The 2017 Namibia ART Guidelines

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Q1-Table 1

List at least four key new recommendations in the 2017 Namibian ART Guidelines

Q2-Table-2

- 46yo, Male, on AZT/TDF/FTC/ATVr
- Diagnosed with a new case of active Pulmonary TB
- How would you ***specifically*** manage his ARVs?

Table 3-Case Scenario-2

- 29 yo, female, on TDF/FTC/EFV and CTX
- HBsAg: non-reactive
- Has established chronic renal failure with CrCl: 13ml/min
- How would you ***specifically*** manage her ARVs and CTX?

Table 4-Case Scenario-3

- 33 yo, male, newly diagnosed HIV
- CD4 185cells/mm^3
- What tests will you do before starting ART?

Table 5-Case Scenario-4

- 43 yo, female primigravida, tested HIV negative at 20 weeks of gestation
- She will come to your clinic at 36 weeks of GA.
- What will you do?

Table 6-Q-2

- Describe the new Viral Load Monitoring recommendations in PBFW

Table 7-Case Scenario-5

- Baby x, born to a woman who was diagnosed with HIV infection early during labor,
- She was started on TDF/FTC/EFV right away with negative urine protein and glucose
- She gave birth SVD to a baby girl of weight 2.8 Kg
- How would you manage the baby girl including HIV testing, prophylaxis and follow up?

Reproductive considerations when one or both sexual partners are HIV positive….

- Table 8- Q4

Table 9-Q4

What factors determine the appropriate choice of ARVs for HIV-infected Children?

Table 10- Q5

When will you switch treatment in Children on ART?

Table-All

What determine the choice of Second line ARVs in children?

All Tables

Which child is eligible HIV-infected Child for HIV DR genotyping?

All Tables

What's PrEP? And Why do we need it for?

All-Tables

- 35yo, male, presented to STI clinic with foul smelling urethral discharge
- You treated him for a Urethral Discharge Syndrome, tested him for HIV and he's HIV negative.
- What will you do for him in relation to PrEP?

All Tables

Do you have a fear of resistance to ARVs in the context of PrEP? Why not or Why?

If you've fear, what would you do?

Section I: Adults

I. Who and When to Start ART

- **Treat all:**
  - prioritize the sick and the youth

- **Accelerate ART initiation**
  - **Aim to start ART with in 1 week**
    - **Day 0 (1st visit):** clinical evaluation, baseline lab test and first ART counseling session. **If ready, ART can be started.**
    - **Day 7 (2nd visit):** review baseline results, assess recall, do second counseling session and start ART if ready and give 2 weeks of appointment.
    - **I**f a patient is not ready during these two visits, plan to provide ongoing counseling and prepare the patient to start ART soon.
    - Pregnant and breastfeeding women should be started on ART the same day

II. What to Start

First Line Regimens

1st Line	ARV regimen [1,2]
Preferred Option	***TDF + XTC[3]+ EFV[600]***
Alternative Options	AZT + 3TC + EFV[600] AZT + 3TC + NVP TDF + XTC[3] + NVP ABC+3TC+NVP (EFV)

- **In circumstances where a patient can't take EFV[600], EFV[400] can be considered after consultation with HIV Specialist or a CM.**
- **A patient who's on EFV[400] should undergo close adherence support and 6 month VL should be scrutinized carefully**

Table 2-Case Scenario-1

- 46yo, Male, on AZT/TDF/FTC/ATVr
- Diagnosed with a new case of active Pulmonary TB
- How would you ***specifically*** manage his ARVs?

Second Line ART

2nd line	ARV regimen
Preferred Options	AZT/TDF/FTC (3TC)/ATV-r
Alternative Options	AZT/TDF/FTC (3TC)/LPV-r

Second Line

2nd line	ARV regimen
Preferred Options	AZT/TDF/FTC (3TC)/ATV-r
	AZT/TDF/FTC (3TC)/LPV-r
Alternative Options	

Third Line

- **Patients failing to second line regimens and those failing to first line regimens with extensive exposure to multi-ARV classes shall get genotype tests done following authorization from a clinical mentor/HIV specialist**
- **Optimized third line regimens will be selected by the HIV DR Central Clinical Committee**
- **Standardized third line regimens may be considered following a structured evaluation of patterns of HIV DR in patients failing to 2nd line regimens**

Adherence Counselling

- Strengthened the adherence counselling and me
  - Approaches to counseling that can enhance adherence and retention in care
  - Tailored counseling approaches based on common barriers to adherence
  - The differentiated care model can be utilized to enhance access to care and hence adherence and retention
- Patients with VL 40-1000 copies/ml should receive enhanced adherence counselling and follow closely”

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- HBsAg: non-reactive
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- How would you ***specifically*** manage her ARVs and CTX?

