

# Effects of Stakeholder's Management and Engagement on the Success of Fixed Dose Combination (FDC) Tenofovir/Lamivudine/Dolutegravir (TLD) Introduction and Transition: Nigeria Experience

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## Opinion

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## Abstract

**Introduction/Objectives:** Managing the expectations and interest of the stakeholders' is key to the success of new drug/regimen introduction and transition. This is because stakeholders are often heterogeneous and diverse, with different levels of interest. Therefore, categorizing stakeholders at the commencement of the process, identifying and managing their expectations and needs will contribute to the creation of a right atmosphere and be catalyst for success of the implementation. This can be attained through the creation of timely and appropriate communication that meets the needs of stakeholders. The objective of this paper is to describe the strategies and activities implemented during TLD transition and to show how engagement with stakeholders contributed to the success of the process.

**Methodology:** Following the adoption of national TLD transition plan and communication messages, stakeholders were identified and mapped by performing a stakeholder analysis. State level dissemination meeting was designed and implemented across all states. A monitoring tool was developed and operationalized to improve visibility in the process. Sites visits was designed and implemented across select states to assess uptake and reasons for deviations from the transition plan.

**Results:** A total of twenty (20) Federal Ministry of Health staff, fifty (50) staff of technical and treatment partners and two thousand four hundred and eighty-three (2,483) healthcare workers (HCW) from one thousand and ninety (1,090) antiretroviral treatment sites across thirty-six (36) and FCT were reached during the dissemination meetings and were adequately trained prior to transition commencement. 12,000 jobs aids and 800,000 Information Education and Communication materials were distributed to health facilities to assist HCW improve their knowledge on the use of TLD. Enhanced mentorship and on-the-job training were provided to not less than 462 healthcare workers during the Integrated National Monitoring and Supportive Visits (INMSV).

**Conclusion:** Engagement of and communication with broad range of stakeholders during the transition process was key to the success of TLD transition as it allowed large numbers of stakeholders at the national, state and health facility level to be reached with relevant information about the transition. This paper describes engagement activities and other practices that facilitated TLD introduction and transition in Nigeria.

**Keywords:** Stakeholder; Engagement; Integrated Monitoring and Supportive Visits; Dissemination Meeting; TLD Transition; Management

**Abbreviations:** ART: Antiretroviral treatment; FDC: Fixed Dose Combination; TLD: Tenofovir/Lamivudine/Dolutegravir; NASCP: National AIDS and STIs Control Program.

## Introduction

Antiretroviral treatment (ART) protocol has been changing considerably in recent years due to scientific innovations and increased evidence of newer antiretroviral drugs with modest clinical and cost advantages over existing ones [1,2]. The newer ARV drugs commonly referred to as optimized products, such as those containing dolutegravir (DTG) are expected to bring about improved treatment outcomes and significant cost savings as they are introduced to country programs [2].

Dolutegravir (DTG) is an Integrase strand transfer inhibitors (INSTI) that was first approved by the United States Food and Drug Administration in 2013 [3,1]. It has shown clinical superiority in comparison to Efavirenz (EFV) in multiple large phase III trials [3-5,1]. Additional benefits of DTG include faster viral suppression ability, a high genetic barrier, lower risk of resistance from poor adherence, prolonged intracellular half-life that allows for once-daily fixed dosing, and low-dosing requirements [1,3]. It has less toxicity profile and a smaller pill size that is treatment adherence-friendly [1,3]. Nigeria processed an initial order for 4.9 million doses of TLD in September 2017 and additional 3.1 million doses in January 2018.

The cost per patient per annum based on the negotiated price is US\$ 75 and additional price reductions are expected [3].

The Nigeria Federal Ministry of Health (FMOH) in December 2017 approved the use of TLD as preferred first-line regimen for ART. The Ministry issued a Rapid Advice in October 2018 announcing TLD as the preferred adult first line [6]. This was developed as an addendum to the recommendations of National Guideline for HIV/AIDS Prevention, Treatment and Care 2016. To maximize health and budgetary benefits from TLD, implementation and uptake of the regimen must be well planned and coordinated. As a result, the National HIV program adopted an innovative strategy that relied on engagement, management and communication with stakeholders for the transitioning of existing patients on non-optimized ARV drugs tenofovir/lamivudine/efavirenz (TLE) and zidovudine/lamivudine/nevirapine (LNZ) to TLD. This was to avoid the experience of past transitions to new first-line ARV regimens that was met with a variety of logistical and implementation challenges, while also yielding several good practices.

