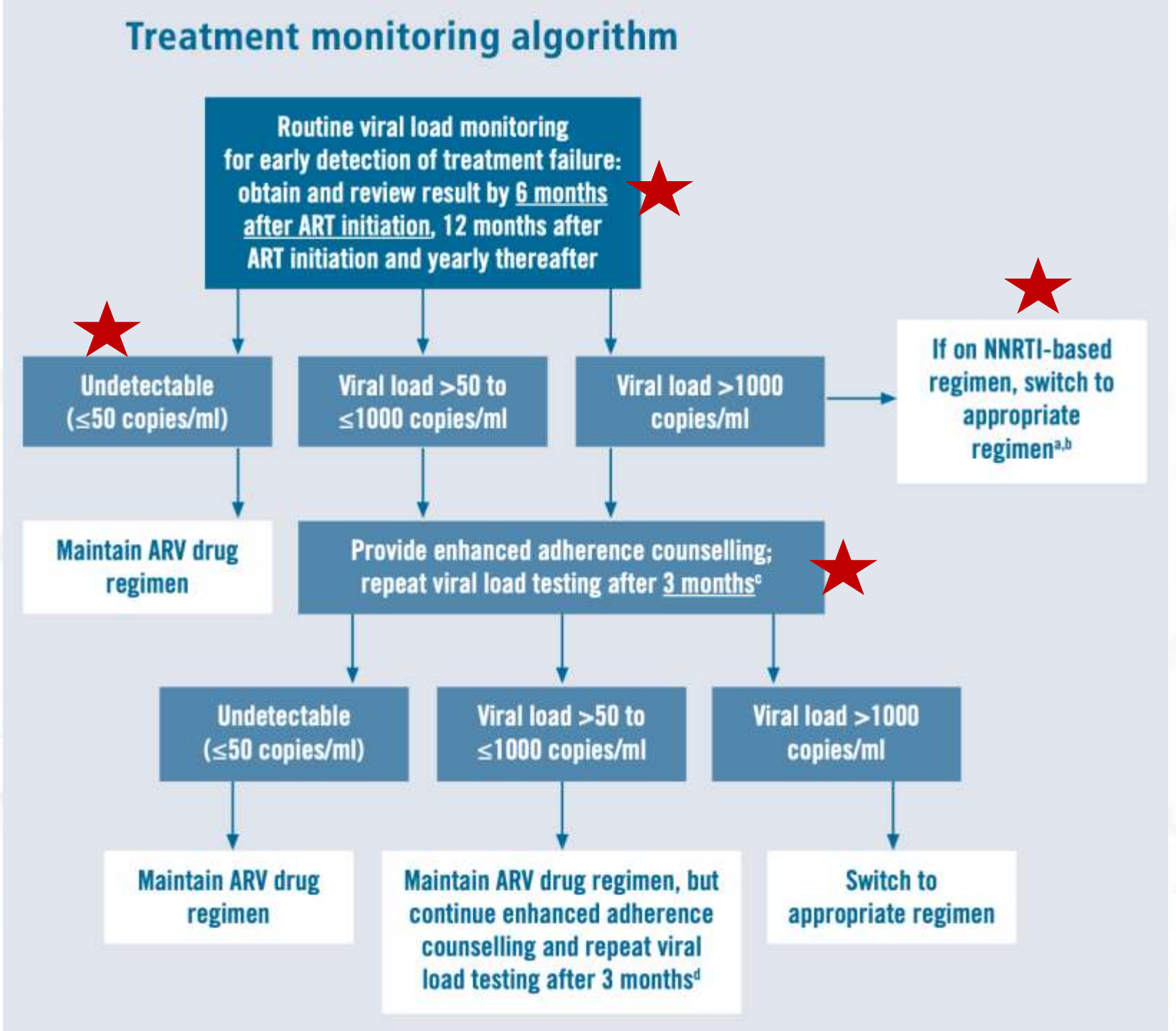
1) Timing of first viral load

2) Timing of repeat viral load after elevated viral load

3) Immediate (single viral load) switch to second-line ART in patients on EFV-based ART

4) Treatment failure threshold (and consideration for a suppression/undetectable threshold)

2021 Updated treatment monitoring algorithm



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Implementation Considerations for Treatment Monitoring of Pregnant and Breastfeeding Women

- **Utilize same-day point-of-care testing for viral load testing in pregnant and breastfeeding women** to expedite result return and clinical decision-making.
  - If not available, viral load testing should be prioritized for this population across the laboratory referral process (specimen collection, testing, and results return).

- **Adherence counselling** should be provided at all ANC and post-natal visits.

- **For all pregnant women, regardless of ART initiation timing**: conduct viral load testing at 34-36 weeks of gestation (or at the latest at delivery) to identify women who may be at **risk for treatment failure** and/or may deliver infants at higher **risk for perinatal transmission**.

Action: If VL > 1,000 cp/ml, follow treatment monitoring algorithm and provide enhanced postnatal prophylaxis for the infant. Consider infant NAT at birth.

In addition:

a) **For pregnant women on ART prior to conception**: conduct a viral load at the 1st ANC visit (or when first presenting) to identify women at increased risk of *in utero* transmission.
Action: If VL > 1,000 cp/ml, follow treatment monitoring algorithm[1] and consider infant NAT at birth, where available.

b) **For pregnant women starting ART during pregnancy**: conduct a viral load by 3 months post-ART initiation to ensure there has been rapid viral suppression.
Action: If VL > 1,000 cp/ml, follow treatment monitoring algorithm. Irrespective of maternal viral load, infants of women starting ART at any time during pregnancy could be considered for birth testing, where available.

- **For all breastfeeding women, irrespective of when ART was initiated**: conduct a viral load test 3 months post-delivery and every 6 months thereafter to detect viremic episodes during the postnatal period.

Action: if VL > 1,000 cp/ml, follow treatment monitoring algorithm, conduct infant HIV testing immediately, and consider re-initiation of enhanced postnatal prophylaxis for the infant.

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Task-sharing of specimen collection and testing

NEW

Good practice statement

2016

Trained and supervised non-laboratory staff, including laypeople, can undertake blood finger-prick for sample collection.

- Point-of-care CD4
- Point-of-care infant diagnosis
- Point-of-care viral load
- Additional tests: ALT, Hb, crypto, syphilis

NEW

WHO recommendation

2019

Lay providers who are trained and supervised to use rapid diagnostic tests (RDTs) can independently conduct safe and effective HIV testing services (*strong recommendation, moderate quality of evidence*).

Task sharing of specimen collection and point-of-care testing with non-laboratory personnel should be implemented when professional staffing capacity is limited.

(Strong recommendation; moderate-certainty evidence)

2021

Diagnostic integration across programmes

Offering TB, EID and targeted VL through integrated testing increased device utilization, without exceeding capacity or impacting TB services

- Integrated testing is operationally feasible with appropriate site selection to balance the expected demand

Near-POC testing can enable faster and increased rates of clinical action for HIV+ infants and PLHIV on ART experiencing viremia

- Same-day result delivery was possible for EID with near-POC device
- Faster clinical action was achieved for both EID and VL improving outcome
- Integrated testing does not impact the potential impact of near-POC testing and is viable option to scale-up near-POC testing which has been shown to be impactful

		Abbott m2000sp	Abbott m-PIMA	Cepheid GeneXpert GX-4, 16, 48, 80	Hologic Panther	Roche CAP/CTM 96	Roche 4800/ 6800/8800
							
Max daily throughput (incl. controls)		96 (8hrs) 288 (24hrs)	8 (8 hrs)	GX4: 16 (8hrs) GX16: 64 (8hrs)	320 (8hrs) 1,220 (24hrs)	168 (8hrs) 312 (24hrs)	384/960 (8hrs) 1,344/3,072 (24hrs)
Test menu	HCV VL	✔[a]	✘	✔[b]	✔	✔	✔[c]
	HBV VL	✔	✘	✔	✔	✔	✔
	HIV EID	✔[a]	✔[a]	✔[b]	✔	✔[d]	✔[c]
	HIV VL	✔[a]	✔[a]	✔[b]	✔[a]	✔[d]	✔[c]
	MTB	✔	✘	✔[b]	✘	✔	✔
	HPV	✔[a]	✘	✔[b]	✔	✔[c]	✔[c]

[a] Technologies with WHO prequalification listing
[b] Technologies endorsed by WHO (Global Tuberculosis Program)
[c] Technologies currently undergoing WHO prequalification review
Information included as of December 20, 2019. Pictures are not to comparable scale.

