

The President's Emergency Plan for AIDS Relief

FY 2012

Technical Considerations

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Working Groups for
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List of Abbreviations

AIS	AIDS Indicator Surveys
ANC	Ante-Natal Clinic
ART	Anti-Retroviral Therapy
ARV	Anti-Retroviral Drugs
CDC	Center for Disease Control
CITC	Client Initiated Testing and Counseling
COP	Country Operational Plan
CPT	Cotrimoxazole Preventive Therapy
CSW/SW	Commercial Sex Worker/Sex Worker
CTX	Cotrimoxazole
DBS	Dried Blood Spot
DHAPP	DoD HIV/AIDS Prevention Program
DHS	Demographic and Health Surveys
DoD	Department of Defense, United States
DOT	Directly Observed Therapy
DST	Drug Susceptibility Testing
EID	Early Infant Diagnosis
FDC	Fixed-Dose Combination
FP	Family Planning
FY	Fiscal Year
GAP	Global AIDS Program—CDC
GBV	Gender-Based Violence
GHI	Global Health Initiative
HAART	Highly Active Anti-Retroviral Treatment
HBV/HCV	Hepatitis B Virus/Hepatitis C Virus
HCW	Health Care Worker
HPV	Human Papillomavirus
HRH	Human Resources for Health
HSS	Health Systems Strengthening
HTC	HIV/AIDS Testing and Counseling
IC	Infection Control
ICF	Intensified Case Finding
IPT	Isoniazid Preventive Therapy
IS	Injection Safety
ITN	Insecticide-Treated Net
LTFU	Lost to Follow-Up
M&E	Monitoring and Evaluation
MARP	Most At-Risk Population
MAT	Medication Assisted Therapy
MCH	Maternal and Child Health
MDG	Millennium Development Goal
MDR-TB	Multidrug-Resistant Tuberculosis
MNCH	Maternal, Newborn, and Child Health
MOD	Ministry of Defense
MOH	Ministry of Health
MOVE	Models for Optimizing Volume and Efficiency
MSM	Men who have Sex with Men
MTCT	Mother-to-Child Transmission

List of Abbreviations (continued)

NACS	Nutrition Assessment, Counseling, and Support
NIH	National Institute for Health
NSP	Needle and Syringe Exchange Program
NVP	Nevirapine
OGAC	Office of the U.S. Global AIDS Coordinator
OI	Opportunistic Infection
OVC	Orphans and Vulnerable Children
PE	Program Evaluation
PEP	Post-Exposure Prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PHPEHRB	Prevention of HIV in Persons Engaged in High-Risk Behavior
PI	Performance Improvement
PITC	Provider-Initiated Testing and Counseling
PLWHA/PLHIV	People Living with HIV/AIDS
PMI	President's Malaria Initiative
PMTCT	Prevention of Mother-to-Child Transmission
PPP	Public-Private Partnerships
PrEP	Pre-Exposure Prophylaxis
PWID	Persons Who Inject Drugs
PwP	Prevention with People Living with HIV/AIDS
PWUD	Persons Who Use Drugs
QA	Quality Assurance
QI	Quality Improvement
QM	Quality Management
RH	Reproductive Health
SCMS	Supply Chain Management System
SI	Strategic Information
SMME	Small, Medium, and Micro Enterprises
SOP	Standard Operating Procedure
STI/STD	Sexually Transmitted Infection/Sexually Transmitted Disease
TA	Technical Assistance
TB	Tuberculosis
TLC	Total Lymphocyte Count
TWG	Technical Working Groups
USAID	United States Agency for International Development
USG	United States Government
VCT	Voluntary Counseling and Testing
(VM)MC	(Voluntary Medical) Male Circumcision
WHO	World Health Organization
XDR-TB	Extreme Drug-Resistant Tuberculosis

Introduction

The technical considerations in this document provide discussion points for program planning by the various Technical Working Groups and are not in any way intended as policy guidance or required criteria within your programs. To the extent there is a conflict between this document and any policy guidance, the policy guidance is authoritative.

The following technical considerations are not guidelines, as PEPFAR is not a normative body. PEPFAR can only fund those interventions that have been recommended by a normative body (e.g., Joint United Nations Program on HIV/AIDS, World Health Organization) and that are included in national guidelines. The technical considerations serve as a guide for program planning.

For PEPFAR programs, we request that you use the contact list of the co-chairs (available on PEPFAR.net) and TWG members to address your technical questions, while keeping your country support team leader informed. Should coordinators wish to request on-site technical assistance, please contact your country support team lead. The country support team lead will forward the request to the chairs of the appropriate technical working group.

Section 1. Prevention

TECHNICAL AREA 1.1: PREVENTION OF MOTHER TO CHILD TRANSMISSION (PMTCT)

PMTCT – activities are aimed at preventing mother-to-child HIV transmission, including primary prevention, prevention of unwanted pregnancies among HIV infected women, ARVs for HIV-infected pregnant women and infants, and treatment, care, and support services for mother-infant pair and their family. The goal is to ensure HIV-free survival of the infants and AIDS-free survival for the mothers. An important focus is to ensure that comprehensive and integrated PMTCT services are available or accessible at different levels of the health care system.

ARVs for PMTCT should be funded through ARV Drugs and Adult Treatment. Funding for HIV testing and counseling in the context of PMTCT should appear under PMTCT and targets should be included in PMTCT. Early infant diagnosis appears under Pediatric Care.

1.1.1 WHAT'S NEW FOR 2012?

A. Increased focus on integration:

Countries are encouraged to scale up comprehensive and integrated PMTCT programs, in line with the Global Health Initiative principles of focusing on women and children's health, strengthening of the health care system, and integration of programs. To this end, PEPFAR released Guidance on Integrating PMTCT of HIV, Maternal, Neonatal, and Child Health, and Pediatric HIV Services in January 2011, available at <http://www.pepfar.gov/documents/organization/158963.pdf>. This document highlights the importance of integration of PMTCT, pediatric HIV, and MNCH program support, identifies an essential package of integrated services and health systems strengthening activities, and recommends action steps to operationalize and evaluate integration efforts.

Additionally, a technical consultation on integration of family planning, HIV, and MNCH programs was sponsored by USAID and CDC in Washington in March 2011, to discuss best approaches for integration; the meeting report and slides can be accessed at: www.pepfar.net. Countries should consider these documents as they plan for scaling up PMTCT by ensuring it is integrated into MNCH and broader adult treatment and prevention programs. Countries are also encouraged to evaluate and share their experience with integrated programs so that best practices may be developed in the context of the emerging concept of "implementation science". However, it is recognized that the success of an integrated program in one country or district depends on many factors and may not always be universally applicable.

B. Call for Virtual Elimination of MTCT

In 2010, WHO, other UN Agencies, and the Global Fund called for "virtual elimination" of MTCT, provisionally defined as < 5 % MTCT in breast-feeding populations and 90% reduction in new pediatric HIV infections. In April, 2011, a high-level Global Task Team (GTT) on the Elimination of New HIV infections among Children and Keeping their Mothers Alive, co-chaired by Michel Sidibé, Executive Director, UNAIDS and Eric Goosby, United States Global AIDS Coordinator (OGAC) was convened to mobilize the agenda of elimination of mother to child transmission (eMTCT) of HIV.

The precise role of PEPFAR with respect to the elimination agenda is still being considered; however, countries are expected to continue to contribute to the elimination agenda by emphasizing scale-up of PMTCT services to high-burden populations to meet or exceed the legislated PEPFAR II goals of:

- 80% of pregnant women HIV tested (in generalized epidemics)
- 85% of HIV + pregnant women receive effective prophylaxis and treatment according to 2010 WHO PMTCT guidelines
- Double the number of at-risk babies born HIV-free from 240,000 in PEPFAR I to 480,000
- 65% of infants born to HIV-positive women receive virologic HIV testing (e.g., DNA PCR) in the first 2 months of life

PMTCT programs that have already met the 80% testing/counseling coverage and 85% ARV coverage goals should continue to move toward 100% PMTCT program coverage, with a focus on improving quality and implementing most effective regimens and best practices for PMTCT. Progress toward reaching pediatric HIV elimination goals will be determined by the population coverage of the interventions.

C. Adaptation and Implementation of 2010 World Health Organization (WHO) Guidelines

I. ARVs for PMTCT

The PMTCT landscape changed significantly in 2010 with the release of new WHO PMTCT ARV recommendations (preceded by “rapid advice” in 2009)

<http://www.who.int/hiv/pub/mtct/advice/en/index.html>. In last year’s technical considerations, the PMTCT/Peds TWG encouraged countries to assist with adapting the guidelines and highlighted the following important changes, including:

- Initiating antiretrovirals (ARV) earlier in pregnancy,
- Continuing ARVs throughout breast feeding,
- Replacing single dose nevirapine with more efficacious regimens (Option A or B) , and
- Prescribing ARVs for the pregnant woman’s own health if her CD4 count is less than 350/mm³, taking into account risks of specific drugs and regimens.

This year, countries are encouraged to focus and share experience with implementation of the new guidelines, in particular to:

- Prioritize pregnant HIV positive women for ARVs, especially women who are eligible for treatment (Clinical Stage III/IV or CD4 \leq 350), as they constitute >70% of total MTCT and >80% of postnatal MTCT. This may require discussion with broader ART working groups to ensure that ARV drugs for pregnant women are prioritized and made available.
- Transition to more efficacious regimens for PMTCT. This should be documented by counting number of women receiving ARVs for PMTCT, disaggregated by type of regimen as required in the next generation indicators.
- Developing strategies to promote follow up in post-natal follow-up and adherence of mother and baby, particularly at Primary Health Care settings, to ensure a high level of adherence for ARV prophylaxis throughout the breastfeeding period.

II. Infant Feeding and Nutrition

In 2010 WHO also issued new infant feeding guidelines which recommend that ARV prophylaxis be administered for the duration of breastfeeding. This prophylaxis can be in the form of:

- Mothers receiving HAART for their own health,
- Mothers receiving triple ARV prophylaxis as per option B of the PMTCT guidelines, or

- Infants receiving daily NVP prophylaxis as per option A of the PMTCT guidelines.

The infant feeding guidelines also call for countries to make a standard infant feeding recommendation for all mothers. In countries where the national government has established breastfeeding as the preferred option, HIV-infected mothers should be encouraged to breastfeed for a minimum of 12 months and beyond until a safe and adequate replacement diet is available. Programmatic emphasis should be placed on postnatal counseling focused on infant feeding, nutrition and health. Special attention should be given to link counseling to early infant diagnosis, to dissuading premature weaning (<12 mo) when the infant is HIV-negative, and to counseling mothers to continue breastfeeding if the infant is HIV positive. (Additional comments are under infant feeding section of this technical consideration.)

1.1.2 APPROACH TO PMTCT SERVICE DELIVERY

PEPFAR PMTCT programs should continue to assist countries in adapting the WHO guidelines with a focus on scale-up, taking into account cost and other practicalities for the country, and bearing in mind advice outlined in this document. As discussed below, the new WHO recommendations offer countries a choice between 2 drug regimens (Option A or B); *these 2 regimens have equivalent efficacy for PMTCT.*

Although much attention is focused on direct provision of ARV prophylaxis and treatment (“prong 3”), it is important to recognize that PMTCT is a complex package of interventions across different clinics, providers and visits over 1-2 years and provides a key entry for women and families into prevention, care and treatment. This approach is based on 2002 WHO recommended comprehensive HIV prevention and care programming that included a four-pronged approach to PMTCT (<http://www.who.int/hiv/pub/mtct/strategic/en/index.html>):

- Primary prevention of HIV;
- Prevention of unintended pregnancies among HIV infected women;
- Prevention of HIV transmission from mother to child; and
- Provision of care and support for HIV infected mothers, their infants, partners and families.

Given PMTCT coverage and progress to date, there is a need to review current PMTCT strategies and ensure that activities and systems are in place to accelerate the scale up of national programs in line with the most recent international recommendations and best practices. PMTCT programming in FY12 should especially address:

A. *Momentum for PMTCT as critical priority for reaching MDGs 4, 5, and 6*

Given the need to address HIV as a key component of reaching MDGs 4, 5, and 6, PEPFAR should support countries, local decision makers, professional associations, and civil society allies in prioritizing policies, strategic plans, budgets, and programming addressing PMTCT.

B. *Targets and a road map to reach them*

Scale-up plans would benefit by having 5-year and annual targets for number of new pediatric infections prevented. Evaluation of costing and missed opportunities along the PMTCT cascade can be used to guide budget priorities. Analysis of bottlenecks and barriers to access and utilization of services and mapping HIV burden with geographic coverage and intervention uptake may be useful. Standard tools exist or are being developed to address different aspects of scale up planning; e.g., marginal budgeting for bottlenecks (World Bank, UNICEF, WHO) a PMTCT drug costing tool

(Clinton HIV/AIDS Initiative , and the RAMP model for estimating missed opportunities in PMTCT programming and the cost for filling those gaps (PMTCT/Peds TWG).

C. Integration with Maternal Child Health (MCH) and Family Planning (FP) Services

PMTCT should be integrated with (and help strengthen) MCH services and should serve as an entry point to other HIV services (e.g., ART, care, pediatric HIV services, OVC, nutrition, PwP, etc) for women, their children, and increasingly, for male partners. Similarly, linkages and wrap-around with family planning services should be pursued where feasible. Minimizing unintended pregnancies (Prong 2) is a key component of a comprehensive strategy to effectively eliminate new pediatric infections. Efforts should be made to support the availability of family planning services to all women who desire them. Programs may consider supporting co-locating and linking PMTCT and family services especially during the antenatal and postpartum periods, training FP clinical providers in generalized epidemics on PMTCT, counseling HIV positive women in PMTCT, and providing postpartum (future) family planning with healthy timing and spacing of future pregnancies.

Safe Motherhood, infant feeding, and child survival interventions should also be incorporated where possible. For example, emergency obstetric care and essential newborn care (including newborn resuscitation where necessary) could be integrated into PMTCT training. In addition, linkages should be reviewed and strengthened between key initiatives such as PEPFAR and PMI, which focus on pregnant women and children. Harmonizing recommendations for PMTCT with existing MCH and FP/Reproductive Health (RH) recommendations will facilitate linkages and improve adherence with both HIV and MCH FP/RH interventions. For example, evidence-based recommendations exist for birth dose immunizations (BCG, polio) and timing of newborn visits. See WHO/UNICEF 2009 Joint Statement on “Home visits for the newborn child: a strategy to improve survival” [Http://www.who.int/child_adolescent_health/documents/who_fch_cah_09_02/en/index.html](http://www.who.int/child_adolescent_health/documents/who_fch_cah_09_02/en/index.html)

Strategies and work plans should support the integration of PMTCT within MCH and FP/RH programs, strengthen human resources and human capacity, and ensure coordination between key programs and interventions.

D. Linkages between program areas

Linkages between program areas are also important. Pregnant women, particularly those with HIV, are at high risk for developing TB and subsequently transmitting it to their infants. TB screening, diagnosis and treatment is an important component of an integrated and comprehensive PMTCT program and should be supported. Programs are also encouraged to consider adopting integrated strategies for preventing MTCT of syphilis and HIV, and to include syndromic STI treatment within PMTCT programs. Support for integrating or linking to malaria prevention, safe water and hygiene, and food supplementation/food by prescription programs should also be considered.

E. Quality and Effectiveness

Every effort should be made to transition short-course PMTCT programs to full, family-based care and treatment programs, and to fully support maximally effective interventions based on current WHO antiretroviral (ARV) PMTCT guidelines (2010) and national guidelines. Ongoing evaluations of the quality of PMTCT services and program impact and implementation of quality/ performance improvement measures should be fully supported.

F. Retention and Adherence

With changes in WHO recommendations requiring longer follow-up for mother and infant, mechanisms should be built into PMTCT programs to encourage long term retention, minimize losses

to follow-up, and improve adherence and quality of delivered services. This requires systems strengthening at community, outreach/referral, and facility levels, particularly of the information system and training of health workers and community health workers.

G. Sustainability/Systems Strengthening, including program management

Intensifying support to strengthen national PMTCT programs that are integrated into broader MCH/RH, Child Survival and HIV systems is a focus of PEPFAR and essential for PMTCT sustainability. Program management often requires strengthening at multiple levels, and building program management capacity at district and/ or other sub-national levels is encouraged. Specifically, PEPFAR programs should consider supporting the following:

- Funding for technical advisor(s) to MoH (at national, regional, district, state and sub-district levels) for various aspects of PMTCT such as overall program design and management, program monitoring, infant nutrition, IEC, health information systems, training, community outreach activities, etc;
- Support for partners to:
 1. Develop capacity for improved methods that will impact the quality & process of PMTCT.
 2. Involve and mentor state, regional, district and sub-district MoH staff to oversee the service provision at the facilities sustainably;
- Support for management training programs (short and long-term training);
- Support to national PMTCT steering committee (technical workgroups); and
- Support update of national ANC, maternity, PNC and Under-5 registers to align with new PMTCT recommendations.

1.1.3 SPECIFIC TECHNICAL AREAS

A. HIV Testing and Counseling (HTC) as a key element of PMTCT package of services

HIV testing and counseling (HTC) is a critical component and gateway to PMTCT. In order to achieve the goals set out by PMTCT programs, quality delivery of HTC should be provided as a core service to pregnant women and their male partners and families.

I. Provider-initiated HIV testing and counseling (PITC)

PITC with same-day rapid test results is the recommended approach for the provision of HTC in PMTCT settings, and should be supported as best practice. This means providers should offer HTC to all pregnant women and their partners in generalized epidemics, and to pregnant women and their partners who may be at high risk of HIV infection in concentrated epidemics. As a part of this best practice, pregnant women testing positive should have their blood drawn for a CD4 count at the same time, if feasible. More information on PITC can be found in the UNAIDS/WHO *Guidance on Provider-Initiated HIV Testing and Counseling in Health Facilities* (2007), available at: http://whqlibdoc.who.int/publications/2007/9789241595568_eng.pdf. Additionally, PMTCT HIV testing and counseling (HTC) job aids have been updated and the link is provided at the end of this section.

II. HTC minimum standards

HTC provided as part of PMTCT services should follow the core principles of HIV testing and counseling, including *consent, confidentiality, counseling, and correct test results*.

HTC services in PMTCT settings should include group pre-test information, as well as individual or couples HTC sessions for conducting the HIV test, providing results, and conducting post-test counseling. Women should be encouraged to test together with their male partners when possible, and results may be given to couples attending the session together as long as both agree to this approach.

Point-of-care HIV rapid tests with finger-prick sample collection and same day return of results should be used when possible. HIV rapid testing should be conducted in a *quality* manner according to national testing algorithm and standard operating procedures (SOPs). *Quality assurance* systems for both the HIV testing and the HIV counseling components of HTC should be in place. *Lay counselors* who have been trained to deliver HTC services may be beneficial in providing HIV rapid testing in PMTCT services and can ease the burden on health care workers. *Mothers support groups* can also be highly beneficial in providing ongoing support or services to pregnant women. See the HTC Technical Consideration for more details on HTC minimum standards.

III. Couples and partner HTC

There are high rates of HIV discordance among couples, low rates of disclosure of HIV status (KAIS, 2009), and low rates of partner testing or male participation in antenatal clinic (ANC) settings (Katz, 2009). This suggests the need for strengthened HIV prevention efforts including partner/couples HTC, in order to reduce transmission risk during pregnancy. Couples HTC with HIV serodiscordant couples has been shown to reduce HIV transmission, increase condom use, and increase ART uptake among pregnant women in ANC settings (Allen et al., 2003; Dunkle et al., 2008; Farquhar et al., 2004). Partner and couples HTC should be actively promoted and offered to all clients as early as possible in ANC settings, and if not possible at L&D or post-delivery. HTC couples testing could be provided by:

- Testing both partners together on first visit; and
- Testing women at first visit, bringing in spouse in subsequent visit for testing at ANC or other HTC sites, and bringing couples together for mutual disclosure of HIV status and supportive counseling.

To scale up couples HTC, various approaches should be considered including : engaging political and community leaders; offering special services for couples (i.e. evening or weekend hours; incentives); conducting promotional campaigns; and improving record keeping to track the number of couples that receive HTC together (see WHO HTC Guide for indicator for couples HTC:

<http://www.who.int/hiv/pub/vct/9789241501347/en/index.html>).

Existing PMTCT HTC job aides have been updated to emphasize partner/couples HTC. These are available at: <http://www.womenchildrenhiv.org/wchiv?page=vc-10-00>. Additionally, PMTCT and HTC TWGs are developing 1-2 day training curriculum for couples HTC in clinical settings. This will be made available when completed, and is based on the existing couples HTC training materials, which can be found at: <http://www.cdc.gov/nchstp/od/gap/CHTCintervention/>.

IV. Re-testing during pregnancy, delivery, postpartum period

Pregnant women are at increased risk for acquiring HIV during pregnancy (Moodley et al., 2009) and men are also at increased risk for getting HIV during a woman's pregnancy (Mugo et al., 2010). Women who become infected with HIV during pregnancy or breastfeeding are at high risk for transmitting HIV to their baby due to the high viral loads associated with acute HIV infection. Thus, in addition to partner testing as early as possible in a woman's pregnancy, in high prevalence areas women who initially test negative during pregnancy should be offered re-testing during the 3rd trimester, or at L&D or during the postpartum period. Re-testing will help identify women who may have acquired HIV during pregnancy and require PMTCT or treatment services.

The recommendation for re-testing in the 3rd trimester is consistent with WHO 2010 recommendations "Delivering HIV test results and messages for re-testing and counseling in adults." This guidance can be found at:

http://www.who.int/hiv/pub/vct/hiv_re_testing/en/index.html.

V. Enhanced prevention messages for pregnant women

Due to the observed high rates of HIV acquisition during pregnancy, programs should incorporate enhanced prevention counseling messages for HIV negative women identified in pregnancy to reduce the risk of acquiring HIV. Sexual risk reduction counseling should include messages on partner reduction, mutual monogamy to a partner of known HIV status, and consistent condom use at every sexual encounter. As part of this counseling, women should be taught how to correctly use condoms through demonstration and practice and provided with an adequate supply of condoms.

VI. Quality Assurance and Quality Improvement for HTC in PMTCT

All HIV testing and counseling programs, including HTC in PMTCT, must have quality assurance (QA) and quality improvement (QI) systems in place for both HIV testing and HIV counseling components.

Key components of quality assurance for HIV rapid testing include the use of validated HIV test kits and an appropriate HIV testing strategy in line with national guidelines and standard operating procedures (SOPs); ensuring all HTC providers have been trained (including practicum); providing ongoing supportive supervision for HIV testing, preferably with lab involvement; implementing practical QA tools such as a standardized pre-printed logbooks/ registers for recording HIV test results and lot numbers; and implementing external quality assurance programs such as proficiency panel testing or sending a certain number of samples to the national reference laboratory for re-testing and confirmation of test results. More information can be provided by PEPFAR's Lab TWG.

Quality assurance for HIV counseling may include counseling support supervision to prevent 'burn out' of HTC service providers and maintain high quality communications between providers and clients or patients. Providers can also utilize self-reflection tools or forms to monitor the quality of their own service provision during a session or over time. HTC sites should also regularly administer client exit interviews to gauge the quality of their service delivery from the client's perspective. Finally, some providers may benefit from observed practice, where – with the consent of the client or patient – an HTC provider is observed either in person or on video by a more experienced HTC provider or supervisor.

VII. PMTCT HTC support tools

The PMTCT HTC Support Tools (developed by the TWG) promote the aforementioned approaches and are endorsed by PEPFAR, WHO, and UNICEF. These tools can be reproduced and adapted for local use, and are available here: <http://www.womenchildrenhiv.org/wchiv?page=vc-10-00>

B. ARV Treatment and Prophylaxis Regimens

I. ART for treatment-eligible pregnant women

Provision of ART to eligible pregnant women (CD4<350 cells/mm³) is a high priority for several reasons, including reducing mother-child (and partner) HIV transmission in women of highest transmission risk during pregnancy, labor/delivery, and breastfeeding; improving survival of mothers and HIV-exposed infants; reducing the risk of resistance; and ensuring a direct link between prevention (prophylaxis) and treatment.

Screening for ART eligibility (i.e. CD4 count and/or clinical staging) should be prioritized for HIV+ pregnant women. This includes providing access to CD4 testing for pregnant women and rapid return of results. CD4 testing at the time of HIV diagnosis is a best practice in PMTCT settings. Pending CD4 test results, HIV positive pregnant women should be started on prophylaxis. However, the increasing availability of point of care (POC) CD4 testing will enable same day results to help determine eligibility for HAART.

Pregnant women eligible for treatment should be “fast-tracked” to receive at least 4-6 weeks of therapy before delivery (the goal is to start at around 14 weeks gestation). Given the urgency to initiate treatment, intensive adherence counseling, monitoring, and support are crucial elements to a quality and successful treatment.

Depending on local programs, ART may be provided on-site (linked to MCH services) or off-site (ideally close by) at separate ARV clinics to ensure that ART for eligible women is started at least 4-6 weeks before delivery. Ideally, all PMTCT sites should provide ARVs for treatment and prophylaxis, although this may not be feasible in all settings.

Programs should closely monitor the *pregnancy status* of HIV-positive women receiving care and/or treatment to ensure that every HIV positive woman who becomes pregnant is documented and linked to a PMTCT program. The number of pregnant or recently pregnant HIV positive women being screened and/or entering longitudinal HIV care should also be monitored.

Since an estimated 50% of HIV positive pregnant women have CD4+ <350 cells/mm³ and thus require ART for their own health, PMTCT programs and partners should assume that at least 30-50% of HIV positive pregnant women in their programs should be on ART.

II. ARV prophylaxis for women not eligible for treatment (CD4+ >350 cells/mm³)

Two options for ARV prophylaxis are offered (Option A or Option B). *These 2 options have equivalent efficacy for PMTCT.* See Table 1a for a summary of the WHO guidelines and a comparison with 2006 guidelines.

PEPFAR programs should provide support to countries to adapt, finalize, disseminate, and implement national guidelines that reflect the new WHO recommendations. Financial support should be coordinated with available Global Fund funding.

Implementation of the new guidelines requires procurement of ARV s and capacity to monitor for anemia and other ARV-related toxicities, as well as additional training of health care providers. Enrollment into and retention of HIV+ pregnant women in ANC needs to be improved in many countries. Providing community outreach targeting pregnant women can help to encourage them to get a check-up at the clinic.

Countries are strongly encouraged to shift to the regimens recommended by WHO in 2010 and only use SD-NVP when other regimens are not available or feasible (e.g., woman presenting at L&D without antenatal care, or in settings with extremely limited resources but with a plan to transition all facilities to using the new WHO guidelines).

C. Inclusion of HIV-specific Information on Mother and Child Health cards

Programs should revise mother and child health cards to include standard spaces for HIV test results, PMTCT and other HIV-related interventions. This is now recommended by WHO and is an important part of linkages and referrals between MCH and HIV services. This is a “best practice” that should be supported in all PEPFAR programs.

D. Essential care for Women and Children Identified in PMTCT Programs

HIV+ pregnant women and their children should be enrolled in longitudinal HIV care to maximize maternal and child survival. Pregnant women should receive the basic pregnancy and postpartum package of services, including voluntary family planning, and comprehensive HIV care when identified as HIV positive. Pregnant women who are HIV negative are at increased risk and should receive intensive counseling on primary prevention.

Provision of maternal Cotrimoxazole (CTX) is a high priority and is associated with dramatic reductions in preterm birth and neonatal mortality. Other care services including clinical screening for opportunistic infections (OIs) such as TB, treatment of OIs and STDs, nutritional evaluation, and psychosocial assessment and counseling should also be included in comprehensive care packages (see Care and Support section of Technical Considerations).

Provision of CTX to HIV-exposed/infected children is the most cost-effective non-ART intervention to reduce morbidity and mortality due to HIV and AIDS. HIV-exposed infants should be provided CTX prophylaxis from age 4-6 weeks; this should be discontinued when an infant/child is confirmed HIV-uninfected and no longer breastfeeding. CTX prophylaxis should be continued in HIV-infected infants and HIV-exposed infants with unknown definitive HIV infection status. Other care services for HIV exposed infants, including immunizations, nutrition counseling, growth monitoring, and screening for OIs such as TB, should also be included (see Pediatric technical considerations).

All HIV-exposed children are highly vulnerable children who should receive interventions included in the PEPFAR basic preventive care package for children. HIV exposed infants receiving long-term NVP prophylaxis require systematic long-term follow up and programs may have to improve how they provide follow up to these babies. HIV-infected infants identified through PMTCT programs need to be started on appropriate treatment early in life to prevent high mortality in infants (see Care and Support section of Technical Considerations).

Improving linkages and referrals between HIV longitudinal care and routine MCH, including family planning services is necessary to implement the complex set of necessary interventions for mothers and infants in the postnatal period.

E. Infant Feeding and Nutrition Support to Promote PMTCT and HIV-Free Survival

The ultimate goal of PMTCT is *HIV-free survival*, which implies a need to both reduce MTCT *and* mortality among infants born to HIV positive mothers. As much as half of MTCT can occur postnatally through breastfeeding; however, infants not breastfed through at least the first year of life are at a substantially elevated risk of death from pneumonia, diarrhea and other diseases.

The 2010 WHO Guidelines on HIV and Infant Feeding specifically call for the following:

- National or sub-national health authorities should decide whether mothers should be principally counseled and supported *either* to breastfeed and receive ARVs *or* avoid all breastfeeding and instead replacement feed from birth.
- HIV-infected mothers who choose to breastfeed and have infants of unknown or uninfected HIV status should breastfeed exclusively for 6 months and then continue breastfeeding, with the addition of adequate complementary foods after 6 months of age, for at least the first 12 months of life. Beyond 1 year, breastfeeding should cease only when a safe and adequate replacement diet can be assured.
- For infants and young children known to be HIV-infected, mothers are strongly encouraged to breastfeed exclusively for the first 6 months and to continue breastfeeding, with adequate complementary feeding, up to 2 years or beyond.
- HIV-infected mothers who decide to stop breastfeeding should stop gradually over one month. ARV prophylaxis for mother or infant should be continued for one week after breastfeeding is fully stopped.

The full 2010 WHO guidelines: *Guidelines on HIV and Infant Feeding* are available online: http://www.who.int/child_adolescent_health/documents/9789241599535/en/index.html.

Programmatically, this translates into a number of priority interventions for PEPFAR-supported PMTCT programs:

- Establish HAART eligibility for HIV+ pregnant and lactating women and prioritize HAART for treatment-eligible pregnant and lactating women;
- Provide ARV prophylaxis to mothers or infants for the duration of breastfeeding if the mother is not eligible for HAART;
- Provide antenatal and postnatal counseling for all HIV+ mothers to support optimum infant feeding, nutrition and health, particularly at key points when infant feeding practices may be changed:
 - For all mothers who breastfeed, promote early initiation of breastfeeding postnatally and exclusive breastfeeding for the first six months of infancy;
 - Counsel breastfeeding mothers on the introduction of safe and adequate complementary foods from six months of age until weaning (foods in addition to breast milk are necessary to meet infant nutrition requirements beyond six months of age);
 - Promote continued breastfeeding for at least the first 12 months of life, safe weaning, and counseling on safe and adequate replacement feeding; and
 - Provide special counseling on infant feeding linked to early infant diagnosis so that both HIV-uninfected and infected infants are not prematurely weaned (i.e., less than 12 months of age);

- Support improved maternal health through routine nutrition assessment, counseling and support (NACS) and regular postnatal clinical assessment and support;
- Assure that the basic preventive care package for infant and child survival is provided, including basic immunizations, Cotrimoxazole growth monitoring, routine micronutrient supplementation, insecticide-treated nets and regular clinical assessments;
- Establish health and nutrition surveillance, referral and tracking systems linking clinics and communities to allow early identification and intervention to address maternal and infant malnutrition and health problems; and
- Promote antenatal and postnatal family planning counseling, including LAM (lactational amenorrhea method) to link exclusive breastfeeding with modern contraceptive methods.

For the purposes of funding maternal and infant nutrition support in the context of PMTCT and postnatal care, PEPFAR country programs should be aware that a number of funding streams can be tapped, including PMTCT, Pediatric Care, Care & Support and OVC (infants born to HIV positive mothers are, by definition, OVCs).

F. Infant HIV Diagnosis

The PEPFAR's II goal is for 65% of HIV-exposed infants to receive a virologic HIV test (such as PCR) within the first 2 months of life. This is a critical part of pediatric HIV care and treatment and a critical part of monitoring PMTCT programs. These activities should appear in the pediatric treatment and care section and be funded through that budget.

The PMTCT, pediatric and lab programs have prepared manuals to support the development of EID services in-country, including a program manager's guide, a complete clinical curriculum with a demonstration DVD, and a guide for laboratories. These manuals are currently under revision but the original versions are available for download at <http://womenchildrenhiv.org/wchiv?page=ch-09-00-eid>.

G. Gender and Psychosocial Support

PMTCT and broader MCH services are important points of entry for gender programming. Male involvement improves uptake of appropriate PMTCT interventions by women including HTC, ARV prophylaxis, and optimal infant feeding practices. Interventions are needed to increase partner testing and male support. Strategies to consider include male-friendly clinics and special male partner clinic days.

Preventing and intervening on gender-based violence should be a key component of PMTCT programs. Activities to provide support for safe disclosure of status are also essential. Programs to empower women are equally important. These include support groups for HIV positive pregnant women and linking HIV positive women to local income generating activities.

Involving mothers-in-law and others that influence and support mothers' decisions and practices might be an effective intervention in some settings.

H. Primary Prevention within the Context of Pregnancy

Pregnant women are at an approximately 2-fold increased biological risk of acquiring HIV. Given the very high fertility rate in sub-Saharan Africa, a high proportion of new infections in women occur in

pregnancy. Recognizing the important role of Prong 1 in PMTCT, primary prevention strategies for HIV-negative women need to be emphasized within ANC programs.

Partner discordance rates have been documented to be high (up to 30-50%) in PMTCT settings. Involving male partners in the antenatal period is a strategic approach to reduce risk through counseling both partners on the importance of mutual fidelity and partner testing, condoms for discordant couples, and other prevention with positives (PwP) interventions. In addition to expanded prevention counseling and services at the time of PMTCT services, coordination and synergy with PEPFAR prevention and HTC activities is strongly recommended.

I. Prevention with Positives (PwP)

Scaled up PMTCT testing and counseling programs identify a large number of HIV positive women (and their positive or discordant partners), provide important opportunities for cross-cutting initiatives such as PwP services, and care and support of the individual and family infected with or affected by HIV (See Prevention with People Living with HIV Technical Considerations for details on how to integrate PwP services into different technical areas including PMTCT).

J. Voluntary Medical Male Circumcision and Neonatal Male Circumcision

Although the focus of the current voluntary medical male circumcision programs for HIV prevention is on HIV-negative older adolescent and adult males, for sustainability VMMC programs should expand services to the neonatal period. PEPFAR programs should actively consider synergies between the PMTCT program and VMMC to potentially target male partners in PMTCT programs and consider pilot projects for neonatal circumcision once VMMC programs are functioning.

K. Community Education/Outreach Activities

Community education efforts should be coordinated to include PMTCT topics (notification of new services, demand creation, supports male partner involvement, etc.) and should focus messages to pregnant women, their partners and young couples.

Raising awareness for community members to utilize health facilities for ANC and delivery is critically important in settings where ANC and delivery uptake are low. Male partners should be a key target group. Outreach to traditional leaders, faith based organizations, and community support groups can also influence and improve antenatal care (ANC) attendance, retention, and delivery in a health facility. Support groups for HIV+ pregnant women should be supported as they provide an effective means of keeping women in care and providing needed support services.

Innovative approaches should also be explored. In Ethiopia, health workers from health centers and hospitals go to the community and provide ANC/PMTCT services to pregnant women and their families. This approach is particularly suitable as a short term demand-creation intervention to reach more women in settings where ANC and institutional delivery rate is low. In other areas, where distance to the delivery facility has been identified as a major barrier, delivery homes have been built beside L&D units so expectant mothers can board close to the facility in anticipation of delivery. Additional community based approaches to increase access and use of maternal health services include birth preparedness activities that help families and communities to plan for childbirth through identifying transport options and saving for facility costs. The role of traditional birth attendants could range from assisting women to attend ANC, to testing and counseling plus referral to a delivery facility. The roles of TBAs differ by country and depend on national policies.

L. Human Resources and Training

The burden of HIV compared with other diseases should to some degree dictate how MCH healthcare workers' time is rationed, and to what degree a given program (i.e. HIV or MCH) compensates them for their time. Investments in PMTCT and pediatric HIV/AIDS treatment and care will be undermined if competing causes of maternal mortality (i.e. hemorrhage, obstructed labor, pre-eclampsia/eclampsia, sepsis) and child mortality (i.e., diarrhea, pneumonia, malaria, neonatal sepsis) are not able to be addressed. Similarly, if family planning programs are not further scaled up or falter, the PMTCT burden will increase accordingly.

Community health workers/volunteers should be utilized to strengthen care seeking behavior and to increase the number of women who utilized HIV and key MCH, FP/RH services (e.g. ANC, safe and clean delivery, postnatal visits). These cadres can improve referral/outreach and long-term follow-up as needed with the new WHO recommendations. Community health workers, HIV support groups (peer support), and lay counselors should work in tandem with MCH healthcare workers. Community-based cadres will be more sustainable if they are part of the country health system.

It is strongly recommended that countries utilize and adapt the WHO/USG PMTCT Generic Training Package <http://www.cdc.gov/nchstp/od/gap/PMTCT> for training HCWs.

USG should support a national PMTCT training strategy and ensure coordination of training among partners and across all sites, regardless of source of funding. This would ensure standardization of training and avoid duplication of efforts.

Both in-service and pre-service training of health workers are needed. In order to improve sustainability, programs should support pre-service PMTCT training for nurses, midwives and other cadres. PEPFAR programs should consider how high-performing sites can assist other sites to improve quality and uptake of PMTCT services.

M. SI and PMTCT Program Monitoring and Evaluation

PEPFAR team and partners should assist national PMTCT program to:

- Adapt and conduct the soon-to-be released WHO generic PMTCT impact evaluation protocols to measure impact and effectiveness of a national PMTCT program on MTCT of HIV rates and/or HIV free survival rates (more details in “***Evaluation of National Program Effectiveness***” under Section D of the PMTCT technical area. Experts from PEPFAR HQs are available to provide technical support to in-country teams on adapting the WHO generic protocol and/or designing a national evaluation/survey of the national PMTCT impact on MTCT rates and/or HIV free-survival rates as needed;
- Adapt and implement the Inter-Agency Task Team (IATT) harmonized PMTCT M&E indicators and guidelines and the PEPFAR II Next Generation Indicators (NGI). Many of the indicators are harmonized between programs and organizations to ease the reporting burden on PMTCT country programs; and
- Collect and report the NGIs. This can be done by through ongoing program monitoring including review of indicator outputs, and program outcomes.
 - The number of pregnant women with known HIV status (includes women who tested HIV and received their results)
 - The number and percent of HIV+ pregnant women who received ARVs to reduce the risk of mother to child transmission (by regimen) (This is a key recent change to the UNGASS indicator and is an ‘essential’ indicator in PEPFAR II)

- Number of HIV+ pregnant women assessed for ART eligibility

Targets for the PMTCT indicators should be based on the program results from the previous year or 6 months (using SAPR data). For countries below the 80% testing/counseling coverage and 85% ARV coverage goals, target setting should strive to reach those levels, but not be unrealistic given program constraints.

For PMTCT programs that have already met the 80% testing/counseling coverage and 85% ARV coverage goals, targets should continue to push the program forward towards 100% PMTCT program coverage. All PEPFAR country programs should support a national facility-based PMTCT monitoring system. As such, PEPFAR should support countries to adapt and implement new international PMTCT M&E indicators.

PEPFAR PMTCT and SI programs should work together to ensure that key PMTCT SI needs are addressed and integrated within the larger SI framework. Program monitoring and evaluation are the key areas where SI and PMTCT can collaborate. PMTCT program data should be monitored through regular data quality assessments that occur between the MoH, implementing partners and the PEPFAR team. Also, depending on where the PMTCT program is at, conducting a program evaluation may be appropriate. Other activities to consider within the realm of SI and PMTCT are:

- Work with SI to include key PMTCT and pediatric information in national surveys and projects (e.g. DHS, AIDS, malaria indicator surveys, etc); and
- PEPFAR should support and actively participate in the regular review of country data along with MOH, national technical groups and partners to ensure data quality, consistent reporting and data use for program planning and improvement.

Linkages between programs can be challenging but are critical to patient health. The following indicators are examples of measures that can be monitored and used to improve quality of services, assess linkages between programs, and develop questions for further investigation:

- Number and percent of HIV positive pregnant women enrolled into HIV care;
- Number of HIV positive pregnant women receiving HAART;
- Number and percent of children born to HIV positive women who are HIV-infected and enrolled into HIV care and treatment;
- Number and percent of HIV- infected infants by maternal regimen received; and
- Proportion of PMTCT service delivery points that provide integrated family planning services

Possible activities include identifying and funding in-country partners (in collaboration with USG SI staff) to:

- Serve as primary national TA providers to MOH and implementing partners for PMTCT monitoring system, while building capacity with MOH counterparts;
- Support training, supervision to sites, and regular TA to MOH for data management, quality assurance, analysis and feedback to sub-national levels and sites;
- Support MOH to use PMTCT data at the national and sub-national levels;
- Harmonize with international SI reporting; and
- Develop PMTCT “mapping” activities e.g. GIS are recommended in order to monitor program, assess coverage and document referrals and linkages to and from programs. PMTCT should be added to other planned mapping activities, when possible.

N. Financing, Procurement and Costing

I. Financing

For PMTCT programs to be sustainable and cost-effective, they need to be implemented by national, state, and local governments, as well as by NGO and FBO networks. Performance-based financing has shown promise as a means of transitioning sites away from direct USG support in the context of decentralization of health services. Incentive funds that high-performing sites receive through performance-based financing can be used by districts to support broader MCH activities. *District level support and approaches have been shown to be a best practice.*

II. Procurement

The USG should aim to support the development of one national procurement system for PMTCT commodities that is integrated with the broader MCH, malaria, TB, and HIV supply chain systems. In particular, PEPFAR programs should ensure procurement and forecasting of ARVs for PMTCT are coordinated with procurement of ARVs for adult treatment programs. Countries are strongly encouraged to use the PEPFAR supply chain management procurement (SCMS) mechanism to strengthen the PMTCT supply chain, as part of a unified approach to supply chain management.

Key items that need to be procured include: ARVs for PMTCT (should be purchased with funds from HTXD (HIV drug section)); HIV test kits and related supplies; Hemoglobinometer and supplies; consumables such as gloves, barrier gowns for deliveries; and commodities essential for basic preventive care package of mothers and children, including CTX, bed nets, isoniazid prophylactic therapy (IPT), safe water, infant diagnosis materials, etc.

Programs should seek to coordinate or leverage support for basic MCH/FP supplies that are often not available, including syphilis test kits (RPR), immunizations, multivitamins, malaria prophylaxis, contraceptives, etc. Many of these are included within the “basic care package.”

III. Costing

In order to appropriately budget for the procurement of PMTCT drugs and supplies, program costing exercises should be done to understand and better estimate financial needs to keep the PMTCT program operational. Costing exercises should include, but are not limited to: cost of scaling up of PMTCT service provision; cost of adaptation of the new WHO PMTCT guidelines; cost of PMTCT interventions and overall program cost effectiveness.

O. Lab Training and Quality Assurance

Laboratory services to support PMTCT programs should be strengthened, including implementation of rapid testing with same-day results, Hemoglobin screening, CD4 screening in antenatal settings, and infant diagnosis with PCR and serology.

Quality assurance for these program elements, especially rapid HIV testing done within clinical sites, should be integrated into laboratory programs and should be part of the training clinical HCWs receive before they start to provide services.

Training of staff on rapid point of care CD4 testing (as it becomes available) will be important.

P. Quality Improvement

Key PMTCT program activities should include evaluation components. PEPFAR PMTCT programs should regularly assess and include the following in their plans:

- PMTCT program performance/implementation (Are PMTCT activities appropriate and following national guidelines? Are the desired outcomes being achieved?);
- Plans for quality improvement of PMTCT programs; and
- Impact and effectiveness of programs (transmission rate, new pediatric infections, HIV-free survival) – some of these efforts should be linked with PEPFAR PHE.

Quality assessment needs to go beyond “coverage and uptake” to address quality issues related to: service delivery and program integration, provider knowledge/training, counseling, PMTCT ARV adherence, infant feeding adherence and barriers, basic MCH care and context of PMTCT programming, links to care. Countries should identify and prioritize problem areas based on their measures of quality of care, and provide plans for intervention.

Quality management requires structures, processes and functions in place at all levels to support the quality improvement work. Countries should provide details of this support (e.g. regular supportive supervision, on-site teams working with, and assisted by, site support teams, clinical mentorship, team function and organizational assessment, community involvement, linkages to other services). HIVQUAL and other available systems implemented to assess quality of other HIV services and programs could be expanded to include PMTCT.

Q. Evaluation of national PMTCT program impact/effectiveness

Many countries are rapidly scaling up PMTCT coverage and are introducing the more effective antiretroviral regimens based on new 2010 WHO PMTCT ARV guidelines. There is international momentum to measure and monitor the impact and effectiveness of these *national* PMTCT programs. For example, South Africa has recently conducted its 2010 national PMTCT impact evaluation, with an official report expected in June 2011. WHO has had a consultation on PMTCT impact evaluation and is expected to release a generic protocol to measure the impact and effectiveness of national PMTCT programs on rates of MTCT and/or HIV free survival within the coming year.

Impact evaluation/survey is also a priority of the PMTCT/Peds TWG and many field staff. PEPFAR team and partners in countries should assist national PMTCT programs in considering, adapting, and conducting the forthcoming WHO recommendations and generic PMTCT impact evaluation protocols. Consideration should be given to integrating the evaluation/survey into the existing MCH/PMTCT system and to repeating the evaluation periodically to follow trends and progress toward national and international PMTCT goals. The PMTCT/Peds TWG will share the generic protocol with the field once it becomes available.

The upcoming WHO generic protocol is designed for high HIV prevalence countries and where mixed feeding is a norm. Countries will need to consider two possible sampling frames: national EID data or the 1st DPT immunization visit. The choice should be based on the program with the higher national coverage. The WHO guidance and generic PMTCT impact evaluation protocol will provide more details. For low HIV prevalence countries, information on impact evaluation will be included in the WHO impact evaluation guidance.

For countries not yet ready to initiate the impact evaluation protocol, a modeling approach can be used. Modeling using existing data on early infant diagnosis results can also provide an estimate of MTCT rates, although this approach typically lacks information on transmission during breastfeeding, ARV adherence to postnatal prophylaxis, and other factors which could lead to unpredictable bias.

Technical assistance from PEPFAR HQ is available to address issues regarding impact evaluation and modeling.

1.1.4 COUNTRY CONTEXTUAL CONSIDERATIONS

Countries should consider the HIV epidemic, country capacity and infrastructure when planning the scale up of PMTCT services. Many challenges directly affect the PMTCT program and scale-up efforts. These include: size of the country and access to healthcare facilities; number of annual births; seroprevalence and absolute number of HIV positive pregnant women; contraceptive prevalence and fertility rates, ANC attendance rates; facility delivery rates; level of MCH/FP infrastructure and capacity; government commitment, resources and program management; program policies; and level of HIV/AIDS program, including ART program. Countries that are better-resourced, smaller, have lower prevalence and/or lower absolute number of HIV-infected women would be expected to achieve more rapid national scale-up. While infrastructure, resources and epidemic burden are key factors impacting PMTCT program progress, the single most important factor contributing to the success of PEPFAR and national PMTCT programs is host country national commitment to PMTCT. It is paramount to the success of PMTCT to have national commitment – PEPFAR country programs should focus on strengthening national commitment and the management capacity to support that commitment.

1.1.5 PARTNER PERFORMANCE CONSIDERATIONS

To maximize efficiency in the field, it is critical to ensure that partners are not duplicating their work and that the goal of the partners is to foster sustainability. Periodic in-country program portfolio reviews should assess: partner understanding of the program and technical considerations, geographic distribution, comprehensive approaches to programming (linking PMTCT with care and treatment), technical leadership in specific areas (e.g., training, EID, monitoring, etc), linkages with districts and MOH, and systems strengthening.

1.1.6 KEY REFERENCES AND RESOURCES

1. WHO. Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: recommendations for a public health approach, 2010 version.
http://whqlibdoc.who.int/publications/2010/9789241599818_eng.pdf
2. PEPFAR Guidance on Integrating PMTCT of HIV, Maternal, Neonatal, and Child Health, and Pediatric HIV Services in January 2011, available at
<http://www.pepfar.gov/documents/organization/158963.pdf>
3. WHO. Guidance on Global Scale-up of the Prevention of Mother-To-Child Transmission of HIV, Toward Universal Access for Women, Infants and Young Children and Eliminating HIV and AIDS among Children

- http://www.who.int/hiv/pub/guidelines/pmtct_scaleup2007/en/index.html
4. WHO. Guidelines on Co-trimoxazole Prophylaxis for HIV-related Infections among Children, Adolescents and Adults, Recommendations for a Public Health Approach (2006)
<http://www.who.int/hiv/pub/guidelines/ctx/en/index.html>
 5. On the WomenChildrenHIV.org website the following documents are available:
<http://www.womenchildrenhiv.org/wchiv?page=vc-10-00>
 - HHS/CDC draft Early Infant Diagnosis of HIV Implementation Guide
 - Testing and Counseling for Prevention of Mother-to-Child Transmission of HIV (HTC for PMTCT): Support Tools
 - WHO and HHS/CDC Prevention of Mother-to-Child Transmission of HIV (PMTCT) Generic Training Package
 6. Guidance for United States Government In-Country Staff and Implementing Partners for a Preventive Care Package for Adults (April 2006).
<https://www.pepfar.net/C3/Guidance/default.aspx>
 7. Guidance for United States Government In-Country Staff and Implementing Partners for a Preventive Care Package for Children Aged 0-14 Years Old Born to HIV-Infected Mothers (April 2006). <https://www.pepfar.net/C3/Guidance/default.aspx>
 8. Padian NS, Holmes CB, McCoy SI, et al. Implementation science for the US president's emergency plan for AIDS Relief (PEPFAR). *J Acquir Immune Def Syndr* 2011;56(3):199-203.

Table 1a: Antiretroviral prophylaxis for pregnant women who do not need treatment for their own health (from 2009 WHO rapid advice guidelines)

ARV Prophylaxis for pregnant women who do not need treatment for their own health		
Key issue	2009 ART guidelines	2006 ART guidelines
When to start ARV prophylaxis	<ul style="list-style-type: none"> As early as 14 weeks of pregnancy 	<ul style="list-style-type: none"> Starting at 28 weeks of pregnancy
Recommended prophylaxis regimens for the mother	<p><u>Option A: maternal AZT</u></p> <ul style="list-style-type: none"> AZT during pregnancy <i>plus</i> sd-NVP + AZT/3TC during labour and delivery <i>plus</i> AZT/3TC x 7days postpartum* <p><u>Option B: triple ARV prophylaxis</u></p> <p>Provided to pregnant women until one week after all exposure to breast milk has ended:</p> <ul style="list-style-type: none"> AZT + 3TC + LPV/r or AZT + 3TC + ABC or AZT + 3TC + EFV TDF + 3TC (or FTC) + EFV 	<ul style="list-style-type: none"> AZT during pregnancy <i>plus</i> sd-NVP + AZT/3TC during labor and delivery <i>plus</i> AZT/3TC x 7days postpartum
Recommended prophylaxis regimens for exposed infants	<p><u>Option A: maternal AZT</u></p> <p><i>Breastfeeding infants</i></p> <ul style="list-style-type: none"> sd-NVP at birth, then daily NVP until one week after all exposure to breastfeeding <p><i>Infants receiving only replacement feeding</i></p> <ul style="list-style-type: none"> sd-NVP at birth, then daily NVP or AZT x 4 to 6 weeks <p><u>Option B: triple ARV prophylaxis</u></p> <ul style="list-style-type: none"> NVP or AZT x 4 to 6 weeks 	<ul style="list-style-type: none"> sd-NVP + AZT x 7 days

TECHNICAL AREA 1.2: SEXUAL PREVENTION

Sexual Prevention – activities (including training) intended to prevent sexual transmission of HIV, the main mode of transmission in generalized epidemics, through a comprehensive platform, which emphasizes the reduction of risky sexual behaviors.

Area – General Population and Youth (PEPFAR Budget code -Abstinence/ be faithful) – activities (including training) to promote abstinence, including delay of sexual activity or secondary abstinence, fidelity, reducing multiple partners and concurrent partners, and related social and community norms that influence these behaviors. Activities should address programming for both adolescents and adults.

Area - Sexual Prevention: (PEPFAR Budget code - Other sexual prevention) - specifically targets HIV preventative efforts among MARPs (PWIDs, MSM, SWs, and SW clients) and vulnerable populations such as alcohol and other drug-using populations, mobile populations, and persons engaged in transactional sex. Additionally, these funds target condom and other prevention other than “abstinence and be faithful” programs for the general population.

1.2.1 BACKGROUND

The UNAIDS Global Report 2010 presents data demonstrating a significant reduction in HIV incidence across many countries where PEPFAR has been engaged in HIV prevention.¹ In addition, there have been major strides in understanding the epidemiology, dynamics and context of HIV infection in epidemics characterized by sexual transmission. Despite these advances, large numbers of people continue to be infected every year via sexual transmission; evidence-based, cost-effective interventions, supported with strong platforms for social and behavior change communication are critical to accelerating reductions in new infections. These programs must be implemented at a level of coverage and intensity capable of substantially reducing incidence in the target populations, and monitored and evaluated sufficiently to demonstrate their efficacy. Key to achieving scale, intensity and quality is accurate and complete data on the epidemic. While many countries and regions now have population-based prevalence data to guide prevention programming, data gaps persist and intensified efforts are urgently needed to improve comprehensive combination prevention programs.

Understanding of the behavioral, biological and structural drivers of the HIV epidemic continues to evolve. Available surveillance data from sub-Saharan Africa show that key drivers of generalized epidemics include: low rates of medical male circumcision and of correct and consistent condom use; multiple (including concurrent) partnerships, including intergenerational sex, commercial and transactional sex; serodiscordancy within couples; high rates of sexually transmitted infections, especially genital herpes; and high levels of alcohol use. Surveys suggest that sub-groups within the general population at elevated risk include: sexually-active young women; widowed, divorced and separated individuals; mobile and migrant populations. These data, while broadly true across the region of highest prevalence, are not a replacement for community-level mapping of risk factors and drivers.

¹ <http://www.unaids.org/en/resources/unaidpublications/2010/>

Prevention for adults and youth in the general population is important in high-prevalence generalized epidemics. In these settings, programs targeting general population adults and youth should be a considerable part of the prevention portfolio. Strategic thinking about the allocation of prevention resources is critical to ensure the most impact on reducing new infections. This strategic thinking needs to be guided by the local epidemiology of the HIV epidemic, including consideration of populations at elevated risk, the drivers of that risk, and geographic areas of high transmission. Once identified, these populations should be reached with interventions that include the core components of evidence-based interventions. Where there are no evidence-based interventions suitable, innovative and promising practices should be put into place alongside a strong evaluation plan. Social and behavior change programs should synergize with and support biomedical and structural interventions, creating demand, supporting adherence, linking communities with clinical facilities and facilities with communities.

In low-prevalence generalized (e.g. “mixed” epidemics”) and concentrated epidemics, an overall focus on distinct sub-groups within the general population and most-at-risk populations, who account for a majority of new infections, will have the largest effect on mitigating the epidemic. In lower prevalence settings, in addition to the focus on most-at-risk populations, comprehensive HIV programming should strategically target bridge populations and those most closely connected to persons engaging in high-risk behavior.

Persons who engage in socially stigmatized behaviors, including sex work, drug use, and male-male sexual behavior are at disproportionately higher risk for HIV. HIV may spread rapidly in these populations, due to more frequent participation in high risk behaviors such as unprotected anal and vaginal sex with partners of unknown HIV-status and sharing of injection equipment, and because risk behaviors, and the sexual networks of persons who engage in these behaviors often overlap (e.g. sex workers who use drugs, MSM who sell sex). In addition, because these populations are often hidden, due to political and socio-cultural discrimination and systematic marginalization, they are often harder to reach, and less likely to have access to services, or to use services when they are available, due to fear of being stigmatized or criminalized. Groups most often considered at elevated risk for HIV and defined as most-at-risk populations (MARPs)² are:

- Persons engaged in sex work
- Clients of persons engaged in sex work
- People who inject drugs
- Men who have sex with men

Sex Work

Recent studies confirm that in many countries, sex workers experience higher rates of HIV infection than in most other population groups.³ However, worldwide less than 50% of sex workers have access to a package of prevention services.^{4,5} Comprehensive, accessible, acceptable, sustainable, high-quality, user-friendly HIV prevention, treatment, care and support services must be scaled up and adapted to different local contexts. Even where services are theoretically available, sex workers face substantial obstacles to accessing HIV prevention, treatment care and support, particularly where sex work is criminalized. Ensuring that sex workers and their clients have meaningful access to essential services demands

² Joint United Nations Programme on HIV/AIDS. (2007). *A Framework for Monitoring and Evaluating HIV Prevention Programmes for Most-At-Risk Populations*. Geneva, Switzerland.

³ The UNAIDS 2008 Report on the Global AIDS Epidemic.

⁴ Vylsteke B, et al. (2008) *Preventing HIV among sex workers*. In: Mayer K, Pizer HF, eds. *HIV prevention*. London UK: Academic Press, 376-406.

⁵Bertozzi S et al. Making HIV prevention programmes work. *Lancet* 2008;373: 831-44.

concerted action to overcome structural factors that limit access. Stigma and discrimination must be effectively addressed through engagement of civil society and policymakers.

People Who Inject Drugs

There are approximately 16 million people who inject drugs (PWID) worldwide, with an estimated 3 million living with HIV.⁶ It is estimated that there are over 5 million PWID in 13 PEPFAR bilaterally-supported countries with drug-driven or emerging HIV epidemics.⁷ Within these 13 countries, an estimated 0.8 million PWID are HIV positive.⁸ Also of particular concern is the estimate that in some PEPFAR countries, as many as 30% of PWID are female. Among PWID, HIV, hepatitis B, hepatitis C and other blood-borne infections are spread primarily through risk behaviors related to multi-person reuse (sharing) of contaminated syringes and drug injection equipment. People who inject drugs are also at risk for acquiring and transmitting HIV through high-risk sexual behaviors, including but not limited to unprotected sex and engaging in sexual behaviors under the influence of drugs or in exchange for drugs.⁹ Of additional concern is the potential bridging effect, whereby an epidemic, initially fueled by the sharing of contaminated injecting equipment, is spread through sexual transmission from PWID to non-injecting populations and through perinatal transmission to newborns.¹⁰ For PWID, access to HIV prevention services, including treatment and care for their drug use, has been sub-optimal in low- and middle-income countries and in some developed countries.

Men Who Have Sex with Men

A growing number of studies now show that HIV is having a severe impact on MSM in low- and middle-income countries. Studies show higher rates of HIV infection among MSM in all regions of the world, including PEPFAR countries with generalized epidemics and those with concentrated epidemics. A systematic review of data from 38 low and middle income countries found that MSM are 19 times more likely to have HIV than the general population.¹¹ The increased risk of HIV infection among MSM calls for the rapid introduction and scaling up of comprehensive HIV prevention programs for MSM and the expansion of enabling environments that support the rights of MSM, enhance HIV prevention, and promote universal access to HIV care, treatment, and support.

Other Populations

Within each country, there may be other populations that have increased vulnerability to HIV due to a combination of behavioral, social, or environmental factors. These factors include frequent separation from a main partner or the family support structure due to mobility or migration, economic disparities related to gender or ethnic group, patterns of alcohol use that facilitates HIV risk behaviors, and incarceration that can compel same-sex behavior. Populations that can be considered to be at higher risk compared to the general population include:

- Military and other uniformed service persons;

⁶ Mathers, B., et al. (2008). Global epidemiology of injecting drug use and HIV among people who inject drugs: a systematic review. *The Lancet*, 372(9651), 1733-1745.

⁷ The thirteen countries referenced here are: Cambodia, China, Indonesia, Vietnam, Georgia, Kazakhstan, Kyrgyzstan, Russia, Tajikistan, Ukraine, Kenya, Tanzania, and South Africa.

⁸ Needle, R., & Zhao, L. (2010). *HIV Prevention among Injection Drug Users: Closing the Coverage GAP, Expanding Access, and Scaling up Core Interventions*. Washington, DC: CSIS Global Health Policy Center.

⁹ Institute of Medicine. (2007). *Preventing HIV Infection among Injecting Drug Users in High Risk Countries: An Assessment of the Evidence*. Washington, DC: National Academies Press.

¹⁰ IBID

¹¹ Baral S. et al. (2007) Elevated risk for HIV infection among men who have sex with men in low- and middle-income countries 2000-2006: A systematic review. *PLOS Med*, 4, 1901-1911.

- Men and women engaging in transactional sex;
- Incarcerated persons;
- Mobile populations (e.g. migrant workers, truck drivers);
- Street and other vulnerable youth; and
- Persons who engage in alcohol and non-injecting drug use-associated sexual risk behaviors

1.2.2 GENERAL POPULATION AND YOUTH (AB Budget code)

HIV prevention programming involves six key elements:

A. Setting epidemiologically sound priorities

Priorities and challenges will differ depending on whether the epidemic is generalized, mixed, or concentrated in nature. PEPFAR should support host country prevention programs to:

- Use available HIV incidence, prevalence, behavioral, and epidemiological data to help determine the appropriate balance between prevention activities among different age groups and risk groups as well as to tailor the response to the geographic distribution of the epidemic in the country;
- Be responsive to changes in HIV transmission over time, localized spatial clustering of HIV infections, and the local context;
- Identify the social and structural factors that may increase HIV risk or vulnerability, such as population mobility, and cross-generational and transactional sex;
- Identify opportunities to empower women and engage men to address harmful social and gender norms and promote protective norms;
- Address alcohol and other substance use/abuse, how they influence sexual behavior and the settings in which they are prevalent; and
- Address the needs of PLHIV and couples in serodiscordant relationships.

B. Developing a strategic prevention portfolio

PEPFAR should contribute to a strategic national HIV prevention portfolio that:

- Includes behavioral, biomedical and structural interventions that are complementary and mutually reinforcing to realize and promote potential synergies between programs (and across budget codes);
- Addresses the sources of new infections at a scale and scope capable of achieving declines in population-level prevalence;
- Focus efforts on key risk groups and contexts;
- Integrates and links program activities to ensure more comprehensive, effective, evidence-based programming, which for countries experiencing generalized or hyper-endemic scenarios will likely include community mobilization, communication, peer education, workplace interventions, condom promotion, scale-up of male circumcision, prevention with persons living with HIV, and provision of different types of testing and counseling (voluntary, provider-initiated, home-based, partner);
- Establishes and reinforces protective norms, attitudes, and behaviors through strategic partnerships with the media, local leaders, and other forms of available social capital; and
- Ensures adequate coverage, quality, and intensity of programmatic efforts that are mutually reinforcing and work at multiple levels (e.g. individual, couple, network, community). For example, mapping coverage of prevention activities against HIV prevalence by area and key

target populations can help to assess at a portfolio level whether programs are appropriately targeted and to make adjustments driven by data, epidemiology, and the local context.

C. Employing effective program models for social and behavior change communication

Interventions and activities should be theory-driven and evidence-based or adapted from evidence-based models. When sufficient evidence for effectiveness is unavailable, an evaluation component should be included to measure output and outcome indicators along a causal impact pathway that is likely to reduce HIV incidence. Social and behavior change communication (SBCC) activities should:

- *Link activities to clear behavior change objectives.* Activities should provide individuals with the relevant motivation and skills needed to adopt safer behaviors rather than solely focusing on improving knowledge or awareness of HIV;
- *Support biomedical interventions relevant to the population and setting.* While promoting risk reduction, SBCC programs should also promote and synergize with HIV testing and counseling, voluntary medical male circumcision (VMMC), prevention of mother-to-child transmission programs, as well as care and treatment programs. Such linked SBCC programs should assess their effectiveness in increasing uptake of and adherence to biomedical interventions as part of their monitoring and evaluation;
- *Address social norms.* Programs should address social norms and other elements of the social, cultural, and community environment that facilitate or prevent the spread of HIV. Such social, cultural, and community norms often influence individuals' abilities to engage in safer behaviors. Activities should recognize that the direct beneficiaries of intervention efforts often should not be the sole targets of those efforts and that efforts to engage leaders, peers, family members, local organizations, and the media may be essential to facilitate the widespread adoption and maintenance of safer behaviors;
- *Address structural barriers to prevention.* Combination prevention should not only focus on individual susceptibility and risk but also on societal factors that affect individual risk and vulnerability. Structural interventions may include policy work with partner governments and civil society to reduce stigma and discrimination; advocacy for adoption and implementation of alcohol policies and legislation if appropriate; efforts to reduce harmful gender norms, make school environments safer for girls, improve educational opportunities for girls, and increase property and other legal rights for women.¹² Additional data to understand the links between these interventions and impact on HIV transmission are still needed;
- *Treat behavior change as a process.* Proposed activities should seek to extend beyond single contacts with key target groups and beneficiaries, to support an ongoing structured implementation approach that delivers an effective intervention “dose” and facilitates and sustains the adoption and maintenance of prevention behaviors. Monitoring and evaluation should be an important part of these program activities; and
- *Above all, prevention programs must be tailored.* Proposed activities should be designed around available information about the needs of key target groups, the factors that expose them to HIV risk, and the context in which they live. Where such information is not available, activities should consider the inclusion of formative assessment efforts as part of their implementation strategy.

D. Supporting a coordinated and sustainable national response

PEPFAR country teams should support national counterparts to:

¹² Please see Technical Considerations from the Gender Technical Working Group.

- Coordinate and harmonize prevention efforts, including those supported by both PEPFAR and other donors, foster clear and consistent messaging that is mutually reinforcing across different partners, share lessons learned, make referrals across programs, and avoid duplication of effort; and
- Establish clear processes and mechanisms to ensure the appropriate integration of prevention programming into care, support, and treatment initiatives, and to reinforce key messages of care, support and treatment within prevention programming.

E. Establishing quality assurance, monitoring, and evaluation mechanisms

All PEPFAR-supported programs should:

- Establish mechanisms to assure the quality of implementation and the use of available data to inform program improvement. These mechanisms can include, but should not necessarily be limited to:
 - The establishment of selection criteria for peer and/or other educators
 - Program monitoring using relevant measures of success and a feedback monitoring loop for mid-course correction and continuous quality improvement
 - Retention and incentive strategies
 - Training and supportive supervision approaches, including refresher trainings
 - Curricula and materials selection, development and/or adaptation
- Share quality program tools, curricula, and models on the key drivers to improve existing activities;
- Conduct formative assessments to improve the design, implementation, revision, messaging, focus and relevance of prevention programming;
- Design strong monitoring plans and provide some clarification of what “reached” means in activities (e.g., exposed to a radio program vs. attended an outreach event vs. completed an eight-session curriculum);
- Develop more meaningful program-level indicators to reflect the optimal mix and quality of prevention approaches (e.g., dose, intensity, multi-level strategies);
- Support evaluation of activities and programs to help determine if positive behavioral changes were made. Ideally, the evaluations would measure behavioral outcomes. A data use and dissemination plan should be developed as well at the beginning of a project; and
- Strengthen PEPFAR prevention staff. All programs should consider including strong technical expertise in prevention to provide strategic leadership and coordination across partners, and to help develop in-country prevention expertise. Country programs need staff who can dedicate adequate time to prevention activities to ensure portfolios are strategic and harmonized, best practices are being followed, and activities are of high quality.

F. Programming for Adults and Youth

Efforts to address **adults** in the general population in high prevalence epidemics are critical, yet challenging, and should consider the following approaches, with a monitoring and evaluation component built into the program activities:

- Where HIV prevalence is high and male circumcision prevalence is low, give priority to scaling up rapid and high quality programs to provide voluntary medical male circumcision, particularly where national policies support MMC scale-up. (See the Male Circumcision Technical Area for more information);
- PEPFAR prevention programs should work with partner governments, UNFPA, Global Fund grant recipients and other donors to ensure a steady, sufficient supply of male condoms, distributed throughout the country/region and available at outlets and prices that make them

accessible to all sexually-active target populations, including young people. Programming to support correct and consistent male condom use should be a central element of all prevention activities. Programs supplying and promoting female condoms should also be part of prevention portfolios where appropriate, with a strong focus on overcoming provider bias and following strong program models from Zimbabwe and Malawi;

- Foster culturally appropriate social norms, attitudes, and beliefs and develop skills to reduce the number of partners, especially overlapping or “concurrent” sexual partnerships, which may create an efficient transmission network for the virus to spread rapidly through a population. Prevention messages should strongly support preventive behaviors by communicating explicitly about the risks associated with multiple partners and concurrent partners, and the appropriate use of condoms;
- Scale-up prevention programming for men to proactively change harmful gender norms that support and encourage multiple partnering, concurrent partnerships, cross-generational sex, and the lack of condom use;
- Encourage testing and counseling for partners of people living with HIV (PLHIV), with a focus on seeking and sustaining care and treatment. PLHIV in partnerships should be trained and encouraged to use condoms consistently and correctly when appropriate to protect the HIV-negative partner from becoming infected;
- Encourage the general population, including couples, to reduce their sexual risks and learn their HIV status. Programs should provide or refer to confidential testing and counseling as well as linkages to care for infected individuals; and
- Combat stigma and the effects of stigma on HIV risk behaviors.

Among **youth**, the following approaches should be considered:

- School education programs that include robust components on preventing sexually transmitted diseases, including HIV, linked to education on pregnancy prevention, for both in-school and out-of-school youth. Efforts should be made to ensure basic standards for curricula and materials, and to improve teacher training to ensure high-quality implementation and completion of curricula. Where appropriate, USG teams should support Ministries or Departments of Education and Health to institutionalize these education programs in schools;
- Provide necessary information and skills building to help youth prepare to make their eventual transition to sexual activity safer and healthier;
- Work with parents and guardians to help improve connectedness and communication to youth about their values and expectations regarding adolescent behavior, as well as stressing the importance of monitoring and supervision of their adolescents;
- Expand access to community-level prevention programs, including peer outreach, and curriculum-based programs for out-of-school youth; and
- Support youth-oriented, mass-media and educational entertainment programs that encourage youth to think critically about HIV prevention, and to influence knowledge, attitudes, behaviors and norms so they make healthy choices. These efforts should be balanced with, and linked to, more targeted interpersonal communication, such that the two can provide mutually reinforcing support for safe behavior;

Among sexually active youth and high-risk youth, the following approaches should be considered:

- Tailor programming for sexually active and most-at-risk youth based on patterns of behavior and their needs;

- Develop skills and norms to promote secondary abstinence, mutual monogamy, and partner reduction. Those who are sexually active should be provided with risk reduction information and skills building, including access to condoms and information on correct and consistent condom use;
- Support programming to engage influential adults within the community to create an enabling environment conducive to the adoption of safer sex behaviors among youth; and
- Sexually-active youth should also be encouraged to learn their HIV status, and programs should provide or refer to confidential youth testing and counseling, and linkages to care for HIV positive youth.

1.2.3 COUNTRY CONTEXTUAL CONSIDERATIONS

Partner Country and Other Donor Funding: In developing a strategic prevention portfolio, the country team should consider and describe how PEPFAR funding complements sexual prevention activities supported by the host country government and other donors in that country. For example, if the Global Fund has a large grant focused on HIV prevention for young people in a particular country, the PEPFAR program may appropriately focus on other populations.

Youth-Adult Balance: Across multiple countries, a key issue is the need for a balance between youth and adult programming that better reflects country-specific epidemiological data. Reaching adolescents remains important in countries where the epidemic has a younger age profile. In generalized epidemics, investing in youth prevention is an important long-term strategy to reduce transmission when young people eventually transition to adulthood, but should not absorb so much of the prevention portfolio investment that key adult populations are left uncovered. The youth-adult balance should reflect country-specific HIV incidence age patterns, or where not available, HIV prevalence age patterns.

Know your epidemic: Many countries, typically those with population-based prevalence between 1-5%, do not fall into the “concentrated” or “generalized” paradigm. These “mixed” epidemics often require a prevention response that includes significant attention to both most-at-risk populations as well as at-risk sub-populations (possibly defined by age, gender, occupation, geographic location, or risk characteristics) in the general population. The balance of focus on most-at-risk populations and at-risk sub populations of the general population in these epidemics will often vary within different regions of the country, depending on the prevalence in different regions as well as the composition and size of different most-at-risk populations. . For this reason, it is essential to know the impacted groups, the geographic variance among those groups, and the key risk factors for HIV transmission in each group. The balance of general population approaches versus most-at-risk population approaches in these “mixed epidemics should be determined at the country level. Countries should use the best available country data to ensure that most-at-risk populations are reached at adequate scale, while not neglecting a focus on general population approaches in the highest prevalence regions.

Please note, as described in the policy section, countries should program based on the epidemiologic profile of their country. The primary consideration for PEPFAR teams should be to respond appropriately to their specific epidemic. For generalized epidemics, there is a reporting requirement (not a budget requirement) if less than 50% of the sexual prevention funds are allocated for activities promoting abstinence/delayed debut or fidelity/partner reduction.

1.2.4 LINKAGES AND WRAPAROUNDS

Recently, there has been increased recognition of the need to integrate and strengthen combination prevention (behavioral, biomedical and structural) interventions across a wider range of other HIV and health services (e.g., PMTCT, care, PwP, ART, TB/HIV, HTC, STI, VMMC, reproductive health, family planning and OVC). The following are important considerations in developing these linkages and wraparounds:

- HIV care and treatment, as well as PMHT and HTC services, represent crucial entry-points for promoting preventive behaviors with HIV-infected individuals. A high priority should be to expand HIV testing for partners of infected individuals, and intensify risk reduction counseling and condom promotion for these individuals and their serodiscordant partners¹³. Strengthening prevention counseling within PMTCT and HTC services should be a further priority. These efforts should not only target HIV positive individuals, but also aim to help HIV-negative individuals stay HIV-free (see PwP technical area).
- Integrating risk reduction counseling and HTC into reproductive health and family planning services has the potential to expand the reach of prevention services to young women of reproductive age, a population at very high risk of acquiring HIV in generalized epidemics.
- Research in several Southern African countries has highlighted the increased vulnerability of orphaned girls and highlights the need to strengthen child protection and HIV prevention education and services within OVC programs.

Country teams should also keep in mind that partners providing clinical services may have limited behavioral expertise, and may need assistance in identifying effective intervention models to systematically integrate behavioral prevention within these other technical services.

Additional linkages should be considered with other development areas such as education, agriculture, democracy and governance, as well as through public private partnerships.

1.2.5 CONDOMS AND OTHER SEXUAL PREVENTION

As PEPFAR continues its support of country programs, the following represent technical considerations for USG country team in planning for FY 2012. These technical considerations emphasize a strategic response to MARPs and other vulnerable populations.

Measuring the epidemic and setting data-driven priorities

Many countries continue to lack or under-utilize existing bio-behavioral data for MARPs and other vulnerable populations; such data are key to inform programming. Both qualitative and quantitative data are important. Because MARPs and other vulnerable populations can be hard to reach, qualitative methods should be employed to understand the social and behavioral dynamics of HIV transmission and as formative work to design interventions.

Although qualitative and quantitative research and epidemiologic data are necessary to better characterize MARPs and other vulnerable populations and inform prevention programming, too often the link between data collection and program design and implementation is lost. A stronger link between epidemiologic, behavioral and socio-cultural data and prevention activities is needed to

¹³ See also Technical Considerations for Prevention with People Living with HIV.

ensure study results and surveillance information become the basis for prioritizing and implementing prevention programs.

Data collection should be conducted within the context of a strategic framework that strengthens human and organizational capacity; data collection, management, analysis and reporting at the national, sub-national, and organizational levels; and supports prevention programming and program implementation.

Creating an enabling environment

MARPs often engage in behaviors that are criminalized and highly stigmatized, creating access and acceptability barriers to initiation to and retention in HIV prevention, care and treatment services. Countries need to be aware of the potential for political backlash against MARPs and MARP-friendly program and research and work closely with government, civil society, and the affected population for creating an enabling environment for ethical treatment of MARPs. This includes encouraging a national response supported by Ministries of Health, other relevant government ministries and agencies, National AIDS Control Programs, and civil society stakeholders to address the complex issues of providing prevention services to these populations. Countries should take steps to ensure that scale-up of prevention programs for MARPs is accompanied by appropriate protections of their rights including the review of policies and regulations that criminalize or deter MARPs seeking services and training for service providers to reduce stigma and discrimination.

For FY12 Countries should:

- Identify policies, laws, regulations, informal mores, and other relevant guidelines/plans/working papers which may present barriers or facilitators for MARPs and other vulnerable populations to initiate or retain in prevention, care and treatment services;
- Prioritize relationship-building with civil society (e.g. non-government organizations, highly regarded MARP community members) to foster a collaborative and supportive environment for prevention efforts targeting MARPs;
- Seek and encourage opportunities to bridge access barriers MARPs may experience with clinical settings or outreach service providers (e.g. support sensitization trainings for service providers working with MARPs to reduce stigma and discrimination); and
- Support advocacy and protective policy work needed to safeguard the rights of MARPs and to effectively implement prevention programs.

Developing capacity within countries

Many countries lack the capacity and resources to provide effective programming for MARPs and other vulnerable populations. Prevention staff should ensure that coordinated technical assistance, both from headquarters and south to south, will focus on developing the appropriate range of technical skills within countries to develop, implement, evaluate, and improve prevention programs for MARPs and other vulnerable populations. This includes providing assistance to improve coordination across partners and to develop in-country expertise.

For FY12 Countries should:

- Develop a strategic plan for technical assistance from both headquarters and south to south providers;
- Conduct training for service providers, stakeholders, and the government partners to support work with MARPs and other vulnerable populations;
- Build capacity of civil society organizations to plan, implement, monitor and evaluate high-quality prevention programs for MARPs, and to advocate for continued funding of HIV prevention with MARPs in the future; and

- Support the development of policies and activities to support workforce development and retention and health system strengthening.

Supporting a package of HIV prevention services and promoting linkage to care and treatment programs

There is substantial evidence for the effectiveness of a core set of interventions for populations at high risk for HIV. These interventions comprise a package of services for MARPs, and may be appropriate for other vulnerable populations depending upon the country context. Programs should ensure participation of the target MARPs or other vulnerable group in the development, implementation, and monitoring of prevention programs. Based on the epidemiologic profile for each country, the country team should scale-up a minimum, core set of interventions adapted for different sub-groups especially vulnerable to HIV.

