Implementation of Option B+ for Prevention of Mother-To-Child Transmission of HIV:

The Malawi Experience

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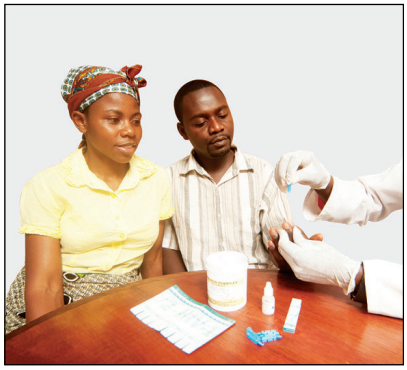

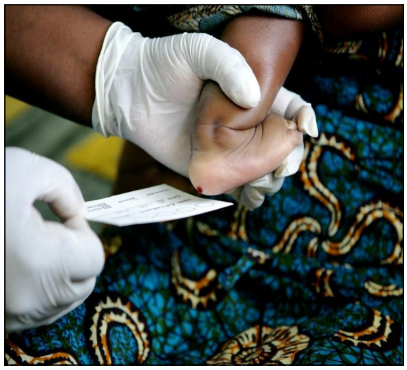

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Abbreviations

5A	Adult formulation of triple ART combination of Tenofovir/Lamivudine/ Efavirenz)
ABC	Abacavir
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral drug
AZT	Zidovudine
CBO	Community-based Organization
CCM AIDS	Country Coordinating Mechanism for HIV/
CD4	Cluster differentiation of subtype 4 T lymphocyte cells
CDC	Centers for Disease Control and Prevention
CE	Cost Estimate
CHAI	Clinton Health Access Initiative
CHAM	Christian Hospitals Association of Malawi
CMED	Centre for Medical and Epidemiological Data (of MOH)
CMS	Central Medical Stores
COIDA	Action Aid, Communities in Development Activities
CPT	Cotrimoxazole Preventive Therapy
CSO	Civil Society Organization
DAPP	Development Aid from People to People
DBS	Dry Blood Spot
DIP	District Implementation Plan
DNA	Deoxyribonucleic acid
DHMT	District Health Management Team
DMPA	depo-Medroxyprogesterone acetate
EFV	Efavirenz
EGPAF	Elizabeth Glaser Paediatric AIDS Foundation
EID	Early Infant Diagnosis
EMTCT	Elimination of Mother-to-Child Transmission of HIV
EPI	Expanded Programme on Immunization
FGD	Focus Group Discussion
FTC	Emtricitabine
GF	Global Fund to fight AIDS, Tuberculosis and Malaria
HCC	HIV Care Clinic
HIMS	Health Information Management System
HIV	Human Immunodeficiency Virus
HSA	Health Surveillance Assistant
HSSP	Health Services Strategic Plan
HTC	HIV Testing and Counselling
ICF	Intensified TB Case Finding
IPT	Isoniazid preventive therapy
KM	Kilometre
LFA	Local Fund Agent
LPV/r	Lopinavir/Ritonavir
MACRO	Malawi AIDS Counselling and Resource Centre
MANET+	Malawi Network of People Living with HIV/AIDS
MCH	Maternal and Child Health

MDHS	Malawi Demographic and Health Survey
M and E	Monitoring and Evaluation
MGDS	Malawi Growth and Development Strategy (MGDS1 = 2006-2011, MGDS2 2012–2016)
M2M	Mothers-to-Mothers
MNCH	Mother, Newborn and Child Health
MOH	Ministry of Health
MSF	Médecins sans Frontières
NAC	National AIDS Commission
NAPHAM	National Association of People Living with HIV/AIDS in Malawi
NGO	Nongovernmental Organization
NTP	National Tuberculosis Programme
NVP	Niverapine
sdNVP	Single-dose Niverapine
OI	Opportunistic infection
OPC	Office of the President and Cabinet
2P	Paediatric formulation of triple ART combination of Zidovudine/ Lamivudine/Nevirapine
PCR	Polymerase Chain Reaction
PEPFAR	US President's Emergency Programme for AIDS Relief
PIH	Public Institute of Health
PITC	Provider Initiated Testing and Counselling
PLHIV	People living with HIV/AIDS
PMTCT	Prevention of Mother-to-Child-Transmission of HIV
RCC	Rolling Continuation Channel (of Global Fund Grant)
RHU	Reproductive Health Unit
SSDI-JHPIEGO	Support for Service Delivery Integrated Programme of Johns Hopkins Programme for International Education in Obstetrics and Gynaecology
STI	Sexually Transmitted Infection
SVD	Stadtverkehr Detmold GmbH
TA	Technical Advisor
TB	Tuberculosis
3TC	Lamivudine
TOT	Training of Trainers
UNC	University of North Carolina
UNICEF	United Nations Children's Fund
SMS	Short Text Messaging System
USG	United States Government
WHO	World Health Organization

Foreword

The coalition of global efforts toward elimination of Mother-To-Child Transmission of HIV (MTCT) has brought hope of ending vertical transmission of HIV from pregnant mother to the child. This is built around a growing body of evidence pointing to the fact that vertical transmission of HIV can be eliminated. As more and more efficacious treatment options become available, it has become increasingly imperative for governments and partners to do all they can to ensure that HIV infected pregnant women and HIV exposed or infected children get the care they very much deserve.

The adoption of a triple antiretroviral drug combination for treatment of pregnant and breastfeeding women are expected to go a long way and to significantly contribute to the elimination of MTCT. This has been strengthened by the new 2013 WHO Consolidated Guidelines on the use of antiretroviral drugs. As a result, several countries in the African Region have already adopted or are planning to adopt option B+ for their national PMTCT programs.

The above realizations and the desire to obtain early lessons to inform decisions of other countries considering B+ informed WHO's decision to partner with the government of Malawi, through its Ministry of Health, and partners to document their experience after one year of B+ implementation. The World Health Organization Regional Office for Africa is pleased to share this report with all governments and partners in the Region and beyond. A lot of effort has been put in compiling this report and we hope you will find it very useful. It is important that these early lessons and recommendations are put into consideration as countries transition to Option B+ as we move towards elimination of new HIV infections among women and keeping their mothers alive.

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Executive Summary

Introduction

Following the release in 2009 of the WHO PMTCT antiretroviral (ARV) rapid advice on treating pregnant women and preventing infection in infants that recommended ARV options 'A' or 'B', Malawi recognized that neither of these two options would best serve the national interest of treating as many women as possible to reduce mother-to-child transmission (MTCT) of HIV. The country, therefore, decided to initiate all HIV-positive pregnant or breastfeeding women on antiretroviral therapy (ART), irrespective of their CD4 count. This approach, a modification of the WHO Option B, is called 'B+'.

The documentation process involved a mixed methodology employing pre-tested tools to collect qualitative and quantitative data on service delivery, national policy environment, plans, financial and human resources, and processes for adoption and implementation of Option B+. Data were also collected on decentralization, task shifting, integration with other programmes, partnerships, community engagement, challenges, limitations and lessons learnt. All the data were appropriately analysed and are presented in this report.

The following methods were used to document this experience: (a) desk review of relevant documents; (b) key informant interviews with relevant MOH officers, service providers, development partners, and implementing partners; (c) field visits to selected regions, districts and health facilities to obtain relevant information and Focus Group Discussions (FGD) with women accessing services; (d) national workshop to share the findings and incorporate the inputs of stakeholders.

Purpose of the documentation

The WHO Regional Office for Africa, in collaboration with the WHO Country Office, the Ministry of Health of Malawi and the implementing partners, undertook to document the Malawi experience in implementing Option B+ in order to build on the country's experience to provide support and relevant information to other countries, inform capacity building initiatives for technical staff to enable them to provide appropriate support to countries, and contribute to the provision of guidance for countries to assess their own situation and experiences and make optimal programmatic choices.

Context and rationale for B+ adoption and implementation in Malawi

Malawi adopted and is implementing Option B+ to: (a) increase access to ART for HIV-positive pregnant or breastfeeding women in a setting that has limited access to CD4 testing; (b) improve mothers' health and reduce post-partum mortality; (c) reduce HIV transmission to sexual partners, especially in stable discordant relationships; (d) avoid starting and stopping prolonged ARV use; (e) reduce stigma resulting from curtailing breastfeeding; (f) reduce malnutrition among infants; and (g) avoid the need for extended infant HIV prophylaxis. The advantages of Option B+ include the simplification of

PMTCT and ART treatment regimens and service delivery; strengthening of linkages between reproductive health and ART programmes at all service delivery levels; protection against MTCT in future pregnancies; and avoidance of stopping and re-starting ARVs, thereby allowing for one public health message, i.e. 'ART is for life'.

Process of Option B+ adoption

The choice, planning and implementation of Option B+, were participatory, involving all key stakeholders. National consultations and decision-making were, to some extent, informed by a feasibility study that Malawi undertook in 2009 on the 2010 WHO recommendations at the request of WHO. A national symposium was held in November 2009 on the Option B+ proposal, focusing on the need for simplification of service delivery. A resource mapping exercise was then carried out, activities were prioritized, consensus reached on the approach, and funding mobilized from various sources, including the Government and development partners. Pre-implementation arrangements included in-country technical meetings to build consensus, discussions on feasibility and the merging of the ART and PMTCT technical working groups (TWGs) into one committee. The revised terms of reference and roles of the committee included development/revision of policies, strategies, plans, training materials, guidelines, tools, monitoring frameworks and simplification of ART regimens with emphasis on transitioning to more favourable first-line combinations, as recommended by WHO.

Key achievements

The implementation of Option B+ in Malawi has resulted in increased availability, accessibility and utilization of PMTCT services. It has been associated with rapid expansion of integrated PMTCT/ART services to all Maternal, Neonatal and Child Health (MNCH) sites. With offer of HIV testing and counselling (HTC) to all women accessing ANC and delivery care, over 80% of those testing positive are initiated on ART in the country. Also notable is an increase in client satisfaction and acceptability of PMTCT services. Focus Group Discussions (FGD) with clients revealed preference for integrated services and Option B+, particularly because it does not require stopping breastfeeding. The FGDs also revealed that health education enhances the knowledge of clients, facilitating improvement in quality and follow-up of mother-infant pairs. The B+ requirements necessitate the adoption and implementation of task-shifting that generally benefit other programmes in the country.

Implementation challenges

Bottlenecks were identified during the scale-up process, most of which have been addressed during implementation, using a problem-solving approach. Persistent bottlenecks include frequent stock outs of non-ARV drugs and HIV rapid test kits; inadequate strategic information management and use especially at the district and subdistrict levels; and incomplete integration of training and other guidelines and tools into the MNCH platform. The issue of same-day testing and initiation on ARVs is still somewhat controversial, with a few health workers and clients expressing reservations or refusing to cooperate. There are also issues to be addressed regarding the quality of laboratory testing.

