CARDIOVASCULAR HEALTH

A program of Resolve to Save Lives
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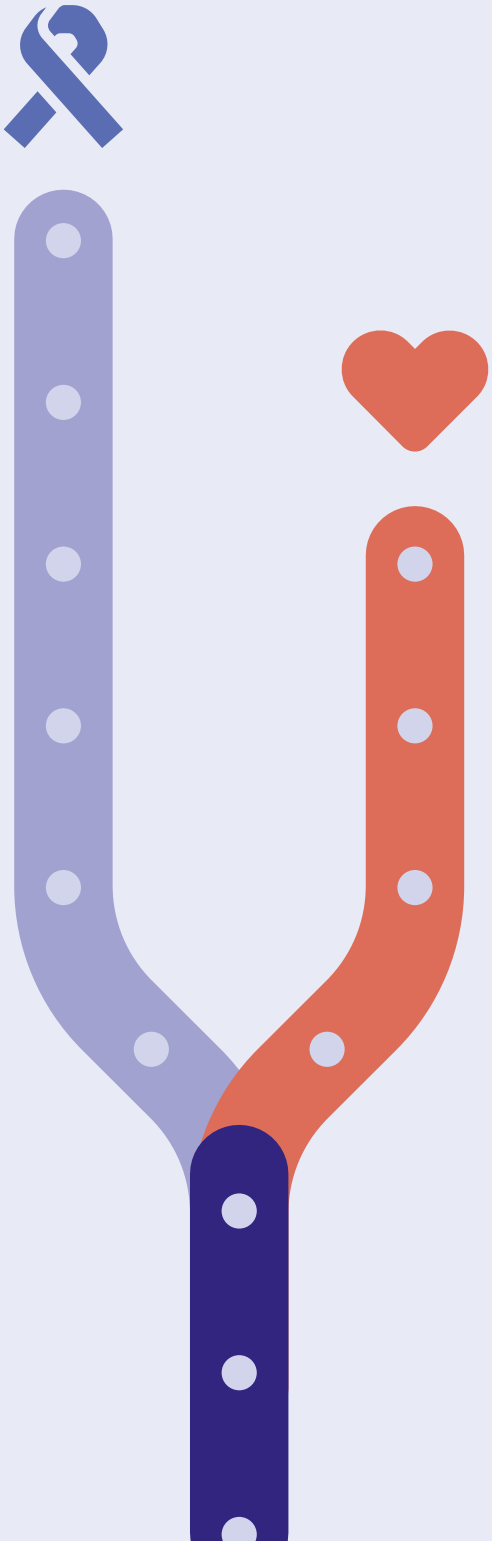
INTEGRATING HYPERTENSION AND HIV MANAGEMENT

A practical Differentiated Service Delivery toolkit



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ABOUT

Resolve to Save Lives (RTSL) is a not-for-profit organization partnering with countries, communities, and organizations to prevent 100 million deaths from cardiovascular disease and make the world safer from epidemics. RTSL supports the implementation of hypertension control programs in nine countries and the PAHO region.

To find out more, visit: https://www.resolvetosavelives.org or Twitter @ResolveTSL.

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ACRONYMS

ART	antiretroviral therapy
CVD	cardiovascular disease
DBP	diastolic blood pressure
DSD	differentiated service delivery
EMR	electronic medical records
HCWs	health care workers
HIV	human immunodeficiency virus
LMICs	low-and middle-income countries
M&E	monitoring and evaluation
MoH	ministry of health
NCDs	noncommunicable diseases
PLHIV	people living with HIV
SBP	systolic blood pressure
SOPs	standard operating procedures
VL	viral load
WHO	World Health Organization

BACKGROUND AND RATIONALE

At the end of 2021, an estimated 38.4 million people worldwide were living with human immunodeficiency virus (HIV). Two-thirds of these people (25.6 million) live in Eastern, Western, Central, and Southern Africa. HIV can be managed with treatment regimens composed of a combination of antiretroviral drugs. Early access to antiretroviral therapy (ART) and support to remain on treatment is critical not only to improve the health of people living with HIV (PLHIV), but also to prevent HIV transmission.[1]

Over the last two decades, the scale-up of ART has become one of the most successful chronic disease interventions in resource-limited settings. The UNAIDS "95–95–95" targets — 95% of PLHIV know their HIV status, 95% of people who know their status are on ART, and 95% of those on ART are virally suppressed — have been universally adopted. Global ART coverage was 75% in 2021, with 28.7 million PLHIV receiving treatment.[2]

The successful expansion of ART coverage is the result of several factors, including the adoption of the global targets, and the development of innovative strategies such as **differentiated service delivery (DSD)**, a practical approach to care delivery that aims to enhance quality, efficiency and accessabiity of care by tailoring the design and delivery of services offered to different groups of patients based on their characteristics and context. Today, a growing number of people on ART access their HIV care through a DSD model.

There is a growing body of evidence that many countries with a high burden of HIV have a substantial overlapping burden of hypertension. In PLHIV aged 50 and older, the global prevalence of hypertension was estimated to be 42%.

As HIV-AIDS-related mortality decreases (in large part due to the effectiveness of ART at prolonging life) and PLHIV age, they are increasingly likely to experience noncommunicable diseases (NCDs), including cardiovascular disease (CVD). CVD accounts for most NCD deaths, killing 17.9 million people annually. Hypertension, or high blood pressure, affects approximately 1.28 billion adults aged 30–79 years globally[3], and is the single most important risk factor for CVD. There is a growing body of evidence that many countries with a high burden of HIV have a substantial overlapping burden of hypertension. In PLHIV aged 50 and older, the global prevalence of hypertension was estimated to be 42%.[4]

Hypertension is underdiagnosed and undertreated in most low-and middle-income countries (LMICs), where the majority of PHLIV live. Although hypertension can be successfully controlled with simple medication regimens, it is estimated that just 10% of people with hypertension in LMICs have it under control.[5] Integrating hypertension treatment into HIV services, as recommended by the World Health Organization (WHO),[6] is therefore an important component of a comprehensive package of care for PLHIV, who are at increased risk of cardiovascular morbidity and mortality. **Figure 1** outlines the benefits integrating HIV and hypertension management.

Figure 1: Benefits of an integrated approach to HIV and hypertension management

Program component	Challenges of parallel management systems for HIV and hypertension	Benefits of a patient-centered, integrated approach
Care delivery	• Follow-up of ART and hypertension may be planned at different frequencies. • Care delivered in different settings • Lack of consideration for medication interactions	• Alignment of follow-up schedules • Care adapted to be delivered in the service location • Medication interactions considered
Pharmacy and supply chain	• Forecasting and procurement not adapted to align medication refill supply • Duplication of supply chain resources	• Alignment of medication refills supported • Use of similar forecasting tools for both chronic diseases. • Efficient use of supply chain resources
Monitoring and evaluation (M&E)	• Separate paper-based tools or electronic medical records (EMR) for HIV and hypertension, resulting in duplication of work for health care workers (HCWs)	• Paper-based tools or EMR developed to include the same baseline demographics and key follow up indicators for HIV and hypertension • Integrated monitoring and continuous quality improvement of both HIV and hypertension programs

The principles of DSD were designed to address the challenges of managing not only HIV but any chronic disease, including hypertension. Existing DSD treatment models for ART can be leveraged for the integration of hypertension management, with the goal of improving both hypertension control rates and HIV outcomes. Provision of hypertension services has been demonstrated to help improve demand for HIV services, especially for harder-to-reach populations, and to improve retention in HIV care.[7] Although integration of HIV and hypertension management may pose a challenge for already overburdened and underfunded health systems, especially in low-resource settings where ART programs are common, DSD models can help reduce unnecessary burdens on facilities by decentralizing care for patients established on ART and with controlled hypertension to the community.

This toolkit provides guidance on how common DSD treatment models for ART can be adapted to integrate hypertension management. It includes:

- An overview of the general principles of DSD for chronic disease management
- Key considerations for the integration of hypertension management into DSD models for clinically stable ART clients
- Guidance on how hypertension management can be integrated into DSD models for ART
- Case studies and examples of how hypertension management has been integrated into DSD models for ART
- Adaptable implementation tools developed for DSD and HIV-hypertension service integration programs

This toolkit is aimed at national and regional program managers and implementing partners who are supporting the integration of hypertension management within an existing HIV DSD program. While it focuses on the integration of hypertension management into existing DSD models for ART, the steps outlined can be applied to hypertension management programs for HIV-negative patients. Guidance for hypertension management featured in this toolkit can also be adapted for care delivery for other chronic NCDs that are co-morbid with HIV, such as diabetes or chronic kidney disease.

General principles of differentiated service delivery for chronic disease management

DSD is a patient-centered approach that aims to address the challenges faced by HCWs and patients when providing HIV and chronic disease care. Over the past decade, DSD has been used to support the scale-up of ART in HIV care; service delivery models are tailored for different groups of PLHIV according to their clinical characteristics, specific population type and context. The goals of DSD are to increase service coverage, quality and efficiency, provide person-centered care, and improve outcomes, within the context of resource and health system limitations. The principles of DSD (Box 1) have been adopted in WHO guidelines and across a wide range of national HIV programs.[8]

Although DSD principles may be applied across the cascade of care (prevention, testing, treatment initiation and maintenance) and for patients with controlled and uncontrolled disease, this toolkit focuses on their application to the integration of hypertension management into existing DSD treatment models for ART for clients with controlled hypertension who are established on treatment.

Building a DSD model for chronic disease management

A DSD model for any chronic disease is based on three patient-related "elements" and four "building blocks." Elements are factors that determine how care or services are structured or "differentiated" to meet the needs of the different categories of patients; building blocks are the components that are shaped, tailored or adjusted in response to the elements to produce the differentiated service. In other words, the elements determine the categories or groups patients are separated into, while the building blocks determine the nature and characteristics (how, when, who, and where) of the services delivered to them within the groups/categories.

Box 1.
Differentiated service delivery

Differentiated service delivery (DSD) is a patient-centered approach that simplifies and adapts chronic disease services across the cascade of care (prevention, testing, initiation and maintenance of effective treatment), in ways that both better serve the needs of people living with chronic diseases and reduce unnecessary burdens on the health care system.