Changing ARVs in Events of Toxicity and Failure

- Same as existing principles
- In an event of toxicity to TDF in patients with no HBV co-infection, change to **ABC** and **NOT AZT** unless there is contra-indication
- In an event of advanced renal insufficiency with CrCl<10ml/min, substitute TDF with ABC even if there is HBV co-infection.
- Dose Adjustment for CTX in an event of renal failure:
  - **CrCl:** 15-30ml/min: 480mg/day
  - **CrCl:** <15ml/min Avoid CTX

Table 4-Case Scenario-3

- 33 yo, male, newly diagnosed HIV
- CD4 185cells/mm^3
- What tests will you do before starting ART?

Lab Monitoring

- Key recommendations:
  - **Baseline**: CD4, HBsAg, Hb, CrCl, Urine dipsticks
  - If HBsAg reactive: ALT before ART initiation, at 2 weeks of ART, repeat HBsAg at 6 months of ART
  - CrAg (reflex) if CD4<200
  - Follow up monitoring:
    - CrCl 6 weeks, 6 months, 12 months and every 12 months
    - VL: 6 months, 12 months and every 12 months

When to Consult HIV Specialist and Central Clinical Committee

- Nurses and doctors (NIMART):
  - In an event of any clinical queries or uncertainties nurses may consult with their colleagues resident doctors, nurse mentors or regional clinical mentors

- Consultation to Central Clinical Committee:
  - All cases with HIV genotype
  - All cases who may need to receive NRTI sparing regimens

Integration of Services into the HIV Clinics needs to be encouraged…

- Cervical Cancer prevention education and screening
- NACS including recording and reporting

Encourage Integration of Services into the HIV Clinics

- Cervical Cancer prevention education and screening

Transitioning Patients to Preferred First Line

- Cut-off for VL: 40 copies/ml with in the last six months

Section II: PMTCT

Table 5-Case Scenario-4

- 43 yo, female primigravida, tested HIV negative at 20 weeks of gestation
- She will come to your clinic at 36 weeks of GA.
- What will you do?

HIV Screening in PBFW

- Women who test HIV negative at the first ANC visit should be re-tested for HIV:
  - 3 months later
  - At 36 weeks
  - 6 weeks PN
  - 6-monthly during BF
- Test all PW presenting with unknown status during L & D
- All women who test HIV negative should receive counseling about how to remain negative

Table 6-Q-2

- Describe the new Viral Load Monitoring recommendations in PBFW

VL Monitoring in PBFW

- On ART:
  - Check the most recent routine VL
    - **VL<40** copies/ml, repeat q3 months until delivery, then 6 weeks post-partum, and every 3 months until end of the breastfeeding period.
    - **VL ≥40** copies/ml, provide intensive adherence counseling and repeat VL after 6 weeks, and manage accordingly
  - If no VL in the last 3 months, then repeat it at first ANC visit and provide adherence counseling.

VL Monitoring in PBFW

- Initiated ART during pregnancy, or in the breast-feeding period:
  - VL at 3 months, then 3-monthly until delivery, then 6 weeks post-partum, and every 3 months until the end of breastfeeding

What are the risk strata for vertical HIV acquisition among HEIs?

- Some infants have higher risk of acquiring perinatal HIV infection compared to others

- ***Higher risk* infants:**
  - Mother on **ART < 4 weeks** at the time of delivery; or
  - Mother's **VL >40 copies/ml in the 3 months** prior to delivery or VL unknown; or
  - Mother's who **got new HIV infection during pregnancy**, breast-feeding or post-partum period

- ***Average risk* infants:**
  - Do not possess any of the above risks

Table 7-Case Scenario-5

- Baby x, born to a woman who was diagnosed with HIV infection early during labor,
- She was started on TDF/FTC/EFV right away with negative urine protein and glucose
- She gave birth SVD to a baby girl of weight 2.8 Kg
- How would you manage the baby girl including HIV testing, prophylaxis and follow up?

What package of care should one provide to high risk HEIs?

1. **HIV Nucleic Acid Test (NAT)** dried blood spot (DBS) within 48 hours of birth

+

2. **Dual infant prophylaxis** (NVP and AZT) to be given for the first 6 weeks of life

+

3. **Intensified Mother/infant tracking**

What prophylaxis will you provide to the HEIs based on risk levels?

