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National Prevention of Mother to Child Transmission Program- The APIN Experience

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HISTORICAL PERSPECTIVES TO APIN PMTCT PROGRAMS: FROM PREVENTION TO LIFELONG ARV TREATMENT

The Nigerian Prevention of Mother-to-Child Transmission (PMTCT) of HIV program is one of the key health sector responses to the HIV/AIDS epidemic in the country. The PMTCT program in Nigeria commenced in 2000 with the inauguration of the PMTCT National Task Team (NTT). The PMTCT NTT was saddled with the responsibility of developing the proposal, framework, guidelines, monitoring and evaluation (M and E) of the PMTCT program. Actual PMTCT services in Nigeria commenced as a pilot project at six sites in July 2002, with one site in each of the six geopolitical zones in the country, and two of the pilot sites in Ibadan and Jos being supported by APIN. The number of sites progressively increased to 250 in 2006, 640 in 2009 and 1,320 by the end of 2012;¹ the APIN program supported up to 103 PMTCT facilities out of the 1320 health facilities in the three states of Lagos, Oyo and Plateau. The PMTCT program in Nigeria has evolved over time from basically a prevention education-based program into a comprehensive treatment and prevention program and the APIN PMTCT program which commenced in year 2000 has been part of this evolution. The APIN supported PMTCT program in its early days was funded by the Bill and Melinda Gates foundation; it essentially featured prevention education for women of reproductive age groups and testing for HIV among antenatal patients. It was implemented

at selected federal teaching hospital clinics and their satellite or feeder sites which were secondary and primary public and private health facilities. Provision of ARVs and robust laboratory monitoring were significant components of the project which was structured as operations research with clear protocols for service delivery.² The Gates grant also supported human capacity development of clinical and laboratory systems in support of comprehensive HIV/AIDS and specifically PMTCT service delivery. From 2004-2013, inclusive of a transition period between 2009-2013 to APIN as a local indigenous USG implementing partner, the Harvard School of Public Health (HSPH) implemented a comprehensive HIV/AIDS prevention and Treatment program, under the APIN project, with funding from the United States President's Emergency Plan for AIDS Relief (PEPFAR). As of 2012, the APIN-PEPFAR program had screened almost one million pregnant women for HIV and contributed nearly 20% of all reported PMTCT care in Nigeria. An evaluation from one of APIN's major PMTCT center in Jos, Nigeria showed that at 18 months, MTCT of HIV was lower among women who commenced ART before pregnancy compared to those women who started ART/triple ARV prophylaxis during pregnancy/delivery (0.4% vs 2.0%).³ This rate is an indication of a successful PMTCT program, and as the systems are further strengthened, it is expected that these rates will decline further.

The APIN program had consistently supported the National HIV response by working with facilities in the private and public health sectors to implement quality PMTCT programs aligned with national priorities and guidelines, usually deriving from evidence from new research and recommendations by the World Health Organization (WHO). By September 2017, APIN had provided continued support for PMTCT program implementation in at least nine states in Nigeria and over five hundred health care facilities in both public and private health care settings.

HIV-infected women are provided antiretroviral therapy according to a pre-determined set of clinical and laboratory criteria, followed up through pregnancy, delivery and up to 12-18 months post-partum to document the final outcome of their HEI infants. The antiretroviral therapy had evolved from single dose therapy, through HAART for a defined period, to the current situation of treatment for life once commenced.

Coordination of the APIN PMTCT Program

The APIN PMTCT program is managed in the PMTCT Unit of the Prevention and Community directorate; where oversight is provided for program implementation and service delivery at the states and facilities. The program officers interface and liaise with the GON personnel at the federal level, National Agency for the Control of AIDS (NACA), the Center for Disease Control and Prevention (USG/CDC), World Bank, World Health Organization (WHO) and other United Nations (UN) group and the Global Fund (GF). APIN supports and contributes to the activities of the National PMTCT task team and supports the implementation of new policies and guidelines on PMTCT at the state level; the National PMTCT task team at different times was led by Professor Isaac Adewole, Professor Solomon Sagay and Professor Oladapo Shittu, all leaders of PMTCT program at APIN supported UCH Ibadan, JUTH, Jos and ABUTH, Zaria sites respectively. Within APIN supported states, program officers are responsible for providing technical guidance and support to the PMTCT sites, coordinating all PMTCT and Early Infant Diagnosis (EID) activities at all levels of care, liaising with the state government at the State Ministry of Health (SMOH), Hospital Management Board (HMB), State Agency for Control of AIDS (SACA), the Primary Health Care Development Agency (PHCDA) and Primary Health Care Board (PHC Board). Other stakeholders in PMTCT services include Civil Society Organizations (CSOs). Community level volunteers are also coordinated directly by the state officers.

The PMTCT service delivery traditionally adopts a mix of community and facility-based strategies; at the community levels, Traditional Birth Attendants and Maternity Homes are supported by CSO technical staff to provide HTS services in ANC to pregnant women and refer HIV positive cases for additional care at PMTCT facilities. Facility level PMTCT services are provided within the context of a comprehensive approach to HIV/AIDS service delivery or through dedicated stand-alone PMTCT units of the hospital. PMTCT service delivery are usually hosted at the ANC clinic as entry points where pregnant women are recruited into the program through HTS in ANC. ART services for pregnant women are either provided within the ANC clinics as done in several secondary and primary levels of care, or through the ART clinics

in tertiary hospitals.

An integrated approach to PMTCT service delivery within the context of overall MNCH service delivery is promoted as much as possible at all levels of care. APIN as an implementing partner funded by different agencies, acts as technical partner to the GON in designing and implementing programs as part of the National response. While implementation happens at all levels and types of care, the public sector constitutes the majority of supported facilities. Overall coordination of the HIV/AIDS response is effected through several agencies at the federal and state levels. In order to clearly define roles and responsibilities, APIN executed several Memoranda of Understandings (MOUs), Partnership agreements, Service Level agreements and Implementation Contracts with key stakeholders and partners. APIN has also consciously engaged many CSOs, who are involved in the direct implementation of PMTCT services in support of government facilities and at the community levels.

