The President's Emergency Plan for AIDS Relief

FY 2013

Technical Considerations

Provided by PEPFAR Technical Working Groups for

FY 2013 COPS and ROPS

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Table of Contents

List of Abbreviations

AIS	AIDS Indicator Surveys
ANC	Ante-Natal Clinic
ART	Antiretroviral Therapy
ARV	Antiretroviral Drugs
BCC	Behavior Change Communications
BF	Breastfeeding
CDC	Center for Disease Control
CITC	Client Initiated Testing and Counseling
CHAI	Clinton Health Access Initiative
CHTC	Couples/Partner HIV 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
EFV	Efavirenz
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
HDSS	High Dead Space Syringes
HPV	Human Papillomavirus
HQ TWG	Headquarters Technical Working Group
HRH	Human Resources for Health
HSS	Health Systems Strengthening
HTC	HIV/AIDS Testing and Counseling
IC	Infection Control
ICF	Intensified Case Finding
IDU	Injecting Drug User
IEC	Information, Education, and Communication
IPT	Isoniazid Preventive Therapy
IS	Injection Safety
ITN	Insecticide-Treated Net
KP	Key Population
L&D	Labor and Delivery
LAM	Lactational Amenorrhea Method
LDSS	Low Dead Space Syringes

List of Abbreviations (continued)

LTBI	Latent Tuberculosis Infection
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
MLP	Mid-Level Providers
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
NACS	Nutrition Assessment, Counseling, and Support
NGI	Next Generation Indicators
NGO	Non-Governmental Organization
NIH	National Institute for Health
NIMART	Nurse-Initiated and Managed Antiretroviral Therapy
NSP	Needle and Syringe Programs
NBTS	National Blood Transfusion Service
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	People Who Inject Drugs
PwP	Prevention with People Living with HIV/AIDS
PWUD	People Who Use Drugs
QA	Quality Assurance
QI	Quality Improvement
QM	Quality Management
RCT	Randomized Controlled Trial
RH	Reproductive Health
RTK	Rapid Test Kit

List of Abbreviations (continued)

SBCC	Social and Behavior Change Communications
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
SW (MSW, FSW)	Sex Worker (Male Sex Worker, Female Sex Worker)
TA	Technical Assistance
TB	Tuberculosis
TLC	Total Lymphocyte Count
TTI	Transfusion-Transmissible Infections
TWG	Technical Working Group(s)
USAID	United States Agency for International Development
USG	United States Government
VCT	Voluntary Counseling and Testing
VL	Viral Load
(VM)MC	(Voluntary Medical) Male Circumcision
WAD	World AIDS Day
WHO	World Health Organization
XDR-TB	Extreme Drug-Resistant Tuberculosis

Introduction

The technical considerations in this document provide advice for program planning by PEPFAR's headquarters technical working groups (HQ TWGs), 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.

We request that PEPFAR team members with technical questions contact the HQ TWGs directly, while keeping your country support team leader (CSTL) informed. CTSLs can provide contact information for those TWG co-chairs, if necessary. Country and Regional teams needing on-site technical assistance (TA) should send their request through their PEPFAR Coordinator (or Point of Contact) to their CSTL. The CSTL will forward the request to the chairs of the appropriate HQ TWG.

Section 1: Prevention

1.1 PREVENTION OF MOTHER TO CHILD TRANSMISSION (PMTCT)

1.1.1 INTRODUCTION

The PEPFAR headquarters PMTCT and Pediatrics TWG has rewritten this section of the Technical Considerations this year to reflect new evidence, new guidance, and new priorities. Areas of focus include:

- Couples HIV testing and counseling (HTC) within the PMTCT platform, followed by linkages to voluntary medical male circumcision (VMMC) programs and interventions for serodiscordant couples;
- Integration of family planning (FP) and HIV service delivery into PMTCT programs;
- Improvement in coverage of eligible HIV-positive pregnant women on antiretroviral treatment;
- Thoughtful and strategic PMTCT program shifts toward World Health Organization (WHO) Options B and B+, including synergies with antiretroviral therapy (ART) programming;
- Program interventions and evaluations aimed at improved retention and adherence of mother-infant pairs;
- Supportive supervision, including data quality management; and
- Support for national, regional, and facility level commodity management and task-sharing strategies.

With the momentum of the Global Plan Towards the Elimination of New HIV Infections among Children by 2015 and Keeping Their Mothers Alive[1], the release of the WHO PMTCT Update supporting the implementation of Option B+[2], and the USG World AIDS Day target of initiating 1.5 million pregnant women on ARVs by 2013, PEPFAR programs are in a prime position to make an incredible impact globally.

1.1.2 HIV TESTING AND COUNSELING (HTC) AND PREVENTION WITHIN THE PMTCT PLATFORM (PRONG 1)

HTC and Retesting during Pregnancy

HTC is a critical component and gateway to PMTCT services for both mothers and exposed infants. Additionally, PMTCT programs present a unique opportunity to offer HIV testing to partners and family members of pregnant women and to link them to appropriate prevention, care and treatment services. Integrating partner and couples HIV testing and counseling (CHTC) into PMTCT services can identify HIV-infected male partners in need of care and treatment, as well as HIV-negative partners who are unknowingly in a serodiscordant relationship and could benefit from VMMC. CHTC used to identify serodiscordant couples has been shown to reduce

[1] Joint United Nations Programme on HIV/AIDS (UNAIDS). GLOBAL PLAN TOWARDS THE ELIMINATION OF NEW HIV INFECTIONS AMONG CHILDREN BY 2015 AND KEEPING THEIR MOTHERS ALIVE. 2011.
[2] http://www.who.int/hiv/pub/ guidelines/9789241501972/en/

HIV transmission, increase condom use, and increase ART uptake among pregnant women in antenatal clinic (ANC) settings[3, 4, 5]. In high-prevalence settings, HIV re-testing is a cost-effective strategy to identify women who may have acquired HIV during pregnancy[6].

Key strategies for HTC in the context of PMTCT within PEPFAR-supported programs include:

- Quality delivery of HTC provided early as a core service to pregnant and breastfeeding women, their male partners, and their families, including in ANC settings, at labor and delivery (L&D) and post-partum. 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;
- Provider-initiated HIV testing and counseling (PITC) **with same-visit return of results** is recommended for the provision of HTC in PMTCT settings;
- Designing HTC strategies and interventions based on the type of epidemic
    - In the context of a generalized epidemic, it is recommended that HTC be offered to all pregnant women and their partners. Women who initially test negative in the first or second trimester should be offered re-testing during the 3rd trimester, at L&D, or during the postpartum period;
    - In the context of a concentrated epidemic, routine HIV testing targeted to geographic settings with higher HIV prevalence among pregnant women is recommended. WHO is currently conducting consultations on this strategy and guidance is anticipated in 2013;
- The provision of routine HIV testing targeted to geographic settings with higher HIV prevalence among pregnant women in the context of concentrated epidemics. WHO is currently conducting consultations on this strategy and guidance is anticipated in 2013;
- Various approaches to scaling up CHTC in antenatal settings, 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; and
- Early identification of HIV exposure and infection status in infants: more on this subject can be found in Section 2.3.2: "HIV Testing of Children: early identification." .

Further guidance on HIV Testing and Counseling can be found in the Technical Considerations for HTC, as well as in the following references:

- WHO 2010 recommendations on "Delivering HIV test results and messages for re-testing and counseling in adults." Link: www.who.int/hiv/pub/vct/hiv_re_testing/en/index.html
- WHO 2012 Guidelines entitled "Couples HIV Testing and Counseling and Antiretroviral Therapy for Treatment and Prevention in Serodiscordant Couples: Recommendations for a Public Health Approach" Link: www.who.int/hiv/pub/guidelines/9789241501972/en/.

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[3] Allen S, Meinzen-Derr J, Kautzman M, Zulu I, Trask S, Fideli U,...Haworth A. (2003). Sexual behavior of HIV serodiscordant couples after HIV counseling and testing. *AIDS,* 17, 733-40.

[4] Dunkle KL, Stephenson R, Karita E, Chomba E, Kayitenkore K, Vwalika C…Allen S. (2008). New heterosexually transmitted HIV infections in married or cohabiting couples in urban Zambia and Rwanda: an analysis of survey and clinical data. *Lancet,* 371, 2183-91.

[5] Farquhar C, Kiarie JN, Richardson BA, et al. Antenatal Couple Counseling Increases Uptake of Interventions to Prevent HIV-1 Transmission. *JAIDS*. 2004;37 (5):1620-6.

[6] Soorapanth,S, Sansom S, Bulterys, Besser, M, Theron G, Fowler MG. Cost-Effectiveness of HIV Rescreening During Late Pregnancy to Prevent Mother-to-Child HIV Transmission in South Africa and Other Resource-Limited Settings. *Epidemiology and Social Science*. J Acquir Immune Defic Syndr 2006; 42:213-221.

- A two day training curriculum for CHTC in clinical settings including PMTCT. Link: www.cdc.gov/nchstp/od/gap/CHTCintervention/.

HIV prevention and PMTCT

High rates of HIV acquisition noted during pregnancy[7] underscore the important role of Prong 1 in PMTCT. Pregnant women are at increased risk for acquiring HIV during pregnancy[8]. Male sexual partners of HIV positive pregnant women are also at increased risk for acquiring HIV[9]; referral for VMMC can reduce their risk by 60-70 percent[10, 11, 12, 13]. Women who become infected with HIV during pregnancy or breastfeeding are at high risk for transmitting HIV to their baby and/or to their HIV-negative male partners[14] due to the high viral loads associated with acute HIV infection.

Key strategies for HIV prevention in the context of PMTCT within PEPFAR-supported programs include:

- *HIV prevention services for HIV-negative pregnant and breastfeeding women and their male partners*, including: counseling to support partner reduction, mutual monogamy to a partner of known HIV status, and consistent and correct male or female condom use at every sexual encounter. Women should be educated on the proper use of condoms and provided an adequate supply of condoms as part of these education efforts;
- *Providing prevention messages and services to pregnant and breastfeeding women diagnosed as HIV-positive ("Prevention with Positives*"), including: ART adherence counseling and support, HIV serostatus disclosure counseling and support, sexual risk reduction counseling, condom promotion and distribution, FP counseling and referrals, sexually transmitted infection (STI) diagnosis and treatment, and linkage to long term HIV care and treatment services; and
- *Actively involving male partners in HIV prevention efforts*, including: linkage of uncircumcised HIV-negative male partners of HIV-positive pregnant and BF women to VMMC services, as well as referral of HIV-positive partners of HIV-negative women for ART . PEPFAR policy now endorses ART regardless of CD4 count for the HIV positive member of a serodiscordant couple wherever national guidelines support it[15, 16].

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[7] Moodley D, Esterhuizen TM, Pather T, Chetty V, & Ngaleka L. (2009). High HIV incidence during pregnancy: compelling reason for repeat HIV testing. *AIDS*, 23, 1255-9.
[8] Moodley et al., 2009
[9] Mugo N, Heffron R, Donnell D, Wald A, Were EO, Rees H…Partners in Prevention HSV/HIV Transmission Study Team. (2011). Increased risk of HIV-1 transmission in pregnancy: a prospective study among African HIV-1 serodiscordant couples. *AIDS,* 25, 1887-1895.
[10] Auvert B, Taljaard D, Lagarde E, et al. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 trial. PLoS Med. 2005;2:e298.
[11] Bailey RC, Moses S, Parker CB, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomized controlled trial. Lancet. 2007;369:643–656.
[12] Gray RH, Kigozi G, Serwadda D, et al. Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial. Lancet. 2007; 369:657–666.
[13] Gray R, Kigozi G, Kong X, et al. The effectiveness of male circumcision for HIV prevention and effects on risk behaviors in a post trial follow-up study. AIDS. 2012;26:609–615.
[14] Curran K, Baeten JM, Coates TJ, Kurth A, Mugo NR, Celum C., HIV-1 Prevention for HIV-1 Serodiscordant Couples. *Curr HIV/AIDS Rep*. 2012 Jun. 9(2):160-70.
[15] HPTN 052.

Further information can be found in sections 1.2, Sexual Prevention; 1.4, Prevention for People Living with HIV; and 1.3.11, Voluntary Medical Male Circumcision.

1.1.3 PMTCT and FAMILY PLANNING INTEGRATION (PRONG 2)

Of the 22 high burden countries targeted in the Global Plan, rates of unmet need for family planning vary between 13 percent and 38 percent[17]. Access to family planning is a critical component of a comprehensive PMTCT strategy. The regular repeat visits for ANC and HIV care and treatment services provide multiple opportunities to provide women with FP counseling and methods. PEPFAR supports the principle of choice and respect for reproductive health rights of all individuals, including women living with HIV and their partners.

Key strategies for FP-PMTCT integration within PEPFAR-supported programs include:

- Addressing the unmet need for FP and reproductive health (RH) through appropriate counseling and referral for contraceptive services;
- Supporting programs to integrate FP into ANCs and throughout the postpartum period, including counseling on exclusive BF over the first six months, the lactational amenorrhea method (LAM), and modern contraceptives; and
- As appropriate, linking PEPFAR-funded activities with those funded from separate accounts (e.g. host country government activities, multilateral and bilateral donors, USAID Population and Reproductive Health resources, etc.) to support PMTCT, RH and FP service integration.

PEPFAR-funded activities that integrate FP in any way must meet all USG requirements for compliance, monitoring and reporting. Further guidance on FP can be found in Section 3.12, HIV and Family Planning, and the following resources:

http://www.who.int/mediacentre/factsheets/fs351/en/index.html

1.1.4 ANTI-RETROVIRAL DRUG (ARV) TREATMENT AND PROPHYLAXIS (PRONG 3)

Improved coverage of ART for eligible pregnant and breastfeeding (BF) women (as defined by country guidelines) is critical for effective PMTCT, as well for reaching U.S. Government (USG) 2013 World AIDS Day (WAD) and Global Plan goals. However, current data suggests that many pregnant or BF women eligible are not being offered treatment. An estimated 50 percent of HIV positive pregnant and BF women have CD4 counts <350/ml, placing them at increased risk of transmitting the virus to their infants and discordant sexual partners, as well as for increased morbidity and mortality themselves. A recent systematic review found that only 43 percent of pregnant women diagnosed as HIV positive in ANC and determined to be eligible for

[16] WHO "Couples HIV Testing and Counseling and Antiretroviral Therapy for Treatment and Prevention in Serodiscordant Couples: Recommendations for a Public Health Approach", April 2012, http://www.who.int/hiv/pub/guidelines/9789241501972/en/.

[17] Joint United Nations Program on HIV/AIDS (UNAIDS). *Together we will end AIDS*. 2012. p 122. http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/20120718_togetherwewillendaids_en.pdf

ART were initiated on treatment[18]. In addition, about 70 percent of pregnant and BF women have CD4 counts below 500, making them increasingly vulnerable to declining health, more likely to transmit HIV to sexual partners, and at higher risk of CD4 falling below 350 by the subsequent pregnancy[19].

ARV strategies for PMTCT are rapidly evolving based on new scientific findings and program experience. Specifically, the dramatic "treatment as prevention" benefits demonstrated in the HPTN 052 study[20] and Malawi's innovative Option B+ approach for PMTCT[21] have the potential to be "game changers" in the approach to PMTCT. These approaches prevent transmission of HIV to partners as well as babies, and protect the health of the mother. In anticipation of a 2013 consolidated guideline for the use of ARVs for prevention and treatment of HIV infection in adults and children, WHO released three interim updates (see table below) highlighting new directions that will likely be incorporated in the PMTCT component of their recommendations. Collectively, these statements specifically promote moving toward ART as the intervention of choice (Option B or B+) for prevention of new HIV infections in pregnant and BF women and their infants, as well as for reducing HIV-related maternal mortality. They also recognize the challenges and uncertainties with all options, and highlight the need for rigorous and enhanced monitoring and evaluation. PEPFAR supports incorporation of these recommendations into country PMTCT programs.

2012 WHO Interim Update	Highlights
Programmatic update: use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants (April, 2012). Link: http://www.who.int/hiv/pub/guidelines/9789241501972/en/	• Permissive of "Option B+" (lifelong treatment for HIV-infected pregnant women regardless of CD4 count or clinical stage) • Emphasizes that Options B and specifically B+ are likely to prove preferable to Option A for operational, programmatic and strategic reasons, while recognizing that Option B+ is not an "easy fix" • Encourages movement toward more simplified approach to PMTCT and closer harmonization with treatment ARV regimens and programming • Highlights the need for strong cost effectiveness, acceptability, retention, and effectiveness evaluation, especially with Option B+ given limited evidence.

[18] Ferguson L, Grant A, Waston-Jones D, Kahawita T, Ong-ech J, Ross D. (epub) Linking women who test HIV-positive in pregnancy-related services to long-term HIV care and treatment services: a systematic review. *Tropical Medicine and International Health.*

[19] Carter RJ, Dugan K, El-Sadr WM, et al. CD4+ Cell Count Testing More Effective Than HIV Disease Clinical Staging in Identifying Pregnant and Postpartum Women Eligible for Antiretroviral Therapy in Resource-Limited Settings. J Acquir Immune Defic Syndr 2010;55:404–410.

[20] Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. 2011 Aug 11;365(6):493-505.

[21] Shouten E, Jahn A, Midiani D, et al. Prevention of mother-to-child transmission of HIV and the health-related Millennium Development Goals: time for a public health approach. Lancet. 378(9787), 16–22 July 2011, p282–284

Use of efavirenz (EFV) during pregnancy: a public health perspective (July 2012) Link: http://whqlibdoc.who.int/publications/2012/9789241503792_eng.pdf	• Presents reassuring evidence that exposure to EFV in early pregnancy has not resulted in increased birth defects or other significant toxicities. • Reviews data suggesting that EFV is clinically superior to nevirapine (NVP)--better long-term viral suppression, fewer adverse events, less toxicity, less risk of resistance • Provides support for the use of EFV to optimize and simplify first-line treatment, including among pregnant women and those of reproductive age
Guidance on couples testing and counseling, including antiretroviral therapy for treatment and prevention in serodiscordant couples (April 2012) Link: http://whqlibdoc.who.int/publications/2012/9789241501972_eng.pdf	• Encourages increasing the offering of HTC to couples and partners • Recommends offering ART for HIV prevention in serodiscordant couples irrespective of clinical or immunologic stage

Because of the limited outcome data available on Option B+ implementation and the significant long-term consequences of treatment discontinuation on mortality and resistance, OGAC will be monitoring the planning and strategies described for countries moving to Option B+. However, regardless of the PMTCT option chosen in country (A, B or B+), PEPFAR-supported PMTCT programs will want to prioritize:

1) Clear demonstration of PEPFAR program implementation supporting national PMTCT policy or guidance. Any PEPFAR-supported program that deviates from the national strategic plan or guidelines (such as an operational pilot) should be presented and explained in the COP executive summary.

2) Co-planning, co-forecasting, and co-budgeting between treatment and PMTCT programs, including the contribution of pregnant women in consensus targeting, budgeting and forecasting for ART and Rapid Test Kits (RTKs) (See sections 2.1.6 and 2.3).

3) Attention to linkages and retention
   a) Clear strategies for timely initiation and retention of eligible (as defined by country guidelines) pregnant and BF women on ART. Decentralization of ART services will likely be a component of any PMTCT scale-up strategy. The location and responsibility for ART initiation, ARV toxicity monitoring, mother-baby pair follow-up, and timing/transition/location of long term treatment and clinical, immunologic and/or virologic monitoring needs to be addressed, likely based on the demand and capacity assessment described above. In addressing these issues, countries will need to balance a streamlined approach with maintenance of quality services, taking into consideration the woman's long term reproductive lifecycle. Task sharing, training, and supervision will be

needed to support these activities. PEPFAR will support programs in developing and evaluating innovative strategies to accomplish program goals.

b) Enhanced monitoring, evaluation and supervision focusing on tracking of linkages and retention. As more pregnant women are initiated in ART, strengthening the linkage between PMTCT and ART programs, ensuring long term retention in services, and improving adherence to ART medications will become increasingly important. Programs are encouraged to prioritize improving health information systems to enable tracking of clients between services within the same facility (i.e. between antenatal and long-term HIV care and treatment) and across health facilities to facilitate retention and identify those who are lost to follow up. PEPFAR plans will need to address updating of registers, strategies for timely identification of bottlenecks, and processes for quality improvement.

4) Strengthening supply chain reliability and resilience for rapid test kits (RTKs) and ARVs in PMTCT settings. Supply chain systems can be improved by supporting ministries of health to harmonize HIV testing algorithms and ART regimen selection between PMTCT and adult treatment programs, and coordinating with other commodity sources (such as Global fund or national systems). Ensuring availability of commodities needed to reach PMTCT targets through improved planning and support for commodity distribution, management, buffer stocks, and monitoring is strongly encouraged. Whenever commodity shortfalls threaten PMTCT programs, please contact your CSTL; a Commodities Task Team has been established to assist country teams with commodities shortages and help with the identification of additional resources (see sections 2.1 and 2.3 for more information).

5) Pharmacovigilance is being supported and coordinated by OGAC through a standard multi-country approach. Some, but not all, countries meeting certain facility infrastructure and sample size criteria, and using tenofivir-lamivudine-efavirenz in early gestation, will be implementing a birth defects surveillance program. Initial countries have been selected. While this approach has mitigated the need for each Option B+ country to develop a birth defects surveillance system, any PEPFAR team interested in participating in or developing a pharmacovigilance program supported by PEPFAR may request support from the PMTCT-Pediatric and Treatment TWGs, via their CSTL.

6) Quantitative assessments of the anticipated increase in demand for PMTCT and ART services in the context of available capacity. PEPFAR teams need to support national governments in determining where and how increasing numbers of HIV positive pregnant and BF women will be absorbed and provided with both ART and maternal, neonatal, and child health (MNCH) services throughout their reproductive years. Assessments of current MNCH and ART service settings at national, regional, district, and site levels can provide critical information to support this planning process. Both assessment and planning should address human resource needs, clinic infrastructure improvement, and exploration of women's preferences. These considerations will be critical to ensuring ART retention as well as delivery of critical MNCH services such as FP, immunizations, nutritional support, and early infant HIV diagnosis.

7) Attention to patient monitoring:
   a) A treatment failure monitoring algorithm in the absence of baseline CD4. The prioritization of early initiation of ARVs, particularly in countries adopting Option B+, has resulted in lack of baseline CD4 in many cases. Yet, monitoring for treatment failure

is critical for quality program outcomes. The Care and Treatment and Laboratory TWGs are in the process of evaluating the use of viral load (VL) monitoring using dried blood spots (DBS), and are available to assist countries interested in exploring VL monitoring options (see section 3.1, Laboratory Infrastructure, and 2.1.6, Treatment). Given that no evidence base or standard approach to monitoring for treatment failure has been developed for women initiated on ART without baseline CD4, PEPFAR teams will need to work with the Ministry of Health to develop an algorithm for monitoring of treatment failure in this population. The Adult Treatment, PMTCT-Pediatric, and Laboratory TWGs are available to provide input to countries in developing such an algorithm.

b) Monitoring for HIV drug resistance (HIVDR): As detailed in Section 2.2, Adult Treatment, support for HIVDR surveillance activities as a core component of the national ART program is encouraged. It is important that PEPFAR programs supporting implementation of expanded access to ART in pregnancy (either through Option B or B+) assist with the design and implementation of targeted HIVDR surveillance activities to ensure that pregnant and BF women with higher baseline CD4 counts are included.

1.1.5 ESSENTIAL CARE FOR WOMEN AND CHILDREN IDENTIFIED IN PMTCT PROGRAMS (PRONG 4)

HIV/AIDS is a leading cause of death among women of reproductive age. The ultimate goals of PMTCT are to maintain AIDS-free survival and health of the mother and HIV-free survival and health of the infant. Preventing MTCT is just one component of a comprehensive package needed to obtain these broader goals. Minimizing maternal health risks and achieving reduced morbidity and mortality among HIV-exposed infants is substantially linked to the achievement of Millennium Development Goals (MDGs) 3, 4, 5, and 6. In order to achieve these goals, in addition to the HIV prevention and FP interventions described previously, PMTCT programs need to integrate and/or design clear linkages to provision of essential care elements including cotrimoxazole prophylaxis (CTX); prevention and treatment of tuberculosis (TB); prevention and treatment of malaria and syphilis; and nutritional assessment, counseling, and support (NACS).

Cotrimoxazole prophylaxis for mothers and infants

The provision of cotrimoxazole **(**CTX) prophylaxis against opportunistic infections for both mothers and their HIV exposed children is an essential element for PMTCT programs. 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/AIDS, especially if there is a delay in the initiation of ART. This intervention could be linked to PMTCT programs at multiple points including, Early Infant Diagnosis (EID), MNCH (antenatally and through FP or under-five clinics), and home-based testing efforts. For more detailed guidance regarding CTX, see the WHO's guidance on CTX prophylaxis for HIV-exposed and HIV-infected infants, children, adolescents, and adults: http://www.who.int/hiv/pub/plhiv/ctx/en/index.html

Key strategies in CTX prophylaxis for HIV-exposed and infected children for PEPFAR-supported programs include:

- Providing HIV-exposed children with CTX prophylaxis beginning at 4-6 weeks of age and continuing until HIV infection has been definitively ruled out after cessation of BF. It

is important to remember that despite postpartum ARV prophylaxis or maternal ART, HIV transmission can still occur during BF,

- Providing CTX to all HIV-positive children less than five years of age and continuing until at least five years of age if WHO immunologic and clinical criteria are met and in accordance with current pediatric and adult guidelines;
- The integration of CTX with MNCH services and inclusion of HIV exposure status/receipt of CTX in the child health card; and
- Ensuring adequate funds for CTX to minimize the risk of stock-outs, especially as the Clinton Health Access Initiative (CHAI), using UNITAID funds, transitions out as the principal purchaser of CTX for children. Headquarters support is available to discuss and strengthen the provision of CTX in a variety of settings.

Prevention and treatment of tuberculosis

Despite international guidelines, TB/HIV activities have not been integrated into most PMTCT settings. The PMTCT/Pediatric HIV Technical Working Group recommends that the TB/HIV activities outlined below, especially intensified TB case finding, Isoniazid Preventive Therapy (IPT) or TB treatment, and infection control, be implemented in all PMTCT programs and included in all PMTCT acceleration plans:

- Screen all pregnant women with HIV for TB at each encounter using the WHO-recommended symptom-based algorithm (including specific questions related to current cough, fever, night sweats, or weight loss) or national TB symptom screening algorithms for people living with HIV. Per national and international guidelines, evaluate those who screen positive and if TB disease is confirmed, immediately initiate anti-TB therapy and evaluate household members for TB;
- Evaluate every HIV-positive pregnant woman who presents with one or more of the symptoms in the WHO TB screening algorithm for active TB disease (using a combination of clinical signs, chest x-ray, sputum microscopy, culture, and internationally-approved molecular diagnostics) in accordance with national guidelines:
    - If the woman is diagnosed with TB disease, immediately initiate anti-TB therapy;
    - If active TB disease is ruled out, provide IPT in accordance with national guidelines. WHO strongly recommends that HIV-infected pregnant women not be excluded from IPT because of their pregnant status, and that sound clinical judgment should be used regarding the best time for IPT initiation;
- HIV-positive pregnant women with active TB should be treated promptly for TB and should also be started on ART as soon as possible (if not already on ART), regardless of CD4 count. Starting ART for TB patients with a CD4 <50 should be considered urgent.
- Routinely screening HIV-positive infants and children for TB as a part of standard clinical care. HIV-infected children who are older than 12 months of age and are not found to have active TB should be given IPT for six months, in accordance with WHO guidelines.
- Evaluate infants and children who are born to mothers with TB disease or who have a history of contact with a TB case for TB disease, regardless of the child's HIV status:
    - If active TB disease is identified, immediately initiate anti-TB therapy;
    - If active disease is ruled out, give IPT for 6 months in accordance with international guidelines;

    - Given the difficulty of identifying TB disease in infants and children, continuously monitor them for signs and symptoms of active TB disease;
- Establish linkages and referral mechanisms between HIV and TB programs to ensure that pregnant women and infants who may have TB are properly evaluated, and those found to have TB disease receive appropriate treatment and follow-up per national policy/international guidelines;
- Establish mechanisms to document, monitor, and evaluate TB screening, diagnostic, and treatment activities as well as outcomes among pregnant women and children; and
- Implement TB infection control activities in PMTCT settings in accordance with international guidelines.

Further information on TB prevention and TB/HIV co-infection can be found in Section 2.4, TB/HIV, and in the following resources:

1) Guidelines for intensified tuberculosis case-finding and IPT for people living with HIV in resource constrained settings. Link: http://whqlibdoc.who.int/publications/2011/9789241500708_eng.pdf
2) PEPFAR Guidance on Integrating PMTCT and Maternal Neonatal and Child Health and Pediatric HIV Services (2011). Link: http://www.pepfar.gov/guidance/pmtct/158785.htm

Malaria and syphilis prevention and treatment

Malaria is a major co-morbidity with HIV and is particularly dangerous in pregnant women due to the increased risk of anemia from both malaria and pregnancy. Maternal syphilis infection increases the risk of HIV transmission to the infant, and can cause stillbirth or congenital syphilis if undetected and untreated. In endemic countries and in accordance with country guidelines, PEPFAR programs may support:

- Distribution and use of ITNs in households of persons with HIV, pregnant women, and children < five years of age;
- Malaria screening, testing if symptomatic, and treatment as part of routine ANC and child health services; and
- Syphilis testing and treatment within ANC/PMTCT settings.

Nutritional assessment, counseling, and support (NACS)

The NACS platform is a set of nutrition and health interventions, with BF support at its core, that are integrated within clinic and community services to establish a continuum of care and support for individuals and families. NACS is being extended to provide a platform for integrated maternal/infant PMTCT postpartum care – The Partnership for HIV-Free Survival (PHFS) – that aims to support country-led implementation of postpartum PMTCT and MCH interventions to improve survival and health of infants and their mothers. PHFS is funded through Nutrition Acceleration funds at the HQ and country level, and is made up of a consortium of technical partners, including WHO, Institute for Healthcare Improvement, USAID's Healthcare Improvement Project, and Food and Nutrition Technical Assistance.

Key strategies for strengthening the post-natal continuum of PMTCT care through the NACS platform include:

- Antenatal and postnatal counseling for all HIV positive and HIV negative mothers to support optimum infant feeding within national guidelines. This counseling includes

nutrition and health information at key points when infant feeding decisions may be made:
    - Before birth when the decision of the primary feeding method is chosen
    - At or before six months with progressive introduction of complementary feeding;
- Encouragement of BF as long as women wish to do it—often through first 2 years of age;
- Providing ARVs to HIV-infected mothers or HIV exposed infants during the BF period, based on national guidelines, to prevent postpartum transmission; and
- Connecting mothers and infants to routine maternal and pediatric services in facilities and communities, and establishing health and nutrition surveillance, referral and tracking systems to facilitate EID, allow early identification and intervention of maternal and infant malnutrition and health problems, and improve immunization coverage. 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

1.1.6 PROGRAM MONITORING, EVALUATION, AND QUALITY

Collecting accurate and complete information about PEPFAR-supported PMTCT interventions is critical to our achievement of the U.S. Government's World AIDS Day 2011 (WAD) targets. PEPFAR PMTCT and Strategic Information (SI) staff will need to work together to ensure that key PMTCT SI needs are addressed and integrated within the larger SI framework (see section 3.2). This year, the PEPFAR HQ PMTCT/Pediatrics TWG, along with SI Advisors, will pay particular attention to helping teams disaggregate data on women or infants treated by ARV regimen within PMTCT indicator P1.2, as part of an effort to ensure quality of program expansion and movement toward more efficacious regimens.

The priority activities for PMTCT monitoring and evaluation (M&E) are:

- *Routine program monitoring:* PEPFAR-funded PMTCT programs should use indicators to describe program performance and identify gaps in services. *At a minimum*, PEPFAR teams will be collecting and reporting on PEPFAR Next Generation Indicators (NGIs) listed below (Link: http://www.pepfar.gov/guidance/c21628.htm). Whenever possible, programs are encouraged to use national reporting tools and data for this purpose:
    - P1.1.D, Pregnant women with known HIV status
    - P1.2.D, HIV-Positive pregnant women who received ARVs to reduce risk of MTCT, with a disaggregation of the ARV regimens (see clarified indicator definition sheet for details)
    - C4.1.D, Percent of infants born to HIV-positive women who received an HIV test within 12 months of birth
    - T1.1.D**,** Number of adults and children with advanced HIV infection newly enrolled on ART with a disaggregation by pregnant women (among other disaggregations). Given recent changes in many country PMTCT guidelines, this indicator language may be inconsistent with national ART initiation eligibility guidelines. PEPFAR recommends counting all eligible pregnant women, per national guidelines, who initiate ART. Country SI advisors and the SI TWG can provide further assistance or clarification;
- *Target setting*: When setting targets for these indicators, PMTCT and SI teams should consult with colleagues from other program areas, especially treatment programs, to

ensure that the targets for other programs are aligned. For example, targets for P1.2.D and T1.1.D, should be incorporated into implementing partner and consensus targeting discussions to ensure that pregnant women initiating ART are accounted for.

- *Data Quality*: In addition to collecting and reporting on the PMTCT indicators, it is critically important that the quality of the data reported is verified. PEPFAR PMTCT teams are encouraged to develop a data quality management plan that describes how the team assesses program data. See section 3.2 for further details. The PMTCT/Pediatrics and SI TWGs can provide tools and resources to support this effort.
- *Evaluation:* PEPFAR PMTCT programs are encouraged to conduct routine program evaluation that fosters quality improvement, informs strategic and ongoing program planning, and contributes to development of best practices. Additionally, where feasible, program effectiveness evaluations that measure transmission rates rather than simply model the outcome of PMTCT implementation efforts are encouraged. WHO has released a short guide explaining the options for measuring and modeling PMTCT outcomes based on country context (http://www.who.int/hiv/pub/mtct/national_pmtct_guide/en/index.html). A generic protocol for a national evaluation/survey of PMTCT effectiveness using a clinic-based approach is forthcoming. The PMTCT/Pediatrics TWG is available to support countries desiring to conduct such an evaluation.
- *Assessing M&E tools and systems to support linkage and retention:* With the increasing adoption and consideration of Option B+ by countries, understanding the ability of health care systems to transition HIV positive pregnant women between antenatal care, early initiation of ARV treatment or prophylaxis, and long term HIV services is increasingly important. Conducting an evaluation of patient monitoring systems and tools and how they support tracking of women on ART from wherever testing and treatment occurs to chronic follow-up is a top priority. The SI and PMTCT/Pediatrics TWG have resources available to support this effort.
- *Transitioning to PMTCT program data for ANC sentinel surveillance:* PEPFAR teams are encouraged to support countries in transitioning from traditional ANC sentinel surveillance methodologies to use of PMTCT program data for ANC sentinel surveillance. WHO guidelines on assessing the quality, accuracy, and reliability of PMTCT data for ANC sentinel surveillance are being finalized. Headquarters SI teams are available to provide support in planning this transition.

1.1.6 COMMUNITY ENGAGEMENT IN PMTCT

Several modeling exercises have demonstrated that in order to reach the goal of elimination of MTCT, all prongs of PMTCT will need to be effectively delivered and sustained as ARV interventions alone will not achieve the targets of <5% transmission of HIV from mother to child, or 90%t reduction of infections among young children by 2015[22]. Community engagement is needed to strengthen all four prongs of PMTCT. All community engagement projects may not work equally well in all contexts. As a result, countries should select and adapt models for community engagement for their particular context based on available resources and infrastructure as well as political and cultural factors. A country's selection and

[22] Ciaranello et al, 2012; Mahy et al 2010; Barker et al, 2011

adoption/adaptation of a specific model will depend on the available resources, infrastructure, political, and cultural factors, and should be evaluated to inform ongoing support for particular community engagement approaches. The UNAIDS report, "Promising practices in community engagement for elimination of new HIV infections among children by 2015 and keeping mothers alive," provides examples of projects that countries could consider adapting (http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/20120628_JC2281_PromisingPracticesCommunityEngagements_en.pdf). Potential strategies for early community engagement for PMTCT within PEPFAR-supported programs include:

- Engaging community health workers to promote the importance of attending MNCH services, including facility based delivery. In Kenya, community health workers receive mobile text messages with reminders of clinic visits for the pregnant women and mother-infant pairs (up to 18 months of age) in their community. All pregnant women are included regardless of their HIV status;
- Engaging traditional authorities, village chiefs, faith leaders and other community leaders to adapt and implement PMTCT best practices in the local context promises to improve early ANC attendance, male involvement, HTC, etc;
- Proactively tracing HIV positive women and exposed infants lost to follow-up. In Malawi, a solar-powered mobile phone system was introduced to coordinate and supervise outreach services[23];
- Providing peer support to facilitate uptake of and retention in PMTCT services. In Kenya, women who interacted with mentor mothers four or more times had an ARV uptake of 97 percent compared to 62 percent uptake among women with no interaction[24].
- Reaching men through behavior change communication that emphasizes the importance of partner support to improve health outcomes for both mothers and infants. In Zambia, male community leaders engaged men in their communities to identify their attitudes and practices that negatively impact women accessing HIV and PMTCT services. Afterwards, positive messages were delivered through faith-based health institutions and trained traditional/cultural leaders. Reports from the project showed that 65 percent of men reached by the program tested for HIV, ANC clients' acceptance of PITC rose from 60 percent to 95 percent, and acceptance of ARV rose from 40 percent to 70 percent among women who tested positive[25].

Other resources to support community engagement activities include:

- "Community strategies that improve care and retention along the prevention of mother-to-child transmission of HIV cascade: a review." *J Int AIDS Soc.* 2012 Jul 11;15(4):1-10.

1.1.7 GENDER

PMTCT programs and outcomes can be improved by assessing and identifying gender norms and inequities, and targeting interventions to overcome them. Barriers to women's access to quality PMTCT services, particularly HTC, support for disclosure, female literacy, and adherence to treatment are especially important.

[23] Nesbit and Smith, 2009
[24] Besser, 2006
[25] Sinkala et al, 2008

Key strategies related to gender and PMTCT within PEPFAR-supported programs include:

- Effectively engaging women's partners, family members, and community support groups 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. Such interventions must clearly define what outcomes are sought when engaging male partners, while ensuring that the burden of getting men into testing and counseling and other health services does not rest solely on women;
- Integrating training, screening and counseling for gender-based violence as part of PMTCT, antenatal and maternity services, as well as strengthening referrals/linkages to gender-based violence (GBV) services. Examples of interventions and resources to address GBV in PMTCT settings can be found at: www.aidstar-one.com/focus_areas/gender/resources/pepfar_gbv_program_guide; and
- Strengthening 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.

1.1.8 HUMAN RESOURCES, TRAINING, CAPACITY BUILDING

Of 57 countries facing a health workforce crisis (<23 doctors/nurses/midwives per 10,000 people), 31 are in Sub-Saharan Africa[26]. Countries and global donors responded to the physician shortage by introducing innovative models of HIV care, such as *task sharing*. Recent studies have shown that appropriate delegation of health care responsibilities of physicians to mid-level providers (e.g., registered nurses, midwives, and clinical officers) has been effective in addressing the severe human resource shortages in many African countries[27, 28] and the Institute of Medicine (IOM) recently identified "task sharing" as an appropriate response to expand health care delivery in low-resource settings[29]. Additionally, studies show that nurse-initiated and managed antiretroviral therapy (NIMART) can lead to health outcomes that are comparable to physician-initiated and prescribed HIV treatment in certain settings[30, 31].

As PMTCT services become more decentralized and integrated with ART, a systematic approach to workforce development and task sharing needs to be orchestrated in parallel to expansion and decentralization of HIV services. This approach would take into consideration factors such as client convenience, maintenance of high quality and efficiency, and need based on HIV prevalence and population size. WHO has released global recommendations and guidelines to help in planning redistribution of tasks among health workforce teams (http://www.who.int/healthsystems/TTR-TaskShifting.pdf).

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[26] http://www.who.int/whr/2006/media_centre/06_chap1_fig10_en.pdf

[27] Buchan, J., M.R. Dal Poz, 2003. Role definitions, skill mix, multi-skilling and "new" workers. In *Toward a global health workforce strategy*, ed P. Ferrinjho and M.R. Dal Poz. Antwerp, Belgium: ITG Press. Pp 275-300.

[28] Morris, M., B. Chapula, B.Chi, A. Mwango, H.Chi, J. Mwanza, H. Manda, C. Bolton, D. Pankratz, J. Stringer, and S. Reid. 2009. Use of task-shifting to rapidly scale-up HIV treatment services: Experiences from Lusaka, Zambia. BMC Health Services Research 9(1):5.

[29] Committee on Envisioning a Strategy for the Long-Term Burden of HIV/AIDS: African Needs and US Interests, IOM, National Academy of Sciences 2010

[30] Callaghan, M., N. Ford, et al (2008). "A systematic review of task-shifting for HIV treatment and care in Africa." Human Resources for Health. 8:8. http://www.human-resources-health.com/content/8/1/8

[31] Sanne, Ian et al (2010). "Nurse versus doctor management of HIV-infected patients receiving antiretroviral therapy (CIPRA-SA): a randomised non-inferiority trial." The Lancet, Volume 376(9734): 33-40.

The following priority areas should be addressed in planning related to PMTCT program expansion:

Determination of the workforce necessary for implementing PMTCT (the "Who").

- Who is competent and capable of delivering high quality PMTCT and/or integrated PMTCT/ART services?
- What policies or commitments have been made regarding national endorsement for task sharing of HIV care and treatment including ART initiation with mid-level providers (MLP) such as clinical officers, nurses and midwives?
- Do MLP have the necessary professional (regulatory) and institutional authority and legal protection for implementing an expanded "scope of practice"? If not, what plans are in place to develop these standards?
- Is there a national laboratory development plan to address standards, accreditation, and workforce development for laboratorians?
- Is there a national framework describing the roles and responsibilities of community health workers/volunteers? Are there standardized national pre- and in-service curricula for this cadre of health worker?

Assuring provider competency and quality (the "How")

- How has PMTCT been (or is planning to be) incorporated into national, institutionally-based provider pre-service and in-service curricula?
- What type of PMTCT quality assurance, clinical mentoring, and/or supportive supervision program is in place to routinely assess whether providers are meeting current standards of practice?
- Are clinical laboratories accredited and is there a quality management system in place for laboratory services?

Strategizing for Staff Deployment (the "Where)

- Does the country have a workforce deployment data base or human resources information system used in HRH allocation decisions?
- What structure or support is being provided to ensure that facility staffing plans been updated to meet the increase in service demand?

Further information on Human Resource for Health can be found in section 3.4.

1.2: SEXUAL PREVENTION

1.2.1 INTRODUCTION

> "Let me begin by defining what we mean by an AIDS-free generation. It is a time when, first of all, virtually no child anywhere will be born with the virus. *Secondly, as children and teenagers become adults, they will be at significantly lower risk of ever becoming infected than they would be today no matter where they are living.* And third, if someone does acquire HIV, they will have access to treatment that helps prevent them from developing AIDS and passing the virus on to others."
>
> Secretary of State Hillary Rodham Clinton, AIDS 2012

To achieve the vision of an AIDS-free generation, we must accelerate and improve our efforts in preventing the sexual transmission of HIV. This means increasing the numbers of people we reach with interventions that help them reduce their risk and protect themselves from acquiring and transmitting the virus. These interventions include risk reduction education and counseling, condoms, HTC, and VMMC. For people living with HIV (PLHIV), it means improving coordination across all interventions to increase access to care and treatment, and to promote adherence to medications. Finally, it also means supporting an enabling environment for these interventions, and addressing the structural barriers and social norms that amplify risk and make it more difficult for individuals and communities to protect themselves and to access HIV services..

In August 2011, PEPFAR released Guidance for the Prevention of Sexually Transmitted HIV Infections (available at: http://www.pepfar.gov/guidance/index.htm). This document provides comprehensive information on PEPFAR's approach to HIV prevention, and should be the reference – alongside technical guidance on HIV programs for men who have sex with men (MSM) and people who inject drugs (PWID) – for PEPFAR country teams as they plan and evaluate their HIV prevention portfolios.

These technical considerations offer additional and updated information on designing, refining and evaluating PEPFAR HIV prevention portfolios, with special attention to how teams might budget these activities. We begin by reviewing a key concept from the Prevention Guidance: the Four Knows.

1.2.2 The Four Knows

PEPFAR's vision of an AIDS-Free Generation is grounded in a commitment to implementing evidence-based interventions appropriate to the specific epidemic, at a scale and intensity capable of reducing new infections, morbidity and mortality. In each national and sub-national situation, there are prevention investments that are more effective at reducing HIV infection than others. Understanding the epidemiological context is the first, essential step in identifying, selecting, and funding the most appropriate and effective HIV prevention measures for that country.

Critical to building an effective portfolio of HIV prevention interventions is having and using accurate and comprehensive information about both the epidemic and the current response, commonly referred to as Know Your Epidemic, Know Your Response[32],[33],[34]. The PEPFAR Prevention Guidance has added two new "Knows" to this list: Know Your Context and Know Your Costs. The collection and analysis of data for the Four Knows should be ongoing and reflected in the COP. Developing and maintaining these categories of data should be core components of all PEPFAR prevention programs. The "Four Knows" are summarized below with a full description in the PEPFAR Prevention Guidance.

1. **Know Your Epidemic:** Epidemiological data on incidence and prevalence of HIV, its geographical distribution at sub-national levels, populations at highest risk of acquiring HIV, and the major epidemic drivers are critical to forging an effective prevention response. PEPFAR funds can and should support activities to gather and analyze this information, primarily from strategic information budgets. Prevention budgets may be used to support certain "Know Your Epidemic" studies, including but not limited to qualitative research and geographical mapping.

Strong PEPFAR programs will invest in data collection and analysis to improve understanding of key populations (KP) – sex workers (SW), MSM, and PWID – in all epidemics. These populations are often highly stigmatized and partner countries may be reluctant to invest in surveillance and programming for them. PEPFAR teams should make it a priority to collect and analyze this data, engaging diplomatically with partner governments where necessary to advance this work.

2. **Know Your Context:** This category includes information that contextualizes epidemiological data, allowing for more effective targeting of specific populations and structural drivers. It includes factors that distally shape the environment of HIV transmission, such as laws and policies and enforcement of those laws/policies. Key examples include legal or cultural restrictions on women's inheritance of property, and policies or norms relating to access to and delivery of HIV and health services.

Know Your Context also includes data on the socio-cultural factors that shape behaviors, attitudes, and norms towards health, disease, sex, gender, and other HIV-related issues, as well as perceptions of HIV services. Particularly important are gender norms that support multiple sexual partnerships and other risky sexual behavior. Also important are cultural attitudes that shape concepts of health and health-seeking behavior, including high-risk traditional practices such as wife inheritance and sexual cleansing of widows. Often rigorous qualitative research is appropriate for gathering data in this area. PEPFAR teams should make investments in building capacity to undertake such research efforts to inform programs.

Data on patterns of population movement also provide critical contextual information in many settings. Mobile and migrant populations who spend long periods of time away from home and have reduced access to health services are especially at risk of acquiring and transmitting HIV[35].

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[32] Merson MH, O'Malley J, et al. (2008). The history and challenge of HIV prevention. *The Lancet*, 372(9637), 475-488.

[33] Wilson D, Halperin DT. (2008). Know your epidemic, know your response?: a useful approach, if we get it right. *The Lancet*, 372(9637), 423-426.

[34] Hankins, C.A. and B.O. de Zalduondo. 2010. Combination prevention: A deeper understanding of effective HIV prevention. AIDS 24: S70-S80.

[35] Coffee M, Lurie MN, Garnett GP. (2007). Modeling the impact of migration on the HIV epidemic in South Africa. *AIDS,* 21(3), 343-350.

Strong PEPFAR teams will collect and analyze the data on population mobility necessary to provide effective programs that meet the needs of populations "at the right time and in the right place". Formative and qualitative studies may also be necessary to understand health-related factors in these populations. Ideally, partner governments will lead efforts to track and understand mobile and migrant populations, and PEPFAR teams can invest in building capacity to support this work.

3. **Know Your Response:** As national HIV prevention responses grow in complexity and scale, it has become increasingly challenging and important to track their scope and coverage.

Understanding the HIV response in a country includes mapping of all prevention activities – including those funded by PEPFAR, partner governments, and other donors. This mapping needs to include the geographic distribution and population coverage of each intervention – for example, the percentage of adults in the targeted geographic area that are reached by community outreach activities. Another example would be to monitor the number or percentage of key populations accessing HIV services. Data should also provide information on the dose of prevention interventions (for those that require multiple doses to be effective), as well as fidelity to an original evidence-based and context-appropriate model. Additional information should consider accessibility and availability of interventions, services, and commodities.

A challenge in achieving a national map of prevention activities lies in coordinating across multiple funders and implementing partners. While partner governments should take the leading role in this coordination, PEPFAR should play a facilitating role where this capacity is limited.

4. **Know Your Costs:** Understanding what our HIV prevention dollars are actually buying is essential to the success of our programs. While practical metrics for prevention remain challenging, it is critical that we use all available data and conduct strategic evaluations where needed to be able to quantify our prevention outcomes obtained with taxpayer funds. Expenditure analysis can provide some insights and should be supplemented with targeting costing exercises in consultation with the PEPFAR Finance and Economics Work Group (FEWG) to ensure study design will answer the desired questions; still, much work remains to be done to better understand the cost of prevention activities in different contexts. As our capacity to measure infections averted improves, PEPFAR country teams should also begin to work with experts to determine the cost per infection averted of our prevention programs. This information is important to ensuring that our investments are as targeted and effective as possible.

1.2.3 Different types of HIV epidemics

Since PEPFAR prevention portfolios should, first and foremost, be guided by country-specific epidemiology, it is useful to briefly revisit the three main types of HIV epidemics: concentrated, mixed, and generalized. Recently, epidemiologists have moved away from prevalence-based thresholds for these epidemics toward definitions such as those elaborated below that are based on transmission dynamics:

- Concentrated epidemics: transmission mainly occurs within key populations: SW, MSM, and PWID;
- Mixed epidemics: a significant proportion of new infections arise in both key populations and the general population;

- Generalized epidemics: most transmission occurs across the general population. It is important to note that even in generalized epidemics, key populations exist and transmission within these groups needs to be addressed.

1.2.4 General principles of HIV prevention programming

Across all epidemic typologies, effective HIV prevention programming involves certain core elements:

- **Setting epidemiologically sound priorities:** PEPFAR programs should be driven by the data collected through the Four Knows, with a primary goal of reducing new infections;
- **Developing a strategic prevention portfolio** that addresses the right populations, at the right time, with the right interventions, in the right places, at sufficient scale to have an impact on HIV incidence;
- **Employing effective program models for social and behavior change communication:** all interventions require certain behaviors in order to be successful. From showing up for HIV testing and counseling, to acquiring and using condoms correctly, to adhering to a drug regimen, HIV prevention efforts rely on effective behavioral programs. PEPFAR teams should use evidence-based models and directly monitor their impact on indicators of service uptake and utilization and changes in risk behaviors;
- **Supporting a coordinated and sustainable national response**: this means coordinating and harmonizing prevention efforts, including those supported by PEPFAR and other donors, as well as establishing 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; and
- **Establishing quality assurance, monitoring, and evaluation mechanisms**.

1.2.5 Planning a Sexual Prevention Portfolio

(a) Planning a Portfolio: Concentrated Epidemics

This section provides advice specifically on designing HIV prevention portfolios for concentrated epidemics among MSM and SW. Technical considerations for epidemics among PWID can be found in section 1.3.7, Biomedical Prevention: Injecting and Non-Injecting Drug Use.

In general, HIV prevention activities for MSM and SW will be funded under the HVOP budget code. However, data collection and analysis may be funded under HVSI, and activities that strengthen local health systems to respond to the needs of KPs may be funded under OHSS. PEPFAR teams may also consider co-funding KP prevention programs under the HVAB budget code to reflect the partner reduction efforts that should be part of prevention activities for some populations.

Sex Workers

In countries all around the world, women, men, and transgender persons, engage in sex work and are at high risk for HIV transmission. A recent meta-analysis demonstrated that in fifty low and middle-income countries, the aggregate HIV prevalence among SW was 12%[36]. Additional analysis showed that in countries with medium and high background HIV prevalence, SW were 11.6 times more likely to be HIV infected than women of reproductive age in the general population[37]. Given that SWare highly affected by HIV and other STIs, it is crucial to design targeted, non-stigmatizing services for this population.

Because individuals sell sex in all PEPFAR countries, culturally relevant, appropriate programs for SW should be included as a key part of prevention efforts in *all* PEPFAR programs. While the Leadership Act legislation states that no funds made available under the Act can be used to promote or advocate the legalization or practice of prostitution, it also explicitly states that nothing in that prohibition should be construed to deny services. Both in the PEPFAR legislation and as a PEPFAR policy, non-stigmatizing, sex-worker friendly HIV prevention, care, and treatment services should be provided to SW.

Services for SW should be comprehensive, including all the components listed in the section on **Prevention Packages for Key Populations**, below. For additional guidance, programs should reference WHO Guidelines on HIV Programming for Sex Workers located at http://www.who.int/hiv/topics/sex_work/en/index.html.

People Who Inject Drugs

Globally 16 million individuals are estimated to be injection drug users, with three million living with HIV. For complete guidance on appropriate interventions for prevention, care and treatment for PWID, please refer to the PEPFAR Technical Guidance: Prevention for People who Inject Drugs:
http://www.pepfar.gov/guidance/combinationprevention/combprevidu/index.htm.

Men Who Have Sex with Men and Transgender Persons

A growing number of studies demonstrate that HIV is having a severe impact on MSM in low- and middle-income countries. MSM experience higher rates of HIV infection than the general population in all regions of the world, including PEPFAR countries. Data from country-specific surveillance surveys have demonstrated the existence of concentrated epidemics among key populations even within larger generalized epidemics. In a review of low and middle-income countries, MSM were found to be 19 times more likely to be living with HIV than people in the general population[38]. Despite the disproportionate HIV disease burden, only 9% of MSM in sub-Saharan Africa have access to HIV prevention services.