Peer education and outreach: Peer outreach relies on indigenous community members to reach hidden populations with HIV prevention information and referrals to important services. When peer education and outreach is accompanied by risk reduction counseling and supplies provision (e.g. condoms, bleach kits) it is especially effective in reducing sexual and/or drug-using risk behaviors.¹⁴

Risk reduction counseling: Risk reduction counseling is an effective intervention for MARPs, whether delivered through peer outreach or in clinic settings and can address both drug and sexual risk behaviors, as appropriate, for the target population. A recent review showed that risk reduction counseling and condom promotion increased condom use and decreased STI or HIV (depending on study outcome) among populations of sex workers.¹⁵ Meta analyses show that risk reduction counseling can have a positive impact on persons who inject drugs sexual risk behaviors¹⁶; however, the effect may decay over time¹⁷, indicating that these behaviors may need to be more intensively targeted and require booster sessions.

Condom and condom-compatible lubricant promotion and distribution: Programs need to ensure a consistent supply and availability of quality male and female condoms as well as condom-compatible lubricants especially for MSM, sex workers and PWID and their sex partners. A recent review of 62 studies from sub-Saharan Africa concluded that interventions promoting condoms can significantly increase levels of self-reported condom use in some populations.¹⁸ Recent data has emerged reviewing the effectiveness and toxicities of various formulations of lubricants. In light of this information, PEPFAR still promotes the use of condom compatible lubricants with the recognition that research is ongoing and more is needed to determine which formulation provides the

¹⁴ Shahmanesh, M., et al. (2008). Effectiveness of interventions for the prevention of HIV and other sexually transmitted infections in female sex workers in resource poor setting: a systematic review. *Tropical Medicine and International Health*, 13 (5), 1-21; Needle, R. H., Burrows, D., Friedman, S. R., Dorabjee, J., Touze, G., Badrieva, L., et al. (2005). Effectiveness of community-based outreach in preventing HIV/AIDS among injecting drug users. *International Journal of Drug Policy*, 16S, S45-S57; and Semaan, S., et al. (2002). A meta-analysis of the effect of HIV prevention interventions on the sex behaviors of drug users in the United States. *Journal of Acquired Immune Deficiency Syndrome*, 30, S73-S93.

¹⁵ Shahmanesh, M., et al. (2008). Effectiveness of interventions for the prevention of HIV and other sexually transmitted infections in female sex workers in resource poor setting: a systematic review. *Tropical Medicine and International Health*, 13 (5), 1-21

¹⁶ Semaan, S., et al. (2002). A meta-analysis of the effect of HIV prevention interventions on the sex behaviors of drug users in the United States. *Journal of Acquired Immune Deficiency Syndrome*, 30, S73-S93.

¹⁷ Copenhaver, M., et al. (2006). Behavioral HIV risk reduction among people who inject drugs: Meta-analytic evidence of efficacy. *Journal of Substance Abuse Treatment*, 31, 163-171.

¹⁸ Foss AM, et al. (2007). A systematic review of published evidence on intervention impact on condom use in sub-Saharan Africa and Asia. *Sexually Transmitted Infection*, 83, 510-516.

best protective effect. At this time, water- and silicon-based lubricants may offer increased protection.

HIV testing and counseling (HTC): Innovative and tailored models for delivering HIV testing to drug users, sex workers, and MSM are needed (e.g., mobile services, home-based testing). Special consideration needs to be given to different testing models including voluntary, provider-initiated and couples and partner testing. Use of rapid test kits with same day results paired with post-test counseling is recommended for MARPs.

Sexually Transmitted Infections (STI) screening and treatment: in many settings STIs are prevalent among MARPs and other vulnerable populations and may facilitate sexual transmission of HIV to partners.¹⁹ Routine STI assessment and treatment should be an integral component of MARP package of services. Approaches to STI control for MARPs especially sex workers vary based on local STI prevalence; however, general principles call for defining a package of confidential services with well-defined treatment components, screening intervals, and standards for delivery. STI services are also uniquely useful in attracting MARPs into services/programs, which provide an opportunity to reach MARPs with other HIV prevention services. Countries should consider integrating STI screening and treatment into HIV care settings and into existing prevention programs for MARPs and other vulnerable populations.

Referrals to male circumcision: Voluntary medical male circumcision (VMMC) is an effective intervention to reduce the risk of male heterosexually acquired HIV infection. Observational studies indicate that VMMC may be even more protective among men with higher risk of heterosexual acquisition.²⁰ UNAIDS/WHO issued normative guidance in March 2007 stating that VMMC should be recognized as an additional important intervention to reduce the risk of male heterosexually acquired HIV infection. Referrals to MC should be made as part of a comprehensive HIV prevention package for clients of female sex workers and other males at high risk of HIV acquisition by their female partners. To date VMMC has not been shown to reduce the risk of HIV acquisition among MSM.

Referrals to HIV care and treatment including PMTCT: HIV care and treatment for MARPs includes antiretroviral therapy (ART), adherence support, and treatment of co-morbidities, opportunistic infection prophylaxis, and access to primary health care. Good treatment adherence has been demonstrated among MARPs when approaches are implemented to facilitate access and acceptability. Additionally, promising new evidence from interim analysis of HPTN 052 clinical trial has shown that early use of ART is a highly effective HIV transmission prevention strategy in discordant heterosexual couples, reducing the risk of sexual HIV transmission by 96%.²¹ Further scientific data and forthcoming PEPFAR guidance are expected.

Referrals to substance use treatment: Substance use treatment reduces the frequency of drug use, which in turn reduces HIV risk behaviors.²² It also improves adherence to disease treatment

¹⁹ Wegbreit J, et al. (2006). Effectiveness of HIV prevention strategies in resource-poor countries: tailoring the intervention to the context. *AIDS*, 20, 1217-1235.

²⁰ Weiss, H., et al. (2008). Male circumcision for HIV prevention: from evidence to action? *AIDS*, 22, 567-574.

²¹ Treating HIV-infected people with antiretrovirals protects partners from infection: Findings result from NIH-funded international study [press release]. Bethesda, MD: National Institute of Allergy and Infectious Diseases; May 12, 2011. (<http://www.niaid.nih.gov/news/newsreleases/2011/Pages/HPTN052.aspx>)

²² Gowing, L., et al. (2008). Substitution treatment of injecting opioid users prevention of HIV infection. *Cochrane Database of Systematic Reviews*, Issue 2. Art No.: CD004145. DOI: 10.1002/14651858.CD004145.pub3; Institute of Medicine. (2006). Preventing HIV Infection among Injecting Drug Users in High Risk Countries: An Assessment of the Evidence. Washington, D.C.: The National Academies Press.

regimens.²³ Treatment modalities include non-pharmacological and pharmacological approaches; often, a combination of the two is used.²⁴ An extensive body of evidence shows that medication assisted therapy (MAT) reduces the frequency of heroin injection and improves substance use treatment retention.²⁵ Methadone maintenance therapy (MMT) is associated with reduced HIV risk behaviors including reduced frequency of injecting and sharing of injection equipment, reductions in the number of sex partners, and exchanges of sex for drugs or money.²⁶ (Further information on substance use treatment is found in the Biomedical Prevention Section for PWID/PWUDs.)

Vaccination, diagnosis and treatment of viral hepatitis: People who use drugs are at increased risk for other blood-borne pathogens such as viral hepatitis due to sharing of injection equipment and higher frequency of unprotected sex. Among people who use drugs, Hepatitis B and C are most common.²⁷ HBV can be transmitted from mother to child, through unsafe injection practices, sharing of contaminated drugs, needles or other injecting equipment, blood transfusion and unprotected sex. The World Health Organization (WHO) recommends a targeted HBV prevention approach to include vaccination of persons who engage in high-risk sexual behavior and people who inject drugs.²⁸

Prevention, diagnosis and treatment of tuberculosis: TB is the leading cause of death among people living with HIV in Africa and a major cause of death elsewhere. It is also the most common presenting illness among people living with HIV who are taking antiretroviral treatment. HIV positive individuals who are infected with TB have a 5-10% annual risk of progressing to TB disease as opposed to TB infected HIV negative individuals who have a 5-10% lifetime risk of progressing to TB disease.²⁹

Drug use is associated with increased rates of TB infection and disease and is a leading cause of mortality among HIV positive people. Most at-risk populations are at increased risk for TB given high rates of HIV infection, which suppresses the immune system making HIV positive individuals more susceptible to TB infection and progression to active TB. People who use drugs and sex workers may experience other risk factors for TB disease such as incarceration, poor living conditions and poverty. WHO recommends the three 'P's for TB/HIV including: isoniazid preventive therapy intensified case finding for TB, and infection control, to reduce the burden of TB among people living with HIV.³⁰

Linkages to other health, social, and legal services: MARPs and other vulnerable populations should be provided with or referred to other health services including family planning, primary health care as well as psychosocial and legal support. Special consideration should be given to MARPS for post-exposure prophylaxis (PEP) due to increased risk of condom breakage and/or sexual violence.

Service delivery models (i.e., mobile versus stationary sites, hours of operations, type of health service provider, etc.) for these core prevention interventions may need to be adapted to reach, engage and retain most-at-risk populations. The country team is encouraged to incorporate tailored or innovative approaches that are likely to increase access and remove barriers to services for these

²³ IBID

²⁴ National Institute on Drug Abuse (1999). Principles of Drug Addiction Treatment: A Research-Based Guide (Rep. No. NIH Publication No. 99-4180). Bethesda, MD: U.S. Department of Health and Human Services.

²⁵ Gowing, L., et al. (2008). Substitution treatment of injecting opioid users prevention of HIV infection. Cochrane Database of Systematic Reviews, Issue 2. Art No.: CD004145. DOI: 10.1002/14651858.CD004145.pub3;

²⁶ IBID

²⁷ IOM (2006). Preventing HIV infection among injecting drug users in high risk countries: an assessment of the evidence

²⁸ WHO (2008). Hepatitis B Fact Sheet

²⁹ WHO (2004). Policy brief: reduction of HIV transmission through drug-dependence treatment

³⁰ WHO (2009). TB/HIV Facts

populations. Use of qualitative methods to guide these adaptations has proven to be an effective strategy.

For FY12 Countries should:

- Develop and implement a package of services for MARPS-specific populations as well as referrals and linkages to care and treatment and other health and support services;
- Establish a clear national strategy for HIV prevention with MARPS and other vulnerable populations and working with partners to better integrate and harmonize their prevention efforts, foster clear and consistent messaging that is mutually reinforcing across different partners, share lessons learned, make referrals to one another, and avoid resource duplication; and
- Identify areas where technical assistance is needed in implementing comprehensive services for MARPs and other vulnerable populations.

Scaling-up for adequate coverage, intensity, quality and scale of prevention programs

Most countries lack a comprehensive strategy or plan for addressing the HIV prevention, care, and treatment needs of MARPs and other vulnerable populations. While many countries have small-scale targeted activities or pilot programs, few countries have taken steps to scale-up successful models or expand coverage. Countries should support national scale up of quality prevention programs for MARPs and other vulnerable populations to ensure an adequate coverage, intensity, and scale to impact the HIV epidemic.

For FY12 Countries should:

- Define interventions or packages of interventions that could be taken to scale for each MARP sub-population;
- Develop a common set of indicators to monitor programs;
- Increase the quality and intensity of prevention intervention delivery; and
- Develop methods to be used for measuring coverage, intensity, and quality.

Establishing quality assurance (QA), monitoring, and evaluation mechanisms

To ensure high quality prevention programs for MARPs and other vulnerable populations, countries should develop quality assurance, monitoring and evaluation plan. Currently PEPFAR HQ is developing quality assurance standards and associated assessment tools and M&E plan for peer education and outreach programs with sex workers. The development process, QA standards, self and external assessment tools and M&E plan will be documented and available for field use. The QA project should finish late in 2010 and has been a one year-4 phase process.

Phase 1: Situational analysis and preparation (Step 1-3)

Phase 2: Draft program and service standards through facilitating workshops (Step 4)

Phase 3: Test and implement agreed-upon standards and assessment tools

Phase 4: Institutionalize standards through ongoing QA/QI, monitoring and evaluation.

Assistance is available on developing QA standards through PEPFAR HQ. Countries are encouraged to utilize this expertise.

For FY12 Countries should:

- Develop a set of core competencies and minimum standards, as well as a system of oversight and supervision, to monitor, assure, and improve these programs;
- Sharing quality program tools, curricula, and models from successfully implemented programs; and

- Develop meaningful program-level indicators that assess the mix and quality of prevention approaches (e.g., intensity, scale, and coverage).

Considerations for Specific Vulnerable Populations and HIV Risk Behaviors

Military

The military of any country are generally: young, mobile, men (although increasingly female) with money. They are trained to consider themselves to be invincible and that mentality can increase their risk for HIV infection. Military personnel are organized into hierarchical structures and can be reached with programs and services that utilize their chain-of-command organizational structure.

Military prevention programs should be data-driven for maximum effectiveness. While programs should be initiated even in the absence of baseline data, efforts should be made for data collection to track programs over time and tailor interventions according to demonstrated risks.

The development, adoption and implementation of a military HIV policy is a foundation for a comprehensive approach to prevention, care and treatment. If policies are not clear and known by all, HIV programs can be limited because those in command and in the ranks will be uncertain of the consequences of getting tested, accessing prevention services or their ability to get care and treatment.

Prevention programs for the military should be provided in new recruit populations at training bases, active duty populations at bases and in the field, and in peacekeeping settings. Programs should include:

- Voluntary medical male circumcision
- Peer prevention programs
- Prevention for PLHIV
- Leadership training
- Programs to address male norms
- Family outreach, including spouse support groups
- Condom promotion and distribution
- STI diagnosis and treatment
- Alcohol reduction programs
- HIV testing and counseling

For FY12 Countries should:

- Assess current military policy on HIV including prevention of HIV-related stigma and discrimination; and
- Assess progress in implementing comprehensive prevention services, including links to care and treatment, for military personnel and their family members.

Incarcerated Populations

In most countries prevalence of HIV infection among this population is much higher than in non-incarcerated populations.³¹ Incarcerated populations present unique risk factors. They often have drug-related offenses, multiple sexual partners, infrequent condom use and limited access to HIV

³¹ United Nations Office on Drugs and Crime, Joint United Nations Programme on HIV/AIDS, and World Bank. (2007). *HIV and Prisons in sub-Saharan Africa: Opportunities for Action*. Geneva, Switzerland.

prevention, care and treatment while incarcerated and post-incarceration. It is important to take into consideration the gender-specific risk patterns and behaviors.

To address these risk factors a comprehensive HIV program needs to be implemented within correctional facilities. The components of a comprehensive HIV program targeted toward incarcerated persons should ideally include: HIV education; HIV testing and counseling that is easily accessible and confidential; condom promotion and distribution; water- and silicon-based lubricants, prevention of sexual violence; post-exposure prophylaxis; STI screening and management; access to and safe disposal of injecting drug equipment, vaccination, diagnosis and treatment of HVB and screening for HVC; measures to reduce demand for and supply of drugs in prisons; drug treatment; and access to HIV care and treatment.³²

For FY12 Countries should:

- Identify research needed to fill gaps in characterizing incarcerated populations;
- Support the development and implementation of a package of services for incarcerated populations as well as referrals and linkages to care and treatment and other health and support services;
- Develop a strategic plan for technical assistance from headquarters to plan for and implement HIV prevention programs in correctional facilities; and
Identify policies that contribute to or protect from incarceration-related HIV risk.

Street Youth and Other Vulnerable Youth

There are an estimated 120 million “street kids” worldwide living in both rich and poor countries.³³ Many street youth engage in illegal activities (e.g., theft), sell or exchange sex because they lack other means of support, or use injection and non-injection drugs. Because of these multiple, overlapping risks and legal and other barriers these youth often do not or cannot access appropriate health services, are marginalized from mainstream HIV prevention services, and may experience stigmatization, discrimination and social exclusion. In cases where most-at-risk and vulnerable youth are below the age of 18 they may need to be removed from exploitive situations (sexual trafficking, child soldiers) and provided with appropriate health, legal and social services. Other youth are vulnerable because of such factors as displacement; ethnicity and social exclusion; having parents, siblings or peers who use drugs; internal and external migration, family breakdown and abuse; harmful cultural practices; incarceration, employment activities (such as domestic work) and poverty.³⁴

There is sufficient evidence to show that many risk-reduction efforts are effective irrespective of the stage of the epidemic. These include 1) information on HIV prevention and treatment, 2) condoms, 3) harm-reduction services if injecting drugs, 4) services for prompt diagnosis and treatment of STIs, and 5) testing and counseling with referral to HIV treatment, care and support services if HIV positive and HIV-prevention counseling if HIV-negative. These services should be complemented by outreach, including peer-based outreach, and adapted to meet the needs of most-at-risk and other vulnerable youth to ensure they are “youth friendly” and appropriate to age, gender-based issues,

³² World Health Organization. (2007). *Effectiveness of Interventions to Address HIV in Prisons..* Geneva, Switzerland.

³³ Joint United Nations Programme on HIV/AIDS. (2007). *HIV/AIDS stigma and discrimination: UNAIDS Best Practice Collection*, Geneva, Switzerland.

³⁴ Inter-Agency Task Team on HIV and Young People: United Nations Population Fund, HIV/AIDS Branch (2007). *Guidance Brief: HIV Interventions for Most-at-Risk Young People*. New York, NY.

legal status, and maturity. There is also evidence that factors, such as family, school and community ties, are protective against HIV-risk taking.³⁵

For FY12 Countries should:

- Identify situational assessments that have been undertaken to understand young people's risk and vulnerability to HIV infection and to map specific venues or areas of high HIV transmission ("hot spots"), e.g., places where youth meet new sexual partners;
- Discuss how assessments, other research and programmatic information have been used to inform HIV strategic plans and to guide prevention programming decisions;
- Describe how programs for young MARPs and street and other vulnerable youth are tailored to meet their specific needs, including those related to age and psychosocial development; and
- Describe the cultural, social and policy barriers to reaching and serving young MARPs and other vulnerable youth.

Men and Women Engaging in Transactional Sex

One explanation for the large number of people living with HIV, particularly in sub-Saharan Africa and for the disparity in the levels of HIV infection between men and women is the exchange of sex primarily motivated by material gain (i.e., the provision of food, clothes, transportation, items for children or family, school fees, somewhere to sleep, or cash). This exchange of money or resources for sex often involves age mixing between older men and younger women (i.e., cross-generational sex). Transactional partnerships may particularly facilitate the rapid spread of HIV and other STIs when the sexual relations involve complex chains of interconnected partners that place an entire social network at risk.

To better understand this risk behavior and to facilitate the use of efficacious interventions and their application, the Prevention of HIV in Persons Engaged in High-Risk Behavior (PHPEHRB) TWG is working with three countries to examine the social and sexual networks of women and men engaged in transactional sex; describe attitudes toward, motivations for, determinates of and social relations of persons in these networks; and document the community context in which they operate. Based on the findings of the formative assessment, phase two of the study will focus on the design, development and pilot of an intervention (or module for potential inclusion in other on-going prevention activities). Intervention-related materials and tools will be developed that can be disseminated for use in other contexts and settings.

For FY12 Countries should:

- Examine existing data sources and monitoring and evaluation outputs to understand the association of transactional sex and HIV;
- Identify policy and advocacy efforts that can be leveraged to change the social acceptability of transactional sex; and
- Leverage existing information on behavioral, social and contextual issues that influence transactional sex and ways to mitigate risk.

³⁵ World Health Organization. (2006). Preventing HIV in Young People: *A Systematic Review of the Evidence from Developing Countries*. Eds. Ross, D., Dick, B., and Ferguson, J. WHO and Inter-Agency Task Team on HIV and Young People. Geneva, Switzerland

Alcohol Use and HIV

Alcohol misuse plays a critical role in sexual risk behavior that can lead to HIV transmission, and also is a factor in health and wellness for persons living with HIV. The association between alcohol use, abuse, and dependence, and increased sexual risks is increasingly recognized in many countries. Alcohol use plays a critical role in sexual risk behavior that can lead to HIV transmission, and also is a factor in health and wellness for persons living with HIV. Multiple studies have found that persons who use alcohol in sexual situations are more likely to have unprotected sex, casual sex, and multiple concurrent partnerships, than persons who do not use alcohol in sexual situations.³⁶ Alcohol consumption is linked with increased risk of STI and HIV infection³⁷, gender-based violence, and non-adherence to anti-retroviral medication. PEPFAR programs should strongly consider alcohol harm reduction programming. A comprehensive national strategy including a combination of approaches that address individual-, community-, and environmental-level change is being implemented by the PHPEHRB TWG. The strategy incorporates the best practices from health policy, behavioral science, epidemiology, addiction treatment and development strategy. Key lessons learned and areas for improvement will be assessed continuously in anticipation of regional and international replication.

For FY12 Countries should:

- Identify research needed to describe country-specific associations between alcohol use and HIV risk behavior;
- Conduct training for and incorporating alcohol abuse screening, brief interventions, and referrals to treatment (SBIRT), and education into existing provider training programs and services for ARTVCT, PMTCT, TB, and STIs;
- Identify policies or regulations that can be strengthened to reduce alcohol-related HIV risk behavior (e.g. sales tax on alcohol purchases, enforcement of underage drinking restrictions, etc.); and
- Develop a strategic plan for technical assistance from headquarters to plan for and implement multi-level alcohol harm reduction programs to reduce HIV risk.

1.2.6 COUNTRY CONTEXTUAL CONSIDERATIONS: CONDOMS AND OTHER SEXUAL PREVENTION

Countries should identify the high risk populations that reflect country-specific epidemiological and behavioral data. Reaching specific MARPs populations is important in countries with concentrated epidemics and in countries where MARPs may act as a “bridge” population or subgroup within the general population engaging in risky behavior. Different package of services and/or service delivery models may be needed depending on the population and local context.

Services and service delivery models need to take into account the country’s cultural and social norms, especially related to MARPs and other vulnerable populations. Understanding these norms can help inform approaches increasing the likelihood of effective implementation within the local context. This is

³⁶ Kalichman, S., et al. (2007). HIV/AIDS Risk Reduction Counseling for Alcohol Using Sexually Transmitted Infections Clinic Patients in Cape Town, South Africa. *Journal of Acquired Immune Deficiency Syndrome*, 44, 594–600.

³⁷ Li Q, Li X, and Stanton B. (2010) Alcohol Use Among Female Sex workers and Male Clients: An Integrative Review of Global Literature. *Alcohol & Alcoholism*, 45(2); 188-199.

important in the context of policies and laws that criminalize MARPs (e.g., PWIDs, MSMs). Reaching MARPs and other vulnerable populations in such an environment presents unique challenges.

1.2.7 LINKAGES AND WRAPAROUNDS: CONDOMS AND OTHER SEXUAL PREVENTION

Prevention programs for MARPs and other vulnerable populations are based on a set of core interventions providing many opportunities for linkages and wraparounds. The package of prevention services includes: risk reduction counseling, condom and lubricant skills building and provision, HIV testing and counseling, STI screening and treatment, MC HIV care and treatment including PMTCT, referrals to substance use treatment (including alcohol use or dependence treatment) and needle and syringe programs,, vaccination, diagnosis and treatment of viral hepatitis, prevention, diagnosis and treatment of tuberculosis, family planning and reproductive health services. A comprehensive approach targeted towards MARPs and other vulnerable populations must include linkages to psychosocial support services, legal services, positive prevention, micro-finance support projects and/or other appropriate wraparound services.

Closer collaboration between USG staff working in prevention and other technical areas will be essential to promote these linkages and wraparounds. Country teams should also keep in mind that partners providing clinical services may have limited behavioral expertise and experience working with MARPs and other vulnerable populations, and may need assistance in identifying effective intervention models to systematically integrate prevention within these other technical services. Additional linkages should be considered with other development areas such as education, agriculture, democracy and governance, as well as through public private partnerships.

TECHNICAL AREA 1.3: BIOMEDICAL PREVENTION

Biomedical Prevention – activities (including training) intended to prevent HIV transmission through biomedical interventions. In PEPFAR, this program area includes four program area budget codes: blood safety; injection safety; voluntary medical male circumcision; and injecting and non-injecting drug use.

Blood safety – activities supporting a nationally-coordinated blood program to ensure a safe and adequate blood supply including: infrastructure and policies; donor-recruitment activities; blood collection, testing (transfusion-transmissible infections, group, and compatibility); component preparation, storage and distribution; appropriate clinical use of blood, transfusion procedures and hemovigilance; training and human resource development; monitoring and evaluation; and development of sustainable systems.

Injection safety – policies, training, waste-management systems, advocacy and other activities to promote medical injection safety, including distribution/supply chain, cost and appropriate disposal of injection equipment and other related equipment and supplies.

Prevention among injecting and non-injecting drug users (e.g., methamphetamine users) – activities including policy reform, training, message development, community mobilization and comprehensive approaches including medication assistance treatment to reduce injecting and non-injecting drug use.

Voluntary Medical Male Circumcision (VMMC) – UNAIDS/WHO issued normative guidance in March 2007, stating that VMMC should be recognized as an important intervention to reduce the risk of male heterosexually acquired HIV infection. In response to the normative guidance and under the leadership of host country governments, Emergency Plan funds can be utilized to support the implementation of safe VMMC. All VMMC services should include a minimum package of prevention services which include routine counseling and testing for all men and, where possible, their partners attending MC services; age-appropriate sexual risk reduction counseling; and counseling on the need for abstinence from sexual activity during wound healing; and promotion of correct and consistent use of condoms. VMMC should be implemented in accordance with national standards and international guidance with active linkages with other HIV prevention, treatment, care and support services as needed. VMMC encompasses a focus on policy, training (task-shifting/sharing), outreach, development of tools for communications, efficient and accessible service delivery, quality assurance, and equipment /commodities related to male circumcision.

1.3.1 BACKGROUND: BLOOD SAFETY

An adequate supply of safe blood in partner countries, prescribed by clinicians trained in the appropriate use of blood, is an important component of the U.S. President's Emergency Plan for AIDS Relief's (PEPFAR) global HIV prevention strategy. Assistance has been provided to strengthen or in some case develop national blood transfusion services, especially in countries with high burden of malaria and maternal mortality. In sub-Saharan Africa, it is estimated that pediatric malaria-associated complications accounts for half or more of all transfusions and obstetric complications for another quarter. Throughout the developing world, chronic blood shortages mean many required transfusions are never received. These shortages are often due to systems that rely on the collection of blood from family and replacement donors who are often at high risk for HIV or other transfusion-transmissible infections (TTIs) and occur only when there is already a patient in need. Such collections may be the norm in emergency situations and frequently are not screened for TTIs or adequately cross-matched for compatibility, increasing the risk of death, infection or other complications for transfusion recipients. Because efficient, quality assurance-based systems are not in place to ensure timely transfusions, blood may arrive too late or in insufficient quantity to save a life.

To help countries build sustainable national blood transfusion services, WHO has provided important recommendations for national blood programs worldwide. These recommendations serve as the technical foundation for PEPFAR's blood safety assistance programs. These guidelines recommend:

- Collection of blood only from voluntary, non-remunerated, low-risk blood donors ;
- Universal blood screening for HIV, hepatitis B and C viruses and syphilis; and
- The appropriate clinical use of blood.

To help countries prioritize blood safety investments the Medical Transmission TWG has focused on seven activities to promote quality management systems, good manufacturing and good laboratory practices:

- **Policy:** the development of a national blood policy and enactment of supporting legislation;
- **Donation:** the collection of blood from regular, low risk, voluntary and non-remunerated donors;
- **Laboratory:**
 - effective and universal screening for HIV, hepatitis B and C virus and syphilis
 - quality typing and crossmatching
 - appropriate storage, processing and distribution of blood and blood products from vein to vein;
- **Appropriate clinical use:** the development of guidelines and hospital transfusion committees to tailor prescribing practices to the blood and blood components that are available and to monitor patient safety and transfusion outcomes;
- **Training:** pre-service, in-service and continuing medical training of blood service and hospital personnel;
- **Monitoring and evaluation:** to measure their progress toward implementing the WHO recommendations; and
- **Sustainability:** to ensure continuity after PEPFAR including the appropriate, accurate and efficient costing of blood and blood products.

Overall:

- Support well-organized and coordinated blood safety activities through a central entity (e.g., MOH, National Blood Transfusion Service – NBTS, other entity) with legal authority to manage the national blood supply;
- Promote policies mandating the collection of blood only from voluntary, non-remunerated, low-risk blood donors;
- Strengthen capacity to test all donated blood for transfusion-transmissible infections, group and compatibility in quality-assured laboratories with opportunities to participate in external proficiency testing programs;
- Emphasize the appropriate clinical use of blood through partnership with clinical services that utilize blood (e.g. Trauma, Obstetrics/Gynecology, Surgery, Pediatrics, Internal Medicine) in the development of national guidelines , training, mentoring and programs to encourage appropriate handling of units to minimize waste;
- Promote a quality assurance system covering all stages of the transfusion process (from donor to recipient) to lead towards accreditation of the NBTS;
- Emphasize training consistent with international standards, as well as with national plans and policies regarding blood safety , and provision for Train the Trainer strategies at the National level to support capacity building and sustainability
 - Coordinate Phlebotomy training with Injection Safety practices and programs
 - Consider task shifting e.g. establishment of phlebotomist as a recognized job category;
- Strengthen capacity to collect and manage data that will allow programs to: distinguish repeat, deferred donors etc.; utilize recruitment technologies (e.g. SMS texting); and utilize data for operational decision making , forecasting, and reporting;
- Ensure quality indicators are utilized to monitor, evaluate, and when necessary, alter or adapt, national blood service strategies and/or practices;
- Strengthen national capacity through human resource and infrastructure development
 - Coordinate with Human Resources for Health, Systems Strengthening in areas of in-service and pre-service training, regarding guidance on training development and assessments, and in support for structured supervision and constructive feedback
 - Participate in development of regional waste management plans
 - Coordinate with laboratory and health care facilities in commodities procurement, equipment maintenance
 - Coordinate with other programs (e.g. lab, immunizations, pharmacy) regarding maintenance of appropriate cold chain from donation to transfusion;
- Encourage collaboration with other national and international partners involved in related activities to expand capacity and avoid duplication:
 - International: Global Fund, World Bank, International Federation of the Red Cross/Red Crescent, etc.
 - National: malaria prevention, patient safety, maternal and child health, etc;
- Encourage collaboration with partners on joint messaging regarding health promotion/social mobilization and youth: Ministries responsible for health, youth, sport etc.; Religious organizations; Peace Corps programs; social and service organizations (e.g. Lions, Rotary, Soroptimist, etc.);
- Support the expansion of blood collection and transfusion services beyond urban areas; and
- Encourage sustainability planning by costing a unit of blood, exploring cost recovery/cost sharing mechanisms, insurance programs etc.

1.3.2 EMERGING ISSUES: BLOOD SAFETY

- **Equitable access:** National blood services are faced with the challenge of providing equitable service to populations that are scattered between dense urban centers and remote rural areas. Delivery of service to remote areas requires maintenance of cold chain and transportation systems that may not routinely be available. This will require innovative strategies regarding power source, inventory management, and adaptation of technologies to enhance transportation capacity so that blood units are promptly made available consistent with their expiration period;
- **Expansion and retention of safe of donor populations** Expanding the donor pool beyond easily accessed populations, such as students, is more costly to blood services especially in regions with high HIV prevalence. In order to expand collections, blood services must gain an understanding of the donor populations through the assessment of the potential eligible donors after exclusions (e.g., related to age, weight, HIV prevalence, anemia, pregnancy, etc.) and geographic distribution. Blood services should prioritize the retention of safe blood donors and design programs to promote repeat blood donations, such that a majority of units are collected from repeat blood donors;
- **Appropriate clinical use:** Assuring appropriate use of blood involves both increasing access and reducing unnecessary transfusions. Assessments of country-specific blood utilization practices must take place. An important part of these assessments will be to determine actual blood consumption patterns by clinical indication and whether those patterns are changing over time. The assessments will also focus on whether blood utilization is consistent with best practice guidelines for appropriate transfusions, number of units ordered per transfusion, inventory management to minimize loss through expiration, and handling in terms of maintenance of the cold chain to the patient bedside. The assessments should also focus on the impact of blood use on key health indicators such as outcomes including maternal and pediatric mortality; and
- **Appropriate country specific collection target:** The WHO-recommended annual collection target is 10-20 units per 1000 population per year. WHO projects that this rate will allow countries to meet their most essential clinical demands for blood. The target number of units needed in any country is not static but is dependent on a variety of factors related to the general health care infrastructure and resources. The assessments should focus on quantifying the adequate blood collection targets on a country-specific basis.

1.3.3 LINKAGES AND WRAPAROUNDS: BLOOD SAFETY

It is important that blood safety programs be integrated with other HIV-related activities such as HTC, PMTCT, Care and Treatment, and MNCH.

Comprehensive blood systems encourage volunteer donation by low-risk populations. For example, blood donor education activities encourage healthy lifestyles, **especially among adolescents who make up a major proportion** of the blood-donor population in these countries. The participation of all who are eligible is crucial to availability of a sustainable blood supply, particularly for emergency situations, vs. relying on families or friends to locate suitable donors of the correct blood type at the time blood is needed or to replace the units. These represent community efforts and are beyond the scope and resources of the blood service alone. Therefore opportunities should be sought to combine or incorporate healthy lifestyle messages and the importance of blood donation in other social mobilization and health promotion messaging.

Pre-donation messages emphasize the importance of self exclusion. It is important for blood transfusion systems and HIV testing and counseling (HTC) programs to establish linkages to make appropriate referrals to HTC for individuals that actively want to know their status and for community testing and counseling programs (not programs aimed at MARPs) to encourage individuals who test negative to maintain a healthy life style and consider becoming regular donors. This is the basis of Club 25, where youth pledge to donate a certain number of units before age 25.

There is increasing recognition worldwide that pertinent medical information obtained during the donation process should be shared with the donor both for their health and to inform whether they need to be deferred from future donation. It is important that donors whose blood is found to be reactive on HIV testing be appropriately counseled and referred for confirmation and appropriate medical management, including Positive Health, Dignity, and Prevention programs where they exist. PEPFAR and WHO are working together to develop guidelines, protocols, and standard messages to be used in the context of counseling donors. It will be important for HIV counseling programs to work with the local blood systems to develop local implementation plans.

Training in appropriate use of blood products should include a focus on obstetric programs and malaria, in affected areas.

Consideration should also be given to assuring that patients that are prescribed a blood transfusion are able to obtain the necessary treatment, just as with essential medications. Often the blood service is responsible for the delivery of safe units of blood or components to the treatment facility but the patient may have to pay fees (e.g. to cover the cost of the bag the blood was collected in, the testing, transport etc.) and the infusion equipment or “giving set” (tubing and needle that connects the bag to the patient.) For example, some programs have provided vouchers to obstetric patients to use if blood is needed at time of delivery.

1.3.4 BACKGROUND: INJECTION SAFETY

Medical injections and related procedures such as phlebotomy are among the most common medical procedures and if performed correctly can save many lives. However, unnecessary and unsafe injection practices place both staff and patients at risk of infection with HIV and other blood-borne pathogens.

The main goals of injection safety programs are to prevent the transmission of HIV and other blood-borne pathogens by reducing the number of unsafe and unnecessary injections.

Unsafe injections may result when:

- Injections are given with used syringes or needles that are not sterile;
- Poor injection technique is used, such as recapping used needles, or using contaminated multi-dose vials/diluents, or using inappropriate injection equipment; and
- Sharps are improperly discarded.

Unnecessary injections result when:

- An injection is given instead of a medically equivalent, accepted and available alternative; and
- An injection is given when not medically indicated.

The risk of spreading HIV and other blood-borne pathogens by unsafe and unnecessary injections can be reduced drastically by establishing and implementing national policies for rational and safe injection use. A comprehensive injection safety (IS) strategy includes:

- Capacity building and training health care workers (HCWs) in safe injection practice, including related infection prevention and control, handling healthcare waste, commodity-supply management and interpersonal communication;
- Strengthening injection safety commodities supply and management systems;
- Applying behavior change communication (BCC) strategies aimed at both the community and health care providers to encourage safe injection practices and reduce demand for medically unnecessary injections; and
- Improving health care waste management.

Eliminating unsafe practices that can transmit HIV from an infected health worker or patient to patients is fundamental to a strong and viable health system. In addition, protecting health workers from infection due to occupational injury, especially in the context of HIV-related services where blood drawing is an integral part of patient care and the risks of this transmission are highest, is critical to sustaining these services and to preserving human resources. Injection safety programs also have addressed the increases in medical waste associated with improving and expanding health care delivery. National or regional plans for safe, final disposal of all medical waste are crucial to protecting communities and will require exploring innovative, low-cost technologies that are easy to deliver and maintain even in remote areas. These coordinated efforts will ensure continued progress in providing safe medical injections while protecting health workers and communities in pursuit of PEPFAR targets and Millennium Development Goals (MDGs).

The Track 1.0 central agreements for Injection Safety have ended. It is expected that, at minimum, partners will continue appropriate injection safety and waste management practices within their existing programs.

- Incorporate and integrate injection safety principles, practices and commodities into all health care delivery both in terms of:
 - Programs, e.g., HIV/ AIDS care and treatment programs, HIV testing and counseling, PMTCT, laboratory, blood safety, voluntary medical male circumcision, whether delivered by USG or host country; and
 - Systems strengthening, e.g., procurement, supervisory and information systems, various in-service and pre-service trainings, financing schemes, etc.
- Focus on prioritizing:
 - Sharps procedures with highest risk of HIV transmission (e.g., phlebotomy, injections at high-prevalence sites); and
 - Evidence-based strategies (e.g., ensuring availability of sharps containers proximate to point of sharps use).
- Ensure activities are consistent with national plans and policies regarding injection safety.

Training and capacity building

- Ensure that all health workers are trained in safe injection practices, including safe blood drawing, standard precautions, waste management and post-exposure prophylaxis for occupational exposure;
- Ensure that, at minimum, post-exposure prophylaxis (PEP) starter packs are available to all health care workers during their clinical duties, including those in remote areas;

- Ensure that training schools incorporate injection safety/universal precautions training into their existing curricula;
- Promote systems to review whether current injection practices comply with national treatment guidelines; and
- Promote a system to provide ongoing supervision, monitoring and evaluation.

Procurement and Supply Chain

- Consistent with local guidelines, ensure that availability of sufficient, appropriate, quality, single-use injection supplies is sustainable by host country; and
- Factor costs of sharps containers, single-dose vials/diluents and other waste management commodities into overall costs of commodities prior to procurement.

Behavior change and advocacy

- Encourage clear and consistent messaging to encourage safe injection practices and reduce demand for medically unnecessary injections in coordination with national strategy;
- Focus on evidence based-interventions for reducing unnecessary injections (e.g., essential medications, updated standard treatment guidelines); and
- Target injection safety messaging at the community, public and/or private health care sector.

Waste Management

- Emphasize the reduction of hazardous waste and the segregation of sharps waste and non-sharps waste at the source;
- Budget to manage the sharps waste that will be generated by the scale-up of HIV-related activities;
- Emphasize cost-effective and environmentally-friendly health care waste management technologies and systems Leverage medical waste cross-sectoral activities (especially the environmental sector);
- Encourage regional planning for appropriate medical waste management; and
- Ensure that activities are linked to national health care waste management strategies.

Note on waste management considerations for appropriate management of contaminated sharps and other medical wastes:

Scaling up of HIV/AIDS-related medical interventions, such as monitoring of CD4/CD8 counts and viral loads related to antiretroviral therapy (ART), HIV testing and counseling, voluntary medical male circumcision (VMMC), and prevention of mother-to-child transmission (PMTCT) is increasing the volume of medical waste and HIV-contaminated sharps generated in health care settings, creating a burden on already strained or inadequate waste management systems.

Countries should work with the Ministry of Health (MOH) and PEPFAR medical-injection-safety staff on strategies to foster effective waste management in the face of these challenges.

1.3.5 COUNTRY CONTEXTUAL CONSIDERATIONS: INJECTION SAFETY

Country teams should consider country-specific needs, other donor and local support for injection safety, as well as the local epidemiology of HIV. When resource constraints limit programs' reach, country teams should give priority to programs, training, safety equipment, etc. in those areas/facilities and programs or services where transmission risk is highest, and especially to AIDS care and treatment centers, PMTCT programs, services focusing on most at-risk populations, etc. To the extent feasible, injection safety principles and program components should be incorporated across the range of health programs.

1.3.6 LINKAGES AND WRAPAROUNDS: INJECTION SAFETY

As injections are given in multiple contexts, injection safety is a cross-cutting area, and linkages with other program areas are essential to success. PEPFAR programs need to focus on incorporating injection safety (including waste management) principles and practices into other programs and to ensure that such principles and practices are applied consistently, effectively and safely nationwide. Among the programs where injection safety needs to be applied are HIV care and treatment, PMTCT, voluntary medical male circumcision, testing and counseling, laboratory services and blood safety. While injections and blood drawing (and related waste management needs), as well as the need for PEP, are increasing with the expansion of PEPFAR programming, such needs also are high within other health services, and programs need to be coordinated and consistent. Therefore, implementing partners need to coordinate and share resources and materials wherever feasible. National policies, strategies and standard treatment guidelines need to be strengthened to ensure safe and necessary injections as well as related infection prevention and control activities and appropriate waste management not only within the range of PEPFAR and other HIV programs but also in general health services, malaria, TB, child survival, maternal and reproductive health programs, etc.

1.3.7 BACKGROUND: INJECTING AND NON-INJECTING DRUG USE

The use and abuse of illicit drugs can promote behaviors that elevate the risk for HIV infection. There is a spectrum of drug use ranging from single use sampling to uncontrolled heavy use. The drug(s) being used/abused, their quantity and pattern as well route of administration are important in determining drug use that promotes high risk behaviors for HIV infection.

For persons who inject drugs (PWID), the total PWID population worldwide is estimated to be 13.2 million.³⁸ Persons who inject drugs are at risk for hepatitis virus, HIV, STIs, and TB infections. UNAIDS, WHO, and UNODC estimate that between 5-10% (2-4 million cases) of all HIV infections globally are attributable to injection drug use.³⁹

Persons who use drugs, particularly PWIDs, are at high risk for acquiring and transmitting HIV. Sharing of contaminated drug injection equipment such as needles and syringes creates risk for acquiring and transmitting HIV. PWIDs and PWUDs can also transmit the virus through high-risk sexual behaviors

³⁸ Aceijas, C., et al. (2004). Global overview of injecting drug use and HIV infection among injecting drug users. *AIDS*, 18: 2295-2303.

³⁹ UNODC. (2005). *World Drug Report 2005*. Geneva, Switzerland.

(e.g., not using a condom). As described in the authorization language for PEPFAR, countries are asked to include HIV/AIDS prevention activities that focus on public health principles of risk elimination and risk reduction to “help avoid substance use and intravenous drug use, needle use and sexual practices that can lead to HIV infection.” A consensus public health principle to reduce drug use-related risk is that effective evidence-based drug treatment is HIV prevention. PEPFAR policy is based on this principle, and supports the use of medication assisted therapy (methadone, buprenorphine, etc.) for treating opioid addiction and providing HIV treatment and care services for all drug users. PEPFAR guidance on comprehensive HIV prevention for PWID can be found at:

<http://www.pepfar.gov/documents/organization/144970.pdf>

The following information can help guide programs in the development of services for people who use injecting and people who use drugs:

A. Specific PEPFAR language on persons who use or inject drugs

PEPFAR reauthorization states countries should “make the reduction of HIV/AIDS behavioral risks the priority of all prevention efforts by....promoting voluntary HIV testing and counseling, addiction therapy and other prevention and treatment tools for persons who inject drugs and other substance users”. Also, in line with PEPFAR Generation II indicators, PEPFAR supported countries will include “a description of - (I) the specific strategies funded to ensure the reduction of HIV infection among persons who inject drugs; (II) the number of persons who inject drugs, by country, reached by such strategies; and (III) medication-assisted treatment for individuals with HIV or at risk of HIV.

B. Comprehensive package of services for people who inject drugs

Scientific evidence supports a comprehensive package of structural, biomedical and behavioral interventions as the optimal HIV prevention strategy for reducing HIV incident infections among people who use injecting drugs.^{40,41,42} The *WHO, UNODC, UNAIDS Technical Guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users*⁴³ has been endorsed by the U.S. Government as the framework for developing a comprehensive package of core public health interventions and as a guiding resource for setting targets and identifying key indicators to monitor the availability, coverage, quality and impact on HIV prevalence of the comprehensive prevention package.⁴⁴ There is strong evidence that these interventions, implemented in a variety of settings (including a range of closed settings)⁴⁵, are effective in reducing risk behaviors, preventing HIV infections, and accessing essential care and treatment services for people who inject drugs.⁴⁶ PEPFAR country teams should reinforce this broad scientific and political endorsement as they seek to work with partner country governments to develop or strengthen national programs for PWID. The core interventions, as outlined in the *Technical Guide*, should include a combination of the following interventions and strategies:

⁴⁰ Institute of Medicine. (2007). *Preventing HIV Infection among Injecting Drug Users in High Risk Countries: An Assessment of the Evidence*. Washington, DC: National Academies Press.

⁴¹ Piot, P., Bartos, M., Larson, H., Zewdie, D., & Mane, P. (2008). Coming to terms with complexity: a call to action for HIV prevention. *The Lancet*, 372(9641), 845-859.

⁴² World Health Organization, United Nations Office on Drugs and Crime, United Nations Programme on HIV/AIDS. (2009). *WHO, UNODC, UNAIDS technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users*. Geneva: WHO/UNAIDS/UNODC.

⁴³ Available at: <http://www.who.int/hiv/pub/idu/targetsetting/en/index.html>.

⁴⁴ IBID

⁴⁵ UNODC/WHO/UNAIDS Publication, *HIV and AIDS in Places of Detention: a toolkit for policymakers, program managers, prison officers and health care providers in prison settings*, 2008.

⁴⁶ Jürgens, R., Ball, A., & Verster, A. (2009). Interventions to reduce HIV transmission related to injecting drug use in prison. *The Lancet Infectious Diseases*, 9(1), 57-66.

1. Community and peer-based outreach;⁴⁷
2. Needle and syringe programs (NSP);
3. Medication assisted treatment (MAT) and other drug dependence treatment or therapy;
4. HIV testing and counseling (HTC);
5. ART for people who use drugs living with HIV;
6. Prevention and treatment of sexually transmitted infections (STIs);
7. Condom and condom-compatible lubricant programs for people who use drugs and their sexual partners;
8. Targeted information, education and communication (IEC) for people who use drugs and their sexual partners;
9. Vaccination, diagnosis and treatment of viral hepatitis⁴⁸; and
10. Prevention, diagnosis and treatment of tuberculosis.

In addition to providing a comprehensive package of services, PEPFAR country teams should build the capacity of host partnership countries to implement these core prevention interventions. Teams are also encouraged to consider support and wraparound linkages to other related host country services such as economic development, reproductive health/family planning service for females who use drugs or meaningful economic rehabilitation services as appropriate. Drug rehabilitation programs could be included in HIV prevention activities.

C. Enabling environment

Many people who use drugs are not currently in, or cannot sustain, long-term addiction treatment programs because of multiple factors, including the limited availability of these programs. Barriers to MAT or other drug dependence treatment include legislation or strict regulation prohibiting prescription of methadone and/or buprenorphine; restrictive inclusion criteria (e.g., failed previous detoxification efforts); limited governmental support for these programs; limited funding; limited capacity within countries to provide services; stigma and discrimination; and ideological views on drug use, particularly among law enforcement practitioners. An enabling environment supported by legislation, policies, regulations and strategies facilitates implementation of a comprehensive HIV prevention package for PWID.

Coverage rates of core interventions are low in many PEPFAR countries in part because current environments are not enabling and gender sensitive. In this context they are not supportive for the introduction and scaling up of MAT, NSP, and other core HIV prevention interventions for PWID. More specifically, reasons for the low coverage rates of and limited access to HIV prevention interventions include: unsupportive national policy; lack of adequate funding; restrictive criteria for eligibility; stigma and discrimination; law enforcement harassment; cost of services to user; poor geographic distribution of services; limited hours of operation; and limited technical capacity.

To optimize the effectiveness of interventions to reduce HIV infections and create an enabling environment, PEPFAR programs in countries should be based on principles related to equity, nondiscrimination, voluntariness, and seek to reach all drug users with services regardless of current injection status. Country leadership, including engagement by multiple sectors of government and collaboration with both civil society and affected populations, is needed to develop and implement, at all levels, the necessary supportive legislation, policies and regulations that facilitate the introduction and scale-up of services.

⁴⁷ WHO does not include community-based outreach as a separate intervention in the comprehensive package; however it is recommended as an extraordinarily effective method of overcoming challenges related to accessing populations of PWIDs.

⁴⁸ To date, there has been only limited programmatic attention to screening, diagnosis and treatment for viral hepatitis in host countries with USG PEPFAR support.

D. Assessment of drug and alcohol use

A crucial first step in addressing HIV risk behaviors in persons who use is the initial outreach to and screening of the persons for drug and alcohol use/abuse and subsequent clinical diagnosis, based on presenting signs, symptoms and reported risk behaviors. Screening can be done in the context of outreach and risk reduction education for people who use or inject drugs, to identify the drug(s) in use and sexual risk behavior and devise an effective evidence-based approach. Identifying low-resource solutions that are comprehensive in addressing HIV prevention as well as drug/alcohol use and abuse provides an effective platform to engage high risk individuals in HIV prevention, care and treatment services.

E. PWUD and HIV

For people who use non-injection drugs recent studies indicate that stimulant drug users (e.g., cocaine and methamphetamine users) may also be at high risk for acquiring HIV.^{49,50,51} Furthermore, no pharmacotherapy has been found to be consistently effective in treating stimulant dependence. Long term psychotherapy remains an effective intervention for reducing sexual risk for HIV infection in stimulant users. For PWUD, a similar comprehensive package of HIV prevention services are needed to impact HIV prevention, care, and treatment in this most-at-risk population and include interventions 3-9 listed above for PWID.

As PEPFAR continues its support of country programs, the following represent technical considerations for USG country team in planning for FY2012. These technical considerations emphasize a strategic response to HIV prevention in the context of injection and non-injection drug use.

F. Measuring the drug/alcohol use/abuse epidemic and setting data-driven priorities for program development

Many countries lack data or under-utilize existing data on people who use drugs. In particular, countries with evidence of emerging epidemics of HIV among drug users lack the data needed to characterize drug-using populations and determine the magnitude of the problem. In sub-Saharan Africa, data are still limited, despite recent increases in drug trafficking and transport in the region and evidence of HIV among drug users (Aceijas 2004, UNODC 2006). While some countries have carried out limited assessments in selected geographic areas, few have approached this more broadly to address the need to define their national drug and alcohol use/abuse epidemic in the context of HIV/AIDS. For further guidance on alcohol use and abuse, please see the Technical Considerations for Most-at-Risk Populations.

Both qualitative and quantitative data are important. Because people who use drugs can be hard to reach, qualitative methods are an important source of information and are particularly relevant to the development of interventions. Qualitative methods can be employed to understand the social and behavioral dynamics of HIV transmission and as formative work to design interventions, as assessments to respond to program problems, and as sentinel systems to monitor emerging trends.

⁴⁹ Shoptaw S & Reback CJ. (2007). Methamphetamine use and infectious disease-related behaviors in men who have sex with men: implications for interventions. *Addiction*; 1: 130-5.

⁵⁰ Des Jarlais, D.C., & Semaan, S. (2007). HIV and other sexually transmitted infections in persons who inject drugs and crack cocaine smokers. In K. Holmes, P.F. Sparling, P.A. Mardh, S.M. Lemon, W.E. Stamm, & J.N. Wasserheit (Eds.), *Sexually Transmitted Diseases*. New York: McGraw Hill.

⁵¹ Edlin BR, Irwin KL, Faruque S, McCoy CB, Word C, Serrano Y, Inciardi JA, Bowser BP, Schilling RF, Holmberg SD. (1994). [Intersecting epidemics--crack cocaine use and HIV infection among inner-city young adults. Multicenter Crack Cocaine and HIV Infection Study Team.](#) *N Engl J Med.* Nov 24; 331(21):1422-7.

Although qualitative and quantitative research and epidemiologic data are necessary to better characterize people who use drugs and inform prevention programming, too often data collection is not used for program design and implementation. A stronger link between epidemiologic, behavioral and socio-cultural data and prevention activities is needed to ensure the results of studies become the basis for prioritizing and implementing prevention programs. Population-based surveillance and size estimate approaches including mixed method design are a way of accessing support and learning about how to make the linkage between data and programs stronger.

Data collection should be conducted within the context of a strategic framework that strengthens analysis and reporting at the national, sub-national, and organizational levels; develops human and organizational capacity and national program management; and supports prevention programming and program implementation.

For FY12, countries should support partnership country governments and/or NGO partners to:

- Characterize people who use injecting and non-injecting drugs (both HIV–infected and non-infected) based on population-based surveillance, quantitative, and qualitative research utilizing standardized, culturally-appropriate drug use screening instruments, such as the ASSIST screen and/or the Addiction Severity Index (ASI) for comprehensive assessments⁵²;
- Demonstrate and strengthen the links between strategic information (SI) and prevention to develop data-driven programs;
- Identify research, including size estimation, mapping, and formative assessments, needed to fill gaps in understanding of people who use drugs; and
- Identify technical assistance needs from headquarters in developing operational plans for conducting mapping, size estimation, and formative assessments.

G. Creating an enabling environment at the national, regional and local level

Drug-using populations often engage in behaviors that are criminalized and stigmatized, creating barriers to accessing HIV prevention, care and treatment services. Countries need to be aware of the potential for political backlash and work closely with government, civil society, and the affected population to facilitate an enabling environment for humane, ethical treatment of drug-using populations. These activities include encouraging a national response supported by Ministries of Health, other relevant ministries and agencies, National AIDS Control Programs, and civil society stakeholders to address the complex issues of providing prevention services to these populations. The national framework should be consistent with normative international guidance for priority prevention program activities, including comprehensive evidence-based substance use treatment programs as advocated by World Health Organization, UNAIDS, United Nations Office on Drugs and Crime, and other international organizations. Countries should take steps to ensure that scale-up of prevention programs for drug-using populations is accompanied by appropriate ethical and human rights protections and include the review of policies and regulations that criminalize or deter MARPs seeking services and training for service providers to reduce stigma and discrimination.

For FY12, countries should support partnership country governments and/or NGO partners to:

- Address policies that serve as barriers (criminalization for seeking health-care, policy to not initiate ART until patient has stopped using drugs, etc.) or facilitators (use of case managers for service coordination, promotion of drug treatment over criminalization, etc.) to drug-using populations accessing HIV-related services;

⁵² <http://www.nida.nih.gov/nidamed/screening/nmassist.pdf>

- Provide trainings for service providers working with drug-using populations to reduce stigma and discrimination and ensure ethical treatment of drug users;
- Assess the legal framework for health care service provision to people who use drugs including law enforcement directives and policies for working with known drug-using populations (e.g., what laws are relevant to starting a program for people who use injecting or non-injecting drugs; are there “safe zones” for PWID; etc?); and Support advocacy and policy work needed to protect the rights of people who use drugs and to implement prevention programs.

H. Developing capacity within countries

Many countries lack the capacity and resources to provide effective programming for drug-using populations. Prevention staff should ensure that coordinated technical assistance, both from headquarters and south-to-south, will focus on developing the appropriate range of technical skills within countries to develop, implement, evaluate, and improve prevention programs for drug-using populations. This includes providing assistance to in-country partners to improve coordination across partners and to develop in-country expertise.

Additionally the development of case management services and peer counselors is critical for drug-using populations which may enter services at different venues, e.g. mobile outreach, public sector clinic or correctional facility. A case management cadre supported with peer counselors can help to ensure continuity of care and facilitate referral and uptake of appropriate services.

For FY12, countries should support partnership country governments and/or NGO partners to:

- Develop a strategic plan for providing technical assistance from both headquarters and south-to-south providers;
- Support and facilitate training for peer educators, service providers, stakeholders, and the government partners to support work with drug-using populations;
- Address policies and activities to support workforce development and retention and health system strengthening;
Build capacity of NGOs to plan, implement, monitor and evaluate high-quality HIV prevention programs for PWUD, and to advocate for continued funding for PWUD programs in the future; and
- Build capacity of NGOs to plan, implement, monitor and evaluate high-quality HIV prevention programs for PWUD, and to advocate for continued funding for PWUD programs in the future.

I. Supporting a package of HIV prevention services linked to care and treatment programs

There is substantial evidence for the effectiveness of a core set of interventions for drug-using populations to reduce their HIV risk behaviors. Programs should ensure participation of civil society including drug-using populations in the development, implementation, and monitoring of HIV prevention programs. Based on the epidemiologic profile for each country teams should scale-up, at minimum, the following core set of interventions adapted for specific drug-using populations. Interventions that are underlined are recommended by WHO/UNODC/UNAIDS as part of a comprehensive package of services for people who inject drugs as noted above. USG-supported interventions should be harmonized with the WHO/UNODC/UNAIDS list of comprehensive services as part of a country’s overall comprehensive strategy for HIV prevention among PWID populations.

J. Peer education and outreach/community-based outreach

Peer outreach relies on indigenous community members to reach hidden populations with HIV prevention information and referrals to important services. At-risk individuals are met at and

provided with services in a range of settings, including but not limited to streets, storefronts, mobile vans, and other places where people who use drugs often congregate. Community-based outreach is an effective strategy for reducing drug- and sex-related risk behaviors because it increases access to and uptake of HIV prevention information, HTC, important risk-reduction skills and materials (condoms, clean needles and syringes, etc.), and provision of opioid overdose prevention medication. In addition, community-based outreach successfully links people who use drugs to additional HIV prevention services such as MAT, HTC, and HIV care and treatment.^{53,54,55,56} Outreach messages should be based on input of drug-users and their partners and tailored to the individual and specific drug-using community.

K. Needle and syringe exchange programs (NSPs)

Studies have shown that NSPs result in marked decreases in drug-related risk behavior (e.g., sharing of injection equipment, unsafe injection practices and frequency of injections), by as much as 60%,⁵⁷ and decreases in HIV transmission, by as much as 33-42% in some settings.^{58,59} Consistent findings from evaluation studies of NSPs reveal that these programs increase the availability of sterile injection equipment, reduce the quantities of contaminated needles and other injection equipment in circulation, reduce the risk of new HIV infections, and result in referrals to other services, such as ART for those eligible and HTC.^{60,61,62,63} Additionally, findings from a range of studies indicate that NSPs *do not* increase the numbers of persons who begin to inject drugs or increase in the frequency of drug use.^{64,65} , are effective in reducing risk behaviors, preventing HIV infections, and accessing essential care and treatment services for people who inject drugs.⁶⁶

Effective NSPs include the distribution of injection equipment and/or the exchange of sterile syringes for previously-used syringes, and opportunities for safe disposal of injection equipment. Taking into account the diverse and local nature of epidemics, and recognizing that some governments may not be ready to adopt NSP either at national scale or at all, PEPFAR teams should support countries in their efforts to determine the number and types of NSP outlets and services necessary to have an impact on the HIV epidemic. To maximize the impact on the epidemic, programs should progress toward regularly reaching as many PWID as could benefit from these services. Effectiveness also depends on

⁵³ WHO, UNAIDS, UNODC. (2004) *Policy Brief: Reduction of HIV Transmission Through Outreach*

⁵⁴ Needle, R., et al. (2005). Effectiveness of Community-Based Outreach in Preventing HIV/AIDS Among Injecting Drug Users. *International Journal of Drug Policy*, 16S. S45-S57.

⁵⁵ Medley, A., et al. (2009). Effectiveness of peer education interventions for HIV prevention in developing countries: A systematic review and meta-analysis. *AIDS Education and Prevention*, 21, 181-206c.

⁵⁶ Institute of Medicine. (2007). *Preventing HIV Infection among Injecting Drug Users in High Risk Countries: An Assessment of the Evidence*. Washington, DC: National Academies Press.

⁵⁷ IBID

⁵⁸ Wodak, A., & Cooney, A. (2006). Do needle syringe programs reduce HIV infection among injecting drug users: a comprehensive review of the international evidence. *Substance Use and Misuse*, 41, 777-813.

⁵⁹ World Health Organization. (2004). *Evidence for action on effectiveness of needle syringe programmes in HIV prevention*. Geneva: WHO.

⁶⁰ Institute of Medicine. (2007). *Preventing HIV Infection among Injecting Drug Users in High Risk Countries: An Assessment of the Evidence*. Washington, DC: National Academies Press.

⁶¹ Wodak, A., & Cooney, A. (2006). Do needle syringe programs reduce HIV infection among injecting drug users: a comprehensive review of the international evidence. *Substance Use and Misuse*, 41, 777-813.

⁶² Normand, J., Vlahov, D., & Moses L. (1995). *Preventing HIV transmission: the role of sterile needles and bleach*. Washington, DC: National Academy Press.

⁶³ Farrell, M., et al. (2007). Effectiveness of drug dependence treatment in HIV prevention. *International Journal of Drug Policy*, 18, 271-280.

⁶⁴ Cox, G., et al. (2000). Syringe exchanges: A public health response to problem drug use. *Irish Medical Journal*, 93(5), 143-146.

⁶⁵ Gibson, D., et al. (2002). Two to sixfold decreased odds of HIV risk behavior associated with use of syringe exchange. *JAIDS*. 31(2), 237-242.

⁶⁶ Marmor, M., et al. (2000). Drug injection rates and needle-exchange use in New York City, 1991-1996. *Journal of Urban Health*, 77 (3), 359-368.

ensuring geographic distribution, and types and numbers of NSP outlets, relative to the size, location, and needs of the population of PWID. To have an impact on the epidemic there should be a range of outlets (fixed and mobile sites, secondary exchange, 24-hour service through pharmacies), operated by civil society and the government.

Another important component of NSP is collection and disposal of used injection equipment. Collection and disposal activities can be compromised due to lack of political support, experience of police harassment and inadequate planning for this effort, and poor attempts at collection and disposal can lead to community concerns about implementation of NSP. PEPFAR country teams should collaborate with multi-sectoral government partners and NGOs to develop innovative approaches for ensuring good collection and disposal procedures not always dependent on outreach workers.

Effective NSPs offer a range of wrap-around services, including but not limited to providing condoms, bleach, other injection equipment, risk reduction information, overdose prevention training, HBV and HCV prevention, screening and services, VCT, and linkages to additional services such as MAT and HIV care and treatment. This represents an effective multi-component program and progress towards implementing the full range of risk reduction strategies and tools to enable PWID to reduce their risk level for acquiring and transmitting HIV.

L. Medication assisted treatment and other drug dependence treatment programs

Drug use treatment programs are also effective in reducing HIV acquisition and transmission. Substance use treatment reduces the frequency of drug use which in turn reduces HIV risk behaviors.⁶⁷ Substance abuse treatment also improves adherence to disease treatment regimens.⁶⁸ Data on sex-related risk behavior change are limited, but suggest that MAT is associated with reductions in the number of sexual partners and exchanges of sex for money or drugs⁶⁹. Therefore, effective HIV sexual prevention program should be coupled to MAT to promote comprehensive HIV prevention for opioid dependent individuals.

Effective substance use treatment is evidence-based and provides, to the extent possible, a comprehensive program tailored to the needs of the patient. These programs include the following common elements:

- A patient/gender centered approach to care and treatment with readily available access to services;
- Individualized drug treatment programs based on a clinical assessment and diagnosis;
- An individualized treatment plan that provides both short and long term goals for the patient and their treatment outcomes and allow for an adequate time in treatment;
- A mix of programs (inpatient treatment and outpatient programs) and venues to permit patient-treatment matching;
- Drug use monitoring;
- Peer support programs including outreach to enhance treatment access and adherence and prevent recidivism;
- Integrated ancillary medical and social wrap-around services to address other health and social service needs such as housing, legal services, STI services, and tobacco addiction;

⁶⁷ Gowing, L., et al. (2008). Substitution treatment of injecting opioid users prevention of HIV infection. Cochrane Database of Systematic Reviews, Issue 2. Art No.: CD004145. DOI: 10.1002/14651858.CD004145.pub3; Institute of Medicine. (2006). Preventing HIV Infection among Injecting Drug Users in High Risk Countries: An Assessment of the Evidence. Washington, D.C.: The National Academies Press.

⁶⁸ IBID

⁶⁹ Farrell, M., Gowing, L., Marsden, J., Ling, W., & Ali, R. (2005). Effectiveness of drug dependence treatment in HIV prevention. *International Journal of Drug Policy*, 16S, S67-S75.

- Specialized treatment programs such as family and women-centered treatment programs and treatment programs during pregnancy; and
- Rehabilitative and relapse prevention service programs.

The program may include behavioral treatment services or medication assisted treatment (MAT) for opioid (e.g. heroin) dependence, or a combination of the two, and should also include case management and counseling services. MAT uses methadone, buprenorphine, buprenorphine/naloxone (suboxone)/naltrexone or other medications/therapies, as they become available, as an effective option for treatment of opioid dependence and preventing the transmission of HIV. MAT has been shown to be an effective treatment for opioid dependence, reducing risk behaviors related to injection drug use, preventing HIV transmission and improving adherence to ART for people who use opioids,⁷⁰ Long term treatment with MAT is associated with reduced HIV risk behaviors including reduced frequency of injecting and sharing of injection equipment, reductions in the number of sex partners, and the exchange of sex for drugs or money,⁷¹ but to date, availability of MAT in most PEPFAR countries is limited. For MAT to have an impact on the overall HIV epidemic, services need to reach, treat, and retain in treatment as many opioid users who seek services as possible.

Medication assisted treatment programs should be an access point for people who use opiates and should refer and link HIV-infected individuals to ARV treatment programs, females who use opiates to PMTCT and a range of other prevention services. PEPFAR funds can be used to support:

- Policy activities that encourage countries to remove barriers to medication assisted treatment;
- Integration of HIV prevention services into existing and future drug treatment programs;
- Establishment of medication assisted treatment programs for drug treatment for individuals with HIV or at risk of HIV; and
- Referral and linkages to other behavioral- or cognitive- therapy drug treatment programs, including support groups, 12 step programs, etc.

M. HIV testing and counseling (HTC)

Innovative and tailored models for delivering HIV testing to persons who use drugs, sex workers, and MSM are needed (i.e. mobile services, HTC in “drop-in” centers, etc). Special consideration needs to be given to different testing models including VCT, provider-initiated testing and counseling (PITC), and couples and partner testing. Use of non-venous blood draw rapid test kits with same day results paired with post-test counseling is recommended for PWID and PWUD.

N. Access to HIV care and treatment

A comprehensive multi-component HIV treatment program for HIV positive substance users should promote recovery through provision of confidential ART, palliative care, PMTCT (for pregnant drug-using women), STI and tuberculosis treatment, substance use treatment (including medication-assisted therapies) and transitional services between treatment facilities and the community. In communities with both HIV and drug use epidemics, co-location of comprehensive HIV and drug treatment services enhances uptake of services and retention in care.⁷² Persons who use drugs in drug treatment, with HIV respond as well to HIV-specific therapy as do other patient groups.⁷³ Special consideration needs to be taken with drug-using populations to minimize adverse drug reactions.

⁷⁰ Institute of Medicine. (2007). *Preventing HIV Infection among Injecting Drug Users in High Risk Countries: An Assessment of the Evidence*. Washington, DC: National Academies Press.

⁷¹ IBID

⁷² World Health Organization. (2006): *Treatment of injecting drug users with HIV/AIDS: promoting access and optimizing service delivery*. Geneva, Switzerland.

⁷³ Institute of Medicine. (2006). *Preventing HIV Infection among Injecting Drug Users in High Risk Countries: An Assessment of the Evidence*. Washington, D.C.: The National Academies Press.

Additionally, promising new evidence from interim analysis of HPTN 052 clinical trial has shown that early use of ART is a highly effective HIV transmission strategy in discordant couples, reducing the risk of sexual HIV transmission by 96%.⁷⁴

O. Sexually transmitted infections (STI) screening and treatment

Approaches to STI control for people who use drugs vary based on local STI prevalence; however, general principles call for defining a basic package of confidential services with well-defined treatment components, screening intervals, and standards for delivery. If possible sexual partners of people who use drugs should also be given preference.

P. Condom and condom-compatible lubricant promotion and distribution for people who use drugs and their partners

Programs need to ensure a consistent supply and availability of quality male and female condoms as well as condom-compatible lubricants to reduce sex-related HIV risk behavior. Evidence shows that drug-using populations increase condom use with targeted interventions.⁷⁵ Recent data has emerged reviewing the effectiveness and toxicities of various formulations of lubricants. In light of this information, PEPFAR still promotes the use of condom-compatible lubricants with the recognition that research is ongoing and more is needed to determine which formulation provides the best protective effect. At this time, water- and silicon-based lubricants may offer increased protection.

Q. Targeted information, education and communication for people who use drugs and their sexual partners/risk reduction counseling

Risk reduction counseling is an effective intervention for drug-using populations whether delivered through peer outreach or in clinic settings and should address both drug- and sexual-risk behaviors. Drug treatment counseling in a treatment setting needs to address HIV sexual risk reduction. Meta-analyses show that risk reduction counseling can have a positive impact on persons who inject drugs sexual risk behaviors,⁷⁶ however, the effect may decay over time,⁷⁷ indicating that these behaviors may need to be more intensively targeted and require booster sessions.

R. Vaccination, diagnosis and treatment of viral hepatitis

Countries should adopt a “comprehensive approach” to preventing blood-borne infections among people who inject drugs (see www.cdc.gov/idu) and integrate hepatitis A and B vaccination into PWID-targeted prevention programs, including NSP. Prevention programs targeting people who inject drugs should also offer hepatitis C virus (HCV) testing as part of the package of HIV prevention program services. Programs have demonstrated that offering HCV testing to people who inject drugs increases access to HIV testing.

Many people who inject drugs are infected with HBV or HCV, and also have other illnesses (such as HIV, alcohol abuse, diabetes, or tuberculosis) and behaviors and life styles that put them at risk for other diseases. Thus, the primary goal of HIV prevention programs for PWID should be access and retention in primary care where available. With careful monitoring by a health care team experienced in hepatitis, addiction, and other pertinent conditions, PWID can be provided the life skills to manage their health care needs and focus on a healthy lifestyle (alcohol and smoking reduction, etc) to

⁷⁴ Treating HIV-infected people with antiretrovirals protects partners from infection: Findings result from NIH-funded international study [press release]. Bethesda, MD: National Institute of Allergy and Infectious Diseases; May 12, 2011. (<http://www.niaid.nih.gov/news/newsreleases/2011/Pages/HPTN052.aspx>)

⁷⁵ Semaan, S., Des Jarlais, D. C., and Malow, R. (2006). Behavior Change and Health-Related Interventions for Heterosexual Risk Reduction among Drug Users. *Substance Abuse and Misuse*, 41, 1349-1378.

⁷⁶ Semaan, S., et al. (2002). A meta-analysis of the effect of HIV prevention interventions on the sex behaviors of drug users in the United States. *Journal of Acquired Immune Deficiency Syndrome*, 30, S73-S93.

⁷⁷ Copenhaver, M., et al. (2006). Behavioral HIV risk reduction among people who inject drugs: Meta-analytic evidence of efficacy. *Journal of Substance Abuse Treatment*, 31, 163-171.

enhance medical outcomes. Country teams should work within the parameters of the MOH guidelines for treatment of viral hepatitis, as treatment for hepatitis C, in particular, may not be feasible in low resource settings.

S. Prevention, diagnosis and treatment of TB

People who inject drugs have a high prevalence of latent TB infection while HIV-infected people who use injecting or non-injecting drugs (alcoholics, for example) are at high risk for co-infection with TB or reactivation of latent TB. In the context of HIV prevention services for people who use drugs, TB screening programs are critical to prevent TB disease, reduce the morbidity and mortality of TB disease, and prevent transmission of TB to others. TB screening for both latent TB infection (LBTI) and symptomatic TB (where there is a high suspicion of TB) is essential at HIV prevention service access points (for example, NSPs, MAT programs, prison/release programs). For those who test positive, referral and direct access to chemoprophylaxis and treatment with directly observed therapy (DOTs) is critical especially in areas of know XDR-TB.

Other components of a package of services for people who use drugs:

A. Referrals to voluntary medical male circumcision

Voluntary medical male circumcision (VMMC) is an effective intervention to prevent transmission of HIV to men through heterosexual contact, therefore for males who use drugs should be referred to MC services, where appropriate.

B. Linkages to other health, social, and legal services

People who use drugs need other health services including family planning, primary health care as well as psycho-social support and legal support. Job-skills training is another important component of a comprehensive package of services for people who use drugs.

C. Services in closed settings

Drug law enforcement remains the dominant response to illicit drug use. However, incarceration and/or involuntary detention does not stop drug use and may actually inhibit access to mechanisms that promote injection cessation by providing limited health care and drug treatment services, such as methadone treatment. Interventions that educate prison or treatment rehabilitation staff and promote health services to people who use drugs during incarceration/detention and at the prison/compulsory treatment release-community interface are critical to address HIV risk behaviors. Possible interventions include the use of outreach or case managers in the prison and treatment centers' release process, the initiation of MAT just prior to release from prison or the accessing HIV prevention and treatment services at the time of release.

For FY12 countries should support partnership country governments and/or NGO partners to:

- Promote the development and implementation of a package of HIV services for drug-using populations as well as linkages among HIV prevention, care and treatment programs and to other health and support services;
- Develop a clear national strategy for HIV prevention with drug-using populations based on epidemiologic data and work with partners to better integrate and harmonize their prevention efforts, foster clear and consistent messaging that is mutually reinforcing across different partners, share lessons learned, make referrals to one another, and avoid resource duplication; and
- Request technical assistance where needed in implementing comprehensive HIV services for people who use drugs.

D. Scaling-up for adequate coverage, intensity, quality and scale of prevention programs

Most countries lack a comprehensive strategy or plan for addressing the HIV prevention, care, and treatment needs of drug-using populations. While many countries have small-scale targeted activities or pilot programs, few countries have taken steps to scale-up successful models or expand coverage. Countries should support national scale up of quality, effective prevention programs for people who use drugs based on the list of essential interventions to ensure an adequate coverage, intensity, and scale to impact the HIV epidemic.

For FY12 countries should support partnership country governments and/or NGO partners to:

- Assess and determine what interventions or package of interventions needs to be taken to scale for people who use drugs;
- Develop a common set of indicators to monitor programs;
- Assess the size of the population for coverage; and
- Increase and measure the coverage, frequency, quality and intensity of prevention intervention delivery.

E. Establishing a quality assurance, monitoring, and evaluation mechanism

To ensure high-quality HIV prevention programs for drug-using populations, countries should develop a quality-assurance monitoring and evaluation plan.

For FY12 countries should support partnership country governments and/or NGO partners to:

- Develop a set of core competencies and minimum standards, as well as a system of oversight and supervision, to monitor, assure, and improve these programs;
- Describe and share quality program tools, curricula, and models from successfully implemented programs;
- Design strong monitoring plans and provide clarification on the meaning and importance of monitoring indicators;
- Develop more meaningful program-level indicators that assess the mix and quality of prevention approaches (e.g., intensity, scale, and coverage); and
- Support evaluation activities, if possible, to help determine positive behavioral, community and biological changes and outcomes.

1.3.8 COUNTRY CONTEXTUAL CONSIDERATIONS: INJECTING AND NON-INJECTING DRUG USE

Identifying and reaching people who use drugs is important in countries with concentrated epidemics and in countries where this population may act as a “bridge” population or subgroup within the general population engaging in risky behavior. Different packages of services and/or service delivery models may be needed depending on local context.

Services and service delivery models need to take into account the country’s cultural and social norms as it relates to drug-using populations. Understanding these norms can help inform approaches increasing the likelihood of effective implementation within the local context. This is important in the context of policies and laws which criminalize people who use drugs. Reaching drug-using populations in such an environment presents unique challenges.

1.3.9 PARTNER PERFORMANCE CONSIDERATIONS: INJECTING AND NON-INJECTING DRUG USE

Partner performance reviews are a recommended practice to strengthen country teams' appreciation of field level implementation. Conducting interagency site visits to prevention partners, both at the headquarters level and to observe field activities greatly enhance the country teams' understanding of the overall prevention portfolio and helps to foster a common vision and strategic approach among prevention country team members and partners.

Reviewing partners' performance should address management issues (e.g. do they have enough staff, do they rely on appropriate technical expertise), financial matters (is their spending on target), and programmatic questions (are they designing appropriate strategies that reflect technical consensus and state of the art knowledge?) that contribute to overall performance.

In reviewing performance of individual prevention partners, country teams should assess partner adherence to the package of services for people who use drugs as well as harmonization with *WHO/UNODC/UNAIDS technical guide for countries to set targets for universal HIV prevention, treatment and care for injecting drug users* (2009). According to these criteria, prevention activities should include: a clearly defined audience; clearly defined goals/objectives; sound behavioral and social science theory; a focus on activities designed to reduce specific risk behaviors; employment of instructionally sound teaching methods; and provision of opportunities to practice relevant risk reduction skills.

Country teams should also assess partners' target setting methodology, and how well they are meeting their targets, including an explanation of why they are not meeting targets, if applicable. Performance reviews should assess if partners are conducting program monitoring (routine tracking of priority information about their project, including its intended inputs and outputs) or evaluation activities (periodic, special or other non-routine but systematic collection of information about program activities, processes, outcomes or impact) to determine the merit or worth of their program and provide feedback for program improvement.

In addition, such reviews should assess whether partner efforts are harmonized and coordinated with the overall USG prevention portfolio, as well as with the government and other donors.

1.3.10 LINKAGES AND WRAPAROUNDS: INJECTING AND NON-INJECTING DRUG USE

Biomedical interventions for people who use drugs are based on a core component of interventions providing many opportunities for linkages and wraparounds. Biomedical interventions targeted towards this population comprise a package of services which include prevention of sexual transmission, HIV testing and counseling, STI screening and treatment, MC, family planning and reproductive health services. A comprehensive approach targeted towards drug-using populations includes linkages to HIV care and treatment, PMTCT, TB/HIV, OVC, and PwP services.