APIN also plays a critical role of mobilizing the health system to support program implementation through advocacy to different stakeholders in government and the civil society.

Development of Protocols, Standard Operating Procedures (SOP) and Job Aids

The PMTCT program is implemented as a structured service delivery public health intervention guided by protocols, guidelines, Standard Operating Procedures (SOPs) and other formal documents. APIN protocols had always been adapted from National guidelines, guided by WHO recommendations. The protocols focus on key components which includes guidance on HIV testing in ANC, antenatal care of pregnant women infected with HIV, obstetric interventions to reduce risk of MTCT, provision of antiretroviral therapy for prevention of mother to child transmission, post-partum care, management of HIV Exposed Infants (HEI) which included infant feeding and ARV prophylaxis.

From 2004-2008, APIN designed and operated a PMTCT protocol in an operational research mode to test the outcomes of different ART interventions among diverse categories of women who are HIV infected in pregnancy at risk of MTCT.²

The following key classes of pregnant women were

identified and managed specifically along the dictates of the protocol:

- HIV infected women that are eligible for HAART will receive a three-drug HAART regimen.
- HIV infected women that attend antenatal services between 28-33 weeks gestation and are ineligible for HAART will receive daily ZDV and single dose NVP at delivery, followed by one week of ZDV.
- HIV infected women that attend antenatal services between >34 weeks gestation and are ineligible for HAART will receive daily ZDV+NVP and single dose NVP at delivery, followed by one week of ZDV.
- Women that present in labor and are HIV-infected will be given single dose NVP at delivery, followed by one week of ZDV.
- HIV infected women that have previously enrolled but not presented at delivery, that present within one week post-delivery

APIN provided support for the FMOH through participation in the National PMTCT task team to produce and implement PMTCT National Guidelines. A major shift in the 2010 guideline was the movement from use of mono or dual therapies to triple ART combination for PMTCT prophylaxis in settings that have the capacity to manage triple ART therapies.⁴ APIN had revised its protocols to reflect changes in the guidelines, so that its strategies are consistent with the national program.

With evidence that lifelong triple ART for all categories of HIV infected persons including pregnant women irrespective of CD4 count or WHO staging confers better outcome on HIV infected pregnant women, this approach was adopted and implemented at all APIN supported PMTCT sites as the standard of care for PMTCT clients between 2014 and 2016 even before the 2016 Nigerian Integrated Guidelines for HIV Prevention, Treatment and Care⁵ was adopted for national use.

Standard Operating Procedures (SOPs)

These documents provide operational guidance to the implementing protocols and guidelines in service delivery settings. They form easy reference materials for HCWs and are deployed as on the job training materials. APIN deployed a number of SOPs to aid the provision of PMTCT service delivery especially where there are no clear guidance or instructions on how best to accomplish certain service delivery elements. Key

examples of such SOPs are the following:

- SOPs for the provision of PMTCT services at the Primary Level of Care.
- PMTCT flow chart and EID flow charts
- SOPs for viral load investigation during pregnancy

Job Aids

These are key extracts from protocols and SOPs which address vital interventions in a step by step basis; it highlights key steps in diagnostic procedures, ARV dispensing, treatment or investigational procedures. Several such job aids were designed and deployed to support the APIN PMTCT program. Key among them are the following:

- HTS serial testing algorithm
- ARV dispensing in PMTCT
- Cotrimoxazole dispensing for PMTCT clients
- Extended nevirapine prophylaxis dispensing
- Dried Blood Spot (DBS) sample collection guide

Capacity Building of HCW for PMTCT Services

The undergraduate or preservice training curriculum for HCWs training does not include HIV medicine and so this is mostly learnt by health care workers (HCW) as part of continuous medical education and professional development. As a result, training of HCWs are purposefully designed to develop their capacity for effective and quality service delivery. Several approaches are employed to achieve the above and are often tailored to the capacity of HCWs at the different levels of health services.

Curriculum based PMTCT trainings

These trainings are typically conducted in line with the National PMTCT guidelines and are mainly of

two types: Integrated Management of Adolescent and Adult Illness/Integrated Management of Pregnancy and Adolescent Conditions (IMAI/IMPAC) for lower levels of care, as well as the Standard PMTCT trainings for secondary and tertiary health facilities.

These two trainings are quite similar in content and issues addressed, but differ significantly in delivery modalities, due to the different educational levels and experiences of cadre of health care workers being trained. While the standard PMTCT training is designed for doctors, nurses and other HCWs in teaching hospital and general hospital/specialist clinic settings, the IMAI/IMPAC curriculum is designed for Community Health Extension Workers (CHEWs), Community Health Officers (CHOs) and nurses working at the primary health care levels.

Early Infant Diagnosis Training

This focuses on the clinical/laboratory components of the EID service delivery process for non-laboratorian HCWs. In scope, the training addresses demand creation strategies for EID services, the initial and follow up management of the HIV Exposed Infants (HEI) including infant feeding counseling, collection, storing and transportation of DBS samples collected to testing laboratories, immediate care and treatment for DNA PCR positive infants

From the training described above, APIN has contributed to the direct capacity building of 1284 health care workers across three states in the federation using support from the Comprehensive treatment and Care PEPFAR grant operated from October 2012 to September 2017.

These health care workers continued to provide indirect capacity building support to thousands of

	IMAI/IMPAC	Standard PMTCT Training	EID	Total Number of HCW Trained
Lagos	183	105	122	410
Oyo	281	87	67	435
Plateau State	318	59	62	439
Total number of HCW trained per thematic area	782	251	251	1,284

TABLE 1 Health Workers PMTCT Training

health care workers through step down trainings, mentorship, supervision of new staffs, hands on training within health care facilities across the three states supported by APIN in the last grant.

