Technical Considerations
Provided by PEPFAR Technical Working Groups for
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<td>ACILT</td>
<td>African Centre for Integrated Laboratory Training</td>
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<td>AFG</td>
<td>AIDS-free Generation</td>
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<td>AIDS</td>
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<td>AIDS Support and Technical Resources (project)</td>
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<td>Abbreviation</td>
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<td>Strategic Information</td>
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<td>Extreme Drug-Resistant Tuberculosis</td>
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Introduction

PEPFAR’s Technical Considerations consolidates into one document recommendations for program planning and implementation across a range of programmatic areas. The Technical Considerations are not intended to serve as policy guidance or establish required criteria within PEPFAR country programs, nor are they guidelines, as these are produced by normative bodies (e.g., the World Health Organization (WHO), the United Nations Programme on HIV/AIDS (UNAIDS)). Rather, the Technical Considerations are meant to assist PEPFAR teams and implementing partners in applying those normative guidelines, as well as the most recent scientific evidence, to the planning and implementation of programs. PEPFAR team members with technical questions may contact headquarters Technical Working Groups (TWGs), keeping their PEPFAR Coordinator and Country Support Team Lead (CSTL) informed. CTSLS can provide contact information for relevant TWG co-chairs, as needed. 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.

Sections of this year’s Technical Considerations adopt the following organizational structure:

- **Introduction**
  - **What’s new in 2014**: highlights new technical, programmatic, or other developments over the past year and covered in the section
  - **PEPFAR Blueprint**: PEPFAR’s *Blueprint: Creating an AIDS-free generation* ([http://www.pepfar.gov/documents/organization/201386.pdf](http://www.pepfar.gov/documents/organization/201386.pdf)) references action steps that cut across all technical areas. To assist PEPFAR teams in aligning PEPFAR’s priorities with country-level programming, each programmatic area highlights how their Technical Considerations relate to Blueprint.
  - **Technical Background**: provides any needed technical background needed to implement technical considerations

- **Technical Considerations**
  - **Section-specific considerations**: provides general considerations
  - **Cross-cutting, linkages and wraparound**: provides considerations on cross-cutting issues (e.g., gender), linkages to other programmatic areas, and wraparounds (e.g., linking to programs from non-PEPFAR United States Government accounts)

- **Additional Resources**: lists resources of potential programming use for teams

A bibliography of citations is included at the end of the document in the “Works cited” Section. This year’s Technical Considerations adopt a numeric references format with references enclosed within parentheses (e.g., “(1) (2)”).
1 What’s new in 2014

1.1 Programmatic framework

The Technical Considerations cover over 20 different programmatic areas. While individual PEPFAR team members are likely to focus only on certain sections, PEPFAR teams are expected to develop overall programs that coherently integrate and optimize linkages between programmatic areas. Figure 1, below, presents a unifying programmatic framework highlighting connections between programmatic areas. This framework is aligned with that included in PEPFAR’s forthcoming Monitoring, Evaluation and Reporting guidance.

Figure 1. Continuum of HIV Response – Technical Considerations conceptual framework

Key features of Figure 1 include:

- HIV Testing and Counseling (HTC) (Section 1.4 and 2.3) is the entry point for the HIV response, resulting in prevention services tailored to HIV-negative populations (to the left of HTC; see Sections 1.2 and 1.3) and, for HIV-positive populations (to the right of HTC), prevention (Sections 1.1, 1.2, 1.3, and 1.5), care and support (Sections 2.1 and 2.3) and treatment (Sections 2.2 and 2.3) services;
Integration of and linkages to other health services (Sections 2.4, 3.7, and 3.11), including impact mitigation (Section 2.5) can and should occur along the entire continuum of the HIV response;

Communities/facilities and community/health systems are interlinked in the HIV response, and all require capacity building/systems strengthening (Sections 3.1, 3.2, 3.3, 3.4, 3.6, 3.9, and 3.11); and

Integrating a gender lens into programming cuts across all technical areas (Section 3.5).

When using the Technical Considerations as a programming guide to develop a Continuum of Response (see FY2014 Country Operational Plan (COP) Appendices), PEPFAR team members are encouraged to use the above-described framework as a point of reference to identify relationships between programmatic areas and which other programmatic areas may need to be considered to ensure appropriate linkages are made and overlapping programmatic issues addressed.

### 1.2 Changes to sections from FY2013 Technical Considerations

Because supply chain management issues and interventions cut across multiple programmatic areas, supply chain management content is addressed in a single new section in this year’s Technical Considerations (3.11 – Supply Chain Management). This new section presents overarching supply chain considerations as well as those related to specific programmatic areas. While selected complementary supply chain management content remains in other sections, teams should cross-reference the supply chain management section throughout the Technical Considerations.

Consistent with the PEPFAR Blueprint’s Roadmap for Driving Results with Science, a new section on Impact Evaluation has been added to this year’s Technical Considerations (3.12 – Impact Evaluation). This section provides guidance on integrating impact evaluation activities funded through Country Operational Plans.

Two sections found in previous years: “Linking with other services” and “Workplace Programs” have been removed from this year’s Technical Considerations. Updated content from “Linking with other services” can be found in PEPFAR’s *Guidance for Orphans and Vulnerable Children Programming* (http://www.pepfar.gov/documents/organization/195702.pdf) (see p. 38 – 43 of that document for guidance on Household Economic Strengthening and p. 26 – 31 for guidance on Education) as well as Section 3.7 (Nutrition and HIV/AIDS) of these Technical Considerations. The “Workplace Programs” section is currently undergoing extensive updating and revisions. Considerations on integrating workplace program issues into PEPFAR programming can be found in last FY2013 Technical Considerations.
1 Prevention

1.1 Prevention of Mother to Child Transmission

1 Introduction

1.1 What’s new in 2014

The 2014 Prevention of Mother to Child Transmission (PMTCT) Technical Considerations reflect a major shift in PMTCT programming highlighted in the 2013 World Health Organization (WHO) Consolidated Guidelines: the provision of antiretroviral treatment (ART) to all HIV+ pregnant and breastfeeding women regardless of CD4 count (Option B or B+). It is incumbent upon PEPFAR to embrace this shift, and work with national HIV programs and Ministries of Health to support this critical transition.

The approach to the traditional four prongs of PMTCT—1) primary HIV prevention, 2) family planning, 3) treatment and prophylaxis during pregnancy and breastfeeding, and 4) ongoing monitoring, treatment, care, and support for women and their families—should be addressed within a combination prevention strategy that incorporates both HIV and maternal neonatal and child health (MNCH) across the continuum of care. Bringing together MNCH, PMTCT, and ART program leadership to determine how to maximize access to services for pregnant HIV-positive pregnant, delivering, postpartum and breastfeeding women and their families while maintaining quality will be one of the most important challenges facing PEPFAR over the next few years.

1.2 PEPFAR Blueprint

Within the PEPFAR Blueprint, the “Road Map for Saving Lives’ aligns with the Global Plan towards Elimination of New Infections Among Children by 2015 and Keeping Their Mothers Alive. This global initiative was launched by PEPFAR and other partners with the goals of decreasing mother to child transmission of HIV to less than 5% globally and reducing AIDS-related maternal mortality by 50%. Countries have already made great strides towards these goals. The 22 highest burden countries have achieved a 38% reduction in the number of new pediatric infections from 2009 to 2012, and the percent of pregnant and breastfeeding women receiving lifelong ART increased from just 25% of those in need in 2009 to 59% in 2012 (UNAIDS). PEPFAR support for PMTCT has been one of the major drivers of this progress towards this effort.

In FY2012 alone, with PEPFAR support, 750,000 HIV-positive pregnant women received ARVs for PMTCT, resulting in 230,000 infant HIV infections averted. 220,000 of these women received lifelong ART. With increased attention and investment over the past year, PEPFAR is on track to meet the target of 1.5 million pregnant women reached with ARVs for PMTCT between World AIDS Day 2011 and World AIDS Day 2013. However despite this success,
UNAIDS reports that ARV coverage is still only 65% among pregnant women, 33,000 mothers died from AIDS-related causes, and over 210,000 infants are born annually with HIV (1)(2).

1.3 Technical Background

Similar to the 2013 PMTCT Technical Considerations, the 2014 version is structured to guide PEPFAR programs in addressing the four prongs of PMTCT through targeted clinical and operational interventions. They also highlight critical considerations for countries as they look to improve access and retention through more integrated service delivery and stronger linkages between MNCH, PMTCT, ART and OVC programs. Specific areas of focus include:

- Primary prevention: Couples HIV testing and counseling (HTC) and condom provision within the PMTCT platform, HIV care and treatment of infected partners in discordant couples, and linkages to voluntary medical male circumcision (VMMC) programs;
- Integrating voluntary family planning (FP) with other PMTCT and ART services;
- Breastfeeding support and other infant feeding and young child nutritional support;
- Improving access to ART within MNCH settings;
- Strengthening access to and quality of MNCH services for HIV-positive women and their infants;
- Supporting retention and monitoring of mothers on ART once initiated;
- Tracking mother-infant pairs, at least through the end of the breastfeeding period;
- Revising monitoring and evaluation systems to capture both PMTCT and ART indicators with harmonized data collection tools;
- Engaging people living with HIV in meaningful ways to monitor quality of programs and support improvement of service delivery at facilities and in communities;
- Ensuring that all PMTCT clients are linked to appropriate social support services available through the orphans and vulnerable children (OVC) portfolio;
- Developing standardized supportive supervision, including data quality management; and
- Expanding and strengthening national, regional, and facility level commodity management and task-sharing strategies.

2 HIV Testing and Counseling and Primary Prevention within the PMTCT Platform (Prong 1)

2.1 HIV Testing and Counseling as a gateway to PMTCT

HTC is a critical component and gateway to PMTCT services for both mothers and HIV-exposed infants. All women receiving ANC, and/or attending labor and delivery, and PNC services should be routinely offered HTC. In high-prevalence settings, HIV re-testing is a cost-effective strategy to identify, and initiate on ART, women who may have acquired HIV during pregnancy or breastfeeding (1). Additionally, PMTCT programs present a unique opportunity to offer HIV testing to partners and family members of pregnant and breastfeeding women and to link them to
appropriate prevention, care and treatment services (see Section 1.4 of the Technical Considerations (HIV Testing and Counseling)). Information on HIV testing for HIV-exposed infants can be found in sub-section 2.1.1 (HIV testing of children for early identification) of Section 2.3 of the Technical Considerations (Pediatric Testing, Care and Treatment).

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

- Training and use of lay counselors for HTC;
- Provider-initiated HIV testing and counseling (PITC) with same-visit return of results;
- Designing HTC strategies and interventions based on the type of epidemic:
  o **Generalized epidemics**: Offer HTC to all pregnant/breastfeeding women and their partners in all ANC, childbirth, postpartum, and pediatric care settings. Women who initially test negative in the first or second trimester should be offered re-testing during the 3rd trimester, at L&D, and during the postpartum period; and
  o **Low level and concentrated epidemics**: Offer routine PITC during ANC targeting geographic settings or population groups with higher HIV prevalence among pregnant and breastfeeding women.

### 2.2 Ensuring the quality of rapid testing

Incorporating quality assurance (QA) systems for rapid testing in all settings providing PMTCT is a PEPFAR priority. While most non-pregnant HIV+ people will still undergo clinical staging or CD4 testing to confirm immunocompromised status before initiating ART, countries that will be offering lifelong ART to all HIV+ pregnant and breastfeeding women regardless of CD4 or clinical stage will be relying solely on rapid test results to determine treatment eligibility. While false negative results will be missed opportunities for PMTCT, false positive results will misdiagnose women and commit them to lifelong ART. PEPFAR has recently launched a Rapid Testing Quality Improvement Initiative (RTQII) to support countries in expanding and strengthening their rapid test quality assurance systems. For further information please see Section 3.1 of the Technical Considerations (Laboratory Infrastructure).

### 2.3 Partner and couples HTC and linkage to HIV or VMMC services

Integrating partner and couples HIV testing and counseling (CHTC) into PMTCT services can identify HIV-positive male partners in need of HIV care and treatment, as well as HIV-negative male partners who can benefit from evidence-based prevention interventions such as VMMC, especially for HIV-negative males in discordant sexual relationships that would benefit the most from VMMC. CHTC used to identify serodiscordant couples has been shown to reduce HIV transmission, increase condom use, and increase ART uptake among pregnant women in antenatal clinic (ANC) settings (3)(4)(5). Countries should adapt their couples HTC strategies to fit the specific family and extra-familial sexual relationship networks prevalent in their populations and evaluate the implementation of those strategies. Various approaches to scaling up couples HTC in MNCH settings include engaging political, religious, and community leaders,
offering special services for couples (e.g., evening or weekend hours; incentives), conducting promotional campaigns, and improving M&E tools and record keeping to track the number of couples that receive HTC together. Any major effort to prevent primary HIV infection among pregnant and breastfeeding women must include identifying their HIV-infected partners and placing them on effective treatment in alignment with the WHO guidance on discordant couples.

Strong linkages from PMTCT to VMMC and HIV care and treatment programs for eligible clients should be prioritized as part of Prong 1 interventions. Referral of HIV-negative male partners for VMMC can reduce the risk of HIV acquisition for men by 60% to 70% (6)(7)(8)(9) (see sub-section 4 (Voluntary Medical Male Circumcision) of Section 1.3 of the Technical Considerations (Biomedical Prevention)). HIV-positive partners in serodiscordant couples should be advised that ART can reduce HIV transmission to the uninfected partner by as much as 96% (10). WHO guidelines and PEPFAR policy now endorse ART regardless of CD4 count for the HIV positive member of a serodiscordant couple wherever national guidelines support it (11). Specific efforts to link key populations (especially female sex workers and women who inject drugs) and their partners to HTC and relevant PMTCT, care and treatment, and family planning services should be a priority.

### 2.4 Other HIV prevention and PMTCT

High rates of HIV acquisition noted during pregnancy underscore the important role of Prong 1 in PMTCT (12). Pregnant women are at increased risk for acquiring HIV, as are male sexual partners of HIV positive pregnant women (12)(13). Women who become infected with HIV during pregnancy or breastfeeding are at high risk for transmitting HIV to their infants and/or to their HIV-negative male partners due to the high viral loads associated with acute HIV infection (14). Key strategies for HIV prevention in the context of PMTCT include mutual monogamy, education on consistent and correct condom use and condom negotiation skills, ensuring an adequate supply of condoms and lubricant, and incorporating prevention with positives interventions. More detailed guidance can be found in Section 1.2 (Prevention of Sexually Transmitted HIV Infections) and 1.5 (Positive Health, Dignity and Prevention for People Living with HIV) of the Technical Considerations.

See sub-section 8 (Additional Resources) of this Section for informational resources about primary prevention of HIV.

### 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% and 38% (15). Access to voluntary family planning (FP) is a critical component of a comprehensive PMTCT strategy. Researchers have estimated that meeting the unmet need for family planning in the 20 countries with the highest burden of HIV would result in six million fewer unintended births and 61,000 fewer children with HIV in the year 2015 alone (16).
The regular repeat visits for ANC and HIV care and treatment services provide multiple opportunities to provide women with FP counseling and services, including long-acting reversible methods (LARC). 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 integrating FP and PMTCT/ART services within PEPFAR-supported programs include:

- Addressing the unmet need for FP through appropriate counseling and provision or referral for contraceptive services, including counseling on exclusive BF over the first six months, the lactational amenorrhea method (LAM), and modern contraceptives;
- Providing safe pregnancy counseling for women living with HIV who wish to have children; and
- As appropriate, linking PEPFAR-funded activities with other programs (e.g. host country government activities, multilateral and bilateral donors, USAID Population and Reproductive Health resources, etc.) to support PMTCT-FP and ART-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 3.10 of the Technical Considerations (HIV and Family Planning Integration) and at http://www.who.int/mediacentre/factsheets/fs351/en/index.html.

### 3.1 Anti-retroviral Drug Treatment (ART) for Pregnant, Postpartum and Breastfeeding Women and Infant Prophylaxis (Prong 3)

The 2013 WHO Consolidated Guidelines on the use of Antiretroviral Drugs For Treating and Preventing HIV Infection (http://www.who.int/hiv/pub/guidelines/arv2013/en/) recommend ART for all HIV-positive pregnant, postpartum and breastfeeding women to protect a women’s own health and prevent HIV transmission to her infant and sexual partner. These guidelines were in large part based on the “treatment as prevention” benefits demonstrated in the HPTN 052 study and Malawi’s early success in implementing their innovative Option B+ approach for PMTCT (17) (18). Key recommendations relevant to PMTCT are summarized below:

- All pregnant, postpartum and breastfeeding women with HIV should initiate ART;
  - In countries with **generalized epidemics**, for programmatic and operational reasons, all pregnant and breastfeeding women should initiate ART as lifelong treatment (Option B+); and
  - In countries with **concentrated epidemics** that have high access to CD4 testing, adequate capacity to provide ART to the pregnant and breastfeeding women eligible for treatment, low fertility rates and/or where breastfeeding for mothers with HIV is
not recommended, consideration can be given to stopping the ARVs in women not eligible for ART after breastfeeding is discontinued (Option B).

- Use of the preferred first-line ART regimen harmonized for adults, pregnant women and older children: a once-daily, fixed-dose combination (FDC) pill containing tenofovir (TDF), lamivudine (3TC) or emtricitabine (FTC), and efavirenz (EFV);
- Option A should be phased out;
- Use of viral load testing is preferred for clinical monitoring;
- Decentralizing delivery of ART to peripheral health facilities;
- Integrating ART services within maternal and child health clinical sites with arrangements for ongoing HIV care and treatment in a delivery model that provides high-quality HIV services, including excellent retention and ART adherence as well as excellent MNCH services;
- Task sharing to allow nurses and midwives to initiate and maintain ART within the national regulatory framework; and
- Task sharing to allow community health workers to dispense ARVs and/or deliver ART between regular clinic visits within the national regulatory framework.

National adoption of WHO guidelines presents countries with an opportunity to create an integrated, decentralized PMTCT-ART program. All facilities providing PMTCT will, in effect, be providing ART. PEPFAR should recognize and emphasize that the structures and services created to support treatment for pregnant and breastfeeding women provide the foundation for providing ART to other uncomplicated HIV-positive clients, especially a woman’s partner and other children. The preparation and coordination needed to ensure a successful transition to this decentralized family-centered approach to PMTCT and ART service delivery cannot be over-emphasized.