1.3.11 BACKGROUND: VOLUNTARY MEDICAL MALE CIRCUMCISION

Voluntary Medical Male Circumcision (VMMC) is the surgical removal of the foreskin from the penis under hygienic conditions. Three randomized control trials indicated at the time of their conclusion that medical adult VMMC reduces men's risk of HIV acquisition by at least 60%, a potential protective effect equivalent to a vaccine.^{78,79,80} Extended follow-up of participants at up to 5 years post-trial indicated that the protective effect increased to 68%.⁸¹ PEPFAR is now supporting voluntary medical male circumcision activities in 14 countries and continues to work side-by-side with host countries, WHO, and other partners in program planning and implementation. Modeling studies predict that the benefits of VMMC are likely to be large in populations with high HIV prevalence and low VMMC prevalence, with one HIV infection averted for every five to 15 VMMC performed^{4,5}. There are numerous countries and regions within sub-Saharan Africa that fit into this category. As uptake increases, so too does the direct and immediate protective effect for HIV-negative males. Furthermore, as HIV prevalence decreases among circumcised men there is an indirect protective effect against HIV for women, women's uncircumcised male sexual partners, and ultimately the whole population, though this may only be apparent in ten to twenty years. In addition, the risk for HPV and cervical cancer among female sexual partners of circumcised males. In addition to the breadth of coverage, the pace of service delivery is also important. Indirect protective effects for women and uncircumcised men increase in relation to the speed at which coverage is achieved. Thus, faster initial scale-up is more cost effective than slower, as the indirect effects accrued earlier equate to more infections averted at a lower cost per infection averted.

UNAIDS/WHO issued normative guidance in March 2007, stating that VMMC should be recognized as an additional important intervention to reduce the risk of male heterosexually acquired HIV infection and that MC should always be implemented as part of a comprehensive HIV prevention package (http://www.who.int/hiv/mediacentre/MCrecommendations_en.pdf). This package includes the provision of HIV testing and counseling services; treatment for sexually transmitted infections; the promotion of safer sex practices, such as abstinence from penetrative sex, reduction in the number of sex partners, and delay in the onset of sexual relations; and the provision of male and female condoms, and promotion of their correct and consistent use. In response to the normative guidance provided by WHO, PEPFAR under the direction of the VMMC Task Force, has become one of the major supporters of MC as a component of a comprehensive HIV prevention program in sub-Saharan Africa. PEPFAR looks to UNAIDS/WHO to set global norms and standards, provide policy and program guidance for the provision of safe and efficient MC services, and conduct high level advocacy.

While ultimate sustainability of VMMC for HIV prevention lies with the relatively easier circumcision of newborn males or lower volume of only performing procedures on newborn males or successive cohorts of adolescent males, the delay in protective effect until sexual debut necessitates a period of VMMC 'catch up' to circumcise older adolescent and adult males at risk now or who will be at risk in the near future. To this end, initial VMMC services should be targeted first to those deemed most at risk, i.e. an HIV-negative man in a sexual relationship with an HIV positive woman, men with multiple concurrent sexual partnerships, and men with reported high risk, especially in areas with low circumcision rates and high HIV prevalence. As targeted activities progress, services for all interested adolescent and adult

⁷⁸ Bailey R, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: A randomised controlled trial. *Lancet Infect Dis* 2007;369:643-56.

⁷⁹ Gray R, et al. Male circumcision for HIV prevention in men in Rakai, Uganda: A randomised trial. *Lancet Infect Dis* 2007;369:657-66.

⁸⁰ Auvert B, et al. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 Trial. *PLoS Med* 2005;2(11):e298. Epub 25 October 2005.

⁸¹ Kong X, et al "Longer-term effects of male circumcision on HIV incidence and risk behaviors during post-trial surveillance in Rakai, Uganda" *CROI* 2011; Abstract 2011

males in the population and male neonates may scale up as well. As a minor surgical procedure, VMMC must be provided in controlled settings by trained, competent medical personnel using proper equipment and supplies. As a public health intervention, VMMC should be provided to as many HIV-negative men who wish to have the surgery as quickly and safely as possible. Careful orchestration of expertise, commodities, and infrastructure is thus essential to program success.

Given the benefits of rapid scale-up, PEPFAR is transitioning assistance following a two-pronged approach that simultaneously 1) supports host country government capacity to provide and sustain VMMC service delivery *and* 2) immediately provides VMMC services to respond to demand. Immediate services could be provided by rapidly deployable and high-volume service delivery (“Rapid Roll-out Response”), as demonstrated by models using expatriate volunteers such as Operation Smile and Unite for Sight. The services could be provided as self-contained (in a tent or other temporary structure), time-limited, fully equipped, independently staffed, and fairly mobile. Other versions of this approach include those that are more reliant on local staffing and resources. For all rapid scale-up approaches, PEPFAR would work in coordination with host country governments to support a coherent plan with quantifiable goals. VMMC models for optimizing volume and efficiency (MOVE) are being developed by WHO and PEPFAR, based upon an initial promising pilot in Orange Farm, South Africa, funded by the French government. While supporting immediate, high volume catch up services, PEPFAR can also begin capacity building for sustainable services for successive cohorts of either newborns or adolescents. The scale up and expansion of voluntary medical male circumcision services is vitally important to HIV prevention. It continues to be a priority intervention under PEPFAR.

Modeling studies predict that the benefits of VMMC are likely to be large in populations with high prevalence of primarily heterosexually-driven HIV and low male circumcision, with one HIV infection averted for every five to 15 circumcisions resulting in a cumulative savings of 6.5 billion USD (with the circumcision of approximately 2.3 million men by 2025) under rapid scale-up scenarios.⁸² High VMMC coverage targets are important since the direct and immediate protective effects of VMMC for HIV-negative males accrue as uptake increases. As uptake increases, so too does the direct and immediate protective effect for HIV-negative males. Furthermore, as HIV prevalence decreases among circumcised men, there is a reduced risk of HIV infection (indirect protective effect) for women, for women’s uncircumcised male sexual partners, and eventually for the whole population, though this may only become apparent in several years and heavily depends on the scale of VMMC uptake. Along with the breadth of coverage, the pace of service delivery is also important. Indirect protective effects for women and uncircumcised men increase in relation to the speed at which coverage is achieved. In addition, VMMC reduces the risk for HPV infection and associated cervical cancer among female sexual partners of circumcised males.

Recognizing that male circumcision is not 100 percent protective, it is essential for countries that are supporting VMMC scale-up to emphasize the importance of continued risk reduction strategies through behavior change communications for clients undergoing VMMC, their partners, and the larger population receiving information/education about MC as well as ensuring condom availability and education.

Though existing health facilities may not be readily equipped to absorb a high demand for VMMC quickly, immediate services for men have been mobilized in some countries utilizing novel implementation approaches, such as mobile/outreach services, volunteer health care workers, and time-limited VMMC campaigns. Such novel approaches, and other country appropriate strategies, should be explored. More conventional service models that are integrated into government health facilities may also be adequate, as long as sufficient staff and space are dedicated to allow for full-time VMMC

⁸² UNAIDS/WHO/SACEMA Expert Group on Modeling the Impact and Cost of Male Circumcision for HIV Prevention (2009). "Male Circumcision for HIV Prevention in High HIV Prevalence Settings: What can mathematical modeling contribute to informed decision making? *PLoS Medicine*. 6(9):e1000109, September 2009

services. Regardless of service setting, VMMC must be provided in an environment that satisfies quality assurance standards for asepsis and be conducted by trained, competent medical personnel using proper equipment and supplies. It is critical to ensure that appropriate follow-up and treatment of any complications is available, which may be a particular concern in mobile/outreach settings.

Safe, quality high-volume VMMC clinical/surgical implementation models have been developed by WHO and PEPFAR⁸³, and PEPFAR programs are strongly encouraged to adopt as many of the recommended efficiencies in the MOVE document as possible, working in coordination with partner country governments.

Key considerations for development of voluntary medical male circumcision interventions include:

- Programs should prioritize implementation of adult male circumcision with the goal of achieving saturation (80%) as quickly as possible, and support implementation in two ‘prongs’. This first prong is a one-time, intensive intervention for adult males that is not intended to be sustained. The second prong is the implementation of neonatal and or adolescent circumcision programs to be completely integrated and sustained within maternal and child health systems. Though the prong targeting adult males may indirectly strengthen health systems through a variety of activities (e.g., quality assurance, M&E), its goal is not infrastructure refurbishment, capacity building, or sustainability. The goal of the first prong is to circumcise adult men who are currently at risk. The prong to circumcise neonates and adolescents should only proceed once the first prong is well underway and coverage levels are high;
- Interventions for male circumcision should include a minimum package of prevention services which include:
 - Pre-operative provider-initiated HIV testing and counseling routinely provided on-site for all men and, where possible, their female partners;
 - Active exclusion of symptomatic STIs and syndromic treatment when indicated;
 - Provision and promotion of correct and consistent use of condoms;
 - Post-operative wound care and abstinence instructions;
 - Age-appropriate counseling on risk reduction, including reducing number and concurrency of sexual partners, delaying/abstaining from sex, and provision and promotion of correct and consistent use of condoms and;
 - Active linkage to other HIV prevention, treatment, care, and support services as needed;
- Working in conjunction with partner country governments, PEPFAR programs should help establish annual national and PEPFAR-funded adult VMMC coverage targets that are sizable enough to appreciably reduce HIV incidence quickly. Any gaps between PEPFAR-funded and national VMMC targets should be addressed. Annual targets should be framed in the broader context of the country’s overall VMMC scale-up strategy;
- Programs supporting VMMC must include requirements for monitoring systems and reporting of VMMC indicators to allow for progress towards established targets can be tracked. Monitoring of VMMC includes the following: collection of service delivery data for frequent, timely dissemination, use MOH (or other) standardized forms/tools for service data collection, training of staff on use of the forms, and a description of how findings are shared with considered by implementation stakeholders;
- VMMC program effectiveness is achieved by calibrating demand (number of men seeking services) with supply (capacity of the system to deliver VMMC services) while targeting

⁸³ WHO, Considerations for Implementing Models for optimizing the volume and efficiency of Male Circumcision Services. 2010. http://www.malecircumcision.org/programs/documents/mc_MOVE_2010_web.pdf.

older adolescent and adult males. The lack of familiarity with VMMC among many high-risk, high HIV prevalence communities and general misinformation about the surgical procedure are major challenges to program implementation and success. Moreover, the sensitivity of HIV/AIDS as a topic and the personal nature of the surgery require that VMMC policymakers and program implementers address communities' beliefs, preferences and needs when implementing VMMC communication campaigns. To facilitate successful implementation, programs should develop and implement public information campaigns that clearly and simply describe the risks and benefits of VMMC and place it into the larger HIV prevention context. Further, addressing firmly held cultural beliefs and gender issues, and avoiding unintended consequences, such as greater risk taking by circumcised men and their partners, is required. Countries should have appropriate strategies, channels, techniques, and tools for mobilizing demand and addressing the myriad of challenges with VMMC communications. The PEPFAR VMMC Task Force is developing a media toolkit which countries will be able to adapt for their local conditions;

- Programs should design a VMMC advocacy strategy and define advocacy issues based on country context and evidence. Countries need to define and prioritize target audiences (supporters and detractors) for VMMC advocacy and understand the different concerns and needs of each audience, while being cognizant of any underlying or unspoken issues. Finally countries should address emerging concerns and manage expectations for all target audiences for VMMC, which is a continuous and iterative process;
- Programs should monitor communication activities (e.g., program implementation) to ensure efficiency. The following are activities to monitor communication: tracking the number of VMMC communication materials produced and diffused (e.g., communication guides and materials for community mobilizers), identify salient issues as new activities and products are planned, differentiate paid advertising from unpaid coverage, and explore the development of a media intensity index (i.e., a means of quantifying the volume of materials produced and disseminated);
- Programs should address appropriate and adequate training for professionals in providing surgical services and mechanisms for assuring initial and continued competency. Health care providers committed/designated to providing a higher volume of services should be prioritized;
- Only surgical methods and/or devices recommended by WHO should be used in service delivery programs;
- Mechanisms for quality assurance, quality standards and quality of care within the program, including plans for surgical complication management, must be in place. Countries are encouraged to follow the WHO Quality Assurance Guidance and Tools for facility self-assessment⁸⁴ and to engage with the Male Circumcision Technical Working Group to schedule and participate in routine External Quality Assurance assessments;
- Voluntary medical male circumcision services should include gender components that addresses male norms and behaviors, promotes safer sexual behaviors including denouncing sexual violence against women, and activities to monitor for increased gender-based violence/coercive sex experienced by women. Opportunities should be explored for ensuring effective counseling for VMMC clients so that their behavior does not put women at greater risk for HIV infection or gender-based violence, and for integrating or linking other male health services and programs that promote gender equitable norms with VMMC services. Both men and women need to be beneficiaries of campaigns and education programs to explain and emphasize partial protectiveness of VMMC and the indirect benefit to women;

⁸⁴ WHO. Male Circumcision Quality Assurance: A Guide to Enhancing the Quality the Safety and Quality of Services. 2008. http://www.who.int/hiv/pub/malecircumcision/who_hiv_mc_q_assurance.pdf

- Adequate commodities management systems for surgical procedures, STI drugs, and integrated HIV testing need to be identified prior to initiating services are refined throughout scale-up. These considerations must include resources and technical expertise in waste management and supply chain management;
- All VMMC services should prioritize active linkages to HIV care and treatment services for clients seeking male circumcision services and/or their female partners who are found to be HIV-infected. ART, when taken as prescribed, has significant care and prevention benefits.⁸⁵ ART can significantly inhibit HIV viral load and replication^{86,87} reduce the morbidity and mortality experienced by PLHIV⁸⁸, and reduce the risk of HIV transmission to sex partners⁸⁹. This may require that sites develop and implement novel mechanisms to facilitate and confirm successful linkage to care (e.g., escorting clients from the VMMC center to the ART center, or enabling staff to register clients for ART at the VMMC center). VMMC represents a rare and valuable opportunity to provide HTC to men and link them to care;
- VMMC programs provide a rare opportunity to reach men in the healthcare setting who might not otherwise be accessible. Hence, VMMC must capitalize on the opportunity and work hard to incorporate HIV testing and counseling into VMMC service. Strong linkages with HIV testing and counseling programs (HTC) are critical. In areas where VMMC is being scaled up, VMMC should be recommended to all HIV negative males who receive HIV testing and counseling services in any HTC setting, especially HTC services for men at high risk of HIV acquisition from heterosexual sex (STI clinic clients). This should also be a key component of prevention packages for HIV negative men, and particular priority should be given to discordant couples where the man is HIV-negative. Moreover, adolescents (<16 years of age) should be offered HTC and programs should ensure counseling messages are age-appropriate;
- Implementers should adhere to WHO guidance on provider initiated HIV testing and counseling (PITC), including the minimum standards of pre-test information, informed consent, post-test counseling based on sero-status, maintaining confidentiality and use of point of care rapid HIV testing algorithms, as appropriate. Quality assurance systems for both HIV testing and HIV counseling components should be in place for ensuring high quality HTC services in these settings. Couples or partner HTC should be recommended and encouraged. Individuals and couples should be actively linked with appropriate HIV prevention, treatment, care and support services based on their test results following HTC or VMMC services. See HIV testing and counseling technical considerations for more information on HTC minimum standards and strategic planning;
- For HIV positive men, it is important to ensure that comprehensive post-test counseling includes information that circumcision is not recommended for HIV positive men due to potential increased complication rates following the surgical procedure for men with immunodeficiency (although circumcision should not be withheld if the client insists). Circumcision for HIV positive men should only be encouraged when medically indicated.

⁸⁵ WHO Treatment Guidelines, 2010.

⁸⁶ Crum NF, Riffenburgh RH, Wegner S, et al. (2006). Comparisons of causes of death and mortality rates among HIV-infected persons: analysis of the pre-, early, and late HAART (highly active antiretroviral therapy) eras. *J Acquir Immune Defic Syndr*, 41:194–200.

⁸⁷ Lima V, Harrigan R, Bangsberg D, Hogg R, Gross R, Yip B, et al. (2009). The combined effect of modern highly active antiretroviral therapy regimens and adherence on mortality over time. *JAIDS*, 50(5):529-36.

⁸⁸ Crum NF, Riffenburgh RH, Wegner S, et al. (2006). Comparisons of causes of death and mortality rates among HIV-infected persons: analysis of the pre-, early, and late HAART (highly active antiretroviral therapy) eras. *J Acquir Immune Defic Syndr*, 41:194–200.

⁸⁹ Quinn TC, Wawer MJ, Sewankambo N, et al. (2000). Viral load and heterosexual transmission of human immunodeficiency virus type 1. Rakai Project Study Group. *N Engl J Med.*, 342:921–929.

- At this time, due to high rates of surgical complications in non-clinical settings, US Government funds cannot be used to train or provide support for traditional providers to perform male circumcision. However, funding can be used to support prevention information, education and evaluations of complications stemming from non-medical circumcision within this context;
- To ensure voluntarism and informed consent, programs should not only provide appropriate informed consent for clients, but should also develop systems to monitor its delivery to guarantee client comprehension and to avoid practices perceived to be coercive;
- Depending on the need for overcoming barriers for VMMC uptake, countries may consider offering reimbursement for travel for clients. Reimbursement or compensation for wages that may be lost during surgical recovery should be used cautiously, to avoid the appearance of coercion. Other enablers should be adapted for the specific geographic and population context and must be monitored closely to avoid inappropriate or unethical practices;
- Clinicians who work overtime to provide VMMC services should be compensated for their time at a scale consistent with national standards. Furthermore, clinicians should not be compensated on a per-procedure basis, to avoid actual or perceived motivation for clinicians to coerce clients to undergo the procedure; and
- Peer mobilizers may be effective in increasing demand for VMMC. Programs that use peer mobilizers must develop systems to monitor their activities to assure the recruited clients are well-informed about VMMC and have not been pressured to attend the program. The TWG is currently developing monitoring tools to address this.

Additional resources can also be found at: www.malecircumcision.org. The Clearinghouse on Male Circumcision for HIV Prevention is a collaborative effort to generate and share information resources with the international public health community, civil society groups, health policy makers, and program managers.

TECHNICAL AREA 1.4: HIV TESTING AND COUNSELING

HIV testing and counseling (HTC) - the gateway to HIV prevention, care, and treatment services, knowledge of HIV serostatus is a critical pre-requisite for access to effective HIV interventions that reduce morbidity, mortality and HIV incidence. During the first 5 years of PEPFAR, all 15 focus countries, as well as many non-focus countries, successfully scaled-up HTC services. Between 2004 and 2009, over 86 million HTC sessions were provided with PEPFAR support. Despite the importance of HTC as an entry point to other HIV services, and the substantial growth of HTC programs in several PEPFAR countries, most people still do not know their HIV status. Those that do often are not successfully linked to services. Continued efforts are needed to ensure access and quality of HTC, along with successful referrals to needed interventions.

1.4.1 BACKGROUND

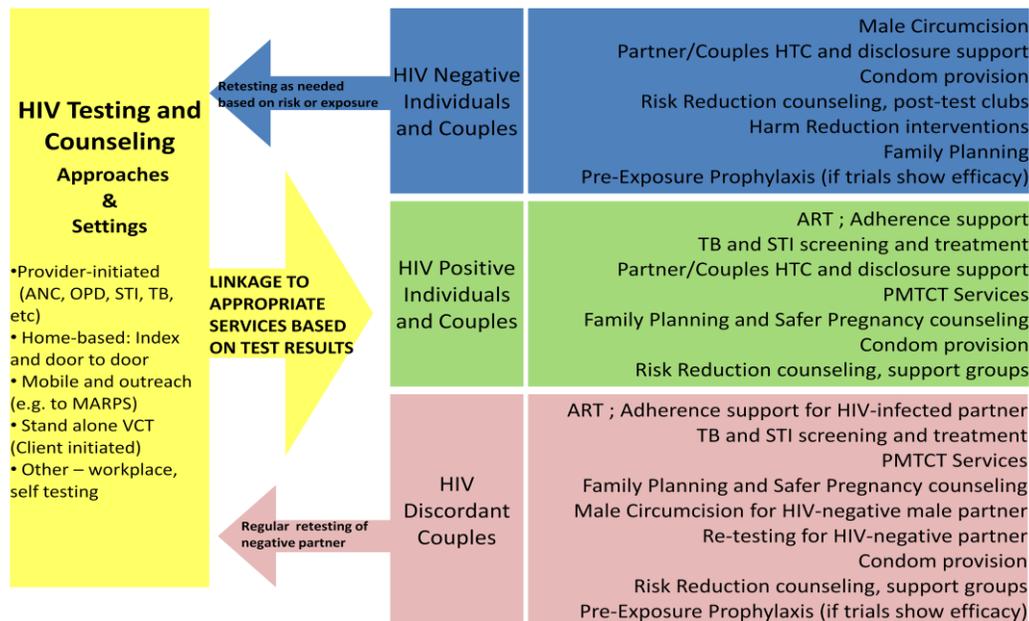
A. HTC is a Critical Gateway to Treatment, Care and Support, and Prevention

HIV testing and counseling (HTC) is an essential component of HIV programming as a **prerequisite** or **minimum standard** for antiretroviral treatment, pre-ART care and support, and biomedical prevention interventions including prevention of mother-to-child transmission (PMTCT) and voluntary medical male circumcision (VMMC). Couples HTC in particular will be a critical element of emerging interventions promoting the use of antiretroviral therapy (ART) as prevention in serodiscordant couples. HTC is a critical gateway to other core prevention interventions such as the minimum package of services for most at-risk populations (MARPs) and prevention interventions for persons living with HIV (PwP), and is strongly linked with behavioral HIV prevention interventions and foundational prevention interventions such as blood and injection safety. HTC will also be central in future prevention interventions currently under evaluation such as pre-exposure prophylaxis (PrEP).

The overarching goals of HTC programs are to:

- Provide services for individuals, couples/partners, and families to learn their HIV status – with particular emphasis on identifying HIV-infected individuals and HIV serodiscordant couples – and with appropriate pre-test information and post-test counseling based on serostatus to enhance the benefits of this services and reinforce linkages; and
- Implement strategies for ensuring that individuals, couples, and families are linked with appropriate follow up HIV treatment, care and support, and prevention services based on their serostatus (see Figure 1).

Figure 1: HTC is Gateway to Treatment, Care and Support, and Prevention Services



B. Knowledge of HIV Status Remains Low

The need to increase rates of HTC coverage and maintain high levels of uptake is underscored by continued low rates of testing, low knowledge of individual and partner serostatus (particularly among HIV-infected persons) and the need to achieve coverage goals of HIV treatment and prevention programs. Based on 2007-2009 estimates from 10 countries (all sub-Saharan African countries, except Dominican Republic), more than 60% of persons living with HIV (PLHIV) have not been tested and received their result, and global ART coverage for those in need was only 36% (WHO, 2010). Furthermore, two nationally representative studies from Uganda and Kenya suggests as many as 80-90% of PLHIV do not know their partner’s HIV status (Kaiser et al., 2011; Bunnell et al., 2008), and among women enrolled in care and treatment in Cameroon, this figure was also low at 46% of patients who knew their partner’s status (Loubiere et al., 2009). Programmatic HTC coverage remains low, with recent Demographic and Health Surveys from 13 sub-Saharan African and 5 non-African countries showing a median of 12% of women and 7% of men having been tested in the 12 months preceding the survey; and a median of 34% of women and 17% of men reporting having ever been tested (WHO, 2010).

HTC and knowledge of HIV serostatus are critical for access to effective prevention interventions and HIV-specific services. Strategic HTC scale-up must continue in order to increase access to treatment, care and support, and prevention services for PLHIV, and to reduce population-level HIV incidence through continued scale-up of PMTCT, VMMC, and treatment. Modeling on male circumcision has demonstrated that 80% coverage would be required to achieve a 45-67% reduction in HIV prevalence in Botswana and Nyanza, Kenya (Nagelkerke, 2007). Assuming efficient linkages from HTC to proven prevention interventions such as PMTCT, VMMC, and treatment, **80% population coverage will also likely be required for HTC** among high-burden populations to realize population level impacts. Importantly, the strength of **linkages between HTC points of diagnosis and other HIV services – both clinic-based and community-based – will fundamentally impact the effectiveness of any HTC programming.** Additionally, specific approaches to HTC may differ in reaching specific populations (e.g. HIV-infected, first-time testers, pregnant women, MARPs) (Sweat, 2011).

Furthermore, published evidence continues to suggest that **HTC is correlated with a positive impact on behavior change**, particularly among HIV-infected individuals and serodiscordant couples. Knowledge of HIV status among HIV-infected persons has consistently been associated with reduced HIV-transmission behaviors among individuals (Denison et al, 2008, Sherr et al., 2007; Voluntary HIV-1 Counseling & Testing Efficacy Study Group, 2000); and discordant couples (Dunkle et al., 2008; Bunnell et al., 2008). Continued scale up of quality HTC may reduce HIV risk behaviors among these populations.

C. HTC Approaches and Settings

The two primary **approaches** to HTC are:

- **Provider-initiated** HTC, occurring through a health care provider as a standard component of medical care; and
- **Client-initiated** HTC, occurring through active seeking of HTC by a client(s) in settings where these services are available.

There are multiple **settings** in which these approaches may be undertaken:

- **Clinical settings** that include antenatal clinic (ANC) settings, Outpatient Departments, TB clinics, STI services, VMMC settings, medical and surgical wards in hospitals, HIV care and treatment clinics, etc. (Provider-initiated); and
- **Non-clinical or community-based settings** that include:
 - Home-based HTC (Hybrid of the two approaches) via index patient or door-to-door HTC
 - Mobile or outreach HTC (Client-initiated) targeting specific communities or populations
 - Stand-alone Voluntary Counseling and Testing or VCT (Client-initiated)

Along with persons in the general population, HTC services should aim to reach the following specific populations: partners of persons living with HIV, pregnant women in ANC, TB and STI patients, HIV-exposed infants and children, sexually active adolescents, most at-risk populations (MARPs) including persons who inject drugs (PWID), men who have sex with men (MSM) and commercial sex workers (CSWs), and other setting-specific vulnerable populations, which may include uniformed/military personnel, migrant populations, truck drivers, and/or fishermen.

1.4.2 STRATEGIC PROGRAMMING FOR HTC

To ensure efficient and effective use of PEPFAR and host country funds, optimal HTC programming should ensure that:

- The mix of HTC approaches is strategically applied to communities and populations most likely to be affected by HIV;
- An emphasis is placed on strengthening linkages and referrals to appropriate follow-up services and ensuring initial enrollment in these services; and
- HTC services are implemented according to international and national minimum standards and guidelines.

A. *Know Your Epidemic, Know Your Response*

There are a number of factors that should be considered in determining the appropriate allocation of resources to HTC approaches, including: epidemic type (both nationally and regionally), populations at risk, existing coverage and utilization of HTC services, proximity to other follow-up services, cost-effectiveness and available resources. HTC programs should aim to maximize the identification of HIV-infected persons and serodiscordant couples; and regions and populations with higher HIV prevalence should be prioritized. However, it should be recognized that HTC functions as a critical gateway to services for both HIV-infected and uninfected individuals (see Fig. 1), and due consideration should be given to these populations in the context of other available HIV services.

Strategic programming of HTC services may require a technical review of epidemiologic data and existing HTC programs and services. Many countries are already familiar with these data and are using these to inform the strategic direction of their HTC programs. Some countries may need additional support to strategically align their HTC services with areas of particularly high HIV burden, and the following framework is meant to assist with decision making for strategic HTC planning:

I. Know Your Epidemic:

- **National HIV prevalence and prevalence for defined geographic areas and populations.** Countries should prioritize geographic areas and populations with the highest proportion of HIV infections.
- **HIV incidence for defined geographic areas and populations.** Where possible, countries should also utilize incidence data to determine where new cases of HIV transmission are occurring, and among what populations. HTC services should be strengthened in geographic areas and populations with high HIV incidence.
- **Demographic and behavioral characteristics of persons testing HIV positive.** Understanding the gender, age, and behavioral characteristics of persons testing HIV positive will help inform who to target for HTC and what HTC approaches should be implemented to reach those persons most at risk.
- **Clinical characteristics of persons testing HIV positive.** HTC programs should also look at HIV care and treatment data to help inform who is getting tested late in their stage of infection. This may include the proportion of persons diagnosed with AIDS at the time of their HIV test, or average CD4 count of persons enrolling in care and treatment. This can help identify where there are barriers for persons accessing HTC and other services, and where HTC approaches need to be strengthened to reach persons earlier in their state of infection.

II. Know Your Context:

Resources

- **Other donor/host country/NGO support for HTC services.** In order to reduce duplication and strategically leverage resources, strategic HTC programming should consider how HTC services are coordinated at the national and local level with input from appropriate stakeholders (host government, donor agencies, non-governmental organizations).

Policy and Legal Environment

- **Alignment and implementation of national HTC guidelines, policies and laws with international guidance.** Programs should consider how well national HTC guidelines, policies and laws are aligned with international recommendations and guidelines, and may

wish to work on addressing areas where gaps currently exist. Programs may also need to support adequate implementation and monitoring of guidelines at the national, regional, or site level.

Social and Cultural Environment

- **Ability of HTC programs to address social and cultural norms.** HTC programs may need to identify and address social and cultural norms (gender issues, multiple partnerships, vulnerabilities of MARPs, stigma, etc.) in order to provide high-quality strategic HTC programming.

III. Know Your Response

Programs and coverage

- **Proportion of people who have tested for HIV in the past year.** This key indicator can assist program planners in estimating uptake of HTC services in different geographic areas and among specific populations.
- **HTC approaches and settings that are successfully identifying high proportions of HIV-infected individuals.** HTC program data can be assessed to determine what HTC approaches (PITC vs. CITC) and settings (health facilities, mobile, home-based, etc.) are most effective in identifying HIV-infected individuals and serodiscordant couples and linking them to appropriate follow-up services.
- **Number of health facilities that offer PITC.** Implementation of PITC in health facilities will vary by epidemic type (see below). Determining where PITC is currently offered in health facilities according to WHO recommendations may help program planners target areas for strategic expansion of HTC efforts.
- **Number and location of all sites that offer HTC services.** Mapping HTC service delivery points (both health facility and community-based settings) may help HTC programs determine if current availability of HTC services corresponds with areas of greatest need (i.e. low proportion of persons testing, high HIV prevalence).
- **Availability of additional HIV treatment, care and support, and prevention services in relation to location of HTC services.** Assessing where additional services are currently available in relation to HTC may help identify barriers to, and strategies for addressing barriers to, successful linkage from HTC to appropriate follow-up services.

IV. Know Your Costs

In order to use donor and host country funds efficiently and effectively, it is increasingly important for countries to prioritize HTC approaches that not only aim to identify HIV-infected persons and discordant couples, but that are also the most cost-effective. In addition to the suggestions for prioritizing HTC services based on epidemic above, countries should collect, assess, and utilize data on the cost of different approaches to inform their decision making.

Cost-effectiveness may be defined differently depending on a program's goals. For example, a program that aims to reach 80% of the population with HTC services may consider a definition that includes "cost per person tested" or "cost per first-time HTC client/patient". A program that aims to reach higher numbers of HIV-infected individuals might define cost effectiveness as "cost per HIV-infected person identified", and a program that aims to reach more discordant couples might define this as "cost per couple tested", or "cost per discordant couples identified". Furthermore, a program that aims to strengthen linkages might include

this in their definition, for example, “cost per HIV-infected person successfully linked with HIV care and treatment services” or “cost per HIV-uninfected man successfully linked with male circumcision services”. Program planners will need to work with country stakeholders to determine how to define cost-effectiveness for their own program needs and goals, and then utilize these data to strategically redirect HTC efforts to be more cost-effective.

B. Strategic Prioritization of HTC Approaches

The following framework suggests prioritizing HTC approaches according to epidemic type and setting. All approaches will require substantial effort to ensure successful linkages from HTC sites to additional HIV treatment, care and support, and prevention services. Countries should consider these suggestions when planning to expand or restructure their HTC programs and in discussions with implementing partners.

Definitions of Epidemic Types

Generalized epidemics refer to countries where HIV is firmly established in the general population. Numerical proxy: HIV prevalence is consistently over 1% in pregnant women nationwide or in a national survey (WHO/UNAIDS). There are *several categories of generalized epidemics* which include the following:

- 1. Hyper-endemic:** HIV has spread to a level greater than 15% in the general population. Numerical proxy: HIV prevalence is consistently over 15% in pregnant women nationwide or in a national survey (WHO/UNAIDS).
- 2. Medium-level:** HIV has spread to a level of 5-15% in the general population. Numerical proxy: HIV prevalence is consistently between 5-15% in pregnant women nationwide or in a national survey (WHO/UNAIDS).
- 3. Mixed:** While there is not yet consensus on a definition for mixed epidemics, it is generally considered to be low-level generalized epidemics (with prevalence ranging from 1-5%), with high rates of transmission among MARPs (with prevalence above 5%). Numerical proxy: HIV prevalence is consistently over 1-5% in pregnant women nationwide or in a national survey and over 5% in one or more sub-populations (WHO/UNAIDS).

Concentrated epidemics refer to countries where HIV has spread rapidly in a defined sub-population, but is not well-established in the general population. Numerical proxy: HIV prevalence is consistently over 5% in at least one defined subpopulation but is below 1% in pregnant women in urban areas (WHO/UNAIDS).

I. Hyper-endemic and Medium-level Generalized Epidemics:

- Target populations for HTC: all patients in health-care settings, all partners of PLHIV, and all residents or members of communities in which estimated HIV prevalence exceeds 5%.
- HTC Approaches: The following HTC approaches should be prioritized in countries with generalized epidemics. Populations and defined areas should be prioritized based on where the greatest burden of HIV exists.
 - **Provider Initiated Testing and Counseling (PITC) for all patients accessing health care services and their partners.** Since the likelihood of exposure to HIV is so high in countries with generalized epidemics, HTC should be recommended for all patients and their partners attending health facilities as part of the normal standard of care, regardless of whether the patient shows signs or symptoms of underlying HIV infection or the patient’s reason for presenting to the health facility.

- **Home-based HIV Testing and Counseling (HB HTC) for *partners and families of PLHIV or TB (index patient model)*; and communities with high population density and *high HIV prevalence or low numbers of people tested (door-to-door model)*.** HB HTC has been found to be a highly acceptable approach in many sub-Saharan African countries. With the consent of the **index patient**, approaching their partner(s) and family members may have high yield for identifying HIV-infected individuals and discordant couples. A **door-to-door** approach may be most effective for reaching large numbers of people in areas with high population density. To achieve program goals, communities with high HIV prevalence or low numbers of people previously tested (or tested in the last year) should be targeted with the door-to-door approach.
- **Mobile and Outreach HTC for communities with *high HIV prevalence, low numbers of people tested, or that are hard-to-reach*.** Mobile and outreach HTC may be most effective for reaching hard-to-reach populations including MARPs, migrant populations, and men, who do not frequently access facility-based health services. To achieve program goals, mobile and outreach services should target geographic areas or populations with high HIV prevalence or low numbers of people previously tested (or tested in the last year).
- **Stand-alone and integrated Voluntary Counseling and Testing (VCT) for additional communities as needed to complement the approaches above.** Depending on the context, countries will need to determine whether stand-alone and/or integrated VCT sites are the best approach for increasing access to and utilization of HTC services and identifying HIV-infected persons. In many countries, coverage and uptake has been limited due to a range of issues including stigma and discrimination, limited access to treatment, care and health services in general, gender issues, and underestimation of personal HIV risk (Sahlu et al., 1999; Stein et al., 2000; Obermeyer et al., 2008; WHO, 2007).

II. *Mixed Generalized Epidemics:*

- **Target population for HTC:** all patients in health-care settings where HIV prevalence exceeds 1%, all partners of PLHIV, and all residents or members of communities in which estimated HIV prevalence exceeds 5%, including MARPs such as Sex Workers (SW), MSM, and Persons Who Inject Drugs (PWID).
- **HTC Approaches:** The following HTC approaches should be prioritized in countries with mixed epidemics. Populations and defined areas should be prioritized based on where the greatest burden of HIV exists.
 - **PITC for *all patients accessing health care services and their partners in health facilities in which HIV prevalence exceeds 1%, and specifically for patients with signs or symptoms suggesting HIV infection in settings with HIV prevalence less than or equal to 1%*.** Decisions about how to implement PITC in mixed generalized epidemics should be guided by an assessment of the epidemiological context. Similar to hyper-endemic and medium-level epidemic types, geographic areas with high HIV prevalence in mixed epidemics should recommend HTC to all patients and their partners accessing health care services, regardless of signs or symptoms. This includes health care facilities that provide services for MARPs, or that operate in high prevalence districts or geographic regions. However, in geographic areas or facilities with HIV prevalence less than or equal to 1%, HTC **may not** be recommended to for every patient, but rather should be recommended specifically to patients and their partners with signs or symptoms consistent with HIV infection.

Consideration should be given to TB, ANC, and STI patients, MARPs, and children known to be exposed to HIV perinatally.

- **Mobile and Outreach HTC for targeted sub-populations, including MARPs (SW, MSM, PWID).** Mobile and outreach HTC services may be effective for reaching MARPs and other vulnerable populations, such as men and migrant workers, who are less likely to access facility-based health services.
- **Home-based HIV Testing and Counseling (HB HTC) for *partners and families of PLHIV or TB (index patient model)*; a door-to-door model may be indicated for communities with *high population density and high (>5%) HIV prevalence*.**
- **VCT sites for additional communities or populations as needed to complement the approaches above.** Depending on the context, countries will need to determine whether stand-alone VCT sites are the best approach for increasing access to and utilization of HTC services among high-risk sub-populations. VCT sites may be appealing to MARPs and hard-to-reach populations in mixed epidemics, particularly if they specifically target these populations and provide MARP-friendly services.

III. Concentrated Epidemics:

- **Target population for HTC:** patients in *selected* health-care settings (noted below), all partners of PLHIV, and sub-populations in which estimated HIV prevalence exceeds 5%, including MARPs (SW, MSM, PWID).
- **HTC Approaches:** The following HTC approaches should be prioritized in countries with concentrated epidemics. Populations and defined areas should be prioritized based on where, and in what specific populations, the greatest burden of HIV exists.
 - **PITC among all adults, adolescents, and children who present to health facilities with signs and symptoms suggestive of underlying HIV infection, including TB, and children known to have been exposed perinatally to HIV.** Decisions about how to implement PITC in concentrated epidemics should be guided by an assessment of the epidemiological context. Unlike generalized epidemics, in concentrated epidemics health care providers **should not** recommend HTC to all persons attending all health facilities, since most people at the health facility will have a low risk of exposure to HIV. However, PITC may also be appropriate for all STI patients, MARPs, ANC and TB patients and their partners.
 - **Mobile and outreach HTC for targeted sub-populations including MARPs (i.e., SW, MSM, PWID).** Since many MARPs do not access health care services due to stigma and discrimination, mobile and outreach HTC approaches need to be equally prioritized to provide HTC in settings where MARPs feel comfortable. Examples may include drop-in centers, mobile unit, or organized testing event for MARPs. Appropriate settings for these services will vary by community and sub-population, and programs should work with local organizations and community representatives to determine where and when to offer mobile and outreach HTC services.
 - **Home-based HIV Testing and Counseling (HB HTC) using the index patient model or partner notification (contact tracing) services may be appropriate for *partners and families of PLHIV or TB*.**
 - **VCT sites for targeted sub-populations including MARPs (i.e. SW, MSM, PWID).** Depending on the context, countries will need to determine whether stand-alone VCT sites are the best approach for increasing access to and utilization of HTC services among MARPs. VCT may also be an effective approach for reaching MARPs through drop-in centers or fixed sites that provide MARP-friendly services.

1.4.3 STRENGTHENING LINKAGES FROM HTC TO OTHER SERVICES

HTC is a gateway to other essential HIV services (see Fig. 1), and is critical for achieving HIV treatment, care and support, and prevention goals. In order to maximize the benefits of HTC and strengthen the impact of HTC programs, renewed emphasis is needed on ensuring successful *linkage* of HTC clients and patients with appropriate follow-up services, based on their test results; that is, in all HTC approaches and settings, clients and patients should be connected to and enroll in these services. Studies have shown that many newly diagnosed patients either do not enroll (Micek et al., 2009) or do not stay enrolled in HIV care and treatment services after diagnosis; as few as 1/6 to 1/3 of persons diagnosed with HIV will initiate ART (Rosen et al., 2011). Therefore, ongoing HTC efforts must place greater priority on *early identification of HIV-infected individuals and serodiscordant partnerships, and linking these persons with appropriate HIV treatment, care and support, and prevention services*. Once individuals and discordant couples have been diagnosed, linking them with appropriate services is necessary to protect their health (Crum et al., 2006) and to reduce the risk of HIV transmission to uninfected partners (Donnell et al., 2010). Furthermore, strategies to ensure early enrollment and retention in care are important to maximize the health and prevention benefits for PLHIV.

There are a variety of client, provider, and structural challenges to ensuring linkage from HTC to other HIV services, and currently linkage and referral systems within HIV prevention, care, treatment, and support programs are generally weak. Although most HTC programs refer clients and patients to follow-up services as part of the minimum standards for HTC, very few provide specific services to facilitate linkage, and very few have monitoring and evaluation (M&E) systems that can track linkages. Identifying, implementing, monitoring and evaluating innovative strategies for linking HTC clients and patients into prevention, care, treatment, and support services is urgently needed.

A. Examples of Strategies to Strengthen Linkages

Although there is insufficient evidence about the effectiveness of various models to ensure linkages, some programs have established systems to address this challenging issue. Strategies may target the individual, the facility, and/or the community; examples of strategies that have been used to facilitate linkage and enrollment of HTC clients and patients into HIV treatment, care and support, and prevention services include:

- Integrating additional services at the HIV testing site, such as point-of-care CD4 testing and isoniazid or cotrimoxazole preventive therapy;
- Integrating or co-locating HTC services with other HIV treatment, care and support, and prevention services;
- Establishing partnerships between HTC sites and HIV treatment, care and support, and prevention sites (both clinic-based and community-based), with policies that define mutual roles, responsibilities, and procedures for escorting, introducing, and enrolling patients into care;
- Improving HTC provider understanding of and engagement with referral sites; various tools or approaches may be used to support providers in this, such as a comprehensive list of local referral services, visits to the referral sites, and/or establishing personal contacts at the referral sites;
- Providing additional counseling or social support services at the HTC site and/or within the community for clients and patients who may need ongoing support and encouragement before attending care and treatment services. Additional counseling might be provide by an expert client or PLHIV who might share their experience with HIV care and treatment, offer practical guidance, and help clients overcome real and perceived barriers to care;

- Providing transportation, child care assistance, nutritional support, or other incentives for providers, clients, or patients;
- Sending SMS reminders, making phone calls, or conducting home-visits (with informed consent) to clients or patients to follow-up on referrals that were given at the HTC site;
- Providing follow-up linkage services in which counselors or case managers are assigned responsibility for following up with clients, facilitating linkages by providing supportive counseling, escort, or transportation services, and documenting that these linkages were completed. Sites should also have supportive supervision systems in place to ensure that linkages are being reinforced by all providers as part of quality HTC service delivery;
- Training providers to create an enabling environment for all clients and patients within the HTC site, particularly for MARPs and other vulnerable populations who may be deterred from following through on referrals due to stigma and discrimination; and
- Establishment of M&E systems that track linkages (see below).

The above list is not exhaustive and should not be viewed as recommended interventions, but rather as illustrative examples that are either being implemented in some countries currently, or that countries may wish to pilot. These and other innovative linkage strategies warrant further exploration and evaluation to determine effectiveness, and successful linkage approaches should be documented and expanded.

B. Monitoring and Evaluating Linkages from HTC to Other Services

In order to assess the effectiveness of models for strengthening linkages, systems should be established for tracking these data. M&E systems should track linkages from the HTC site to other prevention, care, treatment and support services. This means that HTC registers or other data collection tools may need to be modified to capture not only the service that clients/patients were referred to, but also whether they enrolled into or established HIV treatment, care and support, or prevention services (clinic-based or community-based). Electronic client/patient databases (i.e. captured through provider-issued “smart cards”) may be able to more accurately track patients in various departments within a health facility or facilities, but paper-based systems should also be modified to include these indicators. At the program or national level, the following proxy indicator for linkage is included in the new WHO M&E Guide

(<http://www.who.int/hiv/pub/vct/9789241501347/en/index.html>):

of newly diagnosed HIV patients accessing HIV care and/or ART for the first time this year

persons testing HIV positive this year

Countries and programs should consider implementing this indicator and/or establishing systems for tracking the number of people who are referred to a service who actually make it to that referral point and receive services.

1.4.4 STANDARDS IN HIV TESTING AND COUNSELING

In all settings, HTC programs should adhere to the following minimum standards in order to ensure high-quality service provision that meets the needs of clients and patients and provides accurate test results. HTC should always adhere to national guidelines and follow the core WHO principles of *consent, confidentiality, counseling, and correct test results*. All HTC sessions should include *pre-test information, testing*, and appropriate *post-test counseling* based on client or patient's test results, risk, and needs.

To help countries and programs address key technical areas in HTC, the HTC TWG works closely with WHO to establish critical normative guidance in HTC. The following documents have recently been released by WHO and are available online for your reference:

- **Guide for monitoring and evaluating national HIV testing and counseling (HTC) programmes: field test version.**
<http://www.who.int/hiv/pub/vct/9789241501347/en/index.html>
- **Handbook for improving HIV testing and counseling services.**
<http://www.who.int/hiv/pub/vct/9789241500463/en/index.html>
- **Delivering HIV test results and messages for re-testing and counseling in adults.**
http://www.who.int/hiv/pub/vct/hiv_re_testing/en/index.html
- **Guidance on provider-initiated HIV testing and counseling in health facilities.**
<http://www.who.int/hiv/pub/vct/pitc/en/index.html>

A. Rapid HIV Testing

Simple, rapid, HIV test kits that utilize whole blood or oral fluid samples and do not require cold chain are essential to the expansion of HTC services. The use of *point-of-care HIV rapid tests* with *finger-prick sample collection* and an *appropriate algorithm* as a diagnostic tool should be considered in all HTC settings for ease of use, feasibility, and as an opportunity to provide *same-hour results*. This may also reduce loss-to-follow up for clients and patients that do not return for their results.

When selecting rapid test kits, countries should refer to the USAID HIV Rapid Test Kit Waiver list for the list of approved test kits:

http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html.

Persons conducting rapid HIV testing should be trained to deliver these services. CDC/WHO rapid testing training materials can be accessed online at the following link:
<http://wwwn.cdc.gov/dls/ila/hivtraining/>.

B. HTC Commodities and Supply Chain Management

HTC services cannot be provided without adequate supply of essential commodities. However, many countries continue to experience stock-outs or expiry of HIV rapid test kits and other HTC supplies. Efforts should be made to strengthen supply chain management systems to ensure accurate forecasting for the needs of RTKs and other supplies, timely and accurate reporting on test kit and supply usage, timely distribution of test kits to all HTC service delivery points, and appropriate storage of test kits at HTC sites and in central distribution warehouses. Documentation of breaks in

the supply chain or quantification of stock-outs or use of expired supplies (i.e. missed opportunities for providing HTC due to stock outs) may help advocate for improving these systems.

Furthermore, centralized procurement mechanisms, demand forecasting procedures, and coordination between supply-chain managers and program-service managers are needed to ensure continual availability of commodities necessary for HTC. Consideration of use of the Partnership for Supply Chain Management System (PSCMS) in support of these purposes is strongly encouraged.

C. *Re-testing*

Most people who test HIV-negative do not need to be re-tested, and providers may need additional training to change standard messages around the re-testing for the *window period*. Re-testing may be important for persons at continual risk of infection, such as MARPs, pregnant women, and the HIV-negative partner in a serodiscordant couple. Recommendations on re-testing are available in WHO guidance referenced above, and countries should make efforts to implement changes in post-test counseling messages to more accurately target re-testing messages and reduce unnecessary re-testing among low-risk HIV-negative persons.

D. *Task-shifting*

Lay counselors are utilized in many HTC settings to ease the burden on already overworked healthcare staff. Using rapid HIV test kits, and with appropriate training and supervision, lay counselors can provide quality HTC services and are an instrumental part of the healthcare workforce.

E. *Training and Supervision*

In most countries there have been sufficient numbers of HTC providers trained to deliver these services. However, additional training may be needed for in some settings (i.e. health facilities for PITC), to supplement initial HTC training with new approaches (i.e. couples or child HTC), or for supportive supervision and management and Quality Assurance.

Implementing partners should be encouraged not to replicate training curricula or develop new materials when generic materials may already exist. The HTC TWG has standard curricula available for: Couples HTC, PITC (draft), MARPs (draft), VCT and VCT Events (Campaigns).

F. *Partner and Couples HTC*

As noted above, in all countries and settings, regardless of epidemic type, **HTC should be offered to all partners of PLHIV**. This is because of the high risk of transmission from PLHIV to uninfected partners, and observed high rates of serodiscordant partnerships. Couples and partners HTC has been shown to increase uptake of ART among pregnant women (Farquhar et al., 2004), reduce HIV transmission, increase condom use, and reduce the frequency of sex acts with outside partners within serodiscordant couples (Allen et al., AIDS, 2003; Dunkle et al., 2008). Couples should be encouraged to test together when appropriate, and to receive their results together.

In **generalized epidemics**, it is strongly recommended that a partner- or couples-centered HTC approach be integrated into all HTC settings, as appropriate. Although it may also be useful to offer a couples-centered approach to HTC in countries with **concentrated epidemics** or with MARPs – particularly among men who have sex with men (MSM) – there is currently less substantial evidence for the benefits of couples HTC with these populations and additional research in this area may be needed. Furthermore, other strategies for reaching MARPs may warrant more attention to adequately identify HIV-infected individuals in these settings.

G. Linkages and Referrals

As previously discussed, *linkage* is a critical standard of HTC programs and increased effort should be made to ensure that clients and patients are successfully linked with appropriate follow-up services to have greater impact of HTC.

H. Quality Assurance (QA) and Quality Improvement (QI)

Ensuring the quality of HTC service delivery is essential for both testing and counseling processes. Ensuring the provision of correct test results with appropriate counseling and linkage with other services is critical for all HTC programs, and key *quality indicators* may be established to help countries and programs assess and improve the quality of their services over time. In some countries QA/QI working groups with representation from various agencies and technical areas have been formed to strengthen QA/QI efforts. National policies and guidelines may also set out QA and QI requirements or expectations, and the QA Handbook referenced above is also a useful resource. Examples of QA/QI approaches for HIV testing and HIV counseling are listed below:

QA for HIV rapid testing	QA for HIV counseling
<ul style="list-style-type: none">• Use of validated HIV test kits and appropriate HIV testing strategy and algorithm• Standard operating procedures for HIV testing• Ensuring all HTC providers have been adequately trained, including hands-on, practical training• Ongoing supportive supervision, including direct observation• Use of standardized, pre-printed laboratory logbook for recording HIV test kit results and lot numbers• Proficiency testing in coordination with National Reference Lab (External Quality Assurance)• Post-marketing surveillance of rapid test kits	<ul style="list-style-type: none">• Counseling supportive supervision, including weekly/monthly meetings on-site and quarterly meetings with other sites• Provider self-reflection tools• Client exit interviews• Observed practice by supportive supervisor

I. Waste Management

Standard Operating Procedures (SOPs) and guidelines for HTC should indicate proper waste disposal procedures, and all HTC settings and approaches should follow these SOPs. Sharps should be disposed of in designated sharps containers. Used test kits and other contaminated waste should be placed in separate closed containers and incinerated, or should be disposed of according to bio-safety guidelines. HTC providers and support staff involved in handling and disposing hazardous waste should be adequately trained on infection prevention procedures.

J. Monitoring and Evaluation

Monitoring and Evaluation (M&E) of HTC is an essential component of quality service delivery, and allows programs to follow trends in HTC outcomes, utilize program data for strategic planning, and report on key indicators at the national level and to PEPFAR. Data quality should be regularly assessed by supportive supervisors as part of QA/QI systems, and improvements should be made as needed. Key HTC indicators should be captured and reported in every setting where HTC occurs. The aforementioned WHO guidance on M&E for HTC programs is useful for establishing national level indicators for monitoring HTC programs over time, and is aligned with PEPFAR required and recommended indicators.

As M&E systems are strengthened, efforts should be made to also build capacity for program evaluation to complement program monitoring data. Program evaluation may provide a more rigorous assessment of specific HTC interventions or elements that are successful, or where modification needs to be made.

K. Integration with Other Health Services

Many HTC programs have incorporated screening for other health issues or the direct provision of other health services into HTC in order to increase the benefits of this service. With adequate support and training, HTC programs should consider integrating these services:

- TB screening, prevention, and referral services
- Family Planning
- Alcohol screening
- Screening for high-risk HIV-negative clients/patients
- STI screening
- Gender-based violence screening, prevention, and counseling

L. Community Mobilization and Promotion of HTC Services

Community mobilization and promotion of HTC are important for increasing awareness about the availability and benefits of HTC services, and are essential complimentary components of the recommended HTC strategies that countries should prioritize in order to reach 80% population coverage (Schwartlander et al, 2011). Countries and programs are encouraged to develop an HTC logo or signboard for all HTC sites so that these service delivery points can be clearly identified by clients and patients. Well-coordinated and thoughtful multi-media and professional advertising campaigns can increase demand for HTC and address key HTC programming messages. Educational materials such as posters and brochures may also be useful for providing additional information about HTC or follow-up services. Community and religious leaders can also be engaged in community mobilization to increase awareness, demand, and to help address social norms.

M. Condoms

All HTC clients and patients, particularly discordant couples, should have access to male (and female, where appropriate) condoms. All HTC service delivery points should have condoms available and should offer an initial adequate supply to HTC clients and patients as part of post-test counseling, and should refer clients/patients to a location where they may access condoms.

TECHNICAL AREA 1.5: PREVENTION WITH PEOPLE LIVING WITH HIV (PwP)

1.5.1 TECHNICAL CONSIDERATIONS: PwP

HIV prevention with people living with HIV (PLHIV) integrated into routine care is a core component of a comprehensive and integrated HIV prevention, care, and treatment strategy. The following considerations are consistent with guidelines issued by WHO⁹⁰ and CDC⁹¹ on prevention interventions for people living with HIV in both clinic and community settings. They also address the myriad health and prevention needs of HIV positive individuals outlined in the Positive Health, Dignity and Prevention (PHDP) framework⁹².

Prevention interventions with HIV positive persons include both behavioral and biomedical interventions aimed at reducing the morbidity and mortality experienced by HIV positive individuals and reducing the risk of transmission to HIV-negative partner(s) and infants. By focusing on partner and couples HIV testing and counseling, PwP interventions contribute to the identification of HIV positive individuals and serodiscordant couples and partnerships. Partners who are newly identified as HIV positive can then be linked into HIV prevention, care and treatment services. Identification of HIV discordant couples and partnerships represents an opportunity to prevent new infections to the negative spouse or partner(s) through provision of prevention services including routine re-testing and counseling of the HIV-negative partner. PwP interventions also contribute to preventing mother-to-child HIV transmission (PMTCT) through provision of family planning counseling and services to reduce unintended pregnancies among HIV-infected women, safer pregnancy counseling to reduce HIV transmission within HIV serodiscordant couples and to infants, and linkage of HIV positive pregnant women to PMTCT services. Finally, ongoing adherence counseling and support services maximizes the care and prevention benefits of anti-retroviral treatment by supporting optimal adherence among patients on treatment. PwP interventions may also help retain persons in care by addressing the multiple prevention needs of HIV positive individuals.

Evidence supports interventions with people living with HIV as an effective strategy for reducing sexual risk behavior^{93, 94, 95}, STI incidence^{96, 97}, and unintended pregnancies⁹⁸. These interventions can be

⁹⁰ World Health Organization (2008). Essential Prevention and Care Interventions for Adults and Adolescents Living with HIV in Resource-Limited Settings. Available at: <http://www.who.int/hiv/pub/guidelines/EP/en/index.html>. Last accessed: May 20, 2011.

⁹¹ Centers for Disease Control and Prevention (2003). Incorporating HIV Prevention into the Medical Care of Persons Living with HIV: Recommendations of CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. *MMWR*, 52(RR-12):1-24.

⁹² GNP+, ICW, Young Positives, EngenderHealth, IPPF, UNAIDS. 2009. Advancing the Sexual and Reproductive Health and Human Rights of People Living With HIV: A Guidance Package. Amsterdam, GNP+. Available at: http://data.unaids.org/pub/Manual/2009/20090730_srh_of_plhiv_guidance_package_en.pdf.

⁹³ Crepaz, N., Lyles, C.M., Wolitski, R.J., Passin, W.F., Rama, S.M., Herbst, J.H., Purcell, D.W., Malow, R.M., Stall, R. (2006). Do prevention interventions reduce HIV risk behaviours among people living with HIV? A meta-analytic review of controlled trials. *AIDS*, 20, 143-57.

⁹⁴ Kennedy C, Medley A, Sweat M, O'Reilly K. (2010). Behavioural interventions for HIV positive prevention in developing countries: a systematic review and meta-analysis. *Bull World Health Organ*, 88:615–623 doi:10.2471/BLT.09.068213.

⁹⁵ Johnson, B.T., Carey, M.P., Chaudoir, S.R., Reid, A.E. (2006). Sexual Risk Reduction for Persons Living with HIV Research Synthesis of Randomized Controlled Trials, 1993 to 2004. *JAIDS*, 41, 642-50.

⁹⁶ Saleh-Onoya D, Reddy P, Ruiter R, Sifunda S, Wingood G, van den Borne B. (2009). Condom use promotion among isiXhosa speaking women living with HIV in the Western Cape Province, South Africa: a pilot study. *AIDS Care*, 21(7):817-825.

effectively delivered by health care providers^{99, 100}, counselors/social workers¹⁰¹ and lay or peer counselors^{102, 103, 104} in both clinic and community settings. Models also suggest that prevention interventions with PLHIV are cost effective¹⁰⁵.

A. HIV Prevention Messages and Services Should Be Integrated into all Clinical Settings Providing Care to HIV-Infected Individuals

HIV prevention messages and services should be delivered as part of the routine care of HIV positive persons in HIV care and treatment settings. In addition, prevention interventions for people living with HIV/AIDS should be integrated into all clinical settings providing care or services to HIV seropositive persons, such as TB, STI, PMTCT clinics. HIV positive persons with TB have regular and extended contact with health care providers during their TB treatment which presents unique opportunities for consistent delivery of prevention interventions. STI treatment clinics, in settings where they exist as stand-alone services, are also important venues for identifying HIV positive individuals and discordant couples/partnerships and for delivering HIV prevention messages. Similarly, PMTCT programs are critically positioned to provide prevention messages and services (including partner testing) to large numbers of pregnant women and their sexual partner(s). ANC services should encourage both HIV positive and HIV-negative pregnant women to bring in their partner(s) for HIV testing and counseling.

B. HIV Prevention Messages and Services Should Also Be Integrated into Community Settings That Serve Individuals, Couples, and Families Living with HIV

Community programs that serve individuals, couples, and families living with HIV also offer opportunities for providing and reiterating prevention messages and are important venues for provision of services. These programs are especially important for targeting people living with HIV (PLHIV) who know their HIV status but are not yet eligible for anti-retroviral therapy (ART) as these patients may not be accessing regular care or services from clinic settings. PLHIV support groups

⁹⁷ Wingood, G.M., DiClemente, R.J., Mikhail, I., Lang, D.L., McCree, D.H., Davies, S.L., Hardin, J.W., Hook, E.W 3rd, Saag, M., A Randomized Controlled Trial to Reduce HIV Transmission Risk Behaviors and Sexually Transmitted Diseases Among Women Living With HIV: The WILLOW Program. *Journal of Acquired Immune Deficiency Syndrome*, 37:S58-S67.

⁹⁸ King, R., J. Estey, et al. (1995). A family planning intervention to reduce vertical transmission of HIV in Rwanda. *AIDS*, 9(Suppl 1):S45-51.

⁹⁹ Crepaz et al., 2006.

¹⁰⁰ Gardner, L. I., Marks, G., O'Daniels, C. M., Wilson, T. E., Golin, C., Wright, J., et al. (2008). Implementation and evaluation of a clinic-based behavioral intervention: Positive STEPS for patients with HIV. *AIDS Patient Care and STDs*, 22: 1-9.

¹⁰¹ Myers J, Shade S, Rose C, Koester K, Maiorana A, Malitz F, et al. (2010). Interventions delivered in clinical settings are effective in reducing risk of HIV transmission among people living with HIV: results from the Health Resources and Services Administration (HRSA)'s Special Projects of National Significance Initiative. *AIDS Behav*, 14:483-492.

¹⁰² Cornman DH, Kiene SM, Christie S, Fisher WA, Huper PA, Pillay S, et al. (2008). Clinic-based intervention reduces unprotected sexual behavior among HIV-infected patients in KwaZulu-Natal, South Africa: results of a pilot study, *JAIDS*, 48(5):553-60.

¹⁰³ Peltzer K, Tabane C, Matseke G, Simbayi. (2010). Lay counselor-based risk reduction intervention with HIV-positive diagnosed patients at public HIV counseling and testing sites in Mpumalanga, South Africa. *Evaluation and Program Planning* (epub).

¹⁰⁴ Torpey K, Kabaso M, Mutale L, Kamanga M, Mwango A, Simpungwe J, Suzuki C, Mukadi Y. (2008). Adherence support workers: a way to address human resource constraints in antiretroviral treatment programs in the public health settings in Zambia. *PlosOne*, 3(5):e2204.

¹⁰⁵ Marseille E, Shade S, Myers J, Morin S. (2011). The cost-effectiveness of HIV prevention interventions for HIV-infected patients seen in clinical settings. *JAIDS*, 56(3):e87-e94.

and prevention programs directly implemented by PLHIV are well positioned to address the special needs and issues of fellow PLHIV and their partners through sharing of experiences and identification of best practices for disclosure, sexual risk reduction, medication adherence, and other strategies for positive living such as proper nutrition. Other community-based forums for reinforcing prevention messages and services include community and home-based care and support interventions for PLHIV and their families. These can also be important avenues for providing HIV testing and counseling (HTC) services for spouses and child(ren) of PLHIV, along with community and mobile HTC programs.

C. Clinic and Community Programs Need to Offer Ongoing, Comprehensive HIV Prevention Interventions for PLHIV

All clinic- and community-based programs serving PLHIV should offer a comprehensive package of HIV prevention messages and services on an ongoing basis, including delivery of or referral to the following:

- **HIV Testing and Counseling of Sex Partners and Family Members.** Sex partners and children of HIV-infected persons are at high risk for HIV infection, yet studies show that many PLHIV do not know their partner(s)' HIV status¹⁰⁶. HIV testing identifies infected partners and family members in need of HIV care and treatment, and identifies HIV-negative partners who are unknowingly in a serodiscordant relationship and may benefit from additional prevention services. Providers should regularly ask PLHIV about whether they have disclosed to their partner(s) and if their partner has been tested. Counseling and support for partner/couples testing should be ongoing, rather than solely at intake, in order to accommodate for new sexual partnerships, and address the re-testing needs of HIV-negative partners. Where possible, PLHIV should be encouraged to receive couples' HTC together with their sexual partner(s), as this allows partners to learn their HIV status together and to make joint decisions about how to protect their health as individuals, as a couple, and as a family.
- **Interventions for HIV Discordant Couples.** Early identification of HIV discordant couples and partnerships through routine HIV testing programs, and linkage of the HIV-infected individual into prevention, care and treatment services, represents an opportunity to prevent transmission of new infections to the negative spouse or partner(s). Anti-retroviral treatment for the HIV positive partner is associated with both reduced viral load^{107, 108} and reduced risk of HIV transmission to sex partners within discordant partnerships^{109, 110, 111, 112}. ART along

¹⁰⁶ Kaiser R, Bunnell R, Hightower A, Kim AA, Cherutich P, Mwangi M, Oluoch T, Dadabhai S, Mureithi P, Mugo N, Mermin J; KAIS Study Group. (2011). Factors associated with HIV infection in married or cohabitating couples in Kenya: results from a nationally representative study. *PLoS One*. 2011 Mar 15;6(3):e17842.

¹⁰⁷ Coetzee D, Hildebrand K, Boule A, Maartens G, Louis F, Labatala V, et al. (2004). Outcomes after two years of providing antiretroviral treatment in Khayelitsha, South Africa. *AIDS*, 18(6):887-95.

¹⁰⁸ Crum NF, Riffenburgh RH, Wegner S, et al. (2006). Comparisons of causes of death and mortality rates among HIV-infected persons: analysis of the pre-, early, and late HAART (highly active antiretroviral therapy) eras. *J Acquir Immune Defic Syndr*, 41:194-200.

¹⁰⁹ Quinn TC, Wawer MJ, Sewankambo N, et al. (2000). Viral load and heterosexual transmission of human immunodeficiency virus type 1. Rakai Project Study Group. *N Engl J Med.*, 342:921-929.

¹¹⁰ Attia S, Egger M, Muller M, Zwahlen M, Low N. (2009). Sexual transmission of HIV according to viral load and antiretroviral therapy: systematic review and meta-analysis. *AIDS*, 23(11):1397-1404.

¹¹¹ Donnell D, Baeten JM, Kiare J, Thomas KK, Stevens W, Cohen CR, McIntyre J, Lingappa J, Celum C; Partners in Prevention HSV/HIV Transmission Study Team. (2010). Heterosexual HIV-1 transmission after initiation of antiretroviral therapy: a prospective cohort analysis. *Lancet*, 375(9731):2092-8.

¹¹² Del Romero J, Castilla J, Hernando V, Rodriguez C, Garcia S. (2010). Combined antiretroviral treatment and heterosexual transmission of HIV-1: cross sectional and prospective cohort study. *BMJ*, 340:c2205.

with safer pregnancy counseling can reduce the risk of HIV transmission to the negative partner among discordant couples trying to conceive a child¹¹³. This is especially important if the woman is the HIV-negative partner as HIV infection during pregnancy is associated with an increased risk of mother-to-child HIV transmission due to the high viral loads associated with acute infection^{114, 115, 116}.

- **Providing sexual risk reduction** counseling and ongoing support to discordant couples is an effective strategy for reducing the frequency of unprotected sex^{117, 118} and the number of sex acts with outside partners¹¹⁹. In addition, evidence indicates that couples counseling can increase the uptake of PMTCT interventions among HIV positive pregnant women in antenatal clinics¹²⁰. For HIV-negative males, medical circumcision has been shown to reduce the risk of HIV acquisition by at least 60 percent¹²¹. Thus, offering circumcision to the HIV-uninfected male partners of HIV positive women should be routine when addressing the prevention needs of discordant couples. To help ensure that the couple is able to maintain their HIV discordance, the HIV-negative partner in discordant partnerships should be offered HIV testing and counseling at least annually, or in line with WHO retesting recommendations¹²².
- **Support of Safe Disclosure to Sex Partners and Family Members.** Disclosure allows partners and family members to access HTC services as well as care and treatment services, if needed. Disclosure also allows sex partners to make decisions about how to protect themselves from HIV including decisions about condom use and other risk reduction strategies. For HIV positive clients, disclosure can lead to support from their partner(s) and/or family, which improves uptake of, and adherence to, care and treatment programs. For those persons who feel able to safely disclose without incurring harm, strategies for safe disclosure should be discussed. Provider- or counselor-assisted disclosure is an option for those who do not feel comfortable disclosing on their own; couples HTC is another method for individuals to learn their HIV status together in the presence of a trained counselor. Participation in peer support programs should be encouraged to help facilitate and promote safe disclosure.
- **Safer Sex Counseling.** HIV positive individuals should be given information about protecting their own health and the health of their partners and family members through safer

¹¹³ Brubaker SG, Bukusi EA, Odoyo J, Achando J, Okumu A, Cohen CR. (2010). Pregnancy and HIV transmission among HIV-discordant couples in a clinical trial in Kisumu, Kenya. *HIV Medicine*, epub.

¹¹⁴ Gay C, Mwapasa V, Murdoch D, Kwiek J, Fiscus S, Meshnick S, Cohen M. (2010). Acute HIV infection among pregnant women in Malawi. *Diagn Microbiol Infect Dis.*, 66(4): 356–360.

¹¹⁵ Tuomala RE, O'Driscoll PT, Bremer JW, Jennings C, Xu C, Read JS, Matzen E, Landay A, Zorrilla C, Blattner W, Charurat M, Anderson DJ. (2003). Cell-associated genital tract virus and vertical transmission of human immunodeficiency virus type 1 in antiretroviral-experienced women. *J Infect Dis*, 187:375–384.

¹¹⁶ Pilcher CD, Shugars DC, Fiscus SA, Miller WC, Menezes P, Giner J, Dean B, Robertson K, Hart CE, Lennox JL, Eron JJ Jr, Hicks CB. (2001). HIV in body fluids during primary HIV infection: implications for pathogenesis, treatment and public health. *AIDS*, 15:837–845.

¹¹⁷ Crepaz et al., 2006.

¹¹⁸ Kennedy et al., 2010.

¹¹⁹ Allen S, Meinzen-Derr J, Kautzman M, et al. (2003). Sexual behavior of HIV discordant couples after HIV counseling and testing. *AIDS*. 17(5): 733-40.

¹²⁰ Farquhar C, Kiarie JN, Richardson BA, et al. (2004). Antenatal couple counseling increases uptake of interventions to prevent HIV-1 Transmission. *JAIDS*. 37 (5):1620-6.

¹²¹ Siegfried N, Muller M, Deeks JJ, Volmink J. (2009). Male circumcision for prevention of heterosexual acquisition of HIV in men. *Cochrane Database Syst Rev*. 15;(2):CD003362.

¹²² World Health Organization. (2010). Delivering HIV test results and messages for re-testing and counselling in adults. Available at: http://www.who.int/hiv/pub/vct/hiv_re_testing/en/index.html. Last accessed: May 20, 2011.

sex practices, including fidelity to one sex partner of known HIV status, reduction in multiple partnerships, and correct and consistent use of male and female condoms. These interventions protect HIV-infected persons from acquiring new infections such as other sexually transmitted diseases or other strains of HIV that may be difficult to treat. All sexually active HIV-infected persons should also be strongly encouraged and counseled to practice safer sex to prevent HIV transmission. Behavioral interventions that encourage safer sex and offer skills development (e.g. condom negotiation, condom use, etc.) should be part of every medical or counseling encounter with HIV positive persons. PLHIV support group facilitators, peer educators, expert patients and community care providers that interact with PLHIV should have the capacity to provide ongoing support and counseling for safer sex and serve as consistent sources of condoms and other relevant commodities outside of the clinic/facility.

- **Alcohol Use Assessment and Counseling.** Alcohol use is associated with both increased risky sexual behavior^{123, 124} and reduced adherence to ARVs¹²⁵. Alcohol use can also lead to poorer health outcomes among HIV positive individuals including higher viral loads¹²⁶, accelerated disease progression^{127, 128}, and increased levels of depression¹²⁹. Although the rate of alcohol use in many HIV positive persons in sub-Saharan Africa is high, assessment of alcohol use and its impact on the health and behavior of PLHIV as part of patients' care is lacking. Health care providers and counselors in facility and community settings should assess alcohol use in HIV positive persons and encourage abstinence from alcohol or reduction in use. Moreover, patients with substance (i.e. cocaine, marijuana, and/or injecting drugs) and/or alcohol problems should be linked to substance abuse treatment programs, where available but at a minimum should be offered risk reduction counseling by a health care provider. While these technical considerations focus on preventing sexual transmission of HIV, the PwP Task Force also recognizes the importance of preventing HIV transmission among persons who inject drugs through needle /syringe exchange programs and other harm reduction interventions. Guidance for these programs can be found in the Technical Considerations for Biomedical Prevention: Intravenous and Non-Intravenous Drug Use. HIV positive persons who inject drugs and their sexual partner(s) are also an important, yet underserved population in need of sexual risk reduction counseling and other HIV prevention messages and services. Programs working with these populations should integrate HIV prevention into the routine services offered to HIV positive persons who inject drugs.
- **Assessment and Treatment of Other Sexually Transmitted Infections (STIs).** Routine assessment, treatment, and partner management of STIs is important for addressing the care and prevention needs of PLHIV and can improve the health of HIV positive patients, their

¹²³ Shuper PA, Joharchi N, Irving H, Rehm J. (2009). Alcohol as a correlate of unprotected sexual behavior among people living with HIV/AIDS: review and meta-analysis. *AIDS Behav.*, 13(6):1021-36.

¹²⁴ Fisher JC, Bang H, Kapiga SH. (2007). The association between HIV infection and alcohol use: a systematic review and meta-analysis of African studies. *Sex Transm Dis.*, 34(11):856-863.

¹²⁵ Palepu A, Horton NJ, Tibbetts N, Meli S, Samet JH. (2004). Uptake and adherence to highly active antiretroviral therapy among HIV-infected people with alcohol and other substance use problems: the impact of substance abuse treatment. *Addiction*, 99(3):361-8.

¹²⁶ Baum MK, Rafie C, Lai S, Sales S, Page JB, Campa A. (2010). Alcohol use accelerates HIV disease progression. *AIDS Res Hum Retroviruses.*, 26(5):511-8.

¹²⁷ Baum et al., 2010.

¹²⁸ Ghebremichael M, Paintsil E, Ickovics JR, Vlahov D, Schuman P, Boland R, et al. (2009). Longitudinal association of alcohol use with HIV disease progression and psychological health of women with HIV. *AIDS Care*, 21(7):834-41.

¹²⁹ Ghebremichael et al., 2009.

partners and families¹³⁰. Some STIs may be more complicated and difficult to treat in HIV-infected individuals¹³¹. For example, HIV-infected patients with genital herpes (HSV) may experience more protracted, severe episodes and may require antiviral treatment for HSV at higher doses for longer durations¹³². In addition, many STIs can have harmful effects on pregnant women and/or their unborn children and can reduce fertility in both men and women. Thus, women and their partners should be assessed and treated for STIs before becoming pregnant. An STI can be a marker for unprotected sex. This is especially true for new or incident STI cases but may be less true for recurrent incurable STIs like HSV which can recur without sexual activity. HIV positive patients who are co-infected with an STI should be given risk reduction counseling about the importance of condom use to prevent transmission of HIV or other STIs to their partner(s) and decreasing the risk of acquiring another STI. STI treatment of both patient and his/her partner(s) prevents further STI transmission and re-infection between the couple members. PLHIV support group facilitators, peer educators, expert patients and community care providers that interact with PLHIV should have information on how to recognize the signs and symptoms of common STIs and have the capacity to provide basic ongoing counseling for STI prevention. This will enable community workers and peer educators to provide early referral of their clients and peers for STI treatment.

- **Family Planning and Safer Pregnancy Counseling.** Prevention of unintended pregnancy in HIV positive women is an important intervention for prevention of mother-to-child transmission of HIV (PMTCT). Sexual activity tends to increase as health improves among HIV positive persons on ART. However, women often report low rates of condom use in stable relationships. Further, many HIV positive women in sub-Saharan Africa report an unmet need for contraception¹³³. This highlights the critical need to provide family planning counseling and services for HIV-infected persons in order to reduce the number of unintended pregnancies among these women. Family planning counseling and provision of contraceptive services ideally should be integrated within most HIV-related clinical settings. For HIV positive women who desire children, safer pregnancy counseling on methods to reduce the risk of HIV transmission to their partners and children is needed. Pregnant women are at increased risk for HIV seroconversion during pregnancy¹³⁴, and recent evidence indicates that men are also at increased risk for acquiring HIV during the woman's pregnancy¹³⁵. To prevent new HIV infections among pregnant women and their partner(s), it is essential that partner testing or couples HTC and risk reduction counseling be offered to all pregnant women and their partner(s). HIV positive women who become pregnant should be linked to appropriate PMTCT programs. In addition, PLHIV support group and mothers-to-mothers group facilitators and community care providers who interact with pregnant PLHIV

¹³⁰ World Health Organization (2008). Essential Prevention and Care Interventions for Adults and Adolescents Living with HIV in Resource-Limited Settings. Available at: <http://www.who.int/hiv/pub/guidelines/EP/en/index.html>. Last accessed: May 20, 2011.

¹³¹ World Health Organization. (2003) Guidelines for the Management of Sexually Transmitted Infections. Available at: <http://www.who.int/hiv/pub/sti/pub6/en/>. Last accessed: May 20, 2011.

¹³² World Health Organization, 2003.

¹³³ Homsy J, Bunnell R, Moore D, King R, Malamba S, Nakityo R, Glidden D, Tappero J, Mermin J. (2009). Reproductive intentions and outcomes among women on antiretroviral therapy in rural Uganda: a prospective cohort study. *PLoS One*. ;4(1):e4149.

¹³⁴ Moodley D, Esterhuizen TM, Pather T, et al. (2009). High HIV incidence during pregnancy: compelling reason for repeat HIV testing. *AIDS*. 23:1255-9.

¹³⁵ Mugo N, et al. Pregnancy Doubles HIV Risk in Men: First trial of a microbicide in pregnant women. Presented at International Microbicides Conference (M2010), March 22-25, 2010. Pittsburgh, Pennsylvania, USA.

and their partners should have the capacity to provide ongoing family planning counseling and support for safer pregnancies.

- **Condom Distribution and Promotion.** All clinic and community-based programs must discuss the importance of correct and consistent condom use and distribute/provide condoms to all PLHIV at every encounter with a health facility or community care provider or counselor (12 condoms per monthly visit at a minimum for sexually active clients). Engaging and enlisting the support of peer educators, who are themselves HIV positive, is particularly effective for promoting and distributing condoms and lubricants, especially among most-at-risk populations (e.g., men who have sex with men, people who inject drugs, and commercial sex workers), as these populations often have limited interaction with health facilities and HIV prevention programs. Increasing condom distribution supports consistent condom use among HIV positive individuals and discordant couples, and may help increase uptake and normalize routine use of condoms.
- **Adherence Counseling and Support.** Adherence counseling and support should be offered to both HIV positive individuals and serodiscordant couples, as anti-retroviral treatment (ART), when taken as prescribed, can significantly inhibit HIV viral load and replication¹³⁶, reduce the morbidity and mortality experienced by PLHIV^{137, 138}, and reduce the risk of HIV transmission to sex partners^{139, 140, 141, 142}. To maintain optimal treatment efficacy high level adherence is required; however many individuals struggle to take their prescribed ARVs consistently. Thus, interventions that increase adherence to prophylactic medications (e.g., cotrimoxazole) and therapeutic regimens (e.g., ARVs) are an important component of prevention for HIV-positive persons. Effective interventions include pillbox organizers, treatment supporters, provider-delivered education or counseling, couple-based counseling, telephone support, reminder devices, home visits, and directly observed therapy¹⁴³. Adherence support interventions can be successfully delivered in an ongoing manner at clinical, community, or home settings.
- **Development and Support of Client-Driven Prevention Goals.** Encouraging PLHIV to set prevention goals, particularly in clinic and community counseling sessions, provides a mechanism for PLHIV to consider their HIV prevention needs and to aim and accomplish improved prevention behaviors and care. Ongoing review of prevention goals by clinic and community-based health care workers and counselors allows for continuous preventive care which is tailored to each individual's circumstances.
- **Participation in Relevant Peer Support Activities:** Between clinical visits patients and their partners need support to maintain the motivation to achieve their prevention goals. This support can be provided through clinic- and/or community-based peer group programs if

¹³⁶ Crum et al., 2006.

¹³⁷ Crum et al., 2006.