For more information on how DSD has been implemented for HIV, visit:

- Differentiated Service Delivery by the International AIDS Society
- The HIV Coverage, Quality and Impact Network (CQUIN)

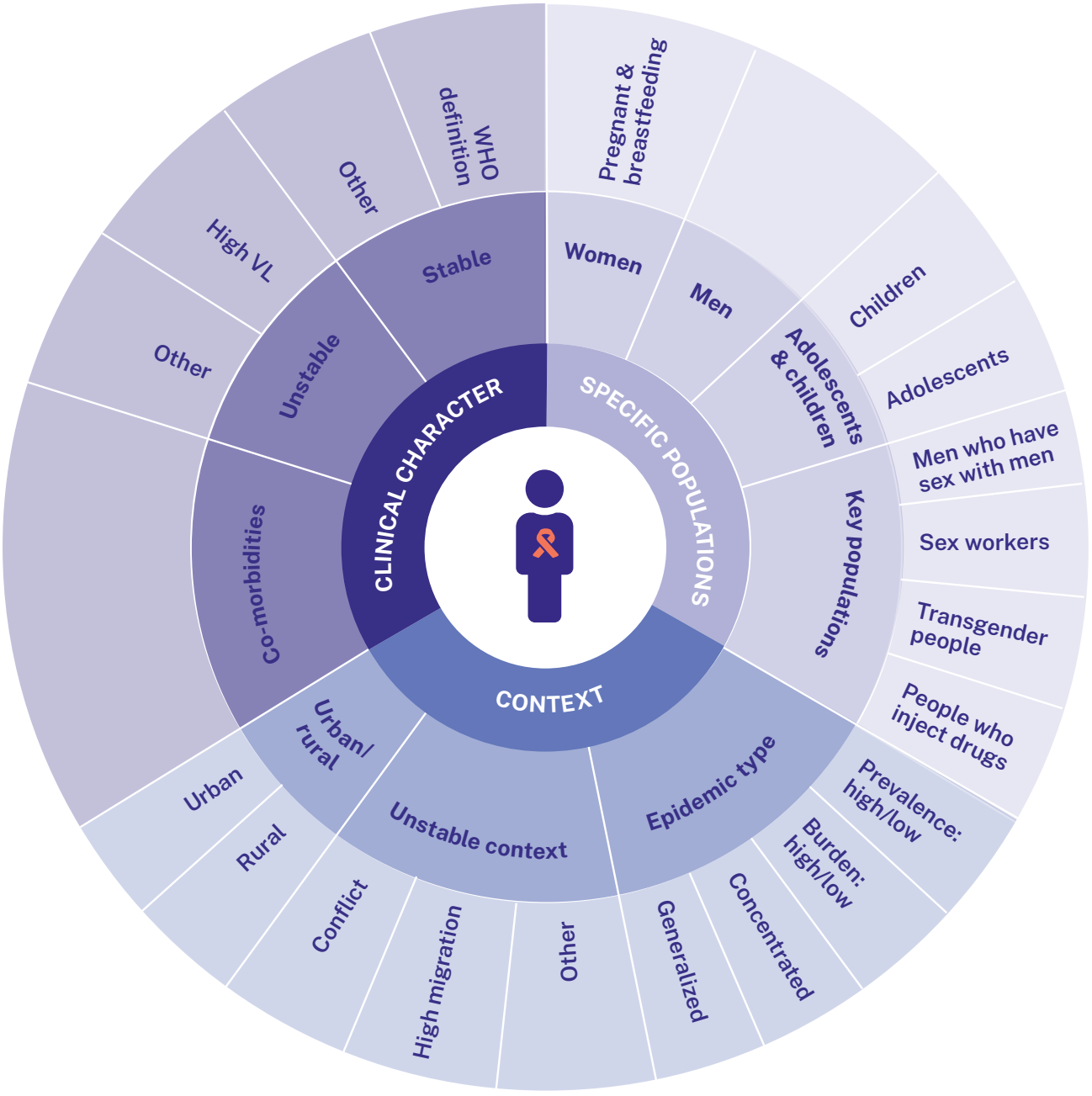
Patient-related elements

The **three elements** of DSD's patient-centered approach include:

1. **Clinical characteristics**, including whether or not the patient's disease is a controlled disease and any comorbidities.
2. **Context**, including whether the treatment setting is urban or rural, in a conflict or stable area; the prevalence of hypertension and current treatment coverage.
3. **Specific population**, including whether the patient is pregnant or breastfeeding, or elderly.

All three elements (see **Figure 2** for a complete description) should be considered when designing a DSD model that integrates hypertension management into existing DSD treatment models for ART.

Figure 2: The elements of differentiated service delivery



Adapted from https://differentiatedservicedelivery.org/

Service-delivery building blocks

DSD focuses less on the "what" of service delivery and more on the "how" — specifically, how to optimize the delivery of clinical, laboratory, pharmacy and psychosocial support services using **four building blocks** that describe different aspects of service delivery (**Figure 3**). These building blocks consist of **where** (service location), **when** (service frequency), **who** (service provider), and **what** (service package).

For example, services for people established on HIV treatment are designed to maximize both choice and efficiency, with less frequent clinical and pharmacy visits and services delivered either at health facilities or in the community by a wide range of health workers, including peers and/or lay health workers. Enabling task-shifting to non-physician clinicians and laypeople can expand the geographic coverage and reach of services.

Figure 3: The building blocks of DSD

Standard DSD models for ART that can be adapted to integrate hypertension management for people living with HIV

As experience with DSD for ART has grown, four common models of differentiated service delivery for patients established on ART have been developed and scaled by Ministries of Health (see **Figure 4**), all of which can be adapted to integrate hypertension management:

- **Group model managed by health care worker**
- **Group model managed by clients**
- **Individual model based at facility**
- **Individual model not based at facility**

Each of these models aims to address different challenges faced by both the health care system and the client. Additional details on the implementation of these models are provided in Annex 1: Standard Operating Procedures and can also be found in existing national guidance documents. Further evidence for each of these models can be found here.

Figure 4: Standard DSD models

Group	**Group model** **managed by health care worker** Clients meet as a group (e.g., of 15–20 clients) at the health facility or at a location in the community to receive their medication refills. The HCW facilitates a group discussion; clients then collect their medication and leave.	**Group model** **managed by clients** Peer-led groups (e.g., of 6–12 clients) meet in the community and nominate one member to collect medication refills from the facility for the other group members; this may be done on a rotating basis, so everyone takes a turn, or there may be a single designee.) Peer group leaders review and document medication adherence and complete a treatment checklist.
Individual	**Individual model** **based at facility** Clients make rapid visits to the health facility for medication refills by bypassing clinical consultation and presenting directly to pick up their medication from an arranged pick-up point in the facility (or pharmacy).	**Individual model** **not based at facility** Clients collect medication refills at a community outreach point, peer-led drop-in center, workplace site, community-based pharmacy or mobile outreach service; they may also receive home delivery.

*Titles and descriptions of each model align with the 2021 WHO HIV Guidelines

In all four models, **clinical visits are separated from medication refill visits** (see Box 2). For patients with controlled HIV and hypertension, there is no need for a clinical examination from a health care professional during a medication refill visit. De-coupling medication refills from clinical visits shortens time spent at the facility for patients while still allowing them to obtain their medications, reduces clinic crowding and allows clinicians to focus their attention on patients requiring more individualized treatment. This is more convenient for clients and more efficient for overburdened health facility staff, leading to an increased capacity to scale-up hypertension services in LMICs.

Box 2.

Separating clinical and medication refill visits

An essential principle of any DSD model is to separate what happens at the clinical visit from what happens at the medication refill visit.

For all patients, a clinical visit involves a consultation with a physician and consists of a clinical assessment for complications, assessment of adherence, blood pressure measurement, annual viral load, and prescription renewal, at a minimum.

At a medication refill visit, the stable, DSD-eligible patient does not need to meet with a physician or have their blood pressure measured. They simply receive their ART and hypertension medication and, depending on the design of the model, may receive education or peer support. If clinical complications (e.g., medication side effects) are identified at this visit or between visits, the patient can attend the facility for review at any time between clinical visits. Treatment literacy to identify side effects and worrying symptoms is therefore essential.

Each of the building blocks should be defined for clinical visits and medication refill visits.

Supporting tools

See Annex 1: Standard Operating Procedures for examples for each model.

Integrating hypertension management into existing DSD programs for ART delivery

To integrate hypertension management into an existing DSD model for ART, the DSD **building blocks** should be used to define how hypertension management will be delivered to PLHIV (**Figure 5**). The goal is for both ART and hypertension medication to be provided on the same day, in the same location, by the same HCW. In settings where ART is provided in an HIV clinic and hypertension management is provided in the outpatient department, services should be combined and offered in the same clinic once HCWs have been properly trained.

Figure 5: The building blocks of integrated differentiated hypertension and ART care

	Hypertension diagnosis	Hypertension medication initiation	Hypertension medication titration	Medication refill
WHEN	At ART initiation/ re-initiation Entry into DSD for ART Clinical visits for ART	At ART initiation/ re-initiation Entry into DSD for ART Clinical visits for ART	Monthly visits until hypertension is controlled, then every 6 months	Same time as ART refill Refill duration of BP medication and ART (ideally 90 days or longer) should be aligned
WHERE	Room where ART is provided	Room where ART is provided	Room or community location where ART is provided	Room or community location where ART is provided
WHO	HCW who provides ART*	HCW who provides ART*	HCW who provides ART*	HCW, lay person, or peer who provides ART refill
WHAT	Correct measurement of BP	Correct selection of initial BP medication according to protocol	Correct measurement of BP and titration of initial BP medication according to protocol	Hypertension and ART refills**

*This could be a trained doctor, clinical officer or nurse, as permitted by local policy
** Whether BP and HIV load are monitored during each clinical encounter may vary by country according to national guidelines

Provision of chronic disease care for both HIV and hypertension should be a multi-disciplinary, team-based approach (including peers, such as expert patients); as is the case for HIV, different members of the health care team may perform different tasks needed for hypertension management. For example, expert patients (Box 3) may be trained to measure blood pressure in the waiting room using automated blood pressure devices; nurses may be trained to initiate, titrate, and maintain treatment for uncomplicated hypertension while doctors are referred those with complications of hypertension, resistant hypertension (which remains uncontrolled after all steps of the standard treatment protocol have been taken) or complex comorbidities.

Box 3.
What is an expert patient?

Expert patients are people living with both HIV and hypertension who are able to provide treatment literacy and adherence support to people living with both conditions. They may receive some additional treatment literacy training and will be trained on clinical algorithms and standard operating procedures for the DSD models being offered, and can support the implementation of DSD for HTN treatment models.

Pilot and national programs that integrate ART and hypertension management have taken both individual and group DSD model approaches (**Figure 6**).