According to the Institute of Development Studies (IDS), the word 'stakeholder' is used to describe anyone who has a 'stake' or an 'interest' in an initiative [7]. Griffiths, et al. describe stakeholders as people who will be affected by a project, or who can influence it, but who

are not directly involved in doing the work. In other words, stakeholders can have an interest in an organization, in a specific initiative or project, or in an overarching policy or objective to which specific initiatives contribute [8]. IDS also defined engagement as a set of activities that facilitate an exchange of knowledge between stakeholders. This may include one-off activities but is usually a longer-term process of mutual exchange of knowledge and learning [7].

Led by the Federal Ministry of Health, there were 3 phases during which the different stakeholders were engaged in the TLD transition process. They include planning (phase in/phase out plan and communication development); State and Service delivery support (dissemination meetings); and transition monitoring and visibility (patient transition monitoring, pharmacovigilance and feedback). The Stakeholders engagement activities in the different phases involved building relationship through constant communications and shared decision making about the transition activities.

## Methodology

The first phase of the engagement activity commenced with meeting of seven representatives from National AIDS and STIs Control Program (NASCP)-2, Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM)-3, and Clinton Health Access Initiative-2. These were group of champions that were highly motivated to drive forward the transition program within their respective organizations. During this meeting, the team developed a step-wise twelve (12) months plan for phase in of TLD and phase out of non-optimized ARVs drugs. The transition plan was presented at the joint meeting of the National Task Team on Antiretroviral Treatment (NTTA) and National Task Team on Prevention of Mother to Child Transmission of HIV (NTTPMTCT). The NTTA and NTTPMTCT are national advisory council on antiretroviral treatment program. Communication messages on TLD (job aids for the health care workers and information education and communication materials for the patient's group) were developed at the joint meeting. The transition plan and the communication message were endorsed for implementation by the joint meeting.

The second phase of the engagement process started with stakeholder analysis. This phase was led by the champions but involved the entire stakeholders in HIV/AIDS program in the country. Key stakeholders

involved in HIV/AIDS program were identified and prioritized based on their level of interest in and influence in the program. A database with details of the stakeholders and their potential role in the transition process was developed to guide communication during the transition process. The stakeholders comprised of Government Agencies, UN Agencies, funders, technical and treatment partners.

The stakeholders were invited to an inaugural meeting that was later referred to as the National Stakeholders meeting on TLD transition. At the meeting, treatment partners were mapped based on the states where they are playing lead role and the goals of the transition were set out. In the follow-on meetings, schedule for state level dissemination meetings and presentation deck were developed while funding for the state level dissemination meetings and printing of the communication materials were decided.

As part of the pre-activity for the state level dissemination meeting, federal ministry of health, technical and treatment partners' staff were provided trainings to empower them with appropriate knowledge and guidance including how initiatives like viral load (VL) monitoring interface with changes to ARV regimens.

State level TLD transition dissemination meetings took place across thirty-six (36) of the federation and the federal capital territory with participants drawn from states ministry of health and health facilities with technical support from National AIDS and STIs Control Program, Clinton Health Access Initiative (CHAI), Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project, AIDS Healthcare Foundation and PEPFAR and GF lead partners and funding support from PEPFAR, GF and CHAI. The dissemination' involved formal communication and roll-out of the transition plan and programmes to states ministry of health and health facilities. Job aids and the IEC materials were distributed as part of the activities for the dissemination meeting.

The third phase consisted of exchange of information about the need and benefits of the transition programme. Central, regional and state level Procurement and Supply Management technical working group meetings (PSM TWG) were organized at federal, regional and state levels on a bimonthly, semiannually and monthly basis respectively to review implementation strategies, discuss barriers and way forward. All stakeholders involved in HIV/AIDS program at the national, regional and state

level participated in the PSM TWG meetings. Government with funding support from PEPFAR organized meetings of all clinicians, pharmacist and laboratory focal persons from antiretroviral treatment sites to review implementation and address challenges hindering progress.