Classification of risk	Infant prophylaxis for the first 6 weeks of life	Infant prophylaxis after 6 weeks of age
Higher risk of HIV transmission to infant	NVP **plus AZT** for 6 weeks	**If breastfeeding AND mother's VL = 40 or more or unknown**, continue with NVP daily **If NOT breastfeeding since birth or in last 4 weeks, OR mother's VL<40**, discontinue infant prophylaxis
Average risk of HIV transmission to infant	NVP for 6 weeks	

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ARV Regimens for PMTCT

- Preferred and alternative ART regimens for pregnant and breastfeeding women **No change**

Reproductive considerations when one or both sexual partners are HIV positive

- Table 8- Q4

III. ART for Children

HIV Diagnosis in average risk HEIs (No Change)

- Continue with routine DNA PCR at 6 weeks
- All sick HEI babies <6 weeks old should have an HIV DNA PCR venous sample
  - Consult a doctor, clinical mentor, nurse mentor or HIV Expert Nurse
- Infants who tested negative at 6 weeks, do a RT at 9 month and follow the current algorithm
  - In case of discordant results, follow the usual serial testing algorithm

Assessing HIV *exposure* in infants

- Do RT to assess HIV exposure in infants <4 months old

- For infants 4-17 months, do RT test on mother
  - *If mother not available, screen baby with RT*

PITC (not included in the ART GL)

- Do the age-appropriate HIV test on all infants and children (*even if previously tested HIV-negative*) who:
  - are admitted to hospital
  - are malnourished
  - have TB
  - have siblings or parents who are diagnosed HIV positive
  - OPD, PHC clinic attendance

Table 9-Q4

What factors determine the appropriate choice of ARVs for HIV-infected Children?

The Choice of ART in Children

- Factors affecting choice of ARVs in children:
  - Age,
  - Weight,
  - Previous PMTCT NVP exposure,
  - Co-morbidities
  - Availability of appropriate formulation choices

What Principles to follow in constructing appropriate regimens?

- **USE** Age-appropriate FDC, ***AS AVAILABLE***
- **AVOID** oral liquid or syrup formulations where possible
- **AVOID** under or over dosing when adult formulations are used
- Tabs that are not easily split should be cut at the dispensing pharmacy using tablet cutters
- **WEIGH** children at each visit and adjust doses appropriately

What are the recommended first Line Regimens for Children in Namibia?

- **Birth to <2 weeks:**
  - AZT/3TC/NVP until the child is 2 weeks old.
    - At that time change NVP to LPV/r

- **2 weeks to <3 months old:**
  - AZT/3TC/LPV/r – until the child is 3 months old. At that time change AZT to ABC

What are the recommended first Line Regimens for Children in Namibia? (2)

- **3 months to 2 years old or <10 kg**:
  - ABC/3TC/LPV/r [ABC/3TC od, LPV/r bd]
- **3 to 9 years old *and* 10 kg to <35 kg:**
  - **NO previous** PMTCT NVP exposure:
    - ABC/3TC/EFV [Give all od]
  - **Previous** PMTCT NVP exposure:
    - **If 3-5 years old or <15 kg**, give ABC/3TC/LPV/r [Give ABC/3TC od, LPV/r bd]
    - **If 6-9 years old and 15 to <35 kg** give ABC/3TC/[ATV+r] [ABC/3TC and ATV+r given as a once daily doses]
- **≥35 kg and at least 10 years old:**
  - TDF/3TC/EFV [Give all od]

Table 10- Q5

When will you switch treatment in Children on ART?

Switch when True Virologic Failure is established!!!

Child on ART for at least 6 months

+

Good Adherence

+

VL>1000 RNA copies/ml

+

Repeat VL after 3 months >1000 or dropped by less than 1 log from the prior value (after intensive adherence counselling)

=

Switch only when adherence challenges are resolved

Table-All

What determine the choice of Second line ARVs in children?