Diagnostic integration across programmes

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CONSIDERATIONS FOR ADOPTION AND USE OF MULTIDISEASE TESTING DEVICES IN INTEGRATED LABORATORY NETWORKS

Good practice statement

Disease programmes, especially HIV and TB, should actively work towards balanced integration of diagnostic services.

						Roche 4800/ 6800/8800
Max daily throughput (incl. controls)		96 (8hrs) 288 (24hrs)	8 (8 hrs)	GX4: 16 (8hrs) GX16: 64 (8hrs)	320 (8hrs) 1,220 (24hrs)	168 (8hrs) 312 (24hrs)	384/960 (8hrs) 1,344/3,072 (24hrs)
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	HIV VL	✔[a]	✔[a]	✔[b]	✔[a]	✔[d]	✔[c]
	MTB	✔	✘	✔[b]	✘	✔	✔
	HPV	✔[a]	✘	✔[b]	✔	✔[c]	✔[c]

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Community perspective

Florence Riako Anam

GNP+, Kenya

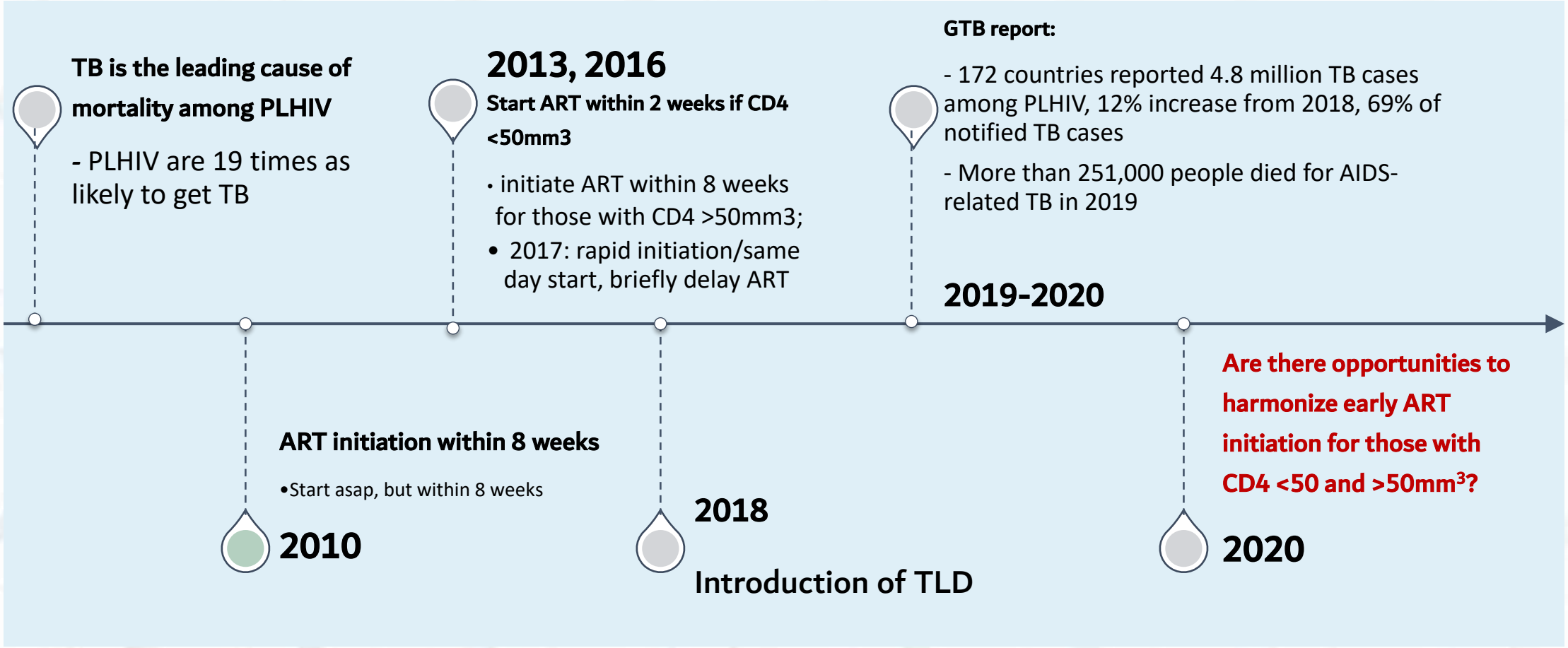
Session 3: Timing of ART initiation for those starting TB treatment

Ajay Rangaraj, Department of Global HIV, Hepatitis and STI programmes, WHO, Geneva

March 2021

Context to update of recommendations:

ART initiation for those undergoing treatment for tuberculosis



Previous WHO Guidance

2016 consolidated guidelines

4.3.5 Timing of ART for adults and children with TB

Recommendations

- **ART should be started in all TB patients living with HIV, regardless of CD4 cell count (strong recommendation, high-quality evidence).[a]** NEW
- TB treatment should be initiated first, followed by ART as soon as possible within the first 8 weeks of treatment (strong recommendation, high-quality evidence).[a]
- HIV-positive TB patients with profound immunosuppression (e.g. CD4 counts less than 50 cells/mm^3) should receive ART within the first two weeks of initiating TB treatment.
- ART should be started in any child with active TB disease as soon as possible and within 8 weeks following the initiation of antituberculosis treatment, regardless of the CD4 cell count and clinical stage (strong recommendation, low-quality evidence).

[a] The quality of evidence for this recommendation was upgraded to high in 2015.

Source (children): Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach. Geneva: World Health Organization; 2013 (http://www.who.int/hiv/pub/guidelines/arv2013/download/en).

2017 rapid initiation guidelines

Timing of ART for people with TB

- Routine TB symptom screening for people with HIV, using an algorithm containing fever, cough of any duration, weight loss and night sweats, will help to identify people who should either be expedited for TB diagnosis (if symptoms) or given preventive TB therapy (if no symptoms). Where feasible, suspected TB should be confirmed through laboratory testing (Xpert® MTB/RIF as the first test and LF-LAM in urine). ART should be briefly delayed while investigating for TB among people with TB symptoms.
- TB treatment should be initiated first, followed by ART as soon as possible within the first eight weeks of treatment *(strong recommendation, high-quality evidence)*.
- TB patients[4] living with HIV who have severe immunosuppression (such as CD4 cell counts <50 cells/mm^3) should receive ART within the first two weeks of initiating TB treatment.
- Caution is needed for people living with HIV with TB meningitis, since immediate ART is associated with more severe adverse events than initiating ART two months after the start of TB treatment.
- Any child with active TB disease should start ART as soon as possible and within eight weeks after initiating TB treatment (other than TB meningitis[5]), regardless of CD4 cell count and clinical stage *(strong recommendation, low-quality evidence)*.

World Health Organization

Countries that initiate ART earlier

Country	year	Policy (Adults and Adolescents)	Policy (Children)
Uganda	2020	Start ART **at** 2 weeks post TB treatment initiation If CD4<50, **BEFORE** 2 weeks	same
Zambia	2020	Start ART as soon as ATT is tolerated (usually **within 2-3 weeks**) regardless of CD4 or WHO staging	same
Kenya	2018	Initiate ART **within 2 weeks** after start of TB treatment	same
Malawi	2018	Start ART **within 2 weeks** of TB treatment initiation **TBT+ART can be started on the same day if patient is stable**	same
eSwatini	2018	Start ART **within 2 weeks** of TB treatment initiation ART can be delayed to 4 wks post-initiation of ATT for patients with TB meningitis. ART should NOT be delayed beyond 8 weeks post-initiation of anti-TB therapy.	same
Nigeria	2016	TB treatment should be initiated first, followed by ART as soon as possible **within the first 2 weeks** of treatment	same

Country	year	Policy (Adults and Adolescents)	Policy (Children)
Lesotho	2016	Start ART **within 2-4 weeks** of TB treatment initiation irrespective of CD4 count	same
Cameroon	2019	Initiate ART **2 to 8 weeks after** start of TB treatment (CD4>50) Initiate ART **within 2 wks** after start of TB rx **(CD4<=50)**	**Initiate ART 2 wks after start of TB treatment (CD4<=50)** **Initiate ART 8 wks after start of TB treatment (>50 CD4)**
Namibia	2019	Defer ART until **4-8 weeks after** start of TB treatment.	same
Zimbabwe	2016	Defer ART for **at least 2 weeks after** start of TB treatment If **CD4<50**, **within 2 weeks** of TB treatment initiation	Initiate ART **within 8 weeks** of TB treatment initiation
South Africa	2020	Initiate ART **8 weeks after** starting TB treatment (CD4>=50) Initiate ART **within 2 weeks** of start TB treatment **(CD4<50)** when client's sx improving and TB sx tolerated (MDR TB: after 2 weeks, when sx improving)	same