Priority investments in Prong 3 (treatment and prophylaxis during pregnancy and breastfeeding) include:

1. **Support of the National PMTCT Strategic Plan**: Clear demonstration of PEPFAR program implementation supporting national PMTCT policy or guidance.

2. **Simplifying Commodity Management**: Harmonization of ART regimens for all adults and pregnant women. Co-planning, co-forecasting, and co-budgeting between treatment and PMTCT programs, including the contribution of pregnant and breastfeeding women in consensus targeting, budgeting and forecasting for ART and Rapid Test Kits (RTKs) (see Sections 2.1 (Adult Care and Support), 2.3 (Pediatric Testing, Care and Treatment) and 3.11 (Supply Chain Management) of the Technical Considerations). During the initial scale-up of ART for all HIV-positive pregnant and breastfeeding women, all costing projections must include newly identified pregnant and breastfeeding women and those women switching from Option A prophylaxis to ART. After the initial scale-up, each new annual cohort of
HIV+ pregnant and breastfeeding women as well as those already initiated in previous years requiring maintenance on ART will create an ever-increasing number of reproductively active HIV+ women on ART.

3. **Strengthening Supply Chain**: Supply chain systems can be improved by supporting ministries of health to harmonize 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 forecasting and support for commodity distribution, management, buffer stocks, and monitoring is strongly encouraged.

4. **Service Integration, Linkage, and Retention**: Clear strategies for timely initiation and continuation of pregnant, postpartum and breast feeding women on ART in maternal and child health clinics, with appropriate arrangements for ongoing HIV care and treatment in a delivery model that provides high-quality HIV services, including excellent retention and ART adherence as well as excellent MNCH services. Linkage should be understood to mean linking women and their children to HIV services provided wherever and by whomever these services will work best. This may or may not mean transfer to another location. New required linkage indicators are included in the forthcoming Monitoring, Evaluation and Reporting (MER) Guidance Document and programs should consider how best to monitor linkages for pregnant and breastfeeding women and their children. Ensuring that PMTCT clients have access to needed social services and support is critically important to improving retention and PEPFAR should ensure that PMTCT and OVC programs are clearly linked.

5. **Decentralization of ART to peripheral health facilities**: To improve ART coverage and retention, decentralization of ART services should be considered within the PMTCT scale-up strategy. The location and responsibility for mother-baby pair follow-up, and timing/transition/location of long-term treatment should be determined based on demand and capacity of peripheral health facilities. According to countries’ political and health system contexts, decentralization of ART services may require extensive discussions with—and capacity building of—health authorities at both the national and sub-national levels (see Section 3.3 of the Technical Considerations (Health Systems Strengthening)). PMTCT advisors should collaborate with ART and HSS advisors when discussing decentralization of ART services within the PMTCT platform.

6. **Strengthening and Expanding Early Infant Diagnosis (EID)**: EID coverage and linkage of HIV-infected infants and children to ART should be scaled up in close coordination with offering ART to pregnant and breastfeeding women. Active case finding, improving DBS results return, increasing the number of sites offering DBS sample collection for EID, and ensuring adequate EID commodities to handle increased infant testing should accompany PMTCT scale-up.
7. **Task Sharing:** Initiation and continuation of ART for adults and children by non-medical doctor health workers is essential to support the scale-up and decentralization of PMTCT programs. Depending on the demand and capacity of health facilities, other community based ART delivery and/or ARV dispensing strategies may need to be implemented to reduce workload. Many preparatory actions (e.g., regulatory, educational, informational) may need to support task sharing within the PMTCT platform (see Section 3.4 of the Technical Considerations (Human Resources for Health)). PMTCT advisors should collaborate with HRH advisors when discussing task-sharing of ART services within the PMTCT platform to identify and resolve all obstacles to task sharing for ART delivery in PMTCT.

8. **Quality Management:** Clinical mentoring and ongoing supportive supervision are necessary to improve quality of PMTCT services and provide needed support to health care workers. Referrals from peripheral health facilities to higher levels of care may be appropriate in instances of ART complications such as severe side effects or ART failure. Strategies for referrals should be developed as part of the service delivery model and included in quality management. Quality management (QM) and quality improvement (QI) are top priorities for PEPFAR – please consult the PEPFAR Quality Strategy for more on QM and QI.

9. **Clinical Monitoring:** Viral load is the preferred method for monitoring individuals on ART. In the absence of VL, CD4 is a reasonable alternative and preferred to symptom-based monitoring. CD4 can also be valuable at the time of ART initiation. It is necessary to assess which women are eligible to stop ART after completion of breastfeeding in countries implementing Option B. It can also be helpful to assess eligibility for cotrimoxazole and other opportunistic infection (OI) prophylaxis.

10. **Community Involvement:** PEPFAR should collaborate with national program staff, health care providers, community and religious leaders and civil society including people living with HIV to develop effective community messaging strategies to explain the benefits and responsibilities of ART for the mother and prophylaxis for the infant, and to encourage early ANC attendance and couples testing. Work with community health workers to support ART adherence, defaulter tracing and retention in care for pregnant and breastfeeding women and their HIV-exposed and infected infants. Messaging at all levels should be consistent and evaluated for effectiveness in encouraging uptake, retention, and adherence. Engage the groups supporting people living with HIV in the monitoring and the evaluation of PMTCT programs and regularly seek input regarding how to improve service delivery in facilities and communities.

11. **Improved Monitoring & Evaluation:** As more pregnant women are initiated in ART, strengthening the relationship 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—including district health management information systems—to enable tracking of
clients between and/or through services within the same facility (i.e., ANC/MNCH services and short- and long-term ART services) and across health facilities to facilitate retention and identify those who are lost to follow up. PEPFAR plans should address updating of registers, strategies for timely identification of bottlenecks, and processes for real-time data use supporting quality improvement (more information can be found in the forthcoming MER Guidance Document).

12. **Operational Research**: Because of the limited outcome data available on providing ART to all pregnant and breastfeeding women, PMTCT programs should identify opportunities for evaluation of PMTCT services to improve evidence based decision making. PEPFAR staff in-country and at headquarters will support programs in developing and evaluating innovative strategies to accomplish program goals. Retention and other mother-infant pair outcomes should be key evaluation endpoints.

13. **Monitoring for HIV drug resistance (HIVDR)**: As detailed in Section 2.2 of the Technical Considerations (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 assist with the design and implementation of targeted HIVDR surveillance activities to ensure that pregnant and breastfeeding women are included.

14. **Pharmacovigilance**: The new WHO 2013 Consolidated ARV guidelines recommend TDF-based regimens for first line therapy in pregnant women and other adults. There are many advantages to using a TDF-based regimen, including the ease of administration as a once-daily regimen and overall simplification of regimens. Many studies highlighting the efficacy of TDF have been performed in settings where screening for kidney dysfunction (usually through a blood test for creatinine and/or creatinine clearance calculation) is possible, and in some of these studies TDF has been associated with the development of renal toxicity, as well as changes in bone density (19)(20). HIV infection itself has been clearly identified as a risk factor for kidney dysfunction, and TDF-containing ARVs effectively treat HIV-related kidney disease (21)(22)(23)(24). On balance, given the low risk of TDF-associated renal dysfunction and demonstrated benefits of ART for HIV-associated renal disease, TDF-based regimens can be used as first-line ART in patients with low-risk of renal disease. Further discussion of HIV and TDF-associated renal dysfunction can be found in Section 2.2 of the Technical Considerations (Adult Treatment).

15. **Birth Defects Surveillance**: Any drug has the potential for risk in pregnancy. Current data do not indicate an increased risk of birth defects with use of any ARV in the first trimester of human pregnancy. Given currently available information on serious side effects of some drugs, costs, dosing, potential drug interactions, and antiretroviral efficacy, the regimen of TDF/FTC or 3TC/EFV appears to be the best choice for first line treatment for pregnant women. The benefits of early initiation of ART (reduced MTCT, improved maternal health)
using this simple, once-daily fixed drug combination likely outweighs any potential risk in pregnant women. Countries implementing B+ as recommended in the consolidated 2013 WHO guidelines are not required to have a birth defects surveillance program. PEPFAR is funding birth defects surveillance programs in selected countries to provide birth defects information to the global community. If any PEPFAR team would like to implement a birth defects surveillance program or requires further information about birth defects risks, please request support from the PMTCT-Pediatric TWG, via your CSTL. Inappropriately designed and implemented birth defects surveillance programs are not only ineffective but may create unnecessary anxiety and apprehension over using ART in women of reproductive age.

4 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 (25). The ultimate goal of PMTCT is 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 reach these broader goals. Minimizing maternal health risks and achieving reduced morbidity and mortality among HIV-exposed infants is substantially linked to the achievement of the Global Plan targets and 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 should integrate and/or design clear linkages to provision of essential care elements including cotrimoxazole prophylaxis (CTX); prevention and treatment of tuberculosis (TB); promotion of intensive TB case identification, implementation of Isoniazid Preventive Therapy (IPT), and TB infection control; prevention and treatment of malaria and syphilis; quality ANC services and delivery; and nutritional assessment, counseling, and support (NACS). Further information can be found in the following resource: Essential prevention and care interventions for adults and adolescents living with HIV in resource-limited settings (www.who.int/hiv/pub/prev_care/OMS_EPP_AFF_en.pdf).

4.1 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 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 (antenatal care and through FP or under-five clinics), home-based testing efforts and community outreach services. 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:

- Provision of CTX to HIV-exposed children beginning at four to six weeks of age and continuing until the risk of HIV transmission ends or HIV infection is ruled out. It is important to remember that despite postpartum ARV prophylaxis or maternal ART, HIV transmission can still occur during BF; HIV-exposed infants receiving CTX prophylaxis should receive clinical monitoring at least every three months;
- Provision of CTX to all HIV-infected children less than five years of age and continuing until at least five years of age; CTX may be discontinued at five years of age if WHO immunologic and clinical criteria are met and in accordance with national pediatric guidelines;
- 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.

4.2 Prevention and treatment of tuberculosis

Despite international guidelines, TB/HIV activities have not been integrated into most PMTCT settings. TB/HIV activities outlined below, especially intensified TB case finding, infection control, and isoniazid preventive therapy (IPT) or TB treatment as needed should 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;
- Evaluate every HIV-infected pregnant woman who presents with one or more of the symptoms in the WHO (or national) TB screening algorithm for active TB disease (using a combination of clinical signs, chest x-ray, sputum microscopy, culture, and Xpert MTB/RIF assay) in accordance with national guidelines;
- HIV-infected 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. Initiation of ART for TB patients with a CD4 <50 should be considered urgent and should occur within two weeks of TB treatment initiation, per WHO guidelines;
- Screen HIV-infected infants and children for TB at each encounter using the WHO-recommended symptom-based algorithm (see Pediatric HIV technical considerations for more information). HIV-infected children who are older than 12 months of age and are
not found to have active TB should be given IPT for at least six months, in accordance with WHO guidelines;

- Evaluate all infants and children born to mothers with TB disease or who have a history of contact with a TB case, regardless of the child’s HIV status;
- Establish linkages and referral mechanisms between PMTCT and TB programs to ensure that pregnant women and infants who are suspected of having TB are properly evaluated, and that 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 of the Technical Considerations (TB/HIV); informational resources can also be found in subsection 8 (Additional Resources) of this Section.

4.3 Malaria and syphilis prevention and treatment

Malaria is a major co-morbidity with HIV and is particularly dangerous in pregnant women and infants and children under five. Women and children receiving treatment for both HIV and malaria should be monitored closely for adverse reactions (increased risk in patients taking amodiaquine-containing artemisinin-based regimens with either efavirenz (hepatotoxicity) or zidovudine (neutropenia)).

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.

4.4 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) 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 NACS Integration.
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 PEPFAR’s 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; and
  - 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 two years of age;
- Providing ARVs to HIV-infected mothers or HIV exposed infants throughout the BF period, based on national guidelines, to prevent postpartum transmission;
- Interventions aimed at increasing adherence among breastfeeding women; and
- Connecting mothers and infants to routine maternal and pediatric services in facilities and communities (see Section 2.5 of the Technical Considerations (Orphans and Vulnerable Children)), 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 on HIV and Infant Feeding are available online (http://www.who.int/child_adolescent_health/documents/9789241599535/en/index.html).

5 Program Monitoring, Evaluation, and Quality

Collecting accurate and complete information about PEPFAR-supported PMTCT interventions is critical to our achievement of the global goal of virtual elimination of mother to child transmission (EMTCT) by 2015. PEPFAR PMTCT and Strategic Information (SI) staff should continue to collaborate to ensure that key PMTCT SI needs are addressed and integrated within the larger SI framework and reflect updated monitoring, evaluation and reporting (MER) operational guidance. PEPFAR teams should also watch for upcoming guidance specific to PMTCT programs via the B+ M&E Framework, which will be sent to country teams in fall 2013.

Of particular importance in 2014, PMTCT and SI staff at headquarters and within the field should be engaged in issues around monitoring, evaluating and reporting on pregnant and breastfeeding women who receive lifelong ART (Option B+). This is part of an effort to ensure that programs implementing lifelong ART for all pregnant and breastfeeding women will be able to monitor and ensure quality of the ART program while expanding ART services into maternal,
neonatal and child health (MNCH) sites. Measuring retention and other key M&E questions around implementing lifelong ART for pregnant and breastfeeding women are described in a document that PEPFAR is in the process of developing (known as “the B+ M&E Framework”). This guidance document will be shared with PEPFAR PMTCT and ART programs in the coming months.

Priority activities for PMTCT monitoring and evaluation (M&E) include:

1. **Assessing M&E tools and systems’ capacity to support linkage and retention:** The PMTCT cascade is comprised of multiple care services that can span across different facilities, registers, and data collection tools. As a result, ensuring that HIV-positive women, HIV-exposed and HIV-infected infants are successfully linked to services is critical to the success of the PMTCT and Pediatrics programs. As many PMTCT and pediatric programs are currently reviewing and revising their national guidelines, the PMTCT/Peds TWG recommends that programs review their data collection tools and systems to assess whether or not the systems are able to link mother-infant pairs and link individuals between services. (Reference M&E section of IATT B+ Readiness checklist or Annex 6 from WHO guidelines) HQ PMTCT and SI teams are available to inform and assist in this process.

2. **Routine program monitoring:** PEPFAR-funded PMTCT programs should continue to use indicators to describe program performance and identify gaps in services. The forthcoming MER Guidance document will provide a full listing of indicators required to be collected and reported upon by PEPFAR teams.

3. **Target setting:** When setting targets for these indicators, PMTCT and SI teams should consult with colleagues from other program areas, especially HTC and treatment programs, to ensure that the targets for other programs are aligned. For example, targets for the PMTCT ARVs indicator and the new-on-treatment indicator, should be incorporated into implementing partner and consensus targeting discussions to ensure that pregnant women initiating ART are accounted for in targets and budgets.

4. **Data Quality:** To ensure that the routine monitoring data collected and reported are accurate, data quality assurances should be conducted on a routine basis. At the global level, the Inter-Agency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and their Children (IATT) is in the process of developing PMTCT data quality standards that include guidance on different types of data quality assurance activities and frequency within which they should occur (26). Additionally, global efforts are underway to eliminate mother to child transmission (EMTCT) by 2015 and data quality plays a key role in this effort. Simply put, in order to show that EMTCT has occurred, nationally reported data must be validated on key PMTCT indicators to ensure high coverage has truly been achieved (27).
In order to contribute to these global efforts, PEPFAR PMTCT teams are strongly encouraged to develop data quality management plans that describe how their programs conduct routine data quality assurance. At a minimum, a PMTCT data quality management plan should include a description of data quality activities for PMTCT indicators, the frequency with which they are conducted and address key questions of interest such as how deduplication is addressed and how data are aggregated at sub-national and national levels. Headquarters PMTCT and SI teams can provide support in this area.

5. Evaluation: Evaluations that measure effectiveness of PMTCT interventions and mother-infant pair outcomes are crucial in describing PMTCT and pediatric program goals, especially in light of global goals to eliminate MTCT of HIV. For this reason, the PMTCT/Peds TWG recommends that the following evaluations be implemented by PMTCT programs:

- PMTCT effectiveness evaluations; and
- Mother-infant pair outcomes at the end of the breast-feeding period.

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.

Measuring maternal and infant pair outcomes at 18 months allows program staff to look at mother-infant pairs that may have passed through all or some of the PMTCT cascade and to assess their health outcomes as well as program quality. This evaluation seeks to understand and describe the mother’s outcomes, the infant’s outcomes and whether or not the mother-infant pairs are linkable using national data collection systems and tools. This type of evaluation requires data collection and abstraction from multiple registers and data sources, and provides a snapshot of the entire cascade, which and can provide useful information to program staff to describe successes and challenges along the PMTCT/ART cascade.

6. Transitioning to PMTCT program data for ANC sentinel surveillance: PEPFAR teams are encouraged to support countries that are exploring their readiness to transition 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.

6 Community Engagement in PMTCT

Community-based activities are a critical element of any PMTCT program and provide a platform to improve services across all four prongs of PMTCT. Specifically, evidence supports the use of community-based systems for demand creation, testing of pregnant women, partner testing, support for retention and adherence provided through expert patients, community liaisons, or mentor mothers, and EID services for HIV-exposed infants (28). The role of community members in the provision of HIV services has and will continue to broaden as ART availability is further decentralized and expanded. Community support has expanded from early models of providing home-based patient support to a full range of supportive services, including distribution of ARVs in some countries. Community-based approaches to service provision (including distribution of ARVs between regularly scheduled clinic visits) offers multiple benefits including less travel burden for patients, decongestion of busy clinics, development of close ties and support among the community groups that share drug pick up, and even self-monitoring of adherence by group members – all of which translate to better retention in the PMTCT and treatment cascade and ultimately, better health outcomes. Ensuring that at a minimum all PMTCT clients are referred for assessment by OVC programs providing socio-economic support services, and that OVC programs are engaged to assist in the identification of mothers and children lost to follow up should be priorities in all PEPFAR countries.

Models for community engagement must be tailored to the realities of each country, taking into account the resources, cultural factors, infrastructure, and political support, including the coordinating role and tasks that providers, pharmacies and other facility-based staff must perform to make community distribution work even on a small scale. As more and more tasks are being shared with community groups, countries should closely monitor the workload being required by communities and identify mechanisms to financially support community groups to ensure that these groups are not over-burdened or overwhelmed and that the services being provided are of the highest quality. Once activities are identified and initiated by a community group, countries should support operational research of such activities to ensure that they are effective, efficient, and sustainable. The impact of community interventions on retention and adherence, as well as the usual clinical parameters, should be monitored and evaluated.

