ASSESSMENT OF SUPPLY CHAIN MANAGEMENT CHALLENGES DURING HIV GUIDELINE TRANSITIONS: EVALUATION OF GHANA'S RECENT TRANSITION

FINAL REPORT

NATIONAL AIDS/STI CONTROL PROGRAMME

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AIDS	Acquired Immune Deficiency
STI	Sexually Transmitted Disease
HIV	Human Immunodeficiency Virus
UNAIDS	The Joint United Nations Programme on HIV/AIDS
LMICs	Logistic Management and Information System
WHO	World Health Organization
ART	Antiretroviral Therapy
DTG	Dolutegravir
EFV	Efavirenz
LPVr	Lopinavir boosted with Ritonavir
HINARI	Health Inter-Network Access to Research Initiative
GSS	Ghana Statistical Service
USAID	United States Agency for International Development
ANC	Antenatal Clinic
PMTCT	Prevention of Mother-To-Child Transmission
IDIs	In-depth Interviews
HIS	Imperial Health Sciences
TCMS	Temporal Central Medical Stores
AZT	Zidovudine
HAART	Highly Active Antiretroviral Therapy
ARV	Ante-Retroviral
PLHIV	Persons living with HIV
SCMP	Supply Chain Master Plan
GF	Global Fund
UNICEF	United Nations Children's Fund
SDP	Service Delivery Points
GSS	Ghana Statistical Service
NACP	National AIDS/STI Control Programme
RMS	Regional Medical Stores

SP	Service Providers
GHS	Ghana Health Service
CHPS	Community Planning and Services
HTS	HIV Testing Services
KII	Key Informants Interviews
TWG	Technical Working Group
EID	Early Infant Diagnosis
NAP+	National Association of Persons Living with HIV

ABSTRACT

Background

As new evidence emerges in HIV care and treatment, guideline changes are inevitable. Supply chain systems must be responsive to such changes to ensure the continuous availability of health products to meet clients' needs. Ghana updated the Antiretroviral Treatment (ART) guidelines in 2019 to introduce Dolutegravir 50mg (DTG50) and Lopinavir/ritonavir 40mg/10mg as the first line, first options for adults and children less than 20kg, respectively. The country also updated the HIV testing algorithm in 2020 from a 2-tier to a 3-tier testing algorithm. These changes, however, were not devoid of challenges: from client hesitancy to accept new ARVs to commodity stockouts to health professionals' non-adherence to new guidelines. This study aimed to identify the contextual issues that contributed to transition-related expiries, commodity availability challenges, and protocol non-adherence by service providers.

Methodology

A mixed-method approach (quantitative and qualitative) was used to elicit information on supply chain management practices during HIV guideline transitions. The qualitative approach employed in-depth interviews of key stakeholders. A checklist was developed to guide the quantitative data collection process from 67 health facilities across the country. The data on the status of HIV commodities were retrospectively collected over 12 months.

Results

ARV expiries during the transitioning period were insignificant. Stock-outs of HIV test kits & ARVs were documented. These were influenced by limited health worker training, inadequate stakeholder engagement at the initial stages of the transition, poor adherence to guidelines, and client reluctance to transition. The transition process was, however, facilitated by continuous stakeholder engagement and buy-in, supportive supervision, commodity re-distributions, and better acceptance of TLD.

Conclusion

The study highlighted the gaps and opportunities for improvement in the recent transitions in HIV treatment and testing in Ghana. It emphasized the importance of training and highlighted continuous stakeholder engagement, supportive supervision, and availability of a documented transition plan as essential considerations for future guidelines transitions.

1.0.BACKGROUND

The first acquired immunodeficiency syndrome (AIDS) cases were reported in 1981. Since then, infection with human immunodeficiency virus (HIV) has spread globally and caused an estimated 74.9 million infections and 32 million AIDS-related illnesses. In its first 15 years, no treatment could control the infection or halt its spread. By 2018, the African region was home to approximately 25.7 million people living with HIV (PLWH), and in that year alone, Africa experienced approximately 1.1 million new infections. Almost two-thirds of all new global infections occur in sub-Saharan Africa (SSA) (Pell *et al.,* 2019; Govere and Chimbari, 2020).

The success of free, large-scale access to antiretroviral therapy (ART) in low- and middle-income countries (LMICs), which began in earnest in 2004, is in large part due to the introduction of a "public health approach" to access advocated by the World Health Organization (WHO) which emphasized standardized treatment regimens that could be purchased in large quantities and delivered at scale (World Health Organisation, 2004; WHO, 2010). In deciding what drug regimens to recommend, the WHO considered efficacy, tolerability, cold chain requirements, drug availability, and cost(Gerstoft *et al.*, 2003; Gallant *et al.*, 2004; World Health Organisation, 2004). The recommendations are then put together in guidelines to help standardize client care and treatment, reduce inefficiencies and optimize the value of healthcare expenditures (Kendall and Frank, 2018).

1.1.WHO HIV Care guidelines and their updates

The development of HIV treatment guidelines is informed by a systematic review of evidence and an assessment of the benefits and harms of alternative options intended to optimize patient care (Graham, Mancher and Miller, 2011). Since the reporting of the first case, testing and treatment modalities have changed with the availability of new evidence (Abdu et al., 2015;Hontelez et al., 2016). From monotherapy with Zidovudine (AZT) to combination therapies, the WHO currently recommends highly active antiretroviral therapy (HAART) consisting of a combination of three medicines due to limitations with mono and dual therapies(Kumar, Lakshmi and Kondapi, 2017). In 2016, the WHO published the consolidated guidelines. It recommended tenofovir disoproxil fumarate (TDF) + lamivudine (3TC) (or emtricitabine, FTC) + efavirenz (EFV) 600 mg as the preferred first-line antiretroviral therapy (ART) regimen for adults and adolescents (WHO,

2015). In 2018, these guidelines were reviewed to include tenofovir disoproxil fumarate (TDF) + lamivudine (3TC) (or emtricitabine, FTC) + Dolutegravir 50mg as the preferred first-line antiretroviral therapy (ART) regimen for adults and adolescents (WHO, 2018). The 2018 guideline review also recommended discontinuing nevirapine-based regimens in adults and adolescents due to documented pre-treatment resistance to nevirapine. Therefore, Nevirapine-based regimens were to be phased out, and clients transitioned to DTG-based regimens (WHO, 2018).

HIV testing has also evolved with new and improved evidence and technologies available. WHO recommended a 3-tier testing algorithm for countries with low (<5%) HIV prevalence. The revised testing algorithm also introduced screening test kits for pregnant women and the general population (Kosack *et al.*, 2017).

1.2.Effect of guideline updates on supply chain management

One notable change in the history of HIV guideline updates has been the changes in the eligibility for treatment using CD4 thresholds. These changed from initiating persons with CD4 below 200 in the 2002/2003 guidelines to removing the thresholds with the treat-all policy in 2016(David Jamieson and Kellerman, 2016). These came along with increasing demand for antiretroviral medication as countries adopted the WHO recommendations. The setting of the 90-90-90 targets for countries by the UNAIDS, a challenge for countries to work towards ending AIDS as an epidemic by 2030, further increased demand for diagnostics(first and 3rd 90) and antiretroviral medication(second 90)(David Jamieson and Kellerman, 2016) and thus put much stress on supply chain systems.

A WHO survey in 2009 revealed that 36 (38%) out of 94 reporting countries had documented at least one stock-out of antiretroviral (ARV) drugs in health facilities(Brennan, 2016) following guideline transitions. Interrupted supply of ARVs puts individual patients at risk of disease progression and death, jeopardizes public health due to the development of ARV drug resistance, hampers progress toward universal access, and diminishes the credibility of ART programs in the eyes of patients, the community, and healthcare providers(Schouten *et al.*, 2011). An increase in the spread of HIV drug resistance will necessitate a change of first-line ARV regimens, which are more expensive and will increase the costs of national ART Programmes.

Therefore, understanding ARV supply chain dynamics during guideline transitions are relevant to the global health community to foster complete and efficient treatment of persons living with HIV. (Bam et al. 2017; Beker et al. 2014; Fayorsey et al. 2013; Hoen 2014; Jahn et al. 2016; Jamieson and Kellerman 2016; Libamba et al. 2006; MSF and TAC 2016:Ripi et al,2014).

Malati and colleagues noted that these guideline changes influence supply chain systems through supply and demand mechanisms (Malati *et al.*, 2017). In terms of supply, they noted that manufacturers require firm orders to schedule production and secure the necessary ingredients to produce a new antiretroviral at scale. This is, however, challenging when new commodities are introduced because countries may not be able to provide a comprehensive transition plan with detailed and accurate plans, including how to manage the new stock and utilize existing commodities. This affects the ability of manufacturers to produce sufficient amounts of new antiretrovirals at an affordable price to meet demand while simultaneously producing sufficient quantities of legacy commodities. It, therefore, affects their ability to balance the production of new and legacy commodities.

The availability of active pharmaceutical ingredients and excipients, package inserts, and labels also affects the manufacture of the final product. Failure of Programmes to incorporate these in their rollout plans leads to unexpectedly longer lead times for commodity delivery (Malati *et al.*, 2017).

Concerning demand, the authors noted that the ability to accurately estimate and meet the demand for newly introduced commodities during guideline transitions is challenged by the non-availability of data and dependence on forecast models rather than actual consumption(Malati *et al.*, 2017). This makes it difficult for manufacturers to understand how quickly to increase production levels. To help mitigate the risk of stock-outs of new commodities and expiry of new commodities, Malati et al.; proposed a risk mitigation matrix (figure 1) to guide Manufacturers, Donors, procurement agents, National HIV Programmes, and other country-level stakeholders(Malati *et al.*, 2017).

		Risks associated with transition to a new ARV		
		Supply	**Demand**	**Financial**
Organizations involved in risk mitigation	Manufacturers	-Organize supply chains -Balance production -Communicate lead times	-Increase production capacity for new ARV	-Complete production of new ARV based on minimum volume guarantee and projected ARV demand from global supply plans -Revisit procurement costs with donors and procurement agents
	Donors/ Procurement agents	-Utilize regional or intermediate warehouse networks to stockpile the new ARV -Hold the new ARV in regional or intermediate warehouses transition -Develop firm orders for manufacturers	-Implement 12–18 month forecast -Collaborate with other donors/procurement agents to devise global supply plans for new ARV -Coordinate procurement between donors and procurement agents	-Consider minimum volume guarantee -Revisit procurement costs with manufacturers
	National HIV program and other country stakeholders	-Create coordinated detailed plans for transitioning to new ARV -Share and discuss transition plans extensively with donors and procurement agents -Keep track of registration process of new ARV	-Implement national quantification exercises for 12–18-month forecast for the new ARV -Devise a delivery plan Monitor uptake and update plan quarterly Monitor stock-on-hand of legacy ARV	-Budget for new ARV procurement -Determine how funding cycles and timelines align with procurement and transition plans for the new ARV

Figure 1 Risk mitigation matrix for transitioning to a new ARV(Malati *et al.*, 2017)

1.3. Antiretroviral therapy guideline transition experiences in lower and middle-income countries

Lower and middle-income countries, especially those in Sub-Saharan Africa (SSA), have been worse hit by the HIV pandemic. Due to the high HIV caseload in these countries and their HIV programs being primarily donor-funded, they are also experiencing supply chain challenges resulting from guideline transitions (Hontelez *et al.*, 2016).

A scoping review showed that although SSA countries historically aligned their guidelines to WHO recommendations quite early after their updates, it took at least two years for some 20 PEPFAR-supported countries to implement the guidelines. This contributed to the observed low treatment coverage and poor patient outcomes in the sub-region(Govere and Chimbari, 2020). In addition to the already strained healthcare system in these countries, some of the reported challenges to guideline transitions from the review included poor community engagement, lack of capacity building for health workers on new policies(especially those in rural settings), and limited

ARV stock and delays in delivery of procured commodities (Govere and Chimbari, 2020). Despite these challenges, some countries had good experiences with guideline transitions.

1.3.1. Introduction of a fixed-dose combination in Malawi

A review of Malawi's 2004 introduction of the fixed-dose combination of stavudine, lamivudine, and nevirapine to the public ART-providing facilities showed that "clear national ART guidelines, implementing partners working together, an intensive training schedule focused on clinical officers and nurses, a structured system of accrediting facilities for ART delivery, quarterly supervision and monitoring, and no stock-outs of antiretroviral drugs" were the primary drivers of the observed improvement in patient survival and retention in care. The major challenge they had with the introduction of this regimen was equitable access to ART sites, especially for patients in rural areas, leading to delayed uptake and high rates of commodity expiry in rural facilities (Libamba *et al.*, 2007)

1.3.2. Transition to dolutegravir in South Africa and Uganda

A stakeholder engagement by Alhassan et al. on the dolutegravir transitions in South Africa and Uganda showed similar challenges and opportunities (Alhassan *et al.*, 2020). In both contexts, national stakeholders identified challenges with ensuring gender equity in rollout due to the potential teratogenicity of dolutegravir, paucity of data on dolutegravir use in pregnancy, potential stock out of effective contraceptives, poorly integrated contraception services, and limited pharmacovigilance in pregnancy. Participants also identified opportunities that could be harnessed to accelerate the transition. These included high stakeholder interest and commitment to transition, national approval, and licensure of a generic tenofovir/lamivudine/dolutegravir regimen, availability of a network of antiretroviral therapy providers, and a strong desire among women for newer and more tolerable regimens (Alhassan *et al.*, 2020).

Following these engagements, the authors proposed a framework for the rollout of the new regimen (figure 2). The critical steps in the framework are guideline development, supply of the commodity, staff capacity strengthening, service delivery, community acceptability and uptake, and post-implementation surveillance (Alhassan *et al.*, 2020).