Preferred 2nd Line ART Regimens if PI based 1st line regimen

- **Children <3 years old and <10kg :**
  - **No previous PMTCT NVP exposure:**
    - give ABC + AZT + 3TC + NVP
  - **Previous PMTCT NVP exposure:**
    - consult HIV specialist/clinical mentor and do genotype
- **Children 3 to 9 years old and 10kg to <35kg:**
  - **NO previous PMTCT NVP exposure:**
    - give ABC + AZT + 3TC + EFV
  - **Previous PMTCT NVP exposure:**
    - consult an HIV specialist or clinical mentor and do genotype
- **Children ≥10 years old or ≥35 kg**
  - give TDF/FTC/AZT/EFV

If a child failed to an NNRTI-containing first line ART…

- **Children <10 years old or <35 kg**
  - AZT/ABC/3TC/LPV/r if <6 years old or <15 kg
  - AZT/ABC/3TC/ATV+r if ≥6 years old and >15 kg

- Adolescents ≥10 years old or ≥35 kg
  - TDF/AZT/XTC/ATV/r

Table-AII

Which child is eligible HIV-infected Child for HIV DR genotyping?

Who's an eligible HIV-infected Child for HIV DR genotyping?

- True Virologic failure to 2nd line
- True virologic failure to first line AND PI was used in first line AND Hx of NVP exposure for PMTCT AND < 10 years of age

What should you monitor routinely, every 3 months in a child on ART?

- Growth monitoring: weight, length or height, HC (if <3 years); plot on growth charts
- Neurologic and cognitive development
- Nutritional status
- WHO clinical staging using “T-stage”
- Eligibility for IPT (if not already completed IPT)

What should you monitor routinely, every 3 months in a child on ART? (2)

- Evaluation of adherence to therapy
- Discussion on HIV disease process and disclosure as appropriate
- Symptoms and signs of medicine toxicity or intolerance
- Symptoms and signs of treatment failure
- Laboratory monitoring as per schedule

Section IV: Adolescents

Adolescents LHIV (1)

1. Overview of adolescent issues
   - Prevalence, Vulnerability, puberty
2. Uptake f HTS
3. Transitioning
   - Standardize transition process from young adolescence to older adolescence then adult care
   - Suggestion to change age category of young adolescent from 10-14 to 10-13

Adolescents LHIV(2)

5. Retention and Adherence:
   - Puberty, 'rebellious' behavior
   - Lack of adolescent-friendly spaces and procedures
   - Poor disclosure practices
   - Limited psychosocial support from caregivers and service providers
   - Lack of standardized tools for assessing risks for poor adherence and identifying vulnerable adolescents
   - Role of Rx supporter, peer support

Adolescents LHIV(3)

- Educate ALHV on avoiding alcohol, smoking and other substance use
- Puberty, sex and sexuality education
- Contraception (dual protection)

HIV Testing, Consent and Uptake

- Consent and assent for HTS, ART

- **Disclosure:** capacitate health workers, care givers and adolescents
  - Mix of Adult and pediatric approaches
  - **Disclosure to peers, partners???????**

Child to adult care transitioning

Age Group	Transition Goals
10-13 years	**Phase 1 Goals** • Full HIV disclosure • Understand disease process • Understand disease markers • Understand prevention measures
14-19 Years	**Phase 2 Goals** • Medication independence • Independent clinic visits • Maintain >95% adherence • Positive living • 2 consecutive undetectable viral load • Orient and enroll in adult ART clinic

Reducing HIV related stigma and discrimination

- Train health providers and caregivers
  - Peer support clubs
- Train adolescents as young champions against children's stigma and discrimination
- Utilize social and educational events including music festivals, drama, fashion to promote dialogue on HIV among adolescents stigma reduction
- Promote dialogues to address fears and misconceptions about HIV that promote stigma and discrimination
- TV, radio, programmes hosted and managed by young champions targeting engagement on social issues affecting adolescents including HIV, alcohol and drugs

Mental health & psychosocial support

- Adolescents who suffer from depression are more likely to be non-adherent

- Activities that can help in identifying and addressing mental health and psychosocial issues :
  - Screening
  - Effective communication skills and building trust
  - Mental health promoting activities should be incorporated in individual and group activities for adolescent support groups.

Sections IV & VI: PrEP & PEP

All Tables

What's PrEP? And Why do we need it for?

Defining Pre-Exposure Prophylaxis (PrEP)

PrEP= use of ARVs before HIV exposure by people who are ***not infected with HIV*** in order to prevent the acquisition of HIV.

Integrating PrEP with Other Preventive Services

- Oral PrEP should be offered as part of the ***'Combination Prevention'*** package that includes;
  - HIV Testing Services (HTS),
  - Male and female condoms,
  - Lubricants,
  - ART for HIV-positive partners in sero-discordant relationship,
  - Voluntary medical male circumcision (VMMC) and
  - STI prevention and management.

Who's Eligible for PrEP

- PrEP is indicated to any sexually active **HIV-negative** person at **substantial risk** of acquiring HIV.