¹³⁸ Lima V, Harrigan R, Bangsberg D, Hogg R, Gross R, Yip B, et al. (2009). The combined effect of modern highly active antiretroviral therapy regimens and adherence on mortality over time. *JAIDS*, 50(5):529-36.

¹³⁹ Quinn et al., 2000.

¹⁴⁰ Attia et al., 2009.

¹⁴¹ Donnell et al., 2010.

¹⁴² Del Romero et al., 2010.

¹⁴³ Simoni J, Pearson C, Pantalone D, Marks G, Crepaz N. (2006). Efficacy of interventions in improving highly active antiretroviral therapy adherence and HIV-1 RNA viral load: A meta-analytic review of randomized controlled trials, *JAIDS*, 43(suppl 1):S23-S35.

desired by the patient. Facilitators of such groups/programs should be well trained and have the capacity to ensure that the prevention messages and services described above are integrated into their support programs.

D. Linking and Retaining Individuals into HIV Care and Treatment Services Is an Important Component of PwP Services

Although access to HIV testing and counselling has rapidly expanded, only about 40% of PLHIV are aware of their status¹⁴⁴ and even fewer know their partner's HIV status^{145, 146}. Ongoing HTC efforts, therefore, must place greater priority on identifying HIV positive individuals and serodiscordant partnerships, and linking these persons with appropriate HIV prevention, treatment, care, and support services. A variety of clinic and community-based HIV testing strategies will be needed to increase the number of PLHIV who know their HIV status. Once individuals have been diagnosed, actively linking them into HIV prevention, care, and treatment services is necessary to protect their health¹⁴⁷ and to reduce the risk of HIV transmission to uninfected partners¹⁴⁸. However, many newly diagnosed patients either do not enroll¹⁴⁹ or do not stay enrolled in HIV care and treatment services after diagnosis¹⁵⁰. Studies indicate that as few as 1/6 to 1/3 of persons diagnosed with HIV will initiate ART¹⁵¹. Thus, strategies to ensure early enrollment and retention in care are important to maximize the health and prevention benefits for persons living with HIV.

Identifying and implementing innovative strategies for linking patients into care is urgently needed as approximately half of individuals newly diagnosed with HIV do not enroll in HIV care and treatment services^{152, 153}. Several strategies have been used to facilitate linkage and enrollment of HIV positive individuals into HIV care and treatment services. For example, provision of HIV prevention and care services at the HIV testing site, including point-of-care CD4 testing, may improve clients' access to these services and facilitate linkage into HIV care and treatment services. Other linkage strategies include co-location of services, physical escort by peer educators, ongoing case management, follow-up counseling by a community health worker, and community support groups.

Among those individuals who do enroll into services, attrition is very high, and as many as half will drop out of care before receiving ART^{154, 155}. Prioritizing retention of individuals who have not yet

¹⁴⁴ UN Joint Programme on HIV/AIDS (UNAIDS). (2010). UNAIDS Report on the Global AIDS Epidemic: 2010, ISBN 978-92-9173-871-7. Available at: http://www.unaids.org/globalreport/Global_report.htm. Accessed on May 5, 2011.

¹⁴⁵ Kaiser et al., 2011.

¹⁴⁶ Loubiere S, Peretti-Watel P, Boyer S, Blanche J, Abega SC, Spire B. (2009). HIV disclosure and unsafe sex among HIV-infected women in Cameroon: results from the ANRS-EVAL study. *Soc Sci Med*, 69(6):885-91.

¹⁴⁷ Crum et al., 2006.

¹⁴⁸ Donnell et al., 2010.

¹⁴⁹ Micek MA, Gimbel-Sherr K, Baptista AJ, Matediana E, Montoya P, Pfeiffer J, Melo A, Gimbel-Sherr S, Johnson W, Gloyd S. (2009). Loss to follow-up of adults in public HIV care systems in central Mozambique: identifying obstacles to treatment. *J Acquir Immune Defic Syndr*, 52(3):397-405.

¹⁵⁰ Rosen S, Fox M, Larson B. [From HIV testing-to-treatment initiation: the missing link](#). Oral abstract session: 18th Conference on Retroviruses and Opportunistic Infections: Abstract no. 110. Available at: <http://www.retroconference.org/2011/Abstracts/42657.htm>.

¹⁵¹ Rosen et al., 2011.

¹⁵² Micek et al., 2009.

¹⁵³ Marcellin F, Abé C, Loubière S, Boyer S, Blanche J, Koulla-Shiro S, Ongolo-Zogo P, Moatti JP, Spire B, Carrieri MP; EVAL Study Group. (2009). Delayed first consultation after diagnosis of HIV infection in Cameroon. *AIDS*, 23(8):1015-9.

¹⁵⁴ Rosen et al., 2011.

¹⁵⁵ Larson BA, Brennan A, McNamara L, Long L, Rosen S, Sanne I, Fox MP. (2010). Early loss to follow up after enrolment in pre-ART care at a large public clinic in Johannesburg, South Africa. *Trop Med Int Health*. 15(Suppl)1:43-7.

begun ART is key to enhancing the impact of prevention services as these patients are more likely to default from care¹⁵⁶ and are at higher risk for transmitting HIV to their partner(s) and child(ren) compared to patients with suppressed viral loads¹⁵⁷. Integrating HIV prevention into care and treatment services may be one way to retain both pre-ART and ART patients in care as it provides patients with the knowledge and skills necessary to protect both their own health and the health of their partner(s) and families. Providing ongoing education and treatment literacy through adherence counseling and support can help patients understand the importance of regular clinic attendance and medication adherence. Peer counselors and psychosocial support groups can also be important sources of supportive counseling for these patients and should be utilized within both clinic and community settings. Establishing a patient follow-up team within the clinic to prioritize patients at higher risk for default for supportive counseling and to track clients who have been lost to follow-up can also help retain both pre-ART and ART patients in care. Using community-based services (e.g. home visits by community health workers) and technology (e.g. mobile phone calls/text messaging) are other innovative strategies that may help retain patients in care.

E. Using Lay (or Peer) Counselors Is a Feasible Model for Task-Shifting Provision of PwP Services within Clinical Settings

Inadequate numbers of health care workers in clinics and large numbers of patients lead to heavy patient loads and severe time constraints for health care providers. Consequently, providers often have little time to discuss HIV prevention issues with their patients. Yet many patients need in-depth discussions on prevention issues, such as overcoming barriers to disclosure, partner testing, and negotiating condom use with partners. Lay counselors have been successfully utilized in HIV clinics to provide ARV medication adherence counseling¹⁵⁸, sexual risk reduction counseling^{159, 160, 161}, and HIV testing and counseling. In addition, several countries have found that including lay counselors in clinics to provide these services is a feasible model of task-shifting which helps reduce the education and counseling burden on health care providers. With appropriate supportive supervision from health care providers, incorporating lay counselors, most of whom are HIV positive, into clinic settings is a potentially cost-effective and supportive model for delivering prevention counseling and partner/couples testing to HIV positive patients in clinical settings. These lay counselors can reinforce prevention messages delivered by health care providers, assist patients in overcoming barriers to engaging in safer behaviors, and provide ongoing support to patients. Where feasible, lay counselors should be identified from amongst capable and willing PLHIV, be trained, and become part of the health care team.

F. PwP/PHDP Requires National Coordination and Leadership

Integrating HIV prevention into the routine care offered to HIV positive individuals in both clinic and community settings requires coordination and collaboration across multiple disciplines—many of which work in parallel programs. Such collaboration is needed to support integration of services and to strengthen referral networks. Furthermore, Prevention, Care and Treatment Programs must work collaboratively on PwP efforts and these programs must be jointly managed and owned by program leadership with meaningful involvement of PLHIV to ensure the continuity and sustainability of in-country programs. Given that prevention interventions with HIV positive persons should be delivered

¹⁵⁶ Larson et al., 2010.

¹⁵⁷ Donnell et al., 2010.

¹⁵⁸ Torpey et al., 2008.

¹⁵⁹ Cornman et al., 2008.

¹⁶⁰ Myers et al., 2010.

¹⁶¹ Peltzer et al., 2010.

in both clinic and community settings, responsibility for these programs should not fall under one domain (e.g. care and treatment, prevention, HIV testing and counseling), but should be shared and coordinated in order to ensure success and buy-in.

Experience from several countries has shown that the best way to achieve coordination and collaboration between USG prevention, care and treatment programs, as well as to engage Ministries of Health and Defense, is through the creation of a national technical working group (TWG) headed by an invested stakeholder or “champion”. The national TWG should be formed through the Ministry of Health and National AIDS Program, and should include members from all services involved in comprehensive prevention efforts (e.g., STI, FP, HIV care and treatment, TB, HTC, PMTCT and Prevention). There should also be meaningful involvement and leadership of PLHIV and civil society in these efforts to ensure sustainability and continuity. The national TWG should develop or strengthen existing Care and Treatment policies and guidelines on integration of prevention interventions into clinic and community settings, as well as ensure that prevention with PLHIV is part of the National Prevention Strategy. The TWG should also address implementation and monitoring issues.

1.5.2 MONITORING AND EVALUATION: PwP

Programs should include indicators to monitor and evaluate delivery, quality, and impact of these prevention interventions and services. These indicators should be harmonized with PEPFAR’s and the country’s national indicators. The PwP Task Force, in collaboration with the Surveillance and Information (SI) TWG, has developed a set of PwP indicators as part of the next generation PEPFAR indicators for countries to consider. The required PwP PEPFAR indicator defines the minimum package of prevention services for PLHIV and encourages partners to routinely deliver such services to PLHIV as part of both clinic and community-based care and treatment services. The indicator can be used to identify the number of PLHIV reached with this minimum package of services. The PEPFAR Next Generation Indicators Guide includes additional information on the indicator and how it is measured. Recommended indicators can be used to monitor individual prevention services delivered to PLHIV (e.g., partner testing, family planning or risk reduction counseling). Countries may wish to align particular elements of the PwP minimum package of services with specific indicators from other program areas. For example partner/couples HIV testing and counseling can be aligned with HTC indicators as found in the newly released WHO M&E Guide¹⁶².

1.5.3 COUNTRY CONTEXTUAL CONSIDERATIONS: PwP

Country teams are encouraged to use existing epidemiologic data, including data from recent Demographic and Health Surveys (DHS) and AIDS Indicator Surveys (AIS), to plan prevention services for PLHIV. As programs are scaled up, countries should prioritize highest prevalence areas and highest burden clinic settings to maximize the number of PLHIV that can be reached with prevention interventions. These prevention interventions should also be expanded to community settings within the same regions. Bidirectional linkages between the clinic and community programs should be developed to increase PLHIVs’ access to PwP messages and services.

¹⁶² World Health Organization. (2011). Guide for monitoring and evaluating national HIV testing and counselling (HTC) programmes: field-test version. Available at: <http://www.who.int/hiv/pub/vct/9789241501347/en/index.html>. Last accessed: May 20, 2011

As HIV prevention interventions for PLHIV progress and scale-up, countries are encouraged to expand the materials, messages, and intervention strategies to include most-at-risk PLHIV, (e.g., commercial sex workers, people who inject drugs, men who have sex with men, etc). Services for uniformed personnel and their families and spouses such as military and police are also encouraged along with services for other vulnerable groups, including migrant workers, miners, transport workers, and refugees.

1.5.4 LINKAGES AND WRAPAROUNDS: PwP

Any program or activity that provides services to HIV positive individuals or identifies HIV positive individuals should provide, or be linked with, prevention services. For example, HTC programs should include prevention messaging for individuals diagnosed as HIV positive, and offer or refer clients and patients to ongoing prevention counseling, as needed. These programs should also actively link these patients into HIV care and treatment programs for ongoing prevention, treatment, care and support services. Similarly, reproductive health and family planning clinics should offer HTC to all clients and provide risk reduction counseling and active linkage to HIV care and treatment for those individuals identified as HIV positive. Passive referral to HIV care and treatment services is insufficient as many newly diagnosed patients do not enroll in HIV care and treatment services¹⁶³. Innovative strategies for actively linking patients into HIV care and treatment services need to be developed and implemented.

HIV clinic settings where partner testing, STI assessment and treatment, and family planning services for HIV positive individuals cannot be integrated into routine care should have strong linkage and referral systems for patients who need these services. HIV positive individuals with other infections such as malaria or TB should be linked to appropriate treatment services. HIV positive pregnant women should be linked to PMTCT services. Individuals with mental health problems should be referred to on-going counseling services and support services. In addition, HIV positive individuals with alcohol or substance abuse problems should be linked with substance abuse treatment programs and needle/syringe exchange programs, where available.

Patients at STI clinics are likely to be engaging in high risk behaviors which place them at risk for incident HIV infection. The high viral loads associated with acute infection coupled with the high risk behavior of patients in STI treatment clinics, make this population a high priority for HIV prevention messages and services including HIV testing and counseling and risk reduction counseling. Providing HIV testing and counseling as part of the routine services offered to patients in STI treatment clinics can also identify patients co-infected with HIV so that these patients can be linked with HIV prevention, care, and treatment programs.

Clinic programs should link HIV positive clients with prevention, care, and support programs in the community. Community-based programs should reinforce provider-initiated prevention messages by adapting clinic-based interventions so that messages and services delivered to PLHIV are consistent across settings and partners. These community programs should have strong bidirectional linkages with clinic programs and provide timely referrals to ensure access to critical prevention, care, and treatment services. These linkages will support the physical, mental, social, and economic well-being of PLHIV, their partner(s), and family.

Section 2. Treatment, Care and Support

¹⁶³ Micek et al., 2009.

TECHNICAL AREA 2.1: ADULT CARE AND TREATMENT

Care and Treatment—Comprehensive and compassionate care should always be a goal in care and support programs. Adult care and support services comprise facility-based and home/community-based activities for HIV-infected adults aimed at extending and optimizing quality of life from the time of diagnosis throughout the continuum of illness, through provision of clinical, psychological, social, spiritual, and prevention services; and for improving the lives of their contacts (HIV-affected persons). For further explanation, see the revised version of *PEPFAR Care and Support Technical Guidance* on PEPFAR.net. This document focuses on adult care and support. See Pediatric Care and Treatment Technical Considerations for guidance concerning care and support for HIV-infected children.

Adult Care and Support—All facility-based and home/community-based activities for HIV-infected adults and their families aimed at extending and optimizing quality of life for HIV-infected clients and their families throughout the continuum of illness through provision of clinical, psychological, spiritual, social, and prevention services. Clinical care should include prevention and treatment of OIs (excluding TB) and other HIV/AIDS-related complications including malaria and diarrhea (providing access to commodities such as pharmaceuticals, insecticide-treated nets, safe water interventions and related laboratory services), pain and symptom relief, and nutritional assessment and support including food. Psychological and spiritual support may include group and individual counseling and culturally-appropriate end-of-life care and bereavement services. Social support may include vocational training, income-generating activities, social and legal protection, and training and support of caregivers. Prevention services may include “prevention for positives” behavioral counseling and counseling and testing of family members. The purchase of OI drugs (excluding TB drugs) should be included under Adult Care and Treatment. ARV treatment should be coded under Adult Treatment and ARV Drugs.

Adult Treatment – including infrastructure, training clinicians and other providers, exams, clinical monitoring, related laboratory services, and community-adherence activities. Clinical monitoring and management of opportunistic infections is classified under Adult Care and Support.

2.1.1 BACKGROUND: ADULT CARE AND TREATMENT

The **key elements** of a strong care and support program are interventions that lead to:

- **Early identification of HIV-infected persons, linkage, and retention in care.** Most HIV-infected persons enter HIV treatment and care programs with advanced disease. There is a need to identify persons earlier in their illness and to create effective linkage and retention mechanisms to maximize the benefits of HIV treatment and care;
- **Reduction in HIV-related morbidity and mortality.** There is an array of important interventions that reduce morbidity and mortality for persons with HIV. Because of proven effectiveness and cost-effectiveness for reducing mortality, provision of cotrimoxazole

(CTX) prophylaxis in accordance with WHO recommendations and TB identification and treatment are very high priority interventions. Other services (prevention of malaria, safe water and hygiene, food and nutrition, and others) that can reduce early morbidity or mortality outcomes are discussed in this document;

- **Improved quality of life.** The assessment and management of pain and other symptoms and provision of appropriate psychological, social, and spiritual support are important elements in improving the quality of life for HIV-infected persons and family members and other contacts affected by HIV disease. In addition to reducing morbidity/mortality, the interventions listed under the second bullet above also contribute to improved quality of life; and
- **Reduction in transmission of HIV infection from HIV-infected to uninfected persons.** Prevention with positives (PwP) programming, integrated into HIV care services, is critical for reducing the risk of ongoing HIV transmission. PwP activities include short term and ongoing behavioral counseling to reduce high-risk behaviors, distribution of condoms, attention to risks imposed by alcoholism and use of other drugs, and screening and treatment of sexually transmitted infections.

Each of the above elements should be supported within a framework of **key cross cutting considerations, including sensitivity to gender-specific issues, linkage of facility-based and community/home-based services, equitable distribution of services** across geographic areas and populations; sustainable **improvement in health care systems; improvement in the quality** of programs, and appropriate **monitoring and evaluation**.

A. Adult Treatment:

From 2004 to present, the effort to scale up adult treatment under the President's Emergency Plan for AIDS Relief (PEPFAR) produced remarkably successful results in terms of three key priorities: access, quality, and sustainability.

PEPFAR was launched in 2003 to combat global HIV – the largest commitment by any nation to combat a single disease in human history. HIV care and treatment has been a cornerstone of this unprecedented effort. The original “2-7-10” goals of PEPFAR were to treat 2 million persons with ART, prevent 7 million new infections, and provide care for 10 million HIV-infected persons and AIDS orphans. Through October 2009, PEPFAR was directly supporting nearly 2.5 million individuals on antiretroviral therapy at more than 6,000 sites in 31 countries and WHO estimates that 5.2 million are receiving treatment in low- and middle-income countries. Treatment programs of this enormous scope not only provide beneficial effects for the health of the individual, they directly prevent hundreds of thousands of new infections each year, and stabilize families, communities and entire countries. These successes contributed to the decision to set ambitious goals for PEPFAR's second phase, including a treatment goal of direct support for more than 4 million individuals. PEPFAR is unambiguously committed to scaling up treatment to meet this goal. However, there still remains significant unmet need for treatment, with an estimated 10-15 million people eligible for treatment in low and middle-income countries.

Treatment scale-up has generally been of high quality, with national outcomes evaluations in Rwanda, Kenya and Mozambique demonstrating 78% 12-month retention rates on treatment and mortality, CD4 count gains, and virological suppression rates similar to rates reported in many European and North American cohorts. These results, and the results from other evaluations of national ART programs, suggest that PEPFAR treatment programs are achieving excellent patient outcomes in resource-limited settings. Furthermore, quality improvement programs have been integrated into many ART clinics to continually improve retention, adherence, and response to ART.

Ensuring the sustainability of ART programs remains an important focus under the new PEPFAR strategy. Sustainability of ART programs in recent years has been greatly enhanced by achieving significant cost savings on antiretroviral drugs (ARVs), strengthening health systems, building local capacity to deliver services, and utilizing cost modeling projections to inform resource allocation and guide scale-up of ART programs. Cost savings have been achieved through the creation of the FDA tentative approval process in 2004, pooled procurement of ARVs by Supply Chain Management System (SCMS), and the rapid uptake of quality generic drugs in PEPFAR-funded programs. PEPFAR supported ART programs have sought to strengthen health systems at community, clinic, District, and National levels through the formation of community health committees; the training and retention of facility-based and community-based local health workers; capacity building of sustainable and effective community-based organizations; ensuring the reliability and integrity of effective supply chains, and laboratory networks; and improving information and quality management.

While strengthened supply chains and lower ARV prices have helped increase access and improve the efficiency of ART programs, an important goal of PEPFAR is to ensure continuous treatment of those started on ART. Hence, cost modeling projections have been used to inform the most efficient and effective use of resources. Collaboration with national ministries of health and other international stakeholders to implement and adapt revisions to national HIV guidelines has promoted coordinated and efficient national ART programs. Furthermore, developing and strengthening indigenous partners to assume leadership of ART programs has helped ensure sustainability of ART programs into the future.

B. Prevention with People Living with HIV:

Recent data from country Demographic and Health Surveys (DHS), AIDS Indicator Surveys (AIS), and research studies in sub-Saharan Africa document the need for effective prevention interventions for HIV positive individuals. For example, in generalized, high-prevalence epidemics, many HIV positive persons are in discordant relationships or partnerships, which represent opportunities to prevent new infections to the negative spouse or partner(s). HIV disclosure rates are often low, resulting in many individuals who do not know that their spouse or partner(s) are living with HIV (Medley et al., 2004). Furthermore, rates of condom use are very low, especially with regular sexual partners. Alcohol use among many persons living with HIV is high, and is often associated with risky sexual behavior (Cook et al., 2006) and poor adherence to ARVs (Kalichman et al., 2007). Sexually transmitted infections (STIs) are prevalent among HIV positive persons and may facilitate sexual transmission of HIV to partners (Wegbreit et al., 2006). In addition, approximately half of HIV positive women sampled in recent DHS Surveys in Kenya and Uganda reported that their last pregnancy was unplanned or unwanted (54% and 49%, respectively; Bunnell, 2007). Among HIV positive women who did not want more children, the majority (64%) reported that their needs for contraception were not being met (Bunnell, 2007). Prevention of unwanted pregnancy in HIV positive women is an important intervention for prevention of mother-to-child transmission (PMTCT). For those PLHIV desiring children PwP services provide an opportunity to access accurate information and counseling support for safer pregnancy options and early referral into PMTCT services.

These findings support the need for efficient and effective prevention strategies for HIV –infected persons. Prevention interventions with HIV-infected individuals protect the health of the infected person and reduce the spread of HIV to sex partners and children. Prevention strategies may be behavioral or biomedical, community- or clinic-based, and focused on individuals, couples, or small groups (Rotheram-Borus et al., 2009). *Behavioral interventions* focus on correct and consistent use of condoms, disclosure of serostatus to sexual partners, partner and child testing, reduction in number of sex partners, reduction of alcohol and other abused substances use, and adherence to HIV medications. *Biomedical interventions* include management of STIs in PLHIV and their sex partners,

management of OIs including TB, family planning counseling that includes support for safer pregnancy options, and services to reduce unintended pregnancy and mother-to-child transmission of HIV. Programs in the US have developed and evaluated prevention interventions for HIV positive persons, and there is now a strong body of literature supporting the effectiveness of prevention interventions for PLHIV across multiple settings (Crepaz, et al., 2006; Johnson, et al., 2006). Emerging evidence from sub-Saharan Africa supports the effectiveness of prevention interventions at reducing risk behavior of PLHIV in resource limited settings (Bunnell et al., 2006; McNeil et al., 2006).

Country teams should focus on implementing comprehensive and evidence-based prevention services for PLHIV that are integrated across HIV disciplines in both clinic and community-based settings. In addition, expanding coverage of prevention services should be prioritized to reach all persons living with HIV with critical prevention messages and services in both clinic and community programs.

2.1.2 ADULT CARE AND SUPPORT

A. Early identification of HIV-infected persons, and linkage to and retention in care.

Early identification and linkage to and retention in care and support services are essential as they ensure access to and continuity of services associated with reduction in morbidity and mortality. A family-centered approach to care and support services is encouraged. The family-centered approach allows for early identification of infected and affected adults and children in need of care and support services (see Pediatric Care and Treatment Technical Considerations) and provides a family-based support for those infected, thus reducing stigma and discrimination and encouraging retention in care and support services.

Many PEPFAR programs are expanding HIV testing and counseling services within community settings to identify and link HIV-infected persons to care and support programs. Mobile and home based testing and counseling services may be a very effective means of targeting vulnerable groups, especially if those groups are highly stigmatized (sex workers, MSM, etc) or reaching areas that are not easily accessible (particularly in rural areas). Traditional stand-alone VCT sites may be most appropriate in dense, urban areas, as opposed to rural areas. Refer to the HIV Testing and Counseling Technical Considerations for further information regarding expanding access to testing opportunities within and outside of facilities.

Minimizing the loss to follow-up of patients from diagnosis to engagement in HIV care and support, with emphasis on pre-ART clients (which may be as high as 70%) is critically important. There are diverse reasons why high numbers of individuals who receive a HIV positive diagnosis do not become engaged in the care continuum across community and facility settings. Countries are encouraged to begin to develop strategies that support improving linkage and retention into care. Initial steps should include a initial formal or informal assessment of the; individual, providers, and institutional barriers to participation in care. Interventions to optimize retention in care may include but are not limited to: provision of basic HIV care services (including prevention of opportunistic infections), TB-screening and management, support for status acceptance and disclosure, partner testing and counseling, PwP services, psychosocial support, nutrition counseling, pain assessment and referral, treatment literacy, and outreach services to trace clients who have defaulted from the program. These services can also be offered at the community level directly or via referrals through community based programs (e.g. Support groups, Community Home-based Care projects etc). Support groups can serve as a link between the health facilities and the community to ensure a

continuum of care. Testing and counseling sites can refer all clients testing HIV positive to the support group in their area.

Populations most at risk for HIV (e.g. men who have sex with men (MSM), people who inject drugs (PWID), commercial sex workers (CSW) are often marginalized and sometimes face extreme individual, provider and institutional barriers to engagement in HIV care and support services. For instance, across multiple countries and regions, MARPs both fear and face judgment and discrimination from health providers, HIV counselors, and others within clinical settings. Countries are encouraged to propose strategies to assess (informally or formally) the barriers faced by various types of MARPs populations in the communities in which you work and prioritizing strategies for helping to address those and other barriers to MARPs participation in HIV care and support services.

B. Reduction in HIV-related morbidity and mortality

Care and Support Programs should support globally recommended approaches to diagnosis and management of Opportunistic Infections and Cancers and other medical conditions that occur in people with HIV through training, and support for appropriate commodities. International guidance is available (for example, IMAI <http://www.who.int/3by5/publications/documents/imai/en/>); additional specific recommendations for diagnosis and management of common opportunistic infections like cryptococcal disease are anticipated soon.

- *Cotrimoxazole prophylaxis (CTX)* — a combination of the antibiotics trimethoprim and sulfamethoxazole — is the mainstay of prevention of certain opportunistic infections in both industrialized and resource-limited countries; it has been shown to reduce morbidity and mortality in sub-Saharan Africa and has been shown to be cost-effective, prolonging the ART-free interval, and even cost-saving in some settings. In 2006, the [WHO published guidelines](http://www.who.int/hiv/pub/guidelines/ctx/en/) (<http://www.who.int/hiv/pub/guidelines/ctx/en/>) on use of CTX in resource-limited settings; all PEPFAR countries should have guidelines for its use in HIV-infected persons. **Malaria prevention**—CTX prophylaxis is highly effective in reducing the incidence of malaria in HIV-infected persons. In malaria endemic areas, insecticide-treated nets (ITNs) have been shown to decrease this risk further. The President’s Malaria Initiative (PMI) operates in many PEPFAR countries and generally targets children and pregnant women, in whom the risk of illness and death is greatest. PEPFAR programs should seek ways to coordinate their activities with PMI to offer ITNs to HIV-infected persons.
- *Safe water and hygiene*—PEPFAR programs are encouraged to ensure PLHIV have access to **safe drinking water** in facility-based care settings and to support PLHIV with home-based drinking water treatment methods and safe storage in communities without a reliable source of safe water. Several technologies are viable for treating water in the home, including chlorination and storage in an appropriate vessel, various types of filters, proper boiling, solar disinfection (SODIS) using heat and UV radiation and combined chemical coagulation, flocculation, and disinfection.

PEPFAR programs should support improvements in hygiene and sanitation, which are essential to reduce the infectious disease burden experienced by PLHIV. Personal hygiene (PLHIV & caregiver hygiene and cleanliness), food hygiene (safe cooking, mixing, storing and disposing of food), ensuring a hygienic environment in facilities, community care points and homes, and safe disposal of human feces will effectively reduce hygiene and sanitation related diseases. Hygiene education should be particularly targeted to patients and to caregivers and volunteers involved in community- and home-based care programs. Hand washing at critical times, with soap and with proper hand washing technique, is the most important hygiene measure to be integrated across all care and support programs. Although

PEPFAR will not support construction of latrines, disposing of excreta safely, isolating excreta from flies and other infectious agents, and preventing fecal contamination of water supplies is likely to reduce the spread of diseases.

- *Detection and treatment of TB*—TB is the principal cause of mortality among HIV-infected persons in most PEPFAR countries. As many as 10% of patients will be found to have active TB at the time of HIV diagnosis, and the lifetime risk of developing TB in HIV-infected persons is about 50%. Screening for active TB should always be part of a basic care package for HIV-infected persons (see HIV/TB Technical Considerations).
 - Intensified case-finding: Every patient should have a documented 4-question screen for TB (http://whqlibdoc.who.int/publications/2011/9789241500708_eng.pdf) at every visit to the ART facility. All patients with a positive screen should be evaluated, through a standardized algorithm, for the presence of active TB.
 - Isoniazid Preventive Therapy (IPT): Efforts should be made to ensure that IPT is available at ART clinics for all eligible patients.
 - Infection control: All ART clinics should ensure that basic administrative and environmental infection control practices are in place to protect patients and staff.
 - New guidance on Intensified case-finding and IPT is available from WHO at http://whqlibdoc.who.int/publications/2011/9789241500708_eng.pdf
- *Weight loss and wasting* are associated with a significantly elevated risk of progression and mortality. Loss of appetite, nausea, difficulty swallowing (associated with oral/esophageal thrush), and diarrhea are common among PLHIV. In addition, micronutrient deficiencies, common among PLHIV, may be linked to poor diet and may be further exacerbated by HIV-associated opportunistic infections. Consequently, nutritional assessment, counseling and support should be integrated into the clinical care of PLHIV. Routine patient management should include assessment of anthropometric status (e.g. weight loss and body mass index), nutrition-related symptoms (e.g. appetite, nausea, thrush and diarrhea) and diet as a basis for nutritional counseling and support. Nutritional support should also include provision of a daily multi-micronutrient supplement for patients whose diets are unlikely to meet vitamin and mineral requirements and therapeutic or supplementary feeding support for clinically malnourished patients. It is essential that care and support programs integrate nutritional assessment, counseling, and interventions into their activities.

In addition, all patients should be linked to social services that can assist in the assessment of their household food security status and provision of assistance to families that are food insecure through wrap-around services, e.g. Title II or World Food Programme food assistance. Home-based care programs can serve as a critical conduit for this wrap-around support and can refer individuals who are chronically ill and show signs of malnutrition (e.g. wasting or low mid-upper arm circumference) to clinical services for HIV testing, care and treatment. More details, including definitions of supplemental and therapeutic feeding, food security, and methods to screen patients for dietary deficiencies that may justify vitamin supplementation, can be found in the Food and Nutrition Technical Considerations.

- *Preventive Care Package*—The concept of providing a **minimum set of evidenced-based care interventions, or a “package of care”** for HIV-infected persons, is described in “[Guidance for United States Government In-Country Staff and Implementing Partners for a Preventive Care Package for Adults - # 1](#)”—available on PEPFAR.net and PEPFAR.gov. Such a set of services can be provided in both facility-based and community/home-based settings. The Emergency Plan recognizes that a “package of care” cannot be standardized for all countries or all populations. Each USG team is encouraged to adapt a basic preventive care package that is appropriate for the country in which it works. **Cotrimoxazole and Isoniazid prophylaxis, for those who are eligible, should be the cornerstone of such a**

- package.** See also Essential prevention and care interventions for adults and adolescents living with HIV in resource-limited settings (<http://www.who.int/hiv/pub/guidelines/EP/en/>).
- *Prevention of cervical cancer*—There is now extensive evidence that infection with high-risk types of human papillomavirus (HPV) is a necessary precursor to cervical cancer. HPV infection is more common and more likely to persist in HIV positive women, compared to HIV-negative women. Further, HIV positive women have a high burden of precancerous lesions and cancer of the cervix, compared to women without HIV. Thus, in the context of HIV infection, cervical cancer can be considered an opportunistic process. The detection and treatment of precancerous lesions can prevent progression to cervical cancer. The optimal approach to screening and treatment to prevent cervical cancer in HIV positive women has not been determined, but given accumulating data and recent technological advances, it is important to provide some support to support screening programs in HIV care and treatment settings.

PEPFAR can support, as part of a comprehensive approach to opportunistic infections, limited efforts to provide screening and treatment to prevent cervical cancer in HIV positive women. Country teams should work collaboratively with WHO and appropriate host country leadership and should document a detailed assessment of capacity to provide services related to cervical cancer. In general, screening should not be provided in ANC settings because of the need to delay interventions in pregnant women. Countries are encouraged to consider approaches which are feasible and cost-effective, such as provision of screening (for example with visual inspection or HPV detection) and management (for example with cryotherapy) in a single visit. A sub-group of the Care and Support Technical Working Group, the Cervical Cancer Taskforce can provide limited technical assistance and should be kept informed about country plans and experience.

- *Mental health issues*—Mental health issues may affect access to, use of, and retention in HIV care and treatment programs. Mental health services may be needed to reduce behaviors that increase the risk of HIV infection or transmission (e.g., alcohol or illegal drug use), reduce adherence to HIV treatments (depression, anxiety, isolation), or to address neuro-psychiatric complications of HIV disease or medication side effects. Additionally, affected family members may need psychological services to cope with the HIV disease or death of a spouse, child or parent. Mental health services can be captured under the scope of clinical, psychological or social services based on the specific aims of the intervention – such as psychiatric care given under the direct care of a clinician, drug rehabilitation services provided by a trained social worker, or peer support group or family counseling provided by trained counselors. Lay community based care givers can be trained with the basic skills for identifying early signs of mental health issues amongst PLHIV and then refer for appropriate care and support service. USG teams are encouraged to identify potential opportunities to support and strengthen mental health services.
- *PLHIV who inject drugs:* People living with HIV who inject drugs have unique HIV care and support needs that are important to distinguish from the HIV care and support needs of the general population.
 - *Overdose Prevention:* PLHIV who inject drugs are at risk of mortality due to drug overdose; naloxone has been proven to reduce the risk of mortality with opiate overdose. HIV care and support can support procurement of naloxone, provider capacity building, efforts to ensure inclusion of naloxone on essential medicines lists and policy and legislative changes that support broader availability of naloxone for people who inject drugs.
 - *Cellulitis and Wound Care:* PLHIV who inject drugs are prone to cellulitis and need careful attention to care of the wounds that they develop through injection drug use. Infectious cellulitis is an infection of the skin that can develop into a life-threatening

condition if not addressed with antibiotics and adequate wound care. PEPFAR programs can work to prevent and manage life-threatening bacterial infection in PLHIV who inject drugs through support for medications, provider training (e.g. providers at needle and syringe exchange sites, HIV clinic or medication assisted treatment for opiate addiction), and other strategies.

- *Viral Hepatitis:* PLHIV who inject drugs are often coinfecting with hepatitis B or C or remain at high risk of hepatitis C infection through unsafe injection behaviors. Coinfection with viral hepatitis can result in more complicated medical management and increased risk of liver failure and end-stage liver disease. There is no vaccine available to prevent hepatitis C, but there are vaccines available for the prevention of hepatitis A and B. Prevention of hepatitis B in a PLHIV who injects drugs can reduce the risk of liver disease. Outbreaks of hepatitis A or B can occur among people who inject drugs through sharing needles, sexual exposure or poor hygiene. Hepatitis C, B, or A can be very severe in someone who already has chronic liver disease from viral hepatitis, hence the importance of vaccination against hepatitis A and B in this population.

C. Improved quality of life

As described by the WHO definition, palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness through the prevention and relief of suffering by early identification and impeccable assessment and treatment of pain and other symptoms that are physical, psychosocial and spiritual (see WHO definition of palliative care (<http://www.who.int/cancer/palliative/definition/en/>)). Special attention should be given to how pain assessment and management is being advanced within care and support programs. Concrete steps can begin with policy activities that assist governments with the development of or the integration of policies for access and use of analgesics into national HIV plans and guidance. In addition, clinical care sites should assess for the presence of pain and other symptoms as part of routine HIV care and treatment. Regular technical assistance to host governments and advocates for access to essential pain medications may be required. USG can work with governments and academia to develop or revise standard training for health care providers in pain assessment and management in pre-professional and professional training. Developing sustainability of national interest in palliative care that ensures PLHIV and chronically the ill have access to “Decent Care” can be addressed by working with advocacy groups to formalize national palliative care organizations. Working with academia to formalize palliative care as a specialized discipline through medical, nursing and allied health professional training curriculum is also encouraged.

D. Reduction in transmission of HIV infection from HIV-infected to uninfected persons

Prevention interventions supporting HIV positive persons are an essential part of a comprehensive HIV prevention strategy and have been shown to be effective at reducing HIV transmission. Prevention interventions with HIV positive persons reduce the risk of HIV transmission to partners and children, improve identification of HIV-infected persons, and improve the health and quality of life of HIV positive persons. These interventions include 1) HIV testing and counseling of partners and children of HIV positive persons, along with couples counseling for discordant couples, 2) condom promotion and distribution, 3) counseling for safe disclosure of HIV status to partners, 4) provider-initiated behavioral risk reduction interventions 5) assessment, diagnosis, and management of STIs, OIs including TB as part of routine HIV care, 6) adherence interventions to prophylaxis and treatment regimens, and 7) linkage to wrap-around family planning programs, including counseling and support for PLHIV desiring children, and 8) alcohol assessment and counseling on reduction or abstinence. See the Prevention with Positives Technical Considerations for more detailed information.

In addition, the 2010 WHO Treatment Guidelines provide the following guidance around treatment as a prevention intervention:

“Studies continue to support the benefits of ART for prevention (*Donnell, 2010*). There is evidence that individuals on fully suppressive ART who are adherent to the therapy are less likely to transmit HIV to sexual partners. Conversely, those with unrecognized HIV infection contribute significantly to onward sexual transmission. At an individual level, ART reduces viral load and infectiousness (*Pao, 2009*). The use of ARV drugs has been proved to reduce MTCT of HIV.”

E. Cross-Cutting Issues

- *Gender* is a critical issue in care and support, with implications for the quality and effectiveness of the care provided and the disproportionate burden on women and girls to provide care. Gender norms and roles can affect women’s and men’s ability to fully benefit from all aspects of care and support. Transgender and MSM in most communities and countries have limited access to HIV prevention care and support services because of associated stigma. Furthermore in many societies, women’s restricted inheritance and legal rights and limited access to credit and to various income-generating and sustainable livelihood opportunities affect the ability of achieve the objectives of social care.

Some key programmatic and policy actions pertinent to gender and care and support include:

- Ensuring equitable access for women, transgender, and men to medicines and other care and treatment services and resources.
 - Identifying child/adolescent-headed households and care-givers, and implementing targeted programs to meet needs, including programs that keep girls in schools, help them manage households, address stigma, and compensate for lost family income.
 - Strengthening linkages with wraparound FP/RH programs for child and female-headed households as well as caregivers.
 - Implementing programs which target men and boys and encourage their participation in care-giving and household functions, their support for female caregivers and reduction of violence in the household.
 - Targeting programs for older women caregivers that provide support networks and access to income-generating resources;
- *Bi-directional referrals and linkages between facility- and community/home-based services*—As it is extremely difficult to provide all care and support services at a single HIV care site or setting, services may be provided by different partners through a continuum of **service networks with effective linkages between facility-, community-, and home-based care programs**. A facility usually represents a site where the majority of clinical services are administered, and community-based sites provide the additional non-clinical components of care and support that all contribute to ensuring the improved treatment and care outcomes of the PLHIV. Some of these community based settings serve to bridge the gap of distance and service provision from clinical facilities to the home as they can be set up to serve as outpost for bringing required clinical care nearer the PLHIV-client. They can also serve as points for mobile care services, treatment initiation, point-of-care CD4, ARV and OI distribution points.etc. In the home, caregivers should be supported by community health workers and other health professionals to continue care and support services in the home, particularly when clients are bed-ridden, lost to follow-up, or present complex situations such as pediatric clients with complex health and social support conditions;
 - In the era of ART, fewer patients may need home-based services (see below);

- Community-based services*—An increasing number of ART and pre-ART clients will need **community based services** to address their physical, psychosocial, and prevention needs. Due to the success of PEPFAR’s rapid scale up of ARTs, fewer persons are suffering from severe symptoms related to advanced HIV disease and, thus, the majority of ART clients are active participants in their communities. In addition, clients that are not eligible for ARTs may not require intense clinical care or social support at either the facility or home care level and may receive basic clinical services in non-clinical settings. In order to meet the HIV care, psychosocial and support needs stable of pre-ART and ART clients, USG teams should consider the **establishment of community level networks** to provide access to: basic clinical monitoring (CD4, TB assessment, STI screening, nutritional assessment and counseling); HIV peer support and counseling to promote healthy living; PwP services to reduce the spread of HIV and stigma associated with testing, treatment and care; and access to necessary social services (food & nutritional support, linkages to IGA and sustainable livelihood programs, RH/FP services). Community level network models have been developed and implemented, such as the ‘hub and spoke model’, by numerous countries. USG teams are strongly encouraged to examine the benefits of these models for increasing the numbers of HIV infected persons receiving care services, improving retention rates, empowering communities to provide services to their peers. To achieve this programs are encouraged to strengthen wherever possible the Hub-and-spoke model for ensuring community based programs are affiliated to a facility that provides supportive supervision of the services provided at the community level. This will further require the establishment of simple M&E tools that allow documentation and formalization of the bi-directional referrals from the facility into community based programs for support and vice versa;
- Human resources and training*—Given the need to integrate some level of clinical and psychosocial assessment and management between facilities, communities, and home-based care (C/HBC) settings, volunteer and other C/HBC providers will need to be provided for adequate access to **training programs, mentoring, and supervisory staff** to ensure quality services based on their expected roles and competencies. Best practices that enable C/HBC providers to deliver quality care and support services, with sufficient backup and/or supervision by trained professionals when necessary are essential to maintaining program quality. Innovative and traditional methods of supervision to support and promote retention of volunteer and professional staff are encouraged, such as enhancing the roles of certain health care professionals (e.g., nurses) to provide greater supervision to C/HBC workers;
- Supply chain management*—Care providers at all levels depend on the supply chain management of the health system in order to access specific drugs and supplies on a regular and reliable basis. In addition to CTX for opportunistic infection (OI) prophylaxis and medications for OI management and pain and symptom relief, providers need access to items necessary for managing clinical conditions (e.g., drug-dispensing equipment, gloves, wound-care and mouth-care supplies, HIV test kits, sterile needles). Product selection procedures, distribution systems and networks, and information-management systems are needed to provide these products. Centralized procurement mechanisms, demand forecasting procedures, and coordination between supply-chain managers and program-service managers are needed to ensure patient enrollment and continual product availability. An accountable system is necessary to protect against the misuse or diversion of opioids used for pain control. The development of a sustainable national supply management system with accountability is needed to increase service capacity to deliver effective care; consideration of use of the Partnership for Supply Chain Management System (PSCMS) for these purposes is strongly encouraged;

- *Monitoring and evaluation*—Strong monitoring systems are essential to ensure that there are measures to assess the quality of care and support programs, an integrated model of care and support, and to minimize double counting of individuals between partners and service outlets. Strategies can include the use of standard program monitoring indicators, integration of on-site supervision systems for all cadres of caregivers, development of performance and curriculum standards, use of patient/client level quality of life monitoring and evaluation tools, and application of standards in commodity/home-based care kits. Monitoring of care and support activities remains a challenging area for many reporting systems. Services can be facility-based, community-based, and/or home-based, and each can have separate, unlinked monitoring systems. Furthermore, the care and support model relies on networks, referrals, and linkages, making it essential that monitoring systems track referrals to determine if linkages and networks are working. See WHO Patient Monitoring Guidelines for HIV Care and Antiretroviral Therapy (<http://www.who.int/hiv/pub/imai/PatientGuide/en/>);
- *Counting persons receiving care and support*, as required for reporting PEPFAR indicators, has proved to be a challenge due to the multiplicity of services that are included as care and support, as well as the potential for duplicate counting resulting from individuals receiving services from more than one partner. The Care and Support TWG believes that clinical services are essential for HIV-infected persons, and the PEPFAR II indicators stipulate that, for HIV-infected persons to be counted as receiving clinical care, **at least one clinical care service must be provided**. For affected persons (family and household members, and other caregivers), at least one service in any care and support service (clinical, support, preventive) will suffice for counting purposes. Programmatically, the Care and Support TWG would hope that multiple services would be provided to both HIV-infected and HIV-affected persons; and
- *Program evaluation*—Care and support programs should include a program evaluation component to review accomplishments, challenges, enhance existing programs, and identify best practices. Evaluations will better inform scale-up and decentralization of care and treatment programs. While program evaluation in many areas of emphasis within care and support is challenging, country teams are encouraged to focus on the following priority areas:
 - Identification of barriers, challenges, and effective interventions to increase linkage to and retention of Pre-ART clients in care and support programs
 - Identification and reduction of missed opportunities for CTX and INH prophylaxis where indicated
 - Incorporation of palliative care into services (e.g. decent care, pain assessment and management)
 - Integration of care and support services in other settings (e.g. PMTCT, TB, ANC)
 - “Mapping” of care and support services to assess coverage and institutionalizing documentation of referrals and linkages to and from care programs
 - Models of service delivery: Linkages and integration across care and support sites, from facility to community-based settings
 - Adherence interventions (e.g. CTX, INH and other OI medications plus support for ART adherence)

In addition to program evaluations, countries are encouraged to conduct population-based studies to evaluate the impact of care and support programs on HIV-infected and affected individuals.

- *Disability*—**Disabled people face significant issues related to obtaining care and support around HIV/AIDS issues. They are at least at equal and often increased risk of becoming HIV positive, but far less likely than their non-disabled peer to access the care**

and services they need. Disabled people are as likely as their non-disabled peers to be sexually active, yet disability stereotyping, stigma, and poor access to information, clinical care, and support can negatively impact the ability of disabled people to get needed prevention and treatment information and services. Risk factors for HIV, such as poverty, sexual violence and abuse, illiteracy and poor access to education, amongst others, are often increased for disabled people, negatively impacting rates of HIV infection amongst disabled populations. Such issues are compounded by limited enjoyment of other human rights by disabled people in many societies, including lack of access to the justice system, poor accessibility to the wider healthcare system, limited access to credit and income-generating opportunities, and little or no respect for decision-making capacity, all issues that increase the problems faced in timely HIV/AIDS prevention and treatment. Moreover, the stigma and marginalization associated with disability can also discourage HIV positive people from self-identifying as being disabled due to their HIV status. This in turn may limit their willingness to access independent living or other disability-related services and supports that could improve their quality of life and inclusion in their community.

Some key programmatic and policy actions pertinent to inclusive disability programming in care and support include:

- Ensuring equitable and effective accessibility of medicines and other care and treatment services and resources for disabled people.
- Ensuring physical accessibility of care and treatment services and resources, and location of such facilities within reach of transportation that is accessible to persons with mobility disabilities.
- Ensuring provision of information on care and treatment options to disabled people in accessible formats, which could include: Braille; large print; plain language; audio; captioned and sign language interpreted video; and/or other accessible formats as appropriate.
- Training healthcare and outreach workers to address disability stigma and stereotyping of disabled people, and to ensure respect for the rights, dignity, and privacy of disabled people.
- Hiring disabled people as peer educators and counselors; healthcare and outreach workers.
- Working collaboratively with disabled people's organizations (i.e. civil society organizations run by disabled people themselves), including independent living centers and other disability non-governmental organizations.

2.1.3 COUNTRY CONTEXTUAL CONSIDERATIONS: ADULT CARE AND SUPPORT

Country teams should be sure to use existing epidemiologic data to plan programs, including recent DHS surveys, AIS surveys, TB prevalence surveys, MARPs size estimation surveys and antenatal care sentinel surveys. Countries may also use mapping and GIS technology to determine the geography scope of existing government and donor HIV care and support efforts and tailor programs to address gaps. In addition, strategic information should be collected, analyzed and used by the USG to determine the levels of funding for partner targets (specifically, client cost per service/s) and methods for allocation of services to locations of greatest need (specifically, mapping exercise of delivery systems to determine gaps in care areas).

2.1.4 PARTNER PERFORMANCE CONSIDERATIONS: ADULT CARE AND SUPPORT

To maximize efficiency in the field, it is critical to ensure that partners have established work plans with regular reporting methods to assure accountability for services and use of funds. Partners should prepare a pipeline analysis prior to an increase in program funding by the USG. Country teams should work with partners to ensure that they are not duplicating services, have gaps in service areas, or are unable to account for specific program activities or expenditures. Partner-level targets should be encouraged at the country level, although there may be agency differences in requirements for including such targets in the reporting.

2.1.5 LINKAGES AND WRAPAROUNDS: ADULT CARE AND SUPPORT

A wraparound activity wraps or links together PEPFAR programs with those from other sectors to provide comprehensive program support and improve the quality of life to HIV/AIDS-affected and –infected communities. Examples of and opportunities for wraparounds, linked to care and support include family planning and reproductive health programs, water and sanitation programs through local activities and linking with UNICEF and World Bank efforts, delivery of bed nets through PMI or collaborating with immunization campaigns, and partnering with food and nutrition initiatives. Wraparounds leverage resources, both human and financial, from entities with different funding sources include other programs funded by the USG (e.g., USAID Development Assistance), the Global Fund, the UN (World Food Program, UNICEF, etc.), the private sector, or other partners. In general, wraparound activities are supported with a mix of funds, primarily from sources other than PEPFAR. However, wraparound activities that directly serve PEPFAR priority populations by supporting HIV prevention or the treatment or care of PLHIV, and are in keeping with other PEPFAR guidance, may be supported with Emergency Plan funds.

2.1.6 HIGHLIGHTS AND WHAT’S NEW: ADULT TREATMENT

The technical considerations for adult treatment have been revised to present priorities for ongoing scale-up of ART in accordance with normative guidelines, while acknowledging challenging financial realities. These priorities are summarized in three categories: 1) Access and Integration, 2) Quality and Oversight, and 3) Sustainability and Efficiency. Highlights of these technical considerations include:

A. Access and Integration

- Ongoing adaptation of new WHO guidelines with emphasis on feasibility and equity of access, when determining implementation strategies for revising recommendations for “when to start” and “what to start”;
- Support for costing and modeling to inform strategies that increase program efficiency and decrease costs, while ensuring quality care delivered in a sustainable fashion;
- Integration of ART with other services, especially TB and MCH; and
- Strategies for expansion of human resources, including revision of policies for task-shifting.

B. Quality and Oversight

- Promotion of a national framework for support and supervision of ART programs;
- Support for efficient and effective algorithms for treatment failure monitoring;
- Surveys for HIV drug resistance;
- Support for a national system of pharmacovigilance;
- Aggressive approaches to improve both adherence and retention of patients on ART;
- Promotion of harmonized quality management (QM) and performance improvement (PI) activities among country teams and implementing partners, which are in alignment with national, Ministry-led, quality plans and initiatives;
- Performance measurement data used for quality improvement at the site level; and
- Standardized, periodic supportive site supervision and regular program reviews as an integral part of USG-supported ART programs.

C. *Sustainability and Efficiency*

- Alignment of PEPFAR strategies for ART with that of national programs and other donors;
- Support for transition of program implementation from international partners to local partners and ministries of health; and
- Development of a standard package of ART services to promote equity and efficiency.

As part of its reauthorization and the PEPFAR II strategy, PEPFAR was charged with supporting increased treatment targets through continued appropriations for treatment funding and the realization of greater efficiency. PEPFAR's treatment strategy over the next five years emphasizes the following:

- Directly supporting more than 4 million people on treatment;
- Scaling up treatment with a particular focus on serving the sickest patients, pregnant women, and those with HIV/TB co-infection;
- Increasing support for country-level treatment capacity by strengthening health systems and expanding the number of trained health workers; and
- Working with countries and international organizations to develop a shared global response to the burden of treatment costs in the developing world, and assisting countries in achieving their defined treatment targets.

To achieve the goals of PEPFAR II, while continuing to support quality ART services, the following technical considerations should serve as a guide to COP planning for FY 2012.

2.1.7 ACCESS AND INTEGRATION: ADULT TREATMENT

A. *National ART Guidelines and Strategy*

PEPFAR country teams should support national stakeholders in revising national ART guidance to reflect the 2010 WHO HIV treatment guidelines. Specifically, support should include encouraging policies and guidelines that promote equity in access, simplified clinical decision-making, and streamlined and cost-efficient procurement. If adoption of the new WHO ART CD4 initiation threshold (i.e., CD4 <350 cells/mm³) is not feasible, then support for prioritizing pregnant women and TB co-infected patients should be considered. As recommended by the new WHO guidelines, strategies should be developed for transitioning programs from the use of stavudine-based regimens

in first-line ART, and technical assistance should be employed to develop standardized national ART regimens and treatment protocols for 1st-line, 2nd-line and, where appropriate, salvage therapy.

The PEPFAR Adult Treatment TWG, working with several other TWGs, including Pediatrics/PMTCT, Care and Support, and SI/Modeling, can help countries develop these strategic approaches to supporting the national program.

Further guidance on implementation of the new guidelines can be found in the WHO Guide for adaptation and implementation of ART guidelines for adults and adolescents, available at http://www.who.int/hiv/topics/treatment/guide_for_adaptation.pdf.

B. Costing and Modeling

Country programs should place special emphasis on identifying and implementing strategies that can increase program efficiency and decrease costs, while ensuring quality care delivered in a sustainable fashion.

Limited funding and specific country contextual considerations may prevent widespread and rapid implementation of all WHO recommendations. Therefore, it is critical that modeling and/or other methods be used to calculate the impact of proposed guidelines changes so that a rational and sustainable plan for implementation can be formulated. To support this approach, country teams should determine the answer to the following: Given the current and projected funding streams available for treatment, and current estimates of the unit costs of providing care and treatment, what is the current projected scale-up plan, both nationally and for the PEPFAR program?

Comprehensive costing and modeling studies can provide insight into achieving greater allocatable and technical efficiency of treatment programs, and improve collaboration with host country governments, Global Fund, WHO, and other international stakeholders. Within the treatment program area, these studies are expected to provide teams with updated per-patient costs across a variety of settings, a better understanding of cost-drivers, and planning for the pace of PEPFAR-supported treatment scale-up that is supportable under varying budget and policy scenarios.

An overview of cost modeling tools is available at:

http://www.aidstar-one.com/focus_areas/treatment/ART_costing_cross_walk

C. Integration of Services

Efforts to integrate treatment services with care, prevention, and TB/HIV services will be critical to ensuring quality care while maximizing program efficiency.

Preventive Care Package:

The Preventive Care Package (see HBHC for details) should be offered at all ART sites and include:

- Cotrimoxazole Prophylaxis
- Safe water
- Malaria prevention
- TB screening (see below)
- Nutrition assessment

- Prevention with Positives (PwP)

I. Tuberculosis (TB)

Efforts to improve linkages between TB and HIV programs should include:

- Improved linkages to ART sites from TB clinics offering PITC to ART sites;
- Integration of ART services and TB treatment at both TB clinics and ART sites; and
- Within sites offering ART:
 - Intensified case-finding: Every patient should have a documented 4-question screen for TB (http://whqlibdoc.who.int/publications/2011/9789241500708_eng.pdf) at every visit to the ART facility. All patients with a positive screen should be evaluated, through a standardized algorithm, for the presence of active TB.
 - Isoniazid Preventive Therapy (IPT): Efforts should be made to ensure that IPT is available at ART clinics for all eligible patients.
 - Infection control: All ART clinics should ensure that basic administrative and environmental infection control practices are in place to protect patients and staff.
 - New guidance on Intensified case-finding and IPT is available from WHO at http://whqlibdoc.who.int/publications/2011/9789241500708_eng.pdf

II. Maternal-Child Health (MCH)

Efforts to enhance linkage between HIV Treatment programs and MCH and primary health care services could include:

- A family-centered approach to promote uptake of pediatric treatment services and encourage retention and adherence to therapy; and
- Integration of ART services and MCH services, including PMTCT and family planning.

III. Other Clinic-Based Care Services

- Ensure linkages with laboratory services needed to diagnose and monitor HIV status, opportunistic diseases, and ARV drug toxicity;
- Patients not yet ready/eligible for ART should be enrolled in an HIV care program (e.g., wellness programs) for periodic follow-up and prompt identification of ART eligibility. Use of “pre-ART” registers and/or other monitoring systems are encouraged; and
- Strengthen the scope of non-ART services onsite and establish coordinated linkages and/or delivery of these services. These could include, but are not limited to, HIV testing and counseling, HIV primary care, opportunistic infection (OI) management, TB management, family planning (FP), reproductive health (RH) planning, nutritional counseling, and linkages with home-based care, positive/secondary prevention, OVC programs, and other supportive social services.

IV. Community Services

- Community programs that serve individuals, couples, and families living with HIV offer opportunities for providing HIV testing and counseling services, and reiterating HIV prevention messages and services (e.g. alcohol and sexual risk reduction counseling, couples/partner HIV testing and counseling, disclosure counseling and support, adherence counseling, and condom promotion and distribution); and
- Community services can help patients overcome stigma, promote adherence, and provide support services for people living with HIV/AIDS (PLWHA).Community-based treatment

programs should also have a preventive care package for all HIV-infected patients that includes clinically-oriented interventions that are preventive, inexpensive, simple to implement, and evidence-based, such as cotrimoxazole (CTX) prophylaxis, measures for safe drinking water and personal hygiene, insecticide-treated nets, nutrition counseling and micronutrient supplementation where appropriate, and HIV counseling and testing of family members and other sexual contacts.

D. Human Resources

Human resource development through hiring, training, and retraining adequate staff should be addressed. Suggested approaches:

- Include both didactic training and follow-up preceptorship and mentoring to ensure appropriate application of skills to the clinical setting. Where possible, utilize quality management and performance improvement activities to support ongoing capacity building;
- Support training for all aspects of ART, including use of nurses, clinical health assistants, and others with appropriate training, for all levels of care and treatment;
- Where policies preclude the use of non-physician staff for ART (i.e., task shifting), advocate for policy changes; and
- Promote activities designed to retain existing workers in the system.

Countries should consider the regional distribution of treatment eligible persons (including vulnerable populations, such as, women, HIV/TB co-infected patients, and PWIDs), site patient loads, and other existing service delivery platforms, when planning where and how to provide HIV treatment services. Decentralization of services and task shifting to appropriately trained nurses, clinical officers, and pharmacy or other cadres may be a very effective means of expanding treatment access.

2.1.8 QUALITY AND OVERSIGHT: ADULT TREATMENT

A. Monitoring Patients for Treatment Failure

- Detection of first-line treatment failure can be challenging, and multiple potential approaches can be used (e.g., clinical, immunologic, and/or virologic criteria). Each approach involves tradeoffs either in test performance, feasibility, and/or cost. Country teams are encouraged to consult the 2010 WHO Guidelines for detecting treatment failure (http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf) and to engage technical expertise to develop an appropriate national approach to monitoring treatment failure.
 - Laboratory monitoring recommendations should be standardized to ensure equity in access for all ART patients.

B. ARV Drug Resistance

- HIV drug resistance surveillance, using PEPFAR-approved methodologies, should be in place for monitoring acquired resistance in patients on ART.

C. Pharmacovigilance

- Standardized laboratory monitoring guidelines for ART toxicity should be developed that are evidence-based and balance maximum utility of scarce laboratory resources and quality of patient care; and
- PEPFAR country teams should support development of national pharmacovigilance capacity to improve the monitoring of ART toxicity and adverse events, including provision of technical assistance.

D. Adherence and Retention

- Structured adherence programs have been shown to improve patient outcomes. All programs should include adherence approaches that optimize response to ART;
- All programs should include plans for routine assessments and evaluation of patients lost to follow-up (LTFU) and have a standard operating procedure (SOP) for addressing the issue. This should include having a system for documenting patients referred to other ART sites and their uptake at those sites; and
- Demonstrated success linking, enrolling, and retaining newly diagnosed HIV-positive individuals into HIV care and treatment services

E. Quality Management and Oversight

- Standardized, periodic on-site supportive supervision and regular program reviews should be an integral part of USG-supported ART programs. Furthermore, PEPFAR HIV programs should support the development of a national framework for quality management, support and supervision of ART programs;
- Quality management (QM) and performance improvement (PI) activities should be promoted. Efforts should also focus on integration of these activities into MOH support of sites; and
- Monitoring and evaluation efforts should support data use for program improvement at the treatment site and be consistent with and inform the national HIV care and treatment patient monitoring system.

2.1.9 SUSTAINABILITY AND EFFICIENCY: ADULT TREATMENT

A. Alignment of PEPFAR with National Program and Other Donors

In keeping with the PEPFAR commitment to the “3 ones”, ensure that: 1) the ART program is an integral part of the national ART plan and strategy, 2) program monitoring and evaluation efforts are consistent with the national plan for patient monitoring, and 3) scale-up plans are coordinated with Global Fund and other donor initiatives. If needed, technical assistance should be provided to assure continuity of Global Fund financing of ART programs.

B. ART Program Transition

A major provision of PEPFAR II is the transition of program implementation from international partners to local indigenous partners and the MOH. This transition to local partners should help make treatment programs more sustainable, may reduce the cost of providing care, and can build local leadership in the fight against HIV. Some international USG partners, including all Track 1.0 partners, are implementing plans to transition ART programs to local partners by the end of February 2012. The transition process is designed and led by the in-country USG team to assure integration into the National HIV Care and Treatment Program and Partnership Framework Implementation

Plans. This includes involving the MOH in decision-making, moving quickly on components that can be transitioned immediately, and developing monitoring and assessment strategies to ensure quality of care during and after the transition. Country teams should learn from the Track 1.0 transition and consider other parts of their care and treatment programs that could be transitioned to local partners and the types of support required before & after transition.

C. Standard Package of ART Services

Developing a standard package of ART services should be strongly considered in order to:

- Promote geographic and epidemiologic coverage to maximize equity, access, and retention in care, consistent with national priorities and plans. Geographical information systems (GIS) mapping tools may be used as a guide with technical support from HQ (especially, the Department of State), as needed;
- Promote rational use and availability of laboratory monitoring;
- Promote retention of patients at specific clinics and discourage “shopping around”; and
- Simplify partner performance reviews.

D. Other Approaches for Efficiency

Other possible approaches for increasing programmatic efficiency and deriving maximal value from funds include:

- Rational geographic distribution of partners (i.e., regionalization);
- Close evaluation of overhead, indirect costs, and partner pipelines;
- More rapid registration of generic formulations of ARVs;
- Maximizing use of generic formulations purchased by pooled procurement;
- Building the capacity of local partners to take over the role of prime partner; and
- Safely rationalizing the use of laboratory monitoring.

2.1.10 COUNTRY CONTEXTUAL CONSIDERATIONS: ADULT TREATMENT

Country teams should be sure to use existing epidemiologic data to plan programs, including recent DHS surveys, AIS surveys, and antenatal care sentinel surveys. Countries may also use mapping and GIS technology to tailor programs. In addition, strategic information should be collected, analyzed, and used by the USG to determine the levels of funding for partner targets (specifically, client cost per service/s) and methods for allocation of services to locations of greatest need (specifically, mapping exercises of delivery systems to determine gaps in care areas).

2.1.11 PARTNER PERFORMANCE CONSIDERATIONS: ADULT TREATMENT

Country teams should consider funding partners who are providing cost-effective, quality programs that adhere to the guidance and technical considerations listed above. To maximize efficiency in the field, it is critical that implementing partners have agreed upon regular reporting methods to assure accountability

for services and use of funds. Country teams should work with partners to ensure that they are not duplicating services, have gaps in service areas, or are unable to account for specific program activities or expenditures. Partner-level targets should be encouraged at the country level, although there may be agency differences in requirements for including such targets in the reporting.

2.1.12 LINKAGES AND WRAPAROUNDS: ADULT TREATMENT

A. HIV Testing and Counseling

HIV testing and counseling (HTC) is an essential component of HIV programming as a pre-requisite or minimum standard for HIV treatment, care and support, and biomedical prevention interventions. In order to reach PEPFAR and country goals for HIV treatment, care and support, and prevention, HIV testing and counseling must continue to be scaled up.

Given resource constraints, at a country level HTC strategies should maximize the identification of HIV-infected persons and serodiscordant couples and should place high priority on linking these persons with necessary and appropriate HIV treatment, care and support, and prevention services. Regions and populations of higher prevalence should take priority.

In all countries and settings, regardless of epidemic type, HTC should be offered to all partners of PLHIV. This is because of the high risk of transmission from PLHIV to uninfected partners and observed high rates of serodiscordant partnerships. Couples and partners HTC has been shown to increase uptake of ART among pregnant women, reduce HIV transmission, increase condom use, and reduce the frequency of sex acts with outside partners within serodiscordant couples. In treatment settings, all patients should be supported with safe disclosure of HIV status to sex partner(s) and other family members, and partner/couples HIV testing and counseling should be offered, as well as, ongoing support for discordant couples.

Linking newly diagnosed HIV positive patients into HIV care and treatment and retaining these persons in care is necessary to protect their health and to reduce the risk of HIV transmission to uninfected partners. However, many newly diagnosed patients either do not enroll or do not stay enrolled in HIV care and treatment services after diagnosis. Thus, strategies to ensure early enrollment and retention in care are important to maximize the health and prevention benefits of ART for persons living with HIV. Strategies for actively linking patients into HIV care and treatment services include co-location of HIV testing and ART services, CD4 testing at the time of diagnosis, physical escort by peer educators, ongoing case management, and follow-up by community health workers.

B. Prevention

HIV prevention for people living with HIV integrated into routine care is a core component of a comprehensive and integrated HIV prevention, care, and treatment strategy. National ART programs should integrate HIV prevention messages and services into the routine care offered to PLHIV at ART sites and in local communities (i.e., Prevention with People Living with HIV [PwP]).

- The large number of persons enrolled in care and treatment represents an excellent opportunity to reach those infected with effective prevention interventions. A comprehensive package of prevention messages and services includes:

- Counseling for safe disclosure of HIV status to sex partner(s) and other family members.
- HIV testing and counseling of sex partner(s) and children.
- Ongoing counseling and support for HIV discordant couples.
- Safer sex counseling (e.g. fidelity to one sex partner of known HIV status, reduction in multiple partnerships, and correct and consistent use of male and female condoms).
- Alcohol assessment and counseling on reduction or abstinence.
- Condom promotion and distribution.
- Assessment, diagnosis, and management of STIs as part of routine HIV care.
- Family planning and safer pregnancy counseling for HIV-infected women.
- Adherence counseling and support for both prophylaxis and treatment regimens.

See the PWP Technical Considerations for more detailed information;

- Prevention for people living with HIV should be integrated into care and treatment clinics and delivered during routine visits and within the community;
- Ensure all medical facilities that offer ART and antenatal services provide PMTCT and have referral mechanisms to ensure HIV-infected women and HIV-exposed children have follow-up in the HIV clinic after delivery, preferably in a family context; and
- Prevention Activities, particularly Positive Health Dignity and Prevention (PHDP) Programs
 - With increasing evidence that successful adherence to ART can reduce onward HIV transmission, it will be important to integrate evidence-based best practices from successful behavior change prevention programs into the continuum of care provided through ART programs. Where feasible, this should include linkages with community-based programs to enhance patient retention and strengthen prevention messaging.

TECHNICAL AREA 2.2: PEDIATRIC CARE, SUPPORT AND TREATMENT

Pediatric Care, Support and Treatment - Since 2009, COPs have included separate sections for pediatrics HIV care and pediatric treatment, providing structure for a comprehensive description of pediatric HIV programming and highlighting the importance in PEPFAR supported programs of efforts to support expanding access to pediatric services. This emphasis is also evident in the PEPFAR reauthorization and 5 year strategy with the mandate that USG-supported programs “provide care and treatment services to children with HIV commensurate to their representation in a country's overall epidemic”. Achieving goals for children exposed, infected or affected by HIV will require sustained commitment and leadership from governments and international organizations, as well as close collaboration and harmonization of efforts within PEPFAR technical areas that address the needs of children in resource-limited settings.

Pediatric HIV Care and Support can be defined as all health facility-based care for HIV-exposed children aimed at extending and optimizing quality of life for HIV-infected clients and their families throughout the continuum of illness through provision of clinical, psychological, spiritual, social, and prevention services. Clinical care should include early infant diagnosis, prevention and treatment of OIs and other HIV/AIDS-related complications including malaria and diarrhea (providing access to commodities such as pharmaceuticals, insecticide treated nets, safe water interventions and related laboratory services), pain and symptom relief, and nutritional assessment and support including food. Other services – psychological, social, and spiritual and prevention services – should also be provided as appropriate. Pediatric care and support services should be counted if they are provided at a facility, while community-based services should be included within programs for orphans and vulnerable children (OVC). It is important that funding for pediatric care activities is not double-counted in OVC. Pediatric TB is an important contributor to morbidity and mortality in HIV affected and infected populations. Please include all pediatric TB activities and efforts under the TB/HIV section.

Pediatric HIV Treatment – Support the government to roll out updated pediatric treatment guidelines; infrastructure development, training clinicians and other providers, clinical and laboratory monitoring of children on treatment, adherence support and strategies to improve retention in the pediatric population, development of capacity to provide laboratory services for children and detect treatment failure. Building capacity to monitor, supervise and implement pediatric HIV treatment services; promote integrated approaches to improve outcomes.

2.2.1 BACKGROUND: PEDIATRIC CARE, SUPPORT AND TREATMENT

A. Achievements

2010 WHO guidelines emphasize the need for early diagnosis and treatment of young children infected with HIV. The guidelines recommend virologic testing of HIV-exposed infants at 4-6 weeks of age and treatment of **all** HIV-infected infants and children <24 months of age regardless of their clinical status or CD4+ percentage, as well as earlier initiation of therapy for children aged 2-5 years based on CD4+ percentage or absolute count.

PEPFAR has dramatically expanded access to life-saving ART for HIV-infected children. As of September 2010, the USG supported 257,750 children on ART, representing an almost 400% increase above the 52,012 children receiving treatment in 2006. Also, much progress has been made in updating pediatric national guidelines, developing scale-up plans, and improving training curricula. Trainings, laboratories, supply chains, and information systems to support pediatric ART have also become stronger, and pediatric care and support services are improving. Many PEPFAR countries report implementation of cotrimoxazole (CTX) prophylaxis in >80% of PEPFAR-supported sites and SCMS has noted a marked increase in global procurement of CTX. Finally, linkages across PMTCT, pediatric care, support, and treatment, and orphans and vulnerable child (OVC) programs have also improved.

B. Challenges

Despite impressive achievements, there is still tremendous work to be done. Most countries fall well short of 80% ART coverage among eligible children. Of the 3,209,660 people enrolled on ART with PEPFAR support at the end of September 2010, 8% were children <15 years of age. Moreover, children who are started on treatment are generally older and at more advanced stages of disease. **Without treatment, pediatric HIV infection follows an aggressive course, with 30-40% of infected children dying within the first year of life and 50% dying by age 2 years.** Among those on treatment, retention and adherence to chronic therapies are additional challenges to improving and sustaining the continuity of care necessary for improved clinical outcomes and quality, while minimizing adverse events and costs. Pediatric HIV services are often inadequately integrated with other maternal, newborn, and child health (MNCH) services or may only be available at centralized, tertiary level facilities, making them difficult for families to access. Overcoming programmatic barriers to continuity of care and setting related targets and funding levels are essential to achieving pediatric care, support, and treatment goals.

C. Planning for the future

There is an urgent need for country programs to capitalize on advances achieved during the past few years and plan for expansion and scale-up of these pediatric HIV care and treatment services.

The key elements of a strong **pediatric care and support** program for HIV-exposed and infected children include:

- Early identification of HIV exposure and infection status;
- CTX prophylaxis;
- Provision of basic child health interventions, which include nutritional assessment and support, safe water and sanitation interventions, malaria prevention and treatment, linkage to other child survival services, and TB prevention, diagnosis, and treatment;
- Prevention and treatment of opportunistic infections (OIs);

- Appropriate pain assessment and management;
- Provision of psychological, social, and spiritual support; and
- Continuity of care/retention of HIV-infected children in care (pre-ART services).

These elements are described in the Pediatric Care and Support section of this document, and are summarized in Diagram 1.

Likewise, key elements of a strong **pediatric treatment** program include provision of ART for all HIV-infected children <2 years of age and eligible older children with appropriate pediatric formulations, as well as necessary clinical and laboratory monitoring and adherence support (see Diagram 1). These elements, which are addressed further in the Pediatric Treatment section of this document, will require:

- Implementation of the 2010 WHO pediatric treatment guidelines;
- Scale-up of pediatric HIV services through health system strengthening; and
- Strengthening follow-up, clinical and laboratory monitoring, and retention of enrolled children.

Planning for the next 5 years must be informed by accurate costing data based on pediatric burden of disease, the most recent guidelines, recommended first and second line regimens, optimal diagnostic and monitoring needs, provision of basic care and support packages, and funding projections. Scale-up plans for pediatric HIV services should be carefully described, including development of both national and program targets, as well as implementation strategies for expansion of comprehensive quality services, with an emphasis on early identification of HIV exposure and infection status, early initiation and expansion of pediatric ART, CTX prophylaxis, improved follow-up, tracking, linkages to and retention in care and treatment, and delivery of other key components of the basic preventive care package. Concentrated efforts at the country level need to be taken to ensure that care, support, and treatment services for children are discussed and planned for as an integral part of national and USG-supported programs. USG-supported partners need to include plans to provide national, district, and/or site-level support to build capacity of health care systems and provide quality care and support services for children. Harmonized approaches and standardized packages of services for children should be developed across USG-partners and programs.

2.2.2 PEDIATRIC CARE AND SUPPORT

A. *Early Identification of HIV-Exposure and Infection Status*

Implementation of early infant diagnosis (EID) and follow up is critical to provide early initiation of life-saving ART for all HIV-infected children <24 months of age. Urgent, provider-initiated testing and counseling (PITC) should be routine for any infant or child presenting to a health facility. We should not miss any opportunity to test a child because **infants born to HIV-infected women are lost to follow-up at very high rates and are at extremely high risk for death due to a mortality rate of ~50% in the <24 month age group.**

Successful scale-up of EID in national programs requires protocol development, planning, expanded lab capacity, decentralized testing, reliable sample transport and return of results to families, training of lab and care providers, and linking to clinical care and treatment. Implementation of these services requires a paradigm shift in service provision from a vertical, episodic model to integrated, longitudinal service delivery. National lab plans will need to address staffing, space, storage capacity and quality assurance and control. Data collection capacity will need to expand as EID programs are

an important source of data for program impact assessment. USG teams should work closely with MOH and other stakeholders to ensure the appropriate and timely use of quality data derived from EID.

HIV antibody testing in infants and children is being expanded gradually and this scale-up needs to be maintained because the majority of children with HIV are currently not identified through PMTCT or EID programs. In addition, most testing algorithms for HIV-exposed infants identified through PMTCT/EID include HIV antibody test at 9, 12 and/or 18 months of age; therefore this testing modality is essential also for quality EID and infant follow-up as well.

Key strategies for early identification of HIV exposure and infection status should:

- Ensure that pediatric HIV testing and counseling policies, algorithms, guidelines, and/or implementation plans consistent with recent WHO guidance are available in country. Guidelines should include family testing and harmonized strategies for case management and referral of sick children at both community and facility levels (see WHO case management & IMCI recommendations at www.who.int/child_adolescent_health/documents/imci/en/index.html);
- Establish and document HIV exposure status in all infants at first contact with the health system, ideally at birth or before 6 weeks of age. National programs should implement the use of updated mother/child health cards that include essential HIV information;
- Scale-up HIV virological testing (PCR testing with dried blood spots [DBS] or plasma) for HIV-exposed infants at 4–6 weeks of age. Country programs should work with the Ministry of Health to develop/update 5 year EID scale-up plans;
- When PCR is not available, utilize algorithms based on serology, clinical exam, history and WHO recommendations, with the aid of CD4⁺ and total lymphocyte count (TLC) as available;
- Adopt guidelines that recommend repeat testing for children who test negative but have ongoing HIV exposure through breastfeeding and for children who test positive by antibody test before 18 months of age or present with signs or symptoms that may be due to HIV infection;
- Because many HIV-infected children are not identified through EID, and because many childhood diseases can represent manifestations of HIV infection, implement universal PITC in inpatient pediatric wards, malnutrition clinics, and TB clinics, as well as other out-patient settings;
- Routinely inquire about whether adults or children already enrolled in HIV care and treatment services have children or siblings who have not been tested for HIV. If so, offer PITC for those children;
- Ensure that national programs and supported partners train health care providers on pediatric PITC;
- Increase the linkages with orphan and vulnerable child (OVC) programs to ensure that the health and HIV needs of OVCs are being addressed;
- Include pediatric populations when validating rapid testing algorithms and use finger-stick blood collection for children whenever possible; and
- In many countries the Clinton Health Access Initiative, funded through UNITAID, has been the main procurer of EID reagents and supplies. As funding through this program comes to an end, country programs will need to ensure that funds and procurement mechanisms are in place to provide a secure, uninterrupted stream of EID reagents, supplies, and logistic support.

B. Cotrimoxazole (CTX) prophylaxis for HIV-exposed and infected children

At an estimated cost of at US \$0.03 per child per day or US \$10/year, provision of CTX to HIV-exposed/infected children is the most cost-effective non-ART intervention to reduce morbidity and mortality due to HIV and AIDS, and CTX can be a lifesaving intervention for those children who experience delays in necessary initiation of ART.

In 2006, WHO published recommendations on the use of CTX prophylaxis for HIV-exposed and infected children. Despite abundant evidence for the lifesaving benefits of CTX, provision and monitoring of CTX remains extremely limited. Though national policies exist, challenges for scale-up include missed opportunities to identify HIV-exposed / infected infants and children, lack of sufficiently detailed national operational plans for scale-up, limited maternal, newborn, and child health (MNCH) or other platforms from which to effectively roll out CTX programming, inadequate training and monitoring systems, inadequate procurement and distribution (including limited forecasting and frequent stock outs due to use for other purposes), limited job aid dosing tools, and inadequate community and provider understanding of the importance of this highly effective intervention. This intervention should be linked to PMTCT programs, EID, MNCH, and home-based testing efforts. For more detailed guidance regarding CTX in infants and children, see the WHO's guidance on CTX prophylaxis for HIV-exposed and HIV-infected infants and children (<http://www.who.int/hiv/pub/plhiv/ctx/en/index.html>).