Technical Assistance Visit

In a bid to further build the capacity of health care workers, a series of technical support approaches have been adopted. These are intended to ensure that knowledge gained during trainings are applied correctly during service delivery, ensure protocol compliance and fidelity when implementing programs and guarantee consistent high levels of quality in service delivery and program implementation.

The technical assistance visits are usually structured and guided by checklists that are designed to review practices in the different domains of the PMTCT program from ANC testing, ARV initiation, follow up in pregnancy, delivery practices, care for HEI infants, and EID service delivery.

The Integrated Supportive Supervision (ISS)

A technical assistance visit approach adopted at the lower level of health services in recognition of the multiple roles health care providers at this level undertake in providing medical services that cuts across other disease entities beyond HIV. The ISS team at the LGA levels comprises of the Medical Officer of Health, the Local Action Committee on AIDS (LACA) managers and the LGA M&E lead. The visits are guided by a standardized ISS checklist that assesses HIV and PMTCT services in addition to malaria, TB, Family Planning, Immunization and other primary care services in the PHCs.

Integration of PMTCT services into MNCH services

APIN continues to promote service integration into overall Maternal, Child and Neonatal Health (MNCH) programs towards ensuring sustainability of PMTCT programs.

The PMTCT programs are implemented within the settings of ANC clinics, labor, delivery wards and postnatal clinics, where women utilizing these services are provided HIV testing as a component of service delivery while HIV positive ones are provided additional PMTCT interventions including ARV

therapy. This approach provides the opportunity to train HCWs working in the broader MNCH programs on providing HIV care and other services to generally improve on ANC, labor, delivery and postpartum care for pregnant and breastfeeding women and their infants, whether HIV infected or not. This integration has also led to significant increase in ANC services utilization, delivery rates, contraception uptake, increased immunization coverage and overall quality of care for PMTCT and other hospital clients.

Health System Strengthening through PMTCT Program Implementation

A key strategy in the PMTCT program implementation is to use the opportunity provided by the funding to further strengthen the critical health systems employed in its implementation. Major investments were deployed to infrastructure upgrades and renovations; this included remodeling of buildings and old service delivery units like ANC clinics, delivery rooms, maternity wards, and outpatient clinics to improve quality service delivery through the provision of better working environment, which in turn increase patient confidence to receive care in such settings. From 2013 to 2017, a total of 151 health facilities were renovated to improve the environment of health care delivery across Lagos, Oyo and Plateau states.

In addition to infrastructure upgrades, APIN also invested in the supply of hospital equipment, clinic supplies, delivery instruments to support MNCH services delivery inclusive of those specific for PMTCT clients. As part of the system strengthening strategies, APIN supported PMTCT facilities with Electronic Medical Record (EMR) systems to enable data management, real-time service delivery reporting, analysis of service delivery data, storage and retrieval of large datasets over several years of implementation. The availability of these data has contributed to the ability of both program managers, funders, government and other stakeholders to plan for other health care interventions and allocation of resources for health that are targeted at both HIV and non-HIV infected women of reproductive age groups. In a bid to improve reporting rates and availability of service delivery data at primary and designated secondary level PMTCT facilities, a mobile phone-based data collection and reporting application named M-SMART

was developed by APIN and deployed to 471 PMTCT sites in 2014 to enable real time reporting of PMTCT service delivery data across APIN states of operations. Its deployment helped move the reporting rates towards the 100% mark, with the report completion rates increasing from a baseline of about 35% to 69% in Plateau, 79% in Lagos and 93% in Oyo state within six months of its introduction.⁶

Specific PMTCT Interventions

PMTCT implementation rests solely on four key pillars, and the national PMTCT guidelines have always been framed around these pillars.⁷ APIN's protocol aligns with these four pillars as detailed below.

Preventing HIV Infection in Women

APIN provides support for the implementation of HIV prevention education at the facility levels and within communities through CSOs; these activities are targeted at adolescents, youths and women of reproductive age, with the aim of helping clients initiate or maintain behavioral modifications towards reduction of risk for acquiring HIV infections and to seek appropriate health services where infected. Another prevention strategy is HIV testing and counseling services, and these are provided at different settings in the APIN program.

Facility-based ANC setting

The ANC clinics provide access to pregnant women to utilize available HIV and PMTCT services. The program is structured to enable pregnant women test for HIV and know their status; to achieve this, health care workers are trained to provide HIV testing to pregnant women at both facilities and community settings. Logistics are put in place for Rapid Test Kit (RTK) quantification, requisition, supply and reporting an addition to provision of clinic consumables to support testing services. With this support, the uptake rate of HIV testing in ANC settings has consistently been well above the 90% target. Between 2008 and 2017, more than 1.2 million pregnant women were supported through PEPFAR funding for HIV diagnostic testing. Of those tested, 946,989 were tested between 2013 and 2017, and 259,375 between 2008 and 2013.