Multiple factors increase the risk of sexually transmitted HIV among MSM. These include individual factors such as inaccurate perception of risk, depression and other mental health issues, history of physical or sexual abuse, number and concurrency of sex partners, as well as structural factors such as laws and policies that deny MSM equal protection and put them at risk

[36] Baral S, et al. (2012). Burden of HIV among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. *Lancet Infect Dis* 2012;12: 538–49.
[37] IBID
[38] Baral, S., Sifakis, F., & Beyrer, C. (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 Medicine,* 4, 1901-1911.

for arrest and prosecution. Homophobia, stigma, and discrimination are obstacles to implementing effective programs for MSM, put MSM at increased risk for HIV infection and limit the availability of appropriate HIV services for this population.

In recent years, the UN Agencies, UGS, the Global Fund, and other organizations have convened expert consultations and issued recommendations to address the urgent need to scale up comprehensive HIV prevention programs for MSM. The fundamental conclusions from these international efforts are that reducing HIV risk among MSM requires rapid introduction, scaling up and strengthening of comprehensive HIV prevention programs for MSM and their sex partners as well as the expansion of laws, regulations and policies that support the human rights of MSM, improve the ability of MSM to access HIV care and treatment and enhance HIV prevention. On July 20, 2012, The Lancet released a series of articles on HIV in MSM (http://www.thelancet.com/series/hiv-in-men-who-have-sex-with-men). These articles provide further epidemiologic and social science evidence of the urgent need to scale up HIV services for MSM throughout the world.

For guidance on appropriate interventions for MSM, please refer to the PEPFAR Technical Guidance: Prevention for Men Who Have Sex with Men: http://www.pepfar.gov/guidance/combinationprevention/combprevmsm/index.htm

The limited data available on HIV among transgender people (TG) demonstrate a remarkably elevated prevalence of HIV in this population, as well as pervasive stigma, discrimination, violence, and other HIV risks. Excluded from other forms of income generation by stigma and discrimination, many transgender people engage in sex work, thereby increasing their risk for HIV acquisition and transmission. A 2008 systematic review[39] compared HIV prevalence among transgender female sex workers (TFSWs) with prevalence among transgender women who do not engage in sex work, male sex workers, and biologically female sex workers. HIV prevalence was 27.3% in TFSWs, 14.7% in transgender women not engaging in sex work, 15.1% in male sex workers, and 4.5% in female sex workers. Meta-analysis indicated that TFSWs experienced significantly higher risk for HIV infection in comparison to all other groups (relative risk [RR] = 1.46, 95% confidence interval [CI]: 1.02 to 2.09), and particularly in comparison to female sex workers (RR = 4.02, 95% CI: 1.60 to 10.11). TFSWs can benefit from targeted HIV interventions. Transgender friendly and appropriate prevention, care, and treatment services are critical to an appropriate HIV response. Given regional variability and complexity of gender identities, it is important for country teams to involve transgender community members in the design and implementation of research and services.

To understand and better respond to HIV among transgender people, countries should consider:

- Conducting rigorous assessments of TGs to identify population size, HIV prevalence and risk factors, barriers and facilitators to HIV prevention, care and treatment and other contextual factors;
- Based on assessment findings, develop and pilot strategies to prevent HIV and respond to care and treatment needs among TGs;
- Use monitoring and evaluation to determine the effectiveness and of implementing prevention and response strategies for TGs'

[39] Operario D, Soma T, Underhill K (2008) Sex work and HIV status among transgender women: Systematic review and meta-analysis. JAIDS Journal of Acquired Immune Deficiency Syndromes 48 (1):97-103

- Identify and respond to programming considerations for other key populations that are relevant for segments of TGs at highest risk (e.g., sex work, drug use, anal sex).

In general, HIV prevention activities for MSM and TG, and SW will be funded under the HVOP budget code. However, data collection and analysis may be funded under HVSI, and activities that strengthen local health systems to respond to the needs of key populations (KPs) may be funded under OHSS.

Measuring the epidemic and setting data-driven priorities

While PEPFAR support for bio-behavioral surveillance among KPs has been increasing, many countries continue to lack, and moreover, under-utilize, population enumeration and bio-behavioral data on key populations. Establishing the size of key populations allows epidemiologists to develop models which estimate and project HIV prevalence or inform countries of the distribution of HIV incidence within their country, garner political and financial support, and improve programming. Arguments to implement prevention, care and treatment programs are more compelling when good size estimates are available, however lack of such studies should not delay start up or provision of key populations services. Governments may find it politically challenging to invest in services because of the stigma toward key populations, yet serving these groups has the greatest potential for curbing the epidemic in some countries.

Too often, however, 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 ensure that study results and surveillance information become the basis for prioritizing, designing, implementing, monitoring and evaluating KP HIV prevention and care and treatment programs. For example, prevention efforts should triangulate data on population size estimates and HIV risk to prioritize populations based on their estimated contribution to new infections. Size estimates can also be used for program planning, e.g. to determine realistic targets, or the number of peer educators or volume of commodities required for a certain population. Likewise, key population program data should be used to assess up-take of HIV services such as HTC and enrolment into HIV care and treatment of HIV-positive SW, PWID, MSM and transgender persons, and inform both new data collection activities and quality improvement for programs.

Creating an enabling environment

KPs often engage in behaviors that are criminalized and highly stigmatized, creating barriers in terms of access and acceptability to initiation of and retention in HIV prevention, care and treatment services. PEPFAR country teams need to be aware of the potential for political backlash against KPs and KP-friendly program and research, and work closely with government, civil society, and the affected population for creating an enabling environment for ethical treatment of KPs. This includes 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. PEPFAR teams should encourage countries to take steps to ensure that scale-up of prevention programs for KPs is accompanied by appropriate protections of their rights through, for example, reviews of laws, policies and regulations that criminalize or deter KPs seeking services and by training service providers to reduce stigma and discrimination.

Developing capacity within countries

Many countries lack the capacity and resources to provide effective programming for KPs 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 KPs and other vulnerable populations.

- 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 KPs and other vulnerable populations (e.g. clinical training, advocacy training, quality standards training, sensitization); and
- Build capacity of civil society organizations to plan, implement, monitor and evaluate high-quality prevention programs for KPs, and to advocate for continued funding of HIV prevention for KPs.

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

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, although targeted, scale up of comprehensive, high-quality prevention, care and treatment programs for KPs, to ensure adequate coverage, intensity, and scale to impact the HIV epidemic.

- Define interventions or packages of interventions that could be taken to scale for each key sub-population;
- Ensure establishment of strong linkages between community- and facility-based KP services, contributing to increased HIV service up-take and enrolment of HIV-positive KP members into HIV care and treatment services; and
- Develop a common set of indicators to monitor programs; consider collaborating with other donors on indicators required by their programs so as to reduce the reporting burden.

Establishing quality assurance (QA), monitoring

To ensure high quality prevention programs for KPs, countries should develop quality assurance and monitoring and evaluation plans. Currently PEPFAR HQ is developing quality assurance standards and associated assessment tools and M&E plan for peer education and outreach programs that target SW, PWID, and MSM[40]. Assistance is available on developing QA standards through PEPFAR HQ.

- Develop a set of core competencies and minimum standards, as well as a system of oversight and supportive supervision, to monitor, assure, and improve programs;
- Share quality program tools, curricula, and models from successfully implemented programs;
- Develop meaningful program-level indicators that assess the mix and quality of prevention approaches (e.g., intensity, scale, and coverage).
- Collaborate with Global Fund to ensure quality monitoring of all programs;
- Monitor KP service up-take and linkages into HIV Care and Treatment.

[40] An example of quality monitoring standards for KP programs can be found here: http://nascop.or.ke/library/Marps/Standards_for_Peer_Education_and_Outreach_Program_for_Sex_Workers.pdf.

(b) Planning a Portfolio: Generalized Epidemics

Country contextual considerations

Key Populations. Prevention programming in generalized settings still requires assessing and addressing the needs of key populations in the general population, as HIV among key populations is typically disproportionately high even in generalized epidemics. The balance of focus on key populations and at-risk sub populations of the general population in these epidemics will often vary within different regions of a country, depending on the prevalence in different regions as well as the composition and size of different key populations. The balance of general population approaches versus key population approaches in these epidemics should be determined at the country level.

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.

Pressure for parity. Many national governments are under political pressure to expand HIV prevention services for the sake of equity across regions or populations. While these pressures are real, and must be taken into account, PEPFAR teams should budget and program on the basis of epidemiology, targeting the majority of resources to those regions and populations in greatest need. Teams should engage U.S. Embassy staff for assistance in negotiating these issues.

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 epidemiology. 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 youth should not absorb so much of the prevention investment that at-risk adult populations are left uncovered. The youth-adult balance should reflect age-specific HIV incidence patterns at the country-level, or where not available, age-specific HIV prevalence patterns.

Programming for social and behavior change (SBCC)

Addressing behavior is integral to every dimension of the country prevention effort. Explicitly addressing relevant behavioral factors should be a part of all prevention interventions, including biomedical ones. To be effective, these behavior change components should be strategically designed, implemented and evaluated based on a proven process[41]. The 2011 PEPFAR Guidance for the Prevention of Sexually Transmitted HIV Infections recognizes two categories of SBCC programming. The first are standalone programs to minimize risk or increase protection. Additional evidence is needed for these programs and thus they should always be implemented as pilots, with a full impact evaluation as outlined in the COP guidance. The second are supportive behavioral interventions to optimize biomedical prevention. This category should be an essential part of every prevention portfolio.

SBCC programs should incorporate the following best practices:

[41] Noar, S. 2008. Behavioral interventions to reduce HIV-related sexual risk behavior: Review and synthesis of meta-analytic evidence. AIDS and Behavior 12: 1090-7165.

- **Support biomedical interventions relevant to the population and setting.** While promoting risk reduction, SBCC programs need to create demand for HTC, VMMC, and PMTCT and 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;
- **Base program design and evaluation on theory.** Behavioral theories offer explanations of how behavior change occurs and describe a variety of factors that may influence behavior[42]. Understanding how to address and measure these factors, or behavioral determinants, is the key to effective SBCC;
- **Link activities to clear behavior change objectives.** Activities should be selected based on the behavioral determinants to provide individuals with the relevant motivation, attitudes, and skills needed to overcome barriers and adopt safer behaviors. Focusing solely on knowledge or HIV awareness is insufficient;
- **Address social and gender norms.** PEPFAR teams should identify opportunities to address social and gender norms and other elements of the social, cultural, and community environment that influence individuals' abilities to engage in safer behaviors and uptake of services. PEPFAR-funded programs should include strategies to empower women and engage men to promote positive norms and behaviors. In addition to the direct beneficiaries of intervention efforts, influencing audiences should also be considered; efforts to engage leaders, peers, family members, local organizations, and the media may be essential to facilitate the widespread adoption and maintenance of healthy behaviors;
- **Engage faith and traditional leaders.** Where possible, PEPFAR teams should proactively engage religious and traditional leaders in designing and delivering contextually appropriate prevention programs. Faith and community leaders can be essential actors in reducing stigma; setting norms and values; and increasing utilization of services;
- **Address structural barriers to prevention.** Combination prevention should not only focus on individual susceptibility and risk but also on societal and economic factors that affect individual risk and vulnerability. Structural interventions may include: policy work with government and civil society to reduce discrimination; actions to make school environments safer for girls and improve educational opportunities; and advocacy to increase property and other legal rights for women and create economic opportunities. 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 extend beyond single contacts with intended audiences, to support an ongoing systematic approach that delivers results 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, tailor the prevention programs.** Activities should be designed around available information about the needs of intended audiences, the factors that expose them to HIV risk, and the context in which they live. Where such information is not available, activities should include a formative assessment as part of the process.

[42] Noar, S.M. 2007. An interventionist's guide to AIDS behavioral theories. AIDS Care 19: 392-402.

Linkages and wraparounds

Recently, there has been increased recognition of the need to integrate and strengthen prevention interventions across a wider range of other HIV and health services (e.g., PMTCT, care, PwP, ART, TB/HIV, HTC, STI, VMMC, RH, FP, and Orphans and Vulnerable Children [OVC]). The following are important considerations in developing these linkages and wraparounds:

- HIV care and treatment, as well as PMTCT 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 PLHIV, including intensifying and tailoring risk reduction counseling and condom promotion, and screening and referrals for gender-based violence[43]. 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, especially those in key populations, stay HIV-free;
- Integrating risk reduction counseling and HTC into RH and FP 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; and
- 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 models to systematically integrate behavioral prevention within these other technical services. Linkages should be considered with other development areas such as education, agriculture, democracy and governance, and through public private partnerships.

Quality assurance, monitoring, and evaluation

Initiating and maintaining quality in prevention programs for large populations can be challenging. Interventions that target individuals or small groups can vary greatly from one educator to another, while evaluating the impact of distal mass media interventions can be difficult. For this reason, it is critical that PEPFAR programs choose evidence-based interventions and bring them to scale with well-designed quality assurance and M&E plans. These plans should:

- Select, develop and/or adapt curricula and materials that are appropriate for the context, risk factors, and intervention type;
- Conduct formative assessments to improve the design, implementation, revision, messaging, focus and relevance of prevention programming;
- Establish appropriate selection criteria for peer and/or other educators;
- Use relevant measures of success and a feedback for program monitoring and a monitoring loop for mid-course correction and continuous quality improvement;
- Utilize mentoring and supportive supervision approaches;
- 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);

[43] See also Technical Considerations for Prevention with People Living with HIV.

- Develop meaningful program-level indicators to reflect the optimal mix and quality of prevention approaches (e.g., dose, intensity, multi-level strategies);
- Build into the program evaluation that compares outcomes of the program with a control group or community, and measures impact on uptake of services and adherence to care regimens alongside self-reported changes in behavior.
- Develop a data use and dissemination plan at the beginning of a project; and
- Strengthen the capacity of PEPFAR prevention staff, including strong technical expertise 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 and activities are of high quality.

(c) Planning a Portfolio: Mixed Epidemics

Prevention programming in mixed epidemics requires significant attention to both key 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 key populations and at-risk sub populations of the general population in these epidemics will often vary within different regions of a country, depending on the prevalence in different regions as well as the composition and size of different key populations. For this reason, it is essential to know the impacted groups, the geographic variance among these groups, and the key risk factors for HIV transmission in each group. Attention should be paid to increasing HIV service up-take and successful enrolment of HIV-positive persons from the priority groups in each country into HIV care and treatment services. The balance of general population approaches versus key population approaches in these epidemics should be determined at the country level. Countries should use the best available country and sub-national data to ensure that key populations are reached at adequate scale, while not neglecting a focus on general population approaches in the highest prevalence regions.

1.2.6 Comprehensive HIV Prevention Packages

Robust HIV prevention programs deliver a minimum package of interventions to each individual or community. This package should be tailored to the specific context and needs of the population and will vary depending on a number of factors, including the nature of the risk behavior and context, the size of the population, the HIV prevalence in that population, and whether the population is stigmatized. Historically, PEPFAR has broadly defined three populations as targets of HIV prevention efforts – most-at-risk or key populations, adults in generalized epidemics and youth in generalized epidemics. The following provides more detail on comprehensive packages for these populations.

(a) Prevention Packages for Key Populations

KPs are persons who are affected by punitive laws, regulations and policies, stigmatized and marginalized, and disproportionately affected by HIV. This includes MSM and transgender persons, PWID, and male and female sex workers (M/FSWs). Studies show that HIV disproportionately impacts key populations in low and middle income countries in all regions of

the world, including those with generalized epidemics, but that only a small proportion of these populations have access to HIV prevention services.

There is substantial evidence for the effectiveness of a core set of interventions that comprise a package of services for KPs. Programs should ensure participation of the target KPs or other vulnerable groups in the development, implementation, and monitoring of prevention programs. Based on the epidemiologic profile for each country, the team should deliver a minimum, core set of interventions which consider the sex- and age-specific needs of different sub-groups especially vulnerable to HIV or with disproportionately low access to programs. **Prevention packages for KPs can be funded under the HVOP budget code and achievements in delivering the entire package tracked under NGI P8.3.D.**

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 provisioning of supplies (e.g. condoms, referral to medication assisted therapy) it is especially effective in reducing sexual and/or drug-using risk behaviors[44].

Sexual and drug use assessment and risk reduction counseling: Taking a sexual and drug using history ensures that service providers know and do not assume the needs of their clients. Service providers should consider this a standard part of care and routinize it as people enter and exit risk stages throughout their lives. Risk reduction counseling is an effective intervention for KPs, whether delivered through peer outreach or in clinic settings and can address both drug and sexual risk behaviors, as appropriate. Meta analyses show that risk reduction counseling can have a positive impact on sexual risk behaviors of persons who inject drugs[45]; however, the effect may decrease over time[46], indicating that these behaviors may need to be more intensively targeted and may 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, SW, and PWID and their sex partners. 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. At this time, water- and silicon-based lubricants may offer increased protection. Packaging and marketed use of lubricant is also important.

HIV testing and counseling (HTC): Innovative and tailored models for delivering HIV testing to KPs are needed (e.g., mobile services, home-based testing). Special consideration should be given to different testing models including voluntary, provider-initiated, and couples and partner

[44] 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.

[45] 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.

[46] 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.

testing. Use of rapid test kits with same day results paired with post-test counseling is recommended for KPs. Venous blood draws should be avoided as a potential access barrier due to concern for vein collapse.

Sexually Transmitted Infections (STI) screening and treatment: Existence of an STI may facilitate sexual transmission and acquisition of HIV [47]. Routine STI assessment and treatment should be an integral component of KP package of services. Approaches to STI control for KPs (especially for SW and MSM) 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 useful in attracting KPs into services/programs, providing an opportunity to reach KPs with other HIV prevention services. Programs should consider integrating STI screening and treatment into HIV care settings and into existing prevention programs for KPs and other vulnerable populations.

Referrals to 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[48]. UNAIDS/WHO normative guidance (2007) states that VMMC should be recognized as an additional important intervention to reduce the risk of male heterosexually acquired HIV infection. Referrals to VMMC should be made as part of a comprehensive HIV prevention package for clients of FSW and other males at high risk of HIV acquisition from their female partners. To date, evidence for VMMC in reducing the risk of HIV acquisition among MSM is inconclusive[49].

Referrals to HIV care and treatment, including PMTCT: Initiation of ART at the earliest possible point is a critical intervention for KPs. PEPFAR teams working in concentrated epidemics should encourage national policies of initiating treatment at higher CD4 cell counts and actively support treatment programs that are designed with KPs in mind. SW and MSM should be rapidly linked to friendly ART services upon diagnosis with HIV, and KP programs should include support for adherence and retention designed around the needs of these populations. Good treatment adherence has been demonstrated among KPs when approaches are implemented to facilitate access and acceptability. Innovative approaches to increasing successful linkage into PMTCT, care and treatment services should be explored and evaluated. All KP programs need to ensure adequate monitoring of linkages to services. Prevention programs for KP need to link up and help facilitate training for clinical PMTCT and ART service providers to make existing services 'key population friendly' and accessible.

Programs can consider the use of internet-based and mobile texting technologies. A Cochrane review in Kenya found mobile phone text messaging at weekly intervals is efficacious in enhancing adherence to ART (improving HIV viral load suppression) compared to standard of care. This might be effectively replicated among KPs to improve ART adherence and continued engagement in other services.

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[47] Cohen, M.S. 2012. Classical sexually transmitted diseases drive the spread of HIV-1: Back to the future. Journal of Infectious Diseases 206: 1-2.

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

[49] Wiysonge Charles, S., J. Kongnyuy Eugene, M. Shey, S. Muula Adamson, B. Navti Osric, A. Akl Elie and Y.-R. Lo. 2011. Male circumcision for prevention of homosexual acquisition of HIV in men. Cochrane Database of Systematic Reviews (no. 6): http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD007496/frame.html

Referrals to substance use treatment: Substance use treatment reduces the frequency of drug use, which in turn reduces HIV risk behaviors[50]. It also improves adherence to disease treatment regimens[51]. Treatment modalities include non-pharmacological and pharmacological approaches; often, a combination of the two is used.[52] Medication assisted therapy (MAT) reduces the frequency of heroin injection and improves substance use treatment retention[53]. 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 exchanges of sex for drugs or money[54].

Prevention, diagnosis and treatment of tuberculosis: Drug use is associated with increased rates of TB infection and disease and is a leading cause of mortality among PLHIV. MSM, Transgender people and SW may also experience exposure to the disease due to incarceration, poor living conditions and poverty. WHO recommends the three 'I's for TB/HIV including: isoniazid preventive therapy, intensified case finding for TB, and infection control, to reduce the burden of TB among PLHIV[55].

Linkages to other health, social, and legal services: KPs 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 KPs for post-exposure prophylaxis (PEP) due to increased risk of condom breakage and/or sexual violence.

Service delivery models (e.g., 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 KPs. The country team is encouraged to incorporate tailored or innovative approaches that are likely to increase access and remove barriers to services for these populations. Use of qualitative methods to guide these adaptations is an effective strategy. Most KP programs institute referrals, but often referrals made are not documented or followed up to determine successful linkages or enrollment.

(b) Prevention Packages for the General Population

In countries where HIV transmission is self-sustaining outside of KPs, high rates of infection occur throughout the adult population. However, even in generalized epidemics, HIV burden is typically unevenly distributed, with certain sub-populations having very high prevalence. One distinguishing factor between these sub-populations at higher risk and key populations is that the former do not experience the same levels of stigma and discrimination or experience the same types of barriers to accessing health and HIV services encountered by KPs.

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[50] 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.

[51] IBID

[52] 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.

[53] 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;

[54] IBID

[55] WHO (2009). TB/HIV Facts

In generalized epidemics, **e**ffective prevention portfolios should primarily focus on those sub-sets of the general population that are at increased risk, delivering a comprehensive package of prevention interventions tailored for the specific needs of each sub-population. While interventions should be targeted and tailored, there is also a need to address community-level and socio-cultural norms. The comprehensive package should comprise many of the same elements as the package for KPs, as appropriate and tailored to the population. In most cases, assessing HIV risk, education about HIV prevention strategies, development of skills to support safer behaviors, condom promotion and distribution, and referral to HTC and to high impact clinical services will be appropriate. In general, drug use assessment, provision of lubricants, STI screening and treatment, and referrals to substance abuse treatment will not be appropriate for the general population. However, PEPFAR teams should be guided by the epidemiology and context of their epidemic in choosing which components to include.

Comprehensive packages for sub-populations in generalized epidemics should be funded jointly under the HVAB and HVOP budget codes. Budgets for programs broadly addressing the general population should also combine HVAB and HVOP funds to support a comprehensive approach to sexual prevention, unless programs are targeting young children.

Critical steps for the prevention packages for the general population include:

- Gather data on the size of each population to be reached and set targets with a goal of reaching sufficient coverage to impact incidence;
- Develop and implement the package of services for each specific population;
- Institute effective linkages between service components that are not co-located;
- Closely monitor referral, linkage and retention;
- Identify areas where technical assistance is needed in implementing comprehensive services; and
- Explore new delivery approaches that effectively reach persons not currently accessing services.

Programming for Adults

In addition to scaling up comprehensive packages for populations with high prevalence, programs 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 VMMC, particularly where national policies support VMMC scale-up;
- Foster culturally appropriate and positive gender 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 HIV 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;
- Combat stigma and the effects of stigma on HIV risk behaviors.

Programming for youth

All young people need broad education about sex, sexuality and reproductive health, including HIV/AIDS. For vulnerable youth, specific HIV prevention needs must be addressed as well. The definition of "youth" remains a challenge, since it can range from 15-34 years, depending on the country. PEPFAR teams should utilize (and explain) country-specific definitions of youth, while recognizing that significant sub-population differences and needs exist between the various age groups within the youth category. In sub-Saharan Africa, many countries with large HIV epidemics also have especially youthful populations, with more than 50% of the citizenry under the age of 18. In these countries, it is especially critical that PEPFAR work with partner governments and other stakeholders to provide strong HIV prevention programs for at-risk young people.

As with other sub-populations, various approaches are needed to address different segments of youth[56]. School education programs should include evidence-based components on preventing sexually transmitted diseases, including HIV, linked to health education. Efforts should be made to utilize curricula and materials that have proven effective in changing youth behaviors in other, similar settings[57,58]. Specific attention should be given to improving 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 HIV education programs in schools.

Approaches shown to be effective include:

- Tailoring programming for sexually active and most-at-risk youth based on patterns of behavior and their needs;
- Developing skills and norms to promote 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;
- Engaging influential adults within the community to create an enabling environment conducive to the adoption of safer sex behaviors among youth;
- Encourage sexually-active youth to learn their HIV status, provide or refer to confidential youth HTC, and ensure linkages to care and treatment for HIV positive youth;
- 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;

[56] Kirby, D.B., B.A. Laris and L.A. Rolleri. 2007. Sex and HIV Education Programs: Their Impact on Sexual Behaviors of Young People Throughout the World. Journal of Adolescent Health 40: 206-17.
[57] Ecker N, Kirby D (2009). International Guidelines on Sexuality Education: An Evidence Informed Approach to Effective Sex, Relationships and HIV/STI Education. UNESCO - United Nations Educational, Scientific and Cultural Organization, Paris.
[58] Napierala Mavedzenge SM, Doyle AM, Ross DA (2011). HIV Prevention in young people in sub-Saharan Africa: a systematic review. J Adolesc Health. Dec; 49(6): 568-86.

- Support youth-oriented, mass-media and "edu-tainment" programs that encourage youth to think critically about HIV and 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; and
- For young members of key populations, comprehensive packages of interventions with the same core components as those for older members, but tailored to be accessible and acceptable to younger people.

In other contexts, interventions might include work with communities, faith-based organizations and traditional leaders, as well as structural interventions to reduce young people's exposure to risk and increase protection.

Better data on the impact of programs for youth is needed. PEPFAR teams should consider funding impact evaluations through the COP of their youth programs.

Adolescent Girls and Young Women in Generalized Epidemics

In Southern Africa, prevalence among young women aged 15–24 years is on average three times higher than among men of the same age (UNAIDS 2010). This disparity may arise from among other issues, systematic disadvantages faced by adolescent girls and young women. In these countries, PEPFAR programs should fund evidenced-based activities that empower adolescent and pre-adolescent girls by fostering and strengthening their social networks, educational opportunities, and economic assets.

PEPFAR programs should also address the men that girls and young women engage in sexual activity with – whether voluntarily or not – through programs that address harmful gender norms, provide HIV prevention, and link male PLHIV with services. At the same time, clinical partners must develop and strengthen innovative platforms that make HIV care and treatment services accessible and acceptable to girls and young women living with HIV and their sexual partners. At a policy level, PEPFAR leadership in country should reach out to other stakeholders to develop longer-term plans for addressing the needs of adolescent girls and young women, mindful that population trends across this region suggest continued growth of this cohort over the next 30 years[59].

Where appropriate, PEPFAR programs should consider the following activities to improve programming addressing at-risk girls and young women:

- Strengthen surveillance efforts both to ensure that adolescent girls and young women are being adequately represented in samples, and that the reasons for their higher risk are well understood in the country context;
- To the extent feasible, disaggregate data by sex and age to allow for tracking of service uptake and provision to adolescent girls and young women;
- Staff working on OVC, Prevention, and Gender issues should work together, and with other stakeholders as appropriate, to ensure that programs complement each other and work in a coordinated way to address the various causes of HIV among adolescent girls and young women;

[59] United Nations, World Population Prospects: the 2010 Revision

- Partners providing pediatric and adult treatment and care, as well as PMTCT, should adapt best practices in youth-friendly reproductive care;
- Where gender-based violence (GBV) prevention and response is being addressed in the context of PEPFAR programs, particularly countries receiving additional central funds through either the GBV Response Scale Up or the Gender Challenge Fund, special consideration should be given, in cooperation with both the OVC and Prevention portfolios, to meeting the needs of adolescent girls and young women;
- Examples of actions that can be implemented in a coordinated manner include:
    - Support positive youth development through peer networks and mentorship programs in elementary and secondary schools and for out of school youth;
    - Develop specific programming for out-of-school adolescent and pre-adolescents, including males and married adolescent girls;
    - 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;
    - Support interventions to prevent and respond to sexual abuse and coercion of minors;
    - Target highly effective prevention interventions, such as VMMC, to sexual partners of girls;
    - Work with male teachers and other male authority figures in the lives of girls, who may engage in sexual activity with them.

Transactional Sex

The exchange of sex primarily motivated by material gain (i.e., the provision of food, clothes, cash, etc) is associated with increased risk of contracting and transmitting HIV[60, 61]. 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.

There is limited evidence for interventions that claim to reduce levels of transactional sex, though cash transfers and other economic strengthening activities are promising[62]. A study that provided cash transfers to vulnerable girls in Zomba, Malawi found delayed onset of sexual debut and reductions in early marriage and pregnancy[63], but this study needs validation in several other contexts before being brought to scale. Interventions that seek to reduce transactional sex are good candidates for impact evaluation through the COP, and PEPFAR teams are encouraged to reach out through their CSTLs to the General Population and Youth TWG to work jointly on such a proposal.

[60] Jewkes R, Dunkle K, Nduna M, Shai NJ (2012) Transactional Sex and HIV Incidence in a Cohort of Young Women in the Stepping Stones Trial. J AIDS Clinic Res 3:158.
[61] Baral S, Burrell E, Scheibe A, Brown B, Beyrer C, Bekker L-G (2011) HIV Risk and Associations of HIV Infection among men who have sex with men in Peri-Urban Cape Town, South Africa. BMC Public Health 11:766.
[62] Pettifor A, MacPhail C, Nguyen N, Rosenburg M (2012). Can Money Prevent the Spread of HIV? A Review of Cash Payments for HIV Prevention?. AIDS and Behavior Oct;16(7):1729-38.
[63] Baird S, Chirwa E, McIntosh C, Ozler B (2010). The short-term impacts of a schooling conditional cash transfer program on the sexual behavior of young women. Health Economics 19(1) 55-68.

Programming for Military Personnel, National Police, Wildlife Officials and other Federal and State Forces

The military is generally made up of young, mobile, men with money, although increasingly, women as well. 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. While prevention 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. Development, adoption, and implementation of a military HIV policy are foundational for a comprehensive approach to prevention, 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: HTC, VMMC, condom promotion and distribution, peer prevention programs, prevention for PLHIV, leadership training, programs to address male norms, family outreach including spouse support groups, STI diagnosis and treatment, and alcohol use reduction programs.

1.2.7 Male and Female Condoms for HIV Prevention

Condom use is a critical element in a comprehensive, effective, and sustainable approach to HIV across the continuum of response and all types of HIV epidemics. Condom distribution and promotion should be a key component of all packages of interventions for all populations, where appropriate.

PEPFAR programs should assist countries in articulating a strategy for condom programming that addresses key *supply* and *demand* issues related to increasing condom use. In PEPFAR programs, both male and female condoms should be made broadly available in accordance with the market preferences of target populations. PEPFAR country programs should assist in assessing the relevant target populations that need to be reached with condom programming, and then assess how different market actors can contribute to provision of condoms for these target populations.

Condom programming should engage the public, social marketing, and private sectors in condom distribution and promotion and should include a plan for increasing sustainability of condom programming. Social marketing programs should provide subsidized and marketed commodities to poor and vulnerable populations where the private sector does not supply these commodities. “Free” public sector condoms should primarily be distributed to population segments lacking disposable income and/or those most at risk of HIV transmission or acquisition.

PEPFAR country programs should emphasize sustainability in condom programming. For example, PEPFAR programs may want to adopt a phased process of gradually increasing cost recovery for social marketing products while simultaneously working with the private sector to improve overall demand for condoms.

Essential to ensuring a steady supply of male and female condoms is improving national commodity forecasting and procurement planning. PEPFAR teams should work closely with national governments to enable them to accurately forecast their needs for male and female

condoms, funding technical assistance in this area when necessary. When condom stockouts or shortages occur in a country, PEPFAR teams are encouraged to fill any gap through an emergency order submitted to USAID's Central Contraceptive Procurement (CCP) project. At the same time that an emergency shipment is processed, PEPFAR country programs should identify the causes of the gaps that occurred and work with national counterparts to devise solutions to prevent similar gaps in the future.

PEPFAR country programs should include programs to create demand for condom utilization, as program experience has demonstrated that these can increase condom sales and utilization. Programs should ensure that high-quality condoms are available and that consumers express a desire/preference for the type of condoms offered. Social marketing programs may want to offer a variety of types of condoms or 'brand extensions.' Programs should also explore a variety of price points for these different options, in line with their overall strategy and total market approach. The experience of contraceptive social marketing suggests that offering a variety of different, but similar, products at different price points will often increase overall demand for a particular prevention method.

In addition, to successfully generate demand for condoms, programs should design behavior change communication and social marketing campaigns based on evidence-based theories relevant to a given setting and target population. For demand creation among sub-groups, programs may utilize a variety of formats from individual to peer to community behavior change interventions. In general, multiple channels can be deployed to ensure that all people receive accurate, culture- and age-appropriate information about condoms and motivational messaging to utilize condoms.

Female condom promotional efforts should be part of an overall condom strategy that takes into account the broader condom market in country and that considers the unique product attributes of the female condom for various populations. Decisions about the volume of female condoms to be purchased and marketed in all epidemics should be based upon the perceived need to expand prevention methods for women, consumer and stakeholder feedback, in-country market analyses, and considerations of planning for sustainable condom programming over the long-term.

In concentrated epidemics, PEPFAR teams should focus female condom programming on female SW and if relevant, on MSM and women who inject drugs. One of the key barriers to effective female condom programming is the capacity of service providers to adequately provide information on female condom attributes and utilization. PEPFAR country programs in concentrated epidemics that distribute the female condom should increase awareness about female condoms among peer educators and sexual and reproductive health service providers. Providing client counseling that includes a demonstration of how to insert the female condom, as well as a discussion of effective strategies for negotiating female condom use, is more likely to result in the adoption and correct use of the method. Also, providers and peer educators require the tools necessary to support successful female condom promotion, such as pelvic models and information, education, and communication materials produced in local languages.

In generalized and mixed epidemics, PEPFAR programs and partners should take special care in marketing female and male condoms so that they do not become exclusively associated with KP and take on a stigmatized status.

1.3: BIOMEDICAL PREVENTION

1.3.1 BLOOD SAFETY

1.3.1.1 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 PEPFAR's global HIV prevention strategy. Assistance has been provided to strengthen or in some cases develop national blood transfusion services, especially in countries with high burdens of malaria and maternal mortality. In sub-Saharan Africa, it is estimated that pediatric malaria-associated complications account 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 availability, 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, HBV and HCV 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 systems and good laboratory practices:

1. *Policy:* the development of a national blood policy and enactment of supporting legislation;
2. *Donation:* the collection of blood from regular, low risk, voluntary, and non-remunerated donors;
3. *Laboratory:*
    a. Documented effective and universal screening for HIV, HBV and HCV viruses and syphilis
    b. Documented quality typing and crossmatching
    c. Documented, appropriate storage, processing, and distribution of blood and blood products from vein to vein;
4. *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;

5. *Training:* pre-service**,** in-service and continuing medical training on blood services for involved personnel;
6. *Monitoring and evaluation:* to measure their progress toward implementing the WHO recommendations; and
7. *Sustainability:* to ensure continuity after PEPFAR's support, including the appropriate, accurate, and efficient costing of blood and blood products.

Core strategies for PEPFAR programs to support blood safety:

- Support well-organized and coordinated blood safety activities through a central entity (e.g. Ministry of Health, National Blood Transfusion Service [NBTS]) 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) that leads to:
  -
- 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 and Health Systems Strengthening Technical Working Groups 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 and 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.

1.3.1.2 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 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 are critical. 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. Strong 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 that maintains 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;

- *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. Assessments should focus on quantifying the adequate blood collection targets on a country-specific basis.

1.3.1.3 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 MCH.

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, versus relying on families or friends to locate suitable donors of the correct blood type at the time blood is needed or to maintain a sufficient inventory. 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 should emphasize the importance of self exclusion. It is important for blood transfusion systems and 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 key populations) to encourage individuals who test negative to consider becoming regular donors. 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 for HIV when screened be appropriately counseled and referred for confirmation and appropriate medical management, including Positive Health, Dignity, and Prevention programs (also known as Prevention with Positives) 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.

1.3.2 INJECTION SAFETY

1.3.2.1 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 of 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 to help ensure adequate safe injection supplies (e.g., safety/single use needles and syringes, evacuated blood collection supplies for phlebotomy, lancets, safety boxes for sharps);
- 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, including training and equipping waste handlers.

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 preserving human resources. Injection safety programs have also 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.

It is expected that, at minimum, PEPFAR-funded implementing partners ensure appropriate injection safety and waste management practices within their existing programs. These include:

- Incorporate and integrate injection safety principles, practices and commodities into all health care delivery, 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); and
- Ensure activities are consistent with national plans and policies regarding injection safety.

Training and capacity building

- Ensure that all HCW 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, PEP starter packs are available to all HCW during their clinical duties, including those in remote areas;
- Ensure that training schools incorporate injection safety/standard 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 and safe phlebotomy supplies is sustainable by partner country; and
- Factor costs of single-dose vials/diluents as well as sharps containers and other waste management commodities into overall costs of commodities prior to procurement.

Behavior change and advocacy

- Promote 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 to the community as well as public and private health care sectors as appropriate.

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:

Scale up of HIV/AIDS-related medical interventions, such as monitoring of CD4/CD8 counts and viral loads related to ART, HTC, VMMC, and PMTCT, is increasing the volume of medical waste (including pharmaceutical) and HIV-contaminated sharps generated in health care settings. This is creating a burden on already strained or inadequate waste management systems.

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

1.3.2.2 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 HIV epidemiology. 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, and 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.

1.3.2.3 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, safely, and ideally nationwide. Among the programs where injection safety needs to be applied are HIV care and treatment, PMTCT, VMMC, HTC, laboratory services and blood safety. While injections and blood drawing (and related waste management needs), as well as the need for occupational 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/necessary injections, infection prevention/control activities, and appropriate waste management. These considerations exist 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.

1.3.3 INJECTING AND NON-INJECTING DRUG USE

1.3.3.1 Background

The use 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, their quantity and pattern, as well route of administration, are important in determining impact on high risk behaviors for HIV infection and strategies to respond.

The total worldwide population of PWID is estimated to be 13.2 million[64]. PWID are at risk for viral hepatitis, HIV, STIs, and TB infections. UNAIDS, WHO, and UNODC estimate that between 5-10 percent (2-4 million cases) of all HIV infections globally are attributable to injection drug use[65]. It is estimated that there are over 5 million PWID in 13 PEPFAR bilaterally-supported countries with drug-driven or emerging HIV epidemics[66]. Within these 13 countries, an estimated 0.8 million PWID are HIV-positive. Also of note is the estimate that in some PEPFAR countries, as many as 30 percent of PWID are female. Recently emerging twin epidemics of both injecting drug use and HIV infection among PWID are present in sub-Saharan Africa.[67,68]

Male and female PWID are not only at risk for acquiring and transmitting HIV through the sharing of drug injection equipment, but also through high-risk sexual behaviors, including unprotected sex and engaging in sexual behaviors under the influence of drugs or in exchange for drugs[69]. This vulnerability underscores the need for responsive programming that better meets the specific needs of both males and females who use drugs. As described in the authorization language for PEPFAR, countries are asked to include HIV/AIDS prevention activities that focus

[64] Aceijas, C., et al. (2004). Global overview of injecting drug use and HIV infection among injecting drug users. *AIDS*, 18: 2295-2303.
[65] UNODC. (2005). *World Drug Report 2005*. Geneva, Switzerland.
[66] The thirteen countries referenced here are: Cambodia, China, Indonesia, Vietnam, Georgia, Kazakhstan, Kyrgyzstan, Russia, Tajikistan, Ukraine, Kenya, Tanzania, and South Africa
[67] Needle, R., & Kroeger, K., et al. (2006). Substance abuse and HIV in sub-Saharan Africa: introduction to the special issue. *African Journal of Drug & Alcohol Studies,* 5(2), 83-91.
[68] Reid, S. (2009). Injection drug use, unsafe medical injections, and HIV in Africa: a systematic review. *Harm Reduction Journal*, 6(24).
[69] 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.

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."

In July 2010, PEPFAR released technical guidance entitled "Comprehensive HIV Prevention for People Who Inject Drugs." This document should guide all PEPFAR prevention programs for PWID and can be found at http://www.pepfar.gov/documents/organization/144970.pdf.

1.3.3.2 Country Contextual Considerations: Injecting and Non-Injecting Drug Use

Identifying and reaching PWUD is important in countries where drug use and HIV risk have been documented. Size estimation, behavioral assessments and other data collection strategies should be used to identify the country and regional-level context. This includes types of drugs used, consumption methods, networking and bridging patterns among PWUD, injection and sexual risk behaviors, access to HIV and other health services, and variations between age and sex groups. 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.

1.3.3.4 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 PWUD 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.

1.3.3.5 Linkages and Wraparounds: Injecting and Non-Injecting Drug Use

Biomedical interventions for PWUD 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, HTC, STI screening and treatment, VMMC, and FP and RH services. A comprehensive approach targeted towards drug-using populations includes linkages to HIV care and treatment, PMTCT, TB/HIV, OVC, and Positive Health, Dignity and Prevention (PHDP or PwP) services.

1.3.4 VOLUNTARY MEDICAL MALE CIRCUMCISION (VMMC)

1.3.4.1 Background

Three randomized controlled trials (RCT) demonstrated that VMMC reduces men‘s risk of HIV acquisition by approximately 60 percent, making it one of the most effective HIV prevention interventions known.[70, 71, 72] Extended follow-up of participants in the Uganda and Kenya RCTs through 60-66 months post-trial indicated that the protective effect increased to 65-68 %, respectively.[73, 74] WHO/UNAIDS issued normative guidance in March 2007, recognizing that VMMC is an additional important intervention to reduce the risk of male heterosexually acquired HIV infection and that VMMC should always be implemented as part of a comprehensive HIV prevention package.[75] This package includes the provision of HTC services; treatment for STIs; 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. PEPFAR continues to look 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.

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[70] 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.

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

[72] 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.

[73] Mehta S, Li H, Moses S, et al. The efficacy of medical male circumcision against HIV acquisition at 66 months post-randomization in Kisumu, Kenya. Presented at XIX International AIDS Conference, August 2012, Washington DC.

[74] 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

[75] World Health Organization, Joint United Nations Programme on HIV/AIDS. 2007. New data on male circumcision and HIV prevention: policy and program implications. Available at http://libdoc.who.int/publications/2007/9789241595988_end.pdf.

In response to the normative guidance provided by WHO, PEPFAR, under the direction of the VMMC Technical Working Group, has become one of the major supporters of VMMC as a component of a comprehensive HIV prevention program in 14 priority countries sub-Saharan Africa. In addition to the RTCs, mathematical models predict that the HIV prevention benefits of VMMC are likely to be large in populations with high HIV prevalence and low VMMC prevalence, with one HIV infection averted by 2025 for every 4 to 44 VMMC performed in a rapid scale-up scenario[76]. As uptake of VMMC 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, and this indirect protection increases in relation to breadth of coverage and the speed at which coverage is achieved[77]. Thus, faster initial scale-up is more cost effective than slower scale-up, as the indirect effects accrued earlier equate to more infections averted at a lower cost per infection averted[78]. Additional benefits for women include a decreased risk of HPV and cervical cancer among female sexual partners of circumcised males[79, 80].

PEPFAR supports a two-prong VMMC implementation strategy. The first is a "catch up" phase that reaches older adolescents and men, that can be completed in a relatively short period of time, and that does not require a sustainable system over decades. A focus on the first prong on males who are or soon will be sexually active will allow a more immediate impact on HIV incidence. The second prong integrates infant VMMC into the antenatal care system as a sustainable program.

Given the benefits of rapid scale-up, prong one – the immediate service availability for adolescents and adults – should be supported through rapidly deployable and high-volume service sites. Such services can be provided as self-contained (in a tent or other temporary structure), time-limited, fully equipped, independently staffed, and in relatively mobile settings. Other versions of this approach include those that are more reliant on local staffing and resources. For all rapid scale-up approaches, PEPFAR should work in coordination with partner country governments to support a coherent plan with quantifiable goals. WHO published "Considerations for Implementing Models for Optimized Volume and Efficiency (MOVE) of Male Circumcision Services for HIV Prevention" in early 2010, based upon observations of a highly efficient service delivery model in Orange Farm, South Africa, funded by the French government[81]. PEPFAR programs are strongly encouraged to adopt as many of the

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76 Njeuhmeli E, Forsythe S, Reed J, Opuni M, Bollinger L, et al. (2011) Voluntary medical male circumcision: modeling the impact and cost of expanding male circumcision for HIV prevention in eastern and southern Africa. PLoS Med 8: e1001132. doi:10.1371/journal.pmed.1001132

77 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

78 Njeuhmeli et al. 2011

79 Wawer MJ, Tobian AA, Kigozi G, et al. Effects of circumcision of HIV-negative men on transmission of human papillomavirus to HIV-negative women: a randomized trial in Rakai, Uganda. Lancet, 2011;377:209-218.

80 Casteluega X, Bosch FX, Munoz N, et al. Male ciricumcision, penile human papillomavirus infection, and cervical cancer in female partners. N Engl J Med. 2002;346:1105-1112.

81 World Health Organization. 2010. Considerations for implementing models for optimizing the volume and efficiency of male circumcision services. Available at http://www.malecircumcision.org/programs/documents/mc_MOVE_2010_web.pdf.

recommended efficiencies in the MOVE document as possible, working in coordination with partner country governments. 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.

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 adopting/continuing other HIV risk reduction strategies, such as consistent condom use and avoidance of concurrent sexual partnerships, for clients undergoing VMMC, their partners, and the larger population in areas where VMMC is being scaled-up. Clients must receive condoms, including instructions on how they are to be used.

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 HCW, 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 VMMC services. Regardless of the service setting, VMMC must be provided in an environment that satisfies quality assurance standards for hygiene/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.

1.3.4.2 Key considerations for development of VMMC interventions

Interventions for VMMC must deliver a minimum package of prevention services which include:

- Pre-operative PITC routinely provided on-site for all men and, where possible, their female partners;
- Active exclusion of men with symptomatic STIs and provision of syndromic treatment when indicated, with re-appointment for VMMC once treatment is concluded;
- Provision and promotion of correct and consistent use of male and female condoms;
- Post-operative wound care and abstinence instructions during the wound healing period;
- Age-appropriate counseling (including couples' counseling) on risk reduction, including reducing the number and concurrency of sexual partners, delaying/abstaining from sex, and provision and promotion of correct and consistent use of male and female condoms; and
- Active linkage to other HIV prevention, treatment, care, and support services as needed.

Programs should ensure appropriate and adequate training for professionals providing VMMC services, including training for managing emergency medical complications, and mechanisms for assuring initial and continued competency. Health care providers committed/designated to providing a higher volume of services should be prioritized for training. Efforts should be made to select only those staff for training who will be able to dedicate time to providing VMMC

services post-training. Programs should monitor how many VMMCs each provider trained with PEPFAR funds actually conducts in the period following his/her training.

Mechanisms for QA, quality standards, and quality of care within the program, including plans for clinical complication management, must be in place. Countries are encouraged to follow the WHO Quality Assurance Guidance and Tools for facility self-assessment[82] and to engage with the PEPFAR VMMC Technical Working Group to schedule and participate in routine External Quality Assurance assessments, sponsored by PEPFAR.

Programs must be prepared and able to handle medical emergencies, including life-threatening emergencies, with the appropriate medical equipment, supplies, and pharmaceutical. Staff trained in their use must always be available when VMMC procedures are being conducted. The PEPFAR External Quality Assurance Toolkit includes a module on emergency preparedness that outlines these requirements for programs. All of the requirements must be met by VMMC sites/programs.

PEPFAR-funded programs will not support circumcision provided under general anesthesia or sedation. If a client is not able to cooperate with the procedure under local anesthesia, then the VMMC should be deferred.

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 sexually active adult males. The lack of familiarity with VMMC among many men in high-risk, high HIV prevalence communities and general misinformation about the procedure are major challenges to program implementation and success. Moreover, the sensitivity of HIV/AIDS as a topic and the personal nature of the procedure require that 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 (beyond those directly related to HIV) and place it into the larger HIV prevention context. Situational analyses in several countries document a preference for circumcised men over non-circumcised men and find positive attributions associated with circumcised men, such as being more responsible, more hygienic and more attractive. Countries are encouraged to use such information from situational analyses as they develop demand-creation strategies in collaboration with local organizations and stakeholders. Further, addressing firmly held cultural beliefs and gender norms, 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 men to choose VMMC and respond appropriately to challenges with VMMC communications. The PEPFAR VMMC TWG is developing a media toolkit which countries will be able to adapt to their local conditions and needs.

A media toolkit with templates of messages and images intended specifically to motivate men $\geq$ 25 years of age is in development, drawing upon all available media used to date, formative work on MC knowledge/attitudes/beliefs, and brainstorming sessions with key informants. Messages/images will include additional benefits of MC beyond just HIV prevention, such as improved hygiene, benefits to female sex partners' health, and women's preferences. Media

[82] 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 69

templates will also target women and couples to motivate "older" men in relationships, which have been the more difficult to reach. The prototypes will be field tested before they're proposed as templates for adaptation.. The anticipated release date for the toolkit is early 2013. Once available, country teams and implementers should use the toolkit as a resource and adapt the templates wherever possible.

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.

VMMC services should address harmful male norms and behaviors that may promote high-risk sex behaviors or limit access and/or adherence to HIV prevention services, including VMMC. In particular, counseling for VMMC should be responsive to issues of violence or coercion as they come up, given the pervasiveness of GBV in the 14 countries where VMMC is targeted. Opportunities should be explored for monitoring experience of violence as an effect of VMMC, linking to or providing GBV screening and response services within VMMC programs, and for integrating or linking other men's 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 promote VMMC beyond the individual level and these programs need to explain and emphasize partial protectiveness of VMMC and the indirect benefit to women.

VMMC programs also provide a rare opportunity to reach men who might not otherwise seek HIV prevention services with information and education about sexual and reproductive health. In places where VMMC is being scaled up, all HTC providers, including VCT providers, should recommend VMMC to all HIV negative males and refer them to VMMC sites. Men at high risk of HIV acquisition from heterosexual sex (STI clinic clients and HIV-negative men in HIV discordant relationships) are a priority for referral. Moreover, adolescents (<16 years of age) should be offered HTC at VMMC sites and programs should ensure counseling messages are age-appropriate. QA systems for both HIV testing and HIV counseling components should be in place for ensuring high quality HTC services in these settings. See section 1.4, HIV Testing and Counseling for more information on HTC minimum standards and strategic planning.

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);
- Identification of salient issues that arise as new activities and products are implemented;
- Differentiation of paid advertising from unpaid coverage; and
- exploration the development of a media intensity index (i.e., a means of quantifying the volume of materials produced and disseminated).

Implementers should adhere to WHO guidance on 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.

Sexually active men are often reluctant to seek HTC services and typically present for ART at more advanced stages of AIDS[83]. VMMC offers a rare opportunity to identify men living with HIV and link them with HIV care and treatment earlier. In VMMC settings, PITC is preferred for HTC. Programs must capitalize on this opportunity and work hard to achieve high uptake of HIV testing among VMMC clients. All VMMC services should prioritize active linkages to HIV care and treatment services for clients seeking VMMC services and/or their female partners who are found to be HIV-infected. Where feasible, point-of-care CD4 should be available for clients newly identified as HIV positive so they can be quickly evaluated for eligibility for ART, as well as suitability for VMMC, if they choose to proceed with circumcision. ART, when taken as prescribed, has significant care and prevention benefits[84]. ART can significantly inhibit HIV viral load and replication[85, 86], reduce the morbidity and mortality experienced by PLHIV[87], and reduce the risk of HIV transmission to sex partners[88]. 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).

For HIV positive men, it is important to ensure that comprehensive post-test counseling includes information that circumcision is not recommended for them for HIV prevention purposes, as VMMC may no longer protect them against HIV and does not lower their risk of transmitting HIV to others. Also, those HIV-positive clients with low CD4 counts may experience delayed healing time and may be at increased risk for other complications. If an HIV-positive client elects to undergo VMMC for reasons other than HIV prevention, he should be allowed to do so, provided he is healthy enough for the procedure. Until further research has been completed, circumcision of HIV-positive men should be provided by surgical instead of device-based VMMC methods.

Efficient supply chain management systems need to be in place prior to initiating services. A complete and adequate list of commodities needs to be identified and refined throughout scale-up. Considerations must be given to the resources and technical expertise required for supply chain management and should include the topic of waste management. It is particularly important for programs to anticipate the volume of commodities that will be needed and the procurement time that may be required to avoid stock-outs of key elements.

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[83] Hawkins, Claudia; Chalamilla, Guerino; Okuma, James; Spiegelman, Donna; Hertzmark, Ellen; Aris, Eric; Ewald, Tarcila; Mugusi, Ferdinand; Mtasiwa, Deo; Fawzi, Wafaie (2011). Sex differences in antiretroviral treatment outcomes among HIV-infected adults in an urban Tanzanian setting. AIDS:1 June 2011 - Volume 25 - Issue 9 - p 1189–1197.
[84] WHO Treatment Guidelines, 2010.
[85] 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.
[86] 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.
[87] Crum et al, 2006
[88] 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. 70

Programs supporting VMMC must include systems for monitoring and reporting of VMMC indicators so that progress towards established targets can be tracked. Monitoring of VMMC includes the following:

- Use of standardized forms/tools (designed by Ministries of Health or others) for service data collection;
- Training of staff on use of the forms, and a description of how findings are used to improve services and shared with implementation stakeholders; and
- Aggregation of data for interpretation and frequent/timely dissemination. The PEPFAR VMMC TWG has developed a Monitoring and Reporting Guide for VMMC that should be used as a reference.

To ensure voluntarism and informed consent, programs should provide appropriate informed consent for clients and develop systems to monitor appropriate administration of informed consent. Only those clients able to comprehend the information provided during informed consent may proceed with the service to guarantee VMMC is elective and not coercive.

Depending on the need for overcoming barriers for VMMC uptake, countries may consider offering reimbursement for travel expenses typically incurred by clients as a result of undergoing VMMC. Such reimbursements should be set based on reasonable transport costs within the specific geographic and population context and must be monitored closely to avoid inappropriate or unethical practices, including coercion.

Community mobilizers may be rewarded for exceptional performance. Programs electing to give rewards to highly successful mobilizers must take steps to prevent the coercion of clients by mobilizers who may otherwise be financially motivated to pressure individuals. Mobilizers should never be compensated on a one-to-one basis, meaning that an individual mobilizer should not receive money for each client that undergoes VMMC. For example, it is better to reward a team of mobilizers that exceed expectations, so that the any reward is based upon collective (vs. individual) success. The above approach limits the likelihood of coercion by separating any immediacy of reward resulting for an individual mobilizer referring a particular client. Reward mechanisms that may even further distance perceived or actual rewards on a per-client/per-mobilizer basis are encouraged.