Supporting tools

See Annex 2 for case studies with more detailed descriptions of each program

Figure 6: Examples of integrated DSD models for HIV treatment and hypertension management

Location	Program management	Model	Client profile	Further information
Kenya	NGO	Group model managed by health care worker	HIV-positive or HIV-negative with hypertension, diabetes or any combination thereof	Medication Adherence Clubs: a potential solution to managing large numbers of stable patients with multiple chronic diseases in informal settlements "They just come, pick and go." The Acceptability of Integrated Medication Adherence Clubs for HIV and Non Communicable Disease (NCD) Patients in Kibera, Kenya
Eswatini	MoH	Group model managed by health care worker	HIV-positive with NCD comorbidities	DSD Models for HIV/NCD integration
Uganda	Research pilot	Individual model based at facility	HIV-positive with hypertension	Integrated HIV/Hypertension Treatment

Planning and implementation of integrated DSD for ART and hypertension management

Figure 7 lists key steps for planning and implementing an integrated DSD model for ART and hypertension management. Additional considerations are provided in the sections that follow.

Figure 7: Steps to consider for integration of hypertension management into existing DSD for ART models

Step	Activity	Resources
Conduct resource and needs assessments Read more: Resource and needs assessment	• Conduct a facility situation analysis and assess which DSD models address HCW and client challenges for ART and hypertension management • Conduct a baseline facility assessment to determine what models can be implemented for integrated ART and hypertension treatment based on clinic and community resources.	Annex 3: Situation analysis resources Annex 4: Hypertension health care facility checklist (baseline assessment)
Select DSD model(s) Read more: Selecting a DSD model for HIV-hypertension integration Entry points for integration of hypertension management into existing DSD models for ART	• Select models of integrated DSD for ART and hypertension for implementation	Annex 1. Overview and Standard Operating Procedures (SOPs) for DSD treatment models
Sensitize and secure buy-in from clinic staff and community	• Hold clinic information sessions introducing integrated models of care; include non-medical staff (e.g., receptionists) • Create buy-in by sensitizing patient community and community actors for acceptance and promotion of the services • For individual models not based at a facility, engagement of community leaders and civil service organizations working on HIV and hypertension/NCDs will be important for demand creation.	
Train clinic staff and expert patients	• Train other clinic staff on SOPs as needed	Annex 1. Overview and Standard Operating Procedures (SOPs) for DSD treatment models Annex 5. Hypertension measurement, diagnosis and treatment resources

Step	Activity	Resources
Prepare for multi-month dispensing Read more: Procurement and pharmacy support for integration of hypertension management with DSD for ART	• Conduct medication forecasting needed for shift to multi-month refills	Tools and Guidance to Facilitate Scaling Up Effective Management of Hypertension: Step 3C
Prepare for specific DSD model(s) selected	• Use SOPs to determine additional preparation required (e.g., identification of group room; identification of community outreach site)	Annex 1. Overview and Standard Operating Procedures (SOPs) for DSD treatment models
Promote DSD	• HCWs/expert patients explain integrated DSD for ART and hypertension to PLHIVs during group literacy sessions • Distribute pamphlets/posters	Annex 5. Hypertension measurement, diagnosis and treatment resources
Enroll patients Read more: Entry points for integration of hypertension management into existing DSD models for ART	• Assess PLHIV with hypertension to see if they meet eligibility criteria for an integrated ART and hypertension DSD model • Offer those who meet the criteria opportunities to join any integrated DSD for ART and hypertension models available at the health facility that meet their preferences	
Implement integrated DSD model(s) Read more: Treatment considerations for patients with hypertension		Annex 1. Overview and Standard Operating Procedures (SOPs) for DSD treatment models Annex 5. Hypertension measurement, diagnosis and treatment resources
Conduct monitoring and evaluation Read more:] Monitoring and evaluation for DSD models	• Where possible, adapt existing monitoring and evaluation tools for ART to include hypertension • Provide additional monitoring and evaluation tools as needed • Adapt supervision and quality improvement systems to ensure DSD for integrated ART and hypertension is implemented according to protocols	Annex 6: Monitoring and evaluation tools for DSD for hypertension management and ART

Coordination and governance

Key program stakeholders should be identified and involved in planning the integration of hypertension management into DSD for ART. These may include:

- Technical clinical experts for HIV and hypertension
- Ministry of Health departments for both HIV and NCDs
- Pharmacy and supply chain experts to support forecasting and supply of extended medication refills for hypertension and integration of the supply chain
- Monitoring and evaluation teams to develop indicators, and health information systems for HIV and NCD services
- HCWs currently engaged in HIV and/or hypertension service provision at different levels of the health system
- People living with HIV and hypertension

The planning and coordination of these activities may be developed through an existing technical working group or specific sub-group, which can be leveraged for DSD planning. If no technical working group yet exists for integration of DSD for hypertension management, a new group can be formed that includes the key stakeholders.

Resource and needs assessment

To effectively integrate hypertension management into DSD for ART models, it is first necessary to assess resources and needs through a situation analysis and facility assessment. Depending on the proposed scale of the integrated program, the situation analysis may be carried out at the national, district or facility level; facility level is ideal. Higher-level situation analyses should include a representative sample of facility types and communities served within the overall health care delivery system.

A general facility assessment should also be carried out to determine which facilities are equipped with sufficient resources to implement an integrated DSD model for ART and hypertension management.

Supporting tools

- Template for oversight and implementation of a population hypertension control program
- Annex 3 provides guiding questions for a situation analysis, and a situation analysis template that can be adapted according to the setting.
- Annex 4 provides facility assessment tools.

Selecting a DSD model for HIV-hypertension integration

The results of the situation and facility analyses should be used determine which current DSD for ART models should be adapted to integrate hypertension, or if a different DSD model(s) should be adopted to address the challenges identified.

Other key operational considerations include:

- Should DSD for hypertension be implemented exclusively for PLHIV or more broadly for HIV-negative people living with hypertension or other chronic diseases?
- For group models, should groups be a mixed group of HIV-positive and HIV-negative hypertension patients or HIV-positive with co-morbidities alone? Factors to be considered will include:
    - Where HIV services are provided (e.g., dedicated HIV clinic or integrated in outpatient/primary health care facilities)
    - Equity
    - Funding (if being led by donor focused on a specific disease)
    - Stigma

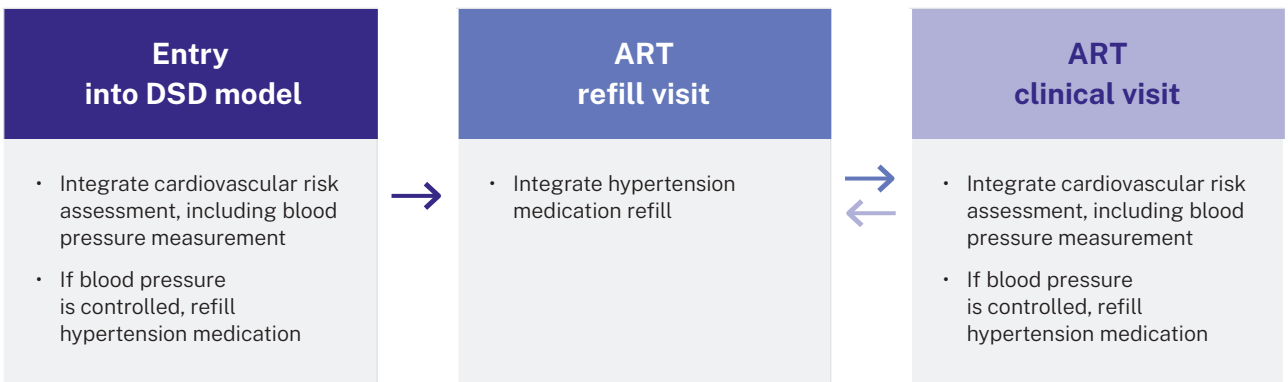
If new models are chosen:

- A mix of DSD models may be selected, with each facility selecting one or two models.
- Most sites choose the individual model based at facility and one other model that addresses a particular barrier at the site.
- Sites in high-volume urban settings usually select facility-based health care worker groups
- In rural settings, where distance to clinic is a challenge, sites often choose the group model managed by clients or the individual model not based at facility

Entry points for integration of hypertension management into existing DSD models for ART

DSD models for ART can be leveraged for integration of hypertension management both to identify PLHIV with hypertension and for ongoing management. Cardiovascular risk factor assessment, including hypertension screening, can be carried out at initiation on ART, at entry into a DSD model and at clinical visits if a BP < 140/90 has not been recorded in the last year.* **Figures 8** and **9** outline the opportunities throughout a DSD model for ART for assessment of cardiovascular risk and the integration of hypertension care.

Figure 8: Opportunities for integration of hypertension management throughout a DSD model for ART



* WHO recommends that all PLHIV have their cardiovascular risk assessed using the same criteria as the general population. Those with a normal BP < 140/90 should have this repeated according to WHO or national guidance.

Figure 9: Scenarios for the integration of hypertension into DSD models for ART

	Scenario	Actions
Enrollment	Hypertension is controlled at enrollment into DSD model for ART	• Enter integrated HIV/hypertension DSD model • Align medication refills and clinical visits
	Hypertension diagnosed at enrollment into DSD for ART	• Enter DSD for ART • Confirm hypertension diagnosis • Initiate hypertension treatment and monthly titration until control reached • When criteria for DSD for hypertension are reached, enter integrated DSD model for ART and hypertension • Align medication refills and clinical visits
Clinical visit	Hypertension diagnosed at clinical visit	• Continue DSD for ART • Confirm hypertension diagnosis • Initiate hypertension treatment and monthly titration until control reached • When criteria for DSD for hypertension are reached, enter integrated DSD model for ART and hypertension • Align medication refills and clinical visits
	Previously diagnosed hypertension not controlled at clinical visit	• Continue DSD for ART • Check adherence and monthly titration until control reached • When criteria for DSD for hypertension are reached, enter integrated DSD model for ART and hypertension • Align medication refills and clinical visits

When a PLHIV is diagnosed with hypertension, the client should be made aware of the different DSD options offered at a clinic for long-term follow up. Once established on care for both ART and hypertension, they can make an informed choice as to which DSD model addresses their access needs most effectively. Providing information about available DSD models for hypertension and ART should be integrated into the counselling sessions during the first six months on treatment.

Supporting tools

Annex 5 has examples of health education and demand creation tools.

Client eligibility criteria for entry into an integrated DSD model for hypertension management and ART

To be eligible for DSD for ART, a PLHIV must be established on ART.[9] Likewise, for a PLHIV with hypertension must have their hypertension under control to be eligible for an integrated DSD model. See Figure 10 for inclusion criteria for a client who is established on ART with controlled hypertension.