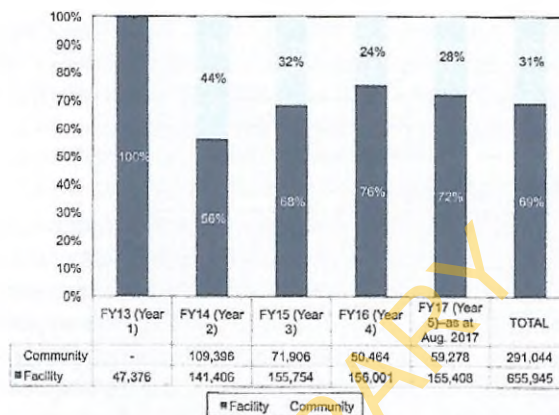


FIGURE 1 Pregnant women counseled, tested, and received results, October 2013–September 2017

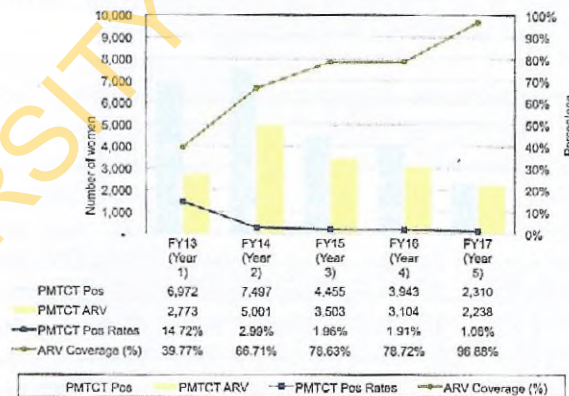


FIGURE 2 PMTCT positivity and PMTCT ARV coverage rates October 2013–September 2017

Community based HTS in Non-formal health sector ANC settings

The program provides support for HIV testing in TBA and Community Birth Attendant (CBA) settings, Maternity Homes and Faith Clinics. CSO volunteer staff who are often laypersons, who have received basic trainings on HTS and universal precautions measures, usually provide these services. HIV infected pregnant women found in these settings are referred to nearest PMTCT facilities to receive ARV prophylaxis.

From October, 2008 to September, 2017, more than 1.2 million pregnant women were counselled

and tested for HIV; 31% (range of 24-44%) of these numbers were tested within the community settings at TBA and other ANC settings outside orthodox facilities.

Overall, the positivity yield from ANC testing streams of either facility or community based testing has gradually declined from as high as 14.7% in 2013 to 1.08% by 2017 indicating an improvement and success in HIV prevention services as well as improved data collection on ANC testing. ART initiation improved appreciably from as low as 40% to 97% within the same period, which indicates an improvement in coverage and linkage of HIV pregnant women to ART services.

Disclosure, Referral and Linkage

Disclosure of HIV status by women to their spouses remain a huge challenge and these women need spousal support if we are to achieve improved uptake and retention in PMTCT services. As part of strategies implemented, APIN introduced the concept of "LOVE LETTERS" which are letters written to invite the spouses to the clinic for couple counselling, HIV testing and disclosure of their wife's status.

Pregnant women who tested positive in community settings and at standalone HTS centers are referred for ART and other PMTCT intervention services at the nearest PMTCT sites. Such referrals are documented using standard triplicate GON approved referral forms and registers. Challenges to completing referrals include self-stigmatization, distance to health facilities, denials, and user fees.

Several enablers have been implemented over the years in the APIN program to help improve referral completion and improved linkage to ART/PMTCT services. These include triplicate referral forms, patient escorts, phone calls and home visits. In April 2017, a Linkage Tracker (LT), a comprehensive line listing of all newly diagnosed positive cases with their demographic and contact details was developed and introduced into the APIN program. This tracker, which has now been adopted by CDC-Nigeria for all their implementing partners, allows program officers to follow up patients in monthly cohorts up until point of enrolment for ART services. The introduction of the LT has helped to significantly improve the linkage rate to ART among PMTCT clients as well as the other patient groups being referred for ART services to 96.9% among pregnant women diagnosed as HIV infected in PMTCT settings.

Preventing Unintended Pregnancies among HIV-Infected Women

The PMTCT program provides support through referral and linkage to HIV infected women to access contraceptive and family planning services which remain a core component of the first and second prongs of the PMTCT program. Depending on the level of care, these services are either available in an integrated manner, or patients may have to visit another facility to access these services. A significant proportion of APIN supported PMTCT facilities are able to provide family planning services in an integrated manner for HIV positive adolescents and women of reproductive age groups. All the intervention described below constitute the complete package deployed by the APIN program to address prongs three and four of the PMTCT program.

Antiretroviral Therapy (ART) services for HIV infected pregnant women

The program has provided technical support for the provision of ART to HIV infected pregnant women from the days of single dose nevirapine in labor and delivery to current practice of life long ART from diagnosis of HIV tagged Option B+. The program has also matured from provision of ARVs for PMTCT at centralized tertiary ART sites to a widespread availability of ARVs at all levels of care including PHCs and community ART pick up points.

Criteria for ARV initiation, timing of ARV commencement and ARV choices for PMTCT have all evolved significantly over time and the program has provided consistent technical support for the training of health care workers, logistic for ARV procurement and supply, ARV dispensing and overall management of the PMTCT value chain. From 2004 to date. The ARV choices have evolved from either ZDV only from 28 weeks, ZDV+3TC from 34 weeks or single dose Nevirapine in labor⁸ to utilization of fixed dose combination HAART from any gestational age of pregnancy using TDF+EFV+3TC as first line ARV.^{9,10} The program supported a schedule of same day ART initiation and structured adherence counselling programs were put in place to support treatment initiation and continuation over extended periods of ARV therapy.

The consolidated approach to providing ARV for PMTCT has led to significant improvements in ARV

coverage for pregnant women; by September 2017, ARV coverage among both known and newly infected HIV positive pregnant women had risen and remained steady at between 95% to 100% at all levels of care supported by the program. Up to 32,280 HIV infected pregnant women benefited from the APIN supported PMTCT program from 2008-2017.