Community mobilizers may be effective at increasing demand for VMMC. Programs that use mobilizers must develop systems to monitor their activities to assure that recruited clients are well-informed about the risks and benefits of VMMC and have not been pressured to attend the program. The TWG is currently developing monitoring tools to address this issue. Clinicians who work overtime to provide VMMC services may be compensated for their time at a scale consistent with national standards. However, clinicians should not be compensated on a per-procedure basis, to avoid actual or perceived motivation to coerce clients to undergo the procedure.

PEPFAR funds may only be used to support surgical circumcision methods that are described in the WHO/UNAIDS/Jhpiego Manual for Male Circumcision Under Local Anesthesia.

PEPFAR funds may only be used to support circumcision using *medical devices* that have been pre-qualified by WHO. WHO's "recommendation" and "pre-qualification" processes are described in an available document entitled "The Framework for Clinical Evaluation of Devices for Adult Male Circumcision." Country teams should anticipate WHO pre-qualification of one

or more adult male circumcision devices in 2013, at which time PEPFAR funds may be used to support VMMC with the pre-qualified device(s). Introduction and incorporation of device-based services may result in additional training and commodities/supply chain costs initially.

Due to high rates of MC-related complications in non-clinical settings, USG funds cannot be used to train or provide support for traditional (non-medical) 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.

Working in conjunction with partner country governments, PEPFAR programs should develop annual operating plans that outline in detail the scale-up approaches for the year to achieve the program goals. The PEPFAR country team should establish annual PEPFAR-funded adult VMMC targets that are sizable enough to appreciably reduce HIV incidence quickly. These annual targets should be framed in the broader context of the country's multi-year VMMC scale-up strategy/targets, as well as the national annual target, if they exist.

Programs should support implementation in two prongs. The first prong prioritizes VMMC for adolescents and adults with the goal of achieving saturation (80 percent) as quickly as possible. This first prong is a one-time, intensive intervention that is not intended to be sustained. The second prong is the implementation of neonatal circumcision programs to be completely integrated and sustained within maternal and child health systems. Though the first prong targeting adolescents and adult males may indirectly strengthen health systems through a variety of activities (e.g., QA, M&E, waste management), its goal is not infrastructure refurbishment, capacity building, or sustainability. The goal of the first prong is to circumcise adolescent and adult men who are currently at risk. The prong to circumcise neonates should only proceed with PEPFAR funds once the first prong is well underway and adult VMMC coverage levels are high.

1.3.4.3 Additional Resources

The PEPFAR VMMC Technical Working Group is drafting a VMMC Site Operational Guidance to be released by the end of 2012. This operational guidance will provide PEPFAR's implementing partners with a comprehensive and consistent process for establishing new VMMC services for HIV prevention. It will draw upon numerous documents developed by UNAIDS/WHO and the PEPFAR VMMC Technical Working Group. This guide will also build on the experiences of and materials developed by existing VMMC programs in southern and eastern Africa. The scope of this document is limited to establishing and supporting quality VMMC services for HIV prevention at the facility/site level**.** The necessary steps involved in scaling up VMMC services at the national, regional, and district levels are beyond the scope of the Site Operational Guide. For a more comprehensive view of the key steps in a national VMMC program, see the WHO Operational Guidance for Scaling Up Male Circumcision Services for HIV Prevention, available at: http://www.who.int/hiv/pub/malecircumcision/op_guidance/en/index.html.

Additional resources can also be found within the PEPFAR Voluntary Medical Male Circumcision Site Operational Guidance and the Clearinghouse on Male Circumcision www.malecircumcision.org. The Clearinghouse 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.

Another resource for VMMC program planners is the WHO/UNAIDS 2008 Operational Guidance for Scaling Up Male Circumcision Services for HIV Prevention, available at: http://www.malecircumcision.org/programs/documents/MC_OpGuideFINAL_web.pdf.

TECHNICAL AREA 1.4: HIV TESTING AND COUNSELING

1.4.1 BACKGROUND

As the gateway to HIV prevention, care, and treatment services, knowledge of HIV serostatus is critical for access to effective HIV interventions that reduce morbidity, mortality and HIV incidence. There has been tremendous scale-up of HTC under PEPFAR. In 2011 alone, over 40 million HTC sessions were provided with PEPFAR support. Despite HTC's importance as an entry point to other services, and the growth of HTC programs, many still do not know their HIV status, and those diagnosed with HIV are often not successfully linked to services. Continued efforts are needed to ensure access to and quality of HTC, along with successful linkages to needed interventions.

The overarching goals of HTC programs are to:

- Provide quality services for individuals, couples/partners, and families to learn their HIV status with appropriate pre-test information or counseling and post-test counseling based on serostatus to enhance the benefits of this service and reinforce linkages;
- Implement strategies for supporting and facilitating the linkage of individuals, couples, and families to appropriate HIV treatment, care and support, and HIV prevention services based on their sero-status. **All PEPFAR programs should be working to support and maximize the linkage of HIV positive persons to prevention, care and treatment, and building strong programmatic connections between testing and treatment programs;**
- Support the scale-up of treatment, VMMC, and PMTCT by setting HTC targets that allow programs/countries to meet treatment, VMMC, and PMTCT targets; and
- Strategically target HTC resources and services to those populations at highest risk of acquiring HIV, and those populations with the highest prevalence – with particular emphasis on identifying HIV-infected individuals and HIV serodiscordant couples.

Knowledge of HIV Status: Coverage and Impact

Despite the significant scale up of HIV testing and counseling, current estimates suggest that more than 60 percent of HIV-infected persons in developing countries are unaware of their infection, and fewer know the HIV status of their partner(s).[89] [90] [91] Moreover, many PLHIV continue to be diagnosed late in their infection, compromising the success of prevention, care, and treatment efforts.[92] 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 percent of women and 7 percent of men having been tested in the 12 months preceding the survey; and a median of 34 percent of women and 17 percent of men reporting having ever been

[89] WHO. Towards universal access: Scaling up priority HIV/AIDS interventions in the health sector 2010 progress report

[90] Deribe et al. High-risk behaviours and associated factors among HIV-positive individuals in clinical care in southwest Ethiopia.. Trop Doct. 2008 Oct;38(4):237-9.

[91] Sarna et al. Sexual risk behaviour and HAART: a comparative study of HIV-infected persons on HAART and on preventive therapy in Kenya. Int J STD AIDS. 2008 Feb;19(2):85-9.

[92] Wanyenze et al. Missed opportunities for HIV testing and late-stage diagnosis among HIV-infected patients in Uganda. PLoS One. 2011;6(7):e21794. Epub 2011 Jul 5.

tested.[93] Effective approaches to HTC may differ in reaching specific populations (e.g. HIV-infected, first-time testers, pregnant women, KPs).[94]

Furthermore, published evidence continues to suggest that HTC is correlated with a positive impact on behavior change among HIV-infected individuals and serodiscordant couples.[95]

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

HTC and knowledge of HIV serostatus are essential components of HIV programming and critical for both an effective combination prevention response, integral to prevention of mother-to-child transmission (PMTCT) and voluntary medical male circumcision (VMMC), and essential for treatment and TB/HIV care (Figure 1). Implementing multiple interventions in the same geographic area and among high burden populations is expected to have synergistic effects, leading to greater overall efficacy to reduce HIV transmission. Modeling studies have recently provided important information to policy makers about the potential impact of prevention interventions including VMMC, test and treat, and the varying coverage levels needed to reduce HIV incidence. Most modeling studies suggest that universal coverage (>80%) is necessary to reduce population level incidence.[96,97,98,99] While these modeling studies have focused more on the coverage levels needed for individual biomedical interventions, no studies have evaluated the combination of these and other interventions including HTC and coverage levels needed. Nevertheless, HTC as a critical gateway to these interventions suggests that equally high coverage among high burden populations and geographic areas is needed as well.

For PEPFAR goals of reduced population level incidence through combination prevention, and continued enrollment of those in need of HIV treatment and care, HTC will provide critical inputs based on: 1) the functional coverage and uptake of HTC programs; 2) the % yield (proportion identified of those tested who are HIV-positive); 3) epidemiology of target populations (including key and other vulnerable populations, geographic prevalence, etc); and 4) the effectiveness of linkage from diagnosis to HIV services. Minimum levels of HTC coverage necessary to support prevention and treatment/care goals will be a function of these variables. (See also below: III. Know Your Response on HTC Target Setting)

Importantly, effective linkages between HTC points of diagnosis and other HIV services – both clinic-based and community-based – are a critical priority for PEPFAR.

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[93] WHO, 2010

[94] Sweat et al. Community-based intervention to increase HIV testing and case detection in people aged 16-32 years in Tanzania, Zimbabwe, and Thailand (NIMH Project Accept, HPTN 043): a randomised study. Lancet Infect Dis. 2011 Jul;11(7):525-32. Epub 2011 May 3.

[95] Two brief and useful reviews of the behavior change impacts of HTC can be found at the following sites:
VCT: http://www.jhsph.edu/research/centers-and-institutes/research-to-prevention/publications/VCT.pdf
PITC: http://www.jhsph.edu/research/centers-and-institutes/research-to-prevention/publications/pitc.pdf

[96] Stover J. HIV models to inform health policy. Current Opinion in HIV & AIDS.2011; :2108–113.

[97] Dodd PJ, Garnett GP, Hallett TB. Examining the promise of HIV elimination by 'test and treat' in hyperendemic settings. AIDS 2010; 24:
729–735.

[98] Granich RM, Gilks CF, Dye C, et al. Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model. Lancet 2009; 373:48–57.

[99] Nagelkerke NJ, Moses S, de Vlas SJ, Bailey RC. Modelling the public health impact of male circumcision for HIV prevention in high prevalence areas in Africa. BMC Infect Dis 2007; 7:16.

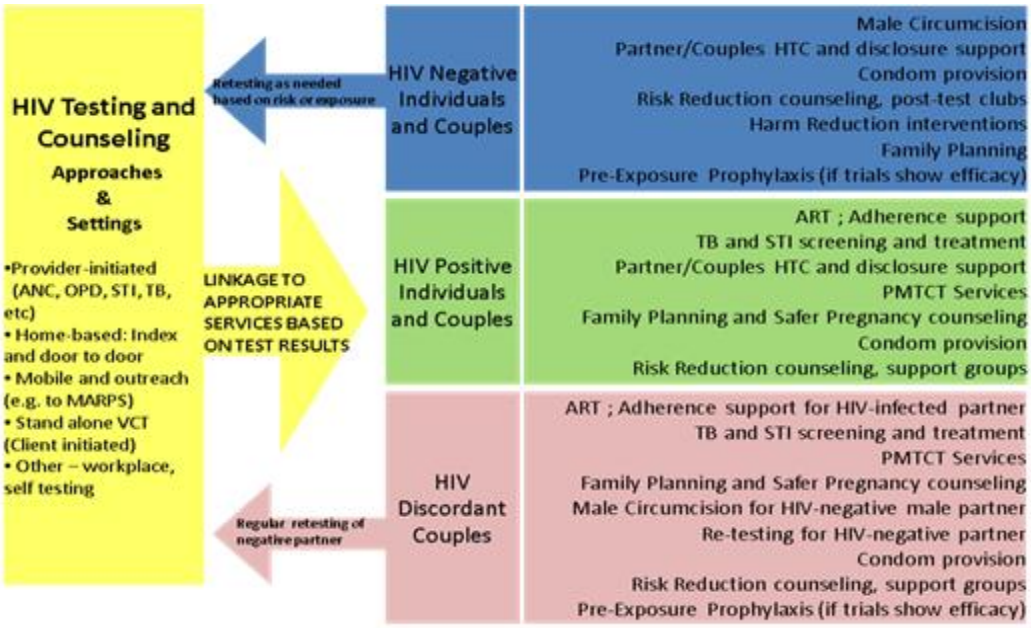

Figure 1: HTC is Gateway to Treatment, Care and Support, and Prevention Services

Couples and partner HTC will be critical elements of emerging interventions promoting the use of ART to prevent HIV transmission between serodiscordant couples. WHO recently released *Guidance on Couples HIV Testing and Counselling including Antiretroviral Therapy for Treatment and Prevention in Serodiscordant Couples* (http://www.who.int/hiv/pub/vct/htc_framework/en/index.html). This document focuses on HTC for couples, and is the first published WHO guidance issuing recommendations for anti-retroviral therapy for prevention purposes.

Furthermore, published evidence (both provider-initiated HTC (PITC) and client-initiated HTC (CITC)) continues to suggest that HTC is correlated with a positive impact on behavior change, particularly among HIV-infected individuals and serodiscordant couples.[100] However, the evidence of impacts on persons who are HIV-negative is mixed. Among HIV-infected persons, knowledge of HIV status has consistently been associated with reduced HIV-transmission behaviors among individuals; and discordant couples. [101] [102] [103] [104] [105] [106] [107] Continued scale up

[100] Ibid.
[101] Fonner VA et al. Voluntary counseling and testing (VCT) for changing HIV-related risk behavior in developing countries. Cochrane Database Syst Rev. 2012; 9:CD001224
[102] Kennedy C et al. Provider-Initiated HIV Testing and Counseling in Low- and Middle-Income Countries: A Systematic Review. AIDS Behav. 2012
[103] Denison et al, HIV voluntary counseling and testing and behavioral risk reduction in developing countries: a meta-analysis, 1990--2005. AIDS Behav. 2008 May;12(3):363-73. Epub 2007 Dec 27.
[104] Sherr et al. Voluntary counselling and testing: uptake, impact on sexual behaviour, and HIV incidence in a rural Zimbabwean cohort. AIDS. 2007 Apr 23;21(7):851-60.
[105] Voluntary HIV-1 Counseling & Testing Efficacy Study Group. Efficacy of voluntary HIV-1 counselling and testing in individuals and couples in Kenya, Tanzania, and Trinidad: a randomised trial. The Voluntary HIV-1 Counseling and Testing Efficacy Study Group. Lancet. 2000 Jul 8;356(9224):103-12.
[106] Dunkle et al. New heterosexually transmitted HIV infections in married or cohabiting couples in urban Zambia and Rwanda: an analysis of survey and clinical data. Lancet. 2008 Jun 28;371(9631):2183-91.
[107] Bunnell et al. HIV transmission risk behavior among HIV-infected adults in Uganda: results of a nationally representative survey. AIDS. 2008 Mar 12;22(5):617-24.

of quality HTC with focused, client-centered counseling may reduce HIV risk behaviors among these populations.

HTC is also a critical gateway to other core prevention interventions such as the minimum package of services for KP and prevention interventions that focus on PHDP, and is strongly linked with behavioral HIV prevention interventions. HIV testing is also linked to biomedical HIV interventions such as blood and injection safety and PEP. HTC will be a central component of pre-exposure prophylaxis (PrEP) as that intervention takes shape.

In August 2011, PEPFAR released revised Prevention Guidance to aid teams in identifying and implementing the optimal combination of prevention activities needed to maximize reduction of new infections as part of the continuum of country HIV response. The Prevention Guidance presents three steps crucial to reducing new HIV infections:

1) Increasing knowledge of HIV status among people living with HIV and their partners;
2) Reducing risk of HIV transmission from people living with HIV; and
3) Reducing HIV acquisition among persons at risk for infection.

While we also need to invest in longer-term strategies to reduce HIV transmission, the bulk of prevention dollars should be invested with a goal of rapid impact. Increasing knowledge of serostatus, especially among PLHIV and discordant couples, and ensuring successful linkages and early enrollment in care and treatment to achieve prevention and health benefits is a critical priority for all PEPFAR programs. The Prevention Guidance endorses Combination Prevention for all PEPFAR Country programs. Countries should be planning strategically to ensure HTC is integrated into a strategic package of prevention services.

PEPFAR Prevention Guidance, http://www.pepfar.gov/guidance/171094.html

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:

- Facility-based settings that include but are not limited to: ANC, Outpatient Departments, TB clinics, STI services, VMMC settings, medical and surgical wards in hospitals, HIV care and treatment clinics, etc. (Provider-initiated); and Stand-alone VCT (Client-initiated).

- 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
    - Workplace, schools

- Closed settings including prisons, compulsory drug treatment centers, etc.
- Campaigns/events which include a combination of settings noted above.

In settings with generalized and mixed epidemics, HTC services should be informed by epidemiological data, and prioritize reaching the following populations: partners of persons living with HIV, pregnant women in ANC, TB and STI patients, HIV-exposed infants and children, sexually active adolescents, KPs, and other setting-specific populations where HIV prevalence is high, which may include uniformed/military personnel, migrant populations, truck drivers, and/or fishermen.

Additionally, private sector health care facilities, laboratories and pharmacies often play a significant role in service delivery, particularly for HTC. Engagement and coordination with these private sector providers of HTC may become increasingly relevant with greater country ownership.

- Guidance on couples HIV testing and counselling including ART for treatment and prevention in serodiscordant couples http://whqlibdoc.who.int/publications/2012/9789241501972_eng.pdf
- Guidance on provider-initiated HIV testing and counseling in health facilities. http://www.who.int/hiv/pub/vct/pitc/en/index.html
- Planning, implementing and monitoring home-based HIV testing and counselling (Forthcoming)
- HIV testing and counseling in prisons and other closed settings http://www.unodc.org/documents/hiv-aids/Final_UNODC_WHO_UNAIDS_technical_paper_2009_TC_prison_ebook.pdf

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 to appropriate follow-up services and supporting initial enrollment in these services;
- Adequate resources are allocated for HTC and evidence-informed linkage interventions for PLHIV and discordant couples;
- HTC targets support treatment, VMMC, and PMTCT services and targets; and
- Quality HTC services are implemented according to international and national minimum standards and guidelines.

Know Your Epidemic, Know Your Response

Strategic programming of HTC services requires a technical review of epidemiologic data and existing HTC programs and services. PEPFAR's revised 2011 Prevention Guidance and WHO's HTC Strategic Framework both recommend a framework for informing the strategic expansion of HTC using accurate and comprehensive information about both the epidemic

and the current response.[108] 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. PEPFAR countries in need of this technical assistance should reach out to the HTC TWG and request assistance for this in their COP. The following framework is meant to assist countries 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 and linking and enrolling in care and treatment services.* HTC programs should also look at HIV care and treatment data to help inform who is getting tested late in their stage of infection and who is not successfully linking and enrolling into care and treatment services.

II. Know Your Context:

Resources

- Coordination with other donor/host country/NGO support for HTC services.

Policy and Legal Environment

- Alignment and implementation of national HTC guidelines, policies and laws with international guidance.

Social and Cultural Environment

- Ability of HTC programs to address social and cultural norms (e.g. gender issues, vulnerabilities of KPs, stigma, etc.)

III. Know Your Response

Programs and coverage

- Proportion of people who have tested for HIV in the past year.

[108] WHO. Service delivery approaches to HIV testing and counselling (HTC): A strategic policy framework. Geneva, World Health Organization, 2012. http://apps.who.int/iris/bitstream/10665/75206/1/9789241593877_eng.pdf.

- 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 and settings have demonstrated success in both identifying HIV-infected individuals and serodiscordant couples and linking them to appropriate follow-up services.
- Number of health facilities that offer PITC.
- Number and location of all sites that offer HTC services. Mapping HTC service to align with areas of need.
- Availability of facility- and community-based HIV treatment, care and support, and prevention services in relation to location of HTC services.
- HTC Target Setting. HTC Targets are closely related to HIV treatment, VMMC, care and PMTCT targets. When setting HTC targets, related programmatic targets should be taken into consideration, as well as other contributing factors (see below) and the capacity of programs to expand *quality* HTC services to meet established HIV program targets. Determinations of necessary numbers of persons tested to contribute to treatment, care and prevention targets will need to be made by country-level assessments; data inputs may include:

    - Previous HIV testing coverage data and percent yields (proportion HIV positive of all tested));
    - Estimated rates of linkage from diagnosis to care and treatment services;
    - Estimated proportion of HIV-positive, treatment ineligible individuals among those diagnosed; and
    - Estimated rate of transition from treatment-ineligible to treatment-eligible.

  Importantly, increases in HTC targets can inappropriately appear to place emphasis on numbers tested *rather than* the quality of interventions, client-provider interactions and the quality and accuracy of the HIV testing itself. Therefore, expansion of HTC services to meet PEPFAR targets must ensure - through adequate funding, ensuring sufficient human and material resources, and systems approaches to quality assurance and improvement - the delivery of quality services for both testing and counseling processes and outputs.

IV. Know Your Costs

In order to use donor and host country funds efficiently and effectively, HTC approaches should prioritize identification of HIV-infected persons and sero-discordant couples. Countries should collect, assess, and utilize data on the cost of different approaches to inform their decision making. Countries should also assess if the HVCT budget allocation is enough to cover testing requirements necessary to meet treatment, care and, if necessary, VMMC and PMTCT targets, and ongoing programs. Assessing if adequate resources are available to support the identification of HIV positive persons and linkage interventions to follow-up services may help HTC programs determine if additional resources are necessary.

HTC Strategic Framework

The following framework has been informed by WHO guidance and 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

1. *Generalized epidemics:* refer to countries where HIV is firmly established in the general population. Numerical proxy: HIV prevalence is consistently over 1% percent in pregnant women nationwide or in a national survey.[109]
2. *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%), percent), with high rates of transmission among KPs (with prevalence above 5%). percent). Numerical proxy: HIV prevalence is consistently over 1-5% percent in pregnant women nationwide or in a national survey and over 5% percent in one or more sub-populations.[110]
3. *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% percent in at least one defined subpopulation but is below 1% percent in pregnant women in urban areas.[24]

Strategic Prioritization of HTC Approaches by Epidemic Type

I. Generalized Epidemics:

- Target populations for HTC: all patients (adults and children) in health-care settings, all partners and children/parents of PLHIV, and all residents or members of communities and populations in which estimated HIV prevalence exceeds 5%. percent.
- 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 high in countries with generalized epidemics, HTC should be recommended for all patients and their partners attending health facilities (including ANC settings) 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.[111]
    - 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

[109] UNAIDS. UNAIDS Terminology Guidelines. UNAIDS/WHO, 2011. http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2118_terminology-guidelines_en.pdf
[110] UNAIDS. UNAIDS Terminology Guidelines. UNAIDS/WHO, 2010. http://www.gfmer.ch/SRH-Course-2010/adolescent-sexual-reproductive-health/pdf/UNAIDS-TerminologyGuidelines-2010.pdf
[111] WHO. Guidance of provider-initiated testing and counseling in health facilities. Geneva, World Health Organization, 2007. http://www.who.int/hiv/pub/guidelines/9789241595568_en.pdf

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 KPs, 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.[112,113,114]

II. Mixed Epidemics:

- Target population for HTC**:** all patients (adults and children) in health-care settings where HIV prevalence exceeds 1%, percent, all partners and children/parents of PLHIV, and all residents or members of communities in which estimated HIV prevalence exceeds 5%, percent, including KPs 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. This includes health care facilities that provide services for KPs, or that operate in high prevalence districts or geographic

[112] Sahlu T et al. (1999) Sexual behaviours, perception of risk of HIV infection, and factors associated with attending HIV post-test counselling in Ethiopia. *AIDS*, 13**:**10 1 263-1 272.
[113] Stein, J. A. and Nyamathia, A. (2000) Gender differences in behavioural and psychosocial predictors of HIV testing and return for test results in a high-risk population. AIDS Care, 12:3, 343-356
[114] Obermeyer C, Osborn M. The utilization of testing and counseling for HIV: a review of the social and behavioral evidence. Am J Public Health. 2007;97:1762–1774.

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, KPs, and children known to be exposed to HIV perinatally.

- Mobile and Outreach HTC for targeted sub-populations, including KPs (SW, MSM, PWID). Mobile and outreach HTC services may be effective for reaching KPs 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%) percent) 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 KPs and hard-to-reach populations in mixed epidemics, particularly if they specifically target these populations and provide KP-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%, percent, including KPs (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, KPs, ANC and TB patients and their partners.
    - Mobile and outreach HTC for targeted sub-populations including KPs (i.e., SW, MSM, PWID). Since many KPs 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 KPs feel comfortable. Examples may include drop-in centers, mobile unit, or organized testing event for KPs. 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 KPs (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 KPs. VCT may also be an effective approach for reaching KPs through drop-in centers or fixed sites that provide KP-friendly services.

Emerging Approaches to HTC – a need for more evidence

There are a number of emerging approaches to HTC requiring further evidence to inform programming.

HIV at-home or self-screening occurs when rapid HIV test kits are used by members of the general public to determine serostatus. Use of these kits may or may not be accompanied by limited training. While this has occurred informally in the past, there have been recent pilot trials exploring self-screening as an intervention. These trials to date have utilized only single rapid HIV tests without immediate confirmatory testing; this approach is sometimes mislabeled "self-testing" (a single test result is insufficient for diagnosis). Such self-screening has been investigated among health care workers in Kenya and MSM in developed countries.[115] There are concerns and opportunities with this HTC approach. Ensuring quality test kits, accurate and reliable test results [116] and access to counseling and linkage to care after diagnosis may be difficult. Nevertheless, self-screening may also provide opportunities to dramatically scale up coverage and access to HIV testing if this approach could be implemented in a way that is acceptable and feasible. Further policy and regulatory analysis and programmatic research is needed to determine how to strategically position self-screening and prepare for its introduction, among HTC modalities within PEPFAR that can maximize benefits and minimize harm. The HTC TWG will be initiating these efforts in the coming year, and welcomes inputs and assistance from PEPFAR teams interested in participating.

Consensual and voluntary partner notification with linked HTC: Partner notification is included as an approach within WHO's Couples HTC Guidelines and has recently been explored in a Malawian pilot program which compared passive and active referral of partners of HIV positive persons to HTC.[117,118] This pilot demonstrated a high yield approach, where 64% percent of returning partners were HIV-positive, and 81% percent of those were newly diagnosed. Partner notification with linked HTC may be cost effective depending on prevalence and relative to other modalities such as door-to-door, index patient, and home-

[115] See: WHO 2011. HIV Self-testing among health workers; and: Kalibala et al. 2011. "Knowing Myself First": Feasibility of self-testing among health care workers in Kenya

[116] In the USA, preliminary studies of the recently FDA-approved, over-the-counter OraQuick rapid test showed 92% sensitivity - meaning 1 out of 12 positive tests would be false negative.

[117] Brown et al. 2011. HIV partner notification is effective and feasible in sub Saharan Africa: opportunities for HIV treatment and prevention; and: Brown et al. 2011. Predicting partner HIV testing and counseling following a partner notification intervention

based HTC.[119,120] Partner notification approaches are used in some home based care models (index patient testing) and have also been applied to HIV in the US for a number of years through Disease Intervention Specialist (DIS) follow-up of the sexual partners of individuals with select sexually transmitted infections, more recently including HIV.[121,122] PEPFAR countries could explore the feasibility and potential cost efficiency of such programs.

PEPFAR does not yet support Pre-Exposure Prophylaxis (PrEP) through its service platforms. If this were to change, HTC would be a critical component of any PrEP program. HTC would be needed to determine those truly uninfected to minimize resistance risks, and for those persons on PrEP periodic retesting will be needed to identify new infections. Optimal intervals for retesting those on PrEP have yet to be determined.

1.4.3 STRENGTHENING LINKAGES FROM HTC TO OTHER SERVICES

HTC is a gateway to other essential HIV services (see Figure 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.

There are also opportunities to leverage existing platforms within HIV adult care, support, and treatment programs to support early HIV diagnosis. As described earlier, high-yield strategies include:

- index patient partner HTC;
- building on existing home visits within home-based care programs;
- partner or couples HTC within home, community or facility-based HIV care, support and treatment settings; and/or
- Active case finding through voluntary, consensual partner notification (see HIV Care and Support Technical Considerations for additional information).

Yet, studies have shown that many newly diagnosed patients either do not enroll 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 based on a review of studies in sub Saharan Africa.[123 124] 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

[119] Armbuster et al. 2011. Exploring the relative costs of contact tracing for increasing HIV case finding in sub Saharan countries.

[121] CDC 2003. HIV Partner Counseling and Referral Services. http://www.cdc.gov/hiv/topics/prev_prog/ahp/resources/guidelines/Interim_partnercounsel.htm

[123] Rosen S, Fox M. Retention in HIV care between testing and treatment in sub-Saharan Africa: a systematic review. PLoS Med. 2011 Jul;8(7):e1001056. Epub 2011 Jul 19.
[124] Micek et al. Loss to follow-up of adults in public HIV care systems in central Mozambique: identifying obstacles to treatment. J Acquir Immune Defic Syndr. 2009 Nov 1;52(3):397-405.

couples have been diagnosed with HIV, linking them with appropriate services is necessary to protect their health and to reduce the risk of HIV transmission to uninfected partners.[125] [126] [127] [128] [129] 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, institutional, 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. In studies that describe barriers to accessing ART, study participants reported that fears of transportation and supplementary food costs, the referral facility's reputation for being unfriendly and confusing, and difficulties in sustaining long-term treatment would limit accessibility.[130,131,132,133] Both experienced and anticipated discrimination hindered widespread ART uptake.[134,135] Simple measures to reduce perceived barriers improved initial access to treatment, but pervasive stigma remained the most formidable barrier. Other factors that have been found to affect HIV clinic attendance include: (a) perceived susceptibility to HIV-related illnesses; (b) denial of HIV status, sometimes associated with using alternative healers; (c) perceptions of illness severity; (d) health systems factors; and (e) patients' expectations or experiences of family support. These findings reinforce the importance of multi-faceted interventions to promote linkage to and continuation of HIV clinic attendance; these interventions also need to address the evolving needs of patients that accompany changes in physical health, and should address local beliefs around HIV etiology.[136,137] Program planners, implementers, and policy makers at country level are encouraged to address develop community and facility-based strategies to support increased linkages between HTC and HIV prevention, care and treatment services.

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[125] Lahuerta M, Lima J, Nuwagaba-Biribonwoha H, Okamura M, Alvim MF, Fernandes R, Assan A, Hoos D, Elul B, El-Sadr WM, Nash D. "Factors associated with late antiretroviral therapy initiation among adults in Mozambique." PLoS One 2012;7(5):e37125. Epub 2012 May 15.

[126] Ingle SM, May M, Uebel K, Timmerman V, Kotze E, Bachmann M, Sterne JA, Egger M, Fairall L; IeDEA-Southern Africa. Outcomes in patients waiting for antiretroviral treatment in the Free State Province, South Africa: prospective linkage study. AIDS. 2010 Nov 13;24(17):2717-25.

[127] Crum NF, Riffenburgh RH, Wegner S, Agan BK, Tasker SA, Spooner KM, Armstrong AW, Fraser S, Wallace MR; Triservice AIDS Clinical Consortium. 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. 2006 Feb 1;41(2):194-200.

[128] Donnell D et al.; Partners in Prevention HSV/HIV Transmission Study Team.
Heterosexual HIV-1 transmission after initiation of antiretroviral therapy: a prospective cohort analysis.
Lancet. 2010 Jun 12;375(9731):2092-8. Epub 2010 May 26.

[129] Cohen MS et al.; HPTN 052 Study Team.
Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. 2011 Aug 11;365(6):493-505. Epub 2011 Jul 18.

[130] Nsigaye R, Wringe A, Roura M, Kalluvya S, Urassa M, et al. From HIV diagnosis to treatment: evaluation of a referral system to promote and monitor access to antiretroviral therapy in rural Tanzania. J Int AIDS Soc. 2009;12:31

[131] Mshana GH, Wamoyi J, Busza J, Zaba B, Changalucha J, Kaluvya S, Urassa M. Barriers to accessing antiretroviral therapy in Kisesa, Tanzania: a qualitative study of early rural referrals to the national program. AIDS Patient Care STDS. 2006 Sep;20(9):649-57.

[132] Nsigaye R et al.

[133] Mshana GH et al.

[134] Ibid.

[135] Ibid.

[136] Wringe A, Roura M, Urassa M, Busza J, Athanas V, Zaba B. Doubts, denial and divine intervention: understanding delayed attendance and poor retention rates at a HIV treatment programme in rural Tanzania. [Internet] AIDS care. 2009;21(5):632–7. doi: 10.1080/09540120802385629.

[137] Ibid.

Although most HTC programs refer clients and patients to follow-up services as part of the minimum standards for HTC, very few provide or leverage existing community or facility-based services to facilitate linkage, and very few have monitoring and evaluation (M&E) systems that can monitor the outcomes of referrals to HIV care and treatment. Identifying, implementing, monitoring and evaluating innovative strategies for linking HTC clients and patients into prevention, care, treatment, and support services is urgently needed. HTC resources may be used to support activities for strengthening and ensuring successful linkages to prevention, care, and treatment (see HVCT Budget Code Narrative in the FY 2013 COP Guidance).

A. Examples of Strategies to Strengthen Linkages to HIV prevention, care, and treatment

Although there is insufficient evidence about the effectiveness of various models to ensure linkages, some countries have developed policies and programs to address this challenging issue. Programmatic strategies may target the individual, the facility, and/or the community barriers to engaging in care; 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:

- Establishing a national policy or strategic framework for referral and linkages between HTC and HIV care and treatment services (e.g. Ethiopia, Swaziland);
- Referral systems from HTC to TB, VMMC, and HIV care and treatment that include named contacts at each site, referral slips addressed to a specific referral center with instructions on who to see, and a clear system to monitor the outcomes of referral process (e.g. Zimbabwe);[138]
- Integrating additional services at the HIV testing site, such as point-of-care CD4 testing[139] and isoniazid or cotrimoxazole preventive therapy;[140,141]
- 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

[138] See: http://www.aidstar-one.com/sites/default/files/Gudukeya.pdf

[139] Jani IV et al. Effect of point-of-care CD4 cell count tests on retention of patients and rates of antiretroviral therapy initiation in primary health clinics: an observational cohort study. Lancet. 2011 Oct 29;378(9802):1572-9.

[140] Namuwenge PM et al. Loss to follow up from isoniazid preventive therapy among adults attending HIV voluntary counseling and testing sites in Uganda. Trans R Soc Trop Med Hyg. 2012 Feb;106(2):84-9. Epub 2011 Dec 10.

[141] Kassa A et al. Evaluation of collaborative TB/HIV activities in a general hospital in Addis Ababa, Ethiopia. BMC Res Notes. 2012 Jan 26;5:67.

HIV care and treatment, offer practical guidance, and help clients overcome real and perceived barriers to care;[142,143,144,145]

- Providing transportation, child care assistance, nutritional support, or other incentives for providers, clients, or patients;[146]
- 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;[147]
- Providing case management through 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;[148]
- Small group interventions targeting PLHIV and designed to support people newly diagnosed as HIV positive through training, support groups, referral systems, healthy lifestyle programs, and advocacy to create a continuum of care that empowers PLHIV as they begin to manage their health;[149]
- Training providers to create an enabling environment for all clients and patients within the HTC site, particularly for KPs and other vulnerable populations who may be deterred from following through on referrals due to stigma and discrimination;[150,151] 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

[142] Tenthani L et al. Involving expert patients in antiretroviral treatment provision in a tertiary referral hospital HIVclinic in Malawi. BMC Health Serv Res. 2012 Jun 8;12(1):140.
[143] Kielmann K, Cataldo F. Tracking the rise of the "expert patient" in evolving paradigms of HIV care. AIDS Care. 2010;22 Suppl 1:21-8.
[144] Craw JA et al. Brief strengths-based case management promotes entry into HIV medical care: results of the antiretroviral treatment access study-II. J Acquir Immune Defic Syndr. 2008 Apr 15;47(5):597-606.
[145] Hatcher A et al. Predictors of linkage to care following community-based HIV counseling and testing in rural Kenya. AIDS Behav. 2012 Jul;16(5):1295-307.
[146] Nsigaye R et al. From HIV diagnosis to treatment: evaluation of a referral system to promote and monitor access to antiretroviral therapy in rural Tanzania. J Int AIDS Soc. 2009;12:31
[147] Hatcher et al 2009
[148] Nsigaye et al.
[149] Integrated Access to Care and Treatment (I-ACT) http://www.iactsupport.org/
[150] Mshana GH et al. Barriers to accessing antiretroviral therapy in Kisesa, Tanzania: a qualitative study of early rural referrals to the national program. AIDS Patient Care STDS. 2006 Sep;20(9):649-57.
[151] WHO. Retention in HIV Programmes – WHO Meeting Report 2011

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:

Countries and programs should consider implementing this indicator, while understanding there are limitations around this proxy measure. Additionally, 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 may be of utility.

- Retention in HIV Programmes – WHO Meeting Report, http://whqlibdoc.who.int/publications/2012/9789241503686_eng.pdf
- PEPFAR Field Driven Learning Meeting - Linkages to and retention in HIV care and support programs, http://www.aidstar-one.com/sites/default/files/AIDSTAR-One_Field_Driven_Learning_Meeting.pdf

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.

A. Rapid HIV Testing and Updated HIV Testing Strategies

WHO has recently updated its HIV testing strategies for HIV diagnosis in both high- and low-prevalence settings. Efforts should work to align national testing strategies with this guidance. Key differences to previously recommended strategies include:

- Testing strategies are based on the prevalence of the population to be tested (i.e. >5% or <5%)
- In cases where screening and confirmatory tests are discrepant, immediate repeat testing should be performed with both tests on a new specimen to eliminate technical, clerical and individual device errors.
- In cases where a screening, confirmatory and tiebreaker tests are discrepant:

- In *high prevalence settings* (populations >5% positive): results should either be reported as inconclusive (with A1+, A2-, A3+) and the client retested after 14 days; or reported as negative (with A1+, A2-, A3-);
- In *low prevalence settings* (populations <5% positive): If screening and confirmation are positive, a third test should still be performed. Results should either be reported as inconclusive (with A1+, A2+, A3-) and the client retested after 14 days; or reported as positive (with A1+, A2+, A3+);

Please refer to WHO's Service delivery approaches to HIV testing and counselling: a strategic HTC programme framework (Section 7.1) for further details:
http://www.who.int/hiv/pub/vct/htc_framework/en/index.html

B. HTC Commodities and Supply Chain Management

Rapid HIV test kit stock outs are as serious and urgent a problem as a pending stock-out of ARVs and should be prioritized. HTC services cannot be provided without an adequate supply of essential commodities that include test kits and essential testing supplies (gloves, capillary tubes, lancets, etc.). Country programs continue to experience stock-outs or expiry of HIV rapid test kits and other HTC supplies. Efforts to strengthen supply chain management systems need to be undertaken to ensure the commodity security of RTKs and related supplies, including timely and accurate reporting on test kit supply and usage, as well as efficient distribution to all HTC service delivery points, with appropriate storage at sites and in central distribution warehouses.

To alleviate potential disruptions in RTK supplies, country teams should consider activities, coordination and specific funding for interventions to address commodity security, including:

- Country level assessments of the supply chain for HIV testing commodities, or quantification of stock-outs or use of expired supplies to help target TA, inform interventions, and advocate for improving these systems;
- Centralized procurement mechanisms, demand forecasting procedures, and coordination between supply-chain managers and program-service managers to help predict threats and ensure continual availability of commodities necessary for HTC.
- Funding for emergency procurements of test kits and related supplies may be warranted depending on country-specific situations.
- Collaboration and communication with Supply Chain Advisors, the Partnership for Supply Chain Management System (PSCMS) and MOH Supply Chain counterparts is encouraged to support of these purposes.

Strong country teams should make every effort to work proactively with government and other donor counterparts to improve forecasting, procurement, storage and delivery processes to avoid stock-outs and shortages. In cases where these measures are insufficient and teams anticipate a central level stock-out, HQ (OGAC and USAID) have mechanisms to provide assistance in procuring emergency supplies of RTKS *if given sufficient lead-time (i.e. 3-4 months).* The first point of contact for these requests should be the Country Support Team Lead. For more information, see communications to the field on the Emergency Commodity Fund.

C. Re-testing

Re-testing is defined as "testing performed…after a defined period of time for explicit reasons, such as a specific incident of possible HIV exposure within the past three months, or ongoing risk of HIV exposure…" 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 KPs, 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.

- 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

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. However, it is important to avoid overburdening lay personnel through task shifting strategies that do not consider the added work and responsibilities and its potential impacts on service quality and counselor moral.

- **WHO Task shifting: global recommendations and guidelines.** http://data.unaids.org/pub/Manual/2007/ttr_taskshifting_en.pdf

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, to supplement initial HTC training with new approaches or for supportive supervision, management and quality assurance.

The HTC TWG has developed a range of standard HTC curricula available for use or adaptation including, Couples HTCCHTC, PITC (adults and children), KPs (draft), rapid HIV testing, VCT, and VCT Events (Campaigns). These materials help preclude the need for independent development of HTC training materials.

F. 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, 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.

- **Handbook for improving HIV testing and counseling services.** http://www.who.int/hiv/pub/vct/9789241500463/en/index.html

I. Gender Considerations

Gender norms and inequities affect men and women's access to and uptake of HTC services. Attention should be paid to assessing, identifying and targeting interventions to overcome barriers to HTC services. Gender-based violence (GBV) GBV is a critical barrier - emphasis should be placed on integrating training, possible screening, and counseling for GBV, and strengthening referrals/linkages to GBV services. Additionally, the introduction of "male friendly" services aimed at increasing men's uptake of HTC are critical, as men are underrepresented in the population of those who seek out HTC in many PEPFAR countries. Strengthened linkages between HTC and family planning (FP) and reproductive health (RH) services are also critical interventions for female patients. Women may be more likely to accept HTC at FP and RH service sites and so PEPFAR programs will want to support quality HTC provision in those contexts. Likewise, women receiving HTC in other clinical or community platforms may also benefit from being offered appropriate referrals to FP and RH services as part of the HTC encounter.

- **PEPFAR Guidance for integrating a gender-based violence response in PEPFAR programming - HTC**

  http://www.aidstar-one.com/sites/default/files/HTC_AIDSTAR-One_GBV_Guidance.pdf

J. 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 and used biomedical waste should be disposed 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.

K. 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.

- **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

L. 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

M. 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. 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, culturally appropriate social marketing can increase demand for HTC and address key HTC and HIV programming messages. Educational materials such as posters and brochures may also be useful for providing additional information about HTC or follow-up services. Involvement and engagement of community and religious leaders through community mobilization can increase awareness, demand, and help address social norms.

N. 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 information, education and 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. For more information about condom provision in PEPFAR-supported programs, See section 1.2.7.

O. Children and Adolescents

Children and adolescents are a frequently overlooked population for HTC programs. HTC programming and access to these populations is important for achieving an "AIDS free generation". There are challenges specific to HTC programming for children and for adolescents that may need to be addressed.

- Coverage may be insufficient

Where epidemiologically appropriate, programs should work to support coverage and uptake of child and youth-friendly HTC services. Novel approaches may reach infants, children and adolescents more effectively (e.g. immunization clinics, school based HTC) and warrant further study.[152]

[152] See for example: Schouten EJ et al. *More HIV-positive infants and mothers identified through HIV testing in immunization clinics*. 19th International AIDS Conference, Washington DC, Abstract THAC0102, 2012. http://pag.aids2012.org/Abstracts.aspx?AID=13252

- HTC Service delivery may not be focused on children and adolescents

Relatedly, staff may not be comfortable or lack skills in providing HTC to these populations. Additional and appropriate training may be necessary. Acceptability of HTC by or for children and adolescents may not be optimal[153] and efforts may be needed to make services child and adolescent friendly.

- There may be **policy barriers**. Consent laws continue to be problematic, with disconnects between age of consent for testing and age of sexual debut. HTC policies (and protocols) often don't address children or adolescent specifically
- **Disclosure** to both children and adolescents is an often cited problem. While there are now WHO guidelines endorsing age-appropriate disclosure, the programmatic "how-to" remains a gap. Fear, stigma, lack of provider skills all contribute in inhibiting disclosure; furthermore there is an absence of support to children and adolescents around their disclosure to others - to whom, how and when. Many of these disclosure issues likely need to be addressed at a country level, and be grounded in the culture and legal frameworks of a given country.
- **Linkage** from diagnosis to care and treatment has not been well studied in these populations.
- Among HIV positive children and adolescents, there's a need to distinguish and recognize **vertically vs horizontally infection**; these distinct populations will have some overlapping and some different needs.

The following guidance provides some programmatic support:

  - **WHO Guidance on HIV disclosure counselling for children 12 years of age and younger**
    http://whqlibdoc.who.int/publications/2011/9789241502863_eng.pdf

  - **Scale up of HIV-related prevention, diagnosis, care and treatment for infants and children: a programming framework**
    http://www.who.int/hiv/pub/paediatric/paediatric_program_fmwk2008.pdf

  - **WHO Recommendations on the diagnosis of HIV infection in infants and children**
    http://whqlibdoc.who.int/publications/2010/9789241599085_eng.pdf

  - **Policy requirements for HIV testing and counseling of infants and young children in health facilities**
    http://whqlibdoc.who.int/publications/2010/9789241599092_eng.pdf

  - **WHO Guidance on HTC in Adolescents (forthcoming 2013)**

[153] See for example: Vreeman et al. 2010. Acceptance of HIV testing for children ages 18 months to 13 years identified through voluntary, home-based HIV counseling and testing in western Kenya. J Acquir Immune Defic Syndr. 2010 Oct;55(2):e3-10.

1.5: PREVENTION WITH PEOPLE LIVING WITH HIV (PWP)

1.5.1 Background

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 as outlined in PEPFAR's Prevention Guidance[154]. The following considerations are also consistent with guidelines issued by WHO[155] and CDC[156] on prevention services for PLHIV 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) framework[157].

Prevention services for HIV-positive persons include both behavioral and biomedical activities 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 (HTC), PwP/PHDP service provision can 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/PHDP services also contribute to preventing mother-to-child HIV transmission (PMTCT) through provision of family planning (FP) 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 (please note that PEPFAR funds may not be used to procure FP commodities; see Section 3.12, FP and HIV Integration for more information). Finally, ongoing adherence counseling and support services maximize the care and prevention benefits of anti-retroviral treatment by supporting optimal adherence among patients on treatment. PwP/PHDP services 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[158, 159, 160], STI incidence[161, 162], and unintended pregnancies[163].

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[154] President's Emergency Plan for AIDS Relief (PEPFAR). (2011). *Guidance for the prevention of sexually transmitted HIV infections.* Retrieved from: http://www.pepfar.gov/documents/organization/171303.pdf

[155] 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.

[156] Centers for Disease control and Prevention (in press). Recommendations for HIV Prevention with Adults and Adolescents with HIV in the United States.

[157] 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_srhr_of_plhiv_guidance_package_en.pdf.

[158] 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.

These services can be effectively delivered by health care providers[164, 165], counselors/social workers[166] and lay or peer counselors[167, 168, 169] in both clinic and community settings, as well as by community and home-based care (CHBC) providers. Models also suggest that PwP/PHDP services are cost effective[170].

1.5.2 Components of Effective PwP/PHDP Programs

Integration of HIV Prevention Messages and Services into all Clinical Settings Providing Care PLHIV

HIV prevention messages and services should be delivered as part of the routine care offered to HIV-positive persons in HIV care and treatment settings. In addition, PwP/PHDP services should be integrated into all clinical settings providing care or services to HIV-positive persons, such as TB, PMTCT, and STI 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. 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 their partner(s) to the clinic for HIV testing and counseling. STI treatment clinics, in settings where they exist as stand-alone services,

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[159] 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.

[160] 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.

[161] 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.

[162] 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.

[163] 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.

[164] Crepaz et al., 2006.

[165] 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.

[166] 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.

[167] 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.

[168] 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).

[169] 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 Zamiba. *PlosOne,* 3(5):e2204.

[170] 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.

are also important venues for identifying HIV-positive individuals and discordant couples/partnerships and for delivering HIV prevention messages.

Integration of HIV Prevention Messages and Services 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 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 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 HTC services for spouses and child(ren) of PLHIV, along with community and mobile HTC programs.

Ongoing, Comprehensive HIV Prevention Services for PLHIV and Serodiscordant Couples

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-positive persons are at high risk for HIV infection, yet studies show that many PLHIV do not know their partner(s)' HIV status[171]. 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 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. In some studies, women living with HIV had cited fear of gender-based violence as a reason not to disclose to their partners[172]. While the data on incidence of GBV in association with disclosure does not suggest enhanced risk[173], women's fears to the contrary may be sufficient to prevent disclosure. HTC

[171] 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.
[172] Deribe K, Woldemichael K, Njau BJ, Yakob B, Biadgilign S, Amberbir A. (2010). Gender differences regarding barriers and motivators of HIV status disclosure among HIV-positive service users. SAHARA J. Jul;7(1):30-9.
[173] Apondi R, Bunnell R, Awor A, et al. Home-based antiretroviral care is associated with positive social outcomes in a prospective cohort in Uganda. J Acquir Immune Defic Syndr. 2007;44:71-76

programs should be responsive to these fears, as well as to other possible negative consequences of disclosure, and offer appropriate support to couples to prevent them.

- *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.* Safer sex counseling should include messages on partner reduction, mutual monogamy to a partner of known HIV status, and consistent condom use at every sexual encounter to prevent transmission of HIV and other sexually transmitted infections (STIs). Behavioral interventions that encourage safer sex and offer skills development (e.g. condom negotiation, condom use) 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[174, 175] and reduced adherence to ARVs[176]. Alcohol use can also lead to poorer health outcomes among HIV-positive individuals including higher viral loads[177], accelerated disease progression[178, 179], and increased levels of depression[180]. 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

[174] 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.
[175] 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.
[176] 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.
[177] 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.
[178] Baum et al., 2010.
[179] 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.
[180] Ghebremichael et al., 2009.

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 harm reduction interventions. Advice for these programs can be found in section 1.3.3, 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.

- *Family Planning (FP) 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). However, many HIV-positive women in sub-Saharan Africa report an unmet need for contraception[181]. This highlights the critical need to offer FP counseling and referrals to PLHIV in order to reduce the number of unintended pregnancies among this population. To increase access to these services, family planning counseling and provision of contraceptive services should ideally be integrated within most clinical settings serving PLHIV including PMTCT and HIV care and treatment, ensuring that all USG requirements for compliance, monitoring and reporting are met. For more information on integrating FP and HIV services, see section 3.14, FP and HIV Integration.

  For PLHIV who desire children, safer pregnancy counseling on methods to reduce the risk of HIV transmission to uninfected partners is needed, as both women[182] and men[183] are at increased risk for acquiring HIV during the women's pregnancy. To prevent new HIV infections among pregnant women and their partner(s), it is essential that partner testing or couples HTC and sexual 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 and their partners should have the capacity to provide ongoing family planning counseling and support for safer pregnancies.

- *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 partners and families[184]. Some STIs may be more complicated and difficult to treat

[181] 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.
[182] Moodley D, Esterhuizen TM, Pather T, et al. (2009). High HIV incidence during pregnancy: compelling reason for repeat HIV testing. *AIDS*. 23:1255-9.
[183] 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.
[184] 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.

in HIV-infected individuals[185]. 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 durations[186]. 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 educations to provide early referral of their clients and peers for STI treatment.

- *Male and Female Condom Distribution and Promotion.* All clinic and community-based programs must discuss the importance of correct and consistent condom use and 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 with high-risk populations (e.g., men who have sex with men, people who inject drugs, 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 serodiscordant 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 replication[187], reduce the morbidity and mortality experienced by PLHIV[188,189], and reduce the risk of HIV transmission to sex partners by 96%[190]. 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

[185] 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.
[186] World Health Organization, 2003.
[187] 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.
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[189] 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.
[190] Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour M, Kumarasamy N…the HPTN 052 Study Team. (2011). Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med*, 365, 493–505.

prophylactic medications (e.g., cotrimoxazole) and therapeutic regimens (e.g., ARVs) are an important component of PwP/PHDP. Effective interventions include pillbox organizers, treatment supporters, provider-delivered education or counseling, couple-based counseling, telephone support, reminder devices, home visits, and directly observed therapy[191]. Adherence support interventions can be successfully delivered in an ongoing manner at clinical, community, or home settings.

- *HIV Serodiscordant Couples.* In sub-Saharan Africa, as many as half of HIV-positive individuals who have a current sexual partner are in a serodiscordant couple[192]. Integrating partner and couples HIV testing and counseling (CHTC) into routine clinic- and community-based services can significantly increase the number of serodiscordant couples who are identified and linked to appropriate prevention, care, and treatment services. Once identified, providing serodiscordant couples with the range of HIV prevention messages and services described above, as well as offering them additional services to meet their unique prevention needs, can substantially reduce the risk of HIV transmission to negative sex partner(s) and children and ensure that HIV-positive partners receive the care and treatment services they need to remain healthy. These services include:
    - *Antiretroviral treatment (ART) for the HIV-positive partner.* ART can reduce the risk of heterosexual transmission by 96% [193]and reduce the morbidity and mortality experienced by the HIV-positive partner[194,195,196]. To maximize the prevention, care, and treatment benefits of ART among serodiscordant couples, and in keeping with WHO normative guidelines, PEPFAR programs may offer treatment to all HIV-positive partners in serodiscordant couples with greater than 350 CD4 cells/µl[197], where this practice is consistent with national guidelines. In addition, where resources allow provision of ART to persons with CD4 counts above 350/mm^3, programs should consider prioritizing serodiscordant couples for early ART initiation[198].
    - *Ongoing risk reduction counseling including condom (and lubricant) distribution.* HPTN 052[199] and other recent studies of discordant couples[200,201] have

[191] 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.
[192] Chemaitelly H, Cremin I, Shelton J, Hallet T, & Abu-Raddad L. (2012). Distinct HIV discordancy patterns by epidemic size in stable sexual partnerships in sub-Saharan Africa. *Sex Transm Infect*, 88, 51–57.
[193] Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour M, Kumarasamy N…the HPTN 052 Study Team. (2011). Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med*, 365, 493–505.
[194]Severe P, Juste MAJ, Ambroise A, Eliacin L, Marchand C, Apollon S,…Fitzgerald D. (2010) Early vesus standard antiretroviral therapy for HIV-infected adults in Haiti. *New Eng J Med*, 363, 257–265.
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[196]Cain LE, Logan R, Robins JM, Sterne JA, Sabin C, Bansi L,…the HIV-CAUSAL Collaboration. (2011). When to initiate combined antiretroviral therapy to reduce mortality and AIDS-defining illness in HIV-infected persons in developed countries: an observational study. *Ann Intern Med,* 154, 509–15.
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[198]Ibid .
[199]Cohen et al., 2011

demonstrated that counseling and condom use can reduce the risk of HIV transmission to a very low level even before the benefits of ART are realized. Sexual risk reduction counseling can ensure that couples are equipped with the knowledge and skills necessary to reduce the risk of HIV transmission both within the couple and to outside partners[202,203,204]. As part of risk reduction counseling, couples should be provided with an adequate supply of condoms. PEPFAR programs should offer female as well as male condoms.