Figure 10: Criteria to define eligibility for DSD for a patient living with HIV and hypertension

	Criteria for inclusion HIV *(WHO definition 2021)*	Criteria for inclusion Hypertension *(WHO 2021 hypertension treatment guidelines)*	Notes
Control target	At least one suppressed viral load result within the past six months (if viral load is not available: CD4 count >200 cells/mm3 or weight gain, absence of symptoms and concurrent infections).	< 140/90 mmHg measured on two occasions at least one month apart	Refer to national guidelines; for those with comorbidities (i.e., ischemic heart disease, chronic kidney disease, diabetes) targets may be lower in some settings.
Duration on current regimen	Receiving ART for at least six months	At least three months on current regimen that has achieved control	This should allow identification of side effects.
Other co-morbidities	No current illness, which does not include well-controlled chronic health conditions	No other uncontrolled co-morbidities requiring more frequent clinical interventions	
Adherence	Good understanding of lifelong adherence; adequate adherence counselling provided	Good understanding of lifelong adherence; adequate adherence counselling provided	

Procurement and pharmacy support for integration of hypertension management with DSD for ART

- The goal for forecasting, procurement and supply chain management should be to align the duration of hypertension medication refills and ART refills.
- Refill duration should ideally be at least three months for both ART and hypertension medication.

To ensure adequate supplies for the transition to multi-month refills for hypertension medication, facility-level medication supply forecasting should be conducted. Multi-month refills require a larger medication inventory on hand, and thus may require a modification to current quantification methods and storage facilities. Management of ART and hypertension medication supply chains should be integrated to maximize efficiencies and support alignment.

Management of ART and hypertension medication supply chains should be integrated to maximize efficiencies and support alignment.

Clinical and pharmacy staff should agree on how multi-month scripting should be documented to ensure that patients do not need to interact with a clinician on their medication refill visit. Existing DSD for ART model protocols should be reviewed to determine any systems or agreements already in place. In some settings, documentation may be electronic; in others, documentation will need to be handwritten and indicated on both the clinic- and patient-held records.

Pre-packing of medications (that is, when medications required for refill visits are prepared prior to the visit) may be a useful strategy in any DSD model. This will include the dispensing, labelling and packing required as per local pharmacy dispensing guidance. Pre-packed medication can then be distributed by any team member and does not require dispensing training. It is most commonly used in the group model managed by clients and the individual model not based at a facility. The number of medications prescribed to clients living with both HIV and hypertension makes pre-packing particularly important for safe distribution in integrated DSD models. When using pre-packing of medication, documentation will also need to be coordinated with pharmacy staff.

Where supplies are limited and it is not possible to align hypertension medication dispensing with ART dispensing, the integrated DSD model's refill mechanism will still decongest the facility and reduce the burden on the patient (Box 4.)

Box 4.

What if we cannot provide multi-month medication refills or align ART and hypertension medication dispensing?

Although multi-month refills are ideal, where supplies are limited or when local regulations restrict prescription duration to one month or less, multi-month refills and/or aligning ART and hypertension refills may not be feasible.

By simplifying the refill visit (e.g., moving it from the health facility to a community site), the integrated DSD model still provides a system that decongests the facility and reduces the burden of collecting medication refills for the client.

For example, if ART refills are provided every three months, but hypertension medication refills are only available monthly, a prescription for three monthly refills can be provided. This way, a client who chooses a community distribution point for their refills may still only have to visit the health facility for clinical visits, and for all other refills, they can walk to their community distribution point.

Fewer patient visits for routine refills will also reduce crowding in the health facility and HCW workload.

Supporting tools

Forecasting tools to support the switch to multi-month refills can be found at Tools and Guidance to Facilitate Scaling Up Effective Management of Hypertension

Treatment considerations for patients with hypertension

Selecting a hypertension treatment protocol

National and international HIV guidelines have adopted a public health approach to optimize, harmonize and simplify care, with a single recommended ART regimen for all adult populations. This has enabled task-sharing and decentralization of care while simplifying laboratory monitoring and supply chains.

The WHO HEARTS package supports the application of these principles to hypertension. In 2021, WHO released hypertension treatment guidelines[10] further supporting the use of simple treatment protocols that clearly define dose and named agents within a drug class at each step. Following a treatment protocol has been shown to reduce the time to achieve hypertension control, reduce titration inertia, simplify supply chains and reduce pill burden for patients, many of whom have multiple comorbidities.

Supporting tools

See Annex 5 for sample hypertension treatment protocols, as well as additional tools and resources on how to choose a blood pressure monitor and cuff and take accurate blood pressure measurements

Drug interactions

All commonly used antihypertensive drug classes may be used with antiretrovirals (**Figure 11**) There are no known interactions between the common antihypertensive drug classes (Calcium channel blockers, ACE inhibitors ARB and thiazides) and the WHO-recommended first line ART regimen (TDF-3TC-DTG). B-blockers are not recommended as a first-, second-or third-line agent for hypertension; caution should be taken if administering with protease inhibitors.

Figure 11: Common drug interactions between antiretroviral and antihypertensive medications

		ANTIRETROVIRAL MEDICATIONS				
		ATV/r	DTG/3TC	EFV	LPV	TDF
ANTIHYPERTENSIVE MEDICATIONS	Amlodipine	⚠	✓	⚠	⚠	✓
	Enalapril	✓	✓	✓	✓	✓
	Hydrochlorothiazide	✓	✓	✓	✓	✓
	Lisinopril	✓	✓	✓	✓	✓
	Losartan	!	✓	!	!	✓
	Telmisartan	✓	✓	✓	✓	✓

✗ Do not coadminister ⚠ Potential Interaction ! Potential weak interaction ✓ No interaction expected

Follow up schedule for integrated DSD for ART and hypertension management

Once a patient's hypertension is controlled, the WHO guidelines recommend that the frequency of clinical visits be reduced. **Figure 12** demonstrates the compatibility of WHO recommendations for the frequency of follow up of patients on antihypertensive medications with controlled blood pressure and the DSD for ART models, allowing for possible integration.

Figure 12: Alignment of WHO hypertension treatment and HIV guidelines, for Integrated DSD for ART and hypertension models[6, 9]

DSD-eligible client profile	Clinical visit timing	Medication refill timing
Patient with controlled hypertension	Every 3–6 months[9]	Multi month refills through chosen integrated DSD for ART and hypertension model
Client established on ART	Every 3–6 months, preferably every six months if feasible[6]	Refills of ART lasting 3–6 months, preferably six months if feasible

Figure 13 outlines the possible follow-up scenarios that may result. **Figure 14** outlines a typical follow up schedule for integrated hypertension management within a DSD model for ART. Important considerations include:

- Clinical and medication refill visits should be aligned with ART.
- The client should be offered a clinical assessment for both HIV and hypertension every six months.
- Ideally, the client should be provided a minimum of three months of medication. Where this is not possible, shorter medication refills for hypertension can be delivered through a DSD refill visit (i.e., without requiring interaction with a physician).

Figure 13: Follow-up scenarios for integrated HIV and hypertension management

		HIV and hypertension control status*, **			
		HIV controlled **Hypertension controlled** VL<1000 copies/ml BP< 140/90	**HIV controlled** **Hypertension uncontrolled** VL<1000 copies/ml BP ≥140/90	**HIV uncontrolled** **Hypertension controlled** VL>1000 copies/ml BP <140/90	**HIV uncontrolled** **Hypertension uncontrolled** VL>1000 copies/ml BP≥140/90
Type of follow up	**Clinical visit (HIV)**	Every 6 months	Every 6 months	Monthly until VL<1000 copies/ml	Monthly until VL<1000 copies/ml
	Clinical visit (hypertension)	Every 6 months	Monthly until BP < 140/90 on two consecutive readings at least 1 month apart	Every 6 months	Monthly until BP < 140/90 on two consecutive readings at least 1 month apart
	Refill duration (HIV)	Every 3–6 months	Every 3–6 months	Monthly	Monthly
	Refill duration (hypertension)	Every 3–6 months	Monthly	Every 3–6 months	Monthly

* Control is defined for HIV as viral load (VL) < 1000 copies/ml and for hypertension as BP < 140/90

** When not controlled the additional monthly follow up could be delivered in the community and BP results discussed with the clinician remotely at the facility.

Figure 14: Follow up schedule for integrated hypertension management in DSD for ART

Criteria for established on ART and BP medication

Hypertension

- BP < 140/90 measured on 2 occasions 1 month apart
- On current medication combination for 3 months
- Has no other co-morbidities requiring more intensive clinical follow up
- Good understanding of lifelong adherence

HIV

- At least one suppressed viral load result within the past 6 months
- Receiving ART for at least 6 months
- No current illness
- Good understanding of lifelong adherence

Clinical visit
- Does client meet the eligibility criteria for DSD?
- Choose DSD model from those on offer (See SOPs)
- Script medication for 6 months (2x 3 months)*
- Client receives 3 months of medication

↓ 3 months

Refill visit
- Receive ART and hypertension medications though DSD model

↓ 3 months

Clinic visit for HIV & HTN
- Perform scheduled BP or laboratory testing for HIV and HTN monitoring*
- Script medication for 6 months (2x3 months)**

BP≥140/90 → **Assess adherence** *Review after 1 month****

BP still ≥140/90 and adherence good, step up treatment according to algorithm
- *Review after 1 month*

BP<140/90 on two readings 1 month apart, return to DSD refill model

↓ BP<140/90 3 months

Refill visit
- Receive ART and hypertension medications though DSD model

BP<140/90 ←

↓ BP<140/90 3 months

Clinic visit for HIV & HTN
- Perform scheduled BP or laboratory testing for HIV and HTN monitoring
- Once yearly, measure annual viral load (VL)
- Script medication for 6 months (2x3 months)**

BP≥140/90 and/or VL>1000 → **Assess adherence** *Review after 1 month*

BP still ≥140/90 and adherence good, step up treatment according to algorithm
- *Review after 1 month*

Follow enhanced adherence and VL algorithms

BP<140/90 on two readings 1 month apart, VL<1000

Return to DSD refill model

↓ BP<140/90

Continue cycle
- Clinical visits every six months, refills every three months

VL<1000 BP<140/90 ←

* Visit to the clinic for a health care provider encounter for the purpose of chronic integrated HIV and hypertension management

** The duration of medication refill should ideally be a minimum of three months and ART and BP medication duration should align. If supply chains cannot support this, prescribe medication to cover the refill period (e.g. 3x 1 month). The DSD model will be adapted for these variations.