Conclusion

The high antenatal attendance rate of 95% in Malawi (2010), the availability of HTC in all ANC outlets, the commitment to integrate ART and PMTCT services, optimization of the use of existing human sources through integration of services and task shifting, supportive policy and guidelines for institutionalizing the programme and its effectiveness facilitate high ART coverage among HIV-positive pregnant women, and Option B+ provides the opportunity to treat them. Available partnerships, involvement of PLHIV, increased male involvement and community engagement and support are also critical components of the PMTCT programme. This documentation has shown that implementation of PMTCT

Option B+ is possible even in resource-limited settings and Malawi has demonstrated that integration of PMTCT and ART programmes is feasible. Ensuring the continuum of care, keeping women and children on treatment in primary health care settings and reducing loss to follow up should be underscored for those considering or already implementing Option B+.

Key recommendations

It is recommended that:

(a) national governments provide clear policies and guidelines, and ensure effective orientation of health workers;

(b) integration be emphasized as the best mode of delivering B+, especially within MNCH platform;

(c) use of task-shifting, supportive supervision and mentoring be optimized to improve the skills and capacity of health workers, as well as community engagement aspects;

(d) capacity be built for data management and use and for laboratory testing, including quality assurance;

(e) supply management (including quantification and forecasting) be strengthened to ensure uninterrupted supply of drugs and commodities.

1. Introduction

1.1 Background

The Prevention of Mother-to-Child Transmission of HIV (PMTCT) programme in Malawi started in 2001, initially being piloted in Embangweni Mission Hospital (Chiradzulu District) and Thyolo District Hospital. The national PMTCT programme was officially launched in 2003. Single-dose Nevirapine was used for the period 2001 to 2008. Malawi introduced AZT combination prophylaxis in 2008 with AZT/3TC being initiated at 28 weeks, followed by sdNVP during labour and AZT/3TC tail for a week. Infants received NVP syrup for a week or more depending on the duration of exposure of the mother to ARVs. At the same time, sDNVP for mothers and infants was phased out in Malawi.

In 2009, Malawi was one of the three countries selected and supported by World Health Organization to conduct a rapid feasibility study as part of the process of developing the 2010 ART guidelines. The study reviewed the policy and programmatic implications for the national HIV care and treatment programmes in introducing earlier ART initiation, use of more expensive ART regimens and routine laboratory monitoring for identification of treatment failure. Key recommendations from this appraisal were that: (a) early ART initiation was feasible in resource-limited settings, but would be best with regimens that are less toxic and do not require rigorous laboratory monitoring; (b) the cut-off CD4 cell count should be raised to ensure better outcome for many more people.**(1)**

The rapid advice on PMTCT, and ART in adults, adolescents and children was released by WHO in December 2009 and recommended two prophylaxis **options** for women not eligible for treatment. **Option A** expanded on the previously recommended (2006 guidelines) approach to PMTCT prophylaxis and includes maternal AZT from 14 weeks of pregnancy, plus single-dose Nevirapine plus AZT/3TC during labour and a week of AZT/3TC postpartum with Nevirapine syrup for the infant from birth till cessation of breastfeeding. **Option B** introduced the use of triple ARVs (based on recommended first-line ART) to the mother from 14 weeks of pregnancy through labour, delivery and until cessation of breastfeeding. These recommendations were launched in 2010.

Malawi convened a stakeholders symposium in January 2010 to examine a feasible option from the new WHO recommendations. Following a recommendation from the stakeholders symposium, Malawi decided to put all HIV-positive pregnant or breastfeeding women on ART for life irrespective of the clinical stage or CD4 cell count. This approach is now known as 'Option B+' which is being implemented since July 2011.

In April 2012, WHO published a programmatic update that recognized the potential advantages and the need to take into consideration the new Option B+ approach within a public health perspective in resource-limited settings. In order to provide countries with appropriate information on the implications of the implementation of Option B+, WHO, in collaboration with Malawi Ministry Of Health (MOH), development partners (donors) and implementing partners, decided to document the Malawi experience in implementing Option B+.

1.2 Rationale for B+ adoption

The rationale for adoption of Option B+ can be summarized according to the two main requirements that Malawi considered to effectively scale up PMTCT.

1. 2.1 Need to accelerate the reduction of HIV transmission in Malawi

Malawi is among the 10 countries with the highest HIV prevalence in the world and an estimated 50 000 new infections every year in a population of 14 million people. An estimated 88% of the new infections are acquired through heterosexual relationships, 10% through vertical transmission from mother to child, and 2% through unsafe blood transfusion and contaminated medical and piercing instruments. From 1985 when the first case of HIV was reported, the prevalence among adults aged 15–49 years rose steadily, peaked at 16.2% in 1999 before declining and stabilizing at about 12% from 2007.**(2)** The implementation of Option B+ is expected to significantly reduce new HIV infections resulting from vertical transmission as well as heterosexual relationships, thereby contributing significantly to overall reduction of new HIV infections in Malawi.

The advantages of Option B+ are the simplification of PMTCT and ART treatment regimens and service delivery; strengthening of linkages between reproductive health and ART programmes at all service delivery levels; protection against MTCT in future pregnancies and between discordant couples; and avoiding stopping and re-starting ARVs, which allows for one public health message, namely "ART is for life".

1.2.2 Need to simplify delivery of PMTCT services

Lack of access to CD4 cell count equipment and systems for successful referral to ART services in most health facilities creates a huge barrier for women who need ART for their own health. As a result, women who require treatment receive only prophylaxis regimens. Scheduled stopping of ARVs as provided for in Option B would also be difficult to implement as it requires a CD4 count to determine if a mother needs ART for her own health. Moreover, stopping ART after cessation of breastfeeding as recommended in Option B poses a risk of viral rebound, resulting in increased risk of HIV transmission to a sexual partner or a baby. Furthermore, under the previous PMTCT options, some mothers did not comply with stopping breastfeeding at six months, thereby putting infants at increased risk.

The long-term effects of frequent ART interruptions (as would happen with option B) have not been well studied though some studies have shown that they may be associated with adverse outcomes.

1. Swaziland (25.9%), Botswana (24.8%), Lesotho (23.6%), South Africa (17.8%), Zimbabwe (14.3%), Zambia (13.5%), Namibia (13.1%), Mozambique (11.5%), Malawi (11.0%) and Uganda (6.5%).

Option B+ also enables safe breastfeeding while avoiding the need for prolonged infant HIV prophylaxis as it is challenging (in terms of storage, dosing, hygiene, etc.) for a mother to consistently give NVP syrup to her baby for 12 to 24 months. Lastly, soon after the breastfeeding period (median duration in Malawi is 23 months) many women in Malawi become pregnant again, given the high rates of fertility in the country and the short time intervals between pregnancies.

1.3 Purpose

The documentation builds on the Malawi country case example in implementing PMTCT Option B+ to support other countries of the Region by providing relevant information and guidance in anticipation of policy discussions, planning and how to mitigate the expected challenges of implementing Option B+. The objectives of the documentation were:

(a) to establish the context and processes that informed the development and adoption of the PMTCT Option B+ approach;

(b) to learn the implementation modalities and assess programmatic requirements for successful implementation of Option B+;

(c) to review current data from and programmatic experience of implementing Option B+ in Malawi and identify key issues, solutions, lessons; and

(d) to provide support for Malawi to improve implementation of Option B+ and for other countries in the African Region that would like to adopt this option.

1.4 Methodology

The process was led by the WHO Country Office in Malawi and the Ministry of Health (MOH), specifically the ART/PMTCT Technical Working Group, with technical and financial support from WHO Regional Office, Intercountry Support Team and headquarters. The following methods were used to document the Malawi experience:

(a) Desk review of relevant documents.

(b) Key informant interviews with relevant MOH officers, service providers, development partners, and implementing partners.

(c) Field visits to selected regions, districts and health facilities to obtain relevant information and Focus Group Discussions (FGD) with women accessing services.

(d) A national workshop to share the findings and incorporate the inputs of stakeholders.

Tools were developed and pretested to ensure the collection of relevant information on service delivery, national policy environment, plans, financial and human resources, processes for adoption and implementation of Option B+, decentralization, task shifting, leveraging other programmes especially maternal, neonatal and child health (MNCH), partnerships and community engagement. The tools were also designed to gather information on the challenges, limitations and lessons learnt. A total of three tools were developed:

- **National/district level Key Informants Interview Guide.** This tool was used to interview the key officials at the MoH headquarters, national level PMTCT partners and district level PMTCT Managers on programme organization, coordination and management at the national level including plans for sustainability; integration of PMTCT services into MCH and other primary health care services; structures and systems in place to support PMTCT activities; levels of involvement of NGOs and CBOs as partners for PMTCT; supply chain of essential PMTCT commodities; monitoring and evaluations

systems for the PMTCT programme; systems, services and benefits of implementing PMTCT in model and typical health facilities; systems, services and benefits of implementing PMTCT in conflict and post conflict areas; funding mechanisms used to support PMTCT scale up and service delivery at various levels; approaches used to support safe infant feeding in PMTCT; and task shifting policy.

- **Health Facility Level Key Informants Interview Guide.** This tool was used to interview key staff at selected health facilities and collect data on service delivery; programme management, including human resources for health; support given to community support groups; and partnerships/collaborations.

- **Community/Health Facility Focus Group Discussion Guide.** This tool was administered to pregnant women, lactating women and community health workers. It was used to collect a wide range of data including knowledge of PMTCT, awareness and availability of services, whether any changes had been noticed in the way the programme was being implemented, opinion on these changes, presence of community groups and networks, community mobilization activities being undertaken, male involvement in PMTCT and general perceptions on the range and quality of services being provided.

For the field visits, eleven health facilities implementing B+ were purposely selected, reflecting regional as well as zonal representation of the five national health zones, different levels of health care delivery (central hospitals, district hospitals, community hospitals and health centres), and facility ownership – Public or Christian Hospitals Association of Malawi (CHAM).

The criteria used to select the 11 health facilities is detailed in Annex 3 and included: Regional and Zone type of ownership, level of health care, volume of clients at the facility, and facility performance in the 12 months immediately preceding this documentation. This approach ensured inclusion of national, regional, district and lower level facilities; public and privately owned facilities; high and low volume facilities; as well as those facilities that were performing poorly and those that were performing well.

Quantitative data from health facilities were analysed using MS Excel to generate simple descriptive tables and charts included in this report. Qualitative data from interviews and focus group discussions were categorized by groups for comparison. Summaries from this analysis are also provided in the report.

It should be noted that this document is not an evaluation of the performance of the Malawi PMTCT programme or of the B+ approach. It is, rather, a description of the factors that informed Option B+ adoption as well as those that affected its implementation, including the challenges and lessons learnt to advise relevant policy processes, improve implementation and provide support to those that may wish to adopt or adapt this approach.

