KEY CONSIDERATIONS FOR DIFFERENTIATED ANTIRETROVIRAL THERAPY DELIVERY FOR SPECIFIC POPULATIONS:

CHILDREN, ADOLESCENTS, PREGNANT AND BREASTFEEDING WOMEN AND KEY POPULATIONS

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ABBREVIATIONS

ART	antiretroviral therapy
ARV	antiretroviral (drug)
CDC	United States Centers for Disease Control and Prevention
HIV	human immunodeficiency virus
NAT	nucleic acid test
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PEPFAR	United States President's Emergency Plan for AIDS Relief
PrEP	pre-exposure prophylaxis
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
WHO	World Health Organization

DEFINITIONS USED IN THIS DOCUMENT

Differentiated service delivery is an approach that simplifies and adapts HIV services to better serve the needs of people living with and at risk of acquiring HIV and reduce unnecessary burdens on the health system. For example, under a differentiated service delivery approach, people who are clinically stable on treatment would have a reduced frequency of clinic visits and medication prescribing, allowing health service resources to focus on care for people who are ill and need intensive clinical follow-up.

Differentiated antiretroviral therapy (ART) delivery is used to describe a series of management approaches that align with the clinical status (clinically stable or unstable) of people living with HIV and their needs and preferences. This document focuses on differentiated ART delivery for clinically stable people living with HIV receiving ART.

Age groups. The following definitions for adults, adolescents and children and infants are used to ensure consistency within these considerations. A child is a person younger than 10 years old; older children are 5–9 years old. An adolescent is a person 10–19 years old inclusive.

Key populations. Groups who, because of specific higher-risk behaviour, are at increased risk of HIV irrespective of the type of epidemic or local context. The members of key populations frequently face legal and social challenges that increase their vulnerability to HIV, including barriers to accessing HIV prevention, testing and treatment services. Key populations include (1) people who inject drugs, (2) sex workers, (3) men who have sex with men, (4) transgender people and (5) people in prisons and closed settings.

EXECUTIVE SUMMARY

Differentiated service delivery, also referred to as differentiated care, is an approach that simplifies and adapts HIV services to better serve the needs of people living with and at risk of acquiring HIV and reduce unnecessary burdens on the health system. For example, under a differentiated service delivery approach, people who are clinically stable on treatment would have a reduced frequency of clinic visits and medication prescribing, allowing health service resources to focus on care for people who are ill and need intensive clinical follow-up. Differentiated service delivery applies across the HIV care continuum, including for HIV prevention, testing, linkage, antiretroviral therapy (ART) initiation, ART delivery and chronic care and can accommodate people living with HIV whether they are clinically stable or unstable, new to treatment or in long-term follow-up.

In 2016, WHO published consolidated guidelines on the use of antiretroviral (ARV) drugs for treating and preventing HIV infection. As part of this revision, WHO recognized that, as ART is scaled up and countries adopt the "treat all" policy, ART services will need to be differentiated to provide adapted packages of care to people living with HIV with varied clinical needs. The four groups of people defined are (1) individuals presenting or returning to care with advanced HIV disease, (2) individuals presenting or returning to care when clinically well, (3) individuals who are clinically stable on ART and (4) individuals who are clinically unstable or receiving an ART regimen that is failing.

This document focuses on the third category of clients – individuals who are clinically stable on ART. The 2016 WHO consolidated ARV guidelines recommend that clinically stable people on ART have less frequent clinic visits and medication dispensing. These recommendations were designed specifically for adults and describe criteria for what constitutes readiness for clinically stable client care, where and by whom that care can be provided and what the essential components of care should be.

At the time the 2016 WHO consolidated ARV guidelines were developed, there was limited evidence and experience around how these criteria should be applied to pregnant and breastfeeding women, children and adolescents and members of key populations. Since then, appreciation has been growing that these types of clients may also benefit from models of care specifically for clinically stable clients.

This document outlines the rationale for and features of differentiated ART delivery for clinically stable clients in these populations. The document complements another new publication: *Differentiated care for HIV: a decision framework for differentiated antiretroviral therapy delivery for children, adolescents and pregnant and breastfeeding women*. An additional decision framework that reflects differentiated ART delivery for key populations will be released in 2018.[1]

[1] Visit www.differentiatedcare.org, the "go-to" resource for differentiated service to download the *Decision Framework and access new resources.*

KEY POINTS

- Clinically stable children, adolescents and pregnant and breastfeeding women as well as members of key populations (people who inject drugs, sex workers, men who have sex with men, transgender people and people living in prisons and closed settings) can benefit from access to clinically stable client differentiated antiretroviral therapy (ART) delivery models.
- Children, adolescents, pregnant and breastfeeding women and members of key populations should not be excluded from clinically stable client care based on their population characteristics: age, pregnancy or breastfeeding status, drug use, occupation, sex, gender identity or sexual orientation. In principle, services should be tailored to keep families together as much as possible to simplify access and reduce cost.
- Differentiated ART delivery can address inequities in the access of key populations to HIV treatment services by developing new ART delivery models that meet the specific needs of key populations and reach marginalized, criminalized and stigmatized groups. Differentiated ART delivery can also enable key population communities to be more involved in HIV treatment and care.
- The recommended visit frequency (when), location (where), service provider (who) and service package (what) – known as the building blocks of differentiated care – have been considered for both ART refills and clinical consultations. Extension of this guidance to children, adolescents and pregnant and breastfeeding women as well as members of key populations has highlighted the importance of psychosocial support and the need to better define how a differentiated ART delivery model can provide psychosocial support components.
- Readiness for clinically stable client care and the building blocks for constructing ART delivery models for clinically stable clients for these populations should align with those recommended by WHO for adults to simplify implementation in countries and facilitate the management of families.

1. INTRODUCTION

Differentiated service delivery, also referred to as differentiated care, is an approach to service delivery centred on people living with HIV that simplifies and adapts HIV services across the cascade of care to reflect the preferences and expectations of various groups of people living with HIV while reducing unnecessary burdens on the health system *(1)*. The approach involves assessing individuals to determine the level of care they need and matching them to appropriate services. It includes offering less intensive and less frequent services that are more easily accessible for people who are clinically stable on antiretroviral therapy (ART); this reduces the barriers to treatment and care for people living with HIV and, at the same time, refocuses health system resources on people who require more intensive care and follow-up. Similarly, it includes offering more intensive care for people who are clinically unstable and/or have advanced disease. Differentiated service delivery applies across the HIV care continuum, including HIV prevention, testing, linkage, ART initiation, ART delivery and chronic care.

The 2016 WHO consolidated guidelines on the use of antiretroviral (ARV) drugs for treating and preventing HIV infection (2016 WHO consolidated ARV guidelines) defined four clinical categories to illustrate the diversity of needs of people living with HIV: people presenting well; people presenting with advanced disease; clinically stable people living with HIV; and clinically unstable people living with HIV. Each population requires different elements of care to support their clinical needs (Table 1) *(2)*.

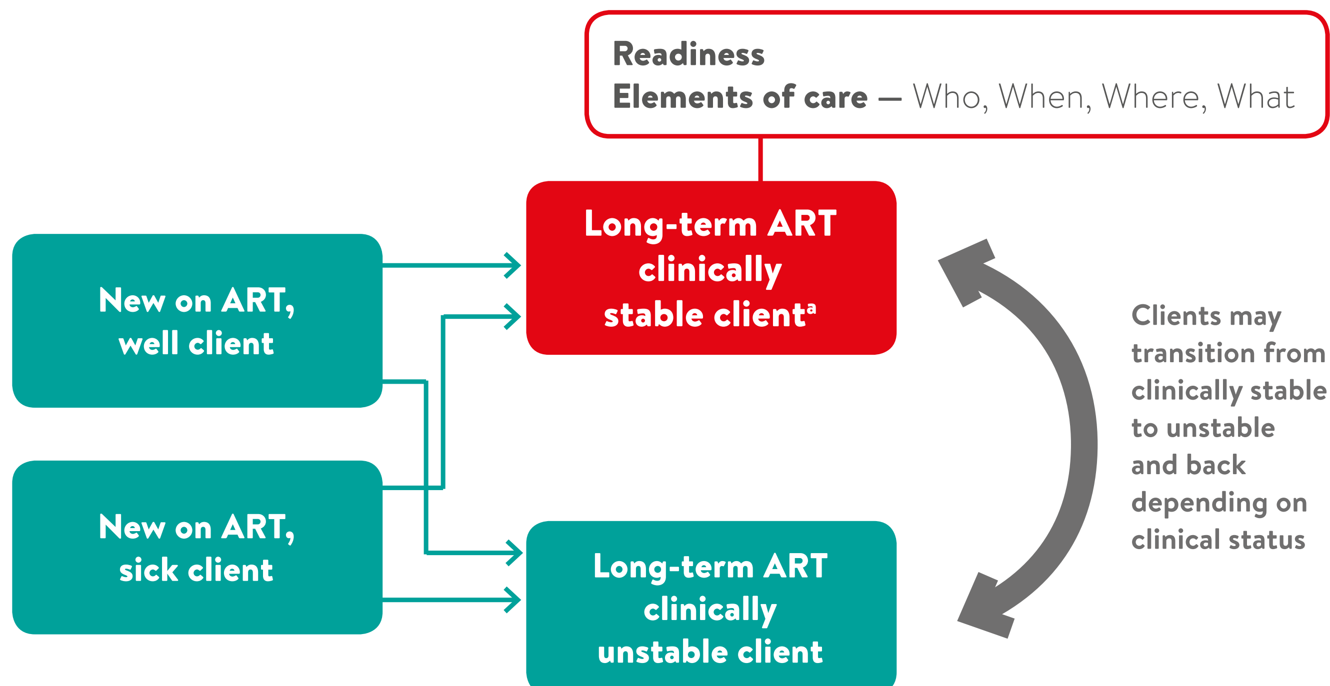
The best documented differentiated service delivery models to date are those that provide ART services for clinically stable people living with HIV *(3)*. For such clients, the 2016 WHO consolidated ARV guidelines recommend a model of differentiated ART delivery that includes less frequent clinic visits, use of non-physician care providers and multi-month refills for ART and other related medications. Certain factors, notably pregnancy, were considered exclusion criteria for entry into a model of ART delivery for clinically stable clients. Since the 2016 WHO consolidated ARV guidelines were published, however, increasing programme experience has shown that, in some cases, children, adolescents and pregnant and breastfeeding women as well as members of key populations can be managed as clinically stable clients. This document aims to address each of these groups and outline the rationale for offering differentiated ART delivery, the

Table 1. Diversity of care needs for people living with HIV

People living with HIV	Key elements of differentiated care package
People presenting when well	Adherence and retention support
People with advanced disease	Clinical package to reduce mortality and morbidity
Clinically stable individuals	Reduced frequency of clinic visits and community ART delviery models
Clinically unstable individuals	Adherence support, viral load testing, switch to second- or third-line ART if indicated, monitoring for drug resistance

Source: 2016 WHO consolidated ARV guidelines *(2)*.

Figure 1. Transitions between categories of clients in a differentiated ART delivery approach



[a] For adults, the 2016 WHO consolidated ARV guidelines provided guidance on readiness and elements of clinically stable client care. This document provides the same considerations for children, adolescents, pregnant and breastfeeding women and members of key populations.

community context within which clients access these models and the key elements that need to be considered in delivering services (Fig. 1).