World Health Organization

Countries that initiate ART earlier

Country	year	Policy (Adults and Adolescents)	Policy (Children)
Uganda	2020	Start ART **at** 2 weeks post T If CD4<50, **BEFORE** 2 weeks	
Zambia	2020	Start ART as soon as ATT is regardless of CD4 or WHO s	
Kenya	2018	Initiate ART **within 2 weeks**	
Malawi	2018	Start ART **within 2 weeks** of TB treatment initiation **TBT+ART can be started on the same day if patient is stable**	same
eSwatini	2018	Start ART **within 2 weeks** of TB treatment initiation ART can be delayed to 4 wks post-initiation of ATT for patients with TB meningitis. ART should NOT be delayed beyond 8 weeks post-initiation of anti-TB therapy.	same
Nigeria	2016	TB treatment should be initiated first, followed by ART as soon as possible **within the first 2 weeks** of treatment	same

The highlighted countries also have harmonised populations with regards to timing of ART initiation to typically within 2 weeks after start of TB treatment

Country	year	Policy (Adults and Adolescents)	Policy (Children)
Lesotho	2016	Start ART **within 2-4 weeks** of TB treatment of CD4 count	same
		eks after start of TB **wks** after start of TB rx	**Initiate ART 2 wks after start of TB treatment (CD4<=50)** **Initiate ART 8 wks after start of TB treatment (>50 CD4)**
		eeks after start of TB	same
Zimbabwe	2016	Defer ART for **at least 2 weeks after** start of TB treatment If **CD4<50**, **within 2 weeks** of TB treatment initiation	Initiate ART **within 8 weeks** of TB treatment initiation
South Africa	2020	Initiate ART **8 weeks after** starting TB treatment (CD4>=50) Initiate ART **within 2 weeks** of start TB treatment **(CD4<50)** when client's sx improving and TB sx tolerated (MDR TB: after 2 weeks, when sx improving)	same

World Health Organization

Results from the systematic review

1. Among **PLHIV with CD4 ≤ 50:**

Starting ART ≤ **2 weeks** after TB treatment may reduce 1-year mortality, compared to starting ART **2-8 weeks** from TB treatment [low certainty]

Supporting evidence: ART ≤ **4 weeks** after TB treatment reduces 1-year mortality, compared to ART **> 4 weeks** from TB treatment [high certainty]

2. Among **PLHIV with at any CD4 count:**

Starting ART ≤**2 weeks** after TB treatment may not increase or reduce 1-year mortality, compared to starting ART **2-8 weeks** from TB treatment [moderate certainty]

Supporting evidence: ART ≤**4 weeks** after TB treatment does not increase or reduce 1-year mortality, compared to ART **> 4 weeks** from TB treatment [high certainty]

World Health Organization

Key considerations:

Critical to rule out clinical signs and symptoms of meningitis*, as initiation of ART in this group of results in increased mortality and morbidity.

*For e.g., either TB or cryptococcal meningitis

Subpopulations:

- Review did not find any information on children
  - Supporting evidence shows that delay of ART is potentially more harmful – in terms of morbidity and mortality
  - Overall incidence of severe IRIS appears to be low, very few deaths from IRIS

World Health Organization

What recommendation was made?

Recommendation

ART should be started as soon as possible within two weeks of initiating TB treatment, regardless of CD4 count, among people living with HIV.[a]

Adults and adolescents
(strong recommendation, low- to moderate-certainty evidence)

Children and infants
(strong recommendation, very-low-certainty evidence)

[a] Except when signs and symptoms of meningitis are present.

Box 5. Clinical considerations for people living with HIV being evaluated for rapid ART initiation

The Guideline Development Group suggested the following update to existing guidance on rapid ART initiation *(2)*:

- **previous clinical consideration:** brief delay in ART initiation while investigating for TB symptoms; and
- **new clinical consideration:** among people living with HIV with signs and symptoms suggesting TB, except for central nervous system disease (meningitis), initiate ART while rapidly investigating for TB, with close follow-up within seven days to initiate TB treatment if TB is confirmed.

Decision Drivers:

- ➡ Lack of substantial harms
- ➡ Minimal impact on programs in terms of costs, feasibility and resources
- ➡ Promotes programmatic simplification
- ➡ Prevents LTFU* following HIV diagnosis
- ➡ Demonstrated benefits of rapid ART initiation

Community perspective

Jacqueline Wambui
AfroCAB Treatment Access Partnership, Kenya

Session 4: Starting and continuing ART and re-engaging in care

Nathan Ford, WHO HQ, Switzerland

Department of Global HIV, Hepatitis and Sexually Transmitted Infection Programmes

World Health Organization

Starting and continuing ART and re-engaging in care

- Initiating ART outside the health facility
- Rapid initiation / same day start
- Frequency of clinical visits and ART pick-up
- Tracing and re-engagement in care

Challenges

- People testing positive in the community often delay starting ART for various reasons: stigma, long waiting times, quality of care
- Rapid ART start not universally adopted; can result in poorer retention
- Variability in frequency of visits & ART dispensing
- A proportion of people disengage from care

Recommendation

ART initiation may be offered outside the health facility

Conditional recommendation; low- to moderate-certainty evidence

HIV testing is increasingly offered in the community

WHO recommends same-day ART start

This new recommendation is supported by a systematic review (3 RCTs, 4 observational studies) which found:

- Increased ART initiation
- Increased retention in care
- Increased viral suppression

Good practice statement

The offer of same-day ART initiation should include approaches to improve uptake, treatment adherence and retention such as tailored patient education, counselling and support

An evidence review found 26 studies supporting uptake of same-day ART start

Strategies could be classified into:

- strategies targeting clients
- strategies targeting health-care providers
- strategies targeting the health system.

Evidence indicated that all these approaches were associated with increased uptake of ART, suppression of viral loads at 12 months and retention in care at 12 months

Recommendations on frequency of clinical visits and ART pick-up

People established on ART should be offered clinical visits every 3–6 months, preferably every six months if feasible

Strong recommendation; moderate-certainty evidence

- 3 RCTs and 3 observational studies found comparable outcomes

People established on ART should be offered refills of ART lasting 3–6 months, preferably six months if feasible

Strong recommendation; moderate- to low-certainty evidence

- 1 RCT and 2 observational studies found comparable outcomes

Recommendation

HIV programmes should implement interventions to trace people who have disengaged from care and provide support for re-engagement

Strong recommendation; low-certainty evidence

Systematic review identified 37 studies to support tracing and re-engagement in care

Overall, 60% of individuals re-engaged in care

Approaches included remote communication (phone, text, mail and email), in-person tracing and a combination

Clients should be provided with the opportunity to consent to tracing

Session 4: Starting and continuing ART and re-engaging in care
Comments

Anna Grimsrud, PhD
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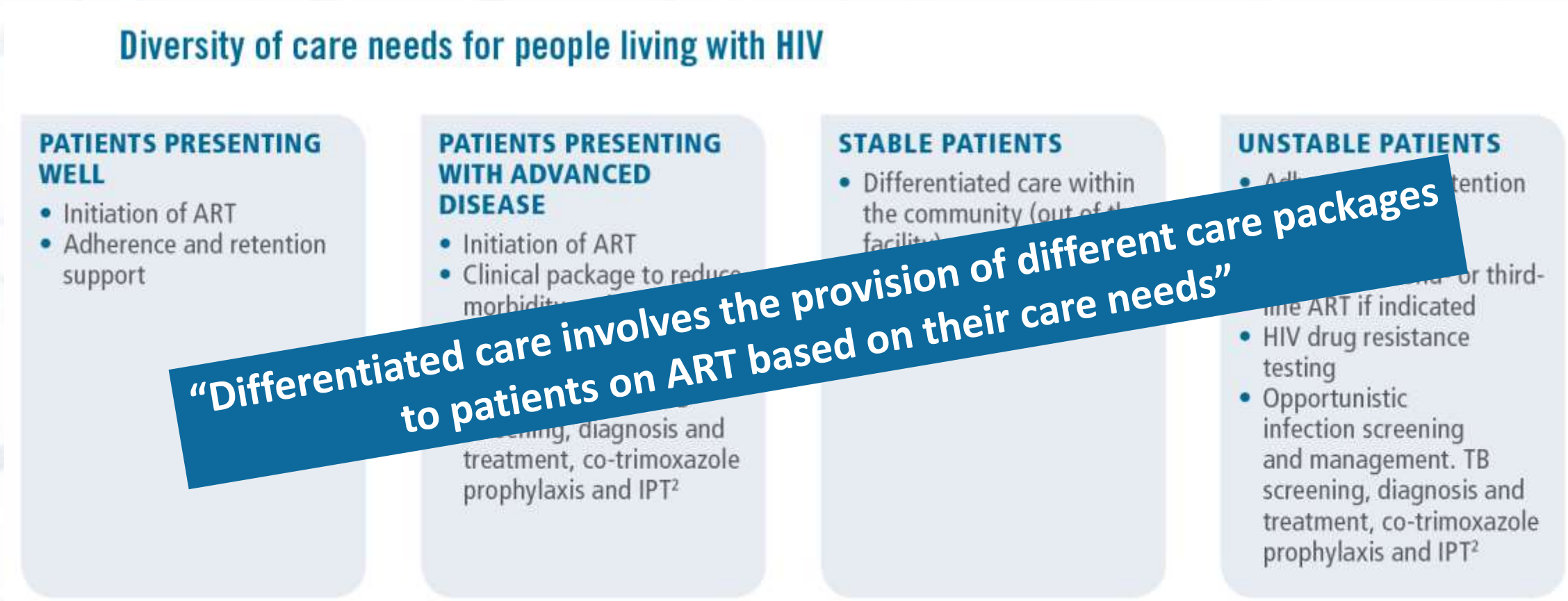
HIV Programmes and Advocacy Department
International AIDS Society