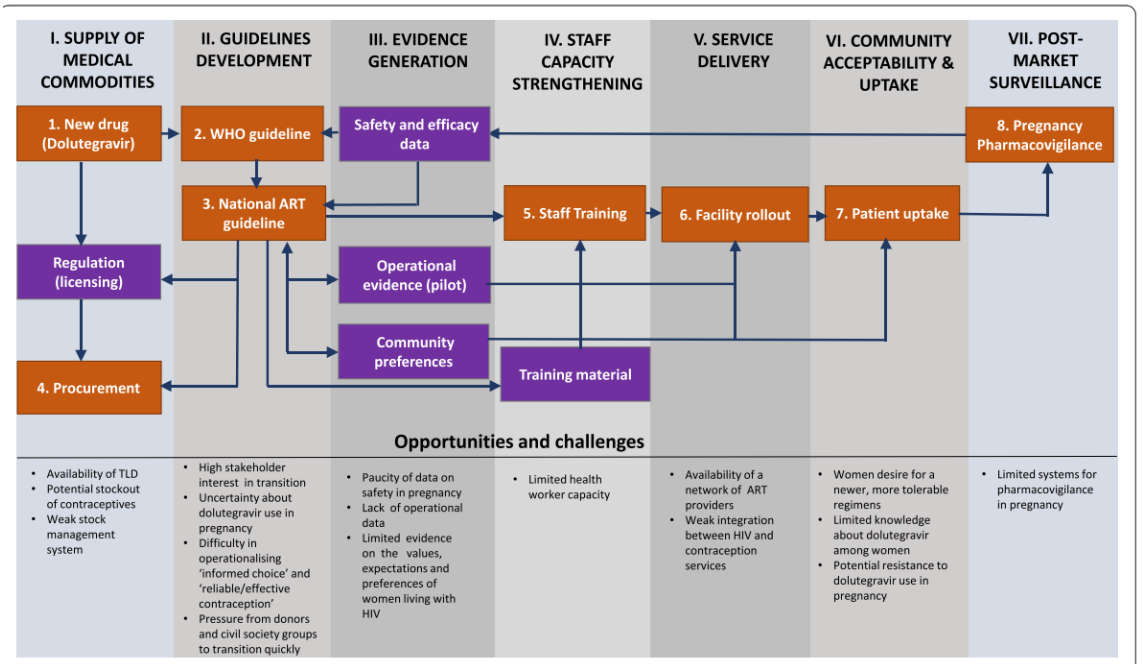


Fig. 1 Potential health system opportunities and challenges to transition to dolutegravir-based regimens. Diagram outlines key elements of the health system involved in transitioning to dolutegravir-based first line antiretroviral regimens among women of childbearing potential, and related potential opportunities and challenges identified in South Africa and Uganda. Orange rectangle shapes represent major activities of the transition process and the purple shapes represent auxiliary activities/elements. Arrows denote relationship between the

Figure 2 Framework for the rollout of new regimen (Alhassan *et al.*, 2020)

1.3.3. Roll out of TB preventive treatment in Sudan

Recognizing that tuberculosis preventive treatment is an essential intervention to decrease morbidity and mortality of tuberculosis among people living with HIV, the South Sudan health ministry included it in the 2017 revised national HIV and tuberculosis treatment guidelines. Nevertheless, this addition did not immediately lead to the scale-up of tuberculosis preventive treatment in HIV care. In 2018, the national HIV and tuberculosis technical working group identified four significant barriers to the implementation and scale-up of tuberculosis preventive treatment in South Sudan:

(i) lack of coordinated sensitization of clinicians and operational guidance for the intervention in clinical care;

(ii) lack of tools to document and monitor scale-up;

(iii) lack of a pilot demonstrating feasibility in HIV care; and

(iv) lack of a clear mechanism to procure isoniazid for preventive treatment for this population(Andrew T. Boyd *et al.*, 2021).

They resolved this by supplementing the guidelines with job aids, providing training for service providers, and rolling the intervention out in a phased approach (Andrew T Boyd *et al.*, 2021).

In summary, lessons from guideline rollouts in SSA have shown that there is the need for extensive community/ stakeholder engagement, provision of capacity building to service providers and offering them job aids, adequate supply planning, rolling out new commodities in a phased approach, and provision of supportive supervision following the rollout.

The WHO, therefore, advised country Programmes to be cautious during guideline transitions because "*where programme resources are already stretched, unplanned adoption of new recommendations with the associated increase in demand for drugs and diagnostics may lead to stock-outs and imbalances in the supply chain*" (WHO, 2016). They further highlighted some key supply chain challenges that countries are likely to face within the context of new guideline revisions and policy implementation. These challenges may be linked to the following:

- Product selection
- Quantification and demand forecast
- Procurement planning and execution, including delivery and timeliness of orders
- The ability of global supply to cope with the increasing global demand
- Storage and distribution, including logistics constraints
- Monitoring of consumption and demand changes
- Frequency of ARV drug pickup
- Shelf-life of ARV drugs
- Risk of stock-outs and Risk of expiries

1.4. HIV Care in Ghana

1.4.1. HIV Programming and Supply Chain Management Practices

Ghana has provided HIV services since the identification of the first case in 1986, gradually adding and expanding services along the continuum of care (testing, opportunistic infection prevention, treatment, viral load monitoring, and psychosocial support) over the past decades. The provision of HAART was added to its comprehensive care in 2002 (Ayisi Addo *et al.*, 2018).

In 2021, the estimated HIV population for Ghana was 345,599 comprising 233,690 (68%) females. The HIV population for adults (15+ years) and children (0-14 years) was 319,021 and 26,578, respectively. The national HIV prevalence was 1.67%. The estimated total new HIV infections was 16,938 consisting of 11,375 (67%) females and 5,564 (33%) males with 2,949 (17%) occurring among children (0-14years). Total AIDS deaths were 9,859 (made up of 4,621 (47%) males and 5,238 (53%) females). Ghana's performance on the 95-95-95 is summarized as follows: in 2021, 72% of all PLHIV knew their HIV status; out of this number, 99% were enrolled in treatment, and 79% of those on treatment had attained viral suppression(Ghana AIDS Commission, 2021).

Ghana's public health supply chain is guided by a Supply Chain Master Plan (SCMP) for 2021-2025. The vision of the SCMP 2021-2025 is to ensure the availability, timely access, and affordability of high-quality health commodities. The SCMP 2021-2025 sets a list of priority reforms and interventions to improve the availability of quality health commodities. The management of HIV commodities is integrated into the general management of other Programme and essential commodities (Ministry of Health Ghana, 2022).

HIV commodities are funded by the Government of Ghana (GoG) and development partners, including the Global Fund (GF), the United States Agency for International Development (USAID), and the United Nations Children's Fund (UNICEF). These commodities are typically procured from overseas. Shipments received in the country are sent to the Central Medical Stores (CMS) and then transported through the regions to the service delivery points SDP. Figure 3 shows the flow of commodities from the central medical stores to SDP in Ghana.

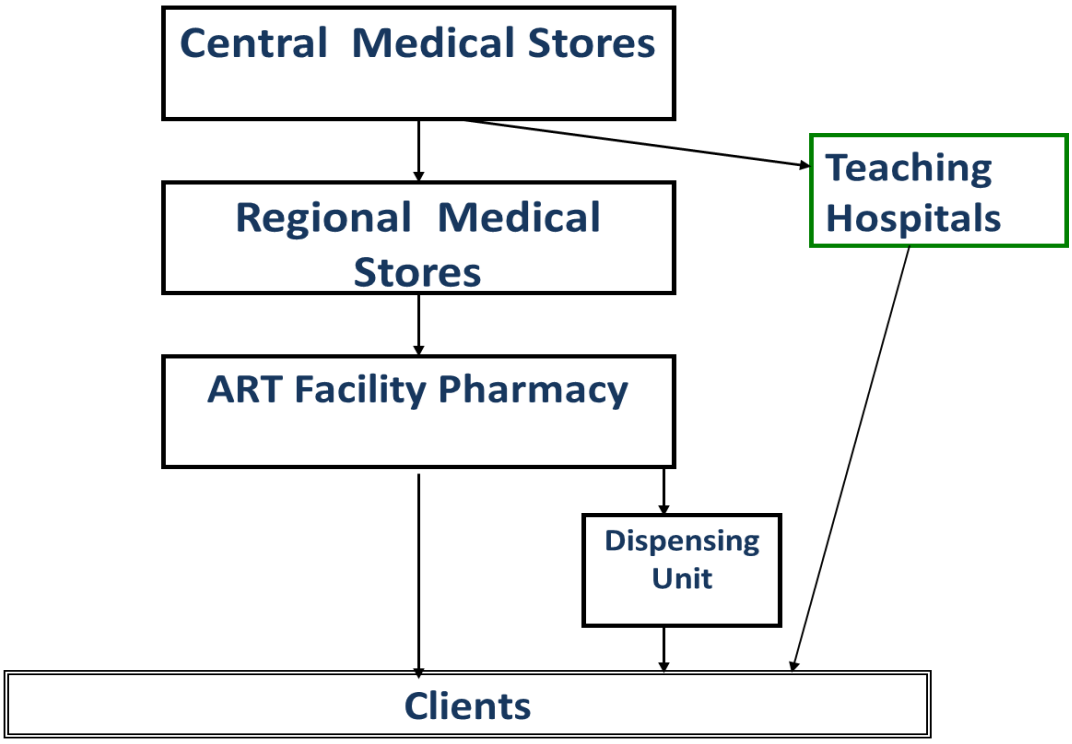


Figure 3:Flow of commodities from the central level to SDPs

Key supply chain interventions such as last-mile delivery of commodities to SDPs via third-party logistics providers (3PL), implementation of an end-to-end electronic logistics management information system (GhiLMIS), and improved inventory management practices have contributed to improved commodity availability at SDPs for service delivery.

1.4.2. Ghana's HIV Guideline Transitions

Ghana's HIV care and treatment guidelines are usually updated in response to updates from the WHO. These updates guide programme implementation and service delivery. Since the introduction of HAART, Ghana has undergone several transitions, the most recent in 2019.

The table below outlines significant updates to HIV care and treatment guidelines since 2002.

Table 1:Summary of guideline updates in Ghana (2002-2019).

Year	Significant Updates
2002	• First comprehensive HIV care guidelines for the country. • Set criteria for initialization of therapy, drug combinations and management and monitoring of opportunistic infections.
2008	• A new baseline for the initiation of antiretroviral therapy which stipulated that all persons living with HIV with CD4 count less than 350 cells/ml were eligible for therapy. • Inclusion of the management of HIV and Hepatitis B co-infection
2012	• Recommended ARVs were revised to exclude stavudine, nelfinavir and didanosine. • Revised criteria for the initiation of therapy for infants and children • Expanded post-exposure prophylaxis to include management of rape survivors
2014	• Focused on the need for early initiation of ART for adults (CD4 count less than 500 cells/ml) • Revised the criteria for initiating therapy for infants and children requiring the enrolment of all infants and children below five years with confirmed HIV on ART.
2016	• "Treat all" policy was introduced • Efavirenz-based regimen was introduced as the preferred first-line for adults
2019	• Dolutegravir-based regimen was introduced as the preferred first line for adults and children above 20kg. • The 3-tier HIV testing algorithm was introduced to replace the existing 2-tier testing algorithm. • Nevirapine-based regimen was to be phased out and clients transitioned to DTG-based regimen.

1.4.3. Supply Chain Outcomes of Ghana's Recent Guideline Updates

Ghana, like most countries, updated the Antiretroviral Treatment (ART) guidelines in 2019 to introduce Dolutegravir 50mg (DTG50) and Lopinavir/ritonavir 40mg/10mg as the first line, first options for adults and children less than 20kg, respectively. Based on WHO recommendations, the country also updated the HIV testing algorithm in 2019 from a 2-tier to a 3-tier algorithm since Ghana has a low (<5%) HIV prevalence (Kosack *et al.*, 2017). The algorithm change also introduced different screening test kits for pregnant women (First Response HIV/Syphilis combo kit) and the general population (First Response HIV kits) (National AIDS/STI Control Programme Ghana, 2019).

Before implementing the guideline transitions, only high burden ART sites in the country were trained due to financial constraints. Post-training, hard copies of the guidelines were sent to regional medical stores for onward distribution to all ART sites. Soft copies of guidelines were distributed extensively to all service delivery points.

Following the 2019 changes, Abacavir/Lamivudine 600mg/300mg (ABC/3TC 600/300) was expected to play a very prominent role as part of the first-line alternate regimen. Dolutegravir 50mg (DTG50) was also expected to account for 65% of all adult first-line consumption, with Efavirenz 600mg (EFV600) accounting for the other 35%. These targets were expected to be achieved at the end of a six-month transition period (September 2019-March 2020). However, consumption of ABC/3TC 600mg/300mg remained low (Figure 4), with over 60,424 packs estimated at $903,495.00, expiring at the end of December 2021(Imperial Health Sciences, 2021).

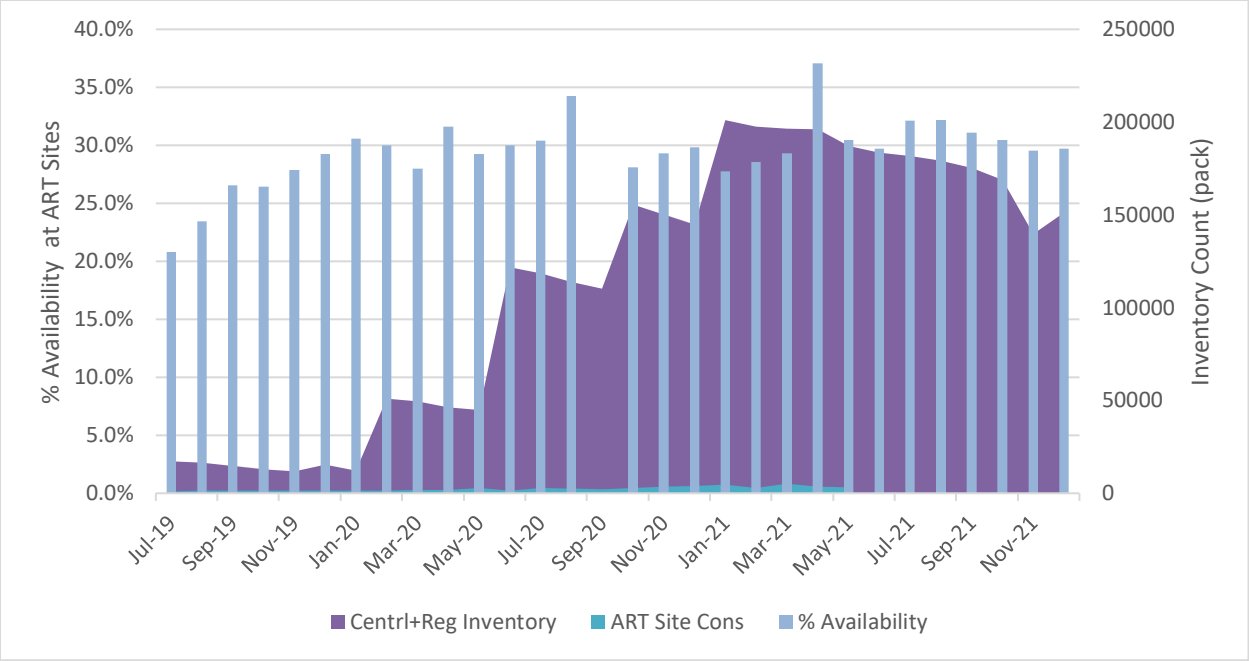


Figure 4: Chart showing the availability and consumption of ABC/3TC 600/300.