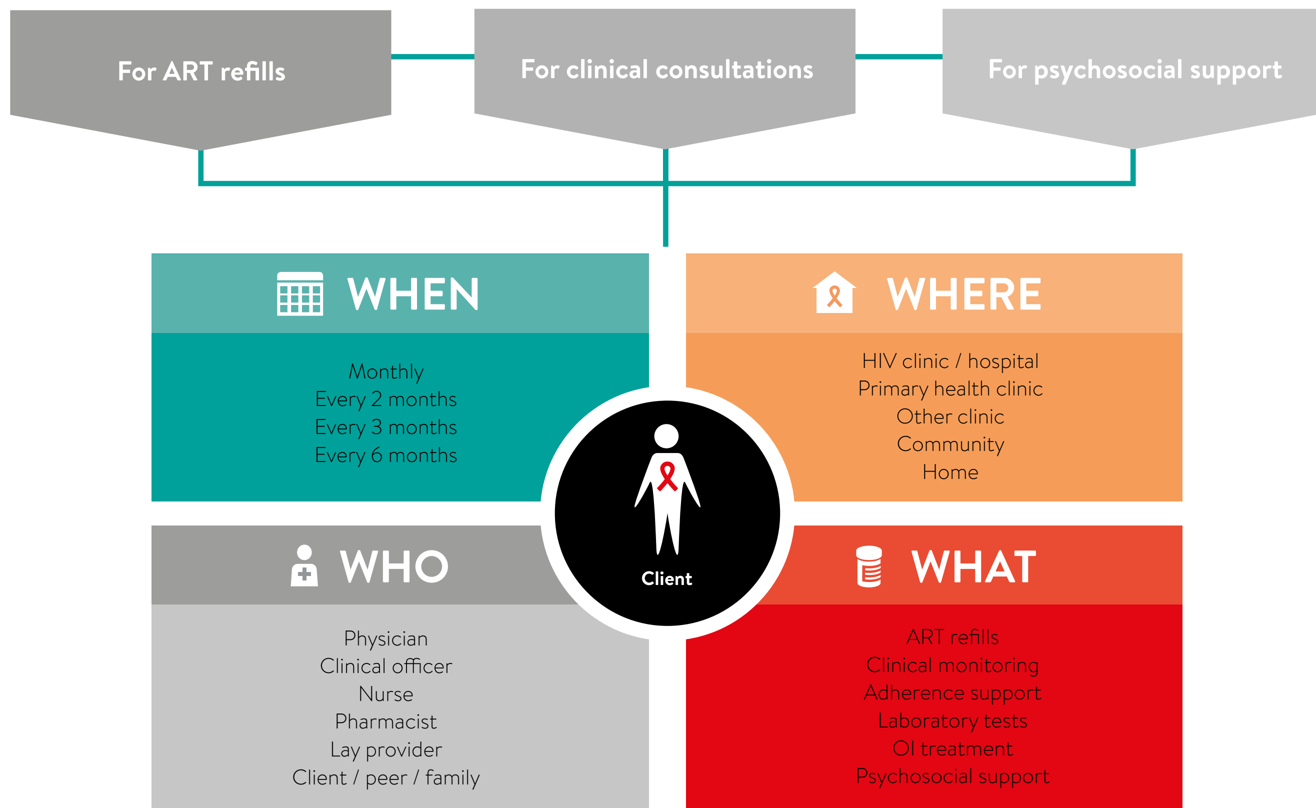
People who are receiving differentiated ART delivery should have access to clinical services as and when they require. Participation in a differentiated service delivery model should not constrain access to health-care services. Thus, clinically stable clients receiving ART services can visit the health facility outside the defined follow-up schedule and see clinicians other than the providers designated by their differentiated ART delivery model.

The groups described here overlap. For example: key populations have children and/or may be adolescents or pregnant or breastfeeding women. Similarly, children, adolescents and pregnant or breastfeeding women may live in families that also contain men who need care. The distinctions between groups are not intended to be divisive but rather provide guidance that enables greater inclusiveness while recognizing specific needs in specific populations.

These key considerations outline the criteria for defining what constitutes a clinically stable client, the service delivery building blocks and the referral criteria for transition from clinically stable client services to services that can meet the more intensive needs of clinically unstable clients.

The building blocks for differentiated ART delivery require consideration across four dimensions. When is care provided (visit frequency)? Where is care provided (location)? Who is providing care (service provider)? What care or services are provided (service package) *(4)*? For clinically stable people living with HIV, these building blocks should be considered separately for ART refills, clinical consultations and psychosocial support (Fig. 2).

Figure 2. Building blocks for differentiated ART delivery *(4)*



2. RELEVANT WHO RECOMMENDATIONS

2.1. Recommendations for clinically stable adults, including key populations

The 2016 WHO consolidated ARV guidelines *(2)* define clinically stable adults living with HIV as: receiving ART for at least one year, 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 (two consecutive viral load measurements of less than 1000 copies/mL) and, in the absence of viral load monitoring, rising CD4 cells counts or CD4 counts above 200 cells/mm^3 *(2,5)*.

The nature of services for clinically stable people living with HIV defined in the 2016 WHO consolidated ARV guidelines include the following elements:

- less frequent (every 3–6 months) clinic visits;
- less frequent (every 3–6 months) medication pick-up;
- community-based care; and
- stopping CD4 count testing for monitoring if viral load testing is available.

2.2. General recommendations for service delivery, including for key populations

The WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations *(6)* and the 2016 WHO consolidated ARV guidelines *(2)* include the following service delivery recommendations (Box 1).

Box 1. WHO recommendations on service delivery

The following options are recommended for decentralizing ART initiation and maintenance:

- initiating ART in hospitals and maintaining ART in peripheral health facilities;
- initiating ART and maintaining ART in peripheral health facilities; and
- initiating ART at peripheral health facilities, with maintenance at the community level between regular clinic visits in settings such as outreach sites, health posts, home-based services or community-based organizations.

Trained and supervised lay providers can distribute ART to adults, adolescents (including those who are members of key populations) and children living with HIV.

- Trained non-physician clinicians, midwives and nurses can initiate first-line ART.
- Trained non-physician clinicians, midwives and nurses can maintain ART.
- Trained and supervised community health workers can distribute ART between regular clinic visits.

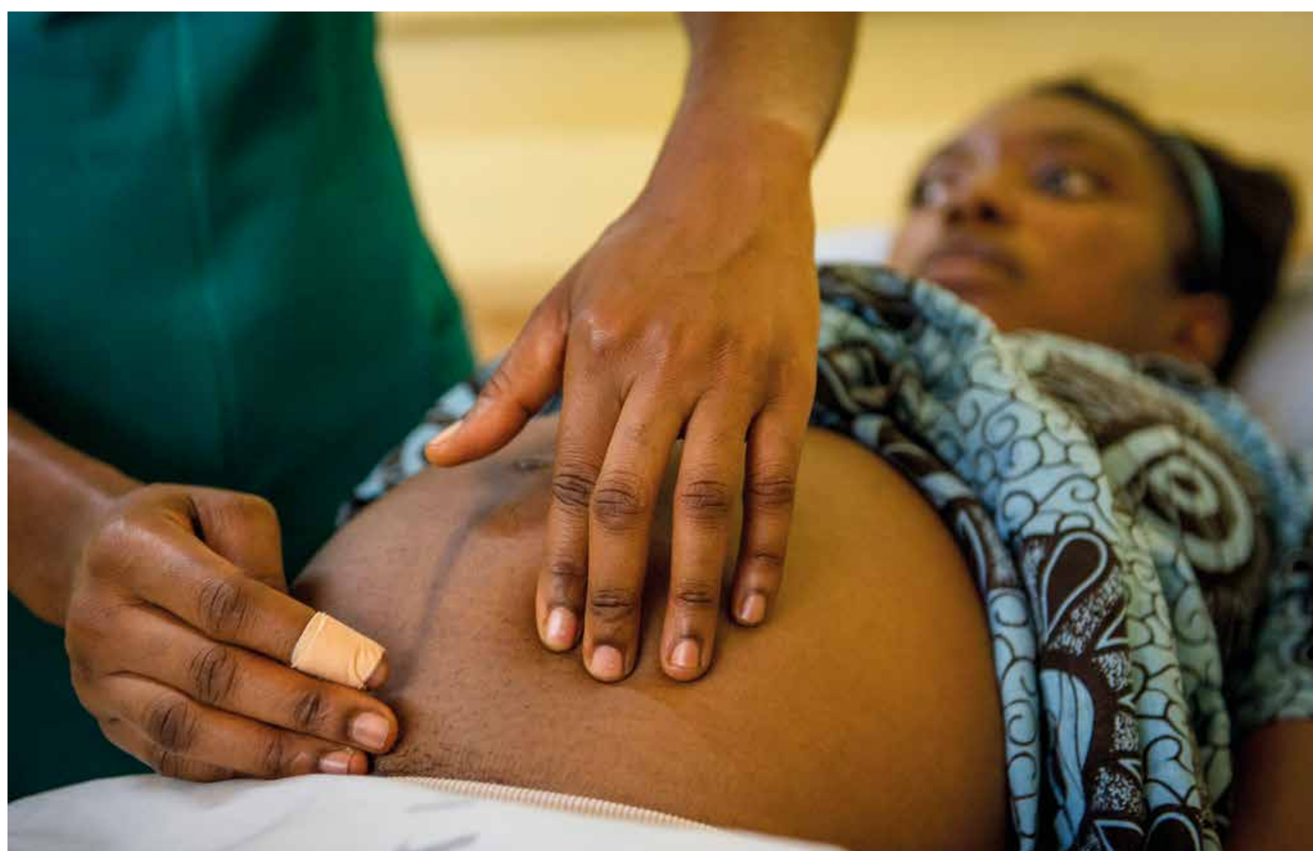
For people who receive opioid substitution therapy and who are living with HIV, ART should be initiated and maintained in settings in which opioid substitution therapy is provided.

3. DIFFERENTIATED ART DELIVERY FOR CLINICALLY STABLE CHILDREN, ADOLESCENTS AND PREGNANT AND BREASTFEEDING WOMEN AND KEY POPULATIONS

Experience in applying differentiated ART delivery has been increasing in a diversity of settings and populations. This has prompted revisiting the previous guidance to consider expanding differentiated models to additional people living with HIV such as children, adolescents and pregnant and breastfeeding women as well as members of key populations.

In November 2016, WHO convened a consultation to reach shared understanding of the application of differentiated ART delivery to children, adolescents, pregnant and breastfeeding women and key populations. Two background evidence reviews provided implementation experience from programmes and organizations *(7)*.

Key considerations for clinically stable people living with HIV who are children, adolescents, pregnant or breastfeeding women as well as members of key populations are summarized below and in Annex 1.



4. KEY CONSIDERATIONS FOR DIFFERENTIATED ART DELIVERY FOR CHILDREN, ADOLESCENTS AND PREGNANT AND BREASTFEEDING WOMEN

Since HIV-related care frequently includes more than one family member, the potential benefits of differentiated ART delivery may be diminished unless they can be applied to all family members. Although family members may have different clinical or psychosocial needs that need to be accommodated, harmonizing differentiated care models with those for adults will simplify implementation in countries. To facilitate a family approach, building blocks should support the visit alignment of children, adolescents and pregnant or breastfeeding women with other family members.

4.1. Clinically stable children living with HIV

Children have a lifetime of ART management ahead of them. Sustained adherence from childhood through adolescence to adulthood is essential to reduce the risk of morbidity and mortality. Access to service delivery options that support a normal experience of childhood (such as limited time in health facilities, uninterrupted school attendance and increased time with peers) should be considered as soon as feasible after treatment initiation, since they may improve retention on ART. Because children often depend on family members to access ART services, aligning visit frequency schedules with a caregiver is a family-centred approach to maintaining and improving clinic attendance and may also affect retention for the family unit.