National TLD transition monitoring tool and adverse drug reaction summary form for the new drug were developed and deployed by the National program. Monthly reports from treatment partners were collated by NASCP to monitor transition progress and to track and ensure timely detection of adverse events and development of appropriate mitigation strategies. The data are analyzed and disseminated to all stakeholders on monthly basis.

As a way of obtaining feedbacks on TLD transition implementation, the national program conducted an Integrated National Monitoring and Supportive Visits (INMSV) to 154 health facilities supported by fifteen (15) implementing partners in 21 states of the federation. The

exercise involved on-site practical hands on mentoring and correction of wrong practices and sensitization of staff members on guidelines and correct processes. Oral and documented feedback were obtained from both the clinicians, Pharmacist, laboratory scientist and the patients on specific key & quality issues as per structured checklists during the visits to monitor progress as well as identify challenges hampering transition implementation. The checklists contained a scoring system wherein different indicators were quantified on basis of their importance to rank health facilities between good, average and poor performing. The information collected during visits was entered in MS Excel based template, which generated ready analyzed feedback in info graphic and numerical forms, which was shared with stakeholders at different levels for corrective actions.

Table 1 below summarized key activities undertaken by the program during TLD transition progress and the various stakeholders that played a role in implementation of the activities.

Activity	Organization(s) that implemented the activities
Development and finalization of national TLD transition plan	NASCP/GHSC-PSM/CHAI
Presentation of finalized national TLD transition plan to joint meeting of NNTA and NTPMTCT for adoption	NASCP
Development of TLD introduction job aids and IEC materials	CHAI/GHSC-PSM/NASCP
Convening of first national level stakeholder's engagement meeting	NASCP/GHSC-PSM
Updating of information systems (tools and registers etc.) with TLD	NASCP/GHSC-PSM
Approval of Communique and Rapid Advice for the roll out of TLD	FMOH
Printing of Communique and Rapid Advice for the roll out of TLD	NASCP
Printing of the Job Aids and IEC materials for the TLD roll out	CHAI/GHSC-PSM
Email dissemination of the Communique and Rapid Advice for the roll out of TLD to national and state stakeholders	NASCP
Convening of national planning meeting for TLD dissemination	NASCP/GHSC-PSM
Mapping of national and state level stakeholders	NASCP/GHSC-PSM
Development of budgets and schedules for State level TLD dissemination meetings	NASCP/GHSC-PSM
Mapping of national and state level stakeholders	NASCP/GHSC-PSM
Notification of State's Ministry of Health leadership about State level TLD Dissemination meeting	NASCP
Development of presentation materials for the State level TLD Dissemination meeting	CHAI/NASCP/GHSC-PSM/NACA/FHI360-GF
Meeting of the state teams/structures to finalize arrangement for the State level TLD dissemination meeting	SMOH and Implementing Partners
Training and orientation for national team for the Dissemination Meeting	CHAI/NASCP/GHSC-PSM
Development of activity reporting template for the State level TLD Dissemination meeting	NASCP/GHSC-PSM
Orientation of national level stakeholders on the use activity reporting	NASCP/GHSC-PSM

template for the State level TLD Dissemination meeting	
Email dissemination of activity reporting template for the State level TLD Dissemination meeting	NASCP
State level TLD dissemination meeting	CHAI/NASCP/GHSC-PSM/NACA /FHI360-GF and Implementing Partners
Distribution of TLD, Job Aids and IEC Materials to the health facilities	GHSC-PSM/CHAI/NASCP
Development of Technical report for the State level TLD Dissemination meeting	NASCP/GHSC-PSM
Dissemination of Technical Report for State level TLD Dissemination Meeting	NASCP
Development of TLD Transition Monitoring tool	NASCP/GHSC-PSM
Collation and analysis of monthly TLD Transition Monitoring Report from treatment partners	NASCP/GHSC-PSM
Dissemination of monthly TLD Transition progress report to stakeholders	NASCP
Development of Adverse Drug Reaction summary form	NASCP/GHSC-PSM
Collation and analysis of monthly Adverse Drug Reaction summary form from treatment partners	NASCP/GHSC-PSM
Dissemination of monthly adverse drug reaction summary report to stakeholders	NASCP
Integrated National Monitoring and Supportive Visit (INMSV) to the health facilities to monitor uptake and adverse drug reaction	CHAI/NASCP/GHSC-PSM/NACA/FHI360-GF and Implementing Partners
Monitoring of consumption patterns and supply plan readjustment	NASCP/GHSC-PSM
Making recommendations on TLD Transition implementation	CHAI/NASCP/GHSC-PSM/NACA/FHI360-GF

**Table 1:** Summarized key activities undertaken by the program during TLD transition progress and the various stakeholders that played a role in implementation of the activities.