2. Bwaila Hospital, Kaluluma Rural Hospital, Katete Comm. Hospital, Matawale HC, Mitundu Comm Hospital, Mtenthera HC, Mzimba District Hospital, Mzuzu Central Hospital, Ndirande HC, Thyolo District Hospital, Zomba Central Hospital.

2. Key steps towards implementation of Option B+

The adoption and implementation of B+ in Malawi went through several steps and processes over a period of two years, starting with national consultation in July 2009 to the beginning of its actual implementation in July 2011.

Box 1 (below) summarizes key steps regarding the adoption of Option B+ and preparation for its

Box 1: The Key steps in the adoption and implementation of B+ in Malawi:

1. National consultations and decision-making.
2. Merging of ART and PMTCT Technical Working Groups.
3. Formulation of ART/PMTCT guidelines.
4. Mobilization of funding.
5. Review of the procurement and supply system.
6. Capacity building of service providers.

2.1 National consultations and decision-making

Following up the WHO rapid feasibility study and the release of the programmatic update for PMTCT, a stakeholders symposium was held in January 2010 to examine a feasible option from the new WHO recommendations. The stakeholders symposium decided that all HIV-positive pregnant or breastfeeding women in Malawi be put on ART for life regardless of the clinical stage or CD4 cell count; this approach is now known as 'Option B+' which is being implemented since July 2011.

2.2 Merging of PMTCT and ART technical working groups

Through consultations and consensus building around Option B+, Malawi realized that implementation of B+ requires ART initiation within MNCH service delivery areas. Hence, integrating PMTCT into MNCH platform was no longer optional but an integral part of Option B+ implementation. As a starting point for this imperative integration, the ART and the PMTCT Technical Working Groups were merged to enable effective planning and to fast track integration of

ART & PMTCT services within the MNCH platform. In April 2010, the merged ART/PMTCT TWG recommended the adoption of Option B+; and that recommendation was approved by senior management of MOH. Several technical working group meetings were held to among others build consensus and define mechanisms and processes for the adoption of Option B+.

Buoyed by the possibility of funding from reprogramming of the Global Fund RCC, MOH continued to make preparations for the implementation of B+. In July 2010, MoH led the process of developing integrated ART/PMTCT policy guidelines, training manuals, training plan and identification of training resources.

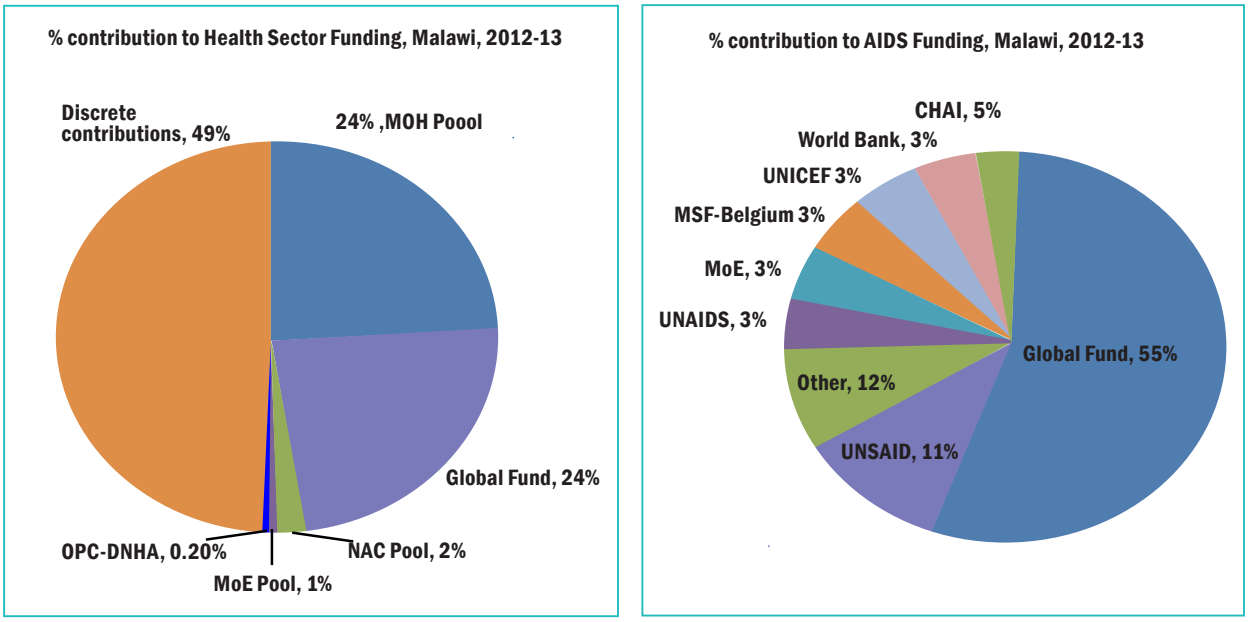
2.3 Formulation of the new national integrated ART/PMTCT guidelines

To ensure smooth implementation of B+, Malawi embarked on reviewing and updating the national PMTCT policy and guidelines. In addition to the merging of the TWG, the HIV department held zonal and district level meetings to discuss the recommendations, obtain buy-ins, and plan for implementation. The zones/district management teams are particularly crucial in planning and implementing the training and mentoring guidelines. The policy review process included considerations around treatment regimen for the general population. However, due to anticipated funding constraints, it was agreed that change of treatment regimens should be done in a phased manner starting with HIV-infected pregnant and breastfeeding women. Children under 14 years were to be changed to 2P (paediatric AZT/3TC/NVP) while patients with TB and HIV co-infections as well as patients with severe adverse side effects (e.g. lipodostrophy) would also be initiated on 5A (TDF/3TC/EFV). The new policy recommendations and guidelines were clearly documented, disseminated and used as the main guidance to implement B+ in the country.

2.4 Mobilization of funding

To assess the financial implications of implementing Option B+, Malawi commissioned a resource mapping study that brought to the fore the funding projections and sources of funding available. The Ministry of Health, with support from the National AIDS Commission (NAC) and development partners, embarked on identification of existing resources within the country. The major areas requiring resources included development of new ART/PMTCT integrated guidelines, training manuals, building capacity of staff on the new guidelines and procurement of ARVs.

Figure 1: Funding projections and sources for Health Sector and AIDS in Malawi, 2012-13



Adapted from the report of the Malawi Health Sector Resource Mapping Report, October 2012.

Discussions on reprogramming of resources in the Global Fund Rolling Continuation Channel (RCC) grant were initiated between MOH, NAC and Global Fund. An agreement was reached, paving the way for reprogramming of the Global Fund (RCC) phase 1 grant to create savings that were used to cater for the Tenofovir-based regimen for Option B+. The reprogramming of US$ 30 million in the Global Fund RCC phase 1 grant by freezing a few selected activities and shortening the grant period from three to two years provided initial money to procure drugs. The phase 2 Global Fund RCC grant was also consolidated into a single stream funding mechanism (SSF) with further reprogramming to make funds available to continue supporting Option B+ implementation. In addition, Government continues to make contributions (through NAC, MoE and MOH pools) to the health sector funding that includes HIV/AIDS (3). This is in addition to catering for health workers and providing the operational infrastructure. However, funding for the HIV/AIDS programme continues to depend heavily on external donors, with Global Fund being the biggest donor, providing about 55% of the HIV funding in Financial Year 2012/2013.

2.5 Review of the procurement and supply system

The supply chain in Malawi is complex, involving more than 120 commodities and about 78 000 inventory items. The procurement and distribution of ARVs is effected through a parallel system that includes mainly ARVs and OI drugs, with UNICEF procuring and distributing ARV's straight to the health facilities, using a subcontractor. This approach helped to facilitate rapid increase in the ART sites from 303 (static) sites in June 2011 to over 600 sites by December 2011 as a result of B+ implementation.

This system, however, initially did not include test kits and other PMTCT commodities such as FP products. These were often out of stock in addition to cotrimoxazole that all HIV infected persons take for life. Other items often out of stock for long periods of time included medicines for opportunistic infections as well as syphilis test kits. Moreover, HIV test kits and family planning products are often used in outreach services for women and children, including in EPI sessions, hence on high demand. A study by CHAI in 2011 revealed that 77% of the facilities experienced this shortage with an average duration of 70 days (4).

As a temporary solution to the stock out crisis, items such as cotrimoxazole, HIV test kits, laboratory reagents, PMTCT drugs, and other OI drugs were incorporated into the parallel system. In September 2010, drugs for Option B+ regimen Tenofovir, Lamivudine and Efavirenz (TDF/3TC/EFV) were ordered using the parallel system. This was followed by training of health workers on integrated ART/PMTCT services, including Option B+. In June 2011, drugs were distributed to all accredited health facilities to ensure readiness for B+ implementation.

2.6 Capacity building of service providers

As part of the preparation for implementing Option B+, training was organized for District Health Management Teams (DHMTs), programme managers, service providers and ward clerks in the management of the integrated programme. Areas covered included provision of Option B+ information, counselling of patients, and provision of ARVs. The programme started with the training of 120 trainers (TOTs), and has since been scaled up to train more than 4600 health workers in the new integrated guidelines. The initial training is followed by two weeks of attachment to a health facility under guidance of experienced providers. This has since been developed into a national clinical mentoring programme to mentor service providers at their places of work in order to reduce costs and improve quality of care at facility level. In total, 390 clinical mentors have been trained to reinforce the didactic training of the service providers. This has been decentralized to the district level where district clinical mentoring teams are being set up and expanded to cover the whole country.

3. Service delivery

3.1 Programme management

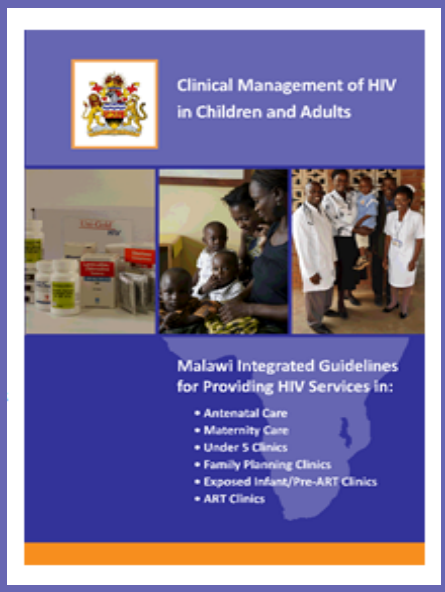
The B+ approach is being implemented under the overall HIV programme arrangement. At the national level, the HIV programme is monitored through the merged ART/PMTCT Technical Working Group (TWG). The TWG has many subcommittees taking care of some specific components of the programme including HIV testing and counselling (HTC), laboratory, procurement and supply management (PSM) subcommittees among others. Membership of the merged committee includes representatives of the UN, other development partners, donor agencies and all major HIV stakeholders within and outside of Government.