*** The number of times the client visits the facility pharmacy in between clinic visits for HIV & HTN management

Monitoring and evaluation for DSD models

Monitoring and evaluation (M&E) activities allow health authorities and their partners to assess the how programs are being implemented and whether they are achieving their intended objectives. DSD creates potential challenges for routine M&E; the information needed to track implementation of DSD for ART models is often not captured by routine M&E systems. Because many DSD for ART services are delivered outside of health facilities, HIV programs must use alternative tools and strategies to capture the relevant data. To track data for both ART and hypertension management, two options may be considered for monitoring and evaluation tools:

- The ART card, which is used to track the patient's ART management at the facility, may be adapted to include the key indicators for hypertension management.
- Existing M&E tools for hypertension (such as patient records or registers) may be adopted alongside the ART M&E tools.

Supporting tools

Some helpful tools for M&E of integrated HIV and hypertension DSD programs can be found at the following links:

- A framework for monitoring DSD for ART models
- CQUIN presentation on how to implement M&E for DSD
- WHO Guide to monitoring and evaluating HIV/AIDS care and support
- Examples of patient records and registers for hypertension monitoring can be found in the Appendix of the WHO Global HEARTS Systems for monitoring module
- Annex 6 has additional monitoring tools for group DSD models.

HIV and hypertension indicators

Hypertension outcomes should be monitored in a similar way to ART, with retention and rates of control reported. If a national system for HIV or hypertension monitoring is already in place, it should be used. **Figure 15** illustrates how indicators for hypertension and ART can be aligned.

Supporting tools

Examples of paper-based tools for monitoring can be found at the following links:

- Resolve to Save Lives hypertension control indicators
- WHO Global HEARTS Systems for monitoring module

Figure 15: Alignment of HIV and hypertension indicators for monitoring and evaluation

Program indicator	HIV	Hypertension
Screening	**Numerator** Number of tests conducted in which a new HIV-positive result or diagnosis was returned to a person during the reporting period (positivity) **Denominator** Number of tests performed where results were returned to a person during the reporting period (testing volume)[12]	**Numerator** Number of people aged 18 years and older who visited the facility and were screened for hypertension in the reporting period **Denominator** Total number of people aged 18 and older who visited the facility in the reporting period[13]
Diagnosis	**Numerator** Number of people who test HIV-positive in the reporting period and have results returned to them **Denominator** Number of people receiving an HIV test in the reporting period[12]	**Numerator** Number of people aged 18 and older who were diagnosed with hypertension† among those who were screened for hypertension at the facility in the reporting period **Denominator** Total number of people aged 18 and older who were screened for hypertension at the facility in the reporting period[13]
Linkage to treatment	**Numerator** Number of people newly diagnosed with HIV and started on ART during the reporting period **Denominator** Number of people newly diagnosed with HIV during the reporting period[12]	**Numerator** Number initiated on hypertension medication **Denominator** Patients with hypertension diagnosis*
Retention	**Numerator** Number retained at 6, 12, 24 months.... **Denominator** Number of new HIV-positive tests[12]	**Numerator** Number retained at 6, 12, 24 months.... **Denominator** patients in the registry before the last 6 months*

Program indicator	HIV	Hypertension
Loss to follow up	**Numerator** Number of people with HIV who were lost to follow-up **Denominator** Total number of people with HIV registered in the facility**	**Numerator** Number of people with hypertension who were lost to follow-up **Denominator** Total number of people with hypertension registered in the facility[13]
Treatment monitoring / Testing coverage	**Numerator** Number of people living with HIV on ART (for at least six months) with VL test results **Denominator** Total number of people living with HIV on ART (for at least six months)[12]	**Numerator** Number of patients with BP measured at least once in 6 months **Denominator** Patients registered in the hypertension registry before the last 6 months*
Availability of core medicines	**Numerator** Number of months with any day(s) of stock-out of any routinely dispensed antiretroviral drug during the reporting period **Denominator** Total number of months[12]	**Numerator** Number of health facilities reporting “no stock-out” of hypertension core medicines in the reporting period **Denominator** Total number of health facilities[11]
Control	**Numerator** Number of people living with HIV on ART (for at least six months) in the facility who have viral suppression (for the purpose of monitoring, defined as VL <1000 copies/mL) **Denominator** Total number of people living with HIV on ART (for at least six months) in the facility[12]	**Numerator** Number of people registered for hypertension treatment in the facility whose BP was controlled*** at the last clinical visit in the prior 3 months, excluding those who were newly diagnosed with less than 3 months of treatment **Denominator** Total number of people registered for hypertension treatment in the facility, excluding those who were newly diagnosed with less than 3 months of treatment[13]

†Based on WHO 2021 guidelines, hypertension diagnosis is defined as
- All patients with systolic blood pressure (SBP)>=140 or diastolic blood pressure (DBP) >=90 mmHg on two separate, consecutive occasions, and additionally
- Patients with history of CVD, high CVD risk, diabetes, or chronic kidney disease and SBP 130–139 mmHg

*Some hypertension indicators are unpublished but developed to match current HIV program indicators

**Some HIV indicators are unpublished but developed to match current hypertension program indicators

*** Based on WHO 2021 guidelines, BP is considered controlled when:
- Systolic blood pressure (SBP) <140 mmHg and diastolic blood pressure (DBP) <90 mmHg
- SBP <130 mmHg among people with history of CVD
- SBP <130 mmHg among high-risk people with hypertension, i.e., those with high CVD risk, diabetes mellitus, chronic kidney disease (CKD)

Incorporating DSD into data collection and information systems for hypertension services

Electronic or digital information systems

DSD patients should be categorized/labelled as enrolled in the DSD program at the point of care within the patient registry. While DSD patients are categorized as controlled if they had a blood pressure of SBP <140 and DBB <90 mmHG at the most recent clinical visit within the previous six months, non-DSD patients are only categorized as controlled if they had a blood pressure of SBP <140 and DBB <90 mmHG at the most recent clinical visit within the previous three months. Thus, for quarterly program reporting, the digital information system should be programmed to factor in a patient's status as a DSD participant (six-month lookback) when determining the patient's control status. DSD patients should be marked distinctly in the overall hypertension registry book or monitoring system for PLHIV. As mentioned above, the definition of controlled blood pressure is different for DSD and non-DSD patients. As such, for quarterly program reporting, for a DSD patient whose most recent blood pressure measurement took place in the previous quarter (i.e., three to six months earlier), that blood pressure value should be carried forward to determine control status. For non-DSD patients, however, the current quarter's blood pressure measurement (i.e., within the past three months) should be used.

Other considerations

For monitoring purposes, programs may consider stratifying reporting by type of DSD model, as well as tracking additional DSD-related program indicators such as:

- Number of hypertension patients/PLHIV on ART or hypertension treatment
- Number of hypertension patients/PLHIV eligible for integrated DSD for ART and hypertension
- Number of hypertension patients enrolled in each type of DSD model offered

Supporting tools

See Annex 6 for examples of group model registers and refill forms.

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CONCLUSION

Scaling up DSD models nationally

The use of integrated DSD models for ART and hypertension has the potential not only to increase enrollment in DSD for ART programs, but also address the epidemic of hypertension and growing burden of CVD in LMICs. By tailoring services to the needs of PHLIV with hypertension while optimizing limited health care resources, integrated DSD models for ART and hypertension can expand treatment coverage, improve BP control, maintain or improve quality of care and help PLHIV live longer, healthier lives.

This toolkit supports the development and implementation of integrated DSD models for ART and hypertension. The guidance provided draws from integrated DSD models for ART and hypertension that have been tested for feasibility and efficacy, in countries including Kenya, Uganda and the Kingdom of Eswatini, as well as from experiences with DSD for ART.

Building on the lessons learned from the scale up of DSD models for ART, integrated DSD models for ART and hypertension show great potential for similar expansion. Moving a model to scale requires supportive government policies and guidelines, as well as champions on both the "supply side" (the health system) and the "demand side" (recipients of care and communities). While DSD models can be more efficient than standard models of care, achieving broad scale coverage will nonetheless require advocacy to increase investment in hypertension services.

ANNEXES

Annex 1. Overview and Standard Operating Procedures (SOPs) for DSD treatment models

The following are examples of standard operating procedures for each of the four common DSD treatment models that can be adapted to include hypertension, and an example of how they may be implemented. Each example includes a description of the four building blocks of care, standard operating procedures, and a country example of how the model has been adapted from ART to hypertension. These protocols are standard examples and should be adapted to local contexts.

Model 1: Group model led by health care worker

Overview: Group model managed by health care worker

Group formation

- Group can have 10–20 members.
- A designated HCW in the clinic (nurse or counsellor) should coordinate group formation.
- Patients that fit criteria for integrated DSD for ART and hypertension will be referred to the club focal point by the HCW.
- Patients should be assigned to a club that meets at a convenient time for them.
- The list of group members with contact details should be kept in the facility hypertension/ HIV group register(s) (Annex 6).
- Each group should be given a group number or identifier, which is indicated on the front of the clinic-and patient-held record.

Preparation

- HCW training on protocol and documentation in both clinic-and patient-held records to support multi-month prescriptions for the period between clinical visits for ART and hypertension.
- Agreement with pharmacy staff to repack and label ART and hypertension medications for distribution at the group refill session. This facilitates groups being led by non-clinicians.
- Allocation of a room or venue for the group to meet and designated booking times (which may be before or after working hours, or on weekends).
- Allocation of a club focal person within the facility.
- Medication (ART and hypertension) quantification and distribution to facilities to support multi-month refills (where applicable).

Refill visits

WHERE	WHO
• In the facility space where the group meets. • Pre-packed medication can be kept in that location for distribution.	• The group should be facilitated by the same HCW at each group refill.
WHEN	**WHAT**
• Each group is booked at a specific time to collect their refill. Ideally, patients should be offered a choice of times. • Groups may also be booked before or after working hours. • The group refill visit may last anywhere from 30–60 minutes.	• Attendance is documented in members' clinic records on arrival. • The group facilitator asks if members have any specific clinical problems to discuss. • The facilitator leads a group discussion, including health promotion information and challenges with medication. • The facilitator distributes pre-packed and labelled medication to each member. • Patients who need individual clinical review can be seen by the facilitator at the end of the meeting or referred to clinic.

Clinical visits

WHERE	WHO
• Health facility	• HCW, physician
WHEN	**WHAT**
• All group members should be aligned to receive their clinical review at the same time (6–12 monthly).	• Clients can attend as a group, but are seen individually by a HCW who measures BP and ensures any follow-up examinations have been carried out. • For all patients, a clinical visit involves a consultation with a physician and consists of a clinical assessment for complications, assessment of adherence, blood pressure measurement, annual viral load, and prescription renewal, at a minimum. • If a member's BP is not controlled at the clinical review they do not have to leave the group, but they must engage in the more frequent clinical review until BP control is regained.