Clinically stable client ART delivery is suitable for children who are at least two years old. Children grow rapidly in the first two years of life, but thereafter when growth is more gradual, ART doses do not have to be adjusted frequently, and dosage changes may only be required three times until a child reaches 10 years (**Annex 2**).

Once children are two years old, they require less intense follow-up for their general health, including visits for immunization, and the criteria for defining clinically stable adults can be applied. There should be no current illness, which importantly includes malnutrition, requiring intensified follow-up. Malnourished children should therefore not be considered clinically stable until malnutrition, especially severe acute malnutrition, has been appropriately managed and is fully resolved.

In addition to the WHO-recommended definition of clinically stable adults, two further criteria should be considered. First, young children are more likely to experience regimen changes, which may warrant stipulating stability on a specific ART regimen for a period of at least three months. Second, age-appropriate disclosure of the child's HIV status to the child strongly supports sustained adherence. Although age-appropriate disclosure is encouraged and caregiver orientation to the disclosure process should be complete, disclosure should not be required for participating in differentiated service delivery models.

4.1.1. Building blocks for clinical consultations and ART refill visits

Annex 2 shows that dosage adjustments are relatively infrequent after two years of age. Although paediatric growth monitoring (for weight and height) should continue as

recommended for age, the estimated average number of dosing changes between two and 10 years of age is three times, based on current weight band dosing charts. Therefore, if the child is clinically stable, the need for weight-based dosage adjustment should not restrict a child's entry into ART delivery models with less frequent clinical visits. Co-trimoxazole dosing only requires a single dosage adjustment between 10 and 19.9 kg. For children 2–5 years old, consideration should be given to clinical and ART refill visits every three months. This should be balanced against the benefits of aligning visits with other family members who are being seen less often than every three months. Once a child is five years or older, semiannual clinical consultation visits should be adequate to manage children who are clinically stable on ART and to identify any clinical changes or changes in the psychosocial environment requiring more intensified management. Nurses can carry out clinical consultations and reissue prescriptions for the full period until the next clinical consultation visit.

For older children (5–9 years old), ART refill visits can be delinked from clinical consultation visits. ART refill visits need not be more frequent than every three months, can be provided outside health facilities closer to the homes of the people living with HIV and can be managed by lay providers. Co-trimoxazole refills can be provided with ART refills. The orphaned and vulnerable children programmes and community health worker platforms can be used to provide community-based support for children enrolled in differentiated ART delivery models.

Annex 3 considers in detail issues relevant to children in each building block (when, where, who and what) for clinical consultation, ART refill visits and psychosocial support for children.

4.2. Clinically stable adolescents

Multiple studies have found that adolescents living with HIV often have poorer adherence and clinical outcomes than adults *(8,9)*.

Adolescents experience both unique and exacerbated personal and health system barriers to maintaining high levels of adherence and continued engagement with care as they progress through major milestones in cognitive and social development. Adolescence is also a time when individuals will need to transition between child health (paediatric) services and adult health services. Adolescents who are also members of key populations face additional challenges in accessing and remaining in HIV treatment programmes. Similarly to children, access to service delivery options that strive to support routine life patterns should be considered as soon as feasible after initiating treatment.

The criteria that define a clinically stable adult are also appropriate for adolescents. One of these stipulates that there should be no current illness, and this includes mental health disorders, which are prevalent among adolescents, especially those living with HIV. The presence of an ongoing mental health disorder would likely require more intensive follow-up than can be provided in a differentiated ART delivery model for clinically stable clients.

4.2.1. Building blocks for clinical consultation and ART refill visits

Semiannual clinical review of adolescents who are clinically stable should provide sufficient opportunity for a clinician to identify and assess any newly arising psychosocial issues, mental health disorders, drug and alcohol use or dependence and/or sexual and reproductive health needs. If possible, clinicians should align family planning consultations with clinical consultation visits. Similarly to children, ART refill visits can be delinked from clinical consultations and need not take place more frequently than every three months, can take place outside of health facilities closer to the person's home and can be managed by lay providers. If adolescents are taking oral contraceptives, these refills

can be provided with ART refills. Given the importance of mental health in adolescent adherence, incorporating monthly psychosocial assessments into adolescent models may be considered.

Both clinical consultation and ART refill visit return dates should be scheduled with the school calendar in mind. If it assists adolescents, efforts should be made to schedule these visits during school holidays. To support access for adolescents after school hours, visits taking place at health facilities should be provided during extended adolescent-specific service hours (such as late afternoon and/or weekends). As a group, adolescents may benefit from additional adherence support interventions during clinical consultation and ART refill visits.

All health-care providers, both professional and lay cadres, should have training to provide adolescent-friendly services *(2)*, including the consideration that an adolescent can also be a member of a key population.

Annex 4 considers each building block (when, where, who and what) in detail for clinical consultation, psychosocial support and ART refill visits for adolescents.

4.3. Clinically stable pregnant and breastfeeding women

Pregnant and breastfeeding women experience increased demands and responsibilities because of pregnancy and caring for their infants and other children. These demands may act as barriers to adherence and retention. The frequency of health-care visits increases, with multiple antenatal, postnatal and infant follow-up visits as well as routine health visits for children younger than five years, which are often provided on different days and even at different sites. In addition, the transition between maternal, newborn and child health services and HIV care clinics for longer-term care may result in loss to follow-up.

Women accessing differentiated ART delivery at conception

An increasing number of women living with HIV who become pregnant are clinically stable on ART and accessing their care through a differentiated ART delivery model for clinically stable clients. While they are pregnant and during the early postpartum period, these women will require additional health-care visits. They should have the choice to continue receiving their ART through the differentiated ART delivery model or to have their ART delivery integrated within their maternal, newborn and child health care.

Women diagnosed and initiating ART during pregnancy

Women diagnosed and initiating ART during pregnancy experience higher rates of loss to follow-up than non-pregnant women, especially after delivery *(10)*. The immediate postpartum period has a relatively intensive visit schedule for both the mother and her infant, but in most cases a woman starting ART during pregnancy will not be enrolled into a clinically stable client ART service until her infant is six months old. By this age, the infant visit schedule becomes much less intensive, and it is more feasible for the mother to be followed in an ART service for clinically stable clients that is either integrated with infant follow-up visits within the maternal, newborn and child health service or alongside it.

A woman who is clinically stable on ART and accessing care through an ART model for clinically stable clients when she conceives has different considerations from those of a woman initiating ART during pregnancy. The former can continue to receive care as a clinically stable client in a differentiated ART delivery model at the same time as attending antenatal care. If feasible, she should have a viral load <1000 copies/mL in the past three months and confirmed antenatal attendance. For the latter, the WHO-recommended criteria for clinically stable adults can be applied, potentially enabling her to join a ART delivery model for clinically stable clients during the breastfeeding period

once she attains clinical stability. In addition, women should have received a first negative nucleic acid test (NAT) result for their infant. Failure to have an NAT taken, failure to return for the result or a HIV-positive result for the infant may indicate suboptimal adherence of the mother and requires intensified follow-up of the mother-infant pair.

4.3.1. Building blocks for clinical consultation and ART refill visits

The WHO 2016 consolidated ARV guidelines *(2)* recommend integrating ART treatment with antenatal and postnatal care for pregnant and breastfeeding women and their infants within maternal, newborn and child health settings. However, women who are clinically stable on ART at conception may benefit from receiving services in parallel in some settings, with ART care provided through a differentiated ART delivery model and antenatal, postnatal and infant care provided at the maternal, newborn and child health clinic.

For women diagnosed and initiating ART during pregnancy, clinical consultations and ART refills should be integrated into maternal, newborn and child health care. Maternal, newborn and child health nurses should undertake clinical consultations. ART refill visits can be provided as part of maternal, newborn and child health care within the health facility or delinked and provided outside health facilities and managed by lay providers. The length of ART refills provided as part of maternal, newborn and child health care should aim to align with follow-up maternal, newborn and child health visits.

For clinically stable pregnant women who continue to be followed in an ART service for clinically stable clients, all efforts should be made to ensure that they are and remain virally suppressed and that a viral load is measured in the last trimester of pregnancy.

Annex 5 considers in detail each building block (when, where, who and what) for clinical consultation and ART refill visits.

4.4. Psychosocial support component for children, adolescents and pregnant and breastfeeding women

Availability of and access to psychosocial support for children, families and pregnant and breastfeeding women support sustained adherence, especially for older children and adolescents. Psychosocial support could be provided as part of the package of care at ART refill visits or separately. Ideally, psychosocial support would ensure the availability of peer support environments such as support groups held regularly at the community level and could be provided by existing community-based organizations or in the clinic when the refill is picked up. The feasibility of providing support groups at the community level depends on the need. If few people living with HIV need services, access to virtual support could be considered, or support services could be provided at centralized locations such as youth-friendly primary health care or paediatric referral centres. All clinical encounters, and especially psychosocial support visits, should provide child caregivers with the confidence, capacity and tools to disclose to their children and adolescents and pregnant or breastfeeding women to disclose to their partners and families.

If community-level psychosocial support interventions are already regularly taking place, adding ART refill collection can be considered, for example, in adolescent or mentor mother support groups. In addition, orphaned and vulnerable children and community health worker platforms can be used to provide community-based support for mothers and families enrolled in differentiated ART delivery models.

Annexes 3–5 provides more detail about psychosocial support for each building block (when, where, who and what) and for each family group.

5. KEY CONSIDERATIONS FOR DIFFERENTIATED ART DELIVERY FOR CLINICALLY STABLE MEMBERS OF KEY POPULATIONS LIVING WITH HIV

Key populations are disproportionately affected by HIV but underrepresented in HIV testing and treatment programmes. They generally have poorer treatment access and challenges in treatment retention compared with other adolescents and adults *(11–14)*. This is partly caused by stigma and discrimination experienced by key population members accessing facility-based services or violence and human rights abuses, which may lead to discontinuing treatment. Criminalization of sex work, drug use and same-sex sexual activity further marginalize members of key populations, and the fear that they may have to disclose sexual identity or high-risk behaviour may deter them from accessing and returning to facility services *(15,16)*.

Decentralizing ART delivery to services located within key population communities or to other sites at which key population members feel comfortable may improve retention in HIV treatment programmes. Integrating services, including providing integrated or one-stop services for key populations, can address HIV and health issues and address many barriers to the ongoing treatment of key populations. Task shifting to key population peers for differentiated ART delivery can increase the involvement of key population communities and organizations in HIV care and treatment. Involving key population communities and organizations as partners and leaders in implementing health services is an evidence-informed approach to improving the quality and acceptability of services *(17–19)*.

The criteria for defining what constitutes a clinically stable client are essentially the same for members of key populations living with HIV as they are for the general adult population.

Clients should: have been on ART for at least a year with evidence of successful response to treatment based on laboratory criteria; have no current illness; and be sufficiently stable to require less intensified support. Key population members may be more likely to have additional health conditions such as TB, viral hepatitis, sexually transmitted infections, substance use and mental health disorders and may need more support, more frequent clinical consultations and referral to additional services at various times during HIV treatment *(2)*. As for all adults and adolescents, decisions to reduce the frequency of clinical consultation and ART refills for key population members should be considered on an individual basis. If adult or adolescent key population members are clinically stable, there is no reason to exclude them from ART delivery for clinically stable clients.

5.1 Specific considerations relevant to key populations

5.1.1. Drug use and drug dependence

WHO recommends that everyone living with HIV who uses drugs be offered HIV prevention, testing, treatment and care and that active drug use not exclude enrolment in HIV or other treatment programmes; however, certain people may require additional adherence support. Additional adherence support can take the form of counselling for people to integrate ART

with their regular drug use and employment of community support workers.