Along the cascade of PMTCT interventions, loss to follow up (LTFU) of mother infant pair occurs at many steps, including when pregnant women do not return for test results after initial ANC registration, between ANC and delivery; result collection and ARV initiation; and between delivery and six weeks appointment for DNA PCR.¹¹ Several studies have demonstrated poor rates of completion of the PMTCT cascade of care and these can be as low as 13% completing the 18 months follow up. Loss to follow up rates as high as 80% in the first six months have also been reported.^{3,12}

Realizing these challenges, the program implemented several interventions to reduce the rate of losses and improve overall retention. Some of the key interventions are described below:

Lowering of entry barriers into PMTCT care and treatment

Same day diagnosis and commencement of ARVs, integration of PMTCT ARV services into routine ANC clinics to avoid multiple clinic appointments for ANC and ARV services, same day appointment for mother-infant pairs (MIP), fast tracking of consultation in ANC clinics for PMTCT clients, waiver of baseline chemistry tests to reduce user fees, reduced emphasis on baseline CD4 and viral load (VL) before initiation on ARV, free hospital deliveries where possible or discounted delivery cost and support for enrolment in the nearest PMTCT site to their homes.

Improving the ease of medication usage

Pre-ARV and ongoing adherence counselling, regimen simplification with Fixed Dose Combinations (FDC) as approved in National guidelines to reduce pill burdens and side effects from medications, adverse drug reaction tracking and prompt management of side effects are some of the strategies adopted to achieve this improvement objective.

Peer Support interventions

Activities include institution of PMTCT focused support groups, deployment of mentor mothers to

support PMTCT clients with “I have been through it” kind of advice and home follow up in cases of missed appointments, tracking of newly diagnosed cases and implementation of the Community Based EID program which is described in detail below.

Disease Monitoring in PMTCT

Disease progression in HIV infected persons are monitored by both clinical and laboratory parameters that are mainly CD4 and VL tests. These are in addition to baseline chemistry and hematology tests prior to commencement of ARV. Tolerability of treatment is assessed by monitoring hemoglobin (Hb), blood urea nitrogen (BUN), aspartate aminotransferase (AST) and alanine aminotransferase (ALT).

The program provided support for increased access and coverage for CD4 and VL monitoring for PMTCT clients through a combination of Point of Care machines for CD4 at lower levels of care, hub and spoke arrangement for VL sample collection logging and return of results from all levels of care to centralized PCR laboratories. Based on 6 months viral load secondary program data analysis in August 2017, the program recorded a 92% and 94% viral load suppression rates among old and new PMTCT clients on ARVs respectively. The average VL suppression rates combining both category of patients was 93%. These VL suppression rates correlated positively with negative DNA PCR results in the HIV Exposed Infants (HEI) born to these women.

Care and Support services to HIV+ pregnant women including Linkage to ART services

Apart from the ARV interventions for PMTCT, HIV infected pregnant women are offered a comprehensive package of care and support services aimed at optimizing their overall outcome, minimizing morbidity and improving overall quality of life. These interventions include the following:

Malaria Prevention and Prophylaxis

Long lasting insecticide treated bed nets (LLINs) are given to all pregnant women and they are encouraged to sleep under the bed nets to avoid mosquito bites. They are also placed on malaria prophylaxis using sulphadoxine pyrimetamine combination tablets

started from as early in late first trimester into early third trimester.

Screening and treatment for opportunistic infections

Patients are routinely screened for TB using a combination of clinical screening questions and Gene-Xpert testing and those that are TB negative are placed on INH prophylaxis for at least 6 months as per national TB infection control guidelines. Patients are also placed on cotrimoxazole prophylaxis for OI prevention.

Linkage to PMTCT support Groups

Pregnant women are encouraged to join PMTCT specific support groups where they are provided with psychosocial support and counselling. Nutritional advice and food supplementations are provided where available.

Positive Health, Dignity and Prevention (PHDP) Interventions

Women are supported to institute additional life style modifications like safer sex practices in pregnancy, safe water use, smoking and alcohol use cessation, and other practices to reduce exposure to infectious agents.

Early Infant Diagnosis Services and Management of HEI infants

The ultimate measure of the success of the PMTCT program is the delivery of an HIV negative infant and so provision of a package of interventions for the HEI is an important extension of the PMTCT services. The program built the capacity of HCWs to provide a composite package of services to HEIs which include infant feeding counselling to promote exclusive breastfeeding and appropriate substituted feeding based on age, ARV prophylaxis, early infant diagnosis through DNA PCR testing, cotrimoxazole prophylaxis, appropriate immunization, referral to ART services in case of an infected infant, and confirmation of negativity at 18 months postpartum prior to discharge from the PMTCT clinics.

Support is also provided for the collection, storage, sample transfer to PCR laboratories and retrieval of results. The EID services have encountered a myriad of challenges which include poor rate of return of HEI to keep the six weeks appointment for DBS

sample collection, long turnaround time from sample collection, transport and return of results and delays in notification of positive results.

In a bid to resolve the challenges of the long turnaround time, APIN implemented the LACA manager support model which depends on LACA managers who supervise HIV/AIDS program implementation at the LGA levels pooling DBS samples taken at all facilities in their LGAs and bringing them to monthly meetings where all the samples are collated for onward transmission to a PCR laboratory and hard copy results of previous samples submitted are shared. In addition to issuance of paper results, SMS printers were deployed to PMTCT sites in all states of operation while the testing laboratories are equipped SMS senders to enable immediate transfer of EID results to facilities.

Community Based EID programs (COMBED)

This is a community-based intervention implemented to improve outcomes for HEI and to address documented gaps in the EID program implementation. The goal of the COMBED initiative is to contribute to achieving eMTCT targets through improved care and follow up of HEI and achieving a sustainable EID program in APIN supported states. The initiative has four main strategic objectives namely:

- Provide support for HIV positive pregnant women to utilize existing PMTCT services through the period of pregnancy labor, delivery and postpartum period
- Support mothers to access PMTCT interventional care for HEI in the immediate postpartum period including ARV prophylaxis, CTX prophylaxis, immunization and nutritional supports
- Support mothers to ensure HEI return for 6-week postpartum appointment and to continue to utilize EID services up to 18months postpartum
- Track and ensure HEI with DNA positive results return and are enrolled into pediatric ART treatment and care programs

The program was designed to be implemented by community lay health workers in partnership with health facility focal persons, who are either nurses, CHEWs or mentor mothers.