Similarly, after the proposed transition period, the uptake of DTG was very slow, while demand for EFV600 remained high. Consequently, there was an overstock of the DTG-based regimen while there was limited availability of EFV600. The situation only improved following the development and implementation of an acceleration plan after the initial target was missed, as shown in Figure 5.

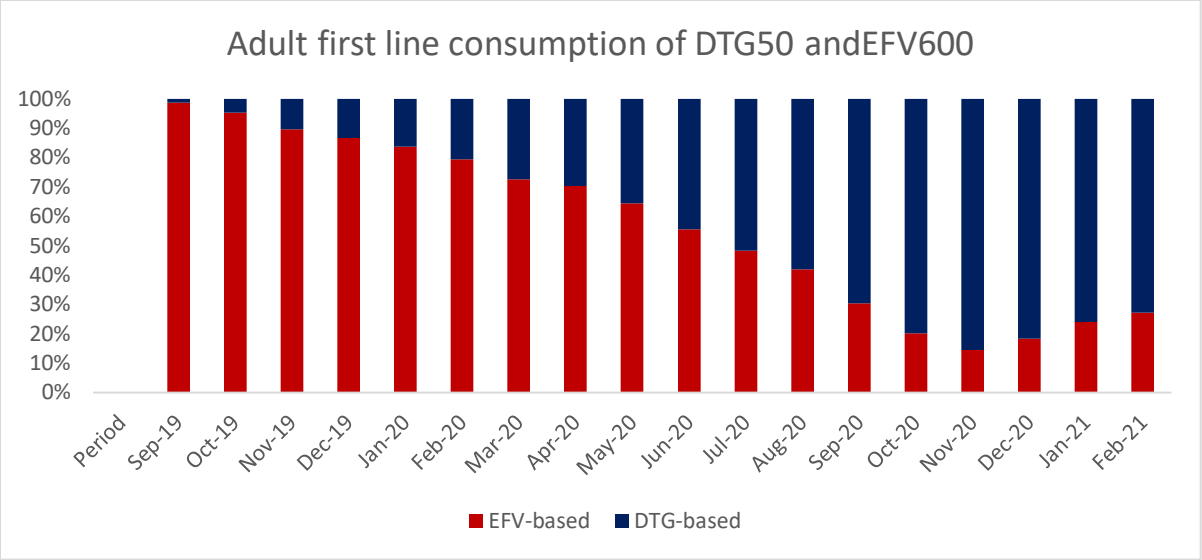


Figure 5:Chart showing consumption of DTG50 and EFV600

The 2019 update also introduced Lopinavir/ritonavir 40/10mg (LPVr 40/10) in October 2020. However, the actual consumption was extremely low compared to the forecasted consumption as shown in Figures 6 and 7. This led to 13,146 packs, estimated at $226,768.5, expiring in July 2022.

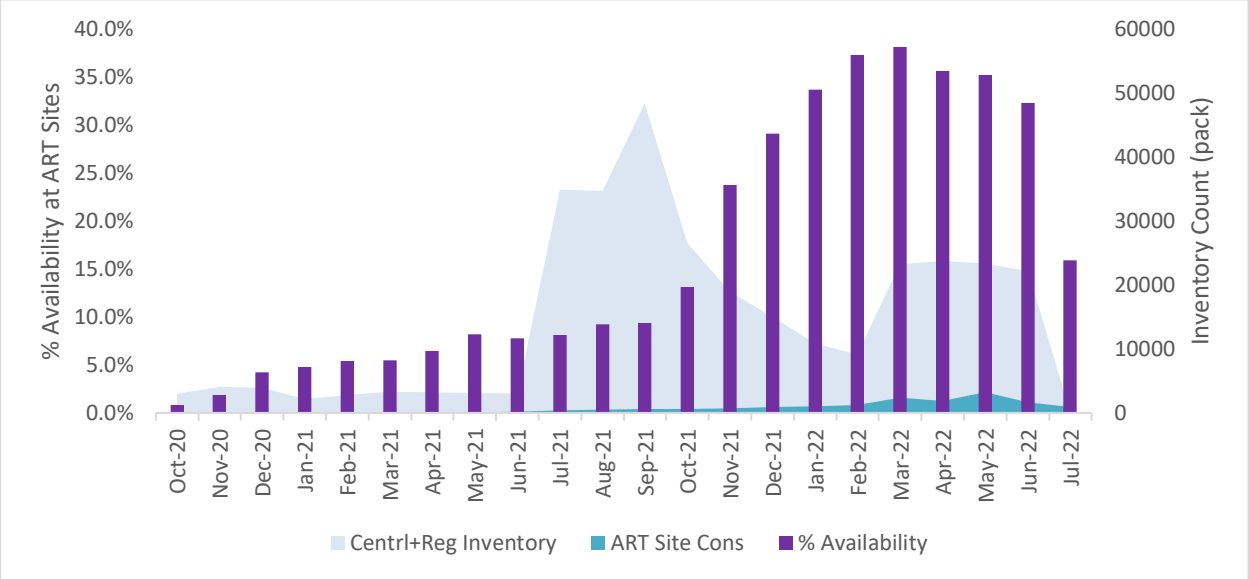


Figure 6: Chart showing the availability and consumption of LPVr 40/10

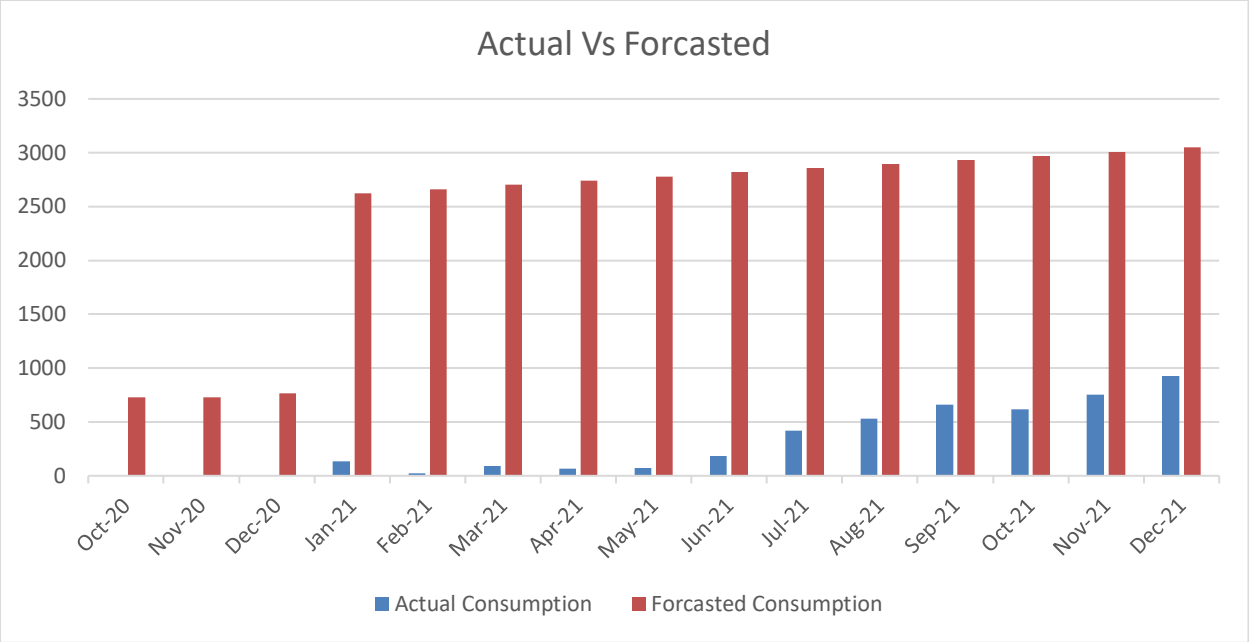


Figure 7: Chart showing the actual and forecasted consumption of LPVr 40/10

1.5.Problem Statement

Ghana, like most countries, updated the Antiretroviral Treatment (ART) guidelines in 2019 to introduce Dolutegravir 50mg (DTG50) and Lopinavir/ritonavir 40mg/10mg as the First line, First options for adults and children less than 20kg, respectively. Based on WHO recommendations, the country also updated the HIV testing algorithm in 2020 from a 2-tier to a 3-tier algorithm since Ghana has low (<5%) HIV-prevalence. These changes introduced new commodities into the supply chain and required some to be phased out. These resulted in some supply chain challenges including commodity stock outs, non-adherence to new guidelines among others. These situations have negative consequences for individuals and populations, as they increase the risk of opportunistic infections, treatment failure, viral resistance and death.

The study seeks to understand the contextual issues that impacted Ghana's recent HIV guideline transitions. The study will also seek to find ways to improve future transitions.

1.6.Research Questions

1. What are the challenges in supply chain management during HIV guideline transitions in low and middle-income countries?
2. What were the contextual issues in Ghana's supply chain management during the recent transitions?
3. Is there a need to develop a framework for supply chain management for HIV guideline transitions?

1.7.Research Objective

To document and disseminate important supply chain outcomes, and lessons learnt from recent transitions in HIV management guidelines in Ghana.

1.7.1. Specific Objectives

1. To identify the challenges in supply chain management during HIV guideline transitions in low and middle-income countries.
2. To identify the contextual issues in Ghana's supply chain management during the 2019 change in ART guidelines.
3. To identify the contextual issues in Ghana's supply chain management during the 2020 change in HIV testing algorithm

1.8.Study Justification

As new evidence emerges in HIV and other public health programmes, guideline transitions are inevitable. It is necessary for supply chain systems to respond to these transitions to ensure service continuity, minimise product losses and help attain epidemic control. This study will help identify the contextual issues that contributed to the transition-related commodity expiries and protocol non-adherence by service providers. The findings of this study would inform stakeholders, including national programmes, donors, implementing partners, procurement, and supply chain professionals, on some supply chain considerations to be incorporated in transition plans. This

would ensure the smooth introduction of new commodities and the phasing out of older ones while ensuring uninterrupted care.

2.0.METHODS

2.1.Study Area

The study was conducted in selected HIV service delivery health facilities across the country. Ghana, formerly known as the Gold Coast, obtained independence from Britain in 1957, making it the first sub-Saharan African country to do so. Since it transitioned to `multi-party democracy in 1992, Ghana has been regarded as one of the most stable countries in West Africa. Ghana is bordered on the north by Burkina Faso, on the west by Côte d'Ivoire, and on the east by Togo. It is located on West Africa's Gulf of Guinea, only a few degrees north of the Equator. The country is located slightly above the Equator, on the Greenwich meridian, which passes through Tema, a seaport about 24 kilometers east of Accra, the capital (Ghana Statistical Service, 2021).

Six thousand six hundred and six (6,606) health facilities provide HIV testing services, with 623 providing ART services as of December 2021 (NACP, 2021)**.**

Figure 8:Map of Ghana

2.2.Study Design

A mixed-method research approach (quantitative and qualitative) was used to elicit information on supply chain management challenges during HIV guideline transitions. The qualitative and

quantitative methods were developed separately, and the results from both methods were triangulated to come out with consolidated findings.

2.2.1. Qualitative method

The qualitative approach employed an in-depth interview of key stakeholders, including officers from the National AIDS/STI Control Programme (NACP), donors, implementing partners, procurement and supply chain professionals, and service providers involved in the supply chain management of HIV commodities. An interview guide was developed to elicit information from the respondents. This allowed for effective description and documentation of the following information:

- Documented plan of the new HIV treatment and testing guidelines.
- Guidance on activities with timelines for the transition process.
- Stakeholders' involvement and roles in the transition process.
- Stakeholders' roles in the processes of disseminating information about changes in treatment and testing guidelines.
- Pre -and post- new guidelines implementation challenges.
- Facilitators and barriers to the implementation of the transitioning process.

The in-depth interviews lasted for about an hour per study participant. The interviews were recorded and transcribed prior to data analysis.

A scoping review of the literature (drawn from Pubmed, HINARI, Cochrane and Embase) was also conducted to synthesize and map out the facilitators and barriers identified as well as proposed solutions during supply chain management of HIV guideline transitions.

2.2.2. Quantitative Method

A checklist was developed to guide the data collection process from selected health facilities within the study area. The data on the status of HIV commodities were retrospectively collected over a 12-month period per category (treatment and testing). The checklist was used to collect data on the following categories:

- Preparation towards Treatment Guideline Transitioning (June to August 2019)
- Treatment Guideline Transitioning Period (September 2019 to August 2020)

- Preparations toward transitioning to the new Testing Algorithm
- Testing Algorithm Transitioning Period (July 2020 - June 2021)

The quantitative data were collected using the Kobo Collect software. The data were exported to Microsoft Excel, where data cleaning and analysis were done. The results obtained were presented in tables, graphs, and charts.

2.3.Study population

The study population included Stakeholders of HIV service delivery as well as supply chain staff from the national to the facility level recruited for this study. The various stakeholders engaged for the study included:

1. Donor/Development/Implementing Partners (USAID, The GF, WHO, UNAIDS, Chemonics Ghana)
2. Programme Managers (National AIDS/STI Control Programme, Ghana AIDS Commission)
3. Warehouse managers from Imperial Health Sciences (IHS), Temporal Central Medical Stores (TCMS), Regional Medical Stores (RMS)
4. Recipients of care (PLHIV)
5. Healthcare workers / service providers (Prescribers, Pharmacists, Nurses).

