**Goal of this chapter**

To provide guidance on key issues related to operations and service delivery that need to be addressed to strengthen the continuum of HIV care and further integrate the provision of ARV drugs into health systems.
9 GUIDANCE ON OPERATIONS AND SERVICE DELIVERY

9.1 Introduction

ARV drugs and related services need to be delivered as effectively, equitably and efficiently as possible by optimizing available human and financial resources, ensuring appropriate links between care settings and services, supporting adherence to lifelong treatment and maximizing retention of patients across the continuum of care. This chapter provides broad guidance in six operational and service delivery areas in which action is essential to ensure the long-term effectiveness and sustainability of ARV programmes. These areas are:

- adherence to ART;
- retention across the continuum of care;
- service delivery, comprising service integration and linkage and decentralization of HIV care and treatment;
- human resources, including task shifting;
- laboratory and diagnostic services; and
- procurement and supply management systems.

New recommendations, developed through the GRADE process, are found in the sections on adherence and service delivery and human resources and include: text messages to promote adherence; ART integration into and linkage with maternal and child health, TB and opioid substitution therapy services; decentralization of ART; and task shifting.

9.2 Adherence to ART

9.2.1 Barriers to adherence

WHO defines treatment adherence as “the extent to which a person’s behaviour – taking medications, following a diet and/or executing lifestyle changes – corresponds with agreed recommendations from a health care provider” (1). For ART, a high level of sustained adherence is necessary to (1) suppress viral replication and improve immunological and clinical outcomes; (2) decrease the risk of developing ARV drug resistance; and (3) reduce the risk of transmitting HIV.

Multiple factors related to health care delivery systems, the medication and the person taking ARV drugs may affect adherence to ART. The individual factors may include forgetting doses; being away from home; changes in daily routines; depression or other illness; a lack of interest or desire to take the medicines; and substance or alcohol use. Medication-related factors may include adverse events; the complexity of dosing regimens; the pill burden; and dietary restrictions. Health system factors may include requiring people with HIV to visit health services frequently to receive care and obtain refills; travelling long distances to reach health services; and bearing the direct and indirect costs of care. Lack of clear information or instruction on medication, limited knowledge on the course of HIV infection and treatment...
and adverse effects can all be barriers to adherence to ART. Moreover, uninterrupted ARV drug supply and continuity of care are essential for people to adhere to their medication. Lack of continuity of care is a strong predictor of non-adherence in the longer term. Adherence to ART may also be challenging in the absence of supportive environments for people living with HIV and due to HIV-related stigma and discrimination (2,3).

**Pregnant and postpartum women**

The pregnancy and postpartum period presents significant biological, social and economic challenges that may affect treatment adherence. Pregnancy-related conditions such as nausea and vomiting may negatively affect treatment adherence. Other challenges during this period may include dealing with the diagnosis of HIV infection (many women learn about their HIV infection during routine screening during pregnancy); concerns about how ART affects the health of the fetus; pill burden; the number of clinic visits during pregnancy; fear of disclosure of HIV status to partners; long waiting times at clinics; and lack of follow-up and transfer to other clinics after delivery (4,5).

**Adolescents**

Adherence challenges faced by adolescents include a potentially large pill burden if they are treatment-experienced; stigma and fear of disclosure; concerns about safety of medications; adverse effects; peer pressure and perceived need to conform; not remembering to take medications; and inconsistent daily routine. The transition from paediatric to adolescent care presents several challenges that may affect treatment adherence in adolescents. These include assuming increased responsibility for their own care (which may lead to treatment interruptions because of forgetfulness); an inability to navigate the health care system; lack of links between adult and paediatric services; lack of health insurance; and inadequately skilled health care providers (6,7). Depression and substance use have also been shown to present challenges in adolescents.

**Infants and children**

Adherence among children is a special challenge. The limited choice of paediatric formulations, poor palatability of liquid formulations, high pill or liquid volume burden, large pill size, frequent dosing requirements, dietary restrictions, loss of primary caregiver, difficulties in swallowing tablets and adverse effects may all affect adherence (3,8,9). Successfully treating a child requires the commitment and involvement of a responsible caregiver. Parents and other family members of children living with HIV may themselves be living with HIV; suboptimal HIV care and treatment for family members could result in suboptimal care for the child.

**Mental health disorders**

Adherence to ART is known to be complicated by mental health comorbidity that results in forgetfulness, poor organization and poor comprehension of treatment plans. Studies have linked uncontrolled depressive symptoms with low levels of adherence to ART and poor treatment outcomes. As a result, several treatment strategies target depression and psychosocial stress to improve adherence to ART, ranging from co-counselling for HIV and depression to appropriate medical therapies for individuals with mental disorders (10–13).

**Substance use disorders**

Individuals with substance use disorders may have poor adherence to ART. Alcohol and other drug use could be associated with forgetfulness, poor organization and diversion of monetary and time priorities (10,14–16).
Most-at-risk populations (including sex workers, men who have sex with men, transgender people and people who inject drugs)

In several settings, most-at-risk populations face multiple challenges to accessing health services. Service delivery approaches to improve longitudinal care and maintain adherence for most-at-risk populations remains a critical gap in many settings. Experience indicates encouraging results with peer-based interventions that include strong social support such as outreach teams, peer educators and health workers providing multidisciplinary, non-judgemental and respectful care.

Incarceration

Incarceration may negatively affect continuity of care, diminish trust and predispose individuals to poor financial and social support both during and after incarceration. Substance use disorders may also be an additional challenge for this population. People who are incarcerated have the additional risk of acquiring TB, resulting in high morbidity and mortality rates in the absence of efficacious HIV and TB treatment (17). However, excellent outcomes can be achieved with adequate support and structured treatment programmes within the prison setting.

9.2.2 Interventions to optimize adherence to ART

No single adherence intervention or package of interventions is effective for all populations and all settings. People’s needs and circumstances may also change over time, and programmes and care providers therefore need to tailor a combination of feasible interventions to maximize adherence to ART based on individual barriers and opportunities.

Programme-level interventions for improving adherence to ART include: (1) avoiding imposing out-of-pocket payments at the point of care, (2) using fixed-dose combination regimens for ART and (3) strengthening drug supply management systems to reliably forecast, procure, and deliver ARV drugs and prevent stock-outs.

The individual-level adherence intervention recommendation in this section relates to the use of mobile phone text messages. There have been simple and robust trials to demonstrate its importance as one of many adherence tools. Adherence interventions, such as text messaging, should clearly be provided as part of a total package of several interventions. Many individual-level adherence interventions are indicated for reasons in addition to improving adherence to ART. For example, nutritional support, peer support, management of depression and substance use disorders and patient education are vital components of routine health and HIV care.

Efforts to support and maximize adherence should begin before ART is initiated. Developing an adherence plan and education are important first steps. Initial patient education should cover basic information about HIV, the ARV drugs themselves, expected adverse effects, preparing for treatment and adherence to ART. Adherence preparation should not delay treatment initiation, when prompt action is necessary.