- *Safer pregnancy counseling for couples who desire a pregnancy.* The most common reason cited for unprotected sex among serodiscordant couples is pregnancy desire.[205] Safer pregnancy counseling,[206] along with ART for the positive partner, is an important intervention for serodiscordant couples trying to conceive a child in order to reduce the risk of HIV transmission to the negative partner during the time of conception. This is particularly important if the woman is the 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[207,208,209].
- *Hormonal contraception among HIV-negative women in serodiscordant couples.* While some observational studies have found that women using progestin-only injectable contraception may be at increased risk for acquiring HIV[210,211,212], other

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[200] Donnell D, Baeten JM, Kiaire J, Thomas KT, Steven W, Cohen CR,…Partners in Prevention HSV/HIV Transmission Study Team. (2010). Heterosexual HIV-1 transmission after initiation of antiretroviral therapy: a prospective cohort analysis. *Lancet,* 375, 2092–8.

[201]Dunkle KL, Stephenson R, Karita E, Chomba E, Kayitenkore K, Vwalika C…Allen S. (2008). New heterosexually transmitted HIV infections in married or cohabiting couples in urban Zambia and Rwanda: an analysis of survey and clinical data. *Lancet,* 371, 2183-91.

[202]Crepaz, N, Lyles C, Wolitski R, Passin WF, Rama SM, Herbst JH…HIV/AIDS Prevention Research Synthesis (PRS) Team. (2006). Do prevention interventions reduce HIV risk behaviours among people living with HIV? A meta-analytic review of controlled trials. *AIDS,* 20, 143-57.

[203]Kennedy CE, Medley AM, Sweat MD, & O'Reilly K. (2010). Behavioural interventions for HIV positive prevention in developing countries: a systematic review and meta-analysis. *Bull World Health Organ,* 88, 615-23.

[204]Allen S, Meinzen-Derr J, Kautzman M, Zulu I, Trask S, Fideli U,...Haworth A (2003). Sexual behavior of HIV serodiscordant couples after HIV counseling and testing. *AIDS,* 17, 733-40.

[205] 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,* 12, 316-21.

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[207]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.

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[209]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.

[210]Heffron R, Donnell D, Rees H, Celum C, Mugo N, Were E,…Partners in Prevention HSV/HIV Transmission Study Team. (2012). Use of hormonal contraceptives and risk of HIV-1 transmission: a prospective cohort study. *Lancet Infect Dis*, 12, 19-26.

[211] Baeten JM, Benki S, Chohan V, Lavreys L, McClelland RS, Mandaliya K,…Overbaugh J. (2007). Hormonal contraceptive use, herpes simplex virus infection, and risk of HIV-1 acquisition among Kenyan women. *AIDS*, 21, 1771-1777.

[212]Morrison CS, Chen P, Kwok C, Richardson BA, Chipato T, Mugerwa R…Salara RA. (2010). Hormonal contraception and HIV acquisition: reanalysis using marginal structural modeling. *AIDS,* 24, 1778-1781.

studies have not found this association[213,214,215,216]. Given the mixed and inconclusive nature of this evidence, the World Health Organization recommends that HIV-negative women at high risk for HIV acquisition, including those in serodiscordant couples, who chose to use a progestin-only injectable for contraception should also be strongly advised to consistently use condoms and other HIV preventive measures to reduce their risk of acquiring HIV[217].

- *Voluntary medical male circumcision (VMMC) for HIV-negative male partners.* VMMC can reduce men's risk of acquiring HIV by 60%[218]. All HIV-negative male partners in a serodiscordant couple should be counseled on the benefits of VMMC and referred to VMMC services, as desired.
- *Annual repeat HIV testing and counseling for the HIV-negative partner.* Annual HIV testing is needed to assess whether HIV transmission has been successfully prevented[219].

- *Development and Support of Client-Driven Prevention Goals.* Encouraging PLHIV to set prevention goals that are tailored to their own unique circumstances 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 reinforcement of behaviors that will protect the health of the person living with HIV as well as the health of their partner(s) and children.
- *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 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.

Linking and Retaining Individuals into HIV Care and Treatment

Although access to HTC has rapidly expanded, only about 40% of PLHIV are aware of their status[220] and even fewer know their partner's HIV status[221, 222]. Ongoing HTC efforts must place

[213]Kiddugavu M, Makumbi F, Wawer MJ, Serwadda D, Sewankambo NK, Wabwire-Mangen F,…Rakai Project Study Group. (2003). Hormonal contraceptive use and HIV-1 infection in a population-based cohort in Rakai, Uganda. *AIDS,* 17, 233-240.
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[217]World Health Organization (WHO) (2012). *Hormonal contraception and HIV: technical statement.* Retrieved from: http://www.who.int/reproductivehealth/publications/ family_planning/ rhr_12_8/en/index.html.
[218]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.
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[220] 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.

greater priority on identifying HIV-positive individuals and serodiscordant couples. A variety of clinic and community-based HIV testing strategies will be needed to increase the number of PLHIV who know their HIV status. These include provider-initiated HIV testing and counseling (PITC) and client-initiated testing and counseling (CITC) in clinic and community (e.g., home-based) settings (see section 1.5, HIV Testing and Counseling).

Once individuals have been diagnosed, actively linking them into HIV prevention, care, and treatment services is necessary as approximately half of individuals newly diagnosed with HIV do not enroll in HIV care and treatment services[223, 224]. 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 of HIV-positive patients will drop out of care before receiving ART[225,226,227,228, 229]. Prioritizing retention of individuals who have not yet begun ART is key to enhancing the impact of prevention services as these patients are more likely to default from care[230] and are at higher risk for transmitting HIV to their partner(s) and child(ren) compared to patients with suppressed viral loads[231]. 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 both regular clinic attendance and HIV 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 tracking 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

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[221] Kaiser et al., 2011.
[222] 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.
[223] Micek et al., 2009.
[224] 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.
[225] Rosen et al., 2011.
[226] 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.
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[228] 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.
[229] Rosen et al., 2011.
[230] Larson et al., 2010.
[231] Cohen et al., 2011.

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.

Prioritize PLHIV at Highest Risk of Transmitting HIV for HIV Prevention Services

Ideally, the full package of HIV prevention messages and services should be offered to all HIV-positive patients at every clinical encounter as standard of care. However, where resources are limited, programs are encouraged to prioritize patients who are at high risk for transmitting HIV to uninfected partners and children for prevention messages and services. Characteristics of these patients are likely to vary by context but may include pre-ART patients who do not yet have suppressed viral loads, patients with substance abuse issues, and/or those patients in a serodiscordant couple.

Use Lay (or Peer) Counselors for Task-Shifting Provision of PwP/PHDP 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 can successfully provide ARV medication adherence counseling[232], sexual risk reduction counseling[233, 234, 235], and HIV testing and counseling in HIV clinics . 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.

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/PHDP 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 PwP/PHDP should be delivered in both clinic and community settings, responsibility for these programs should not fall under one domain (e.g., care and treatment, prevention, HTC), but should be shared and coordinated in order to ensure success and buy-in. There should also be meaningful involvement and leadership of PLHIV and civil society in these efforts to ensure sustainability and continuity.

[232] Torpey et al., 2008.
[233] Cornman et al., 2008.
[234] Myers et al., 2010.
[235] Peltzer et al., 2010.

Country teams should work with the Ministry of Health and National AIDS Program to ensure that PwP/PHDP is included in national guidelines and policies (e.g., Care and Treatment, the National Prevention Strategy) and to address implementation and monitoring issues. Country teams should clearly describe their plans and activities to integrate PwP/PHDP into the technical areas (prevention, treatment, care, PMTCT, etc.) and implement in clinic and community settings. These plans should include clear and measurable objectives addressing integration of PwP/PHDP, national plans for training facility and community-based service providers, national implementation, methods for documenting and reporting PwP/PHDP service provision, and ensuring PwP/PHDP services are implemented with high quality and fidelity.

1.5.3 MONITORING AND EVALUATION: PwP/PHDP

Programs should ensure that there are systems in place to document PwP/PHDP service delivery in both clinic and community settings. The PwP Task Force, in collaboration with the Strategic Information (SI) TWG, has defined a required PwP/PHDP indicator that specifies the minimum package of prevention services that should be routinely delivered to PLHIV as part of both clinic- and community-based care and treatment services. Ideally the components of the PwP/PHDP indicator would be incorporated into existing systems used to document services provided to PLHIV, such as an individual patient care card in clinics. This will allow programs to collect and report on provision of PwP/PHDP services during routine patient visits. If existing systems are not available then other documentation systems will need to be developed and implemented to collect data for this indicator. The PEPFAR Next Generation Indicators Guide includes additional information on the indicator and how it is measured. In addition to the required PwP/PHDP indicator, the PwP Task Force has developed a set of recommended indicators for countries to consider that can be used to monitor individual prevention services delivered to PLHIV (e.g., partner testing, family planning or risk reduction counseling). Programs can also collect additional indicators to monitor and evaluate quality, outcomes, and impact of prevention services for PLHIV. Whenever possible, these indicators should be standardized across partners and used nationally for ease of reporting and to inform PwP/PHDP program improvement. Countries may wish to align particular elements of the PwP/PHDP 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 Guide[236].

1.5.4 COUNTRY CONTEXTUAL CONSIDERATIONS: PwP/PHDP

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 services. These prevention services should also be expanded to community settings within the same regions. Bidirectional linkages between clinic and community programs

[236] 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: 21 August 2012.

should be developed and strengthened to increase PLHIVs' access to PwP/PHDP messages and services.

As HIV prevention services for PLHIV progress and scale-up, countries are encouraged to expand the materials, messages, and intervention strategies to include members of key populations (sex workers, people who inject drugs, and men who have sex with men). Services for uniformed personnel and their families and spouses such as military and police are also encouraged along with services for other groups with high HIV prevalence, including migrant workers, miners, transport workers, and fisherfolk.

1.5.4 LINKAGES AND WRAPAROUNDS: PwP/PHDP

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 services[237]. 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 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

[237] Micek et al., 2009.

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. Care and Treatment

2.1: ADULT CARE AND SUPPORT

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. To assure access to the continuum of care and to support timely initiation and maintenance on ART, programs should attempt to optimize linkage and entry into care following HIV testing, and retention in pre-ART and ART care. Clinical care to reduce HIV-related morbidity and mortality should include evaluation for ART eligibility so that ART can be initiated at the appropriate time; prevention and treatment of Opportunistic Infections (OIs), and other HIV/AIDS-related complications including malaria, diarrhea, and Cryptococcal disease (including provision of commodities such as pharmaceuticals, insecticide-treated nets, safe water interventions and related laboratory services); nutrition assessment, counseling and support (NACS); pain and symptom relief; and screening and treatment to prevent cervical cancer in HIV-infected women (given specific funding considerations, see Prevention of Cervical Cancer below). 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 include partner/couples HIV testing and counseling, risk reduction counseling, adherence counseling and support, STI diagnosis and treatment, family planning counseling, and condom provision. The purchase of OI drugs (excluding TB drugs) should be included under Adult Care and Support. ARV drugs should be coded under Adult Treatment and ARV Drugs.

2.1.1 INTRODUCTION

Introduction: Refocusing care and support activities to support current PEPFAR goals

In the early phases of PEPFAR, care and support programming included a broad range of services aimed at providing clinical, psychological, social, spiritual, and preventive services to HIV-infected and HIV-affected persons. With the refocusing of PEPFAR goals, as articulated by Secretary Clinton and President Obama in their respective November and December 2011 speeches, care and support programming must be redesigned to support the primary care and treatment-related goal: to have 6 million persons on ART with PEPFAR support by the end of 2013. Furthermore, as more programs transition towards country ownership and sustainability, the need to prioritize key services is essential. Accordingly, care and support programming should aim to provide services across the continuum in an integrated manner, paying particular attention to three broad areas: 1) linkage and retention (to link HIV-infected persons into care and to retain them in care throughout the pre-ART and ART periods to ensure timely initiation

and maintenance on ART), and 2) provision of non-ART services known to improve morbidity and mortality and reduce HIV transmission during the pre-ART and ART phases of HIV care, and 3) timely initiation of ART for all eligible clients.

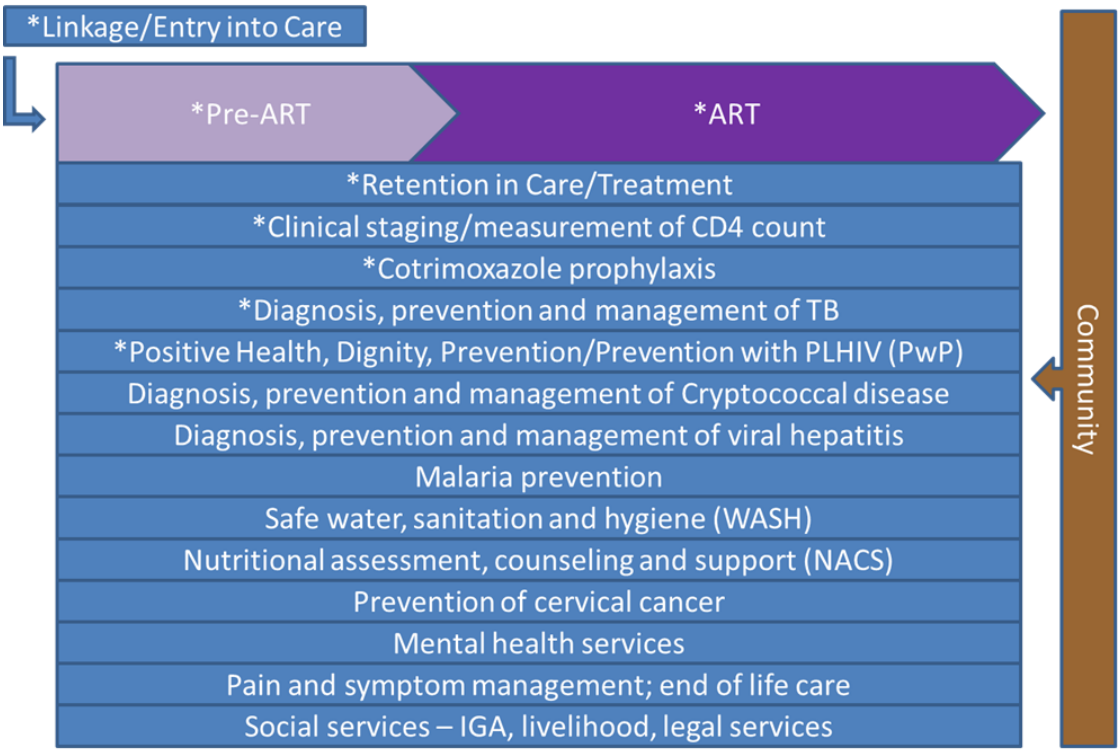
The importance of non-ART clinical services (e.g., cotrimoxazole prophylaxis) varies according to the phase of HIV infection; many of these services have the greatest impact on morbidity and mortality when HIV-infected persons are severely immunocompromised, specifically during the critical period prior to initiation of ART, and during the first several months on ART; they may be of lesser importance during the early phase of HIV infection, when CD4 counts are high, or when patients have been on ART for 6-12 months or more. It is important to note that Care and Support programming includes provision of non-ART services in both the pre-ART and the ART phases of HIV care, especially as PLHIV live longer and require lifelong care.

In prioritizing activities to include in a package of care, it is important to consider the strength of the evidence supporting each activity, particularly with regard to reduction of morbidity and mortality, along with the expected public health impact, and implications for preventing ongoing transmission of HIV. Activities which focus primarily on improving quality of life, but have no documented morbidity, mortality or prevention benefit may be of lower priority relative to activities which have documented impact on morbidity, mortality or prevention. WHO provides information on a recommended Package of Care Interventions in the WHO 2010 treatment guidelines[238]. Recommended interventions include early HIV diagnosis and linkage to care, CD4 testing, pre-ART care, positive prevention activities, TB interventions (intensified case-finding, isoniazid preventive treatment, and TB infection control), cotrimoxazole prophylaxis, treatment preparedness, and early initiation of ART. PEPFAR programs, in consultation with ministries of health, should weigh the need and public health impact of potential services for PLHIV and their families, and prioritize activities in accord with government priorities. Thus country programs should determine a "package" of care services individualized for each country, based on need, public health impact, and country priorities. Countries should also consider the needs of specific populations, e.g. women, adolescents, or key populations with specific needs; specific considerations for some of these populations are discussed below (see Section 2.1.5, Special Populations).

Programs are encouraged to profile their communities to determine priority care and support activities. The diagram below indicates the potential range of care and support services. As indicated in the diagram, virtually all of these services are applicable in the pre-ART and ART phases of HIV care. Though many of these services can be provided in either facility or community settings, the diagram below emphasizes the key role of the community, which can potentially provide critical support for many or all of the services below.

[238] WHO, Antiretroviral therapy for HIV infection in adults and adolescents: recommendations for a public health approach, 2010 revision, pp 61-63, http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf

Schematic diagram of Care and Support Services



**Included in WHO Package of Care Interventions, WHO 2010 ART Guidelines*[1]

Note that the term "palliative care," in the PEPFAR context, refers to pain and symptom management and end-of-life care. All these services are discussed further below.

The sections below describe the evidence supporting specific Care and Support interventions and their potential public health impact, particularly regarding morbidity and mortality. In the figure above and the discussion below, services are not listed in any particular order.

The Care and Support Technical Working Group is currently reviewing activities within the Care and Support portfolio to examine existing evidence on public health impact of these activities and re-assess priorities. Following review of the literature and consultation with stakeholders, new guidance will be drafted to assist countries in determining priority care and support activities.

2.1.2 EARLY IDENTIFICATION OF HIV-INFECTED PERSONS, AND LINKAGE AND RETENTION IN CARE

Early identification of PLHIV and linkage to and retention in care are essential as they ensure access to and continuity of services associated with reduction in morbidity and mortality, including pre-ART services and ART. Optimizing early identification, linkage and retention in pre-ART and ART care will be critical to attaining PEPFAR's goal of assuring 6 million HIV-infected persons on ART by 2013.

Linkage and retention in care continue to pose significant challenges in virtually all settings. Some patients who test positive never access care and treatment services; of those who do, there is significant loss to follow-up at each step along the continuum of care, particularly prior to initiation of ART. There are particular challenges for patients not yet eligible for ART. Retaining these "ART-ineligible" clients in care is particularly important to assure prompt initiation of ART when patients become eligible, to provide services which reduce morbidity and mortality (e.g. cotrimoxazole and TB interventions), and to provide key HIV prevention interventions (i.e. prevention for PLHIV/PwP services). Rosen, synthesizing available data from sub-Saharan Africa, reported that up to 2/3 of patients may be lost to follow up (LTFU) between HIV testing and initiation of ART[239]; many of these are lost during this "ART-ineligible" phase. Though tracing studies have shown that some of these clients may be receiving care in other sites, or may re-engage in care later, the scope of the problem is still extremely concerning.

Studies examining retention on ART suggest significantly higher retention rates, though still not optimal; Fox, in a meta-analysis of 33 studies from sub-Saharan Africa, reported retention on ART at 36 months of 72%[240]. Of note, evolving trends towards earlier initiation of ART, such as the trend towards Option B+ for PMTCT and implementation of WHO recommendations for early initiation of ART for serodiscordant couples, will have significant implications for retention and adherence. As patients start ART earlier, often when asymptomatic, this may pose additional challenges to maintaining them on lifelong treatment.

Improving linkage and retention in care. There are many potential factors that may contribute to low rates of linkage and retention in care; these may vary across different regions and populations. The table below lists a number of factors which may affect linkage and retention in care.

[239] Rosen S, Fox MP (2011) Retention in HIV Care between Testing and Treatment in Sub-Saharan Africa: A Systematic Review. PLoS Med 8(7): e1001056. doi:10.1371/journal.pmed.1001056

[240] Fox, M. P. and Rosen, S. (2010), Patient retention in antiretroviral therapy programs up to three years on treatment in sub-Saharan Africa, 2007–2009: systematic review. Tropical Medicine & International Health, 15: 1–15.

Factors affecting linkage and retention in care						
	Personal Characteristics	Socioeconomic	Health Care System	Social	Psychosocial	Clinical
Risk factors for patient loss	•Younger age •Infants, children, adolescents •Male •Pregnant or post-partum •Marginalized or key populations	•Distance/ transportation •Family/job commitments •Competing expenses (food, lodging, etc)	•Poor quality of care •Wait time •Drug shortages •Fees •Frequency of appointments	•Homelessness •Incarceration •Cultural beliefs	•Denial •Stigma •Fear of disclosure •Mental health conditions •Substance abuse	•Asymptomatic – no perceived need for care •Pre-ART •Advanced HIV infection
Protective factors – may favor retention			•Perceived value of services (e.g. free cotrimoxazole, other commodities) •Integrated services (vs. referral) – "one stop shop" •Services offered in community •Monitoring/ data systems that facilitate patient monitoring/tracking	•Family/social support		

Countries are encouraged to examine linkage and retention, including assessing barriers and facilitators, and to develop strategies to improve linkage and retention. As an initial step, an assessment--formal or informal--of patient, provider, and institutional barriers to participation in care should be undertaken to inform the development of appropriate strategies. Strategies should focus on identified barriers and facilitators, and should be tailored to meet identified needs in different settings and populations. A combination of approaches may be needed to address different barriers/gaps. Of note, strategies involving the community may be particularly important and have significant impact, as described below.

To optimize linkage and retention, programs need to ensure routine monitoring systems are in place; ideally this might include systems to monitor missed appointments and follow up with patients, to document and confirm patient transfers, and potentially to trace patients who are LTFU. Of note, PEPFAR programs are required to report on retention on ART (Indicator T1.3.D – "percent of adults and children known to be alive and on treatment 12 months after initiation of ART.")

More data are becoming available on interventions to improve linkage and retention. A number of potential interventions to improve linkage and retention are listed below. This is not meant to be a comprehensive listing, and there are limited data available for many of these approaches. There is evidence to support a number of these interventions, as indicated in the references listed. This may provide some information for countries as they consider strategies to improve linkage and retention.

Strategies to improve linkage to care: Efforts to strengthen linkage of HIV-positive persons to care and treatment are critically needed and should be prioritized at the point of initial HIV testing. Examples of strategies which have been implemented include:

- offering point of care (POC) CD4 testing at HTC sites[241]
- escorting and tracking newly diagnosed individuals to ensure they enroll in care
- integrating HTC services into care and treatment settings
- providing education and/or counseling on the benefits of early care and treatment
- offering case management services
- utilizing community-based programs such as home-based care to follow newly diagnosed PLHIV and facilitate clinic enrollment

Please see section 1.4, HIV Counseling and Testing, for more detailed discussion and recommendations concerning linkage to care.

Strategies to improve retention in care: A wide variety of interventions have been proposed to improve retention in care. Examples of interventions which have been implemented include:

- Community support groups – use of PLHIV community support groups to provide support, counseling and other services[242]; some may even distribute ART and monitor adherence[243]
- Community/home-based care – use of community health workers or HBC providers to monitor PLHIV, provide services/support, and promote retention in care[244]
- Patient tracing[245] (physical +/- phone)
- Mobile phone interventions[246,247]
- Provide valued commodities/services which may increase uptake of care – e.g. cotrimoxazole[248], possibly other components of "preventive care package" or nutritional support

[241] Jani IV, Sitoe NE, Alfai ER, et al (2011) Effect of point-of-care CD4 cell count tests on retention of patients and rates of antiretroviral therapy initiation in primary health clinics: an observational cohort study. Lancet 2011; 378:1572-79

[242] Zachariah R, Teck R, Buhendwa L, et al. Community support is associated with better antiretroviral treatment outcomes in a resource-limited rural district in Malawi. Transactions of the Royal Society of Tropical Medicine and Hygiene 2007; 101:79-84

[243] Decroo T, Telfer B, Biot M, Maïkéré J, Dezembro S, Cumba LI, Dores CD, et al. Distribution of antiretroviral treatment through self-forming groups of patients in Tête province, Mozambique; J Acquir Immune Defic Syndr 2011;56;e39-e44

[244] Rich ML, Miller AC, Niyigena P, et al. Excellent clinical outcomes and high retention in care among adults in a community-based HIV treatment program in rural Rwanda. J Acquir Immune Defic Syndr. 2012 Mar 1;59(3):e35-42.

[245] J. McMahon, J. Elliott, S. Hong, M. Jordan. Effects of patient tracing on estimates of lost to follow-up, mortality and retention in antiretroviral therapy programs in low- and middle-income countries: a systematic review [abstract]. XIX International AIDS Conference, July 22-27, 2012, Washington, DC, USA

[246] Lester, RT, Ritvo P, Mills EJ, et al.; Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomised trial. Lancet, 2010; 376: 1838-45

[247] Horvath T, Azman H, Kennedy GE, Rutherford GW. Mobile phone text messaging for promoting adherence to antiretroviral therapy in patients with HIV infection. *Cochrane Database of Systematic Reviews 2012, Issue 3. Art. No.: CD009756. DOI:*10.1002/14651858.CD009756.

[248] Kohler PK, Chung MH, McGrath CJ, Benki-Nugent SF, Thiga JW, John-Stewart GC. Implementation of free cotrimoxazole prophylaxis improves clinic retention among antiretroviral therapy-ineligible clients in Kenya. AIDS 2011 Aug 24;25(13):1657-61.

Other approaches focus on structural or health systems issues – e.g. decentralization; integrating services, or improving linkages between services; and task-shifting to address HR shortages. Programs may also focus on quality improvement – e.g. addressing structural barriers (limited hours, fees, frequency of visits, etc); addressing drug shortages; reducing clinic wait time; improving access to key lab results (e.g. POC CD4 testing); and improving monitoring and data systems to facilitate patient monitoring and tracking. Programs might also consider other approaches to attempt to improve the functioning of clinics, e.g. clinic flow analyses to improve patient flow and reduce wait time, or approaches to triage or stratify patients into different streams of care (e.g. "express care" for patients who only need a brief visit). Programs are encouraged to evaluate such health systems interventions to determine their impact on retention.

Additional information is available from WHO in the form of a meeting report ("Retention in HIV programmes: Defining the challenges and identifying solutions; Meeting report, 13-15 September 2011, Geneva, Switzerland," http://www.who.int/hiv/pub/meetingreports/retention_programmes/en/)

2.1.3 CARE AND SUPPORT SERVICES

The sections below describe the evidence supporting specific Care and Support interventions and their potential public health impact, particularly regarding morbidity and mortality. Services are not listed in any particular order.

- ***Clinical staging, measurement of CD4 count, and diagnosis and treatment of existing opportunistic infections*:** These services are critical to maintenance of health in HIV-infected persons who present with advanced HIV infection and thus are most likely to benefit from prompt initiation of ART. For those who enter HIV care with higher CD4 counts, retention in care and periodic CD4 measurement will ensure timely initiation of ART, and thereby avoid the significant mortality associated with the initiation of ART at low CD4 counts. Currently, 6- to 12-month mortality in persons initiating ART in PEPFAR countries is 6–10%. This early mortality should be considered preventable. Because of the universal importance of clinical staging or CD4 measurement to determine eligibility for ART and other interventions (e.g. Cotrimoxazole), and to monitor patients in the pre-ART and ART phases of care, these should be considered essential services which all programs should provide. As clinical staging or CD4 measurement is a key step in determining eligibility for ART, these interventions will directly contribute to PEPFAR's goal of increasing the number of HIV-infected persons on ART.

- ***Cotrimoxazole prophylaxis (CTX)*** — A combination of the antibiotics trimethoprim and sulfamethoxazole, generically termed Cotrimoxazole (also known as Cotrim, Bactrim, or Septra) is the mainstay for prevention of certain opportunistic infections in both industrialized and resource-limited countries. CTX has been shown to reduce morbidity and mortality in sub-Saharan Africa and has been shown to be cost-effective and even

cost-saving in some settings[249,250]. In pre-ART patients, CTX is of greatest benefit for those with the lowest CD4 counts; it is generally recommended for all persons with CD4 <350 or WHO clinical stage 2, 3, or 4; but in some countries CTX is recommended for all HIV-infected persons. CTX also confers a survival benefit in persons on ART for up to 72 weeks after ART initiation, with nearly 50% reduction in mortality[251]. In 2006, WHO published guidelines on use of CTX in resource-limited settings (http://www.who.int/hiv/pub/guidelines/ctx/en/); all PEPFAR countries should have guidelines for CTX use in HIV-infected persons. Because of the universal importance of CTX prophylaxis and its documented impact on morbidity and mortality, CTX prophylaxis should be considered an essential service which all programs should provide.

- ***Detection and treatment of tuberculosis (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%. Because of the universal importance and public health impact of TB interventions, screening and treatment for active TB should be considered an essential service which all programs should provide (see also section 2.4, TB/HIV). TB services should include:
    - 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 health care visit. All patients with a positive screen should be evaluated for the presence of active TB through a standardized algorithm. Patients with active TB should be treated promptly for TB and should also be started on ART as soon as possible, regardless of CD4 count. Starting ART for TB patients with a CD4 <50 should be considered urgent.
    - Isoniazid Preventive Therapy (IPT): Efforts should be made to ensure that IPT is provided at HIV clinics for all eligible patients in accordance with country guidelines.
    - Infection control: All HIV clinics should ensure that basic administrative and environmental infection control practices are in place to protect patients and staff.
    - Guidance on intensified case-finding and IPT is available from WHO at http://whqlibdoc.who.int/publications/2011/9789241500708_eng.pdf

- ***Prevention interventions*** supporting HIV positive persons are an essential part of comprehensive HIV prevention, care and treatment services. These interventions can reduce the risk of HIV transmission to uninfected partners and children, improve identification of previously undiagnosed HIV-infected persons, and improve the health

[249] Anglaret X, Chêne G, Attia A, Toure S, Lafont S, Combe P et al.; Cotrimo-CI Study Group. Early chemoprophylaxis with trimethoprim-sulphamethoxazole for HIV-1-infected adults in Abidjan, Côte d'Ivoire: a randomised trial. *Lancet* 1999;353:1463–8. doi:10.1016/S0140-6736(98)07399-1 PMID:10232311

[250] Wiktor SZ, Sassan-Morokro M, Grant AD, Abouya L, Karon JM, Maurice C et al. Efficacy of trimethoprim-sulphamethoxazole prophylaxis to decrease morbidity and mortality in HIV-1-infected patients with tuberculosis in Abidjan, Côte d'Ivoire: a randomised controlled trial. *Lancet* 1999;353:1469–75. doi:10.1016/S0140-6736(99)03465-0 PMID:10232312

[251] Walker AS, Ford D, Gilks CF, Munderi P, Ssali F, Reid A, Katabira E, Grosskurth H, et al. Daily co-trimoxazole prophylaxis in severely immunosuppressed HIV-infected adults in Africa started on combination antiretroviral therapy: an observational analysis of the DART cohort. *Lancet 2010;*375:1278-286.

and quality of life for people living with HIV (PLHIV). HIV testing offered to the sex partners and family members of PLHIV can identify infected partners and family members in need of HIV care and treatment, as well as identify HIV-negative partners who are unknowingly in a serodiscordant relationship. Offering anti-retroviral treatment to HIV-positive partners in serodiscordant relationships can reduce the risk of heterosexual transmission by 96%[252].

Other important prevention interventions for PLHIV include:

1) Adherence counseling and support for ARV treatment regimens,
2) Risk reduction information/counseling including condom use, partner and alcohol reduction,
3) Support for safe disclosure of HIV status to partners,
4) Family planning or safer pregnancy counseling,
5) Assessment, diagnosis, and management of STIs as part of routine HIV care, and
6) Condom promotion and distribution.

These interventions can be effectively delivered by health care providers[253, 254], counselors/social workers[255] and lay or peer counselors[256, 257, 258] in both clinic and community settings. In addition, these prevention activities contribute to maintaining the health of PLHIV and reducing transmission to their partners and children, in line with the targets for an AIDS-free generation.

Ideally, the full package of HIV prevention messages and services should be offered to all HIV-positive patients at every encounter as standard of care. However, where resources are limited, programs are encouraged to prioritize patients who are at high risk for transmitting HIV to uninfected partners and children for prevention messages and services. For example, prioritizing individuals who have not yet begun ART for HIV prevention messages and services is key as these patients are more likely to default from care[259] and are at higher risk for transmitting HIV to their partner(s) and child(ren) compared to patients with suppressed viral loads[260]. Characteristics of other patients at

[252] Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour M, Kumarasamy N et al. (2011). Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med*, 365, 493–505.
[253] Crepaz et al., 2006.
[254] 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.
[255] 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.
[256] 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.
[257] 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).
[258] 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 Zamiba. *PlosOne,* 3(5):e2204.
[259] Larson et al., 2010.
[260] Cohen et al., 2011.

high risk for onward transmission are likely to vary by context but may include patients who have difficulties adhering to ART, who have substance abuse issues, and/or those patients in a serodiscordant partnership.

It is critical at this stage when country programs are working towards achieving the goals of an AIDS-free generation that countries describe concisely SMART (specific, measurable, achievable, realistic and time-bound) plans to support full integration of the Prevention with PLHIV/PwP principles into the platforms of care and support. Further guidance on these interventions can be found in section 1.5, Prevention for People Living with HIV.

- ***Screening and treatment to prevent Cryptococcal Meningitis (CM)*** — CM accounts for more than 500,000 deaths in sub-Saharan Africa annually, likely exceeding deaths from TB in HIV-infected persons in this region.[261] Persons with CD4 counts <100 cells/mL are at highest risk. CM is preceded by the presence of Cryptococcal Antigen (CrAg) in blood. A recently available lateral flow assay (LFA) for CrAg has made it possible to inexpensively screen patients for Cryptococcal infection, and subsequently treat those with positive CrAg screening tests to prevent CM. This "screen and treat" approach will likely reduce Cryptococcal disease-related morbidity and mortality and may be cost-saving in settings with CrAg prevalence great than 3% (most areas in SSA).[262] Thus, screening patients who have CD4 counts <100 cells/mL for CrAg using low-cost assays (either latex agglutination or LFA) and pre-emptively treating those who test positive with anti-fungal therapy (oral fluconazole), should be considered prior to ART initiation in settings with high prevalence of CrAg. WHO has recently published rapid advice on the diagnosis, prevention and management of Cryptococcal disease in HIV-infected adults and children, available at: http://whqlibdoc.who.int/publications/2011/9789241502979_eng.pdf

- ***Diagnosis, prevention and management of viral hepatitis in HIV-infected persons*:** There is increasing recognition of the importance of viral hepatitis, particularly Hepatitis B and C, in HIV-infected individuals. Five to ten percent of people living with HIV are also infected with hepatitis B (HBV). In sub-Saharan Africa, the prevalence of HBV co-infection among PLHIV varies regionally and is estimated at 5-17%[263]. The prevalence of hepatitis C (HCV) co-infection among PLHIV from key populations ranges from 4-8% in HIV-positive MSM to an estimated 60-90% in HIV-positive injecting drug users. Data on HIV-HCV co-infection in sub-Saharan Africa is sparse and often of very poor quality. However, the prevalence of HCV among those with HIV is estimated to be highest in west and central Africa (1-24%) and lower in east and southern Africa (0-9%)[264].

[261] Park BJ, Wannemuehler KA, Marston BJ, Govender N, Pappas PG, Chiller TM. Estimation of the current global burden of cryptococcal meningitis among persons living with HIV/AIDS. AIDS **2009**;23:525-30.
[262] Meya DB, Manabe YC, Castelnuovo B, et al. Cost-effectiveness of serum cryptococcal antigen screening to prevent deaths among HIV-infected persons with a CD4+ cell count < or = 100 cells/microL who start HIV therapy in resource-limited settings. Clin Infect Dis **2010**;51:448-55.
[263] Hofmann, C. et al. "Clinical implications of HIV and hepatitis B co-infection in Asia and Africa." Lancet Infect Dis. 2007 Jun;7(6):402-9.
[264] Modi, AA. AIDS Rev. 2007 Jan-Mar;9(1):25-39. Viral hepatitis and HIV in Africa.

Co-infection involving HIV and HBV and/or HCV is linked with more rapid progression of viral hepatitis-related liver disease, including cirrhosis, end-stage liver disease, hepatocellular carcinoma and liver disease related mortality[265,266]. There is also some inconclusive evidence that infection with HBV and HCV may accelerate the progression of HIV[267,268].

In HIV-positive individuals co-infected with HBV and/or HCV, ART may diminish liver disease progression by preserving or restoring immune function and reducing HIV-related immune activation and inflammation[269,270,271,272,273,274]. These data suggest earlier treatment of HIV infection in persons co-infected with HBV, and possibly HCV, may reduce the risk of liver disease progression. In most United States and European guidelines, screening for HBV and HCV is recommended at diagnosis of HIV. In addition, initiation of ART is recommended for patients co-infected with HBV, and in some cases for HCV, regardless of CD4 count.

The latest version of the WHO HIV Treatment Guidelines (2010) does not contain a recommendation for screening for HBV or HCV in HIV-infected general populations in resource limited settings, although the panel placed high value on promoting HBV diagnosis. In addition, there was no recommendation to start ART at CD4>350 for either HBV or HCV, unless, in the case of HBV, "chronic-active" hepatitis could be demonstrated by either liver biopsy or HBV viral load (often impractical in resource limited settings).

PEPFAR country teams should follow national guidelines for the diagnosis of HBV and HCV in HIV Care and Treatment programs, as epidemiologically appropriate. However, as PEPFAR relies on WHO for normative guidance regarding ART, early initiation of ART for those co-infected with HBV or HCV should not be supported, unless, in the case of HBV, "chronic-active" hepatitis can be documented. PEPFAR funds should not be used to support treatment for HCV, which is currently injection based, associated with many toxic side effects, and extremely expensive. HBV can be treated with some of the same antiretroviral drugs used to treat HIV. Patients with known HIV-HBV co-infection

[265] Thein HH, Yi Q, Dore GJ, Krahn MD. Natural history of hepatitis C virus infection in HIV-infected individuals and the impact of HIV in the era of highly active antiretroviral therapy: a meta-analysis. AIDS. Oct 1 2008;22(15):1979-1991.
[266] Thio CL, Seaberg EC, Skolasky R, Jr., et al. HIV-1, hepatitis B virus, and risk of liver-related mortality in the Multicenter Cohort Study (MACS). Lancet. Dec 14 2002;360(9349):1921-1926.
[267] Greub G, et al. Clinical progression, survival, and immune recovery during antiretroviral therapy in patients with HIV-1 and hepatitis C virus coinfection: the Swiss HIV Cohort Study. Lancet. 2000;356(9244):1800-1805.
[268] Chun, Helen et al. Hepatitis B Virus Coinfection Negatively Impacts HIV Outcomes in HIV Seroconverters Journal of Infectious Disease 2012 Jan 15;205(2):185-93. Epub 2011 Dec 5.
[269] Macias J, Berenguer J, Japon MA, et al. Fast fibrosis progression between repeated liver biopsies in patients coinfected with human immunodeficiency virus/hepatitis C virus. Hepatology. Oct 2009;50(4):1056-1063.
[270] Verma S, Goldin RD, Main J. Hepatic steatosis in patients with HIV-Hepatitis C Virus coinfection: is it associated withantiretroviral therapy and more advanced hepatic fibrosis? BMC Res Notes. 2008;1:46.
[271] Ragni MV, Nalesnik MA, Schillo R, Dang Q. Highly active antiretroviral therapy improves ESLD-free survival in HIVHCV co-infection. Haemophilia. Mar 2009;15(2):552-558.
[272] Peters MG, Andersen J, Lynch P, et al. Randomized controlled study of tenofovir and adefovir in chronic hepatitis B virus and HIV infection: ACTG A5127. Hepatology. Nov 2006;44(5):1110-1116.
[273] Matthews GV, Avihingsanon A, Lewin SR, et al. A randomized trial of combination hepatitis B therapy in HIV/HBV coinfected antiretroviral naive individuals in Thailand. Hepatology. Oct 2008;48(4):1062-1069.
[274] Brau N, et al. Slower fibrosis progression in HIV/HCV-coinfected patients with successful HIV suppression using antiretroviral therapy. J Hepatol. 2006;44(1):47-55.

with CD4<350 should be treated with ART including at least 2 drugs active against HBV. For more information on the treatment of known HIV-HBV co-infection, please see the WHO HIV Treatment Guidelines (2010), available at: http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf. PEPFAR funds should not be used to support treatment of HBV mono-infection.

- ***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 from malaria is greatest. PEPFAR programs should seek ways to coordinate their activities with PMI to offer ITNs to HIV-infected persons.

- ***Safe water, sanitation and hygiene****:* Diarrhea is an important cause of morbidity and mortality in people living with HIV. Diarrhea may also reduce the absorption of antiretroviral medications. Safe water interventions have been shown to reduce the incidence of diarrhea in HIV-infected persons. Thus, PEPFAR programs are encouraged to ensure that 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. 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.

  Hand washing at critical times, with soap or ash and with proper hand washing technique, is the most important hygiene measure to be integrated across all care and support programs. Consistent and correct hand-washing can be facilitated by installation of a simple, home-crafted hand-washing device called a tippy tap. Disposing of excreta safely, isolating excreta from flies and other infectious agents, and preventing fecal contamination of water supplies are critical to reduce the spread of disease. PEPFAR can provide some support for construction of water/sanitation facilities associated with health care facilities; all such projects are subject to PEPFAR guidance for construction and renovation and require specific review and approval (see FY 2013 COP Guidance and Appendices, sections on Construction and Renovation). In 2010, the WHO published guidelines on *How to Integrate Water, Sanitation into HIV Programs*: (http://www.who.int/water_sanitation_health/publications/9789241548014/en/); as appropriate, PEPFAR countries are encouraged to include safe water, sanitation and hygiene in their programs.

- ***Nutritional assessment, counseling and support:*** 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, although intervention trial data supporting morbidity/mortality benefits are limited, nutritional assessment, counseling and support (NACS) should be integrated into care of HIV-infected persons. 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. Care and support programs should integrate NACS in both pre-ART and ART care.

Where possible, all patients should be linked to community services that can assist in the assessment of their economic and household food security status and provision of assistance to families that are destitute and food insecure through wrap-around services, e.g. Title II or World Food Programme food assistance and Feed the Future. 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 care services. More details, including definitions of supplementary and therapeutic feeding, food security, and methods to screen patients for dietary deficiencies that may justify micronutrient supplementation, can be found in section 3.8, Food and Nutrition.

- ***Prevention of cervical cancer:*** There is now extensive evidence on the association between HIV, human papillomavirus (HPV, the necessary precursor to cervical cancer), and precancerous lesions and cancer of the cervix. HIV-positive women are more likely to be infected with HPV, to have HPV infections that persist, and to have precancerous lesions and cancer of the cervix. Thus, in the context of HIV infection, cervical cancer can be considered an opportunistic process. Detection and treatment of precancerous cervical lesions can prevent progression to cervical cancer. The optimal approach to screening and treatment to prevent cervical cancer among HIV positive women has not been determined; however, given accumulating data and recent technological advances, as part of a comprehensive approach to opportunistic infections, PEPFAR can provide support for screening and treatment to prevent cervical cancer in HIV+ women. ART does not appear to reduce the risk of cervical cancer; thus screening and treatment to prevent cervical cancer remain important regardless of whether or not a woman is on ART.

  With regard to planning and program implementation, country teams should work collaboratively with appropriate host country leadership, WHO, and other key partners. To assure sustainability, country leadership must be committed to ongoing support for cervical cancer prevention. Teams should be familiar with national cervical cancer prevention policy and assess in-country capacity to provide services related to cervical cancer. In addition, country teams need to be aware of the technical complexity and quality assurance needs of cervical cancer prevention programming.

  PEPFAR-supported cervical cancer prevention programs should target HIV-infected women and use feasible and cost-effective approaches (i.e., single- or 2-visit approaches using screening with visual inspection, and treatment with cryotherapy). PEPFAR can support procurement of supplies and equipment for cryotherapy and loop electrosurgical excision procedure (LEEP, for treatment of more complex lesions). To optimize accessibility for HIV-positive women, services should be provided in HIV care and treatment settings if possible. Teams should assure systems for referral and follow up are in place if appropriate treatment is not available on-site. A sub-group of the Care and

Support Technical Working Group, the Cervical Cancer Taskforce, can provide some technical assistance and should be kept informed about country plans and experience.

In general, screening should not be provided for pregnant women or in ANC settings because of the need to delay interventions in pregnant women. PEPFAR does not provide funding for primary prevention (HPV vaccine), cytologic screening (Pap smears), or treatment for invasive cervical cancer.

- ***Mental Health:*** Mental disorders are common co-morbid conditions affecting PLHIV[275] and may affect access to and adherence to medication and retention in HIV care and treatment programs[276]. Mental health and substance abuse services may be needed to reduce behaviors that increase the risk of HIV infection or transmission e.g., alcohol or illegal drug use[277,278] and increase vulnerability to sexual exploitation or impair judgment required to engage in safe sexual practices[279,280,281]. Mental health services may also be needed to treat conditions such as depression or anxiety that may reduce adherence to HIV treatment[282,283,284]; or to address neuro-psychiatric complications of HIV disease[285] or medication side effects.

  Affected family members may need psychological services to cope with the HIV disease or death of a spouse, child or parent. Integrating mental health treatment and preventive services must be considerate of the existing health infrastructure and cultural context and 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. This will require a collaborative approach with mental health and primary health care providers, identifying standard operating procedures for seamless integration of mental health care components at varying health system levels. Lay community based care givers can be trained with the basic skills for screening and identifying early signs of mental health issues among PLHIV and then can refer for appropriate services. PEPFAR teams are encouraged to identify potential opportunities to support and strengthen mental health services.

- ***Pain management:*** The need for pain management has diminished with the wide-scale implementation of ART, but patients still frequently present with advanced HIV infection and painful opportunistic infections (e.g., candida esophagitis, cryptococcal meningitis). Special attention should be given as 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 and integration of policies for access and use of analgesics into national HIV plans and guidance. In addition, clinical

[275] Owe-Larsson B, Sall L, Salamon E, Allgulander C. HIV infection and psychiatric illness. *Afr J Psychiatry (Johannesbg)* 2009; **12**: 115-28)
[276] Smith Fawzi MC, Eustache E, Oswald C et al.. *Soc Sci Med* 2012
[277] Collins, et al. 2006
[278] Smit el al. 2006
[279] Shuper PA, et al 2010
[280] Crepaz N, Marks G. et al 2002
[281] Baliunas D, Rehm, et al, 2010
[282] Fairfield, et al, 1999,
[283] Ammassari et al., 2002
[284] Catz, Kelly, & Bogart, 2000
[285] Heaton RK, Franklin DR, Ellis RJ et al. *Neurovirol* 2011

care providers should assess for the presence of pain and other symptoms as part of routine HIV care and treatment. PEPFAR teams can work with governments and other partners to develop or revise standard training for health care providers in pain assessment and management in pre-professional and professional training.

- ***End of life care*:** The need for end of life care has also diminished with the wide-scale implementation of ART, but there will always be patients in need of these services. End of life services (e.g., hospice care) should always be available to provide this assistance. However, such interventions are of limited public health benefit, and PEPFAR should work with governments and other donors to encourage country ownership and transition support for these services.

2.1.4 CROSS-CUTTING ISSUES

- ***Optimizing efficiency and sustainability*:** PEPFAR programs should prioritize identifying and implementing strategies that can increase program efficiency and decrease costs, while ensuring sustainable delivery of quality care. Reducing program duplication, decreasing costs, and creating efficiencies and synergies between PEPFAR, government and other donor resources, can help assure optimal use of funding and maximal public health impact. Use of expenditure analysis to examine actual program costs across geographic regions and partners can help to identify possible efficiencies and rationalize spending (see section 3.11, Finance and Economics).

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

  - Rational geographic distribution of partners (i.e., regionalization)
  - Assessment of services provided by PEPFAR partners, government and other donors within geographic regions to minimize duplication and enhance efficiencies
  - As appropriate, development of a standard package of care services for each country program to optimize equity and efficiency *(see discussion of care services in Introduction above)*
  - Close evaluation of overhead, indirect costs, and partner pipelines
  - Maximizing use of generic formulations purchased by pooled procurement
  - Safely rationalizing the use of laboratory monitoring
  - Support for transition of program implementation from international partners to local partners and ministries of health, including building capacity of governments and local partners

- ***Assuring quality care:*** PEPFAR programs need to prioritize assuring quality care throughout the continuum of care, whether provided in a facility, community, or home-based care setting. Strategies to improve quality of care 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 to commodity procurement. Programs may also consider implementation of formal quality

improvement programming. Monitoring of care and support activities remains a challenging area for many reporting systems. Data quality assessments will facilitate improvement in care by ensuring that data collected through routine patient and program M&E practices are of high quality. Since services may be facility-based, community-based, and/or home-based, the quality of services provided includes attention to networks, referrals, and linkages between these services. See WHO Patient Monitoring Guidelines for HIV Care and Antiretroviral Therapy (http://www.who.int/hiv/pub/imai/PatientGuide/en/).

- ***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 rapid scale up of ART in many settings, fewer persons are suffering from severe symptoms related to advanced HIV disease and the majority of ART clients are active participants in their communities. In addition, clients who are not yet on ART but remain stable may not require intensive 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 and support needs of stable pre-ART and ART clients, PEPFAR teams should consider the establishment of community level service delivery models to assist with linkage to and retention in HIV care and to provide access to basic HIV care services such as CTX prophylaxis and TB screening, as appropriate. Community care models may also be helpful in providing other care services such as 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, and social services, including linkages to income-generating activities and sustainable livelihood programs.

  Numerous programs have developed and implemented community level service delivery models, such as the 'hub and spoke model', in order to create efficiencies and maintain quality. USG teams are strongly encouraged to examine the benefits of these models for expanding outreach services and increasing the numbers of HIV infected persons receiving care services, improving retention, and empowering communities to provide services to their peers. To achieve these goals, programs are encouraged to strengthen the "Hub-and-Spoke" model to ensure that community based programs are affiliated with facilities that provide supportive supervision of community service delivery. This will require the establishment of simple M&E tools that allow documentation and formalization of the bi-directional referrals between facility and community based programs. It is recommended that programs formulate a reconfigured list of priority care and support services that could be considered standard/required for ART and pre-ART patients enrolled in care. Provision of services in the community by community health workers or community-based organizations offers many advantages, especially given human resource shortages, inadequate infrastructure, and challenges related to distance and lack of transportation, particularly in rural areas. Facility based programs also need to acknowledge and formally coordinate with community based services in order to assure the continuum of response to comprehensively address patient needs.

- ***Bi-directional referrals and linkages between facility- and community/home-based services:*** Efforts to integrate services are underway but it remains extremely challenging to provide all care and support services at a single HIV care site. Services may be

provided by different partners through a continuum of service networks with effective linkages between facility-, community-, and home-based care programs with systems in place to ensure that clients reach their referral destinations and receive appropriate care, minimizing loss to follow up between one service point and another. Usually the majority of clinical services are administered at the facility, and community-based sites provide the additional non-clinical components of care and support that all contribute to ensuring improved treatment and care outcomes. Some community-based models serve to bridge the gap of distance and service provision between the health facility and the home as they provide some clinical care services in the community, such as mobile care services, ARV refills, OI distribution and other services.

- ***Gender:*** Gender inequality is a fundamental driver in the HIV epidemic, and integrating strategies to address gender inequity and change harmful gender norms is an important component of PEPFAR HIV programs, including Care and Support activities.

  Care and Support programs should promote:

  1. Gender-equitable service provision, using strategies to engage both men and women.
  2. Gender-based violence prevention and response given that violence increases HIV risk and can be a barrier to service access.
  3. Redress of structural inequities and the gender norms that drive the HIV epidemic and impede the response.

  See section 3.5, Gender, for more detailed information.

- ***Human resources and training*****:** Given the need to integrate clinical and psychosocial assessment and management between facilities, communities, and home-based care (C/HBC) settings**,** training programs, mentoring, and ongoing supervision are required for clinical and non-clinical (lay persons and other C/HBC) providers to ensure quality services, based on their expected roles and competencies. The content and nature of these efforts will vary considerably, depending on the cadre of health providers and the sites at which services are provided. 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 community health workers 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 and, formalizing cadres of community health workers and integrating them into the health system.

- ***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 OI prophylaxis, and medications for OI management and for 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.

- ***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 (HIV and Disability - A Companion to Chapter 13 of Health People 2010; HHS.gov). 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.

2.1.5 SPECIAL POPULATIONS

- ***People who inject drugs (PWID):*** People living with HIV who inject drugs may have a number of complex medical, psychological and social needs, in addition to the basic needs faced by PLHIV described above. Specific guidance regarding recommended interventions for PWID is available from WHO (WHO/UNODC/UNAIDS Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users, 2009, available at http://www.who.int/hiv/pub/idu/targetsetting/en/) and from PEPFAR (Comprehensive HIV Prevention for People who Inject Drugs, Revised Guidance, 2010, http://www.pepfar.gov/documents/organization/144970.pdf); see also section 1.3.3, Biomedical Prevention: Injecting and Non-Injecting Drug Use. Specific issues for care and treatment programs are described below.
  - *Increasing access to HIV care and treatment:* People who inject drugs face many barriers to HIV care and treatment, due to stigma, harsh and punitive social and legal environments, rigid and bureaucratic health systems, limited availability of effective substance abuse treatment, limited patient resources, challenges related to substance abuse, and often homelessness or incarceration. For these reasons, linkage and retention in care pose particular challenges for PWID, and ART coverage is often disproportionately low. PEPFAR programs, working with governments, health care providers, law enforcement, NGOs, and peer and community groups, must work to create enabling environments and address barriers to care. In particular, increasing access to effective drug treatment, such as medication-assisted treatment (MAT, e.g. methadone for opioid dependence), has been shown to reduce injecting drug use and to improve retention and adherence to ART. Ideally, HIV care and treatment and MAT services should be integrated or co-located; provision of case management services and/or peer support may also help improve access to these critical services for PWID.
  - *Viral Hepatitis:* PLHIV who inject drugs are at very high risk for hepatitis B and C; please see section above on viral hepatitis. WHO guidance is available at http://www.who.int/hiv/pub/guidelines/hepatitis/en/index.html
  - *Overdose Prevention*: PLHIV who inject opioid drugs are at significant risk of death due to drug overdose; naloxone has been proven to reduce mortality due to opiate overdose. Care and support programs can support procurement of naloxone, provider training and capacity building, efforts to ensure inclusion of naloxone on essential medicines lists, and policy and legislative changes that support broader availability of naloxone for PWID.
  - *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 clinics or MAT sites), and other strategies.