2.3.1. Inclusion Criteria

Donor/development/implementing partners, Programme managers, supply chain officers, recipients of care, and health care providers involved in HIV service delivery and supply chain management who had occupied their current position for at least 36 months, including the period under review, and gave consent to participate were eligible.

2.3.2. Exclusion Criteria

Donor/development/implementing partners, Programme managers, supply chain officers, recipients of care, and health care providers involved in HIV service delivery and supply chain management, who had occupied their current position for less than 36 months, were excluded from

the study. Eligible participants who did not consent to participate or were not available during the time of data collection got excluded from the study.

2.4.Sample Size Determination

The country was zoned into three (3) divisions, namely, Southern (Greater Accra, Central, Eastern, Western, Western North, Volta regions), Middle (Ashanti, Bono, Ahafo, Bono East and Oti regions) and Northern (Northern, North-East, Savannah, Upper East, and Upper West regions) zones. One region from each zone was randomly selected. The Western, Ashanti and Northern regions were selected to represent the southern, middle, and northern zones, respectively. This approach ensured a nationally representative sample despite time and budgetary constraints.

The sample frame consisted of all ART and ANC/PMTCT sites in the selected regions, excluding the teaching hospitals. Teaching hospitals were excluded because they have a different protocol for ethical clearance, which would have delayed the data collection process and the entire study duration. The total number of facilities in the three regions was 1,533 (167 ART sites and 1,366 ANC/PMTCT sites).

Sampling was done as follows:

- Regional hospitals in each of the selected regions were purposively selected due to their high client load for ART and testing services.
- 70% of the required sample were selected from ART sites. ART sites (excluding regional hospitals) were sampled using a simple random sampling technique to allow an equal opportunity for selection. Although ART sites account for only 10.9% of the population, their contribution to HIV care and treatment is considered very high and the most impacted by guideline transitions.
- ANC/PMTCT sites proximal to the sampled ART sites were conveniently selected.

The number of facilities included in the study was determined using Cochran's formula below:

$$n = z^2 * \frac{p * q}{e^2}$$

Where:

n = the desired sample size,

z = set at 1.645, assuming a confidence interval of 90%

p = population proportion, set at 50%

q = 1 – p, and

e = margin of error, set at 10%.

The minimum study sample size was 68. The selected sample was allocated proportionally to the regions based on the total number of ART sites and ANC/PMTCT sites in each region.

Table 2:Distribution of Facilities by Region and by Facility Type

Region	Number of facilities	Ratio	Regional Hospitals included	ART Sites included	ANC/PMTCT sites included	Number of facilities sampled
Ashanti	694	45%	1	21	9	31
Western	393	26%	1	11	5	17
Northern	446	29%	1	13	6	20
Total	**1,533**	**100%**	**3**	**45**	**20**	**68**

2.5.Data Collection Tool

The project team designed a semi-structured interview guide to collect qualitative data. In-depth interviews (IDIs) with stakeholders were conducted either in-person or through virtual platforms using the developed interview guide. The quantitative assessments employed the use of semi-structured questionnaires at all levels of supply chain management in Ghana. The questionnaires were developed in both electronic (using kobo collect) and manual formats. All the data collection tools were designed in English.

2.6.Data Collection Procedure

Prior to the data collection process, permission was sought and obtained from all the sampled participants and heads of the selected health facilities. Respondents were allowed to schedule a suitable time that enabled full participation in the process of data collection.

Key Informant Interviews (KIIs) were conducted in July 2022. A total of 24 interviews were conducted. Sixteen interviews were conducted with individuals from 11 organizations and five from the Regional Medical Stores (RMS). Eight (8) interviews were conducted among Service Providers (SP) from the three regions.

Participants for the interviews were contacted via email through a letter introducing the study and requesting an interview. To accommodate the current climate of the COVID-19 pandemic, potential participants were given the option for an individual face-to-face interview or through a virtual platform. No response was received from one key informant and one service provider from the email request. All interviews, except one, were conducted virtually via zoom and phone call. The in-person interview ensured adherence to the Ghana Health Service (GHS) Ethics Review Committee guidelines for researchers during the COVID-19 pandemic by maintaining social distance and masking during the entire interview period. Verbal permissions were sought and recorded. The shortest interview lasted 15:45s and the longest 53:44s. The average time for all interviews was 29:13s.

2.6.1. Covid-19 Protocols

Due to the current pandemic, the Principal Investigator ensured all covid-19 prevention protocols were strictly adhered to during the data collection process. With the support of the NACP, study facilities were provided with commodities for Covid-19 prevention and other infections. Nose masks were distributed to all those involved in the study.

2.6.2. Quality assurance

To ensure data capture was of the highest standard, the team adopted the following strategies:

i. Training of data collectors: Prior to the data collection exercise, all data collectors were oriented on the objectives and scope of the exercise during a day's virtual training. The capacity

of data collectors was also built on the administration of manual and electronic data collection tools.

ii. Pilot testing of survey tools: On developing the data collection tool, it was pilot-tested to obtain valuable feedback on its application in real-life settings and provide an opportunity for fine-tuning.

iii. Daily review of collected data: The research team ensured that all quantitative data collected were reviewed at the end of each day to enable quick identification of potential gaps or errors that needed immediate rectification.

2.7.Data Processing and Analysis

2.7.1. Qualitative

All interviews were conducted in English, recorded, and transcribed verbatim. Transcripts and audio files were stored in computerized folders, with backup files generated in cloud accounts for security purposes. The individual who conducted the interviews audited for accuracy of all transcripts before data analysis. In a few instances, the transcriptions had to be revised to reflect the true content of the interview. When audio recordings were transcribed, any identifiers were removed, and pseudonyms or arbitrary generic codes were substituted. Therefore, to maintain anonymity of the respondents due to their easily identifiable position, specific positions occupied by KIs will not be disclosed in this report. Only the organizations which they represented were used subsequently to mask participants. Service Providers were identified by the regions they represent. Participants from RMS were also identified as follows.

- Ashanti RMS (RMS1)
- Northern RMS (RMS 2 and RMS 3)
- Western RMS (RMS 4 and RMS 5

The data was analyzed inductively with NVivo QSR software using approaches recommended by Braun and Clarke (2006). It involved:

- familiarization with the data

- gathering initial codes
- searching for themes
- reviewing themes
- defining and naming themes
- producing results

First, each transcript was read multiple times to familiarize with data. To gather initial codes, participants' responses were coded as top-level codes to broad categories like "engagement," "supply chain" and "challenges with implementation." Next, aggregate codes were created from each top-level code as initial codes. In the next stage, which entailed searching for themes, similar codes were regrouped into relevant categories and themes for presenting the results. The fourth step involved reviewing of themes. Five members of the project team did this at a meeting. In the fifth step, the themes were named and defined, after which the results were generated.

2.7.2. Quantitative

The quantitative data gathered, employed the use of semi-structured questionnaires deployed to service providers in 67 out of the 68 sampled facilities. One facility in the Western region could not be accessed during the data collection period due to a poor road network. The data collected were exported to Microsoft Excel, where data cleaning and analysis were done. The results obtained were presented in tables, graphs, and charts.

The analysis was done according to the following variables:

- commodity availability,
- expiry of commodities,
- HIV testing availability at ART and non-ART sites,
- adherence of service providers to the new treatment and testing guidelines.

2.8. Ethical Considerations

2.8.1. Ethics approval

The Ghana Health Service Research and Development Division granted the team ethical approval before the commencement of this study. The Director General of Ghana Health

Service also issued introductory letters to all participating facilities to facilitate the data collection process.

2.8.2. Informed Consent

Informed consent from the study participants was obtained prior to the interviews conducted as potential participants received and understood all the information they needed to decide whether they wanted to participate in the study. This included information about the study's benefits, risks, and institutional approval.

2.8.3. Voluntary Participation

Each respondent was informed before the interview that they were under no obligation to participate in the study and that participation was a voluntary decision; hence, they could withdraw from the study at any time if they wished.

2.8.4. Confidentiality and Anonymity

The study maintained subject confidentiality and anonymity throughout the data collection process as participants were assured that under no condition whatsoever would their names or any other contacts be linked to the data analysis and dissemination of the study findings.

2.8.5. Data Storage and Security

In accordance with nationally recommended data protection protocols and security, qualitative and quantitative data were stored in a password-protected file in locked cabinets with backup files generated in cloud accounts for security purposes and made only accessible to the principal investigator and supervisors. Study codes were assigned to each participant and used as a form of identification on abstraction forms, questionnaires and audio-recorded interviews. Data gathered were intended to be used for programmatic and publication purposes. The stored data collected would be destroyed after ten (10) years.

2.8.6. Compensation

Although participants were not compensated or paid for participating in the research, their inputs were recognized and appreciated. Participants are expected to benefit directly and indirectly from this study if findings are formulated into policies.

2.9.Conflict of Interest

The principal investigator and his team have no conflict of interest to declare.

2.10. Funding

This project is funded by the Global Health Supply Chain Group with support from the Ghana Health Service.

3.0.RESULTS

This section describes the demographic information of study participants and facilities and summarizes the study findings using the framework for the rollout of new regimen (Alhassan et al., 2020).

3.1.Description of study facilities for survey implementation and profile of organizations and respondents for key informant interview

3.1.1. Description of study facilities

The study was successfully carried out in all three selected regions. The quantitative component of the survey took place in 67 out of the sample 68 facilities representing 98.5%. One facility in the Western region could not be accessed during the data collection period due to a poor road network.

Of the 67 facilities, the majority (30) facilities representing 44.7%, were from the Ashanti region and the least (17) facilities representing 25.4% from the Western region.

Regarding facility type, 28 facilities (41.8%) were regional and district hospitals, 27 (40.3%) from health centers and the rest (17.9%) from polyclinics and CHPS centers.

For service provision, most (68.7%) of the studied facilities were ART centers and the rest were PMTCT and HTS sites. See table 3 below.

Table 3:Description of study facilities

Region	Number of facilities	Type of Facility				Services Provided		
		CHPS	Health Centre	Hospital	Polyclinic	ART	HTC only	PMTCT
Ashanti	30	3	11	14	2	22	7	1
Northern	20	3	7	9	1	12	3	5
Western	17	3	9	5	0	12	5	0

Region	Number of facilities	Type of Facility				Services Provided		
Grand Total	**67**	**9 (13.4%)**	**27 (40.3%)**	**28 (41.8)**	**3 (4.5%)**	**46 (68.7%)**	**15 (22.4%)**	**6 (9.0%)**

3.1.2. Participating organizations and respondents for key informant interview

A total of 24 interviews were conducted as follows:

Sixteen (16) Key Informants (KI) interviews were conducted with individuals from 11 organizations and five (5) individuals from the Western, Northern and Ashanti Regional Medical Stores.

Eight (8) interviews were conducted among Service Providers (SP) from the three regions. Table 4 contains a summary of the demographics of the participants.

Table 4:. Demographic characteristics of participants

Variable	**N**
Service Providers	
Gender	
Male	2
Female	6
Region	
Ashanti Region	3
Northern Region	2

Variable	N
Western Region	3
Key Informants	
Gender	
Male	11
Female	5
Organisation/Facility	
NAP+	1
GHSC-PSM	1
USAID	2
The Global Fund	1
WHO	1
JSI Care Continuum	1
NACP	1
Imperial Health Logistics	3
Regional Stores Manager	5

3.2.Contextual issues identified in Ghana's HIV supply chain management

3.2.1. Contextual issues related to the 2019 change in ART guidelines

The quantitative tool assessed facility awareness of the change in treatment guidelines, the period they became aware, training of service providers before implementation of the treatment guideline changes, the inclusion of a supply chain component in training, availability of the new treatment guidelines at the facility as well as adherence to the new treatment guidelines.

Majority of the ART facilities (97.8%) were aware of the changes in the 2019 HIV care and treatment guidelines and were trained (91.3%) prior to its implementation. All the trainings (100%) included supply chain component.

The study found that all the ART facilities assessed (100%) were implementing the treatment guidelines. The findings of these have been summarized in table 5 below:

Table 5:Assessment of the contextual issues in Ghana's Supply Chain management during the 2019 change in treatment guidelines

Variables	Frequency	Percentage (%)
Facility's awareness of the changes in the 2019 HIV care and treatment guidelines, N=46		
Yes	45	97.8
Not sure	1	2.2
Period facility became aware of the changes in 2019 HIV care and treatment guidelines, N=45		
April to June 2019	7	15.6
July to September 2019	17	37.8
October to December 2019	11	24.4
January to March 2020	5	11.1
Other[1]	5	11.1

Variables	Frequency	Percentage (%)
Training of service providers prior to implementation of 2019 HIV treatment guideline changes? N = 46		
Yes	42	91.3
No	4	8.7
Inclusion of supply chain component of the training, N=42		
Yes	42	100
No	0	0
Availability of New care and treatment guidelines, N= 46		
Yes	37	80.4
No	9	19.6
Adherence of Treatment guidelines (Facility implementation of new treatment guideline), N=46		
Yes	46	100
No	0	0

3.2.2. Contextual issues related to the 2020 change in HIV testing algorithm

The quantitative tool assessed facility awareness of the change in the HIV testing algorithm, period they became aware, training of service providers prior to implementation of the new testing algorithm, the inclusion of a supply chain component in the training, availability of the new treatment guidelines at the facility as well as adherence to the new treatment guidelines.

A significant proportion (15%) of facilities were not aware of the new HIV testing algorithm.

68.7% of health facilities were trained prior to the implementation of the new testing algorithm. A significant proportion of facilities (21.0%) were not implementing the new testing algorithm.

The findings are summarized in table 6 below.