Key strategies for scaling up CTX prophylaxis for HIV-exposed and infected children should:

- Ensure that carefully-written CTX policy and guidelines for HIV-exposed/infected children are available in country, and that they are consistent with WHO guidelines. Scale up nationwide coverage of CTX prophylaxis so that:
 - All HIV-exposed children receive CTX beginning at 4-6 weeks of age and continue until HIV is excluded
 - All children <5 years of age diagnosed with HIV receive CTX and continue until at least 5 years of age if WHO immunologic and clinical criteria are met
 - Children >5 years of age diagnosed with HIV receive CTX in accordance with current pediatric and adult guidelines;
- Integrate CTX with MNCH services and include HIV exposure status/receipt of CTX in the child health card;
- Given that PEPFAR indicators track CTX provision and coverage, consider setting targets for CTX coverage to drive country programs; and
- In many countries, the Clinton Health Access Initiative, using UNITAID funds, has been the principal purchaser of CTX for children. As this program transitions out, countries will need to ensure that adequate funding for CTX is included to minimize the risk of stock-outs. USG teams should be closely involved in working with other donors and national programs to ensure that this low-cost intervention remains readily available to programs.

C. Basic child health interventions for HIV-exposed, infected, and affected children

Provision of a minimum set of evidenced-based interventions or a package of integrated services for HIV-exposed/infected children is described in both the PEPFAR PMTCT/Pediatric HIV/MNCH Integration Guidance (see Diagram 1 below) and the Basic Care Package for Children. Each country should adapt these recommendations to suit its context. Country teams will need to develop appropriate plans to leverage and coordinate funding and technical expertise between PEPFAR and

other USG and non-USG partners to assure key child health services are delivered. Examples of key care interventions include but are not limited to:

I. Nutritional assessment, counseling, and support (NACS)

Nutrition status plays a crucial role in the health and development of infants and children infected or affected by HIV. Most nutrient requirements are the same for HIV-infected and uninfected infants and children, although children born to HIV-infected parents are at documented substantially greater risk of growth faltering and malnutrition. WHO has recently developed *Guidelines for an Integrated Approach to Nutritional Care of HIV-Infected Children (6 Months to 14 Years)* (2009), which are meant to be integrated within IMCI in clinic settings.

Examples of pediatric nutrition interventions that should be integrated within PEPFAR programs include:

- Anthropometric, biochemical, clinical, dietary and household food security assessment;
- Provision of counseling based on WHO and national infant feeding, nutrition and WASH guidelines;
- Provision of complementary feeding support for all infants from 6 months up 24 months of age, and therapeutic or supplementary feeding support for children with evidence of growth faltering;
- Provision of multi-micronutrient supplements for children whose diet is unlikely to meet vitamin and mineral requirements;
- Routine vitamin A and zinc supplementation and control of intestinal parasites (e.g. anthelmintics) as per national childhood health programs; and
- Nutrition surveillance, referral and tracking systems for children in nutritional assessment, counseling, and support (NACS) and care and treatment programs.

For additional detail, refer to the Food and Nutrition and PMTCT Technical Considerations.

II. Safe water, sanitation, and hygiene interventions

These interventions serve as the cornerstone for infection prevention in household, community, and health facility settings. Integration of interventions such as the following into both family and health worker behaviors offers the opportunity to prevent sepsis, diarrhea, pneumonia, and other life-threatening illnesses common among HIV-infected infants and children as well as the broader pediatric population:

- Provision of simple, low-cost, high impact interventions to reduce the burden of diarrhea on the nutritional and health status of HIV-exposed/infected children and ensure access to safe drinking water in facility-based and household settings (e.g. bleach/hypochlorite product, water storage in appropriate container, soap, hand washing and hygiene education); and
- Ensuring that treated water is used for preparation of nutrition products (complementary foods, formula).

III. Malaria prevention and treatment

- Distribution and use of ITNs in households of persons with HIV, pregnant women, and children < 5 years of age; and
- Malaria screening and treatment as part of routine child health care.

IV. Referral and follow-up for routine child health and survival services

- Newborn resuscitation and care (thermal care, hygienic cord care, prophylactic eye care);
- Complete and timely immunization;
- Case management of diarrhea, pneumonia, and sepsis;
- Growth and development monitoring; and
- Community outreach efforts for follow-up and ongoing care.

V. Prevention, diagnosis, and management of tuberculosis (TB)

Children living with HIV have a higher risk of developing primary TB and have more rapid progression and poorer outcomes than HIV-uninfected children. Diagnosis of TB is more difficult in children, and TB-HIV programming for HIV-infected children and TB case-finding among children of TB-infected adults has received less attention. Emphasis and priority should focus on:

- Scaling up HIV testing of children with TB;
- Enhanced case finding of TB in HIV-infected children (e.g. routine screening for TB in children and their family members);
- Active case finding among HIV-exposed/infected children with adult family and household members with TB;
- TB infection control; and
- Improving capacity for TB diagnosis in children, including activities that support evaluation of new diagnostic techniques in pediatric populations.

For more information on TB, see HIV/TB Technical Considerations.

D. *Prevention and clinical management of other opportunistic infections (OI's)*

Pediatric programs should support nationally recommended approaches to diagnosis and management of OI's and co-morbidities, and should ensure that these approaches are consistent with WHO guidance, when available. In 2010, WHO published guidance on the management of diarrhea and pneumonia in HIV-infected infants and children

(www.who.int/child_adolescent_health/documents/9789241548083/en/index.html) and WHO is updating guidance for prevention, diagnosis, and management of other common OIs and co-morbidities. Information on the management of sick children in both community and health facility settings is available on the integrated management of childhood illness (IMCI) website, including how to approach HIV testing, preventive care and OI treatment.

(http://www.who.int/child_adolescent_health/topics/prevention_care/child/imci/en/index.html).

E. *Palliative care*

Palliative care usually requires a multidisciplinary team approach that aims to improve the quality of life for children and their families through prevention of and relief from pain and suffering. Interventions and services include the early identification, assessment, and treatment of pain and other symptoms, through physical, psychosocial, and spiritual approaches. These services are provided at the facility, community, and household levels and are crucial through the disease continuum for both the child and family, from diagnosis to bereavement support. Special attention should be given to:

- Careful pain assessment and management for children within care programs; and

- Development and implementation of appropriate access to opioids for children, as well as related policies and education.

F. Psychological, social, and spiritual support

There are special considerations and challenges for pediatric and adolescent populations when addressing psychological and social support needs. All programs should make provisions to work with families and caregivers to provide the support children and adolescents need. Children growing up and entering puberty with perinatally-acquired HIV and adolescents with new sexually-acquired HIV need additional support, and such support should be well-linked with OVC services. Examples include:

- Support groups for children, adolescents, caregivers and families;
- Support for disclosure and informing about HIV and treatment and care adherence;
- Forums to address caregivers concerns and needs;
- Community and home-based services; and
- Broader, government-affiliated social support services.

G. Retention of HIV-infected children in care (i.e. continuity of care in pre-ART services)

Although the WHO 2010 guidelines for initiation of treatment will significantly increase the number of children eligible for treatment, there will still remain some children who are not eligible for treatment initiation. However, these children will still require routine follow-up visits and programs will need to institute services to ensure that they are retained in care. Routine review of medical records is an important activity that programs need to institute to identify children lost to follow-up.

H. Pediatric Care and Support Targets

The PEPFAR reauthorization states that USG-supported programs must “*provide care and treatment services to children with HIV commensurate to their representation in a country’s overall epidemic*”. To establish country-based targets, accurate pediatric data must be obtained using modeling that accounts for incidence and prevalence estimates of pediatric HIV as well as estimates of care and treatment needs. Baseline estimates of children in need of care and treatment by country are available in the Children and AIDS Fifth Stocktaking Report, 2010 (http://www.unicef.org/publications/index_57005.html).

Target-setting for pediatric indicators should include consideration of the number of HIV-infected and HIV-exposed children that are in the country, and should build on current achievements. If the number of children receiving a care or support service has grown over the past year at 5%, then the targets for FY2012 should use that growth level as their minimum target for the year. Targets should be developed for the following indicators:

- Number of children <18 provided with a minimum care service;
- Number of HIV-positive children <15 who receive a minimum of one clinical service;
- Number of children <15 who receive cotrimoxazole prophylaxis; and
- Number and percent of infants who received an HIV test within 12 months of birth (the EID indicator).

2.2.3 PEDIATRIC TREATMENT

Improving access to and quality of pediatric ART programs continues to be a priority for the next phase of PEPFAR. Several distinct efforts are required to accomplish this, and include: (1) implementation of updated treatment recommendations for infants and children; (2) scale-up of pediatric HIV care and treatment services through health system strengthening; and (3) strengthening the follow-up, clinical monitoring, retention, and adherence support for infants, children, and adolescents enrolled in care and treatment services.

A. *Implementation of updated (2010) treatment recommendations for infants and children*

- **Initiate ART for all HIV-infected children <24 months of age.** The 2010 WHO treatment guidelines recommend treating all HIV-infected children <24 months of age. This recommendation was based partially on data from the Children with HIV Early Antiretroviral Therapy (CHER) trial conducted in South Africa, which revealed that the risk of death was 76% lower in HIV-infected infants (less than 12 months of age) who received immediate treatment compared to the risk among infants whose treatment was delayed until CD4% values fell below 20% (Violara A, Cotton M, Gibb D. Early antiretroviral therapy and mortality among HIV-infected infants. *New Engl J Med* 2008; 359:2233-2244) and on the high mortality of HIV-infected children 12 to 24 months of age. These data and guidelines underscore the importance of early diagnosis and treatment of HIV infection among HIV-infected children in the first 24 months of life, regardless of CD4 count and clinical status.
- **Revised immunologic thresholds for initiating ART in children ≥2 years of age.** All HIV-infected children with WHO clinical stage 3 or 4 disease should initiate ART. Additionally, the 2010 WHO treatment guidelines recommend earlier initiation of therapy for children over two years of age, as follows:
 - 2-5 years: CD4 ≤25% or ≤750 cells/mm³
 - >5 years: CD4 ≤350 cells/mm³ (same as adolescents/adults)
- **Recommended first-line regimen for HIV-infected infants (age <12 months) exposed to nevirapine (NVP).** 2010 WHO guidance on optimal first-line ART regimens for HIV-infected infants exposed to single dose NVP (or other non-nucleoside reverse transcriptase inhibitor-containing maternal antiretroviral therapy regimens) states that a protease inhibitor-based triple antiretroviral therapy regimen should be used as part of a three drug combination regimen. However, it is recognized that in many resource-constrained settings, lopinavir/ritonavir is not available, affordable, or feasible for use. In these situations, whatever regimen is available should be used and initiation of treatment should not be delayed.

While many countries have made or are in the process of making changes in their pediatric guidelines to include 2010 recommendations, support is needed to develop appropriate job aids and training materials for their implementation at clinical sites.

B. *Scale-up of pediatric HIV care and treatment services through health system strengthening*

- Scaling up pediatric HIV care and treatment services is partly dependant on strengthening pediatric diagnostic services (see Pediatric Care and Support) as well as follow-up and referral systems (see #3, below). Further work to scale up pediatric HIV care and treatment services includes system strengthening at national, provincial, district, and site levels as follows: Support the decentralization of HIV treatment services for children:

- Support for development of clinical services for children at mid and distal levels of the health care system
- Support policies, training and ongoing mentoring for nurses to initiate and maintain children on ART, with periodic supervision by a pediatrician or other qualified physician, as needed
- Strengthening national programs and health care systems to expand pediatric services:
 - Provide support for a pediatric HIV team within the National HIV Program.
 - Create or support pediatric specific technical work groups at country level with implementing partners and stakeholders to support rapid development of tools, disseminate findings, best-practices and data collection instruments
 - Support collaborative work between pediatric, PMTCT and maternal, newborn, and child health (MNCH) programs to ensure integration of pediatric HIV services at all levels of the health care system
- Strengthening regions and districts:
 - Encourage implementing partners to develop regional and district approaches for provision of preventative, clinical, and community-based services for children and their families.
 - Work with national programs to strengthen regional and district public health teams monitor and supervise pediatric program service roll-out
- Strengthening the pediatric HIV capacity in USG country teams:
 - Include members with expertise in pediatric HIV care and treatment in country teams
 - Address pediatric specific issues in all relevant USG funded activities/programs (e.g.: TB program pediatric issues, adolescents, etc)

C. Strengthening the follow-up, clinical and laboratory monitoring, and retention of children enrolled in care and treatment services to ensure continuity of care

Early referral to care, on-going clinical assessment and monitoring, and retention in care and treatment services are essential. Programs should assess barriers and challenges to retention in care and implement measures to address these. Additional critical monitoring and assessment issues include:

- Site-specific tools for tracking exposed and infected infants and children such as child health cards with integrated HIV information
- Longitudinal medical records across the care continuum: Countries should work with implementing partners and national programs to develop appropriate medical record-keeping approaches to enable follow-up of HIV-exposed/infected children (clinical care forms) and data recording across health facility, outreach/referral, and community-based activities.
- Close follow-up from PMTCT sites, including community support for identification, follow-up, referral, and linkage with facilities
- Age-appropriate clinical and laboratory monitoring for patients in care or on treatment including:
 - CD4 % and counts
 - Assess for toxicities and adverse events
 - Response to therapy or failure
 - Adherence support strategies
- Retention into care issues (e.g.: financial and social barriers; access; transitioning care, etc.)

D. Pediatric Treatment Targets

The PEPFAR reauthorization states that USG-supported programs must “*provide care and treatment services to children with HIV commensurate to their representation in a country's overall epidemic*”. To establish country-based targets, accurate pediatric data must be obtained using modeling that accounts for incidence and prevalence estimates of pediatric HIV as well as estimates of care and treatment needs. Baseline estimates of children in need of care and treatment by country are available in the Children and AIDS Fifth Stocktaking Report, 2010 (http://www.unicef.org/publications/index_57005.html).

Targets for pediatric treatment should take into account the number of children in the country who are eligible for ART, but should also be developed by reviewing the previous years' achievements in initiating children on ART. Targets should be a blend of the realistic and the aspirational.

Targets should be developed for the following indicators:

- The number of children <1 and <15 who are newly initiated on ART; and
- The number of children <1 and <15 who are receiving ART (current)

It is highly desirable for country programs and USG-supported partners to gather age-disaggregated data for the pediatric population in care or on treatment.

2.2.4 CROSS-CUTTING AREAS: PEDIATRIC TREATMENT

These are areas where attention to the special needs of pediatric populations is required in order to provide quality services for HIV-exposed and infected children and include:

A. Laboratory capacity to support pediatric HIV programs

- To ensure early diagnosis of HIV in infants, children and adolescents, countries should:
 - Develop PCR capability and expand systems for dried blood spot (DBS) testing for infants
 - Strengthen EID laboratory and specimen collection, transport, and delivery procedures and result turn-around times. Evaluate system effectiveness. Capacity should be strengthened at reference centers and nationally
 - Expand the use of HIV-rapid antibody testing in children (e.g. finger stick sample collection)
 - Develop QI/QA systems for EID and PITC
- To ensure appropriate disease staging and treatment monitoring capacity, countries should:
 - Ensure availability of CD4 cell counts and percentages, as well as hematology and biochemistries
 - As viral load capacity is developed in countries, make this laboratory monitoring test available to the pediatric population
- Strengthen integrated laboratory service capacity for diagnosis of opportunistic infections and other infectious complications in children.
 - Expand diagnostic testing for other common, life-threatening childhood diseases: Malaria, TB, sepsis, etc

B. Supply chain management, procurement of drugs and supplies, and costing

Important procurement and supply chain management considerations for pediatric commodities include:

- Coordinate procurement with national programs, Global Fund, Clinton Foundation and PMI;
- Special considerations for pediatric ARVs, including new regimens for infants, liquid formulations, pediatric fixed dose combinations, age-specific dosing, etc.
 - Pediatric FDCs are preferable for implementation in resource-limited settings, and while most of them are of acceptable quality, providers should consult the WHO document *Access to HIV/AIDS drugs and diagnostics of acceptable quality* for guidance (<http://www.who.int/hiv/amds/selection/en/index.html>);
- Increased demand for EID and HIV-rapid test commodities;
- Need for PMTCT combination or single drug regimens during infancy;
- Need to expand CTX prophylaxis, procurement of other drugs to prevent or treat OI's, provide appropriate pain management and symptom relief (e.g., opioids);
- Procure appropriate supplies to measure and dispense oral solutions (e.g., measuring spoons, syringes);
- Commodities to collect or process pediatric blood samples;
- Lab equipment capable of processing small amounts of blood for regular hematological, biochemical analysis and CD4 testing;
- ARV costing studies that estimate pediatric-specific costs within country programs; and
- Efforts to assist countries streamline pediatric formulations to reduce redundancies and facilitate forecasting are essential cost-saving activities. As the Clinton Health Access Initiative transitions out of pediatric ARV procurement work with in-country stakeholders, it is critical to secure pediatric ARV supply chain management.

C. Human capacity development (HCD)

An important barrier to the expansion and scale-up of pediatric HIV programs has been the lack of sufficient numbers of health care providers with expertise and confidence in the management of or provision of services for HIV in children. This continues to be a factor in the ability to expand services for children in 2010.

Efforts to strengthen appropriate skills among existing health care providers at all levels of the health care system are critical to significantly increase the numbers of children receiving quality health care services. To effectively build capacity, training per se is but one of several key steps. A comprehensive approach is essential, including: training; facilitation of trainees with resource materials & apparatus; follow-up of the trainees; mentorship; and supportive supervision. At the country level, programs will therefore need to:

- Improve the capacity of existing health care providers to deliver comprehensive health care services to children, including HIV testing and counseling, disclosure support, HIV care and treatment and home-based care services. This can only be accomplished using a comprehensive HCD strategy;
- Cross-train health care providers in MNCH, Family Planning, PMTCT, TB, etc;
- Shift tasks to non-physicians, including updating related policies and training health/clinical officers and nurses to initiate/monitor ART;
- Integrate pediatric care and treatment modules into in-service and pre-service training for all health care providers;
- Train and mentor health care providers with emphasis on:
 - Provision of follow-up services for HIV-exposed infants
 - HIV testing and counseling for infants, children and adolescents
 - Disclosure and adherence support

- CTX prophylaxis in children
- ART in children and adolescents
- Increase availability and capacity to provide care and treatment services for adolescents
- Develop capacity to transition adolescents to adult services as this population matures, including approaches to transfer relevant clinical information from pediatric to adult treatment sites;
- Use experienced staff and sites as resources to train new cadres of health care providers, including hands-on mentoring, which is essential to create a cadre of workers with confidence to manage pediatric HIV; and
- Emphasize pre-service training for new clinical and laboratory staff.

D. Need for improved program monitoring and evaluation

The expansion of pediatric HIV services requires the parallel development of capacity for program monitoring and evaluation. There is the need to support a unified and integrated national system for pediatric HIV monitoring in order to: (1) Standardize data collection and monitoring procedures; (2) Provide information to evaluate program performance; and (3) Facilitate reporting of sub-national, national and international Pediatric HIV indicators

To optimize monitoring of pediatric (and other) programs, PEPFAR programs must:

- Actively participate in the regular review of country data along with MOH, national technical groups, and partners;
- Use data from EID services. Despite the rapid growth of access to EID services, few countries are collecting relevant PMTCT and pediatric program data from EID. Efforts to improve EID as an important source of programmatic data are essential and include
 - Harmonized requisition forms that include essential PMTCT and pediatric program data elements
 - Routine analysis and dissemination of data in country;
- Provide technical assistance to MOH and implementing partners for pediatric HIV monitoring;
- Develop data collection mechanisms for follow-up across facility, outreach/referral, and community-based programs;
- Support training, supervision to sites, TA to MOH for data management, quality assurance, analysis and feedback to sub-national levels and sites;
- Plan to conduct routine program evaluation, including outcome based studies of their Pediatric HIV programs. As the number of children on prolonged treatment increases, so does the need to have effective ways to monitor this population to detect early warning signs related to the emergence of resistance in treated populations (acquired resistance);
- Evaluate and disseminate best practices across PEPFAR-supported countries; and
- Support national activities to evaluate the quality of services provided to children.

E. Need for pediatric HIV surveillance activities

There continues to be a need to have more accurate estimates of the HIV epidemic in the pediatric population, and countries should include pediatric components in surveillance efforts/activities.

2.2.5 COUNTRY CONTEXTUAL CONSIDERATIONS: PEDIATRIC TREATMENT

Countries should consider the HIV epidemic, in-country logistical challenges and existing MCH service delivery platforms when planning where and how to provide pediatric HIV services. Decentralization of services and task shifting to appropriately trained nurses or clinical officers may be a very effective means of reaching children who may not otherwise be able to access pediatric HIV services, as such services are currently largely located at tertiary care health facilities rather than in community health centers or health posts.

It is crucial to use existing epidemiologic data to plan pediatric HIV programs, including the most recent estimates of infected children, updated annually in the WHO/UNICEF/UNAIDS-authored *Universal Access Report*. (Link: <http://www.who.int/hiv/pub/2009progressreport/en/index.html>) Target setting for pediatric HIV care and treatment is challenging as data for strategic planning are often not readily available. For those desiring assistance in this regard, TA is available to country teams via the PEPFAR PMTCT/Pediatric HIV TWG.

2.2.6 PARTNER PERFORMANCE CONSIDERATIONS: PEDIATRIC TREATMENT

To maximize efficiency in the field, it is critical to ensure that partners are not duplicating work. Country teams should work with partners to ensure they are using up-dated materials whenever possible and that efforts are harmonized with host country priorities and national goals. In addition, country teams should ensure that partners are devoting sufficient time and effort at national, district, and site levels to address the needs of the pediatric population.

2.2.7 LINKAGES, WRAPAROUNDS, AND INTEGRATION: PEDIATRIC TREATMENT

The scaling up of effective pediatric HIV care, support and treatment services cannot be achieved without linkages, wraparounds and integration with other related sectors and services. Each offers an opportunity for early identification, enhanced care and treatment and improved retention in care for the child and the family. Additionally, this allows for access to services not traditionally provided by pediatric HIV programs to the child and family, resulting in more comprehensive care and support services. Country programs should work with partners to ensure effective linkages exist among partners so patients can effectively access all needed services. In most countries, the efficiency of such linkages, wraparounds, and integration will be greatly enhanced if HIV planning is coordinated with evidence-based planning and prioritization processes that are occurring within country for MNCH, FP/RH, etc. These include but are not limited to use of tools such as Marginal Budgeting for Bottlenecks, Lives Saved Tool, RAPID, SPECTRUM, etc.

Linkages and wraparound programming can assist with identification of infected children and provision of care, treatment and support to children, adolescents, and their families. PEPFAR country teams are encouraged to identify opportunities for integration within their programming and areas where integration is critical to ensure the provision of a recommended package of integrated pediatric services (Diagram 1) for all exposed and HIV infected infants which may also result in improved care for all children (HIV

positive and negative). Great potential exists for integration of pediatric HIV services with PMTCT, MNCH, malaria, TB, water/hygiene, sanitation, and adult HIV activities. This should occur at the home, community, and facility level. For example, adults currently enrolled in TB or HIV treatment programs may have children at home who should be HIV tested and who are at high risk for disseminated TB due to exposure to co-infected parents or caregivers. Without appropriate linkages these children will remain undiagnosed and at high risk.

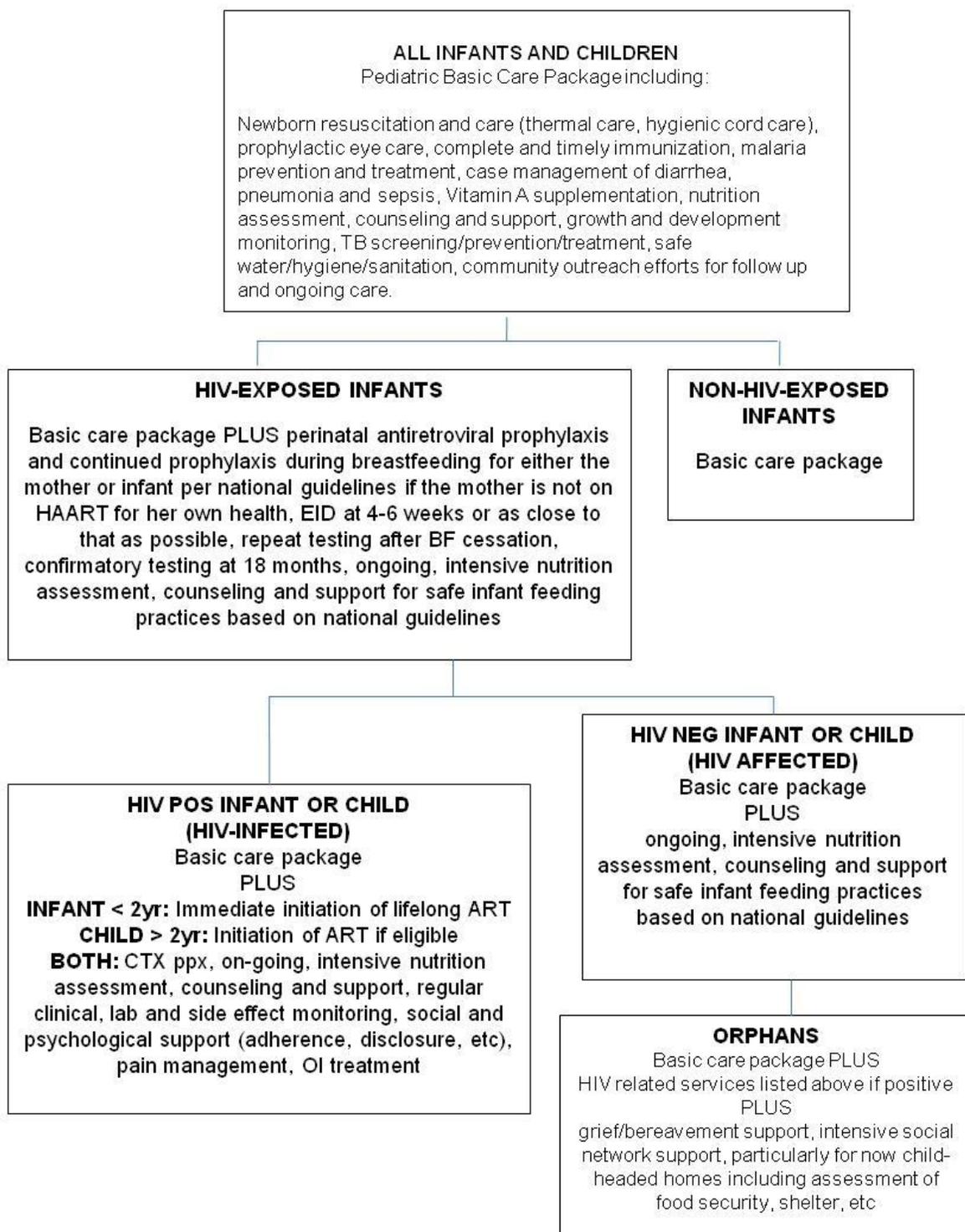
There is an increasing need to focus efforts to address the care and treatment needs for adolescents. Expanding work to support youth-friendly services at all levels of the health care system are necessary. Inclusion of specific prevention with positives, adherence support, and reproductive health interventions are increasingly important for USG and country programs.

In many countries, there may be sufficient rationale for integration. An initial needs assessment and a subsequent action and evaluation plan should be developed to effectively deliver integrated services. Countries that have more successfully integrated activities usually had a champion for integration that had decision-making capabilities as well as a national-level team to spearhead this effort. Such a national team often arose naturally from existing in-country coordinating bodies. A general framework for thinking about integration is provided in the PEPFAR Guidance on the Integration of PMTCT, Pediatric HIV and MNCH Services produced by the PMTCT/Pediatric HIV TWG.

Examples of specific activities that can be undertaken within an integrated package include:

- Identification of HIV-exposure and PMTCT services received on child's road to health card;
- Early infant diagnosis and provision of CTX prophylaxis for exposed and infected children at child health clinics (immunization, well-baby and out-patient) and inpatient wards;
- Ensure basic care packages for infected mothers and children includes MNCH services
- Increase cross-training opportunities for all HIV and MNCH staff;
- Integration of PITC, preventive care, and OI treatment into routine MNCH services and in management of sick children at the primary health care level;
- Collaborative planning and communication among pediatric, PMTCT and MNCH programs to ensure integration of HIV services at all levels of the health care system;
- Coordination with home-based care and OVC programs including identification of HIV + children, care and treatment adherence support and follow-up, educational, psychological and nutritional support, economic strengthening, shelter, legal protection, and food security; and
- Screening, diagnosis and treatment of children and families with TB and latent TB infection in accordance with host country National TB Program guidelines and TB/HIV testing of children in TB-affected households.

Diagram 1: Essential Components for Pediatric HIV Support, Care and Treatment



TECHNICAL AREA 2.3: ARV DRUGS

2.3.1 ARV DRUGS TECHNICAL CONSIDERATIONS

- A. A point person for supply chain management, including ARV drugs, should be considered. This person should be responsible for assuring competitive drug procurement and ensuring adequate ARV drug stores are maintained for partners and possibly the host government.
- B. All USG teams are strongly encouraged to use the Partnership for Supply Chain Management (SCMS) for ARV and other commodity procurement, when present systems are not adequately functioning. SCMS can provide the full scope of supply chain management services, including overall management, procurement (including drug forecasting), freight and freight forwarding, quality assurance, information systems management, and in-country technical assistance and support of national supply chain systems, as well as, obtain lowest reported prices for all ARVs, generic or innovator, by leveraging the economies of scale created by USG pooled procurement.
- C. It is clear that there are still cost savings to be found in some countries through greater procurement of generic ARVs rather than branded ARVs and through greater pooled procurement. PEPFAR country teams should carefully monitor both the procurement plans of partners and variability of ARV prices in comparison with the annual ARV survey to ensure that generics are procured to the greatest degree possible and that procurement agents are consistently obtaining the best possible prices for ARVs, including costs of shipping and handling.
- D. In addition, USG teams should promote the development of detailed national and/or USG procurement plans (if not already done) and promote strengthening of national supply chain systems to forecast, procure, manage, distribute, and assure quality of a wide range of HIV-related commodities.
- E. A number of factors, including variable funding flows and procurement and supply management issues at the country level, can undermine the availability of critically important medicines at the country level, including antiretroviral drugs (ARVs) in HIV/AIDS programs. Additionally, unanticipated “emergency” situations such as natural disasters or conflict can threaten the availability of ARVs in a country. This can hamper overall program efficiency by encouraging the maintenance of large buffer stocks across multiple countries. In response, PEPFAR has established an Emergency Commodity Fund (ECF) to respond to such emergencies and assist in maintaining the continuity of essential HIV/AIDS treatment, with support provided on a short-term basis (less than one year) to address imminent stock-out needs, based upon availability of supply. USG teams should familiarize themselves with eligibility criteria to access the ECF and plan an appropriate level of buffer stock accordingly. Please note that this fund does not replace the need for buffer stock within a country. Country teams should continue to plan and program for acceptable levels of buffer stock according to sound forecasting and management principles.
- F. ARVs purchased with PEPFAR funding must have FDA-approval or FDA-tentative approval. With recent changes in ADS 312.5.3.c, source-origin waivers are no longer necessary for non-ARV pharmaceuticals, but may require a restricted commodity approval. More information can be found at: http://www.usaid.gov/our_work/global_health/aids/TechAreas/treatment/scms.html.

TECHNICAL AREA 2.4: TB/HIV

TB/HIV (HVTB) – includes exams, clinical monitoring, related laboratory services, treatment and prevention of tuberculosis (including medications), HIV testing and clinical care of clients in TB service locations, TB screening, and diagnosis, treatment and prevention of TB in PLWHA. Funding for these activities, including commodities and laboratory, should be included in the TB/HIV budget code rather than other budget codes. The location of HIV/TB activities can include general medical settings, HIV/AIDS clinics, home-based care and traditional TB clinics and hospitals. Pediatric TB/HIV services should be included in this budget code.

2.4.1 TB/HIV TECHNICAL CONSIDERATIONS

Note: The TB/HIV Technical Considerations have been revised in light of important new developments in 2010-2011, including new WHO guidelines on ICF and IPT and USG guidance on implementation and rollout of the Cepheid Xpert® MTB/RIF assay (Xpert).

Tuberculosis (TB) remains the most common infectious cause of death among people living with HIV (PLHIV) in sub-Saharan Africa. The PEPFAR Five Year Strategy recognizes the need to urgently address the TB/HIV syndemic and commits to aggressively expand implementation of the Three Is (intensified case finding, isoniazid preventive therapy, and infection control) and antiretroviral treatment (ART) for co-infected individuals. Furthermore, under President Obama's Global Health Initiative (GHI), integrated programming is to be enhanced. TB/HIV collaborative activities are prototypic of the key concepts of coordination, collaboration, integration and systems strengthening that are central to GHI. In addition PEPFAR is increasingly focusing on using an implementation science framework to improve program delivery and provide information on the efficiency, effectiveness, and impact of PEPFAR activities. As a result, there is greater emphasis on monitoring and evaluation of TB/HIV programs to ensure delivery of quality services, demonstrate impact, and suggest program adjustments to improve outcomes.

Studies of individuals on antiretroviral therapy (ART) in sub-Saharan Africa document high rates of TB not only among those initiating ART, but also among those on ART, particularly in the first six months of therapy. If not adequately addressed, TB has the potential to undermine the great strides that PEPFAR has made in rapidly expanding HIV care and treatment, and in decreasing TB/HIV-associated mortality and morbidity.

In most countries, HIV prevalence among individuals diagnosed with TB disease (as well as those who present with symptoms of TB) is much higher than that of the general population. In 2010, WHO reported that among the 9.4 million incident TB cases registered in 2009, an estimated 1.1 million were HIV-infected. In sub-Saharan Africa, TB/HIV co-infection rates have been reported to be 50-80%, and it is estimated that the African region shouldered 80% of the global co-infection burden. The estimated 380,000 deaths from TB among people with HIV, accounted for 21% of all HIV-related deaths and 35% of the 1.1 million reported cases of HIV-associated TB in 2009. These estimates are thought to be a more accurate reflection of TB/HIV associated morbidity and mortality than previous estimates, as they are derived from direct measurements of TB/HIV-co-infection in a much larger patient population due, in large part, to rapid expansion of provider-initiated testing and counseling (PITC) in TB settings.

According to the 2010 WHO Global TB Report, in 2009, 26% of individuals with TB knew their HIV status (up from 22% in 2008), including 53% of TB patients in the African Region. Globally, 300,000 PLHIV with TB disease were enrolled on cotrimoxazole preventive therapy (CPT), and almost 140,000

were enrolled on antiretroviral therapy (75% and 37% respectively of those who tested HIV positive). To prevent TB, almost 80,000 PLHIV were provided with isoniazid preventive therapy (IPT). Although this is an increase from previous years it represents < 1% of the estimated number of PLHIV worldwide, the great majority of whom are eligible for preventive TB treatment.

This highlights progress in recent years as well as the need for more intensified efforts to detect and successfully treat TB cases, and to offer HIV testing and counseling (HTC) to all people with TB, so that they can enroll in HIV care and begin antiretroviral therapy (ART) and cotrimoxazole preventive therapy (CPT) as early as possible. In addition, it underscores the role that TB clinics can provide in identifying and effectively linking PLHIV to appropriate HIV care and treatment services. It is equally clear that HIV programs have an important role in furthering TB screening and case detection. Individuals with HIV often present with undiagnosed TB, and it is imperative that clinicians routinely screen for TB at each clinical encounter (using the simplified, WHO-endorsed 4-symptom screening tool) and act rapidly to diagnose and treat the disease in those with both classic and non-specific symptoms. Additionally, HTC settings represent the first opportunity for such integration and symptomatic screening with referral should be considered a minimum standard of care, particularly for persons testing HIV positive and their spouses/partners.

Antiretroviral therapy dramatically reduces TB incidence as demonstrated by a 67% (95% CI 61–73%; range, 54–92%) reduction in tuberculosis incidence rates in nine observational cohort studies in which 37,879 patients were enrolled¹⁶⁴. Early initiation of ART during TB treatment reduces mortality. One trial showed that the initiation of antiretroviral therapy during tuberculosis therapy in patients with confirmed tuberculosis and HIV co-infection reduced mortality by 56% (95% CI, 21 to 75)¹⁶⁵.

Therefore, in 2009, the WHO revised its ART guidelines with the strong recommendation that ART should be started in *all* adults and adolescents with HIV and TB disease *irrespective of CD4 cell count*. Therefore, in supporting the scale-up of national ART programs, TB clinics remain the highest yield sites for HIV case-finding, and plans for scale-up and decentralization of ART services should consider the existing network of TB clinics in the country. It is apparent that, in addition to early initiation of ART, it will be necessary to focus on the 3Is: intensify TB case-finding (ICF) and ensure that those with the disease are properly treated, strengthen TB infection control (IC), and expand access to isoniazid preventive therapy (IPT) to minimize morbidity and mortality among PLHIV.

The WHO Interim Policy on Collaborative TB/HIV Activities outlines essential interventions to reduce the burden of HIV among people with TB and reduce the burden of TB among PLHIV. Over the past seven years, PEPFAR programs have supported efforts to implement these interventions in countries with Ministries of Health (MOHs) and partners. Activities have included the development of national policies, guidelines and operational tools, provision of technical assistance to MOHs and partners, and basic program evaluations.

Emphasis is on the following priorities:

- Provider-initiated HIV testing and counseling (PITC) and linkage to HIV care and treatment for people with TB;
- TB intensified case-finding (ICF) and TB treatment among PLHIV;
- TB infection control (IC) activities in both TB and HIV care and treatment settings;

¹⁶⁴ Lawn SD, Wood R, De Cock KM, Kranzer K, Lewis JJ, Churchyard GJ. Antiretrovirals and isoniazid preventive therapy in the prevention of HIV-associated tuberculosis in settings with limited health-care resources. *Lancet Infect Dis.* 2010 Jul;10(7):489-98.

¹⁶⁵ Abdool Karim SS, Naidoo K, Grobler A, Padayatchi N, Baxter C, Gray A, Gengiah T, Nair G, Bamber S, Singh A, Khan M, Pienaar J, El-Sadr W, Friedland G, Abdool Karim Q. Timing of initiation of antiretroviral drugs during tuberculosis therapy. *N Engl J Med.* 2010 Feb 25;362(8):697-706.

- Isoniazid preventive therapy (IPT) for PLHIV who do not have active TB disease;
- Laboratory services to support TB diagnosis and treatment;
- Provision of cotrimoxazole prophylaxis (CPT) in TB clinics to PLHIV diagnosed with TB disease (with the ultimate goal of ART provision in TB clinics);
- Strengthening program monitoring and evaluation (M&E);
- Surveillance and management of multi-drug resistant TB (MDR TB); and
- Strengthening general TB control (DOTS).

These technical considerations highlight policies, interventions, and activities which the USG TB/HIV TWG and its partners have identified as the most effective in addressing the dual infections of HIV and tuberculosis.

A. Support coordination between TB and HIV programs at all levels to ensure continuum of care for individuals with both TB and HIV infection.

Depending on the size of the TB/HIV portfolio, USG should consider hiring a TB/HIV coordinator. In addition, USG teams should consider providing resources for TB/HIV personnel to work within the Ministry of Health at the national, provincial, and district levels, and/or within major PEPFAR implementing partners to provide supervision, linkages, training, and strategic information, etc. USG staff or PEPFAR-supported staff hired by the MOH can be supported to work on specific priority areas (based on specific country context and the MOH's needs), such as infection control, TB lab strengthening, DOTS quality improvement or TB/HIV M&E.

B. Implementation of provider-initiated HIV testing and counseling (PITC) in TB clinical settings, followed by provision of HIV treatment, care and support services on-site or through an active linkage/referral system for individuals with TB who test positive for HIV.

Support the development of national policies, training, infrastructure, procurement of HIV rapid test kits, and development of referral/tracking systems for HIV care or provision of HIV treatment in TB clinics. Specifically, support the adoption of the revised WHO ART guidelines to ensure that all individuals with TB/HIV receive ART as soon as possible regardless of CD4 count.

- Train providers at TB clinics to perform HIV testing and counseling using rapid HIV tests for all individuals suspected or diagnosed with TB (including children). Refer and follow-up individuals with TB who test positive for HIV to ensure that they are started on ART as soon as possible (per WHO guidelines), and enrolled in ongoing HIV care and treatment services;
- Ensure minimum standards are met for all HIV testing and counseling as outlined in the 2007 WHO PITC Guidance including External Quality Assurance (EQA) for both testing and counseling processes;
- Consider supporting “one-stop” models that provide integrated TB and HIV services e.g., CPT and ART in TB clinics; and
- Develop and pilot prevention interventions for PLHIV (also referred to as Prevention with Positives or PwP) in TB clinical settings. Generic PwP materials have been developed and are currently being adapted for TB clinical settings; countries may choose to adapt these and pilot them in selected sites.

C. Intensified TB case-finding among PLHIV

In 2010 the WHO published guidelines for intensified tuberculosis case-finding (ICF) and isoniazid preventive therapy (IPT) for PLHIV in resource-constrained settings. These guidelines recommend

the use of a simplified, evidence-based screening algorithm that relies on four clinical symptoms (current cough, fever, weight loss, or night sweats) to identify those eligible for either IPT or further diagnostic work-up for TB and other conditions.

- Support the development of national guidelines, facility policies, screening tools/algorithms, and recording systems necessary to screen individuals with HIV for TB, and document results;
- Ensure that all PLHIV are screened for TB including pregnant women and children;
- Ensure that all PLHIV for whom TB cannot be excluded in the screening step undergo diagnostic evaluation for TB using the DOTS-based national TB control strategy and the International Standards for TB Care (ISTC);
- Develop systems to ensure that individuals receive timely and accurate TB diagnoses when diagnostic services for TB (i.e. smear microscopy, TB culture, chest radiography,) are not available on-site at HIV care facilities. This may include developing transport systems to send specimens to higher level laboratories or supporting transport of individuals to health facilities where chest radiography is available. These systems should be made available to patients at no additional cost and include TB infection control measures. Consider adopting Cepheid Xpert® MTB/RIF (Xpert) to improve identification of TB and MDR TB disease where appropriate;
- Consider diagnostic “fast tracking” of individuals with TB symptoms to promote timely treatment and reduce the risk of nosocomial transmission to susceptible individuals (both those receiving care and their providers). This should also include a “retrieval” or back-referral system to help ensure that individuals with TB continue to access HIV care;
- Strengthen the HIV patient monitoring system (suggest adaptation and use of the WHO IMAI HIV care/ART patient monitoring system) to monitor and document TB screening, TB status, and TB treatment of PLHIV. Expand ICF activities to include high risk contacts of PLHIV with TB, including children and mothers in high TB prevalence areas; and
- Support expansion of TB screening and case finding while addressing prevention of mother-to-child HIV transmission (PMTCT) in antenatal clinics, HIV testing and counseling settings, and ART clinical settings.

D. Surveillance for and management of drug-resistant TB

Recent outbreaks, surveys, and improved surveillance have documented the growing problem of drug-resistant strains of TB in communities with high rates of HIV. However, most countries have little data describing the scope of the problem, making it difficult to develop appropriate diagnostic and treatment algorithms. In addition, in many countries, guidelines outlining expansion and enhancement of laboratory systems necessary to diagnose and manage drug-resistant (DR) TB are urgently needed.

Actions to immediately begin to address this problem include:

- Develop capacity for TB culture and drug susceptibility testing (DST) through lab strengthening and treatment with second-line drugs for patients with multi-drug resistant-/extensively drug-resistant-TB (MDR-/XDR-TB). Consider pilot-testing Cepheid Xpert® MTB/RIF (Xpert) in high MDR TB prevalent areas;
- Support access to TB culture and DST if DR TB is suspected, particularly in PLHIV, using national TB guidelines, and refer/support/provide access to second-line TB treatment for patients with DR TB;

- Collaborate with national and international partners to design and conduct surveys to determine the geographic distribution, as well as the extent and pattern, of DR TB in high risk countries; and
- Leverage support and technical assistance from the WHO Green Light Committee (GLC) and Global Drug Facility (GDF) to improve access to treatment for patients with MDR/XDR TB.

E. Strengthen laboratory services necessary to implement TB/HIV program activities

- Strengthen TB diagnostic capabilities by fortifying existing sputum smear microscopy laboratory networks and upgrading them to introduce light emitting diode (LED) or fluorescent microscopy in high volume sites (including logistics, infrastructure, quality assurance programs, personnel, and training);
- Strengthen national reference laboratories to provide quality assurance, mycobacterial culture, and TB DST;
- Support training of laboratory staff throughout the laboratory network in external quality assurance (EQA) for smear microscopy, and at the central or reference laboratories for TB culture, DST, and rapid diagnostic methods;
- Consider requesting technical assistance to assess and provide recommendations regarding laboratory biosafety and infection control;
- Support development and implementation of new diagnostic algorithms to incorporate newer diagnostic methods for TB and MDR-TB, and procedures to diagnose smear negative, extrapulmonary, and pediatric TB as they become available; and
- Focus on improving quality as well as access to TB laboratory services for PLHIV through a spectrum of activities including strengthening on-site TB labs at ART clinics, and supporting specimen transport and lab information management systems.

F. Phased Implementation and Evaluation of Xpert MTB/RIF

Principal considerations for USG-funded Activities

I. Background

The Cepheid Xpert® MTB/RIF assay (Xpert) is a new fully automated molecular diagnostic test for tuberculosis disease (TB). It can detect *Mycobacterium tuberculosis* complex (MTB) DNA and mutations associated with rifampicin (RIF) resistance directly from sputum specimens in less than 2 hours. The assay is more sensitive for detecting TB than sputum-smear microscopy with similar accuracy as culture on solid media. The ability of the Xpert assay to detect smear-negative TB provides a significant advantage over smear microscopy, especially for persons with TB who are also HIV-infected. Training (1–3 days) and biosafety requirements (similar to direct sputum smear microscopy) are minimal. Introduction of Xpert in a country is expected to result in earlier diagnosis of TB (especially among those who are HIV infected) and multidrug-resistant (MDR) disease; earlier initiation of treatment; better institution of infection control measures; and reduced morbidity, mortality and transmission. The World Health Organization (WHO) has endorsed its use.

II. Intended Audience and Use

The following considerations have been prepared by CDC, OGAC and USAID to aid USG staff in using Xpert in their programs and guiding National TB Programs in roll-out. These considerations

are consistent with current WHO recommendations^{166,167} and limited field experience, and will be periodically updated to reflect new experience, recommendations, and the shift from roll-out to scale-up.

III. Principal Considerations

- A. How should USG support in-country coordination and planning?
 1. Xpert should be incorporated into, and rolled-out in the context of, the National Laboratory Strategic Plan, when feasible.¹⁶⁸
 2. Roll-out of Xpert and scale-up of other laboratory tests should be coordinated with scale-up in capacity for TB treatment and patient monitoring through the National TB Control Program (NTP) and National AIDS Control Program (NAP).
 3. USG should support the NTP to coordinate all Xpert activities among all partners.
- B. Which TB suspects would most benefit from receiving Xpert as an initial diagnostic test^{98, 99?}
 1. All persons living with HIV who have signs and symptoms of TB meeting the criteria of current WHO recommendations for intensified TB case finding (i.e., one or more of the following: current cough, fever, weight loss or night sweats¹⁶⁹).
 2. Those seriously ill and suspected of having TB regardless of HIV status.
 3. Those with unknown HIV status, suspected of having TB, and presenting with strong clinical evidence of HIV infection in HIV-prevalent settings.
 4. Individuals known or suspected of having TB **and** at high risk of MDR TB.¹⁷⁰
- C. What priorities should in-country teams consider in placement of Xpert during the roll-out phase?
 1. Placement at facilities that provide initial diagnostic testing for priority TB suspects:
 - District or sub-district level where Xpert provides an opportunity to achieve rapid TB diagnosis with sensitivity equivalent to solid culture. Examples of such sites are HIV testing and treatment centers, AFB microscopy centers, health care clinics, or district hospital laboratories that provide initial diagnostic testing for the TB suspect populations discussed in section B above.
 - Central, regional, or reference laboratories that perform initial diagnostic testing for the TB suspect populations discussed in section B above.
 - Central, regional, or reference laboratories involved in the supervision or quality assurance of peripheral laboratories conducting Xpert.
 2. Placement in laboratories where sputum specimen transport is not necessary or is rapid (<24 hr) or suspect referral is feasible (note: potential for coordination with existing specimen transport networks – e.g. HIV, malaria). Placement at centralized facilities for testing of samples from peripheral areas may significantly reduce the benefit of the test because of transport delays.
 3. Among such sites, priority should be given to facilities serving areas, populations, or suspect groups that would benefit most from Xpert:
 - Those with increased prevalence of known or suspected HIV-associated TB (including locations in the private sector or congregate settings, such as prisons);

¹⁶⁶ http://whqlibdoc.who.int/publications/2011/9789241501545_eng.pdf

¹⁶⁷ http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf

¹⁶⁸ In countries without a National Lab Strategic Plan, an interim strategy should be developed that includes an Xpert implementation plan.

¹⁶⁹ http://whqlibdoc.who.int/publications/2011/9789241500708_eng.pdf

¹⁷⁰ http://whqlibdoc.who.int/publications/2008/9789241547581_eng.pdf (chapter 5)

- Those with increased prevalence of known or suspected MDR TB (including locations in the private sector or congregate settings, such as prisons);
 - Among these sites, additional factors to consider for prioritizing placement include:
 - Where workload capacity would enable Xpert to be used close to its operating capacity (4-module machine: 15-20 tests per day, 16-module machine: 48-80 tests per day) and;
 - With laboratory personnel who can be trained, perform the testing and keep equipment in good working order
 - 4. During the roll-out phase, priority should be given to sites that are able to evaluate the performance and impact of Xpert on diagnosis, treatment initiation, and treatment outcomes. WHO recommends that Xpert machines should initially be clustered either within districts or regions to facilitate impact evaluation.
- D. What are the laboratory infrastructure requirements for Xpert?
1. Temperature-controlled space to store cartridges (2-28°C) and to perform test (max 30°C);
 2. Stable and uninterrupted power supply (may be achieved with universal power supply [UPS], generator, or batteries);
 3. Biosafety requirements similar to direct sputum smear microscopy;
 4. Sufficient security to minimize theft of machine and associated computer; and
 5. Adequate waste management (similar to microscopy, but greater volume of solid waste, including plastics).
- E. What are the important programmatic and laboratory systems factors to consider when planning for the roll-out and scale-up of Xpert?
1. Epidemiology and geographic distribution of TB, HIV-associated TB, and MDR TB;
 2. Country-specific legal and regulatory requirements (e.g., medical device registration, importation regulations and procedures, in-country device evaluation);
 3. Plan for human resource development to ensure adequate supply of trained laboratory personnel to perform the test;
 4. Inventory and supply management systems, including forecasting and appropriate scheduling of orders to avoid stock-outs of cartridges and TB drugs (e.g., cartridge shelf-life is 18 months but procurement time should be considered);
 5. Plans for assay verification at each testing site, quality assurance, and accreditation and certification programs;
 6. Availability and adequacy of specimen transport and patient referral systems;
 7. Plan and capacity for rapid reporting of results to clinicians and local public health authorities;
 8. Access to and availability of quality-assured first- and second-line conventional growth media-based drug susceptibility testing (DST) for patients with rifampicin (RIF)-resistant TB;
 9. Plan to address access to and availability of quality first-line and second-line anti-TB drugs;
 10. Access to and availability of quality-assured sputum smear microscopy and culture for treatment monitoring;
 11. Plan and capacity for monitoring and evaluation (e.g., capacity to record and report basic program and laboratory performance indicators); and
 12. Budget for equipment, operating costs (including required annual calibration of Xpert modules), and first-line and second-line anti-TB drugs.
- F. How much does implementation of Xpert currently cost?

With FIND-negotiated pricing structures for low and middle-income countries, implementation of one Xpert 4-module machine may cost up to US\$100,000 for the first year including US\$19,000 for purchase and installation, US\$71,000 annual operating costs, and US\$10,000 HR costs (Table 1). This assumes at-capacity use at a volume of 15-20 tests per machine per day and using approximately 4,000 cartridges per machine per year. At current prices, it will cost approximately US\$80,000 in future years to keep the machine operating at full capacity.

Table 1. Approximate year-one costs of Xpert (4 module machine)

Equipment	Xpert 4-module	\$17,000-17,500
	Shipment, UPS, printer	\$1,700*
Maintenance	Annual calibration	\$1,800**
Consumables	Cartridges	\$16.86***
HR costs	Tech annual salary	To be determined locally
	Training and TA****	To be determined locally

*approximate costs depending on local situation

**current cost based on shipping of individual modules to and from Cepheid in Toulouse, France; may decrease with development of alternative calibration mechanisms

***current cost; will decrease depending on volume sales

****see section G for additional information

According to WHO, the use of Xpert significantly increased TB case-finding (by roughly 30%) when used as a replacement or add-on test to microscopy. Use of Xpert as a replacement for conventional culture and DST also significantly increased MDR TB case-finding (roughly three-fold). Cost-comparisons show that the current running costs of Xpert are substantially greater than those of microscopy, though similar to the cost for performing culture and drug susceptibility testing.

According to WHO modeling:

- Implementing Xpert to meet diagnostic targets for MDR TB will have a lower cost than conventional culture and DST for diagnosis of MDR TB, both globally and in varied country settings;
- Cost of testing all HIV positive individuals suspected of having TB will have a similar cost as conventional culture for diagnosis of TB; and
- Cost-effectiveness of testing of all persons suspected of having TB will be strongly dependent on screening and diagnostic algorithms at country level.

G. How can we generate evidence for scaling-up during roll-out of Xpert?

As countries pursue roll-out, systematic collection of data will help to describe implementation best practices, inform eventual scale-up, and provide guidance to countries for introduction of Xpert. There should be a minimum basic data set (Table 2) collected routinely by countries during implementation to allow for simple indicators to quantify the impact of Xpert. These data will be used to answer the following questions:

1. How does the introduction of Xpert testing impact the workload of the laboratory and the number of conventional diagnostic tests performed (e.g. sputum smear microscopy, culture, DST, and chest radiography)?
2. What are the main indications for requested testing?
3. How many tests are positive for TB and for rifampicin resistance?

4. Is rifampicin resistance a reliable surrogate marker for MDR TB?
5. How is the overall laboratory system and program workload affected after the introduction of Xpert?
6. What are the main logistical and operational issues related to Xpert implementation?

Table 2. Minimum basic data to be collected (recommended by WHO¹⁷¹)

Key laboratory data for assessment of Xpert implementation
<ol style="list-style-type: none"> 1. Number of sputum microscopy tests performed for diagnosis 2. Number of sputum tests performed for treatment follow-up 3. Total lab-technician hours logged in the TB lab 4. Number of Xpert tests (disaggregated by the reason for testing) 5. Number of positive Xpert tests 6. Number of RIF-resistant Xpert tests 7. Placement of the unit (district lab, ART clinic, etc.) 8. Number of units and type (number of modules) 9. Monthly number of days unable to operate Xpert 10. Reasons why Xpert could not be operated
Additional laboratory data for assessment of Xpert implementation
<ol style="list-style-type: none"> 1. Number of culture tests performed for diagnosis 2. Number of culture tests for follow-up 3. Number of DST performed for diagnosis 4. Number of DST performed for follow-up 5. Number of conventional test results (disaggregated by smear, culture, DST)
Complementary patient data
<ol style="list-style-type: none"> 1. Number of confirmed new TB cases by type of laboratory test result 2. Number of TB suspects tested by Xpert for TB diagnosis 3. Number of TB cases detected by Xpert 4. Number of Xpert tests per investigated suspect 5. Number of Xpert tests per confirmed TB case 6. Number of individuals at risk of MDR TB 7. Number of individuals at risk of MDR TB tested by Xpert 8. Number of individuals at risk of MDR TB tested by Xpert found to be RIF resistant 9. Number of RIF resistant TB cases tested for isoniazid (INH) 10. Number of RIF resistant TB cases tested for fluoroquinolones (FQN) and second-line (SL) injectables 11. Proportion of RIF resistant TB cases tested for INH and found to be resistant 12. Proportion of MDR TB cases tested for FQN and SL injectables found to be resistant to both 13. Number of newly detected TB cases during the previous month and put on treatment 14. Number of newly detected RIF resistant cases during the previous month and put on treatment

¹⁷¹ <http://www.stoptb.org/wg/gli/assets/documents/Xpert%20Implementation%20Document.pdf>

G. Scale-up isoniazid preventive therapy (IPT) in PLHIV:

Isoniazid preventive therapy (IPT) for TB can safely be given to PLHIV without TB disease, reducing the risk of developing TB by 33% to 62% for up to 48 months. IPT has proven efficacy in PLHIV with documented latent TB infection or exposure to an individual with active TB. In situations where testing for latent TB infection is not feasible, IPT is recommended for all PLHIV residing in areas that have a latent TB infection prevalence of >30%. The *WHO Guidelines for intensified tuberculosis case-finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings* were published in 2010. The guidelines strongly recommend at least 6 months of IPT for children and adults, including pregnant women, people living with HIV, those receiving ART and those who have successfully completed TB treatment. The revised guidelines also emphasize that IPT is a core component of HIV prevention and care, and should be the primary responsibility of AIDS programs and HIV service providers. More recently, additional evidence has shown that the combined use of IPT and ART in PLHIV significantly reduces the incidence of TB, and the use of IPT in patients who have successfully completed a course of TB therapy has been shown to markedly reduce the risk of subsequent TB. To improve uptake of this intervention:

- Teams should work with Ministries of Health to identify HIV sites that are successfully providing ART and implementing ICF among PLHIV accessing care and treatment services. In these sites, IPT can be implemented and expanded as part of the phased national roll-out of ICF and IPT; and
- Components of the roll-out should include development of policies and operational guidance for IPT that address issues such as supply chain management, training and supervision, patient monitoring and follow-up, and monitoring and evaluation.

H. Implement infection control (IC) measures to prevent TB transmission in both TB and HIV care and treatment settings:

Nosocomial (hospital) transmission of MDR and XDR TB among PLHIV resulting in extremely high case-fatality rates has been documented in sub-Saharan Africa. This finding, as well as the significant overall impact of TB on morbidity and mortality among PLHIV and the increasing prevalence of DR TB in many PEPFAR-supported countries, clearly demonstrates the critical importance of expanding TB IC activities in health care facilities and other congregate settings, including HIV care and treatment sites. PEPFAR-supported efforts to assist countries with development of national IC action plans and to train national level consultants are currently under way. The 2009 *World Health Organization Policy on TB Infection Control in Health-Care Facilities, Congregate Settings and Households* is available to assist countries in finalizing national guidelines and developing strategic plans. IC demonstration projects are being conducted in several PEPFAR countries. Tools developed and lessons learned from these projects will be documented and shared widely.

- National TB and HIV coordinating bodies should prioritize the scale-up of TB IC. TB IC activities should also be coordinated with other ongoing IC and occupational health programs/activities in clinical settings, e.g., blood safety, injection safety practices, and respiratory IC. Activities should be implemented and scaled up broadly to minimize the risk to both patients and health care workers at the country level;
- Support the development of policies and plans (including training tools for health care workers) to implement/monitor IC measures in adult and pediatric health facilities. USG should consider funding a TB IC coordinator(s) at the national and/or lower levels to assist countries with implementing TB IC activities; and
- Include TB IC in plans to renovate health facilities to maximize TB IC (refer to the WHO Policy on TB Infection Control in Health Care Settings, Congregate Setting, and

Households). Integration of IC principles in renovations should be a priority, especially in HIV settings, where an increasing number of PLHIV with TB infection are accessing HIV prevention, care, and treatment services. Include plans for scaling-up IC activities in clinical settings. For example, countries may organize courses for training-of-trainers and for clinic level health care workers to rapidly increase TB IC knowledge and practices in TB and HIV clinical settings.

I. Integrate “prevention for PLHIV” (also referred to as PwP) into TB clinical settings

Many countries have made significant progress in scaling-up HIV testing and facilitating access to HIV care and treatment among TB patients. However, integrating HIV prevention messages and services into the routine care offered to PLHIV attending TB clinics has not been instituted widely. This is a major missed opportunity, as a high percentage of individuals attending TB clinics also have HIV infection, regular contact with providers, and are able to participate in prevention interventions during TB treatment visits. Prevention services for PLHIV in TB settings include both behavioral and biomedical interventions aimed at reducing the morbidity and mortality experienced by PLHIV co-infected with TB, and reducing the risk of transmission to HIV-negative partner(s). These interventions include provision of or referral to the following services: disclosure counseling and support, partner/couples HIV testing and counseling; alcohol and sexual risk reduction counseling; adherence counseling and support; STI diagnosis and treatment; family planning and safer pregnancy counseling and services; and condom distribution.

- USG should support adaptation and implementation of existing PwP materials in selected TB clinical sites to explore the feasibility of these interventions, and develop an approach for scale-up if the interventions prove successful. Strategies for actively linking TB patients into HIV care and treatment services should also be addressed and include co-location of TB and ART services, physical escort (by peer educators or others) from TB clinics to HIV care and treatment services, ongoing case management, and follow-up by community health workers.

J. Monitor and evaluate progress of HIV testing and counseling among TB patients, linkage to HIV care and treatment for TB patients found to be HIV positive, and provision of CPT for HIV-infected TB patients

- Support National TB Programs (NTPs) to ensure that key HIV variables including HIV testing and counseling, HIV serostatus, and provision of ART and CPT are incorporated into national TB surveillance systems. Support the development and implementation of electronic TB/HIV recording and reporting systems where feasible;
- Support the NTP to ensure that PLHIV with TB have access to CPT through trained facility staff, and explore barriers to provision of CPT in TB clinics (e.g., supply chain management issues related to cotrimoxazole, provider concerns);
- Support HIV programs to include TB variables in HIV monitoring systems to better document TB screening, diagnosis, TB treatment, and IPT among PLHIV. This includes strengthening documentation for TB screening at all HIV testing and counseling service delivery points;
- Support national review meetings and processes to ensure that TB/HIV data are comparable, consistent, comprehensive, accurate, and based on one national TB/HIV monitoring and evaluation system;
- Work at national and sub-national levels to support the use of data for planning, resource allocation, and program improvement in both TB and HIV programs;
- Support evaluation of the revised TB recording and reporting system to assess and improve the quality of data collected on HIV variables (HIV testing, provision of CPT/ART, etc.).

- Conduct operational research to better understand challenges to accessing HIV care and treatment among TB patients who are diagnosed with HIV in TB clinics; and
- Ensure that every partner planning to implement a TB/HIV related activity has a plan for monitoring and evaluating that activity.

K. Strengthen Capacity for TB Control and Contribute to Improved TB Case Detection and Treatment Success

The revised *WHO Global Plan to Stop TB 2011-2015* was released in 2010. This plan recommends moving toward universal access to TB diagnosis and treatment modalities and addressing key cross-cutting issues to reach vulnerable populations, including women and children.

- Improve case-detection rates: the majority of TB cases in sub-Saharan Africa are undetected; the TB case-detection rate is only 49%, resulting in needless morbidity, mortality, and transmission. Given that the TB epidemic is fueled by the HIV epidemic in most sub-Saharan African countries, intensifying TB case-finding (ICF) through regular TB screening among PLHIV can significantly contribute to overall TB case-detection;
- Improve treatment success rates: Most TB programs in sub-Saharan Africa have not met the WHO target of 85% treatment success, resulting in individuals experiencing excessive morbidity and mortality and transmitting TB to others, particularly PLHIV. In addition, the failure to prevent and successfully treat susceptible TB leads to the development (and subsequent transmission) of drug-resistant TB, which is particularly devastating to PLHIV, many of whom succumb to the disease. It is therefore imperative to improve treatment success rates in order to reduce the generation of new MDR TB cases. HIV care and treatment partners should ensure that all individuals diagnosed with TB disease have access to TB treatment through a DOTS program and receive follow-up to ensure treatment completion;
- Improve coordination with existing maternal and child health programs/activities, and measure progress and impact; and
- Increase access to/ensure procurement of quality-assured child-friendly formulations of anti-TB drugs.

2.4.2 COUNTRY CONTEXTUAL CONSIDERATIONS: TB/HIV

Countries should approach implementation of the key technical areas identified by the TB/HIV TWG working group using a stepwise approach toward national scale-up that should include:

- Establish policies/guidelines and coordinating bodies at the national level;
- Engage civil society and establish partnerships to harness expertise in community advocacy for TB and TB/HIV efforts;
- Develop a strategic plan for implementation;
- Ensure that adequate resources are available to support implementation e.g., commodities, laboratory, staffing, supervision/support, M&E systems, etc;
- Train health care providers as needed for implementation and follow-up, with supportive supervision;
- Pilot implementation in selected sites and revise approach as needed;
- Scale-up to additional sites; and

- Review data on a regular basis to track progress and measure quality of services being provided in order to direct resources accordingly.

It is expected that countries will be at different points in the stepwise approach for various priority areas within TB/HIV. For example, some countries may have completed steps 1-5 as they relate to PITC among TB patients, and therefore, for COP FY'12, the focus should be on scaling-up to additional sites and reviewing data on a regular basis to track progress/measure quality of services. In contrast, in the area of TB IC, some countries may have recently established a national policy/guideline and coordinating body, and should focus on the subsequent steps in COP FY'12. The TB/HIV TWG is particularly keen to work with countries receiving additional resources to devise technically sound and appropriate scale-up plans.

Data that is generally useful for planning TB/HIV activities includes:

- HIV prevalence in the general population (stratified by geographic area);
- HIV prevalence among TB patients (stratified by geographic area), age (2 age groups for children: 0-4 years old and 5-14 years old), and gender;
- TB incidence and prevalence in the general population (stratified by geographic area), age (2 age groups for children: 0-4 years old and 5-14 years old), and gender;
- Estimated MDR-TB prevalence;
- Geographic mapping of partner coverage of TB/HIV activities; and
- Data on the current level of scale-up of key activities by geographic area/site.

2.4.3 PARTNER PERFORMANCE CONSIDERATIONS: TB/HIV

To maximize efficiency in the field, it is critical that partner activities:

- Align with the country policy;
- Are not duplicated within the country;
- Develop sufficient human resources and train local staff to ensure sustainability; and
- Conduct M&E periodically and report quality data to the national program, USG, and site-level staff.

2.4.4 LINKAGES AND WRAPAROUNDS: TB/HIV

COP FY12 should provide information on how other USG and other donor TB resources (e.g. Global Fund Against AIDS, TB, and Malaria [GFATM], Clinton HIV/AIDS Initiative [CHAI], Bill & Melinda Gates Foundation [BMGF], etc.) contribute to accelerating TB/HIV collaborative activities, particularly in relation to National TB and HIV/AIDS program strategic plans. Specifically, country teams should describe how PEPFAR resources will leverage and complement ongoing or planned non-PEPFAR USAID funding for TB and/or TB/HIV activities. To maximize USG resources and avoid duplication, we encourage USG teams to develop a USG-wide strategic vision that addresses TB and TB/HIV funding. There are a number of approaches to accomplishing this objective (e.g., joint technical assistance visits by USAID TB and PEPFAR TB/HIV experts, interagency technical working groups, annual one-day planning retreats, interagency portfolio reviews, etc.). TA is available to facilitate this strategic process. We anticipate that these efforts to link all USG support to TB in a cohesive country strategy will also be

reflected in the State Department Foreign Assistance Operational Plan (F/OP). TB/HIV activities should be closely linked to other relevant technical areas including laboratory, HIV testing and counseling, sexual prevention (including PwP), adult/pediatric care & treatment, health systems strengthening, strategic information, etc. HIV testing and counseling in TB clinic settings, including the purchase of HIV rapid test kits, should be included under the TB/HIV technical area. Similarly, laboratory support to strengthen TB diagnosis and management should be included under the TB/HIV technical area. USG should ensure that Xpert MTB/RIF is incorporated into, and rolled-out in the context of, the National Laboratory Strategic Plan and coordinated with scale-up of TB treatment and patient monitoring capacities through the National TB Control Program (NTP) and National AIDS Control Program (NAP). If TB programs expand to provide clients with ART, such services should fall under the ARV Drugs and Adult/Pediatric Care & Treatment technical areas.

TECHNICAL AREA 2.5: ORPHANS AND VULNERABLE CHILDREN

2.5.1 INTRODUCTION: ORPHANS AND VULNERABLE CHILDREN

Orphans and vulnerable children are defined as “Children who have lost a parent to HIV/AIDS, who are otherwise directly affected by the disease, or who live in areas of high HIV prevalence and may be vulnerable to the disease or its socioeconomic effects,”¹⁷² in the 2008 Hyde-Lantos Act that reauthorized PEPFAR. The international community defines children as individuals from birth up to 18 years of age. Support for orphans and vulnerable children (OVC) is integral to the President’s Emergency Plan for AIDS Relief’s (PEPFAR) wider efforts to mitigate the broad socio-economic impact of HIV/AIDS.

The goal of the OVC technical area is to improve child well-being by mitigating the impacts of AIDS, reducing children’s risk and vulnerability, and increasing their resilience. In FY 2010, PEPFAR supported more nearly four million children. While this is a substantial increase over the half-million children served with PEPFAR funds in 2004, it represents only a small portion of the millions more in need. The current 2013 goal is to reach five million OVC; therefore, countries should continue to scale up comprehensive programming in collaboration with key government ministries and communities.

The 2008 PEPFAR legislation reiterates that country programs are expected to allocate at least 10% of total prevention, care, and treatment resources towards OVC programs. After painting the broad context for orphans and vulnerable children issues, programmatic priorities and principles for planning and guiding PEPFAR funded programs for orphans and vulnerable children are provided.

2.5.2 ORPHANS AND VULNERABLE CHILDREN SITUATION

The OVC situation can be characterized by three defining factors – magnitude, complexity and duration. Together these three factors sum up the challenges faced by the OVC/HKID PEPFAR country programs in their efforts to effectively mitigate the impact of HIV/AIDS on children and reduce their risk and vulnerability.

Magnitude refers to the large number of children, from infants to adolescents, who are affected by HIV, and emphasizes the necessity of targeting resources to those who are in need of additional support and applying the most cost-effective approaches.

A. Magnitude: The Scale of the Orphans and Vulnerable Children Situation

In 2010, the estimated number of children who had lost one or both parents to AIDS was over 16 million worldwide of which nearly 15 million (90%) were in Sub-Saharan Africa. Although these numbers portray a disturbing trend they do not capture the full magnitude of the even larger group of children affected by the disease. Because orphan estimates are based on household surveys,

there is also a small but significantly vulnerable population of children living in the street or in institutions not accounted for in these numbers. Untold numbers additionally live with parents who are ill from AIDS and who are thus unable to provide adequate care for their children. Importantly from a resource planning consideration, the numbers also do not include the millions of children who “live in areas of high HIV prevalence and may be vulnerable to the disease or its socioeconomic effects.” Despite the difficulty in enumerating the population of children that are considered OVC, the challenge posed by

¹⁷² The Tom Lantos and Henry J. Hyde Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, PL 110–293, 122 STAT. 2918, (2008), cited on <http://www.pepfar.gov/about/index.htm>

the magnitude of the situation is clear. By any estimate, the vast numbers of children who are potential beneficiaries for USG assistance far outstrip resources available - a keen reminder of the need to assist country partners to identify and to target resources to those who are most in need of additional support.

B. Complexity: Challenges in Discerning and Addressing the Unique Needs of the OVC Population

Complexity refers to the interplay of contextual and individual factors that compromise a children's well being or contribute to their risk; factors that vary by age and location. It also underlines the importance of utilizing available data and evidence to target children with interventions most likely to positively impact their unique self and context.

Identifying and addressing the vulnerable populations in need of additional support is challenging due to the interplay of individual and contextual factors that influence the degree and type of support needed by children, from infants to adolescents¹⁷³. In a world of limited resources and a multitude of need, the use of sound data to define target populations, rather than using preconceptions about vulnerability, is critical. To inform a more accurate picture of vulnerability in the context of AIDS, researchers analyzed data from 60 population-based surveys (DHS and MICS) across 36 countries.¹⁷⁴ Findings of the multi-variate

analysis showed that "...Orphaning and the presence of a chronically ill or HIV positive adult in the household do not consistently identify the children with the worst outcomes." In other words, while orphaning and household illness do matter to children, in terms of worst outcomes, other factors, especially poverty, often matter more. If AIDS affected households are living in poverty, a condition exacerbated by HIV/AIDS, affected children are at even greater risk for malnutrition, disease, and limited access to education and health programs.

Gender issues and the need for protection also impact especially vulnerable children. Children without adequate adult supervision experience an increased possibility of violence and sexual abuse. According to a recent study in Swaziland for example, where numerous children have lost one or both parents to AIDS, over 33% of females experienced sexual violence before they reached the age of eighteen.¹⁷⁵ Because high-risk settings occur in both concentrated and generalized epidemics, the gap in protection of children, particularly girls, is relevant in all countries where PEPFAR has OVC programs. Children of brothel based sex workers in South East Asia for example often require protective as well as prevention interventions. In addition, vulnerable children are also more likely to engage in risk behaviors, running the risk of acquiring HIV themselves and continuing the deadly cycle.

Needs of children vary by age, from the new born needing nourishment as well as the attachment and love of a mother to adolescents who are building skills to lead independent, productive lives. The contextual factors that contribute to vulnerability vary from one country to another, and often within various regions of the same country.

The variance and complexity of the needs of orphans and vulnerable children accent the challenges in designing appropriate programs to reduce vulnerability and stress the importance of not only "knowing your epidemic" within each country, but also of "knowing your children" in each country'. Reducing child vulnerability requires greater investments in multiple host country systems, particularly social,

¹⁷³ This includes children who are themselves MARPS, PLHA, MSM, FSW and their sub-categories.

¹⁷⁴ "Who is the Vulnerable Child?" Using data from DHS and MICS to Identify Vulnerable Children in the Era of HIV/AIDS; Futures Institute, Draft 16 February 2009

¹⁷⁵ Avid Reza, et. Al. 'Sexual violence and its health consequences for female children in Swaziland: a cluster survey study', Lancet 2009; 373: 1966-72

education, health, and governance to protect children, as well as better coordination across OVC and other PEPFAR areas of prevention and gender¹⁷⁶.

C. Duration: Fostering an Enduring Response for Long-Term Needs

Duration denotes both the long-term, multi-generational impact of the AIDS pandemic and points to the necessity of building capacity in host governments and local partners for a sustainable response to the long term needs.

This third defining characteristic – duration – has two aspects: first, the duration of the need, the far reaching, long term nature of the OVC situation and secondly, the necessity of an enduring, sustainable response to these needs. The duration of need has been aptly depicted as a succession of three waves. The first wave of rising HIV infections is followed by the second wave of AIDS illness and death. The third wave represents the cumulative and long-term impact of the pandemic on an ever-growing number of children. Even if a cure were found for AIDS tomorrow, the needs of children already impacted by the pandemic would remain. Duration also implies importance of addressing the long-term needs of children as they grow into adulthood. Inadequately addressing the needs of children impacted by this pandemic has long-term consequences throughout their life time, even impacting their children and society at large.

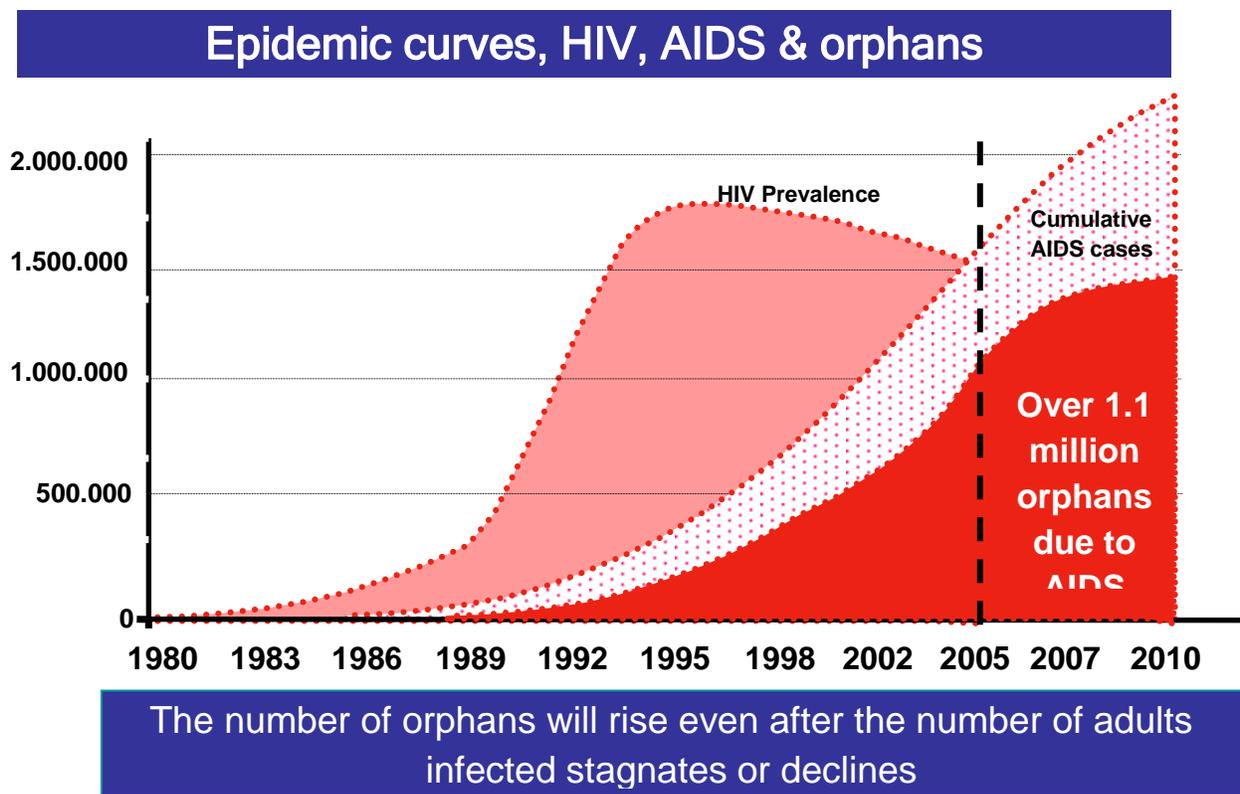


Figure 2 – Three Waves of HIV

¹⁷⁶ OVC programs depend a great deal upon social services systems which may or may not be included as part of health system strengthening, yet represent a crucial area of system support necessary to address a growing OVC population and range of issues.

These long-term consequences necessitate an enduring response to their needs now and in the future. This response requires an increased emphasis on country ownership and leadership and a transition from short-term funding to finding long-term, sustainable methods. Suggested priority actions to foster an enduring response will be discussed next, followed by considerations for program planning and management.

2.5.3 PRIORITIES FOR OVC PROGRAMMING

In the face of the great magnitude of complex needs that will endure for the foreknown future, PEPFAR OVC programs are required to make the most effective and efficient use of resources available. Comprehensive programs that cut across the range of children’s needs are required to reduce the impact of AIDS, and to strengthen both children and families now and in the future. Programs therefore span a broad and complex range of multi-sectoral interventions intended to build capacity within families, communities, and governments to support the development of orphans and vulnerable children. Programs should consider focusing on the following priorities:

- Strengthen families as primary caregivers of children;
- Support the capacity of communities to create protective and caring environments;
- Build the capacity of social service systems to protect the most vulnerable; and
- Allocate resources for children according to need in the context of HIV/AIDS.