To improve the documentation of the EID services, the program also introduced the **Road to Final Outcome** card, which is a tracer/appointment

card that provides a reminder to mothers about the services their infants are due for and the timing. The card also helps the health care provider offer missed or due services to HEI when they show up in a PMTCT site, even if it is not the primary point of service start up for the mother-infant pair.

APIN's Contribution towards Increasing National PMTCT Coverage

APIN, initially as a project of HSPH, and later as an independent partner, implemented comprehensive HIV treatment and care services between 2004 and 2013 with funding from the PEPFAR program in nine states of Nigeria with presence mainly in tertiary facilities, specialist hospitals, faith-based hospitals and a few general hospitals.

In a bid to scale up PMTCT services to lower levels of care, the program established satellite sites as its service expansion model. Using tertiary facilities as hubs, satellite sites were activated in Lagos, Oyo and Plateau states. In Oyo state, UCH supported three satellite sites; in Borno state, UTH supported three satellite sites; in Lagos state, LUTH supported three sites; while in Plateau State, JUTH supported 13 satellite sites.

Additional expansion of PMTCT services to PHC levels was initiated and completed between June and October 2011. The PHCs were activated mainly as PMTCT sites and linked as spokes to established facilities in Lagos, Oyo and Ogun states. Some of the facilities serving as hubs for these PHC PMTCT sites were actually satellite sites that had been graduated to ART sites in the three states. This expansion covered a total of 25 LGAs and 75 PHC facilities across the three states. In addition to PMTCT site expansion, five of the sites in Abeokuta under Sacred Heart Catholic Hospital (SHCH), Lantoro, also doubled as an ART decentralization sites, as part of the GON managed ART decentralization program. These facilities served as ARV drug pick up sites for stable ART patients managed at SHCH Lantoro who lived close to these facilities.

Rapid Scale up of PMTCT services 2013-2014

At an abysmally low national PMTCT rate of 17% in 2012¹³ there was an urgent need to rapidly increase coverage. Based on previous successes achieved at implementing PMTCT services at lower levels of care, a rapid health facility assessment was conducted with the aim of identifying and activating more facilities to provide PMTCT services. The facility assessment was conducted simultaneously in Lagos, Oyo and Plateau states between March and April 2013.

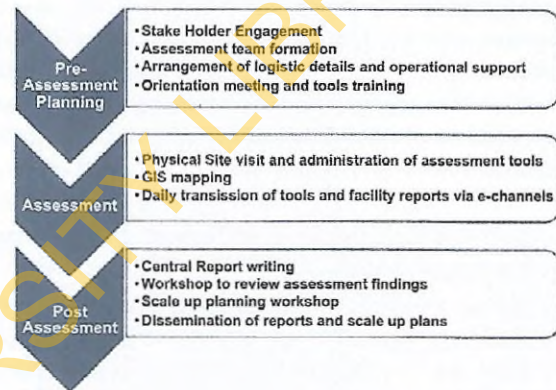


FIGURE 3 Rapid facility assessment process

The comprehensive list of all public and registered private health facilities in each state was reviewed and needed information was obtained for qualifying sites based on standardized assessment criteria using pre-tested questionnaires. The basic criteria for qualifying sites for PMTCT services included availability of ANC and delivery services, a minimum component of staff to provide PMTCT services and an appreciable ANC patient load among other factors.

In all, the assessment was conducted in 2210 facilities spread across 70 LGAs; 33 in Oyo (1070 facilities), 20 in Lagos (764 facilities) and 17 (396 facilities) in Plateau states.

At the end of the assessment and having applied the qualifying criteria for a PMTCT site, a total of 550 facilities were identified as suitable to be activated as new PMTCT sites; 229 facilities in Oyo, 76 in Lagos and 245 in Plateau state were prioritized for training of health care workers and activation as PMTCT sites.

S/N	Type of Facility	Oyo	Lagos	Plateau	Total
1	Public	571	139	354	1,054
2	Private	499	605	42	1,146
	Total	1,070	744	396	2,210
	No of LGAs	33	10-APIN, 10-FHI-360	17	

TABLE 2 Sites Assessed for Scale Up of PMTCT Services

Criteria for Prioritization

In selecting facilities for prioritization and activation for service delivery, three key criteria were considered and these included:

- Availability of at least two² health care workers to provide ANC and PMTCT services
- ANC patient load of 240 clients per year, i.e. at least 20 new ANC clients per month
- HIV prevalence of the facility location equal to or more than the state level prevalence

The PMTCT scale up plan was designed to activate 50% of the facilities that qualified in the table below by September 2013 and the rest of the facilities within a year of completion of the facility assessment.

However due to several factors including geographical spread, logistic requirements for site activation, infrastructure upgrade requirements and sometimes discovery of factors that made sites not suitable for activation despite positive survey findings, not all the facilities were activated for PMTCT service delivery. One hundred and twenty sites were activated in Oyo, 79 in Lagos and 235 in Plateau state.

The success achieved with the scale up of PMTCT services was not without challenges that included

the additional need for technical support for new sites spread over wide geographical locations. Low capacity at the facility level to provide comprehensive disease monitoring for positive women in care and treatment, and high loss to follow up rates especially in the postpartum period. Difficulty in organizing HIV infected pregnant women into community support groups due to few positive pregnant women spread out over large communities. Challenges of linkages to continued care and treatment for women post-delivery due to the far distance of comprehensive sites from the new PMTCT sites and poor utilization of EID services despite adequate counselling.