Communities should be engaged not only in providing the services needed but also in the decision-making process for new policies, monitoring and evaluation of these policies, and the review committees that provide solutions to problems identified through monitoring efforts. No other group knows the firsthand benefits and challenges of PMTCT services in the same way that communities do. Engaging the community—including deliberate and meaningful engagement of groups representing people living with HIV—in these processes is critical to utilizing the knowledge within a community to better provide the services they need. A small field based
study in Uganda found that the use of a community-based monitoring approach could lead to increased quality and quantity of primary health care provision and there is growing evidence to support engagement of communities in monitoring the provision of HIV services (29). Allowing communities the opportunity to be a part of the solution making process can provide a sense of ownership and responsibility for the members of the community, leading to a more sustainable response. Civil society organizations (CSOs) can also play a supportive role in ensuring that reproductive rights and other human rights are respected. CSOs can help to ensure that key populations in need of PMTCT services (most likely female sex workers and women who inject drugs) are directly linked with the appropriate clinical and community-based services.

Other resources to support community engagement activities include and operational research guidance can be found in sub-section 8 (Additional Resources) of this Section.

7 Cross-cutting, linkages and wraparounds

7.1 Linkages and wraparounds

The WHO recommendation to provide ART to all pregnant and breastfeeding women not only prevents HIV transmission from mother to infant, but if continued for life also maintains the mother’s health, prevents transmission to uninfected partners, and supports prevention of HIV transmission in subsequent pregnancies. Operationally, providing ART to all HIV positive pregnant, postpartum and breastfeeding women presents an opportunity for ART decentralization and integration into primary health care settings, thereby potentially increasing access not only for pregnant women, but also their partners, children, and communities. Incorporating primary prevention strategies, including linkages to VMMC, treatment for serodiscordant couples and family planning into PMTCT programs, will be critical to decreasing incident infections during pregnancy and breastfeeding. Consequently, PEPFAR should work with ministries of health and implementing partners to transition to more integrated MNCH, PMTCT, and ART service delivery approaches.

7.2 Gender

PMTCT programs and outcomes can be improved by assessing and identifying gender norms and inequalities, and targeting interventions to overcome them. PMTCT programs should consider factors such as barriers to women's access to PMTCT services, limited resources, lack of support from partner and family, and child care options, female literary, etc., when designing activities and monitoring outcomes. Understanding societal expectations related to men’s health seeking behavior and involvement in the health of their partners and families, helps to inform strategies to engage men appropriately and effectively. Gender-based violence (GBV), including intimate partner violence (IPV), is a serious issue in many high burden countries and may hinder PMTCT programs, for example, where the experience or fear of violence may affect the ability to disclose or to adhere to treatment. Special care should be taken to address GBV, keeping in mind safety and confidentiality, in PMTCT programs.
Key strategies related to gender and PMTCT within PEPFAR-supported programs include:

- Effectively engaging women’s partners, family members, including co-wives and informal “wives” where they exist, and community support groups in PMTCT programs (e.g., couples testing and counseling, men’s clubs, etc.) at service delivery and community levels. Efforts to promote testing of men and to build their support for their female partners are critical. Such interventions must clearly define desired outcomes when engaging male partners, and should be implemented in a way that does not inadvertently exacerbate existing differences in access or gender inequalities. For example, activities should take care that the burden of getting men into testing and counseling and other health services does not rest solely on women, or that women who do not have a male partner are not negatively affected in terms of accessing services.

- Integrating training and counseling for gender-based violence (GBV) as part of PMTCT, antenatal and maternity services, as well as strengthening referrals/linkages to GBV services. Recently released WHO Clinical and Policy Guidelines: Responding to Intimate Partner Violence and Sexual Violence against Women recommends against universal screening for GBV, but calls for providers to be trained to ask about exposure to intimate partner violence when assessing conditions that may be caused or complicated by the violence and where it may serve as a barrier to optimal care; 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.

Resources on evidence and promising strategies related to gender and PMTCT can be found in sub-section 8 (Additional Resources) of this Section.

7.3 Human Resources for Health

Of 57 countries facing a health workforce crisis (<23 doctors/nurses/midwives per 10,000 people), 31 are in Sub-Saharan Africa (30). Countries and global donors have responded to the shortage of medical doctors by introducing innovative models of HIV care, such as task sharing. Recent studies have shown that appropriate delegation of health care responsibilities of medical doctors to mid-level providers (MLPs) (e.g., registered nurses, midwives, and clinical officers) has been effective in addressing the severe human resource shortages in many African countries, and the Institute of Medicine (IOM) recently identified “task sharing” as an appropriate response to expand health care delivery in low-resource settings (31)(32)(33). Additionally, studies show that nurse-initiated and managed antiretroviral therapy (NIMART) can lead to health outcomes that are comparable to medical doctor-initiated and prescribed HIV treatment in certain settings (34)(35).

As PMTCT services become more decentralized and integrated with ART, a systematic approach to workforce development and task sharing should 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 (see sub-section 8 (Additional Resources) of this Section).

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

7.3.1 **Determination of the workforce necessary for implementing PMTCT (the “Who”)**

- Who is competent and capable of delivering and supporting high quality PMTCT and/or integrated PMTCT/ART services (according to PMTCT Prong and stage services are received along the Continuum of Care)?
- 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 (such as clinical officers, nurses and midwives) and ART administration with lower-level cadres (e.g., Community Health Workers)?
- 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?

7.3.2 **Assuring provider competency and quality (the “How”)**

- How has PMTCT been (or is being planned to be) incorporated into national, institutionally-based provider pre-service and in-service curricula for all providers, including medical doctors?
- 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?

7.3.3 **Strategizing for Staff Deployment (the “Where”)**

- What systems are in place to ensure that the distribution of HRH qualified and authorized to provide/support PMTCT services aligns with population needs for PMTCT? (Does the
country have a workforce deployment data base or Human Resource Information System used in HRH deployment 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 Resources for Health can be found in Section 3.4 – Human Resources for Health.

### 7.4 Male engagement (36)

A substantial number of studies suggest that gender-specific barriers impede women’s ability to adhere to services for PMTCT and HIV treatment and care. Women may need permission from their male partners to travel to access services, including antenatal care, HIV testing, care and treatment, and safe delivery. Some women might not have the autonomy in their households to decide where they give birth, evidence by a recent study from rural Uganda (37). In many societies, not breastfeeding implies that a woman has a HIV positive status, and replacement milk is not affordable to mothers without the financial support of their male partner. The discrimination that can result from straying from social norms and the cost of infant feeding can lead to a significant gap between women’s intentions to protect their children from HIV and the feasibility of a feeding method (38)(39)(40).

However, men often lack the information or understanding of their role in relation to preventing HIV, family planning, and helping their families to access HIV prevention, testing, care and treatment services. Currently, most awareness and implementation efforts related to HIV prevention and care are directed heavily towards women, thereby disregarding the cultural norms that often inform women’s decision-making regarding these issues(41)(42)(43)(44). In qualitative research assessing barriers to male involvement in PMTCT services, men expressed cultural perspectives on gender roles and the belief that PMTCT services are something related only to women as key barriers to their participation (45)(46).

There is evidence that “constructive” male engagement can positively address gender inequality and the impact of such interventions on making women less vulnerable to HIV. When male partners attend ANC with their female partners during pregnancy, and are tested for HIV at the same time, for instance, women are more likely to accept HIV testing (47). There is also a higher uptake of ARV prophylaxis and treatment, and better adherence to the suggested infant feeding option when male partners participate in PMTCT services (48)(49). More generally, an extensive literature review by the WHO (50) highlights benefits of men’s engagement in PMTCT of HIV, barriers to men’s engagement, and promising strategies to involve men, as well as conceptual and methodological issues that merit further consideration and research.

As it relates to PMTCT, constructive male involvement and engagement in PMTCT seeks to:
1. Support women in their decision-making process while upholding their reproductive health rights—not to coerce them into accepting services.

2. Expand access to HIV services for men.

However, there is evidence that if not done adequately, involving men in PMTCT can actually have a negative effect on women’s service utilization. A recent Cochrane Review on the effectiveness of male involvement in PMTCT outcomes (36) found 3,072 references, but only one study that met the inclusion criteria. The study was performed in 2003-2004 in Tanzania. Pregnant women in the intervention group were provided with a letter inviting their male partners to accompany them to their next visit, in which they were offered voluntary HIV counseling and testing (VCT) together or separately. Women in the control group received the VCT individually during their first visit. The proportions of women that received VCT and collected their HIV test results were significantly lower in the intervention group than in the control group. Most of the women in the intervention group did not return to the clinic for the subsequent visit and most of those that returned accompanied refused to receive VCT together with their male partners. The invitation letter had a negative impact on the PMTCT uptake in that setting.

7.4.1 Specific recommendations for PEPFAR Programing

Given the possibility of negative unintended consequences of involving men in PMTCT, teams are encouraged to only include a male involvement component in PMTCT programs when it reflects the recommendations for constructive male engagement outlined in the WHO 2012 document and when programs can ensure that women’s rights will be upheld (http://www.who.int/reproductivehealth/publications/rtis/9789241503679/en/index.html). In addition, teams have a responsibility to monitor the quality of PMTCT services, including unintended negative consequences using both quantitative and qualitative methodologies.

The following interventions are highly discouraged:

- Making the presence of a male partner a pre-requisite for women accessing PMTCT services;
- Programs where a letter targeting male partners is the only intervention in a PMTCT program seeking to involve men; and
- Giving preference to women who attend PMTCT services with their male partners should not be supported as a stand-alone approach given potential for unintended negative consequences that women may face; however this may be considered when implemented as part of a holistic approach to male engagement in PMTCT programming.

8 Additional Resources

Primary prevention of HIV:
WHO 2013 on the “Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection”:

WHO 2010 on quality assurance and HTC services “A Handbook for Improving HIV Testing and Counseling Services”:

WHO 2010 recommendations on “Delivering HIV test results and messages for re-testing and counseling in adults”: www.who.int/hiv/pub/vct/hiv_re_testing/en/index.html


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

TB prevention and TB/HIV co-infection:

WHO policy on collaborative TB/HIV activities: guidelines for national programmes and other stakeholders:

Guidelines for intensified tuberculosis case-finding and IPT for people living with HIV in resource constrained settings:

Supporting community engagement:


Gender:

Male Involvement in the Prevention of Mother-to-Child Transmission of HIV:
• Program Guide for Integrating GBV Prevention and Response in PEPFAR Programs: www.aidstar-one.com/focus_areas/gender/resources/pepfar_gbv_program_guide

Human Resources for Health:

• Task Shifting: Global Recommendations and Guidelines: http://www.who.int/healthsystems/TTR-TaskShifting.pdf
1.2 Prevention of Sexually Transmitted HIV Infections

1 Introduction

1.1 What’s New in 2014

Updates on Key Populations and Youth: This year’s Technical Considerations for preventing sexually transmitted HIV includes updated information on prevention packages for all key populations, including transgender persons, as well as enhancements to the sub-section on youth prevention.

New and Improved Indicators: PEPFAR’s forthcoming Monitoring, Evaluation and Reporting (MER) Guidance includes revised indicators for measuring prevention interventions, as well as new disaggregations for many existing indicators that will increase the information available for tracking service uptake by populations of interest.

Implementation Tool for WHO Sex Worker Guidance: WHO has released a new implementation tool to accompany its guidance on programs for sex workers.

1.2 PEPFAR Blueprint

PEPFAR’s Blueprint highlights prevention of sexually transmitted HIV in three of its roadmaps:

- **Roadmap for Saving Lives:**
  - Increase access to, and uptake of, HIV testing and counseling, condoms and other evidence-based, appropriately-targeted prevention interventions;

- **Roadmap for Smart Investments:**
  - Increase access to, and uptake of, HIV services by key populations;
  - Strengthen PEPFAR’s continued focus on women, girls and gender equality; and
  - Strengthen programmatic commitment to and emphasis on reaching and supporting young people with HIV services.

- **Road Map for Driving Results with Science:**
  - Evaluate the efficacy of optimized combination prevention; and
  - Support innovative research to develop new technologies for prevention (e.g., microbicides, vaccines).

1.3 Technical Background

To achieve the vision of an AIDS-free generation, we must accelerate and improve our efforts to prevent the sexual transmission of HIV. This means reaching more people with interventions that help them reduce their risk of acquiring and transmitting the virus. 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 antiretroviral therapy (ART). Importantly, it also means
supporting an enabling environment for these interventions by 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 combination prevention technical guidance on HIV programs for men who have sex with men (MSM) and people who inject drugs (PWID) (available at: http://www.pepfar.gov/reports/guidance/combinationprevention/index.htm)—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.

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 to reduce new infections, morbidity and mortality. Critical to building an effective portfolio of HIV prevention interventions is collecting and using accurate and comprehensive information about the epidemic, the current response, the context, and the costs. The collection and analysis of data relating to these “Four Knows” should be a foundation of all PEPFAR prevention programs. Critical components of the “Four Knows” are summarized below; a full description can be found in the PEPFAR Guidance for the Prevention of Sexually Transmitted HIV Infections (http://www.pepfar.gov/documents/organization/171303.pdf).

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, key populations (KP) and the major epidemic drivers are critical to forging an effective prevention response.

2. **Know Your Context**: Data on a) factors shaping the environment of HIV transmission, such as laws requiring the death penalty for same-sex activity; b) socio-cultural factors shaping behaviors, attitudes, and norms towards health, disease, sex, gender, and other HIV-related issues, as well as perceptions of HIV services; and c) patterns of population movement.

3. **Know Your Response**: Data on the geographic distribution and population coverage of all prevention activities funded by PEPFAR, partner governments, and other donors. Data should also provide information on the dose of prevention interventions; fidelity to an original evidence-based and context-appropriate model; and consider accessibility and availability of interventions, services, and commodities.
4. **Know Your Costs**: Data on costs of programs (e.g., results of expenditure analysis and targeted costing exercises).

3. **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. In identifying priority populations for programs to target, it is essential to validate data on risky behaviors with data confirming elevated HIV prevalence;

- **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 (see also the PEPFAR Guidance on Prevention of Sexually Transmitted HIV Infections (p. 51) for several examples of how PEPFAR country teams might consider the relative importance of each core intervention depending upon the type of HIV epidemic in the country);

- **Employing effective program models for social and behavior change**: all interventions require certain behaviors in order to be successful. From seeking out HIV testing and counseling, to acquiring and using condoms correctly and consistently, to adhering to a drug regimen, HIV prevention efforts rely on effective behavioral programs. PEPFAR implementing partners should use evidence-based models and directly monitor their impact on indicators of service uptake and utilization and changes in risk behaviors and biological markers;

- **Supporting a coordinated and sustainable national response**: this means coordinating and harmonizing prevention efforts, including those supported by PEPFAR, national governments and other donors. It also means establishing clear processes and mechanisms to ensure the appropriate integration of prevention programming into care, support, and treatment initiatives, and to reinforce key messages relating to care, support and treatment within prevention programming; and

- **Establishing quality assurance standards, monitoring, and evaluation mechanisms**: to remain effective, HIV prevention programs need to be consistently monitored and evaluated. Implementing partners will be primarily responsible for day-to-day monitoring and reporting, but external quality assurance is critical to ensure the fidelity of programs to the original model.

4. **Addressing the needs of key populations across all epidemic types**

Key populations (KP) are persons who are affected by punitive laws, regulations and policies, are stigmatized and marginalized, and are disproportionately affected by HIV. This includes men who have sex with men (MSM), transgender persons (TG), sex workers (SW), and people who
infect drugs (PWID). 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, care and treatment services. This section provides recommendations with a focus on designing HIV prevention packages for MSM, TG and SW (see also the PEPFAR Guidance on Prevention of Sexually Transmitted HIV Infections (p. 51) for several examples of how PEPFAR country teams might consider the relative importance of each core intervention in concentrated epidemics). Technical considerations for epidemics among PWID can be found in section sub-section 3 (Injecting Drug Use) of Section 1.3 of the Technical Considerations (Biomedical Prevention).

4.1 Sex Workers (SW)

In countries all around the world, women, men, and transgender persons engage in sex work and are at high risk for HIV acquisition and transmission. A meta-analysis demonstrated that in fifty low and middle-income countries, the aggregate HIV prevalence among SW was over 12% (51). In countries with medium and high background HIV prevalence, SW were 11.6 times more likely to be HIV infected than women in the general population (51).

Because individuals sell sex in all PEPFAR countries, culturally relevant, appropriate programs for SW should be included as a key part of HIV 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 “shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides”.

Services for SW should be comprehensive, including all the components listed in sub-section 6.1 (Prevention Packages for Key Populations) of this Section. For additional guidance, programs should reference the WHO guidelines: Prevention and treatment of HIV and other sexually transmitted infections for sex workers in low- and middle-income countries (http://www.who.int/hiv/pub/guidelines/sex_worker/en/index.html) as well as the implementation tool for this guidance (http://www.who.int/hiv/pub/sti/sex_worker_implementation/en/).

4.2 Men Who Have Sex with Men (MSM)

The UNAIDS Action Framework uses the term ‘men who have sex with men’ to describe males who have sex with other males, regardless of whether or not they have sex with women or have a personal or social identity associated with that behavior, such as being ‘gay’ or ‘bisexual’. MSM experience higher rates of HIV infection than the general population in all regions of the world. 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 (52). Despite the disproportionate HIV disease burden, low coverage of even the most basic prevention services exists globally (53).

PEPFAR, UN Agencies, 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. These international efforts have concluded that reducing HIV 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 and other supportive interventions that support the human rights of MSM, improve the ability of MSM to mobilize and strengthen communities in safe spaces to access HIV care and treatment and enhance HIV prevention. 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).

4.3 Transgender persons (TG)

In using the term ‘transgender persons,’ we refer primarily to transgender people whose assigned birth sex was male, but who now identify as female or who now exhibit a range of what are usually deemed female characteristics. Multiple studies have found elevated HIV prevalence among ‘male-to-female’ transgender people (also known as TG women) whereas the same has not been demonstrated for ‘female-to-male’ transgender people. The limited data available demonstrates pervasive stigma, discrimination, violence, and other HIV risks among TG populations. Excluded from other forms of income generation by stigma and discrimination, many TG women engage in sex work, thereby increasing their risk for HIV acquisition and transmission. A 2012 systematic review and meta-analysis demonstrated a global HIV prevalence of 19% among TG women. In addition, it found that TG women have a staggering 48.8 times the odds of HIV infection compared to the general population. 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 services and research.