Table 6:Assessment of the Contextual issues in Ghana's Supply Chain Management during the new HIV testing Algorithm in 2020

Variables	Frequency	Percentage (%)
Awareness of 3-Tier testing algorithm, N=67		
Yes	57	85
No	10	15
Training of service providers prior to implementation of the new HIV testing algorithm in 2020, N=67		
Yes	46	68.7
No	21	31.3
Implementation of 3-Tier Testing Algorithm, N=67		
Yes	53	79
No	14	21

Variables	Frequency	Percentage (%)
Period of initiating the 3-tier testing algorithm, N=49		
2020 – July to September 2020	15	30.6
2020 – October to December 2020	11	22.4
2021 – January to March 2021	11	22.4
2021 – April to June 2021	4	8.2
2021 – July to September 2021	7	14.3
2021 – October to December 2021	1	2

3.3.DTG-Based Regimen Transitioning

The number of clients on DTG-based and EFV-based regimens were assessed. 30% of clients on treatment had been transitioned to a DTG-based regimen as of March 2020, when the initial transitioning target of 65% was expected to have been achieved.

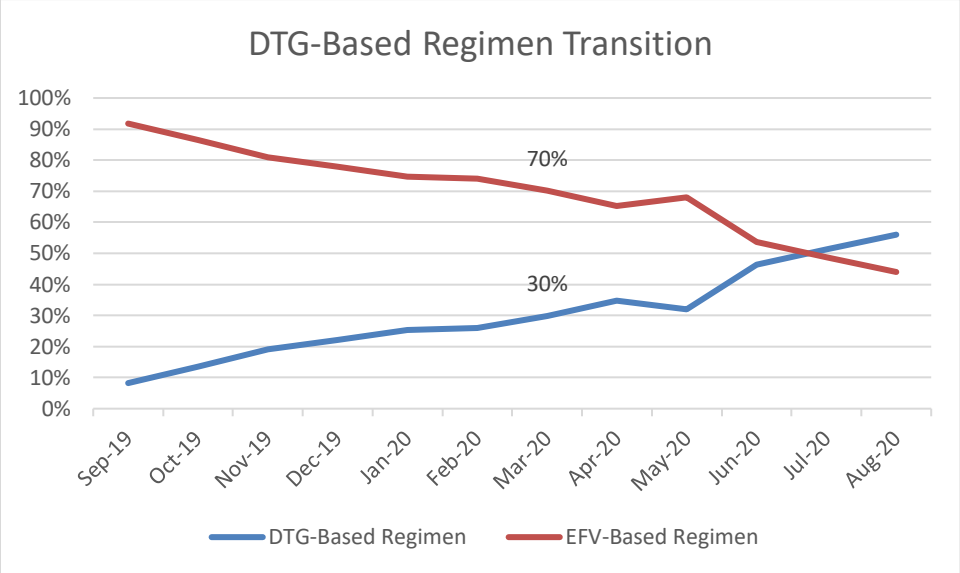


Figure 9: DTG-Based Regimen Transition

3.4.Product Availability During the Transition Period

Average stock-out days was used as a proxy to commodity availability at health facilities during the transition.

3.4.1. Availability of Adult ARVs During Treatment Guidelines Transitioning

The average stock-out days per month was observed to be high (18 days) for TLD at the beginning of the transition (September 2019). However, it reduced gradually 6 days in August 2020. The average stock-out days for TLE, however, ranged between 4 and days during the same period. The average stock-out days for ZLN, which was being phased out showed an upward trend from 11 to 18 days. Figure 9 highlights the above findings.

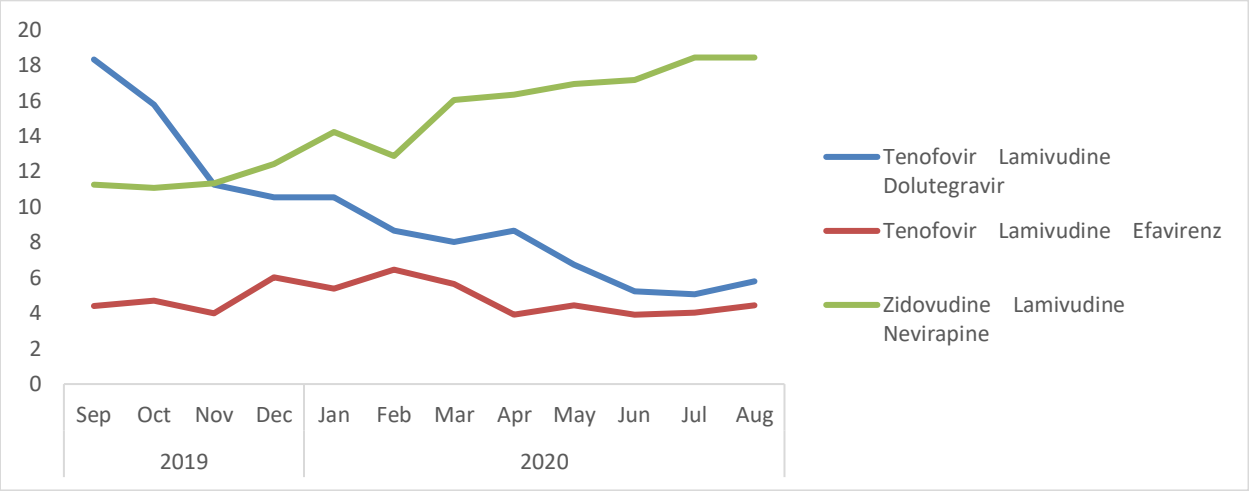


Figure 10: Trend-Average stock out days for adult ARVs

3.4.2. Availability of Test Kits During Testing Algorithm Transitioning

The average stock-out days per month was observed to be high (19 days) for both SD Bioline and HIV Syphilis Combo test kits in July 2020, when the guideline transition began. By June 2021, the average stock-out days had reduced to 8 days and 6 days for SD Bioline and HIV Syphilis Combo, respectively. Figure 10 highlights the above findings.

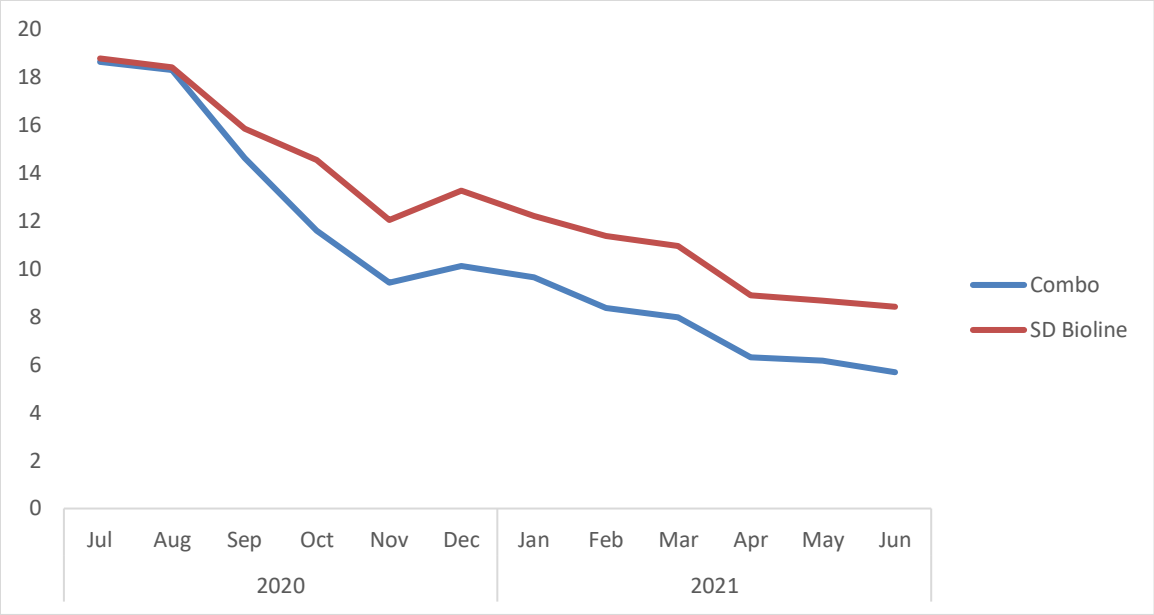


Figure 11: Trend-Average stock out days for HIV test Kits

3.4.2.1.Effect of Training on availability of HIV Commodities

The average stock-out days for trained facilities for both newly introduced HIV test kits showed a downward trend from 16 days in July 2020 to 3 days and 2 days in June 2021 for SD Bioline and HIV Syphilis Combo, respectively. For the untrained facilities, however, the average stock-out days remained comparatively high at 24 days and 17 days for SD Bioline and HIV Syphilis Combo, respectively. Figure 11 below highlights the findings.

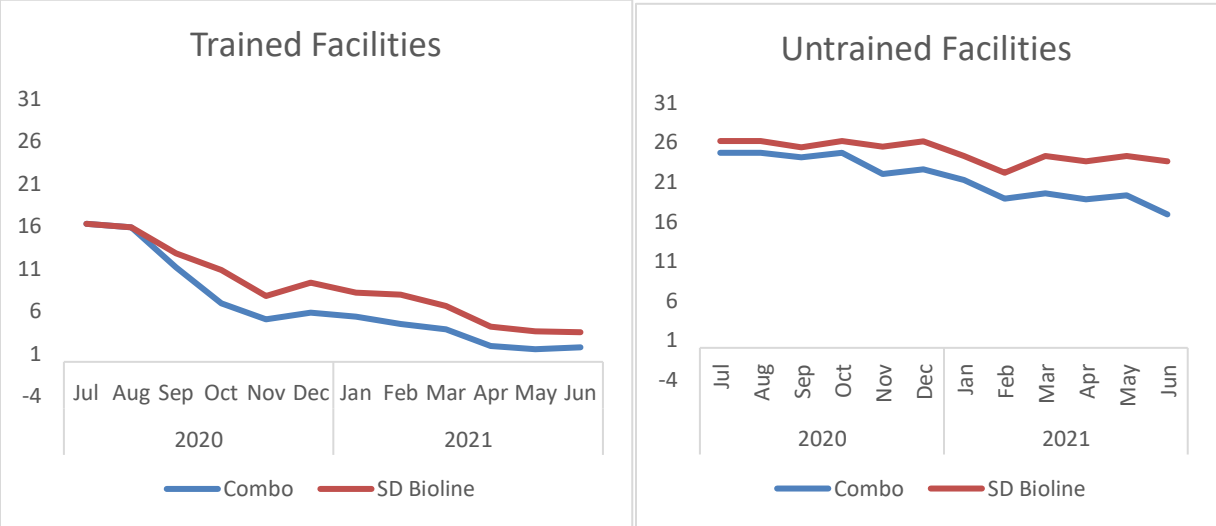


Figure 12: Trained vs Untrained Facilities- Average stock out days for HIV test kits

3.4.2.2.Effect of Guidelines Availability on TLD Availability at Facilities

There were no significant differences in the average stock-out days for facilities with guidelines and those without, as illustrated by figure 12 below.

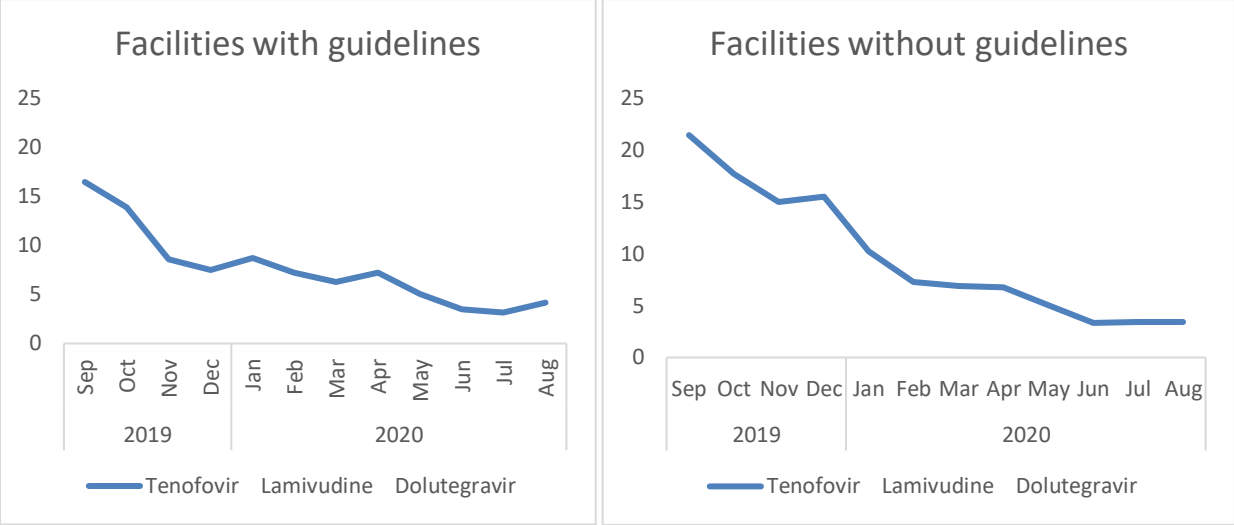


Figure 13: Effect of guideline availability on average stock out days of TLD

3.5.Expiry of Adult ARVs at Facilities from July 2019 to June 2020

The quantity of adult ARVs expiring during the transitioning period was insignificant. Table 7 below provides more details.