A. *Strengthen Families as the Primary Caregivers of Children*

A family is the optimal environment for healthy child development. Prolonged stress and dysfunction in families can lead to multiple vulnerabilities for children, many that have lifelong implications for children’s health and well-being. Efforts to improve the situation of vulnerable children center on preventing family dissolution, restoring stability to children and families in crisis, reintegrating children living outside of family care back into families; and building the resiliency of both families and children against future risk.

It is estimated that over 95% of children affected by AIDS in Sub Saharan Africa, continue to live in families¹⁷⁷ -- a phenomenon that provides tremendous opportunity for the OVC response to prevent further child vulnerability by preserving families, including importantly, the extended families, who take in children. Efforts to strengthen families so that they are better positioned to weather adversity have the dual promise of both preventing and mitigating AIDS’ impacts. Family-centered interventions that feature the full participation of children and families themselves, including importantly those that stabilize households economically, promote food security and improve psycho-social well-being are fundamental to building an enduring response. Such interventions build more than economic stamina to withstand hard times; they build resilience by engaging children and families as active participants in their future.

Efforts to improve the situation of orphans and vulnerable children center on preventing family dissolution, restoring stability to children and families in crisis, reintegrating children living outside of family care back into families; and building the resiliency of both families and children against future risk.

¹⁷⁷ Richter, L., et. al., “Learning Group 1 Strengthening Families, An obvious truth: Children affected by HIV and AIDS are best cared for in functional families with basic income security, access to health care and education, and support from kin and community”, Joint Learning Initiative on Children and HIV/AIDS (JLICA) 2008.

The evidence for the effectiveness of family strengthening interventions, especially economic interventions, in PEPFAR OVC programs is encouraging. In Kenya and Tanzania for example micro-savings led to reductions of 10% in food insecurity at a cost of only \$1.61 per beneficiary.¹⁷⁸ In addition to economic strengthening, psychosocial (PSS) interventions are also an essential part of family strengthening, especially PSS interventions that promote improved family relationships such as parenting skills, that reduce and mitigate risk by promoting self-confidence, and that help children and families cope with HIV/AIDS-related issues including disclosure, stigma and bereavement. More intensive interventions that address SGBV and other types of abuse, alcoholism and mental illness, are also vital to improved child and family well-being. Some studies have shown that increasing the frequency and length of home visits has a positive effect on the family's wellbeing while other studies have demonstrated that support groups for caregivers have been more helpful for guardians than home visits¹⁷⁹.

The evidence base also clearly indicates the importance of early child development and keeping children in school as key contributors to children's, as well as society's, long term success and development¹⁸⁰.

B. Support the Capacity of Communities to Create Protective and Caring Environments

Community groups provide critical support to children and families. Building community capacity is essential to accomplishing the mandate of PEPFAR's second phase to ensure a locally-owned and sustainable response.

Communities are often the first responders to children and families in crisis. They help to identify children and families in need and often provide vital safety nets in the form of food, household help, and emotional support. Building community capacity that sustains and enhances community structures is critical to accomplishing the mandate of PEPFAR's second phase. While the community approach may appear to some as more intuition than science, results from the MEASURE Evaluation studies provide evidence to support the long held assumption that community committees do indeed identify some of the most vulnerable children for support, a particularly appropriate targeting strategy in high prevalence settings. Models to engage and support community structures include informal neighborhood groups to faith based, civil society and politically structured committees.

C. Build the Capacity of Social Services Systems to Protect the Most Vulnerable

Although families and communities are the frontline response for orphans and vulnerable children they do not

Social services systems are chiefly responsible for efforts to promote the social and economic well-being of children, women, and families; including importantly strategies that address orphans and vulnerable children; protection from abuse, violence, and exploitation, including gender based violence; and the socio-economic needs of PLHA. Strengthening these systems, and related civil society structures, is vital to the OVC response and to the achievement of sustainable advances in health for all marginalized populations. Public-private partnerships that work in harmony with systems strengthening are a sub-component of this objective.

¹⁷⁸ Hutchinson, P., Thurman, T. "Analyzing the Cost-Effectiveness of Interventions to Benefit Orphans and Vulnerable Children: Evidence from Kenya and Tanzania," MEASURE Evaluation for USAID, Tulane University School of Public Health, April 2009

¹⁷⁹ Sherr, L., Zoll, M. "How good at doing good? Reviewing the PEPFAR OVC Factor", unpublished, May 2011.

¹⁸⁰ Irwin, L. G., A. Siddiqi, and C. Hertzman. 2007. Early Child Development: A Powerful Equalizer. Final report for the World Health Organization (WHO)'s Commission on Social Determinants of Health. Geneva, Switzerland: World Health Organization.

negate the need for a strong public (and private) systems for social services; nor do they replace

governmental responsibility for essential services such as primary health care and schooling, protection, and clean water. A functioning social services system provides a vital safety net for children and families under stress, and coordinates a successful OVC response at country level. Through strong linkages with justice systems, social services ministries and departments are also critical to reducing child abuse, neglect and exploitation; to addressing gender based violence; and to tracking achievements in the welfare of all children. When equipped with the human resources, and the management and information structures and systems required for sound performance, social services ministries can play an integral role in tracking key child/family well-being indicators, and in organizing internal and external resources to optimize social services coverage. Social services also play a lead role in actualizing a “systems of care” approach by helping children and their families secure access to other essential services such as health and education. Efforts to strengthen these ministries (often the least funded) are critical to the OVC response, and also to the larger AIDS response and Global Health Initiative.

While community workers/volunteers play a significant role in supporting children and families, they are not an adequate replacement for the social service professionals required to supervise programs, provide triage for mental illness, or to manage cases involving situations such as child sexual abuse. Increased attention to standardized and certified training programs for all levels of staff are essential for an adequate response to the needs of vulnerable children and their families. Because human resources alone cannot provide a durable foundation for an OVC response, systems strengthening, in the form of improved MIS and more efficient management and administrative structures, expanded budgets, and planning capacity are also necessary.

D. Allocate Resources for Children According to Need in the Context of HIV/AIDS

Given the variability in individual, family and contextual factors across settings, application of a preset minimum package of interventions or services that PEPFAR would provide to all children would be unrealistic, costly and perhaps ineffective in addressing the real needs of the family or child. Contextual factors that contribute to risk and actual need, such as presence of conflict or famine, and accessibility to essential services such as civil registration and primary schooling, vary across settings. Instead, PEPFAR has identified a menu of intervention categories that reflect the range of child and family risk, and potential areas of external support, that can be locally adapted according to context. These core areas are outlined in Table 1 below.

Although the first priorities for the OVC area are to build the capacity of families, communities and governments to sustainably meet children’s basic needs, programs do play a role in ensuring that children receive essential services including importantly, health, education, and psycho-social support, as noted in the table above. Generally speaking, OVC programs are better situated to *improve access* to health and education services, in particularly for socially marginalized children and families, than to deliver them directly. OVC programs, for example, play an important role in the community aspects of health care by educating children and families about positive health behaviors, proper nutrition and hygiene; by identifying and referring children and families to clinics when appropriate; and providing health insurance schemes. OVC providers typically build linkages to child survival and other key health initiatives, rather than duplicate them.

Provision of essential services is not only context specific but also age and gender specific. Programs need to encompass children’s distinct age related vulnerabilities in particularly at the two ends of the spectrum – children under age 5 and over age 12. According to an evaluation of Track 1 OVC

partners, both age groups but particularly children under age 5 are not proportionately represented within programs.¹⁸¹

PEPFAR encourages focus on distinct sub-groups most at risk for HIV, as these sub-groups that account for most new infections in the broader population. Within OVC programs, special attention is needed for children of such Most at Risk Populations (MARPS) or children who are themselves MARPS. Populations classified as MARPS or at HIV higher risk than the general population are “persons engaged in sex work, clients of persons engaged in sex work, drug-using populations, men who have sex with men” and other so-called bridge populations made vulnerable by a combination of behavioral, social or environmental factors. Bridge populations include those in military settings separated from families for a long time, youth altogether outside families sometimes referred to as “street youth”, or persons engaging in alcohol-associated HIV sexual risk behaviors. One of the key findings in Phase one of PEPFAR was that strategic targeting of OVC overlapping the MARPS sub-groups has been often overlooked in both generalized and concentrated epidemic settings. Interventions for children integrated into current activities aimed at MARPs present an opportunity to prevent risk across generations and to potentially engage adults in a way that is particularly meaningful to them as parents and less threatening¹⁸².

Allocating resources for OVC will of necessity take into account the larger context of child vulnerability and resilience within a particular setting. Targeting based on the intersect between AIDS and multiple other factors including poverty, disability, lack of adult care and protection, and orphanhood ensures that the limited resources available through external support are focused on the disadvantaged. In weighing priorities, an attempt to do the greatest good for the greatest number of children should be made which includes the early addressing of needs for greatest impact. Moreover, interventions should be tailored to target specific sub-populations within the overall OVC sector, including children who are PLWHA, FSW, MSM, drug injecting youth, by utilizing appropriate services that take into account the developmental stage of the child.

2.5.4 CONSIDERATIONS FOR PROGRAM PLANNING AND MANAGEMENT: ORPHANS AND VULNERABLE CHILDREN

A. Use evidence to design programs. Given the duration and extent of the HIV/AIDS pandemic and other humanitarian interventions focused on children, there is a plethora of peer-reviewed and community driven research, which should be the basis of all program and activity design. All evidence-based interventions should also be consistent with established national quality service standards and in alignment with national strategies/plans of action for children (NPA).

B. Fortify monitoring and evaluation systems to gauge effectiveness of interventions and achievements in child and family wellbeing and to build an evidence base for future interventions. Basic Program Evaluations (BPE), conducted externally, should be built into RFAs. Developing a strong evidence base for OVC programs requires strong evaluation design and should ideally include randomized controlled trials with baselines or at minimum comparison and controlled groups.

¹⁸¹ Yates, D. et. Al.

¹⁸² For example, by helping to set up night shelters for children in brothel communities, projects have been able to establish trust with female sex workers who shied away from more obvious HIV interventions. While the **anti-prostitution clause** still applies in PEPFAR phase 2, creative, out of the box solutions are encouraged. Numerous non-governmental organizations and public health experts believe that the anti-prostitution clause is harmful and should be removed. <http://www.pepfar.gov/about/index.htm>

C. Promote coordination of care at all levels. Coordination of care should take place first of all at the child and household level. Effective referral systems between facilities and communities are an essential element to the provision of comprehensive services. Mobilize internal and external community resources to encourage a coordinated multi-sectoral approach that establishes links between multiple groups (family and community, civil society entities, government, and private or business sector) to provide an effective mix of child-centered and family support services. Such community structures include but are not limited to clinics, schools, churches, and child protection committees. Coordination should also take place among multiple partners, other USG programs for children, and other donors (Global Fund, UNICEF, World Bank, etc.) Promote improved safe water, sanitation and hygiene practices within the different community structures to prevent diarrhea and ensure better health of children and their families. Incorporate water, sanitation and hygiene into early childhood education programs, in school and childcare settings and include curriculum related to water, sanitation and hygiene in parenting skill trainings, community activities and OVC training materials.

Section 3. Cross-Cutting

TECHNICAL AREA 3.1: LABORATORY INFRASTRUCTURE

Laboratory infrastructure – development and strengthening of laboratory systems and facilities to support HIV/AIDS-related activities including: strengthening of laboratory leadership and management; purchase of equipment and commodities; strengthening of laboratory supply and equipment management systems; promotion of quality management systems, laboratory monitoring and evaluation, and laboratory information systems; and provision of staff training and other technical assistance. Specific laboratory services supporting TB testing goes under TB/HIV. Laboratory services supporting counseling should go under Counseling and Testing or PMTCT. Laboratory services supporting care should go under Adult or Pediatric care and support. Laboratory services supporting treatment should be included under Pediatric or Adult Treatment Services.

3.1.1 INTRODUCTION

The goal of the PEPFAR laboratory program is to support countries to strengthen sustainable and integrated laboratory network systems in order to provide quality diagnostic tests to meet PEPFAR goals for prevention, treatment, and care of HIV-infected persons and the broader health system. USG programs should encourage and support countries in developing coherent strategic plans for improving integrated laboratory services for patient care. The long-term goal of technical assistance to national laboratory programs is the establishment of national integrated quality-assured networks of tiered laboratory services. The most significant advantage of such networks is the provision of clear lines of authority and organization for developing national laboratory policy, quality assurance programs, and standardized training and testing. Successful programs require early establishment and on-going reinforcement of local referral networks both within and among implementing partners. Patient and specimen referral networks should be harmonized such that they reflect a continuity of care and are responsive to the needs of clinical decision making. Cumulatively, these local networks provide the support structures for a country's national network of tiered laboratory services, and an efficient mechanism for referral of complex testing and validation of new technologies or testing algorithms. Over the past 5 years, PEPFAR has supported approximately 2,000 laboratories and about 20,000 HIV testing sites in all 15 focus countries.

The stated purpose of Congress in PEPFAR's reauthorization was "to help partner countries to: a) strengthen health systems; b) expand health workforce; and c) address infrastructural weaknesses". To that end, the Laboratory Technical Working Group has focused its attention on the following 7 technical areas which are designed to strengthen sustainable and integrated laboratory services.

A. Quality Management Systems

Each country should have a Quality Assurance (QA) plan to ensure that laboratory testing is available, accurate, reliable and timely, and there should be a national quality system in place, encompassing all tiers of the laboratory network, to support the plan and to monitor and evaluate the laboratory's capacity to support program goals. This should include national standards for testing and training of staff involved in QA, laboratory supervisors and staff, and non-technical staff involved in testing services. A limited number of regional referral hubs should be designated to develop as

referral centers for complex testing methodologies, such as advanced CD4⁺ monitoring capacity (so that they might provide for quality assurance of these efforts), early infant diagnosis, viral load, TB culture, and drug sensitivity testing. QA efforts require considerable effort and should be a clear element in programming support for laboratory networks (e.g., support for QA dedicated staff, travel to perform periodic on-site supervision activities, etc.).

The developmental focus of Quality Management Systems should be directed toward accreditation of testing laboratories. Full accreditation and levels of accreditation can be assessed by a standardized set of criteria defined by the WHO Accreditation of Laboratory Networks standard, or other acceptable international and national standards. Full accreditation is defined by meeting acceptable criteria in order to receive certification by a recognized approved accreditation organization, such as College of American Pathologists (CAP), International Organization for Standardization (ISO), South African National Accreditation System (SANAS), Southern African Development Community Accreditation Service (SADCAS), or other World Health Organization (WHO) approved accreditation organizations. Accreditation certificates are a formal recognition that a laboratory is competent to perform clinical testing.

Laboratories may also be assessed using the WHO/AFRO Laboratory Accreditation Checklist. This checklist can be used for all levels of laboratories in a tiered laboratory system. Laboratories will be evaluated in a step-wise process towards full laboratory accreditation using scores on the checklist. Laboratories will be assigned a level of progress toward full accreditation based on their assessment score. Laboratories that meet the minimum accreditation level (partial accreditation) will be counted as being accredited. However, if a partially accredited laboratory does not achieve at least one level higher towards full accreditation from that of the previous year, this laboratory will not be counted.

B. Training and Retention Systems

One of the mandates of PEPFAR II is to promote pre-service training for 140,000 health care workers, including laboratory professionals, with the intent to strengthen the capacity of institutions to develop and implement policies for training laboratory workers to rapidly and accurately diagnose and manage HIV-infected individuals and those co-infected with TB. Strategies should be developed to ensure retention of laboratory workers once they are trained, including, but not limited to, competitive pay and opportunities for advancement and continuing education, and links with professional organizations.

Pre-service training should engage local university and other partners (e.g., Ministry of Education, Ministry of Health, etc.) to promote sustainability of the pre-service training initiative and to ensure the training adequately meets the needs of the country. Funding must be allocated for the roll-out of comprehensive training tools that have been developed centrally, including the WHO/CDC HIV Rapid Test training package and the Laboratory Management training package. Adequate training for performance and reporting of the rapid tests are critically important since these assays are performed by non-laboratory staff. In addition, management training for laboratory managers and supervisors is essential for effective service provision due to the lack of leadership and an effective laboratory management system. Implementing partners should be identified to coordinate laboratory management leadership and training on a national scale. Ideally, this will incorporate regional training venues and should include information suitable for laboratory managers/directors and senior supervisory technicians in their local setting. Written standard operating procedures for specimen tracking, testing procedures, results reporting, equipment maintenance, and inventory management should be in place and strictly followed. Further, regional training centers should be established from among the designated facilities, and standardized training packages used universally among implementers. For example, training needs assessments have been done and prioritized short-term,

hands-on essential courses are now offered for laboratory staff from PEPFAR and Global AIDS Program (GAP) countries at the African Centre for Integrated Laboratory Training (ACILT), in Johannesburg. For in-country training support, consideration should be given to the list of the HHS/CDC/GAP International Laboratory Branch cooperative agreement partners; the American Society for Clinical Pathology (ASCP); the American Society for Microbiology (ASM), the Association of Public Health Laboratories (APHL), Clinical Laboratory Standards Institute (CLSI), African Field Epidemiology Network (AFENET), and Foundation for Innovative New Diagnostics (FIND). It is recommended that funding for these partners should be allocated to a general Laboratory Consortium until an appropriate partner is identified based on the scope or work. However, in order to build in-country or regional capacity to sustain laboratory strengthening efforts, partnership with indigenous laboratory organizations and training institutions is encouraged. Transition from use of international partners to country-owned programs should be encouraged.

C. Equipment Maintenance Systems

Several factors influence decision-making about laboratory equipment. Among the most important factors are those concerning maintenance requirements. In general, two types of maintenance are required: laboratory-initiated and manufacturer/service provider-initiated. In many PEPFAR-supported laboratory venues, both types of maintenance provide challenges for laboratory staff. Laboratorians may not be adequately trained or have access to necessary parts or reagents (e.g., calibration materials) to perform necessary equipment maintenance. Primary- and secondary-level laboratory venues are often distant from major cities. Obtaining manufacturer/service provider-maintenance for instruments at these sites can be both expensive and time consuming. In the absence of appropriate maintenance, the laboratory cannot provide quality test results. Development of equipment maintenance service contracts is vital to ensure the ongoing integrity of equipment function and reliability of testing results. When purchasing new equipment, consideration of extended manufacturer/service provider maintenance should be included where possible. To support sustainability, host governments should be encouraged to allocate funds for equipment maintenance and training of biomedical engineers.

Consistent with the guidance recommendations agreed upon at the Maputo Consensus Conference, service contracts should include, at a minimum, the following items:

- Defined number of service visits and cost of any additional calls;
- Acceptable response for routine and urgent service calls (e.g., 95% of all urgent calls for such issues as equipment down will be responded to within 24 hours);
- At least one preventative maintenance visit per year;
- Coverage for costs of freight if parts or equipment must be shipped out;
- Coverage for parts, labor and travel;
- Stipulation for service and maintenance training for staff/engineers;
- Loaner equipment available within defined period;
- Access to spare parts may need to be included;
- Mechanism for shipping back unrepairable equipment at vendor cost;
- Penalties and mechanisms for escalation when defined service response rate is not met;
- Details of hotline services including hours of operation;
- Service documentation provided to user;
- Define the term and cost of the contract;
- Define all equipment covered under the contract; and
- Mechanism for contract review.

D. Supply Chain Management Systems

A nationally standardized system of supply chain management to support HIV/AIDS-related laboratory services should be instituted in line with the guidance recommendation document of the Maputo Consensus Conference. Procurement is only one element of the supply chain. Functions such as effective forecasting, tendering processes, warehousing, distribution, and inventory management systems must be in place to have a reliable supply chain system. In particular, the following parameters should be considered:

- Defined forecasting and inventory management systems should be operational in each laboratory;
- Reagent rental and standing orders for reagent delivery should be options if appropriate;
- Central coordinating bodies should perform regular reviews and verify sustainable integrated supply chain management systems;
- Lot assurance should be provided by suppliers;
- Pack size should meet facility and transportation requirements;
- Cold chain requirements should be met in transport and storage at each site;
- Effective clearance procedures and duty waivers should be available;
- National policy should exist for minimum expiry dates on reagents when delivered to sites (i.e. reagents should have at least 80% shelf-life when delivered to the country's national stores);
- Feedback from users on reagent/supply delivery systems should be obtained and a national supply chain system design with all relevant stakeholders is encouraged;
- Reliable distributors/agents should exist in-country;
- Replacement policy for unusable or expired products should be defined in contracts if manufacturer delivers them as such;
- Quality assessment of products to be used in-country should be performed if possible;
- Quality should drive procurement more than cost;
- Sole sourcing should occur only with justification;
- Countries should access negotiated global pricing schemes such as Global Drug Facility, AMDS, FIND, and others. Global pricing for equipment and reagents may be useful to reduce high local costs; however for generic consumables (such as cotton swabs, markers, etc) local procurement may be more cost-effective;
- A centralized, transparent procurement system is desirable; and
- Streamlined purchasing and payment processes should be in place to avoid stock-outs.

Point-of-care diagnostic technologies are created for use in resource-limited settings by persons with little or no laboratory training. According to the WHO, for these tests to be effective they should meet several characteristics listed in the acronym ASSURED; they should be affordable, sensitive, specific, user-friendly, robust, rapid, equipment-free, and delivered to those who need it. Countries are encouraged to develop an analytical framework that integrates product specifications, current laboratory infrastructure, and patient care needs to inform the purchase and optimal placement of new diagnostic technologies.

The supply chain management plan should be coordinated among all partners and include identification of responsible persons and contacts that can be reached in event of difficulties or unexpected needs at each level of the procurement and distribution chain. Countries are encouraged to consider assigning funds supporting laboratory equipment, supplies, and reagents to the capital fund for procurement through the SCMS. The PEPFAR Laboratory Technical Working Group and

the International Laboratory Branch Laboratory Liaisons for each country will work with country teams as needed to identify appropriate equipment and reagents based on service needs.

Many countries use PEPFAR's Supply Chain Management System (SCMS) for the purchase of and technical assistance for commodity needs. SCMS's mission is to strengthen or establish secure, reliable, cost-effective and sustainable supply chains to meet the care and treatment needs of people living with or affected by HIV and AIDS. SCMS can provide technical assistance to build local capacity in such areas as forecasting and quantification, local procurement and warehousing/distribution of laboratory commodities, as well as setting up Laboratory Information Systems (LIS) for test kits, reagents and related laboratory commodities. These activities have helped in the development of mechanisms for the collection and analysis of available information on consumption and use of laboratory products, including systems for laboratories commodities to enable timely replenishment of supplies for hundreds of laboratories.

E. Laboratory Information Systems

Electronic and paper-based Laboratory Information Systems (LIS) support operations of clinical and public health laboratories by streamlining laboratory data collection, storage, analysis, and reporting. Development and deployment of LIS should remain a top priority for all countries, which are at various stages of evaluating and/or implementing LIS.

Several countries have implemented pilot LIS and are now in the process of planning for nationwide scale-up. The following is a rough set of guidelines for approaching this challenge: (1) initiate strategic and financial planning with an in-country working group, (2) develop a detailed project plan with an information technology project manager leading a project team, (3) define LIS needs, (4) select a provider and solution that meets needs within budget, (5) develop or adapt an LIS, (6) train users, (7) implement the LIS, (8) support and maintain the LIS, and (9) plan for evaluation, updates, and next phase. Technical assistance is available from headquarters to assist with LIS selection and implementation.

A generic, standardized logbook for recording results of HIV rapid tests is available for countries to customize. Countries that do not have standardized record keeping systems in place are encouraged to contact headquarters for technical assistance. Implementation of this tool would be a major step forward in improving data quality and is an integral component to the overall quality assurance program for HIV rapid testing. Documentation of information relating to test kits used, their expiration dates, who performed the testing, etc. are critical for identifying the source of errors. Laboratory managers should be encouraged to utilize data for decision making.

F. Sample Referral Systems

Priority should be given to those laboratory networks with the greatest capacity to contribute to program goals. Local referral networks have an immediate impact on efforts to expand ART programs by bringing together neighboring facilities to jointly establish common standards of practice. The simplest model for this is that of district hospitals supporting several satellite health centers through referral testing services, quality assurance (QA) measures and training. Similarly, regional or zonal hospitals may serve as referral or reference hubs for networks of neighboring district hospitals. Implementation efforts should be designed to provide early recognition of successful referral networks and develop these laboratories to serve as models that might be replicated as services expand nationally. In order to ensure successful coordination of efforts, it is important that the narrative of laboratory activities be cross referenced to clinical

services in the relevant program sections. Functions of laboratory networks can be expanded to include hubs for model quality management systems (accredited laboratories) and bio-safety.

High-burden countries funded by PEPFAR have expanded CD4 testing supported by trainings, mentoring, external quality assessments and procurement of instruments and supplies provided by international public and private partners. The need for new technologies that would allow point-of-care testing is driving evaluations of innovative instruments and assays that are on-going in several countries. Alternatively, mobile laboratories with state-of-the-art equipment are being used in South Africa to provide patients in rural areas with access to CD4, hematology, chemistry and viral load testing – use of mobile laboratories is also planned for implementation in other PEPFAR countries.

G. Policies

Laboratory testing for diagnosis of HIV infection and other opportunistic infections (OI), and for monitoring of patients during care and treatment, are essential elements of PEPFAR. Thus, support for building capacity in public, private and other clinical laboratories should be addressed not only in the Laboratory Infrastructure section but also in all relevant sections (ARV treatment, Palliative Care, TB/HIV, PMTCT, Testing and Counseling, Strategic Information and Blood Safety). For this comprehensive approach to be synergistic, the laboratory components should emphasize efforts with all implementing partners to:

- Standardize best laboratory practices and provide associated training;
- Provide for uniform quality assurance measures among laboratories;
- Standardize common equipment, commodities, and supportive maintenance training; and
- Support a unified approach to procurement and distribution of laboratory commodities.

Plans should address the following laboratory-related PEPFAR indicators:

- Adequate number of clinical laboratories

In order to support PEPFAR programs, an adequate number of clinical laboratories are needed to perform testing for HIV/AIDS diagnostics, and care and treatment services. Determining the number of laboratories that can perform testing would measure the USG support to build laboratory capacity. This indicator will also serve as a proxy for measuring coverage of HIV/AIDS patient laboratory monitoring. Knowing the number of HIV/AIDS clinical laboratories and the testing needs for the area served by those laboratories will indicate if testing coverage is adequate or if more capable laboratories are needed.

 - All countries with USG agencies and/or PEPFAR-funded partners providing HIV/AIDS diagnostics and monitoring test services should report on this indicator. Data should be aggregated in time for PEPFAR reporting cycles.
 - The number of laboratories is obtained from program records of the PEPFAR-funded partners. A clinical laboratory is counted if it meets the criteria of having the capacity, infrastructure, personnel, and equipment, or is performing testing for the diagnosis of HIV infection with either rapid test, EIA or molecular methods and is performing other clinical laboratory tests in any of the following areas: hematology, clinical chemistry, serology, microbiology, HIV/AIDS care and treatment monitoring with CD4 testing or HIV viral loads, TB diagnostic and identification, malaria infection diagnosis, and OI diagnosis. A clinical laboratory can be a physical or mobile structure and must have dedicated laboratory personnel. A facility that does testing for only HIV rapid test diagnosis, such as a VCT or PMTCT site, should not be counted.

- The laboratory infrastructure will determine a laboratory's capacity to do serology, hematology, microbiology, clinical chemistry, and CD4 testing. A tiered laboratory network is an integrated system of laboratories in alignment with the overall health delivery network in a country. In resource-limited settings, there are 3 to 4 levels of laboratories in the national network: 1. Primary health center lab, 2. Secondary district/regional lab, 3. Tertiary regional or provincial lab 4. National reference lab. All laboratories that meet the minimum definition of being capable of or actually performing HIV diagnostic *and* patient monitoring tests should be counted regardless of tiered capacity.

This indicator represents the sum of all PEPFAR-supported laboratories that perform HIV/AIDS related clinical laboratory testing for HIV diagnostics including rapid test, EIA, and molecular methods and have the capacity to perform patient monitoring testing for HIV/AIDS and/or for related infection diagnosis – these tests would include either CD4, hematology, clinical chemistry, HIV viral load, TB diagnostic and identification, malaria diagnosis, STI diagnosis, and OI diagnosis.

- Number of accredited laboratories

Presently, the laboratory infrastructure for HIV, malaria, and TB testing and quality assurance remains weak in most PEPFAR-supported countries. There is therefore an urgent need to strengthen the laboratory. The establishment of accreditation systems will help countries to improve and strengthen the capacity of their laboratories. Accreditation provides documentation that the laboratory has the capability and the capacity to detect, identify, and promptly report all diseases of public health significance that may be present in clinical and research specimens. The accreditation process further provides a learning opportunity, a pathway for continuous improvement, a mechanism for identifying resource and training needs, and a measure of progress.

- This indicator measures the progress and extent to which USG-support has built laboratory capacity, quality, and sustainability by determining the number of accredited clinical laboratories and the laboratories' ability to maintain accreditation over time.
- All countries with USG agencies and/or PEPFAR-funded partners providing HIV/AIDS diagnostics and monitoring test services should report on this indicator. Data should be aggregated in time for PEPFAR reporting cycles.
- The number of accredited laboratories is obtained from program records of the PEPFAR-funded partners. A PEPFAR-supported clinical laboratory is counted as being accredited if it has received national or international accreditation that meets the WHO Accreditation of Laboratory Networks standard, or has received partial accreditation (see Technical Consideration 1, QMS).
- Any fully accredited laboratory that loses accreditation compared to the last reporting year will not be counted.

This indicator monitors the scale up of accreditation practices in testing facilities (laboratories) supported by PEPFAR. This indicator assesses the quality systems of a laboratory and the ability of a laboratory to maintain quality. Determining the number of accredited clinical laboratories, the progress of a laboratory towards accreditation, and the laboratory's ability to maintain accreditation over time provides documentation that the laboratory has the capability and the capacity to perform quality-assured clinical laboratory testing for HIV diagnostic and care and treatment services. Maintaining accreditation is a continuous process and can serve as a measure of sustainability of quality laboratory service. This indicator counts the number of partially accredited laboratories which may not deliver full quality services necessary to support PEPFAR. At the same time it will measure a

laboratory's effort to improve on quality as compared to if the laboratory was unmonitored or unaccredited.

3.1.2 COUNTRY CONTEXTUAL CONSIDERATIONS: LABORATORY INFRASTRUCTURE

- A. PEPFAR related laboratory activities should not happen in a vacuum but rather be fully integrated into clinical laboratory support activities. The most frequently cited examples of this are the interplay in diagnosis of malaria, TB and other OIs; however “best laboratory practices” and quality assurance measures should be applied holistically in improving laboratory services. An integrated laboratory approach should include the following key elements: Training and retention
- Leveraging with existing USG efforts will be critical. In order to meet the PEPFAR II target of training 140,000 health care workers, as a core part of the health work force, a coordinated and leveraging strategy needs to be embraced with the existing US government efforts overseas, such as the Field Epidemiology and Laboratory Training Program (FELTP), whose aim is to provide competency-based training to healthcare professionals and health paraprofessionals. In the program, field epidemiologists and public health laboratorians are jointly trained in long courses (i.e., 2-year public health leadership training) and short courses (i.e., 1–2 week public health implementer training) to acquire skills and develop competencies while providing a public health service; and
 - Any effective strategy must proactively involve stakeholders (e.g., national governments, the private sector, development partners, and multilateral bodies). Training should also focus on retaining laboratory workers by targeting existing employees or identifying target groups who may not otherwise have considered a career in laboratory health services. Hands-on training and mentorship should be prioritized for successful skills transfer.
- B. Establishing new regional training centers and sustaining existing ones.
- C. Strengthening referral transport systems for specimens.
- D. Implementing practical and sustainable quality management systems:
- Policies for certification of HIV testing by non-laboratory staff;
 - WHO Laboratory accreditation scheme – stepwise approach for reference and peripheral laboratories; and
 - Laboratory management training programs.
- E. Effectively coordinating donors and partner's efforts (World Bank and Global Fund for AIDS, TB, and Malaria, etc.) on laboratory strengthening efforts.
- F. Standardization of testing and equipment to facilitate equipment maintenance, and development of equipment maintenance service contracts.

3.1.3 PARTNER PERFORMANCE CONSIDERATIONS: LABORATORY INFRASTRUCTURE

Laboratory activities should be based on strategic planning that supports expansion of ART and Care services by building on basic HIV diagnosis and monitoring of ART patients (e.g., CBC, differential, creatinine, ALT, and CD4 count). To this end, service-based models should be utilized by all partners and include plans for renovations, staffing, training, equipment and associated service contracts, reagent management needs, inventory and forecasting of supplies, plans for instituting quality assurance

measures, data records and reporting, data processing, and monitoring and evaluation of services. An implementing partner should be identified to work with the USG and partners and country representatives to develop a strategic plan for each tier of laboratory service that describes minimal requirements needed to effectively support programs. Ideally, a common matrix to be applied by all partners would standardize descriptions of the recommended testing at each facility, and include guidelines for expansion of services.

3.1.4 LINKAGES AND WRAPAROUNDS: LABORATORY INFRASTRUCTURE

Laboratory infrastructure development has many opportunities for linkages and wraparounds. All clients seen for testing and counseling should be referred for appropriate laboratory diagnostic testing consistent with relevant clinical diagnosis (e.g., all presumptive HIV positive individuals should be referred for confirmatory testing), necessitating effective linkages between Point of Care testing facilities and referral laboratories. Country programs should work with partners to ensure that effective linkages exist between partners to ensure that patients receive comprehensive testing services. In addition, Point of Care testing settings may provide opportunities for linkages with other USG or multilateral programs, including home-based testing linked with home-based care programs, or family planning services offered in PMTCT settings. In areas where mobile populations are at high risk of contracting HIV, the country team may work with the Millennium Challenge Compact to ensure that Point of Care testing services are available along the newly built roads.

TECHNICAL AREA 3.2: STRATEGIC INFORMATION

Strategic information – Aims to build capacity in country for HIV/AIDS behavioral and biological surveillance, facility surveys, monitoring program results, reporting results, supporting health information systems, supporting countries to establish and/or strengthen such systems, supporting training and retention of local cadres of personnel needed to direct all SI activities, and related analyses and data dissemination activities fall under strategic information. Program area-specific monitoring and routine evaluation should be incorporated under the specific program area.

3.2.1 INTRODUCTION: STRATEGIC INFORMATION

Strategic Information (SI) is the cornerstone of evidence-based planning and decision-making for all components of all programs and integral to national health systems strengthening. Data are fundamental to partner government's ability to document its needs, activities, and results with its own policy-makers, as well as with PEPFAR, and other donors. Data demonstrated the need for PEPFAR and has been critical for on-going country planning and decision-making for implementing partners, USG teams and national counterparts, PEPFAR agency headquarters, and Congress and the White House.

Data use continues to be of great significance, given the need to accomplish much more work under more limited funding. The figure below depicts the diversity of data sources and timing.

SI is divided into three technical areas that, though separate, are highly integrated. These are Health Information Systems (HIS), Monitoring and Evaluation (M&E), and Surveillance and Surveys.

- HIS is responsible for the collection, flow and management of data, assuring the seamless movement of information through the entire range of effort from individual service programs to centralized, national and headquarters data systems;
- M&E supports the generation of the data that flows in this system, and strengthens the quality as well as the analysis, interpretation, and use of information produced; and
- Surveillance and surveys supports systematic data collection, analysis, and interpretation, representing samples of national populations, service populations, risk populations, and service delivery locations, among others.

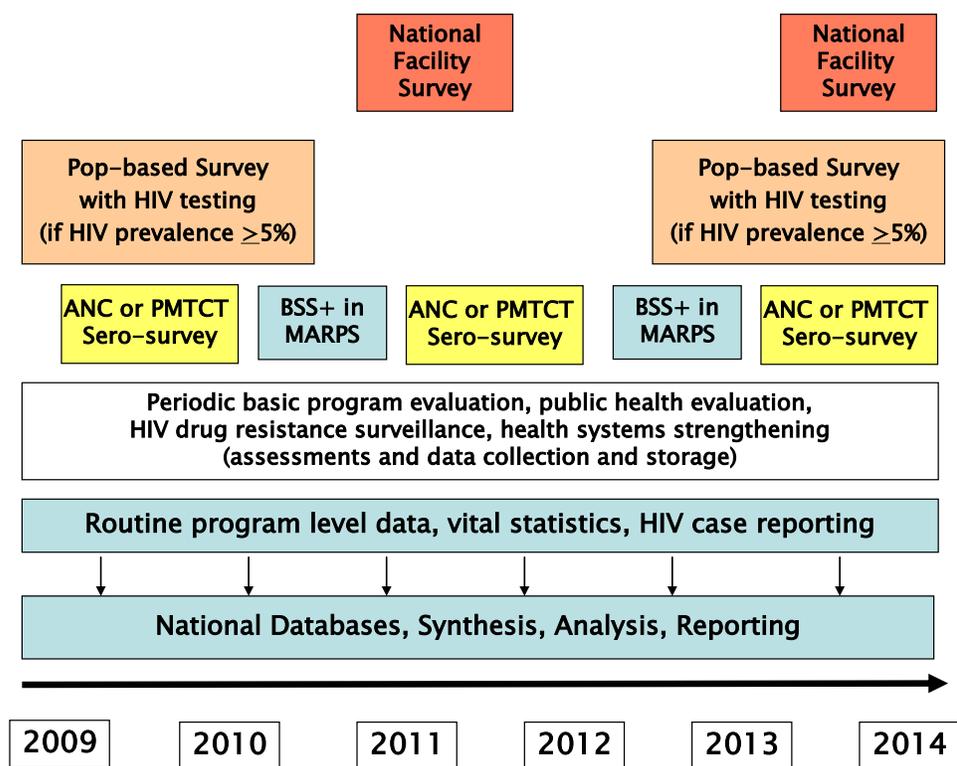


Figure 1. Sources and timing of PEPFAR II data.

The following are the key goals for building country capacity across all SI areas:

- Improve integration and collaboration of HIS, Surveillance and Surveys, and M&E efforts at all levels of the host country government;
- Provide greater support to national capacity building to collect accurate data, manage, analyze, and use data;
- Improve partnership with other technical programs; and
Increase coordination with other international donors and agencies.

Overall, these goals can be accomplished through continued support of the development and implementation of program area-specific monitoring systems; program evaluation activities; standardized surveillance and surveys; building health management information systems; and strengthening of local personnel to take on responsibility to direct and implement these systems.

PEPFAR II will require a transition from “emergency” to a routine public health service delivery and development program. SI will support this transition by:

- Adopting a “systems approach” to building national SI capacity, through the application of national SI assessments and five year strategies which emphasize building individual, organizational, and institutional capacity; and
- Facilitating the development of national SI coordinating mechanisms to improve collaboration, reduce redundancy and improve system efficiencies.

PEPFAR seeks to support partner governments in their work to integrate PEPFAR SI systems and partner systems into the overall national system and increase the emphasis on SI system strengthening – by developing leadership, building stronger organizations and improving the policy environment, and ensuring the advancement and sustainability of technical capacity.

3.2.2 GENERAL CONSIDERATIONS FOR PLANNING: STRATEGIC INFORMATION

General considerations in the overall country operation planning process include:

- How the work of the USG team and all supported partners:
 - Supports building the capacity of the national SI strategy and the partnership framework;
 - Supports and advances national capacities to collect, manage, analyze and use data;
 - Supports the broader, national technical program areas for monitoring, evaluation, surveillance, survey, or information systems; and
 - Works in a supportive fashion toward common goals;
- How the USG team supports and contributes to partner country government past activities in this area (e.g., country has supported two large population based surveys with HIV testing in the past 5 years) given the country context;
- How the USG program supports partner country government's and complements other donors' activities, and how all activities fit into the national strategy or Partnership Framework, if it exists;
- Develop a 5-year USG SI strategy that leads to a National SI strategy. This can be part of the Partnership Framework, as an update to an existing SI strategy, or creation of a new SI strategy;
- Develop a shared understanding of goals and strategies that partner governments and USG teams can support for the coming year;
- How these activities are harmonized with national SI strategy and/or information/reporting systems;
- Strategies for sustainability and, where applicable, transition to country government ownership; and
- Supporting government partners in their work to collaborate with partners to demonstrate how each is bringing added value and synergies to the effort. These partners may be national government entities, local NGOs, international agencies, or international NGOs.

Building in-country capacity for SI:

Capacity development efforts in SI may target government, nongovernmental organizations, communities, and the private sector, in the context of promoting partner government leadership under national monitoring and evaluation, health information systems or surveillance and surveys strategic plans. All SI efforts in PEPFAR should explicitly consider the degree to which host country capacity to know and appropriately respond to their epidemic is improved as a result of those efforts, and all capacity development under PEPFAR should ultimately result in measurable improvements in HIV outcomes and impacts.

There are three components of capacity building that are required to ensure overall successful performance of the HIV response: individual, organizational and system. When planning for SI

activities, capacity building should be considered at all three levels. In fact, improving capacity at one level may require concurrent interventions at another level.

Monitoring the impact of capacity development efforts provides an opportunity for USG country teams to demonstrate the transition of the PEPFAR program strategy from an emergency response focusing on direct service delivery to individuals, to one that focuses on developing sustainable country capacity and ownership.

A. Build and support a future SI workforce:

Consistent with shifting the emphasis of PEPFAR to national system strengthening is ensuring a future SI workforce. This would involve efforts that advocate for and establish long-term human resource strategies in SI coupled with supportive policy and system reform strategies. Organizational capacity and systems reforms are essential so that SI professionals are not only trained, but their hiring, placement in established SI positions, and retention where they are most needed in the health system and civil society organizations is ensured. Linkages to in-country universities will be needed to develop and support on-going educational needs for local new and current M&E professionals, and the capacity of these local universities to meet those needs.

B. Build SI capacity throughout the organization and system:

To support data use, especially in high level decision making, it is not sufficient to rely solely on a cadre of SI professionals. It is important to complement this effort by introducing SI to other components of the health system. This can promote an organizational culture of data use and create a supportive environment throughout the system for SI activities. This can also promote the integration of health information systems throughout country systems and national plans for monitoring and evaluation, surveillance and surveys, and health information systems.

3.2.3 HEALTH INFORMATION SYSTEMS: STRATEGIC INFORMATION

Effective health information systems (HIS), both electronic and paper-based, have played a large part in the success of PEPFAR. Large volumes of information are being continuously generated on the nature, trends, impact of and response to the HIV epidemic at a rate that often overwhelms traditional paper methods for data collection, storage, and management. However, this huge generation of data can compromise data security and quality, poses challenges to data analysis, delays report generation, and limits the full use of data for management, policy, clinical, and programmatic decision making. A balance needs to be made between generation of data and the conversation of that data into useful information.

HIS supports data collection, analysis, and an information knowledge chain for the sharing and utilization of data across HIV program areas, spanning from point of delivery of patient services through aggregate-level monitoring and reporting systems. In order for PEPFAR to succeed in the long term, HIS must be sustainable through ongoing local coordination and collaboration across stakeholders led by local country “champions.” Interoperability, systems integration, and capacity building are important strategies for sustainable national health information systems. HIS activities should increasingly emphasize value-added approaches, rather than developing competing solutions. To be sustainable in resource-constrained settings, HIS activities should invest in low-cost, high-impact, interoperable information systems, training and retention of local expertise, and integration of technology and paper-based systems. As the next five years of PEPFAR transfers responsibility and financing of HIV programs to partner country governments, national health information system architecture must be devised country-by-country. Efforts along this

path must be well centered within the affected national institutions, principally with MOH and social service, as well as with the Ministry of Finance, infrastructure and communications technology (ICT), research centers, and schools of higher education.

As country programs continue to invest in any aspect of an HIS, it is important to bring focus and coherence to these efforts during FY 2012. When making decisions regarding the introduction or expansion of any component of information systems, country teams should do so fully cognizant of the country context. This context ranges from the presence, or development if needed, of a comprehensive national HIS strategy—into which any new or expanded components must fit—to the nature of applications and systems specific to particular service programs (e.g., HIV treatment, blood safety, OVC, etc.). Future decisions need to ensure compatibility with the country strategy, avoidance of duplicative, poorly functioning, or costly systems, and the development of the local expertise to manage and use the new components. Successful systems are present in most countries, and every effort should be made to build on and work with those successes rather than introduce competing solutions. If a new system is proposed, a justification addressing the added value within the country context, as well as its relationship to and compatibility with existing systems, will be required.

Although electronic health information systems have been very useful at creating efficiencies, enhancing security and confidentiality of data, in many contexts there is still need for paper-based systems. In certain cases, having an electronic-based system is more costly and more advanced than what is needed for low-resource settings and community-based work. It is important to consider how best to improve processes and ensure quality data in systems given the limitations of paper-based systems.

A. Strengthen National Health Information Systems Framework

Even though there may be differing needs at these various levels of implementation, it is critical that these systems be integrated into a coordinated and interoperable HIS strategy, founded on the structure of the national HIS architecture and content. To achieve interoperability, it is important for SI teams to follow international standards and guidelines produced by WHO, UNAIDS, International Standards Organization (ISO), International Telecommunications Union (ITU), UNICEF, among others, to support and assist partner governments in the design of such a strategy, if it is not already established. Reference information is also available at <http://www.healthmetricsnetwork.info/>, and <http://www.who.int/healthmetrics/en/>.

Implementation of specific solutions includes:

- Documenting use cases, i.e., collecting information needs and systems functionality to support beneficiaries of respective system(s);
- Gathering of functional information system requirements;
- Maintaining an inventory of existing systems, which are evaluated on an ongoing basis, from which implementing partners may select;
- Selection, design, and/or coverage level of appropriate software and technologies (ensuring not to duplicate extant or concurrent efforts). Entries should always include:
 - Name of system (and acronym as appropriate)
 - Proposed initial and recurring costs per FY Status (proposed, in development, in pilot testing, deployed locally, being scaled, etc.)
 - Relevance to a HIS strategic plan (written or planned)
 - Extent to which it adheres to a national standard, if one exists, and/or it matches a commonly accepted international standard (data content standards, technology standards, such as protocols for exchanging data between systems, ICT standards)
 - Current and projected number of sites
 - Whether the system contains individual-level data

- Prime partners
- Description;
- Monitoring the development of systems and the implementation of strategic plans; and
- Evaluating the implementation and performance of the system(s), including adequate personnel at level to direct and manage the systems(s)

B. Strengthen the National Policy and Promote Use of Standards

The goal of interoperability is built on internationally recognized standards. Countries are at different stages of health information systems development with many countries having entirely paper-based systems while others use a combination of electronic and paper-based systems. Countries need to be supported with strategies to harmonize paper-based and electronic information systems and implement standards which support interoperability, such as national policies for data exchange, privacy, confidentiality, and security.

It is also important to document in-country HIV-related HIS, including the relationship to Ministry of Health (MOH) routine health information systems with the goal of integrating HIV facility-based systems into broader regional or national health information systems (HIS). Strong national leadership improves HIS sustainability and country ownership. Having strong national health information systems policies for both paper and electronic-based systems and trained personnel greatly facilitates effective communications with stakeholders and fosters broader health systems strengthening.

C. Strengthen HIS Human Resource Capacity

Identifying, developing, and utilizing public health informatics training curricula used in local institutions of higher learning and/or self-paced distance learning and e-learning formats are important strategies, as well as south-south collaborations, all of which have proven to be strategic in achieving sustainable results in developing local capacity to implement, manage, and maintain national HIS activities. Human resource plan should include capacity for HIS, including job descriptions, qualifications, and recruitment/retention strategies. An effective supervision plan will support high quality data collection and analyses and retain a competent workforce.

D. Increase Collaborations with the International Community and Private Sector

Countries should work to expand telecommunication capacity and infrastructure; for example, to expand universal access to the Internet or other computing services by working across Ministries of Health, Finance, Information/Telecommunications, the U.N. International Telecommunications Union (ITU), and the private sector. It is important to continue to partner with multilateral organizations, including WHO, for effective coordination in addressing national HIS demands and priorities.

E. Data Management

Enabling the national collection, aggregation and transmission of core indicator data from service delivery, district, and national levels, to inform clinic and program management decisions at all levels, including USG and other donors, is an important goal of HIS. It involves data quality, data transmission and data exchange formats, and security and confidentiality.

3.2.4 MONITORING AND EVALUATION (M&E): STRATEGIC INFORMATION

The international community has reached general agreement on the overall purpose and components of an M&E system. These are outlined in *Organizing Framework for a Functional HIV Monitoring and Evaluation System*, published by UNAIDS in 2008. The most recently updated book on this topic is *Making Monitoring and Evaluation Systems Work* published in 2009 by the World Bank. Also known as the *12 Components Framework*, these are generally being adopted and implemented by many countries. The purpose of a fully functional, unified, national M&E system is to ensure:

- The generation and utilization of quality information to support effective prevention, care and treatment program design, management, and implementation;
- Provision of support to national governments for evidence-based guidance for strategic decision-making about the country response to the epidemic; and
- Response to donor and country reporting requirements and needs through unified coordinated monitoring systems.

Illustrative components of a national M&E system include:

- National M&E strategic plan for HIV/AIDS programs;
- Coordination bodies/task forces that support a unified M&E system for the country;
- Coordinated program monitoring systems that capture input and output data;
- Processes for ensuring data quality;
- Process and outcome evaluations of priority prevention, care, and treatment programs;
- Strategies for use of data for multiple stakeholders; and
- Workforce plan to develop and maintain necessary levels of expertise for now and in future years.

The accompanying assessment tool, found in Point B below, is an optional starting point for national-level M&E planning. Discussions to develop a national-level M&E plan should take place in collaboration with UNAIDS, Global Fund, and World Bank. It will be important that one assessment is used by all agencies for M&E planning.

As PEPFAR continues its support of national M&E systems, the following represent technical considerations for USG country teams in planning for the FY 2012 Country Operational Plan. These technical considerations continue to emphasize quality and sustainability in all areas of Monitoring and Evaluation.

A. Routine Program Monitoring Systems

- **Strengthen nascent HIV M&E systems:**
To strengthen the national monitoring system, it is critical to focus on strategies to build nascent HIV M&E systems including, those within military health systems. Partner governments, with support from USG teams, should evaluate and enhance national HIV care/treatment patient monitoring systems and integrated TB/HIV monitoring systems. Another important focus should be on supporting the adaptation and implementation of PMTCT monitoring standards and tools into national MCH monitoring systems. Much work also will need to be done to assess existing community-based monitoring systems for HIV prevention, HIV care and OVC services and to develop stronger linkages between facility and community-based monitoring systems.

- **Facility-based monitoring systems:** Much progress has been made in many countries in the development and/or implementation of facility-based monitoring systems to support HIV care and treatment, but there often remains a need for national harmonization of these systems. In addition, there has been little progress on nationalizing facility-based monitoring systems for PMTCT activities (particularly the continuum of prevention to care and treatment), provider-initiated counseling and testing, and monitoring of TB/HIV interventions. Thus, facility-based monitoring systems continue to be in need of strengthening and harmonization within countries and among systems.
- **Community based monitoring systems:** Non-facility based monitoring and evaluation systems need to be developed and strengthened and integrated with national information systems. Non-facility based programs may include selected prevention interventions such as behavior change communication, activities in support of orphans and vulnerable children, and home-based care activities.
- **Improve M&E for HIV-related integrated health and social services:** HIV has far-reaching effects on the health, social welfare, and economic well-being of infected and affected people. The converse is also true, that health, social welfare, and economic well-being affect HIV prevention, care, and treatment successes. Programs increasingly go beyond the traditional boundaries of HIV prevention, care, and treatment to better mitigate the impact of the epidemic. For example, some programs provide economic opportunities for persons living with HIV, ensure land rights for women, and support educational opportunities for HIV-affected orphans and vulnerable children. It is important that partner governments, with support of the USG teams, monitor and evaluate these innovative programs to measure progress and success with respect to HIV program goals and objectives. This might be achieved by adapting existing systems used to monitor other health or social services or by creating innovative ways to monitor and evaluate referrals and linkages among various service types and their impact on HIV-infected and affected populations.

B. Data Quality in Routine Program Monitoring Systems

Continue to assess and improve data quality:

SI portfolios should support development and implementation of data quality standards and procedures throughout the partner government system. The need for a data quality strategy should be emphasized for national and PEPFAR programs. The USG country team should collaborate with the Global Fund and other multilateral donors to support partner governments in their efforts to assess the strengths and weaknesses of monitoring and evaluation (M&E) systems; the capabilities of the program managers to collect, analyze, and report data related to the achievements of the program/project(s); and of the data-collection and reporting systems per program area, including the ability to report valid, accurate, and high quality data related to implementation. The results of such an assessment will enable the countries to identify and define strategic opportunities, select tools and approaches, and apply and assess how those approaches succeeded.

To achieve partner government's HIV prevention, care, and treatment goals and PEPFAR's 4-plus-12-12 goals, it is necessary to accurately capture accomplishments in the field; therefore, the quality of the data is integral to documenting these successes with precision, and making sound, evidence-based decisions about programming and resource allocation. Good target setting and results reporting are inextricably linked. In order for targets to be meaningful and realistic, the quality of the data on which they are based must meet minimum standards of acceptability.

All USG teams should work with partner governments to have a process in place for monitoring the quality of the program results collected by their partners. This process should also be an essential part of their portfolio review. Guidance for the portfolio review process can be found on PEPFAR.net at <https://www.pepfar.net/C5/C10/Portfolio%20Reviews/default.aspx>, along with country developed forms and examples.

Data reviews should involve comprehensive data quality assessments, including a review of client record keeping protocols, management systems for collecting and using program reporting information, accuracy of the information within the system, and sub-partner information management. The assessment should also look at how data are coordinated and reported into the national system. Partners should be able to demonstrate competence in developing and analyzing performance indicators and in managing performance indicator data to ensure audit-worthiness.

There are several tools to assess the quality of data collected. This involves taking stock of data quality assessment and improvement efforts to date to determine where substantial problems continue to exist in the quality of data on key indicators, and to design new strategies to improve data quality in these areas.

The following tools are available to assist with this process:

The Monitoring and Evaluation Systems Strengthening Tool
The Data Quality Audit Tool
The PEPFAR Data Quality Assurance Tool for Program-Level Indicators

They can be found on PEPFAR.net at www.globalhivmeinfo.org and at [https://www.pepfar.net/C12/C16/Annual%20Progress%20Report%20\(APR\)%20a/default.aspx](https://www.pepfar.net/C12/C16/Annual%20Progress%20Report%20(APR)%20a/default.aspx)

The Data Quality Assurance Tool for Program-Level Indicators contains information on double counting, comparing program results over time, and documenting outliers. These tools have not yet been updated to reflect Next Generation Indicators.

C. Data Use for Evidence-Based Program Planning and Improvement

- **Strengthen the partnership of M&E and programs:**
Data are more likely to be used in support of national programs when a data analysis, use, and dissemination plan, including identification of various users of the data, is included in the beginning stages of the program planning cycle. Information from M&E efforts can assess problem areas, identify intervention points, and suggest the need for new approaches. Thus a future direction is to strengthen collaboration between M&E and program specialists in-country, especially within government and civil society organizations, and among USG country teams to ensure that M&E operates more effectively in support of program and that programs better utilize information from M&E efforts to foster cost-effective, evidence-based approaches.
- **Promote better analysis and use of program monitoring data:**
Promoting more complex use of available information must include: advancing the efforts to build country capacity and synthesize multiple data sources to better describe the epidemic and better program the response; ensuring the analysis of program outputs with population denominators to estimate coverage to determine whether programs are targeting those areas and populations most in need of prevention, care, and treatment services; and using cohort analysis techniques to better utilize the information that we collect on the same people over time in our PMTCT, TB, HIV care and treatment, and OVC programs.

As HIV programs have expanded and matured, monitoring and evaluation systems have evolved in order to fulfill necessary reporting requirements to governments and international donors. Much effort is expended to collect population, community- and facility-based data; however, implementers commonly note that the information is often not used effectively, if at all, for decision making. This results in a lost opportunity to improve the quality of decisions around HIV programs and policies.

Data Use is critical to planning, assessing, strategizing, and determining next steps in public health programs. Population-level sources of data can be utilized at the national level to strategize and reprioritize activities, while routine monitoring data can be fed back into sub-national and community-based programs to support evidence-based planning and program improvement, design, implementation, and management of prevention, care, and treatment programs.

Another example of improved analysis and use of data is the use of population size estimation methods in high-priority populations for HIV prevention interventions. Data collected can be used to determine interventions as well as the resources needed for the interventions. It can also be useful when examining the program outcomes and when determining program effects. Information collected as part of size estimation exercise is used to determine coverage and overall reach of the programs.

A country's SI portfolio should include a specific plan, developed by the partner country as part of their plan, on how data will be more effectively utilized to improve programs at the national, sub-national, and community levels. Interventions intended to facilitate data use should be implemented as part of country SI plans. To facilitate data use, country plans should consider interventions that address the following issues:

- Is data quality being addressed by the country program in order to enhance trust in existing data sources, health statistics and other sources of data?
- Is there adequate interaction between program planners and researchers/M&E staff to ensure that appropriate data are being collected and that resulting data are accessible to data users?
- Are policy makers and program managers at all levels of the health system encouraged to use existing data sources to inform decision making?
- Are HIV programs being evaluated?
- Are data being fed back to service providers and program managers for program planning and improvement?
- Are service providers and program managers empowered to make data-informed decisions?
- Is the local expertise being developed to lead and support the collection, analysis and use of the necessary data for current and future monitoring and evaluation of programs?

D. Program Evaluation and Operations Research

Build country capacity to conduct program evaluation and operations research: Program evaluation (PE) plays a critical role in a fully functioning M&E system, and is necessary for delivery of effective, evidence-based programming. Basic program evaluation refers to studies that guide program and policy development, and are locally focused on how a program is implemented and the direct effect of a program on the populations using or benefiting from the program resources. As prevention, care, and treatment programs continue to scale up, process and outcome evaluation

should be used to document implementation and to determine the short-term effectiveness of programs for the country and for donors, including PEPFAR.

Program evaluation projects use scientifically sound evaluation methodology but tend to be methodologically simpler than Implementation Science (IS) studies. For example, PE studies tend not to generalize beyond the people served in the program and do not compare program models or use a randomized design. Instead basic program evaluation tends to include needs assessments, formative and process evaluations, and some outcomes evaluations, and the use of both quantitative and qualitative methods.

According to PEPFAR reauthorization language, operations research is the application of social science research methods, statistical analysis, and other appropriate scientific methods to judge, compare, and improve policies and program outcomes, from the earliest stages of defining and designing programs through their development and implementation, with the objective of the rapid dissemination of conclusions and concrete impact on programming. Operations research focuses on the day-to-day activities or “operations” of programs, and can be considered part of a larger evaluation agenda (i.e., part of either PE or IS). It provides answers to perceived program problems, and helps to identify and solve program problems. It provides program managers and policy makers with the information they need to improve existing program delivery activities and plan future ones.

For example, evaluation activities may include: process evaluations to investigate and document implementation of priority prevention, care, and treatment programs; outcome evaluations to investigate and document short-term and intermediate effects of priority prevention, care, and treatment programs; exploratory studies to determine the parameters of a problem situation affecting service delivery; and field intervention studies to test new approaches to overcoming a program problem.

E. Harmonization, Integration, and Sustainability

- **Shift the emphasis from USG reporting to national M&E systems strengthening:** A routine reporting system is critical for the management of the national and PEPFAR portfolios, for efficient and timely data transmission, for program management, and for reporting required program outputs. Shifting emphasis to national systems strengthening implies incorporating the use of the national system and indicator set by all agencies, donors, and implementing partners working in a country, and support for the reporting flow within the national systems rather than through parallel PEPFAR partner information systems. By focusing on the national system and adjusting the PEPFAR reporting structure, we can better integrate PEPFAR reporting and target setting into national M&E systems.

The international HIV community has reached general agreement on the overall purpose and components of an HIV M&E system and these are generally being adopted and implemented by many countries. (See *Organizing Framework for a Functional National HIV Monitoring and Evaluation System*, April 2008.) Countries should develop a long-term strategy to achieve system strengthening and system integration objectives. If one has not already been completed, a first step in USG’s continued support for the improvement, integration, and expansion of national M&E systems may be a national M&E system assessment. The global UNAIDS Monitoring & Evaluation Reference Group (MERG) has finalized an M&E assessment tool that was released in 2009 and was designed to be compatible with the Organizing Framework document. This tool includes standardized questions to assess the status of each of the components of an HIV M&E system. The SI portfolio should demonstrate and support how USG country teams strive toward national harmonization, integration, and sustainability in the area of M&E.

- **Support the measurement and monitoring of transition processes in PEPFAR:**
In order to track whether PEPFAR is successfully transitioning responsibilities to local governments and implementing partners, we will need to measure and monitor the transition of PEPFAR to local ownership at all levels. This work can expand upon work previously done in the field of M&E of organizational capacity building and can be applied to the transition of PEPFAR to country ownership as negotiated in the Partnership Frameworks as well as the transition of large agreements and associated responsibilities from US-based partners to local partners. The role of M&E in transition is to support the transition of M&E functions from international to local partners, to monitor the scale and quality of the programs that are transitioning, and to evaluate the overall transition process according to a diverse set of measures, including those of country ownership, local capacity development, quality of care in the program, etc.

3.2.5 SURVEILLANCE AND SURVEYS: STRATEGIC INFORMATION

PEPFAR supports countries moving towards having full responsibility for all surveillance and survey activities; in particular, those activities which seek to measure changes in their HIV epidemic. The monitoring of HIV prevalence and HIV-related risk behaviors at the national and local levels is critical to assuring that program activities are responding to the state of the epidemic. National surveillance and survey activities should be planned to measure changes in the HIV epidemic, track the impact of the portion of the national response supported by PEPFAR, and to provide data for future activity planning for the country.

As such, countries should be encouraged to develop national training programs to develop and support on-going educational needs to develop local experts in surveillance and surveys. Along with individual development, countries should also consider the capacity of local higher education providers to meet those needs. Countries should develop the system and organizational capacity to become a place for continued professional growth and training for experts in surveillance and surveys. These experts should then be able to serve as internal resources for the partner governments when implementing National surveillance and surveys strategies.

Strategic Planning

Partner Governments, with support from USG teams and implementing partners, should develop a five-year surveillance strategic plan addressing the HIV/AIDS epidemic in the country. These plans should be used to more effectively plan and implement national HIV surveillance and survey activities. This strategic plan should outline specific activities to be carried out, always considering a feasible implementation schedule for such activities, as well as the available human and financial resources. Once the strategic plan has been established, countries should routinely evaluate the surveillance activities being implemented. A listing of surveillance guidance documents can be found at the following WHO link: <http://www.who.int/hiv/pub/surveillance/en/>

Dissemination of Data

The timely publication of surveillance findings is a vital component of the partner government's use of strategic information for evidence-based planning and decision making. It is therefore important that the results of surveillance and survey activities be disseminated by the partner government as quickly as possible. The partner government should take responsibility for making sure all publications, reports and data are made publicly available as soon as feasible, ideally within six months of the conclusion of the activity.

A. *Surveillance and Survey Activities*

- **Laboratory support**

The enhancement of national laboratory capacity is critical to the success of both clinical management and strategic information collection. **N.B.** Laboratory support refers to specific assessments and trainings related to new lab procedures for surveillance (e.g. incidence assays, drug resistance), development of training materials, and specimen collection and testing, including that for ANC, other sentinel surveillance activities, and TB/HIV surveillance activities. The aspects of capacity building which include establishing national laboratories, including regulations, etc, are an important part of capacity building, but are not included in this guidance;

- **Sentinel surveillance (Generalized epidemics)**

Countries with generalized HIV epidemics (ANC sentinel surveillance prevalence >1%), have typically relied on sentinel surveillance among pregnant women attending antenatal care clinics. Partner governments should use sentinel surveillance data to monitor the HIV epidemic nationally and locally. Partner governments should ensure this surveillance activity is conducted no less than every two years, using consistent sites over the years. Internationally accepted guidelines for ANC surveillance were established by WHO.

The 2003 ANC surveillance guidance document can be found at this link: http://data.unaids.org/publications/irc-pub06/jc954-anc-serosurveys_guidelines_en.pdf

Due to concerns about the inability to provide HIV test results originating from unlinked anonymous surveys of ANC clients and the abundance of PMTCT program data, there is growing interest in using PMTCT program data for surveillance purposes rather than continued ANC sentinel surveillance. Partner governments need to take a lead role in considering feasibility studies to evaluate the utility of PMTCT program data to replace existing HIV sentinel surveillance among pregnant women attending antenatal care clinics;

- **Sentinel surveillance (Concentrated and mixed epidemics)**

Countries with concentrated HIV epidemics (ANC or other general population sentinel surveillance prevalence <1% and at least one high risk group >5%) typically rely on sentinel surveillance among the population groups at highest risk of infection, also known as most at-risk populations (MARPs). Populations and methods will vary by country or region but typically the groups include injection drug users, men who have sex with men, commercial sex workers and the sex partners of each of the preceding groups. Partner governments should be encouraged to collect behavioral data with HIV serostatus through their surveillance system. Partner governments should take responsibility for ensuring this surveillance activity is conducted every 2-3 years, depending on the specific epidemic conditions. Further, it is reasonable to conduct these types of surveillance activities in generalized epidemics though not at the expense of ANC surveillance;

- **Population-based behavioral surveys**

Population-based behavioral surveys are an important component of an HIV surveillance system and partner governments should note that with proper sampling, this can provide nationally-representative indicators on HIV. While output data is needed to determine and monitor short-term performance of programs, an understanding by Partner governments and their partners of how programs have changed attitudes and behaviors, or have improved individual health status, is very critical for program planning. Because the effects of programs take some years to be observed at the population level, partner governments should carry out population surveys every 3 or 5 years.

Partner governments may decide to incorporate HIV testing into population-based behavioral surveys. However, this is only recommended in countries with generalized or mixed epidemics and not in countries with concentrated epidemics. Partner governments should consider the UNAIDS recently issued guidance on key questions to ask when considering inclusion of HIV testing in population-based surveys.

For more information, please look the recent UNAIDS guidance on population surveys: http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/20101207_HI_Vtesting_in_surveys_WG_en.pdf;

- **Behavioral surveillance of at-risk populations**

Behavioral surveillance is identified by many acronyms: BSS (behavioral surveillance system or surveys), BSS+ (behavioral surveillance survey with serologic testing), ISBS (Integrated Serologic and Behavioral Surveillance), and IBBS (Integrated Biologic-Behavioral Surveys).

Behavioral surveillance systems can be used to measure change in relevant behavioral risk over time. Since the transmission of HIV is largely predicated on human behaviors, it is essential for partner governments to understand behavioral trends in a population to assess both the potential for continued transmission and the success of programs aimed at breaking the cycle of transmission. For countries with concentrated epidemics (ANC or other general population sentinel surveillance prevalence <1% and at least one high risk group >5%), partner governments should consider conducting behavioral surveys of the relevant most-at-risk and higher risk populations every two years. Most-at-risk-populations may include injecting drug users, commercial sex workers, men who have sex with men, and their sex partners; higher risk populations may include migrant workers, mobile populations, uniformed service members, street children, etc (see MARPs technical considerations for additional definitions). Partner governments with populations that have generalized and/or mixed epidemics should consider implementing a behavioral surveillance survey about every 2–3 years in both the general (low risk) and higher risk populations.

Reliable size estimates of at-risk populations have been consistently identified as a key data gap in many countries. Data collected as part of size estimation exercise can be used by partner governments to determine interventions as well as the resources needed for the interventions. These data can also be used to determine coverage and overall reach of the programs. When possible, partner governments should consider conducting size estimation activities simultaneously with behavioral surveillance of high risk populations;

- **TB/HIV co-surveillance:**

Tuberculosis and HIV co-infection is very common and often these epidemics are referred to as a syndemic. Partner governments should include HIV counseling and testing within TB clinics as a means for identifying HIV-infected people. Similarly, in those countries where TB is endemic, TB screening should be offered in HIV clinic or counseling and testing sites to identify TB-infected persons. Monitoring co-infection has become very important with the development of extensively drug resistant TB, largely among HIV-infected persons. Monitoring co-infection is very useful for partner governments in their efforts to do program planning and assess the success of existing programs to identify and treat both infections. This should be an on-going activity;

- **Recent HIV infections**

Measuring of incidence of any infection is typically used as a gold standard of surveillance. There are assays (for example, BED assay) that when applied to cross-sectional sample serum

specimens, and using a mathematical adjustment factor, suggests a recent infection rate for the population under surveillance. However, the level of misclassification with these assays varies substantially by geography. If assays such as these are used, it is recommended that, partner governments should use a false-recent rate (FRR) adjustment factor to calibrate the incidence estimate. This FRR should be locally estimated in samples that are representative to the population for which incidence is being estimated. Further guidance on the use of these assays can be found elsewhere;

Other methods for estimating incidence are also possible, and include mathematical modeling, cohort incidence, and looks at recent exposures to HIV by behavior, such as by considering trends in prevalence among youth;

- **HIV [AIDS] case surveillance**

The ability to count the number of HIV-infected persons in a country is a priority of HIV surveillance. It requires a case reporting system that can be de-duplicated so that the same person cannot be reported to the system more than once, regardless of where s/he is tested or reported. In late 2006, the WHO released a new HIV case definition using 4 stages of HIV infection (<http://www.who.int/hiv/pub/guidelines/hivstaging/en/index.html>).

The four stages are based on CD4 counts or clinical symptoms. They range from Stage I (asymptomatic/CD4 >500) to Stage IV (severely symptomatic/CD4 <200). This new definition offers new challenges for effective case reporting systems. Training staff and creation of appropriate case report forms and data management systems is critical to the development of case surveillance. Technical assistance may be requested through the Survey and Surveillance Technical Working Group (SSTWG);

- **HIV drug resistance**

Given the limited number of ARV regimens available in resource-limited countries, it is important to monitor and minimize HIV drug resistance (HIVDR). The SSTWG recommends following three standard methods developed by the WHO to monitor the development and transmission of drug resistant strains of HIV. The highest priority is the monitoring of HIVDR Early Warning Indicators in ART clinics. The second method is a survey to monitor the emergence of HIVDR and factors potentially associated with HIVDR in a patient cohort during the first 12 months of ART. The third method, known as a threshold survey, evaluates transmitted HIVDR; this method is the lowest priority. In addition, a PEPFAR-specific HIVDR framework has been developed, emphasizing the use of existing ART patient cohorts and/or blood specimens to evaluate HIVDR patterns and associated factors in patients whose ART has failed. The PEPFAR-specific methodology is particularly suited to sites with existing cohort studies or routine blood collection yielding remnant specimens for genotyping;

- **Mortality data and surveillance**

Cause-specific mortality is difficult to obtain owing to the lack of vital registration systems in resource constrained settings. However, the ultimate progress of an HIV treatment program is measured by shrinking AIDS mortality. One interim option for obtaining cause-specific mortality data and building up vital registration systems is implementing a Sample Vital Registration with Verbal Autopsy (SAVVY) system. SAVVY is a nationally-representative system which allows for registration of vital events when a true national vital registration system is weak or absent. SAVVY tools can also be used to link a mortality survey to a national census such as was done in Mozambique with the 2007 census. This method provides a baseline for measuring the impact of scaled-up initiatives that aim to reduce

AIDS-related mortality. Both SAVVY and post-census mortality surveys can serve as stepping stones to move countries toward a complete, fully functioning vital registration system so that AIDS mortality data would be consistently available to monitor the effect of HIV treatment programs and initiatives;

- **Surveillance and surveys in military populations**

HIV prevalence and behavioral risk surveillance in military populations is critical for military HIV programs and an important component of a comprehensive country-wide assessment and response to HIV. HIV prevalence and behavioral risk data collected in active duty populations is used by military policy makers and HIV program managers to develop and review HIV/AIDS policies, tailor and monitor effective prevention programs and to plan care and treatment services. Prevalence studies among military recruits may, depending on national recruitment policies, provide a good, low-risk proxy population of young men. Prevalence surveys should be performed no more than every two years; and

- **Qualitative research**

Qualitative research is an important and often underutilized source of information for the development of surveillance and surveys, as well as for greater clarity around surveillance and survey findings. In many instances, qualitative work becomes the basis for understanding the social and behavioral underpinnings of HIV.

Qualitative research typically focuses on specific communities or subgroups, those for whom interventions need to be developed. Assessments and other forms of qualitative research should be conducted as part of program design and before the implementation or scaling-up of interventions (including prevention, care, treatment, and other program areas). Qualitative research also should be used to monitor the progression of interventions and to quickly investigate the emergence of new trends that can have an impact on the evolving epidemic.

B. Other Activities

- **Modeling infections averted**

The number of new infections averted as a result of expanded programs must be estimated through modeling since it cannot be measured directly (i.e., by definition, it is a non-event). The modeling of infections averted is dependent on the results of a country's surveillance system. Country teams are asked to expedite electronic copies of surveillance reports to the Census Bureau upon official release to <ipc-hiv@census.gov>.

Countries are not expected to fund modeling of infections averted work. However, partner governments may want to work with implementing partners to identify, through modeling or other planning tools, how to best allocate investments across program areas to maximize the specific prevention program areas that may have an impact on averting HIV infections;

- **Evaluation**

The evaluation of old and new surveillance techniques are encouraged and can help facilitate the strategic planning process. It is strongly recommended that basic evaluations of all surveillance systems be carried out about every 3–5 years. This is generally a cost-free exercise involving only staff time; and

- **Other surveys**

Many other surveys may be carried out as part of prevention or other activities to provide in-depth information on emerging populations at risk. Technical assistance/consultation for

survey design, sampling methods, analysis, training materials, and protocols are available through the SSTWG.

C. Human Subjects Review Requirements in Surveillance and Surveys and Monitoring and Evaluation Activities

All surveillance and survey protocols and relevant monitoring and evaluation activity protocols must be submitted for human subjects review locally as well as to the headquarters of any agency conducting an activity and/or providing financial or implementation support to an implementing partner for an activity.

3.2.6 GEOGRAPHIC MAPPING, SPATIAL DATA AND GEOSPATIAL TOOLS

National plans for increasing the efficiency and coverage of activities should be developed in a geographic context. Geographic mapping is a cross-cutting activity that touches each of the technical areas contained in this document. Geography allows us to link surveillance, demographic, service, human resource, financial and other types of data to answer important program questions, such as:

- What is the geographic distribution of HIV prevalence or incidence in relation to HIV/AIDS service delivery points?
- Do PEPFAR-supported services duplicate services provided by other funders or the private or public sectors in the same local area?
- How many people live within the catchment areas of facilities that offer a service?
- Where is PEPFAR supporting services in relation to other important program elements of the Global Health Initiative?
- Where will the expansion of a service increase coverage or equity?

A. PEPFAR and National Spatial Data Infrastructures (NSDI)

Most countries have NSDI initiatives or an explicit spatial data component in a larger national information and communication infrastructure. Revised Office of Management and Budget Circular No. A-16 describes NSDI as “the technology, policies, standards, human resources, and related activities necessary to acquire, process, distribute, use, maintain, and preserve spatial data.” NSDI policies govern access to and sharing of key spatial data that concern specific countries should be aware of and handle all relevant spatial data it generates in accordance with these policy frameworks. Examples of these data sets are health district boundaries or health facility and school locations. A data management plan for spatial data is recommended to ensure these data become part of the NSDI of the country where the partner government is supporting health services.

Spatial data are routinely generated and referenced as geography embedded data sets created for a wide variety of program and policy purposes by partner governments. Spatial data are also created independently of specific program results, surveys, surveillance, or research enterprises. For example, there may be an occasion to develop a digital map file of health districts or health facility location independently of an effort to aggregate an indicator to the health district level or to map health facility-based service availability data. These data are generated at every geographic scale and can be used for multiple applications.

Some spatial data generated are not governed by partner government NSDI and can be considered part of PEPFAR's own SDI, which is distributed throughout the implementing agencies. In accordance with the President's Open Government Directive, these spatial data should, when possible, be published online through websites such as Data.gov to maximize transparency and coordination. When data cannot be made directly available, metadata can be published through web-based metadata catalogs.

B. Spatial Data Standards and Metadata

PEPFAR teams, implementing partners and partner governments sometimes generate place spelling conventions and geographic coding schemes independent of each other. This practice is a substantial barrier to the integration of data within geographic information systems and hinders the ability to plan programs based on a common geographically informed awareness. Uniform geographic names are obtainable through The U.S. Board on Geographic Names, which establishes official geographic feature names in addition to principles, policies, and procedures governing the use of foreign names. These names are also embedded in the Geographic Names Database (<http://earth-info.nga.mil/gns/html/index.html>). To the extent possible, PEPFAR-funded databases should include these naming standards in addition to local naming standards and place codes.

For spatial datasets that fall outside of a specific NSDI but are still part of PEPFAR's SDI, the Content Standard for Digital Geospatial Metadata (CSDGM), Vers. 2 (FGDC-STD-001-1998) can be used (<http://www.fgdc.gov/metadata/csdgm/>). This standard was established by the Federal Geographic Data Committee and applies to all Federal agencies, which are ordered to use this standard to document geospatial data created as of January 1995. The standard is also referred to as the "FGDC Metadata Standard".

For country-specific data where metadata standards are specified by an NSDI, spatial data can follow the FGDC Metadata Standard and include any additional metadata elements enumerated in the local standard.

C. Spatial Data and the Preservation of Confidentiality

In some instances, spatial data can be used by partner governments to uniquely identify individuals, especially when linked with other data elements. This issue arises, for example, in population based surveys such as Demographic and Health Surveys. In DHS methodology, sample cluster latitude and longitude are displaced with random error specifically to prevent the identification of survey respondents. Care must be taken in determining whether the release of specific spatial data could be inappropriately leveraged with other data.

D. Geospatial Tools

The appropriate tool used by partner governments for spatial information management and analysis will often be a map but in some cases may be a spreadsheet. A variety of commercial and free and open source tools to support geographic mapping are available and may be used by partner governments. Elementary spatial analysis can be conducted in spreadsheets or using digital globes, like NASA's World Wind. More advanced spatial analysis, management of spatial data and displays of spatial data can be accomplished using a geographic information system.

3.2.7 COUNTRY CONTEXTUAL CONSIDERATIONS: STRATEGIC INFORMATION

For surveillance purposes, countries have traditionally been categorized as either concentrated/low level epidemics or generalized epidemics. In concentrated/low level epidemics, surveillance and surveys should be conducted among populations most at risk for HIV infection such as commercial sex workers, persons who inject drugs and men who have sex with men. However, even countries with generalized epidemics should consider collecting data among these groups, especially if general HIV prevalence is approaching 1%.