To understand and better respond to HIV among transgender people, the following actions are recommended:

- Conduct sound 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 of implementing prevention and response strategies for TGs; and
• Identify and respond to programming considerations that are relevant for segments of TGs at highest risk (e.g., sex work, drug use).

4.4 Measuring the epidemic and setting data-driven priorities for KP programs

While PEPFAR support for biologic-behavioral surveillance among KP has been increasing, many countries continue to lack, and moreover, under-utilize, size estimation and biologic-behavioral data on key populations. Establishing the size and risk factors of key populations allows epidemiologists to develop models with which to estimate and project HIV prevalence or inform countries of the distribution of HIV incidence within their country, garner political and financial support, and improve program coverage and quality. Arguments to implement prevention, care and treatment programs are more compelling when good population size estimates are available. However, lack of such studies should not delay start up or provision of key populations services. With limited resources, choices between data collection and programming should be balanced. 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 countries where HIV is concentrated in these populations. In hostile environments, safety of KP must be respected and ensured in all programming and research.

A strong link between epidemiologic, behavioral and socio-cultural data and prevention activities is necessary 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, size estimates should 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.

4.5 Creating an enabling environment

KP often engage in behaviors that are criminalized and highly stigmatized, creating barriers to initiation and retention in HIV prevention, care and treatment services. PEPFAR country teams need to be aware of the potential for political backlash against KP and KP-friendly programs and research, and work closely with government, civil society, and the affected population to create an enabling environment for ethical treatment of KP. This includes encouraging a national response supported by the Ministry of Health, other relevant Ministries and agencies, the National AIDS Control Program, and civil society stakeholders to address the complex issues of
providing rights-based prevention services to these populations. PEPFAR teams should encourage countries to take steps to ensure that scale-up of prevention programs for KP is accompanied by appropriate protections of their rights through, for example, reviews of laws, policies and regulations that criminalize or deter KP from seeking services and by training service providers to reduce stigma and discrimination.

4.6 Developing capacity within countries

Many countries lack the capacity and resources to provide effective programming for KP and other vulnerable populations (see sub-section 5 (Planning a Portfolio: Generalized Epidemics) of this Section for details on distinctions between KP and other vulnerable populations). PEPFAR prevention staff should ensure availability of coordinated technical assistance, both from headquarters and south-to-south, to help develop the appropriate range of technical skills within countries to design, implement, evaluate, and improve prevention programs for KP and other vulnerable populations. PEPFAR teams should support countries to:

- 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 KP 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 KP, and to advocate for continued funding of HIV prevention for KP.

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

While many countries have small-scale targeted KP 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 KP to ensure adequate coverage, intensity, and scale to impact the HIV epidemic. PEPFAR teams should support countries to:

- Define interventions or package of interventions that could be taken to scale for each key population and potential partners to leverage funding (i.e., Global Fund);
- Aim for service integration, co-location, and if necessary, KP-specific sites. This means, ideally providers are cross-trained to provide multiple services at a single visit. 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, collaborating with other donors on indicators required by their programs so as to reduce the reporting burden.

5 Planning a Portfolio: Generalized Epidemics

In epidemics where transmission is not restricted to key populations, HIV prevention interventions will need to address other populations with high prevalence as well as broader community norms and practices that shape risky and protective behaviors. Ultimately, successful prevention portfolios in these generalized epidemics must maximize their contribution to reducing HIV incidence at the population-level. Recent studies point to tremendous heterogeneity in the distribution of HIV prevalence at the sub-national and community level(54). Given limited resources relative to need in these settings, PEPFAR programs should focus on those geographic regions and localities where the most transmission is occurring, taking into consideration regional and sub-regional levels and trends in HIV prevalence, as well as the population size of the different regions and sub-regions.

In order to maximize impact on HIV incidence within these geographic areas of focus, PEPFAR country teams will also need to balance approaches that address the needs of different vulnerable populations with elevated HIV prevalence with those of key populations. These other vulnerable populations (OVP) within generalized epidemics will vary in each context and may include transport workers, miners, fishing communities, commercial farm and plantation workers, and day laborers, among others. Typically, in the highest prevalence epidemics, young women in their twenties are also a broad demographic group who are highly vulnerable to HIV acquisition. The appropriate balance of programming across these populations will vary with the local epidemiology. Addressing the broader underlying community, socio-cultural and structural factors that increase risk and vulnerability will also be important to achieving sustained change.

5.1 Country contextual considerations

5.1.1 Partner country and other donor funding

In developing a strategic prevention portfolio, the country team should consider 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.

5.1.2 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.
5.1.3 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.

5.1.4 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 as young people eventually transition to adulthood. But youth should not absorb so much of the prevention investment that at-risk adult populations are left underserved. The youth-adult balance should reflect age-specific HIV incidence patterns at the country-level, or where not available, age-specific HIV prevalence patterns.

5.2 Programming for social and behavior change (SBC)

Addressing human behavior is integral to every dimension of the HIV 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 (55).

The 2011 PEPFAR Guidance for the Prevention of Sexually Transmitted HIV Infections recognizes two desirable sets of outcomes of social and behavior change (SBC) programming. The first is minimized risk or increased protection; the second is increased acceptability, demand for, and uptake of proven, high impact biomedical interventions. PEPFAR SBC programs should not address either of these outcomes in isolation. Prevention programs need to address both sets of outcomes, as part of a comprehensive approach that:

- Helps communities understand their risk of HIV;
- Mobilizes them to adopt behaviors that reduce their risk and to use products and services that prevent HIV acquisition and transmission; and
- Supports changes in social and gender norms through approaches that focus collectively on communities to ensure long-term sustainability of HIV prevention efforts.
Condoms remain a key tool for HIV prevention. Increased promotion of and access to condoms should be a core component of sexual prevention programming.

SBC programs should incorporate the following best practices:

- **Support biomedical interventions relevant to the population and setting.** While promoting risk reduction, SBC programs need to increase acceptability of and create demand for HTC, VMMC, and PMTCT and care and treatment programs. Such linked SBC 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(56). Understanding how to address and measure these factors, or behavioral determinants, is the key to effective SBC;

- **Link activities to clear behavior change objectives.** Focusing solely on knowledge or HIV awareness is insufficient. Activities should be selected based on behavioral determinants to provide individuals with the relevant motivation, attitudes, and skills needed to overcome barriers and adopt safer behaviors and increase uptake of clinical services;

- **Address social and gender norms.** SBC programs should address gender norms and inequities as well as 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 improve educational opportunities and to make school environments safer for girls; and advocacy to increase property and other legal rights and create economic opportunities for women. Additional data to understand the links between these interventions and impact on HIV transmission are still needed (for more information, see (57));
• **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 that informs program design.

6 **Comprehensive HIV Prevention Packages**

Robust HIV prevention programs deliver a minimum package of interventions for individuals or communities at high risk. 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. PEPFAR programs should be providing comprehensive prevention packages for three types of populations: key populations in all epidemics; other adult populations with high rates of HIV prevalence; and at-risk adolescents.

6.1 **Prevention Packages for Key Populations**

There is substantial evidence for the effectiveness of a core set of interventions that comprise a package of services for KP. Programs should ensure participation of the target KP 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, including access to family planning for females.

6.1.1 **Peer education and outreach**

Peer outreach relies on local community members to reach key 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 (58)(59)(60).

6.1.2 **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 KP, 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 (60); however, the effect may decrease over time (61), indicating that these behaviors may need to be more intensively targeted and may require booster sessions.

6.1.3 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 TG. The use of condom-compatible lubricant (water- and silicon-based lubricant) has been associated with a decreased risk of condoms breaking. However, lubricant use on its own is not a proven method of HIV or STI prevention. Please see sub-section 6.3 (Male and female condoms and lubricants for HIV prevention) of this Section for more details on appropriate lubricant procurement.

6.1.4 HIV testing and counseling (HTC)

Programs should provide HIV testing and counseling services that are trusted by and accessible to KP. HTC services must respect the basic tenets of self-determination, privacy, and informed decision-making. Mandatory or coerced testing is never appropriate. This is a particularly important issue for sex workers, who in some settings may face coercion to be tested from brothel owners, clients, or as part of the registration process for a sex worker program. HTC services should be provided with the fewest possible restrictions or requirements. Gender assessments and analyses can identify important gender-related barriers to service access and uptake for KP. Testing hours and days of week need to be adjusted to respond to the needs of KP and delivery sites should vary depending on the expressed preferences of the population:

- Mobile community outreach;
- Health facilities;
- Safe spaces (drop-in centers);
- Bars, clubs and brothels; and
- Homes or households.

Special consideration should be given to different testing models including provider-initiated and couples and partner testing. Use of rapid test kits with same-day results paired with post-test counseling is strongly recommended for KP. Finger-prick blood sample is the preferred collection method. Venous blood draws should be avoided as a potential access barrier due to concern for vein collapse and intravenous drug use disclosure to HTC provider. Re-testing should be done annually, or more frequently depending on risk. Quality control checks, such as proficiency testing should be routinized and quality standards put in place to monitor quality counseling. See Section 1.4 of the Technical Considerations (HIV Testing and Counseling) for more general technical considerations for HTC.
6.1.5 Sexually Transmitted Infections (STI) screening and treatment

Existence of an STI may facilitate sexual transmission and acquisition of HIV (62). Routine STI assessment and treatment should be an integral component of a KP package of services. Approaches to STI control for KP (especially for SW, MSM and TG) 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. Free and KP-friendly STI services are also useful in attracting KP into services/programs, providing an opportunity to reach KP by providing a more holistic sexual health approach. Programs should consider integrating STI screening and treatment into HIV care settings and into existing prevention programs for KP and other vulnerable populations according to PEPFAR Guidance on diagnosis and treatment of STIs (63).

6.1.6 Referral to male circumcision

VMMC is an effective 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 in countries where VMMC is being scaled up. To date, evidence for VMMC in reducing the risk of HIV acquisition among MSM is inconclusive (64). WHO does not recommend circumcision as an HIV prevention measure for MSM. See sub-section 4 (Voluntary Medical Male Circumcision) of Section 1.3 of the Technical Considerations (Biomedical Prevention) for more general technical considerations for VMMC.

6.1.7 Direct service delivery or referral to HIV care and treatment, including PMTCT

PEPFAR teams should continue to support Ministries of Health, national HIV/AIDS control programs, and other stakeholders to adopt the new WHO guidelines in a phased approach and to ensure that programs include a focus on key populations where appropriate (http://apps.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf). KP should be rapidly linked to friendly care and ART services upon diagnosis, and KP programs should include support for adherence and retention designed around the needs of these populations. Innovative approaches to increasing successful linkage into PMTCT, care and treatment services should be explored and evaluated. Prevention programs for KP need to link with clinical services including PMTCT, care, and antiretroviral treatment. Healthcare workers who provide these services should be trained to make existing services more accessible and appropriate for KP. All KP programs need to ensure adequate monitoring of linkages to services. Programs should consider the use of internet-based and mobile technologies to support adherence. A Cochrane review found short weekly mobile phone text messaging efficacious in enhancing adherence to ART in patients with HIV infection in Kenya (65) among heterosexuals. Such strategies may also serve to improve ART adherence and continued engagement in other services among KP.
6.1.8 Direct service delivery or referral to substance use treatment for MSM, TG, and SW who use drugs

Substance use treatment reduces the frequency of drug use, which in turn reduces HIV risk behaviors (66). It also improves adherence to disease treatment regimens (66). Treatment modalities include non-pharmacological and pharmacological approaches; often, a combination of the two is used (67). See sub-section 3 (Injecting Drug Use) of Section 1.3 of the Technical Considerations (Biomedical Prevention) for more information on treatment for injecting drug use.

6.1.9 Prevention, diagnosis and treatment of tuberculosis

Drug use is associated with increased rates of TB infection and disease, and TB is a leading cause of mortality among PLHIV. MSM, TG, and SW may also experience exposure to the disease due to incarceration, poor living conditions and poverty. Services for prevention and treatment of TB should be friendly and accessible to KP. See Section 2.4 of the Technical Considerations (TB/HIV) for more general considerations on TB.

6.1.10 Linkages to other health, social, and legal services

KP should be provided with or referred to other health services including family planning, primary health care as well as psychosocial and legal support. SW, PWID, MSM, and TG are among the most vulnerable to gender-based violence (GBV) and usually face stigma, discrimination, and violence perpetrated by health care workers and law enforcement officials (68) (69) (70). Effective linkage to user-friendly post-exposure prophylaxis (PEP) and post-rape care is especially important for KP due to higher risk of HIV exposure as well as high rates of violence against these populations. Strong programs will ensure health care workers and counselors are trained to identify and respond to harmful gender norms that may create or increase barriers to service uptake for KP, as well as increase their vulnerability to violence. Programs should also establish effective referral and coordination mechanisms to GBV services designed specifically for KP.

Service delivery models (e.g., mobile versus stationary sites, hours of operations, type of health service provider) for these core prevention interventions may need to be adapted to reach, engage and retain KP. The PEPFAR 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 formative research, including qualitative methods, to guide these adaptations is an effective strategy. Referrals alone are not enough; mechanisms should be put in place to document successful linkages. Data collection and surveillance reporting that includes indicators for KP will assist countries in monitoring KP engagement in the HIV care and treatment continuum. Identifying gaps in the continuum can provide critical information for focusing limited prevention resources.
6.1.11 Programmatic piloting and implementation science of new prevention advances within key populations

Several observational studies have suggested that provision of ART to HIV-infected persons has prevention benefits (71)(72). The 2011 HPTN 052 trial demonstrated a 96% reduction in infections among HIV-negative heterosexual partners in sero-discordant relationships when the HIV-positive partner was provided ART at CD4 counts between 350 and 550 cells/mm$^3$ (17).

While WHO guidelines have not reviewed the prevention effect of ART on KP, it is feasible that ART could significantly reduce the risk of HIV transmission for KP as well. PEPFAR teams are encouraged to report and disseminate lessons learned and best practices on operational issues such the acceptability and impact of HIV treatment in same-sex relationships or among populations who use injecting drugs.

PEPFAR teams may consider projects to evaluate the feasibility and effectiveness of such approaches among KP, keeping in mind the WHO guidelines that prioritize access to ART for the sickest first.

6.2 Prevention Packages for the General Population

6.2.1 Programming and prevention packages for adults at high risk

In epidemics where HIV has diffused beyond key populations, effective prevention portfolios should primarily focus on those sub-sets of the general population that have been demonstrated to be at increased risk of HIV acquisition and transmission. Programs should be tailored to the specific needs of each sub-population. For example, while migrant workers are typically at risk, the specific needs of migrant mine workers will be different than those of migrant day laborers. In order to be successful, the prevention package approach should be complemented by activities that mobilize communities (73) to address community-level and socio-cultural norms. Addressing these and other structural-level issues will be critical for sustained HIV incidence reductions at the population-level (74).

Every comprehensive prevention package for these populations should include at a minimum the following components:

- Targeted interventions to address the sexual risk behaviors and health-seeking behaviors that mediate individuals’ HIV risks. Effective prevention programs help individuals more accurately assess their risk, and increase their motivation, intentions and skills to protect themselves against HIV acquisition (75);
  - Where sero-discordant relationships are common, interventions should also include efforts to increase risk perception about sero-discordance within long-term stable couples; and
Where transactional sex is common, interventions should also include efforts to increase risk perception about the exchange of sex for goods or services; implementing partners might also consider activities that address the underlying economic drivers of transactional sex (see sub-section 6.2.3 (Reducing vulnerability among Adolescent Girls and Young Women in Generalized Epidemics) of the Section for more information).

- Promotion and, where appropriate, provision of condoms (see sub-section 6.1.3 (Condom and condom-compatible lubricant promotion and distribution) of this Section);
- Provision of or direct referral to HIV testing and counseling (see Section 1.4 of the Technical Considerations (HIV Testing and Counseling) for more information) with a formal system for linking HIV positive clients to care and HIV negative clients to VMMC or other appropriate prevention services; and
- Programs that promote the acceptability and uptake of voluntary medical male circumcision (see sub-section 4 (Voluntary Medical Male Circumcision) of Section 1.3 of the Technical Considerations (Biomedical Prevention) for more information), prevention of mother-to-child-transmission (see Section 1.1 of the Technical Considerations (Prevention of Mother to Child Transmission)), voluntary family planning, antiretroviral treatment (see Section 3.10 of the Technical Considerations (HIV and Family Planning Integration)) and TB testing and treatment (see Section 2.4 of the Technical Considerations (TB/HIV)). These programs should provide and track the success of referrals.

In general, KP-specific interventions such as drug use assessment, provision of lubricants, STI screening and treatment, and referrals to substance abuse treatment will not be appropriate for the general population. PEPFAR teams should be guided by the epidemiology and context of their epidemic in choosing which components to include.

Critical steps in the development and delivery of prevention packages for subgroups within the general population include:

- Identify groups with high prevalence through population-based surveys that include HIV testing and integrated biologic-behavioral surveys of populations of interest;
- Gather data on and estimate the size of each population to be reached and set targets with a goal of reaching sufficient coverage to impact incidence;
- Carry out formative research to better understand the specific risks and vulnerabilities that interventions for each population need to address;
- 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, retention;
- Track coverage over time;
• Identify areas where technical assistance is needed either to improve quality or increase coverage; and
• Explore new delivery approaches that effectively reach persons not currently accessing services.

Beyond scaling up these packages for particular risk groups, programs should also seek to foster culturally appropriate and positive socio-cultural and gender norms and beliefs. Working with communities—especially with traditional leadership—to proactively challenge norms that support and encourage gender-based violence, high numbers of sexual partners, concurrent partnerships, inter-generational sex, and refusal to use condoms can help to create the enabling environment within which comprehensive packages can succeed. Community-based prevention programs should also combat stigma and the effects of stigma on HIV risk behaviors. Given the weak evidence base, all community interventions need to include a strong monitoring and evaluation component.

Best practice media interventions can also reinforce other prevention approaches. The strongest effects of media have been on condom use and knowledge of modes of HIV transmission. However, media interventions have also demonstrated success in reducing high risk behaviors and improving risk perception, self efficacy to negotiate condom use, interpersonal communication about HIV prevention behaviors, and uptake of HIV testing. Increased exposure to media usually results in stronger behavioral effects. Evaluations suggest media campaigns are most effective when implemented through multiple channels with messages closely coordinated with individual and community-level interventions. Mass media interventions that achieve significant impact while achieving broad coverage tend to be highly cost-effective, and can be scaled up more rapidly than other interventions. Although the evidence for media interventions is mixed, many older programs that had little or no effect did not reflect current best practice and had weak evaluation designs (76)(77). All mass media interventions should include a monitoring and evaluation component to measure impact.