- ***Adolescents*:** Adolescents infected perinatally or vertically have different clinical needs; however, all require care and support services. As children on ART are expected to live long healthy lives, the need to improve services, policies and programs in order to serve adolescents living with HIV (ALHIV) and their families/ caregivers is critical. Programs are encouraged to be considerate of the multiple needs of ALHIV. In addition to a strong focus on self-care that includes adherence and retention on ART and adoption of individualized prevention strategies, other critical issue to address among ALHIV include particularly complex clinical and psycho-social/mental health (including substance abuse) issues. Please refer to section 2.3, Pediatric Care and Treatment for guidance on how to provide multi-disciplinary care and support to meet the needs of adolescents.
- ***Aging populations:*** Diagnosis of HIV or AIDS at older ages presents new challenges for HIV medical care and service providers. Older persons are less knowledgeable about HIV/AIDS and condom use. They are less likely to consider themselves at risk for infection or get tested for HIV. Individuals living longer while being treated for HIV infection may begin to develop chronic health conditions related to aging at an accelerated pace. These issues present new challenges to prevention and treatment strategies which formerly focused solely on younger age groups. Furthermore, as patients mature on ART, programs will need to establish an approach that accommodates the integration of services that cater to aging populations, including non-communicable, chronic conditions such as diabetes and hypertension.

2.1.6 MONITORING AND EVALUATION

Monitoring of care and support activities remains a challenging area for many reporting systems. Since services may be facility-based, community-based, and/or home-based, the quality of services provided includes attention to networks, referrals, and linkages between these services. 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 and/or in more than one location (such as in facility-based and community-based services). The PEPFAR II "Next Generation Indicators" include three that are reportable to OGAC across PEPFAR country programs: 1) Care (which includes services to HIV-infected and -affected persons and OVC), 2) HIV Clinical Care (provision of at least one clinical care service to HIV-infected persons in care), and 3) receipt of CTX prophylaxis. As indicated above, the clinical care stipulates that, for HIV-infected persons to be counted as receiving clinical care, at least one clinical care service must be provided. Programmatically, the Care and Support TWG hopes that multiple services would be provided to HIV-infected persons. Generally speaking, when an HIV-infected person is enrolled in care, multiple clinical services are provided beginning with the first visit. Details of these services should be provided in program descriptions. When services are provided in multiple

locations, including in facility- and community-based programs, methods should be in place to de-duplicate numbers reported across PEPFAR country programs to OGAC, such that patients are counted only once, regardless of the number of services being provided.

- ***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 and ART clients in care and treatment,
    - Identification and reduction of missed opportunities for CTX prophylaxis where indicated,
    - "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 persons.

2.1.7 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).

2.1.8 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, do not 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.

2.1.9 LINKAGES AND WRAPAROUNDS: ADULT CARE AND SUPPORT

A wraparound activity wraps or links together PEPFAR programs with programs from other sectors to provide comprehensive programmatic support and to 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, 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, PEPFAR funds may be used to support wraparound activities that directly serve PEPFAR priority populations by supporting HIV prevention or treatment or care of PLHIV, and are in keeping with other PEPFAR guidance.

2.2: ADULT TREATMENT

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.

2.2.1 BACKGROUND: ADULT TREATMENT

From 2004 to present, the effort to scale up adult treatment under 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 treatment has been a cornerstone of this unprecedented effort and as of the end of FY 2011, PEPFAR directly supported over 3.9 million persons on lifesaving ART.

Supporting national treatment programs to increase access to those in need of treatment remains a central priority of the PEPFAR program. Further, in 2011, a groundbreaking study, HPTN 052, definitively demonstrated that provision of antiretroviral therapy reduced HIV transmission to HIV-uninfected partners in sero-discordant couples by 96 percent, an efficacy on par with vaccination[286]. ART is now viewed by the scientific community and PEPFAR not only as essential for decreasing morbidity and mortality, but also as a highly effective approach to prevent HIV transmission and achieve an AIDS-free generation. In recognition of these benefits, on World AIDS Day 2011, President Obama announced PEPFAR's new ambitious treatment target of six million persons directly supported on treatment by 2013. This goal will increase the size of the PEPFAR treatment program by 50 percent.

Expanding access to include treatment for prevention services should be driven by local priorities and context, and strategically adopted with prioritization of coverage for those most in need. PEPFAR's policy of supporting national treatment programs to increase access to those in need of treatment for their own health as a first priority remains a central tenant of the PEPFAR program. PEPFAR also endorses and will assist national programs in the implementation of recent WHO Guidelines on treatment for sero-discordant couples regardless of immune status[287]. In addition, PEPFAR will support national programs interested in adoption of the new PMTCT Option B+ "test and treat" approach for pregnant women described in the recent WHO Programmatic Update[288].

Key populations (men who have sex with men and transgenders, sex workers, and people who inject drugs) typically have HIV prevalence that exceeds that of the general population and are key beneficiaries of treatment as prevention services. However, stigma, discrimination, and fear of legal sanctions often preclude their access to services. Therefore, it is essential that ART

[286] Cohen M et al. Prevention of HIV-1 infection with early ART. New England Journal of Medicine, 2011 Aug 11; 365(6):493-505.
[287] WHO Guidance on couples HIV testing and counselling, including antiretroviral therapy for treatment and prevention in serodiscordant couples; http://whqlibdoc.who.int/publications/2012/9789241501972_eng.pdf
[288] WHO Programmatic Update; Use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants; http://www.who.int/hiv/pub/mtct/programmatic_update2012/en/

programs support a non-stigmatizing clinical environment that enables key populations to have meaningful access to treatment services, including both facility and community-based care and support.

As programs mature and healthier populations are considered for treatment not only for their own health but also as prevention, there must be increased attention to systematically ensuring adherence and retention on ART and the quality of ART programs. This will maximize the beneficial effects for individuals receiving treatment and ensure that the broad and important contributions of ART to preventing vertical and sexual transmission of HIV infections are achieved.

There must also be increased attention to a strengthened facility-based continuum of care that is appropriately linked to community-based care, as well as support for activities that foster conducive environments for service uptake, adherence, and retention. PEPFAR teams should also enhance their programmatic efforts to identify eligible PLHIV through testing and counseling activities (i.e. PMTCT, VMMC, PITC, VCT) and link those patients to ART services.

In addition, increasing levels of attention should be paid to issues of HIV drug resistance. In most PEPFAR-supported countries, routine HIV drug resistance surveillance is not considered an integral part of national ART programs. However, the WHO, in collaboration with PEPFAR, has adopted an updated framework for routine HIVDR surveillance activities likely to have maximal public health impact and that are relatively simple to implement, while successfully informing public health policy.

Treatment scale-up to date has generally been of high quality, with national outcomes evaluations in Rwanda, Kenya, and Mozambique demonstrating 78 percent 12-month retention rates on treatment and mortality, CD4 count gains, and virologic suppression rates similar to that 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 and are on an excellent trajectory to maintain these high levels of service. Furthermore, quality improvement programs have been and should continue to be integrated into many ART clinics to continually improve retention, adherence, and response to ART.

Ensuring the sustainability of ART programs also 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.

In 2011, field teams with treatment portfolios participated in treatment consensus targeting for 2012 and 2013. The aggregate of these data was used to derive the target of six million on treatment by 2013. Country teams are expected to achieve or exceed these targets. SAPR and APR calls will provide opportunities for country teams to report progress, identify challenges, and engage headquarters support for course corrections and additional resources, as necessary.

Information regarding budget allocations to treatment is provided below in 2.2.4B, Access and Integration: Adult Treatment – Costing and Modeling. As the FY 2013 COP Guidance states, country teams are expected to budget appropriately and realistically to meet treatment targets. Special consideration should be given to costing and budgeting for pregnant women in need of treatment for their own health and PMTCT. Regardless of their entry point (PMTCT or Treatment program), treatment for eligible pregnant women should be forecasted, costed, and fully and adequately budgeted for in PEPFAR supported programs.

2.2.2 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. These priorities are summarized in four categories: **1) Treatment as Prevention 2) Access and Integration, 3) Quality and Oversight, and 4) Sustainability and Efficiency.** Highlights of these technical considerations include:

A. Treatment as Prevention

- Continued support of national ART programs prioritizing ART for those in need of treatment for their own health as a first priority.
- Monitoring entry CD4 levels to ensure effective HIV counseling and testing, and referrals. As treatment programs grow, entry CD4 counts should continue to rise and eventually reach 350. Continued presentation of patients with lower CD4 counts is an indication that HCT and referral strategies need to be strengthened.
- Support of WHO guidelines on treatment of serodiscordant couples (2012) and the WHO PMTCT Programmatic Update (2012) including Option B+.

B. 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.

C. 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;
- 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;
- Standardized, periodic supportive site supervision and regular program reviews as an integral part of USG-supported ART programs; and
- Support for a national system of pharmacovigilance.

D. 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;
- Transitioning to Technical Assistance models; and
- Development of a standard package of ART services to promote equity and efficiency.

PEPFAR's treatment strategy over the next two years emphasizes the following:

- Directly supporting more than six 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 2013.

2.2.3 TREATMENT AS PREVENTION: ADULT TREATMENT

Several observational studies have suggested that provision of ART to HIV-infected persons regardless of their immune status has prevention benefits.[289,290] The evidence base was strengthened with the reporting of data from the HPTN 052 trial, released in 2011. This study demonstrated a significant reduction in new infections among HIV-negative partners in serodiscordant relationships – 89 percent reduction in overall new infections and 96 percent

[289] Donnell D et al. Heterosexual HIV-1 transmission after initiation of antiretroviral therapy: a prospective cohort analysis. The Lancet. 2010, 375(9731):2092–2098.
[290] Attia S et al. Sexual transmission of HIV according to viral load and antiretroviral therapy: systematic review and meta-analysis. AIDS. 2009, 23:1397–1404.

reduction in linked infections – when the HIV-positive partner was provided ART early (with a CD4 count between 350 and 550 cells/mm3).[291]

To reduce HIV incidence to levels needed to achieve Secretary Clinton's goal of an AIDS-free generation, treatment will need to be expanded to healthier HIV-infected populations. PEPFAR supports expanding access to ART for serodiscordant couples, and countries interested in adopting Option B+ for pregnant women with higher CD4 counts. However, PEPFAR remains committed to prioritizing ART for those who need it for their own health. This is not only ethically imperative, but also is a strategy that maximizes the prevention benefits of treatment. Recent modeling studies suggest that treatment of those with CD4 counts <350 is likely to reduce the greatest proportion of new infections.[292]

A. Treatment of Serodiscordant Couples

In April 2012, WHO released formal guidance on testing, counseling and treatment for all HIV-positive individuals in serodiscordant relationships, regardless of CD4 count.[293] These guidelines stress the importance of scaling-up couples testing and counseling and recommend the provision of antiretroviral therapy to HIV-positive partners in a serodiscordant partnership, regardless of CD4 count.

Despite strong support in principle for expanding treatment access to include provision of ART to all HIV-positive individuals in serodiscordant relationships, PEPFAR support for the use of ART for prevention should be driven by local priorities and context and strategically adopted with prioritization of coverage of those most in need, in light of resources provided by all funding sources. In particular, as stated in the WHO guidance, "where resources for ART are limited, priority should always go to treating those who need ART for their own health over offering earlier treatment to some people for the purposes of preventing HIV transmission to others." PEPFAR country teams are encouraged to work closely with host-country governments to revise country ART guidelines and provide operational guidance on expanded use of ART in serodiscordant partnerships, as appropriate.

Understanding that this is a new tool available to curb the HIV epidemic, PEPFAR implementing partners are also encouraged to report and disseminate lessons learned and best practices on operational issues such as:

- The acceptability and impact of HIV treatment in same-sex relationships or among populations who use injecting drugs. While WHO guidelines have not reviewed the prevention effect of earlier ART on homosexual couples or other key populations, scientific consensus is emerging that ART significantly reduces the risk of HIV transmission regardless of the population or setting.
- Best practices on linking serodiscordant couples identified through couples counseling and testing programs to ART services, especially when ART care is frequently provided in an individualized setting. Please refer to the HTC Technical Considerations for more information on implementation of couples HIV testing and counseling.

[291] Cohen M et al. Prevention of HIV-1 Infection with Early Antiretroviral Therapy. NEJM. 2011, 365:493-505.
[292] Hallet et al. PLoS Med. 2012 Jul;9(7):e1001245. Epub 2012 Jul 10.
[293] Guidance on couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples: recommendations for a public health approach. WHO. April 2012. Available at: http://www.who.int/hiv/pub/guidelines/9789241501972/en/

- Best practices to identify HIV-infected men through HIV testing at maternal and child programs, where early treatment of the HIV-infected man could prevent both transmission to his female partner and to potential offspring.

B. Supporting the WHO PMTCT Programmatic Update (2012), including Option B+

All PMTCT interventions recognized by WHO (Options A, B, and B+) require the provision of ART to women who need it for their own health for both treatment and reduction of MTCT (at CD4<350).[294] However, despite impressive improvements in overall treatment coverage, treatment coverage of pregnant women remains unacceptably low due to structural barriers such as access to a CD4 count and programmatic barriers. One programmatic barrier includes the practice of "siloed" planning of PMTCT and treatment programs, resulting in under-forecasting and underfunding of treatment for pregnant women. PEPFAR is committed to improving ART coverage of pregnant women; the FY 2013 COP Guidance requires co-planning, co-forecasting, and co-budgeting for treatment of pregnant women across treatment and PMTCT programs (also see section 1.1, Prevention of Mother to Child Transmission).

In addition, PEPFAR will support interested national programs in adoption of the new PMTCT Option B+ "test and treat" approach for HIV-infected pregnant women, described in the recent WHO Programmatic Update as likely preferable for operational, programmatic, and strategic reasons. However, because of the limited outcome data available on Option B+ implementation and the significant long-term consequences of treatment discontinuation on mortality and resistance, OGAC will pay particular attention to the planning and strategies described for countries moving to Option B+ (also see section 1.1, Prevention of Mother to Child Transmission).

2.2.4 ACCESS AND INTEGRATION: ADULT TREATMENT

A. National ART Guidelines and Strategy

Updated WHO HIV treatment guidelines are anticipated in early 2013. In the meantime, PEPFAR country teams should continue to support national stakeholders in revising and implementing 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. As recommended by the 2010 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 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.

[294] WHO PMTCT Programatic Update 2012; http://www.who.int/hiv/pub/mtct/programmatic_update2012/en/

B. Costing and Modeling

Country teams are expected to forecast and budget appropriately to meet PEPFAR treatment targets in the context of all available funding streams. Special consideration should be given to costing and budgeting of pregnant women in need of treatment for their own health and PMTCT, regardless of their entry point (PMTCT or treatment program).

PEPFAR teams should also pay special attention to the commodities situation in their host countries. Funding gaps for commodities affecting PEPFAR treatment targets may be related to funding flows of Global Fund grants (e.g. delayed signing, delayed disbursement, unanticipated gap between grants, conditions precedent); government budgetary shortfalls; or issues related to in-country procurement processes. As Global Fund faces a transitional funding period and moves toward a new funding model, to be implemented over the course of 2013-2014, this may present both commodities challenges as well as further entry points for PEPFAR and Global Fund coordination to ensure sufficient commodity stocks.

PEPFAR teams should work with other stakeholders to budget *realistically* to ensure that commodities for all PEPFAR treatment targets are available. *OGAC headquarters must be immediately made aware if there is a potential funding shortfall that could affect PEPFAR treatment targets; OGAC has established a Commodities Task Team to assist country teams with commodities* shortages and help with the identification of resources.

PEPFAR teams should also work closely with the Global Fund Prime Recipient and Fund Portfolio Manager and implementing partners in country, particularly with commodities and logistics experts, to share information on commodities and evaluate how Global Fund resources and performance should shape PEPFAR forecasting and budgeting. Systematic sharing of commodities data from both PEPFAR and Global Fund partners is needed to accurately budget, particularly in countries where sites and targets overlap. PEPFAR teams should be vigilant for potential disruptions of supplies of essential commodities particularly of other funders and should actively engage early and intently. PEPFAR teams should adequately budget for buffer stocks, and intervene where Global Fund and/or country systems have broken down (or are experiencing challenges). This, in some cases, may involve procuring a greater proportion of ART than in years past.

It is a high priority for both PEPFAR and Global Fund to ensure that drugs are procured, distributed, and available to the people we all serve, on time and with appropriate, risk-aware procurement practices in place. PEPFAR teams that have questions about opportunities to elevate Global Fund-related issues via technical and diplomatic channels, that need to obtain commodities data for responsible forecasting, or that face challenges with Global Fund processes should actively engage headquarters in support of these issues.

At the same time, country programs should continue to place emphasis on identifying and implementing strategies that can increase program efficiency and decrease costs, while ensuring quality care delivered in a sustainable fashion. Reducing program duplication, decreasing costs, and creating efficiencies and synergies between Global Fund and PEPFAR resources will further help to increase coverage and save more lives.

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.

Adult Care and Support Services

The Adult Care and Support TWG has significantly revised the Care and Support Technical Considerations (see Section 2.1) to align with PEPFAR's new goals, and in line with an ongoing reassessment of Care and Support priorities. This new approach defines "core services," which should be offered by all care and treatment programs; these are critical services which apply across geographic regions and patient populations. In addition to the universal need for these services, there is strong evidence supporting their morbidity/mortality benefit, expected public health impact, and implications for preventing ongoing transmission of HIV. This category includes services related to linkage and retention in care; core clinical services (clinical staging or CD4 measurement; cotrimoxazole prophylaxis; and diagnosis, prevention and management of TB); and core prevention services (prevention with PLHIV/PwP).

In addition to these core services, many other services are also important, but the need for these may vary across geographic regions or patient populations. Further, there may not be clear evidence for reduction of morbidity or mortality for some of these interventions; so the potential public health impact may not be clearly defined. Thus PEPFAR programs, in consultation with ministries of health, should weigh the need and expected public health impact of these services for PLHIV and their families, and determine which additional services should be provided, beyond the core services described above.

Of note, Care and Support programming includes provision of these core and additional services in both the pre-ART and ART phases of HIV care, as many of these services are important for both pre-ART and ART clients.

Though many core and additional services can be provided in either facility or community settings, the community can play a key role through providing critical support for many or all

of these services, including key support for linkage and retention. PEPFAR programs are encouraged to consider possible roles for increased community involvement to improve the quality, availability and accessibility of care services.

The Care and Support Technical Considerations also include additional information on linkage and retention, including potential interventions to improve linkage and retention.

PEPFAR programs should work with ministries of health, key stakeholders and communities to examine linkage and retention, including assessing barriers and facilitators, and to develop strategies to improve linkage and retention. Strategies should focus on identified barriers and facilitators, and should be tailored to meet identified needs in different settings and populations. As noted, strategies involving the community may be particularly important and have significant impact.

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. Patients with active TB should be treated promptly for TB and should also be started on ART as soon as possible, regardless of CD4 count. Starting ART for TB patients with a CD4 <50 should be considered urgent.
    - Isoniazid Preventive Therapy (IPT): Efforts should be made to ensure that IPT is provided at ART clinics for all eligible patients in accordance with country guidelines.
    - Infection control: All ART clinics should ensure that basic administrative and environmental infection control practices are in place to protect patients and staff.
    - 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)

Initiating and retaining women on ART and in long-term HIV care and treatment will require strengthened linkages between PMTCT and ART programs now and will become increasingly critical as more countries shift to Option B+. 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;
- Integration of ART services and MCH services, including PMTCT and family planning;
- Implementation of effective strategies to link and enroll women into HIV clinical care (e.g., physical escorts to the HIV clinic, fast-tracking), accompanied by ongoing case management by dedicated linkage staff; and

- Instituting tracking systems to identify women who fail to enroll in ART services either during pregnancy or post-partum or who are lost to follow-up.

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 a pre-ART care program (e.g., wellness programs) for periodic follow-up and prompt identification of ART eligibility. Many other important services can be offered as part of pre-ART care, including interventions documented to reduce morbidity and mortality (e.g. co-trimoxazole (CTX) prophylaxis and TB interventions) and HIV prevention interventions, as well as other key care services.
- Use of "pre-ART" registers and/or other monitoring systems are encouraged;
- 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, especially of partner(s) and children of PLHIV,
    - HIV primary care,
    - opportunistic infection (OI) management,
    - TB management,
    - family planning (FP) and 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;
- Promote activities designed to retain existing workers in the system; and
- Task shifting delivery of HTC services and other HIV prevention services (ie. sexual risk reduction counseling, adherence counseling and support, condom provision, etc) to trained lay workers (i.e. lay counselors, peer counselors, community health workers, expert patients) can reduce the burden on health care providers and meaningfully involve PLHIV in HIV prevention efforts.

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.

2.2.5 QUALITY AND OVERSIGHT: ADULT TREATMENT

A. *Quality Oversight of USG-supported ART* Programs: Quality considerations for successful ART scale-up and sustainability, while achieving and maintaining a high quality of patient care, include:

- QM/QI Support: USG should continue to support quality management (QM) and quality improvement (QI) programs and activities among implementing partners; these should be harmonized and aligned with national, Ministry-led, quality plans and initiatives.
- Performance Data: Performance measures and indicators should be routinely collected and reported. They should be based upon and aligned with national standards of ART care and reviewed routinely to guide QI at partner and site levels.
- Retention and Adherence: Lifelong retention in care and ART adherence require aggressive, facility-based approaches to monitor and improve both retention and adherence.
    - Successful retention and adherence rely upon routine monitoring of performance measurement and quality improvement, when performance gaps are identified.
    - All programs should have a system for and demonstrate successful linking, enrolling, and retaining newly diagnosed HIV-positive individuals into HIV care and treatment services.
    - All programs should include context- and culturally-appropriate adherence approaches and measures (i.e. documentation of self-reported adherence and/or pharmacy refill tracking) that optimize response to ART.
    - All programs should demonstrate the ability to collect accurate retention data, include plans for routine monitoring of those at risk for falling out of care, and have a system for tracking patients lost to follow-up (LTFU). This might include having a system for monitoring missed appointments daily or weekly and documenting patients referred to other ART sites and their uptake at those sites. Specific interventions for LTFU prevention and retrieval should be described.

- Site Supervision: Each program should have a standardized and routine supportive site supervision system, which is complementary to and consistent with the country MOH strategy. Some of the benefits of periodic site supervision include:
    - Identifying problem areas to guide QI interventions.
    - Improving collection and reporting of high-quality performance data.
    - Building capacity among staff at the site level through mentoring and problem-solving activities.

B. *Monitoring Patients for Treatment Failure*:

The increasing ART coverage in resource-limited settings in the absence of routine viral load monitoring is raising concerns about the development of resistance to first-line ART regimens, long-term individual patient outcomes, and increased risk of transmission of HIV, including drug-resistant HIV. Several studies have shown that the WHO-recommended surrogate markers of virologic failure, such as dropping or inadequate rises in CD4 counts or weight loss, are poor predictors, and their use in treatment switch decisions is not optimal. To sustain the progress made in reducing morbidity and mortality from HIV through ART, it is important that HIV-infected patients continue to have access to safe, tolerable, and potent ARVs. To accomplish this, the use of viral load testing to monitor HIV treatment will need to be expanded.

The high cost of commercially available viral load tests, the required expansion of infrastructure at the ART sites and in HIV PCR laboratories, and the stringent cold chain requirements for processing and shipment of specimens for VL testing are only a few examples of the barriers that prevent the expansion of VL testing. However, several evaluations are ongoing to assess the use of dried blood spot cards and point-of-care VL diagnostics, which aim to address many of the current barriers to VL testing.

Increasing the availability of viral load monitoring remains a challenge in most PEPFAR-supported countries. Wherever possible, PEPFAR should assist the country in expanding the capacity for VL testing through activities such as procurement of reagents and/or platforms and support for transportation systems for processing and shipment of specimens.

C. *ARV Drug Resistance*

- As ART scale-up to achieve World AIDS Day targets continues, ongoing concerns about the potential for increasing HIVDR need to be addressed. In most PEPFAR-supported countries, routine HIVDR surveillance is not considered an integral part of national ART programs; however, COP guidance for 2013 now states that HIVDR surveillance activities should be incorporated into national ART programs and repeated at least every two years. In addition, to prevent HIVDR, PEPFAR supports robust monitoring of ART programs to ensure maximal virologic suppression.
- The WHO, in collaboration with PEPFAR, has adopted an updated framework (available at http://www.who.int/hiv/pub/drugresistance/en/index.html) for routine HIVDR surveillance activities that are relatively simple to implement, while successfully informing public health policy. This updated framework has five elements:
    - Cross-sectional survey of baseline HIVDR in adults initiating ART at representative sites.
    - Cross-sectional survey of acquired HIVDR in adults and children on ART for >12 months at sentinel sites.
    - Survey of HIVDR in children <18 months of age newly diagnosed with HIV.

        - Survey of transmitted drug resistance (TDR) in recently infected populations.
        - Monitoring of HIVDR Early Warning Indicators (EWIs).
    - Countries may not find it feasible to implement all five components of this strategy and therefore should prioritize activities that help answer the following questions:
        - Is the prevalence of transmitted HIVDR high enough to potentially impact the efficacy of empiric first-line ART?
        - Is the pattern of HIVDR in patients failing first-line ART likely to significantly impact the efficacy of second-line ART?
    - The monitoring of indicators that are believed to indicate risk of HIVDR, such as EWIs, should be incorporated into the overall monitoring of a national ART program.
    - While other sources of funding for HIVDR surveillance activities may exist, PEPFAR program implementation funds should be allocated to fill any identified gaps.

D. 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.

2.2.6 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", PEPFAR programs should 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 (see above 2.2.4B "Access and Integration – Costing and Modeling " for further details).

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. 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 recently completed Track 1.0 ART Program 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. Transitioning from support of ART service delivery to a technical assistance (TA) model

In addition to the transitioning of program implementation under PEPFAR II international partners to local indigenous partners and the MOH, transitioning is also occurring from support of direct ART service delivery to a TA model. This involves moving from treatment site-level support to support at the district and higher levels. Activities falling under TA for ART include:

- Support of a national supportive supervision system
  - System development and evaluation
  - System integration and expansion
  - System quality assurance
- Support for periodic revision of national ART treatment guidelines and their dissemination
- Support for ancillary service in support of ART treatment
  - Supply chain management
  - Laboratory monitoring
  - Human resources for health
- Support for national M&E systems to guide ART programs
  - National and regional use in program planning
  - Site level use for quality improvement (QI)
- Support for training of MOH staff in support of ART service provision
  - Training-of-trainers to train site level staff
  - Training of MOH staff at the national and regional levels in mentoring/supporting of site-level staff
- Support for national, regional, or local quality improvement plans and initiatives

As USG support moves to the TA model, PEPFAR and each of its country offices need to develop indicators to measure both the services provided and the short-term and long-term impact of the services. While the long-term impact of a specific TA project is harder to measure, overall quality indicators such as multi-year retention on ART may be helpful. For example, if support of quality improvement training is provided, assessment of the number of sites with active QI committees and the number who can give examples of recent successful QI projects would be short-term measures of impact.

TA projects need to be in line with national strategic plans. As new projects are funded, funding opportunity announcements (FOAs) need to describe not only inputs and activities, but also include clearly defined outputs and outcomes. Since there are currently no PEPFAR-wide standards for TA activities, country teams will need to be creative in developing these. They will also need to continually monitor their utility in assessing the projects. PEPFAR meetings will provide an opportunity for country teams to share successes in this area, so that others can adopt their practices.

D. 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.

E. Other Approaches for Efficiency

Other possible approaches for increasing programmatic efficiency and deriving maximum 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.

2.2.7 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 in collaboration with partner government counterparts, 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).

2.2.8 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.

2.2.9 Strategic Information, Monitoring and Evaluation Technical Considerations for Treatment

PEPFAR treatment and strategic information (SI) programs, including monitoring and evaluation (M&E), should work together to ensure that key treatment SI needs are addressed and integrated within the larger SI framework. Given the M&E technical priorities of strengthening routine program monitoring, ensuring high data quality, supporting data use for evidence-based program

planning, conducting program evaluation and operational research, and building M&E capacity, there are many opportunities for treatment and M&E priorities to support each other in COP 2013. Please see the M&E COP 2013 technical considerations section for more information.

The priority activities for adult treatment M&E in COP 13 are:

- Routine program monitoring and implementation of the PEPFAR NGI
- Ensuring high data quality of all PEPFAR indicators
- Routine program evaluation
- Adult HIV surveillance
- Data quality. High-quality data are crucial for monitoring the ability to meet program goals in realizing an AIDS-Free Generation. High-quality data means that the data are accurate, reliable, complete, sufficiently precise, and collected/reported in a timely fashion with integrity. USG teams must (a) be prepared to demonstrate strong programmatic and fiduciary accountability for the USG investments in international and local partners, (b) monitor the quality of HIV treatment programs before, during, and after transition, and (c) support the transition of M&E and QI responsibilities to local partners, who will continue patient and program monitoring systems into the future. In addition to collecting and reporting on the essential/required treatment indicators (T.1.1D, T1.2.D, and T1.3.D), it is critically important that the quality of the data reported is assessed. PEPFAR treatment and SI teams are encouraged to develop a data quality management plan that describes how the team assesses program data. At a minimum, a data quality management plan should include information on validating indicators, process for de-duplication, and a strategy for ongoing improvement that is supportive of program goals. The Adult Treatment and SI TWGs have access to tools and resources available to support this effort.
- Data quality assessments (DQAs). Data quality assessments should be undertaken by USG teams on a routine basis for the treatment program level data (i.e., beyond the DQAs undertaken by individual partners as part of their agreements). These data quality assessments should be coordinated across agencies with host governments whenever possible. Country teams should build capacity of the MOH to continue these DQAs on a routine basis. (Reference Section X above)
- Evaluation. Program evaluation should occur periodically to foster quality improvement, inform strategic planning, and contribute to development of best practices. Headquarters support is available to discuss and support the planning of program evaluations. (Reference Section X above)
- Linkages. With the goal of achieving an AIDS Free Generation (AFG), understanding the ability of systems to link HIV-infected adults and children from testing to care and treatment is increasingly important. Conducting an evaluation of patient monitoring systems and tools and how they support linkages of newly identified positive children from testing to treatment is a priority. The SI and Adult Treatment TWG have resources available to support this effort. (Reference Section X above)

2.2.10 LINKAGES AND WRAPAROUNDS: ADULT TREATMENT

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. HTC targets should be aligned with the scale up of treatment and PMTCT, and budgets should be sufficient to support the testing needed to achieve treatment and PMTCT targets and linkage to care activities.

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.

A. 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 (see Section 1.5, Prevention with People Living with HIV).

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.
- 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.
- Ongoing counseling and support for HIV discordant couples which includes all of the activities listed above in addition to:
    - anti-retroviral treatment for HIV-positive partners, which can reduce the risk of heterosexual transmission by 96%[295];
    - voluntary medical male circumcision (VMMC) for HIV-negative male partners, which can reduce the man's risk of acquiring HIV by 60%[296];
    - counseling on dual method use for HIV-negative women in serodiscordant couples who chose to use a progestin-only injectable for contraception as there is mixed evidence on whether these types of contraception increase her risk of acquiring HIV[297];
    - safer pregnancy counseling for couples who desire a pregnancy.

See section 1.5, Prevention with People Living with HIV, for more detailed information;

- Prevention for people living with HIV should be integrated into care and treatment clinics and delivered during routine clinic visits as well as within community programs;
- 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

B. Ensure that bidirectional linkages between facility and community-based programs exist in order to enhance patient retention and strengthen prevention messaging.

[295] Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour M, Kumarasamy N…the HPTN 052 Study Team. (2011). Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med*, 365, 493–505.
[296] 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.
[297] World Health Organization (WHO). (2012c). *Hormonal contraception and HIV: technical statement.* Retrieved from: http://**www.who.int/reproductivehealth/publications/ family_planning/ rhr_12_8/en/index.html.**

2.3: PEDIATRIC TESTING, CARE AND TREATMENT

2.3.1 Introduction: Pediatric testing, care and treatment

Achievements and challenges

In 2012 WHO reported that over 8 million persons had been initiated on ART worldwide, reaching approximately 57% of adults in need of treatment. However, global pediatric HIV treatment coverage is only 28%. Approximately 330,000 new pediatric infections worldwide occur yearly, but the number of newly enrolled children on ART each year is well below that figure. The majority of infections in persons aged < 15 years occur in infants (vertical transmission); all infants are eligible for treatment http://www.who.int/hiv/pub/paediatric/paed_prelim_summary/en/index.html.

Pediatric treatment programs are challenged to catch up with children already infected and children who become newly infected. Efforts to expand coverage for children continue to be a priority for PEPFAR. The momentum created by the PEPFAR World AIDS Day target of reaching 6 million persons with ART, the UN Treatment 2.0 initiative to treat 15 million persons by 2015, and the Elimination of Pediatric HIV and Keeping Mothers Alive initiatives should be used by country teams to garner support to eliminate pediatric AIDS and reduce AIDS-related mortality/morbidity. Increasing access to treatment services for infected children is a key component of these initiatives.

New developments in 2012:

- FDA approved several new antiretrovirals for use in children (see section 2.3.4 Treatment)
- New formulations available and more becoming available in 2013 (see section 2.3.4 Treatment)
- Exciting new data showing that early treatment initiation (< 3 months old) and continuation of effective regimen has potential to almost eliminate HIV from child's reservoir
- In 2013, WHO is scheduled to release updated HIV care and treatment guidelines based on a public health approach for adults, pregnant women and children in resource limited settings; the consolidated guidelines will provide updated guidance, including recommendations regarding the use of new drugs and formulations for children.

Headquarters support is available to provide technical assistance regarding testing strategies to identify infected infants and children, care and support programming, national guidelines development for 1st and 2nd line regimens, and ARV rationalization.

PRIORITIES

2.3.2. HIV Testing of Children: Early Identification

1. Early Identification of HIV-Exposure and Infection Status

Despite high early mortality (50% at 2 years) associated with delayed ART initiation, missed opportunities for HIV testing of infants and children are common. Implementation of early infant

diagnosis (EID) programs, including DNA PCR testing and follow-up of all infected infants, is critical to early identification and initiation of life-saving ART. Routine provider-initiated testing and counseling (PITC) should be provided to any infant or child presenting to a health facility with an unknown HIV exposure or infection status.
http://www.who.int/hiv/pub/paediatric/testing_counselling/en/index.html

Successful national EID programs require coordinated program development and planning: expanded lab capacity for DNA PCR testing, decentralized collection of dried blood spot (DBS) specimens, reliable and rapid sample transport and return of results to families, training of lab and clinical care providers, and effective linkage to clinical care and treatment.
http://www.who.int/hiv/pub/paediatric/diagnosis/en/index.html.

Innovative strategies, such as the use of SMS printers for return of results to facilities and SMS appointment reminders for families of HIV-exposed infants may improve follow-up. Headquarters support is available to discuss and strengthen EID programs.

Continued scale-up of HIV antibody testing for infants and children remains critical. Lack of DNA PCR capacity should not prohibit early testing of infants with HIV antibody tests to assess HIV exposure. Access to high quality HIV antibody testing is essential even in settings with access to DNA PCR testing as most testing algorithms for HIV-exposed infants identified through PMTCT/EID programs include HIV antibody tests at 9, 12 and/or 18 months of age.

Key strategies for early identification of HIV exposure and infection status for PEPFAR-supported programs should include:

- Ensure that pediatric HIV testing and counseling policies, algorithms, guidelines, and implementation plans are consistent with recent WHO guidance and are widely available.
- Ensure that national programs and supported partners train health care providers to test infants and children for HIV.
- Establish and document HIV exposure status of 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 HIV exposure status.
- Scale-up HIV virological testing at 4-6 weeks of age (PCR testing with DBS or plasma) and return of results for HIV-exposed infants.
- When PCR is not available, utilize algorithms based on serology, clinical exam, history and WHO recommendations, with the aid of CD4 count and total lymphocyte count (TLC) as available.
- Adopt guidelines that recommend repeat testing for:
    - infants who test negative but have ongoing HIV exposure through breastfeeding
    - infants who test positive by antibody test before 18 months of age
    - infants or children who present with signs or symptoms that may be due to HIV infection.

- Implement and monitor universal PITC in inpatient pediatric wards, malnutrition clinics, TB clinics, and other outpatient settings. Most HIV-infected children are not identified through EID, and many childhood diseases can present with manifestations similar to those of HIV infection.
- Implement and monitor family-centered approaches to HIV testing, with routine PITC for children of HIV-infected adults and siblings of HIV-infected children.
- Increase linkages with orphan and vulnerable child (OVC) programs to ensure that the health and HIV needs of OVCs are being addressed

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.

2. Psychosocial Support (see Community Services section)

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.

3. Disclosure

Disclosure of HIV status can be challenging for healthcare workers, especially when dealing with young children. Lack of disclosure may affect the well-being of both the caregiver and the child and may have a detrimental effect on access to care and treatment, adherence, and long-term retention. National guidelines should include clear recommendations regarding disclosure of a child's HIV status, including guidance for when and how to disclose. WHO recommends that children of school age (approximately 6-12 years old) should be told their HIV status; younger children should be gradually provided with information leading up to full disclosure http://www.who.int/hiv/pub/hiv_disclosure/en/.

2.3.3. PEDIATRIC CARE AND SUPPORT

1. 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. CTX can be a lifesaving intervention for those children who experience delays in necessary initiation of ART. 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 in CTX prophylaxis for HIV-exposed and infected children for PEPFAR-supported programs should include:

- All HIV-exposed children receiving CTX beginning at 4-6 weeks of age and continuing until HIV is excluded,
- All children <5 years of age diagnosed with HIV receiving CTX and continuing until at least 5 years of age if WHO immunologic and clinical criteria are met,

- Children >5 years of age diagnosed with HIV receiving CTX in accordance with current pediatric and adult guidelines,
- The integration of CTX with MNCH services and inclusion of HIV exposure status/receipt of CTX in the child health card

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. Headquarters support is available to discuss and strengthen the provision of CTX in a variety of settings.

2. 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.

Key strategies in child health interventions for HIV-exposed, infected, and affected children for PEPFAR-supported programs should 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. 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;
- Nutrition surveillance, referral and tracking systems for children in nutritional assessment, counseling, and support (NACS) and care and treatment programs.

For additional detail, see sections 1.1, PMTCT, and 3.8, Food and Nutrition.

II. Safe water, sanitation, and hygiene interventions

These interventions serve as the cornerstone for infection prevention in household, community, and health facility settings:

- 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, testing if symptomatic, 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;
- Sexual and Reproductive Health (SRH) services for adolescents
- Training of health care providers in specific adolescent SRH issues
- Provision of education on SRH for adolescents who are HIV +
- Services to discuss with adolescents on how to disclose to their partner

For more information on TB, see section 2.5, HIV/TB, and the TB section in PMTCT.

3. Prevention and clinical management of TB and other opportunistic infections (OI's) (see also PMTCT section on Tuberculosis)

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).

4. 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.

5. Psychological, social, and spiritual support (see Community services section)

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

The WHO 2010 guidelines for initiation of ART have significantly increased the number of children eligible, but there still remain some children who are not eligible. However, these children will still require routine follow-up visits, laboratory monitoring, and programs will need to institute services to ensure that they are retained in care.
Key strategies to ensure retention for HIV-infected children in care in PEPFAR-supported programs should include:

- Annual clinical and laboratory assessment for the need to transition to ART
- Routine review of medical records to identify and re-engage children lost to follow-up.

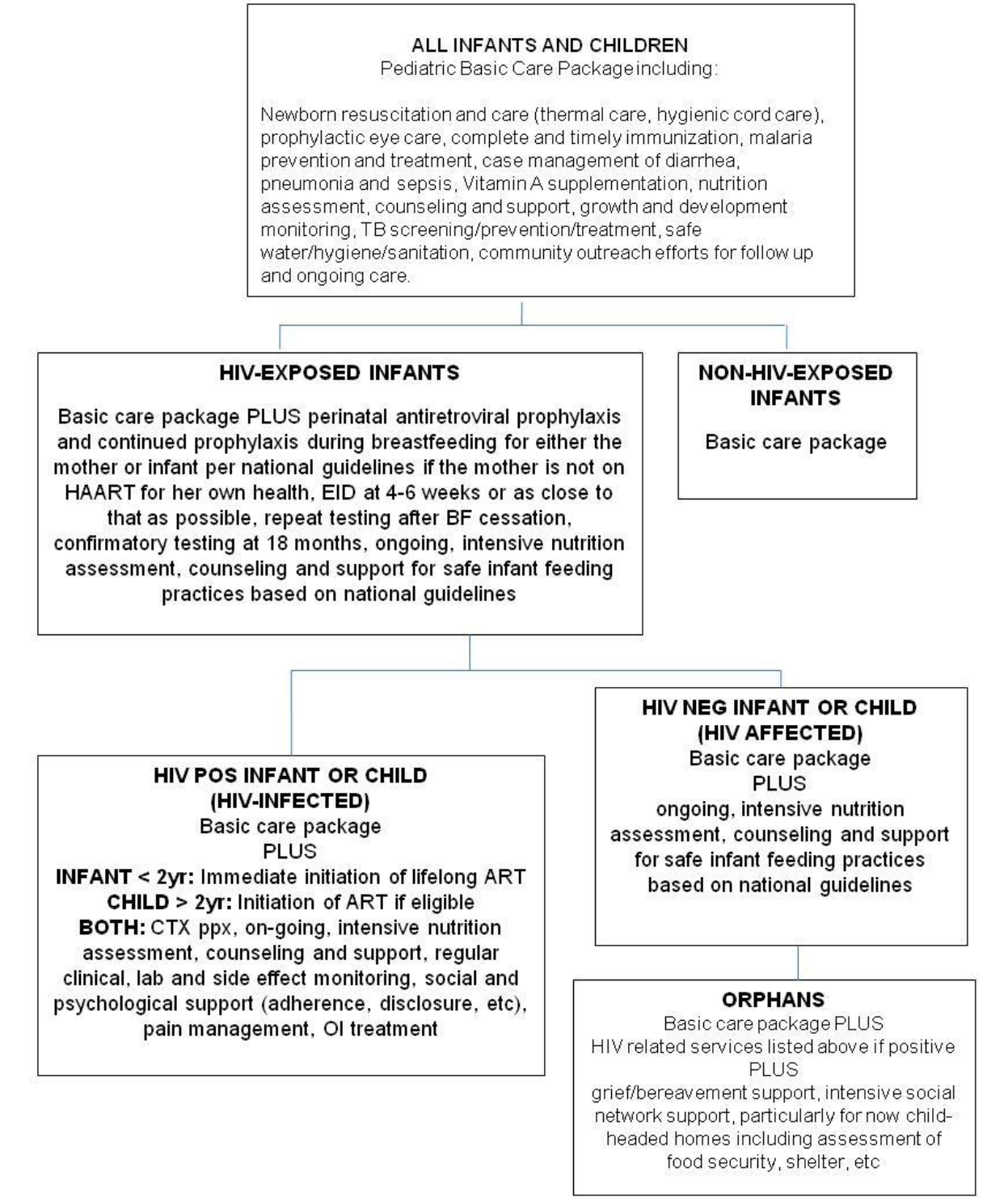
7. Pediatric Care and Support Targets

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". T*o 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).

Diagram 1: Essential Components for Pediatric HIV Support, Care and Treatment



2.3.4. Treatment of HIV infected infants, children and adolescents

1. Scaling-up pediatric HIV treatment

Scaling up pediatric HIV care and treatment services depends on having sufficient numbers of health care workers working in multidisciplinary teams, equipped to diagnose and treat HIV in children within a supportive health systems structure. Therefore, strengthening pediatric diagnostic services (see Pediatric Care and Support), follow-up and referral systems, within an expansion of trained health care workers, mentoring, and monitoring (see Human Resource Development), are critical. Plans for increasing pediatric coverage should include:

- expansion the cadre of health care workers who can initiate and monitor children on treatment
    - implement task-shifting approaches for pediatric HIV treatment as treatment services are decentralized
- increase in testing and effectively follow-up HIV-exposed infants
- implementation PITC of older children and adolescents
- improvement of access to early infant diagnosis
- description of how partners are working with the MOH, District or Regional Health teams, clinical staff at sites to improve pediatric treatment services at all levels of the health care system.
- policies, training and ongoing mentoring for nurses to initiate and maintain children on ART, with periodic supervision by a pediatrician or other qualified physician
- Review of the pediatric "cascade" from identification to adequate follow-up on ART to identify drop-offs and address them.

2. Implementation of 2010 WHO Guidelines

- *Treatment of HIV infected infants and children 0-24 months of age***:** All children 0-24 months of age are eligible for treatment, regardless of immunologic or clinical status. Early initiation of treatment saves lives and should be a priority for treatment programs. If country guidelines are not in line with WHO guidance, the national process to revise them should be initiated.
- *Treatment of children 2-5 years of age:* Treatment regimens and eligibility criteria continue to be guided by age appropriate CD4 (percentage and counts) and clinical criteria. Transitions to non-D4T-containing regimens should be encouraged. It is worth noting that in 2013, WHO will release new guidelines that may recommend treating all 2-5 year olds regardless of CD4 cell count, based on meta-analyses.
- *Treatment of HIV infected children 5 and older:* Treatment initiation criteria for this age remains guided by CD4 and clinical criteria. Transitions to non-D4T-containing regimens should be encouraged. The current CD4 cut off for this group is <350 as for adults.

http://www.who.int/hiv/pub/paediatric/paed_prelim_summary/en/index.html

Headquarters support is available to discuss and participate in meetings for development of national guidelines and their implementation.

Choice of 1st line regimen

There remains substantial concern that many HIV-infected infants and children on nevirapine (NVP) are on sub-optimal ART because of exposure to PMTCT. Evidence from controlled trials

supports this concern: up to 40% of infected infants harbor NVP-resistant HIV from PMTCT ([298]) or maternal ART during pregnancy or breastfeeding. Efforts to move towards 1st line regimens that include lopinavir/ritonavir in lieu of NVP should be increased. The use of a lopinavir/ritonavir-containing first line regimen in infants has been slow in rolling out in most countries due to the lack of available heat stable formulations, the concern about losing a potential drug class for children who fail initial therapy, and cost. More stable lopinavir/ritonavir pediatric formulations will become available in 2013; initial studies with a sprinkle and chewable tablet of this combination form showed equivalence to lopinavir/ritonavir syrup (abstract, IAC), and there was a superior virologic responses in infants treated with of a lopinavir/ritonavir containing 1st line regimen compared with infants treated with a NVP containing regimen regardless of their exposure history to NVP. [299]

Over the past few years the number of HIV-infected children transitioning into adolescence has greatly increased. This group of children will need to be monitored to address adherence issues and to identify treatment failure as early as possible. As more children enrolled in care or on ART become adolescents (10-19 years of age), country programs will need to develop more youth-friendly clinical and community services to cater to the specific treatment, support and general health needs. An important aim of these programs is to provide an environment that is conducive to engaging and retaining adolescents in care and ensuring the successful transition of their care into adult services. Working with the MOH and partners to define the package of services that adolescents with HIV/AIDS require and implementing models of service delivery specific for this population is a priority for USG programs.

3. Adherence support (see also Community section)

Successful treatment outcomes for children require that programs support strategies and implement activities to sustain adherence to ART. For young children, adherence to treatment will depend on the pediatric formulation used and on providing support and education to parents and caregivers. Caregiver support groups, routine adherence assessments and home-based visits can be used to improve or maintain adherence to treatment. In older children and adolescents efforts to support adherence are of particular importance and should be a component of all programs.

4. Disclosure support:

An important stumbling block for scaling up pediatric programs has been the concern of health care providers around disclosure of the HIV status to children; this concern has been one of the factors limiting the roll out of HIV testing and counseling services for children in some countries. In most instances pediatric disclosure is a process that should ideally begin as early after diagnosis by preparing the parent/caregiver for disclosure. Interestingly, many HIV-infected children reach adolescence without knowing the nature of their disease and this has important consequences on adherence and may delay transitioning of otherwise ready adolescents into more appropriate care settings and may also be a barrier in providing needed support services for children. Health care workers are in need of training around this issue and countries need support to develop guidance for disclosure for children.

[298] Arrive E, Newell ML, Ekbouevi DK, et al. Prevalence of resistance to nevirapine in mothers and children after single-dose exposure to prevent vertical transmission of HIV-1: a meta-analysis. Int J Epidemiol 2007; 36:1009-1021.
[299] Violari A, Lindsey JC, Hughes MD, et al. Nevirapine versus ritonavir-boosted lopinavir for HIV-infected children. N Engl J Med 2012;366(25):2380-9.

5. Country pediatric ARV formularies and cost of pediatric ARVs:

The number of pediatric ARV formulations has increased since 2003, making choices for treatment greater. However, since different combinations of different formulations can lead to the same regimen, smaller orders of pediatric ARV drugs are now made to maintain ARV supplies. Because order size is often low and divided across many different ARV drugs and formulations, manufacturers wait until a minimum number of orders is reached before producing a batch. This makes pediatric ARV production irregular and procurement in any specific country difficult. A WHO-recommended solution is creating an "essential medicines" list of formulations that covers the regimen needs of the county's children. http://www.who.int/medicines/publications/TRS958_2010. This approach increases the volume of individual drug orders, increases the regularity of production and the volume of production, and reduces costs and stock-outs. The future sustainability of the pediatric ARV drug supply relies on such a rationalization of the national pediatric ARV formulary to a limited number of drugs and formulations that satisfy the recommended regimens and meet the needs of the majority of children. http://www.who.int/hiv/pub/meetingreports/iatt_meeting/en/index.html.

Key strategies for maintaining adequate supply of pediatric ARV formularies for PEPFAR-supported programs should include:

- Ensuring that progress toward a national pediatric ARV formulary occurs
- Assisting countries streamline pediatric formulations to reduce redundancies and facilitate forecasting
- Strengthening supply chain reliability and resilience for ARVs in pediatric treatment settings.

PEPFAR teams should also pay special attention to the commodities situation in their host countries. Funding gaps for commodities affecting PEPFAR treatment targets may be related to funding flows of Global Fund grants (e.g. delayed signing, delayed disbursement, unanticipated gap between grants, conditions precedent); government budgetary shortfalls; or issues related to in-country procurement processes. As Global Fund faces a transitional funding period and moves toward a new funding model, to be implemented over the course of 2013-2014, this may present both commodities challenges as well as further entry points for PEPFAR and Global Fund coordination to ensure sufficient commodity stocks.

PEPFAR teams should work with other stakeholders to budget realistically in this context to ensure that commodities for all PEPFAR treatment targets are available. *OGAC headquarters should be immediately made aware if there is a potential funding shortfall that could affect PEPFAR treatment targets;* OGAC has established a Commodities Task Team to assist country teams with commodities shortages and help with the identification of resources. PEPFAR teams should also work closely with the Global Fund Secretariat in Geneva and implementing partners in country, particularly with commodities and logistics experts, to share information on commodities and evaluate how Global Fund resources and performance should shape PEPFAR forecasting and budgeting. More systematic sharing of commodities data from both PEPFAR and Global Fund partners is needed to accurately budget, particularly in countries where sites and targets overlap. In addition, PEPFAR teams should adequately budget for buffer stocks (link to SCMS guidance, and intervene where Global Fund and/or country systems have broken down (or

are experiencing challenges). This, in some cases, may involve procuring a greater proportion of ART than in years past.

Headquarters support is available to discuss and prepare for national-level meetings for the rationalization of pediatric ARV formularies. Among others, the Clinton Foundation has partnered with relevant organizations in some countries to conduct pediatric ARV rationalization workshops. This effort will be particularly important as new drugs and formulations become available to treat children.

6. New antiretroviral drugs and formulations for children:

Since 2011, several new formulations have been approved for use in children by the US Food and Drug Administration (FDA):

1) tenofovir for children 2-18 years (NRTI)
2) raltegravir for children 2-18 years (integrase inhibitor)
3) fosamprenavir for children 4 weeks to 18 years of age (protease inhibitor)
4) darunavir for children >3 years (protease inhibitor)
5) etravirine for children 6 to 18 years (NNRTI).
6) Fixed dose combinations (FDC) of AZT with 3TC and NVP FDA approved
7) FDC of AZT and 3TC FDA approved
8) FDC of ABC and 3TC FDA approved
9) FDC of Lop/r with 3TC and (AZT or ABC) in the works

While these new drugs will increase treatment choices for ARV-naïve and -experienced children, guidance on their large scale use in pediatric populations has not yet been developed.

7. Surveillance for HIV Drug Resistance:

A few reports from resource-limited settings have described multi-class drug resistance in a number of HIV-infected infants exposed to combination ARVs or HAART in utero and/or postnatally (through infant prophylaxis or through ARVs in breast milk of women on ART). Countries should include in their plans efforts to monitor HIV DR in this pediatric sub-group. The WHO recommends conducting studies on left over DBS samples of HIV infected infants to monitor the emergence of drug resistance in this sub-group of children.[1] Headquarters assistance is available for information or on new or ongoing protocols.

The WHO, in collaboration with PEPFAR, has adopted an updated framework (available at http://www.who.int/hiv/pub/drugresistance/en/index.html) for routine HIVDR surveillance activities that are relatively simple to implement while successfully informing public health policy. The WHO framework calls for HIV DR Surveillance activities to simultaneously include adult and pediatric populations. This updated framework has five elements:

- Monitoring of HIVDR Early Warning Indicators (EWIs) http://www.who.int/hiv/pub/drugresistance/en/index.html)

- Survey of HIVDR in children <18 months of age newly diagnosed with HIV using left over DBS samples ([300]).
- Cross-sectional survey of baseline HIVDR in adults initiating ART at representative treatment and PMTCT sites
- Cross-sectional survey of acquired HIVDR in adults, children and adolescents on ART for >12 months at sentinel sites
- Survey of transmitted drug resistance (TDR) in recently infected populations
- Acquired and/or transmitted HIV DR studies in specific populations (e,g,: pregnant women, adolescents)

Because it may not be feasible to implement all five components of this strategy, countries should prioritize survey activities that help answer these 2 questions for all populations:

- Is the prevalence of transmitted HIVDR high enough to potentially impact the efficacy of empiric first-line ART?
- Is the pattern of HIVDR in patients failing first-line ART likely to significantly impact the efficacy of second-line ART?