Patient education and counselling and peer support

Patient education and counselling are essential both when ART is initiated and throughout the course of treatment. Informing and encouraging people receiving ART and their families and peers are essential components of chronic HIV care. Studies show that counselling improves adherence to ART, and in some settings there is an association between peer support and high rates of adherence and retention (18–23).
Substance use and mental health interventions

Studies indicate that improving well-being by treating depression and managing substance use disorders improves HIV treatment outcomes. The systematic review identified very-low-quality evidence from one observational study evaluating opioid substitution therapy for improving adherence. After 12 months, the rates of unsuppressed viral loads were comparable among people who inject drugs using opioid substitution therapy and people who inject drugs without opioid substitution therapy (24). The systematic review also identified very-low-quality evidence from one randomized trial evaluating the treatment of depression for improving adherence. After 12 months, the risk of non-adherence was similar among those who received depression treatment and those who did not (25). WHO recommends co-treatment of depression and substance use disorders irrespective of HIV status, and concurrent treatment should be evaluated in relation to adherence to ART. Other services for people living with HIV who use drugs, such as needle and syringe programmes, drug dependence treatment and peer outreach, provide opportunities for supporting treatment adherence.

Nutritional support

Nutrition assessment, care and support are essential components of HIV care. HIV programmes should ensure that existing national policies on nutritional support are observed when it is necessary and feasible to maximize adherence to ART and achieve optimal health outcomes in food-insecure settings.

Nutritional support could include nutritional counselling, cash transfers and subsidizing food costs and/or food vouchers. ART in conjunction with nutritional support could accelerate recovery. The systematic review identified one study from low- and middle-income countries with low-quality evidence showing that nutritional support provided by community health workers to people receiving ART reduces the risk of non-adherence after one year among food-insecure individuals relative to the standard of care (26).

Financial support

Financial support may include reimbursement for the costs of receiving HIV care (including drugs, diagnostics, clinical services and transport vouchers) and may potentially mitigate the burden of HIV in disadvantaged settings. The systematic review identified very-low-quality evidence that financial support reduces the risk of non-adherence one year post-intervention relative to the standard of care (27). Programmes and care providers should consider a broader programmatic approach for reducing the costs of care for people living with HIV that would include avoiding out-of-pocket payments at the point of care, decentralizing and coordinating care and exploring opportunities to minimize health facility visits. Programmes need to consider ethical implications and equity in providing food and financial support or other similar interventions for people living with HIV and not others. Standardized criteria for supporting people receiving ART may need to be developed based on national poverty levels.

Reminder and engagement tools

**New recommendation**

- Mobile phone text messages could be considered as a reminder tool for promoting adherence to ART as part of a package of adherence interventions (*strong recommendation, moderate-quality evidence*).
Background

Forgetfulness and changes in daily routines are often cited as the main reason for poor adherence to ART in most settings, although the specific reasons for forgetting to take medication could vary. Reminders and communication that engage people in taking ARV drugs could be an important intervention to improve adherence through behavioural change.

The use of mobile text messages for supporting adherence and in health care delivery in general has increased as access to phone technology expands (28). Using this, however, requires adequate national regulations to protect the privacy of the people receiving text messages (29,30). Programmes may explore public-private partnerships to accelerate the scaling up of mobile phone–based interventions.

Rationale and supporting evidence

Mobile phone technology may be a convenient reminder mechanism to engage people living with HIV in care. Moreover, since mobile phones are widely used globally, using them may not require major changes to people’s daily routines. Mobile phone text messaging is also relatively inexpensive or without marginal cost, is a succinct way of sending a message without the need to talk and offers a record of messages.

The systematic review identified five randomized trials and two observational studies on mobile phone text messaging for improving adherence to ART. High-quality evidence from two randomized trials found that text messages contributed to reduced unsuppressed viral loads after one year (31,32). This finding was consistent with high-quality evidence from three randomized trials that found reduced non-adherence levels after one year (31,33,34).

Four observational studies evaluated the use of text messaging for less than one year. Very-low-quality evidence from one observational study found reduced unsuppressed viral loads after nine months (35). Although moderate-quality evidence from two randomized trials showed similar non-adherence levels after 4–6 months (36,37), very-low-quality evidence from two observational studies suggests reduced non-adherence levels after 6–9 months (35,38). Overall, the systematic review supports the use of text message reminders, although the quality of the data was variable and duration of follow-up short (up to one year).

Other patient reminders

Other patient reminder tools include alarms, phone calls, diaries and calendars and are used to send brief reminders about the timing of ARV drugs, drug dosage and appointments. The evidence does not demonstrate that these interventions support treatment adherence better than the standard of care.

The systematic review identified four randomized trials. Moderate-quality evidence from one randomized trial found that the risk of unsuppressed viral loads was similar after 18 months of follow-up using alarms versus the standard of care (19). Low-quality evidence from one randomized trial also found that rates of non-adherence and unsuppressed viral loads were similar after three months using phone calls compared with the standard of care (39). Very-low-quality evidence from one randomized trial further found that the risk of unsuppressed viral load and non-adherence was similar after 15 months using diaries relative to the standard of care (40). Finally, low-quality evidence from one randomized trial found that non-adherence was similar using calendars relative to the standard of care after one year of follow-up (41). Using these interventions requires further exploration among different populations and settings.
9.2.3 Monitoring adherence to ART in routine programme and care settings

Objective monitoring of adherence to ARV drugs is necessary for effective and efficient treatment planning and ongoing support. Each facility visit brings opportunity for assessing and supporting treatment adherence. Effectively monitoring adherence requires a combination of approaches based on human and financial resource capacity, acceptability to people living with HIV and to health workers and the local context.

Viral load monitoring

These guidelines recommend viral load monitoring to diagnose and confirm treatment response and failure. Although treatment failure is often caused by lapses in adherence to ART, it may also result from other factors (such as drug stock-outs, drug interactions or malabsorption). However, viral load monitoring does not provide an opportunity for care providers to monitor non-adherence in real time and prevent progression to treatment failure. Viral load monitoring must therefore be combined with other approaches to monitoring adherence.

Pharmacy refill records

Pharmacy refill records provide information on when people living with HIV pick up their ARV drugs (42,43). When people obtain pharmacy refills at irregular intervals, this may indicate non-adherence to ART; however, in many routine care settings, people may pick up their medications when receiving care irrespective of their adherence level. This behaviour could lead health care providers to overestimate adherence by solely using pharmacy refill records. A recent validation study to assess the usefulness of various adherence monitoring approaches found pharmacy records to be more reliable than self-report (44). In many settings, pharmacy refill records are already a part of national monitoring and evaluation frameworks and can also provide additional information on adherence to ART when used in combination with other tools.

Self-report

Asking people living with HIV or their caregivers how many doses of medication they have missed since the last visit (or within a specified number of days in the past) can help to estimate non-adherence. However, although this method is commonly used, people may not remember missed doses accurately or may not report missed doses because they want to be perceived as being adherent and to avoid criticism. Counselling on the importance of remembering and/or documenting ARV drug doses and an environment that promotes and enables honest reporting of non-adherence are critical components of monitoring adherence to ART in routine care settings (45).