6.2.2 Programming and prevention packages for youth in generalized epidemics

Prevention programs for young people, especially for adolescents who have not yet become sexually active, represent an opportunity to reverse highly diffused epidemics and achieve an “AIDS-Free generation.” In sub-Saharan Africa, many countries with large HIV epidemics have especially youthful populations, with more than 50% of the citizenry under the age of 18. Moreover, population trends across this region suggest continued growth of this cohort over the next 30 years (78). 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.
The definition of “youth” remains a challenge, since it can range from 15 to 34 years, depending on the country. PEPFAR teams should use (and explain) country-specific definitions of youth where they are appropriate, but resist pressure to provide youth programs to what are clearly adult populations. Just as with adults, prevention programs should be designed to take into account the significant sub-population differences and needs between various age groups within the youth category. Not all youth are at equal risk, and not all at-risk youth will be effectively reached by the same interventions.

The following recommendations are made with a caveat: better data on the impact of HIV prevention programs for youth is needed. PEPFAR teams should consider funding impact evaluations through the COP of their youth programs.

6.2.2.1 Components of a package for youth

Components of a package for youth in the general population in high prevalence countries should include:

- **Skills-based HIV prevention curricula:** All young people need broad education about sex, sexuality and reproductive health, as well as education about HIV and AIDS and the skills to practice safer behaviors. Well-designed and well-implemented, adult-led curriculum-based programs have been demonstrated to change young people’s behaviors (79). Curriculum-based programs can help delay sexual activity, and help make young people’s eventual transition to sexual activity safer and healthier. For young people who are sexually active, these programs can provide risk reduction information and skills, including information and skills relating to correct and consistent condom use, access to condoms. For young women and girls, these programs can also increase self-esteem and agency (80);

- **Provision of, or referral to, confidential, youth-friendly HTC,** including active linkage to care and other appropriate services for both HIV positive and negative clients. For sexually active young people, this may include referrals to clinics providing gender-sensitive and comprehensive reproductive health care, or provision of HTC within these clinics; and

- **Youth-oriented mass and social media:** Young people are consumers of and heavily influenced by media. Several recent systematic reviews of the effectiveness of mass media communication on HIV-related behaviors have demonstrated a positive impact both on knowledge and on high-risk sexual behavior (77)(55). For example, the Betrand study showed that mass media interventions targeting youth were associated with increased knowledge of HIV transmission, improved self-efficacy in condom use, positive changes in certain social norms, increased interpersonal communication about HIV, increased condom use, and increased awareness of health providers. However, not all mass media programs are equally effective; a recent assessment of a long-standing mass media program targeting youth in South Africa found little impact on self-reported
behavior (81). Consistent targeted HIV communication programs in South Africa appear to have had a direct effect on behavioral outcomes such as uptake of HIV counseling and testing, condom use, and male circumcision. The South African National Communication Survey (82), found that condom use at first sex began to increase consistently after 1995, when large-scale HIV communication programs promoting the use of condoms to prevent HIV first began. The survey also reported that people who were exposed to HIV communication were more likely to test for HIV, and that all impacts followed a dose-response curve; the more an individual is exposed to HIV communication programs, the more likely he or she is to adopt and maintain preventive behaviors. The consensus, however, is that media are most effective when used to reinforce prevention messages from more targeted interpersonal interventions. See the PEPFAR Guidance for the Prevention of Sexually Transmitted HIV Infections for more information (http://www.pepfar.gov/documents/organization/171303.pdf).

### 6.2.2.2 School-based versus community-based programs

Schools provide a unique opportunity to easily reach large numbers of young people. Where a large proportion of the youth population is enrolled in secondary school, as in some countries in Southern Africa, PEPFAR teams should consider support to Ministries or Departments of Education and Health to strengthen the delivery of high quality, curriculum-based HIV prevention education at the secondary level. Wherever feasible, school systems should adapt curricula and materials that have proven effective in changing youth behaviors in similar settings (83)(84). Specific attention should be given to improving teacher training to ensure high-quality implementation and completion of curricula.

In countries where many young people do not continue on to secondary school, school-based prevention efforts should focus on the later grades of primary school. In these settings, PEPFAR teams should also consider working with communities, faith-based organizations and traditional leaders to reduce young people’s exposure to risk and increase protection. High quality, curriculum-based prevention programs for youth that include peer outreach have been shown to be effective in changing behaviors at the community-level. These models represent an approach to reaching out-of-school youth, especially young women and adolescent girls. Ensuring the quality of these efforts is key.

### 6.2.2.3 Creating a supportive social environment

Engaging influential adults within the community is often critical to creating the enabling environment necessary for the success of youth prevention programs. These adults may be traditional leaders, religious leaders, teachers, parents and healthcare providers. All have a stake in young people, and in the community values that aim to shape their sexual behavior. Programs aimed at young people should seek to engage community leaders as well as young people in the development, implementation and evaluation of programs. At the same time, planners need to take into account the stigma against HIV and cultural disapproval of sexual activity among youth.
(common among many adults), striking a balance between obtaining buy-in from these adults and providing critical services for young people.

### 6.2.2.4 Prevention programs targeting parents

Interventions with parents and guardians of pre-risk youth can help improve their connectedness and communication to youth about values and expectations regarding adolescent behavior, as well as monitoring and supervision of their adolescents (85). However, there is not yet evidence that these programs reduce HIV acquisition, and these programs may not consistently reduce risky behavior among adolescents.

### 6.2.2.5 Especially vulnerable young people

For the most vulnerable youth, such as orphaned youth, street children, and domestic workers who lack parental protection, more comprehensive programs are needed that not only promote risk reduction, but also seek to reduce vulnerability, mitigate harmful outcomes, and provide young people with second chances (86).

### 6.2.3 Reducing vulnerability among Adolescent Girls and Young Women in Generalized Epidemics

In Southern and East Africa, incidence rises steeply among young women aged 15–24 years, and prevalence in this population is on average three times higher than among men of the same age (UNAIDS 2010). This disparity may arise from systematic disadvantages faced by adolescent girls and young women, as well as from cultural expectations and pressures around proving fertility (87) and relying on sex as a means to address economic wants and needs (88). Transactional sex—the exchange of sex primarily motivated by material gain (i.e., the provision of food, clothes, cash, etc.)—may be common in this population and is also associated with increased risk of contracting and transmitting HIV (89)(90). 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 spread of HIV and other STIs when the sexual relationships involve chains of interconnected partners.

In countries where women aged 15 to 24 are at very high risk, PEPFAR programs should supplement the risk reduction approaches described in the preceding section by working with governments, other development partners and civil society stakeholders to reduce the vulnerability of adolescent girls and young women. Staff working on orphans and vulnerable children (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. In particular, given the robust literature on the protective role of school reducing girls’ risk of acquiring HIV (91), PEPFAR teams should advocate for education-sector investments that expand schooling opportunities for girls and help them to stay in school (92).
Other approaches that address both impact mitigation for OVC as well as HIV prevention include programs that build social support and social capital within groups of girls, as well as programs that support positive youth development through peer networks and mentorship programs (93).

Programs that address economic vulnerability can also support HIV prevention for girls and young women. Evidence is emerging that altering the economic condition of young women can have an impact on HIV incidence, though the causal pathways are complex and not completely understood (94). A study in Malawi found that a cash transfer program could reduce HIV and HSV-2 infections in adolescent schoolgirls (95), though the statistical analysis within that study has been criticized (94). A recently released study on cash transfers in Lesotho found that HIV incidence was significantly lower among those who participated in a lottery scheme compared to a control group (96).

PEPFAR country teams should consider the many influences on economic drivers, including individual-level characteristics such as agency, household-level factors such as parental influence, and the influence of social networks and peers (97)(98)(99). Interventions for economic strengthening or empowerment have a complex relationship to risk factors for HIV transmission; it is important to avoid interventions that may exacerbate risks or create new risks for the target population. Unfortunately, this has been the experience with credit-led microfinance (microcredit) (100) and typical approaches to income-generating (microenterprise) (101).

Interventions that build assets, resilience and future-oriented behaviors, such as savings-led microfinance (micro-savings) (102) and matched savings schemes (especially when linked with education) (103), show some promise in addressing economic drivers. For example, matched savings schemes linked to education have reduced intentions to engage in sexual risk taking (103). Other promising approaches include integrating economic incentives with other complementary and relevant interventions, such as combining savings groups with discussion modules on gender-based violence (GBV) (104). Additionally, both conditional and unconditional cash transfers have emerging evidence of effectiveness for prevention-related outcomes (94)(105)(106).

GBV also plays an important role in the vulnerability of girls and young women to HIV infection (107). Not only does sexual assault pose a risk of HIV infection, the threat of violence often prevents girls and young women from successfully negotiating condom use (108) and data suggests that violent men have higher rates of HIV infection, putting their sexual partners at greater risk (109)(110). Programs that directly address GBV and gender norms have had some limited success in reducing rates of GBV, though not on HIV incidence (111). PEPFAR-funded programs targeting adolescents and young women should include components addressing GBV. Likewise, PEPFAR-funded programs targeting GBV in countries where girls and young women are at high risk of HIV should include GBV prevention and care components aimed at girls and
young women. In both cases, programs should include a particular focus on increasing risk perception with respect to violent partners. Strong programs will support age-specific services, protocols, and counseling for post-rape care, reproductive health, and HIV care and support, and linkages to child protective services should be established for child and adolescent survivors of GBV. Additional resources on the clinical management of children and adolescents who have experienced sexual violence, as well as PEPFAR’s GBV Program Guide are available at the end of this section.

Another complex factor in girls’ and young women’s HIV risk is early marriage, also called child marriage. In some contexts, early marriage appears to increase risk (112)(113)(114), in others to have no effect (115)(116). When considering marriage as a risk for girls and young women, PEPFAR teams should carefully review existing data; the domestic violence module of the Demographic and Health Survey collects data on marriage and violence that can be triangulated against HIV prevalence data to determine if a relationship between the two exists (113). Programs that effectively reduce rates of early marriage at the community level are rare (117) although programs to keep girls in school can delay marriage (118)(119).

PEPFAR programs should also address the men with whom girls and young women engage in sexual activity—whether voluntarily or not—through programs that address harmful gender norms, provide HIV prevention, and link male PLHIV with services. This includes work with male teachers and other male authority figures in the lives of girls, who may engage in sexual activity with them.

The evidence-based for all of these approaches is limited; prevention packages for women 15 to 24 require more validation before being brought to scale. Accordingly, it is essential that these efforts be implemented on a pilot basis for the near future, and incorporate rigorous evaluation.

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

In comparison to the general population, uniformed populations are younger, more mobile, have a more consistent income, lower rates of condom use (120), and higher rates of heavy drinking (121). Historically, militaries have been comprised of predominantly male personnel, although women are being increasingly recruited (122). Social constructs of masculinity for military personnel may include elements of risk-taking behavior, aggression and lowered perception of risk which may lead to greater risk behaviors associated with acquiring HIV infection (123). Uniformed personnel are organized into hierarchical structures that provide unique opportunities to reach large portions of the military population with programs and services tailored to rank, duties, and position. Development, adoption, and implementation of HIV policies within uniformed services are foundational for a comprehensive approach to HIV prevention, care and treatment. While prevention programs should be initiated even in the absence of baseline data,
efforts should be made for routine data collection to monitor and evaluate programs, demonstrate effectiveness, measure outcomes, and tailor interventions according to documented risks.

Prevention programs for uniformed services should be provided in new recruit populations at training bases, active duty populations at bases and in the field, and in peacekeeping settings. Where appropriate, these prevention programs should be offered to spouses, partners, dependents, and surrounding communities. Programs should include: HTC, VMMC, condom promotion and distribution, HIV prevention and risk reduction education, prevention for PLHIV, programs to address male norms and behaviors, STI diagnosis and treatment, and alcohol use reduction activities (124). These programs should carefully consider opportunities to tailor activities and services to military personnel and structures. For example, while socially marketed condoms should be promoted to populations that can pay for condoms, free condoms should be made available to military personnel deployed to hazardous or remote locations (125)(126). Condoms should be readily available to all military personnel free of charge. Additionally, deployments provide unique opportunities for military personnel to routinize HTC services. As capacity of personnel and the institutionalization of HIV programs and services allow, programs should be transitioned to ownership by the partner country military.

DoD funding supports programs at military bases, military hospitals, and clinics; often these sites offer services to the surrounding civilian population, as well as to military personnel. Other uniformed services that do not report to the Ministry of Defense, such as police departments and border security services, are supported by other agencies.

6.3 Male and female condoms and lubricants 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. Where programs are reaching populations having anal intercourse, lubricants should also be promoted and distributed.

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, male and female condoms and lubricants should be made available and accessible to target populations in accordance with their product preferences.

In most countries where PEPFAR operates, people access condoms through three routes or market sectors: public, private and socially marketed. Publicly provided condoms are free and typically found at clinics and HTC sites. Privately marketed condoms are sold at market value at a variety of outlets such as pharmacies, kiosks and vending machines. Socially marketed condoms are sold at a subsidized rate, and branded with an aim of increasing uptake among populations with a lower income. A “total market approach” (TMA) to condom distribution and promotion uses all three of these routes. Within TMA “free” public sector condoms will
primarily be distributed to population segments lacking disposable income and, especially those most at risk of HIV transmission or acquisition. Socially marketed condoms will be sold to individuals with some ability to pay but who are not yet able to afford a more expensive, private sector condom. Private sector condoms will be marketed and sold to higher income segments of the population. PEPFAR implementing partners should adopt TMA in their condom programming.

Whenever possible, social marketing programs should adopt a phased process of gradually increasing cost recovery for social marketing products while simultaneously working with the private sector to improve the market share of sustainable, private sector condoms.

Improving national commodity forecasting and procurement planning is essential to ensuring a steady supply of male and female condoms. PEPFAR teams should work closely with national governments to enable them to accurately forecast their needs for male and female condoms and lubricants, funding technical assistance in this area when necessary. When condom or lubricant 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. For former non-focus countries, these emergency orders can be processed through the Commodity Fund while former focus countries can access PEPFAR’s new centrally-funded ‘Condom Emergency Fund’. 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 condoms, as program experience has demonstrated that these can increase condom sales and use. Programs should ensure that high-quality condoms and lubricants are available and that these products align with consumers expressed desires and preferences, including specialty condoms (i.e. scented). Programs should design high-quality 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 will want to use a variety of formats from individual to peer to community behavior change interventions. In general, multiple channels can be deployed to reinforce key messages and in generalized epidemics, to ensure that all people receive motivational messaging to use condoms.

It is important to use water- or silica-based lubricants with condoms, particularly during anal intercourse, as these lubricants have been shown to significantly reduce the likelihood of condom breakage during anal sex. Recently, some laboratory and animal studies have indicated that some lubricants may cause cell inflammation and affect tissues in the vagina and rectum, raising the possibility that some lubricants might make individuals more vulnerable to HIV infection and other STIs. It is important to note that none of these studies was done as part of randomized controlled trial in humans, and it remains unclear whether these studies have any implications for the safety of lubricants in humans.
For now, the available evidence clearly suggests that use of water-based lubricants with condoms during anal sex should be strongly encouraged. USAID currently procures water-based lubricants which can be procured from the CCP. For more information on lubricants, see the WHO/UNFPA/FHI Advisory Note, *Procurement of additional lubricants with male and female condoms* (http://apps.who.int/iris/bitstream/10665/76580/1/WHO_RHR_12.33_eng.pdf).

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 specific 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 regarding use of the female condom, in-country market analyses, and considerations of planning for sustainable condom programming over the long-term.

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.

7 **Alcohol and other drug use and HIV**

Alcohol misuse plays a critical role in sexual risk behavior that can lead to HIV transmission, and also is a factor in health and wellness for persons living with HIV/AIDS. The association between alcohol use, abuse, and dependence, and increased sexual risks is increasingly recognized in many countries. Multiple studies have found that persons who use alcohol in sexual situations are more likely to have unprotected sex, casual sex, and multiple concurrent partnerships, than persons who do not use alcohol in sexual situations (127). Alcohol consumption is linked with increased risk of STI and HIV infection (128), gender-based violence, and non-adherence to anti-retroviral medication.

Research is needed at the country level to support the limited data available. This research is needed to confirm that interventions to reduce consumption at the individual level which are effective in developed countries, are also effective in low and middle income countries. Interventions that focus on mobilizing communities or changing policies have had modest success, and should be considered in locations where data suggests that alcohol misuse and HIV
prevalence are co-located. For more information, see the 2013 PEPFAR Alcohol and HIV webinar and bibliography (http://www.globalhealth.gov/global-programs-and-initiatives/pepfar/hivaidsalcohol.html).

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 (129). This vulnerability underscores the need for responsive programming so that we can better meet the specific and comprehensive needs of both men and women who use drugs. See sub-section 3 (Injecting Drug Use) of Section 1.3 of the Technical Considerations (Biomedical Prevention) for further information on PWID.

8 Quality assurance standards, 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 (e.g. gender assessments are strongly encouraged to understand norms and inequities that may contribute to disparities in risk behaviors and service uptake);
- Establish appropriate selection criteria for peer and/or other educators;
- Establish clear criteria for “reached” in the context of prevention programs (e.g., exposed to a radio program vs. attended an outreach event vs. completed an eight-session curriculum) and ensure that monitoring systems are designed to capture participation on the basis of these criteria;
- Use relevant measures of success and a feedback for program monitoring and a monitoring loop for mid-course correction and continuous quality improvement;
- Use mentoring and supportive supervision approaches;
- Develop meaningful program-level indicators to reflect the optimal mix and quality of prevention approaches (e.g., dose, intensity, multi-level strategies);
- Build evaluation into prevention programs, starting with the design phase. These evaluations should include some kind of comparison between the outcomes in participants of the program with outcomes in a control group or community, and measure impact on uptake of services and adherence to care regimens alongside self-reported
changes in behavior. See the PEPFAR Implementation Science and Impact Evaluations Guidance for more information;

- Develop a data use and dissemination plan at the beginning of a project; and
- Strengthen the capacity of PEPFAR prevention staff to provide technical expertise and 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.

8.1 KP-Specific QA Considerations

To ensure high quality prevention programs for KP, 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 plans for peer education and outreach programs that target SW, PWID, TG and MSM (see sub-section 10 (Additional Resources) of this Section for more information on quality monitoring standards for KP programs). 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; and
- Monitor KP service up-take and linkages into HIV Care and Treatment.