## Results

Twenty (20) Federal Ministry of Health staff, fifty (50) staff of technical and treatment partners were provided mentorship on national rollout of TLD. This was to ensure requisite knowledge and information among the staff thus preparing them to effectively support the health facilities in the transition process.

Two thousand four hundred and eighty-three (2,483) healthcare workers from one thousand and ninety (1,090) antiretroviral treatment sites across thirty-six (36) states of the federation and federal capital territory were reached in the dissemination meetings and were adequately trained at the time of the transition. 12,000 job aids and 800,000 IEC materials were distributed to the health facilities to assist health care worker improve their knowledge and skills on the use of TLD.

Enhanced mentorship and on-the-job training were provided to not less than 462 healthcare workers during the Integrated National Monitoring and Supportive Visits (INMSV). The INMSV revealed that 95.8% of the health facilities visited had commenced the use of TLD as the preferred first line ART; 91% had at least one trained

clinician, Pharmacist (88.6%), and Laboratory Scientist (96.4%) to support the TLD transition implementation. TLD job aids, updated National HIV/AIDS treatment guidelines, communique and Rapid Advice for the roll out of TLD were available in 87.6% of the health facilities. 96% had tools and registers for documenting daily activities; 69.3% had temperature control device in the bulk store where the drugs are stored; 45.5% had a functional pharmacovigilance committee.

## Conclusions

Effective engagement of and communication with broad range of stakeholders during the transition process allowed Nigeria to rapidly disseminate the transition plan across the country. Although, it was not without its challenges, the main being lack of flexibility in scheduling, logistical support and funding. Stakeholders may have had conflicts with each other and perceived or direct conflicts of interest, but well-developed mechanisms for managing these conflicts were deployed by NASCP.

The outcome of the national monitoring and supportive visits suggests that the success of the transition to TLD was strongly dependent on the amounts



of information provided to the participants during the dissemination meeting. While healthcare worker training is typically an essential component of transitions, the NMSV also found that on-the-job mentoring and user-friendly job aids are more effective at supporting good practices during transition.

To maintain relationships among stakeholders, it is believed that uninterrupted engagement over the transition period is necessary.

### Disclaimer

The findings and conclusions in this paper are those of the authors and do not necessarily represent the official position of the USAID or GHSC-PSM.

### Competing Interest

The authors of this manuscript declare that they have no competing interests.

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### References

1. World Health Organization (2017) Transition to New Antiretroviral Drugs in HIV Programmes: Clinical and Programmatic Considerations.
2. Optimize (2017) Experiences Transitioning to New Adult First-Line Antiretroviral Regimens: A Multi-Country Case Study, pp: 1-20.
3. Babaye Y, Nyirenda RK (2018) Status Report on HIV Drug Treatment Transition from Tenofovir/Lamivudine/Efavirenz (TLE 600mg) to Tenofovir/Lamivudine/Dolutegravir (TLD) in Malawi. Public Health Open Access medwin publishers 2(1): 1-2.
4. Dow DE, Bartlett JA (2014) Dolutegravir, the Second-Generation of Integrase Strand Transfer Inhibitors (INSTIs) for the Treatment of HIV. Infectious diseases and therapy 3(2): 83-102.
5. Snedecor SJ, Radford M, Kratochvil D, Grove R, Punekar YS (2019) Comparative efficacy and safety of dolutegravir relative to common core agents in treatment-naïve patients infected with HIV-1: a systematic review and network meta-analysis. BMC infectious diseases 19(1): 484.
6. National AIDS & STI Control Program (NASCP) (2018) Rapid Advice recommendations for First Line Antiretroviral Therapy in Nigeria.
7. Institute of Development Studies (2013) Introduction to Stakeholder engagement. The Global Guide to Research Impact.
8. Griffiths J, Maggs H, George E (2007) Stakeholder Involvement: Background paper prepared for the WHO/WEF Joint Event on Preventing Noncommunicable Diseases in the Workplace. Geneva: WHO.