Pill counts

Counting the remaining pills in bottles may help to assess adherence. Pill counts usually take place at routine health care visits. However, some people may throw away tablets prior to health care visits, leading to overestimated adherence (45,46). Although unannounced visits at people’s homes could lead to more accurate estimates, this approach poses financial, logistical and ethical challenges. Counting pills also requires health care personnel to invest significant time and may not be feasible in routine care settings.
9.3 Retention across the continuum of care

9.3.1 Background

Retaining people living with HIV across the continuum of care is essential for optimal health outcomes. Among those who do not have immediate indications for ART, care visits provide opportunities for screening, prevention and treatment of other conditions and comorbid illnesses, including providing co-trimoxazole prophylaxis, PMTCT, isoniazid preventive therapy and regular screening for TB and clinical and laboratory monitoring to allow timely initiation of ART once the indications arise. For people who are eligible for ART at the time they test HIV-positive, rapid linkage to care is critical; delays of days or weeks with people already being ill with TB or other opportunistic infections increases the risk of mortality (47,48). For people living with HIV who are receiving treatment, uninterrupted ART and continual monitoring are essential for sustained viral suppression and optimal treatment outcomes.

Retaining people living with HIV in care, especially people who are not yet eligible for ART and those who are eligible but have not yet initiated treatment, poses a great challenge. Synthesis of available literature from sub-Saharan Africa showed that 54% of those who are not yet eligible for ART were lost to follow-up before becoming eligible, while 32% of the people living with HIV who were eligible for ART were lost before initiating treatment (49,50). Outcomes among those lost to follow-up may vary, as loss to follow-up reported at the health facility level can include people who have self-transferred to another facility, unascertained deaths and true losses to follow-up. People who discontinue care — especially those who are not eligible for ART at initial assessment — frequently return to care only after they become ill with advanced HIV disease, when early mortality after initiating ART is significant (51,52). Data on the proportion of people who remain on ART over time in low- and middle-income countries show that most discontinued care occurs within the first year of starting therapy. In some settings, many people living with HIV who are lost to follow-up in the first months after initiating ART have died (53). In 2011, the average retention rate at 12 months after initiating ART was 81% (92 reporting countries), 75% at 24 months (73 reporting countries) and 67% at 60 months (46 reporting countries) (53).

Multiple factors relating to the health care delivery systems and patients could facilitate or hinder retention in HIV care. Interventions to improve linkage to and retention in HIV care, from diagnosis and across the continuum of care, need to address issues reported by the people receiving care and related to the health system and require a more targeted evaluation in different settings and populations (54–57).

9.3.2 Good practices for retention across the continuum of care

Optimizing retention in HIV care requires interventions at multiple levels of the health care system as well as implementation research. Given the broad array of challenges and heterogeneity of barriers across settings, no single approach is likely to work for everyone in all settings. Improving the understanding of barriers and innovative strategies to address them are important priorities in implementation research and public health.

Studies show that the direct and indirect costs of care affect the ability of people living with HIV to remain in care. They consistently report that the distance from health care facilities is a barrier to retention in diverse settings and along the continuum of HIV care. Related transport costs and loss of income while seeking care serve as disincentives when health facilities are located far from the person’s home. Bringing services closer to
communities, where feasible, reduces the indirect costs of care for the people living with HIV and their families and improves retention.

Waiting times at the facility during consultation are frequently high, especially in settings with a high burden of HIV infection (58,59). Reorganizing services, such as systems for appointment, triage, separating clinical consultation visits from visits to pick up medicine, integrating and linking services and family-focused care may reduce waiting times at the health facility (59,60).

Many people living with HIV who are not yet eligible for ART may not attend clinic appointments and may not return to care until they are symptomatic. Regularly following up these individuals is important to ensure continual monitoring and timely initiation of ART. Countries have used approaches and achieved positive outcomes, including providing co-trimoxazole prophylaxis free of user charges, on-site or immediate CD4 testing with same-day results and peer support to improve retention in care (22,61,62).

Key populations generally experience more barriers to accessing health services. Interventions harnessing social support have emerged as a promising approach to counteract the structural, economic, service delivery and psychosocial constraints that affect retention in care.

Table 9.1 summarizes the factors related to the health system and people receiving ART influencing retention and adherence and potential interventions.

**Table 9.1 Factors related to the health system and people receiving ART affecting retention and adherence with possible interventions**

<table>
<thead>
<tr>
<th>Factors related to the health system</th>
<th>Possible interventions</th>
</tr>
</thead>
</table>
| High direct and indirect costs of receiving care | • ART and related diagnostics and services free of charge at the point of care  
• Decentralize ART where feasible  
• Scheduled facility visits  
• Reduce waiting time at the facility level:  
  • Appointment system  
  • Separate clinical consultation visits from appointments for picking up medicines  
  • Link, integrate and coordinate care  
  • Family-focused care (organizing services around the needs of the family) when appropriate |
| Stock-outs of ARV drugs | Optimize pharmaceutical supply management systems to forecast, procure and deliver ARV drugs. Use fixed-dose combinations to simplify forecasting and supply management systems |
| Lack of a system for monitoring retention in care | Implement systems for patient monitoring across the continuum of care, including cohort analysis and patient tracking systems |
### Table 9.1 (continued)

<table>
<thead>
<tr>
<th>Factors related to the health system</th>
<th>Possible interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of a system for transferring people across different points of care</td>
<td>Interlinked patient monitoring system across services for HIV, TB, maternal and child health and PMTCT; system for transitioning from paediatric to adolescent and adult services and from maternal and child health and TB services to chronic HIV care</td>
</tr>
<tr>
<td>Pill burden and complex ARV drug regimens</td>
<td>Use fixed-dose combinations to reduce the pill burden and simplify the regimens</td>
</tr>
<tr>
<td>Lack of accurate information for patients and their families and peer support</td>
<td>Engage and integrate community health workers, volunteers and people living with HIV in peer support, patient education and counselling, and community-level support</td>
</tr>
<tr>
<td>Adherence support</td>
<td>Task shifting for involving community health workers Linking with community-level interventions and resources such as peer adherence support Using known effect reminder methods (such as text messaging) Peer support also provides opportunities for in-person reminders</td>
</tr>
<tr>
<td>Poor relationship between patient and care provider</td>
<td>Train health workers on how to: reduce stigma; improve treatment preparedness, adherence and retention; provide adherence support and care for key populations; and provide simplified approaches for educating patients and their families</td>
</tr>
<tr>
<td>Lack of time for educating people in HIV care</td>
<td>Task shifting and sharing among clinic team members People living with HIV as patient experts and peer supporters A team approach to care</td>
</tr>
<tr>
<td>Adverse drug effects</td>
<td>Preparedness and knowledge of how and when to self-manage adverse effects and when to return to the clinic</td>
</tr>
<tr>
<td>Factors related to the people receiving HIV care</td>
<td>Possible interventions</td>
</tr>
<tr>
<td>Forgetfulness, life stress, stigma and discrimination</td>
<td>Using text messaging to keep patients engaged Peer and family support Link to community support group</td>
</tr>
<tr>
<td>Comorbidity, substance and alcohol use disorders and mental health disorders</td>
<td>Manage HIV with mental health disorders, alcohol and other substance use disorders and link with community and social support</td>
</tr>
<tr>
<td>Patient knowledge and beliefs related to HIV infection, its course and treatment</td>
<td>Integrate the education of patients and their families and counselling, broader community literacy and education and community engagement</td>
</tr>
</tbody>
</table>
9.4 Service delivery

9.4.1 Good practices in providing chronic care (63)

In many countries, health services are organized primarily to provide episodic acute care. As HIV begins to become a manageable, chronic condition, programme managers and care providers need to consider how current health delivery systems can be reorganized to provide chronic care.