At the district level, the District Health Officer (DHO), District Nursing Officer (DNO) and the District Medical Officer (DMO) are included in the DHMT and are responsible for overseeing all programmes at district level, including HIV and AIDS programmes. In addition, the DHMT plays a leadership role and manages resources at district level. District ART/PMTCT Coordinators are officers or programme managers responsible for tracking the progress of the ART/PMTCT programme, particularly regarding the operationalization of the guidelines, data collection, compiling district reports and supervision of lower level health workers.

The implementation of new integrated PMTCT/ART guidelines providing for Option B+ services started in June 2011. The initial stages of implementation included the distribution of new ARVs to all B+ implementing sites, rapid expansion of integrated PMTCT/ART services to all sites offering MNCH, promotion of provider-initiated family planning for all PLHIV in care (depo-provera and condoms), and pre-ART programme involving the provision of Cotrimoxazole Preventive Therapy (CPT) and Isoniazid Preventive Therapy (IPT). It also included early initiation of ART at CD4<350 cells per µL in adults, and CD4 <750 cells per µL in children aged 2-5 years, as well as universal ART for children less than 2 years. The PMTCT strategy provides for improving access to and utilization of ART/PMTCT services within ANC and delivery care settings. Before this integration, ARVs were obtained from ART sites and there were fewer ART outlets compared with ANC outlets. The PMTCT programme is now integrated with antenatal care, childbirth and postpartum care, under-five growth monitoring and EPI services, exposed infant pre-ART clinics, and ART clinics. It is also increasingly being integrated into family planning services.

There have been several efficiency gains, including one guideline, one training, one supervision system and one supply chain. For example, the *Integrated guidelines for providing HIV services* provide an opportunity for linking up and consolidating several HIV programme components into one document that is very user-friendly.

Figure 2: New Integrated Guidelines for provision of HIV services



INTERGRATED GUIDELINES ONLY 79 PAGES

- Integration strategy
- PITC
- WHO clinical staging
- Oi management
- Standard patient monitoring (Clin. + lab)
- Provider-initiated family planning
- CPT, IPT, ICF
- Infant feeding
- Pre-ART
- HIV exposed child FUD (incl. NVP, EID)
- Art regimens and formulations
- Rules for prescription and dispensing ARVs
- Starting, continuing, stopping ART
- Managemnt of L&D for HIV+ women
- PEP
- Transition plan
- M&E

Some of the health workers interviewed for their opinion regarding B+ were very happy with the new integrated guidelines. The current policy is that all women who report for antenatal care and childbirth in health facilities are offered HIV testing. The MOH provides all pregnant women and under-five children with free health passports while non-pregnant women and men pay a nominal fee for the health passports.

When women and children report for postnatal care, and any other time thereafter, their passports are checked for their HIV testing status and the results for those tested. Those women who are not tested for HIV are offered the test, while those whose test results are known are managed according to the guidelines. During the FGDs, women participants said they preferred the integration of PMTCT services with other services such as under-five child care services, family planning, HTC and ANC. This is because when the services are provided in separate rooms, clients have to accordingly go to one room after another, and this takes a lot of their time.

> **'The new policy is straightforward, I don't have to doubt my knowledge on WHO staging before initiating a woman on ART, which was a challenge previously and resulted in fewer clients being initiated on ART, most of the times [only] when a woman was obviously sick.'**
>
> **(Key Informant, district hospital.)**

Drugs for PMTCT clients are dispensed from various points: some at the ANC points while others are referred to general ART clinics. Some of the clients who initially obtained their drugs from the ANC point are referred to ART clinic on the subsequent visit while others keep obtaining their supplies from the ANC points until six weeks after delivery. The main criteria governing where one receives the initiation/supplies is the availability of a room and/or trained service provider. This practice has some limitations, including possible losses between referral points.

3.2 Availability and accessibility

The policy of routine HIV testing of all pregnant women was introduced in 2007. Since then all pregnant women have been offered HIV testing at the first contact at the ANC clinic. HIV testing is also offered on other subsequent antenatal care visits, on being admitted for labour and delivery, in the postnatal ward after delivery at the facility or from home, and on presentation with a sick child at the facility. On all the above occasions, women have an option to opt out. Women are also offered HIV testing and counselling in the under-five clinics, family planning clinics, TB and STI clinics with varying efficiency. Pregnant and breastfeeding women who test HIV positive are counselled for life-long Option B+ ART, which is initiated on the same day of the testing. This is significantly different from the previous PMTCT process that included pre-test group counselling, opt out, collection of blood samples, testing of samples and then one-on-one post-test counselling and provision of ART after a period of preparation, including adherence counselling.

3.3 Maximizing the use of existing human resources for health

As in most developing countries, there is critical shortage of health workers at all levels of service delivery in Malawi. Current staffing levels fall short of the WHO guidelines on human resource requirements for the delivery of the essential health package in resource-limited settings. To overcome this, measures to ensure continued delivery of integrated ART/PMTCT services are being implemented. These include maximizing the use of existing human resources within the MNCH services, task-shifting, training, mentoring, coaching and supportive supervision.

To reduce the gap in human resources for health (HRH), especially with the introduction of B+, Malawi has introduced task shifting to enable professional workers to delegate some tasks such as prescription and initiation of ART clients to treatment and care from clinicians to nurses; HIV testing and counselling, collection of dry blood spots among HIV-exposed children from laboratory technicians to nurses and Health Surveillance Assistants (HSA); haemoglobin testing among pregnant women from laboratory technicians to nurses; and the offering of family planning methods like contraceptive pills and depo-provera from nurses to community Health Surveillance Assistants.

The process of task shifting involved regulatory bodies of Malawi, including the Medical Council, the Nurses and Midwives Council of Malawi and the Ministry of Health. The task-shifting policy has helped the country move forward in decentralizing HIV testing among pregnant women in maternal and child settings, thereby increasing uptake of both PMTCT and ART. It has also allowed more women to access modern family planning methods, especially in rural and hard-to-reach areas and facilitated expansion of geographical coverage of early infant diagnosis services among others. To address and sustain skills development and mentoring, the HIV department has developed a national Clinical Mentoring programme that supports providers at service delivery points. The model involves district-based clinical mentoring teams coordinated at zonal level.

MOH works with civil society and community-based organizations (CBOs) with which most of the community mobilization and patient support work is shared. These groups have mentor mothers and expert clients who are PLHIV and promote HIV counselling and testing and adherence to ART. Some lay persons, mostly women living with HIV, are recruited and trained as expert patients/counsellors/mentor mothers for HIV test and adherence monitoring.

Malawi's scale up of PMTCT and B+ in particular has been significantly boosted by shifting the tasks of HTC to Health Surveillance Assistants (HSA's) and ART initiation to Nurses. Additionally, Medical Assistants, Clinical Officers, Nurses/Midwives and Doctors are also trained in the provision of Provider Initiated HIV testing and counselling (PITC). For example, HSA have had significant work shifted to them: they have been trained to provide information and counselling for PMTCT or HTC; and in conducting rapid HIV test as well as EID, using Dried Blood Spot (DBS) sample collection. Most of the HSAs are based in the community where they act as the link between the community and the health facility. They provide support to CSOs, CBOs, NGOs and the health facilities.

3.4 Supply management

HIV/AIDS commodities, including ARVs, use a parallel structure of procurement and distribution, and are currently distributed straight from the central level to the facility. Stock management at facility level is done using stock cards and verified by the supervision team during their quarterly visits. Quantification and distribution of drugs are linked to the quarterly supervision visits to all facilities. Data on the number of patients on each regimen, stock in hand at the time of the supervision exercise and the data on cohort analysis at the site are entered into the HIV unit database and used for generating distribution lists. Initial estimations for Option B+ ARVs and test kits were based on ANC attendance figures and determined on the basis of the number of expected HIV-positive pregnant women per facility.

There are physical stock checks at all PMTCT/ART sites every three months, national quantification and procurement every six months and distribution of HIV commodities to all sites every three months. The proposal on drugs to be procured is then sent to NAC for approval after which it is sent to Global Fund which, in turn, disburses funds directly to UNICEF in Copenhagen to effect procurement. The HIV department of MOH generates the distribution list and hands it to UNICEF for distribution directly to the health facilities through Stadtverkehr Detmold GmbH (SDV). This system was introduced after Global Fund had lost confidence in the storage and distribution system of the Central Medical Stores (CMS). This followed several reported cases of loss of Global Fund-procured commodities in the supply chain that relied on the Central Medical Stores for procurement, storage and distribution. It was agreed, however, that this arrangement would remain a temporary measure and it is planned that the function will be transferred back to CMS after relevant systems-strengthening reforms have been undertaken. It is noted that ARVs have always been in stock for both the old regimen and the new Option B+ regimen.

3.5 Laboratory services

Laboratory services fall under the Health Technical Support Services Directorate within the Ministry of Health that oversees pharmacy, laboratory and radiology services. Malawi has one central laboratory at the Community Health Sciences Unit (CHSU). There are three reference laboratories in the three central hospitals where DNA PCR tests are conducted. All the 28 districts and rural hospitals have one laboratory each. There are CD4 cell count machines in all the 28 districts, although some of them are reportedly not working. Each district has a laboratory technician who is responsible for the management of laboratory services. Community hospitals also have laboratory technicians while health centres do not have any laboratory personnel. HSAs are trained to conduct basic laboratory services like HIV rapid tests, tuberculosis microscopy, syphilis and malaria testing, and also to collect specimen for DNA PCR, using the dried blood spot (DBS) technology.

Specimens for DNA/PCR are sent to referral centres for processing. Generally, this is working well but in certain cases it takes a long time for the results to reach the referring facility. Recently rapid short text messaging system (sms) technology was introduced for sending data from one facility to another, as well as giving feedback on specimen results. The use of the technology has been particularly helpful in shortening turnaround time for early infant diagnosis results from the central laboratory to the health facilities. Initially, the turn-around time was between 40-50 days but this has been reduced to about 14 days following the introduction of sms use. Training in the use of the rapid sms technology has been completed for many of the facilities but does not as yet cover the whole country. It is hoped that when the staff are adequately familiar with it the tracking of infants will significantly improve.

3.6 Data management, monitoring and evaluation

Alongside policy and guidelines development, there has been the development or review of other tools that included those for data capture and reporting. Registers were reviewed and revised in preparation for B+ implementation. This enabled the country to capture some important data including longitudinal patient tracking and retention monitoring. The country mainly uses paper-based system of data capture with electronic systems being piloted in a few sites, mainly research centres.