These challenges brought to the fore the need for more focused technical support targeted at addressing them on a case by case basis. It also provided opportunities to challenge new thinking about PMTCT programming and service delivery. For instance, poor capacity of service delivery was addressed through organized PMTCT trainings for facility staff and continuous mentoring. The challenges of increased technical support across multiple facilities was solved through clustered site visits and supportive supervision while the challenges of poor linkage to care was addressed by upgrading PMTCT sites that

S/N	Level of Care	Oyo	Lagos	Plateau	Total
1	Primary	191	69	152	412
2	Secondary	28	7	93	128
	Total	229	76	245	540

TABLE 3 Sites Prioritized for Activation

met the criteria of comprehensive facilities providing continuous ART services for postpartum clients.

APIN's Response to PMTCT Programming Innovation towards Community Sustainability

In order to achieve the desired PMTCT program outcomes, several interventions that lie outside the formal health systems continue to be implemented. Major examples are the TBA engagement for HIV testing in ANC, testing of pregnant women for HIV in outreach settings, tracking loss to follow up PMTCT clients, the COMBED initiatives to improve EID services and final outcomes for HEI and escort managed linkage to ART services. These interventions are mainly donor driven, and it is feared that in the event of massive cuts or withdrawal of donor support, the gains achieved over the years may be halted and in fact may witness massive reversals. APIN continues to support partner state governments to develop sustainability plans for comprehensive HIV services including PMTCT and constantly engages the government for its successful implementation.

The Health System in Nigeria

The weak health systems make it very difficult to implement health programs, particularly in the public sector. The system challenges include human resources inadequacy, poor infrastructure, weak administrative and financial systems, inadequate funding, incessant strike actions and inadequate demonstrated political will to support and provide counterpart funding. APIN has invested heavily in health system strengthening, covering human capacity development, infrastructure upgrades, improvement in monitoring and evaluation systems, strengthening of commodity logistics supply chain systems and laboratory upgrades among others. Despite these investments, shortage of manpower and the inability to sustain program investments remain persisting challenges.

The Future of PMTCT in Nigeria- Implications for APIN

The PMTCT program is central to any successful HIV/AIDS program implementation due to its importance

in three key areas; decreasing prevalence by eliminating MTCT, reduction of new infections among sexually active young people, and ensuring that females are sufficiently empowered to take sound economic, social and cultural decisions that potentially impact their health and the health of their households. To this end, the future of the PMTCT program may be centered on the following contextual areas that align with the strategic interests of the APIN PMTCT program.

Improving Coverage and Access to PMTCT services

Despite the documented scale up efforts, continued support and expansion of PMTCT services is still largely donor driven. With dwindling donor funding for community prevention, including PMTCT services, it gets increasingly difficult for vulnerable and marginalized women in particular to have access to quality PMTCT program. APIN will continue to engage and support the GON with a viable sustainability plan to bridge the gaps and provide additional investment to ensure that services continue unhindered, even as donor funding dwindles further.

Private Sector involvement

While it is generally believed that up to 60% of persons seeking health services do so in the private setting, the documented contribution of the private sector to PMTCT services has been very minimal.^{14,15} APIN will continue to seek opportunities for private sector collaboration through other funding opportunities, including the performance-based funding mechanism of the World Bank and other agencies, with a view to promoting a sustainable government owned PMTCT program.

Congregational based approach to PMTCT

Religious gatherings present opportunities to reach pregnant women as demonstrated by the NIH funded baby shower trial, a congregational approach to reaching pregnant women and their spouses for the purposes of getting HIV testing done in pregnancy among other tests and receiving appropriate interventions. The study found that 91% of the pregnant women in the intervention group completed an HIV test with 2% positivity rates.¹⁶ Significantly, more women in the intervention group (11 times more than the pregnant women in the control group) received an HIV test. In addition, women in the intervention group were

six times more likely to begin HIV treatment during pregnancy.¹⁶ The APIN PMTCT program will adopt this strategy as one of the proven mechanisms for reaching more women and potential PMTCT clients.

Community based PMTCT and ART services

The new frontiers in community PMTCT services will need to focus on how to consistently meet the needs of women utilizing TBA/CBA services in a less disruptive way, especially after they are diagnosed positive. APIN will consider provision of ARVs outside hospital settings by trained lay health providers domiciled in the community who are affiliated with orthodox clinics. This hopefully will improve ARV initiation and retention rates for HIV infected women. Same-trained lay health providers may assist in collecting DBS samples for babies and VL samples for mothers.

Novel approaches to new case findings

Self-testing and self-reporting of HIV test results by pregnant women, as well as members of the general population, provide an exciting opportunity for HIV case finding among all population groups. While this promotes ease of uptake without the concerns associated with testing by health providers, it will require a structured approach that guarantees consistent quality and reliable results. It will also be necessary for a mechanism to be put in place for such women who test positive to report for additional PMTCT interventions. Introduction of toll free lines or anonymous call systems may help improve reporting of such cases. APIN will gradually integrate these approaches into its PMTCT program, initially as a pilot and later scaled up, depending on feasibility and effectiveness.

Treatment as Prevention

The 2016 Nigeria National guideline recently adopted the OPTION B+ approach for managing PMTCT clients on a life-long basis, without breaks in ARV usage between pregnancies. This is currently implemented by APIN and the approach has the added advantage of consistent VL suppression for adherent women in between and during pregnancies, translating to less opportunities for MTCT. To increase retention and sustained VL suppression for such patients, key issues like ease of ARV pick-ups, prompt management of Adverse Drug Reactions (ADRs), access to ANC and delivery services, as well as easy access to other

reproductive health services will be strengthened by APIN.

Strengthening PMTCT ART services at lower levels of care

Closely related to expanding treatment for life for HIV infected pregnant women is the need to increase capacity at lower levels of care to support provision of PMTCT services. The ability to recognize ADR in patients, manage ARV complications, recognize and treat opportunistic infections, interpret laboratory results, identify patients failing therapy and effective adherence counselling skills, remain critical management gaps. APIN will continue to build capacity of health workers at all levels to manage these complications. Additional system strengthening interventions addressing commodity and drug logistics, health management information systems, program management skills, finance and administrative support for programs will continue to be APIN's priorities towards sustainable PMTCT service delivery.