For people dependent on opioids who are receiving ART, evidence indicates that opioid substitution therapy can lead to improved ART adherence, higher rates of suppressed viral loads, and reduced ART discontinuation rates *(20)*. WHO recommends that ART be initiated and maintained in settings where opioid substitution therapy is provided *(2)*.

For people who use or are dependent on drugs who meet all other criteria for clinical stability, providing access to clinically stable client ART delivery may be an effective way of improving treatment retention and outcome. Further research is needed to better understand outcomes and, as with all clients, the decision to provide less frequent clinic visits should be made on a case-by-case basis.

5.1.2. Prisons and closed settings[1]

The standards of care and treatment available inside prisons, detention centres and other closed settings often do not match those found in the community and, in some instances, HIV treatment may not be available at all *(21,22)*.

For people living in prisons and other closed settings who are receiving HIV treatment, differentiated ART delivery while incarcerated may be less relevant, since treatment is provided within the prison setting without the possibility of decentralizing services and without the need to reduce the frequency of ART refills. For example, in many prisons and closed settings,

[1] In this document, the term "prison or closed setting" is used for all places of detention, and the term "person living in a prison or closed setting" has been used to describe everyone held in such places, including adult and adolescent males and females detained in criminal justice and prison facilities during the investigation of a crime; while awaiting trial; after conviction and before sentencing; and after sentencing.

all medications are provided in the form of directly observed therapy. Where HIV treatment protocols in closed settings and prisons include regular clinical consultations, clinically stable clients may be able to receive less frequent clinical consultations.

For people who have been receiving treatment within prisons or other closed settings and are to be released, the decision to offer differentiated ART delivery can be made with the same considerations as for other adults and can be: *(1)* assessed before release by prison health-care providers and linkage made with community-based health providers for differentiated ART delivery or *(2)* assessed after release by the referral health facility but supported by prison health-care providers by ensuring adequately completed referral documentation, including but not limited to the period on ART and the laboratory results received while in custody. Transitioning from prison to the community may require additional support as individuals integrate back into the community and adapt to a less-structured environment. The post-release period poses a range of risks, including for people who use drugs, who may relapse into drug use. Providing naloxone after release can prevent opioid overdose among people leaving prison or other closed settings.

For prisoners, access to differentiated ART delivery should be supported by a clear referral and linkage strategy addressing: movement from the community to prison, movement from the prison to the community on release and movement between prisons during inter-prison transfers of prisoners *(21)*.

5.2. Clinical consultation and ART refill visits: building blocks for key populations

For clinically stable members of key populations living with HIV, the frequency of clinical consultation and ART refills can be reduced following the same rationale as for any other clinically stable adult. In particular, the highly mobile nature of sex workers' work and late working hours should be considered in scheduling clinical consultation and ART refill visits.

5.2.1. Clinical consultation

Similar to other adolescents and adults, clinically stable members of key populations living with HIV can be clinically reviewed at out-of-facility or primary health care clinics. Wherever members of key populations receive services, efforts should be made to ensure that they do not experience discrimination or stigmatizsation. This can be achieved through stigma reduction and sensitization training for all health-care workers, including non-clinical service providers.

In addition, clinical consultation can also take place at community-based key population organizations that offer health services at either a fixed site or during outreach, where existing nurses or physicians can conduct clinical consultations. For community-based key population organizations that do not normally provide health services, clinical consultations may be conducted through scheduled visits by nurses or physicians from other health services. Members of key populations living with HIV may prefer that clinical consultations take place at these sites, especially if stigmatizsation and discrimination at facility-based services are issues. Specifically for people who are also receiving opioid substitution therapy, clinical consultation for HIV treatment can take place at opioid substitution therapy sites.

Some members of key populations may prefer to access HIV services within facilities at which they may choose not to self-identify as a key population member. They may also prefer that their peers not know their HIV status, meaning that community-based ART delivery would be less preferable to them.

Similar to all adults and adolescents, clinical consultations should include screening for drug and alcohol use and dependence and screening for mental health disorders.

At clinical encounters, consideration should be given to ensuring that the members of key populations have access to the full package of comprehensive HIV services as described by WHO as appropriate to their needs. These include: HIV prevention (condoms and lubricant, behavioural interventions, sterile needles and syringes for people who inject drugs and opioid substitution therapy for people dependent on opioids); prevention, screening and management of TB, viral hepatitis and mental health disorders and sexual and reproductive health services. Post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) for serodiscordant partners of key population members living with HIV can be considered where available. These can be provided on site at integrated services (one-stop shops) or through referral to other sites *(6)*.

5.2.2. ART refills

ART refills can be provided as described above either at each clinical consultation visit or dispensed between clinical visits but need not be more frequent than every three months. Community-based key population organizations, including needle and syringe programmes, can support group ART delivery models managed by health-care workers or peers. Through existing outreach services, community-based organizations can provide support for out-of-facility individual models of ART delivery: for example, through regular outreach to sex worker venues.

Both the 2016 WHO consolidated ARV guidelines *(2)* and the WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations *(6)* recommend that trained and supervised community health workers be able to distribute ART between clinical visits. This includes personnel such as outreach workers, peer navigators, other peers and other lay providers. These same personnel can assess whether clients have any health concerns that may trigger referral. In addition, at ART refill, prevention

commodities such as condoms and lubricants and sterile needles and syringes for people who inject drugs can be provided at the same time.

Specifically, for the people living with HIV who are also receiving opioid substitution therapy, ART refills can be provided through opioid substitution therapy sites.

Annexes 6–10 consider in detail each building block (when, where, who and what) for clinical consultation and ART refill visits for each key population.

5.3. Psychosocial support component for key populations

Psychosocial support refers to a broad range of social and psychological interventions and is especially important for key populations. Social interventions include assistance with basic needs: food clothing, accommodation and employment. Psychological interventions include counselling, brief interventions, motivational interviewing or more structured interventions such as psychotherapy. Psychosocial support for key populations is important to assist in addressing mental health issues, psychosocial stress, experience of violence, stigma, social isolation and other problems that may be more common among these individuals.

Providing psychosocial support has been shown to increase adherence to both HIV and drug dependence treatment *(23,24)*. Many community-based organizations focused on key populations already provide psychosocial support. Psychosocial support should include assessment of psychosocial needs, supportive counselling and links to family and community services. Unfortunately, psychosocial services are not available in many settings.

Psychosocial support can be provided by trained providers or through peer support groups and could be provided either at clinical consultation or at ART refill, if feasible. Support groups could be formed within existing ART refill groups or, alternatively, existing support groups and community-based services could also provide ART refills. At psychosocial support visits, prevention commodities can also be provided.

In situations when mental health screening shows that mental health disorders are present, a mental health professional should undertake accurate diagnosis and treatment, which will typically require referral out of differentiated ART delivery to a specialized facility or provider (Annex 11).

6. COMMUNITY-BASED IMPLEMENTATION TOOLS

The following tools for practical guidance on implementing community-based, comprehensive HIV and sexually transmitted infection services for key populations:

- men who have sex with men: Implementing comprehensive HIV and STI programmes with men who have sex with men: practical guidance for collaborative interventions *(25)*;
- sex workers: Implementing comprehensive HIV/STI programmes with sex workers: practical approaches from collaborative interventions *(26)*;
- transgender people: Implementing comprehensive HIV and STI programmes with transgender people: practical guidance for collaborative interventions *(27)*; and
- people who inject drugs: Implementing comprehensive HIV and HCV programmes with people who inject drugs: practical guidance for collaborative interventions *(28)*.

7. CONSIDERATIONS FOR REFERRAL BACK TO FACILITY-BASED CLINICAL CARE

Clinically stable people living with HIV who are on ART can see clinicians less frequently and receive longer ART refills, often out of the facility, because the risk of HIV mortality and morbidity is low. If this risk rises because of treatment failure or onset of a new clinical condition, this should be identified and supported by an appropriate intensification of care. Priority therefore needs to be given to functioning referral systems not only at clinical consultation visits but also ART refill and psychosocial visits.

Most commonly, referral will be to ART clinics, which are facility-based and clinician-led and may have more resources to address the needs of clients. Consideration could be given to remaining in the ART service for clinically stable clients with additional individual clinical or psychosocial visits added to manage the identified risk.

Reasons for back referral need to be established for referring individuals from ART services for clinically stable clients to more intensive ART services. If possible, these should be the same across population groups to support effective implementation. The proposed referral reasons are:

- an acute intercurrent illness requiring more frequent clinical management, including but not limited to developing comorbidity or infection, mental health disorder, an adverse drug reaction or malnutrition in children;
- viral load >1000 copies/mL;
- psychosocial issues or mental health disorders requiring more intense support or management; and
- harmful drug or alcohol use or dependence as defined by ICD-10 or other diagnostic criteria and that affect adherence to ART.

CONCLUSIONS

This document provides key considerations on when clinically stable children, adolescents and women who are pregnant or breastfeeding as well as members of key populations (people who inject drugs, sex workers, men who have sex with men, transgender people and people living in prisons and closed settings) can benefit from access to ART services for clinically stable clients, including less frequent clinic visits and multi-month refills for ART and other medications. The guidance provides the rationale and the approach to expand differentiated ART delivery to populations of people living with HIV who previously may not have been considered “eligible” for ART delivery models for clinically stable clients.

Differentiated service delivery is essentially a person-centred approach. This document and the annexes, which summarize key considerations for ART delivery for clinically stable clients in various populations, should help HIV programme managers and implementers to safely apply differentiated care approaches to children, adolescents, pregnant and breastfeeding women and members of key populations. Such strategies will enable the Fast-Track targets for scaling up to be reached while providing a safety net of high-quality treatment and care.

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ANNEXES

ANNEX 1. SUMMARY OF KEY CONSIDERATIONS FOR CHILDREN, ADOLESCENTS, PREGNANT AND BREASTFEEDING WOMEN AND MEMBER OF KEY POPULATIONS

Criteria for defining clinically stable clients for differentiated ART delivery

The criteria for defining clinically stable children, adolescents, pregnant and breastfeeding women and members of key populations should be aligned with those used to define clinically stable adults in the 2016 WHO consolidated ARV guidelines: clients who have:

- received ART for at least one year;
- no adverse drug reactions that require regular monitoring;
- no current illnesses, including such conditions as malnutrition in children, mental health conditions or postpartum depression;
- a good understanding of lifelong adherence; and
- evidence of treatment success: two consecutive viral load measurements of <1000 copies/mL, rising CD4 cell counts or CD4 counts >200 cells/mm^3.

There may be additional criteria for specific populations.

- **Children:** should be at least two years old, taking the same regimen for more than three months and caregivers counselled and oriented on the disclosure process.
- **Adolescents:** should have access to psychosocial support.
- **Women clinically stable on ART when conceiving:** already accessing the differentiated ART delivery model plus at least one viral load test of <1000 copies/mL in the past three months and accessing antenatal care.
- **Women initiating ART during pregnancy:** since a woman initiating treatment during pregnancy would only become eligible to enter a differentiated ART delivery model in the postpartum period, an HIV-negative result for her infant with a nucleic acid test (NAT) at six weeks and evidence of accessing infant follow-up care are additional requirements.
- **Drug use or drug dependence, including alcohol:** although drug use and drug dependence should not exclude enrolment in ART programmes, determining whether a client is clinically stable and can receive reduced clinical care and support within a differentiated ART delivery model requires individual assessment by a clinician.