The PMTCT programme has identified five high-level results to be achieved by 2015, and 29 other PMTCT indicators that are mostly for local use at the service outlet level to monitor progress. Data is extracted from maternity registers and compiled into monthly reports that are then aggregated into quarterly reports.

Malawi high level targets to be achieved by 2015, as highlighted in the EMTCT Plan:

- **Addressing unmet need of family planning from 18.5% to zero.**
- **Raising CPR from 35.4% to 53.9%.**
- **Scaling up PMTCT coverage from 47% to 95%.**
- **Scaling up paediatric ART from 43% to 83%.**
- **Reducing paediatric infections from 30% to 5%.**

Data is captured on forms and stored in facility-based registers that are used to generate periodic reports. The majority of the reporting utilized the Health Management Information System (HMIS) platform, notwithstanding its shortfall. Additionally, for HIV data in general, data is extracted on a quarterly basis by teams assembled nationally but including representation from district management teams. These data are then entered into a national database, analysed and reports generated and posted on the MOH web site every quarter. As a consequence of this approach, districts and subdistrict levels are not actively engaged in the data management process and as such data analysis and use at these levels are quite limited.

3.7 Supervision and quality assurance

An intensive quarterly support supervision and monitoring system, organized and led at national level, is being implemented. Through this system, data is collected and made regularly available at national level. It starts with 20 teams of three composed of national, zonal and district level staff who visit the health facilities. The supervision takes three weeks every quarter. It has been observed that the time spent at each of the 652 service outlets is not enough and as

such mentoring is not adequately done. The system serves to mainly satisfy partners' requirements of quarterly reports and, as far as availability of national level data is concerned, the system is good. The supervision exercise generates data that is crucial for the HIV department and is used for quantification, forecasting, procurement, and distribution of HIV commodities.

Box 2: Quarterly Support supervision in Malawi:

Malawi's HIV/AIDS department (MOH) conducts quarterly support supervision throughout the country. That involves teams visiting all the ART/PMTCT sites in Malawi to verify and collect data, conduct a cohort analysis, collect stock data, and conduct clinical mentoring. Twenty supervision teams of three members each are composed of: experienced HIV clinicians; nurses and M&E staff from health facilities in the public and private sector; district and zonal PMTCT and ART coordinators; programme officers and technical staff from the HIV/AIDS department as well as technical staff from key implementing partners. Each quarter, a one-day pre-supervision meeting is organized for all supervisors participating in the upcoming round to share programme updates, discuss observations from the previous round, distribute materials, and organize logistics, transport and accommodation. Standard supervision forms are used to guide the supervision protocol, update site information, and collect M&E reports. Custom forms with previous data for each site are printed from the HIV Department database. The supervision form includes:

(a) Contact details of HIV service providers at each site.
(b) Quality of service checklists.
(c) Follow up on action points noted during previous visits.
(d) Next visit date.
(e) M&E reports from HTC, ANC, maternity, exposed child and pre-ART follow-up, ART and TB.
(f) Physical drug stock-level assessment.
(g) Identification of sites as priority for Clinical Mentoring Programme.

The supervision protocol includes a systematic review and verification of primary records (patient cards and registers) at all sites. This effectively provides a quarterly quality audit for M&E records and has resulted in exceptional accuracy and completeness of HIV Programme data in Malawi. At the same time, the systematic chart review helps to identify complex cases or deviations from clinical protocol, allowing the supervision team to provide targeted mentoring and clinical advice. The quarterly supervision exercise also aims to boost staff morale and motivation through the award of Certificates of Excellence by the Ministry of Health to sites that obtain an excellent score on the quality of service checklist. One copy of the supervision form is returned to the central level, where data is entered in a MS Access database to produce national reports and to manage programme logistics and the commodity supply chain. A second copy of the supervision form is left at the sites for future reference. The involvement of a growing number of health workers from sites throughout the country who participate in the quarterly supervision exercise has helped to build a strong identity for the national HIV Programme and has greatly facilitated communication between programme staff at the national, zonal, district and facility levels. The TB and HIV programmes are working towards a full integration of their respective site supervision exercises.

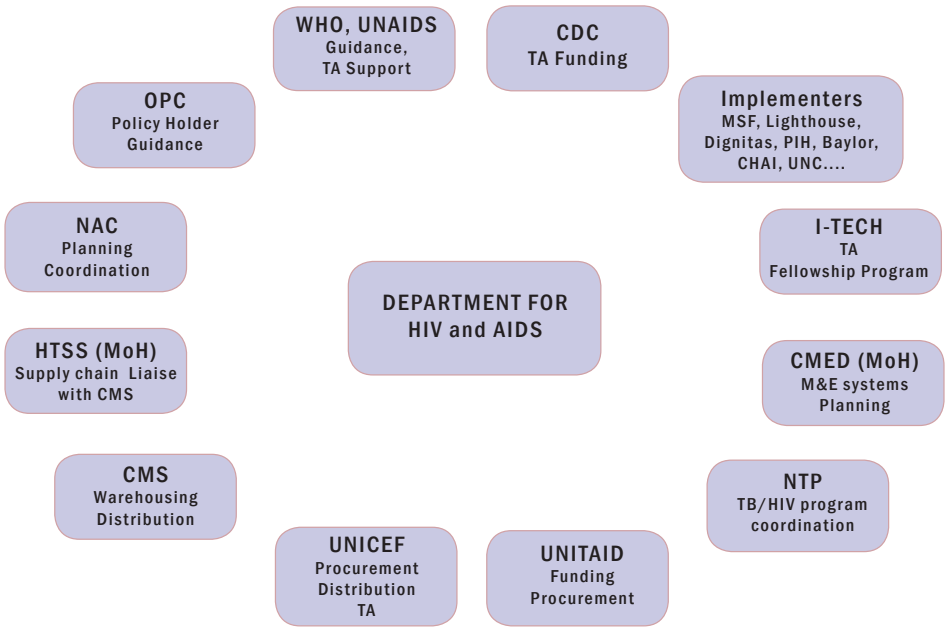
However, although this system is centralized and costly (costs more than US$ 100 000 every quarter), it does not help to build capacity at district level. Moreover, whereas the HIV programme currently has resources for this at national level, the zones and districts have limited resources and are not able to conduct regular supervision at their levels.

The HIV department has also introduced district clinical review meetings. Service providers from the sites are invited to such meetings and are provided with their own data for analysis. After the analysis, district teams develop activity plans to address identified challenges. This is one way of strengthening data management and the use of capacities at lower levels. Additionally, through one of the partners, Baobab Health, electronic data recording is being introduced, which, it is hoped, will make analysis of performance data easier and faster, thereby making more time available for discussion of performance within health facilities and, consequently, accelerating improvement in programme management. The introduction of the e-Recording system, however, is a slow process in addition to being expensive.

3.8 Community linkages and partnerships

Globally, evidence shows that developing partnerships is one way of leveraging resources and avoiding duplication and an essential component of any national health care delivery programme. Especially in resource-limited settings, no single national government would be able to shoulder a programme alone. Malawi has a thriving network of partners in the national ART/PMTCT programme. Indeed, as already presented in Figure 1, Global Fund is the major partner contributing about 55% of HIV funding. Others include UN agencies, USG (PEPFAR, CDC and USAID), UNC, JHPIEGO, MSF-Belgium and France, Banja La Mtsogolo (Marie Stopes), Malawi AIDS Counselling and Resource Centre (MACRO), Elizabeth Glaser Paediatric AIDS Foundation (EGPAF), Baylor Paediatric, AIDS Initiative and Mothers-to-Mothers. Other partners involved are DAPP, NAPHAM, World Vision, Diginitas, MSH, PIH, Lighthouse, Malawi College of Medicine, Catholic Relief Foundation, Adventist Development Relief Agency, Action Aid, Communities in Development Activities (COIDA), Estates, Johns Hopkins University, Dream, and University of North Carolina (UNC).

Figure 2: New Integrated Guidelines for provision of HIV services



Partnership forums in Malawi include the Technical Working Groups that provide for coordinated management of the programme, including the implementation of 3-ones as well as catering for gaps identified as barriers to achievement of objectives. At the district level, partner involvement in the development of the district implementation plans facilitates the maximization of the resources available from all partners. Most partner resources are channelled through NGOs working in the districts. These NGOs, in turn, work with the MOH district staff to reduce their own staffing needs, which has the advantage of having one programme and not parallel services.

> As a policy, all NGOs working in any district are coordinated by the District Health Management Team and the district assembly, and they all participate in the development of the District Implementation Plans (DIPs). The NGOs also invite the DHMT representatives to meetings for the development of the NGO implementation plans. This way, the district health response to the identified problems is coordinated from the start. While many international NGOs bring resources into the districts, others assist in the scale up plan by using resources from the district health office to provide free care to the population.

Malawi has very strong community groups and networks. HIV-positive clients require the support of community-based partners such as "expert clients", who are other women living with HIV and who know the advantages of adherence to treatment. They provide support to overcome the side-effects of the medication and provide information on healthy lifestyles, using their own experience. These support groups are vital for the promotion of and adherence to Option B+.

In Malawi, PLHIV are involved at three levels of the HIV programme as follows: the recognized large institutions such as Malawi Network of People Living with HIV (MANET+) and National Association of People Living with HIV and AIDS in Malawi (NAPHAM) are represented on the high-level governing body, namely the Country Coordinating Mechanism (CCM). Many are organized as nongovernmental organizations and are funded by the National AIDS Commission for advocacy activities. In addition, many HIV-positive persons are involved in support groups as expert clients, and in "Mothers-to-Mothers" (M2M) that mobilizes people in the community to utilize PMTCT services. M2M is a group working with women at the health facility and community levels. These support groups also encourage mothers to take their exposed children to follow-up clinics for HIV testing to ensure early infant diagnosis and follow up. While psychosocial support is provided by M2M and expert clients in the communities, HSAs try to follow up defaulters.

Community Service Organizations (CSOs) have been very useful in mobilizing the communities to promote male participation in safe motherhood services, including PMTCT. People who attend all safe motherhood services as couples are attended to first in order to motivate other women to come with their partners at subsequent visits. However, despite this attempt to motivate pregnant women to come with their partners, it is estimated that only about 10% of partners of pregnant women come to the institutions for testing. One of the effective ways of encouraging partners of pregnant women to accompany their wives to attend ANC clinics has been the establishment of partnership with traditional leaders. These leaders are highly respected in Malawi and have helped to mobilize men in their communities to accompany their spouses to safe motherhood clinics. Although male involvement has significantly increased with the commencement of B+, there is still much room for improvement. As some female FGD participants observed, there are still many men who do not take part in these services.