Once people are diagnosed and enrolled in chronic care, follow-up visits should be scheduled and planned. Waiting until people present with symptoms or preventable complications is costly and inefficient. People living with HIV require care that anticipates their needs at different stages of the care continuum. Compared with the acute care model, planned chronic care models provide opportunities for prevention, early identification of issues and timely intervention.

Chronic care requires broad support for people living with HIV from their communities and health care teams to stay in care, adhere to treatment and cope with stigma. People living with HIV and their families need to be informed about HIV infection and the anticipated side effects of medicines and supported to adhere to treatment. Health care teams play an important role in linking people living with HIV with community-level interventions, resources and support.

A system to keep information on the people receiving care at health facilities is critical for ensuring the continuity of chronic care. A patient registry serves a reminder function for follow-up services. Health care teams can use it to identify people’s needs, to follow-up and plan care, to monitor responses to treatment and to assess outcomes for both individuals and for the overall treatment cohort. Information systems can be paper-based or based on an electronic registry, depending on local context. Programmes should develop a systematic strategy for collecting and aggregating key information that supports better management of the patient and ensures high-quality care. A robust patient information system is also critical for high-quality monitoring and evaluation of programmes and for supply management systems.

When effective operational solutions such as successful service delivery models and processes of care are identified in existing systems, programmes need to consider scaling up such models of care.

9.4.2 Integrating and linking services

Chronic care requires integrating and linking related services to ensure comprehensive and consistent patient management over time, including providing related services in single settings, systems to share information and effective referrals across settings and providers. Integrating and linking services are likely to reduce missed opportunities for initiating ART, enhance long-term adherence support and optimize patient retention in care. Programmes for HIV, sexual and reproductive health, maternal and child health, TB and drug dependence need to collaborate to successfully implement ART and related services at different levels of the health system. Issues to be considered include mobilizing and allocating resources; training, mentoring and supervising health workers; procuring and managing drugs and other medical supplies; and monitoring and evaluation.
9.4.2.1 Delivering ART in antenatal care and maternal and child health settings

New recommendation
- In generalized epidemic settings, ART should be initiated and maintained in eligible pregnant and postpartum women and in infants at maternal and child health care settings, with linkage and referral to ongoing HIV care and ART, where appropriate (strong recommendation, very-low-quality evidence).

Background
In 2011, coverage of effective ARV drug regimens for PMTCT reached 57% in low- and middle-income countries. However, in the same year, only 30% of pregnant women who needed ART for their own health received it, compared with 54% ART coverage for all eligible adults in low- and middle-income countries (53). Ensuring access to ART for pregnant women with HIV who are eligible for treatment continues to be a challenge, as does provision of ARVs for PMTCT among pregnant adolescent girls living with HIV, female sex workers and women who inject drugs.

Because many women living with HIV only access health services at the time of pregnancy, maternal and child health settings provide a key opportunity to expand access to ART for those who need treatment (56,57). In most generalized epidemic settings, maternal and child health services are provided at the primary care level, where pregnant women and children predominantly access health services. Existing WHO guidance recommends that provider-initiated HIV testing and counselling be implemented in all antenatal and maternal and child health care settings in generalized epidemics and that it should be considered in antenatal and maternal and child health settings for key populations in concentrated and low-level epidemics (64).

These 2013 guidelines recommend that triple-drug ART or ARV prophylaxis be initiated among all pregnant and breastfeeding women living with HIV, regardless of CD4 count, and that countries decide whether to continue this for all pregnant and breastfeeding women or just those who are eligible for treatment for their own health. Therefore, ART should be available in maternal and child health clinics or easily accessible in a linked clinic approach. Countries with generalized epidemics may consider a phased approach to providing ART in maternal and child health settings and effectively transforming such settings into ART sites, giving priority to facilities with the largest burden of HIV and building health systems to ensure uninterrupted ART, adherence and retention.

A challenge is to continue ART beyond the mother-to-child transmission risk period. Not all maternal and child health settings will have capacity to provide long-term HIV care and treatment for women, their partners and infants. These settings will need to assess the best time for referring and linking mothers and their infants to chronic HIV care. This assessment may include the women’s progress in treatment and the capacity and quality of HIV care in the maternal and child health setting as well as the acceptability and proximity of alternative HIV care settings.
Rationale and supporting evidence

The systematic review evaluated the effect of delivering HIV care and treatment in antenatal care and maternal and child health settings on access to ART, mortality, morbidity and retention on ART in generalized epidemic settings. One cluster-randomized trial and three observational studies assessed the impact of delivering ART in antenatal care and maternal and child health settings compared with referring people to HIV care clinics for ART. This positively influenced adherence to ART during pregnancy, enrolment in care and the uptake of ART among women living with HIV. Comparable outcomes were observed for maternal mortality, morbidity, immune response, infant HIV testing uptake, mother-to-child transmission and satisfaction with care. The quality of some of these studies was downgraded because of relatively few events (65–70).

The alternative to providing ART in antenatal care and maternal and child health settings is to refer eligible women and infants to HIV facilities to receive HIV treatment. Referral systems may contribute to the low ART coverage among pregnant and breastfeeding women and infants (57). Referral-based models may further require women and infants to receive care at separate service delivery points that may require pregnant women to travel and wait in queues to receive HIV care and treatment. Studies from Malawi (55), Uganda (56) and Zimbabwe (57) have found that long queues at HIV clinics and the cost of transport from homes to clinics were among the main reasons for loss to follow-up for pregnant and breastfeeding women.

Although HIV programmes may invest to expand access and reduce health facility waiting times, delivering ART in settings where pregnant and breastfeeding women are already receiving care could improve access and provide opportunities for a continuum of care from providing HIV testing to ART at a single site that is also providing antenatal and postnatal care.

In a recent study, women had positive experiences in antenatal care clinics providing ART. They reported that the personnel had “treated them” well and “given them helpful counselling” and that their babies had received “good care” and were free from HIV infection because of this. Other research has explored the operational feasibility of providing ART in maternal and child health care settings and its acceptability to health care personnel in antenatal care clinics. Providers felt that integration increased efficiency, decreased the time people spent in clinics, improved relationships with providers and adherence to ART because of decreased stigma and increased confidentiality. All these factors increased the satisfaction of the people receiving care and may have contributed to improving the quality of care (66,71).
9.4.2.2 Delivering ART in TB treatment settings and TB treatment in HIV care settings

New recommendations

- In settings with a high burden of HIV and TB, ART should be initiated for an individual living with HIV in TB treatment settings, with linkage to ongoing HIV care and ART (strong recommendation, very-low-quality evidence).