The monitoring of HIVDR EWIs should ideally be incorporated into the overall monitoring of a national ART program and include both adult and pediatric components. It is important to note that these population-based approaches may not be sufficient to inform optimization of treatment regimens and that specific studies may be needed alone or in addition to surveillance information on HIV DR for this purpose. While other sources of funding for HIVDR surveillance activities may exist, PEPFAR funds should be allocated to fill any identified gaps for both adult and pediatric HIV DR activities.

Additional support and information is available from the Adult and Pediatric/PMTCT TWGs.

8. Pediatric Treatment Targets:

Targets for pediatric treatment should take into account the number of children in the country who are eligible for ART, pediatric treatment coverage levels, and previous years' achievements. 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)

Although not required reporting at this time, 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. Limited data are available on children on treatment who are less than 5 years of age and adolescents from 10-18 years of age (10-14 early adolescence and 15-18 late adolescence).

Countries that are not reaching treatment targets for children should ensure that HIV testing services for children are being implemented systematically for all ages, including for adolescents. Working with the MOH and USG-supported partners to gather information on

[300] Bertagnolio S, Penazzato M, Jordan MR, Persaud D, Mofenson LM, Bennett DE; Pediatric HIV ResNet Working Group. World Health Organization generic protocol to assess drug-resistant HIV among children <18 months of age and newly diagnosed with HIV in resource-limited countries. Clin Infect Dis 2012; 54 (Suppl 4):S254-60, 2012.

testing practices, positivity rates among children in various high-yield entry points and in settings were large number of children and adolescents access health services is desirable and can better inform the strategic roll out of counseling and testing and treatment services. Testing children of adults enrolled in care or on ART, at in-patient wards, out-patient acute care services, and in TB and malnutrition clinics continue to be important areas were systematic testing approaches should be implemented.

9. ***Laboratory monitoring of children on ART***

Laboratory monitoring of children on ART should aim to:

- monitor response to treatment
- identify toxicities related to antiretrovirals and/or drugs used for prophylaxis against opportunistic infections.

Laboratory monitoring of response to ART: Providing access to CD4 percentages and counts continues to be important 1) at baseline, 2) at regular intervals for children >2 years not yet eligible for ART,3) to monitor response to treatment or 4) identify failure. However, CD4 drops usually are a late event of treatment failure and when possible viral load determinations should be used. Point of care CD4 assays are now becoming more available in countries and should be used in pediatric populations.

Viral load monitoring (detection of treatment failure): access to viral load testing is still limited in most settings. The use of Dried Blood Spots for quantification of viral load (VL) is gradually being evaluated and introduced to a limited extent in countries. PEPFAR technical assistance support for this will be available from multiple TWGs (PMTCT/Peds, Treatment, Lab). VL monitoring using DBS has several advantages that make its use particularly attractive for infants and children: small blood volumes, no use of plasma, no cold chain, and ease of transport to processing laboratories. While correlation of viral load levels between plasma and DBS seem to be quite good this method has not been operationalized for field conditions; validation/operational studies of this method are being conducted. The use of a targeted viral load testing strategy to confirm or identify treatment failure has been implemented on a limited scale and mainly in adult populations.

Viral load testing can also be used as a means to evaluate the quality of treatment programs. Collection of viral load samples coupled with information on ART regimens, duration of treatment, CD4 count, clinical status and other parameters can be useful to assess suppression rates at various time points after treatment initiation and should be included when evaluating pediatric programs as possible.

ARV-related toxicities, side effects and adverse events: ARVs have defined toxicity profiles and the selection of needed basic clinical laboratory assays can be informed by the drugs included in 1st and 2nd line regimens. Capacity to detect anemia is important when AZT is part of a regimen. Some drugs may cause abnormalities in liver enzymes or renal function and capacity to monitor these parameters should be developed. It is important for programs to select methods and equipment that require small sample volumes and that can detect abnormalities caused by pediatric ARVs.

2.3.5. Human capacity development (HCD)

An important barrier to the expansion and scale-up of pediatric HIV programs is the lack of sufficient numbers of health care providers with expertise and confidence in the management of or provision of HIV services for infants, children and adolescents. Task shifting to allow nurses and other cadres of health providers to provide pediatric HIV services, specifically counseling and testing and initiation and management of ART, is essential to ensure adequate access to care. Continued mentoring and supervision increases confidence in providing pediatric services. The PMTCT/Pediatric HIV TWG can provide examples of successes and technical assistance to support countries in adopting these strategies.

Efforts to strengthen pediatric-specific skills among existing health care providers at all levels of the health care system and to incorporate this knowledge into pre-service training for new providers are critical to significantly increase the numbers of children receiving quality services. A comprehensive approach is essential, including: training; provision of needed resource materials; ongoing mentoring and supportive supervision. At the country level, programs will therefore need to:

- Ensure health care workers are up to date on the latest national guidelines for pediatric treatment (i.e. usually per WHO, test-and-treat for all under 24 months).
- Shift tasks to non-physicians, including updating related policies and providing training to initiate/monitor ART and needed care interventions, such as cotrimoxazole prophylaxis;
- Improve the capacity of existing and new health care providers to deliver comprehensive health care services to infants, children and adolescents, including HIV testing and counseling, retention and adherence support, disclosure support, HIV care and treatment, and home-based care services. ;
- Cross-train health care providers in Pediatric HIV, MNCH, Family Planning, and PMTCT services;
- Integrate pediatric care and treatment modules into pre-service and in-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, both for exposed infants identified through PMTCT programs but also through targeted strategies for identifying older children such as offering testing for all children of adults enrolled in HIV services, in pediatric out-patient clinics and in-patient wards and in OVC services
    - Disclosure, retention, and adherence support
    - CTX prophylaxis as indicated
    - Initiation and ongoing maintenance of 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.

2.3.6. Community services linkages with Pediatric care and treatment programs

Because it is extremely difficult to provide all pediatric care and support services, including adherence support, at a single HIV care site or setting, services may be provided by different partners through a continuum of service networks with (e.g. care, routine immunization, OVC and nutrition services) and through effective linkages between facility-, community-, and home-based care programs.

- Linkages and collaboration between health facilities and community/home services build and strengthen bi-directional referrals; these increase access to HIV care services and improve retention of HIV-exposed/infected children in care.
- Community-based services provide additional non-clinical components of care and support that contribute to improved care outcomes of HIV-exposed/infected children.
- Community-based services bridge distances between clinical facilities and the home.
- Peer counselors, community health workers, and other community-based health professionals support home caregivers to provide the needed care and support services in the home.
- Community programs that serve mothers refer infected mothers and their HIV-exposed infants to health facilities for counseling, early HIV diagnosis, disclosure counseling, and cotrimoxazole prophylaxis.
- Community services such as peer support and HIV+ groups, particularly for adolescents, help families with HIV infected children to overcome stigma, promote adherence, and provide support for mother and HIV-infected children and linkage to HIV care.

These services provided at the facility, community and household levels are crucial through the disease continuum for both the child and family, from diagnosis to bereavement support.
Some specific activities include:

- Link community-based groups (leader spouses, women, people living with HIV) with communities programs to bring HIV-exposed children for testing and immunization, encourage HIV-infected mother to bring older children for HIV testing, and for tuberculosis screening.
- Ensure that home-based care workers refer HIV-exposed/infected/children to HIV services, and ensure that family health, nutrition and HIV care needs are being addressed.
- Train community-based groups and service providers to carry out and monitor linkage activities.
- Adolescent specific support groups that allow HIV+ adolescents the opportunity to network with each and discuss some of the challenges they face at schools and in their communities.
- Community-based services between the clinical facilities and the staff at schools to remove some of the stigma associated with HIV and educate the staff on the importance of confidentiality

Community level activities to support ART adherence in pediatric populations
Functional linkages between the pediatric ART program and community services should reduce losses to follow up and improve long-term outcomes.
Some specific activities to promote linkages between pediatric ART program and community-based activities include:

- At treatment initiation, link mother and/or guardian of infected child to a local/neighborhood patient support group/community support program to further support adherence.
- Train and monitor lay counselors and community-based groups (e.g. people living with HIV, peer mother) to conduct home visits, provide adherence counseling for pediatric ART and follow-up HIV-exposed/infected children.
- Maintain peer mother program to conduct home visits to assist mother on how to handle ARV medications, advise on problems that may arise, the appropriate storage and administration, and link children to OVC and nutrition services in their community.
- Use innovative technologies e.g. SMS reminders to follow up with community health workers
- Mobilize and measure community actions to expand pediatric access to ART programs.

2.3.7. Strategic Information, Evaluation and Monitoring Technical Considerations

PEPFAR Pediatric Care and Treatment (Peds) and Strategic Information (SI) programs (including M&E) should work together to ensure that key Peds SI needs are addressed and integrated within the larger SI framework. The M&E technical priorities are: 1) strengthening routine program monitoring, 2) ensuring high data quality, 3) supporting data use for evidence-based program planning, 4) conducting program evaluation and operational research and 5) building M&E capacity. There are many opportunities for Peds and M&E priorities to support each other in COP 13. Please see the M&E COP 13 technical considerations section for more information.

The priority activities for Pediatric Care, Support and Treatment M&E in COP 13 are:

1. Routine program monitoring

The Pediatric Care and Treatment program should use their indicators to describe program performance and identify gaps in services. At a minimum, countries should be collecting and reporting on the following PEPFAR Next Generation Indicator (NGI): C1.1.D, Number of eligible children providing with a minimum of one care service; C2.1.D, Number of HIV-positive children receiving a minimum of one clinical service; C5.1.D, Number of eligible clients who received food and/or other nutrition services; T1.1.D, Number of children with advanced HIV infection newly enrolled on ART; and, T1.2.D, Number of children with advanced HIV infection receiving ART therapy (current).

When setting targets for these indicators, Pediatric and SI teams should consult with colleagues from other program areas to ensure that the targets for other indicators are aligned. For example,

if setting targets for T1.1.D, Pediatric, SI, Care and Treatment staff should ensure that the target for the pediatric ART disaggregation takes into consideration the targets set for the pediatric disaggregation in C2.1.D to ensure that it reflects the cascade of care and treatment.

2. Data Quality

It is critically important to assess the quality of the reported data. PEPFAR Peds and SI teams should develop a data quality management plan that describes how the team assesses program data. At a minimum, a data quality management plan should include:

- how to validate indicators
- a process for de-duplication
- a strategy for ongoing improvement that is supportive of program goals.

The PMTCT/Peds and SI TWGs have access to tools and resources available to support this effort.

3. Evaluation

Program evaluation should occur periodically to foster quality improvement, inform strategic planning, and contribute to development of best practices. *Headquarters support is available to discuss and support the planning of program evaluations.*

With the goal of achieving an AIDS Free Generation (AFG), understanding the ability of systems to link HIV+ children from testing to care and treatment is increasingly important. Conducting an evaluation of patient monitoring systems and tools and how they support linkages of newly identified positive children from testing to treatment is a priority. The SI and PMTCT/Peds TWG have resources available to support this effort.

2.3 ARV DRUGS TECHNICAL CONSIDERATIONS

PEPFAR teams should work with other stakeholders to budget realistically to ensure that commodities for all PEPFAR targets are available. OGAC must be immediately made aware if there is a potential funding shortfall that could affect PEPFAR treatment targets; OGAC has established a Commodities Task Team to assist country teams with commodities shortages and help with the identification of resources. *(Also see section 2.2.4B ACCESS AND INTEGRATION: ADULT TREATMENT – Costing and Modeling)*

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 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 nor for appropriate resource planning. Country teams should continue to plan and program for acceptable levels of buffer stock according to sound forecasting and management principles.

As many USG teams already have supply chain advisors in place, these individuals should be considered as a primary point of contact on issues related to supply chain management, including ARV drugs. These advisors will liaise with other technical staff, implementing partners and Ministry officials to ensure the availability of ARVs.

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.

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.

In cases where it is not already occurring, USG teams should promote the development, and regular review, of national HIV supply plans, including the contribution of PEPFAR and

promote strengthening of national supply chain systems to forecast, procure, manage, distribute, and assure quality of a wide range of HIV-related commodities.

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.

2.4: TB/HIV

TB/HIV (HVTB) – includes TB screening and diagnosis, treatment and prevention of tuberculosis (including medications), clinical monitoring and related laboratory services, and HIV testing and clinical care of clients in TB service locations. Funding for these activities, including commodities and laboratory services, should be included in the TB/HIV budget code. The location of TB/HIV activities may 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 activities contribute to an AIDS-free generation

PEPFAR support has been instrumental in expanding HIV testing of TB patients. This effort has revealed that in many PEPFAR supported countries, especially in Sub-Saharan Africa, HIV prevalence among TB patients is shockingly high, ranging in some countries as high as 40-80%[301]. In 2009 WHO revised its antiretroviral therapy (ART) guidelines to recommend that all HIV-infected TB patients, regardless of CD4 count, be initiated on ART. Additionally, a growing body of evidence suggests that initiating ART soon after starting TB treatment significantly increases survival among HIV-infected TB patients. TB clinics are therefore high yield sites for identifying persons living with HIV (PLHIV) eligible for ART. However, in 2010, despite WHO recommendations, only 46% of HIV-infected TB patients globally and 42% in sub-Saharan Africa were initiated on ART[302]. For 17 high TB/HIV burden PEPFAR countries in sub-Saharan Africa[303], this translated into only 154,000 of 366,000 reported HIV-infected TB patients being initiated on ART; 212,000 eligible HIV-infected TB patients missed life-saving ART.

Improving uptake -- especially early uptake -- of ART among HIV-infected TB patients could substantially contribute to PEPFAR's goals of ensuring an AIDS-free generation and initiating ART for 6 million PLHIV by the end of 2013. Countries should assess the current level of ART coverage among HIV-infected TB patients and set country specific targets for ART initiation among HIV-infected TB patients to improve patient outcomes and help meet PEPFAR goals. Country programs should identify barriers to initiating ART for HIV-infected TB patients and develop and scale-up successful models of service delivery to achieve these targets. Approaches might include provision of ART in TB clinics or primary health care settings or strong referral systems between TB and HIV programs, along with strengthened M & E systems to ensure follow-up of patients.

Achieving PEPFAR's new goals also calls for improving survival of PLHIV in care and treatment by reducing HIV-associated morbidity and mortality. HIV-associated TB remains the leading cause of morbidity and mortality among PLHIV. As a result, if it is not adequately addressed, TB has the potential to undermine the great strides that PEFPAR has made in rapidly

[301] WHO, Global tuberculosis control: WHO report 2011, http://www.who.int/tb/publications/global_report/en/
[302] Ibid.
[303] Botswana, Cote d'Ivoire, DRC, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Swaziland, Uganda, Tanzania, Zambia, Zimbabwe, ibid.

expanding HIV care and treatment. Prevention and treatment of HIV-associated TB is even more critical as PEPFAR strives to achieve these new goals. Country programs should accelerate scale up of intensified TB case finding, isoniazid preventive therapy, and TB infection control, and measure the impact of these interventions in terms of reducing the morbidity and mortality among PLHIV.

2.4.2 Background

Tuberculosis (TB) remains the most common infectious cause of death among 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 early initiation of ART for co-infected individuals. TB/HIV collaborative activities are prototypic of the key concepts of coordination, collaboration, integration and systems strengthening. 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 and demonstrate impact, and increased interest in implementation research to identify program adjustments to improve outcomes.

As Ambassador Goosby has articulated, there is an increasing need to define priorities and align resource allocation decisions to ensure that PEPFAR more strategically, sustainably, and efficiently meets its goals; allocation decisions must be driven by potential for greatest impact. Bringing TB/HIV activities to scale, including early access to ART and providing basic care packages including cotrimoxazole, clearly meets this criterion. Investment in TB/HIV should therefore be maintained throughout PEPFAR programs. COP budgets that decrease support for TB/HIV will be scrutinized and require further consultations. Interventions described in this document can inform programming in support of critical TB/HIV scale-up.

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. Thus screening and treatment for TB is important throughout the continuum of care, and particularly critical for patients at ART initiation and during the early phase of ART.

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 as high as 50-80%, and it is estimated that the African region shoulders 80% of the global co-infection burden. The estimated 380,000 deaths from TB among PLHIV 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 (often as a result of PEPFAR support).

According to the 2011 WHO Global TB Report, in 2010 34% of individuals with TB knew their HIV status (up from 26% in 2009), including 59% of TB patients in the African Region. Globally, 376,000 PLHIV with TB disease were enrolled on co-trimoxazole preventive therapy (CPT), and almost 225,000 were enrolled on antiretroviral therapy (77% and 46% respectively of those who tested HIV-positive). To prevent TB, almost 178,242 PLHIV were provided with isoniazid preventive therapy (IPT). Although this is an increase from previous years it represents 12% of the reported PLHIV newly enrolling into HIV care, the great majority of whom are eligible for preventive TB treatment.

2.4.3 Early ART reduces mortality

The statistics above demonstrate some progress in recent years, but also highlight 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 ART and cotrimoxazole preventive therapy (CPT) as early as possible. Several recent trials demonstrate that early initiation of ART during TB treatment reduces mortality. One trial showed that the initiation of ART during TB therapy in patients with confirmed TB/HIV co-infection reduced mortality by 56%[304]. In 2009, 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*. Despite the revised WHO recommendations, more than half of HIV-infected TB patients are not initiated on ART, underscoring the role that TB clinics need to play in identifying and effectively linking PLHIV to HIV care and treatment services. TB clinics remain one of the highest yield sites for HIV case-finding, and plans for scale-up and decentralization of ART services should consider existing networks of TB clinics as potential ART sites.

2.4.4 ART reduces TB incidence

Antiretroviral therapy dramatically reduces TB incidence, as demonstrated by a 67% reduction in tuberculosis incidence rates in nine observational cohort studies in which 37,879 patients were enrolled[305]. However, TB rates still remain high among PLHIV established on long term ART. It is thus 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.

2.4.5 Screening for TB and case detection need to be strengthened

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[306]) and act rapidly to diagnose and treat the disease in those with both classic and non-

[304] 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.

[305] 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.

[306] WHO, Guidelines for intensified tuberculosis case-finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings, 2011, http://whqlibdoc.who.int/publications/2011/9789241500708_eng.pdf

specific symptoms, and provide IPT to those who screen negative for these symptoms[307]. Use of TB suspect registers in HIV care and treatment settings might be an effective way to ensure diagnostic evaluation of all identified persons with presumptive TB and to initiate TB treatment among those diagnosed with TB. Additionally, HTC settings represent the first opportunity for such integration, and symptom screening with referral should be considered a minimum standard of care, particularly for persons testing HIV-positive and their spouses/partners.

The WHO 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 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.

These technical considerations highlight policies, interventions, and activities which the PEPFAR TB/HIV TWG and its partners have identified as the most effective in addressing the dual infections of HIV and tuberculosis. Emphasis is on the following priorities:

1. ***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, each of the USG implementing agencies 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, M&E support, 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 laboratory strengthening, DOTS quality improvement or TB/HIV M&E.

2. ***Implementation of provider-initiated HIV testing and counseling (PITC) in TB clinical settings, followed by provision of HIV care and treatment 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, 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) and their partners.
- Ensure enrollment into HIV care and initiation of ART for all HIV-infected TB patients. Programs should assess the current level of ART uptake among HIV-infected TB patients and set achievable target for % of HIV-infected TB patients who would get initiated on ART (according to WHO ART guidelines this should be 100%), Country programs should assess the barriers to initiation of ART among HIV-infected TB patients and develop models or scale-up existing models of service delivery to achieve these targets.

[307] Ibid.

This would range from provision of ART in TB clinics to strengthening of referral and linkages with improved M & E systems.

- 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 counseling and testing processes.
- Consider supporting "one-stop" models that provide integrated TB and HIV services e.g., CPT and ART in TB clinics.
- Develop and pilot prevention interventions for PLHIV (also referred to as Prevention with Positives (PwP) or Positive Health Dignity and prevention (PHDP)) in TB clinical settings with a special emphasis on HIV testing for partners and family members of TB patients. Generic PwP/PHDP 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.

3. 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. Xpert® MTB/RIF, smear microscopy, TB culture, chest radiography,) are not available on-site at HIV care facilities. This may include developing integrated transport systems to send specimens to higher level laboratories, improving result reporting systems, and 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. Promote use of TB suspect registers to follow up and ensure proper diagnostic evaluation of all identified TB suspects.
- Support roll-out of Xpert® MTB/RIF (Xpert®) to improve identification of TB and MDR TB disease, including point of care placement where appropriate and integration of Xpert® into existing reporting systems, algorithms, etc. Refer to implementation and technical approach guidance documents for USG-funded Xpert® MTB/RIF activities here:
    - http://www.pepfar.gov/documents/organization/197192.pdf
    - http://www.pepfar.gov/documents/organization/197191.pdf

- 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.
- 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

4. 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 or require updating to include new diagnostic tools..

Actions to immediately begin to address this problem include:

- Develop capacity for quality-assured TB culture and drug susceptibility testing (DST) through laboratory strengthening and treatment with second-line drugs for patients with multi-drug resistant-/extensively drug-resistant-TB (MDR-/XDR-TB).
- Consider phased roll-out of 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.
- Leverage support and technical assistance from the WHO Green Light Committee (GLC) and the Global Drug Facility (GDF) to improve access to treatment for patients with MDR/XDR TB.

5. Strengthen laboratory services necessary to implement TB/HIV program activities

- Ensure that TB laboratory and diagnostic services are appropriately addressed in the context of the National Laboratory Strategic Plan.
- Strengthen TB diagnostic capabilities by fortifying existing sputum smear microscopy laboratory networks and upgrading them to introduce light emitting diode (LED) fluorescent microscopy in a phased manner (including logistics, infrastructure, quality assurance programs, personnel, and training).

- Support scale-up of XPert MTB/RIF according the WHO recommendations and national guidelines. For further information on the phased implementation and evaluation of Xpert® MTB/RIF, refer to the principal considerations for USG-funded activities here: http://www.pepfar.gov/documents/organization/197192.pdf and here: http://www.pepfar.gov/documents/organization/197191.pdf
- 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, Xpert® MTB/RIF, TB culture, DST, and other **rapid diagnostic methods, where appropriate.**
- Consider requesting technical assistance to assess and provide recommendations regarding laboratory biosafety and infection control.
- Support development and implementation of new diagnostic algorithms and associated systems to incorporate newer diagnostic methods for TB and MDR-TB, and procedures to diagnose smear negative, extrapulmonary, and pediatric TB as they become available.
- Focus on improving quality as well as access to TB laboratory services for PLHIV through a spectrum of activities including strengthening on-site TB laboratories at ART clinics, and supporting specimen transport and laboratory information management systems.

6. 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:

- USG 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.
- 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.

7. 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.
- 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.

8. Integrate "prevention for PLHIV" (also referred to as PwP or PHDP) 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 are co-infected with HIV, have regular contact with providers, and are able to participate in HIV prevention centered 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). In addition to providing services to TB patients, TB clinics also provide a unique opportunity and venue in which to offer HIV-related services to their partners and family members. Priority interventions for partners and family members include on-site provision of HIV testing and disclosure counseling, sexual risk reduction counseling (including provision of condoms), and adherence counseling and support, should they require treatment. Other prevention related interventions (e.g., substance abuse counseling; STI diagnosis and treatment; family planning and safer pregnancy counseling) should be provided on-site or by referral.

Whenever possible, the full package of HIV prevention messages and services should be offered to all HIV-positive patients at every encounter as standard of care. However, where resources are limited, programs are encouraged to prioritize patients who are at high risk for transmitting HIV to uninfected partners and children for prevention messages and services. For example, prioritizing individuals who have not yet begun ART for HIV prevention messages and services is key as these patients are more likely to default from care[308] and are at higher risk for transmitting HIV to their partner(s) and child(ren) compared to patients with suppressed viral loads[309]. Characteristics of other patients at high risk for onward transmission are likely to vary by context but may include patients who have difficulties adhering to ART, who have substance abuse issues, and/or those patients in a serodiscordant partnership.

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USG should support adaptation and implementation of existing PwP/PHDP 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.

[308] Larson et al., 2010.
[309] Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour M, Kumarasamy N…the HPTN 052 Study Team. (2011). Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med, 365, 493–505.

Further guidance on these interventions can be found in the section 1.5, Prevention for People Living with HIV.

9. 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 and implementation research to better understand challenges to accessing HIV care and treatment among TB patients who are diagnosed with HIV in TB clinics.
- Ensure that every partner planning to implement a TB/HIV related activity has a plan for monitoring and evaluating that activity.

10. 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 to prevent 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.
- Increase access to/ensure procurement of quality-assured child-friendly formulations of anti-TB drugs

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:

1. Establish policies/guidelines and coordinating bodies at the national level
2. Engage civil society and establish partnerships to harness expertise in community advocacy for TB and TB/HIV efforts
3. Develop a strategic plan for implementation
4. Ensure that adequate resources are available to support implementation e.g., commodities, laboratory, staffing, supervision/support, M&E systems, etc.
5. Train health care providers as needed for implementation and follow-up, with supportive supervision
6. Pilot implementation in selected sites and revise approach as needed
7. Scale-up to additional sites
8. 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 2013, 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 2013. 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

- Data on the current level of scale-up of key activities by geographic area/site

2.4.6 Partner Performance Considerations

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
- Conduct M&E periodically and report quality data to the national program, USG, and site-level staff

2.4.7 Linkages and Wraparounds

PEPFAR teams should ensure that 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.) are coordinated in work on TB/HIV activities, particularly in relation to National TB and HIV/AIDS program strategic plans. Specifically, PEPFAR resources should 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.

2.5 Technical Considerations

The new **Guidance for Orphans and Vulnerable Children Programming**, released in July 2012, represents the most up-to-date overview of evidence-based programs for OVC (http://www.pepfar.gov/documents/organization/195702.pdf). Please refer to this guidance, as well as COP Guidance, when programming funds for this population.

Section 3. Cross-Cutting

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, strengthening of laboratory supply & commodities, equipment management systems, promotion of quality management systems, laboratory monitoring and evaluation, laboratory information systems, development of human resources, 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. Transition from use of international partners to country-owned programs, similar to the track 1.0 partners, should be encouraged.

3.1.1 INTRODUCTION

The goal of the PEPFAR laboratory program is to support countries to strengthen integrated laboratory networks and systems in a sustainable manner 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 to implement laboratory services, strengthen systems, and support and/or establish country or regional laboratory institutions. Each country should be encouraged and supported to develop a coherent laboratory strategic plan and policy for improving integrated laboratory services for patient care. Patient and specimen referral networks should be harmonized to reflect a continuity of care and responsiveness 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 & validation of new technologies or testing algorithms. Over the past five years, PEPFAR has supported approximately 2,000 laboratories and about 20,000 HIV testing sites in all PEPFAR-supported 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 seven technical areas which are designed to strengthen sustainable and integrated laboratory services.

Each country should have a Quality Assurance (QA) plan to ensure that laboratory testing, including HIV rapid testing, is available, accurate, reliable and timely. There should be a national quality system in place, encompassing all tiers of the laboratory network, to support the plan and monitor & evaluate the laboratory's capacity to support program goals. This system 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 and developed as referral centers for complex testing methodologies, such as advanced $CD4^+$ monitoring capacity (to provide quality assurance of these efforts), early infant diagnosis, viral load, TB culture, and drug sensitivity testing. Functional QA systems are critical for test result outcomes, require considerable effort, and should be a clear element in programming support for laboratory testing, with dedicated staff, travel to perform periodic on-site supervision activities, etc. As HIV rapid testing continues to expand, several elements should be put in place to ensure that accurate HIV test results are produced[310] including use of dried tube specimens, standardized logbooks and broad coverage of proficiency testing to all sites.

To ensure that laboratory systems are strengthened as part of the overall health systems, the developmental focus of Quality Management Systems should be directed towards achieving international accreditation of testing laboratories. As such, a stepwise approach using internationally-accepted standards should be implemented to encourage, support and recognize the implementation of QMS in laboratories. Full accreditation is defined by meeting acceptable criteria in order to receive accreditation by a nationally-, regionally-, or internationally-recognized accreditation body, such as the College of American Pathologists (CAP), International Organization for Standardization (ISO), South African National Accreditation System (SANAS), and Southern African Development Community Accreditation Service (SADCAS).

The WHO AFRO-African Society for Laboratory Medicine (ASLM) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) offers an innovative and practical approach to strengthening laboratories and guiding them towards accreditation. This framework supports countries in their efforts to strengthen their national laboratory services through the stepwise quality improvement process towards fulfillment of the requirements in the ISO 15189 standard for medical and public health laboratories. Similar regional efforts and approaches in other non-African PEPFAR-supported countries are underway and highly encouraged. The establishment of programs preparing laboratories for accreditation will help countries to improve and strengthen the qualitative capacity of their laboratories. Laboratories will be evaluated in a stepwise process towards full laboratory accreditation using scores on the SLIPTA or similar accreditation preparedness checklists recognized by the respective national, regional, or international standard and assigned a level of progress towards full accreditation based on their audit score.

Training and Retention Systems

One of PEPFAR's mandates 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. Emphasis and priority should be on human resource development for laboratory workforce for: a) short-term training on a certified and competent workforce, and b) long-term training based on standardized pre-service curriculum. 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.

[310] Parekh et al. Scaling up HIV rapid testing in developing countries: comprehensive approach for implementing quality assurance. Am J Clin Pathol. 2010 Oct; 134(4): 573-84.

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 rollout 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 Division of Global HIV/AIDS (DGHA) 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/DGHA 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), the African Society for Laboratory Medicine (ASLM), Chiekh Antia Diop University (CADU), 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 local indigenous laboratory organizations and training institutions is encouraged.

A. Equipment Maintenance Systems

Several factors influence decision-making about laboratory equipment. Among the most important factors are those that concern 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.

B. 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.

C. 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.

D. 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.

E. 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 laboratory, 2. Secondary district/regional laboratory, 3. Tertiary regional or provincial laboratory 4. National Reference / public health laboratory. 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. 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 & 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

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 both 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.

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.

Strong programs will:

- Establish new regional training centers and sustaining existing ones.
- Strengthen referral transport systems for specimens.
- Implement practical and sustainable quality management systems:
    - Policies for certification of HIV testing by non-laboratory staff;
    - WHO-ASLM or related processes towards laboratory accreditation; and
    - Laboratory management training programs.
- Effectively coordinate donors and partner's efforts (World Bank and Global Fund for AIDS, TB, and Malaria, etc.) on laboratory strengthening efforts.
- Standardize 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 used 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. Please see the FY 2013 COP Guidance Appendix 11 for more information on how PEPFAR funds may be used for renovation.

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), with a focus on effective linkages between Point of Care testing facilities and referral laboratories. PEPFAR staff should work with partners to

ensure that effective linkages exist between partners such 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.

3.2 STRATEGIC INFORMATION

Strategic information (SI) – SI supports a range of activities aimed both at collecting and analyzing information critical for an effective HIV response, as well at building national capacity to perform these activities. Examples include HIV/AIDS behavioral and biological surveillance, facility surveys, monitoring of program results, reporting of results, supporting health information systems, training and retention of local cadres of personnel needed to direct all SI activities, and related analyses and data dissemination activities.

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 have 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 that affects the availability of this data.

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 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 program M&E information produced; and
- Surveillance and surveys support systematic data collection, analysis, and interpretation, representing samples from national populations, service populations, risk populations, and service delivery locations, among others.

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 partner government;
- Provide greater support to national capacity building to collect accurate data, manage, analyze, and use data for better decision-making and policy formulation;
- 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 information systems (HIS) and strengthening of local personnel to take on responsibility to implement, integrate and direct these systems.

PEPFAR requires a transition from an "emergency" program to a routine public health service delivery and development program. SI supports this transition with the:

- Adoption of 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
- Facilitation of the development of national SI coordinating mechanisms to improve collaboration, reduce redundancy and improve system efficiencies.

For countries where PEPFAR's contribution is significant, PEPFAR supports 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 national systems and organizations, 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 implementing partners:
    - Supports building the capacity of the partner government to develop national SI strategy;
    - 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 supported and contributed 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;
- Develop or update a 5-year USG SI strategy that leads to a National SI strategy that:
    - Forms a shared understanding of goals and strategies that partner governments and USG teams can support for the coming year;
    - Describes how the USG's SI activities support the partner government's National SI Strategy and complements other donors' activities, and how all activities fit into the national strategy or Partnership Framework, if it exists;

- 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 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:

There are three components of capacity building that are required to ensure overall successful performance of the HIV response: individual, organizational, and system-wide. 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. Linkages with in-country universities will need to be developed and supported for individual-level M&E professionals. Organizational capacity and systems reforms are essential and enable SI professionals to be placed in established SI positions and retained where they are most needed in the health system and civil society organizations.

It is not sufficient to rely solely on a cadre of SI professionals, improved organization, and system strengthening to support data use. There needs to be a culture of data collection and data use to enhance , outcomes of the HIV program which will in turn promote a system-wide culture of data use This can also strengthen the use of health information systems throughout country and enhance national plans for M&E, surveillance and surveys, and health information systems.

3.2.3 STRATEGIC INFORMATION BUILDING A SUSTAINBLE SYSTEM

As countries build and strengthen the capacity of National SI systems, there needs to be consideration for how the components relating to M&E, HIS, Surveys and Surveillance fit together and are integrated to improve SI in-country and create a functioning SI system on all levels. The international community has reached general agreement on the overall purpose and components of this system that integrates all of SI activities (PEPFAR uses the term SI to encompass M&E, HIS, and Surveys and Surveillance). This can be found in the *12 Components of a Functional National HIV SI System*. [311]

The components of this framework include:

1. *Organizational Structures with SI* – Assess and consider implementing a network of organizations responsible for HIV SI at the national, sub-national, and service-delivery levels.

2. *Human Capacity for HIV SI* - Ensure adequately skilled human resources at all levels of the SI system in order to complete all tasks defined in the annual costed national HIV SI work plan.

[311] http://www.unaids.org/en/media/unaids/contentassets/documents/document/2010/20080430_JC1769_Organizing_Framework_Functional_v2_en.pdf.

3. *SI Partnerships* - Establish and maintain partnerships among in-country and international stakeholders who are involved in planning and managing the national HIV SI system.

4. *SI Strategic Plan* - Develop and regularly update a national SI strategic plan including identified data needs, national standardized indicators, data collection procedures and tools, and roles and responsibilities for implementation of a functional national HIV SI system.

5. *Costed SI Work Plan* - Develop an annual costed national SI work plan, including the specific and costed HIV SI activities of all relevant stakeholders and identified sources of funding. Use this plan for coordination and assessing progress of SI implementation throughout the year.

6. *SI Advocacy, Communications, and Culture* - Ensure knowledge of and commitment to HIV SI and the HIV SI system among policymakers, program managers, program staff, and other stakeholders.

7. *Routine Monitoring* - Produce timely and high quality routine program monitoring data.

8. *Survey and Surveillance* - Produce timely and high quality data from surveys and surveillance.

9. *SI Database* - Develop and maintain national and sub-national HIV databases that enable stakeholders to access relevant data for policy formulation and program management and improvement.

10. *Supervision and Data Auditing* - Monitor data quality periodically and address any obstacles to producing high-quality data (i.e., data that are valid, reliable, comprehensive, and timely).

11. *HIV Evaluation, Research, and Learning* - Identify key evaluation and research questions, coordinate studies to meet the identified needs, and enhance the use of evaluation and research findings.

12. *Data Dissemination and Use* - Disseminate and use data from the SI system to guide policy formulation and program planning and improvement.

The following represent Technical Considerations for USG country teams in planning for the FY 2013 Country Operational Plan.

3.2.4 STRATEGIC INFORMATION MONITORING AND EVALUATION (M&E)

The *12 Components of a Functional National HIV SI System* framework described above responds to the need for a well-planned, integrated SI system. This section will specifically address the M&E components and highlight the complexities of a fully functional, unified, national M&E system to support:

- the generation and utilization of quality information for effective HIV prevention and HIV 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,
- the response to donor and country reporting requirements and needs through unified coordinated monitoring systems.

These Technical Considerations continue to emphasize quality and sustainability in all areas of M&E.

1. National HIV/AIDS M&E Strategic Plan

M&E is part of program planning and should be considered a critical component of the National HIV/AIDS Strategy. Stakeholders from multiple sectors need to endorse and use a joint M&E plan to coordinate the implementation of M&E activities for which they agree to take responsibility. The purpose of a strategic M&E planning process is to: collaboratively work with stakeholders in a systematic manner to identify key priority program areas; examine the strategic questions to monitor and evaluate program performance; identify appropriate indicators for various stages of program implementation; ensure that proposed evaluations are conducted in an appropriate sequence, on a reasonable timeline and appropriately funded; and, develop a data analysis, data use and dissemination plan to ensure that findings are used and shared in a timely manner. A well developed National M&E Strategic plan helps make sure that major components of M&E receive adequate attention while also permitting evaluation of emerging issues as they arise. Having a sound M&E strategic plan contributes to the program mission and helps to demonstrate impact of the program. The USG needs to have an M&E plan for internal coordination, performance measurement and accountability, and also support the development and revision of the National M&E Plan. This collaborative process entails:

- establishing and participating actively in the HIV M&E technical working group/committee coordinated by NAC
- helping develop and conduct an M&E assessment that will enable stakeholders in HIV to identify strengths, weaknesses and recommend actions to inform the strategic planning process;
- addressing key questions for program management and improvement (e.g., Are we doing the right things? Are we doing them correctly? Are we doing them on a large enough scale to make a difference?)
- prioritizing M&E activities that will build one M&E system
- ensuring that the M&E plan is fully funded and that there is an M&E unit with the adequate number of qualified staff
- evaluating the implementation of the plan to determine whether what was planned and implemented helped achieve intended program goals
- revising M&E plan annually

2. Capacity Building

Earlier this year, the PEPFAR Capacity Building and Strengthening Framework was distributed. This framework addresses three integrated components: the individual/workforce; the organization; and, the system.

Building and strengthening M&E capacity within country means that those working in M&E are adequately skilled and also have the infrastructure developed that allows for completion of all activities defined in the M&E Strategic Plan. This process usually starts with an M&E capacity assessment that informs the capacity building activities to be undertaken at the different levels. Examples of capacity building activities that consider individual, institutional and system level strengthening include developing M&E career paths and curricula, training academic institutions, and supervising and mentoring M&E staff. The assessment will also inform the development of metrics and serve as the baseline to measure national M&E technical independence/sustainability overtime. This will enable managers to systematically track progress in M&E system implementation and performance and to identify areas of improvement.

Planning and implementing capacity building activities for and by national AIDS programs are part of the effort to develop a unified and effective national HIV M&E system and measure capacity building implementation and outcomes over time. This will enable managers to systematically track progress in M&E system implementation and performance and to identify areas where improvements are needed.

A resource for developing an M&E capacity building assessment and implementation plan can be found in the World Bank publication "Making Monitoring and Evaluation Systems Work" https://openknowledge.worldbank.org/bitstream/handle/10986/2702/533030PUB0moni101Official0Use0Only1.pdf?sequence=1" as well as the UNAIDS 12 Components Monitoring and Evaluation System Strengthening Tool, http://www.unaids.org/en/media/unaids/contentassets/documents/document/2010/1_MERG_Assessment_12_Components_ME_System.pdf; and the UNAIDS HIV M&E Capability Building Guidance: http://www.unaids.org/en/media/unaids/contentassets/documents/document/2010/5_4_MERG_Guidance_HIV_ME_Capacity_Buidling.pdf

Several tools are available to help with different elements of the M&E strategy. These are listed at the end of this document.

3. Integrated Routine Program Monitoring

Strengthen national HIV M&E systems:

The goal of routine program monitoring systems is to produce timely and high quality data that can be used to improve programs and inform decision making. Strengthening national M&E systems is very challenging. Assessments and activities must be coordinated across different sectors, service areas, and implementation levels. Few countries have mature, integrated routine program monitoring systems, either at facility- or community-based levels. It is essential for USG teams to reach out to partner governments to develop strategies to strengthen national M&E systems accordingly, including those within military health systems.

- *Facility-based monitoring systems:* Although a lot of progress has been made to date, facility-based patient monitoring systems for prevention, care, and treatment services still

need to be strengthened. In particular, PMTCT monitoring standards and tools that covers the continuum of prevention to care and treatment need to be implemented. Facility-based M&E systems should also address provider-initiated counseling and testing and integrated TB/HIV interventions. M&E for referrals of facility-based prevention, care and treatment services continue to need strengthening in many countries.

- *Community-based monitoring systems:* Community- based M&E systems need to be developed, strengthened and integrated into national information systems. Community-based programs often include prevention interventions, home-based care activities, and programming to support orphans and vulnerable children. In order to strengthen community-based monitoring systems, innovative techniques, such as community-based participatory methods and rapid sample methods, can be used to improve data collection. Stronger linkages between facility- and community-based monitoring systems also need to be developed and implemented.

Improve M&E for integrated health 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 ways to monitor and evaluate referrals and linkages among various service types and their impact on HIV-infected and affected populations.

4. Data Quality

Ensuring that all data from programs at all levels, from implementing partners to partner governments and USG teams, is high quality and has been validated is a priority for partner governments and PEPFAR and should be a part of routine program monitoring. Strong PEPFAR teams will support quality control throughout the reporting system, from the district level to the national level, as well as from USG implementing partners through to headquarters. Partner governments, in collaboration with PEPFAR country teams, should develop or in some cases update and implement a national data quality management plan for all program areas, specifically focusing on reported data of program indicators. Partner governments, with the support of USG teams and implementing partners, should work to understand what measures will ensure better data quality and integrate this or update the plan.

At a minimum, a data quality management plan should include: 1) the frequency and methods by which the partner government and USG country team assesses program data; 2) language describing what steps are taken to ensure that reported indicators are not double-counting (i.e., ensuring that the number of people receiving a service are being counted, not the number of services being provided); 3) how the implementing partners aggregate and report program data; 4) how the partner government or USG team reviews and validates program data reported by the

implementing partner; and, 5) challenges that may exist for high quality program data given current patient monitoring systems.

There are several tools to assess the quality of data collected. A few examples are listed below with descriptions:

- ***The M&E Systems Strengthening Tool:*** The overall objective of the M&E Systems Strengthening Tool is to help national programs and associated projects improve their M&E and the quality of data generated to measure success of implemented activities. More specifically, the M&E Systems Strengthening Tool has been designed to:

    - *Assess the national M&E Plan and capacities of the program's/project's implementing entities;*
    - *Evaluate how the M&E activities of programs/projects are linked and integrated within the National M&E System;*
    - *Help to develop a costed action plan to strengthen M&E systems.*

- ***The Data Quality Audit (DQA) Tool:*** The DQA Tool focuses exclusively on verifying the quality of reported data, and assessing the underlying data management and reporting systems for standard program-level output indicators. The DQA Tool is not intended to assess the entire M&E system of a country's response to HIV/AIDS, Tuberculosis, or Malaria. In the context of HIV/AIDS, the DQA Tool relates to component 10 (i.e., supportive supervision and data auditing) of the "Organizing Framework for a Functional National HIV M&E System."

  Two versions of the DQA Tool have been developed: (1) the "Data Quality Audit Tool" which provides guidelines to be used by an external audit team to assess a program/project's ability to report quality data; and, (2) the "Routine Data Quality Assessment Tool" (RDQA) which is a simplified version of the DQA Tool for auditing that allows programs and projects to assess the quality of their data and strengthen their data management and reporting systems.

- ***The PEPFAR Data Quality Assurance Tool for Program-Level Indicators:*** This tool contains information on double counting, comparing program results over time, and documenting outliers; tools have not yet been updated to reflect Next Generation Indicators, but the methods to address DQ issues are still relevant.

These tools can be found at www.globalhivmeinfo.org and at https://www.pepfar.net/C12/C16/Annual%20Progress%20Report%20(APR)%20a/default.aspx.

Additionally, headquarters has resources available to support partner governments and USG country teams in their efforts to develop and update data quality management plans.

5. Evaluation

Evaluation plays a critical role in a functioning M&E system. It is an integral part of program planning, which supports implementation processes and determines program effectiveness. More work is needed to incorporate M&E and evaluation planning from the very inception of a program, rather than leaving these issues unaddressed until the end of a program.

- *Build country capacity to plan and conduct program evaluation (PE) and operations research:* PE projects use scientifically sound evaluation methodology, and the scope of PE can go from non-experimental, mixed methods (quantitative and qualitative methods), to experimental designs. Building in-country capacity to design and implement PE (i.e., process, outcome, impact) and operations research, is necessary to ensure the quality of on-going evaluation and its contribution to decision-making and to ensure the sustainability of health systems. To increase ownership of the processes and results, it is important for USG teams to engage national entities in the prioritization and planning of evaluation and research activities.
- *Develop evaluation plans that respond to main questions of national stakeholders:* PE refers to studies that systematically guide program and policy improvement and development, and focuses on how a program is implemented and its effects on the target populations. As prevention, care, and treatment programs continue to scale up to achieve an AIDS-Free Generation, and as USG programs continue to work hard to successfully meet World AIDS Day targets, PE will be key for evidence-based decision making and accountability. Therefore, PE plans should be developed and implemented as part of both USG and national M&E strategic plans to ensure that *only* prioritized questions are answered. This requires that financial resources be available for conducting planned evaluations.
- *Support the design and implementation of process, outcome, and impact evaluations and operations research:* Process and outcome evaluations should be used to measure implementation fidelity and to determine the short-intermediate term effectiveness of programs, respectively, for the country and for donors, including PEPFAR. Impact evaluation should be used to measure the changes in outcomes that can be attributed to a particular intervention. This involves counterfactual analysis that compares what actually happened with what would have happened in the absence of the intervention. Results from PE inform health providers, decision-makers, and program planners on facilitators, barriers, and best practices of HIV/AIDS programs. This enables stakeholders to be strategic in their efforts to achieve an AIDS Free Generation.

  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 implementation science). Operations research provides answers to program problems, and helps solve these accordingly. It provides program managers and policy makers with the necessary information to improve program delivery.

6. Data Dissemination and Use

As HIV programs have expanded and matured, monitoring and reporting systems have evolved in order to fulfill necessary reporting requirements to governments and international donors. Much effort is expended to collect population-level, community-based, and facility-based data; however, implementers commonly note that the information is 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.

Correct data interpretation and use is critical to planning, assessing, strategizing, and determining next steps in public health programs. Population-level data sources 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 strategic planning, program improvement, evaluation design, and management of prevention, care, and treatment 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.

3.2.5 STRATEGIC INFORMATION: HEALTH INFORMATION SYSTEMS

The *12 Components of a Functional National HIV SI System* framework described above responds to the need for a well-planned, integrated SI system. This section will specifically address the HIS components.

The Health Information Systems Technical Working Group (HIS TWG) has worked to develop a six-step HIS strategy. This strategy enables PEPFAR Country Teams to work with partner governments to ensure that both entities generate and analyze the programmatic data needed to manage their work. The strategy also ensures that the findings are reported to stakeholders while simultaneously laying the foundation for a robust citizen-centric health information infrastructure.

Once the national government, with any needed support from the PEPFAR program, has addressed the implementation of systems sufficient to collect and make available program-required information, the next six recommended steps are:

1. Move M&E reporting through partner government systems
2. Derive M&E data from patient-centric data systems
3. Evolve an Enterprise Architecture to drive system implementation decisions
4. Ensure systems implement data exchange standards needed to ensure system interoperability
5. Link implemented systems to develop a Health Information Exchange (HIE) infrastructure
6. Work with broader international communities to move towards a shared HIE capability

The HIS TWG will require that Country Teams respond to the following questions in the future:

- In the context of the six step strategy outlined in these Technical Considerations, determine the progress of your country program and discuss actions you propose to take to complete all six steps.
- Identify current barriers to completing the six-step strategy as well as the technical assistance you may require to complete all steps.

The following considerations should also be emphasized when planning for HIS systems in country:

A. The evolving role of HIS in large scale HIV focused health programs

B. Strengthen national health information systems framework
C. *Strengthen national policies and promote use of information standards*
D. *Strengthen HIS human resource capacity*
E. *Increase collaborative activities locally, regionally, and globally*

A. The evolving role of HIS in large scale HIV focused health programs

The development of a national health information infrastructure must be tailored to the 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. The emergence of the concept of eHealth [312], broadly defined as the use of information and communication technologies (ICT) for health, should be recognized and an appropriate position towards eHealth initiatives should be developed. The *National eHealth Strategy Toolkit* [313] is a suggested starting point for articulating a coherent eHealth strategy.

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 information system components. Successful information 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 and 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. When weighing the pros and cons of electronic vs. paper-based systems, it is important to consider how best to improve processes and ensure quality data.

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 that support interoperability.

B. Strengthen National Health Information Systems Framework

Two key strategic documents should frame the overall HIS plan in a PEPFAR program. The first is the national HIV strategic plan. This strategic plan may include explicit references to data

[312] *Building foundations for eHealth: progress of Member States: report of the WHO Global Observatory for eHealth*. Geneva, World Health Organization, 2006 , Available online at: http://www.who.int/goe/publications.
[313] *National eHealth Strategy Toolkit*, World Health Organization (WHO) and the International Telecommunication Union (ITU), Geneva, Switzerland, 2012. Available online at: http://www.itu.int/pub/D-STR-E_HEALTH.05-2012.

systems that support any component of the national HIV program, whether it be electronic medical records for patient care, data systems for HIV case surveillance, or data systems for M&E. The second is the national HIS strategic plan. If such a plan exists, it is critical to determine the balance between the public health perspective, and the patient care perspective, including any reference to the ongoing role of paper based systems. The HIS strategic plan may explicitly focus on eHealth initiatives, and HIV may or may not be an explicit priority concern in the HIS strategic plan. PEPAR-related HIS activities must be carefully developed to support these national strategic documents.

A key aspect of achieving efficiencies and economies of scale in HIS is to focus on designing/developing interoperable systems. 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), and UNICEF, among others, to support and assist partner governments in pursuing interoperability as a strategic goal in adopting or developing any system.

The actual activities towards developing systems and solutions should include at least the following:

- 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).Documentation 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
- 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)

C. Strengthen national policies and promote use of information standards

As national health systems seek to better establish and track patient data, the need to simultaneously protect patient privacy and confidentiality has is resulted in legislation and policy development to establish proper protections. Unique patient identifiers are typically a key element of these protections. In many countries, the development of a national health identification number, is seen as a crucial aspect of the development of the health system, and

essential to the provision of high quality care. PEPFAR county teams are strongly encouraged to help facilitate the development of governance and information standards towards improved patient identification.

It is important to describe in writing the in-country HIV-related HIS. For PEPFAR country teams, it will also be important to document the relationship of PEPFAR-funded HIS 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)), since 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. As part of developing this leadership, a certification process may be established to increase oversight and quality control for any system that may be in use by an implementing partner. Implementing partners who are using systems that are unlikely to pass such certification requirements, once the certification process has been developed, should be strongly encouraged to respond proactively and migrate to more suitable solutions.

D. 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. These approaches have proven to be strategic in achieving sustainable results in developing local capacity to implement, manage, and maintain national HIS activities. The plan for human resource capacity building should include a component for HIS-specific capacity. This plan may include: 1) developing a minimum set of health IT position/job descriptions, qualifications; 2) developing training and education opportunities using local resources where possible, but reaching out to regional or global partners where needed; 3) developing recruitment and retention strategies, including establishing a professional development path that includes in-service continuing education and options for professional certifications.

E. Increase Collaborative activities locally, regionally, and globally

As a supporting element of PEPFAR goals and processes, HIS activities offer many opportunities for collaboration that can improve cost efficiencies and dissemination of best practices. Opportunities can exist between implementing partners, with international organizations that provide HIS expertise, and with government and private sector partners. Such collaborations can include:

- Expansion of telecommunication infrastructure that benefits the health sector may require working across Ministries of Health, Finance, Information/Telecommunications, the U.N. International Telecommunications Union (ITU), and the private sector.
- Adopting a specific health information system solution offers opportunities to engage both local and regional private sector partners. Emerging businesses that support a growing health information technology (semi-) commercial sector may be suitable partners to control total cost of ownership of software solutions, while facilitating sustainable systems.
- Multilateral organizations, including WHO, bring rich experience across low and middle income countries LMIC initiatives including HIS, not only within PEPFAR

- In-country or regional academic partners who have educational programs that bring relevant expertise to HIS activities should be engaged in efforts that focus on innovation and sustainability of health information systems.

F. 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. Key elements of data management needs are: 1) tools for data quality assessment and improvement; 2) tools and standard formats for data exchange; and, 3) tool support and mechanisms to implement data de-identification needed for a range of data use settings.

G. Assessing the need for Technical Assistance in HIS development

Understanding how to align country-specific PEPFAR needs in health information systems with national initiatives should be the first objective of the country SI team. If it is unclear how to articulate HIS needs within the dual country strategies as indicated above, the country team is strongly encouraged to request technical assistance to help refine a suitable vision for HIS activities that is both supportive of PEPFAR objectives and aligned to country context.

STRATEGIC INFORMATION: GEOGRAPHIC MAPPING, SPATIAL DATA, AND GEOSPATIAL TOOLS

National plans for increasing the efficiency and coverage of SI 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 domains, including health. Country teams should be aware of and handle all relevant spatial data generated through PEPFAR activities 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 partner country.

Spatial data are routinely generated 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 across the health sector.

Some spatial data generated are not governed by partner government NSDI and can be considered part of PEPFAR's own spatial data infrastructures (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. More advanced spatial analysis, management of spatial data, and displays of spatial data can be accomplished using a geographic information system. Technical assistance on geospatial tools and the acquisition, management and use of spatial data is available from PEPFAR HQ.

3.2.6 STRATEGIC INFORMATION: SURVEILLANCE AND SURVEYS

The *12 Components of a Functional National HIV SI System* framework described above responds to the need for a well-planned, integrated SI system. This section will specifically address the surveillance and surveys components.

A. General considerations

*Surveillance Strategic Planning***.** Partner governments, with support from USG teams and implementing partners, should develop a five-year HIV/AIDS surveillance strategic plan that is in agreement with the national SI Strategic Plan. This surveillance 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 surveillance 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/

Country ownership. PEPFAR supports country-ownership for all surveillance and survey activities. The monitoring of HIV infection (prevalence and/or incidence) and related risk factors at the national and local level is critical to assure that (PEPFAR-supported) program activities are responding effectively and to provide data for future activity planning.