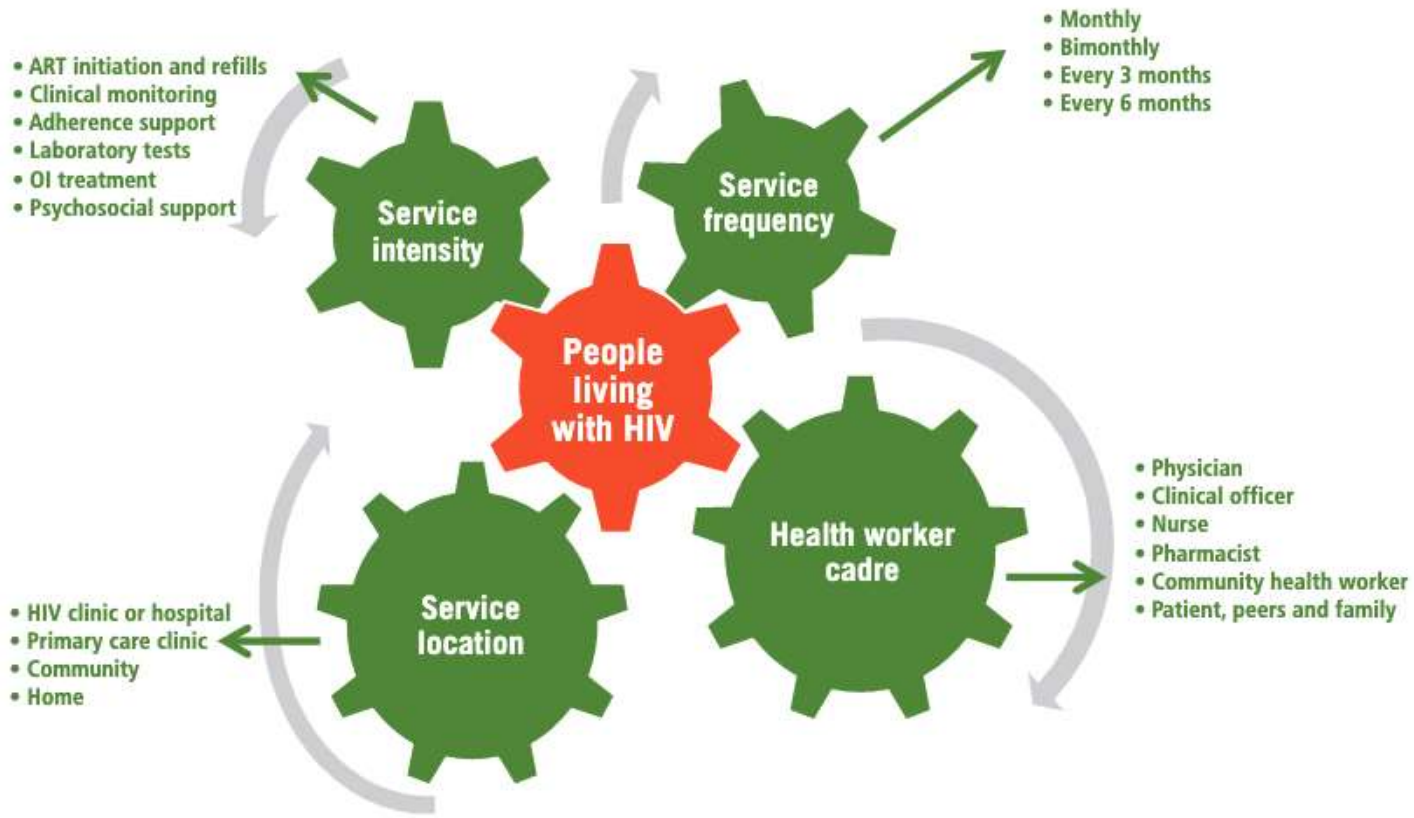
We've come a long way since 2015



"Differentiated care involves the provision of different care packages to patients on ART based on their care needs"

World Health Organization, 2015, Policy brief: consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: what's new.

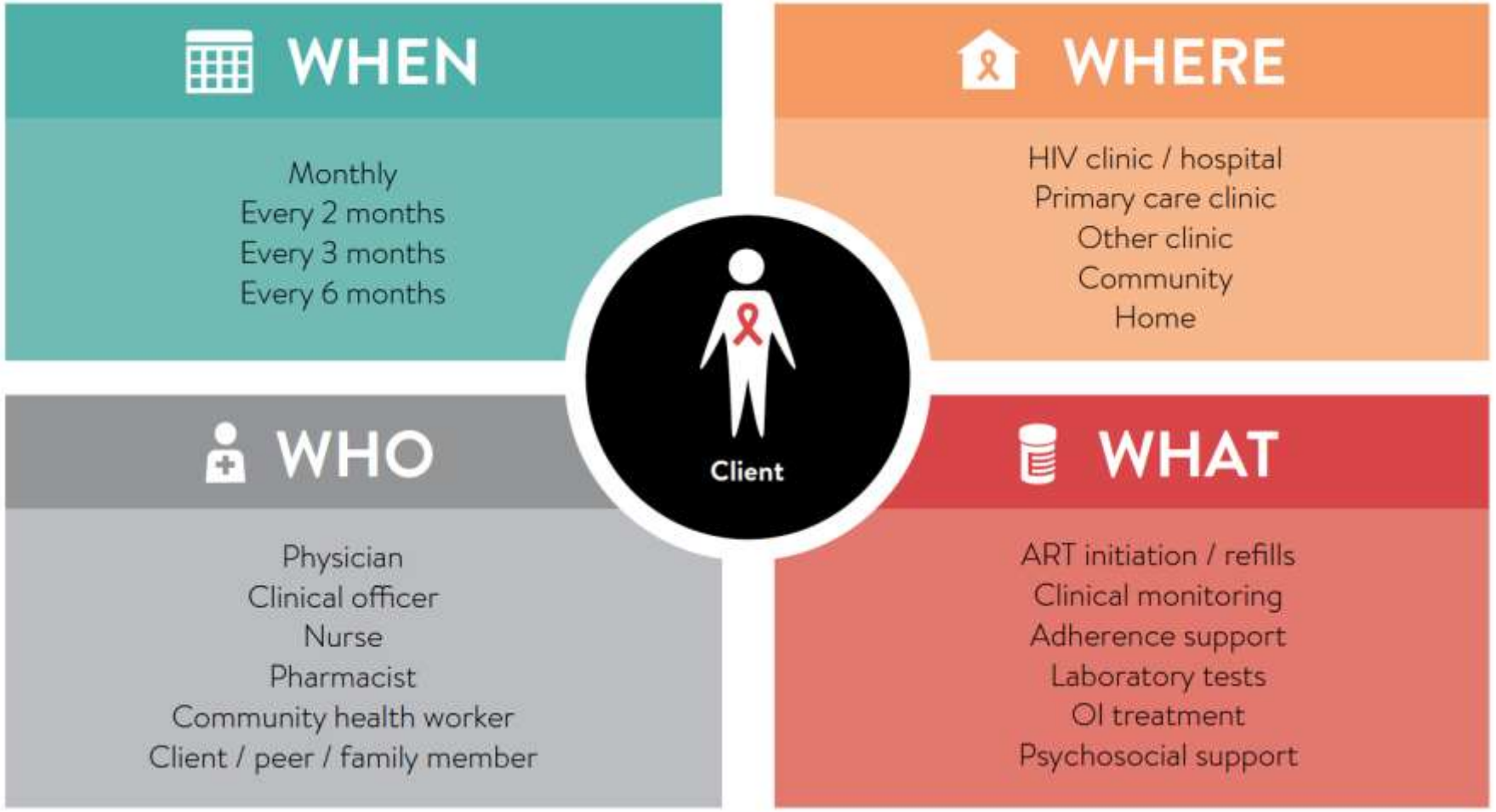
Differentiated care



World Health Organization, 2016, Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach – 2nd ed.