- In settings with a high burden of HIV and TB, TB treatment may be provided for an individual living with HIV in HIV care settings where TB diagnosis has also been made (strong recommendation, very-low-quality evidence).

Background

In 2011, 79% and 48% of the people with TB who were known to be living with HIV received co-trimoxazole prophylaxis and ART, respectively (72). The percentage of people with TB with a documented HIV-positive test result who received ART exceeded 75% in only 6 of the 41 countries with the highest burden of HIV and TB, globally.

Since 2010, WHO has recommended ART for everyone with TB who is living with HIV, regardless of their CD4 count. TB treatment should be initiated first, followed by ART as soon as possible within the first eight weeks of starting TB treatment. Co-trimoxazole prophylaxis is also recommended for all TB patients with HIV. These service delivery recommendations are intended to facilitate expanded ART coverage for people with HIV and TB and to support the early diagnosis and treatment of TB among people living with HIV.

Although the treatment of TB has been decentralized to the community level in most settings, HIV treatment remains difficult to access in many places. Data from a WHO survey indicate that the ratios of the number of health facilities providing TB treatment to the number of health facilities providing ART ranged from 1.3 to 30.2 (72). Moreover, despite a high burden of HIV and TB coinfection, services for HIV and TB treatment may be offered at geographically different sites. Although HIV and TB programmes may invest financial and human resources to improve access and reduce the time associated with receiving care, offering ART and TB treatment at a single point could improve access and adherence to HIV and TB treatment by providing a continuum from HIV testing to HIV and TB co-treatment at a single site.

Implementing TB infection control measures is crucial in HIV care settings to minimize the risk of nosocomial (occurring in a health care setting) transmission of TB. See section 8.1.2 for WHO recommendations on TB infection control in health care settings.

Rationale and supporting evidence

Since people with HIV and TB who do not initiate ART and co-trimoxazole prophylaxis have high mortality and since the combination of ART and co-trimoxazole improves survival (73–75), increasing ART and co-trimoxazole coverage is probably paramount in reducing the large number of people who die from having HIV and TB globally. The systematic review evaluating the effectiveness of delivering ART in TB treatment settings identified 19 observational studies, many of which showed increased ART uptake and timeliness of ART initiation. However, data on mortality and TB treatment success were inconsistent. The systematic review evaluating the effect of delivering TB treatment in HIV care settings identified five observational studies: two studies reported decreased mortality
and another showed comparable mortality rates. TB treatment success rates and ART uptake were comparable across studies. The quality of evidence was weighed along with programmatic risks and benefits; acceptability; values; preferences; cost implications; feasibility; critical contextual constraints; and contextual relevance. There was consensus that, although the quality of evidence was not high using the GRADE method, there was sufficient rationale to proceed with strong recommendations (76–96).

9.4.2.3 ART in settings providing opioid substitution therapy

New recommendation

- ART should be initiated and maintained in eligible people living with HIV at care settings where opioid substitution therapy (OST) is provided (strong recommendation, very-low-quality evidence).

Background

Data from 49 countries indicate that injecting drug use increases the risk of acquiring HIV infection 22-fold relative to the general population, and in countries in eastern Europe up to 40% of the people acquiring HIV infection are people who inject drugs and their sexual partners (97). Existing WHO guidance states that consideration should be given to recommending HIV testing and counselling to all people attending drug dependence treatment services in generalized, concentrated and low-level epidemics when this is socially acceptable and epidemiologically appropriate. Plans for provider-initiated testing and counselling in such settings should emphasize supportive social, policy and legal frameworks (64).

These guidelines recommend the same criteria for eligibility for ART for all adults regardless of drug use behaviour. Limited global data are available on ART coverage among key populations; however, where data are available, there are often gaps between the coverage among people who inject drugs relative to that of the general population. In 2010, a report including 19 low- and middle-income countries in Europe and central Asia indicated that only 22% of people living with HIV who inject drugs and are eligible for ART received it (53).

For treating opioid dependence, WHO recommends opioid substitution therapy (with methadone or buprenorphine) combined with psychosocial assistance (98). Where there are many opioid-dependent people living with HIV, treatment of opioid dependence should be integrated with and administered in conjunction with HIV treatment. Although ART outcomes improve among people living with HIV who inject drugs and are also accessing opioid substitution therapy, enrolment in settings providing opioid substitution therapy should not be a prerequisite for initiating or maintaining ART for people who use opioids. Nevertheless, providing ART in settings providing opioid substitution therapy may expand access to ART for people who inject drugs.

Common comorbidities such as alcohol use disorders, mental health disorders, TB and viral hepatitis also need to be addressed as part of a comprehensive package of harm reduction interventions, requiring a multi-skilled workforce and close collaboration within the health sector.
Given the high incarceration rates of people who inject drugs, efforts should be made to ensure that ART is available as part of prison health services and continuity of HIV care and ART when people transition from incarceration to the community.

**Rationale and supporting evidence**

In many countries, people who inject drugs are a marginalized population with limited access to and utilization of health care services. Drug overdose and AIDS are leading causes of death in this population (99). Randomized trials found that opioid substitution therapy decreases illicit drug use and increases retention in care relative to placebo (98). Observational studies found that opioid substitution therapy decreases mortality relative to not being in care (100). ART outcomes also improved among people with HIV who inject drugs and are accessing opioid substitution therapy (16). The systematic review found one randomized trial and three observational studies evaluating the effect of delivering ART in settings providing opioid substitution therapy. Most of these studies had small sample sizes that limited the statistical power. Some studies observed trends for improved viral suppression and reduced mortality, whereas others found comparable rates of viral suppression and mortality (101–103).

This recommendation focuses on expanding access to ART by delivering the service in settings providing opioid substitution therapy. Coverage of opioid substitution therapy also remains low in many settings, and policy-makers should evaluate whether providing opioid substitution therapy in settings providing HIV care and treatment is feasible. Where health authorities or the health sector do not manage drug-dependence services, HIV programmes need to collaborate closely with social welfare departments and community and nongovernmental organizations that provide these services.

**9.4.3 Decentralizing HIV treatment and care**

**New recommendations**

The following options should be considered for decentralization of ART initiation and maintenance.

- Initiation of ART in hospitals with maintenance of ART in peripheral health facilities *(strong recommendation, low-quality evidence)*.
- Initiation and maintenance of ART in peripheral health facilities *(strong recommendation, low-quality evidence)*.
- Initiation of ART at peripheral health facilities with maintenance at the community level (that is outside health facilities in settings such as outreach sites, health posts, home-based services or community-based organizations) between regular clinical visits *(strong recommendation, moderate-quality evidence)*.
9. Guidance on operations and service delivery

9.4 Service delivery

Background

Although rapidly scaling up HIV programmes has significantly improved access to ART and increased the health and survival of people living with HIV, it also poses significant challenges to health systems. Decentralizing ART to primary care settings may ease the burden of routine management on other parts of the health system and may improve equity by promoting access to ART in rural areas. In several settings, transport cost is a significant barrier to access and retention in care. In many settings with a high burden of HIV infection, hospitals have long waiting times because of a large flow of patients needing care. Decentralizing HIV care and treatment could reduce the workload for health care personnel, thereby reducing waiting times for people with HIV and people receiving care at hospitals for other conditions and bring HIV services closer to people’s homes. HIV-related services such as TB care and maternal and child health services are decentralized to primary care in several settings. People living with HIV, affected communities and community-based interventions play a pivotal role in providing HIV testing, care and treatment and social support. Decentralizing HIV care and treatment can further strengthen community engagement, linking community-based interventions with health facilities, and may optimize access to services, care-seeking behaviour and retention in care.