Workforce Training & capacity. Countries should be encouraged to develop national educational and training programs to develop and support local experts in surveillance and surveys. Along with individual development, countries should also consider the capacity of local higher education providers to meet these 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 who in turn may provide training and education for in-country staff.

*Laboratory support***.** National laboratory capacity is critical to the successful collection of strategic information. Laboratory support refers to specific assessments and trainings related to new lab procedures (e.g. incidence assays, drug resistance), development of training materials, and specimen collection and testing. The aspects of capacity building which include establishing national laboratories, including regulations, are an important part of capacity building; please see section 3.1, Laboratory Infrastructure, for more information.

Human Subjects considerations. All surveillance and survey protocols and relevant M&E 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.

Sampling. Rigorous sampling designs are necessary to generate representative findings. Recognizing that HIV infections are present in all age groups, investigators should consider inclusion of older adults (50+ years) and/or children aged 5-14 years as appropriate for the country-specific context.

Data collection. Countries should consider taking advantage of paperless, electronic data collection through the use of smart phones, tablets, or netbooks. Electronic data collection has the potential to improve data quality and can save staff time. (Audio-) Computer assisted self-interviews have the potential to solicit more candid responses about stigmatizing behaviors than face-to-face personal interviews. Group settings for computer or paper based data collection may further increase data quality and efficiency and should be considered.

Data measures. In addition to basic demographics and direct risk factors for HIV infection, countries should consider measuring the following: stigma, social support, access to services, past HIV testing and HIV test result, self-reported circumcision status, same sex partners, unprotected anal sex, selling and buying sex by both men and women, depression, alcohol and drug use, sexual violence.

Biomarkers. Whenever HIV testing is included, countries should consider measuring sexually transmitted diseases as indicated by prevalence, and, as feasible, CD4 counts and viral load among HIV-infected respondents. Other useful biomarkers include HSV-2 as well as bacterial or parasitic sexually transmitted pathogens. In addition, HIV-infected individuals often have chronic co-morbidities such as impairment of renal and hepatic function, dyslipidemia, or diabetes. Certain survey or surveillance activities may lend themselves to additional biomarker testing to address information gaps in the area of Neglected Tropical Diseases and the Global Health Initiative.

Testing results should be provided to survey participants as soon as practicable. If the testing is available in a rapid test format, the protocols should be put in place to provide results back immediately. Otherwise, provisions to return results must be integrated into surveillance protocols.

*Data Dissemination***.** Surveillance is "information for action". The timely publication of surveillance findings is a vital component 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 and surveillance stakeholders 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. Surveillance data stemming from PEPFAR funded activities should be managed through shared data ownership, i.e., partner government, USG agencies, and implementing partner. Delinked (anonymized) data should be made available to any interested third parties for further (in-depth) analysis. Due to national security concerns, military surveillance data may be held internally to be used for decision-making and evidenced-based planning and shared confidentially rather than made public.

*Evaluation of surveillance systems***.** The evaluation of surveillance systems is 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. Guidelines such as those issued by the CDC are available at http://www.cdc.gov/mmwr/pdf/rr/rr5013.pdf (*Updated Guidelines for Evaluating Public Health Surveillance Systems*)

The HIV epidemic has proven to be influenced by many political, structural and social factors, so the surveillance process needs to adjust as the epidemic, control measures, and knowledge about the disease change. Although the primary aim of surveillance is to measure trends in specific indicators, surveillance systems risk becoming stagnant if they are no longer producing relevant information. Planning for and evaluating surveillance systems should therefore be a cyclical process in which data needs and data gaps are assessed on an ongoing, regular basis

B. Surveillance and Survey Activities

Sentinel surveillance among pregnant women (Generalized epidemics):

Countries with generalized HIV epidemics (HIV prevalence among antenatal clinic (ANC) attendees >1%), have typically relied on sentinel surveillance among pregnant women attending ANC clinics. Partner governments should use sentinel surveillance data to monitor the HIV epidemic nationally and locally. Stable, mature epidemics may require ANC surveys no more than every two to three years. Sites should be consistent. Internationally accepted guidelines for ANC surveillance have been 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

All ANC surveillance systems should include testing for *treponema pallidum* (syphilis); syphilis related findings should be reported along with HIV prevalence estimates. Partner governments should be encouraged to include other routinely available ANC data, such as related to maternal and child health, as feasible, to help address GHI information needs.

Transition from ANC sentinel surveillance to surveillance based on PMTCT program data:

Due to growing concerns about the ethics of unlinked anonymous testing (UAT) surveys of ANC clients there is significant and rising interest in replacing UAT-based ANC sentinel surveillance (ANC SS) with routine data generated by expanding PMTCT HIV testing services. Using routine PMTCT program data for surveillance has important potential advantages, including:

- PMTCT-based surveillance ensures pregnant women sampled by surveillance consent to HIV testing, are provided with their test results, and are referred to HIV care and treatment services if test results are positive
- Improving PMTCT program data for use in HIV surveillance would strengthen routine program performance and provide better data for monitoring and evaluation of PMTCT programs
- Costs associated with PMTCT-based surveillance are anticipated to be low compared to ANC SS

CDC/WHO guidelines for assessing the utility of PMTCT program data for surveillance are being finalized. All countries conducting traditional UAT-based ANC SS (or consented unlinked testing for ANC SS) should include an assessment concurrently with every ANC SS round, and including as many sentinel sites as possible in the assessment.

The objective of a PMTCT utility assessment is to rigorously evaluate the utility of PMTCT data for surveillance, including:

1. The agreement of ANC-based and PMTCT-based HIV test results
2. The magnitude of non-consent bias inherent in PMTCT program data compared to ANC SS data
3. The coverage of PMTCT services at ANC SS sites
4. The completeness and validity of routinely collected PMTCT program data
5. The quality of PMTCT HIV rapid testing quality assurance practices

Where PMTCT program data and performance are suboptimal, the assessment will assist in identifying gaps and providing evidence to inform program improvement.

To address the five areas listed above, a comprehensive PMTCT utility assessment should include three methodological elements:

1. Three questions added to the standard ANC SS form to prospectively capture information about PMTCT HIV acceptance and testing among pregnant women sampled by ANC SS. This will allow for the assessment of PMTCT uptake, agreement between ANC SS and PMTCT HIV testing results and prevalence estimates, and selection bias associated with differential HIV prevalence among PMTCT HIV testing consenters and non-consenters;
2. A data quality assessment to examine the quality of routinely collected PMTCT data
    a) A site assessment to gather information on site PMTCT HIV testing, recording and patient flow procedures to identify factors that could inhibit HIV testing uptake and data capture;
    b) A retrospective "data abstraction" or "rapid review" of PMTCT records from before and during the ANC SS period to quantify the completeness and validity of site PMTCT records;
3. A rapid checklist assessment to examine PMTCT HIV rapid testing quality assurance practices.

These methods can be scaled to match local country context, but the adoption of rigorous assessment methods are suggested where possible.

Behavioral and Biologic Surveillance among Key populations and higher risk populations:

All countries, whether facing generalized, mixed or concentrated HIV epidemics, harbor key populations that are at increased risk of HIV infection. The behaviors that put individuals at risk are:

- Injecting drugs with used needles
- Having unprotected anal sex
- Having sex with many partners without protection

All countries should therefore conduct periodic behavioral surveillance activities among (relevant) populations who engage in the behaviors listed above: people who inject drugs (PWID), men who have sex with men including transgendered individuals (MSM), and sex

workers (SW) and their clients. In recent years, women having anal sex have been identified as at increased risk of HIV infection from this behavior.[314]

Within generalized and mixed epidemics, HIV burden is typically unevenly distributed, with certain sub-populations having very high prevalence. One distinguishing factor between these sub-populations at higher risk and key populations is that the former experience less stigma and discrimination. Sub-populations that typically have very high HIV prevalence include but are not limited to migrant workers, truck drivers, members of the military, and fishermen. PEPFAR teams should also support periodic behavioral surveillance activities among these populations.

Partner governments are responsible for ensuring such surveys among relevant groups are conducted every 2-3 years, depending on the specific epidemic conditions, in key (urban) settings. Such surveys are often termed "behavioral surveillance" which in turn is identified by various 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). Where partner governments are unable or unwilling to undertake these surveys, PEPFAR programs should both work to shift those policies and support survey activities in the interim. See the 2012 PEPFAR Guidance for the Prevention of Sexually Transmitted HIV Infections for more information.

Whenever possible, biomarkers (HIV, syphilis, and perhaps other STIs) should be included in these surveys and sampling design should aim at yielding representative samples. Risk to participants should be minimized and whenever possible, data collection should be anonymous for populations engaging in illegal activities.

Behavioral surveillance methods:

Behavioral surveillance is the systematic and ongoing collection of data about risk and health-related behaviors to correlate trends in behaviors with changes in disease over time. By measuring risk behaviors that are more proximate to the time of HIV infection, it is possible to identify and respond to trends in behaviors that are associated with increased risk of acquisition and transmission of HIV infection. Similarly, surveillance of HIV testing and care-seeking behaviors is important because the timing of testing and treatment is related to the time any one individual may unknowingly expose others to HIV infection.

The UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance has produced guidelines on surveillance among populations most at risk for HIV UNAIDS: http://www.unaids.org/en/media/unaids/contentassets/restore/20110518_Surveillance_among_most_at_risk.pdf

Formative assessment in preparation for behavioral surveillance:

Populations at higher risk for HIV infection are commonly more fluid (i.e., membership in a risk group is not necessarily lifelong) than other populations. For this reason, it is important to conduct a formative assessment (sometimes called a pre-surveillance process) before implementing any behavioral surveillance activity. Countries whose surveillance systems do not monitor relevant and appropriately defined subpopulations are at risk of failing to detect emerging epidemics or assess the source of new infections to target intervention efforts where

[314] Guidelines on surveillance among populations most at risk for HIV UNAIDS: http://www.unaids.org/en/media/unaids/contentassets/restore/20110518_Surveillance_among_most_at_risk.pdf

they will make the most difference. Therefore each behavioral surveillance cycle should include a formative assessment phase to plan appropriately, avoid making mistakes that will cost time and money and provide more useful information for prevention.

The UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance has produced a guidance on conducting these assessments: The pre-surveillance assessment: Guidelines for planning serosurveillance of HIV, prevalence of sexually transmitted infections and the behavioral components of second generation surveillance of HIV.

http://data.unaids.org/pub/Manual/2005/20050101_gs_guidepresurveillanceassmnt_en.pdf

Size estimation of key populations:

Reliable size estimates of key populations are often a crucial data gap. Various methods for size estimation exist, some of which can be integrated in surveys. Countries should generate population size estimates for key populations in order to facilitate advocacy, policy and funding decisions, and program planning.

The UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance has produced a guidance on conducting size estimations: Guidelines on Estimating the Size of Populations Most at Risk to HIV:
http://www.unaids.org/en/media/unaids/contentassets/restore/2011_Estimating_Populations_en.pdf

Surveillance among pediatric populations:

The main objective of pediatric surveillance is to use existing clinical and program data to establish a pediatric HIV case reporting system. Such a system would utilize routinely collected data from healthcare facilities and programs, such as early infant diagnosis (EID), prevention of mother to child transmission of HIV (PMTCT), and HIV care and treatment. Pediatric surveillance data should enable national HIV/AIDS programs to better characterize the pediatric HIV epidemic and inform policy and planning for prevention and care and treatment programs.

Pediatric surveillance uses of facility-based, EID, PMTCT, and/or care and treatment data to generate case reports of HIV-infected children. Clinical and programmatic data that are in existing records may be utilized, while incorporating surveillance-specific developments and standardization of data collection and reporting procedures. Pediatric surveillance may initially involve active case surveillance in clinical facilities, program service sites, and laboratories, with dedicated staff identifying HIV-positive pediatric cases and collecting case report information based on clinic registers, medical records, and/or laboratory requisition records. Access to records between facilities, sites, and laboratories may be coordinated for the purpose of monitoring data flow and quality.

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 governments and their partners of how programs have changed attitudes and behaviors, or have improved individual health status, is 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 UNAIDS guidance on key questions to ask when considering inclusion of HIV testing in population-based surveys:

http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/20101207_HIVtesting_in_surveys_WG_en.pdf;

TB/HIV surveillance:

Tuberculosis and HIV co-infection is very common and often these epidemics are referred to as a syndemic. Surveillance of TB/HIV co-infection is important in both TB and HIV settings. Partner governments should include HIV testing within TB clinics as a means for identifying HIV-infected people and linking them to HIV care and treatment services. Surveillance in TB settings should focus on estimating the prevalence of HIV in the population diagnosed with TB disease. Surveillance may also collect data on the flow of TB patients through the HIV testing/care/treatment cascade (in which TB patients are tested for HIV, linked to HIV services, receive HIV diagnostic services [such as CD4 testing], and started on antiretroviral treatment in a timely manner).

Similarly, persons in HIV care and treatment should be regularly screened for TB to identify persons with active TB disease and link them to TB diagnostic and treatment services. Surveillance in HIV settings should focus in estimating the incidence of TB among persons diagnosed with HIV. Surveillance may also collect data on the flow of patients through the intensified case finding (ICF) cascade (in which patients in HIV care or treatment are regularly screened for TB, referred for TB diagnostic evaluation, and started in anti-TB treatment or isoniazid prophylaxis in a timely manner) .

Recent HIV infections:

To describe current HIV transmission dynamics, HIV incidence or recency of infection should be measured whenever feasible. HIV incidence can be: measured through observational cohorts; derived through mathematical modeling, including synthetic cohort models, which compare age-specific HIV prevalence from repeat surveys; approximated by measuring HIV prevalence in young adults or other recent initiators of high risk behavior; and, estimated with the help of laboratory assays.

If using lab based methods, the field of laboratory-based incidence estimation is particularly dynamic with the development of new, improved assays. Countries should contact PEPFAR or CDC Atlanta's Division of Global HIV/AIDS for the latest guidance on using laboratory tests for recent infection to estimate HIV incidence. Commercial tests for recent HIV infection are available (e.g., the Limited Antigen Avidity EIA), and may be used to test serum or plasma specimens. Kits will soon be available for testing dried blood spot specimens. Estimating HIV incidence through the use of laboratory assays on cross-sectional samples usually requires very large sample sizes or high HIV incidence, such as AIDS Indicator or Demographic and Health Surveys, large samples from ANC surveys, or VCT and PMTCT clients. Rarely would a survey be conducted for the main purpose of HIV incidence estimation. Special statistical considerations apply and relevant guidance is available entitled "When and how to use assays for recent infection to estimate HIV incidence at a population level" available at:

http://whqlibdoc.who.int/publications/2011/9789241501675_eng.pdf

HIV [AIDS] case surveillance:

With the rapid scale up of HIV prevention, care and treatment services in sub-Saharan Africa in the last seven years has come development of clinical and laboratory monitoring systems. HIV case surveillance, a key component of public health surveillance, was not feasible until clinical/laboratory monitoring systems were in place. To date, other surveillance methods have been used to monitor the epidemic. As PEPFAR continues to transition to country ownership, systems strengthening and sustainability, HIV case surveillance can play a crucial role to build and maintain a strong public health monitoring and response system.

HIV case-based surveillance is an integral component of "Second Generation HIV Surveillance", providing valuable data on major risk exposures, clinical/immunologic status at time of diagnosis, numbers of HIV and AIDS cases, and the demographic and geographic distribution of cases. Further, HIV case-based surveillance is fundamentally an activity that strengthens health monitoring systems, because it involves the routine recording, reporting, management, and analysis of programmatic events.

Countries (particularly those with significant electronic patient record systems) are encouraged to consider piloting a case surveillance system in a subset of service sites or a particular geographic area. 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, 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 creating 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 (HIVDR):

As ART scale-up to achieve World AIDS Day targets continues, ongoing concerns about the potential for increasing levels of HIVDR need to be addressed. Furthermore, in support of 'treatment as prevention' priority, using the WHO framework as a guide, funds need to be allocated to support priority HIVDR surveillance activities that contribute to answering the following questions:

1) Is the prevalence of transmitted HIVDR high enough to potentially impact the efficacy of empiric first-line ART?

2) Is the pattern of HIVDR in patients failing first-line ART likely to significantly impact the efficacy of second-line ART?

WHO, in collaboration with PEPFAR, is in the process of developing an updated framework (available at http://www.who.int/hiv/pub/drugresistance/en/index.html) for routine HIVDR

surveillance activities that are relatively simple to implement and successful informing public health policy. This updated framework has five elements:

- Cross-sectional survey of baseline HIVDR in adults initiating ART at representative sites
- Cross-sectional survey of acquired HIVDR in adults and children on ART for >12 months and >24 months at sentinel sites
- Surveys of HIVDR in children <18 months of age newly diagnosed with HIV
- Surveys of transmitted drug resistance (TDR) in recently infected populations
- Monitoring of HIVDR early warning indicators

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 are 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 are used by military policy makers and HIV program managers to develop and review HIV/AIDS policies, tailor and monitor effective prevention programs, and plan care and treatment services. Use of HIV incidence assays and other biological markers are also recommended where feasible. Standardized military specific Seroprevalence and Behavioral Epidemiology Risk Surveys (SABERS) protocols and surveillance tools are available for local adaptation. HIV prevalence studies among military recruit applicants may, depending on national recruitment policies, provide a good, low-risk proxy of HIV prevalence in young men in general. Prevalence surveys should be performed no more than every two years. Capacity development of military personnel should be integrated into all steps, from planning to final dissemination of results. Dissemination of survey findings to other national stakeholders should be encouraged.

Qualitative research:

Qualitative research is an important and often underutilized method that can provide greater clarity around quantitative 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.

C. Other Activities

Burden of disease modeling and projections:

Tailored software packages such as Spectrum/EPP lend themselves to translating the findings of HIV prevalence surveys to the burden of HIV disease in a country, province, or specific population, including the number of incident and prevalent infections, vertical infections, AIDS deaths, and the absolute need for prevention, care and treatment services. This software package is regularly updated and disseminated through UNAIDS. PEPFAR country programs should support partner governments for such estimation work and use these findings for their COP planning.

More info can be found at UNAIDS:
http://www.unaids.org/en/dataanalysis/datatools/spectrumepp2011/

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 AIM module in Spectrum can estimate infections averted, and The Census Bureau has also developed an alternate framework to estimate HIV infections averted.

Outside of the estimation work that occurs on a national level with Spectrum, 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.

To aid in the Census Bureau's work, country teams are asked to expedite electronic copies of surveillance reports to the Census Bureau upon official release to <pop.ipc.hiv@census.gov>.

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 is available through the PEPFAR SSTWG.

3.2.7 STRATEGIC INFORMATION: COUNTRY CONTEXTUAL CONSIDERATIONS

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 M&E. International standards suggest at least 5-10 percent of a program budget should be dedicated to M&E of the program. Regardless of the exact percentage, routine M&E should be integral to all PEPFAR programs.

3.2.9 STRATEGIC INFORMATION: LINKAGES AND WRAPAROUNDS

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.

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.)

3.3.1 INTRODUCTION

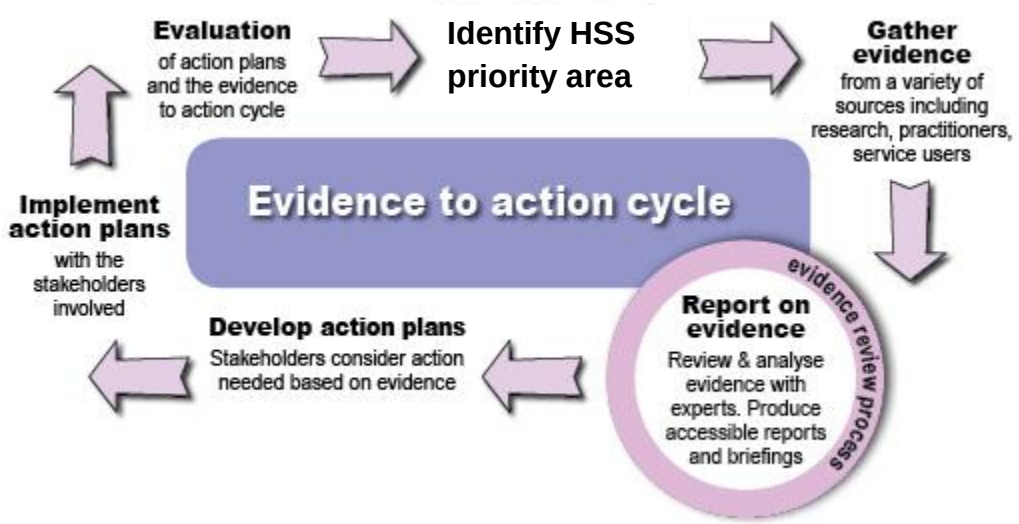
Much of PEPFAR's work has strengthened health systems. Yet health systems strengthening (HSS) work has not been well defined and has varied from country to country. This guidance seeks to systematize that work, place it within a coherent conceptual framework, and recommend promising practices.

- 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, equity, accessibility, patient-centeredness, and safety; 2) Leadership and Governance, including health policy development and implementation, regulation, strategies, and accountability, strengthening regulatory frameworks; 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, accountability and inventory management; 5) Information Systems for monitoring and evaluating health-related activities not only health management information systems but also laboratory, human resources and logistics management systems; and 6) Human Resources for Health (HRH), including planning, production 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 effective, equitable and high 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.

Figure 1: Health Systems Strengthening through Evidence based decision making



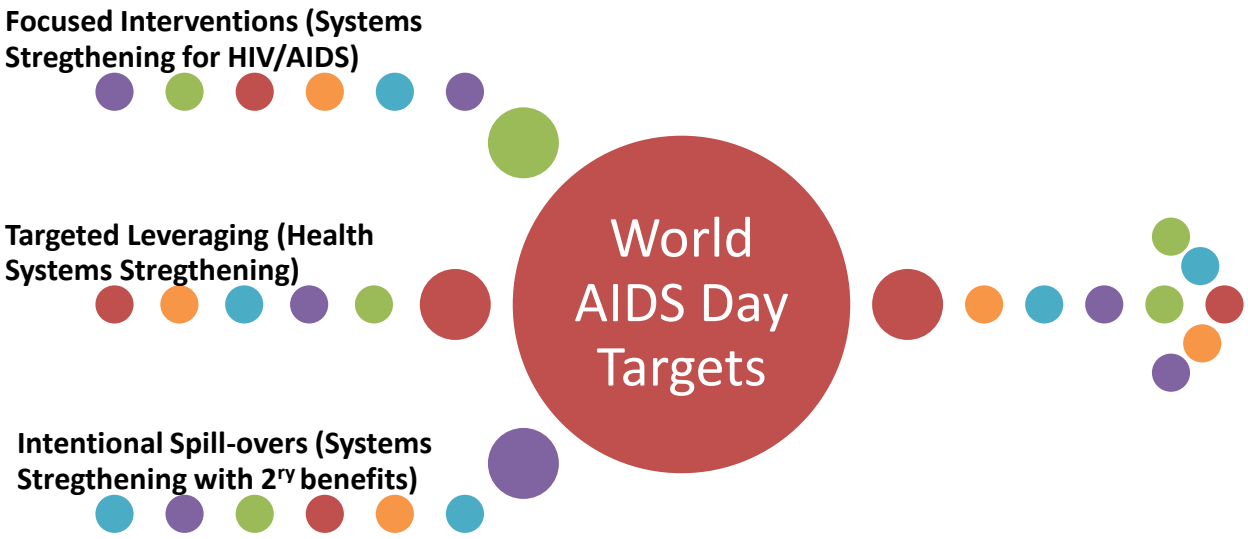
Adapted from http://aboutfamilies.org.uk/

The PEPFAR HSS technical working group encourages the use of the above framework to develop an action plan to meet their HSS objectives. It is important to identify health systems priorities to achieve World AIDS Day Targets for an AIDS-free generation and to prioritize those activities. Please note that not all health systems issues can be addressed in a given funding cycle, though efforts can be made to identify and develop possible solutions and strategies. Strategies should be driven both by data collected about the current status of the health system, as well as on the strength of evidence for interventions. PEPFAR teams should carefully monitor and evaluate the strategy in terms of its effectiveness, cost-efficiencies, and long term sustainability. The PEPFAR HSS technical working group encourages country teams to develop interventions that are specifically tailored to the needs of their country's health system needs.

The 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, depicted in Figure 2.

Figure 2: Working towards AIDS Free Generation through Systems Strengthening



Focused Interventions for HSS encompasses 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).

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, improvement of national supply chain management system – which benefits all health programs or joining other donors in developing a comprehensive national health insurance program that includes coverage for HIV/AIDS services).

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, integration of HIV with other disease programs: HIV and reproductive health or MCH services to extend the benefits to other diseases).

The conceptual framework 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 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, equitable, safe, high quality* personal and non-personal health interventions to those who need them, *when and where* they are needed, with *efficient use* 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 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
- Developing mechanisms to reduce pilferage and leakage through the system and better accountability.

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;
- Establishing ways to build interoperability amongst various available systems 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*. To better understand and impact health systems policy, PEPFAR country teams are encouraged to draw on national legal and regulatory experts for research and analysis on key health systems governance issues such as task sharing for ART, VMMC, and PMTCT.

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;
- Strengthening sub-national capacity to delivery health services by supporting the decentralization process;

- Develop, support or strengthen existing regulatory bodies and councils in the country 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 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.

G. Finance

Healthcare finance and financial management are areas that have not traditionally been addressed by 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 is a substantial need to enhance management within health systems, and thereby contribute to increases in quality, efficiency and accessibility of health care. Promoting leadership within the health sector can 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 leveraged with host country and other donors 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

These technical considerations provide 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**
Focused: HIV-focused treatment, care, and prevention activities						
Leveraging: collaborating with other partners to generate HIV/AIDS and other benefits						
Intentional Spillover: impacts on HSS at no or minimal cost to USG						

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
Focused: HIV-focused treatment, care, and prevention activities	• Strengthen ARV referral systems and care networks, service integration • Basic laboratory services for monitoring ART side effects, community linkages • Outreach to special populations (MARPs) • Decentralization of ARV services and planning to districts	• Develop sufficient ARV service providers via task-shifting, improved HR efficiencies, in-service trainings, capacity building of HIV training institutions	• 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)	• 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	• Strengthen systems to plan, monitor and improve ARV delivery using DHS/AIS, SPA, ARV M&E, drug resistance surveillance • Implementation of HIVQUAL (continuous quality improvement for HIV) • PHEs focusing on treatment questions	• 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
Intentional Spillover: impacts on HSS at no or minimal cost to USG	• 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	• Improve HR efficiencies across clinic/hospital • Broader institutional capacity-building • Task-shifting in non-HIV services & departments • Doctors/nurses able to address PHC needs	• Governments perform 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	• Newly acquired forecasting and delivery skills used for other drugs and vaccines • ARV procurement systems adopted for other drugs	• Quality improvement drives models for other diseases • DHS/AIS/MIS informs other disease programs (TB, malaria, MCH) • PHE efforts stimulate operational research in other areas	• 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
Leveraging: collaborating with other partners to generate HIV/AIDS and other benefits	• 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	• DfID, IHP+ joint partnership in expanding pre-service training • Expansion of community health worker schemes and trainings in partnership with MCH programs • HRH strategic planning	• 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 policies/procedures	• 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 and procurement systems)	• 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	• 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
Focused: Treatment, care and prevention activities	• 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	• 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	• 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	• 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)	• 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	• 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
Intentional Spill Over: Impacts on HS at no or minimal cost to USG	• 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	• 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	• 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	• 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	• 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	• 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
Leveraging: collaborating with other partners to generate HIV/AIDS and other benefits	•	•	•	•	•	•

Building Local Evidence for Health Systems Strengthening:

In a recent 2012 International AIDS Society conference pre-meeting on "Systems Strengthening for an AIDS-Free Generation", attendees articulated a strong need for operational research to understand local health systems bottlenecks, and issues with the implementation of interventions. The PEPFAR HSS technical working group encourages regular assessment of health systems (Health System Assessment Approach: A How-to Manual), including the impact evaluation of new health systems interventions.

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 are 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 HSS issues that can be resolved effectively during the five-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?

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 and other health 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 pre-service education.

However, one of the key lessons learned within PEPFAR is that making a sustainable impact on the health workforce in PEPFAR countries, requires moving beyond the idea of simply increasing the "number of people trained." With the chronic problems of 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. As a result, "Human Resources for Health, (HRH)" as a technical area in PEPFAR aims to strengthen the overall health workforce system in PEPFAR countries, following the WHO life cycle approach of the health worker (from education and training, through recruitment, retention, and retirement).

As PEPFAR transitions from an emergency response to a sustainable program, improving workforce planning and management, training, recruitment, and retention become even more important programs for countries to support. Similarly, PEPFAR's investments in HRH should be governed by the principles of fostering country ownership and sustainability. 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 in order to improve health outcomes. The priority outcomes for PEPFAR were announced on World AIDS Day, 2011 and include increased HIV treatment, PMTCT coverage, and voluntary male circumcision. HRH investments in PEPFAR should directly support the achievement of these goals.

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:

1. Support national HRH planning and management, including development of human resource information systems.
2. Strengthen pre-service education institutions to improve the quality and output of graduates.
3. Ensure the standardization, quality, and coordination of in-service training through, for example, continuing professional development programs.
4. Advance innovative and cost effective models of service delivery and skill mix, including task-shifting/sharing, introduction of new cadres, integrating community health workers into the continuum of response, developing multi-disciplinary teams, and supporting implementation science.
5. Investigate and apply recruitment/retention strategies, especially in rural and underserved areas.
6. Advance health worker regulation and policy, including capacity-building of regulatory bodies and professional associations.

The objectives cover areas of intervention that were selected to help PEPFAR reach its Congressional target and support all components of the HRH system that are essential for maximizing the return on PEPFAR's investment in creating new health care workers. Additionally, PEPFAR investments in HRH should look to directly support new targets announced on World AIDS Day, including the expansion of ART, PMTCT, and VMMC. Where appropriate, interventions should be targeted at health workers that provide HIV/AIDS services, but can be used to improve the overall health workforce. As a priority of PEPFAR II, country teams should work to build in-country capacity, ownership, and sustainability of HRH through its HRH interventions.

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 find opportunities for coordination and collaboration to ensure these activities are not overlapping or duplicating services. Under the GHI, it is important to identify opportunities where PEPFAR can also coordinate and collaborate and/or help leverage other USG HRH investments that are being made with non-PEPFAR funds. Additionally, coordination should extend with other donors and host governments (for instance, through Partnership Frameworks and GHI Strategies) to encourage investment and support for a comprehensive HRH system in each country not possible with PEPFAR dollars alone. Other important coordinating mechanisms where country team and country stakeholder involvement is encouraged include National HRH TWGs, HRH Observatories, and Country Coordination Mechanisms (CCMs).

PEPFAR resources should focus on investing in health workforce interventions that are evidence-based and integral to well functioning country health systems and delivery of quality HIV/AIDS services. Before developing HRH activities, it is important to understand the health workforce dynamics (i.e. supply, demand, migration, etc) in your country to ensure the appropriate targeting of PEPFAR resources. This includes understanding broader social, economic, and political factors that are impacting HRH.

It is important to analyze and address how gender issues intersect with HRH. Not only is attention to Women, Girls, and Gender Equality a core principle of PEPFAR and the GHI, it is essential to building a qualified and sustainable health work force. Gender issues may include, but are not limited to, training providers on the importance of appropriate and respectful care to all clients, including women, girls and marginalized groups; understanding how gender issues

may impact health worker team dynamics; and addressing gender inequities that may impact recruitment and retention in pre-service and in-service education, training, and career advancement. Additionally, attention should be placed on whether there are specific gender implications in task shifting/sharing. For example, given that doctors are often predominantly male and nurses are predominantly female, are there differences in power and issues such as control of information and respect within the work place as well as patient/client perceptions of capacity and competence of the services being offered? Are there implications for how smoothly the transition of tasks will take place and how effective this transition will be in the long run?

3.4.2 INTERVENTIONS

A. Support national HRH planning and management, including development of human resource information systems

Workforce Planning

Supporting countries to plan and manage their health workforce more effectively is a critical step to meeting PEPFAR goals and to ensuring sustainability of health outcomes. Planning and management of the health workforce is an overarching theme of the six HRH objectives. A foundation for workforce planning is a national HRH plan: a strategic framework for the comprehensive development of a country's health workforce over time. 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 a HRH assessment or an HRIS - to project the supply and demand for health workers in the country over several years (usually 5-10);
- identifies approaches that will allow the country to train, recruit and retain the numbers and types of health workers needed to accomplish national health goals; and
- includes a strategy and timeline for conducting these activities, and indicators that will be used to measure progress[315].

PEPFAR-supported HRH activities should align with this national plan, where one exists. Many countries have developed national HRH plans, though often they are not being implemented. This is typically because they are not adequately costed, or resourced, or because they do not address the role of other key stakeholders, such as the Ministry of Education in pre-service education or the role of the Ministry of Finance, when planning expanded recruitment and deployment of public sector staff. PEPFAR teams should work with other donors to help countries establish or improve the national HRH plan, and help identify and overcome obstacles to its implementation.

More routine forms of workforce planning are also critical to the achievement of national health goals and PEPFAR priorities. Examples include the annual budget formulation process and routine deployment decisions made by HR managers or chief professional MOH staff. PEPFAR teams should strengthen MOH capacity to make strategic, data-driven workforce deployment decisions, which help achieve specific national HRH plan and health goals. In particular, PEPFAR teams planning for supporting the scale-up of ART, PMTCT, VMMC,

[315] Models and Tools for Workforce Planning and Projections. Human Resources for Health Observer, 3. World Health Organization, 2010.

and other technical priorities should work with the MOH to ensure that the right level and skill mix of staff is deployed at the right health facilities to ensure successful program implementation. Several tools for workforce planning are available on the WHO website: http://www.who.int/hrh/tools/planning/en/index.html.

Human Resource Information System (HRIS)

A HRIS is a systematic procedure to acquire, store, manipulate, analyze, retrieve, and distribute relevant information about the health workforce, including workforce demographics and capacity, training needs, and migration patterns. A HRIS facilitates evidence-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 HRIS if one does not exist. A HRIS in the form of a national electronic database can provide more accurate, reliable, and timely information for use by decision makers. However, a well-functioning paper-based system (or a paper-electronic hybrid system) may be preferable in settings that face challenges in maintaining electronic systems. It is recommended the HRIS be established within the MOH or other indigenous organizations capable of collecting and assessing HR data in a sustainable manner.

An HRIS ideally encompasses each stage of the health workers lifespan, from Pre-Entry (education, pre-service training), through Entry (registration, licensing), and Existence (deployment, management, skills, continuing professional development and in-service training, promotion), to Exit (migration, retirement, death).[316] HRIS enable rapid access to information, such as numbers of healthcare workers registered by cadre, their credentials, current working location, and education and training, which assists host governments and USG teams to more accurately assess workforce needs and to target PEPFAR resources. HRIS should be designed with interoperability and scalability in mind, to facilitate compatibility with other information systems and maximize the use of comprehensive data for greatest benefits. Ideally, HRIS contain routine reports on key information required by decision makers that can easily be disseminated. Given the varying levels of IT capacity across PEPFAR countries, an incremental and technologically-appropriate strategy is recommended, including a clear plan for how the HRIS will be sustainably maintained.

A first step to creating a HRIS is developing a clear understanding of the information needs of the end user (see WHO 2011 tool on functional requirements analysis). In addition, fostering the strategic use of HR data for policy and decision-making is paramount, and requires robust capacity-building among diverse stakeholders, including HR managers, chief professional staff (e.g. Chief nursing officer), and other MOH decision-makers. WHO-supported national health workforce observatories can be a resource for improving the strategic use of HR data in your country.

B. Strengthen pre-service education institutions to improve the quality and output of graduates

To meet the PEPFAR II Congressional target of 140,000 new health workers, PEPFAR is supporting the production new graduates from pre-service educational institutions. Pre-

[316] *Rwanda HR Information Systems Report*. Krishanmurthy, Ramesh, et al. World Health Organization. 2011.

service education is defined as the basic education required to provide a set of basic skills or competencies needed by all health care workers within a specific cadre (e.g. physicians, midwives, nurses) that will be used throughout their careers. Pre-service education should be competency-based and built on task analysis according to a predefined scope of practice. 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 would not have served in previously. PEPFAR captures pre-service through two measures- training that is greater, or less than, 6 months. Training greater than 6 months contributes directly to the PEPFAR 140,000 HRH target. 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 including accreditation, indicators of progress, the development of quality standards for health service monitoring, or instead focus resources on retaining the newly graduated health workers and the effective distribution of health workers.

Strengthening pre-service institutions requires the involvement of multiple stakeholders including the MOH, educational institutions, professional associations, regulatory bodies, local organizations and communities and is necessary for building ownership and sustainability of PSE investments. Countries may use PEPFAR funds to strengthen pre-service education where it contributes to HIV/AIDS service delivery. Examples include: faculty development on innovative teaching methods; integration of evidence-based information on infectious diseases into existing courses; improving infrastructure to increase training capacity or quality; strengthening pre-service institution management organizational development, management systems and decision making which can often be a significant barrier to PSE scale-up; and providing student scholarships and/or critically needed equipment and supplies. Costing of pre-service interventions is also encouraged. Additionally, in-service and pre-service training systems can be integrated and linked via preceptorships for new graduates, agreement of 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;
- Health care workers seeking degrees in public health, public administration, epidemiology, pharmacology, monitoring and evaluation, informatics, etc.;
- Paraprofessionals and community health workers, including social workers.

Please note the following parameters[317, 318]:

- Training should be in a university, vocational training program, or other accredited educational institution (for professionals and paraprofessionals);

[317] "The Sub-Saharan African Medical School Study: Data, Observation, and Opportunity," Bill and Melinda Gates Foundation, 2011; also in The Lancet, March 26, 2011.
[318] "Health Professionals for a New Century: Transforming Education to Strengthen Health Systems in an Interdependent World," The Lancet, December 4, 2010.

- Education and training reform should align with population-based health care needs in both undergraduate and post-graduate training programs. Local and regional epidemiology and burden of disease as well as practice context including such elements as available equipment, supplies, technology, level of health facilities, health system structure and health care professionals available should be considered and training adapted to fit with these realities and needs;
- 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. New WHO Guidelines on *Transforming and Scaling Up Health Professional Education* are expected in the coming year and can serve as a reference for addressing new and emerging issues in health professional education.

Different aspects of country ownership should be integrated into pre-service education activities.

- In-country USG offices should plan and support the capacity development of local and regionally-based organizations that will eventually be able to apply for and win competitive awards as a prime PEPFAR implementing partner.
- Attention should be paid to the development of the next generation of national leaders. Pre-service education should include appropriate management and leadership components that establish a foundation of critical thinking and problem-solving skills that can be utilized in future positions at multiple levels, including national, district and facility-based settings.

C. Ensure the standardization, quality, and coordination of in-service training, such as through continuing professional development programs

A combination of supportive supervision, mentoring, on-the-job-skills reinforcement, continuing education, and periodic reassessment of skills and knowledge is critical to maintaining and supporting health care worker skills and performance. Such interventions are important to maximize the utility of the existing health workforce to the best effect. Emphasis needs to also be on developing sustainable systems that can continually build the capacity of its workforce.

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.

In-service training (IST) continues to represent a large portion of HRH investment across PEPFAR implementing agencies. Many country teams have been assessing there IST portfolios to identify gaps and areas of duplication. In addition, focus should be placed on improving the efficiency and effectiveness of IST practices and building capacity of country-owned, sustainable IST systems.

Recommendations:

- *Strengthen training institutions and systems*: routinely engage country stakeholders in IST; develop in-country capacity of IST coordination, planning, curriculum development, evaluation, and accreditation; use existing in-country training mechanisms, local infrastructure and resources where possible; support the development of continuing professional development (CPD) systems and integrating IST.
- *Coordinate training*: track IST to facilitate coordination among training partners; work with stakeholders to minimize disruption in the provision of health services during training period.
- *Maintain a continuum of learning from pre-service to in-service*: build collaboration between in-service and pre-service training providers to ensure consistency in learning approaches and content; work with regulatory and professional bodies and obtain formal recognition of IST for continuing education or CPD.
- *Design and delivery of training*: align IST with national training and HR plans; ensure that training is in compliance with national policies and strategies; work with country stakeholders to assess proficiency and training needs and in developing goals and objectives of training; use evidence-based learning principles and methodologies (including use of interdisciplinary team-based learning approaches and methodologies that foster active learning); use most cost-effective modalities for training delivery; develop and support implementation of participant selection strategies.
- *Support learning*: encourage the sharing of resources and materials across IST partners; develop post-training support tools; use appropriate technology for learning; increase IST provider communication with trainees and their supervisors for strengthening training preparation and follow-up.
- *Evaluation and improvement*: establish a process for evaluating the quality and effectiveness of training (includes both skills transfer and improved health worker performance); establish process for incorporating lessons learned and feedback received to enable continuous improvement of training programs and professionals.

Performance Assessment and Quality Improvement

PEPFAR country HRH activities should include support to the appropriate government agencies to design and institutionalize approaches and standardized tools that assess the quality of care provided by health workers in the workplace. Furthermore, PEPFAR country HRH activites should develop strategies to assist government agencies to develop systems for continuous quality improvement (CQI) of HRH skills and knowledge, such as building capacity for 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. The "improvement collaborative" is one methodology, which organizes groups of facility-level teams to work on a single area of service delivery that has been widely used with documented success. In countries such as Niger, this approach has also been integrated with performance management techniques and has demonstrated impact on both HRH performance and service delivery outcomes.

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 institution or 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 all levels of the health system, including within the MOH and within important non-governmental service delivery providers. Sustainable national management and leadership training programs can be developed by strengthening local management training institutions and integrating management skills-building in pre-service educational programs.

Building the capacity of MOH leadership and management is a key step to fostering country ownership and governance of HIV/AIDS programs. Capacity-building should be targeted at a national, provincial, and district level staff, and should equip them to effectively plan, manage and evaluate HIV/AIDS 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. 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.

Twinning Partnerships and Volunteer Program

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).

Twinning partnerships have been established in medicine, nursing, pharmacy, social work, clinical associates, laboratory, biomedical engineering, public health management, and prevention. Volunteers are placed in professional positions in Ministries of Health, academic institutions and clinical facilities.

D. Advance innovative and cost effective models of service delivery and skill mix 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

Task-shifting/Sharing

An important strategy to improve the performance of existing health workers to meet HIV/AIDS goals is to support "task-shifting", or the more recently termed "task-sharing".[319]

In January 2008, the WHO, with PEPFAR support, released *Global Recommendations and Guidelines for Task Shifting for HIV/AIDS*, available at http://data.unaids.org/pub/Manual/2007/ttr_taskshifting_en.pdf. The guidelines identify four types of task-shifting among clinical staff (such as from a doctor to a nurse) but also among non-clinical cadres, such as pharmacists, laboratory technicians, administrators and medical records managers. These guidelines also identify key elements—such as an enabling regulatory framework and quality assurance mechanisms—that should be in place for effective and sustainable task-shifting. Country teams should review these guidelines before undertaking a task-shifting or task-sharing approach, and be sure to engage professional leadership including MOH, professional councils, associations, and the academic sector to ensure broad buy-in and coordination.

A key area of task-shifting that can have a strategic impact on PEPFAR goals is the delegation of initiation and management of antiretroviral therapy (ART) from doctors to non-physicians clinicians (NPCs), including nurses. In a number of recent studies and clinical trials, nurse provision of ART has been shown to have comparable health outcomes to physician provided treatment (Sanne, I., 2010; Humphreys, C., 2010). Nurses and other NPCs can be a vital resource to expanding ART, Option B+ and other services, especially at lower levels of care where doctors are not present. It is critical to implement task-shifting/sharing within the context of a multi-disciplinary team framework in order to assure that one cadre is not overburdened with new tasks, but rather professional and non-professional health care workers are provided appropriate workloads and supervision.

Task-shifting to community health workers (CHWs) is also an important strategy to increase the pool of health workers in countries with limited HRH capacity. As many countries are scaling-up their CHW programs, PEPFAR partners should work with CHWs within the context of a country's system, supporting their performance and integration 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 which may include supervision, teamwork, and financial and non-financial incentives.

[319] Task-shifting generally refers to a delegation of specific tasks to staff with less training and qualifications, while task-sharing refers to a non-hierarchical reassignment of tasks among health workers that is more fluid and needs-based (IOM, 2011). Both aim to improve the efficiency and effectiveness of service delivery by maximizing the performance of health workers.

E. Validate and apply recruitment and retention strategies, especially in rural and underserved areas

High attrition of health workers is a critical problem in many PEPFAR countries and includes both internal (e.g. private sector and urban-based employment) and external (e.g. out of the country to more developed countries) migration. Supporting efforts to improve health worker retention are important for maximizing the return on PEPFAR's significant investment in the production of new health workers and in supporting broader PEPFAR goals. PEPFAR country teams that are investing in pre-service education should consider education interventions that can impact retention of students and future graduates. Additional support to host governments should be provided to ensure that appropriate retention strategies exist, and help ensure that new graduates are effectively recruited and retained in the national health system, and are deployed to the areas of greatest need. As outlined in the WHO *Guidelines for Increasing Access to Health Workers in Remote and Rural Areas*[320], areas of intervention to be considered are:

- Education
- Regulation
- Financial Incentives
- Personal and Professional Support

Many PEPFAR countries are developing creative financial and non-financial schemes to encourage the retention of health workers. For example, Namibia's support for health worker's housing in rural areas; Zambia's collaboration with the MOH 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, which retains new graduates in the health system during the year-long MOH recruitment process. One additional innovative model to be piloted in the near future is the *HRH Housing Fund* that is being negotiated through the Development Credit Authority (DCA) out of the Southern Africa Regional Mission.

Country stakeholder engagement (including national government and health worker associations) is integral in building ownership during the development of retention schemes. The choice of retention interventions should be informed by an in-depth understanding of factors that impact retention, which may differ throughout a country or amongst health worker cadres. Sources of information can be collected through comprehensive situational analysis, a labor market analysis, and through methodologies that assess individual decision making of health workers such as the discrete choice experiment (DCE). 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 increased retention on patient care (e.g. number of patients who are receiving ART from retained providers) is encouraged. Costing of retention interventions is encouraged.

[320] "Increasing Access to Health Workers in Remote and Rural Areas Through Improved Retention: Global Policy Recommendations," WHO, 2010.

F. Advance health worker regulation and policy, including through capacity-building of regulatory bodies and professional associations

Regulatory bodies and professional associations play a key role in the advancement of health professions across PEPFAR countries, and are key PEPFAR partners. In most settings in Africa, health professional regulatory bodies (e.g. Regulatory Boards or Councils) have the mandate to regulate specific health professions (e.g. nurses, or doctors) for the protection of public health. This regulation may include[321,322]:

- Setting the standards of quality and excellence of care for the profession;
- Establishing professional credentialing requirements, including standards for registration and (re-) licensure;
- Establishing the scope of practice for the profession;
- 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);
- Revising legislation that governs the profession (e.g. the Nurse Practice Act);
- Monitoring professional conduct and managing disciplinary procedures.

Many councils lack the capacity and/or the autonomy to take on these roles effectively, and at times are left out of key decisions facing their profession by the MOH and donors. PEPFAR teams should engage professional regulatory bodies as leaders of their profession, in partnership with the MOH, professional associations, and the health professional academic sector, on key decisions facing the profession. PEPFAR should build the capacity of regulatory bodies to ensure that the professional regulatory framework-as defined above is up-to-date and in line with current practice in the country and with international guidelines. Lastly, PEPFAR teams should look for ways to strengthen regulation more consistently across multiple regulatory bodies within a country, such as by encouraging more peer interaction and learning between professional bodies.

In some settings, the professional association takes on some of the regulation role, but in most contexts, the professional association has the distinct mandate to advocate for the advancement of the profession by, for example, negotiating the terms of working conditions and compensation levels, and promoting professional development. Associations may directly provide professional development or training opportunities for their members, lobby the government for improvements in pay, or work collaboratively with other professional stakeholders to advance policy or programs. Associations may have no funding or full time staff, and are run primarily by volunteers. Their membership may be small and members may not appreciate the advantages of being active participants in the association.

To strengthen professional associations, PEPFAR support 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 (by, for example, increasing their role in the provision of in-service

[321] ICN, The role and identity of the regulator: An international comparative study, 2009, International Council of Nurses: Geneva.
[322] ICM, Global Standards for Regulation, 2011, International Confederation of Midwives: The Hague.

training, especially in the context of a continuing professional development program), or by improving their skills in policy, advocacy, and coalition building.

3.4.5 ADDITIONAL CONSIDERATIONS

Monitoring and Evaluation and HRH Research

Monitoring and evaluation (M&E) of HRH programs and the development of an evidence base of effective HRH programs are both emphasized throughout the six HRH objectives. In addition to measuring outputs towards the 140,000 PEPFAR HRH legislative target, countries should plan for comprehensive M&E of their HRH programs. M&E for HRH should look across all program areas doing HRH, for instance PMTCT in-service training required for scale up or continuous mentoring for prevention educators. This may require working with other program areas to identify their HRH activities and M&E needs. In addition, countries should plan for investing in strengthening the information systems (training, equipment, management) that provide quantitative and qualitative data for monitoring and evaluating the progress and impact of HRH interventions. Additionally, where possible, investment in HRH research is encouraged.

Transition of PEPFAR Salary Support

As part of its effort to expand access to HIV/AIDS services, PEPFAR has been partially or wholly subsidizing the salaries of large numbers of health workers in over 30 countries. However, USG subsidization of health worker salaries is not a sustainable approach to meeting HRH needs for the long term. To be consistent with the principle of country ownership, PEPFAR teams should work with partner governments to assess the costs of these salaries and develop an appropriate plan for the eventual assumption of these salaries by governments or other national entities. This transition must be accomplished without interruption of services offered by the health workers currently being supported by PEPFAR, and therefore, should be approached with careful planning by country teams. A few PEPFAR countries have successfully transitioned health worker salaries or are in the process of doing so. These countries can serve as models for other countries in deciding which approach is most appropriate to the specific context.

Guidance on salary support and other financial incentives appears in the PEPFAR publication, *Support for Host Government Staffing* (August 2006). We expect that this document will soon be revised to reflect the importance of gradually transitioning PEPFAR-supported staff to local, regional, or national government systems or indigenous private organizations and the need for countries to develop plans for this transition.

3.5: GENDER

3.5.1 BACKGROUND

A. Definitions

Gender - refers to a socially defined set of roles, responsibilities, entitlements and obligations associated with being a man and a woman, as well as the relationships between and among men and women. The social definition and expectations of what it means to be a man or a woman varies across cultures and varies over time. Transgender individuals, whether they identify as men or women, can be subject to the same set of expectations.

Sex – is the classification of people as male or female. At birth, infants are assigned a sex based on a combination of bodily characteristics including: chromosomes, hormones, internal reproductive organs, and genitalia.

Gender equity – The principle that, where the needs of men and women are different, resources and programmatic attention should be in proportion to those needs; equal opportunities should be ensured; and if necessary, differential treatment and attention should be provided to guarantee equality of results and outcomes and redress historical and social disadvantages experienced by men or women.

Gender equality – concerns women and men, and involves working with men and boys, women and girls to bring about changes in attitudes, behaviors, roles, and responsibilities at home, in the workplace, and in the community. Genuine equality means more than parity in numbers or laws on the books; it means expanding freedoms and improving overall quality of life so that equality is achieved without sacrificing gains for males or females. It is the state or condition that affords women and men equal enjoyment of human rights, socially valued goods, opportunities, and resources.

Gender identity refers to a person's deeply felt internal and individual experience of gender, which may or may not correspond with the sex assigned at birth. In most societies, there is a basic division between gender attributes assigned to males and females. In all societies, however, some individuals do not identify with some (or all) of the aspects of gender that are assigned to their biological sex, resulting in individuals dressing and/or behaving in ways others may perceive as being outside the norm. In some circumstances these gender expressions may be described as transgender.

B. Gender and HIV/AIDS

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 prevent and/or respond to HIV/AIDS. Addressing gender norms and inequities, transforming power dynamics, and promoting gender equality are therefore important strategies for achieving PEPFAR's overall prevention, treatment, and care goals.

C. PEPFAR's gender strategy and programming

To promote gender equality and mitigate structural and other gender inequalities, PEPFAR employs a two-pronged approach: a) gender integration into all HIV prevention, treatment, and care, 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 to address norms and behaviors;
4. Increasing women's and girls' legal rights and protection; and
5. Increasing women's and girls' access to income and productive resources, including education.

PEPFAR places a high priority on confronting the changing demographics of the HIV/AIDS epidemic. This includes understanding and strengthening data around the impact of the epidemic on specific populations including, for example, young women, men who have sex with men (MSM), transgendered individuals and sex workers, and evidence around successful programming that addresses their unique needs and vulnerabilities. PEPFAR also focuses significant resources and effort on preventing and responding to gender-based violence (GBV), which contributes to the spread of HIV/AIDS both directly by the violence itself and indirectly by limiting the ability to negotiate sexual practices, to disclose HIV status and to access services due to fear of GBV.

Structural issues that shape the enabling environment for HIV programs and services vary from one country to another. Interventions that include addressing harmful gender norms and inequities, overcoming gender-specific barriers to prevention, treatment, and care interventions, creating opportunities for economic empowerment and education, shaping a supportive legal and policy environment, overcoming stigma and discrimination, and preventing and responding to GBV are essential to the achievement of PEPFAR's prevention, treatment, and care goals.

D. Cross-cutting budget attributions

Given the increased focus on gender, country teams are expected to report financing for gender programs through two cross-cutting, secondary budget attribution codes: one on GBV and one on gender equality. These measures allow us to map existing GBV and gender-related programming across countries and regions, as well as to monitor increased investments in this area. Improving collection and analysis of data related to expenditures for gender-focused activities will bolster our ability to maximize efficiency of PEPFAR interventions. See FY 2013 COP Guidance for budget attribution definitions.