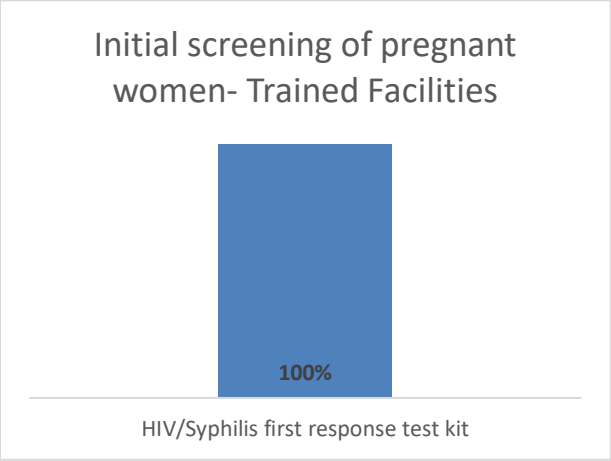
Table 7: Adult ARV Expiry at Facilities (July 2019 to June 2020)

Period	ABC + 3TC	DTG 50mg	EFV 600	Nev 200mg	TL	TLD	TLE	ADZ + 3TC	ADZ + 3TC + NEV
Sep-22	0	10	14	0	0	0	0	0	50
Oct-22	0	0	0	0	0	0	0	0	0
Nov-22	0	0	0	0	0	0	0	0	0

Period	ABC + 3TC	DTG 50mg	EFV 600	Nev 200mg	TL	TLD	TLE	ADZ + 3TC	ADZ + 3TC + NEV
Dec-22	0	0	0	0	0	0	0	0	0
Jan-23	0	0	0	0	0	0	0	0	0
Feb-23	0	0	0	0	0	0	0	0	0
Mar-23	0	0	0	0	0	0	0	0	0
Apr-23	0	0	0	0	89	0	0	0	0
May-23	0	0	0	0	0	0	0	0	0
Jun-23	0	0	0	0	0	0	0	0	0
Jul-23	3	0	0	0	0	0	0	0	0
Aug-23	0	0	36	0	0	0	0	0	0
Total	**3**	**10**	**50**	**0**	**89**	**0**	**0**	**0**	**50**

3.6.Effect of Training on Adherence to HIV Testing Algorithm

All trained facilities used the right kit for the initial screening of pregnant women, however, 5% of untrained facilities used the wrong kit.



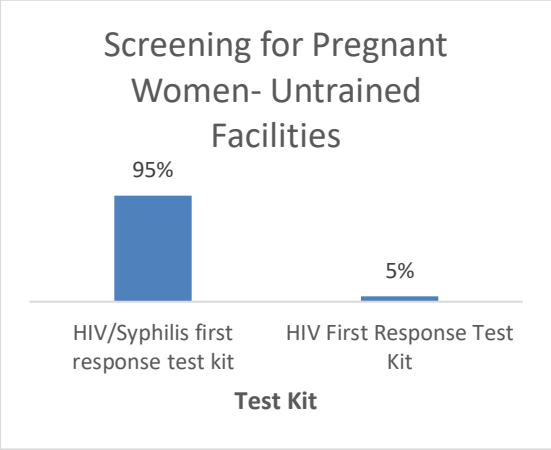


Figure 14: Screening of Pregnant Women, Trained vs Untrained Facilities

3.7.Summary of Key Findings from Quantitative Study

The quantitative study showed that 15% of facilities were not aware of the new HIV testing algorithm. 68.7% of health facilities were trained prior to the implementation of the new testing algorithm. 21.0% were not implementing the new testing algorithm. It was found out that 30% of clients on treatment had been transitioned to a DTG-based regimen as of March 2020, when the initial transitioning target of 65% was expected to have been achieved.

The average stock-out days per month was observed to be 18 days for TLD in September 2019 and reduced to 6 days in August 2020. That of TLE however ranged between 4 and days during the same period while ZLN, which was being phased out showed an upward trend from 11 to 18 days.

The average stock-out days per month was observed to be 19 days for both SD Bioline and HIV Syphilis Combo test kits in July 2020 and by June 2021, this had reduced to 8 days and 6 days for SD Bioline and HIV Syphilis Combo, respectively.

The average stock-out days for trained facilities for both newly introduced HIV test kits showed a downward trend from 16 days in July 2020 to 3 days and 2 days in June 2021 for SD Bioline and HIV Syphilis Combo, respectively. For the untrained facilities, however, the average stock-out days remained comparatively high at 24 days and 17 days for SD Bioline and HIV Syphilis Combo, respectively. There were no significant differences in the average stock-out days for facilities with guidelines and those without.

The quantity of adult ARVs expiring during the transitioning period was insignificant. All trained facilities used the right kit for the initial screening of pregnant women, however, 5% of untrained facilities used the wrong kit.

3.8.Study findings from key informant interviews

Findings are reported using the framework for rollout of new regimens (Alhassan *et al.*, 2020), which covers guideline development and transition process, supply of commodities, staff capacity

strengthening, service delivery, community acceptability, and uptake, and post-implementation surveillance.

3.8.1. Guideline development and transition process

The level of engagement during the transition varied among the participants interviewed. Some organizations were engaged in the guideline processes.

"My organization was part of those that were actually advocating to a change of a dolutegravir base regimen. We had advocated as far back as I think late 16, 17 late 2018 when within our organization we had heard that DTG was the new molecule that was doing wonders on the global market as we'd put it…so, when it did happen on the country level, we were part of the ART training. We were in the series of meetings with WHO and all the other partners when the discussion was ongoing to - for the country to change from nevirapine based regimen for the push of DTG" (IP1)

"We were part of the update and also subsequent reviews of the updated documents…So, we are involved erm throughout the process" (DP1)

On the other hand, many participants revealed their facilities/organisations were engaged after the revision of the testing and treatment guidelines. After being informed of the revisions, they engaged in various roles relating to advocacy and information dissemination, technical support, funding, and training during the implementation process.

"We are engaged…except that it's the form of engagement that has – that is a problem. So, the engagement comes in the form of let's say advocacy. WHO will have a meeting. They will say this is the new recommendation and countries should try and transition as early as possible." (NACP)

"We support the procurement of health products and then we provide also funds for supply PSM cost. So PSM cost that means storage, distribution, and distribution from the central level to the service delivery point…. we also support training, training cost, just to support the program to

make sure they train people...we also support the development and the dissemination of the tools, I mean, the revised treatment guidelines or you know the testing guidance policy" (DP2)

"We were just part of the advocacy but we were not driving the change… if we did go to supportive supervision and we realised that a facility was not practicing what it ought to be in terms of erm the new guidelines then we would chip in and then try to bridge the gap" (DP1)

Some organisations assumed responsibilities for implementing these changes in some selected regions in the country.

"in the Western region and now Western North and Ahafo region, we were leading the transition process…[for] health facilities to move from the old testing algorithm to the new testing algorithm. So, we do all the training…then follow the training update [and] on-site follow up visits… (IP2)

We also are part of implementation because we have implementing partners who are implementing for us, initially, it was in the Western Region and then now, in Western North and Ahafo Regions (DP1)

A few facilities and organisations (n=2) revealed they had not been engaged about the changes in the treatment and testing guidelines before its implementation. A regional medical stores manager describes the absence of training and information about the changes in treatment and testing regimen despite the order to request these new commodities.

"To be frank with you, we or we were not given any prior training to the transition…normally the way we do our requisitions [is] if the access comes to central level, then they do allocations with the various medical stores. So, they will ask you to request for those commodities. So, it was one of those periods that we were informed to request for Tenofovir, Lamivudine, Dolutegravir-that is TLD that they were transitioning from TLE to TLD so we should place allocation for Western region…the engagement was not adequate" (RMS 4)

One individual representing an organisation for PLHIV also described an absence of engagement about the revised guidelines. According to them, their office had still not been informed about these changes or reasons for the revisions.

"That issue about engaging people and then information and all that was completely lacking. So yes, we have many questions and then if one has to now convince our community about anything, I just – I have to read about it all. But at least we should be able to know what is happening, why, so that we can explain and then encourage people to embrace you know, whatever new is coming on" (NAP+)

3.8.2. Supply of commodities

Participants described the supply chain conditions during the transition process. Two subthemes were discovered under this theme.

Commodity availability: The availability of the new medication regimen varied according to the participant interview. For some participants, initially, there were challenges with commodities that impacted the prescription of the newer commodities.

"…when people started transitioning from the old regimen which is called TLE onto the new regimen which is called TLD there was a lot – there was enough quantities of TLE, the old regimen than for TLD, the new regimen. So, when a facility says that 'oh I have a lot TLE but few TLD and you are asking me to transition my patients from TLE onto TLD, if I should transition then I will get stock-out and we will move back onto TLE. So, it doesn't make sense to transition the people onto TLD'…there were a lot of TLEs few TLD but overtime from the national level a lot of TLD were supplied and then the TLE supply too reduced overtime…it's way way much better now" (IP2).

Other participants in other regions and organisations did not report challenges with availability of the new regimen during the initial implementation period.

"So, commodities were available anyways. The two were available. And so, they were taking the

Teno-Lami-Efavirenz and you know for new clients that were coming they started them with the Teno-Lami-Dolutegravir And so, I think gradually they were able to transition them" (RMS 1)

When it came to the availability of testing kits, there were, and still remains, challenges with commodity availability.

"The first test for the pregnant women was different from the test for the general population and the test kit for pregnant women are not supposed to be used for general population. So sometimes you could have shortage in the first response for general population, you have a lot of first response for pregnant women but you cannot use it for general population. And that challenge still persists…where there is a lot of combo which is for the pregnant women, the normal first response is in short supply but you cannot use the combo for the general population" (IP2).

"When you also take something like the HIV testing-testing kit, there was also this initiative to say that this particular one will be used for pregnant women and then this particular one will be used for the general population. But it got to a time and we realised that what we said will be used for the general population were rather being consumed more and what will be used for the pregnant women was not being consumed. So, it got to a point we realised that those ones were rather plenty. The ones for the pregnant women were rather plenty in the system with the risk of being expiring. While the one supposed to be for the general population was [in short supply]" (IP1)

"Probably because of my – the demands at my end. Our site is a referral site to serve other communities around us. So, there is a lot of pressure on our SD BIOLINE. Because every case that is referred, they need to do a confirmatory test. Ahaa. So, there is some level of pressure on it after it's referred. So that is why sometimes we run out of it" (SP2, Western Region).

Expiries/wastage: There were very few accounts of expiries and/or wastage during the transition period. Many facilities had a plan to phase out the legacy commodity to minimise the waste and expiry

"the country had a plan for transitioning… I know that as at now, there's still some people on TLE and others on TLD because I think the idea was to have a gradual transitioning even though, we would have preferred a faster transition but the country sort of phased it off to reduce wastage when it comes to the TLE" (DP1).

"at the central level, expiries are to the barest minimum unless it can't be used again because it is out of use. But where we can use it, we make sure it is sent out. Also, we practice the FEFO system – the stock rotation of FEFO – first expiry first out. [Interviewer: okay]. So, using that we have a ERP system – a management system that supports the human effort whereby if stocks are expiring it keeps you alert. If they are close to expiring let's say a year it is flagged. So, you know that this product is flagged. If an order comes there is no way the order will pick something that is 2 years should there be some that is expiring a year or less. So, all these things come into force and then it prevents issues of expiring stocks and all those things." (CMS2).

"We use the stock levels to also determine erh the - to minimize…the expiries… before we bring in and start issuing to you, we will make sure that you've used all of it – a lot of it… we will tell you that okay based on what is happening now, [for] your next stock you have to request for this particular new one and then we will give you…as much as possible we try to let them exhaust that" (NACP)

"During the transition, because RMS we became aware that we have new treatment regimen. we were not really requesting from the central level; I'm talking about the old regimen… So, we didn't have much expiry of the old-yeah yea we didn't have much expiries" (RMS 2)

"We never encountered any expiry with the TLE because they phased it our gradually. And even it got to a point the TLE that they brought were quite few. So, as I said initially, we were just using the TLE and they were just augmenting it with the erh erh little TLD that they brought. So, we never had any expiries for the TLE" (RMS 4)

In some instances, legacy commodities were redistributed and used in other ART facilities to minimize expiries and wastage.

"The other facilities when they have drugs which is heading towards expiry. They do call us because we have a chunk number of erh HIV clients in the facility. They push their [commodities]– if they don't push it here, they send it to teaching hospital… So, most of the nearby facilities when they have drug which is heading towards let's say 5 months to 6 months to expire, they do call our pharmacist 'Oh we have this medication. Six to five months it will expire. What do we do?' We let them bring it. Then we use it for them" (SP1, Northern Region)

"Most facilities consumed almost all the TLE before transitioning onto the TLD… the control programme also said that if we are over stocking TLE, report to the regional medical and they will pick it up… all those over stock [were] sent back to the regional medical store which was picked up back to the national level. So that's-that's the main strategy that was put in place to avoid the TLE getting expired in the facilities…the National AIDS Control programme was able to mop out the overstock from facilities through the RMS back to Accra" (IP2)

"recently we - they delivered tenofovir-lamivudine dosages to us and they were expiring in October. So, when we noticed that, we took more of them so that we can discard that together with the dolutegravir" (SP 7)

There were, however, some supply chain issues that were experienced in the initial implementation phase with regard to forecasting

the ones [commodities] that we say we are phasing out, the consumption of those ones are much much higher than the consumption of those that we are actually phasing in. So, we realised that although we had forecasted…that within this particular time we are going to be phasing [out] these products… what we said will be consumed less was rather being consumed more. Such that it got to a point, those ones were rather getting stocked out and then the ones that we say…we will be phasing in rather were-were the ones that we had overstocks and we could risk expiring. (IP1)

However, the desire to see the transition quickly to the new medication regimen accounted for some shortages of the new commodities and expiries of the old commodities.

"There were also issues around managing the old medication - the old stock… that led to avoidable erm expiry… we had a situation where there were shortages of some commodities in certain places compared to others. While other places will have expiries of some of the old medication… the initial plan and guidelines was that clients will be given the option to move and some will not move. And so those that will not move or will take time to move were factored into the erh what do you the-the procurement plan…but when it got to implementation, there was a push and they ended up having almost everybody transitioned completely – whole scale…So, we had a situation where there were shortages…there was more need for the new medication than had been projected and then there will be expiries for the old one" (DP3).

"we had a lot of the TLE so we thought we have to um dispose it off because it will expire…even as we speak we still have TLE…we wanted to dispose of the TLE before, because it will expire…so we were reluctant to um use the TLD…[but] they were on us that we should try to transition…and we were also thinking about the expiring of the cure… I'm very sure some [will] expire" (SP8, Western Region).

3.8.3. Staff awareness and capacity strengthening

Many participants interviewed were aware of the changes in treatment and testing guidelines. A majority of the service providers learned about the revision in testing and treatment guidelines through training to prepare their facilities to transition to these guidelines. All but one service provider indicated they were aware of the changes. Some facilities became aware of the changes after receiving a letter from the Director General of the Ghana Health Service indicating this transition. A few quotes from respondents on awareness:

"We had erm documentation … they brought letters as to these changes. They brought a memo to us from I think from director general or so" (SP8, Western Region)

"the whole team was invited to a workshop and then we were introduced to the treat all policy…and then the three testing and then the erm DTG-base regimen (SP7, Ashanti Region)

Information about the new guidelines was also disseminated through print media in health

facilities.