Example SOP: Group model managed by health care worker

When	Where
• Every 3 months • At fixed meeting time for the group	• Refill takes place in room allocated for group refills
Who	**What**
• The group can be facilitated by a nurse, counsellor, or expert client	• Group discussion and peer support • Medication refill
Clinical review is twice a year	

Step 1 Day before appointment	• Pull patient files • Identify which clients are receiving medication in this model
Step 2 Day before appointment	• Send patient file or script to dispensing point for pre-packing or dispensing of medication
Step 3 Day of the appointment	• Send client record and pre-packed medication to group meeting room • Clients attend group meeting at booked time • If clinical problem raised, refer to clinician
Step 4 Day of the appointment	• Group facilitator leads discussion for 20–30 minutes • Distributes medication to the clients • Completes documentation • Confirms next group medication refill date
Step 5 Day of the appointment	• Trace clients that did not attend

Model 2: Group model managed by clients

Overview: Group model managed by clients

Group formation

- Groups are formed by a designated HCW.
- Once clinic staff identifies eligible patients, groups of 6–12 members are formed (ideally by geographical area).
- Once formed, each group should be assigned a group number; the list of group members with contact information should be kept in the facility-held community group register (Annex 6).
- The group number should be indicated on the front of patients' clinic records and on any patient-held card.

Group leader

- Each group should select a representative group leader who receives additional training on how to conduct the community medication refill meeting and complete the community medication refill form (Annex 6). The group leader does not have to be an expert patient but should have basic literacy and numeracy skills.
- Facility staff trains group leaders. If there are several new groups, the group leaders can be trained together.
- Suggested topics for training:
  - Recap on basics of hypertension treatment literacy. See:
    - Section 2.3 on Hypertension Treatment from the India Hypertension Control Initiative Training Manual
    - PAHO online course on management of hypertension for primary care teams
    - Johns Hopkins University videos on why hypertension is important, how to diagnose hypertension, and what to do after a diagnosis of hypertension
  - Refill visit schedule
  - Completing the community group medication refill form

Preparation

- HCW training on protocol and documentation in both clinic-and patient-held records to support multi-month prescriptions for the period between clinical visits for ART and hypertension.
- Agreement with pharmacy staff to repack and label ART and hypertension medications for distribution at the group refill session. This facilitates groups being led by non-clinicians.
- Allocation of a room or venue for the group to meet and designated booking times (which may be before or after working hours, or on weekends).
- Allocation of a club focal person within the facility.
- Medication (ART and hypertension) quantification and distribution to facilities to support multi-month refills (where applicable).

Refill visits	WHERE	WHO
	• The group meets at a designated point in the community (e.g., a group member's home). • Refills are collected at the facility.	• The group representative meets with HCW to review the community medication refill form.

Refill visits

WHEN	WHAT
• The group is given an appointment date to collect the refill. • The frequency of the refill should reflect the maximum duration of medication refill available.	**On the day before the refill:** • The group meets. • The group leader facilitates the filling out of the community medication refill form and addresses any questions. • A group member is nominated to collect medication for the group; if any member has a clinical problem, they should be nominated to collect medication so that they can be examined by a clinician at the facility. **On the refill day:** • The nominated member goes to the clinic, where the clinician reviews the group refill form and addresses any questions/concerns with the group representative. • The clinician completes the section of the group refill form indicating the medication prescription and completes individual clinic-held records for each patient. • Medication is dispensed (pre-packed for each group member in a labeled bag). • The group representative returns to the community to distribute the medication.

Clinical visits

WHERE	WHO
• Health facility.	• HCW, Physician.

WHEN	WHAT
• All group members should be aligned to receive their clinical review at the same time (6–12 monthly).	• They can visit the health facility as a group, but will be seen individually by a HCW who measures BP and ensures any follow-up examinations have been carried out. • Aligning the clinical visit for the group encourages patients to attend their review visits and allows those whose BP is not controlled to receive peer support. • If a member's BP is not controlled at the clinical visit, they may remain in the group, but they must return for more frequent follow-up visits until BP control is regained.

Example SOP: Group model managed by clients

When	Where
• Every 3 months	• Group meets at pre-agreed venue in community • Medication is collected from the facility • Medication is then distributed at an agreed distribution point or to clients' homes

Who	What
• Group leader facilitates pre-refill meeting • Clinician sees group representative at facility	• Medication refill

Clinical review is twice a year

Step 1 **Day before appointment**	• Pull patient files • Identify which clients are receiving medication in this model
Step 2 **Day before appointment**	• Group meets at agreed location and completes community refill form • Group nominates representative to collect medication
Step 3 **Day of the appointment**	• Representative attends clinic • Clinician reviews community medication refill form • Medication is dispensed for all group members in labeled bags • Clinician completes the community medication refill form and other documentation
Step 4 **Day of the appointment**	• The group representative distributes medication to group members • Group members sign to confirm receipt • Completed community medication refill form is handed back to group leader
Step 5 **Day of the appointment**	• Trace clients that did not attend

Model 3: Individual model based at facility

Overview: Individual model based at facility

- Patients visiting for a medication refill bypass clinical consultation and present directly to collect their medication from an arranged pick-up point in the facility.
- Enables patients to make rapid visits to the health facility to pick up 3–6 months worth of medication at a time, often directly from the pharmacy.
- This is the most commonly implemented model.

Preparation

- HCW training on hypertension protocol in use and documentation for ART and hypertension medications in both clinic-and patient-held records to support multi-month prescriptions for the period between clinical visits.
- Agreement on location of pick-up points for ART and hypertension medication refills.
- HIV and hypertension documentation training for staff assigned to medication pick-up points.

Refill visits

WHERE

- Possible locations include: regular pharmacy, a specific quick pick-up window at the pharmacy, a designated room at the health facility where pre-packed medication is kept.
- Medication quantification and distribution to facilities to support multi-month refills (where applicable).

WHO

- Pharmacist or other allocated staff at the pick-up point.
- If medications are pre-packed, distribution at the fast-track pick-up site may be performed by a lower cadre HCW or peer.

WHEN

- Determined locally.
- Ideally, the patient should be able to attend any time during pick-up point opening hours on the refill day or two to three days before. This gives the patient flexibility.
- Extended pharmacy opening hours, before or after standard working hours, may support access for working patients.

WHAT

- The patient goes directly to the pick-up point (no clinic visit).
- The staff dispensing the medication asks if the patient has had any problems (e.g., medication side effects).
- Patients with concerns are directed to a clinic; patients without concerns receive their medication.
- Refill documentation is completed on both clinic-and patient-held records.

Example SOP: Individual model based at facility

When	Where
• Every 3 months • Any time during clinic opening hours	• Direct from dispensing point

Who	What
• The client does not see the clinician, only the medication dispenser (pharmacist, nurse, or lay worker)	• Medication refill only

Clinical review is twice a year

Step 1 **Day before appointment**	• Pull patient files • Identify which clients are receiving medication in this model
Step 2 **Day before appointment**	• Send patient file or script to dispensing point for pre-packing or dispensing of medication
Step 3 **Day of the appointment**	• Client attends dispensing point any time during clinic opening hours • Client does not have individual clinician assessment unless there is a problem
Step 4 **Day of the appointment**	• Medication is dispensed • Documentation and M&E completed • Confirm next medication refill or appointment date
Step 5 **Day of the appointment**	• Trace clients that did not attend

Model 4: Individual model not based at facility

Overview: Individual model not based at facility

- Clients collect 3–6 months of medication at a time directly from a community-based pharmacy, a peer-led drop-in center, a mobile outreach service, or via home delivery.
- This model is most often implemented in geographically hard-to-reach areas.

Preparation

- HCW training on protocols and documentation in both clinic-and patient-held records to support multi-month prescribing for the whole period between clinical visits for ART and hypertension.
- Medication (ART and hypertension) quantification and distribution to facilities to support multi-month refills (where applicable).
- Agreement with pharmacy staff to pre-pack and label ART and hypertension medication for distribution at the mobile outreach site. Pre-packaging facilitates distribution being performed by non-clinicians at refill visits.

Refill visits

WHERE	WHO
• A community location should be identified in collaboration with patients. This may be an existing community outreach site (e.g., one used for maternal and child health) where hypertension refills may be integrated into the existing service.	• **Option 1:** All patients are seen by the nurse running the outreach activity. • **Option 2:** Pre-packed medication can be distributed and documentation performed by a lay cadre or expert patient.
WHEN	**WHAT**
• A fixed day and time are set for the outreach activity. • Frequency must ensure continuity of medication, ideally with the ability to provide at least three-month refills to patients.	• Patients attend the mobile outreach site individually during designated time. • Pre-packed medication is distributed to patients. • There is no need for a clinical interaction.

Clinical visits

WHERE	WHO
• If feasible, and if privacy can be ensured, it may be possible to perform the 6–12 monthly clinical review at the same outreach site • If this is not possible, patients should attend the facility for review.	• HCW, Physician.
WHEN	**WHAT**
• 6–12 monthly	• The clinician reviews each patient individually and can perform the indicated examinations.

Example SOP: Individual model not based at facility

When	Where
• Every 3 months • At fixed date and time	• At fixed mobile outreach site

Who	What
• Clinician or lay cadre	• Medication refill

Clinical review is twice a year

Step 1 **Day before appointment**	• Pull patient files • Identify which clients are receiving medication in this model
Step 2 **Day before appointment**	• Send patient file or script to dispensing point for pre-packing or dispensing of medication
Step 3 **Day of the appointment**	• Clients' clinical record, M&E tools, and medication transported to the outreach site • Clients attends outreach site at agreed time
Step 4 **Day of the appointment**	• Medication distributed by the nurse or lay worker who completes the documentation • On return to clinic, complete any documentation for M&E
Step 5 **Day of the appointment**	• Trace clients that did not attend

Annex 2. Case Studies

Group model managed by health care worker: Nairobi, Kenya

Combined "medication adherence clubs" (MACs) were implemented for hypertension, diabetes mellitus and HIV patients. HIV and non-communicable disease patients were informed about the option of joining MACs through daily health talks in waiting bays, patient empowerment meetings and posters in the clinic. Patients were screened by clinicians during routine follow–up and if they met the inclusion criteria (see below) were offered the option of attending a MAC. MACs were nurse-facilitated groups of 25–35 stable hypertension, diabetes mellitus and HIV patients who met quarterly to: (i) confirm their clinical stability, (ii) have a short health talk and (iii) receive pre-packed medications. A typical session lasted less than 2 hours. Routine patient follow-up with clinical officers occurred yearly, or when a patient developed complications or no longer meets the inclusion criteria. In all, MACs coped with 2,208 consultations that would have been included in the regular clinic during the first year of implementation. The study supports the development of MACs as an efficacious method of reducing clinicians' workload, caring for multiple different types of stable chronic disease patients simultaneously and increasing the flexibility of care delivery for patients. It also demonstrates a low loss to follow-up (3.5%), likely reflecting patient satisfaction, a key element in care of chronic conditions. Offering free care and medications may have been another strong incentive for patients to remain in care. With further scale-up, a greater number of single provider clinic visits can be offloaded.