- Substantial HIV acquisition risk may include;
  - HIV negative people in sero-discordant relationships with a partner who is not confirmed as virologically suppressed (VL <40 copies/ml)
  - All HIV negative people in sero-discordant relationships, regardless of VL of the partner, who want to conceive
  - Partner(s) of unknown HIV status

Eligibility Criteria for PrEP (2)

- Recent/recurrent STIs
- Multiple and/or concurrent sexual partners
- History of inconsistent or no condom use
- Recurrent PEP users
- History of sex whilst under the influence of alcohol or recreational drugs.

All-Tables

- 35yo, male, presented to STI clinic with foul smelling urethral discharge
- You treated him for a Urethral Discharge Syndrome, tested him for HIV and he's HIV negative.
- What will you do for him in relation to PrEP

To Whom is PrEP Contraindicated?

- HIV positive
- High index of suspicion for HIV primary infection (characterized by flu-like symptoms)
- History indicative that persons might be in window period following potential exposure
- Abnormal CrCl<60ml/min

To Whom is PrEP Contraindicated? (2)

- TDF for PrEP should not be co-administered with other nephrotoxic drugs, for example, aminoglycosides
- Unwilling or unable to return for 3-monthly HIV testing, counselling and safety monitoring visits
- Known allergies to any of the PrEP drugs
- Unwilling to get tested for HIV

Note

When there is suspicion of HIV primary infection and/or a history of possible recent HIV exposure; PrEP can be deferred for 4 weeks and the client re-tested to ascertain HIV status.

PrEP ARV Regimen and Rational Use

- Daily oral tenofovir/emtricitabine (TDF/FTC 300mg/200mg) or TDF/3TC 300mg/300mg

- Note:
  - PrEP may be used intermittently during periods of perceived HIV acquisition risk, rather than continually and lifelong, as is the case with antiretroviral treatment.

What should you screen for and do before initiating PrEP?

- Assess risk and eligibility thorough history (sexual) and physical examination
- Provide contraceptive counselling and offer services
- Do HIV Rapid test
- Confirm eligibility
  - Check CrCl and HBsAg
- Provide STI treatment if indicated
- Educate client about PrEP, its benefits, side-effects and management

What should you screen for and do before and while initiating PrEP?

- Educate client about signs and symptoms of acute HIV infection
- Discuss with client on the adoption of healthy life-styles such as avoiding alcohol, tobacco and recreational drugs
- Provide condoms and lubricants
- Provide one-month TDF/FTC (FDC) prescription
- Arrange follow up visit

PrEP: One-month follow-up

- Same as at PrEP initiation visit PLUS:
- Assess tolerability, side effects and effective use (adherence)
- Actively manage side effects
- Provide contraceptive services
- **Tests**: HIV Rapid test, CrCl,
- Provide 3 month prescription and follow up date

PrEP: Month 4 follow-up and 3-monthly visits

- Repeat procedures done at one-month follow-up
- Conduct the following tests:
  - Month 4- HIV Rapid test, STI symptom screening, CrCl,
  - 3 monthly afterwards- HIV Rapid test, Pregnancy test, HBsAg (at 6 months only)
  - 6 monthly afterwards- CrCl, STI symptom screening, rapid syphilis test and HIV Rapid test

All Tables

Do you have a fear of resistance to ARVs in the context of PrEP? Why not or Why?

If you've fear, what would you do?

ARV Resistance: Is it a Concern?

- Risk of TDF or FTC resistance during use of PrEP is generally low
  - Meta-analysis[1]: randomization to PrEP higher risk of resistance compared with placebo among those acutely HIV-infected when starting PrEP (FTC > TDF)
  - Consistent with Partner's PrEP Study Continuation
- Risk of drug resistance with PrEP has to be weighed with overall benefits
  - If PrEP withheld, more HIV infections would have occurred, which would
  - Require life-long therapy with an annual risk of drug resistance 5% - 20%
- Levels of resistance with PrEP expected to be less than if HIV is left unchecked

When will You Stop PrEP?

- PrEP should generally not be stopped for the entire period of risk exposure.

- PrEP should be stopped:
  - When HIV test is positive
  - At client's request
  - For safety concerns/side effects (CrCl<60ml/Min)

- If a client tests HIV positive, discontinue PrEP and refer for enrolment into HIV care.