"With the new treatment guidelines, there-there was some leaflets, posters, all over which they gave to us. And we share to the various units and the wards. Even currently when you go to our OPD some of the literatures are posted there and the wards (sic)" (SP1, Northern Region)

"at the end of the workshop, you know they hand over materials, brochures, posters, treatment guidelines and sometimes even softcopies of these things are posted on our pages – Our ART pages. Ahaa. So, we have all those materials… sometimes the presentations are even posted on the page just so that it will help us on the training" (SP7, Ashanti Region)

There were, however, deficiencies in the dissemination of information on the transition to health facilities. Some facilities were trained about the changes, while other facilities were not given information about the transition to a newer testing and treatment guideline.

The other issue is training. You cannot be training people because the people are a lot. In fact, as we are moving on there are 6000 PMTCs sites, over 600 ART sites. Each of the teams is not one person…So if you have to always revise…you need to train all these people again. And sometimes, there's – , there is no money for that. So, you are relying on partners who don't have money. And sometimes they will tell you do limited dissemination. But as you do it, there are gaps already. So, you go onto the field and people are not following the guideline and it leads to gaps in quality of the service and implementation. So, is a – that is one of the issues-problem. It introduces challenges, training issues (NACP)

"when we go on the field…we realised that there are facilities who are not too aware or are not doing what-what it ought to be…that was in the early stages…especially when it came to the testing algorithm. There were some that were not doing the three tests al-algorithm especially when it came to the lower-level facilities. Usually when we went to the big facilities, they were aware and they were doing it. But when you went to the lower-level facilities, they were not-not aware" (IP1)

Service Providers varied on their assessment of the training they received for the transition to the new testing and treatment guidelines. For some participants, the quality and quantity of the training was adequate for them to transition to the new guidelines.

"We were given enough time to go through the training and then we had the hands-on practical on how to do the testing especially with the first test kits that were being added…the main focus was on the treatment regimen and then the main testing algorithm. So, to me for my opinion I think the three days was enough time to be able to do them" (SP2, Western Region).

"It was very interactive and whatever challenges that could hinder the implementation of the new protocols, people were allowed to voice them out then they were addressed or some reassurance [given]" (SP3, Northern Region).

"Some of the skills we were equipped with was how we will counsel our clients to access [check] the new molecule we were going to use. Because you know some of our clients have been on this old regimen for years and they were even stable clients…you needed to do a lot of counselling for them to accept the new regimen. So that was counselling skills – adherence counselling skills" (SP5, Ashanti Region)

Very few expressed dissatisfaction, particularly about the training period, and would have preferred more sessions.

"The timing it was very short… It was very important workshop… at least 4 days it could have been okay so that we take our time so that we'll [not] rush over some of the activities. And you know mostly our - some of our staff they are aging…when they sit for a while – when they listen for a something for a long time, they lose concentration" (SP1, Northern Region)

"They should have – they should have extended the days. Because they wanted us to do more practical's work. But we couldn't get the time to do more practical work" (SP4, Western Region)

Some KIs believed the training was inadequate as it was limited in the number of health facilities

chosen, which had implications for the transition process.

"So erm the training I will say there was a lot of back and forth about the training…the feedback that I get generally is that the training was not sufficient and erh erm was inadequate… mostly in terms of the number of erm - sometimes it's even with the-the timing. If you take the testing erm I think it has to do with the number of facilities that have been trained" (DP3).

"Not all the ART sites were trained. So those who were trained, they were aware that now there is transition. Okay? There is a new treatment regimen. But for the smaller ART sites who were not trained initially, they didn't know about it. So, for them, they were not requesting" (RMS 2).

Only one service provider said they had not received any training on the new testing and treatment guidelines.

"the focal person for the municipal… I spoke to her last week concerning this… that I wanted them to come and train us on that and that but she also said she too has been talking with [someone] at the regional level…and informed me that er first week in August he'll do his best and come there with his team… to train or give some measures so that we can know how to go…about the counselling, the treatment and how we can even get us to the e-tracker so that we can know what to do" (SP6, Ashanti Region).
remarkably high

3.8.4. Community acceptability and uptake

Client reluctance: The majority of service providers and some key informants described a reluctance among clients to transition from their existing treatment regimen to a new one during the initial phase. This had an impact on some requests from the regional medical stores for the new treatment regimen.

"Some facilities said clients were reluctant to taking…the new product because they were just used

to term TLE. People were apprehensive because of you know side effects of the medication. So, when we were starting it wasn't that smooth…there was some hesitancy in taking it…they [facilities] were not even requesting at all. So, some were not picking at all. Then they were saying they have now enough TLE and clients preferred that…so it took some time before we were able to get everybody on board" (RMS 1).

"Some clients of course were reluctant. They-they are afraid that they have settled on this one. Whatever side effects they might have experienced in the early stages of taking their medication they have been able to overcome that. And then trans - changing them from that medication onto another, erm just a few I know were not comfortable" (SP2, Western Region).

"The main challenge was with the treatment... acceptance of the new regimen… by our clients. As I already said, some of our clients have been on this old regimen for a long time and they were stable, they were fine. So, they thought that they didn't need to switch" (SP5, Ashanti Region)

In some cases, the reluctance by clients was attributed to uncertainties about the effect of the drug on pregnancy.

"There was an issue of the drug not being conducive during pregnancy-with that being the first trimester pregnancy. So, there was that hesitancy to use it" (IP2).

"There were those that were using the TLE. There was this-I wouldn't know whether it's misconception or there was-there was no clarity when it came to women of childbearing age when it came to pregnant women in the use of TLDs. So initially when-when this started, we realised that the-the old regimen that was the TLE was-was being consumed at a faster rate than what we had anticipated for-for TLD." (IP1)

"…I refused to go on dolutegravir. They said I have passed that [reproductive] age. I said, NO, it is not a matter of being past that age. I really need to understand this thing. I really need to speak to or let young people know or people who are still in the reproductive age know that it's safe or

whatever and all that" (NAP+)

3.8.5. Post-implementation surveillance

All service providers reported that they received supportive visits and had avenues to relay concerns during the transition process.

"We have a notebook which we have in the various wards and at the OPD...for complaints about the- medication, testing. Ahaa so if you have any this thing about the testing or the medication or any complain about the ART team or any concern about ART, we indicate it in the book…and all the various wards they have it" (SP1, Northern Region).

"I remember that erm some time back [some NACP staff] came to the facilities. I'm not too sure when but I remember during the transition when-when we started. They came around to monitor and probably erm as a supervision visit kind of – supporting supervision visit to find out how we were going through the transition… and find out if we were going through any challenges" (SP2, Western Region).

Organisations that were responsible for the transition processes also engaged in continuous monitoring and supervision.

"After you have done [training] you embark on monitoring and supportive supervision. You will notice that though you have disseminated, there are gaps. People are not following it. So you continue to fill the gaps…so we need to do a continuous dissemination through monitoring and supervision" (NACP)

3.9.Summary of key findings from Qualitative study

Some of the stakeholders interviewed were engaged in the guideline development processes. Many more were however engaged after the revision of the guidelines. After being informed of the

revisions, they engaged in various roles relating to advocacy and information dissemination, technical support, funding, and training during the implementation process. A few stakeholders (representing the PLHIV, and the commodity managers) however revealed they had not been engaged about the changes in the treatment and testing guidelines before its implementation. Service providers particularly learned about the changes through the training organized, or through the letter from the Director-General of the Ghana Health Service, indicating these changes. Information about the new guidelines was also disseminated through print media in health facilities. There were however some facilities who had no information whatsoever about the transition to a newer testing and treatment guidelines.

For some participants, the quality and quantity of the training was adequate for them to transition to the new guidelines. Very few would have preferred more sessions, while others believed the training was inadequate as it was limited in the number of health facilities chosen, which had implications for the transition process. One service provider had not received any training on the new testing and treatment guidelines.

On commodity availability, some of those interviewed reported on challenges with commodities that impacted the prescription of the newer commodities. Other participants in other regions and organisations did not report challenges with availability of the new regimen during the initial implementation period. Availability of test kits was however a challenge to all interviewed.

There were very few accounts of expiries and/or wastage during the transition period. In some instances, legacy commodities were redistributed and used in other ART facilities to minimize expiries and wastage.

Most service providers and some key informants described a reluctance among clients to transition from their existing treatment regimen to a new one during the initial phase. This had an impact on some requests from the regional medical stores for the new treatment regimen. In some cases, the reluctance by clients was attributed to uncertainties about the effect of the drug on pregnancy.

With regards to post-implementation surveillance, all service providers reported that they received supportive visits and had avenues to relay concerns during the transition process. Organisations that were responsible for the transition processes also engaged in continuous monitoring and supervision.

4.0. DISCUSSION

As new evidence emerges in HIV treatment for better health outcomes, it is important to focus on treatment guideline transitions especially the supply chain systems. This is necessary to ensure service continuity, minimise product losses and help attain epidemic control. This study was to document and disseminate important supply chain outcomes, and lessons learnt from recent transitions in HIV management guidelines in Ghana. The recent transition which included the use of dolutegravir, and the three-test algorithm was plagued with some gaps, however, useful lessons learned can be applied to future transitions to improve efficiency.

Generally, the study found that Ghana was affected by the uncertainties around the safety of dolutegravir, which influenced client uptake of the commodity. Although the initial treatment transition target was to transition 65% of clients on treatment (CoT) to DTG-based regimen by March 2020, the survey indicated only 30% of CoT had been transitioned. The limited involvement of some key stakeholders during the revision and the implementation of new treatment guidelines may have contributed to the slow treatment transitioning. These findings are consistent with (Dorward *et al.*, 2018; Twimukye *et al.*, 2021; Zakumumpa *et al.*, 2021) studies which identified slow transition of DTG among LMICs and in Uganda to be due to uncertainties regarding the drug safety and poor stakeholder engagements during such transitions. Also, Scoff et al identified facilitators of effective HIV care transitions to include collaborating with stakeholders beyond the organization and generating buy in among staff (Scott *et al.*, 2017).These findings are also similar to the previously discussed ART commodity and guideline transition experiences of other lower and middle-income countries. Like Uganda and South Africa (Alhassan et al., 2020).

The slow uptake of the newly introduced ARVs was also because of the reluctance of some service providers to transition clients to newly introduced ARVs due to uncertainty about the adequacy of stocks of the newly introduced ARVs to meet demand.

ARV expiries during the transitioning period were insignificant, as per the findings of the survey and the key informant interviews. Legacy ARVs continued to be used until stocks were depleted. This finding is consistent with a study conducted in Uganda where ART Clinicians/Prescribers perceived some shortages associated with the new drug hence decided to continue with the old

regimen to ensure stocks are depleted before they switch clients (Zakumumpa *et al.*, 2021;Dorward *et al.*, 2018).

Generally, the availability of the newly introduced ARVs and test kits was low at the facilities at the beginning of the transition and improved over time. Average stock-out days for the newly introduced test kits (HIV Syphilis Combo and First Response) remained high throughout the transitioning period for untrained facilities. The frequent stock-out of test kits in untrained facilities could have resulted in missed testing opportunities and may also drive facilities not to adhere to the testing protocols. Gils et al identified stocks outs as a common practice during drug transitions which could increase the risk of antiretroviral resistance, treatment failure, discontinuation of therapy as well as morbidity and mortality (Gils *et al.*, 2018).

Also, the study found majority of ART facilities (98%) indicated their awareness of the treatment transition. However, 15% of all facilities were not aware of the change in the testing algorithm. All facilities (100%) that were unaware of the change in the testing algorithm were non-ART sites (PMTCT, HTS). This is because non-ART sites were not part of the initial training organized for service providers.

Trained facilities also performed relatively better than untrained facilities when adherence to the new testing algorithm was assessed. All trained facilities (100.0%) adhered to the new testing policy, whereas 5% of untrained facilities did not. The training done prior to and during the transition did not represent the different levels of healthcare where HIV services were offered. Non-ART sites (PMTCT, HTC) were not included in these trainings, which was reflected in their performance (high average number of stock-out days and 5% of facilities not adhering to testing policy). This findings is not different from what was experienced in Swaziland where trained facilities proved to be more effective in HIV service delivery than non-trained facilities after transitions (Kamiru *et al.*, 2009; Bennett *et al.*, 2015).

Key facilitators during the implementation of the treatment and testing transitions include the following:

- Stakeholder engagement and buy-in: In as much as not all key stakeholders were engaged on the transitions, stakeholder engagement was perceived as one of the key factors that facilitated the transition process. Stakeholders came together to develop a DTG acceleration plan which

hastened the initially slow pace of the transition. The plan included, among others; a directive from the Director General of the Ghana Health Service to facilities to implement the new treatment guidelines; restriction of the quantity of TLE in distribution from the central level to health facilities; improved collaboration between all stakeholders. It also recommended using all available opportunities to train and provide supportive supervision on the transition.

- Supportive supervision: Implementing partners and service providers indicated the benefits of supportive supervision during the transitions. These provided avenues for facilities to relay concerns during the transition process and also allowed capacity gaps to be addressed.
- Commodity re-distributions: The NACP collaborating with partners, facilitated the re-distribution of commodities to prevent expiries and stock-outs in some facilities. This is one of the reasons for the low expiries of legacy commodities reported.
- Benefits of DTG-based regimen: Despite the initial apprehension about DTG-based regimen, the benefits of the medication, including reduced pill burden and fewer side effects, contributed to improved uptake. Also, a study by the Ghana Health Service to monitor the outcomes of DTG in the country provided some assurance to service providers and clients regarding its safety and efficacy.

5.0. CONCLUSION

The study highlighted the gaps as well as opportunities for improvement in the recent transitions in HIV treatment and testing in Ghana. The findings confirmed the limited engagement of some key stakeholders before the implementation of the transitions and the initially slow pace of the treatment transition. It emphasized the importance of training for driving awareness and adherence to new treatment and testing policies. In addition, the study highlighted the importance of stakeholder engagement and buy-in, supportive supervision, commodity re-distributions and the benefits of DTG-based regimens to clients as the key facilitators during the implementation of the treatment and testing transitions.