Harmonization of HIV indicators and HIV information systems are critical. USG country programs should be working closely with the government and their partners to assure this harmonization and avoid development of information systems that are duplicative or separate from national systems.

In addition to the overall support for SI activities in the country plan, further deliberations are necessary to determine what percentage of program-level funding should be set aside for basic program monitoring and evaluation. International standards suggest at least 5-10 percent of a program budget should be dedicated to monitoring and evaluation of the program. Regardless of the exact percentage, routine monitoring and evaluation should be integral to all PEPFAR programs.

3.2.8 LINKAGES AND WRAPAROUNDS: STRATEGIC INFORMATION

SI supports the overall PEPFAR mission while simultaneously strengthening national health systems. Many of the programs supported through PEPFAR are inter-linked and integrated, and SI plays a role to strengthen the information acquisition and use associated with these efforts. Specific work by SI should be tied to these different programmatic activities and to the country systems designed to manage and use the emergent data.

TECHNICAL AREA 3.3: HEALTH SYSTEMS STRENGTHENING

Health Systems Strengthening – include activities that contribute to national, regional or district level systems by supporting finance, leadership and governance (including broad policy reform efforts including stigma, gender etc.), institutional capacity building, supply chain or procurement systems, Global Fund programs and donor coordination. (Please note, as stated in the introduction, other activities will also contribute ultimately to reporting budget attributions to HSS. These calculations will be handled at HQ).

3.3.1 INTRODUCTION

Much of PEPFAR’s work in its first five years has strengthened health systems. Yet health systems strengthening (HSS) work has not been well defined and has varied from country to country. This guidance seeks to systematize that work, place it within a coherent conceptual framework, and recommend promising practices.

- **Definition of the Health System:** The health system includes all the individuals and organizations that focus primarily on ensuring health outcomes. It includes national, state, district and community levels, and the public, NGO and private commercial sectors. Health systems carry out six key functions: 1) Service Delivery, including its quality, efficiency, accessibility, patient-centeredness, and safety; 2) Leadership and Governance, including health policy development and implementation, regulation, strategies, and accountability; 3) Financing, including the mobilizing of funds, organizing risk pools for funds, allocating funds to programs, and planning for long-term sustainability; 4) Medical Products, Vaccines, and Technologies, including selection, procurement, distribution, use, and inventory; 5) Information Systems for monitoring and evaluating health-related activities; and 6) Human Resources for Health (HRH), including planning and management, deployment, retention, and performance management (for further information about each of these functions, see Technical Considerations, below).

Therefore, HSS represents a broad scope of work to improve a health system’s ability to provide quality services to a community and intersects with virtually all technical areas. Capturing this work within PEPFAR budget codes is done through combining some entire technical areas (e.g., Laboratory Infrastructure, Strategic Information), relevant activities within other technical areas (e.g., Human Resources for Health, construction, service delivery), and all activities within the OHSS technical area.

As part of the Global Health Initiative (GHI) PEPFAR will expand its connections and collaboration with other USG global health programs to establish a coordinated USG approach for HSS. For PEPFAR, this work should result in improving efficiencies and sustainable results in prevention, care and treatment. It is important to also note that HRH is an important priority area for PEPFAR.

SCOPE OF PEPFAR’S ENGAGEMENT IN HSS

HSS potentially represents a broad area of work. Given PEPFAR’s mandate and resource constraints, the scope of the USG’s involvement in HSS through PEPFAR in the context of HIV programming will need to be strategic and aligned with other USG efforts around HSS. PEPFAR thus engages in HSS in three ways:

- **Focused Interventions** in HSS is work that PEPFAR does to address health system gaps specific to the achievement of PEPFAR and national HIV/AIDS goals for HIV/AIDS

prevention, treatment, and care (for example, developing information systems to improve ARV delivery).

- **Secondary Benefits/Intentional Spillovers** are achieved when PEPFAR designs and implements HIV-focused activities in anticipation that these activities can and will benefit non-HIV/AIDS elements of the health system at no (or very low) additional cost to the USG (for example, capacity building for ARV procurement systems can also be used to purchase MCH commodities).
- **Targeted Leveraging** is work PEPFAR does when it engages with other development programs and partners to jointly sponsor broad-based health system investments that have an HIV/AIDS link (for example, joining other donors in developing a comprehensive national health insurance program that includes coverage for HIV/AIDS services).

The conceptual framework, included in the technical considerations, is a tool to support country teams in assessing health systems gaps, defining USG comparative areas for involvement, and mapping other donor efforts to support prevention, care and treatment. Country teams are **not** required to program to each level of engagement or across all functional areas. Country teams are encouraged to use the framework to help them assess their potential to maximize their scope of engagement across technical areas, given PEPFAR's mandate, USG comparative advantage and resource constraints, and program accordingly.

3.3.2 WHAT ARE HSS INTERVENTIONS?

The following provides guidance on what constitutes HSS activities regardless of what technical area they fall under. Note that the definitions provided are for the functions of the health system.

A. *Service Delivery (including care, treatment & prevention)*

Good health services are those which deliver **effective, safe, quality** personal and non-personal health interventions to those who need them, **when and where** needed, with **minimum waste** of resources.

HSS is spending that strengthens systems that *support service delivery by the host government at any or all levels (national, provincial, district, local).*

- Policy work that facilitates the quality, safety, and/or relevance of services;
- Development & dissemination of service guidelines to implement national policy;
- Establishment of continuous quality improvement programs, related training and guidelines;
- Work that establishes a nationally owned process to identify and promulgate best practices, and cost-effective practices, from within country and facilitate their application;
- Work that establishes systematic planning of service delivery points to extend access;
- Creation of institutional networks and/or improved referral systems beyond any one disease; and
- Construction or refurbishment and related policy work that promotes spillover effects.

HSS is **not** spending that simply augments service delivery.

- Direct provision of services, including expansion & salaries;
- Direct in-service training that does not build capacity for training; nor
- Policy or guidelines that target only PEPFAR-supported sites.

B. Medicines and Technologies (including drugs, treatment, and laboratory infrastructure)

A well-functioning health system requires equitable access to essential **medical products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness**, and their scientifically sound and cost-effective **use**.

HSS **is** spending that strengthens *host country's systems* for procurement and distribution of medical commodities and technologies, and ensure their quality.

- Improving the efficiency and effectiveness of existing procurement systems to ensure timely and cost-effective purchase and distribution (see also above, re: service delivery);
- Parallel acquisition and distribution systems when these systems are implemented *through formally established host-country entities* that will continue beyond PEPFAR support;
- Establishing a nationally owned system of quality assurance across the public and private sectors; and
- Provision of laboratory infrastructure and equipment that promotes spillover effects.

HSS **is not** spending to acquire, distribute and use medical commodities.

- Purchase and distribution of drugs, testing supplies, and other commodities;
- Establishment of commodity procurement and distribution systems for expediency, without formal establishment of continuing, controlling entities with host-country commitment;
- Policy or guidelines that target only PEPFAR-supported sites; nor
- Direct training that targets only PEPFAR-supported lab sites or commodity systems, or other subsets of the national health system.

C. Finance

A good health financing system **mobilizes** adequate resources from reliable sources to pay for health needs, **pools** resources to foster efficiency and spread costs, and **allocates** resources in ways that promote efficiency, equity and health impact.

HSS **is** spending that improves the efficiency, responsiveness and accountability in the host government's financial systems for health, including financial management.

- Work to identify and resolve bottlenecks in the flow of funds through the health system;
- Promotion of transparency and accountability in resource allocation processes and decisions;
- Policy and guidelines that promote the quality of financial management, and related training;
- Costing and cost-modeling to support financial analysis and related program decisions;
- National health accounts and other activities that promote and analyze resource tracking; and
- Development of systems and approaches that support host-country efforts for resource mobilization and greater resource efficiencies such as social insurance schemes, outsourcing of select services to private sector, equitable cost sharing strategies, etc.

HSS **is not** spending intended to improve the management and accountability of PEPFAR funds.

- Development of implementing partners' ability to adhere to USG requirements for budgeting, resource tracking and reporting – including training;
- Hiring of staff to manage PEPFAR program funds; nor
- Audits or other examinations of financial management processes designed to determine compliance with USG regulations.

D. Information (including SI)

A well-functioning health information system is one that ensures the **production, analysis, dissemination and use** of reliable and timely information on health **determinants**, health systems **performance** and health **status**.

HSS **is** spending that improves the performance of host country's *information systems* for health.

- Work to identify and resolve bottlenecks in information flows through the national HIS;
- Data use to promote the relevance, responsiveness and transparency of program decisions by planners in the national health system, at all levels;
- Enhancement of the monitoring, evaluation and surveillance functions through nationally owned HMIS and related systems, that extend beyond PEPFAR's reporting needs; and
- Building local capacity to interpret research and employ research results in policy dialogue.

HSS **is not** spending intended to improve monitoring, evaluation and reporting for PEPFAR.

- Development or maintenance of databases or other parallel HMIS for PEPFAR reporting;
- Hiring of staff to coordinate or conduct monitoring, evaluation and reporting for PEPFAR; nor
- Evaluation and research to inform PEPFAR strategies that have not been adopted by host-countries.

E. Leadership and Governance

Leadership and governance involves ensuring strategic **policy frameworks** exist and are combined with effective **oversight, coalition building**, the provision of appropriate **regulations and incentives**, attention to **system-design**, and **accountability**.

HSS **is** spending that promotes an enabling policy environment within national health systems; promotes governance that results in a relevant, responsive, health system; and enables substantive engagement of civil society in a continuing fashion.

- Support for policy analysis and related consultations that yield responsive policies;
- Work to develop a culture of leadership, innovation and problem solving for change;
- Development of management skills for strategic planning, monitoring and supervision, and ongoing decision making;
- Promotion of a culture of accountability of the health system for health outcomes, and engagement of civil society in that process;
- Strengthening the capacity of civil society organizations to engage in advocacy and policy dialogue;
- Strengthening of local coordinating mechanisms for implementation of Global Fund or other external grants; and
- Engagement of the private sector toward fuller integration of the national health system or for lasting public-private partnerships in which host-country governments are a partner

HSS **is not** spending that improves the capacity of partners to manage PEPFAR activities, or fulfills management functions on behalf of host-country governments or other governance structures.

- Establishing management policies to comply with PEPFAR requirements;

- Development of the management capacity of implementing partners' ability to adhere to USG processes and other expectations; nor
- Seconding staff to line positions for management, strategic planning, and related functions.

F. Human Resources

A well-performing health workforce consists of sufficient **numbers** and **mix** of staff (including volunteers) that are **fairly distributed, efficient, responsive, and competent** to achieve the best health outcomes possible given available resources and circumstances.

HSS **is** spending that secures and sustains greater availability of qualified healthcare professionals across the health system.

- Establishing and enhancing pre- and in-service training systems, including a cadre of skilled trainers;
- Development and implementation of effective hiring, deployment and retention strategies for HRH;
- Development of an active HRIS, managed by local entities on a continuing basis; and
- Development and implementation of policy and guidelines for task-shifting and supportive supervision.

HSS **is not** spending for human resources that meet only PEPFAR implementation needs, or do not enhance local capacity to further training.

- Seconding staff to line positions for PEPFAR-specific program implementation;
- Direct training that does not include development of training systems and capacity; nor
- Development and implementation of HR policies that apply only to PEPFAR-supported staff.

More info on HSS functions previously not widely addressed under PEPFAR

G. Finance

Healthcare finance and financial management are areas that have not traditionally been addressed under PEPFAR. Resource mobilization, cost-effectiveness, and efficient resource allocation receive greater emphasis during this next phase of PEPFAR. Promising activities to strengthen the healthcare finance function include:

- Country programs should seek to better understand resource flows through assessments of National Health Accounts;
- Strengthening Ministries' of Finance capacity: to engage effectively with donors, NGOs and the private sector; improve management and strategic planning, and link health care programming with other development efforts;
- Performance-based financing & linkages to HRH incentives;
- Costing and resource planning for sustainable country programming;
- Public and private sector financial management trainings, though not just for management of USG grants;
- Insurance schemes to increase access to HIV/AIDS services;
- Promotion of policies that allow for increased resource efficiencies through outsourcing of select services to private sector or community organizations;
- Reliance on more indigenous organizations and commodities, etc; and

- Resource mobilization through innovative public-private partnerships, equitable cost sharing strategies, etc.

B. Leadership and Governance

There exists substantial space to enhance management within health systems, and thereby contribute to increases in quality, efficiency and accessibility of health care. A step further, promoting leadership within the health sector holds potential to catalyze and consolidate shifts in national approaches to prevention, care and treatment. Good governance requires the participation of civil society and an enabling policy environment. Promising practices to strengthen leadership and governance include:

- Strengthening Ministries' of Health capacity to engage effectively with donors, NGOs and the private sector; improve management and strategic planning, and link health care programs with other development efforts;
- Strengthening citizen oversight of HIV and other health programs: engaging civil society in policy dialogue, advocacy, planning and public oversight; promoting the policy environment's responsiveness to the needs of civil society; and
- Policy formulation and effective policy implementation: stakeholder mapping and strategies for their engagement; inclusion of affected populations in the process, and civil society more broadly; practice guidelines and dissemination.

3.3.3 COUNTRY CONTEXTUAL CONSIDERATIONS: HEALTH SYSTEMS STRENGTHENING

Priorities for intervention across the six key functions should be determined at the country level. The strength of health systems vary from country to country. USG investments should be strategic and targeted leveraging with host country and other donors should be maximized to reach prevention, care, and treatment goals. However, country teams should keep in mind that HRH, a critical element of HSS, is a priority under PEPFAR legislation.

Assessing HSS in your Country Context

As country teams are encouraged to apply a broad-based HSS perspective to their programs, implementation of comprehensive health system assessments will help to identify system gaps and bottlenecks, and establish priorities for intervention. A standard protocol for the health system assessment approach is available at <http://www.healthsystems2020.org/content/resource/detail/528/> . The process includes means for stakeholder involvement in its deployment, analysis, and interpretation of results for setting priorities. Health system assessments are the most rigorous means of establishing priorities.

An alternative, albeit more subjective, means of establishing HSS priorities is use of the HSS framework provided at the end of this section. This template can be used to frame the country program's engagement in HSS. For example, it may be used first to map gaps in the health system, and then current activities from all participants in HSS. Finally, and with the previous overlays, the template can be used to describe the scope and nature of HSS activities within the overall program.

Additionally, Annex 5 of the Partnership Framework Guidance, which is included at the end of this section, provides a good framing of the importance of HSS and key questions to support country HSS priority setting. The Partnership Framework Guidance is resource to other web linkage support for health finance and, health information.

3.3.4 LINKAGES AND WRAPAROUNDS: HEALTH SYSTEMS STRENGTHENING

This guidance provides scope within which to benefit the broader health system through intentional spillovers and targeted leveraging. Well-designed activities that fit within these levels of engagement should benefit other health care services such as those for malaria, MCH, family planning, TB/HIV and support common objectives, including those outlined under the Global Health Initiative. As such, country teams are encouraged with other elements of the national and USG public health programs, and other donors, to identify opportunities to optimize the benefit from investments in HSS to other public health objectives.

PEPFAR’s Approach to Health Systems Strengthening – Sample Framework

	Service Delivery	Human Resources	Health Finance	Medical Products, Vaccines and Technologies	Information Systems	Leadership/Governance
<u>Focused:</u> HIV-focused treatment, care, and prevention activities						
<u>Intentional Spillover:</u> impacts on HSS at no or minimal cost to USG						
<u>Leveraging:</u> collaborating with other partners to generate HIV/AIDS and other benefits						

PEPFAR's Approach to Health Systems Strengthening: Illustrative model applied to PEPFAR's 3 million on ARV treatment goal

	Service Delivery	Human Resources	Health Finance	Medical Products, Vaccines and Technologies	Information Systems	Leadership/ Governance
<p>Focused: HIV-focused treatment, care, and prevention activities</p>	<ul style="list-style-type: none"> Strengthen ARV referral systems and care networks. Service integration Basic laboratory services for monitoring ART side effects, community linkages Outreach to special populations (MARP) Decentralization of ARV services and planning to districts 	<ul style="list-style-type: none"> Develop sufficient ARV service providers via task-shifting, improved HR efficiencies, in-service trainings, capacity building of HIV training institutions 	<ul style="list-style-type: none"> Sustainable ARV financing including ARV price negotiations, ARV cost modeling, mainstreaming ARVs into national health plans and insurance schemes Optimizing costs per person treated (performance-based budgeting of Tx partners) 	<ul style="list-style-type: none"> Supply chain and procurement systems for ARVs, CD4 and other lab reagents to monitor ARV Tx employed MOH staff trained on ARV procurement and forecasting Assessments on how best to integrate ARVs into general drug supply chain systems 	<ul style="list-style-type: none"> Strengthen systems to plan, monitor and improve ARV delivery using DHS/AIDS, SPA, ARV M&E, drug resistance surveillance Implementation of HIVQUAL (continuous quality improvement for HIV) PHES focusing on treatment questions 	<ul style="list-style-type: none"> Recognition of HIV as national problem, reducing stigma and increases testing rates Anti-stigma policies enacted Multi-sector strategic planning for ARV scale-up HIV accreditation for both public and private sector National ARV treatment guidelines HIV focused management training for NACs, DACs, and others Journalism training on HIV/ART
<p>Intentional Spillover: Impacts on HSS at no or minimal cost to USG</p>	<ul style="list-style-type: none"> Improved referral systems for other diseases Basic lab services for all patients HIV Tx model adapted for other chronic diseases (e.g. depression, hypertension) Decentralization strategies used for other health issues 	<ul style="list-style-type: none"> Improve HR efficiencies across clinic/hospital Broader institutional capacity-building Task-shifting in non-HIV services & departments Doctors/nurses able to address PHC needs 	<ul style="list-style-type: none"> Governments performing cost modeling for other health issues Governments better negotiate better non-HIV drug pricing Financial accountability increases beyond HIV in gov't and NGO sectors 	<ul style="list-style-type: none"> Newly acquired forecasting and delivery skills used for other drugs and vaccines ARV procurement systems adopted for other drugs 	<ul style="list-style-type: none"> Quality improvement drives models for other diseases DHS/AIDS/MIS informs other disease programs (TB, malaria, MCH) PHE efforts stimulate operational research in other areas 	<ul style="list-style-type: none"> More open policies for other health and social issues Multi-sector and civil society engagement approaches adopted for other health issues National guidelines created for other diseases Journalists use HIV training to report on other health issues
<p>Leveraging: collaborating with other partners to generate HIV/AIDS and other benefits</p>	<ul style="list-style-type: none"> Clinic renovations = increased use of HIV and non-HIV services MCH assessments and strategic planning lead to improved MCH services and ART coverage of HIV+ pregnant women, integration of reproductive health services 	<ul style="list-style-type: none"> DFID, JHPI+ joint partnership in expanding pre-service training Expansion of community health worker schemes and trainings in partnership with MCH programs HRH strategic planning 	<ul style="list-style-type: none"> National health accounts and costed national health plans Health insurance schemes cover HIV and non-HIV services & drugs Support to MOF improves other ministries → better health finance polices/procedures 	<ul style="list-style-type: none"> Multi-donor efforts to assess and strengthen national procurement/logistics systems for essential drugs (eventually allowing ARVs, other drugs used in HIV care, lab reagents to be mainstreamed into general supply chain systems) 	<ul style="list-style-type: none"> Quality MOH HMIS improved and ARV M&E integrated into this system HRIS created/ improved Data for decision-making courses developed for key health decision-makers 	<ul style="list-style-type: none"> Health Systems assessments pinpoint key system weaknesses to be addressed if further ARV scale-up and other disease control efforts are to succeed General management training for hospital administrators and district officials leading to better services and planning General accreditation and performance assessment schemes strengthened

PEPFAR's Approach to Health Systems Strengthening: Illustrative model applied to PEPFAR's 12 million new infections prevented goal

	Service Delivery	Human Resources	Health Finance	Medical Products, Vaccines and Technologies	Information Systems	Leadership/ Governance
<p>Focused: Treatment, care and prevention activities</p>	<ul style="list-style-type: none"> Adoption and scaling up of evidence-based prevention services such as male circumcision, alcohol treatment, and prevention with positives Improvement of the supply/safety of blood Scaling up of PMTCT through MCH Integration and strengthening 	<ul style="list-style-type: none"> Strategic planning, policy changes, and interventions to increase in-country prevention expertise Circumcision skills (via task shifting, in-service trainings) Training and support of substance abuse experts/counselors Training of counselors for prevention with positives Training of STI service providers 	<ul style="list-style-type: none"> Promoting cost efficiencies and sustainability by assisting host governments to fund HIV prevention efforts Promoting affordable private sector HIV prevention services (PMTCT, male circumcision, STI tx) Performance based budgeting of HIV prevention partners 	<ul style="list-style-type: none"> Develop/sustain supply chain and procurement systems for free and socially-marketed condoms Strengthen general supply chain, procurement, and forecasting systems for STI drugs, HIV test kits, PMTCT drugs (incl. FP options) 	<ul style="list-style-type: none"> Strengthening systems to plan, monitor, and improve HIV prevention services via HIV surveillance systems DHS/AIS, SPA, MARP assessments and mapping Identify new prevention methods through PHEs Data-driven decision making courses to utilize resources efficiently 	<ul style="list-style-type: none"> Multi-sector strategic planning and implementation for HIV prevention Strong civil society role in HIV prevention efforts National leadership related to faithfulness, condom use, and alcohol abuse Strong HIV prevention guidelines, decentralization
<p>Intentional Spill Over: Impacts on HS at no or minimal cost to USG</p>	<ul style="list-style-type: none"> Improved evidence-based methodology for other health interventions Improved safety and supply of other patient materials and information Strengthened PMTCT/MCH relationship addresses other key issues for maternal and child health 	<ul style="list-style-type: none"> Improved strategic planning skills utilized to effectively manage staff and address other key disease areas Improved policies expanded to address key gaps in HRH Tracking of counselors who have undergone training to continue professional development and improve service delivery 	<ul style="list-style-type: none"> Cost-effective models applied to other health sector initiatives Increased integration and collaboration with the private sector in addressing acute and chronic disease burdens Performance based financing practices applied to treatment, care, and other disease initiatives 	<ul style="list-style-type: none"> Supply chain management systems and logistics practices applied to overall distribution of health commodities Forecasting systems utilized to improve the availability and access to RH and FP commodities 	<ul style="list-style-type: none"> Improved information systems to monitor other prevention and surveillance activities for TB and highly infectious disease outbreaks MOH knowledge base in mapping assessments used to analyze other health and nutrition areas Data-driven decision making methods employed throughout health sector 	<ul style="list-style-type: none"> Coordination across sectors establishes relationships and protocols to address other wider health and social issues Increased civil society role creates foundation for public forum and political voice Decentralization practices and strengthening of guidelines applied to TB, malaria, other diseases
<p>Leveraging: collaborating with other partners to generate HIV/AIDS and other benefits</p>	<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> 	<ul style="list-style-type: none">

3.3.5 ANNEX V FROM THE PARTNERSHIP FRAMEWORK GUIDANCE:

Health system strengthening priority-setting

Efforts to strengthen health systems in the context of PEPFAR Partnership Frameworks recognizes that well-functioning health systems can effectively prevent, care for and treat HIV/AIDS, that effective interventions exist to strengthen health systems, and that strong health systems can sustain the response to HIV/AIDS over time.

Specific health system weaknesses pose critical barriers to achieving PEPFAR objectives and to ensuring country capacity to sustain the response to HIV/AIDS over time. These weaknesses vary by country and they impact prevention, care and treatment differently. Partnership Framework Implementation Plans are based on assessing issues related to service delivery, workforce, information, medical products and technologies, financing, and leadership and governance.

Partnership Framework Implementation Plans should prioritize health system strengthening issues that can be resolved effectively during the 5-year timeframe and that represent the most pressing system constraints to achieving programmatic goals and objectives within the country.

Priority setting: The questions below are illustrative. They will help you set priorities based on strengths and weaknesses in your country.

- Address service delivery issues: How well do care networks function? Are referral systems in place? Are HIV/AIDS services effectively integrated into health care? What community linkages function? What arrangements ensure outreach to special populations (MARPs)? How does decentralization influence service delivery? Do district officers and clinic and hospital management staff have supervisory and planning skills? What is status of efforts to improve supply/safety of blood? To scale up PMTCT thru MCH integration and strengthening? To adopt and scale up evidence-based prevention services such as male circumcision, alcohol treatment, Prevention with Positives, STIs, ARVs?
- Address health workforce issues: Is there a national HRH strategic plan? How is task-shifting being used to develop sufficient ARV service providers? How are HR systems being made efficient? What are arrangements for in-service training, pre-service training, and capacity building of training institutions? What is status of strategic planning, policy changes, interventions to increase in-country prevention expertise, circumcision skills, substance use experts/counselors, counselors for prevention with positives, STI service providers, etc.?
- Address health information issues: What plans are in place to strengthen systems to plan, monitor, and improve ARV delivery services, including DHS/AIS, SPA, ARV M&E, drug resistance surveillance, death registries, HIVQUAL (continuous quality improvement), and data for decision making courses? What is status of systems to plan, monitor, and improve HIV prevention services via HIV surveillance systems, DHS/AIS, SPA, MARP assessments and mapping, new prevention PHEs, data for decision-making courses, etc.?
- Address medical product and technology issues: What is status of development of supply chain systems for ARVs, CD4 and other lab tests to monitor ARV treatment? Are ARVs integrated into general supply chain, procurement, and forecasting systems? What is status of supply chain and procurement systems for free and socially-marketed condoms? What is the

status of the general supply chain, procurement, and forecasting systems for STI drugs, HIV test kits, PMTCT drugs?

- Address health financing issues: What has been done to create sustainable ARV financing? Discuss status of ARV cost negotiations, ARV cost modeling, efforts to assist host government funding of ARVs, promoting affordable private sector ARV treatment, optimizing costs per person treated (e.g., via performance-based budgeting of treatment partners)? What support does host government need to promote cost efficiencies and sustainability by funding HIV prevention efforts, promote affordable private sector HIV prevention services (PMTCT, male circumcision, STI treatment), introduce performance-based budgeting of HIV prevention partners, etc.?
- Address health leadership & governance issues: What is status of multi-sector strategic planning for ARV scale-up, patient rights/anti-stigma policy development, national ARV guidelines, private/public sector regulation (HIV accreditation), communication/integration of partners/donors (3 Ones)? How effective are multi-sector strategic planning and implementation for HIV prevention? How strong is civil society's role in HIV prevention efforts? In national leadership related to faithfulness, condom use, and alcohol abuse? How strong are HIV prevention guidelines in context of decentralization?

TECHNICAL AREA 3.4: HUMAN RESOURCES FOR HEALTH

Human Resources for Health - Effective health systems depend on a trained and motivated workforce that can carry out the services needed to achieve PEPFAR goals. It is widely recognized that the lack of a trained workforce is a major barrier to scaling up HIV services across PEPFAR countries. Recognizing this challenge, PEPFAR reauthorizing legislation directs PEPFAR by FY2014 to train and support retention of 140,000 health care professionals, paraprofessionals, and community health workers providing HIV/AIDS prevention, treatment and care, with an emphasis on training and in-country deployment of critically needed doctors and nurses. This requires PEPFAR country teams to make significant investments in the pre-service education. To help PEPFAR report to Congress on this mandate, in FY 2012 country teams are required to report on the number of new health workers who graduated from a pre-service educational institution within the reporting period.

However, one of the key lessons learned from PEPFAR I is, that to make a sustainable impact on the health workforce in PEPFAR countries, we need to go beyond “number of people trained”. With the chronic problems of outmigration, brain drain, and attrition faced in countries, we recognize that investments in training will not lead to sustained workforce improvements if we do not also invest in recruiting and retaining those new graduates into the health system. Indeed, “Human Resources for Health” as a technical area in PEPFAR aims to strengthen the overall health workforce system in PEPFAR countries, which includes improving workforce planning and management, training, recruitment, and retention. The aim of HRH investments is to improve the density and equitable distribution of health workers, relevant to population need, and the quality of their performance to improve health outcomes.

3.4.1 INTRODUCTION

To help country teams prioritize HRH investments, the HRH TWG developed “**Priority Areas of PEPFAR HRH interventions**”, in the January, 2009 “State of the Program Area” (SOPA). In the fall of 2010, the HRH TWG revised these priorities into six objectives:

- A. Strengthen pre-service education institutions to improve the quality and output of graduates
- B. Ensure the standardization, quality, and coordination of in-service training, such as through continuing professional development programs
- C. Advance innovative and cost effective models of service delivery and skill mix, including through task-shifting/sharing, introduction of new cadres, integrating community health workers into the continuum of response, developing multi-disciplinary teams, and supporting implementation science
- D. Investigate and apply recruitment/retention strategies, especially in rural and underserved areas
- E. Support national HRH planning and management, including through development of human resource information systems
- F. Advance health worker regulation and policy, including through capacity-building of regulatory bodies and professional associations

Overarching emphasis throughout these six objectives are supporting governments in formulating and implementing national HRH plans and developing and disseminating the evidence-base for HRH interventions. The objectives cover areas of intervention that were selected to help PEPFAR reach its

Congressional target while also establishing sustainable country capacity to increase the quantity and quality of its health workforce. Where appropriate, interventions should be targeted at health workers that provide HIV/AIDS services, but can be used to improve the overall health workforce. Sustainability and country ownership of these HRH interventions is a priority in PEPFAR II. Under the GHI, it is important to identify opportunities for where PEPFAR can help leverage other USG HRH investments. Additionally, country teams should coordinate with other donors and host governments (such as through Partnership Frameworks) to encourage comprehensive HRH investment not possible with PEPFAR dollars alone.

A. Workforce Planning

A national HRH plan is a critical framework for a comprehensive response to health workforce development in PEPFAR countries. PEPFAR-supported HRH activities should align with this national plan, where one exists. An effective national HRH plan uses the best available data on the health workforce and on the health needs of the country – such as through an HRH assessment or an HRIS- to project the supply and demand for health workers in the country over several years. The plan should also identify approaches that will allow the country to train, recruit and retain the numbers and types of health workers needed to accomplish national health goals (including PEPFAR targets). The plan should include a strategy and timeline for conducting these activities, and indicators that will be used to measure progress.

Many countries have developed a national HRH plan. However, some are not being implemented because they were not costed or resourced. Additionally, many plans developed by the MOH do not adequately address the multisectoral components of workforce planning, such as the role of the Ministry of Education in pre-service education, the role of the Ministry of Finance when planning expanded recruitment and deployment of public sector staff. Where possible, PEPFAR teams should help countries establish or improve the national HRH plan, and help identify and overcome obstacles to its implementation.

The following are some of the questions that an HRH plan should address:

- How many health workers and what types will be needed to meet the country's health needs in the coming years? To meet PEPFAR targets? How will they be produced?
- How do we ensure the health workers that are produced through pre-service education are then recruited into the national health system?
- Where can job realignment or task-shifting be used to enhance productivity of existing staff or produce new cadres of workers that can fill essential roles in the health system?
- Is policy change needed to support the task-shifting of new cadres in the health system?
- How are community health and social workers being trained, compensated, and linked to the larger health system? Are they provided a chance for career progression?
- What are the plans for retention – both financial and non-financial- to maintain critical qualifications and types of health workers in rural or other underserved areas?
- What is planned to ensure the health and safety of the health workforce required to provide HIV and other health services?
- What will each activity cost to implement, and what portion of these costs will be assumed by the government and/or by donors?
- How will donors be coordinated to support implementation of the plan?

B. Human Resources Information Systems (HRIS)

A national electronic health workforce database or HRIS provides more reliable and up-to-date information on workforce demographics, training needs, migration patterns and workforce capacity than does a paper-based or assessment- driven data system. An HRIS is the first step in evidenced-based HRH decision making, and is critical for effective targeting of HRH resources to the areas of greatest need.

PEPFAR has supported the development of HRIS in a number of countries and country teams are encouraged to develop an HR database if one does not exist. It is recommended that the HRIS be established within the MOH or other in-country organizations capable of collecting and assessing these data in a sustainable manner. Information such as the number of health care workers registered by cadre, and their credentials, deployment location, continuing education/ in-service training, and demographics, can assist host governments and USG teams to more accurately assess workforce needs and to target PEPFAR resources. Given the varying levels of IT capacity across PEPFAR countries, an incremental and technologically appropriate strategy is recommended, with a clear strategy for how the HRIS will be sustainably maintained.

C. In-service Training

In-service training should be designed and delivered as a series of coordinated, strategic interventions addressing gaps and imbalances in skills and practice, rather than ad hoc events to accomplish specific activities. PEPFAR teams should support the development of a national training plan for both in-service training and pre-service education to fill both short-term and long-term skills needs and to improve the coordination of training. This plan should be in line with the national HRH plan and made in collaboration with professional associations. All PEPFAR-supported training should be in line with the national training plan, and should use nationally approved curricula and training materials where possible. The training plan should consider a special focus on training of health workers in stigma and discrimination, where this has not yet occurred.

Training recommendations:

- Programs should work with national partners to establish job competency requirements that are linked to delivery of specific services for different job levels;
- Programs should work with national partners to develop goals and objectives for appropriate training for both staff and external partners;
- Training objectives and content need to be tied to sound technical approaches and practices that can absorb changes in specific protocols. This is especially important in light of the rapid changes in ARV treatment options;
- Training should include four basic steps of the training process:
 - Assessment of staff proficiency and training needs
 - Development and implementation of training to address skill/knowledge deficiencies
 - Evaluation of skills transfer and improvement
 - Evaluation of improved health worker performance; and
- Programs should establish a process for assessing and analyzing the quality and effectiveness of training activities.

Countries should link in-service training programs with pre-service educational institutions to promote ongoing learning and skills development, such as by making in-service training available as continuing education required as part of certification and credentialing, or by making training available as an incentive for retention and professional development.

D. Pre-service Education^{183, 184}

To meet the new Congressional target for PEPFAR II of 140,000 ‘new health workers’ by 2014, PEPFAR needs to support the production of 140,000 new graduates from pre-service educational institutions. Pre-service education is defined as the basic education required to provide a set of basic skills competencies needed by all health care workers within a specific cadre (e.g. physicians, midwives, nurses) that will be used throughout their careers. Curricula are not static but evolve with the changing medical conditions and evidence based practices. Long-term training is defined as “pre-service” if it formally equips a health worker to serve in a new role or position that s/he did not serve in previously. This requires country teams to carefully consider with the MOH and other stakeholders how PEPFAR can best support pre-service education in each country. Where a country is already producing adequate numbers of health workers, the PEPFAR country team may want to focus on improving quality of the training, or instead focus resources on retaining the newly graduated health workers and the effective distribution of health workers.

Countries may use PEPFAR funds to strengthen pre-service education where it contributes to HIV/AIDS service delivery, such as by training and sponsoring faculty, developing or strengthening curricula, improving infrastructure to increase training capacity or quality, and providing student scholarships and/or critically needed equipment and supplies. In-service and pre-service training systems can be linked via preceptorships for new graduates, agreement on job competencies, and sharing of curricula.

PEPFAR funds may be used to support pre-service education of:

- Health professionals such as medical doctors, nurses and midwives, pharmacists, social workers, and laboratorians;
- Auxiliary workers or “associate professionals” such as clinical officers, assistant or general nurses, and laboratory and pharmacy technicians; and
- Health care workers seeking degrees in public health, public administration, epidemiology, pharmacology, monitoring and evaluation, informatics, etc.

Please note the following parameters:

- Training should be in a university, vocational training program, or other accredited educational institution;
- Education and training reform should align with population-based health care needs in both undergraduate and post-graduate training programs;
- All personnel receiving support for pre-service education should agree to serve in areas of need and to deliver HIV/AIDS prevention, care, and/or treatment upon completion of their program. Retaining these personnel in-country is a prerequisite for any U.S. Government funding; and
- Pre-service educational programs should include a strong monitoring-and-evaluation component to demonstrate the linkage to improved access to and quality of HIV/AIDS care.

Countries are encouraged to look at innovative approaches that leverage resources from other donors and or partners investing in pre-service education.

¹⁸³ “The Sub-Saharan African Medical School Study: Data, Observation, and Opportunity,” Bill and Melinda Gates Foundation, 2011; also in *The Lancet*, March 26, 2011.

¹⁸⁴ “Health Professionals for a New Century: Transforming Education to Strengthen Health Systems in an Interdependent World,” *The Lancet*, December 4, 2010.

E. Task-Shifting

In January 2008 the WHO, with PEPFAR support, released Global Recommendations and Guidelines for Task Shifting. These guidelines are available on the WHO web site (www.who.int) and are intended to assist countries as they implement or expand task shifting as an HRH strategy to increase workforce capacity. While Task Shifting is an important HRH strategy, it is important to implement Task Shifting within the context of a multi-disciplinary team framework in order to assure that all professional and non-professional health care workers are provided appropriate levels of supervision and timely access to necessary referral services and providers.

The WHO has identified are 4 broad categories of task shifting practices:

- Task shifting I: the extension of the scope of practice of non-physician clinicians, (clinical officers, physicians assistants, etc) in order to enable them to assume some tasks previously undertaken by medical doctors and other more senior cadres.
- Task shifting II: the extension of the scope of practice of nurses and midwives in order to enable them to assume some tasks previously undertaken by senior cadres (medical doctors and non physician clinicians such as clinical officers).
- Task shifting III: the extension of the scope of practice of community health workers, including PLHA, in order to enable them to assume some tasks previously undertaken by senior cadres (nurses, midwives, medical doctors, clinical officers).
- Task shifting IV: people living with HIV/AIDS, trained in self-management, assume some tasks related to their own care that would previously have been provided by health workers.

Task shifting can also be extended to non-clinical cadres, such as pharmacists, pharmacy and laboratory technicians or technologists, administrators and medical records managers.

Task shifting should occur within a supportive policy environment with the full engagement of professional councils, associations, and the MOH leadership that regulate and define the practice for each cadre. Failing to ensure that task-shifting is integrated into the regulatory bodies of the host countries jeopardizes the sustainability and legitimacy of these efforts. The performance of all cadres of health workers should be assessed against clearly defined roles, competency levels and standards.

Task-shifting to community health workers is one HRH strategy that can increase the pool of health workers in countries with limited HRH capacity. PEPFAR partners should use lay and community health workers within the context of a system that ensures proper support and supervision, as well as fair compensation, and that is integrated into the overall public and private health system. Strategies for ensuring quality of care include standardization of competencies and tasks, initial training and periodic retraining, and support through supervision and teamwork.

F. Performance Assessment/Quality Improvement

A combination of supportive supervision, on the job skills reinforcement, continuing education, and periodic reassessment of skills and knowledge is critical to maintaining and supporting health care workers skills. PEPFAR country HRH activities should include approaches to assess the quality of care provided by trainees once they are in the workplace and to develop strategies to assist them in continuous quality improvement of their skills and knowledge, such as through a strategy of ongoing problem identification and problem-solving. This includes exploring the role of multi-disciplinary clinical teams or optimizing staff skill mix to improve service delivery.

*G. Retention*¹⁸⁵

Supporting retention activities is especially important in PEPFAR II, to ensure PEPFAR's significant investment in the production of new health workers through pre-service education is not lost through the pervasive problem of brain drain of health workers towards urban areas, toward more developed countries, and to the private sector. Where PEPFAR country teams are investing in pre-service education, a retention strategy should exist to help ensure new graduates are effectively recruited and retained in the national health system, and in the areas of greatest need.

Many PEPFAR focus countries are developing creative, financial and non-financial schemes to encourage the retention of health workers. These include Namibia's support for housing in rural areas and Zambia's collaboration with the Ministry of Health on its Rural Physicians Retention Scheme. Other examples include the provision of free ART to health workers and their families who are working at HIV/AIDS care and treatment sites, and Mozambique's 'gap-year' funding, retaining new graduates in the health system during the year-long MOH recruitment process.

It is important to work very closely with the national government and health worker associations in the host country during the development of these retention schemes, as well as with other donors. An essential feature of any retention scheme is to include a monitoring and evaluation component to measure the impact of the scheme on the health worker satisfaction, performance, and retention. Efforts to examine the outcome of this effort on patient care (e.g. number of patients who are receiving ART from retained providers) are welcomed.

H. Management and Leadership Development

Strong leadership and management enable organizations to improve their services within resource constraints. Improving management and leadership at multiple levels of an organization that oversees or implements HIV/AIDS programs can create a sustained cycle of improvements, better services for clients and ultimately improved health outcomes. Support for the development of leadership and management skills should take place at both the national level and at the service delivery level. Sustainable national management and leadership training programs can be developed by strengthening local management training institutions and promoting management skills-building in pre-service educational programs.

Support should also be focused on the service delivery level. Physicians, nurses and other health care professionals charged with leading and managing HIV/AIDS programs and facilities in PEPFAR countries may be well trained for their clinical duties, but they rarely get the opportunity to develop leadership and management skills needed to achieve highly-effective service delivery. Similarly, health workers are often charged managing personnel but have not been properly prepared for this role. Leadership and management development are an integral part of the sustainability of prevention, care and treatment programs and PEPFAR encourages the support of management and leadership skills to achieve improved program outcomes.

I. Strengthening Health Professional Regulatory Bodies and Associations

In many countries, the health professional councils and associations are key participants in many areas of regulation that determine the quality of the health workforce and the care they provide, including but not limited to:

¹⁸⁵ "Increasing Access to Health Workers in Remote and Rural Areas Through Improved Retention: Global Policy Recommendations," WHO, 2010.

- Setting the standards of quality and excellence of care for providers/cadres;
- Setting the education and graduation standards for pre-service education;
- Setting standards for and accrediting academic institutions;
- Setting standards for and often providing continuous professional development (CPD); and
- Providing and maintaining all licensure/certification records.

Many councils lack the capacity to take on these roles effectively. In the case of professional associations, they may have no funding or full time staff, and are run primarily by volunteers. Their membership may be small and not see the advantages of being active participants. PEPFAR funds may be used to support and provide assistance to councils to improve regulatory functions such as licensing and registration; training accreditation; and continuing education. With respect to professional associations, PEPFAR support activities may include: 1) advancements that strengthen their internal structure and organizational effectiveness (management, leadership and fundraising skills; governance and strategic planning; member needs and service) and 2) activities that allow them to enhance the skills of individual members or increase their influence outside the association (CPD for members, advocacy for policy change, coalition building, etc.). The most effective approach combines both categories of activity.

J. Twinning/ Volunteers

Twinning partnerships and the use of volunteer mentors can help countries to build local capacity through a peer-to-peer model of collaboration and technical exchange. Twinning arrangements match individuals or institutions with comparable areas of work in long-term relationships of mentorship, training, and technical assistance. These ongoing partnerships facilitate bidirectional skills transfer and help to expand the pool of trained providers, managers and other health care staff. Twinning partnerships are typically formed between a U.S. partner and a country partner but participants may also come from within the PEPFAR country or region, offering an opportunity for “south-to-south” technical exchange.

Twinning partnerships may include any number of partners, such as government agencies (including state and local departments of health); pre-service educational institutions; health worker regulatory boards and professional associations; health science centers; community and faith based organizations; third party country governments; and/or organizations with linguistic or cultural ties to a host nation (e.g. a diaspora community).

K. Salary Support

Guidance on Salary support and other financial incentives appears in the PEPFAR publication (August 18, 2006 News to the Field) titled, *Support for Host Government Staffing*.

3.4.2 COUNTRY CONTEXTUAL CONSIDERATIONS: HUMAN RESOURCES FOR HEALTH

Before developing HRH activities, it is important to understand the health workforce dynamics in your country, to ensure the appropriate targeting of PEPFAR resources. This involves understanding the number of health workers graduating from pre-service educational institutions, the vacancy rate in the MOH, the average recruitment time into public and private sectors, the out-migration of health workers, the distribution and skill-mix of health workers across the country and levels of the health system,

retention challenges (such as workplace safety issues or lack of supervision and mentorship), the existence and quality of ongoing training and certification, the disease burden and demand for services. For example, it is not appropriate to invest deeply in pre-service education, if a country is already producing an adequate number of health worker graduates and the issue is with their retention. This information can be obtained from WHO surveys, the MOH, regulatory boards, the national HRIS (where one exists), and/or through discussions with stakeholders. It is also important to understand the gender dynamics impacting HRH as Women, Girls, and Gender Equality is a core principle of PEPFAR and the GHI. For example, do providers need to be trained on the importance of appropriate and respectful care to all clients, including women, girls and marginalized groups? Are there certain gender issues that are impacting health worker team dynamics?

3.4.3 PARTNER PERFORMANCE CONSIDERATIONS: HUMAN RESOURCES FOR HEALTH

There are multiple partners from across PEPFAR implementing agencies that are conducting HRH activities. It is critical that country teams work closely with partners to ensure these activities are not overlapping or duplicating services.

3.4.4 LINKAGES AND WRAPAROUNDS: HUMAN RESOURCES FOR HEALTH

Due to the leveling of PEPFAR funding in many countries, PEPFAR needs to coordinate closely with other sources of donor funding to support a comprehensive HRH system in each country. PEPFAR resources should be focused on the health workforce providing HIV/AIDS services, on the congressional target of 140,000 new health workers, and around the key areas of intervention that will help us achieve that goal while developing sustainable HRH capacity in countries. However, PEPFAR can augment its investment by leveraging other donors to invest in HRH, such as:

- The Global Fund to Combat HIV/AIDS, TB, and Malaria: has a health systems strengthening funding category, and has significantly invested in all aspects of HRH, most recently in the sector-wide retention scheme in the Zimbabwe health system;
- The UK Department for International Development (DFID): has a major partnership with PEPFAR in Zambia, Ethiopia, Mozambique, and Kenya to coordinate around HRH and is investing in other countries through its International Health Program (IHP);
- USAID MCH program: has a Congressional target to produce 100,000 community health workers by 2013 and works in 30 countries;
- Presidential Malaria Initiative & Neglected Tropical Disease Initiative: large USG programs that also rely on the health workforce in countries where they work;
- NIH Fogarty International Center: makes available short and long-term training grants available in almost all PEPFAR countries for advanced health-related degrees and for HIV clinical, operations, and health services research training; and
- Japan International Cooperation Agency (JICA): has a national target of training 100,000 health workers through a combination of in-service and pre-service training.

TECHNICAL AREA 3.5: GENDER

Gender - refers to the attributes, constraints and opportunities associated with being a man and a woman. The social definition and expectations of what it means to be a man or a woman varies across cultures and varies over time. The transformation of gender-related power dynamics is a key guiding principle of the PEPFAR gender program framework. Differences in power between and among men and women are evident within couples, families, and communities and in their relationships with the healthcare system and other stakeholders and institutions. Gender influences individuals' status within society, roles, norms, behavior, and access to resources – all of which influence dynamics of the HIV/AIDS epidemic and the success of programs to address it.

3.5.1 INTRODUCTION

The overall goals of PEPFAR gender programming are to:

- Facilitate achievement of program goals for treatment, prevention, and care;
- Strengthen program quality and sustainability;
- Guarantee women's and men's equitable access to programs;
- Prevent or ameliorate program outcomes that may unintentionally and differentially harm women and men; and
- Increase women's and girls' access to and control of strategic and protective health, social and economic assets which assist in preventing, mitigating the effects of HIV/AIDS.

In support of these goals, PEPFAR employs a two-pronged approach: a) gender mainstreaming or integration into all prevention, care, and treatment programs, and b) programming to address five cross-cutting gender strategic areas:

1. Increasing gender equity in HIV/AIDS activities and services, including reproductive health;
2. Preventing and responding to gender-based violence;
3. Engaging men and boys;
4. Increasing women's and girl's legal rights and protection; and
5. Increasing women's and girl's access to income and productive resources, including education.

Legislation for the next phase of PEPFAR recognizes the importance of gender, elevates its priority, underscores the technical approach adopted under the first phase of PEPFAR (including the five gender strategic areas), and outlines concrete gender planning, implementation, and reporting requirements. This includes “specific targets, goals, and strategies... to address the needs and vulnerabilities of women and girls to HIV/AIDS,” and a “study of progress toward achievement of policy objectives,” that includes “an assessment of efforts to address gender-specific aspects of HIV/AIDS including gender-related constraints to accessing services and addressing underlying social and economic vulnerabilities of women and men.”

PEPFAR places a high priority on confronting the changing demographics of the HIV/AIDS epidemic: we recognize that in many places the epidemic is increasingly young, poor, and female. PEPFAR is also focusing significant resources and effort on responding to gender-based violence (GBV), which fosters the spread of HIV/AIDS both directly by the violence itself and indirectly by limiting women's and girls' ability to negotiate sexual practices, to disclose HIV status and to access services due to fear of GBV.

Given the increased focus on GBV, we encourage countries to ensure accurate reporting of financing for gender programs through the GBV cross-cutting budget code. This indicator allows us to map existing GBV programming across countries and regions, as well as to monitor increased investments in this area. Please ensure that contractors and grantees that are working in areas like prevention, treatment and OVC, and are addressing GBV through activities that might include, for example, community mobilization and behavior change, the provision of sexual violence services including the provision of post-exposure prophylaxis, integration of GBV services in facility and community-based programs, and child protection services, account for their financial investments and provide accurate reporting on this critical element.

Finally, the societal issues around gender and HIV/AIDS are complex, and can vary from one country to another; however, addressing these challenges successfully is critical to the achievement of PEPFAR's prevention, treatment, and care goals. Assisting and supporting local partners through programs aimed at building supportive social environments for more gender equitable norms are particularly important in this area.

As scheduled, three PEPFAR gender special initiatives have recently come to an end: the Male Norms Initiative; the Sexual and Gender-Based Violence (SGBV) Initiative; and the Vulnerable Girls Initiative. Results include a step-by-step guide for setting up post-rape care services, a set of manuals for working with vulnerable girls at various levels, and a guide to working with men within service delivery settings and in the community.

(See http://www.aidstarone.com/focus_areas/gender/pepfar_gender_special_initiatives)

Gender is considered cross-cutting within the PEPFAR program framework. This means that gender activities are programmed within the other relevant PEPFAR technical areas. Country program should integrate gender into the various different technical areas. Section A below presents illustrative examples of the types of gender activities that could be included in the various technical areas.

Please note that the activities described under Sections A and B are not mutually exclusive; that is, they represent two mutually reinforcing approaches to integrating gender across PEPFAR programs.

3.5.2 RECOMMENDED ILLUSTRATIVE GENDER ACTIVITIES PRESENTED BY GENDER TECHNICAL AREA

A. PMTCT

- Assessment and identification of barriers to women's access to quality PMTCT services and targeted interventions to overcome the barriers;
- Effective linkages to family planning/reproductive health services, infant feeding and support, and organization of basic necessities such as nutrition, housing, and financial and legal assistance;
- Interventions to effectively engage women's partners in PMTCT programs (e.g., couples testing and counseling, men's clubs, etc) at service delivery and community levels – to promote testing of men and to build their support for their female partners; and
- Screening and counseling for gender-based violence as part of PMTCT services, or referrals/linkages to these services

B. Sexual Prevention

- Assessment and identification of gender norms, among general population and high risk populations, that perpetuate multiple partnering, concurrent partnerships, cross-generational sex, transactional sex, gender-based violence, alcohol misuse, and lack of condom use;
- Targeted interventions and messages that address and transform harmful gender norms, held by men and women, that support negative HIV behaviors and outcomes;
- Increase both programming and access to female condoms. The female condom is the only female-initiated method available that can be worn by women for protection against both unintended pregnancy and sexually transmitted infections. A growing body of evidence shows that effective female condom promotion by both women and men can increase the proportion of protected sex acts;¹⁸⁶
- Assessment of barriers to women's and men's, girls' and boys' access to prevention messages and services, and targeted interventions to overcome these barriers;
- Assessment of and attention to unique risks and prevention needs of male and female sex workers, including gender based violence;
- Prevention of and response to gender-related stigma against MSM and transgender persons;
- Livelihood and economic empowerment programs appropriate to the needs of women and girls, boys, MSM, transgender and other vulnerable populations;
- Community-based and structural interventions to eradicate the exploitation of women and girls, MSM, transgender, and other vulnerable populations by sex trafficking, rape, and sexual abuse;
- Linkages with interventions to support girls' equal education and ensure that school environments are safe for girls; and
- Linkages with interventions to increase economic empowerment, property and other legal rights of women, transgender population, and orphans.

Note on Adolescent Girls: Pre-adolescent and adolescent girls face systematic disadvantages, including in health, education, nutrition, labor force participation, and the burden of household tasks. Because of social isolation, deprivation, economic disadvantage, and discriminatory cultural norms, many girls are forced to marry at very young ages and are extraordinarily vulnerable to unintended pregnancy, HIV, sexual violence, and physical exploitation. Lacking a full range of opportunities and devalued because of gender bias, many girls are seen as unworthy of investment or protection by their families, communities and governments.¹⁸⁷

C. Programming recommendations

- Support positive youth development through peer networks and mentorship programs in elementary and secondary schools and out of schools, where many of the most vulnerable adolescents can be found;

¹⁸⁶ Shane, B; Herdman, C; Dahlquist, K; Agarwal, D; K. Ambaye Nigussie, K; Blumenthal, P; Deperthes, B; Edouard, L; Jackson, H; Malunga, G; Kraus, S; Nyamukapa, D; Schuller, A; Spieler, J. (2006). The female condom: significant potential for STI and pregnancy prevention. *Outlook*, 22(2).

Vijayakumar G, Mabude Z, Smit J, Beksinska M, Lurie M. A Review of Female-Condom Effectiveness: Patterns of Use and Impact on Protected Sex Acts and STI Incidence. *Int J STD AIDS*, 17(10):652-9.

Hatzell, T.; Feldblum, P. J.; Homan, R. K.; Gmach, R. D. (2003). The Female Condom: Is "Just as Good" Good Enough? *Sexually Transmitted Diseases*, 30 (5):440-442

¹⁸⁷ *Start with a Girl: A New Agenda for Global Health*, Center for Global Development, <http://www.cgdev.org/content/publications/detail/1422899/>

- Develop specific programming for out-of-school adolescent and pre-adolescents who often the most vulnerable, especially married adolescent girls;
- Promote youth-friendly “safe spaces” for health information and service delivery activities;
- Involve youth, parents, schools, communities and religious leaders when designing programs;
- Provide age-appropriate sexual and reproductive health and HIV/AIDS education and interventions;
- Foster positive adult-child communication;
- Link health activities to education and viable livelihoods programs;
- Work with communities to change behavior and attitudes towards child marriage and support community programs that implement specific interventions to increase age at marriage; and
- Support interventions to prevent and respond to sexual abuse of minors.

D. Biomedical Prevention

- Assessment and identification of unique risks and needs of male and female people who inject drugs; targeted interventions to meet these needs such as women- friendly PWID services that include provision or referral to comprehensive sexual and reproductive health services, PMTCT, and legal and economic strengthening activities;
- Risk reduction programs targeted to the specific needs of women and men and that address harmful gender norms;
- Gender analysis conducted as part of planning for pre-exposure prophylaxis programming; and
- Analysis of and attention to social change process related to globalization and their impact on local gender constructions and gender conflicts, marriage patterns, and emerging sexual practices.

E. Male Circumcision

- Effective communication campaigns and education programs directed to the entire community, including women and men to explain benefits and risks of MC to them and their partners; among other things, these messages should explain that there is no known direct benefit to women, that male circumcision is partially protective for HIV negative men, that it cannot prevent HIV positive men from transmitting HIV, that there is potential of heightened risk when surgical wound is not fully healed before having sex, and that male circumcision must be combined with other risk-reduction strategies in order to achieve effective protection;
- Formative research and active program monitoring on unintended consequences of MC for women and men (e.g., reductions in rates of condom use, increases in coercive sex, increased number of sex partners, further stigmatization of HIV positive women, and difficulties for women to negotiate safe sex or insist on condom use, particularly with a circumcised man); use of these data to prevent and mitigate harmful consequences;
- Effective counseling interventions, including engagement of community-based interventions, for MC clients and their partners to mitigate risks of gender- based violence and HIV infection;
- Engagement of community leaders, especially faith-based and traditional cultural leaders, in building positive connotations around VMMC and advocating for healthy sexual behaviors; and
- Male-friendly HIV/AIDS programs, other male health services, and promotion of healthy male norms integrated or linked with MC roll-out; innovative models to promote male circumcision through key health services for women, e.g. family planning and maternal and child health services.

(See http://www.malecircumcision.org/publications/documents/UN_info_pack_insert_5.pdf)

F. Adult Care and Treatment

- Strengthening of comprehensive health care services, including the provision of PEP, for victims of rape and other gender-based violence;
- Assessment and identification of barriers that women and men selectively face in accessing services, adhering to treatment, or receiving on-going care; targeted interventions to overcome these barriers;
- Targeted care and treatment services and programs to stigmatized and vulnerable populations, e.g., MSM, commercial sex workers, disabled, etc;
- Effective linkages of care and treatment services with family planning and reproductive health services, and cervical cancer screening and treatment; Integration of HIV/AIDS services into family planning and reproductive health clinics in order to facilitate women's access to services;
- Family-centered approaches to care and treatment;
- Assessment of the gender dynamics of care-giving; interventions to ensure a gender-equitable burden of care, including greater responsibility and participation of men as community and family caregivers; while not threatening or displacing women's leadership in desirable related domains;
- Programs to increase women's access to productive resources in order to support them in their care giving roles;
- Male-friendly HIV/AIDS services to encourage men's participation in health care and to help break down barriers preventing communication between men and women on health matters;
- Programs to increase access to legal protection, including in cases of land and property grabbing and disinheritance, for women, transgender, and other vulnerable populations;
- Recognize and address barriers to access, including: transportation to services/or financial resources where necessary; flexible hours of operation with access to multiple integrated services; confidentiality and privacy; appropriate facilities (e.g., separate entrances or waiting areas for women and girls when needed); support of family members; cultural competence; and assistance with language barriers; and
- Provide alternative service delivery options (e.g., home visits and mobile units) for clients unable to reach or unlikely to use facility-based services.

G. TB/HIV

- Assessment and identification of barriers to women's and men's access to TB/HIV services and targeted interventions to overcome those barriers;
- Effective linkages between TB, HIV, PMTCT services and other services for women in order to facilitate their access to integrated care and uptake of each service;
- Monitoring of TB treatment adherence for males and females to assess gender-related barriers; identification and reduction of barriers to support adherence;
- Assessment and mitigation of gender-related stigma associated with TB and HIV; and
- Targeted services to ensure equitable access to TB care and treatment for men and women, including vulnerable populations.

H. Orphans and Vulnerable Children

- Monitoring, prevention, and mitigation of orphaned girls' and boys' vulnerability to sexual abuse, transactional and inter-generational sexual relationships, exploitation, and HIV;
- Assessment of the gender profile and dynamics of care-giving; interventions to ensure a gender-equitable burden of care, including greater responsibility and participation of men as community and family caregivers;
- Livelihood and economic empowerment programs for female heads of households;
- Support for OVC boys and girls equal access to education; interventions to ensure that school environments are safe for girls; vocational training for OVC boys and girls, both in-school and out-of-school; and
- Advocacy, policy development, and policy implementation and monitoring for inheritance and property rights of women and orphans.

I. HIV Testing and Counseling (HTC)

- Assessment and identification of barriers to women's and men's access to HTC services and targeted interventions to overcome those barriers;
- Interventions, such as "male friendly" services (i.e. mobile and outreach services, evening/weekend clinic hours) to increase men's uptake of services;
- Provision of gender-equitable couples/partner HIV testing and counseling to relieve the burden on women for disclosing to their male partners;
- Training of HTC providers to assess and mitigate risk of violence abandonment, and gender-related stigma, or fear of these, that clients/patients may face when disclosing their HIV positive status to partners or family members;
- Actively link clients and/or patients with gender-based violence services as needed, and integrate screening and counseling for gender-based violence as part of HTC services where training and support are available; and
- Family-centered approach that supports HTC for couples/partners and children.

J. Pediatric Care and Treatment

- Assessment and identification of barriers that girls and boys selectively face in accessing services, adhering to treatment, or receiving on-going care; targeted interventions to overcome these barriers;
- Strengthening of comprehensive health care services, including PEP, for child victims of rape and other forms of gender-based violence;
- Targeted care and treatment services and programs to stigmatized and vulnerable pediatric populations, e.g., street youth, OVC, domestic workers, etc;
- Effective linkages of HIV care and treatment services with other pediatric services;
- Family-centered approaches to care and treatment;
- Assessment of the gender dynamics of care-giving; interventions to ensure a gender-equitable burden of care, including greater responsibility and participation of men as community and family caregivers; and
- Provision of integrated services through wraparound approaches including family planning, reproductive health, maternal and child health and the management of opportunistic infections; effective referral linkages to support postnatal follow up of HIV+ mothers and exposed infants.

K. ARV Drugs

- Procurement and supply management of antiretroviral post-exposure prophylaxis drugs for rape care services.

L. Strategic Information

- Data analysis to better understand the gender dimensions of HIV/AIDS epidemics—including disaggregation by age to understand the special needs of adolescent girls and boys in the 10-14 and 15-19 age ranges;
- Collection and analysis of sex-disaggregated data to assess gender differences in such areas as service utilization, sexual behavior, health-seeking behaviors, risk perception. And adherence to treatment;
- Development and strengthening of data monitoring systems to enable sex-specific program target-setting and reporting;
- Program evaluation of gender-focused HIV/AIDS programs; and
- Formative research on the five PEPFAR gender strategies and evaluation of their impact on HIV/AIDS outcomes.

M. Health Systems Strengthening

- Monitoring of health systems strengthening interventions (e.g., service delivery, information systems, human resources, health finance, medical products/vaccines/technologies, leadership, governance) for their impact on health equity/disparities and gender equity/disparities.

3.5.3 RECOMMENDED ILLUSTRATIVE ACTIVITIES BY GENDER STRATEGIC AREA

A. Gender Strategic Area 1: Increasing gender equity in HIV/AIDS activities and services, including reproductive health

PEPFAR-supported programs should promote proactive and innovative strategies to ensure that men and women, girls and boys, have access to prevention, care and treatment services. This includes tailoring services to meet the unique needs of various beneficiary groups.

- Setting sex-disaggregated targets that reflect the characteristics of the epidemic and collecting sex-disaggregated service delivery data; using results to adapt recruitment strategies as necessary and to improve quality of program services;
- Assessment and identification of barriers that women and men selectively face in accessing programs and services and in enjoying program/service benefits; targeted interventions to overcome these barriers, e.g., examining factors such as cost, transportation, and child care, appropriate appointment schedules, provider bias and attitudes, sufficient women health workers, and guarantees of privacy and confidentiality;
- Assessment and identification of opportunities and socio-cultural ‘entry points’ that can be built upon and strengthened for delivery of HIV/AIDS services and programs, and for addressing potentially harmful gender norms and practices that impede uptake of services;

- Integration of HIV/AIDS services into family planning and reproductive health clinics in order to facilitate women's access to services;
- Male-friendly HIV/AIDS services to encourage men's participation in health care;
- Strategies such as couples testing and counseling, family-centered services, and programs for men as part of CT and PMTCT, to promote uptake of services by women and men;
- Female-friendly IDU services that include comprehensive sexual and reproductive health, PMTCT, and gender-sensitive risk reduction services, or referral to those services; and
- Linkages and referrals with other services such as family planning, reproductive health, maternal and child health, male circumcision, social services, psychological services, etc.

B. Gender Strategic Area 2: Engaging Men and Boys

Men can play a critical role in HIV/AIDS outcomes as clients of health services, as supportive partners, and as active participants in promoting gender equality. Recognizing that men can either impede or enhance health interventions, PEPFAR encourages programs that promote positive male engagement and behavior change.

- Programs (including workplace and school-based) that encourage men to be responsible in their sexual behavior, child rearing, and to respect women and girls – including the reduction of sexual violence and coercion, number of sexual partners, and cross-generational and transactional sex;
- Prevention programs that reach and engage mobile male populations, including migrant workers, truck drivers, and members of uniformed services, to increase risk perception and promote healthy and responsible sexual behavior;
- Organizational program practices that support constructive male involvement, e.g., challenging gendered divisions of labor and sexual harassment, and developing workplace responses to domestic violence;
- Behavior change programs that promote gender equality and the positive role men can play in the health and well-being of their partners, families and communities in order to increase their HIV preventive behaviors; support their partners upon disclosure; access appropriate HIV treatment; and engage more fully in caretaking of HIV positive individuals;
- Couples testing and counseling aiming to increase men's involvement in HIV/AIDS prevention, treatment, and care programs and to reduce stigma and violence against women;
- Programs that seek to change the gender norms/roles that promote risky behaviors and dissuade men's health-seeking;
- Programs that reduce stigma and discrimination of men who have sex with men and attitudes about masculinity that lead to the social isolation of MSM and transgender populations; and
- Program evaluation of replicated or new programs to address male norms and behaviors to determine outcomes and impact.

C. Gender Strategic Area 3: Prevention and Response to Gender-based Violence

Women and girls who experience or fear violence may be unable to make their own decisions about sex, negotiate safer sex, disclose their status, or access treatment and care services. Similarly, marginalized populations, such as MSM and transgender populations often are at increased risk of physical and sexual violence, which may serve as a barrier to preventive behaviors and may limit use of HIV/AIDS services.

- Screening and counseling for gender-based violence within HIV/AIDS prevention, care, and treatment programs;
- Strengthening referrals from HIV/AIDS services to GBV services and vice versa;
- Strengthening rape care services, including the provision of HIV PEP;
- Interventions aimed at preventing gender-based violence, including interpersonal communication, community mobilization, group learning, and mass media activities;
- Programs that address societal and community norms that perpetuate violence against women, girls and other marginalized population; that promote gender equality; and that build conflict resolution skills;
- Strengthening linkages between health, legal, law enforcement, and judicial services and programs to prevent and mitigate gender-based violence;
- Support for review, revision, and enforcement of laws and for legal services relating to gender-based violence, including strategies to more effectively protect young victims and punish perpetrators;
- Research and program evaluation regarding the associations and interplay between GBV and HIV/AIDS, and HIV/AIDS services;
- Address violence and coercion by building women's and girls' protective assets including creating safe and supportive community based platforms through which to deliver health, social and economic assets; and
- Community-based and structural interventions to build social density, cohesion and safety spaces for vulnerable populations subject to sexual abuse, sex-trafficking and rape—particularly for adolescent girls.

D. Gender Strategic Area 4: Increasing women's and girls' access to income and productive resources

Providing women and girls with economic opportunities empowers them to avoid high risk behaviors, seek and receive health care services, and provide better care for their families.

- Programs to ensure that girls are given equal opportunity to attend school and/or vocational training (in marketable skills) and participate in income generation activities;
- Women and girls' training and technical assistance in business development and business management;
- Programs and wraparounds to increase girls' access to education, e.g., support for tuition fees, school uniforms, and other school supplies;
- Working with governments to develop policies that increase women's access to economic resources, including credit, markets, and land;
- Programs that foster the granting, distribution of, or communal access to productive land for women and HIV/AIDS-affected individuals;
- Encouraging the formation of associations, savings clubs, lending collectivities and forums that facilitate woman-to-woman learning for economic empowerment and advancement;
- Access to micro-finance and other economic strengthening activities including through wraparound programs; and
- Research and program evaluation regarding the associations between income and productive resources and HIV/AIDS.

E. Gender Strategic Area 4: Increasing women's and girls' legal rights and protection

Policies, laws and legal practices that discriminate against women, girls and other marginalized populations reinforce vulnerability and impact of HIV/AIDS. Women denied enforceable legal rights and protections, including to property and equitable inheritance, are often unable to meet the basic needs for themselves and their children.

- Interventions to promote and enforce equal rights to land, property, and other productive assets for women;
- Support programs that work with governments, NGOs, and traditional authorities to eliminate gender inequalities in civil and criminal code, and in traditional practices;
- Interventions to increase awareness and commitment among health, judicial and legal sectors, community leaders and traditional authorities on the legal rights of women and girls related to HIV/AIDS prevention, treatment and care;
- Promotion of gender equitable HIV/AIDS policies and effective legislation at the national and community level; and
- Research and program evaluation regarding the associations between legal rights and HIV/AIDS.

F. Gender Strategic Area 5: Increasing women's and girls' access to income and productive resources, including education

Providing women and girls with economic opportunities empowers them to avoid high risk behaviors, seek and receive health care services, and provide better care for their families.

- Programs to ensure that girls are given equal opportunity to attend school and/or vocational training (in marketable skills) and participate in income generation activities;
- Women and girls' training and technical assistance in business development and business management;
- Programs and wraparounds to increase girls' access to education, e.g., support for tuition fees, school uniforms, and other school supplies;
- Working with governments to develop policies that increase women's access to economic resources, including credit, markets, and land;
- Programs that foster the granting, distribution of, or communal access to productive land for women and HIV/AIDS-affected individuals;
- Encouraging the formation of associations, savings clubs, lending collectivities and forums that facilitate woman-to-woman learning for economic empowerment and advancement;
- Access to micro-finance and other economic strengthening activities including through wraparound programs; and
- Research and program evaluation regarding the associations between income and productive resources and HIV/AIDS.

3.5.4. COUNTRY CONTEXTUAL CONSIDERATIONS: GENDER

The societal issues around gender and HIV/AIDS are complex, and can vary from one country to another, between sub-groups within countries, and by type of epidemic. In generalized epidemics, women bear a disproportionate burden of disease. In concentrated or mixed epidemics, men may have higher prevalence

rates than females. However, gender issues, including those addressed under the gender strategic areas are present and relevant in both concentrated and generalized epidemics.

Addressing gender in HIV/AIDS programs and services requires careful analysis of social processes that shape gender norms and disparities and then programming to those disparities. Countries should consult available data sources such as DHS, AIS, BSS and other studies that will help understand the gender aspects of the epidemics and program accordingly.

3.5.5 LINKAGES AND WRAPAROUNDS: GENDER

Linkages and Wraparounds for gender-related work include:

- Linkages and integration of GBV programs. Countries receiving funding through the Women's Justice and Empowerment Initiative (WJEI) should describe specific actions to ensure program linkages;
- Joint programs addressing gender equity through activities promoting rule of law, good governance, agricultural sector capacity, access to and use of land, economic opportunity, and sustainable resource management;
- Collaboration and program integration with the education sector, particularly around girls' education;
- Collaboration between PEPFAR and UNAIDS/Global Fund related to gender programming and/or work with national AIDS programs and Ministries;
- Linkages with child protection programs, such as UNICEF, to address sexual violence and coercion against adolescent girls and boys; and
- Integrate services whenever appropriate, by linking PEPFAR-funded activities with those funded from separate accounts supporting reproductive health and family planning, to meet the comprehensive care needs of women and girls by: (a) providing counseling and referrals (linkages) to family planning programs for women HIV/AIDS prevention, treatment, and care programs – ideally at the same site; (b) providing family planning clients with HIV prevention including HIV testing and counseling, particularly in areas with high HIV prevalence and strong voluntary family planning systems – again, ideally at the same site; (c) integrating family planning services in PEPFAR-funded PMTCT and HIV care and treatment programs; and (d) provision of HIV prevention messaging and support, as well as HIV testing and counseling within antenatal care, maternal and child health, and family planning programs.

TECHNICAL AREA 3.6: PUBLIC-PRIVATE PARTNERSHIPS

Public-Private Partnerships - PEPFAR defines PPPs as collaborative endeavors that combine resources from the public sector with resources from the private sector to accomplish HIV/AIDS prevention, care, and treatment goals. PPPs enable the U.S. Government and private-sector entities to maximize their efforts through jointly defined objectives, program design and implementation, and through the sharing of resources, risks and results. Three hallmarks of PPPs are that they help ensure sustainability of programs, facilitate scale-up of interventions, and leverage significant private-sector resources.

3.6.1 INTRODUCTION

PPPs are important for three reasons:

- (1) They leverage additional resources to meet PEPFAR goals.
- (2) They provide valuable expertise that often cannot be found in the government.
- (3) PPPs can be a platform for long term sustainability.

Simply put, by utilizing the skills, resources and access that the private sector provides, we can help to make PEPFAR programming more effective and reach greater numbers of people.

Country teams are encouraged to build and support local PPPs that draw on the private enterprises' extensive infrastructure and supply/value chains to target at-risk populations, as well as to utilize the management, marketing and core business expertise private enterprises bring to bear. Through the long-term commitments that companies have made by virtue of their investment in PEPFAR-supported countries, there exists greater potential to enhance the sustainability of country programs, positioning PPP funding as capital to catalyze sustainable action.

Additionally, interested country teams are encouraged to contact the OGAC PPP Office to explore opportunities to buy into existing multi-country partnerships.

PPP models, technical assistance opportunities, and information on multi-country PPPs are available upon request. Please contact PEPFAR's PPP TWG.

These technical considerations are intended to be a basic resource for the country teams as they consider whether and how to implement and/or scale-up PPPs as appropriate to their country contexts.

A. Definition of a PPP

As mentioned above, PPPs bring additional resources to PEPFAR programs. Matching leveraged resources can be financial resources, in-kind contributions and intellectual property. For purposes of reporting, a collaboration is considered a PPP if US Government funds are matched at a minimum ratio of 1:1 with other resources. In the event the private sector partner contributes resources in-kind, country teams should monetize the contribution by estimating its market value, in coordination with the partner. While the definition of a PPP requires a 1:1 match from the private sector for reporting, country teams are strongly encouraged to partner with the private sector whenever it increases the effectiveness of programs.

The key aspect of a public-private partnership is this: **a private sector partner must be contributing resources.** If it's a contract with a private company, it's not a PPP. If it's an activity that will build off an existing investment but with no new money or in-kind contributions, it's not a PPP. PPPs are

activities where both parties invest new resources toward a common purpose. If in doubt, ask yourself, “Is the partner giving something of real value to the partnership?”

In addition, given the increased emphasis on country ownership, Operating Unit teams should look for opportunities to meaningfully incorporate input and contributions of host country governments in PPPs. While not required, the “public” component of a PPP should wherever possible include host country government contributions, both human and financial resources.

Countries should also consider support to build national government capacity to negotiate and enter into PPPs. While this type of activity would not be technically considered as a “PPP” for reporting purposes, PEPFAR-supported technical assistance to develop national, state or local government entities’ capacity to enter into PPPs with the private sector can make a lasting contribution to national programs.

The following are critical core elements of PPPs. These include:

- **Coherence with country strategy and PEPFAR goals in prevention, care and treatment:** PPPs must help advance programs and reach PEPFAR targets;
- **Added value:** PPPs reach more beneficiaries with additional resources;
- **Quality and sustainability:** PPPs should include transition strategies that will allow for the integration and mainstreaming of program activities within the existing host country infrastructure, e.g., health care systems;
- **Effective monitoring and evaluation:** Monitoring and evaluation of PPPs is expected to document results, enable cost-effectiveness analysis, and ensure accountability; and
- **Resources Leveraged:** PPPs by definition must include resource inputs from PEPFAR and from private sector partner(s), and meet the requirement of a 1:1 leverage. In the event the private sector partner contributes resources in-kind, country teams should monetize the contribution.

B. Partner Determination

Private sector partners include a wide range of organizations such as: foundations, U.S. and non-U.S. private businesses, business and trade associations, unions, venture capitalists, and social entrepreneurs.

USG country teams may consider new partnerships with private entities in a variety of sectors with diverse core competencies. Country teams are responsible for vetting potential partners to ensure their suitability. Private entities are diverse and have different motivations. To that end, country teams should approach potential partners recognizing the unique goals and capabilities of each, and adapt programs accordingly.

To the extent possible, existing financial mechanisms (cooperative agreements, USAID/Global Development Alliance [GDA], APS processes, grants, etc.) should be used. While we support these mechanisms, PPPs are not limited to them. PPPs can and have been developed and implemented without co-mingling USG and private sector funds or developing new implementation mechanisms. Once concept papers and proposals have been reviewed and approved by country teams and/or OGAC as appropriate, and due diligence completed, country teams should also follow up with a memorandum of understanding (MOU) with the partner(s) and a detailed work plan.

3.6.2 COUNTRY CONTEXTUAL CONSIDERATIONS: PUBLIC-PRIVATE PARTNERSHIPS

As countries begin to implement PPPs, it should be noted that they are complex and can require significant time to manage. We encourage country teams to work with the private sector partners within the PPP to assist with the management burden. Additionally, we encourage country teams that have not yet done so to designate a PPP advisor/facilitator. Countries with a PPP focal point have demonstrated the greatest success in engaging with the local private sector and managing the PPP portfolio.

As detailed in this document, the best PPPs are driven by needs in the field and have a local champion to guide them through implementation. To identify problems and gaps in programs, there is no substitute for dedicated PPP field staff. Having dedicated staff, preferably with dedicated budget, allows PPPs to become embedded in field activities more than is possible with HQ staff acting as support. A number of PEPFAR countries have hired dedicated PPP staff, including Tanzania, Mozambique, South Africa, Kenya and Uganda (outsourced). Other countries have chosen to include PPPs as part of overall program area strategies, and program staff work objectives, or to develop implementation mechanisms primarily dedicated to the development of PPPs to support the PEPFAR program.

3.6.3 LINKAGES AND WRAPAROUNDS: PUBLIC-PRIVATE PARTNERSHIPS

Since PPPs can and should be integrated across program areas, the potential linkages to other development activities are varied. However, many PPPs lend themselves to incorporating wraparound activities, and the pursuit of this with the relevant agencies, other donors or private sector partners is strongly encouraged.

TECHNICAL AREA 3.7: WORKPLACE PROGRAMS

3.7.1 BACKGROUND

The rapid spread of HIV/AIDS is having an increasingly adverse impact on the operations of many companies and employee households. In countries and communities where HIV/AIDS is most concentrated, companies have experienced increased production costs, reduced profits and greater difficulty delivering products and services. Employees experience long periods of absenteeism, extensive out-of-pocket expenses for medical care and the trauma of caring for family and friends who are ill with HIV/AIDS.

Workplace programs address this challenge. A workplace program is a program that works with management and workers to ensure workers' access to one or more of the following services: training programs, condoms, and voluntary testing and counseling or works with management and workers to implement a workplace policy which incorporates the following four components No mandatory HIV testing; No denial of employment, No job termination if fit to work, and Medical Confidentiality.

A workplace program also works with a workforce to improve its capacity in providing health care such as working with hospitals, or to include in educational curriculum of schools.

Workplace programs should be a vital component of prevention programming. Done well, the results of workplace programs are truly impressive. In South Africa, 75% of DaimlerChrysler employees accessed VCT services during the first two years of their HIV/AIDS program. The services were also available to the surrounding community and family members. Yet even among companies that recognize the impact of HIV/AIDS, prevention services are often not offered to employees. In a survey of 1,653 sub-Saharan companies that have a formal HIV/AIDS policy, only 43 percent offered access to VCT services.