> 'Some men are very difficult. For instance, there was a woman who was HIV positive and on treatment, but the husband did not get tested and one day when they quarrelled the man took the woman's ARVs and threw them in the toilet'
> **(FGD participant, Thyolo District Hospital.)**

In order to improve male involvement, women feel that there is need to involve more chiefs (traditional leaders) who would take the lead in encouraging men in their communities. Although there are some reports of men refusing that women accept the B+ regimen, husbands remain the most available psychosocial support for HIV-positive women, and have been extremely useful when they accept and support their wives. A woman in FGD said:

> When I was informed that I was HIV positive during ANC, I immediately went to tell my husband at his workplace. We came back together for him to test for HIV. He was found to be HIV negative. But we are still together.' 'It was difficult to disclose to my husband because I was afraid that my husband would accuse me of transmitting the virus to him since I had not heard of him being promiscuous but then I gathered courage and explained to him; he accepted it and never reacted badly.'
> **(HIV+ Pregnant women FGD participants, Zomba Central Hospital)**

Some other local leaders support PMTCT activities by encouraging people, including men in their communities, to go for HIV testing so that those found to be HIV-infected could be assisted in time at the various health facilities. Some of the issues that discourage men from accompanying their pregnant partners include the fact that MCH facilities in Malawi are not user-friendly to the men. During one of the focus group discussions men reported that they feel out of place when they escort their spouses for MCH services. They particularly mentioned being uncomfortable with the sitting plan and the 'singing' that goes on in MCH delivery points.

3.9 Private sector

In general, the role played by the private sector in Malawi is quite little as a partner in the national ART/PMTCT services. All the private sector safe motherhood service outlets are providing PMTCT services. Malawi has approximately 1030 health facilities and institutions and the private sector has 209 health facilities, representing 20% (these include faith-based institutions) of the total of health facilities. HIV prevention, care and treatment services in the private sector are supported by Malawi Business Coalition against AIDS (MBCA). MBCA supports the delivery of HTC, PMTCT, and ART services. The Government supports MBCA with ARV drugs, HIV test kits and other supplies for its clients in ART care. The clients can then access these services at a cost.

4. Key achievements

The implementation of PMTCT Option B+ in Malawi has significantly transformed and revolutionized delivery of PMTCT services. It has resulted in several gains with numerous lessons for all countries and partners that would like to transition to B+. Some of the key achievements are discussed below.

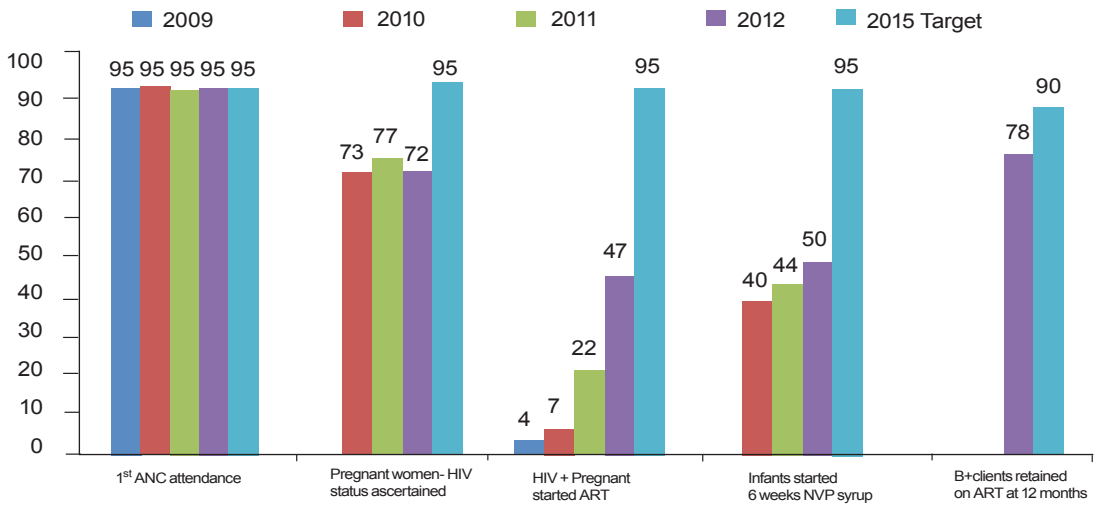
4.1 Increased availability and accessibility of PMTCT services

Implementation of B+ has resulted in rapid expansion of integrated PMTCT/ART services to all MNCH sites. The number of sites providing ART increased from 300 (Q2 2011) to 641 (Q3 2012), with 573 of these providing B+ services. (6) HIV testing and counselling (HTC) services are offered to all women accessing ANC and delivery care. Over 70% of the pregnant women testing positive are initiated on the B+ regimen.

From Figure 4 below, it is evident that at national level, the first ANC attendance has remained high (95%) throughout the four years for which there were data. Testing to ascertain the HIV status of ANC women has also been high (72-77%) over the same period.

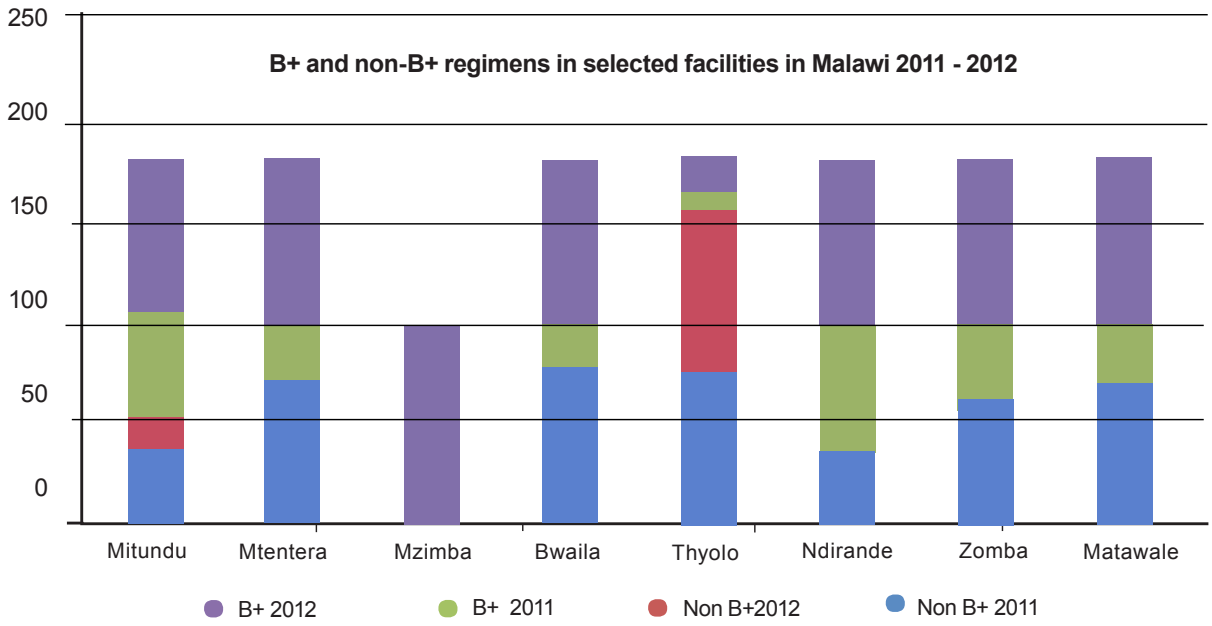
At the national level, available data shows that there are significant achievements in the scale up of Option B+. In the one year period during which this option has been implemented, 32 578 exposed children were enrolled in follow-up HIV care, representing about 42% of all HIV-exposed children, with 517 of the 534 PMTCT service outlets having follow-up services for exposed children. Since the introduction of Option B+, 99 183 (68%) of 146 930 women at ANC had their HIV status ascertained; 7182 (88%) of 110 153 women at maternity had their HIV status ascertained. In total, 106 365 (72.4%) of the women who came for some form of ANC care had their HIV status ascertained.

Figure 4: National PMTCT Programme Performance (%) on selected indicators: 2009–2012 and progress towards 2015 national targets



An additional 2698 breastfeeding women started ART due to Option B+ (in WHO clinical stage 1 or 2) through other maternal and child health clinics, with 5913 (97%) of new ART initiations due to Option B+ (in WHO clinical stage 1 or 2) and 181 (3%) due to a low CD4 count and/or WHO clinical stage 3 or 4. Initiating HIV+ pregnant women on ART has generally been increasing since 2009 but the biggest increase (from 22% to 47%) occurred between 2011 and 2012 when B+ was introduced. Also, initiating HIV-exposed infants on NVP has been on the increase. Regarding retention in care, 78% of breastfeeding HIV+ women in 2012 were retained on B+ regimen. With respect to the choice of ARV regimens for HIV+ pregnant women, a sample of facilities was selected for assessment of how it has been affected by the introduction of B+. Figure 5 below shows the changes in eight facilities that had data available.

Figure 5: Choice of regimens for HIV+ pregnant women in selected facilities in Malawi: 2011 and 2012



'It is good to have a HIV- free child when you are reactive. My first child died prematurely from HIV." "I am happy to start ART early as I will [not become sick from HIV] and go unnoticed." "I would actually recommend this policy to all my friends who happen to be in my position.' **(FGD participant, Mzuzu Health Centre.)**

It is evident that in 2012, six out of the eight facilities had put all HIV+ pregnant women on B+ regimen except Mitundu (85%) and Thyolo (21%). It is also noted that B+ regimens started making inroads in 2011 while at the same time the proportion of non-B+ combinations was declining. It is clear from available data that the country is moving to cover all the PMTCT facilities with B+.

HIV testing (and receiving of results) among ANC clients has been consistently above 80% in the sites that were visited during the preparation of this documentation. In addition, during focus group discussions, HIV-infected pregnant women participants expressed preference for B+. They also felt that public health facilities are the most important source of health care; but they noted that there were not enough health workers in these facilities. Furthermore, they felt that the public facilities are better than private ones in terms of service provision because the women are examined properly. They observed that, in private hospitals, services are fast but they had to pay a fee that most of them could not afford. Women felt that public health facilities offer them all the antenatal care services they need.