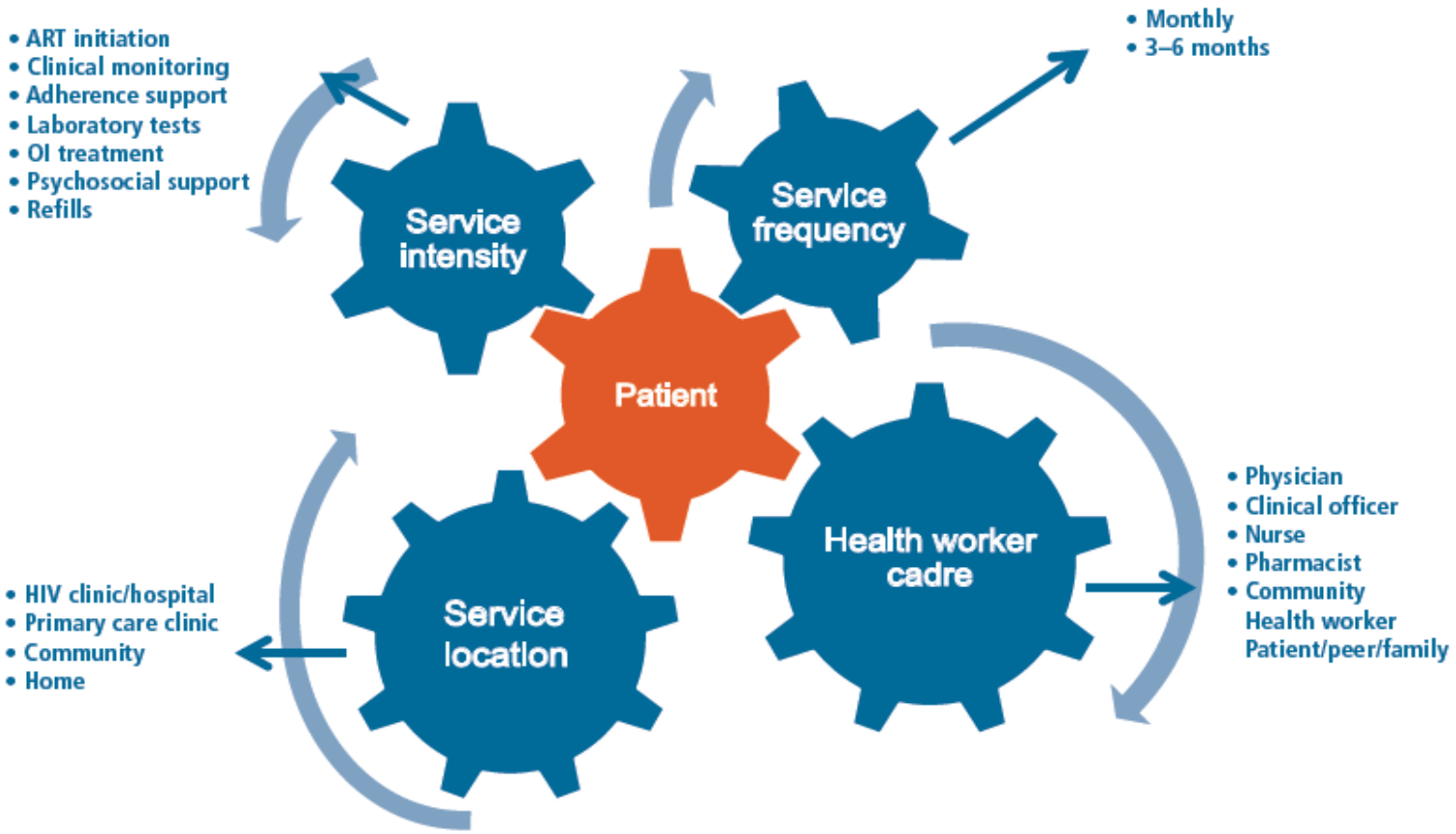
PEP

- ATV/r (preferred 3rd ARV)
- Alternatives: LPV/r or EFV
- Children<10: ABC+3TC preferred
  - AZT+3TC alternative

Other Key areas in the Guidelines

- More emphasis on HE, screening and management of NCD
- Integration of services
- Differentiated Care Model

DCM



Source: WHO 2015 Policy brief: consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: what's new.

Models of Differentiated Care

Facility-based Models

- **Standard of Care**
  (Main ART and NIMART sites)
- **Fast Track ART Refill**
- **ART Adherence Clubs**
  (e.g. Teen Clubs, Youth Adults Clubs, Mother's Clubs, Men's clubs etc.)

Out-of Facility Based Models

- **ART Outreach**
- **Community ARV Refill Groups (CARGs)**