6.0.RECOMMENDATIONs

- Trainings must be prioritized in future transitions. Coverage should transcend all levels of the health system to include service providers at central level warehouses (CMS), regional medical stores and all service delivery points offering HIV care and treatment services. Multiple training delivery methods (workshops, on-the-job trainings, virtual instructor led, e-learning) should be used to widely disseminate and sustain trainings.

- Quarterly monitoring and supportive supervisory visits should be conducted to Regional Medical Stores and SDPs to assess adherence to new treatment guidelines and supply chain practices. This will afford the opportunity to promptly address any concerns and inform remedial actions to facilitate the guideline transitioning process.

- Stock monitoring and a responsive commodity re-distribution mechanism should be in place to respond promptly to supply chain interruptions triggered by guideline transitions. Regional health directorates must support facilities within their jurisdictions to promptly re-distribute commodities in excess supplies or at risk of expiry to ensure equitable distribution of HIV commodities across service delivery points.

- Continuous stakeholder engagements before and during guideline transitions is recommended to facilitate the transition process. The National HIV program, prior to future guideline transitions should collaborate with donors, implementing partners and other key stakeholders to develop a comprehensive costed transition plan. Transition plans must be shared all stakeholders. A technical working group should be formed with clearly defined mandate to monitor the progress of implementation of the transition.

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8.0.APPENDICES

8.1.APPENDIX 1 – Qualitative Interviewing Guide

- **Target 1: Implementing/Donor partners/CSOs (NAP+) – NAP+, GHSC-PSM, USAID, GF, UNAIDS, WHO, Equip Gh, Care Continuum, WAPCAS**

1. To what extent were you aware of the treatment and testing transitions?
2. What did the transitioning process entail? (what you knew about the process)
3. Are those processes documented in a plan and did the plan have clear guidance on activities with timelines?
4. How well was this plan disseminated?
5. How involved were you in the treatment and testing guideline transitioning process?
6. How would you assess the level of collaboration between stakeholders to manage recent guideline transitions?
7. What were the challenges, if any, with the current treatment and testing guideline transitions (contextual issues, forecasting and supply planning, procurement, training, printing, financing gap, dissemination of guidelines etc.)? *Ask follow on questions on specific challenges.*
8. What were the opportunities or successes, if any, associated with the transitioning?
9. What suggestions would you make to improve future HIV guideline transitions?

- **Target 2: National level stakeholders (NACP, SSDM, P&S, GAC)**

1. To what extent were you aware of the treatment and testing transitions?
2. What did the transitioning process entail? (what you knew about the process)
3. Are those processes documented in a plan and did the plan have clear guidance on activities with timelines?
4. How well was this plan disseminated?

5. How involved were you in the treatment and testing guideline transitioning process?
6. In your view, how would you assess the adequacy of plans put in place to manage existing/legacy commodities?
7. How would you assess the level of collaboration between stakeholders to manage recent guideline transitions?
8. What mechanisms were put in place to make central and regional level warehouses more responsive to commodity availability challenges in-country?
9. What mechanisms were put in place to prepare for and monitor the transition?
10. What were the challenges, if any, with the current treatment and testing guideline transitions (contextual issues, forecasting and supply planning, procurement, training, printing, financing gap, dissemination of guidelines etc.)? *Ask follow on questions on specific challenges.*
11. What were the opportunities or successes, if any, associated with the transitioning?
12. What suggestions would you make to improve future HIV guideline transitions?

- **Target 3: Warehouse managers (RMS, IHS, TCMS)**

1. To what extent were you aware of the treatment and testing transitions?
2. What did the transitioning process entail? (what you knew about the process)
3. Are those processes documented in a plan and did the plan have clear guidance on activities with timelines?
4. How well was this plan disseminated?
5. How involved were you in the treatment and testing guideline transitioning process?
6. In your view, how would you assess the adequacy of plans put in place to manage existing/legacy commodities?
7. How would you assess the level of collaboration between stakeholders to manage recent guideline transitions?
8. What mechanisms were put in place to make central and regional level warehouses more responsive to commodity availability challenges in-country?
9. What mechanisms were put in place to prepare for and monitor the transition ?

10. What were the challenges, if any, with the current treatment and testing guideline transitions (contextual issues, forecasting and supply planning, procurement, training, printing, financing gap, dissemination of guidelines, commodity availability etc.)? *Ask follow on questions on specific challenges.*
11. What were the opportunities or successes, if any, associated with the transitioning?
12. What suggestions would you make to improve future HIV guideline transitions?

- **Target 4: Service Providers (SC focal persons, Other HCW)**

1. To what extent were you aware of the treatment and testing transitions?
2. What did the transitioning process entail? (what you knew about the process)
3. How involved were you in the treatment and testing guideline transitioning process?
4. In your view, how would you assess the adequacy of plans put in place to manage existing/legacy commodities?
5. What mechanisms were put in place to prepare for and monitor the transition ?
6. Can you explain whether the staff managing ARVs and HIV test kits at SDPs were provided the requisite skills towards implementation of the new updates?
7. Did you observe any challenges with the treatment and testing guideline transitions (contextual issues, training, dissemination of guidelines, commodity availability, etc.)? *Ask follow on questions on specific challenges.*
8. What were the opportunities or successes, if any, associated with the transitioning?
9. What suggestions would you make to improve future HIV guideline transitions?

8.2.APPENDIX 2 – Quantitative Tool

QUESTIONNAIRE: SITE LEVEL

1. Interviewer Name:
2. Date of data collection:
3. Facility Name:
4. Region:
5. District:
6. Facility Type:
    - CHPS
    - Health Center
    - Polyclinic
    - Municipal/District Hospital
    - Regional Hospital
    - Teaching Hospital
7. Service Offered
    - ART
    - PMTCT
    - HTC Only

Preparation towards Treatment Guideline Transitioning (June to August 2019)

(Preamble to be included here)

8. Is the facility aware of changes in the 2019 HIV care and treatment guideline?

- Yes
- No

9. If yes, when did the facility become aware?
    - April to June 2019
    - July to September 2019
    - October to December 2019
    - January to March 2020
    - Other, please specify…….
10. Did the facility receive any training prior to implementation of 2019 HIV treatment guideline changes?
    - Yes
    - No
11. Did the training include any supply chain component?
    - Yes
    - No
12. If yes, what did the supply chain component entail? Choose all that apply
    - Order requisitioning
    - Inventory management
    - Demand generation
    - Logistics reporting
    - Other, kindly specify……..
13. Was the facility provided with reference materials in respect of the changes to the treatment guideline?
    - Yes

- No

14. If yes, kindly indicate which reference materials were provided? Select all that apply

- Job Aids
- Care and Treatment Guideline
- IEC Materials (posters, flyers, leaflets etc)
- Educational videos
- Other, please specify……..

15. Which of the materials above did you find most useful? Select one only

- Job Aids
- Care and Treatment Guideline
- IEC Materials (posters, flyers, leaflets etc)
- Educational videos
- Other, please specify……

16. Does the facility have a copy of the new care and treatment guidelines?

- Yes
- No

Treatment Guideline Transitioning Period (September 2019 to August 2020)

17. Is this facility implementing the new treatment guidelines?

- Yes

- No

18. If no, indicate reason for not starting.

    …….

19. If yes, when did the facility begin implementation of the new treatment guideline?

    - MM/YYYY

20. When did the facility first receive any DTG-based formulation?

    - MM/YYYY

21. What were some of the barriers to the treatment guideline transitioning?

    - Non-availability of new ARVs at next level warehouse.
    - Prescriber unwillingness to transition existing clients
    - Prescriber unwillingness to initiate new clients on new ARTs
    - Inadequate knowledge regarding guideline transitioning
    - Other, kindly specify……

22. Adult Treatment Transition

Month	**# of adults given first line ART**	**# of adults given TLD**	**# of adults given TLE**	**# of adults given TLN**	**# of adults given ALD**	**# of adults given ALE**	**# of adults given ALN**	**# of adults given ZLD**	**# of adults given ZLE**	**# of adults given ZLN**
Sep-19										
Oct-19										

Month	# of adults given first line ART	# of adults given TLD	# of adults given TLE	# of adults given TLN	# of adults given ALD	# of adults given ALE	# of adults given ALN	# of adults given ZLD	# of adults given ZLE	# of adults given ZLN
Nov-19										
Dec-19										
Jan-20										
Feb-20										
Mar-20										
Apr-20										
May-20										
Jun-20										
Jul-20										
Aug-20										

23. Paediatric treatment transition

Month	# of children given ART	# of children given ALN	# of children given ALE	# of children given ALD	# of children given ALL	# of children given ZLN	# of children given ZLE	# of children given ZLD	# of children given ZLL	# of children given other regimen
Sep-19										

Month	# of children given ART	# of children given ALN	# of children given ALE	# of children given ALD	# of children given ALL	# of children given ZLN	# of children given ZLE	# of children given ZLD	# of children given ZLL	# of children given other regimen
Oct-19										
Nov-19										
Dec-19										
Jan-20										
Feb-20										
Mar-20										
Apr-20										
May-20										
Jun-20										
Jul-20										
Aug-20										

24. Adult ARV Availability during transition period (analyse existing data)

	# of Stock out days								
Month	TLD	TLE	ZLN	TL	DTG50	EFV600	ZL	AL	NVP200

	# of Stock out days								
Sep-19									
Oct-19									
Nov-19									
Dec-19									
Jan-20									
Feb-20									
Mar-20									
Apr-20									
May-20									
Jun-20									
Jul-20									
Aug-20									

25. What reasons accounted for stock out of adult ARVs during the transitioning period?

……..

26. Paediatric ARV availability during transitioning period

	# of Stock out days						
Month	**ZL paed**	**NVP 50mg disp**	**NVP Syr**	**AL paed**	**EFV 200**	**Lop/R 100/25**	**Lop/R 40/10**
Sep-19							
Oct-19							
Nov-19							
Dec-19							
Jan-20							
Feb-20							
Mar-20							
Apr-20							
May-20							
Jun-20							
Jul-20							
Aug-20							

27. What reasons accounted for stock out of pediatric ARVs during the transitioning period?

……

28. Adult ARV expiries during transition

	Quantity Expiring								
Month	**TLD**	**TLE**	**ZLN**	**TL**	**DTG50**	**EFV600**	**ZL**	**AL**	**NVP200**
Sep-19									
Oct-19									
Nov-19									
Dec-19									
Jan-20									
Feb-20									
Mar-20									
Apr-20									
May-20									
Jun-20									
Jul-20									
Aug-20									

29. What reasons accounted for adult ARV expiries during the transitioning period?

…….

30. Paediatric ARV expiry during transition.

	Quantity Expiring						
Month	**ZL paed**	**NVP 50mg disp**	**NVP Syr**	**AL paed**	**EFV 200**	**Lop/R 100/25**	**Lop/R 40/10**
Sep-19							
Oct-19							
Nov-19							
Dec-19							
Jan-20							
Feb-20							
Mar-20							
Apr-20							
May-20							
Jun-20							
Jul-20							
Aug-20							

31. What reasons accounted for paediatric ARV expiries during the transitioning period?
    …….
32. Kindly list other supply chain challenges encountered during the treatment guidelines transitioning period……..
33. Kindly provide recommendations to improve future HIV treatment guideline transitions.
    ……..

Preparations towards transitioning to new Testing Algorithm

34. Is facility aware of recent changes to the HIV testing algorithm?

- Yes
- No

35. Did facility receive any training prior to transitioning to new 3-tier testing algorithm?

- Yes
- No

36. Did the training include any supply chain component?

- Yes
- No

37. If yes, what did the supply chain component entail?

- Order requisitioning
- Inventory management
- Demand generation
- Logistics reporting
- Other, kindly specify……..

38. Was facility provided with reference materials in respect of the changes to the HIV Testing Algorithm?

Yes

No

39. If yes, kindly indicate which reference materials were provided? Choose all that apply

- Job Aids
- Care and Treatment Guideline
- IEC Materials (posters, flyers, leaflets etc)
- Other, please specify……..

40. Which of the materials above did you find most useful? Choose one only

- Job Aids
- Care and Treatment Guideline
- IEC Materials (posters, flyers, leaflets etc)
- Other, please specify……

Testing Algorithm Transitioning Period (July 2020 - June 2021)

41. Is facility implementing the new 3-tier HIV testing algorithm?

- Yes
- No

42. If no, indicate reason for not starting.

…….

43. If yes, when did facility begin implementation of the new 3-tier testing algorithm?

- MM/YYYY

44. What is the recommended test kit for the initial screening of pregnant women?

    …….

45. What is the recommended test kit for the initial screening of the general population (excluding pregnant women)?

…….

46. Has facility stocked first response HIV/Syphilis combo test kit before?

- Yes
- No

47. If yes, when did facility first receive stock of HIV/Syphilis combo test kit?
    MM/YYYY

48. Has facility stocked first response SD bioline test kit before?

- Yes
- No

49. If yes, when did facility first receive stock of SD bioline test kit?
    MM/YYYY

50. What are some of the barriers to transitioning to the new 3-tier HIV testing?
    …….
51. Test Kit availability during the transition period

	Stock out at end of month			
Month	**HIV FR**	**Combo**	**Oraquick**	**SD Bioline**
July 2020				
August 2020				
September 2020				

October 2020				
November 2020				
December 2020				
January 2021				
February 2021				
March 2021				
April 2021				
May 2021				
June 2021				

52. What reasons accounted for stock out of test kits during the transitioning period?

……..

53. HIV test kit expiries during the transition period.

	Quantity expiring			
Month	**HIV FR**	**Combo**	**Oraquick**	**SD Bioline**
July 2020				
August 2020				
September 2020				
October 2020				
November 2020				
December 2020				
January 2021				
February 2021				
March 2021				
April 2021				
May 2021				
June 2021				

54. What reasons accounted for expiry of HIV test kits during the transitioning period?

    ……

55. Kindly list other supply chain challenges encountered during the HIV testing algorithm transitioning period……..

56. Kindly provide recommendations to improve future HIV testing guideline transitions.

……..