Rationale and supporting evidence

The systematic review identified two observational studies evaluating how decentralization of initiating and maintaining ART in peripheral health facilities affects patient attrition (patient death and losses to follow-up). Attrition declined after 12 months, resulting largely from significantly reduced losses to follow-up. The systematic review identified four observational studies evaluating how maintaining ART at peripheral health facilities affected patient attrition. Attrition declined after 12 months, due to losses to follow-up and death. The systematic review also identified two cluster-randomized trials evaluating how community-based maintenance of ART affects attrition. Comparable rates of attrition were observed after 12 months (104–115).

When deciding which decentralization option to implement, programme managers may consider (1) the number of people living with HIV likely to attend decentralized settings; (2) whether decentralization brings services closer to people who would otherwise travel long distances to receive ART; and (3) whether decentralizing ART reduces the workload at centralized facilities. This recommendation calls for links to the supply of diagnostics and medicines, services, training and supervision of health workers to maintain the quality of care. In addition, in several settings, decentralizing ART will involve task shifting to ensure an appropriate mix of health care personnel at peripheral facilities.

A WHO operations manual for delivering HIV care and treatment at primary health centres in high-prevalence, resource-limited settings (116) provides additional guidance.

Implementation considerations for decentralizing ART

Box 10.5 discusses implementation considerations relevant to programme managers.
9.5 Human resources

9.5.1 Building human resource capacity

Within the past decade, in the context of the rapid scaling up of HIV care and treatment, in-service training has assumed a key role in rapidly upgrading the competencies of health practitioners.

All health workers, including community health workers, need to be regularly trained, mentored and supervised to ensure high-quality care and the implementation of updated national recommendations. Given the rapidly evolving knowledge on HIV care and treatment, countries need to consider a system for supporting health workers’ continuing education, including clinical mentoring and regular supportive supervision. The use of new technologies such as computer-based self-learning, distance education, online courses and phone-based consultation may supplement classroom in-service training and support the efficient use of health workers’ time and other resources (116,117).

It is, however, equally important to fully embrace and strengthen HIV care and treatment in existing pre-service courses leading to health workers graduating and being certified in various disciplines. Health workers also need to be equipped to manage HIV as a chronic condition, and to work in a team and need to be familiar with the national guidelines and care protocol. In several countries, people living with HIV, other community workers and volunteers are already involved in delivering HIV testing, counselling, care, treatment and social support services. In addition, people living with HIV are involved in training health workers as expert trainers. Involving people living with HIV in both training health workers and delivering HIV services may have the additional benefit of overcoming HIV-related stigma.

Countries should consider long-term reform that could support human resource strategies related to task shifting and introducing new types of health workers (such as for HIV testing or peer counsellors) on a sustainable basis within a comprehensive and nationally endorsed regulatory framework (laws and proclamations, rules and regulations, policies and guidelines). Although volunteers can make a valuable contribution on a short-term or part-time basis, all trained health workers who are providing essential health services, including community health workers, should receive adequate wages and/or other appropriate and commensurate incentives (116).

9.5.2 Task shifting for HIV treatment and care

New recommendations

- Trained non-physician clinicians, midwives and nurses can **initiate** first-line ART (*strong recommendation, moderate-quality evidence*).
- Trained non-physician clinicians, midwives and nurses can **maintain** ART (*strong recommendation, moderate-quality evidence*).
- Trained and supervised community health workers can **dispense** ART between regular clinical visits (*strong recommendation, moderate-quality evidence*).
9.5 Human resources

Background

Reorganizing, integrating and decentralizing HIV treatment and care will require re-examining the roles and tasks of teams of health care providers involved in delivering chronic HIV care. Task shifting involves the rational redistribution of tasks among health workforce teams. With this approach, specific tasks are reassigned, where appropriate, from highly qualified health workers to health workers with shorter training and fewer complementary qualifications to more efficiently and effectively use the available human resources. Task shifting should be implemented alongside other strategies designed to increase the total numbers and capacity of all types of health workers.

Health care personnel remain insufficient in many settings with a high burden of HIV. Although increasing the capacity of countries to train more health care personnel is crucial, clinical tasks need to be shared and shifted to ensure that enough health workers are available to care for people with HIV. Task shifting improves access to ART at sites without physicians (such as rural health facilities, TB services and maternal and child health services). Task shifting also allows physicians to spend more time managing more complex clinical conditions such as coinfection and other comorbidities, toxicity of ART or treatment failure.

WHO guidance in 2008 (118) recommended that nurses and non-physician clinicians may initiate and maintain first-line ART and that community health workers may monitor people receiving ART during long-term follow-up. Since these recommendations were largely based on programme review and good practices, the evidence related to task shifting for ART was reviewed when developing these consolidated guidelines.

In this guideline, initiation of ART includes assessment for ART eligibility (based on clinical and/or immunological criteria); assessment for opportunistic infections; adherence counselling; and the prescribing of first-line ART. Maintenance of ART includes ongoing clinical assessment; monitoring for toxicity, treatment failure (clinical, immunological and virological) and opportunistic and other coinfections; adherence counselling; and the further prescribing of ART. Dispensing ART includes assessment for any new signs and symptoms, adherence monitoring and support and dispensing medication to patients who are already on ART between regular clinic visits.

Rationale and supporting evidence

The systematic review identified three randomized trials and six observational studies addressing task shifting. Overall, the data showed no difference in mortality and losses to care when nurses or non-physician clinicians initiate or maintain people on ART or when community health workers maintain people on ART, relative to physicians providing this care. The quality of care in these studies was ensured by (1) providing training, mentoring, supervision and support for nurses, non-physician clinicians and community health workers; (2) ensuring clear indications for patient referral; (3) implementing referral systems and (4) implementing monitoring and evaluation systems. Patient education could help people and their families understand that care provided by nurses and community health workers is not of lower quality than that provided by physicians (106–108,111,113,114,119–121).

Shifting the initiation and maintenance of ART to adequately trained and supervised nurses and community health workers may enable substantial cost savings through (1) the ability to decentralize care to primary care facilities; (2) lower overhead costs for delivering quality care (with comparable or better outcomes) by nurses, non-physician clinicians and community health workers compared with physicians; and (3) decreased facility and utility costs (if care is being delivered in health facilities complemented with community-level services).
9.6 Laboratory and diagnostic services

9.6.1 Overview

These guideline recommendations support increased access to HIV care and treatment, which will also require increased access to laboratory and diagnostic services. To ensure that testing services are accurate and reliable, relevant quality assurance systems need to be developed and strengthened.