8.2 PEPFAR’s Monitoring, Reporting and Evaluation Strategy and Guidance

In FY 2014, PEPFAR will roll out a new strategy for Monitoring, Reporting and Evaluation (MER) and an accompanying guidance document. The MER includes both a new approach to monitoring and evaluation and new indicators. Please consult the MER as you plan M&E for your programs.

9 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 for community-based programs should be promotion of and referral to HIV testing for partners of PLHIV and other individuals identified to be at increased risk. HTC services should also include intensified and tailored risk reduction counseling and condom promotion, and screening and referrals for gender-based violence. Strengthening prevention counseling within PMTCT services should be a further priority. These efforts should not only target HIV-positive individuals, but also aim to help HIV-negative individuals at high risk, especially those in key and other highly vulnerable populations, stay HIV-free;

Where HIV prevalence is high and male circumcision prevalence is low, priority should be given to scaling up rapid and high quality programs to provide VMMC, particularly where national policies support VMMC scale-up;

Integrating risk reduction counseling and HTC into reproductive health and family planning services has the potential to expand the reach of prevention services to young women of reproductive age, a population at very high risk of acquiring HIV in generalized epidemics; 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.

10 Additional Resources


• Example of quality monitoring standards for KP programs: http://nascop.or.ke/library/Marps/Standards_for_Peer_Education_and_Outreach_Program_for_Sex_Workers.pdf
1.3 Biomedical Prevention

1 Blood Safety

1.1 Introduction

An adequate supply of HIV- and pathogen-free blood is critical for HIV prevention and a foundation of every national response to the epidemic.

1.1.1 What’s New in 2014

New sections this year address the appropriate use of blood for transfusion, use of a sustainable blood establishment computer system (BECS), and implementing a quality management system.

1.1.2 PEPFAR Blueprint

Blood safety is critical to a viable health system and safe transfusions have been critical to maternal health and malaria programs. Within the Blueprint, blood safety is specifically mentioned under the Road Map for Smart Investments.

1.1.3 Technical Background

Throughout the developing world, the lack of stored blood components often results in a reliance on the collection of blood from family and replacement donors only when there is already a patient in need of transfusion. Such emergency collections may not be screened for transfusion-transmissible infections (TTIs). These “just in time” transfusions increase the risk of death, infection or other complications. Even in countries that have a stored blood supply, inadequate numbers of volunteer donors and weak screening systems severely undermine the ability of the system to provide safe blood in a timely fashion.

To help countries build safer national blood transfusion services, the World Health Organization (WHO) has provided important recommendations for national blood programs (http://www.who.int/bloodsafety/en/). The following recommendations serve as the technical foundation for PEPFAR’s blood safety assistance programs:

- Collecting blood only from voluntary, non-remunerated, low-risk blood donors;
- Universal screening for HIV, hepatitis B virus (HBV) and hepatitis C virus (HCV), and syphilis;
- Training clinicians in the appropriate clinical use of blood;
- Implementing good laboratory and manufacturing practices in blood grouping, compatibility testing, component preparation, and the storage and transportation of blood and blood products; and
- Implementing a national quality system for all aspects of blood collection, processing, storage, and transfusion in addition to the blood center laboratory systems.
1.2 Technical Considerations

1.2.1 Activities

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


2. Donation: Collection of blood from regular, low risk, voluntary, and non-remunerated donors.

3. Specific laboratory methods and product-processing unique to blood centers including:
   - Documented effective and universal screening for HIV, HBV and HCV viruses, and syphilis using methods that have been shown to be the most sensitive in blood centers (e.g., immunoassays);
   - Documented quality typing and cross-matching (pre-transfusion testing);
   - Documented participation in a testing program provided by an external agency to measure the proficiency of the blood bank laboratories in performing screening for TTIs as well as blood-typing; and
   - Documented, appropriate storage, processing, distribution of blood and blood products, and recognizing and investigating adverse transfusion reactions.

4. Appropriate clinical use of blood:
   - Development of national guidelines; and
   - Development of hospital transfusion committees to tailor prescribing practices to the blood and blood components that are available, to monitor patient safety and transfusion outcomes, and to implement the national guidelines.

5. Sustainable blood establishment computer systems (BECS): Strengthen capacity to collect and manage data that will allow blood centers to register and recall donors, manage TTI screening results, optimize donor rescheduling, distinguish repeat and deferred donors, use recruitment technologies for donor mobilization (e.g. Single Messaging System (SMS) texting, scheduling); and use data for operational decision making, forecasting, and reporting.

6. Quality management systems: Establish external quality assurance program with the goal of acquiring accreditation by an international blood center accreditation agency (e.g., AABB, African Society for Blood Transfusion).

7. Training: Pre-service, in-service and continuing medical training on blood use and blood services for involved personnel.

9. Sustainability: Ensure continuity after PEPFAR’s support, including the appropriate, accurate, and efficient costing of blood and blood products.

1.2.2 Core Strategies

- Support establishment of a well-organized, coordinated and central governmental entity with legal authority to manage the entire blood supply of the nation (e.g., Ministry of Health, National Blood Transfusion Service [NBTS]);
- 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, blood 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 use blood (e.g., trauma, obstetrics/gynecology, surgery, pediatrics) 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 blood collection, processing, screening, storage, and transfusion process that:
  - 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); and
  - Strengthen capacity to collect and manage data in an automated, retrievable, and sustainable system.
- Ensure quality indicators are used 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 laboratories and health care facilities in commodity 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;
• 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, 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.

1.2.3 Emerging Issues

Equitable access: Providing equitable services to populations that are scattered between dense urban centers and remote rural areas is a challenge. Delivery of service to remote areas requires maintenance of cold chain and transportation systems that may not routinely be available. Addressing this gap requires innovative strategies regarding power source, inventory management, and adaptation of technologies to enhance transportation capacity so that blood units are promptly distributed and made available consistent with their expiration period.

Expansion and retention of safe donor populations: In order to ensure an adequate supply of blood, donor pools must be expanded beyond easily accessed populations, such as students. Identifying such donor pools is 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 by assessing the pool of potential donors with regards to geographic distribution and factors that may exclude them from donating due to related to age, weight, HIV status, anemia, pregnancy, etc. 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 use 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. Assessments should also focus on:

• Whether blood use is consistent with best practice guidelines for appropriate transfusions;
• Number of units ordered per transfusion;
• Inventory management to minimize loss through expiration;
• Handling that maintains the cold chain to the patient bedside; and
• Impact of blood use and availability on key health indicators such as changes in mortality due to maternal hemorrhage and pediatric malaria.
Appropriate country specific collection target: the WHO projects that annual collection of 10-20 units per 1,000 population per year will allow countries to meet their most essential clinical demands for blood. The target number of units needed in any specific country may vary and 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.

1.2.4 Cross-Cutting Content, Linkages & Wraparounds

- **Community Programs:** Comprehensive blood donor education activities encourage healthy lifestyles, especially among adolescents, who make up a major proportion of the blood-donor population in these countries. PEPFAR partners can combine or incorporate healthy lifestyle messages and the importance of blood donation in other social mobilization and health promotion messaging. These pre-donation messages should emphasize the importance of self-exclusion;

- **HIV Testing and Counseling (HTC):** Organizations collecting blood transfusion systems and HTC programs must have the capacity to make appropriate referrals to HIV testing and counseling, for individuals who want to know their status;

- **Positive Health, Dignity, and Prevention (PHDP):** 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 PHDP (also known as Prevention with Positives) where they exist. WHO and the Centers for Disease Control and Prevention have recently completed 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. See Section 1.5 of the Technical Considerations (Positive Health, Dignity and Prevention for People Living with HIV) for more information on PHDP; and

- **Maternal and Child Health:** Training in appropriate use of blood products should first focus on medical facilities in areas that are greatly affected by women with hemorrhagic obstetric complications and children under five years of age with malaria, especially where HIV prevalence is high.

Consideration should also be given to assuring that patients who are prescribed a blood transfusion are able to obtain a transfusion, 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 additional fees for the processing, handling, and infusion of blood such as the costs of the blood collection bag, of screening assays, and of the infusion tubing and needle. These costs may be a barrier to the receipt of a critically needed transfusion
and need to be addressed. For example, some programs have provided vouchers to obstetric patients to use if blood is needed at time of delivery.

2 Injection Safety

2.1 Introduction

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.

2.1.1 What’s New in 2014

The WHO Patient Safety Programme, which previously launched two highly successful Global Patient Safety Challenges on hand hygiene and surgical safety, is preparing to launch a new worldwide Challenge promoting safe use of syringes and needles for therapeutic purposes. This campaign will include extensive communications along with a new tested intervention package and various tools including training videos suitable for scale-up in low-resource settings as well as a regional platform to support scale-up with minimal external support.

2.1.2 PEPFAR Blueprint

Injection safety (IS) is at the foundation of a strong health system, and while generally not listed among the prominent programmatic elements needed to achieve the Blueprint goals, nonetheless is essential to achieving them. Injection safety programs primarily are concerned with protecting patients and the community from unsafe and unnecessary injections and related procedures that can result in HIV transmission. IS programs also are crucial to protecting healthcare workers (HCWs) from HIV and other blood-borne infections, and such programs include post-exposure prophylaxis (PEP), which protects HCWs if they are exposed accidentally. They are a crucial component of all medical procedures that include the use of syringes or sharps. Poor IS can undermine the safety and effectiveness of HIV interventions including medical male circumcision, prevention of mother to child transmission (PMTCT), HIV testing and counseling (HTC), tuberculosis (TB), care and support, laboratory testing as well as blood safety.

2.1.3 Technical Background

The main goals of IS 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, or if previously used/contaminated multi-dose vials/diluents are used, or if inappropriate injection equipment is used;
• Poor injection technique is used, such as recapping of used needles; or
• Sharps are improperly discarded.

Unnecessary injections result when:

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

2.2 Technical Considerations

Eliminating unsafe practices that result in patient-to-patient or healthcare worker-to-patient HIV transmission is fundamental to a strong and viable health system. IS 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.

Strong IS programs are based on establishing and implementing national policies for rational and safe injection use. A comprehensive IS strategy includes:

• Capacity building and training of healthcare workers in safe injection practice skills, including related infection prevention and control practices, appropriate handling of 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);
• 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;
• Improving health care waste management, including training and equipping waste handlers; and
• National policies and implementation plans for providing post-exposure prophylaxis (PEP) to HCW exposed to HIV. WHO has issued guidance on the provision of PEP (http://whqlibdoc.who.int/publications/2007/9789241596374_eng.pdf).

At a minimum, PEPFAR-funded implementing partners must ensure appropriate injection safety and waste management practices within their existing programs. This involves incorporating and integrating injection safety principles, practices and commodities into all health care delivery through:
• Programs (e.g., HIV/AIDS care and treatment programs, HIV testing and counseling, PMTCT, laboratory, blood safety, voluntary medical male circumcision, whether delivered by United States Government (USG) or host country);
• Systems strengthening (e.g., procurement, supervisory and information systems, various in-service and pre-service trainings, financing schemes, etc.); and
• Focus on prioritizing: Sharps procedures with highest risk of HIV transmission (e.g., phlebotomy, injections at high-prevalence sites); evidence-based strategies (e.g., ensuring availability of sharps containers proximate to point of sharps use); and ensuring that activities are consistent with national plans and policies regarding injection safety.

2.2.1 Training and capacity building
• Ensure that all HCWs are trained in safe injection practices, including safe blood drawing, standard precautions, waste management and post-exposure prophylaxis for occupational exposure;
• Ensure that PEP starter packs are available to all HCWs during their clinical duties, including those in remote areas, and that all HCWs have access to full 28-day dosing;
• 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.

2.2.2 Procurement and Supply Chain
Consistent with local guidelines, it is important to ensure that the availability of sufficient, appropriate, quality single-use injection and safe phlebotomy supplies is sustainable by the partner country. Shortage and stock-outs of equipment can severely undermine injection safety. Section 3.11 of the Technical Considerations (Supply Chain Management) provides detailed information about injection safety activities and interventions—along with cross-cutting supply chain management technical considerations—that country teams should consider to avoid potential supply chain disruptions.

2.2.3 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 to public and private health care sectors as appropriate.
2.2.4 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 management 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.

Scale up of HIV/AIDS-related medical interventions, such as HTC, Voluntary Male Medical Circumcision (VMMC), monitoring of CD4/CD8 counts and viral loads, and PMTCT, is increasing the volume of medical waste 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, safe waste management in the face of these challenges.

2.3 Cross-Cutting Contents, Linkages & Wraparounds

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, TB, voluntary medical male circumcision (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.

2.4 Additional Resources

3 Injecting Drug Use

3.1 Introduction

3.1.1 What’s New in 2014

Specific priority actions for FY2014: This year’s Technical Considerations for People Who Inject Drugs (PWID) includes updated information on prevention intervention as well as specific recommendations for the upcoming fiscal year based on context and maturity of the PWID program.

Harmonized Indicators: PEPFAR’s new Monitoring, Evaluation and Reporting (MER) Guidance includes revised indicators that harmonize with other global indicators for monitoring medication-assisted treatment for people who inject drugs.

WHO, UNODC, UNAIDS Target-setting Guide: The World Health Organization (WHO) has released an updated technical guide for countries to set targets for universal access to HIV prevention, care, and treatment for people who inject drugs.

3.1.2 PEPFAR Blueprint

Four of the roadmaps highlighted in PEPFAR’s Blueprint speak to programming for PWID:

- **Roadmap for Saving Lives:**
  - Increase access to, and uptake of, HIV testing and counseling, condoms and other evidence-based, appropriately-targeted prevention interventions.

- **Roadmap for Smart Investments:**
  - Increase access to, and uptake of, HIV services by key populations;

- **Road Map for Shared Responsibility:**
  - Increase support for civil society as a partner in the global AIDS response.

- **Road Map for Driving Results with Science:**
  - Support innovative research to develop new technologies for prevention.

3.1.3 Technical Background

In 2011, 14.0 million people between the ages of 15 and 64 were estimated to be injecting drugs, while 1.6 million people who inject drugs (PWID) were living with HIV. A recently published analysis of HIV incidence data from eight countries in Asia indicates high HIV incidence rates among PWID (0.0-43.6 per 100 person-years) with risk factors for incident HIV infection among
PWID including young age, frequent injection use, and sharing of needles or syringes (130). While the greatest focus of injection drug use research and interventions has been in the Asia region, it's important to note that new emerging drug trafficking routes suggest that the African continent is becoming increasingly vulnerable. However, data about injection drug use for this region remain scarce (131).

Access to HIV prevention, care and treatment services has been sub-optimal for PWID in most countries. A report on syringe programs (NSPs), medication assisted therapy (MAT) and anti-retroviral therapy (ART) in 13 countries found that coverage for each of these interventions is low (132). PWID not only have poor access to ART, but they also tend to begin ART later, at a more advanced stage of infection than other groups, resulting in poorer treatment outcomes.

The following technical considerations and PEPFAR’s guidance on comprehensive HIV prevention for PWID (http://www.pepfar.gov/documents/organization/144970.pdf) are meant to guide countries and regions in providing effective programs and services that mitigate the impact of injection drug use on HIV and improve health outcomes for PWID. For further guidance on alcohol use and other non-injecting drugs, please see sub-section 7 (Alcohol and other drug use and HIV) of Section 1.2 of the Technical Considerations (Prevention of Sexually Transmitted HIV Infections).

3.2 Technical Considerations

3.2.1 Country Context

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 drug users, 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. Service delivery models need to take into account the country’s cultural and social norms as it relates to drug-using populations in order to increase the likelihood of effective implementation within the local context.

3.2.2 Measuring the drug use epidemic and setting data-driven priorities for program development

Many countries lack data or under-utilize existing data on people who use drugs. While some countries have carried out limited assessments in selected geographic areas, few have approached this more broadly to address the need to define their national drug use epidemic in the context of HIV/AIDS.

For FY2014, countries should support partner country governments and/or NGOs to:
• Describe characteristics of people who use drugs (e.g., types of drugs used, routes of administration, network characteristics, drug use and sexual risk factors, disease burden, access to services) based on population-based surveillance, quantitative, and qualitative research utilizing standardized, culturally-appropriate drug use screening instruments;
• Identify data gaps and HQ technical assistance needs in areas of PWID surveillance and PWID implementation science, including size estimation, mapping, and formative assessments, needed to fill gaps in understanding risk and needs of people who use drugs;
• Strengthen routine Monitoring & Evaluation (M&E) of PWID programs to monitor access, use and coverage of evidence-based interventions at community and facility levels, including linkages and enrolment of HIV-positive PWID in HIV care and treatment services; and
• Demonstrate and strengthen the links between strategic information (SI) and prevention to develop data-driven programs.

3.2.3 Developing capacity
Prevention staff should ensure that coordinated technical assistance, both from headquarters and south-to-south, as well as capacity building through in-country international staff for host country nationals will focus on developing the appropriate range of technical skills within countries to develop, implement, evaluate, and improve prevention, care and treatment programs for PWID. This includes providing assistance to in-country partners to improve coordination across partners and to develop in-country expertise.

For FY2014, countries should support partner country governments and/or NGOs to:

• Develop a strategic plan and/or ensure inclusion of PWID components into national strategic plans for HIV/AIDS, for HIV prevention and/or key populations;
• Develop technical assistance (TA) plans involving headquarters and south-to-south TA providers;
• Support and facilitate training for peer educators, service providers, stakeholders, and the government partners to scale-up programs and services for drug-using populations;
• Address policies and activities to support workforce development and retention and health system strengthening, as it pertains to providing programs and services for drug-using populations; and
• Build capacity of governments and CSOs to plan, implement, monitor and evaluate high-quality HIV prevention programs for PWID, and to advocate for continued funding for PWID programs in the future.

3.2.4 Comprehensive Package of Interventions
Scientific evidence supports a comprehensive package of structural, biomedical and behavioral interventions as the optimal strategy for reducing HIV incident infections among PWID (129)
The WHO, UNODC, UNAIDS Technical Guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users (134), updated in 2012, is used as a framework for developing a comprehensive package of core interventions and as a guiding resource for setting targets and identifying key indicators to monitor the availability, coverage, quality and impact of the comprehensive prevention package. There is strong evidence that these interventions, implemented in a variety of settings (including closed settings) (135), are effective in reducing risk behaviors, preventing HIV infections, and enhancing access to essential services for PWID (136). The Technical Guide has been explicitly endorsed by the UN in multiple venues including the Commission on Narcotic Drugs, the UNAIDS Program Coordinating Board (137), and the Economic and Social Council (ECOSOC) of the UN General Assembly (138). Country teams should reinforce this broad scientific and political endorsement as they work with partner country governments to develop or strengthen national programs for PWID.