2021 Differentiated service delivery for HIV treatment

Revised



From 2016…

Stable individuals are defined as those who have received ART for at least one year and have no adverse drug reactions that require regular monitoring, no current illnesses or pregnancy, are not currently breastfeeding and have good understanding of lifelong adherence and evidence of treatment success (i.e. two consecutive viral load measurements below 1000 copies/mL). In the absence of viral load monitoring, rising CD4 cell counts or CD4 counts above 200 cells/mm^3, an objective adherence measure, can be used to indicate treatment success.

World Health Organization, 2016, Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach – 2nd ed.

2021 Criteria for determining whether a person is established on ART

Revised

To support the implementation of these recommendations, WHO has developed criteria for determining whether a person has been successfully established on ART:

- receiving ART for at least six months;
- no current illness, which does not include well-controlled chronic health conditions;
- good understanding of lifelong adherence: adequate adherence counselling provided; and
- evidence of treatment success: at least one suppressed viral load result within the past six months (if viral load is not available: CD4 count >200 cells/mm^3 or weight gain, absence of symptoms and concurrent infections).

Criteria for determining whether a person is established on ART

Revised

To support the implementation of these recommendations, WHO has developed criteria for determining whether a person has been successfully established on ART:

- receiving ART for at least six months;
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Criteria for determining whether a person is established on ART

Revised

To support the implementation of these recommendations, WHO has developed criteria for determining whether a person has been successfully established on ART:

- receiving ART for at least six month
- no current illness, whic c health conditions;
- good u quate adherence counselling provide
- evidence ess: at least one suppressed viral load result within th months (if viral load is not available: CD4 count >200 cells/mm³ or weight gain, absence of symptoms and concurrent infections).

- Does not EXCLUDE those who are currently pregnant
- Does not EXCLUDE those with well-controlled chronic health conditions
- No age criteria

Criteria for determining whether a person is established on ART

Revised

To support the implementation of these recommendations, WHO has developed criteria for determining whether a person has been successfully established on ART:

"The definition of being established on ART (stability) should be applied to all populations, including those receiving second- and third-line regimens, those with controlled comorbidities, children, adolescents, pregnant and breastfeeding women and key populations."

- r
- r alth
- good understanding of lifelong adherence; adequate adherence counselling provided; and
- evidence of treatment success: at least one suppressed viral load result within the past six months (if viral load is not available: CD4 count >200 cells/mm^3 or weight gain, absence of symptoms and concurrent infections).

Section 1.5 Differentiated service delivery for HIV treatment

“The principles of differentiated service delivery can be applied to prevention, testing, linkage to care, ART initiation and follow-up and integration of HIV care and coinfections and comorbidities.”

“In any given differentiated service delivery model for HIV treatment, the building blocks need to be defined separately for clinical consultations, ART refills and psychosocial support.”

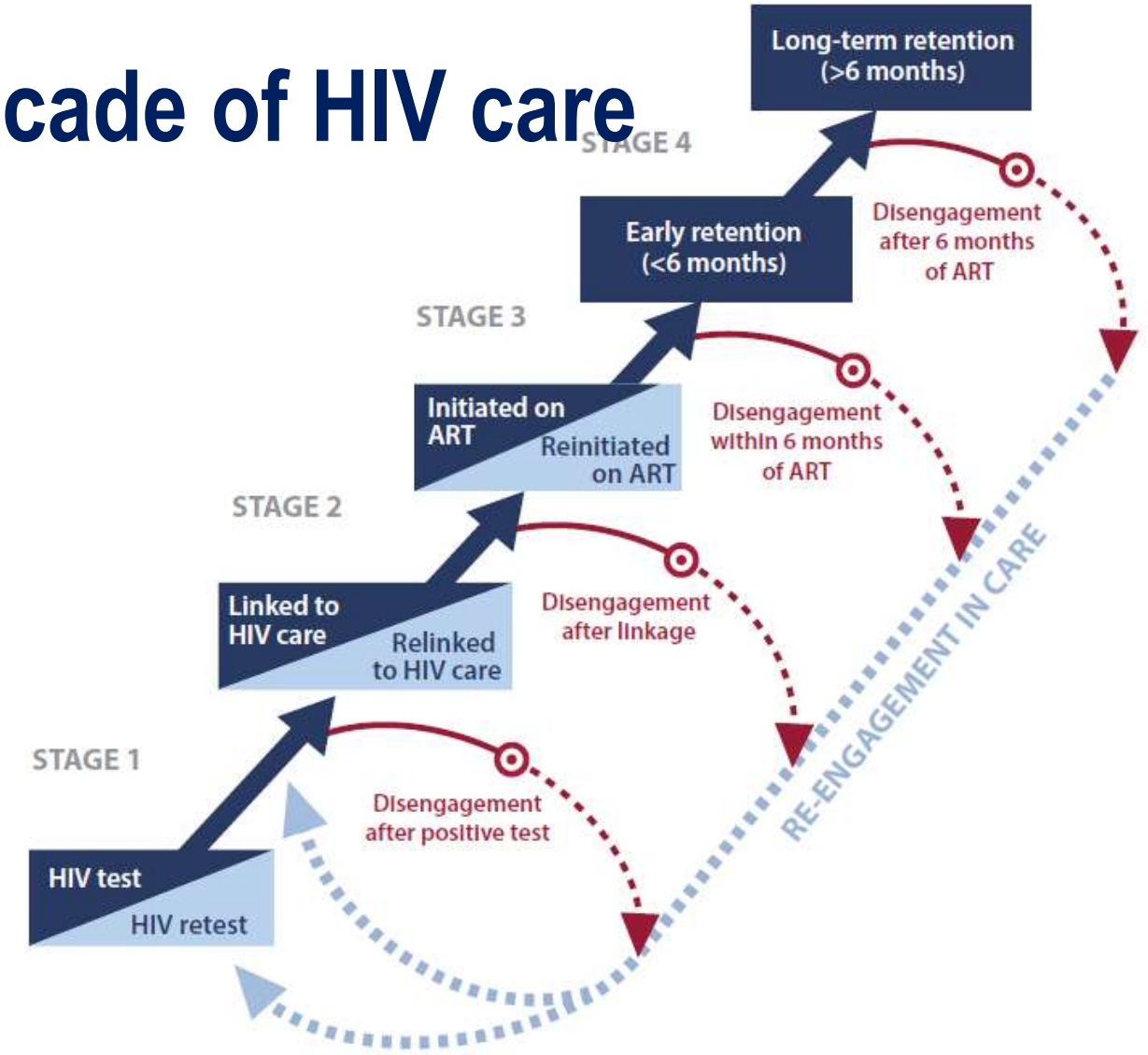
“Multi-month refills may also be used for children older than two years, since dosage adjustments become less frequent beyond that age .”

“Multi-month refills and dispensing may be used alone or within any of the four categories of differentiated service delivery for HIV treatment listed below”

Four categories of differentiated service delivery for HIV treatment

- Group models managed by health-care workers;
- Group models managed by clients;
- Individual models based at facilities; and
- Individual models not based at facilities.