Building blocks for ART delivery for clinically stable clients

Building blocks[1]	ART refill	Clinical consultation	Psychosocial
When	Every 3–6 months	Consider every six months for pregnant or breastfeeding women and children older than five yearsa Consider every three months for children 2–5 years old[a]	Every 1–6 months[b]
Where	Primary health care Maternal, newborn and child health services in primary health care Outreach from a facility Drug dependence treatment services, including opioid substitution therapy clinics Out of facility, including home-based ART refills or the premises of community-based organizations	Primary health clinic Maternal, newborn and child health clinic Outreach from a facility Drug dependence treatment services, including opioid substitution therapy clinics	Primary health care Drug dependence treatment services, including opioid substitution therapy clinics Out of facility Virtual Social media
Who[c]	Lay providers Caregivers Peers Peer navigators Outreach workers	Nurses Midwives Clinical officers Doctors	Lay providers Caregivers Peers Peer navigators Outreach workers

[1] The building blocks are: when (how often are services provided); where (location where services are provided); who (who provides the service) and what (which services are provided) for clinically stable clients.

Building blocks[1]	ART refill	Clinical consultation	Psychosocial
What	ART refill Adherence check Check whether the person needs to be referred to a clinician **Children** Co-trimoxazole refill Disclosure process check-in **Pregnant or breastfeeding women** Check attendance at maternal, newborn and child health services **Key populations** HIV prevention and harm reduction	Clinical consultation in accordance with the appropriate clinical guidelines, including tuberculosis (TB) screening and providing TB preventive treatment as applicable[d] Laboratory tests: viral load test annually and, where feasible, every six months for pregnant or breastfeeding women. If viral load testing is not available, CD4 count every six months Prescribing ART until next clinical consultation Referral for intensive or specialized care as needed **Children** Dosage check and possible adjustment Routine health check, including immunization status and TB screen Disclosure process review and check-in with caregiver **Adolescents** Mental health assessment (annual) Drug and alcohol screening **Pregnant or breastfeeding women** Check attendance at maternal, newborn and child health services (if not integrated service) Mental health assessment (annual) Drug and alcohol screening **Key populations** Mental health assessment Drug and alcohol screening HIV prevention, including harm reduction, sexually transmitted infections, viral hepatitis and TB services either on site or through referral[c]	Peer support environment Ongoing caregiver counselling and support to facilitate disclosure Check-in to assess general life factors that may affect adherence, including addressing gender-based violence among women and adolescent girls Check whether the person needs to be referred to a clinician **Key populations** Check need for legal advice Addressing violence and providing HIV prevention, including harm reduction Support after release from prisons

[a] Although six months is generally accepted for clinically stable adults and older children, pregnant and breastfeeding women may need more frequent visits because of the ongoing requirement for scheduled visits during the antenatal and postnatal periods. In addition, more frequent visits every three months could be considered for younger children 2–5 years old because of the need for close follow-up in this younger population and the potential need for dose adjustment. This should be balanced on a case-by-case basis against the benefits of aligning visits with other family members who are being seen less often than every three months.

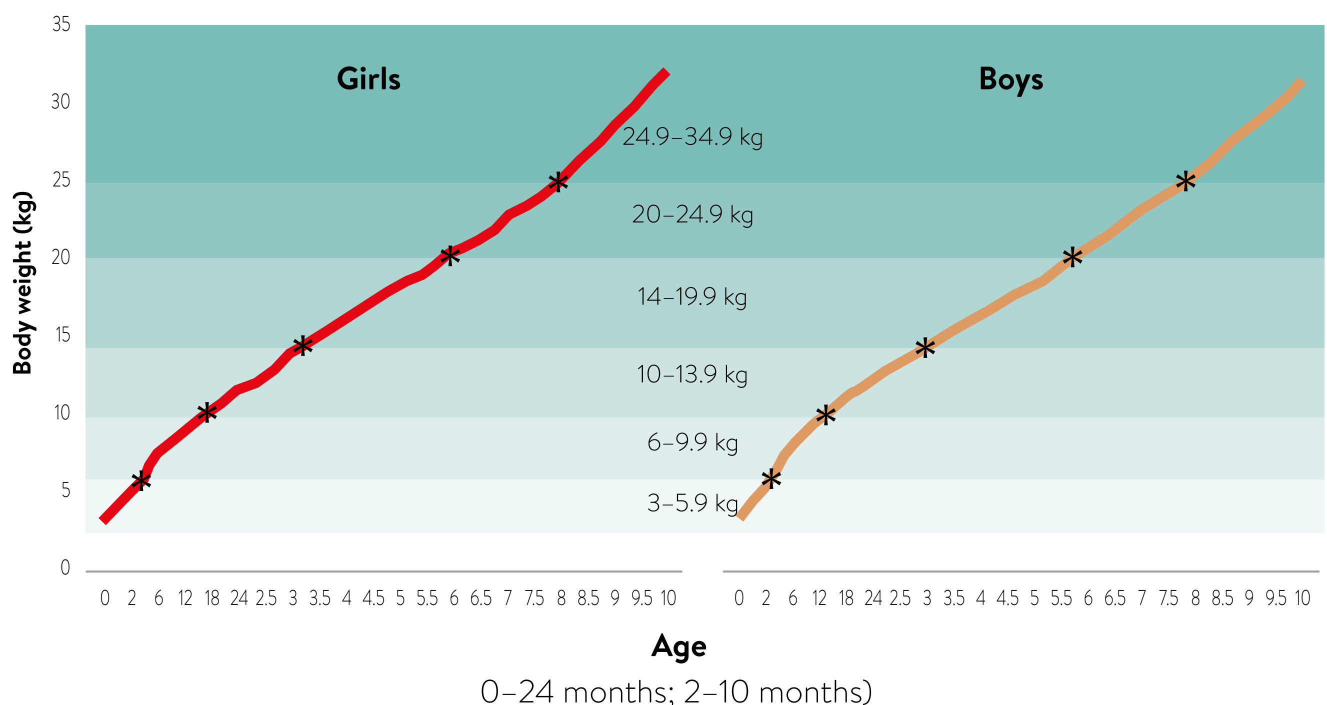
[b] Psychosocial support can be provided alongside ART refills and/or clinical consultations, and additional visits are not necessarily required.

[c] Mid-level health workers can undertake routine clinical consultations, with doctors and specialists engaged for complicated cases.

[d] In settings with a high risk of TB infection, offering TB screening more frequently than every six months may be appropriate. TB screening could also be conducted during ART refill visits.

ANNEX 2. CHANGES IN ART DOSAGE DO NOT HAVE TO INCREASE THE FREQUENCY OF CLINIC VISITS FOR CLINICALLY STABLE CHILDREN LIVING WITH HIV

WHO 50th percentile weight-for-age growth curves for girls and boys



Source: Kelsey Mirkovic, CDC (xdj1@cdc.gov); Henry Miller, USAID (hmiller@usaid.gov)

- The coloured horizontal bands delineate ART weight dosing bands.
- The pink and blue curves are the 50th percentile weight-for-age growth curves for girls and boys, respectively.
- Each time a growth curve crosses a weight band (as indicated by *), a change in ART dose would be anticipated.
- In theory, only five changes in ART dose are expected before age 10 years:
  - ~ three months
  - ~ one year
  - ~ three years
  - ~ five years
  - ~ seven years

ANNEX 3. KEY CONSIDERATION TABLES FOR DIFFERENTIATED ART DELIVERY FOR CLINICALLY STABLE CHILDREN (2–9 YEARS OLD)

1. Criteria for defining clinically stable clients

Category	Criteria	Considerations
Age threshold	**≥2 years**	▪ Infrequent age band dosage adjustments after two years (Annex 1) ▪ Most immunizations completed
Clinical criteria	**Same as adults**	▪ 12 months on ART ▪ Malnutrition should be assessed and would be considered a current illness, precluding entry into an ART delivery model for clinically stable clients. ▪ WHO already recommends two viral load tests (or CD4 count if no viral load testing is available) during the first year on ART for children, which supports the requirement for defining clinically stable clients of two viral loads <1000 copies/mL.
Additional possible non-clinical criteria	**Same regimen for more than three months** **Orienting the caregiver about age-appropriate disclosure**	▪ Young children are more likely to experience regimen changes, which may warrant stipulating stability on a specific ART regimen. ▪ Age-appropriate child disclosure supports sustained adherence. Caregivers should be oriented to engage with this process at appropriate ages.

2. Building blocks for the ART delivery model

2.1. Clinical consultation visits

Bulding blocks		Considerations
When	**Every 3–6 months**	■ For children 2–4 years old, consideration should be given to seeing them every three months. ■ Seeing an older child (5–9 years old) twice a year provides sufficient opportunity for the clinician to assess weight and adjust dosages (see Annex 1). Clinically stable children older than five years do not need a clinical consultation more than twice a year. ■ Consideration should be given to selecting times and dates that suit children attending school such as scheduling visits during school holidays.
Where	**Primary health care**	■ Clinical care should ideally be provided at the primary health care level closer to the homes of people living with HIV. ■ When low concentrations of children do not justify training primary health care personnel to carry out clinical consultations of children, these could still be done at referral or a centralized paediatric site but should not compromise ART refills taking place in primary health care.
	Outreach from primary health care	■ If mobile services are provided to adults receiving ART in remote areas, children should also be included. ■ The outreach team would require additional drug stock to enable dosage adjustments at the outreach point.
Who	**Nurses** **Midwives** **Clinical officers** **Doctors**	■ The 2016 WHO consolidated ARV guidelines already recommend nurses to initiate and maintain ART, including for children.

Bulding blocks		Considerations
What	Clinical consultation of children	■ Follow country guidelines for clinical assessment of children, including but not limited to TB screening, adherence check and disclosure progress. TB screening and assessment of exposure to TB contacts should be maintained during every encounter with the health system. ■ In settings that are endemic for TB and have a high risk of TB infection, offering TB screening more frequently than every six months may be appropriate. TB screening could also be conducted during ART refill visits. ■ Referral for intensive or specialized care if warranted based on assessment.
	Dosage checks and possible adjustment	■ Important to assess current weight and expected weight gain over the following six months and if required, adjust ART dosages accordingly. ■ The 2016 WHO consolidated ARV guidelines recommend co-trimoxazole for all children younger than five years. This can be discontinued once the child reaches five years and older and is clinically stable on ART (viral load <1000 copies/mL for less than six months or CD4 count >350 cells/mm3) unless the child lives in an area in which malaria or severe bacterial infection is prevalent, and then prophylaxis should be continued until adulthood. Only one dosage adjustment is required between 10 and 19.9 kg.
	Laboratory tests	■ The 2016 WHO consolidated ARV guidelines recommend annual viral load assessment for clinically stable children (if viral load testing is not available, CD4 counts can be used).
	Rescript	■ The scripting period should cover the period until the next clinical consultation (not until the following ART refill visit).

2.2. ART refill visits

Bulding blocks		Considerations
When	Every 3–6 months	■ ART refills can either be provided at each clinical consultation visit or can be dispensed between clinical visits but need not be more frequent than every three months.
Where	Primary health care Out of facility	■ ART refills should be provided as close to people's homes as possible. Out-of-facility individual or group collection ART delivery models can be considered.
Who	Lay providers	■ The 2016 WHO consolidated ARV guidelines already recommend that trained and supervised community health workers be able to distribute ART between clinical visits to children. ■ Carrying out dosage adjustments at clinical consultation visits only makes lay providers managing ART refill visits for children more feasible.

Bulding blocks		Considerations
What	ART and co-trimoxazole refills	■ Both ART and co-trimoxazole refills should be dispensed based on dosages reflected in the clinician's script.
	Referral check	■ Clear referral pathways should be put in place for referral to a clinician if any health concerns are identified.
	Adherence check	■ Can include self-report or caregiver report, pill count or pharmacy records.
	Disclosure progress check-in	■ Disclosure is a process and should be monitored and supported until full disclosure is achieved at the appropriate age.