The following core interventions can include a combination of the following HIV prevention interventions and strategies recommended by the WHO, and they should be carried out in a manner consistent with human rights obligations (139). Note that PEPFAR funds do not necessarily support all of these interventions:

- Peer education and community-based outreach¹;
- Needle and Syringe Exchange Programs (NSP) (as a wraparound programs supported by other donors);
- Medication Assisted Therapy (MAT) and other drug dependence treatment;
- HIV testing and counseling (HTC);
- ART for PWID living with HIV;
- Prevention, early diagnosis and treatment of sexually transmitted infections (STIs);
- Condom programs for PWID and their sexual partners;
- Provision of or referral to voluntary family planning (FP) services for PWID, as well as their sexual partners²;
- Targeted information, education and communication (IEC) for PWID and their sexual partners;
- Vaccination, diagnosis and treatment of viral hepatitis³; and
- Prevention, diagnosis and treatment of tuberculosis.

¹ WHO does not include community-based outreach as a separate intervention in the comprehensive package; however, it is recommended as an extraordinarily effective method of overcoming challenges related to accessing populations of PWIDs.
² WHO does not include family planning as a separate intervention in the comprehensive package; however, ensuring access to family planning services for all key populations is a priority for PEPFAR programs.
³ For more information, see sub-section 3.6 (Diagnosis, prevention and management of viral hepatitis in HIV-infected persons) of Section 2.1 of the Technical Considerations (Adult Care and Support).
For FY2014 countries should support partner country governments and/or NGOs to implement this comprehensive package of interventions in a step-by-step manner:

- Countries with nascent PWID programs should begin by building partnerships, enabling environments and quality evidence to design and initiate PWID programs;
- Countries with some existing PWID programs (e.g., currently providing a few elements of the package to a portion of the PWID population) should aim to prioritize implementation of service elements increase the number of services provided over time and work to achieve effective linkages and retention in services; and
- Those countries with more advanced stages of programming for PWID should focus on bringing evidence-based and successful programs to scale and aim for coverage of the PWID population.

3.2.5 Peer Education and Community Outreach

Supported by WHO, UNODC, and UNAIDS, community-based outreach is an effective strategy for reducing drug- and sex-related risk behaviors because it increases access to and uptake of HIV prevention information, HTC, important risk-reduction skills and materials, and provision of overdose prevention medication. In addition, community-based outreach successfully links PWID to additional HIV prevention services such as MAT, HTC, and HIV care and treatment.

In FY2014, countries should consider:
- Working with governments and implementing partners to standardize peer education and outreach programs targeting drug-using populations, as quality and makeup of programs can have wide variations. Tools and materials to adapt are available from headquarters; and
- Request technical assistance where needed in developing, improving quality of, and scaling up outreach interventions for PWID.

3.2.6 Wraparound Needle and Syringe Programs

Studies have shown that NSPs result in marked decreases in drug-related risk behavior (e.g., sharing of injection equipment, unsafe injection practices and frequency of injections), by as much as 60%, and decreases in HIV transmission, by as much as 33% to 42% in some settings. Consistent findings from evaluation studies of NSPs reveal that these programs increase the availability of sterile injection equipment, reduce the quantities of contaminated needles and other injection equipment in circulation, reduce the risk of new HIV infections, and result in referrals to other services, such as HTC and ART for those eligible. Additionally, findings from a range of studies indicate that NSPs do not increase the numbers of persons who begin to inject drugs or increase the frequency of drug use.
PEPFAR funds cannot be used to purchase needles or syringes for NSP programs. Taking into account local context and epidemiology, PEPFAR teams should support countries in their efforts to determine the number and types of NSP services necessary to have an impact on the HIV epidemic. Effectiveness depends on ensuring geographic distribution, and types and numbers of NSP outlets, relative to the size, location, and needs of the population of PWID. A range of outlets (fixed and mobile sites, secondary exchange, 24-hour service through pharmacies) operated by civil society and the government have the greatest impact.

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

Recent studies have shown that high dead space syringes (HDSS) retain over 1,000 times more blood after use and rinsing than low dead space syringes (LDSS). In mathematical models, this difference was enough to prevent or reverse injection-related HIV epidemics (148). Ecologic data that examined syringe type and HIV prevalence in over 50 areas and found that PWID use HDSS in every area where HIV prevalence among PWID was over 6%. Biologic-behavioral surveys have linked sharing HDSS but not LDSS to prevalent HIV infection. These data may be of value to share with governments and/or NGO partners to inform NSP interventions.

3.2.7 Medication-Assisted Therapy

Studies have shown that the most effective treatment for opioid dependence is MAT (66). MAT uses methadone, buprenorphine, buprenorphine/naloxone (suboxone)/naltrexone or other medications/therapies, as they become available, to treat opioid dependence and prevent the transmission of HIV. MAT has been shown to be an effective treatment, reducing risk behaviors related to injection drug use, preventing HIV transmission and improving PWID adherence to ART(129), but to date, availability of MAT in most PEPFAR countries is limited. For MAT to have an impact on the overall HIV epidemic, services need to reach, treat, and retain in treatment as many PWID who seek services as possible.

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

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

3.2.8 New Prevention Advances

Efficacy and adherence trials done among PWID show that pre-exposure prophylaxis (PrEP) with tenofovir nearly halved (48.9%) HIV incidence among injection drug users. In a separate analysis of participants known to be adherent, because they were observed taking their medication and had tenofovir detected in their blood, the risk of HIV acquisition was reduced by approximately 74 percent (149). In this study, PrEP adherence among PWID was noted to be 84%. Normative guidance on the use of PrEP among PWID has not been issued, therefore any such interventions should be implemented only in the setting of pilot programs or implementation science.

3.2.9 Enabling Environments and HIV Prevention

Interventions for PWID should be provided in an “enabling environment” created by supportive legislation, policies, regulations, and strategies (134). Such legislation, policies, regulations, and strategies facilitate implementation of a comprehensive HIV prevention package for PWID. PEPFAR programs should be based on principles of equity, nondiscrimination, and voluntariness. In addition, all programs should be conceived with the participation of affected populations. Country leadership, including engagement by multiple sectors of government and collaboration with civil society, is needed to develop and implement, at all levels, the necessary supportive legislation, policies and regulations that facilitate the introduction and scale-up of services.

For FY2014, countries should support partner country governments and/or NGOs to:

- Assess and address policies and social norms that serve as barriers or facilitators to drug-using populations accessing HIV-related services;
- Provide trainings for service providers working with drug-using populations to reduce stigma and discrimination and ensure ethical treatment of drug users;
- Assess the legal framework for health care service provision to people who use drugs including law enforcement directives and policies for working with known drug-using populations; and
- Support advocacy and policy work needed to respect the rights of people who use drugs and to implement prevention programs.

3.2.10 Expanding Services

PEPFAR programs for PWID should be data-driven, offer a comprehensive package of services, and address human rights, stigma and discrimination as critical elements in combating HIV/AIDS (139). Where appropriate, PEPFAR teams should use existing platforms to accelerate the scale-up of services for PWID.
For FY2014 countries should support partner country governments and/or NGOs to:

- Assess and determine what interventions or package of interventions needs to be taken to scale for people who use and/or inject drugs, prioritizing evidence-based interventions that contribute to HIV incidence reduction among PWID;
- Support governments in implementing what is possible, and also work with governments to advocate for progress in improving supportive legislation, policies, regulations and strategies;
- Develop or adapt a common set of indicators to monitor programs;
- Assess the size of the population for coverage; and
- Increase and measure the coverage, frequency, quality and intensity of prevention intervention delivery.

3.2.11 Establishing a quality assurance, monitoring, and evaluation mechanism

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

For FY2014 countries should support partner country governments and/or NGOs to:

- Develop a set of core competencies and minimum standards, as well as a system of oversight and supervision, to monitor, assure, and improve these programs;
- Describe and share quality program tools, curricula, and models from successfully implemented programs;
- Design strong monitoring plans and provide clarification on the meaning and importance of monitoring indicators;
- Develop more meaningful program-level indicators that assess the mix and quality of prevention approaches (e.g., intensity, scale, and coverage); and
- Support evaluation activities, if possible, to help determine positive behavioral, community and biological changes and outcomes; and
- Support implementation science to identify the most effective interventions within each epidemic context, to support delivery of high-quality services to clients, and to evaluate innovative strategies to improve and strengthen comprehensive services for PWID.

3.2.12 Partner Performance

Partner performance reviews are a recommended practice to strengthen country teams’ understanding of field level implementation. Conducting interagency site visits to prevention partners, both at the headquarters level and to observe field activities greatly enhance the PEPFAR 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, PEPFAR teams should assess partner adherence to the package of services for people who use drugs as well as harmonization with WHO/UNODC/UNAIDS technical guide for countries to set targets for universal HIV prevention, treatment and care for injecting drug users (revised guide, 2012). 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 PEPFAR prevention portfolio, as well as with the host government and other donors.

3.3 Wraparounds and Linkages

Biomedical interventions for PWID are based on a core component of interventions providing many opportunities for linkages and wraparounds. Biomedical interventions targeted towards this population comprise a package of services which include prevention of sexual transmission, HIV testing and counseling, STI screening and treatment, and VMMC. Strong programs will also provide or refer to family planning (FP) services as a critical element of a comprehensive package of services for PWID and partners of PWID. While the FP needs of females who inject drugs (FWID) are not well-documented, high rates of exchanging sex for drugs, housing or protection, and limited ability to negotiate condom use, puts them at high risk of both unintended pregnancy and HIV infection(150). A comprehensive approach targeted towards drug-using populations includes linkages to HIV care and treatment, PMTCT, TB/HIV, FP, OVC, and PHDP services.
3.4 Additional Resources

- 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:
  

- WHO, UNODC, UNAIDS Technical Guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users
  
http://apps.who.int/iris/bitstream/10665/77969/1/9789241504379_eng.pdf

4 Voluntary Medical Male Circumcision

4.1 Introduction

Three randomized controlled trials (RCT) demonstrated that voluntary medical male circumcision (VMMC) reduces men’s risk of HIV acquisition by approximately 60%, making it one of the most effective HIV prevention interventions known (6)(7)(9). Extended follow-up of participants in the Uganda and Kenya RCTs through five and six years post-trial indicated that the protective effect was sustained or increased at 67-73% and 58%, respectively (151)(8). Additional benefits for women include a decreased risk of HPV and cervical cancer among female sexual partners of circumcised males (152)(153). The World Health Organization (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 (154).

4.1.1 What’s New in 2014

Four new issues are addressed as requirements in the 2014 COP CIRC Budget Code Narrative section on Policy Guidance, bringing the total number of Policy Guidance requirements for VMMC implementing partners to six (see PEPFAR COP Guidance for FY2014). The new requirements address clinical documentation, informed consent, reporting of client deaths, and a lower age limit for adolescent male clients.

In May 2013, WHO issued a pre-qualification decision for PrePex, the first medical device for adult VMMC. Pre-qualification of a second medical device for adult VMMC, the Shang Ring, is expected from WHO by the end of the 2013 calendar year (155). PEPFAR funds can be used to support VMMC using pre-qualified devices in accordance with the WHO Framework for Clinical Evaluation of Devices for Male Circumcision (156) and approval by the Ministry of Health and/or Ministry of Defense. The Male Circumcision (MC) Technical Working Group (TWG) has issued recommendations to country teams on how PEPFAR funds may be used to support evaluation and introduction of devices. Requisite evaluations of PrePex and/or Shang Ring will probably have been completed in most countries by September 2014. Thus, the 2014 Country Operational Plan (COP) funds, which will largely support service delivery in FY 2015,
may include both conventional surgical and medical device-based VMMC, assuming continued favorable results from evaluations in the interim and the successful negotiation of satisfactory device price (s) with manufacturer (s).

4.1.2 PEPFAR Blueprint

VMMC is featured prominently throughout the PEPFAR Blueprint: Creating an AIDS-free Generation. Mathematical modeling results presented in the Executive Summary highlight antiretroviral therapy (ART) and VMMC scale-up as the two greatest contributors to reduced HIV incidence. The Blueprint’s Road Map for Saving Lives commits PEPFAR resources to the scale-up of combination treatment and prevention interventions through four Action Steps. Action Step #3 is to increase the number of males who are circumcised for the prevention of HIV, and includes ten commitments to implement this Action Step. The Road Map for Smart Investments highlights VMMC as a vehicle for engaging men and boys to know their HIV status, and if positive, be linked with care and treatment services. Additionally, it is a vehicle for men and boys to address harmful gender norms and promote gender equality in the interest of improving the health and well-being of women and girls, among whom HIV infection remains disproportionately prevalent (157).

4.1.3 Technical Background

_USG agencies implementing PEPFAR programs, funded implementing mechanisms, and service sites supported by PEPFAR should be familiar with all information described in the 2014 COP CIRC Budget Code Narrative and COP Guidance Priority Section on VMMC. In the interest of avoiding duplication, these requirements, recommendations, and considerations have not been repeated in this section, but all still apply._

All PEPFAR-supported VMMC services must include a pre-defined minimum package of clinical and prevention services. Because male circumcision is not 100% protective, every VMMC package must include counseling on and promotion of other HIV risk reduction strategies, such as consistent condom use and avoidance of multiple sexual partnerships, for clients undergoing VMMC, their partners, and the larger population in areas where VMMC is being scaled-up.

4.2 Technical Considerations

As described in the 2014 COP CIRC Budget Code Narrative, mechanisms for assessing and ensuring ongoing quality and safety of services must be in place. PEPFAR’s VMMC TWG conducts interagency external quality assurance (EQA) assessments to objectively gauge the safety, quality, and compliance of programs with clinical standards of care, international best practices, and PEPFAR Policy Guidance. Though EQA assessments may occur on an as-needed basis, continuous quality improvement (CQI) self-assessment should be routinely conducted at all PEPFAR-funded sites and coordinated with EQA assessments where and when EQA
activities occur. Section 13 of *PEPFAR’s Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations* (158), provides additional information about EQA and CQI activities, and the PEPFAR instruments for EQA assessments and CQI self-assessments, are available from the VMMC TWG (158). In accordance with the 2014 COP Prevention Technical Area Narrative (TAN), PEPFAR VMMC programs are expected to receive technical assistance visits from the VMMC TWG at least once every two years, primarily for program safety and quality assessments, that may include EQA assessments, as appropriate.

Programs should ensure appropriate and adequate training for health care workers and non-clinical staff providing VMMC services and include mechanisms for assuring initial and continued competency post-training. Health care providers designated to provide a higher volume of services or services at a fixed frequency should be prioritized for training. Programs should monitor how many VMMCs are actually conducted by each provider trained with PEPFAR funds following his/her training. Those performing a “low” number in specific periods and/or cumulatively, as determined in conjunction with the training programs, may be prioritized for supportive supervision, competency assessment, or retraining. For additional information related to training, please see *PEPFAR’s Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations*, Section 6 (158).

Over the course of lifecycle of VMMC (including launch, expansion, maintenance, and contraction) programs need to continually assess and recalibrate the balance of VMMC supply (capacity of the system to deliver VMMC services) and demand (number of men seeking services). The AIDSTAR-One Case Study Series *Matching Supply with Demand: Scaling Up Voluntary Medical Male Circumcision in Tanzania and Zimbabwe* provides examples of country efforts to maintain this balance (159), and Section 5 of *PEPFAR’s Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations*, defines the scope of potential service delivery models that can be leveraged to keep VMMC supply nimble and responsive to demand (158). Most VMMC programs benefit from naturally occurring demand when launching services due to the presence of informed early adopters or culturally supportive environments in service delivery areas; however, the same programs must also proactively generate demand in order to reach performance targets. Demand creation involves making available simple, compelling, and accurate information on the risks and benefits of VMMC (including those beyond HIV prevention) that can be delivered through multiple credible channels to reach VMMC target audiences, including mass media, community engagement, and interpersonal communication; demand also hinges on high service quality, both clinical and interpersonal, to create a cascade of favorable word of mouth from VMMC clients to their uncircumcised peers and those who influence them. Most importantly, programs must work to understand and consider the personal and cultural values of their target audiences, identify gender-related barriers for their target audiences (e.g., potentially harmful male norms), and work with local community gatekeepers to ensure VMMC can serve their constituents while
preserving dignity and tradition. PEPFAR/CDC developed *The Voluntary Medical Male Circumcision (VMMC) Demand Creation Toolkit*, a resource summarizing considerations for the development and execution of VMMC demand creation strategies, which is expected to be released prior to the 2014 COP Technical Considerations (160). The toolkit offers strategic recommendations, template tools to support the spectrum of demand creation work, and creative template social and behavior change materials (e.g., using positive male norms in messages and involving women as influencers and decision-makers for seeking VMMC), including stock photos, for testing and adaptation to fit local language, culture, and preferences. The *PEPFAR Monitoring, Evaluation and Reporting Operational Guidance* also outlines the necessary approach to VMMC demand creation monitoring and evaluation, including community engagement and linkages to other health and HIV services (161).

Programs should design a VMMC advocacy strategy and define socio-political issues in need of advocacy based on country context and evidence. Countries need to identify 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.

WHO published *Considerations for Implementing Models for Optimized Volume and Efficiency of Male Circumcision Services for HIV Prevention (MOVE)* in early 2010, based upon observations of a highly efficient service delivery model in Orange Farm, South Africa (162). PEPFAR programs are strongly encouraged to adopt as many of the recommended efficiencies in the MOVE document as possible, working in coordination with partner country governments. Though existing health facilities may not be readily equipped to absorb a high demand for VMMC quickly, immediate services for men have been mobilized in some countries utilizing novel implementation approaches, such as mobile/outreach services, volunteer health care workers, and time-limited VMMC campaigns. Such novel approaches, and other country appropriate strategies, should be explored. Conventional service models that are integrated into government health facilities are also encouraged, as long as sufficient demand, staff, commodities and space are dedicated to VMMC services. It is critical to ensure that appropriate follow-up and treatment of any complications is available, which may be a particular challenge in mobile/outreach settings.

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 can 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.

Programs supporting VMMC must include systems for monitoring and reporting of VMMC indicators so that progress towards established targets can be tracked. For more information, please see the *PEPFAR Guidance for Monitoring and Reporting VMMC Indicators* (163), the *PEPFAR Monitoring, Evaluation and Reporting Operational Guidance* (161) and Section 11 of *PEPFAR’s Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations* (158).