> 'The greatest advantage is that when you attend antenatal services in public facilities for the first time you are offered an HIV test and if you are found to be HIV-positive you are given drugs to prevent the transmission of HIV from mother to child and this is the thing that private hospitals cannot do such that you can end up delivering a baby without knowing your HIV status and yet you are infected.' **(HIV+ pregnant woman FGD participant, Bwaila**

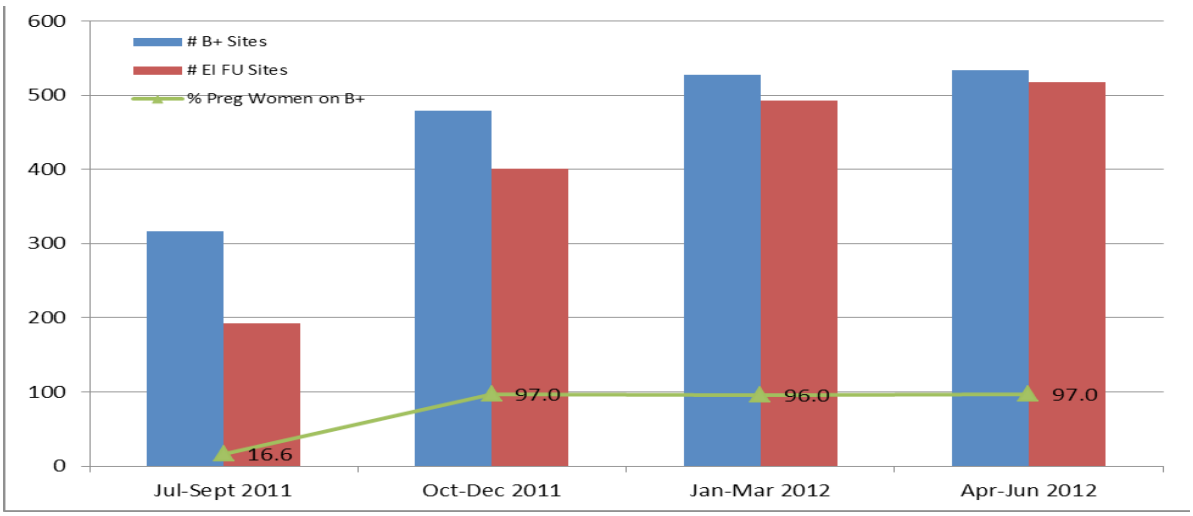
4.2 Client satisfaction

In this documentation, we also looked at client satisfaction regarding the services being provided. Implementation of B+ has made services more acceptable and appreciated and many more clients are retained in care and are showing satisfaction. The results of the national cohort 'survival' analysis by MOH from Q3 2012 showed that 83% of clients were retained in care for six months (n = **9130**) and 78% (n = **2392**) were retained in care for 12 months.

> 'In the past, pregnant women used to have CD4 testing before being started on ART but these days they are able to start as soon as they are diagnosed. They are now receiving the drugs for prevention of mother-to-child transmission of HIV unlike in the past when they used to receive drugs only when they are in labour.' **(FDG participant, Matawale Health Centre).**
>
> 'At the beginning we were told to stop breastfeeding at six months. We were facing many problems in the community in terms of what to give the baby from that period and the community used to label us as HIV-positive because they knew that anybody who stops breastfeeding early was HIV positive but now things have changed as we continue breastfeeding for two years and so people do not notice anything.' **(FGD participant, Mzimba District Hospital).**

As shown in Figure 6 below, there has been a significant increase in the number of sites providing B+ as well as the number of sites conducting Exposed Infants follow up. Focus Group Discussions (FGD) with clients show that there is a preference for integrated services and Option B+, inter alia, because it does not require stopping breastfeeding. FGD participants are of the view that health education enhances the knowledge of clients, facilitating improvement in quality and follow-up of mother-infant pairs. Discussions with women attending ANC services show that opinion about B+ services is positive.

Figure 6: Changes in the numbers of sites accredited for B+, Exposed Infant Follow up and the percentage of pregnant women initiated on B+ during the first year of B+ implementation



The provision of incentives such as the award of a "Certificate of Excellence" to health facilities that have performed well on the quarterly supervision checklist is regarded as a good practice. The fact that about 60% of the facilities have yet to attain this certification means that there is still much work to do to accelerate the scale-up plan and improve quality of care.

Discussions in focus groups indicate that the participants are generally satisfied with the quality of PMTCT services they are receiving. For example, the health education they receive is considered adequate and they seem to be adequately knowledgeable about PMTCT in general and Option B+ services in particular. They recognize the changes in the provision of PMTCT services with Option B+.

5. Issues and challenges

Though Malawi has made progress in the implementation of B+, significant challenges remain to be addressed. This section sets forth some of the challenges and the country's effort to address them.

5.1 Health infrastructure

In Malawi, Option B+ was introduced through existing safe motherhood services in a physical infrastructure that was built without anticipating the needs for provision of ART/PMTCT services and for a much smaller population. Therefore, space is a major limitation. As expected, early initiation of ART as in Option B+ leads to increased clientele and utilization at the health facility, resulting in pressure on the space available for the service.

Furthermore, the available space does not ensure adequate confidentiality for counselling, testing and provision of ARVs or adequate space for pharmaceuticals. Moreover, the physical infrastructure was built without consideration of male participation in safe motherhood service delivery, which leads to missed opportunities for use by men to promote Option B+. For example, there are situations where more than one service provider/client pairs are present in one room during service provision, which compromises privacy. Malawi is currently conducting a nationwide infrastructure needs assessment that will be used to advocate for funding for infrastructure improvements in the health facilities. In the PSM system, as a short-term measure, Malawi has reverted to a quarterly (from 6 monthly) distribution of HIV commodities including ARV's to the health facilities to reduce the storage burden being faced by the facilities.

5.2 Continuum of care and mother-baby pair follow-up

There is inadequate linking of maternal and paediatric care. As a result, the majority of mothers are not clear about the paediatric follow-up schedule. This reduces the coverage for testing of HIV-exposed children, receipt of HIV test results and initiation on paediatric ART. In addition, clients are sometimes initiated on ART from one service point and then required to attend follow up/refills from another point. Some of these clients end up not returning. Yet, there is no follow-through mechanism to track them. It was thought to be better if every MNCH service point could initiate ART and also provide refills and make follow-ups. Malawi guidelines provide for initiation of ART (Option B+) within the MNCH and follow-up including refills until delivery. It is now being considered to extend follow-up in MNCH for Option B+ mothers up to the age of 24 months to facilitate mother-baby follow-up until the baby is discharged from exposed infant care.

5.3 District programme management

The collection and management of HIV data (including PMTCT) is done quarterly, organized and led by a team assembled by the national level, with district representation. This has erased the incentive for the district and lower levels to collect and manage the data and reporting. It has also contributed to the creation of limited data management capacity at lower levels. To address this issue, the MOH has started to involve the District Health Management Team by conducting district clinical review meetings involving the health care providers. All facility-based data are analysed and facility/district-based activity plans are developed on a quarterly basis to encourage the use of own data for planning.

The management of client cards also needs attention, including standardization. For example, some "pink cards" (records of HIV-exposed children) were being kept in the Early Infant Diagnosis room while others were kept in the ART room, thus making follow-up of such children very difficult, with some children missing follow-up altogether. The national guidelines provide for making pink cards available in all areas where exposed infants may be encountered to facilitate enrolment i.e. Maternity, under 1, OPD, pediatric ward, ART/PMTCT clinic, under 5, etc. However, after enrolment all pink cards should be transferred to the HIV Care Clinic for continued care. This is currently not being done effectively and needs to be addressed.

5.4 Procurement and supply management systems

Procurement of HIV medicines and commodities is still a major challenge. Whereas ARVs are always in stock due to a parallel push system, HIV test kits are frequently out of stock. This causes a disconnection as HTC is the entry point to care and treatment. The push system also does not include other essential drugs and commodities, notably OI drugs such as cotrimoxazole. There is also lack of capacity at health facility and district levels for quantification and estimation of medicine needs and requirements.

As a temporary measure, the Ministry of Health has included HIV test kits as a controlled item handled through the push system alongside ARVs and cotrimoxazole. Additional measures have also been put in place to improve accountability such as the introduction of the daily activity register.

5.5 Same day testing, counselling and initiation

Currently, clients accessing PMTCT services are counselled, tested and initiated on ART on the same day. This policy aims to reduce missed opportunities. However, our interaction with both the health care providers and clients reveal some misgivings about this practice. Some health workers are not comfortable about initiating women on the same day, arguing that the clients would not have been adequately prepared. Some of the clients also say they need time to prepare psychologically for this, as they could be getting to know their status for the first time. Others argue that they need to discuss the results with their spouses or a relative before initiating treatment.

As such, it was reported that some women accept drugs but never take them or return to the facility. Although thought to be limited in number, it is felt that this category of clients may be responsible for some of the cases of 'loss to follow-up'.

5.6 Quality of HIV testing

An important issue regarding B+ implementation in Malawi is the quality of HIV testing. Data from the MOH has revealed that out of the total number of ANC women whose HIV status was ascertained, only an estimated 75% (2009 and 2010) and 80% (2011) were correctly identified. In the year 2012, up to 20% of HIV-infected pregnant women received a negative result (false negatives), while about 0.4% of HIV-negative pregnant women received a positive result (false positives). To solve this problem, the country has introduced mandatory confirmatory testing before initiating ART in all clients. In addition, skills-intensive training in HTC has also been conducted for all counselors to improve on the quality of testing.

5.7 Male involvement/Family centeredness

Although Malawi has done a commendable job in trying to involve male partners in PMTCT, especially through the use of village chiefs, much more remains to be done. Female participants in FGDs as well as health workers feel that greater male involvement is critical for increased uptake and retention. It is also observed that the programme currently does not cater for the whole family and it is proposed that it should consider catering for the ART needs of mothers, children and fathers.

5.8 Follow-up of cross-border clients

Sometimes, nationals of neighbouring countries cross the border to Malawi and access PMTCT services, including ART. However, the cross-border follow-up protocol and procedures are difficult and poorly understood by health workers. When these clients do not voluntarily return, they are considered lost to follow up. It is feared that cases of this nature may contribute to the development of HIV drug resistance and render programme performance lower than it should be since it cannot adequately account for them once they are lost to follow up. It should be noted that this cross-border issue is not limited to only PMTCT but affects other programmes as well. There is need to involve neighbouring countries and explore ways of addressing this.

5.9 Human resources for health

Malawi has worked innovatively through task-shifting to address the acute shortage of health workers. This, coupled with training, has ensured implementation of B+. However, their numbers are still inadequate and the workforce quite constrained. Besides, there is need to widely disseminate the task-shifting policy so that everyone is aware of what tasks have been shifted to whom. There is also inadequate training in integrated service delivery. Although there have been efforts to provide continuous clinical mentoring to health workers to ensure they are adequately skilled, this programme has been implemented only in a few districts. The quarterly zonal clinical mentoring meetings also serve to obtain progress reports, discuss challenges and define the way forward.

6. Lessons learnt

Malawi has demonstrated that implementation of B+ is possible, even in resource- limited settings. Many lessons have been learnt by and from Malawi. The lessons should lead to further improvement in the implementation of the programme by Malawi and other countries that may wish to transition to this approach. They include the following:

(a) Strong government leadership has been an important factor and has created an enabling environment for the adoption and implementation of B+.