2.3. Psychosocial support

Bulding blocks		Considerations
When	Every 1–6 months	■ Psychosocial support could be provided as part of the package of support at ART refill visits (see above) or can be provided completely separately. ■ Such support could be taken up at a frequency meeting the specific needs of the person living with HIV or caregiver.
Where	Primary health care Out of facility Virtual environment	■ Psychosocial support is ideally provided as close to the person's home as possible. ■ If low concentrations of children (especially of similar ages) make support groups at the community level unfeasible, virtual support could be considered or, alternatively, less frequent attendance at more centralized locations such as primary health care or a paediatric referral centre.
Who	Lay providers Peers	■ Community-based organizations, including providers of services for orphaned and vulnerable children, should be considered for providing these services.
What	Peer group environment	■ Both caregivers and children starting to approach pre-adolescence benefit from peer support environments such as support groups.
	Referral check	■ Clear referral pathways should be put in place for referral to a clinician if any health concerns are identified.
	Disclosure support	■ Caregivers benefit from ongoing support to undertake and complete the disclosure process. This should be considered as part of the psychosocial support package.

ANNEX 4. KEY CONSIDERATIONS FOR DIFFERENTIATED ART DELIVERY FOR CLINICALLY STABLE ADOLESCENTS

1. Criteria for defining clinically stable clients

Category	Criteria	Considerations
Clinical criteria	**Same as adults**	■ These criteria include no current illness, which includes no mental health disorders, which are more prevalent among adolescents, especially adolescents living with HIV. ■ For countries that only recently implemented viral load monitoring, one viral load test <1000 copies/mL and evidence of a previously rising CD4 count or CD4 count >200 cells/mm3 can be considered, though the preference, where possible, is for two viral load tests <1000 copies/mL.

2. Building blocks for the ART delivery model

2.1. Clinical consultation visits

Bulding blocks		Considerations
When	**Every 3–6 months**	■ In general, clinically stable adolescents do not need to be clinically reviewed more than twice a year. This provides sufficient opportunity for a clinician to identify and assess adherence, any newly arising psychosocial issues, mental health disorders and/or sexual and reproductive health needs. ■ Clinical consultations should be scheduled with the school calendar in mind. If it helps adolescents, efforts should be made to schedule clinical consultations during school holidays. ■ If possible, providing extended adolescent-friendly service hours (late afternoon and/or Saturdays) could be considered to support adolescent access after school hours.
Where	**Primary health care**	■ Clinical care should ideally be provided in primary health care closer to the people's homes. ■ If possible, providing clinical consultations within adolescent-friendly designated service space could be considered.
	Outreach from primary health care	■ If mobile outreach services are provided to adults receiving ART in remote areas, adolescents should also be included.

Bulding blocks		Considerations
Who	**Nurses** **Midwives** **Clinical officers** **Doctors**	■ The 2016 WHO consolidated ARV guidelines already recommend nurses to maintain ART for adolescents. ■ Adolescent-friendly orientation of service providers should be considered (see the WHO guidelines on making health services adolescent friendly).
What	**Adolescent clinical consultation**	■ Follow country guidelines for adolescent clinical assessment, including but not limited to TB screening, psychosocial health and sexual and reproductive health assessments and adherence check. TB screening and assessment of exposure to TB contacts should be maintained. ■ In settings that are endemic for TB and have a high risk of TB infection, offering TB screening more frequently than every six months may be appropriate. TB screening could also be conducted during ART refill visits. ■ Most adolescents should have achieved adult dosage weight bands, with no further dosage adjustments required. If the adolescent is below the adult threshold weight, follow the approach for children: check the weight and manage any dosage adjustments required until the next clinical consultation.
	Mental health assessment	■ The prevalence of mental health disorders among adolescents necessitates annual mental health assessment. This may include drug and alcohol screening.
	Laboratory tests	■ The 2016 WHO consolidated ARV guidelines recommend annual viral load assessment for clinically stable adolescents (if viral load testing is not available, CD4 counts every six months).
	Rescript	■ The ART and family planning scripting period should cover the period until the next clinical consultation (not only until the following ART refill visit).

2.2. ART refill visits

Bulding blocks		Considerations
When	**Every 3–6 months**	▪ ART refills can either be provided at each clinical consultation visit or can be dispensed between clinical visits but need not be more frequent than every three months. ▪ If adolescents attend school away from home, extending ART refill periods to accommodate school terms should be given priority. ▪ If possible, providing extended adolescent-specific service hours (late afternoon and/or weekends) should be considered to support adolescent access after school hours.
Where	**Primary health care** **Out of facility**	▪ ART refills should be provided as close to people's homes as possible. Out-of-facility individual or group collection ART delivery models can be considered. ▪ Pregnant or breastfeeding adolescents should continue to be supported within differentiated ART delivery models for clinically stable adolescents.
Who	**Lay providers**	▪ The 2016 WHO consolidated ARV guidelines already recommend that trained and supervised lay providers be able to distribute ART between clinical visits, including to adolescents. ▪ Adolescent-friendly orientation of lay providers should be considered (see the WHO guidelines on making health services adolescent friendly).
What	**ART refill**	▪ ART refills should be dispensed based on dosages reflected in the clinician's script. ▪ If possible, family planning repeat visits should be aligned with ART refill visits. If oral contraception is provided, refills could be distributed along with ART refills.
	Referral check	▪ Clear referral pathways should be put in place. Lay providers should always check whether there are any health or psychosocial concerns, triggering a referral.
	Adherence check	▪ Can include self-report, pill count or pharmacy records.

2.3. Psychosocial support

Bulding blocks		Considerations
When	**Every 1–6 months**	■ Psychosocial support should be available and accessible either as part of the package of support at ART refill visits (see above) or separately. ■ Such support should be available for take-up at a frequency appropriate to the specific needs of the adolescent.
Where	**Primary health care** **Out of facility** **Virtual environment**	■ Psychosocial support is ideally provided as close to people's homes as possible. ■ If low concentrations of adolescents make support groups at the community level unfeasible, virtual support could be considered or, alternatively, less frequent attendance at more centralized locations such as youth-friendly primary health cares or individual one-on-one home support. ■ Pregnant or breastfeeding adolescents should continue to be supported within adolescent peer support environments.
Who	**Lay providers** **Peers**	■ Community-based organizations, including the providers of services for orphaned and vulnerable children and lay providers, could be considered for providing these services.
What	**Peer group environment**	■ Adolescents benefit from peer support environments such as support groups.
	Referral check	■ Clear referral pathways should be in place. Every contact with an adolescent should be used for checking whether there are any health or psychosocial concerns, triggering a referral.
	Onward disclosure support	■ Despite growing independence, adolescents benefit from caregiver support. Psychosocial support packages should consider supporting adolescents to disclose their status to adult support structures and involve such adults in their care.

ANNEX 5. KEY CONSIDERATIONS FOR DIFFERENTIATED ART DELIVERY FOR CLINICALLY STABLE PREGNANT AND BREASTFEEDING WOMEN

1. Criteria for defining clinically stable clients

1.1 Clinically stable on ART at conception

Category	Criteria	Considerations
Already accessing an ART delivery model for clinically stable clients		▪ Women would already have met the WHO criteria for clinical stability.
Additional possible clinical criteria	**Viral load <1000 copies/mL in the past three months**	▪ Viral load suppression is critical to prevent mother-to-child transmission. Annual viral load monitoring for clinically stable people living with HIV (recommendation of the 2016 WHO consolidated ARV guidelines) may mean that the last viral load assessment was 3–12 months previously. ▪ Recent viral load testing should be used to establish a low risk of mother-to-child transmission and the consequent appropriateness of maintaining ART service for clinically stable clients parallel to antenatal care.
	Check access to antenatal care	▪ Opportunity to check whether women are accessing antenatal care in parallel to HIV care through an ART delivery service for clinically stable clients.
	HIV-negative NAT result when the infant is six weeks old	▪ Opportunity to check whether the woman has attended the infant six-week PCR and received the result. ▪ An HIV-positive NAT result for an infant may indicate suboptimal adherence and requires intensified support for both mother and infant, which may not be feasible in an ART service for clinically stable clients.

1.2 Initiating ART during pregnancy

Category	Criteria	Considerations
Clinical criteria	**Same as adults**	■ A woman diagnosed and starting ART in pregnancy who has been receiving ART for 12 months, successfully achieved two consecutive viral loads <1000 copies/mL and is not currently ill or experiencing side-effects should not be considered an increased risk compared with a non-pregnant woman living with HIV.
Additional possible clinical criteria	**HIV-negative PCR result when the infant becomes six weeks old**	■ Opportunity to check whether the woman has attended the infant six-week PCR and received the result. ■ An HIV-positive PCR result for an infant may indicate suboptimal adherence and requires intensified support for both mother and infant, which may not be feasible in a differentiated care model.

2. Building blocks for the ART delivery model

2.1. Clinical consultation visits

Bulding blocks		Considerations
When	**Every 3–6 months**	■ In general, clinically stable pregnant and breastfeeding women do not need HIV clinical consultation more than twice a year. ■ If possible, clinical consultations should be aligned with maternal, newborn and child health service visits scheduled in the same month.
Where	**Primary health care and maternal, newborn and child health services at primary health care**	■ Clinical care should ideally be provided at primary health care level closer to the homes of people living with HIV. ■ If possible, as recommended in the 2016 WHO consolidated ARV guidelines, HIV clinical consultations should be integrated with antenatal or infant care follow-up visits provided by maternal, newborn and child health services, especially for women starting ART during pregnancy who have not yet interacted with HIV clinic services.
	Outreach from primary health care	■ If mobile outreach services are provided to adults receiving ART in remote areas, pregnant and breastfeeding women and their infants should also be seen and provided with integrated HIV and maternal, newborn and child health care.
Who	**Nurses or midwives**	■ The 2016 WHO consolidated ARV guidelines already recommend that midwives and nurses maintain ART for pregnant and breastfeeding women.

Bulding blocks		Considerations
What	**Clinical consultation for preventing mother-to-child transmission**	■ Follow country guidelines on clinical assessment for preventing mother-to-child transmission, including but not limited to TB screening and post-delivery mental health and sexual and reproductive health assessment. ■ In settings that are endemic for TB and have a high risk of TB infection, offering TB screening more frequently than every six months may be appropriate. TB screening could also be conducted during ART refill visits. ■ The 2016 WHO consolidated ARV guidelines recommend integrating HIV into a maternal, newborn and child clinical health-care package.
	Laboratory tests	■ For clinically stable pregnant women already accessing ART services for clinically stable clients, all efforts should be made to ensure that women have and continue to have suppressed viral loads and that the viral load is measured in the last trimester of pregnancy. ■ For clinically stable breastfeeding women, where feasible, the viral load can be measured every six months (more frequently than for clinically stable non-breastfeeding women).
	Rescript	■ The ART and family planning (post-delivery) scripting period should cover the period until the next clinical consultation (not only until following the ART refill visit).
	Maternal, newborn and child health check (if not integrated)	■ If clinical care is not integrated, HIV clinical consultations should include a check that the person is attending maternal, newborn and child health-care visits.