	Clinical visit	Refill visit
WHEN	Every 12 months	Every three months
WHERE	Not stated	At MAC location
WHO	Not stated	Same nurse for ART and hypertension
WHAT	HIV and hypertension clinical review and investigations as indicated in national protocols	ART and hypertension medication refills

Individual model based at facility: Kampala, Uganda

Patients at the ART clinic have their blood pressure checked at each clinical visit. HCWs providing ART are trained to diagnose hypertension and initiate, titrate, and maintain hypertension treatment. Once established on ART and hypertension treatment, a patient may enroll in an individual model based at facility, where they have a clinical visit every 6 months and are provided with 3-month refills for both ART and hypertension medications. In between clinical visits, patients collect their medication refill directly from pharmacy. To date, 1,134 hypertensive PLHIV are receiving their care through this integrated model; over 70% of patients in this group have achieved HTN control, and the HIV viral load suppression rate is over 95%.

	Clinical visit	Refill visit
WHEN	Every six months	Every three months
WHERE	Same clinic room as ART	Pharmacy pick up point
WHO	Same nurse as ART	Same nurse as ART
WHAT	HIV and hypertension clinical review and investigations as indicated in national protocols	ART, prophylaxis, and hypertension medication refills

Group model managed by health care worker: Eswatini

Patients form treatment clubs — groups of 15–20 patients who are established on ART, hypertension and/or diabetes medications. The groups are scheduled bimonthly or quarterly at a fixed time and meet for between 30–45 minutes. They are led by a nurse and lay health worker who facilitates some group discussion on selected health education topics. Medication refills given for two or three months for all diseases are pre-packed by the pharmacy in named labeled bags. The group facilitator distributes these bags to the patients at the end of the meeting. Once every six months, the whole group is scheduled for their clinical review, with the same nurse performing the clinical review for HIV, hypertension and/or diabetes. To date, 149 patients have been enrolled in this group model. Despite challenges with stock availability, all patients achieved control of their NCDs and remained virologically suppressed.

	Clinical visit	Refill visit
WHEN	Every 6 months	Set time for the group every 2–3 months
WHERE	Same clinic room as ART	Specified area in the facility for the group to meet
WHO	Nurse and lay health worker	Nurse and lay health worker
WHAT	ART and hypertension medication clinical review and investigations	ART, hypertension, and diabetes medications

Annex 3: Situation analysis resources

Conducting a situation analysis for integrated DSD for ART and hypertension management

Step 1: Assess data

- What is the burden of HIV, current progress against the HIV 95–95–95 targets, and number of patients/PLHIV registered in each DSD ART model?
- What is the burden of hypertension and what are the current screening, treatment, retention and control rates among PLHIV?
- How many patients may be eligible for integration of hypertension management into a DSD ART model?

Step 2: Assess policies

- What DSD models for ART are currently being offered and endorsed by the Ministry of Health?
- What is the frequency of clinical and ART refill visits in each model?
- What is the existing national guideline for the diagnosis and management of hypertension?
- Using the DSD building blocks as a framework, assess national policies or guidance on:
    - which cadre of HCW can carry out blood pressure measurement (for screening, diagnosis, monitoring) and hypertension treatment (initiation, titration and maintenance);
    - where hypertension treatment can be provided; and
    - frequency of clinical and medication refill visits for hypertension.

Step 3: Assess existing models of care for ART and hypertension

- Map DSD for ART models currently being implemented.
- Use the DSD building blocks to describe how clinical and refill visits for hypertension are currently provided (i.e., when, where and how hypertension care is delivered).

Step 4: Assess medication supply

- Determine which hypertension medications are included in the national Essential Medicines List.
- Assess quality assurance and cost to patients for preferred hypertension medications.
- Assess current supply chain, stockouts, storage and inventory processes for HIV and hypertension medications.
- Forecast changes needed to support multi-month refills and distribution of hypertension medications as part of DSD.

Step 5: Gather client perspectives

- How do PLHIV in DSD models for ART currently access hypertension services?
- Would integrating hypertension services into DSD models for ART address client access challenges?
- Is integrating hypertension services into DSD models for ART acceptable to clients?
- If HIV services are not provided in a dedicated clinic, would a chronic disease approach (including HIV-negative individuals) be acceptable for group models?

Step 6: Gather health care worker perspectives

- Are HCWs who provide ART trained to diagnose and treat hypertension?
- Are there settings in which the same HCW is already providing ART and hypertension care but on separate days?
- What is the current workload for HCWs involved in HIV and hypertension management in each facility? How many ART and hypertension patients are seen per day/week?
- Do HCWs see advantages to integrating hypertension management into existing DSD for ART models? If so, what would these be?
- Would HCWs support group models that include both HIV-positive and HIV-negative patients with chronic diseases? Why or why not?

Step 7: Identify external influences that may affect service delivery

- Do group models implemented during COVID-19 need to be adapted?
- Are there fluctuations in the supply chain?

Step 8: Analyze assessment data and define the key challenges for both the health system and clients

- Review of results from the assessments and define the challenges faced by the health system (e.g., high volume of clients) and clients (e.g., long distances to travel and long waiting times).

Customizable situation analysis template

- National and facility-level situational analysis templates (Excel file)

Situation Analysis for Integration of hypertension into DSD for ART : Facility (Use in combination with the facility assessment tool for clinical readiness)			
Facility or regional Data HIV		Number people living with HIV	
		Number people living with HIV on ART	
		Number people living with HIV on ART with suppressed VL	
Facility or regional data Hypertension		Prevalence of hypertension	
		Estimated number of people living with hypertension	
		Number of people diagnosed with hypertension	
		Number of people living with hypertension on treatment	
		Number of people on treatment with controlled hypertension	
		Estimated number of clients fitting the eligibility criteria for DSD for hypertension	
DSD for ART	DSD Models Offered	Facility fast track Y/N	
		Facility group model Y/N	
		Community individual model Y/N	
		Community group model Y/N	
	No clients on ART per model	Facility fast track	
		Facility group model	
		Community individual model	
		Community group model	
	Are the following elements of hypertension treatment currently performed at this facility	Initiation	
		Up Titration	
		Maintenance	

			Doctor	Clinical Officer	Nurse	Community health worker	Peer
How are hypertension services delivered	Who provides the different steps of hypertension care for PLHIV	Initiation					
		Up Titration					
		Maintenance					
		Does the same HCW provide ART and hypertension care (Y/N)?					
	When are hypertension services provided for PLHIV	How often are stable hypertension clients seen by a clinician					
		Is this standard across all clinicians					
		What duration of medication is given to stable clients					
		Is this standard across all clinicians					
		How many days per week are hypertension service offered ?					
		Is hypertension treatment provided on the same day as ART					
	Where are hypertension services provided for PLHIV		Same room as ART	Same clinic as ART	Different clinic but same facility as ART	Different facility to ART	
		Indicate Y/N					

			Doctor	Clinical Officer	Nurse	Community health worker	Peer
Health care worker workload		Number of each cadre					
		Number trained on hypertension protocols					
		Number ART consultations/day/HCW					
		Number hypertension consultations /day / HCW					

Client perspectives		Do clients with hypertension currently in a DSD ART model prefer integration into model	
		How long do clients spend at site from registration to leaving with medication	

Situation Analysis for Integration of hypertension into DSD for ART: Facility

Annex 4: Hypertension health care facility checklist (baseline assessment)

Facility name: _____ Region/District name: _____

Facility type: _____ Facility hours: _____

Facility staffing (N=number)

Physicians/Med Officers (N): _____ Nurses (N) : _____ Pharmacists (N): _____ CHWs (N): _____

New HTN patients registered in prior month (N): _____ Avg daily HTN patients seen (N): _____

Total HTN patients registered (N) to date: _____ Total Catchment population (N): _____

Is the HTN treatment algorithm displayed for staff to reference? ☐ Yes ☐ No

Facility supervisor: _____

Reviewer: _____

Date: _____

1	**BP measurement**	
1.1	Number of functional (F) and non-functional (NF) BP devices	Digital: F _____ NF _____ Manual: F _____ NF _____
1.2	Frequency of BP device inspection (digital) / calibration (manual)	☐ 6-monthly ☐ Annually ☐ Not done
1.3	BP measured for all adult outpatients who come to the clinic	☐ Yes ☐ No
1.4	Location of BP measurement in facility	☐ Registration area ☐ NCD clinic ☐ Exam room ☐ Other
1.5	**Observe 5 patient BP measurements (refer to BP checklist below):**	**Circle # out of 5 meeting criteria:**
1.5.a	BP measured with patient at rest (sitting quietly)	0 1 2 3 4 5
1.5.b	Proper positioning (back support, arm at heart level, feet on ground)	0 1 2 3 4 5
1.5.c	Correct cuff size used	0 1 2 3 4 5
1.5.d	Exact BP recorded, not rounded (i.e. 142/92 not 140/90)	0 1 2 3 4 5
1.5.e	For patients with initial BP>140/90, repeat BP measured after 3–5min	0 1 2 3 4 5
1.5.f	For patients with repeat BP>140/90, referred to medical officer	0 1 2 3 4 5