Scaling up of Point of Care Technologies (POC) in PMTCT services

Currently, disease monitoring for PMTCT clients on ARVs is largely dependent on hospital visits for sample collection and processing due to the technical skills involved. The deployment of DBS method for EID and the introduction of point of care technologies have helped improve coverage for such services. Introduction of POC technologies for disease monitoring tests in PMTCT, especially for viral load monitoring will be seriously considered, developed and deployed for widespread use at lower levels of care. These POC diagnostics will help reduce turnaround times, and will impact wait times from sample collection to result issuance. It will also shorten the clinical decision time frame when managing PMTCT clients. It will hopefully come at a lower cost and will be more affordable for programs and hospitals to deploy.

Managing PMTCT client transitions between different levels of care

Due to the decentralized nature of the PMTCT program, basic services are provided for HIV infected pregnant women at lower levels of care, but a number

of such patients require advanced services that necessitate referrals to higher levels of care, and this can be very challenging for such patients in certain locations. Such services include management of medical co-morbidities like TB-HIV or HBV/HCV-HIV, ART services for infected HEI and advanced obstetric care among other services. The APIN PMTCT program, working with other stakeholders, will continue to strengthen systems to make these such services accessible to all those who need them.

Operations Research into improving PMTCT service delivery

Gaps have been identified in current PMTCT service delivery models and there are ongoing efforts to improve the efficiency of PMTCT services. APIN will continue to prioritize operations research into different models of service delivery to constantly provide evidence to support interventions that will improve mother and HEI outcomes in PMTCT. Potential OR include issues around uptake of PMTCT services, waiting times in PMTCT clinics, improving turnaround times for VL and other laboratory tests, ARV dispensing mechanisms, improving hospital delivery rates, promoting adherence to ARV in OPTION B+ setting and improving EID service. It is hoped that findings from such research will continue to provide evidence to further fine-tune the national PMTCT program.

APIN Research Contribution to National PMTCT Program

The APIN PMTCT program, through its many research and evaluative works, has contributed to knowledge that continues to inform PMTCT program modification in Nigeria.

HIV testing in ANC is the basic entry point into PMTCT and targeting the right population for testing is key in identifying those with HIV infection. Sagay et al documented that women 20-29 years old have a 4-fold risk of HIV infection than other age groups, emphasizing the need for targeted, age specific programs.¹⁷ Recent studies have documented a declining HIV prevalence rate as low as 1.8% among first time tested pregnant women in labor, and even a lower rate of 0.6% among those repeating tests in same pregnancy at an advanced gestational

age.¹⁸ Acceptability for HIV testing among pregnant women and those in labor has been documented to be as high as 90%^{19,20} and this has led to reduced missed opportunities for HIV diagnosis and PMTCT interventions.

Partner consent and support can substantially enhance adherence to PMTCT interventions. Studies from the APIN supported PMTCT program have shown high rates of disclosure of up to 89% among HIV infected pregnant women to their spouses. A significant proportion of such male partners (up to 87%) were supportive of their partners, while violence and positions of indifference were reported in 1% and 7% respectively of such cases after disclosure.²¹ Contrary to widely held beliefs, women should be encouraged and supported by health care workers and through other mechanisms to disclose their HIV status to improve PMTCT outcomes.

Viral load levels, among a myriad of factors, is one of the main determinants of MTCT of HIV and adherence to ART is a major correlate of suppressed VL. Studies from the APIN PMTCT programs demonstrated high levels of ARV adherence (greater than 95%) in more than 80% of HIV infected pregnant women on ARV therapy and the desire to protect the unborn child is the most common motivator for adherence, while fear of being known as HIV infected is the greatest concern among the poorly adherent patients.²²

Retention in PMTCT care and treatment is a key factor in achieving a favorable outcome in PMTCT. Published studies from the APIN program by Holly Rawizza et al and Oladokun et al, addressed these issues extensively within the context of the APIN program. The major drop off point in the PMTCT cascade of care is the period just before delivery.^{3,23} A number of studies have focused on the evaluation of the PMTCT program and outcomes of HIV exposed infants.

A special edition of the Current HIV Research Journal in 2015 focused on evaluation of the HIV program in Nigeria including the PMTCT program. One of such evaluations from Jos, Nigeria showed that at 18 months, MTCT of HIV was lower among women who commenced ART before pregnancy compared to those women who started ART/triple ARV prophylaxis during pregnancy/delivery (0.4% vs 2.0%).³ This difference was statistically significant. Home delivery was associated with higher transmission than facility

delivery. Type of delivery or infant feeding options had no significant impact on MTCT rates by 18 months.²³ Completion rates of 66% of women initiating PMTCT programs and the greatest loss in the PMTCT cascade of care commonly happens just before delivery with a documented drop off rate of 21%.²⁴ A few studies also documented non-HIV related outcomes. Ezechi et al²⁵ documented preterm birth among HIV patients of about 11% (181 of 1626 eligible study participants) with 10.3% having low birth weight; the study concluded that spontaneous preterm delivery is significantly associated with unmarried status, baseline CD4 count less than 200cell/mm³, presence of opportunistic infections at delivery among other key factors. Intimate partner violence (IPV) is also a key concern that is closely related to PMTCT outcomes in Nigeria. About 66% of women reported spousal abuse after HIV diagnosis²⁶ and such outcomes have been responsible for poor disclosure rates by PMTCT clients and the attendant effect of poor adherence to ART and clinic visits.

Additional APIN PMTCT related publications can be found at <https://www.apin.org.ng/apin-publications/>. These publications and many more have helped document scientifically the success and challenges of the APIN PMTCT program that will be by future research endeavors.

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