3.7.2 TECHNICAL CONSIDERATIONS: WORKPLACE PROGRAMS

These technical considerations are intended to be a basic resource for the country teams as they consider whether and how to implement and/or scale-up PPPs as appropriate to their country contexts.

A. Definition of Workplace Programs

As mentioned above, a workplace program is a program that works with management and workers to ensure workers' access to one or more of the following services: training programs, condoms, and voluntary testing and counseling or works with management and workers to implement a workplace policy which incorporates the following four components No mandatory HIV testing; No denial of employment, No job termination if fit to work, and Medical Confidentiality.

A workplace program also works with a workforce to improve its capacity in providing health care such as working with hospitals, or to include in educational curriculum of schools.

The complexity of situations created by HIV/AIDS requires flexible responses. Addressing HIV/AIDS is a task for all sectors of society. A workplace HIV/AIDS program will not operate in isolation from government, local communities, other companies or a variety of groups in civic

society. Rather, it will be one of many contributors to an overall national effort to control the disease and its impact. A comprehensive HIV/AIDS workplace program includes the following elements:

- **HIV/AIDS Policy Development:** A written policy that covers HIV that compliments local or relevant laws and describes the parameters of legal and other workplace issues such as reasonable accommodation, discrimination, confidentiality, hiring and other employment practices, universal precautions, co-worker anxiety, insurance and other healthcare issues, and implementation of workplace education efforts. The policy should be developed with representation from all levels of employee groups in the working environment. The policy should be disseminated to all employees and updated on a regular basis. Information on HIV/AIDS, ways of preventing transmission, places to seek information and services and ongoing company and union support for responsible sexual behavior;
- **Training for managers, supervisors and labor leaders:** Training includes imparting knowledge of the organization's policy and strengthening the ability of leaders and managers to exercise the skills necessary to address the full scope of HIV issues in the workplace;
- **HIV/AIDS prevention and care initiatives:** These should be available to employees and dependents within the workplace or readily accessible outside the workplace. These initiatives are likely to include: up-to-date information on HIV/AIDS, STIs and TBHIV/AIDS transmission and prevention; male and female condom; STI diagnosis and treatment; testing and counseling for HIV on a voluntary and confidential basis, with means to provide support for employees and/or family members who are HIV positive; treatment for HIV and associated diseases; care support (including flexibility in work schedules and assignments); access to all appropriate drugs; legal and care giving support for dependents of infected employees; annually updated information on employee benefits, and mitigation services designed to provide such follow-up activities as counseling, community support and home-based care;
- **HIV/AIDS education:** Education for employees'/workers' families through the employee/worker or directly from the employer to the family;
- **Pro-active commitment to avoid stigma and discrimination and maintain confidentiality:** Special training for managers and peer educators on these issues is part of this commitment;
- **Employee involvement:** Employees should be involved at all levels and in all aspects of workplace responses to the epidemic, including: involvement in designing or revamping of workplace policies and programs; selection of peers within the workforce who can provide information, counseling, and/or prevention supplies to colleagues; peer educators among middle and senior management.
 - HIV-related community service, volunteerism and philanthropy to encourage employees, managers, and labor leaders to engage in individual support of HIV/AIDS initiatives in their communities and to encourage corporate and labor union support of HIV/AIDS initiatives. Involvement in and support for community HIV/AIDS efforts is a collaborative undertaking. No single company, government authority or civic group can cover all aspects of HIV/AIDS in a community. As part of their social responsibilities, companies contribute to and support community prevention and care efforts. Contributions may be financial or in-kind. They can include paid time off for training workplace peer educators or inducements to conduct similar work in neighboring communities. A company's involvement in community HIV/AIDS prevention has been found to increase its profile and public respect.
 - Managers can work with their counterparts in other companies by raising the issue of HIV/AIDS prevention and care during formal and informal meetings, encouraging other companies to adopt or expand HIV/AIDS prevention programs, and working

through business associations to advocate and negotiate with government and international organizations to expand HIV/AIDS prevention and care efforts.

- Workers also have a central role to play in community prevention. Information received in the workplace can be brought back to communities and workers can encourage their employers to provide information to communities. Some of the most effective outreach programs have involved company employees, who have, as volunteers, promoted HIV/AIDS prevention in the communities where they live, worship and socialize. Union and other workers' representatives can assure that HIV/AIDS prevention and care are part of discussions and negotiations with companies; and
- **Monitoring and review:** The effectiveness of HIV/AIDS initiatives should be monitored and reviewed regularly, with a willingness to adapt program and policies accordingly and as the epidemic and employee needs evolve. Model monitoring and evaluation programs including worker survey are available upon request.

B. Workplace Determination

The workplace encompasses a vast range of organizations. The different nature of these workplaces affects the impact of HIV/AIDS, the responses mounted, and the way in which research on HIV/AIDS is conducted. There are four, sometimes overlapping, types of workplaces:

- **The formal sector:** This comprises larger companies and parastatals. Frequently, it is this type of workplace that is referred to when we talk about HIV/AIDS and the workplace. Our knowledge of the impact of HIV/AIDS and the response to HIV/AIDS is most advanced in these workplaces. Estimates of prevalence are being developed, company policies are often in place and programs – including the provision of anti-retro-viral drugs- are being implemented. Despite this, a range of problems remains. These include limited understanding of the long-term impact on companies, problems in getting policies implemented within the workplace environment, stigma, treatment and the contributory role that companies play in the epidemic, such as using migratory labor forces;
- **Small, medium and micro enterprises (SMMEs):** These smaller companies range from the formal to the informal and survival sectors of the economy. While this encompasses a wide range of workplace and working conditions, with regard to HIV/AIDS, knowledge of the diseases impact is less clear and company responses are less advanced. A clear challenge in this area is the difficulty of mounting responses and conducting research due to the small size of individual operations;
- **The public sector:** These workplaces range in size but as part of national, provincial or local government they face different challenges to those faced by profit-oriented organizations. It is clear that while these organizations are expected to deliver services to society – including services related to HIV/AIDS – there is relatively little understanding of the impact of the disease on these organizations and their response to HIV/AIDS has been limited; and
- **Service industries:** These industries range across the previous categories based on size and profit. They include health, domestic work, security and sex industries. While extremely heterogeneous, these industries can be grouped together for two reasons. First, they are frequently not thought about as workplaces because the service provided is often regarded as menial (domestic and security work), taboo (e.g. sex), or constructed as a 'calling' rather than a job (e.g. nursing). Second, there is a set of issues which, while not common to all these industries, often overlap. These include the high percentage of women workers, 'atypical' employment contracts, and low levels of 'social protection' (such as medical aid scheme and pension provision). We often know little about these workplaces generally, despite their

presence, and even less in regard to HIV/AIDS. Such workplaces often face additional occupational hazard regarding HIV/AIDS (health and sex) but, in general, responses to HIV/AIDS are limited.

Large companies may have staff and other resources to offer all these elements of a comprehensive HIV/AIDS prevention and care program. Medium-size and smaller companies are unlikely to have the resources to sustain a comprehensive program. In such cases, numerous sources of financial and technical assistance from government and non-governmental sources can be tapped. It is very unusual that a company will run an HIV/AIDS program entirely on its own. Rather, companies of all sizes usually collaborate with outside groups in the design and implementation of one or more of the components noted here.

C. Best Practices and Lessons Learned

Several examples of workplace programs stand out from the group because of their comprehensiveness and engagement of the private sector. One such model is USAID's Health Initiatives for the Private Sector (HIPS) project in Uganda, in which PEPFAR outsourced the building of workplace programs to a contractor. The HIPS project engages locally-owned businesses, achieving resource leverage and consistent results. Also, an ILO program targeting MARPS in China and PEPFAR/India's approach to workplace programs highlight best practices in designing workplace programs in a concentrated epidemic. In both cases, extensive studies were conducted beforehand to determine what industries and geographic areas were most at risk, and then those groups were targeted with low-cost prevention and stigma messaging.

Lessons that have been learned in the course of some workplace projects account for some of their biggest successes. These lessons included the following:

- To advocate and inform the development of national policies and/or legislation, it is essential to create an environment of trust and mutual respect through a national mechanism in which many voices can be heard;
- Ensuring that the voices of people living with HIV be heard was part of the initial project design;
- Worker Organizations need more capacity-building opportunities;
- The subject of AIDS makes people uncomfortable, and some aspects of HIV and AIDS are often overshadowed by obsession over the cause and transmission; and
- Successful projects wisely spend time building a foundation at startup.

3.7.3 COUNTRY CONTEXTUAL CONSIDERATIONS: WORKPLACE PROGRAMS

Workplace programs can be designed to address the root of the epidemic that exists in a particular country. For countries that have a generalized epidemic, a traditional program that reaches all employees in a work setting is effective. For countries that have a concentrated epidemic, workplace programs can be designed to reach specific target groups.

For example the Department of Labor (DOL) project in Guyana is targeting the most at risk populations in the public transportation sector (including mini-bus, taxi and speedboat operators) through institutional capacity building and stigma and discrimination reduction. The Project works with the United Minibus

Union, the Guyana Public Transportation Association and the Speed Boat Operators Association to deliver services to this population. The DOL project in China has produced ‘*Never abandon, never give up*’, a short Charlie Chaplin-style film aimed at reducing HIV stigma and promoting condom use among the country’s migrant workers.

3.7.4 LINKAGES AND WRAPAROUNDS: WORKPLACE PROGRAMS

Well designed workplace programs, by their nature, build linkages with constituency groups and services providers. Linkages need to be developed between the Government, business groups and labor groups for a program to be successful. Many employers do not have the resources or capacity to provide services, such as testing and counseling and treatment, so linkages need to be developed with services providers. The workplace becomes to catalyst for groups of people to get tested and, if positive, get treatment.

Workplace programs can be a mechanism for the delivery of wraparound activities. Workplaces can be the distribution point for mosquito nets. TB and malaria prevention messaging and activities can be built into HIV/AIDS workplace programs very easily. Larger companies with resources can help sponsor programs for orphans and vulnerable children in the community.

Workplace programs can also be a delivery point for other wraparound prevention activities. For example, Nile Breweries Ltd., a subsidiary of SABMiller, is performing male circumcision at their Kampala brewery’s health clinic.

TECHNICAL AREA 3.8: NUTRITION AND HIV/AIDS

Nutrition and HIV/AIDS - Nutrition support is a critical component of HIV/AIDS care and treatment. HIV and malnutrition interact in a vicious cycle. For many PLHIV, the infection causes or aggravates malnutrition through reduced food intake, increased energy needs, impaired nutrient absorption, and nutrient losses associated with frequent and persistent diarrhea. Malnutrition can hasten the progression of HIV, further weakening the immune system, increasing susceptibility to opportunistic infections and reducing the effectiveness of both ART and treatment of opportunistic infections. With ART, HIV/AIDS becomes a chronic disease, which requires chronic nutrition management and support, particularly with increased risks of arteriosclerosis, diabetes, anemia and osteoporosis associated with HIV and ART. Food insecurity and malnutrition remain highly prevalent in most countries where PEPFAR supports programs, particularly in Sub-Saharan Africa. Thus, nutrition and food security support is a critical component of a comprehensive HIV/AIDS programs to improve clinical outcomes for PLHIV and to mitigate the impact of the disease on HIV-affected families and OVC.

3.8.1 FOOD AND NUTRITION ACTIVITIES SUPPORTED BY PEPFAR

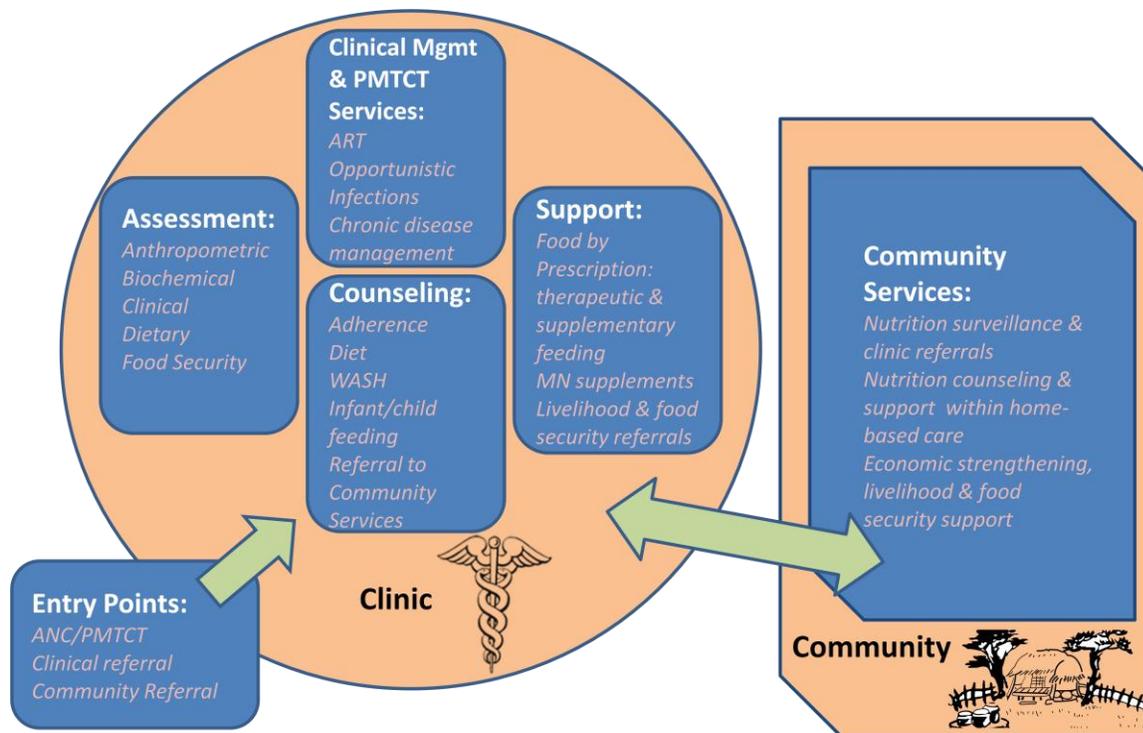
A. Program Priorities

The PEPFAR Food and Nutrition Technical Working Group (F&N TWG) has identified three areas of programmatic focus: (1) Nutrition Care, (2) PMTCT, Postnatal Care & Infant Feeding, and (3) Economic Strengthening, Livelihood and Food Security Support. The three focus areas highlight critical elements for country teams to consider as they develop a nutrition portfolio within their Country Operational Plan (COP).

I. Nutrition Care

Recognizing the critical role nutrition care plays in HIV treatment, care and support, PEPFAR country programs and their partners are integrating nutrition assessment, counseling and support (NACS) into routine HIV services and are strengthening the capacity of cadres of government health care providers to implement nutrition care. This approach has led to strong government ownership of nutrition strategies, programs and services within national HIV programs. Outcomes from these activities have been quite promising, including improved nutritional and clinical status among clients and stronger health systems as a result of the establishment of nutrition services, information systems, and referral networks.

The following schematic depicts NACS from a patient perspective, based on the Food by Prescription (FBP) Program, which was first established in Kenya and is now being scaled up as the national program in more than 400 HIV/AIDS Comprehensive Care Centers, as well as being adopted, adapted and implemented as standard of care in more than a dozen other countries. Patients enter into NACS care through multiple entry points, including community and clinic referrals. Comprehensive nutrition assessment informs prospective clinical management and counseling of patients, as well as determining appropriate support for the individual and family at the clinic and community levels.

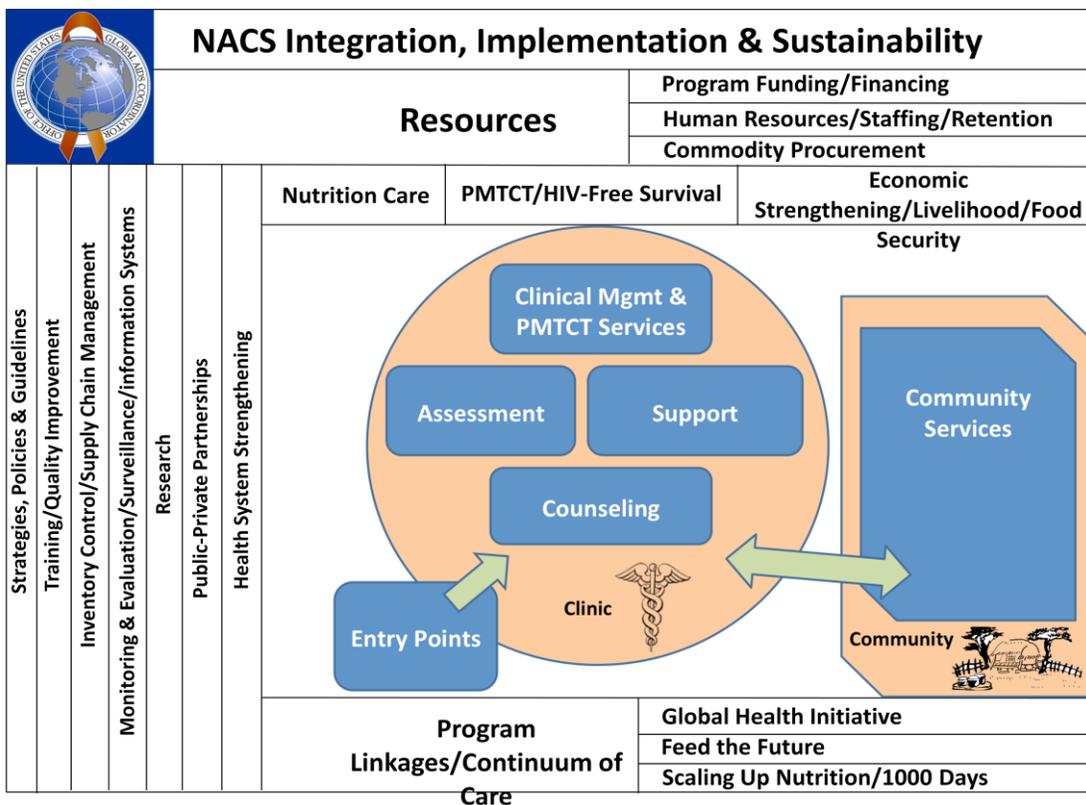


The following are primary components of NACS for individuals attending health clinics for HIV care and treatment:

- *Integration of NACS within clinical management and community support for PLHIV and families, as well as OVC.* Ensuring that nutrition assessment and counseling occurs consistently and effectively establishes a foundation on which all other nutrition and food security interventions are based. Nutrition assessment establishes eligibility for specialized food products and/or micronutrient supplements, but also informs and guides the specific nutrition and health counseling that is provided to all HIV/AIDS patients and OVC, as well as providing a basis for referring individuals and families to community services to address household food insecurity;
- *Prioritization of nutrition assessment and counseling within NACS.* While food support is often the most visible nutrition intervention and attracts the greatest attention, nutrition assessment and counseling are critically important components of care and support for PLHIV and OVC. PEPFAR programs should ensure that nutrition assessment and counseling are integrated within all HIV care and treatment services, particularly at the clinic level, as *standard of care*, even where therapeutic and supplementary feeding support is not (yet) provided;
- *Provision of therapeutic and supplementary feeding support for undernourished PLHIV and OVC.* Therapeutic and supplementary feeding through Food by Prescription (FBP) is a critical component of HIV care and support and is most effectively utilized when provision is based on established eligibility criteria. Specialized food products, including therapeutic foods, e.g. Plumpy’Nut or other ready-to-use therapeutic foods (RUTFs), and supplementary foods, e.g. corn-soy blend or other fortified blended flours (FBFs), are prescribed for a limited duration on the basis of clear anthropometric entry and exit eligibility criteria or nutrition vulnerability. RUTF and FBF are provided, typically monthly, as a take-home ration for the individual patients, not to be shared within the household. Recipients are

- counseled that they need to consume the food as “medicine”, in addition to their other “meds”, e.g. ARVs and cotrimoxazole;
- *Prioritization of NACS feeding support within and across sites based on relative vulnerability:*
 - Complementary/replacement food for all HIV-exposed infants from 6 months up to 2 years of age, irrespective of anthropometric status;
 - Supplementary food to women in PMTCT program who are underweight or fail to gain adequate weight in pregnancy or underweight during lactation;
 - Therapeutic/supplementary food to OVC with evidence of growth faltering (wt/ht <-2 z-score); and
 - Therapeutic/supplementary food to adult HIV/AIDS patients w/ BMI <18.5;
 - *Provision of multi-micronutrient supplements when indicated.* Multiple micronutrient deficiencies are common in PLHIV, especially among those who are food-insecure. When the diet is likely to be inadequate to meet vitamin and mineral requirements, provision of multi-micronutrient supplements is advised. In addition, OVC, especially under-5s, should be prioritized for daily multi-micronutrient supplements, routine vitamin A supplementation, and zinc supplementation as an adjunct to the management of severe acute diarrhea;
 - *Provision of water, sanitation, and hygiene (WASH) counseling and support within NACS.* Counseling on safe food preparation and storage, point-of-use water purification treatment and other hygiene and sanitation practices are an integral component of NACS within care and treatment services;
 - *Establishing linkages and two-way referral support between clinical centers and community services.* Chronically ill individuals with evidence of wasting identified through community nutrition surveillance should be immediately referred to clinical services for comprehensive clinical assessment, care and treatment, including NACS. Conversely, bi-directional referral systems are needed to link patients and families with community-level economic strengthening, livelihood and food security assistance, as well as community health services (e.g. HBC and CHWs); and
 - *Provision of HAART, cotrimoxazole and treatment for opportunistic infections and comorbidities per clinical guidelines.* The benefits of improved food and nutrient intake can be greatly muted by uncontrolled health conditions that compromise appetite, absorption, metabolism and nutrient losses. A majority of clinically malnourished PLHIV (BMI <18.5) who initiate HAART will gain weight, even without feeding support.

The following schematic indicates the program activities necessary to establish NACS within HIV/AIDS care and treatment program at clinic and community levels, as well as the need to link with other initiatives that are addressing the capacity of health systems to provide nutrition support to the general population, particularly the Global Health Initiative, Feed the Future and Scaling-Up Nutrition (SUN)/1000 Days, which focuses on pregnancy through the first two years of life. PEPFAR country programs developing a strategy for integrating NACS within care and treatment services may use this framework to categorize and define key activities for funding and implementation.



Country teams may also find the following NACS milestones useful in prioritizing activities and measuring implementation progress.

INITIAL MILESTONES

- National NACS coordinating group established
- NACS in national HIV/AIDS coordinating agency established
- National HIV & nutrition strategy developed
- Prevalence of wasting among PLHIV known
- National HIV & nutrition guidelines produced
- National training materials produced
- Service provider materials produced
- NACS program initiated at ≥15 sites

ADVANCED MILESTONES

- Service providers trained at ≥75% of NACS sites
- Nutrition counseling/assessment at ≥75% of NACS sites
- Nutrition included in HIV/AIDS M&E
- QI system in place for NACS
- Nutrition integrated into community HIV/AIDS services
- NACS program scaled up to majority of HIV/AIDS clinic sites
- Evaluation of NACS services conducted

II. PMTCT and HIV-Free Survival

HIV-free survival is the ultimate goal of PMTCT. As much as 50% of MTCT occurs postnatally through breastfeeding, but infants who are not breastfed through the first year of life are at a substantially elevated risk of mortality from pneumonia, diarrhea and other infections. New WHO guidelines on PMTCT include recommendations for ARV interventions that can drastically reduce the risk of MTCT prenatally *and* postnatally, especially among mothers who receive HAART for their own health (CD4 < 350) and are responsible for >70% of total MTCT (>80% of postnatal MTCT)¹⁸⁸.

The new WHO infant feeding guidelines also recommend provision of ARV prophylaxis to mothers not currently receiving HAART or to their infants for the duration of breastfeeding. In countries where the national government has established breastfeeding as the primary option for PMTCT mothers per WHO guidelines, HIV-infected mothers should be encouraged to breastfeed for a minimum of 12 months and beyond until a safe and adequate replacement diet is available. Programmatic emphasis should be placed on pre- and postnatal counseling focused on ART adherence, infant feeding practices, nutrition and health. Special attention should be given to link counseling to early infant diagnosis to dissuade premature weaning (<12 mo) if the infant tests HIV-negative, while counseling mothers to continue breastfeeding if the infant is HIV positive. Regular assessment, counseling and support should be provided to encourage exclusive breastfeeding for the first six months of life, appropriate complementary feeding beyond six months of age and to provide pre/post-weaning support beyond 12 months of breastfeeding.

Establishing a PMTCT *continuum of care*, including PMTCT registries and at least quarterly clinical visits, should facilitate tracking of mother-infant pairs, a focus on improving maternal nutritional status and provision of basic child survival interventions through the first 24 months of life. Programmatically, this translates into a number of priorities as listed below and shown in the following table:

- Emphasis on HAART for all PMTCT women who are eligible for their own health (CD4 <350);
- Provision of ARV prophylaxis to mothers or infants for the duration of breastfeeding if the mother is not eligible for HAART (CD4 >350);
- Provision of antenatal and postnatal counseling to support optimum infant feeding, nutrition and health, particularly at key points when infant feeding practices may be changed, such as beyond 6 months when complementary foods are introduced and at weaning;
- Promotion of exclusive breastfeeding for the first six months of life among mothers who breastfeed while assuring adherence to maternal HAART or ART maternal/infant prophylaxis;
- Promotion of appropriate complementary foods from six months of age until weaning (note: complementary foods in addition to breast milk are absolutely necessary to meet infant nutrient requirements beyond 6 months of age even though this can be considered “mixed” feeding) and assuring a safe and adequate replacement diet following weaning;
- Promotion of breastfeeding for at least the first 12 months of life and deferring weaning until a safe and adequate replacement diet can be assured;
- Provision of special counseling on infant feeding in conjunction with early infant diagnosis so that HIV-uninfected and infected infants are not prematurely weaned (i.e. less than 12 months of age);

¹⁸⁸ World Health Organization. *Guidelines on HIV and infant feeding: Principles and recommendations for infant feeding in the context of HIV and a summary of evidence*. Geneva: World Health Organization; 2010.

- Promotion of improved pre- and postpartum maternal nutritional and health status, including regular NACS assessment and supplementary feeding support if failure to gain adequate weight in pregnancy or underweight by Mid-Upper Arm Circumference (MUAC) or Body Mass Index (BMI);
- Provision of the basic preventive care package for infant and young child survival, including routine immunizations, growth monitoring, micronutrient supplementation, insecticide-treated bed nets, and regular clinical referral, assessment and treatment for infections (Guidance for United States Government In-Country Staff and Implementing Partners for a Preventive Care Package for Children Aged 0-14 Years Old Born to HIV-Infected Mothers, 2006, www.pepfar.net); and
- Provision of antenatal and postnatal counseling and support for family planning, including LAM (lactational amenorrhea method) in conjunction with exclusive breastfeeding during the first 6 months of infancy and transition to a modern method of contraception.

	ANC Visits	Delivery/ Birth	Early Postnatal	Postnatal EPI Visits 6, 10, & 14 weeks	6 months	9 months	12 months	15, 18, 21 & 24 months
Women:	<ul style="list-style-type: none"> •PITC •CD4 & clinical mgmt •ART Tx or prophylaxis •Maternal NACS •Infant feeding counseling 	<ul style="list-style-type: none"> •CD4 & clinical mgmt •ART Tx or prophylaxis •Maternal NACS •Infant feeding counseling—EBF/ERF 	<ul style="list-style-type: none"> •CD4 & clinical mgmt •ART Tx or prophylaxis •Maternal NACS •Infant feeding counseling—EBF/ERF 	<ul style="list-style-type: none"> •CD4 & clinical mgmt •ART Tx or prophylaxis •Maternal NACS •Infant feeding counseling—EBF/ERF •FP 	<ul style="list-style-type: none"> •CD4 & clinical mgmt •ART Tx or prophylaxis •Maternal NACS •Infant feeding counseling—CF •FP 	<ul style="list-style-type: none"> •CD4 & clinical mgmt •ART Tx or prophylaxis •Maternal NACS •Infant feeding counseling—CF •FP 	<ul style="list-style-type: none"> •CD4 & clinical mgmt •ART Tx or prophylaxis •Maternal NACS •Infant feeding counseling—weaning (AFASS) •FP 	<ul style="list-style-type: none"> •CD4 & clinical mgmt •ART Tx or prophylaxis •Maternal NACS •Infant feeding counseling—weaning (AFASS) •FP
Infants: EBF= exclusive breast feeding ERF= exclusive replac- ement feeding CF= comple- mentary feeding		<ul style="list-style-type: none"> •Initiation of EBF/ERF •ART prophylaxis 	<ul style="list-style-type: none"> •EBF/ERF •ART prophylaxis •Infant NACS/ Growth monitoring 	<ul style="list-style-type: none"> •EBF/ERF •ART prophylaxis •Infant NACS/ Growth monitoring •EID •CTX •DPT 1, 2, 3 	<ul style="list-style-type: none"> •CF •ART prophylaxis •Infant NACS/ Growth monitoring 	<ul style="list-style-type: none"> •CF •ART prophylaxis •Infant NACS/ Growth monitoring •EPI/measles 	<ul style="list-style-type: none"> •CF/weaning •ART prophylaxis •Infant NACS/ Growth monitoring 	<ul style="list-style-type: none"> •CF/weaning •ART prophylaxis •Infant NACS/ Growth monitoring •Post-weaning HIV testing

III. Livelihoods and Food Security

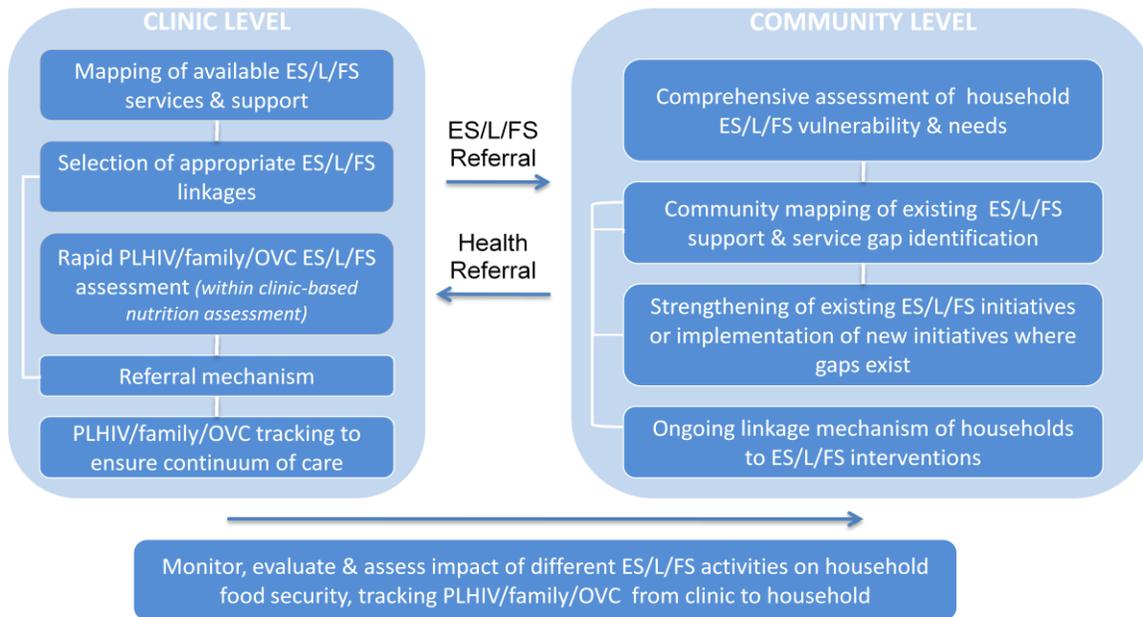
Through provision of NACS and other services, care and treatment facilities assist in meeting the health needs of PLHIV, their families and OVC. However, these services are not able to address underlying food and economic insecurity that can compromise treatment success and long-term survival of PLHIV. Neither are they able to address needs of OVC and their caregivers. Thus, NACS clients need to be linked with services that provide economic strengthening, livelihood and food security (ES/L/FS) support.

Priority interventions for ES/L/FS assistance include:

- Assessment of promising ES/L/FS practices and gaps with regard to effective targeting, cost-effectiveness, potential for replication and scale-up, and sustainability;

- Establishment of mechanisms to connect and track individuals in clinical care and treatment with ES/L/FS services in their communities;
- Development of tools to assess client/household economic and food insecurity as a basis for referral to appropriate ES/L/FS services;
- Design of appropriate strategies and programs to strengthen the capacity of communities to provide ES/L/FS support to PLHIV and their families, including OVC; and
- Creation/fostering of synergistic linkages among PEPFAR NACS programs, Feed the Future, Title II and other ES/L/FS programs.

The following schematic indicates EL/L/FS activities that occur at the clinic and community level and how they are linked bi-directionally to improve food security and meet basic needs of NACS patients and their families:



PEPFAR does not support provision of basic food commodities (“food baskets”) to address household food insecurity, with the exception of limited food assistance to OVC and caretakers. Where possible, food-insecure households and even OVC and caretakers should be referred to Title II, the World Food Program or other programs providing direct household food assistance.

3.8.2 POLICIES, SERVICE DELIVERY, AND COMMODITIES

NACS and other food and nutrition activities that can be supported with PEPFAR resources fall into three broad categories: *Policies, Service Delivery, and Commodities*:

A. Policies

- Development and/or adaptation of food and nutrition policies and guidelines – providing a framework for integrating food and nutrition activities within the care and support of PLHIV and their families, including OVC. This includes policies and guidelines that foster linkages with other support programs that address ES/L/FS assistance needs in the targeted population.

B. Service Delivery

- Curricula development, training and quality improvement– for clinic health care workers, home-based care providers, community health workers, lay/peer counselors and others to enhance their ability to integrate and carry out NACS activities; pre- and in-service training programs; and development of appropriate job aids and Quality Improvement systems to integrate nutrition surveillance and support within care and treatment services; and
- Nutrition assessment and counseling – anthropometric, clinical, dietary, food security and WASH (water/hygiene/sanitation) assessment to support care and treatment of PLHIV and their families, as well as OVC; nutrition counseling to maintain or improve nutritional status, prevent and manage food- and water-borne illnesses, manage dietary complications related to HIV infection and ART, and promote safe infant and young child feeding practices; nutrition assessment, counseling and referral linked to community nutrition surveillance and home-based care support.

C. Commodities

- Micronutrient supplements – provision of supplements according to WHO guidance, e.g. vitamin A, zinc and multi-micronutrients for OVC, and multi-micronutrient supplements where individual dietary assessment determines a likelihood of inadequate intake to meet vitamin and mineral requirements of PLHIV within NACS programs;
- Specialized foods – competitive procurement of processed foods from local, regional or international companies that meet internationally recognized standards for safety and quality:
 - Therapeutic and supplementary foods – NACS support for nutrition rehabilitation of severely and mild-to-moderately malnourished PLHIV and OVC. Eligibility criteria and protocols for therapeutic and supplementary feeding should be based on WHO and national guidelines, as well as OGAC/PEPFAR policy guidance.
 - Supplemental, complementary and replacement feeding – NACS provision of specialized foods for nutritionally vulnerable women in PMTCT programs to improve birth outcomes and to support lactation, as well as complementary feeding (with breastfeeding beyond 6 mo of age) and replacement feeding (post-weaning) support. Infant formula may be provided on an emergency basis for individual infants where breastfeeding is not an option (e.g. maternal death or incapacitation); and
- Equipment – procurement of adult and pediatric weighing scales, stadiometers, MUAC tapes, and other equipment required to conduct effective nutrition assessment.

3.8.3 KEY ISSUES: FOOD AND NUTRITION

A. Prioritizing Resources for OVC Interventions

PEPFAR resources can be used to support food for HIV-affected OVC irrespective of nutritional status. However, given limited funding, PEPFAR country teams should be strategic in prioritizing among objectives and essential nutrition support for OVC, recognizing that the most nutritionally vulnerable OVC are under-fives, especially under-twos. *PEPFAR country teams should also leverage NACS program support to seek other donor sources of funding, particularly for food and other commodities.* OVC programs that utilize a food component can increase their impact on children's nutritional status by including nutrition assessment and counseling, as well as by providing nutritionally appropriate food.

B. Nutrition Assessment and Counseling

While food support is often the most visible nutrition intervention and attracts the greatest attention, nutrition assessment and counseling are critically important components of care and support for PLHIV and OVC. PEPFAR programs should ensure that nutrition assessment and counseling are integrated within all HIV care and treatment services, particularly at the clinic level, as *standard of care*. In many settings, the equipment, materials, and human resource capacity needed for nutrition assessment and counseling are missing or weak. While training is a key component of capacity building, it should be linked with *quality improvement* to ensure the translation of training within clinical services, and to a *human resource plan* that promotes retention of trained staff. Nutrition assessment and counseling should be extended to all care and treatment sites as rapidly as possible, even where the procurement and distribution of food, i.e. Food by Prescription, is limited by inadequate funding and supply chain systems.

C. Coordination

An interagency approach, within the USG and other multi- and bi-lateral donors, to joint programming at the country level is common practice in a number of PEPFAR countries to strengthen food and nutrition support within HIV/AIDS programs. This joint effort encourages USG and international agencies to draw on their respective comparative advantages, mobilize more resources, and improve coordination to address the immediate and longer-term food and nutrition needs of PLHIV and their families, including OVC. In addition, WHO and international partners have developed guidelines for the inclusion of food and nutrition support of PLHIV within GFATM proposals, which should be encouraged and supported by PEPFAR country teams. With limited PEPFAR resources devoted to ES/L/FS strengthening, it is critical to identify models of support and coordination with GFATM, Feed the Future, Title II, WFP, World Bank, and other development donors to expand support for nutrition and food security programs. Most important, this interagency coordination needs to fully engage with national governments and programs at the country level.

D. Quality Improvement

Clinic-based NACS support is most effective and sustainable when fully integrated into existing HIV/AIDS care and treatment services, rather than being a parallel system. However, integrating NACS services into HIV/AIDS and health services and scaling-up those services have proven difficult. One of the greatest challenges is that in a busy clinic setting, it can be difficult for staff to find time to provide nutrition services. Additionally, health care workers and counselors often have not received sufficient training in nutrition care. In other cases, health care workers are sufficiently trained, but cannot execute that training because of organizational/system constraints. QI approaches have proven to be critical to achieving efficiencies that allow NACS to be successfully integrated within health services. Application of QI within clinics – defining individual roles and responsibilities, establishing performance standards, creating job aids and information systems, task shifting and improved time allocation, supervision systems and patient management – are key to health systems having the capacity to provide comprehensive services, including NACS, to patients in care and treatment.

E. Links between Clinical and Community Services

Community services are also important entry points for NACS interventions. Food and nutrition services provided through community programs include assessment and ES/L/FS support for food-insecure PLHIV, families and OVC; nutrition counseling in home-based care settings and PLHIV support groups; and nutrition surveillance, outreach and follow-up by community health workers. To optimize these services, PEPFAR programs should support reciprocal referral systems between

communities and clinic services. The community aspect should include trained volunteers and health workers who can conduct basic nutrition screening of children and adults, e.g. MUAC, and refer malnourished individuals to clinic health and nutrition services, including HIV counseling and testing for “chronically ill” and wasted individuals who do not know their HIV status or who previously tested positive, but were not yet eligible for ART. In addition, NACS patients who are initially determined at the clinic level to need household ES/L/FS support should be further assessed and referred to community support that is individually suited to themselves and their families, e.g. food production, (re)employment, income-generation activities, micro-credit and vocational training.

F. Monitoring and Evaluation (M&E)

M&E of NACS interventions is important at service delivery, program and national levels in order to assess cost-effectiveness and impact of programs, strengthen approaches, inform service provision and program management, and inform reporting, advocacy and resource allocation. M&E of NACS activities should be integrated within the national HIV/AIDS M&E and health information systems. Nutrition indicators are included in both the Essential Reported and Recommended sections of the PEPFAR Next Generation Indicators. Additionally, M&E guidance for nutrition and HIV programs will be available through the F&N TWG in the fall of 2011.

G. Costing

There is an increasing need to equip and assist policy leaders and stakeholders with timely and accurate data for evidence-based decision-making for NACS services. Many programs are seeking costing and impact data for evidence-based decision making to support their role in national-level policy and program planning dialogues for nutrition support within HIV care and support services. For further information about resources available to conduct costing assessment for NACS programs, please contact the F&N TWG.

H. Food Procurement

Unlike Title II, PEPFAR is authorized to procure food locally or regionally (i.e. non-U.S. sources). However, there is a need to assure that these foods comply with specifications for their formulation and nutrient composition, packaging, and international standards for safety and quality. Systems are necessary for forecasting need, conducting competitive procurements, and then efficiently transporting, storing, and distributing food products on site. Other agencies, particularly UNICEF and WFP, have established quality assurance and distribution systems for processed foods, particularly RUTF and fortified blended flours, which offer a foundation and precedent for PEPFAR programs. Various models and country examples exist that PEPFAR teams can adopt, including: 1) contracting the Partnership for Supply Chain Management Systems Project (PfSCMS) to competitively procure food products; 2) supporting or partnering with UNICEF or WFP to procure and distribute food products; or 3) contracting directly with food manufacturing companies or having development partners implement the program under a sub-contract with a food manufacturing company. PEPFAR country teams should determine which option is most appropriate in their context. In addition, a number of countries are initiating Public-Private Partnerships to assist food processing companies to strengthen capacity in product development and meeting food quality and safety standards so they can compete for PEPFAR food procurements, as well as improve the safety and quality of commercially marketed foods.

I. PEPFAR and Feed the Future (FTF) Integration

FTF, GHI and PEPFAR all prioritize the first 1,000 days of life (pregnancy through 24 months postpartum) for mothers and infants and the essential synergy between nutrition with health care for all adults and children. Thus, clinic- and community-based programs should be strategically linked and complementary – FTF working primarily at the community level, PEPFAR strengthening the capacity of clinics to provide NACS services, while connecting with community support. These programs can be mutually strengthened through joint strategy and program development to maximize synergies and leverage resources. Opportunities abound to connect vulnerable individuals and families, including OVC, identified through NACS programs to household ES/L/FS activities, including agriculture and income-generating activities supported by FTF. For the treatment of acute malnutrition, FTF and PEPFAR programs are harmonizing approaches based on national protocols, e.g. Community-based Management of Acute Malnutrition (CMAM), including production, procurement, distribution, and management of RUTF. Finally, PEPFAR and FTF are working in concert with international agencies and stakeholders to establish consensus around indicators and M&E systems that will allow tracking, management and evaluation of joint and complementary activities.

3.9.1 LINKING WITH FOOD AND NUTRITION, SAFE WATER, EDUCATION AND OTHER SERVICES THAT SUPPORT HIV PREVENTION, TREATMENT, AND CARE

PEPFAR reauthorization and the priorities of the Obama Administration place HIV/AIDS interventions squarely within the context of the broader development agenda. Directly addressing and strengthening these linkages where appropriate may increase benefits across a number of public health and broader development objectives depending on the country context. Wraparound programming, as defined in previous COP guidance, continues as a primary approach and co-locating program interventions within facilities or target populations provides important opportunities for synergies. A wraparound activity wraps or links together PEPFAR programs with those from other sectors to provide comprehensive program support and improve the quality of life to HIV/AIDS-affected and –infected individuals and/or communities. Wraparounds leverage resources, both human and financial, from entities with different funding sources in order to complement PEPFAR goals and maximize the effectiveness of programs. Wraparound activities may include other programs funded by the USG (e.g., USAID Development Assistance), the Global Fund, the UN (World Food Program, UNICEF, etc.), the private sector, or other partners. In general, wraparound activities are supported with a mix of funds, primarily from sources other than PEPFAR. However, wraparound activities that directly serve PEPFAR priority populations by supporting the prevention, treatment, or care of HIV/AIDS and are in keeping with other PEPFAR guidance may be supported with PEPFAR funds. In many cases the other sources of funding are used to provide the platform and PEPFAR funds are used to support those activities with our priority populations. In other cases, PEPFAR provides the platform (e.g. home based care infrastructure) for wraparounds, such as delivery of bed nets through PMI, immunizations, or medications for neglected tropical diseases. As with all PEPFAR programming, the benefits and results potential for investments in wrap-around programming must be weighed against other priorities by the PEPFAR country team.

3.9.2 ECONOMIC STRENGTHENING

A. Why Economic Opportunity is Important to HIV/AIDS Programming:

The importance of linking HIV/AIDS affected population to economic opportunity cannot be overstated. It is well-documented that HIV/AIDS is diminishing the productivity of the workforce in various countries, which in turn not only increases dependency ratios and impedes economic growth on the macroeconomic level, but also reduces the resources available to the families of those key income-earners on a microeconomic level. Many households are currently struggling to spread shrinking amounts of income over growing expenses. These expenses are growing due to increased health care costs, and often also due to the presence of additional dependents (OVC). Households need access to improved ways to build and protect their assets so that they may sustainably manage their needs.

Highly vulnerable households present unique challenges in the context of economic programming. These households tend to be even more isolated from the mainstream economy, have far fewer assets, and suffer from more disadvantaged (or exploitative) relationships with the private sector. The need for asset-building is comparatively greater, yet the resources to support it are very limited. Their capacity is less developed to make informed choices about how to engage with mainstream markets and allocate their scarce resources. PLWHA often view investment decisions and perceive risk in different ways, and in much shorter time horizons, than others.

This is particularly true for women and increasing women's access to income and productive resources is a key strategy in PEPFAR Gender programming. PEPFAR recognizes that the lack of access to economic resources increases women's and girls' vulnerabilities to HIV/AIDS.

Therefore, it can be an important strategy for PEPFAR country programs to seek ways to strengthen economic activities as well as seek to support the creation of new opportunities for poor households. It is important to note, however, that there is a strong competition for resources, even in relatively well-funded PEPFAR programs, and country teams need to make difficult choices about programming. PEPFAR does not have a comparative advantage in designing and managing economic strengthening programs; however, in instances where such platforms may exist with other funding, PEPFAR resources may be used to enable HIV/AIDS target populations including people in care and treatment programs and OVC and their caretakers, to these resources.

B. Key Definitions

Countries should estimate the **total** amount of funding from their country budgets, not including central funds, attributable to economic strengthening activities, including:

- **Economic Strengthening:** The portfolio of strategies and interventions that supply, protect, and/or grow physical, natural, financial, human and social assets. Generally refers to programs targeting children, youth, and their caregivers. These activities can include a variety of microfinance, vocational training and/or income generation;
- **Microfinance:** The range of financial products and services tailored to meet the needs and demands of low-income or otherwise vulnerable populations. This includes group and individual lending, savings, insurance, and other financial products. Microfinance is distinguished from mainstream finance by its outreach to isolated and poor populations and its efforts to make financial services accessible and approachable to them in terms of product design and delivery systems;

- **Microenterprise:** A very small-scale, informally organized business activity undertaken by poor people. Generally refers to enterprises with 10 or fewer workers, including the microentrepreneur and any unpaid family workers; many income-generating activities fall into this category;
- **Microcredit:** A form of lending which involves very small sums of capital targeted towards microentrepreneurs and poor households. Microcredit can take the form of individual or group loans, and have varying terms, interest rates and degrees of formality. Microcredit is a *type* of microfinance;
- **Livelihoods:** A livelihood comprises the capabilities, assets (including both material and social resources) and activities required for a means of living. The sustainable livelihoods framework, developed by DFID (2001), may be a useful way to analyze whether a household is able to manage shocks and maintain or enhance its capabilities and assets both now and in the future, while not undermining the natural resource base. It is an analytical tool that can be applied to future or existing programming. For more information please see the document on the PEPFAR Extranet; and
- **Market Development:** A fundamental approach to economic development that recognizes and takes advantage of the fact that products and services are most efficiently and sustainably delivered through commercial systems. Market development encompasses more targeted strategies such as microfinance and microenterprise development.

C. Illustrative Types of Programming

There is a wide array of options available to country programs in this area. To begin with, here is a list of the most common categories of interventions:

- Microenterprise;
- Microfinance (including savings, insurance, and credit);
- Vocational/skills training;
- Job creation;
- Asset transfers;
- Income generating activities;
- Programs that increase knowledge about inheritance and property rights (particularly for women and children); and
- Strengthening small scale agricultural production.

The selection of a particular type of intervention will vary based on the needs/strengths assessment, as well as any market analysis in the program area. Some interventions are better suited to certain populations or age groups than others. For example: A loan program for very young OVCs may be inadvisable, but a savings program designed to incentivize paying for secondary school could be appropriate. As another example, note that there is a wide variety of loan or credit programming options. Some partners are experienced in setting up rotating credit schemes in communities, while others operate as more formal microfinance institutions (MFIs). Proximity to a road or market may indicate greater potential for some microenterprise activities, while a market analysis might inform an OVC program about the skills that the private sector is seeking in new employees.

D. Suggestions for Programming

There is a wide array of options in the area, and thankfully there is also a wealth of best practice information to help inform country programs. Here are a few summary points:

- **Each partner's capacity should be considered before entering into a wholly new area.** For example, if a partner is an excellent community organizer and trainer, it could be very effective at setting up rotating savings & credit groups. However, it will likely not be successful unless it is receiving training and significant technical assistance from another organization already experienced in this area. Similarly, a program working on PMTCT could be interested in finding low-intensity labor options for pregnant women but may not currently have the ability to identify those market opportunities. Country programs should assess which of their partners truly have the capacity, staff, and organizational structure to take on a new program area and think creatively about ways to fill any gaps that are identified;
- **Partnerships can be effective ways to leverage expertise.** For example, if an organization has done a successful job of engaging communities and helping to identify OVCs, it may be interested in looking for ways to improve their economic situations. However, it may be more efficient, effective, and sustainable for that organization to partner with an existing Microfinance Institution (MFI) rather than create its own loan program. The MFI may already be operational in the area but need assistance creating appropriate services and products for OVCs or HIV/AIDS affected populations. Furthermore, when OVCs or HIV/AIDS affected populations access existing MFIs, this creates an opportunity to strengthen referral systems and increase access to services such as VCT, PMTCT, psycho-social support, etc. A situation such as this is mutually beneficial to each organization without causing either to stretch away from their core mission or expertise;
- **Country programs should be cautious about overextending existing programs.** PEPFAR programs have established many different types of community groups and resources over the last five years. They have established community and household resources on a variety of social and health issues and solved many challenges by engaging with indigenous groups. Caution should be exercised, however, when thinking about adding new responsibilities or activities to these groups. Evidence from the field indicates that the formation of small businesses, group loan structures and various employment programs should be based on economic needs, strengths, and market linkages. When groups that were formed for different needs (e.g. caring for OVCs) are morphed into other kinds of groups (rotating savings and credit associations), the results are often unsustainable. This does not mean that a partner organization could not found such a group in the same community; however, it does mean that we should not assume that group cohesion for one purpose will automatically translate into another;
- **Programs can be used to address the unique institutional challenges that are part of working in a region with high HIV prevalence.** HIV/AIDS-affected households and communities are grappling with the impact that HIV is having on their livelihoods. Programs that develop and change workplace policies that address employee rights and benefits related to HIV/AIDS; workplace training programs that address stigma and discrimination; and efforts to lift legal barriers to women's employment, control of resources, property ownership, and access to credit are ways to mitigate these difficulties;
- **Programs should have a robust monitoring and evaluation component.** As more country programs are including economic strengthening programs, it is important to collect and analyze data that measures progress toward achieving program objectives in order to inform program management strategies and policy. Measuring and documenting the impact of microfinance and other economic strengthening activities on HIV/AIDS infected and affected people and communities will allow implementers to continue to improve programming; and
- **Let the market drive the design of economic programs.** The most successful income generation, job training, etc. programs are those that begin by looking at the existing market. Country programs should seek to support those programs that demonstrate a market-led focus

or ones that have significant partnerships with private sector actors and/or value chain development experience. There have been ineffective examples of programs that trained youth on skills that no company needed, taught families how to grow products that were not worth much money, or overly subsidized all inputs and transportation.

PEPFAR country programs have the potential to make significant, positive contributions in improving the access of HIV/AIDS-affected populations to economic opportunities. There are many available resources to support the design of such programs. The key will be for country programs to encourage partnership and innovation, with a focus on market-led interventions.

3.9.3 EDUCATION

PEPFAR places a high priority on building partnerships that provide a better future for children, teachers and communities. For too many young people, education has been a casualty of the HIV/AIDS pandemic. Partnerships to ensure that children both infected and affected by HIV/AIDS have access to education (which is critical to their ability to lead normal, productive lives), and that schools are a safe resource center for these children, are central to the PEPFAR approach. Given this, and that evidence has demonstrated that a good basic education can be protective against AIDS, PEPFAR considers crosscutting activities within the education sector one of its highest priorities.

Partnerships with the education sector is an important PEPFAR strategy for reaching children to ensure that they have access to education and are encouraged to learn about HIV prevention. PEPFAR supports initiatives that utilize basic education's power for HIV prevention through its strong coordination in planning and implementation at the country level. Protecting young people from contracting HIV/AIDS is unquestionably one of the most important missions of PEPFAR. Schools can be important venues for teaching age-appropriate prevention as well as identify and support children who are orphaned or vulnerable as a result of AIDS. Therefore, it is critical that countries identify areas where linkages and partnerships between the education sector and HIV/AIDS are taking place. While there are multiple opportunities for potential partnership in any given country, other USG funded education programs are an important starting point. It is important that these areas are clearly identified, as they are vital to the achievement of PEPFAR's prevention, treatment, and care goals.

Countries are strongly encouraged to identify areas where there are crosscutting educational activities and to use clear language to describe how the country programs incorporate these activities into their various program areas as outlined in the key operating principles. Adhering to and building upon these principles significantly improves educational opportunities for HIV/AIDS-affected children and young adults, and it is vital that they are correctly identified. (Please note the Key Operating Principles and boxes outlining key sample activities and benchmarks listed below.) Countries should also estimate the total amount of funding from their country budgets, not including central funds, attributable to activities that include specific support to these programs within the education sector.

Country programs are encouraged to support activities that crosscut with the education sector to maximize opportunities for comprehensive programming through jointly funded programs and referrals. Below are some of the key operating principles, example activities, and potential benchmarks/indicators to help define activities that include crosscutting education elements.

A. Key Operating Principles

- PEPFAR and education programs should geographically co-locate, where possible. This should be seriously considered when expanding programs in order to sustain synergies and give the programs more sustainable results;
- Both PEPFAR and education implementing partners should have a full understanding of the activities supported in each sector to promote ideas for joint programming. For example, it may be helpful to invite education partners to PEPFAR partner meetings and vice versa. Because of education's focus on children and young people, OVC activities are often an ideal window and area of overlap;
- Integrated school-based programs should not only address the students, including orphans and vulnerable children, but also engage the support structures for young people, including teachers, parents, and community members, to help develop sustainable support for healthy decision-making;
- Programs should consider working with a variety of educational institutions, including primary, secondary, and tertiary institutions, teacher training institutions, community schools, alternative basic education centers, and job skills training in both urban and rural settings;
- Programs should take advantage of the technical expertise and best practices in both sectors;
- Programs should mainstream gender considerations into planning, monitoring, and evaluation to ensure quality and minimize unintended consequences for boys, girls, men, and women;
- Where possible, build on existing programs in one sector; and
- Consider placing an HIV/AIDS technical expert on the staff of education activities and vice versa.

Sample Activities:			
Peer education programs	Scholarship programs for AIDS-affected OVC	Development and dissemination of integrated curricula	Adoption of OVC identification, support and surveillance tools in educational settings
In-service and pre-service teacher trainings	Partnerships with Ministries of Education	Provision of counseling and related services at educational settings	Supporting equal access to education for boys and girls vulnerable to HIV
School-wide seminars and Anti-AIDS clubs	Workplace programs for teachers and administrators	Development of joint national policies on HIV/AIDS and education	Linking students and teachers to appropriate health services
Interventions to increase school safety and reduce sexual violence	Monitoring of school-based HIV education activities	HIV/AIDS education and VCT programs with teachers' unions	Policy, legal, and community-based initiatives to address sexually-predatory teachers

Possible Collaboration Benchmarks and Indicators:

Possible Collaboration Benchmarks and Indicators:	
Amount of resources from each sector for joint activities	Number of individuals over the age of 14 in educational settings reached through community outreach that promotes HIV/AIDS prevention through behavior change other than abstinence and/or being faithful
Number of annual student pregnancies at target schools	Number of individuals in educational settings trained to promote HIV/AIDS prevention through behavior change other than abstinence and/or being faithful
Number of OVC provided with educational scholarships and other support through school settings	Number of individuals in educational settings trained to promote HIV/AIDS prevention through abstinence and/or being faithful
Number of individuals in educational settings who received testing and counseling for HIV and received their test results	Number of individuals trained in HIV-related community mobilization for prevention, care, and/or treatment
Number of individuals in educational settings reached through community outreach that promotes HIV/AIDS prevention through abstinence and/or being faithful	Number of individuals in educational settings trained in techniques to address the special needs of vulnerable children (e.g. child caregivers)

TECHNICAL AREA 3.10: DISABILITY

Disability—broadly understood to be an evolving concept which encompasses the interaction between people with physical, sensory, mental, intellectual or other impairments and various barriers that may hinder their full and effective participation in society on an equal basis with others. Disability may be expressed and experienced differently in different socio-cultural contexts, and societal norms surrounding disability can greatly influence the status of disabled people in society, their roles, norms, behavior, and access to resources relative to the wider population. It is notable that disability intersects with all other population groups, as anyone can acquire a disability at any stage of their life. Disability-inclusive programming is relevant for both HIV positive people who may be considered disabled as a consequence of their HIV positive status, and for disabled people more broadly who may find themselves at increased risk of HIV infection because of societal discrimination on the basis of disability. Successful inclusion of disabled people and disability issues in PEPFAR programming has the potential to positively influence the success of all programs addressing the HIV/AIDS epidemic.

3.10.1 BACKGROUND

The overall goals of disability-inclusive PEPFAR programming are to:

- Facilitate achievement of program goals for prevention, treatment, and care;
- Strengthen program quality and sustainability;
- Guarantee disabled people's equitable access to programs;
- Prevent or ameliorate program outcomes that may unintentionally and differentially harm disabled people; and
- Increase disabled people's access to and control of strategic and protective health, social and economic assets which assist in preventing and mitigating the effects of HIV/AIDS.

Disabled people are as likely as their non-disabled peers to be sexually active, yet disability stereotyping, stigma, and inaccessibility of facilities, information, and programming can leave disabled people excluded from programs addressing the HIV/AIDS epidemic. Inaccessibility of HIV/AIDS related facilities and information, and lack of education combined with high rates of illiteracy, can leave disabled people unaware of even basic HIV prevention or treatment information. Commonly held, and incorrect, beliefs that disabled people are not sexually active, that they are less likely to be the victims of rape or other forms of sexual abuse (including gender based violence), or that they are less likely to use drugs or alcohol, may lead some health care providers to turn disabled people away even when they do seek testing, information or treatment. Similarly, the folk belief that disabled persons are not sexually active may also lead some people to target disabled people for rape and other coercive sex acts where it is thought that sex with virgins may cure their own HIV infection, which only increases their risk of sexual abuse and HIV infection. An additional risk is that ineffective and inaccessible communication methods, especially for blind, deaf, or intellectually disabled people, may leave disabled people without appropriate information regarding prevention or treatment, or even the ability to communicate with healthcare professionals and HIV/AIDS outreach workers in conditions that uphold their right to privacy and promote candor. This is compounded by the fact that decreased rates of marriage amongst disabled populations can increase numbers of sex partners, and the additional discrimination faced especially by women and girls with disabilities can decrease their confidence and ability to negotiate safer sex.

These risk factors intersect negatively with other societal barriers and diminish the enjoyment of human rights by disabled people. These human rights limitations in turn create additional risk factors for HIV infection. For example, disabled people frequently have poor access to education systems, healthcare systems, income-generating opportunities, and even transportation systems. Poor access to the justice system in many countries means that acts of violence, including sexual and gender-based violence, are rarely effectively investigated or prosecuted, leaving disabled victims vulnerable and at increased risk of further violence. Low recognition or respect for the legal capacity of disabled people can leave them unable to exercise the right to make decisions about their lives or have those decisions adequately supported and respected. Lack of supports to facilitate living independently in the community can leave disabled people trapped in institutional settings, where HIV prevention and treatment programming may be non-existent and rates of violence and abuse can be significantly higher.

Initial studies of disability and HIV/AIDS indicate that these and other risk factors leave disabled people at high risk of HIV infection, most likely at rates higher than those found in the wider population. At the same time, marginalization and stigma associated with disability can also discourage HIV positive people from self-identifying as having a disability. This makes many individuals newly disabled because of AIDS hesitate or refuse to reach out to the disability community to access disability-related services and supports that could improve their quality of life and increase their inclusion in the community. Marginalization and stigma associated with being HIV positive can similarly discourage disabled people from identifying with, or reaching out for support from the wider HIV/AIDS community.

Where possible it is envisioned that wider PEPFAR programming be inclusive of disabled people and disability issues, so that HIV/AIDS prevention and treatment outcomes can be improved for all people, including disabled people. However, this should not preclude disability-specific interventions where appropriate (for example, to reach disabled people who might not otherwise be included in HIV/AIDS prevention, treatment, care and support activities). When addressing issues of accessibility in program design and implementation, care should be taken to ensure physical and information access for people of different disabilities (e.g. ramps, documents in Braille, plain language or other alternative formats, captioning of videos, use of sign language interpreters, etc).

A. *PMTCT*

- Assessment and identification of barriers to disabled women's access to quality PMTCT services and targeted interventions to overcome the barriers;
- Effective linkages of disabled women to accessible family planning/reproductive health services, infant feeding and support, and organization of basic necessities, such as nutrition, accessible housing, and financial and legal assistance;
- Interventions to effectively engage disabled women's partners in PMTCT programs (e.g., couples counseling and testing, men's clubs, independent living centers ,etc.) at service delivery and community levels – to promote testing of men and to build their support for their female partners;
- Screening and counseling for disability and gender-based violence as part of PMTCT services, or referrals/linkages to these services, and outreach to service providers to ensure that the services are accessible to disabled people; and
- Screening and early detection of children who may experience developmental delays and associated disabilities because of in-utero exposure to the HIV virus, and referrals/linkages to appropriate support services.

B. *Sexual Prevention*

- Assessment and identification of societal norms, disability stigma and societal barriers that perpetuate multiple partnering, concurrent partnerships, cross-generational sex, transactional sex, disability and gender-based violence, alcohol misuse, and lack of effective condom use;

- Targeted and accessible interventions and messages that address and transform harmful attitudes towards disabled people that currently foster negative HIV behaviors and outcomes;
- Assessment of barriers (e.g. physical, informational, attitudinal or other) to disabled people's access to prevention messages and services, and targeted interventions to overcome these barriers;
- Assessment of, and attention to, unique risks and prevention needs of male and female sex workers, including sex workers with disabilities, around the issue of disability and gender based violence;
- Livelihood and economic empowerment programs appropriate to the needs of disabled people, including women and girls with disabilities;
- Community-based and structural interventions to eradicate the exploitation of disabled people, including disabled women and girls, by sex trafficking, rape, and sexual abuse;
- Linkages with interventions to support equal education for disabled people in mainstream school settings and ensure that school environments are safe and accessible to disabled students;
- Linkages with interventions to increase property and other legal rights of disabled people, especially disabled women and girls; and
- Targeted and accessible interventions to empower disabled people, especially youth with disabilities and women and girls with disabilities, to have the knowledge and self-confidence to negotiate safer sex with sex partners.

C. *Biomedical Prevention*

- Assessment and identification of unique risks and needs of male and female IDUs with disabilities; targeted interventions to meet these needs such as accessible disability-friendly IDU services that include provision or referral to accessible comprehensive sexual and reproductive health services, PMTCT, and legal and economic strengthening activities;
- Risk reduction programs targeted to the specific needs of disabled people;
- Disability analysis conducted as part of planning for pre-exposure prophylaxis programming; and
- Training for providers of biomedical interventions on the need to ensure accessibility of interventions to disabled people, especially disabled people who may have increased need of certain services, e.g. access to medical injections, phlebotomy services etc, because of their disabilities.

D. *Voluntary Medical Male Circumcision (VMMC)*

- Effective and accessible communication campaigns and education programs directed to disabled people to explain benefits and risks of VMMC to them and their partners; among other things, these messages should explain that there is no known direct benefit to women, that male circumcision is partially protective for HIV negative men, that it cannot prevent HIV positive men from transmitting HIV, that there is potential of heightened risk when surgical wound is not fully healed before having sex, and that male circumcision must be combined with other risk-reduction strategies in order to achieve effective protection;
- Targeted outreach to disabled people and, where relevant, their families, on the potential benefits of VMMC, especially where men and boys with disabilities may have been excluded from VMMC on the basis of their disability;
- Effective counseling interventions for VMMC clients with disabilities so that their behavior does not put women at greater risk of disability or gender-based violence and HIV infection;
- Formative research and program monitoring on unintended consequences of VMMC for women and men with disabilities (e.g., reductions in rates of condom use, increases in coercive sex, increased number of sex partners, further stigmatization of HIV positive women, and difficulties for women to negotiate safe sex or insist on condom use, particularly

with a circumcised man); use of these data to prevent and mitigate harmful consequences; and

- Disabled male-friendly HIV/AIDS programs, other accessible disabled male health services, and promotion of healthy male norms integrated or linked with VMMC roll-out; innovative models to promote male circumcision through key health services for women including disabled women, e.g. family planning and maternal and child health services.

E. Adult Care and Treatment

- Strengthening of comprehensive health care services that are accessible to disabled people, including PEP, for victims of rape and other forms of disability and gender-based violence;
- Assessment and identification of barriers that disabled people face in accessing information, services, adhering to treatment, or receiving on-going care; targeted interventions to avoid and overcome these barriers;
- Targeted care and treatment information, services and programs to disabled people;
- Effective linkages of accessible care and treatment services with family planning and reproductive health services, and accessible cervical cancer screening and treatment for girls and women with disabilities; integration of HIV/AIDS services into family planning and reproductive health clinics in order to facilitate disabled women's access to services;
- Family-centered approaches to care and treatment, mindful of the need to ensure respect for the privacy, opinions and decision-making of disabled people;
- Assessment of the dynamics of care-givers and personal attendants for disabled people; and outreach to care-givers and personal attendants as appropriate to ensure that they are adequately trained to handle additional responsibilities that may result from the need for them to support effective provision of HIV/AIDS-related treatment, care and support to disabled people; and
- Working collaboratively with disabled people's organizations (i.e. civil society organizations run by disabled people themselves), including independent living centers and other disability non-governmental organizations.

F. TB/HIV

- Assessment and identification of barriers to disabled people's access to TB/HIV services and targeted interventions to overcome those barriers;
- Effective linkages between TB, HIV, PMTCT services and other services for disabled women in order to facilitate their access to integrated care and uptake of each service;
- Monitoring of TB treatment adherence for disabled people to assess disability-related barriers; identification and reduction of barriers to support adherence;
- Assessment and mitigation of disability-related stigma associated with TB and HIV; and
- Targeted services to ensure equitable access to TB care and treatment for disabled people.

G. Orphans and Vulnerable Children

- Monitoring, prevention, and mitigation of orphaned and disabled girls' and boys' vulnerability to sexual abuse, exploitation, and HIV;
- Support for orphaned disabled girls and boys so that if the immediate family is unable to care for a child with disabilities, alternative care within the wider family is provided and, failing that, care within the community in a family setting;
- Assessment of the dynamics of care-givers and personal attendants for disabled people; and outreach to care-givers and personal attendants as appropriate to ensure that they are adequately trained to handle additional responsibilities that may result from the need for them to support effective provision of HIV/AIDS-related treatment, care and support to disabled children, and/or the disabled children of HIV positive parents;
- Livelihood and economic empowerment programs for parents or other family members caring for disabled children;

- Support for disabled and/or disabled OVC boys and girls to ensure equal access to mainstream education; interventions to ensure that school environments are safe for students with disabilities; vocational training for disabled and/or disabled OVC boys and girls, both in-school and out-of-school; and
- Advocacy, policy development, and policy implementation and monitoring for inheritance and property rights of women and orphans with disabilities.

H. Testing and Counseling

- Assessment and identification of barriers to disabled people's access to testing and counseling services and targeted interventions to overcome those barriers;
- Training of health providers to provide appropriate reasonable accommodations to disabled people, to increase disabled people's uptake of services and in support of testing and disclosure where disabled people fully understand the implications of results and available response options;
- Training of health providers to provide accessible counseling to assess and mitigate for risk of violence, abandonment, or fear of these that disabled people may face in disclosing HIV-positive status;
- Screening and counseling for disability and gender-based violence as part of CT services, or referrals/linkages to these services;
- Assessment and mitigation of disability-related stigma associated with disclosure of HIV positive status; and
- Family-centered approach that supports testing and counseling of partners and children of disabled people.

I. Pediatric Care and Treatment

- Assessment and identification of barriers that children and youth with disabilities face in accessing services, adhering to treatment, or receiving on-going care; targeted interventions to overcome these barriers;
- Strengthening of comprehensive health care services, including PEP, for disabled child and youth victims of rape and other forms of disability and gender-based violence;
- Targeted care and treatment services and programs to stigmatized and vulnerable disabled pediatric populations, many of whom may have invisible disabilities e.g., street youth with disabilities, children and youth with disabilities who are not in school full-time;
- Effective linkages of HIV care and treatment services with other pediatric services provided to children and youth with disabilities;
- Family-centered approaches to care and treatment, mindful of the need to ensure respect for the privacy, opinions and decision-making of disabled children and youth, their views being given due weight in accordance with their age and maturity, on an equal basis with other children, and to be provided with disability and age-appropriate assistance to realize that right;
- Assessment of the dynamics of care-givers and personal attendants for disabled people; and outreach to care-givers and personal attendants as appropriate to ensure that they are adequately trained to handle additional responsibilities that may result from the need for them to support effective provision of HIV/AIDS-related treatment, care and support to disabled children, and youth and/or the disabled children and youth of HIV positive parents;
- Provision of integrated services through wraparound approaches including family planning, reproductive health, maternal and child health and the management of opportunistic infections; effective referral linkages to support postnatal follow up of HIV positive mothers and exposed infants; and
- Support to families of children and youth with disabilities to enable such pediatric populations to be able to live with their families and enjoy the right not to be separated from

their families on the basis of a disability of either the child or one or both of the parents or other care-givers.

J. ARV Drugs

- Procurement and supply management of antiretroviral post-exposure prophylaxis drugs for rape care services to disabled victims of disability and gender-based violence; and
- Training of health providers regarding the need to ensure that information about ARV usage is accessible to disabled people so that they can make informed decisions about their care and maximize the efficacy of ARV regimen.

K. Strategic Information

- Data analysis to better understand the disability dimensions of HIV/AIDS epidemics—including disaggregation of data by disability to understand the specific needs of disabled people;
- Collection and analysis of disability-disaggregated data to assess differences in such areas as service utilization, sexual behavior, health-seeking behaviors, risk perception, and adherence to treatment;
- Development and strengthening of data monitoring systems to enable disability program target-setting and reporting, including in programs where disability is integrated into mainstream programs; and
- Program evaluation of disability-inclusive and disability-focused HIV/AIDS programs.

L. Health Systems Strengthening

- Monitoring of health systems strengthening interventions (e.g., service delivery, information systems, human resources, health finance, medical products/vaccines/technologies, leadership, governance) for their impact on health equity/disparities and disability equity/disparities; and
- Promotion of enjoyment of the highest attainable standard of health without discrimination on the basis of disability, including through providing disabled people with the same range, quality and standard of free or affordable health care and programs as provided to other persons, including in the areas of sexual and reproductive health and population-based public health programs.

3.10.2 LINKAGES AND WRAPAROUNDS: DISABILITY

Linkages and Wraparounds for disability-related work include:

- Linkages and integration of GBV programs. Countries receiving funding through the Women’s Justice and Empowerment Initiative (WJEI) should describe specific actions to ensure program linkages;
- Joint programs addressing disability equity through activities promoting rule of law, good governance, agricultural sector capacity, access to and use of land, economic opportunity, and sustainable resource management;
- Collaboration and program integration with the education sector, particularly around education of disabled girls;
- Collaboration between PEPFAR and UNAIDS/Global Fund related to disability-inclusive programming and/or work with national AIDS programs and Ministries, as well as working collaboratively with disabled people’s organizations (i.e. civil society organizations run by disabled people themselves), including independent living centers and other disability non-governmental organizations; and
- Wraparounds involving HIV/AIDS and family planning/reproductive health or maternal and child health programs, including cervical cancer screening.

TECHNICAL AREA 3.11: FINANCE AND ECONOMICS

3.11.1 BACKGROUND

Country teams need to consider both financing of PEPFAR activities and financing of the partner country's health system. Whether designing PEPFAR service delivery activities or support for systemic finance reform, a useful conceptual framework for efficiency suggests three areas for efficiency gains:

- **Technical efficiency** is achieved when the maximum output is realized for a given set of resources. Resources can be human or financial resources, equipment or other inputs to the production of services. Technical efficiency requires that all the resources are fully utilized, i.e., that down-time is minimized. Wastage and loss also will be minimized. Technical efficiency typically can be realized over the short run with strong management processes that promote accountability; it is informed by cost analyses;
- **Productive efficiency** requires optimization of the resource mix and production process for a specific type of service. Increases in productive efficiency, therefore, may require rethinking service delivery models to substitute less costly resources for more expensive ones, or to employ strategies that increase effectiveness with low marginal cost. Examples include task-shifting, strategic integration of services, and scaling up of new, highly effective interventions. Productive efficiency can be achieved over the medium term, as best practices are identified and disseminated; productive efficiency decisions are informed by cost-effectiveness analysis; and
- **Allocative efficiency** is achieved when the optimal distribution of resources is made across program areas to maximize their benefit. In example, human, financial and other resources could be distributed across care, treatment and prevention programs to minimize HIV incidence, or to maximize life expectancy. Achieving allocative efficiency requires a longer term process, as it builds on technical and productive efficiency and is informed by resource allocation models.

There are several types of economic analyses that yield cost estimates; each produces different information that informs questions of efficiency in different ways. Cost estimates are very useful to support program management and accountability, but time and financial resources are required to do them well. Expenditure analysis has been developed to complement other economic analyses by providing routine, rapid estimates of PEPFAR's cost per output.

- **Targeted cost studies** are designed to produce estimates of the unit cost of a particular service or a discrete set of services. For example, targeted costing studies help to estimate the cost per year on ART, the cost per client in PMTCT, or the cost per caretaker trained for OVC support. Because targeted costing studies also help to identify key cost drivers, they can be help to identify areas of intervention or for modification to service delivery models that promote technical efficiency and productive efficiency. Targeted costing studies are particularly useful for planning and budgeting for scale-up, and as benchmarks to promote accountability.
- **Cost projection models** use unit cost calculations to estimate resource requirements over some future period, usually about five years. Cost project models inform questions of resource requirements for scale-up, gap analysis and sustainability. They are particularly useful to support planning, budgeting and resource mobilization. Cost project models that have been used for HIV/AIDS programs include the PEPFAR ART Costing Model (PACM), the HIV/AIDS Program Sustainability Analysis Tool (HAPSAT), and the SPECTRUM suite of models.

- **Cost-effectiveness analysis** compares costs and effectiveness of two or more alternative approaches to the same health problem; effectiveness commonly is measured as health outcomes. Cost-effectiveness analysis frequently used to compare new or promising technologies to current practice, and helps policy makers with the selection of service delivery model or program approach. Cost-effectiveness analysis is well suited to inform questions of productive efficiency.
- **Costing of national strategic plans** uses activity-based costing to estimate the financial resources required for implementation of the national HIV/AIDS strategy. These can be useful for budgeting and resource mobilization efforts in partner countries. When iterated with strategic planning and coupled with a resource allocation model such as GOALS, costing of national strategic plans also helps to inform priority setting and resource allocation.
- **Expenditure analysis** under PEPFAR is intended as a rapid assessment of USG cost-per-output. It helps country teams better to understand how much was spent to achieve program results and whether there are areas within the program that would benefit from enhanced management. Expenditure analysis estimates a set of financial indicators including total expenditure by technical area and by partner, and average expenditure per client by technical area and by partner. Expenditure analysis is meant to supplement, not replace, the economic analyses described above; it is useful to promote portfolio management and accountability, and helps to identify potential sources of technical and productive efficiency.

In designing their COP, country teams should consider the following questions:

- What metrics is the team using to assess and monitor efficiency within its programs?
- What has been the team's experience with routine expenditure analysis? What are future plans?
- How have the results of routine expenditure analysis been used for COP planning?
- What additional cost analyses, e.g. targeted costing studies or projection models, have been conducted and how have the results been used in COP planning?
- Describe how cost analysis has been used for portfolio management, including examples of how cost information has been used with individual partners to enhance efficiency.

A good health financing system **mobilizes** adequate resources from reliable sources to pay for health needs, **pools** resources to foster efficiency and spread costs, and **allocates** resources in ways that promote efficiency, equity and health impact. Health finance was not traditionally addressed under PEPFAR's initial phase. Resource mobilization, cost-effectiveness, and efficient resource allocation receive greater emphasis under the second phase. Promising activities to strengthen the health finance function include:

- Country programs should seek to better understand resource flows through assessments of National Health Accounts or National AIDS Spending Assessments;
- Strengthening Ministries' of Finance capacity: to engage effectively with donors, NGOs and the private sector; improve management and strategic planning, and link health care programming with other development efforts;
- Performance-based financing & linkages to HRH incentives;
- Costing and resource planning for sustainable country programming;
- Public and private sector financial management trainings, though not just for management of USG grants;
- Insurance schemes to increase access to HIV/AIDS services;
- Promotion of policies that allow for increased efficiencies through outsourcing of select services to private sector or community organizations; and
- Resource mobilization through innovative public-private partnerships, equitable cost sharing strategies, etc.

Appendix 1: PEPFAR Technical Working Groups

Name	Section
Prevention of Sexual Transmission in the General Population (including youth)	Prevention
Prevention of HIV in Persons Engaged in High Risk Behaviors (PHPEHRB)	Prevention
Medical Transmission	Prevention
Testing and Counseling	Prevention
PwP Taskforce	Prevention
Male Circumcision	Prevention
Human Resources for Health	Prevention
Care and Treatment Steering Committee	Care and Treatment
Adult Treatment	Care and Treatment
PMTCT/Pediatric AIDS	Care and Treatment
TB/HIV	Care and Treatment
Care and Support	Care and Treatment
Orphans and Vulnerable Children	Care and Treatment
Food, Nutrition, and HIV/AIDS	Cross-Cutting
Public-Private Partnerships	Cross-Cutting
Laboratory	Cross-Cutting
Gender	Cross-Cutting
Health Systems Strengthening	Cross-Cutting
Disability	Cross-Cutting
Strategic Information Steering Committee	Strategic Information
Monitoring and Evaluation	Strategic Information
Surveillance and Survey	Strategic Information
Health Information Systems	Strategic Information
Finance and Economics	Strategic Information