Cyclical cascade of HIV care



Ehrenkranz et al, The revolving door of HIV care: revising the service delivery cascade to achieve the 95-95-95 goals, *under review*

Re-validated Recommendations

People established on ART should be offered clinical visits every 3–6 months, preferably every six months if feasible

People established on ART should be offered refills of ART lasting 3–6 months, preferably six months if feasible

NEW Recommendation

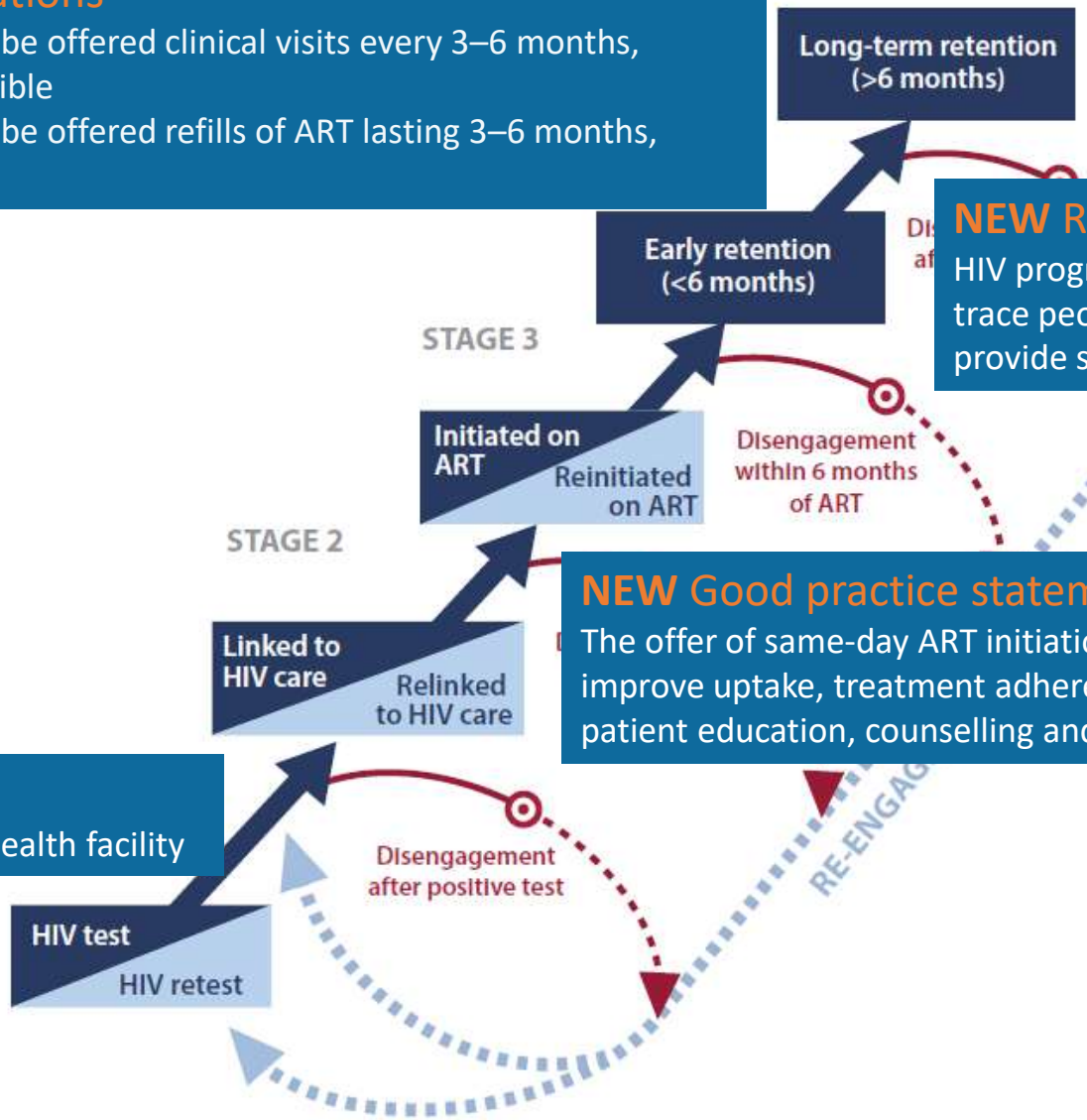
HIV programmes should implement interventions to trace people who have disengaged from care and provide support for re-engagement

NEW Good practice statement

The offer of same-day ART initiation should include approaches to improve uptake, treatment adherence and retention such as tailored patient education, counselling and support

NEW Recommendation

ART initiation may be offered outside the health facility



Ehrenkranz et al, The revolving door of HIV care: revising the service delivery cascade to achieve the 95-95-95 goals, *under review*

Session 5: Providing psychosocial interventions to adolescents and young people living with HIV

Wole Ameyan, Technical Officer, Adolescent HIV

Global HIV, Hepatitis and Sexually Transmitted Infections Programmes
World Health Organization

Mental health, psychosocial well being and adolescents

Evolving identities, knowledge and experience

DEVELOPMENT

Up to half of adult mental health problems begin during childhood and adolescence. 75% by age 24

BURDEN

Numerous psychosocial stressors

ENVIRONMENT

Poorer adherence, retention, outcomes

IMPACT

World Health Organization

Systematic review

Research question:

Should psychosocial interventions be considered to improve engagement in care and other health outcomes?

A diverse group of 30 studies, across seven countries, measured adherence to ART, ART knowledge, viral load, sexual risk behaviors, sexual risk knowledge, retention in care, and linkage to care.

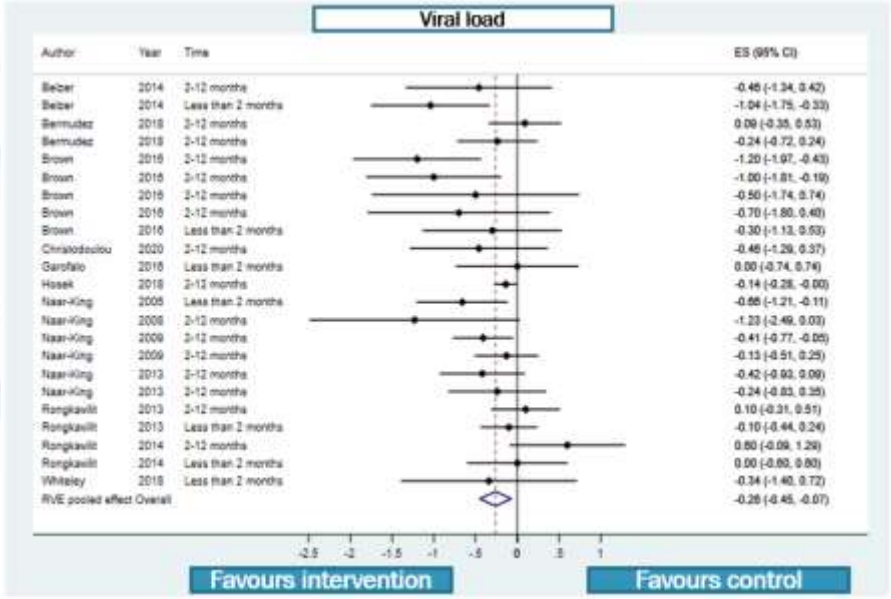
World Health Organization

Key results

Key messages

- Psychosocial interventions showed important, significant, positive effects on adherence to ART and reduction in viral load
- Psychosocial interventions showed positive improvements on all other outcomes

	All time points			
	Effect size	p-value	95% Confidence Intervals	
Adherence to ART	**0.3907**	0.0098*	0.1059	0.6754
ART knowledge	*0.1263*	*0.0052*	*0.1131*	*0.1395*
Retention in care	0.2823	0.1630	-0.1425	0.7072
Sexual and reproductive health behaviours	0.3261	0.1534	-0.1542	0.8064
Sexual and reproductive health knowledge	*0.2671*	*0.0899*	*-0.0957*	*0.6298*
Linkage to care	-	-	-	-
Viral load	**-0.2607**	0.0157*	-0.4518	-0.0696
Viral suppression (OR)	1.938		1.001	3.756
Undetectable viral load (OR)	1.827		1.074	3.110
Improved transitioning to adult services	-	-	-	-



New recommendation 2021

Psychosocial interventions should be provided to all adolescents and young people living with HIV

(Strong recommendation; moderate-certainty evidence)

Priority	This issue is a priority for adolescents and young people.
Quality of evidence	Overall certainty of evidence is moderate. Clinically relevant (significant) desirable effects identified for adherence to ART and level of viral load.
Values	Strong acceptance and preference by adolescents and young people living with HIV
Benefits and harms	Despite the observation of publication bias, no harmful effects were identified in our work.
Resources	While these can be substantial to ensure positive findings, integration into existing services and digital modes of delivery bring costs down.
Equity	These interventions have the ability to improve health equity, address stigma and provide both interpersonal and structural support.
Acceptability	Interventions were identified as acceptable, especially when engaging adolescents in design and implementation.
Feasibility	Interventions were feasible, with low rates of attrition and adaptations to meet needs across a diversity of settings.

Implementation considerations

- **Quality** — Within global ethics, principles and standards for providing quality health-care services for adolescents.
- **Context** — Package of differentiated services adapting content and delivery for different subpopulations.
- **Peer driven** — Peer driven approaches and involvement and engagement of adolescents.
- **Invest** — Integration within the package of services and investment in training, supervision and support for peers, health workers and service providers.
- **Engage** — Community support and involvement of parents, guardians and community members.