Within a country, a multiplicity of testing settings may exist, such as laboratories, maternal and child health clinics, HIV testing and counselling sites, community-based testing and thus a multipronged and networked approach to selecting diagnostics and laboratory systems should be planned and adopted. Since an increasing number of new diagnostic tests and point-of-care systems is entering the market, the use of only high-quality diagnostics and equipment needs to be ensured. Strategic planning for properly placing and harmonizing testing platforms should be carried out to ensure appropriate use and cost–effectiveness.

9.6.2 Implementation considerations and good practices

This guidance to strengthen laboratory and diagnostic services emphasizes the importance of leadership and governance, high-quality laboratory services, expanding testing services and developing the health workforce:

- to strengthen and expand laboratory and diagnostic services;
- to support a dedicated specimen referral system;
- to increase access to HIV viral load testing;
- to support the expansion of diagnostic services to include testing at the point of care;
- to train and certify health workers who perform the testing; and
- to ensure high-quality diagnostics and plans for implementation, including quality assurance.

9.6.3 Strengthening and expanding laboratory and diagnostic services

The following areas are important to strengthen the network of laboratory and diagnostic services for implementing the guideline recommendations:

- standardizing testing methods to streamline procurement, quality assurance and training;
- incorporating new testing approaches and systems into national laboratory strategic plans and policies;
- evaluating diagnostics for their performance and operational characteristics to validate testing algorithms (with back-up options) before introduction;
- carrying out strategic planning for properly placing and harmonizing testing platforms to ensure appropriate use and cost–effectiveness;
- expanding current laboratory networks to support and monitor the decentralization and integration of testing services or to provide access to testing when diagnostic services are unavailable at service delivery sites; and
- allocating appropriate resources to ensure the availability of testing services, including human and financial resources.
9.6.4 Supporting a dedicated specimen referral system

Laboratory referral systems and procedures for collecting and processing specimens need to be strengthened to increase access to viral load testing and other testing (for example, CD4 and early infant diagnosis). Providing for and strengthening a dedicated, efficient, safe and cost-effective specimen referral system requires reliable specimen transport with adequate conditions for whole blood, plasma and dried blood spot specimens and rapidly and dependably reporting test results back to the referring site with linkage to care. Rapidly reporting results is essential for timely care.

9.6.5 Increasing access to HIV viral load testing

The guidelines call for monitoring the response to treatment and diagnosing and confirming treatment failure with viral load testing. This will require strengthening the existing laboratory services and phased expansion of monitoring services into peripheral facilities and can include:

- strengthening and leveraging existing CD4 and early infant diagnosis networks;
- ensuring that laboratories have adequate infrastructure, technical testing expertise and quality assurance and quality improvement programmes;
- ensuring an appropriate mix of high-volume centralized laboratory testing and testing at the point of care for facilities in remote locations; and
- the use of dried blood spots as a tool to increase access to viral load testing.

9.6.6 Expanding diagnostic services to point-of-care settings

Decentralizing laboratory and diagnostic services requires that all aspects of testing be in place before implementing services, including:

- using only high-quality, evaluated and reliable diagnostic tests;
- supervising and monitoring point-of-care testing for quality and reliability;
- implementing a strategy for managing supply chain and equipment service; and
- establishing data management systems for timely identification of quality issues and regional and national data reporting.
Table 9.2 provides guidance on organizing testing services at various levels of the health care delivery system.

### Table 9.2 Tiered laboratory network at various levels of the health care delivery system

<table>
<thead>
<tr>
<th>Health care delivery level</th>
<th>Laboratory service</th>
<th>Human resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>National</td>
<td>Enzyme immunoassays for diagnosis, Higher throughput CD4, HIV molecular technologies including HIV viral load testing and quantitative and qualitative early infant diagnosis, HIV resistance testing</td>
<td>Senior laboratory specialists</td>
</tr>
<tr>
<td>Regional or provincial</td>
<td>Enzyme immunoassays for diagnosis, Higher throughput CD4, HIV molecular technologies including HIV viral load testing and quantitative and qualitative early infant diagnosis</td>
<td>Laboratory specialists and senior technicians</td>
</tr>
<tr>
<td>District</td>
<td>Enzyme immunoassays for diagnosis, Low-throughput CD4, Chemistry, haematology and microbiology</td>
<td>Laboratory technicians and assistants</td>
</tr>
<tr>
<td>Primary care</td>
<td>HIV rapid diagnostic tests and other point-of-care tests, Collecting DBS</td>
<td>First-level trained health workers such as nurses and clinical officers</td>
</tr>
<tr>
<td>Community-based</td>
<td>HIV rapid diagnostic tests</td>
<td>Community health workers</td>
</tr>
</tbody>
</table>

Source: adapted from: WHO expert meeting report on short, medium, longer term product development priorities for HIV-related diagnostics, 6–7 June 2012, Geneva, Switzerland (122).
9.6.7 Providing guidance for developing health workers’ capacity, including staff training and certification

Countries require guidelines for the qualification of personnel who will perform the laboratory tests. The guidelines should include training requirements for specific tests and the process for certification and recertification. All health workers assigned to perform point-of-care testing must be trained and proficient on the testing procedure, specimen collection and quality assurance before implementing these services.

9.6.8 Implementing comprehensive quality management systems

Developing a comprehensive quality management system including external quality assessment and quality control is essential. The quality management system should:

- be implemented within the laboratory network and all remote testing sites;
- be incorporated into the routine testing procedures and monitored;
- ensure that testing sites undertake quality control, as appropriate;
- ensure that testing sites are enrolled in an external quality assessment scheme (proficiency testing programme);
- ensure the use of standard operating procedures for all processes, including specimen collection and processing, test methods, interpreting results and reporting;
- ensure the use of standardized logbooks or electronic data management and reporting, including identifying errors and potential misclassification; and
- ensure that equipment and facilities are maintained, both preventive and corrective.

9.7 Procurement and supply management systems

9.7.1 Overview

Ensuring adequate and continuous availability of quality and affordable essential medicines, diagnostics and other consumables at service delivery sites is a critical role of procurement and supply management systems. The increasing number of people who need chronic HIV care, especially in settings with a high burden of HIV infection, necessitates an uninterrupted supply of HIV-related health products. This can be achieved only if the procurement and supply management system is strengthened at all levels of the health system. Moreover, ARV drug regimens and formulations and HIV treatment recommendations need to be regularly updated in response to new developments and emerging evidence. This requires a more efficient and dynamic supply management system to prevent waste and shortages.

9.7.2 Rationale and supporting evidence

Successful HIV programmes are only possible if all services providing ART are equipped with an uninterrupted and sustained supply of high-quality ARV drugs, preferably WHO-prequalified products. Other pharmaceuticals that are needed to support ART services include medicines to prevent or treat opportunistic infections, and laboratory reagents, supplies and equipment to diagnose HIV and opportunistic infections, monitor the progression of HIV infection and treatment response and detect adverse drug reactions. Since a single health facility may not carry out the dispensing of all needed pharmaceuticals, in some settings clients would need to be able to access services through a referral system.
9.7.3 Implementation considerations and good practices

Management support is integral to each component of the procurement and supply management cycle: selection, procurement, storage and distribution, use and monitoring. It includes a variety of activities at all levels of the health care delivery system: from the national programme level down to where medicines are dispensed and diagnostics are used. The main activities include managing the information system, ensuring timely information flow between stakeholders at different levels and securing financial and other resources, including the medicines and diagnostics needed for the programme. The following provides broad guidance on key activities at each stages of the supply management cycle.