(b) Preparations and planning, including the adoption of relevant policies, strategies and guidelines, have been essential in the successful implementation of the B+ programme in Malawi. Furthermore, careful planning for effective use of available financial resources in the country and the presence of donors willing to discuss and agree on viable funding options are all important in ensuring the success of the B+ programme.

(c) An integrated approach, whereby ART is provided within the MNCH platform has greatly facilitated implementation of B+. This proves that integration of HIV and MNCH services is possible and highly synergistic. Malawi has also demonstrated that integrating PMTCT into ART programmes is probably a best practice.

(d) Task-shifting has addressed key gaps in the HRH and Malawi has demonstrated that this is possible provided there is clear policy guidance and adequate engagement of all key stakeholders. For example, non-medical doctors such as Clinical Officers, Nurses and Midwives are initiating ART and the programme is working well. Furthermore, Health Assistants have been trained to conduct rapid laboratory diagnosis of HIV.

(e) Partnerships with key development partners and other stakeholders, including agreements and facilitation on the use of resources, are important in ensuring smooth start, implementation and sustainability. This has been made possible due to the strong and good MOH coordination of development partners, local/international NGOs and community-based NGOs, resulting in a concerted effort that has ensured success.

(f) The use of community health workers has been successful in encouraging women to return to care. Discussing treatment with partners leads to improved retention in care. In addition, community engagement and support, including the involvement of males (partners) and PLHIV, have been essential in ensuring the success of the programme.

(g) The high antenatal attendance rate of 95% in Malawi (2010), the provision of HIV testing and counselling in all ANC outlets utilizing HSA's (task shifting), the commitment to integrate ART and PMTCT services, and maximization of the use of existing human sources in the MNCH system through integration of services and task shifting have provided the opportunity for programmatic successes in implementing B+.

7. Conclusion

Malawi has made a strong statement by initiating and committing itself to implementing Option B+ and has shown great determination to succeed. The integration of ART into PMTCT services and introduction and strengthening of task-shifting in ART has made possible the scale up of Option B+ in the country through decentralization of ART/PMTCT services. Malawi's experience with PMTCT "Option B+" is neither perfect nor ideal but the country has demonstrated clearly that it is possible for a low-resource country to successfully implement Option B+ as a strategy to reduce HIV-related disease burden, move closer to achieving zero new HIV infections among children and keep mothers alive. Malawi's experience shows that initiating ART is easy when capacity is built, but maintaining clients on ART, however, requires promoting quality counselling, strengthening community support structures, and maintaining a good client tracking system. It is also critical that the country's monitoring and evaluation (M&E) system is strengthened to facilitate adequate follow up and collection of strategic information for accountability and progress tracking.

8. Recomendations

For those considering or already implementing Option B+, there is a need to ensure the continuum of care, and retain women and children on treatment in primary health care settings within the MNCH platform and reduce loss to follow up. In this regard, it is recommended that:

- national governments should provide clear policies and guidelines and ensure effective orientation of health workers;
- integration be emphasized as the best mode of delivering B+, especially within MNCH platform;
- services be decentralized to improve coverage and empower lower level decision-making;
- use of available HRH be optimized, and supportive supervision and mentoring be used to improve human resource skills and capacity of health workers;
- capacity be built and supported for data management, use of updated data collection tools and new technology (mobile phone, eHealth), as well as provision of feedback from national level to lower levels;
- capacity of health workers be strengthened to improve supply management (quantification) and to ensure uninterrupted supply of drugs and commodities;
- cultural/gender and structural barriers be addressed to increase community engagement and male involvement in health programmes;
- partnerships be strengthened to ensure good collaboration, active engagement and common agreements on use of resources for successful implementation of the programme.
- adequate resources be mobilized to meet the demands of implementing B+.

Specifically for the Government of Malawi and partners, it is important that:

- procurement of ARVs and HIV test kits be strengthened and harmonized to reduce stock-outs of test kits and other drugs such as cotrimoxazole as well as Family Planning products;
- capacity for data management be strengthened and district and lower level managers and workers be empowered to collect, analyse, disseminate and use data at these levels;
- HIV drug resistance monitoring and prevention be institutionalized and strengthened as an integral part of the programme.
- Capacity of health workers in laboratory testing be strengthened; and regular quality assurance checks undertaken by reference laboratories to ensure that, due to false results, clients are not started on ART when they are negative or denied ARVs while they are positive.

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Annex 1: Critical steps in the supply chain in Malawi

No	Activity	Responsible party
1.	Patient and stock data from PMTCT/ART sites (quarterly)	MOH
2.	Data entry and cleansing	MOH
3.	Forecasting and quantification (half-yearly)	MOH
4.	Request for cost estimates (CEs) to UNICEF	MOH
5.	Compilation of CEs	UNICEF
6.	Checking of cost estimates (make amendment as necessary and send request to UNICEF)	MOH
7.	Progress update and disbursement request (PU/DR) to NAC	MOH
8.	Verification and compilation of PU/DR, submission to LFA	NAC
9.	Verification of PU/DR (attend to queries) submission to GFATM	LFA
10.	Review of PU/DR, (attend to queries), release funds to UNICEF	GFATM
11.	Confirmation of purchase order to UNICEF	MOH
12.	Procurement, packing, insurance, shipping, clearance	UNICEF
13.	Distribution list based on latest stock/consumption data	MOH
14	Preparation of release and distribution docs for SVD	UNICEF
15.	Delivery of supplies to sites	SVD
16.	Collation and verification of delivery notes	MOH

Annex 2: Summary of PMTCT procedures and regimens before and after B+ implementation

PMTCT procedures and regimen before July 2011			PMTCT procedures and regimen since July 2011		
All pregnant women offered HIV testing with option to opt out at first contact		Spouse encouraged (through pregnant woman) to report for HIV testing	All pregnant women offered HIV testing with option to opt out at first contact (ANC/ Maternity)		Spouse encouraged (through pregnant woman) to report for testing
ART only for women in stage 3 and 4 HIV or CD4 <250 cells per µL		HIV-positive spouse sent to ART clinic for regular monitoring for eligibility for lifelong ART when CD4 dropped to <250 cells per µL	5A(TDF/3TC/EFV) ART and CPT for all HIV- positive pregnant and breastfeeding women irrespective of their clinical / immunological status (no CD4 count screening)		HIV-positive spouse sent to ART clinic for pre-ART services and monitored regularly for eligibility for lifelong ART when CD4 dropped to <350 cells per µL or when WHO stage 3 or 4 condition develops
sdNVP at onset of labour for HIV- positive pregnant women. Introduced AZT combination prophylaxis from 28 weeks with AZT/3TC/NVP at onset of labour and AZT/3TC post-partum for 1 week	HIV-exposed newborn put on NVP daily for 1 to 4 weeks depending on duration of ART in mother during pregnancy			HIV-exposed newborn routinely put on NVP daily from birth until six weeks	
Monitored regularly in ART clinic for eligibility for ART when CD4 dropped to <250 cells per µL (no national pre-ART programme available then)	All babies commenced breastfeeding within an hour of birth Exclusive breastfeeding up to six months then stop			All babies commenced on exclusive breastfeeding within an hour of birth	
	DNA-PCR at six weeks			DNA-PCR at six weeks	
	CPT for HIV-exposed children until proven negative			All HIV- exposed newborns commenced on CTP at six weeks (stopped at 24 months if not found to be HIV-infected in subsequent tests)	

				Universal ART for all confirmed HIV-infected children below 24 months. Lifelong ART preferably with 2P commenced for all HIV-infected infants and continued with CTP	
	Exclusively breastfed for six months then stopped permanently			Exclusively breastfed for six months then commenced on supplements	
				Continue breastfeeding for about 24 months and wean gradually over 1 month	
				HIV rapid test at 12 and 24 months for all exposed infants regardless of PCR result at six weeks	
				Lifelong ART commenced for all HIV- positive infants and continued with CTP if HIV-positive at 12 or 24 months (if positive only on one of these two occasions, DNA PCR used as a tie breaker).	

Annex 3: Characteristics of the sites selected for the facility-level data during the documentation of B+ implementation experience in Malawi

SN	Name of the site	Region in which located	District in which located	Ownership (Gov., CHAM)	Level of health care (referral, district hospt, com hospt. , HC)	Number of clients (volume) (high, average, low)	Performance last 12 months (very good, good, average, poor)
1	Bwaila Hospital	Central	Lilongwe	Government	District hospital	Very High	Very Good
2	Kaluluma Rural Hospita	Central	Kasungu	Government	Community hospital	Low	Average
3	Katete Community Hospital	North	Mzimba	CHAM	Health centre	Low	Good
4	Matawale Health Centre	South	Zomba	Government	Health centre	Average	Good
5	Mitundu Community Hospital	Central	Lilongwe	Government	Community hospital	Average	Good
6	Mtenthera Health Centre	Central	Lilongwe	Government	Health centre	Low	Good
7	Mzimba District Hospital	North	Mzimba	Government	District hospital	Average	Average
8	Mzuzu Central Hospital	North	Mzimba	Government	Referral hospital	Average	Average
9	Ndirande Health Centre	South	Blantyre	Government	Health centre	High	Good
10	Thyolo District Hospital	South	Thyolo	Government	District hospital	High	Good
11	Zomba Central Hospital	South	Zomba	Government	Referral hospital	High	Good

Notes on site selection criteria:

Patients' volume

- Very high
- High
- Average
- Low

Performance

- Very good: centre of excellence, continuously able to test pregnant women and exposed children and initiate both women and children on ART treatment without referral.
- Good: continuously able to test women and children. However, refer especially children for ART initiation.
- Average: Services always available.
- Poor: Constant interruption of services.

Annex 4: Composition of the national ART/PMTCT TWG

1. Director, HIV and AIDS Department
2. Director, SWAp
3. Director, Clinical Services
4. Director, RHU
5. Director, NTP
6. Director, Preventive Services
7. Director, Nursing Services
8. Director, Health Technical Support Services
9. Director, CMS
10. PS, Nutrition, HIV and AIDS
11. Executive Director, NAC
12. Representative, Ministry of Education
13. Representative, WHO
14. Representative, UNICEF
15. Country Coordinator, UNAIDS
16. Director, Baylor
17. Director, Reach Trust
18. Director, Lighthouse
19. Director, MBCA
20. Directors, CHAI
21. MSF Thyolo
22. Executive Director, CHAM
23. Dr Newton Kumwenda, John Hopkins University
24. Dr Chitsa Banda, Malawi Defence Forces
25. Executive Directors, MACRO
26. Executive Director, NAPHAM
27. Director, CDC-GAP
28. HIV and AIDS Adviser, DFID
29. Chief of Party, MSH
30. Dr Johnstone Kumwenda, College of Medicine
31. Director, EGPAF
32. Staff, Department of HIV and AIDS (Secretariat)