E.USG Institutional Framework

PEPFAR's gender strategy and programming are supported by a number of U.S. Government and agency specific guidance and policies which collectively elucidate the United States' commitment to promoting gender equality as an integral component of foreign assistance and development efforts. These include:

- Secretary's Policy Guidance on Promoting Gender Equality (http://www.state.gov/documents/organization/189379.pdf)
- USAID Policy on Gender Equality and Female Empowerment

(http://transition.usaid.gov/our_work/policy_planning_and_learning/documents/GenderEqualityPolicy.pdf)

- United States Strategy to Prevent and Respond to Gender-based Violence Globally (http://www.state.gov/documents/organization/196468.pdf)
- United States National Action Plan on Women, Peace and Security (http://www.whitehouse.gov/sites/default/files/email-files/US_National_Action_Plan_on_Women_Peace_and_Security.pdf)

In addition to the above, the Women, Girls and Gender Equality (WGGE) Principle of the Global Health Initiative (GHI) outlines ten key program elements and examples of specific interventions aimed at addressing gender inequities related to health. The WGGE Principle is noted across the GHI's other principles, highlighting the role and importance of addressing gender inequities across integrated platforms and interventions. The WGGE principle supplemental guidance is available here: http://www.ghi.gov/resources/guidance/161891.htm

F. Resources

To assist with strategic and programmatic planning, PEPFAR developed a number of resources aimed at facilitating integration of gender within HIV programs and platforms in collaborative partnership with in-country civil society and government service providers, U.S. government and multilateral agencies and other partners. These include the *Program Guide for Integrating Gender-Based Violence Prevention and Response in PEPFAR Programs*, which offers tools and guiding principles for GBV integration in prevention, PMTCT, testing and counseling, treatment, care and support, and OVC interventions. (See http://www.aidstarone.com/focus_areas/gender_technical_area for this guide and other resources.)

3.5.2 RECOMMENDED ILLUSTRATIVE ACTIVITIES BY GENDER STRATEGIC AREA

Gender is cross-cutting within the PEPFAR program framework. This means that within each technical area programming, strong country programs will identify gender-specific barriers or facilitators, harmful gender norms, and other gender-related issues relevant across various technical areas and integrate activities to address those issues. The following section outlines illustrative examples of the types of activities that could be integrated across PEPFAR programs to reduce these gender inequities and improve programming across HIV prevention, treatment, and care. They are categorized under PEPFAR's five cross-cutting gender strategic areas. For specific guidance on addressing gender in one technical area (e.g. Testing & Counseling), please refer to that section of the Technical Considerations.

Gender Strategic Area 1: Increasing gender equity in HIV/AIDS activities and services, including reproductive health

Strong PEPFAR-supported programs promote evidence-based 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. PEPFAR teams should:

- Set sex-disaggregated targets that reflect the characteristics of the epidemic and collect

sex- and age-disaggregated service delivery data;

- Use the results of this data to adapt recruitment strategies as necessary and improve quality of program services;
- Identify and assess barriers that women, men and transgender individuals selectively face in accessing programs and services and in enjoying program/service benefits;
- Design and implement 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;
- Monitor and evaluate strategies to overcome identified gender-specific barriers or leverage gender-specific facilitators to programs and services;
- Assess and identify 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 and the adoption of healthy behaviors;
- Integrate HIV/AIDS services into family planning and reproductive health clinics in order to facilitate women's access to services;
- Provide male-friendly HIV/AIDS and reproductive health services to encourage men's participation in health care;
- Use strategies such as couples testing and counseling, family-centered services, and programs for men as part of HTC and PMTCT, to promote uptake of services by women and men;
- Provide gender-friendly services for male and females who inject drugs that include, for example, comprehensive sexual and reproductive health, PMTCT, male or female-only hours, and gender-sensitive risk reduction services, or referral to those services; and
- Active linkages and referrals with other services such as family planning, reproductive health, maternal and child health, male circumcision, social services, psychological services, etc.

Gender Strategic Area 2: Prevention and Response to Gender-based Violence (GBV)

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, sex workers 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. PEPFAR teams should consider:

- Screening and counseling for GBV within HIV/AIDS prevention, care, and treatment programs;
- Providing referrals from HIV/AIDS services to GBV services and vice versa;
- Providing post-rape care services, including the provision of HIV PEP, in PEPFAR-funded sites;
- Interventions aimed at preventing GBV, 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 marginalized populations; that promote gender equality; and that build conflict resolution skills; and build on existing male engagement work in this area;

- Strengthening linkages between health, legal, law enforcement, judicial services, and education, and programs to prevent and mitigate GBV; and developing coordinated, integrated and multi-sectoral prevention and response;
- Support for review, revision, and enforcement of laws and for legal services relating to GBV, including strategies to more effectively protect young victims and hold perpetrators accountable;
- Research and program evaluation regarding the epidemiology of GBV and HIV in specific populations, including MSM, transgendered persons, sex workers, young women, and children, with particular attention to GBV against HIV positive people; and strengthening evidence around effectiveness of coordinated approaches to addressing GBV in the context of PEPFAR through rigorous evaluation;
- Strengthening national level capacity to facilitate prevention and response efforts, including service sector data collection, and development and implementation of policies and training curricula;
- 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 safe spaces for vulnerable populations subject to sexual violence and coercion and sex-trafficking, particularly for adolescent girls.

Gender Strategic Area 3: Engaging Men and Boys to Address Norms and Behaviors

Men 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 to increase positive male norms, address harmful gender norms, and improve overall service and programming outcomes. PEPFAR teams should consider:

- 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., sharing domestic and child care responsibilities, addressing 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;
- Programs that engage men in participating in and supporting female partners' use of integrated services, including FP/RH and PMTCT;
- 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, and improve communication between partners;
- 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;
- Program monitoring and evaluation programs to address gender norms and behaviors and improve male engagement to determine outcomes and impact; and
- Specific focus on engaging women in determining best ways to engage male partners, women's needs, impact of interventions for women/female partners, and potential negative consequences of interventions.

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. PEPFAR teams should consider:

- 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;
- Research and program evaluation regarding the associations between legal rights and HIV/AIDS;
- Translation of laws and policies into common vernacular in order to ensure that it is accessible to and provided to the public; and
- Training of local law enforcement and members of the judiciary on laws that promote gender equality and protect women's and girls' rights.

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. PEPFAR teams should consider:

  - Programs to ensure that girls are given equal opportunity to attend school and/or vocational training (in marketable skills) and participate in economic

strengthening activities;

- Women's 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, land, savings, and social assistance;
- 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 collectives and forums that support 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.

3.5.3. COUNTRY CONTEXTUAL CONSIDERATIONS: GENDER

Given that gender issues vary between countries and epidemiological contexts, a gender analysis is essential to designing and implementing an effective HIV/AIDS response. A gender analysis is a tool for examining the differences between the roles that women and men play in communities and societies; the different levels of power they hold; their differing needs, constraints and opportunities; and the impact of these differences on their lives.[323] PEPFAR teams can use the results of the analysis to inform prevention, care, and treatment priorities, including steps to collect sex- and age-disaggregated data.

[323] USAID Gender Equality and Female Empowerment Policy.

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 enhance their efforts through jointly defined objectives, program design and implementation, and through the sharing of resources, risks, and results. Hallmarks of PPPs help assist the sustainability of programs, facilitate scale-up of interventions, strengthen country ownership, and leverage significant private-sector resources.

3.6.1 INTRODUCTION

PPPs are important for many reasons including:

- They leverage additional resources to meet PEPFAR goals.
- They provide valuable expertise that often cannot be found in the government.
- PPPs can be a platform for innovation and sustainability.

By utilizing the skills, resources and access that the private sector provides, PPPs can help to make PEPFAR programming more effective and reach greater numbers of people.

Country teams are encouraged to build and support local PPPs within the COP that draw on a diverse set of stakeholders from the private sector inclusive of health and non-health care specialty areas such as; insurance, service providers and health care facilities, managed care, equipment manufacturers, banking and financial institutions, mining companies, transportation, textiles, pharmaceuticals, multimedia, telecommunications, information systems, and entertainment.

Examples of shared value created by partnerships may include leveraging the private health sector's infrastructure, delivery services and supply chain to target at-risk populations, as well as to utilizing the management, marketing and core business expertise that private business enterprises bring to bear either through global partnerships with multinationals or collaborations with small indigenous business owners.

Through these partnership commitments, there exists a greater potential to enhance the sustainability of country programs.

New ideas and opportunities to scale and expand best practices will be regularly reviewed and discussed interactively with the country teams and the Interagency Technical Working Group. PPP models, technical assistance opportunities, and information on multi-country PPPs are also available upon request. Country teams are encouraged to contact the OGAC's Private Sector Engagement (PSE) Office and PEPFAR's PPP TWG to assist during this process to full take advantage of these opportunities. Inquires can be sent through the appropriate CSTL.

These technical considerations are intended to be a basic resource and guidance for the country teams as they consider the development, implementation, and scale-up of PPPs as appropriate to their country context and COP strategies.

A. Definition of a PPP

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. 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 or private health sector that directly pays for the delivery of services, it's not a PPP. If it's an activity that will build off an existing investment but with no new financial resources or in-kind contributions towards the partnership activity, 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?" Also please consult with OGAC PSE team and TWG for consultation as needed.

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. 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. This may include opportunities for a PPP desk officer at the MOH or strengthening of private health sector associations and business coalitions as viable partners in the delivery of health services. 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, private health sector providers and 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 as described above.

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. The OGAC's PSE Team and Interagency TWG are available to assist during this process.

To the extent possible, existing financial mechanisms (cooperative agreements, USAID/Global Development Alliance [GDA], APS processes, grants, etc.) and due diligence protocols 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 are strongly encouraged to follow up with a detailed work plan. While not required a memorandum of understanding (MOU) with the partner(s) is recommended.

C. Measurement and reporting

In addition to standard reporting of financial or in-kind contributions, it is also important to assess the impact of the PPP on core PEPFAR goals as well as on the dimensions of innovation, sustainability, and scalability. The following provides some suggested tips for narrative reporting on PPPs within the COP and APR:

- *Impact:* Description of impact related to care, treatment, prevention, and health systems country and global PEPFAR goals. The PPP should generate measurable outputs that strive to compare favorably with current PEPFAR programmatic methods.
- *Innovation:* How is the PPP program, product or service perceived by the local community as being new or novel to the local setting of implementation?
- *Sustainability:* Is there potential for development of a social business or non-profit model for financial sustainability within a period of five to ten years? Does the PPP have the ability to cover full or partial operating expenses with either operating revenues or shared streams of income from a diverse number of committed partners beyond the initial PEPFAR investment?
- *Scalability:* Does the PPP have potential to grow by an order of magnitude beyond the initial proposal (i.e., 5x number of clients served, providers trained, facilities accredited, or geographies served) within five to ten years? Is there an experienced dedicated professional team to help grow the PPP within country or regionally.

- *Financial contributions:* Resource inputs from PEPFAR and private sector partner(s) that leverage a 1:1 match. In the event the private sector partner contributes resources in-kind, country teams should monetize the contribution. Please contact the OGAC PSE Office through your CSTL if there are any specific questions regarding the quantification of private sector partner contributions, especially for local businesses or private health sector providers within country.

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.

As detailed in this document, the best PPPs are driven by identifying needs and gaps in the field, country ownership principles, and have a local champion to guide them through implementation. Having dedicated staff, 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 in the past have hired dedicated PPP staff, including Tanzania, Mozambique, South Africa, and Kenya. Other countries have chosen to integrate PPPs as part of overall program area strategies. Program officers identify opportunities for PPPs, manage the PPPs and provide the programmatic and technical oversight.

3.6.3 LINKAGES AND WRAPAROUNDS: PUBLIC-PRIVATE PARTNERSHIPS

Since PPPs can and should be integrated across technical and cross cutting program areas, the potential linkages to other development activities are varied. However, many PPPs lend themselves to incorporating wraparound activities that can help create stronger COP programmatic impact and outcomes, and the pursuit of this with the relevant agencies, other donors or private sector partners is strongly encouraged.

3.7: WORKPLACE PROGRAMS

3.7.1 BACKGROUND

The HIV/AIDS epidemic can have an adverse impact on the operations of many companies and employee households. In countries and communities where HIV/AIDS epidemics are generalized, 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:

1) No mandatory HIV testing;
2) No denial of employment;
3) No job termination if fit to work, and
4) 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 can 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

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 WPs 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 four components of 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;
- *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. 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 program, 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 offering voluntary medical male circumcision at their Kampala brewery's health clinic.

3.8: 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.

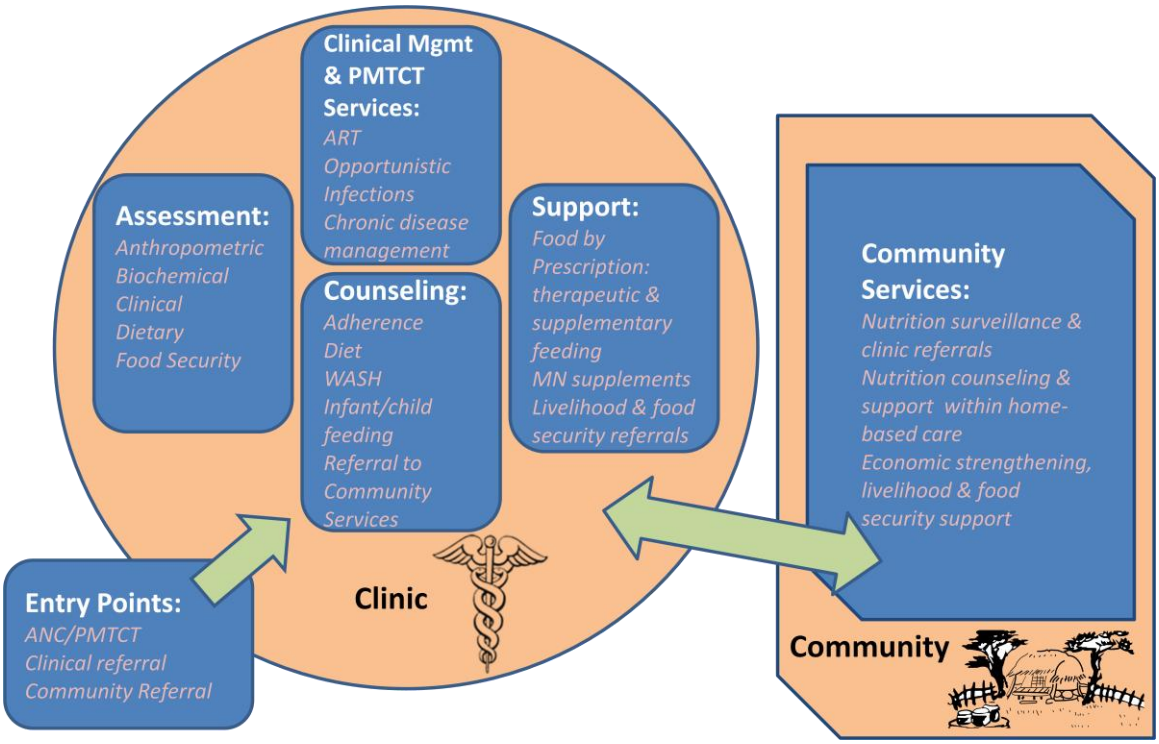
3.8.1 Food and Nutrition Activities Supported by PEPFAR

Program Priorities

The 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).

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 health care workers to provide nutrition care. The NACS approach has led to strong government ownership of nutrition strategies, programs, and services within national HIV and broader health programs. Outcomes from these activities have been quite promising, including improved nutritional and clinical status among clients and stronger health systems with the establishment of NACS service delivery, information systems, and referral networks.

The following schematic depicts NACS from a patient perspective. NACS is derived from the Food by Prescription (FBP) Program, first established in Kenya and now adopted and being scaled up as ***standard of care*** in 16 countries – 14 in sub-Saharan Africa, as well as Haiti and Vietnam. Patients can enter into NACS care through multiple entry points, including community and clinic referral. Comprehensive nutrition assessment is critical to inform clinical management and counseling of patients, as well as to determine appropriate support for the individual and family at both clinic and community levels.



The following are key 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 are conducted 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 resilience and 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 critical components of care and support for PLHIV and OVC. Strong PEPFAR programs will 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 may not (yet) be 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, typically 3-6 months, on the basis of clear

anthropometric entry and exit eligibility criteria or vulnerability (particularly infants 6-24 months of age). 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 RUTF or FBP as "medicine", in addition to their other "meds", especially ARVs, cotrimoxizole, and TB drugs if co-infected.

- *Prioritization of NACS feeding support within and across sites based on relative vulnerability:*
    1. Complementary food for ***all*** HIV-exposed infants from 6 months up to 2 years of age, irrespective of anthropometric status;
    2. Supplementary food to women in PMTCT programs who are underweight or fail to gain adequate weight in pregnancy or are underweight during lactation;
    3. Therapeutic/supplementary food to OVC with evidence of growth faltering (wt/ht z-score <-2 in under-5s or BMI/wt z-score <-2 in children 5-19 years of age); and
    4. 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. Children, particularly 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 at both the clinic and community levels.

- *Addressing gender issues in the provision of NACS.*
    1. Identify and address barriers to women's and girls' access and adherence to quality nutrition services, including screening for gender-based violence and referrals to services.[324]
    2. Design and implement interventions to effectively engage women's partners, family members, and community groups at service delivery and community to create a supportive environment for nutrition programs.
    3. Address the gender norms that influence men's and boys' health-seeking behaviors and their willingness to utilize NACS services.

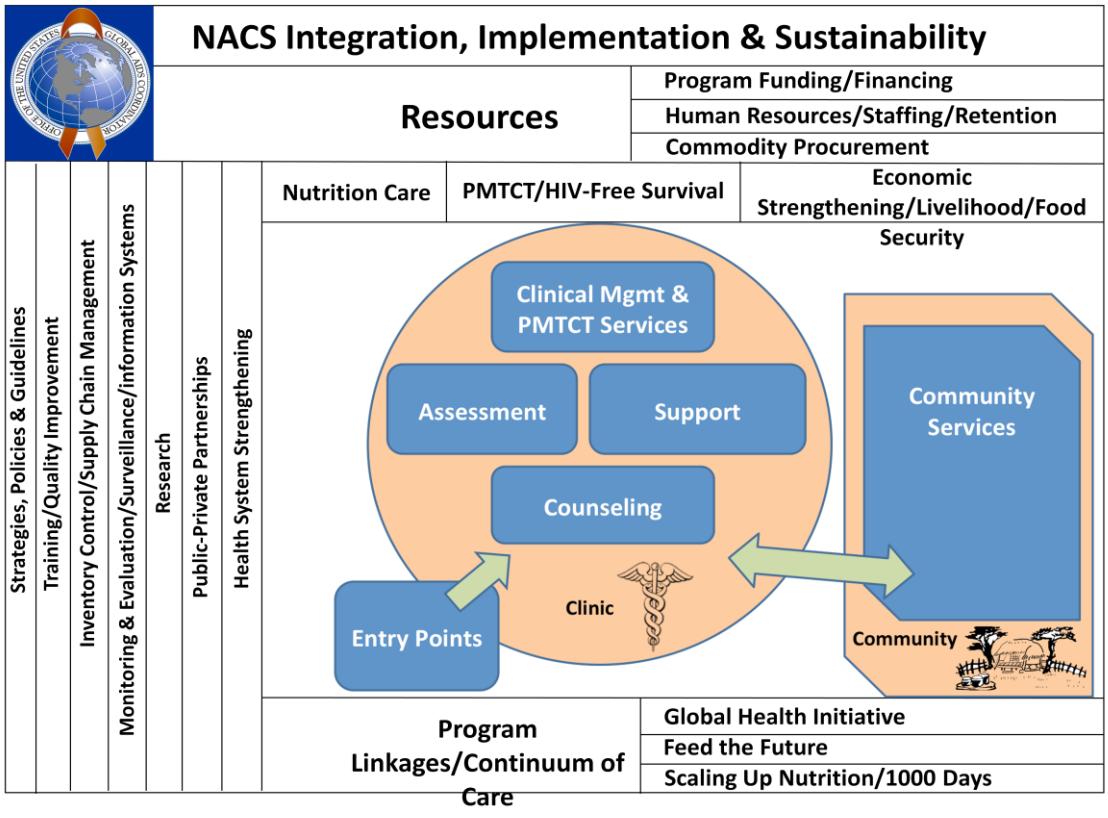
- *Establishing linkages and two-way referrals between clinics and community services.* Chronically ill individuals with evidence of wasting identified through community nutrition surveillance should be immediately referred to clinical services for comprehensive clinical assessment, care and treatment, including NACS. Conversely, bi-directional referral systems are needed to link patients and families with community-level

[324] *PEPFAR Gender-Based Violence Guidance*: http://www.aidstar-one.com/focus_areas/gender/resources/pepfar_gbv_program_guide

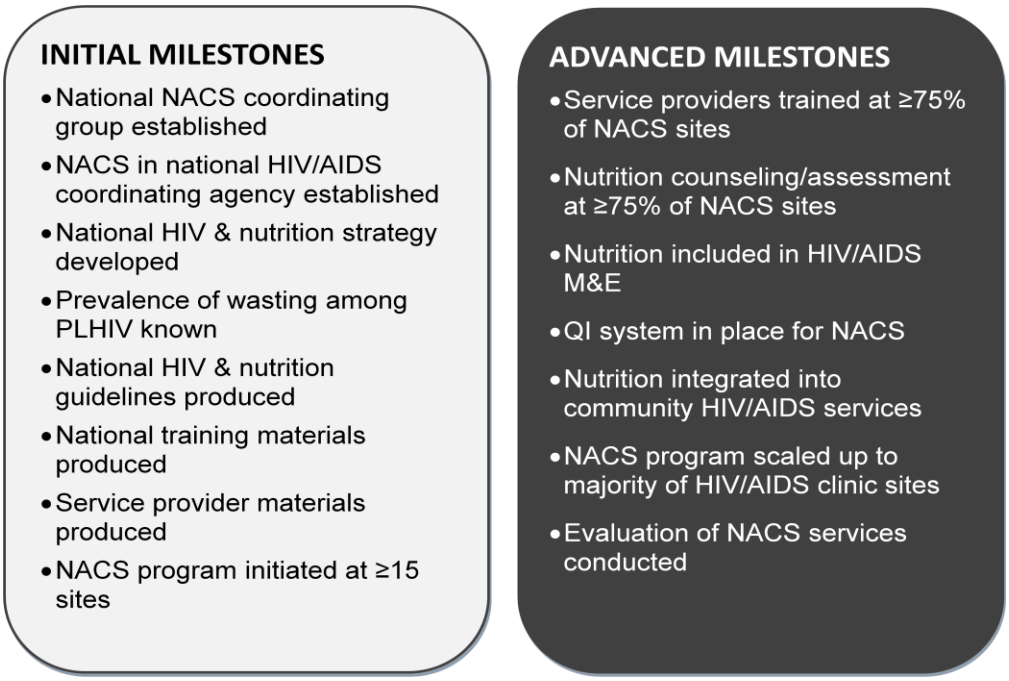
economic strengthening, livelihood and food security assistance, as well as community health services (e.g. HBC and CHWs).

- *Provision of ART, cotrimoxazole and treatment for opportunistic infections and co-morbidities 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 ART will gain weight or at least stabilize their weight, even without therapeutic or supplementary 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 maternal/infant nutrition support beginning in pregnancy and extending 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.



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 on ART for their own health (CD4 < 350) and who represent more than 80% of total MTCT. With ART, MTCT is typically reduced to <5% (the goal of eMTCT) versus >35% without ART.

The new WHO PMTCT guidelines also recommend provision of ARV prophylaxis to mothers not currently receiving ART 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, HIV-infected mothers should be encouraged to breastfeed for a minimum of 12 months and continue breastfeeding 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 through the second year of life.

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 ART with good adherence and retention for all PMTCT women who are eligible for treatment for their own health.
- Provision of ARV prophylaxis to mother/ infant for the duration of breastfeeding if the mother is not eligible for ART.
- 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.
- Promotion of adequate complementary feeding beyond six months of age.
- Promotion of breastfeeding for at least the first 12 months of life, deferring weaning until a safe and adequate replacement diet can be assured in the second year of life.
- 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. <12 months of age).
- Promotion of improved pre- and postpartum maternal nutritional and health status, including regular NACS support and supplementary feeding support if there is inadequate weight in pregnancy or the mother is underweight as assessed by MUAC or BMI.
- Provision of the basic preventive care package for infant and young child survival, including routine immunizations, growth monitoring, micronutrient supplementation, insecticide-treated bednets, 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).
- 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.

Note: A number of countries, including Kenya, Uganda, Tanzania, Mozambique, South Africa and Lesotho, are participating in a Partnership for HIV-Free Survival (PHFS), under PEPFAR support and in collaboration with WHO, to implement the 2010 WHO PMTCT Guidelines in select districts with an emphasis on postnatal care, infant feeding practices and linking mothers/infants to ARV services. A PHFS learning network will be established to inform scale-up of the 2010 WHO PMTCT Guidelines. If other countries are interested in the PHFS, please contact the F&N TWG through your CSTL.

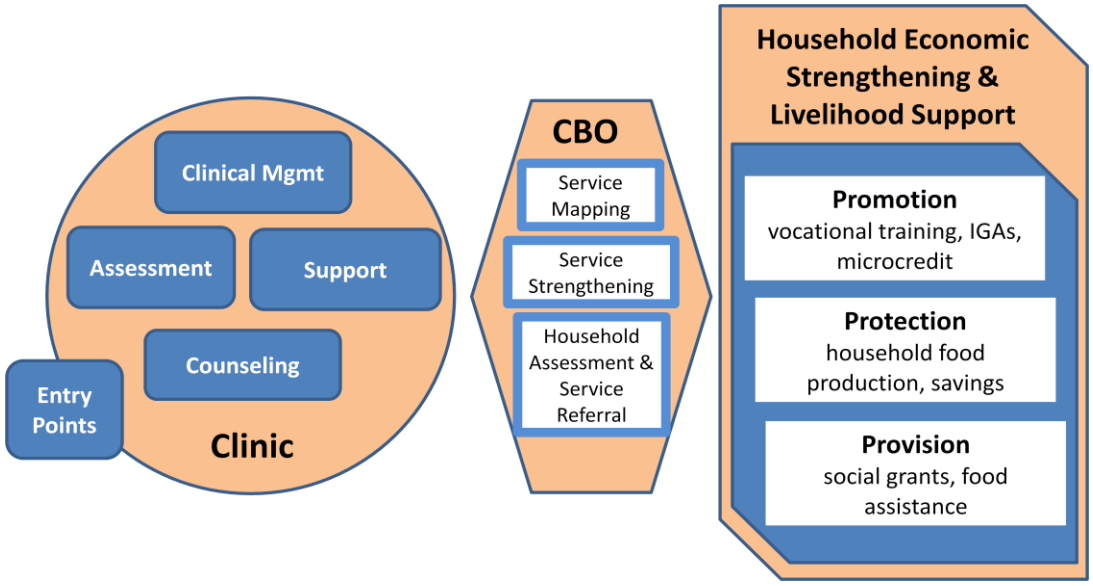
III. *Livelihoods and Food Security*

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 economic and food 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 community 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 in community support with regard to effective targeting, cost-effectiveness, and potential for program replication, scale-up and sustainability.*
- *Establishment of mechanisms to refer and track individuals in clinical care and treatment connected with ES/L/FS services in their communities.*
- *Development of tools to assess household resilience and food security as a basis for referral to appropriate community 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.*
- *Creation/fostering of linkages between NACS and Feed the Future, Title II and other ES/L/FS programs.*

The following schematic highlights the need for a community-based organization (CBO) or other entity that is critical working with patients/families referred from clinical care to assess household resilience and food security, link them with appropriate community services, and track outcomes.



Note: 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, households and OVC/caretakers in need of food assistance should be referred to Title II, WFP or other programs providing direct household food assistance.

3.8.2 Policies / Service Delivery / 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*:
Policies

- *Development and/or adaptation of food and nutrition policies and guidelines* – providing a framework for integrating NACS activities within the care and support of PLHIV and their families, including OVC, as well as broader health services. This also includes policies and guidelines that foster linkages with other support programs that address ES/L/FS assistance needs in the targeted population.

Service Delivery

- *Curricula development, training, quality improvement and health system strengthening* **–** 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 QI systems to integrate nutrition surveillance and support within care and treatment services.
- *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.

Commodities

- *Micronutrient supplements* – provision of supplements according to WHO guidance, e.g. vitamin A, zinc and multi-micronutrients for children, and multi-micronutrient supplements where individual assessment determines a likelihood of inadequate dietary 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 months 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).
- *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

Nutrition Assessment and Counseling

While food support is often the most visible nutrition intervention and attracts the greatest attention, nutrition assessment and counseling are critical 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 into practice within clinical services, and to a *human resource plan* that promotes hiring and retention of appropriate 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 therapeutic and supplementary food, i.e. Food by Prescription, is currently limited.

Interagency Coordination

An interagency approach to joint programming is underway in a number of countries to strengthen nutrition support within national HIV/AIDS programs. This joint effort will encourage 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. It is critical to engage and coordinate with GFATM, Feed the Future, Title II, WFP, World Bank, and other development donors to expand support for economic resilience and food security.

Quality Improvement

Clinic-based NACS support is most effective and sustainable when fully integrated into existing HIV/AIDS care and treatment and other health services, rather than being a parallel system. However, integrating NACS and scaling-up services have proven difficult. One of the greatest challenges is that in a busy clinic setting, it can be difficult for health staff to find time to provide nutrition services in addition to their other responsibilities. Additionally, health care workers and counselors often have not received sufficient training in nutrition care. In other cases, health care workers are trained, but cannot execute that training because of organizational and operational constraints within the clinic. QI approaches are 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.

Links between Clinical and Community Services

Community services are also important entry points for NACS. NACS services provided through community programs include household resilience and food security assessments, nutrition counseling linked to home-based care and 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. use of MUAC tapes to categorize nutrition status, and refer undernourished individuals to clinic services, particularly "chronically ill" individuals who do not know their HIV status and those 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 ES/L/FS support should be referred to community support that is specifically suited to the needs and capacity of individual households with regard to food production, employment, income-generation activities, micro-credit and vocational training.

Addressing Gender Inequalities Influencing Access to and Utilization of NACS Services

An analysis of the root causes of gender inequalities that influence individuals' and communities' well-being is essential in order to take specific actions to ensure that nutrition care and support is provided in a way that meets the unique needs of women and men, boys and girls. Specific interventions that address the underlying structural factors that cause malnutrition, including gender inequality, cultural practices, and the norms and behaviors that influence access to and utilization of food, create the enabling environment needed for long term food security and health outcomes.

Monitoring and Evaluation (M&E)

M&E of NACS interventions is important at service delivery, program and national levels in order to assess the cost-effectiveness and impact of programs, strengthen service provision and program management, and inform reporting, advocacy and resource allocation. M&E of NACS should be integrated within the national 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 is available from the F&N TWG; please contact your CSTL for more information.

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 to inform national-level policy and program planning dialogue in support of NACS integration within HIV and health services. For further information about resources available to conduct costing assessment of NACS programs, please contact the F&N TWG through your CSTL.

Food Procurement

Unlike Title II, PEPFAR is authorized to procure therapeutic and supplementary foods 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 at clinics. UNICEF and WFP have established quality assurance and distribution systems for therapeutic and supplementary foods that offer a foundation and precedent for PEPFAR. There are a number of options for PEPFAR procurement of therapeutic and supplementary foods, including: 1) the Partnership for Supply Chain Management Systems Project (SCMS); 2) supporting or partnering with UNICEF or WFP; 3) contracting directly with

food manufacturing companies and/or 4) having development partners implement procure 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 strengthen local food processing companies in product development and meeting food quality and safety standards so they can compete for PEPFAR food procurements.

PEPFAR and Feed the Future (FtF) Integration

Feed the Future (FtF), GHI and PEPFAR all prioritize the first 1,000 days of life (pregnancy through 24 months postpartum) for mothers and infants. Clinic- and community-based programs should be strategically linked and complementary – FtF working primarily at the community level and PEPFAR strengthening the capacity of clinics with outreach, connection and support to communities. These programs can be mutually strengthened through joint strategy and program planning and coordination 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. 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 LINKING WITH OTHER SERVICES THAT SUPPORT HIV PREVENTION, TREATMENT, AND CARE

3.9.1 INTRODUCTION

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 PEFPAR 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 microentrepeneurs 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:

- *Consider each partner's capacity 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. Assess which of 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;

- *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;
- *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;
- *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. PEPFAR teams should 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 HIV, 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 HIV-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

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 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, consider the steps that can 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 PWID with disabilities; targeted interventions to meet these needs such as accessible

disability-friendly PWID 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 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;
- 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 and HIV infection; 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 impacted by HIV/AIDS;
- 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.

3.11: FINANCE AND ECONOMICS

3.11.1 BACKGROUND

PEPFAR programs have resulted in millions of lives saved and wide-ranging economic, workforce, societal and national security benefits. These results have been important to the program's continued strong bipartisan support in Congress, and from Presidents Bush and Obama. The global economic crisis has forced all partners to do more to meet unmet needs with finite resources. In recent years PEPFAR has intensified its efforts to implement an evidence-based program, in the most efficient way possible. Those efforts led to PEPFAR's Impact and Efficiency Acceleration Plan, which includes improving the collection and use of economic and financial data, increasing the efficiency of HIV/AIDS program implementation, and collaborating with governments and multilateral organizations to maximize the impact of the resources provided by the United States.

As PEPFAR teams use the Plan to shape their programming and budgeting decisions, they should consider both financing of PEPFAR activities and financing of the partner country's health system.

A key tool for planning and budgeting is the PEPFAR expenditure analysis which will be rolled out in selected countries in 2012 and to all PEPFAR countries in the coming years. Countries with access to expenditure analysis when preparing FY2013 COP budgets will need to illustrate how these data were used in determining program allocations and specifically reference the use of the unit cost estimates in setting budgets relating to achievement of the World AIDS Day targets. These budget allocations should reflect attempts to achieve efficiency from a variety of perspectives.

1. *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 used in 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.
2. *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.
3. *Allocative efficiency* is achieved when the optimal distribution of resources is made across program areas to maximize their benefit. For 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 can inform program planning; each produces different information which is appropriate for different questions. Several types are detailed below. Detailed costing studies 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, i.e. financial indicators. Countries are strongly encouraged to engage with the Finance and Economics Work Group (FEWG) through their CSTL to ensure that funded economic evaluations will provide the needed answers for program evaluations and management.

3.11.2 Types of Economic Analysis

1. *Targeted costing 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 help to identify areas of intervention or modifications 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. They are resource intensive and thus can have significant time delays in having data to apply to programs.
2. *Cost projection models* use unit cost calculations to estimate resource requirements over some future period, usually about five years. Cost projection 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 projection 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.
3. *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 is 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.
4. *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 informs priority setting and resource allocation.
5. *Expenditure analysis* under PEPFAR is intended as a rapid assessment of USG cost-per-result. 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 program area and by partner, by cost category, by geographic area, and stratifications of these. 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 efficiency.

3.11.3 Considerations for COP Planning

In designing their COP, country teams are strongly encouraged to consider the following questions:

1. What metrics is the team using to assess and monitor efficiency within its programs?
2. How have the results of routine expenditure analysis been used for COP planning?
3. How expenditure analysis has been used for portfolio management, including examples of how cost information has been used with individual partners to enhance efficiency.
4. How expenditure analysis has been useful in planning focused economic analyses (detailed costing studies)
5. Are any other economic studies needed for program planning and have those activities been reviewed with the FEWG to ensure technical rigor and appropriateness?

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. Promising activities to strengthen the health finance function include:

1. Developing a better understanding of resource flows through assessments of National Health Accounts or National AIDS Spending Assessments or activities to map PEPFAR expenditure analysis to national level expenditures;
2. 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;
3. Performance-based financing and linkages to HRH incentives;
4. Public and private sector financial management trainings, though not just for management of USG grants;
5. Insurance schemes to increase access to HIV/AIDS services;
6. Promotion of policies that allow for increased efficiencies through outsourcing of select services to private sector or community organizations;
7. Resource mobilization through innovative public-private partnerships, equitable cost sharing strategies, etc.

In order to ensure activities are well-coordinated and take advantage of previous and ongoing work, country teams are strongly encouraged to engage with the Finance and Economics Work Group when planning investments into economic and finance activities.

Countries participating in expenditure analysis for FY2012 reporting will receive supplemental guidance during their country launches in September/October 2012.

3.12 FAMILY PLANNING AND HIV INTEGRATION

3.12.1 Background

As current COP guidance makes clear, PEPFAR supports the integration of voluntary family planning (FP) and HIV/AIDS services. In an era when approximately 33 million adults and children are living with HIV/AIDS and women of childbearing age account for nearly half of the infected population, FP can play a critical role in responding to the HIV/AIDS epidemic. Women and girls account for over 60 percent of those living with HIV in sub-Saharan Africa, and access to integrated health services, including HIV and voluntary FP services, is essential to meeting their health care needs and attaining broader USG goals of the virtual elimination of MTCT and achievement of an AIDS-free generation.

HIV/AIDS and FP programs often serve similar populations, particularly in countries with generalized HIV epidemics driven by heterosexual transmission. Per COP guidance, PEPFAR funds cannot be used to purchase FP commodities, including contraceptives. However, female and male condoms can be purchased with PEPFAR funds. FP commodities can be funded and made available by other sources including national governments, the private sector, USAID FP programs, or other donors.

PEPFAR's mandate involves the prevention, treatment and care of HIV/AIDS, and all integrated activities should be carried out according to that mandate, and in keeping with PEPFAR guidance. As noted in COP guidance, all USG programs are subject to legal restrictions relating to abortion and involuntary sterilization. See the current fiscal year COP guidance for more information.

- Integration of HIV/AIDS and FP activities may be cost-effective and appropriate, depending on the country context, within programs for prevention-of-mother-to-child transmission (PMTCT), care and treatment, services for key populations, and health systems strengthening.

Key areas of focus for HIV and FP integration activities include:

- Developing and disseminating technical guidance materials related to HIV and FP integration;
- Strengthening the policy environment for appropriate integration of HIV and FP platforms and services;
- Evaluating the efficiency and effectiveness of HIV and FP integrated service delivery;
- Supporting quality assurance efforts that support HIV and FP integrated activities;
- Conducting operations or implementation science research on effective HIV and FP integration approaches; and
- Strengthening public health and primary health care systems, including commodity procurement, information systems, and logistics and distribution systems to improve the availability of HIV and FP commodities within integrated programs (Note that PEPFAR funds cannot be used for procurement of FP commodities).

3.12.2 HIV and Hormonal Contraception

Following findings from recently published epidemiological studies, the World Health Organization (WHO) convened a technical consultation regarding hormonal contraception and HIV acquisition, progression and transmission. The consultation considered whether the guideline *Medical eligibility criteria for contraceptive use, Fourth edition 2009* (MEC) should be changed in light of the new studies.

The group concluded that the WHO should continue to recommend that there are no restrictions on the use of any hormonal contraceptive method for women living with HIV or at high risk of HIV. However, the group recommended that a new clarification (under Category 1) be added to the MEC for women using progestogen-only injectable contraception at high risk of HIV:

"Some studies suggest that women using progestogen-only injectable contraception may be at increased risk of HIV acquisition, other studies do not show this association. A WHO expert group reviewed all the available evidence and agreed that the data were not sufficiently conclusive to change current guidance. However, because of the inconclusive nature of the body of evidence on possible increased risk of HIV acquisition, women using progestogen-only injectable contraception should be strongly advised to *also always use condoms*, male or female, and other HIV preventive measures. Expansion of contraceptive method mix and further research on the relationship between hormonal contraception and HIV infection is essential. These recommendations will be continually reviewed in light of new evidence."

PEPFAR teams should refer to the report from this consultation for more information and to inform their work in FP integration.[325]

3.12.3 Defining a Country-Specific Approach to HIV and FP Integration

Smart Integration

Integrating FP services into HIV clinical settings can expand access to this key health service for HIV-infected persons and offer potential increased synergy and efficiency across programs. Approaches to integration will vary by country. Strategic integration decisions will require consideration of the country-specific context, especially the country's HIV epidemic. Specifics such as HIV prevalence, numbers of people served, and cost-effectiveness will be important factors in integration choices.

Guiding Principles of Voluntary FP and HIV/AIDS Integration

PEPFAR upholds the right of individuals to voluntarily decide the number, timing, and spacing of their children and to have the information and means to do so, and the right to make these decisions voluntarily within a context free of discrimination, stigma, coercion, duress, or deceit.

[325] http://www.who.int/reproductivehealth/topics/family_planning/hc_hiv/en/index.html

HIV/AIDS and FP integrated program activities must respect a client's right to make informed decisions about his or her reproductive life, including the decision to use or not use a FP method. HIV-positive women who wish to have children should have access to safe and non-judgmental pregnancy counseling services in order to meet their reproductive health needs, protect their own health, and prevent HIV transmission to their partners and children.

Stigma and discrimination are significant barriers to addressing HIV/AIDS. Women living with and affected by HIV may refrain from seeking FP services and safe pregnancy counseling to avoid experiencing stigma and discrimination. While some progress has been made in reducing stigma and discrimination within service delivery settings, there is an ongoing need to raise awareness of these issues and to promote normative behavior and policy change in the countries where PEPFAR works. PEPFAR teams should consider ways to address stigma and discrimination barriers faced by HIV-positive individuals seeking FP services and safe pregnancy counseling in PEPFAR-supported programs. Helpful steps may include design and implementation of activities that promote voluntary and informed decision-making (e.g., including anti-stigma and discrimination messages in provider training materials and HIV/AIDS and FP integration policy documents, developing and disseminating patients' rights materials, etc.).

Consistent with USG policy and PEPFAR's COP Guidance, the following principles should be reflected in all PEPFAR programs that are integrated with FP activities:

- HIV-positive individuals should be provided with information on, and be able to exercise voluntary choices about their health, including their reproductive health.
- The USG, including PEPFAR, supports a person's right to choose, as a matter of principle, the number, timing, and spacing of their children, as well as use of family planning methods, regardless of HIV/AIDS status.
- Family planning use should always be a choice, made freely and voluntarily, independent of the person's HIV status.
- The decision to use or not to use family planning should be free of any discrimination, stigma, coercion, duress, or deceit and informed by accurate, comprehensible information and access to a variety of methods.
- Access to and provision of health services, including antiretroviral treatment, for an HIV-positive person should never be conditioned on that person's choice to accept or reject any other service, such as family planning (other than what may be necessary to ensure the safe use of antiretroviral treatment).
- HIV-positive women who wish to have children should have access to safe and non-judgmental pregnancy counseling services.
- Field teams are expected to prioritize opportunities to link PEPFAR-funded activities with those funded from separate USG accounts or other non-USG sources of funds supporting reproductive health and family planning to ensure access to voluntary family planning as part of comprehensive care for HIV/AIDS. As PEPFAR funds cannot not be used to procure FP commodities this is especially important for procurement of such commodities.

3.12.4 Opportunities for Programming

Prevention of Mother to Child Transmission (PMTCT)

PEPFAR supports a very wide network of PMTCT programs and service delivery sites across the globe. PMTCT platforms provide an ideal opportunity for the integration of HIV/AIDS activities with FP, maternal health and other reproductive health services. In the context of the Global Plan to prevent new pediatric infections and keep mothers alive, PEPFAR supports a comprehensive approach that includes key activities in each of the four programmatic prongs for PMTCT. PMTCT platforms can strengthen antenatal care, including the identification and treatment of sexually transmitted infections (STIs), safe delivery, post-partum care, neonatal care, exclusive breastfeeding for the first six months (as appropriate), and under 5 child health care. The PMTCT platform can thus provide wide-ranging benefits to HIV-positive and HIV-negative women and children. WHO recommends that the provision of voluntary FP services, commodities, information, counseling, or referral to these services should be part of an integrated package of services for pregnancy, delivery and, in particular, post-partum care, for women who wish to space the births of their children or cease childbearing. In addition, as part of comprehensive care, HIV-positive women who desire to have children should have access to safe pregnancy counseling in order to protect their own health and reduce the risk of HIV transmission to their partners and children.

FP efforts can be integrated within this platform at the levels of policy, program administration, and service delivery. All of these examples offer opportunities for PEPFAR programs to use limited resources to leverage other key programs and strengthen the maternal, newborn, and child health platforms in each PEPFAR country. PEPFAR PMTCT programs are encouraged to develop synergies and leverage funding between HIV and FP programs. Countries should explore integration opportunities to link PEPFAR-funded activities with those supported by national government, other USG agencies, and other bilateral or multilateral donors.[326]

Care and Treatment

Integration of FP counseling and services to people living with HIV (PLHIV) into routine care is a core component of comprehensive and integrated HIV prevention, care, and treatment services as outlined by WHO[327] and PEPFAR's Prevention Guidance[328]. Many HIV-positive women in

[326] Further guidance can be found in: *PEPFAR Guidance on Integration of Prevention of Mother-To-Child Transmission, Maternal, Newborn, and Child Health and Pediatric HIV Services*, 2011.
[327] 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.
[328] President's Emergency Plan for AIDS Relief (PEPFAR). (2011). *Guidance for the prevention of sexually transmitted HIV infections.* Retrieved from: http://www.pepfar.gov/documents/organization/171303.pdf

sub-Saharan Africa report an unmet need for contraception[329], highlighting the importance of offering FP counseling and services to people living with HIV.

For PLHIV who desire children, partner testing and safer pregnancy counseling are essential to reduce the risk of HIV transmission to uninfected partners as both women[330], and men[331] are at increased risk for acquiring HIV during women's pregnancies. The most common reason cited for unprotected sex among serodiscordant couples is pregnancy desire.[332] Safer conception counseling, along with ART for the positive partner, is an important intervention for serodiscordant couples trying to conceive a child in order to reduce the risk of HIV transmission to the negative partner during the time of conception. This is particularly important if the woman is the 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[333,334,335]. HIV-positive women should also be counseled on safe timing of pregnancies based on their health status, and HIV-positive women who become pregnant should be linked to appropriate PMTCT programs.

HIV care and treatment settings offer routine services to HIV-positive persons and are well-situated to address FP issues. FP counseling and provision of contraceptive services should ideally be integrated within most HIV care and treatment settings serving PLHIV to increase access to and uptake of these services. Integration of services in care and treatment settings allows health care providers to counsel both women and men on FP issues specific to their HIV status. Many women who access FP services outside of the HIV clinic may not disclose their HIV status and therefore may not get proper care or counseling. Where full integration of services is not feasible or cost-effective, HIV care and treatment providers should at least assess the FP needs of their clients, counsel them on appropriate options and services, and link them to these services. As noted previously, the reproductive health rights of PLHIV should be protected through access to and the provision of non-judgmental and non-discriminatory FP services in a safe environment.

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[329] 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.

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

[331] 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.

[332] 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*, 12, 316-21.

[333] 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.

[334] 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.

[335] 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.

Prevention with Key Populations

Provision of or referral to FP services is a critical element of a comprehensive package of services for key populations, such as females who exchange sex for money or goods, and those who inject drugs, as well as other vulnerable groups such as the female partners of men who have sex with men or men who inject drugs. As highlighted above, programming to address the FP needs of key populations should consider the epidemic context, the particular needs of sub-populations being targeted and the cost-effectiveness of investments. Within concentrated epidemics, integration of FP services into targeted HIV programs for key populations is likely to be more cost-effective than integration of HIV services into general population-focused FP, antenatal care and maternal and child health platforms.

Emerging research has documented the significant unmet need for contraception among key populations, and programs should consider the FP needs of key population groups. For example, in one study 30 percent of sex workers in Andhra Pradesh, India reported experiencing an unintended pregnancy[336]; and in another, 28 percent of sex workers in Cambodia reported having had abortions due to poor access to contraception[337]. While the FP needs of female injecting drug users are not well-documented, high rates of exchanging sex for drugs, housing or protection, and limited ability to negotiate condom use while doing so, puts them at high risk of both unintended pregnancy and HIV infection[338]. It is important to note that females who exchange sex for money or goods often have high unmet need for FP even when they report high levels of condom use during transactional sex.

PEPFAR encourages the integrated delivery of HIV/AIDS and FP counseling and services (either through referral or directly on site) tailored to the unique needs of these diverse key populations. Opportunities to integrate FP into services targeting key population groups exist within prevention, and care and treatment settings.

For example, targeted HIV prevention programs can:

- Provide counseling and referral to FP programs within drop-in centers or via peer educators, as well as referral for PMTCT/ANC for pregnant clients.
- Include "condom plus" dual protection messages in all behavior change communications messages directed toward key populations.

Within HIV care and treatment settings, programming options might include:

- Provision of FP services within "key population-friendly" HIV care and treatment settings.
- Training of providers in care and treatment settings to provide FP services to key populations in a non-judgmental, non-stigmatizing manner.
- Close monitoring of referrals between sites serving key populations and FP service

[336] India HIV/AIDS Alliance (2012). Issue Brief: HIV/SRHR Integration for Sex Workers. New Delhi. India HIV/AIDS Alliance, p. 2.
[337] Morineau, G et al. Contraception. 2011 Aug;84(2):194-8. Epub 2011 Jan 20 Falling through the cracks: contraceptive needs of female sex workers in Cambodia and Laos.
[338] Pinkham, S & Malinowska-Sempruch K. Women Harm Reduction and HIV. Reproductive Health Matters. 2008 May; 16 (31): 168-81.

delivery sites to ensure uptake of services.

Within generalized epidemic contexts, key population groups may not be reached by general population-focused MCH or FP services due to stigma. In these contexts, where targeted programs for key populations exist, strategies that support key population groups in accessing general population-focused FP services should be considered. Examples of integrated program strategies to achieve this may include:

- Programs to support trained peers to accompany clients to FP settings; and
- Training FP providers on stigma issues related to key populations.

Health Systems Strengthening

System strengthening may include program activities related to developing or enhancing existing policies and guidelines, leadership and governance, financing, human resources, information systems, and supply chains. Close coordination between PEPFAR country teams, MOHs and other donors will help to prevent duplication, maximize efficiencies, and assess the appropriateness of harmonized national systems around integrated FP and HIV-related services. Some activities to support quality integration of HIV/AIDS and FP services include:

Human Resources

- Assist countries in determining the most effective mix of health care staff to integrate FP into the existing package of services for HIV/AIDS.
- Design, integrate and/or coordinate HIV and FP training curricula and accompanying materials (including pre-service and ongoing in-service training) for new and existing health care providers.
- Support mentorship and supervision for healthcare workers, focusing on skills and information needed for integration of HIV and FP services.

Information Systems

- Support development of or enhance existing integrated local health management information systems to ensure harmonized reporting of patient and program data.
- Support development and implementation of patient tracking and follow-up tools, especially as they relate to referral for FP and other related services.

Financing

Given that PEPFAR programs cannot purchase FP commodities, in pursuing HIV and FP integration, PEPFAR teams may:

- Participate in national government-led committees on contraceptive security to ensure availability of contraceptive commodities financed by non-PEPFAR sources to integrated platforms.
- Engage in dialogue with other donors, national government, USAID FP staff and the private sector regarding financing options to support FP commodity availability within integrated platforms also supported by PEPFAR.

Supply Chain Management

Shortages and stock-outs of drugs and contraceptive commodities can severely undermine the ability to effectively integrate HIV and FP services. There is a lack of data on what specific types of supply chain improvements or models best support the delivery of integrated services. Therefore, country teams are encouraged to work closely with national government counterparts to develop context-specific strategies for strengthening and increasing the coordination of supply chains for HIV and FP commodities.

In some cases, this may mean movement toward an integrated supply chain for drugs and commodities needed for delivery of integrated HIV and FP services. PEPFAR programs are encouraged to support program activities that would increase such coordination or integration to ensure a continuous, responsive, uninterrupted, and equitably distributed supply of all relevant commodities. The following are examples of supply chain strengthening activities that support integration of HIV and FP programming:

- Promote strengthening of national supply chain systems to forecast, procure, manage, distribute, and assure quality of a wide range of HIV and FP-related commodities.
- Develop and operationalize integrated product selection procedures, distribution systems and networks, and information-management systems.
- Centralize procurement mechanisms, demand forecasting procedures, and coordination between HIV and FP supply chain managers and program service managers to ensure patient enrollment and continual product and commodity availability.
- Promote the development of detailed national and/or USG procurement plans (if not already done).

3.14.5 Management Requirements and Legislative Compliance

HIV and FP integrated program activities must respect a client's right to make informed decisions about his or her reproductive life. The principles of voluntarism and informed choice are prerequisites for good quality of care and must form the basis of integrated programs. These principles are articulated in legislative requirements that govern the use of USG foreign assistance funds and USG FP assistance, and are implemented through standard clauses in agency contract and assistance agreements.

The legislative requirements most relevant for implementation of HIV and FP activities relate to restrictions on support for certain abortion-related activities, prostitution and sex trafficking, and requirements to uphold voluntarism and informed choice, including providing medically accurate information on condoms.

PEPFAR takes these requirements very seriously and expects compliance in all program activities. Each USG agency is responsible for maintaining compliance with these requirements in their project activities.

PEPFAR agency leads should ensure that each agency is prepared to conduct activities to reduce vulnerabilities and prevent violations of the requirements as well as monitor for compliance. In addition, agency leads should ensure that each agency has procedures in place to respond to vulnerabilities and reports of possible violations of the requirements and take swift corrective action. If vulnerabilities or reports of possible violations arise, each agency should follow its established procedures, including notifying the PEPFAR coordinator.

Illustrative activities to reduce vulnerabilities and prevent possible violations of the requirements include:

- Training agency staff on the requirements
- Training implementing partners and other key stakeholders.
- Asking partners to provide cascade training to sub-partners and health service delivery level personnel where applicable
- Discussing USG requirements with government counterparts in ways that effectively convey the underlying concepts
- Reviewing contracts and assistance agreements for inclusion of appropriate clauses
- Developing and disseminating contraceptive methods wall charts (available at http://www.k4health.org/toolkits/communitybasedfp/do-you-know-your-family-planning-choices-wall-chart) and other materials that address the requirement to provide clients with comprehensible information on the risks and benefits of their chosen FP method
- Reviewing technical/training materials produced with PEPFAR support (these may provide opportunities to refer to the requirements or general principles)

Illustrative monitoring activities include:

- Developing or adapting existing monitoring tools to include specific observations or questions related to compliance with the requirements
- Developing a monitoring plan that specifies the persons responsible for monitoring, schedules, and localities
- Discussing with partners their compliance monitoring activities and requesting periodic reports
- Documenting monitoring results and follow-up actions
- Incorporating compliance monitoring into routine field site visits

Each agency should contact its compliance team for further assistance on monitoring for compliance, available tools, and recommended response procedures. PEPFAR coordinators should encourage agencies to share locally adapted monitoring tools and approaches.