2	**Information systems**				
2.1	Type of information system used				☐ Paper ☐ Electronic ☐ Both ☐ Neither
2.2	Patients given unique identifiers (IDs)				☐ Yes ☐ No
3	**Treatment (based on review of 5 patient records)**				**Circle # out of 5 meeting criteria:**
3.1	Blood pressure measurements are documented				0 1 2 3 4 5
3.2	Medication (names/doses) are documented				0 1 2 3 4 5
3.3	If BP>140/90, HTN medication was prescribed/intensified per protocol				0 1 2 3 4 5
4	**Medication Availability**				
4.1	Number of days for which HTN medication prescriptions dispensed				7 10 30 60 90 Other ___
4.2	Drug inventory register maintained and updated				☐ Yes ☐ No
4.3	Drug name* *Modify drug names for region	Current stock (number of tablets)	Any stock outs in last 3 months? (Y/N)	Monthly consumption (number of tablets)	Is stock sufficient for next quarter, i.e., is current stock > monthly consumption x3 months? (Y/N)
	Amlodipine				
	HCTZ				
	Lisinopril				
	Others (specify) _____				
5	**Laboratory Testing Availability on Site**				
5.1	Creatinine Y / N Electrolytes (Na+/K+) Y / N Urine protein Y / N Other _____				
6	**Task Sharing (Circle all that apply)**				
6.1	BP measurement performed by	Nurses	Health Worker/Asst.	Physician	Other _____
6.2	HTN medication initiated by	Nurses	Health Worker/Asst.	Physician	Other _____
6.3	Medication refilled by	Nurses	Health Worker/Asst.	Physician	Other _____

7	Referral Network and Follow-Up	
7.1	Hospital refers hypertension patients to health centers/posts	☐ Yes ☐ No
7.2	Resistant HTN* patients are referred to specialist	☐ Yes ☐ No
7.3	Follow up appointments are systematically scheduled	☐ Yes ☐ No
7.4	System in place to identify and outreach to patients lost to follow-up	☐ Yes ☐ No

*Resistant HTN=Uncontrolled BP (>140/90) after completing all protocol steps or adherent on 3 HTN meds

Summary of Supportive Supervision visit

Indicators	Observations	Recommendations
BP measurement		
Information systems and patient data recording		
Treatment		
Medication Availability		
Lab Availability		
Task Sharing		
Referral Network and Follow-up		
Other		

Annex 5. Hypertension measurement, diagnosis and treatment resources

Measuring and diagnosing hypertension

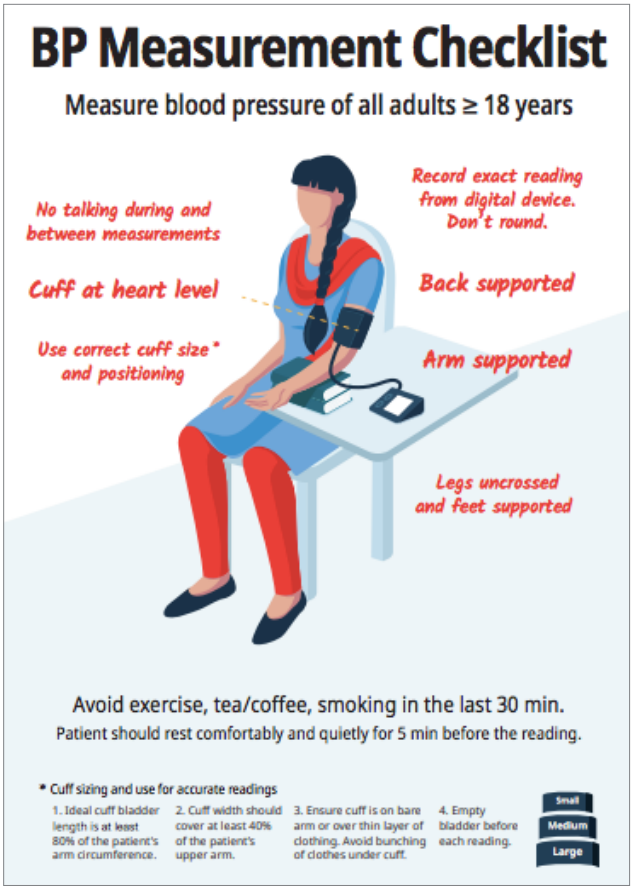
Measuring blood pressure is the only way to diagnose hypertension, as most people with raised blood pressure have no symptoms. Effective treatment algorithms for hypertension are dependent on accurate blood pressure measurement. The following links provide resources to aid in the measurement and diagnosis of hypertension, including information on how to select a device and properly sized cuff, and take an accurate measurement.

Selection of blood pressure devices:

- How to Choose an Automated Blood Pressure Monitor Recommendations for low-and middle-income country settings
- Automated BP devices fact sheet
- WHO Technical specifications for automated non-invasive blood pressure measuring devices with cuff
- Validated Device List
- Electronic (Oscillometric) Blood Pressure Monitors Suggested Requirements for External Validation Studies
- Hypertension Frequently Asked Questions — Blood Pressure Measurement

Accurately taking a blood pressure reading

- WHO HEARTS — Evidence Based Treatment Protocols module
- BP Measurement Checklist
- Johns Hopkins University: How to diagnose hypertension (video)



Simple hypertension treatment protocols

Each program/country should select and adapt the hypertension treatment protocol that best suits their circumstances. Countries may select one or more protocols to adapt, depending on local preferences (which may be influenced by usual practice, resources and demography). Selection of a single option greatly facilitates logistics, training, supervision, evaluation and overall program implementation. The simpler the protocol, the more likely it is to be followed and to achieve the program objective. Examples of treatment protocols can be found in the following resources:

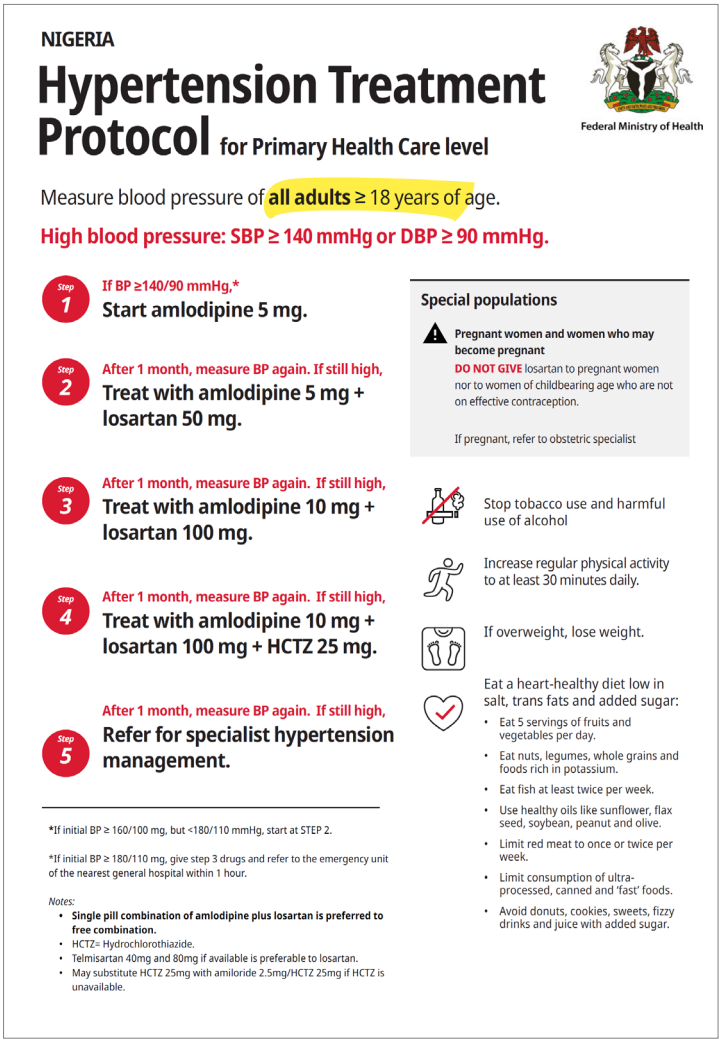
- WHO HEARTS – Evidence Based Treatment Protocols module
- Step 2 in the Resolve to Save Lives 6-step guide for starting a hypertension program
- Hypertension control resource library
- Sample hypertension protocol from Nigeria

Provider resources

- 10 best practices for hypertension

Patient education and demand creation resources

- Myths and facts about hypertension
- Hypertension brochure



NIGERIA

Hypertension Treatment Protocol for Primary Health Care level

Federal Ministry of Health

Measure blood pressure of **all adults** ≥ 18 years of age.

High blood pressure: SBP ≥ 140 mmHg or DBP ≥ 90 mmHg.

Step 1 — If BP ≥140/90 mmHg,* **Start amlodipine 5 mg.**

Step 2 — After 1 month, measure BP again. If still high, **Treat with amlodipine 5 mg + losartan 50 mg.**

Step 3 — After 1 month, measure BP again. If still high, **Treat with amlodipine 10 mg + losartan 100 mg.**

Step 4 — After 1 month, measure BP again. If still high, **Treat with amlodipine 10 mg + losartan 100 mg + HCTZ 25 mg.**

Step 5 — After 1 month, measure BP again. If still high, **Refer for specialist hypertension management.**

*If initial BP ≥ 160/100 mg, but <180/110 mmHg, start at STEP 2.

*If initial BP ≥ 180/110 mg, give step 3 drugs and refer to the emergency unit of the nearest general hospital within 1 hour.

Notes:

- **Single pill combination of amlodipine plus losartan is preferred to free combination.**
- HCTZ= Hydrochlorothiazide.
- Telmisartan 40mg and 80mg if available is preferable to losartan.
- May substitute HCTZ 25mg with amiloride 2.5mg/HCTZ 25mg if HCTZ is unavailable.

Special populations

Pregnant women and women who may become pregnant

DO NOT GIVE losartan to pregnant women nor to women of childbearing age who are not on effective contraception.

If pregnant, refer to obstetric specialist

Stop tobacco use and harmful use of alcohol

Increase regular physical activity to at least 30 minutes daily.

If overweight, lose weight.

Eat a heart-healthy diet low in salt, trans fats and added sugar:

- Eat 5 servings of fruits and vegetables per day.
- Eat nuts, legumes, whole grains and foods rich in potassium.
- Eat fish at least twice per week.
- Use healthy oils like sunflower, flax seed, soybean, peanut and olive.
- Limit red meat to once or twice per week.
- Limit consumption of ultra-processed, canned and 'fast' foods.
- Avoid donuts, cookies, sweets, fizzy drinks and juice with added sugar.

Annex 6: Monitoring and evaluation tools for DSD for hypertension management and ART

Example registers and medication refill forms

Registers should be completed along with documentation of the clinical visit or refill visit on the patient treatment card.

- Registers and refill forms (Excel file)
  - Facility-based group register (tab 1)
  - Community-based group medication refill register (tab 2)
  - Community-based group refill form (tab 3)
- Example WHO ART card adapted for hypertension integration

Examples of patient treatment cards for hypertension

To be used in conjunction with ART card.

- CVD patient treatment card
- Chronic condition monitoring card used by the MSF Zimbabwe team
- Example Hypertension Register developed by the Makerere University Joint AIDS Program (MJAP)