The views and opinions of adolescents living with HIV

Nicola Willis

Executive Director, Zvandiri AFRICAID

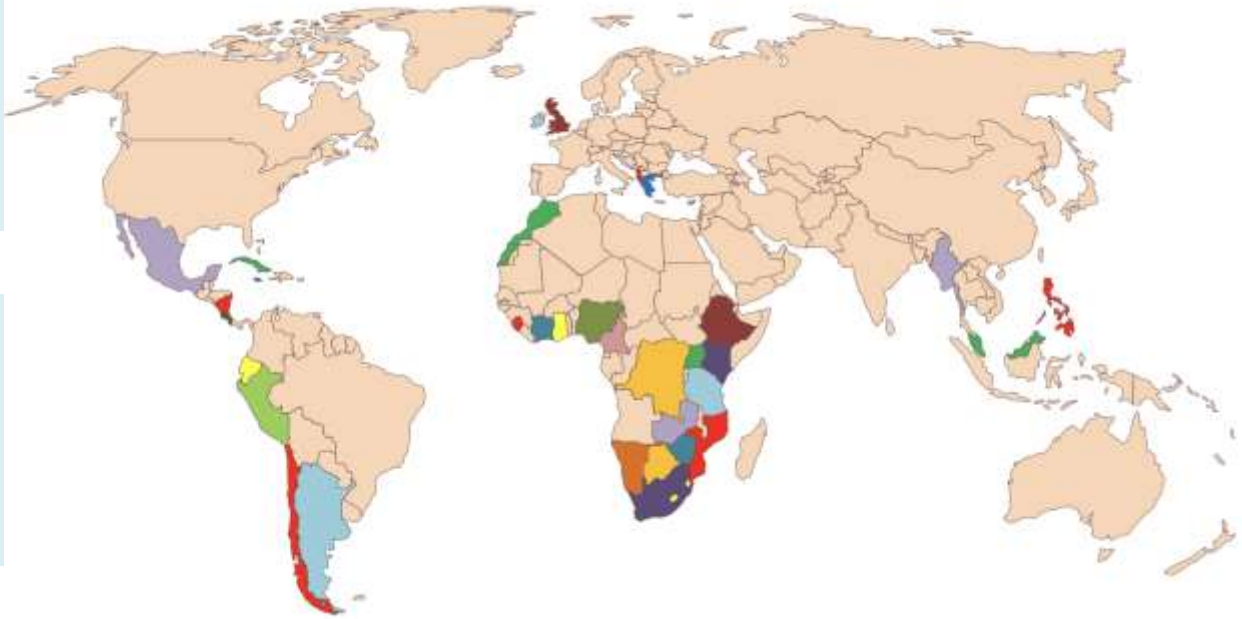
Methods

36 question, online survey

- 388 ALHIV, 45 countries
- 10-24 years old

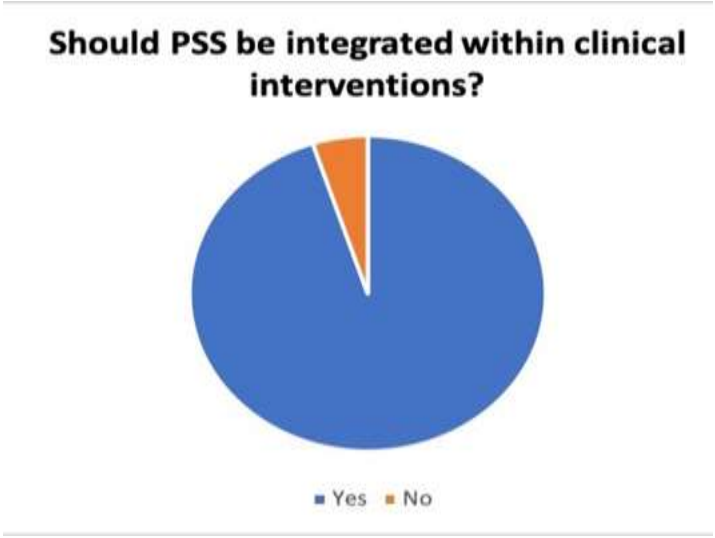
10 FGDs

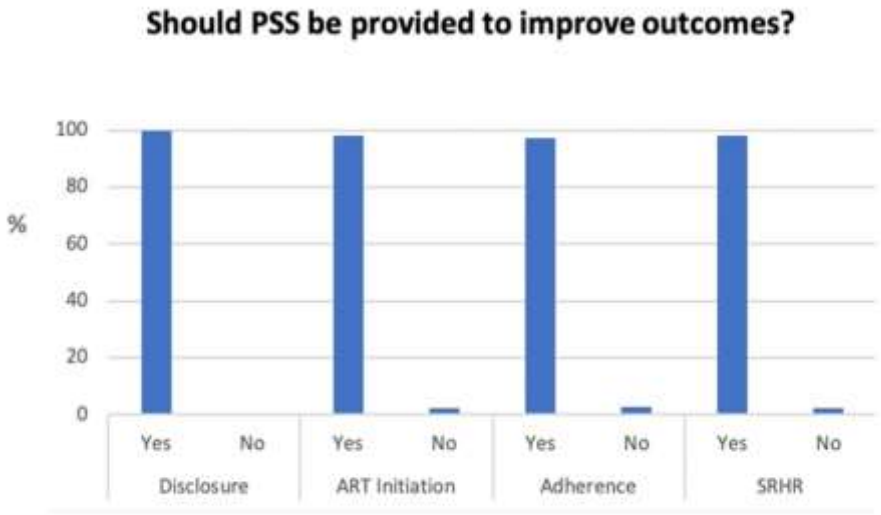
- 61 ALHIV, 388 ALHIV, 10 countries
- 10-24 years old



World Health Organization

Should PSS interventions be considered to engage in care and other health outcomes?





YES

- ALHIV described the impact of appropriate psychosocial support as being potentially transformative across <u>all the HIV treatment outcomes</u>

Growing up is very difficult with so many changes and having support in such a big aspect can make a massive change." (Survey)

World Health Organization

What difference does PSS make?

Without Psychosocial Support:

"You end up thinking why should I live?

I am a failure in life, a failure in taking medication, failure to suppress my VL and maintain CD4 level. Therefore, you will not be looking super cool to the community because everyone is denying and rejecting you so you will not be able to cope up with the society and to cope up with everything in the environment.
(FGD)

With Psychosocial support

"It will make me feel like I belong, am loved and that my world has not ended." (Survey)

"It will mean zero missed appointments, zero missed drugs, zero viral loads." (Survey)

World Health Organization

Acceptability / Values and preferences

Why does PSS make a difference to these outcomes?

Young people told us PSS:

- Improves HIV literacy
- Addresses social barriers to optimal adherence

Helps ALHIV to:

-

- Understand social and clinical opportunities of viral suppression
- Be supported to become undetectable
- Reframe what it means to live with HIV

"Adherence can have a huge effect on mental health and for many including myself can make you feel like you've failed. Without the support many struggle with adherence and blame themselves when actually be a number of factors." (Qu're)

"Creating a platform where young adolescent role models are used to inspire others to do well in their adherence and keeps hope alive." (Qu're)

"Happiness, I think. When they told me and explained to me what it meant (being undetectable), my mind was dancing (laughs), I was very happy". (FGD)

World Health Organization

What should PSS look like?

- Wrap around care
  - Who? Peers, healthcare workers, trusted adults
  - How? Locally and individually specific

- Multicomponent differentiated support delivery

- Existing platforms provide a structure through which to scale up PSS interventions (e.g counsellors, support groups, peer-led interventions)

- Sustained throughout adolescence across all outcomes

Their key message…..