9.7.3.1 Selecting pharmaceuticals and diagnostics

Countries adapting these guidelines may need to update national medicine lists to include newly recommended ARV drug regimens and formulations and diagnostics. The advantage of using the essential list concept is to enable a health system to limit other more expensive or WHO-delisted medicines and diagnostics from being purchased and accelerating the registration of WHO-prequalified products to facilitate quality-assured procurement (123). If a selected fixed-dose combination or other ARV drug regimen is not on the national list or not registered in the country, HIV programme managers need to coordinate with the national drug regulatory authority and request that these drugs be put on the list and registered.

Detailed national ART guidelines, for example, that provide recommendations for managing toxicity or treatment failure and recommended formulations for weight and age can help to standardize prescribing and dispensing practices and facilitate forecasting for ARV drugs.

Synchronized introduction of new guidelines with forecasting, procurement and distribution planning during the phasing in and phasing out of new and old ARV drug products will minimize the waste of products that are being phased out and shortages of newly recommended products.

In several settings, paediatric formulations are not widely available. The national medicine list should be optimized for paediatric ARV drug formulations, to include fixed-dose combinations, scored or dispersible products that facilitate adherence and supply management. Countries may consider removing less preferred products and aligning paediatric formulations with those of adults, where possible.

Health workers need to be trained at different levels in managing pharmaceuticals and diagnostics, including forecasting, procurement and distribution and ensuring adequate supervision throughout the supply system.

9.7.3.2 Procurement

A uniform and harmonized national procurement system is required for efficiently procuring quality-assured affordable ARV drugs and diagnostics (124,125). Procurement should be based on appropriate selection of products and need-based forecasting, considering consumption, expanding services, phasing in and phasing out formulations and implementing new recommendations. Transparent procedures should be adopted to achieve best-value procurement and a quality assurance system implemented to procure, store and distribute high-quality pharmaceuticals, diagnostics and other health products (124,126).
Procurement systems should:

- procure the most effective, heat-stable, fixed-dose quality-assured ARV drug formulations in the right quantities, at the lowest possible cost and in a timely manner;
- request that the partners supporting the national HIV programme consolidate and harmonize ARV drugs and diagnostics procurement and supply management systems and pool demands for ARV drugs and diagnostics, exploring options for pooling under a common tender system;
- use a publicly accessible database to facilitate access to information about prices and support competition (127–130); and
- follow the principles described in the United Nations interagency guidelines for donated drugs (131).

**9.7.3.3 Storage and distribution**

Appropriate storage and distribution of HIV medicines, diagnostics and other commodities are important components of the supply management system (Table 8.3). Product integrity and quality need to be maintained during storage and distribution (125,132), and waste from spoilage and expired products should be minimized. Integrated supply systems should be promoted when planning for decentralization, building on what exists and strengthening capacity where required. For example, existing immunization programme infrastructure, including cold chains, could be used to expand the supply of paediatric formulations, such as LPV/r liquid formulations. Facilities should have adequate storage space, trained personnel and the tools to manage supplies effectively. The number of storage levels should be rationalized to reduce the supply pipeline.

Accurate inventory records should be maintained and a system created to track products that enter and leave the supply system. A routine consumption-based reordering cycle at service delivery sites should be established. Flexibility should be introduced in the supply system such as procedures for reporting and redistribution of excess ARV drug supplies, more frequent ordering and filling of non-routine orders to minimize expiry and stock-outs. Pharmaceutical and diagnostic products need to be adequately stored, especially if ART delivery is further decentralized and is dispensed from an increasing number of peripheral health facilities. Measures are required during transport and storage to prevent theft and fraud such as vehicle tracking systems, secured storage areas, audits and labelling of ARV drug products procured by HIV programmes.

**9.7.3.4 Use and monitoring**

Robust information systems ensure the availability of accurate and timely consumption data on ARV drugs and other information required for effectively monitoring the performance of the entire supply system and for forecasting the ARV drugs and diagnostics needed. Monitoring procurement and supply management through the effective use of early warning indicators prevents stock-outs and overstocks leading to expiry (126).
Table 9.3 Summary checklist of pharmaceutical supply management issues

<table>
<thead>
<tr>
<th>Phase</th>
<th>Activity</th>
<th>Determination</th>
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<tbody>
<tr>
<td>Planning</td>
<td>Selecting products</td>
<td>Updated national HIV guidelines</td>
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<tr>
<td></td>
<td></td>
<td>Updated national lists to include newly recommended ARV drug regimens and formulations and diagnostics</td>
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<tr>
<td></td>
<td>Estimating and quantifying ARV drug</td>
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<tr>
<td></td>
<td>requirements</td>
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<tr>
<td>Procurement</td>
<td>Selecting and locating suppliers</td>
<td>Open and transparent communication with industry</td>
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<td></td>
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<td>Prequalified suppliers</td>
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<td>Implementing review mechanisms</td>
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<td></td>
<td>Assuring the quality of products and</td>
<td>Criteria for manufacturer prequalification</td>
</tr>
<tr>
<td></td>
<td>sources</td>
<td>Implementing a prequalification system</td>
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<td></td>
<td></td>
<td>Using the WHO certification scheme, inspecting and testing the quality of samples</td>
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<td>Pre-shipment physical inspection with random sampling for laboratory testing</td>
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<td></td>
<td></td>
<td>Systems for records and supply monitoring</td>
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<td></td>
<td>Arranging for purchasing</td>
<td>Ongoing assessment of purchasing options</td>
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<td></td>
<td></td>
<td>Need for special labelling and packing</td>
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<td></td>
<td></td>
<td>Need for reserve or buffer stocks</td>
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<td></td>
<td></td>
<td>Managing purchasing arrangements</td>
</tr>
<tr>
<td>Distribution, rational use</td>
<td>Receiving supplies in the country</td>
<td>Port clearance, including availability of funds for paying duties and taxes</td>
</tr>
<tr>
<td>and monitoring</td>
<td></td>
<td>Securing appropriate warehousing at all levels needed</td>
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<td></td>
<td></td>
<td>Physical inspection on arrival of each consignment with random sampling for laboratory testing</td>
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<td></td>
<td>Distributing in the country</td>
<td>A logistics system for timely distribution to end-users</td>
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<tr>
<td></td>
<td>Rationally using and monitoring pharmaceuticals</td>
<td>Providers adequately trained</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Systems for monitoring and reporting, including monitoring adverse effects feeding into the selection; rational prescription; and forecasting in place</td>
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<tr>
<td></td>
<td></td>
<td>At the central level, any problem such as theft, recall by the supplier, poor quality and adverse drug reactions should be recorded and reported at different levels to all relevant bodies. This would involve developing problem-reporting forms, indicating to whom they should be sent, and what action should be taken</td>
</tr>
</tbody>
</table>