2.2. ART refill visits

<table>
<tr><th colspan="2">Bulding blocks</th><th>Considerations</th></tr>
<tr><td>When</td><td>Every 3–6 months</td><td>▪ ART refills can either be provided at each clinical consultation visit or can be dispensed between clinical visits but need not be more frequent than every three months.
▪ If ART refills take place at primary health care, they should be aligned with the scheduled maternal, newborn and child health visits in the same month.</td></tr>
<tr><td rowspan="2">Where</td><td>Primary health care and maternal, newborn and child health services at primary health care</td><td rowspan="2">▪ ART refills should be provided as close to people's homes as possible. Consideration could be given to delinking refill collection from maternal, newborn and child health care.
▪ ART refills can be collected by individuals (at facilities or at other distribution points) or by groups of clients (in a community ART distribution model).</td></tr>
<tr><td>Out of facility</td></tr>
<tr><td>Who</td><td>Lay providers</td><td>▪ The 2016 WHO consolidated ARV guidelines already recommend that trained and supervised lay providers be able to distribute ART between clinical visits to all adults (no exclusion for pregnant and breastfeeding women).
▪ Consideration can be given to using lay providers equivalent to mentor mothers for task shifting ART refill distribution.</td></tr>
<tr><td rowspan="4">What</td><td>ART refill</td><td>▪ If possible, family planning repeat visits should be aligned with ART refill visits. If oral contraception is provided, refills could be distributed along with ART refills.</td></tr>
<tr><td>Referral check</td><td>▪ Clear referral pathways should be put in place. Lay providers should always check whether there are any health or psychosocial concerns, triggering a referral.</td></tr>
<tr><td>Adherence check</td><td>▪ Can include self-report, pill count or pharmacy records.</td></tr>
<tr><td>Maternal, newborn and child health check-in</td><td>▪ Consideration could be given to lay providers checking to determine whether the woman is attending maternal, newborn and child health visits.</td></tr>
</table>

2.3. Psychosocial support

Bulding blocks		Considerations
When	**Every 1–6 months**	■ Psychosocial support should be available and accessible either as part of the package of support at ART refill visits (see above) or provided separately. ■ Such support should be available for take-up at a frequency appropriate to the specific needs of the pregnant or breastfeeding woman.
Where	**Primary health care**	■ Psychosocial support is ideally provided as close to people's homes as possible.
	Out of facility	
Who	**Lay providers**	■ Community-based organizations and lay providers equivalent to mentor mothers could be considered for providing these services.
	Peers	
What	**Peer group environment**	■ Pregnant and breastfeeding women benefit from individual and/or group peer support, especially when integrating delivery, infant feeding and early childhood development support and guidance.
	Referral check	■ Clear referral pathways should be in place. Every contact with a pregnant or breastfeeding woman should be used for checking whether there are any health or psychosocial concerns, triggering a referral.
	Onward disclosure support	■ The ongoing adherence and retention of women diagnosed and starting ART in pregnancy or after delivery are compromised by non-disclosure to the partner. Psychosocial support packages should consider supporting partner disclosure and involving the partner in ongoing care.

ANNEX 6. KEY CONSIDERATIONS FOR DIFFERENTIATED ART DELIVERY FOR SEX WORKERS WHO ARE CLINICALLY STABLE

1. Criteria for defining clinically stable clients

Category	Criteria	Considerations
Clinical criteria	**Adults**	■ From an HIV management perspective, a person living with HIV who has been receiving ART for 12 months, successfully achieved two consecutive viral loads <1000 copies/mL and is not currently ill or experiencing side-effects should be considered clinically stable. ■ If countries have only recently implemented viral load monitoring, one viral load <1000 copies/mL and evidence of a previously rising CD4 count or CD4 count >200 cells/mm3 could be considered.

2. Building blocks for the ART delivery model

2.1. Clinical consultation visits

Bulding blocks		Considerations
When	**Every 3–6 months**	■ Consider flexible hours to enable sex workers to attend outside work hours.
Where	**Primary health care**	■ Similar to other adults, primary health care clinics are suitable for sex workers to receive clinical consultation visits, but personnel should be sensitized to sex workers' needs, and stigma reduction should form part of routine personnel training.
	Community-based organizations	■ Sex worker community-based organizations, including fixed sites and outreach that already provide health services, can conduct clinic consultation visits with existing clinical personnel. ■ Through secondment, or scheduled visits of health-care providers from other HIV treatment services, other community-based organizations can also provide this service. ■ Some sex workers may prefer to receive ART services outside the sex worker community to maintain anonymity and workplace confidentiality.

Bulding blocks		Considerations
Who	**Nurses** **Midwives** **Clinical officers** **Doctors**	■ The WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations recommend nurses to maintain ART for key populations. ■ Sensitizing service providers to sex worker needs should be considered.
What	**Clinical consultation**	■ Following standard guidelines and including screening for sexually transmitted infections, drugs, alcohol use and dependence and mental health.
	Laboratory tests	■ The 2016 WHO consolidated ARV guidelines recommend annual viral load assessment and, if viral load testing is not available, CD4 counts every six months.
	Rescript	■ The scripting period should cover the period until the next clinical consultation (not until the following ART refill visit).
	Prevention	■ Prevention commodities, such as condoms and lubricants and sterile needles and syringes for people who inject drugs.
	Comprehensive services	■ Referral or on-site provision of a range of services is recommended: opioid substitution therapy for people dependent on opioids, preventing mother-to-child transmission if relevant, TB and viral hepatitis screening, prevention and treatment and sexual and reproductive health services, non-HIV sexually transmitted infections, health care for their children and access with their children. ■ In settings that are endemic for TB and have a high risk of TB infection, offering TB screening more frequently than every six months may be appropriate. TB screening could also be conducted during ART refill visits.

2.2. ART refill visits

Bulding blocks		Considerations
When	**Every 3–6 months**	■ ART refills can either be provided at each clinical consultation visit or be dispensed between clinical visits.
Where	**Primary health care**	■ Similar to other adults, primary health care clinics are suitable for sex workers to receive ART refills, but personnel should be sensitized to sex workers' needs, and stigma reduction should form part of routine personnel training.
	Community-based organizations	■ Community-based organizations related to sex workers can support group ART delivery models managed by sex workers or peers, although in some settings HIV status among sex worker peers is not routinely disclosed because of issues surrounding workplace confidentiality. ■ Through existing outreach services, community-based organizations can provide support for out-of-facility individual models of ART delivery: for example, through regular outreach to brothels or sex worker hotspots.
Who	**Lay providers**	■ The WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations and the 2016 WHO consolidated ARV guidelines recommend that trained and supervised community health workers be able to distribute ART between clinical visits. This includes personnel such as outreach workers, peer navigators and other lay providers.
	Peers	
	Outreach workers	
What	**ART refill**	■ ART should be dispensed based on dosages reflected in the clinician's script.
	Referral check	■ Clear referral pathways should be put in place. Providers should always check whether there are any health concerns, triggering a referral.
	Adherence check	■ Can include self-report, pill count or pharmacy records.
	Prevention	■ Prevention commodities, such as condoms and lubricants and sterile needles and syringes for people who inject drugs.

ANNEX 7. KEY CONSIDERATIONS FOR DIFFERENTIATED ART DELIVERY FOR MEN WHO HAVE SEX WITH MEN WHO ARE CLINICALLY STABLE

1. Criteria for defining clinically stable clients

Category	Criteria	Considerations
Clinical criteria	**Adults**	▪ From an HIV management perspective, people receiving ART for 12 months, successfully achieving two consecutive viral loads <1000 copies/mL and not currently ill or experiencing side-effects should be considered clinically stable. ▪ If countries have only recently implemented viral load monitoring, one viral load <1000 copies/mL and evidence of a previously rising CD4 count or CD4 count >200 cells/mm3 could be considered.

2. Building blocks for the ART delivery model

2.1. Clinical consultation visits

Bulding blocks		Considerations
When	**Every six months**	
Where	**Primary health care**	■ Similar to other adults, primary health care clinics are suitable for men who have sex with men to receive clinical consultation visits; however, personnel should be sensitized, and stigma reduction should form part of routine personnel training.
	Community-based organizations	■ The WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations recommend nurses to maintain ART for key populations. ■ Sensitizing service providers to the needs of men who have sex with men should be considered.
Who	**Nurses** **Midwives** **Clinical officers** **Doctors**	■ The 2016 WHO consolidated ARV guidelines already recommend nurses to maintain ART for clinically stable people living with HIV, including key populations. ■ Men who have sex with men–friendly orientation of providers should be considered (see the WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations).
What	**Clinical consultation**	■ Following standard guidelines and including screening for sexually transmitted infections, drug and alcohol use and dependence and mental health.
	Laboratory tests	■ The 2016 WHO consolidated ARV guidelines recommend annual viral load assessment (if viral load testing is not available, CD4 counts every six months).
	Rescript	■ The scripting period should cover the period until the next clinical consultation (not until the following ART refill visit).
	Prevention	■ Prevention commodities, such as condoms and lubricants and sterile needles and syringes for people who inject drugs and consideration given to post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) for serodiscordant partners.
	Comprehensive services	■ Referral or on-site provision of a range of services is recommended: opioid substitution therapy for people dependent on opioids, TB and viral hepatitis screening, prevention and treatment, non-HIV sexually transmitted infections and sexual health services. ■ In settings that are endemic for TB and have a high risk of TB infection, offering TB screening more frequently than every six months may be appropriate. TB screening could also be conducted during ART refill visits.

2.2. ART refill visits

Bulding blocks		Considerations
When	**Every 3–6 months**	▪ ART refills can either be provided at each clinical consultation visit or be dispensed between clinical visits.
Where	**Primary health care**	▪ Similar to other adults and adolescents, primary health care clinics are suitable for men who have sex with men to receive clinical consultation visits, but personnel should be sensitized, and stigma reduction should form part of routine personnel training.
	Community-based organizations	▪ Relevant community-based organizations can support group ART delivery models managed by people living with HIV or men who have sex with men. ▪ Through existing outreach services, community-based organizations can provide support for out-of-facility individual models of ART delivery: for example, through regular outreach to hotspots.
Who	**Lay providers**	▪ The WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations and the 2016 WHO consolidated ARV guidelines recommend that trained and supervised community health workers be able to distribute ART between clinical visits. This includes personnel such as outreach workers, peer navigators and other lay providers.
	Peers	
	Outreach workers	
What	**ART refill**	▪ ART should be dispensed based on dosages reflected in the clinician's script.
	Referral check	▪ Clear referral pathways should be put in place. Providers should always check whether there are any health concerns, triggering a referral.
	Adherence check	▪ Can include self-report, pill count or pharmacy records.
	Prevention services	▪ Prevention commodities, such as condoms and lubricants and sterile needles and syringes for people who inject drugs.

ANNEX 8. KEY CONSIDERATIONS FOR DIFFERENTIATED ART DELIVERY FOR TRANSGENDER PEOPLE WHO ARE CLINICALLY STABLE

1. Criteria for defining clinically stable clients

Category	Criteria	Considerations
Clinical criteria	**Adults**	▪ From an HIV management perspective, people who have been receiving ART for 12 months, successfully achieved two consecutive viral loads <1000 copies/mL and are not currently ill or experiencing side-effects should be considered clinically stable. ▪ If countries have only recently implemented viral load monitoring, one viral load <1000 copies/mL and evidence of a previously rising CD4 count or CD4 count >200 cells/mm3 could be considered.