For ALHIV, PSS is the catalyst that will transform the effectiveness of clinical care and achievement of viral suppression and living well with HIV.

https://www.youtube.com/watch?v=kys44Xx2tyA&t=12s

World Health Organization

Perspectives from a young person

Cindy Amaiza

Y+ Kenya, Kenya

WHO Youth Advisor to the Adolescent Service Delivery Working Group

Session Session 6: Integrating & linking services

Nathan Ford, WHO HQ, Switzerland
Morkor Newman, WHO HQ, Switzerland

Department of Global HIV, Hepatitis and Sexually Transmitted Infection Programmes

World Health Organization

Service integration: existing recommendations

- HIV testing should be offered in all services in generalized epidemics
- Integration of ART in maternal and child-health care settings, TB treatment settings (and vice versa), where OST is provided
- Integration of HIV and STI prevention services, including PrEP, with family planning settings
- Adolescent-friendly services implemented in HIV services
- Assessment and management of cardiovascular risk and depression

NEW Recommendation

Diabetes and hypertension care may be integrated with HIV services

Conditional recommendation; very-low-certainty evidence

Updated Recommendation

Sexual and reproductive health services, including contraception, may be integrated within HIV services

Conditional recommendation; very-low-certainty evidence

Diabetes and hypertension care

Background

- 15 million people prematurely of NCDs each year; 85% in LMICs
- 425 million people in LMICs live with diabetes
- Diabetes and hypertension are the major cardiovascular risk factors
- Live expectancy of PLHIV has increased substantially
  - PLHIV have an increased risk of NCDs, in particular CVD and diabetes

Diabetes and hypertension care may be integrated with HIV services

Systematic review

5 RCTs. Small effects found in terms of BP/diabetes control, viral suppression and CD4 control

Values and preferences and feasibility

Diabetes

83% said integration was very important or important

69% said integration was very feasible or feasible

Hypertension

78% said integration was very important or important

69% said integration was very feasible or feasible

Cost

Uganda and Kenya: $US 1.16/person

Implementation considerations

- A focus on **improving investment** in the overall health system will be important to support the integration of hypertension, diabetes, and HIV services
- **Aligning the provision** of noncommunicable disease commodities with differentiated service delivery for HIV treatment models should be considered.
- There is a need for establishing **integrated data systems** and providing consistent **cross-training** of health care providers

Sexual and reproductive health services

- Significant interest in integrating sexual and reproductive health (SRH) and HIV services.
- Among the 1.9 billion women of reproductive age group (15-49 years) worldwide in 2019,
  - 1.1 billion have a need for family planning;
  - 270 million have an unmet need for contraception
- Need for family planning satisfied by modern methods,
  - Sustainable Development Goals (SDG) indicator 3.7.1, was 75.7% globally in 2019,
  - less than half of the need for family planning was met in Western and Central Africa

Sexual and reproductive health services, including contraception, may be integrated within HIV services

Systematic review

6 studies. Integrating HTS services and FP services may lead to an increase in the uptake of HTS and FP. Most studies favoured integration

Values and preferences and feasibility

98% said integration very important or important

Can reduce stigma, increase access and quality

Cost

Most efficiency gains, reduced consultation times

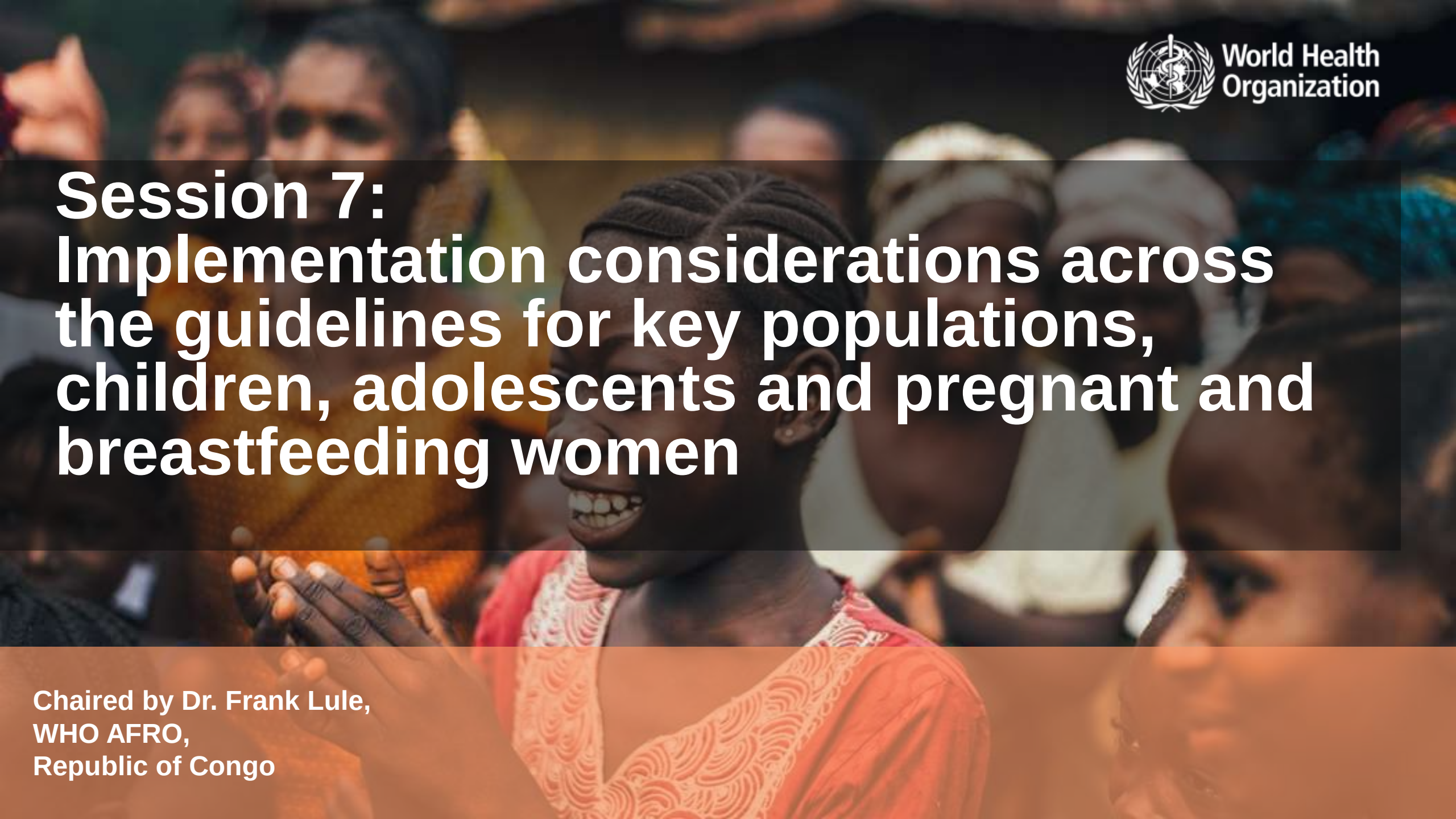
Implementation considerations

- **Strategies** are needed to improve the accessibility, acceptability, affordability, uptake, equitable coverage, quality, effectiveness and efficiency of services
- **Laws and policy barriers** to accessing sexual and reproductive health services, including for adolescents, need to be addressed.
- **Integration of care for intimate partner violence and sexual assault** is strongly recommended by WHO
- **Aligning the provision of sexual and reproductive health services**, including contraception commodities, with differentiated service delivery
- Careful planning and coordination, including establishing **integrated data systems** and providing **consistent cross-training** of health-care providers.
- **Political will** and significant coordination, collaboration and integration across disease programmes are important

Health care provider perspective

Erica Burton

International Council of Nurses, Canada



World Health Organization

Session 7: Implementation considerations across the guidelines for key populations, children, adolescents and pregnant and breastfeeding women

Chaired by Dr. Frank Lule,
WHO AFRO,
Republic of Congo

Erika Castellanos

(Global Action for Trans* Equality (GATE), The Netherlands)

Dr. Angela Mushavi

(Ministry of Health, Zimbabwe)

Thank you

WHO would like to acknowledge and thank the numerous contributors to these guidelines that were developed during the COVID-19 pandemic and will continue to engage with the global HIV community and Member States to ensure the continuity and quality of care for people living with HIV during and beyond the COVID-19 pandemic.

Our sincere thanks to all the following individuals who helped make this webinar a success

Aleny Couto (MoH, Mozambique)

Ilesh Jani (MoH, Mozambique)

Frank Lule (WHO AFRO, Republic of Congo)

Imelda Mahaka (Pangaea Zimbabwe AIDS Trust, Zimbabwe)

Florence Riako Anam (GNP+, Kenya)

Jacqueline Wambui (AfroCAB Treatment Access Partnership, Kenya).

Anna Grimsrud (International AIDS Society (IAS), Switzerland)

Nicola Willis (Zvandiri, Zimbabwe);

Cindy Amaiza (Y+ Kenya, Kenya)

Erica Burton (International Council of Nurses, Canada)

Erika Castellanos (Global Action for Trans* Equality (GATE), The Netherlands)

Angela Mushavi (MoH, Zimbabwe)

Thank you also to the WHO adolescent HIV service delivery working group for your thoughtful and important contributions during these challenging times.

UPDATED RECOMMENDATIONS ON HIV PREVENTION, INFANT DIAGNOSIS, ANTIRETROVIRAL INITIATION AND MONITORING

WHO gratefully acknowledges the contributions of many individuals and organizations to the development of this guideline.

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