2. Building blocks for the ART delivery model

2.1. Clinical consultation visits

Bulding blocks		Considerations
When	**Every six months**	
Where	**Primary health care**	▪ Similar to other adults and adolescents, primary health care clinics are suitable for transgender people to receive clinical consultation visits, but personnel should be sensitized to transgender people and their health needs, and stigma reduction should form part of routine personnel training.
	Community-based organizations	▪ Relevant community-based organizations, including fixed sites and outreach that already provide health services, can conduct clinic consultation visits with existing clinical personnel. ▪ Through secondment, or scheduled visits by health-care providers from other HIV treatment services, other community-based organizations can also provide this service.
Who	**Nurses** **Midwives** **Clinical officers** **Doctors**	▪ The WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations recommend nurses to maintain ART for key populations ▪ Sensitizing service providers to the needs of transgender people should be considered.
What	**Clinical consultation**	▪ Following standard guidelines with attention given to specific primary transition-related health-care needs such as hormone therapy and including screening for sexually transmitted infections, drug and alcohol use and dependence and mental health.
	Laboratory tests	▪ The 2016 WHO consolidated ARV guidelines recommend annual viral load assessment (if viral load testing is not available, CD4 counts every six months).
	Rescript	▪ The scripting period should cover the period until the next clinical consultation (not until the following ART refill visit).
	Prevention	▪ Prevention commodities, such as condoms and lubricant and sterile needles and syringes for people who inject drugs. Consideration should be given to providing PEP and PrEP for serodiscordant partners.
	Comprehensive services	▪ Referral or on-site provision of a range of services is recommended: opioid substitution therapy for people dependent on opioids, TB and viral hepatitis screening, prevention and treatment and sexual and reproductive health services, including transition-related health care. ▪ In settings that are endemic for TB and have a high risk of TB infection, offering TB screening more frequently than every six months may be appropriate. TB screening could also be conducted during ART refill visits.

2.2. ART refill visits

Bulding blocks		Considerations
When	**Every 3–6 months**	▪ ART refills can either be provided at each clinical consultation visit or be dispensed between clinical visits.
Where	**Primary health care**	▪ Similar to other adults and adolescents, primary health care clinics are suitable for transgender people to receive ART refills, but personnel should be sensitized to transgender people and their health needs, and stigma reduction should form part of routine personnel training.
	Community-based organizations	▪ Transgender community-based organizations can support group ART delivery models managed by transgender people living with HIV or peers ▪ Through existing outreach services, community-based organizations can provide support for out-of-facility individual models of ART delivery
Who	**Lay providers** **Peers** **Outreach workers**	▪ The WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations and the 2016 WHO consolidated ARV guidelines recommend that trained and supervised community health workers be able to distribute ART between clinical visits. This includes personnel such as outreach workers, peer navigators and other lay providers.
What	**ART refill**	▪ ART should be dispensed based on dosages reflected in the clinician's script.
	Referral check	▪ Clear referral pathways should be put in place. Lay providers should always check whether there are any health concerns, triggering a referral.
	Adherence check	▪ Can include self-report, pill count or pharmacy records.
	Prevention	▪ Prevention commodities, such as condoms and lubricants and sterile needles and syringes for people who inject drugs.

ANNEX 9. KEY CONSIDERATIONS FOR DIFFERENTIATED ART DELIVERY FOR PEOPLE WHO INJECT DRUGS WHO ARE CLINICALLY STABLE

1. Criteria for defining clinically stable clients

Category	Criteria	Considerations
Clinical criteria	**Adults and adolescents**	■ From an HIV management perspective, people who have been receiving ART for 12 months, successfully achieved two consecutive viral loads <1000 copies/mL and are not currently ill or experiencing side-effects should be considered clinically stable. ■ If countries have only recently implemented viral load monitoring, one viral load <1000 copies/mL and evidence of a previously rising CD4 count or CD4 count >200 cells/mm3 could be considered. ■ Drug use or drug dependence should not exclude people from receiving HIV treatment. ■ When assessing people who use or are dependent on drugs for differentiated ART delivery, special consideration should be given to the frequency of clinical consultation visits as described in the narrative.

2. Building blocks for the ART delivery model

2.1. Clinical consultation visits

Bulding blocks		Considerations
When	**Every six months**	
Where	**Primary health care**	■ Similar to other adults and adolescents, primary health care clinics are suitable for people who inject drugs to receive clinical consultation visits, but personnel should be sensitized to their needs, and stigma reduction should form part of routine personnel training.
	Community-based organizations	■ Relevant community-based organizations, including fixed sites and outreach that already provide health services, can conduct clinic consultation visits with existing clinical personnel. ■ Through secondment, or scheduled visits by health-care providers from other HIV treatment services, other community-based organizations, including needle and syringe programmes, can also provide this service.
	Opioid substitution therapy clinics	■ The WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations recommend initiating and maintaining HIV treatment at opioid substitution therapy sites for people living with HIV who are dependent on opioids; this should include regular clinical consultations.
Who	**Nurses** **Midwives** **Clinical officers** **Doctors**	■ The WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations recommend nurses to maintain ART for key populations. ■ Sensitizing service providers to the needs of people who inject drugs should be considered.

Bulding blocks		Considerations
What	Clinical consultation	■ Following standard guidelines and including screening for drug and alcohol use and dependence and mental health.
	Laboratory tests	■ The 2016 WHO consolidated ARV guidelines recommend annual viral load assessment (if viral load testing is not available, CD4 counts every six months).
	Rescript	■ The scripting period should cover the period until the next clinical consultation (not until the following ART refill visit).
	Prevention	■ Prevention commodities, such as condoms and lubricants and sterile needles and syringes for people who currently inject drugs.
	Comprehensive services	■ Referral or on-site provision of a range of services is recommended: opioid substitution therapy for people dependent on opioids, evidence-informed treatment for dependence on other substances, preventing mother-to-child transmission when relevant, screening for TB and viral hepatitis B and C, other sexually transmitted infections, prevention and treatment and sexual and reproductive health services. ■ In settings that are endemic for TB and have a high risk of TB infection, offering TB screening more frequently than every six months may be appropriate. TB screening could also be conducted during ART refill visits.

2.2. ART refill visits

Bulding blocks		Considerations
When	**Every 3–6 months**	▪ ART refills can either be provided at each clinical consultation visit or can be dispensed in between clinical visits.
Where	**Primary health care**	▪ Similar to other adults, primary health care clinics are suitable for people who inject drugs to receive ART refills, but personnel should be sensitized to people who inject drugs, and stigma reduction should form part of routine personnel training.
	Community-based organizations	▪ Community-based organizations related to people who inject drugs, including needle and syringe programmes, can support group ART delivery models managed by the people who inject drugs or peers. ▪ Through existing outreach services, community-based organizations can provide support for out-of-facility individual models of ART delivery.
	Opioid substitution therapy clinics	▪ Evidence shows that integrating ART and opioid substitution therapy services improves retention in ART. Providing ART refills through opioid substitution therapy services is a pragmatic approach to supplying ART to people receiving opioid substitution therapy and other evidence-informed drug dependence treatment programmes.
Who	**Lay providers** **Peers** **Outreach workers**	▪ The WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations and the 2016 WHO consolidated ARV guidelines recommend that trained and supervised community health workers be able to distribute ART between clinical visits. This includes personnel such as outreach workers, peer navigators and other lay providers.
What	**ART refill**	▪ ART should be dispensed based on dosages reflected in the clinician's script.
	Referral check	▪ Clear referral pathways should be put in place. Lay providers should always check whether there are any health concerns, triggering a referral.
	Adherence check	▪ Can include self-report, pill count or pharmacy records.
	Prevention services	▪ Condoms and sterile needle/syringes.

ANNEX 10. KEY CONSIDERATIONS FOR DIFFERENTIATED ART DELIVERY FOR PEOPLE LIVING IN PRISONS OR OTHER CLOSED SETTINGS WHO ARE CLINICALLY STABLE

1. Criteria for defining clinically stable clients

Category	Criteria	Considerations
Clinical criteria	**Adults and adolescents**	▪ From an HIV management perspective, people who have been receiving ART for 12 months, successfully achieved two consecutive viral loads <1000 copies/mL and are not currently ill or experiencing side-effects should be considered clinically stable. ▪ Receiving ART for 12 months means consistently receiving treatment whether in prison (or another closed setting) or in the community. ▪ If countries have only recently implemented viral load monitoring, one viral load <1000 copies/mL and evidence of a previously rising CD4 count or CD4 count >200 cells/mm3 could be considered.

2. Building blocks for the ART delivery model

2.1. Clinical consultation visits

Bulding blocks		Considerations
When	**Every six months**	▪ Prisons and closed settings that offer HIV treatment may already have protocols for the frequency of consultations, and adapting these may not be possible. ▪ However, when possible, for the people living in prisons and closed settings who are clinically stable, reduced clinical visits may be considered or feasible with the same justification as for other adults and adolescents.
Where	**Prison or other closed setting**	▪ If ART is not available in prison and other closed settings, consideration should be given to having outside treatment providers provide ART treatment in these closed settings.
Who	**Nurses** **Midwives** **Clinical officers** **Doctors**	▪ The WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations recommend nurses to maintain ART for key populations. ▪ Often in prison and other closed settings, health personnel may not be available
What	**Clinical consultation**	▪ Following standard guidelines and including screening for sexually transmitted infections, drug and alcohol use and dependence and mental health.
	Laboratory tests	▪ The 2016 WHO consolidated ARV guidelines recommend annual viral load assessment (if viral load is not available, CD4 counts every six months).
	Prevention	▪ Prevention commodities, such as condoms and lubricants and sterile needles and syringes for people who inject drugs.
	Comprehensive services	▪ On-site provision of a range of services is recommended: opioid substitution therapy for people dependent on opioids, TB and hepatitis screening, prevention and treatment and sexual health services and sexually transmitted infections.
	Linkage	▪ For people receiving ART in prison or other closed settings, effective linkage between the prison and the community is crucial so that HIV treatment is not disrupted on release from prison. Also, continuity of treatment and care between prison facilities and departments should be maintained. ▪ For the people who have been receiving treatment in the community, linkage between ART services and prison health services should ensure ongoing treatment following incarceration.
	Support after release	▪ Psychosocial support is crucial for the people leaving prison or another closed setting. ▪ Providing post-release naloxone for preventing opioid overdose should be considered.

ANNEX 11. PSYCHOSOCIAL SUPPORT FOR MEMBERS OF KEY POPULATIONS WHO ARE CLINICALLY STABLE

Bulding blocks		Considerations
When	**Every 1–6 months**	■ If available, psychosocial support can be provided at the same time as ART refills or clinical consultation or more frequently. ■ Some people require more frequent support than others. ■ In many settings, high-quality psychosocial support will not be available for key populations.
Where	**Community-based organizations**	■ Community-based key population organizations often have good experience in providing psychosocial support and are the preferred site for accessing this service for many key populations.
	Opioid substitution therapy	■ Opioid substitution therapy clinics typically provide psychosocial support to people receiving therapy.
	Prison or other closed setting	■ Prisons may have on-site access to psychosocial services or may facilitate the involvement of community providers to give psychosocial support.
	Phone hotlines	■ Hotlines staffed by trained peer counsellors can provide psychosocial support.
Who	**Social workers** **Lay providers** **Peer navigators** **Outreach workers**	■ Trained lay providers can provide psychosocial support, including outreach workers at community-based key population organizations and peers.

Bulding blocks		Considerations
What	**Peer support**	▪ Peers can act as role models and offer non-judgemental and respectful support that may contribute to reducing stigma, facilitating access to services and improving acceptability.
	Legal support	▪ Legal advice and links to other legal services.
	Responding to violence	▪ Access to post-rape care, including emergency contraception, post-exposure prophylaxis for HIV and other sexually transmitted infections and hepatitis B immunization. ▪ Monitoring and documenting incidents of violence and other human rights abuses are also important.
	Support after release from prisons	▪ Psychosocial support is crucial for people leaving prison or another closed setting.
	Social interventions	▪ Including basic needs such as food, clothing, accommodation and employment. ▪ These may not be available in all settings.
	Psychological interventions	▪ Including counselling, brief interventions, motivational interviewing or more structured interventions such as psychotherapy. ▪ These may not be available in all settings.

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