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. Section 14 of *PEPFAR’s Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations* provides additional information on reimbursing clients for incurred expenses related to undergoing VMMC (158).

Community mobilizers may be rewarded for exceptional performance (see the Health Care Worker Salary Report section of PEPFAR COP FY2014 Guidance for more information about acceptable forms of health care worker financial support). 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. Section 14 of *PEPFAR’s Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations* provides additional information on performance-based incentives for community mobilizers (158).

Clinicians who work overtime to provide VMMC services may be compensated for their time at a scale consistent with national standards (see the Health Care Worker Salary Report section of PEPFAR COP FY2014 Guidance for more information about acceptable forms of health care worker financial support). However, clinicians should not be compensated on a per-procedure basis, to avoid actual or perceived motivation to coerce clients to undergo the procedure. Section
PEPFAR’s Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations provides additional information on appropriate approaches to clinician compensation (158).

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 (164). PEPFAR funds may only be used to procure medical devices that have been pre-qualified by WHO, unless special exceptions have been explicitly granted by OGAC for evaluation purposes. Due to high rates of MC-related complications in non-clinical settings, PEPFAR funds cannot be used to train or provide support for traditional (non-medical) providers to perform male circumcision, by surgical, device-based, or other methods. However, funding can be used to support prevention information, education and evaluations of complications stemming from non-medical circumcision within traditional circumcision contexts.

Programs should support implementation framed in two prongs. Prong One encompasses funding to provide VMMC services to adolescent and adult males, prioritizing those 10-29 years of age, with the goal of achieving high uptake as quickly as possible. This first prong is a one-time, intensive intervention that is not intended to be sustained. Prong Two is the implementation of a long-term approach to ensure high male circumcision coverage levels are sustained, either through early infant male circumcision or circumcision of annual cohorts, such as cohorts of boys aging into adolescence or young men entering military service. Though the first prong targeting males that are already adults/adolescents may indirectly strengthen health systems through a variety of activities (e.g., QA, M&E, waste management), the goal of prong one is not infrastructure refurbishment, or sustainability. The goal of the first prong is to circumcise adolescent and adult men who are now or will soon be at risk of heterosexual HIV acquisition for the purpose of rapidly reducing HIV incidence. In accordance with the 2014 COP Prevention TAN, PEPFAR agencies should begin working now with partner country governments to develop strategies for the second prong. PEPFAR funding and technical assistance in the second prong is intended to support the formative work needed to thoughtfully plan and resource a long-term sustainable approach to high male circumcision coverage, though PEPFAR funds may also support delivery of Early Infant Male Circumcision (EIMC) service delivery. Because EIMC services must be sustained indefinitely, long-term funding sources must be identified. Other stakeholders, such as UNICEF and World Bank, may be particularly important to such planning.

In accordance with the 2014 COP Prevention Technical Area Narrative, countries supporting EIMC and/or sustained circumcision of cohorts of adolescents is part of strategies/documents to transition similar long-term programs to the partner country government. VMMC advisors are encouraged to include Health Systems Strengthening advisors in the development of Prong Two strategies.
4.3 Cross-cutting Content, Linkages, and Wraparounds

4.3.1 Gender

VMMC services should address harmful male norms and behaviors that may promote high-risk sex behaviors, limit access and/or adherence to HIV prevention services, including VMMC, or directly or indirectly contribute to gender-based violence (GBV). In particular, given the pervasiveness of GBV in the 14 countries where VMMC is targeted, counseling for VMMC should address issues of violence or coercion as they come up. Opportunities should be explored for monitoring experiences of coercive sex and GBV, in general in these countries, and any trends examined for correlation with VMMC service introduction/expansion. Programs are encouraged to evaluate whether provide GBV screening in VMMC sites for partners of VMMC clients identifies problems. If problems were identified, the effectiveness of on-site response services should also be evaluated. Other strategies to reduce harmful male norms and promote positive male norms can be explored within the waiting rooms of VMMC clinical settings as well as through demand creation efforts. The integration or referral/linkage of other men’s health services and programs that promote gender equitable norms with VMMC services are encouraged.

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. Women’s risk of HIV acquisition is decreased as VMMC is scaled-up because as HIV prevalence decreases in men as a result of becoming circumcised, women’s probabilities of encountering HIV-infected partners are also reduced. Women with circumcised male sex partners also have reduced risk of sexually transmitted infections, including carcinogenic strains of HPV, and cervical cancer (152)(153).

4.4 Referrals and Linkages

Please see the PEPFAR Monitoring, Evaluation and Reporting Operational Guidance document, (161) and Section 7 of PEPFAR’s Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations for important information about referrals and linkages to/from VMMC service sites (158).

4.5 Additional Resources

- 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)
- WHO/UNAIDS 2008 Operational Guidance for Scaling Up Male Circumcision Services for HIV Prevention:
1.4 HIV TESTING AND COUNSELING

1 Introduction

As the gateway to HIV prevention, care, and treatment services, knowledge of HIV serostatus is a critical component of PEPFAR’s plan for achieving an AIDS-free generation. There has been tremendous scale-up of HIV Testing and Counseling (HTC) under PEPFAR. In 2012 alone, over 45 million HTC sessions were provided with PEPFAR support. Despite these gains, many people living with HIV (PLHIV) 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:

- Identify PLHIV through the provision of quality HTC services for individuals, couples, and families;
- Effectively link individuals and their families to appropriate HIV treatment, care and support, as well as HIV prevention services, based upon their serostatus; and
- Support the scale-up of high impact interventions to reduce transmission, morbidity and mortality by setting HTC targets that allow programs/countries to meet anti-retroviral treatment (ART), voluntary medical male circumcision (VMMC), and prevention of mother-to-child transmission (PMTCT) targets.

1.1 What’s new in 2014

New PEPFAR Guidance for Monitoring, Evaluation, and Reporting (MER) includes updates for HTC programs along with other technical areas. HTC indicators have been revised to capture information on where HTC services are delivered as well as more precise data on the age of recipients. Disaggregations on status as a member of a key population and modality of counseling (individual, couples, and index-partner) are recommended as well. The MER also includes new outcome indicators, linkage indicators for monitoring linkage to care and treatment services for HIV+ persons, and quality indicators. Teams should refer to this guidance as part of their Country Operational Plan (COP) planning process to determine how to support partners in meeting new reporting requirements.

The rollout of Option B+ and other “Test and Treat” approaches, alongside generally high volumes of testing, requires complimentary focus on the quality of testing to ensure correct diagnoses. All countries should be supporting the scale-up of quality assurance systems. In support of these efforts, the centrally managed HIV Rapid Testing Quality Improvement Initiative (RT QII) will support a select set of priority countries to ensure the quality of HIV rapid testing and expand upon quality improvement work.
In addition to existing recommendations, a number of new HTC guidelines have been released within the 2013 *WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infections* (http://www.who.int/hiv/pub/guidelines/arv2013/download/en/index.html). New guidelines are noted under relevant sections.

### 1.2 PEPFAR Blueprint

HTC is an integral component of the *PEPFAR Blueprint: Creating an AIDS Free Generation*. Within the *Road Map to Saving Lives* HTC is highlighted as one of the evidence-based prevention strategies and a gateway to other effective interventions. HTC plays an important role within the *Roadmap to Smart Investments* with an emphasis on increasing access to HTC through strategic and responsive programming and support for effective supply chains for HIV diagnostics. The *Roadmap for Driving Results with Science* highlights the need for continued evaluation and research of our programmatic efforts to provide scientific evidence to improve the delivery and uptake of services. Evaluating HTC as part of combination prevention to reach PLHIV earlier and the gateway to the continuum of care is necessary to optimize service delivery, to identify approaches that maximize rates of linkage between diagnosis and care and treatment, and to have impact in the fight against AIDS.

### 1.3 Technical Background

Despite the significant scale up of HTC, current estimates suggest that more than 60% of HIV-infected persons in developing countries are unaware of their infection, and fewer know the HIV status of their partner(s) (165)(166)(167). Moreover, many PLHIV continue to be diagnosed and enrolled into care late in their infection, compromising the success of prevention, care, and treatment efforts (168). A combination of facility and community-based HTC strategies along with effective linkage interventions are necessary to identify PLHIV earlier and support and ensure their enrollment into care and treatment services. Certain HTC approaches may be more effective in reaching specific populations (e.g., HIV-infected, first-time testers, pregnant women, key populations (KP)) (169). Additionally, published evidence continues to suggest that HTC is correlated with a positive impact on behavior change among HIV-infected individuals and serodiscordant couples (170)(171)(172)(173)(174)(175)(176)(4) (177) (178)(179).

The 2012 WHO *Strategic HTC Programme Framework* expands the traditional three C’s of HTC (consent, confidentiality, and counseling) to also include “connections to care, treatment, and other services” and “correct test results.” These changes highlight both the importance of linkages between HTC programs and prevention, treatment, care, and support services and the importance of ensuring the delivery of accurate test results (179).
1.3.1 Strengthening linkages from HTC to other services

Once individuals have been diagnosed as HIV-positive, actively linking them into HIV prevention, care, and treatment services is critical for their own health as well as to prevent HIV transmission to uninfected sex/needle-sharing partner(s) and children. Improving availability and access, as well as scale-up of ART and PMTCT services through PEPFAR, depends on successful linkages to care (LTC). However, the impact of passive referral (which has been standard of care) of newly HIV diagnosed persons enrolling in HIV care and treatment has been limited (180). There is substantial complexity in health seeking behavior and multiple pathways into HIV care following diagnosis that should be considered in seeking to strengthen linkage to care and treatment (181).

Review of the literature has identified key factors associated with low rates of both care-seeking behavior and LTC. These factors include, but are not limited to: feeling healthy, young age, denial of diagnosis, fear of stigma, and relationship status (182)(183). Beyond the individual’s decision to seek care, structural or contextual barriers may impede an individual’s ability to access care. Examples include distance to services, lack of transportation, and lack of education. Healthcare system barriers include, inter alia, inadequate counseling, poor referrals by health care providers, stigmatizing or unfriendly services, inconvenient hours of operation and long wait times (184)(185). Evaluation of multiple individual, contextual, and healthcare system factors which pose difficulties for people living with HIV and limit their engagement in care may allow for targeted interventions focusing on susceptible individuals (181)(186)(187)(188).
2 HTC Program Strategies and Considerations

2.1 Strategic Programming for HTC

The 2012 WHO Strategic HTC Programme Framework describes diverse models for HTC services, including provider-initiated testing (PITC) in health care facilities, stand-alone centers offering client-initiated HTC (VCT), and a range of community-based approaches. PEPFAR programs should choose service delivery models on the basis of the specific populations they are seeking to reach, cost–effectiveness, and available resources. The mix should facilitate diagnosing as many PLHIV as early as possible to enable timely linkage to care and treatment services. The 2013 WHO Consolidated ARV Guidelines recommend that community based testing efforts are prioritized, in addition to facility based testing, as they are likely to find PLHIV at an earlier stage of infection. In particular:

- In generalized HIV epidemics, community-based HIV testing and counseling with linkage to prevention, care, and treatment services is recommended, in addition to provider-initiated testing and counseling (strong recommendation, low-quality evidence); and
- In all HIV epidemic settings, community-based HIV testing and counseling for key populations, with linkage to prevention, care, and treatment services is recommended, in addition to provider-initiated testing and counseling (strong recommendation, low-quality evidence).

This is especially important as WHO guidelines now recommend expanded treatment eligibility for adults, pregnant and breastfeeding women, and children, while maintaining priority for the sickest patients. HTC strategies should prioritize high-risk and hard to reach populations who are most vulnerable and marginalized (see priority populations below). While precise coverage levels for HTC have not been evaluated, programs should aim to achieve high testing coverage among high burden populations and geographic areas in order to prevent individuals from unknowingly transmitting HIV. Community mobilization and promotion of HTC are important for increasing awareness about the availability and benefits of HTC services as well as the availability and value of ART for all PLHIV, and are essential complimentary components of the recommended HTC strategies. Well-coordinated, culturally appropriate social marketing can increase demand for HTC and follow-up services.

2.1.1 The Four “Knows”

PEPFAR’s revised 2011 Guidance for the Prevention of Sexually Transmitted HIV Infections and WHO’s Strategic HTC Programme 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 (179). Many countries are already familiar with these data and are using them to inform the strategic direction of their HTC programs. Some countries may
need additional support to strategically align their HTC services with areas and populations of high HIV burden. The HTC Technical Working Group (TWG) has developed tools and workshops to assist PEPFAR teams, partner governments and other stakeholders in this kind of strategic planning. The following framework is meant to assist countries with decision making for strategic HTC planning.

2.1.1.1 Know Your Epidemic

- **National HIV prevalence and prevalence for defined geographic areas and populations.** Countries should prioritize geographic areas and populations with the highest burden of HIV infections;
- **HIV incidence for defined geographic areas and populations.** Where possible, countries should also use 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; and
- **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 understand who is getting tested, enrolling in care, and initiating ART late in their stage of infection. Where possible (e.g., where services such as point-of-care CD4 testing are available), programs should also look at the rates of late-stage diagnosis within their testing programs. Finally, countries should look at cross-cutting program data, such as numbers of persons testing HIV-positive relative to numbers of persons enrolling in care and initiating ART, to understand where there are relative successes and challenges in linking and enrolling patients from HTC programs into care and treatment services. The 2013 MER Guidance includes new linkage indicators that countries are required to collect and report. Countries with the ability track diagnosed individuals from HTC to care and treatment should capture this information through the new PEPFAR indicator. Countries who do not currently have the ability to track linkages should work with their HTC and care and treatment partners to develop appropriate procedures to meet reporting requirements.

2.1.1.2 Know Your Context

- **Policy and Legal Environment.** Teams and implementing partners should understand and respond to relevant national HTC guidelines, policies and laws, as well as any policies or laws that might hinder access for certain populations, (e.g., laws that criminalize homosexuality or age of consent laws for testing adolescents);
• **Social and Cultural Environment.** HTC programs should understand the social and cultural norms that affect both access to HTC and linkage to care (e.g., gender issues, vulnerabilities of KP, stigma, etc.) and take steps to mitigate the impact of those norms; and

• **Resources.** PEPFAR teams should understand the HTC “landscape,” coordinating with other donors, relevant offices in the Ministry of Health, and implementing partners (both those supported by PEPFAR and those supported by other partners).

### 2.1.1.3 Know Your Response

• **HTC coverage and testing behavior:** Using estimates of numbers of PLHIV at the national—and where available, sub-national level—programs should look at the proportion of people tested for HIV in the past year and received their results, the proportion of people who have ever tested, and trends in testing behavior over time to determine where gaps in testing and linkage are highest;

• **Yield of HTC settings and modalities:** HTC program data can be assessed to determine what HTC approaches and settings have identified higher proportions of HIV-infected individuals, partners and family members. Programs may also have data on number of clients linked to appropriate follow-up services;

• **Location of HTC and other HIV services relative to HIV prevalence:** HTC programs should be able to map HTC services to align with areas of need, by examining the:
  - Number and location of all sites that offer HTC services;
  - Number of health facilities that offer PITC; and
  - 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 care, treatment, VMMC, 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 reduce the percent of undiagnosed PLHIV in a country and contribute to treatment, care and prevention targets will need to be made by country-level assessments. Because of historically low rates of LTC, PEPFAR teams and partners should not assume that all previously tested and diagnosed PLHIV will not need to be re-tested. Re-testing at an HTC site that has strong LTC activities may be the most effective way to assist previously diagnosed but not enrolled PLHIV to access care. HTC targets can be calculated for each region of a country, based on estimates or available data such as:
  - Estimated adult population of PLHIV, based on HIV prevalence and population size;
  - Number of patients enrolled in HIV care and treatment;
• Per HTC modality or setting: Number of HTC clients tested, percent HIV-positive, estimate of percent who will be ART-eligible, percent eligible who will link to treatment;
• Number of clients tested in other programs (e.g., PMTCT, TB, VMMC), percent HIV-positive, percent ART-eligible, and percent linked to treatment; and
• Percent of persons who will become ART-eligible from pre-ART registers.

Programs can review data such as these to inform decisions on which modalities to scale up, in which regions, in order to increase case-finding and to reach ART and other program targets. This approach can also be applied to other program areas and to plan for commodities needed.

Setting broad HTC targets can place an inappropriate emphasis on achieving high numbers tested rather than on identifying PLHIV through a high-quality testing intervention. Therefore, expansion of HTC services should be carefully strategized to maximize yield and linkage, rather than purely to achieve a numerical target. Moving forward, PEPFAR will be increasingly focused on metrics of yield and linkage over numbers tested. Additionally, HTC services should ensure—through adequate funding, 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 (see forthcoming PEPFAR Quality Strategy).

2.1.1.4 Know Your Costs

In order to use donor and host country funds efficiently and effectively, HTC approaches should prioritize those approaches that most effectively and inexpensively identify HIV-infected persons and sero-discordant couples. Countries should collect and assess data on the cost of different approaches from a variety of sources to inform their decision making. These sources might include PEPFAR-funded costing studies, expenditure analysis, and published literature. When planning COPs, teams should assess the HVCT budget allocation against HTC targets to ensure sufficient funds for the testing necessary to meet treatment, care and, if necessary, VMMC and PMTCT targets, as well as the cost of any ongoing programs.

2.1.2 HTC Strategic Framework

The following framework and table has been informed by the WHO (2012) Strategic HTC Programme Framework 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.
Table 1. Likely Applications of Various HIV Testing and Counselling Modes in Different Epidemic Situations

<table>
<thead>
<tr>
<th>HTC model</th>
<th>Concentrated or low-level epidemic</th>
<th>Generalized epidemic</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Facility-based</strong></td>
<td>----------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------</td>
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<tr>
<td>Clinical settings</td>
<td>Cost-effectiveness needs assessment</td>
<td>PITC in all health-care settings</td>
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<tr>
<td>ANC</td>
<td>PITC in these services, which serve key populations</td>
<td>PITC in every health-care contact</td>
</tr>
<tr>
<td>TB, STI clinics, OST, NSP</td>
<td>PITC in prisons and other closed institutions</td>
<td>PITC in all health-care settings</td>
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<tr>
<td>General and other specific clinics</td>
<td></td>
<td>PITC in facilities located to serve key populations</td>
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<tr>
<td><strong>Other facilities—e.g.:</strong></td>
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<tr>
<td>Stand-alone VCT</td>
<td>Located to serve key populations</td>
<td>For those self-identifying as at risk who find these facilities more suitable than clinics</td>
</tr>
<tr>
<td>Drop-in centres</td>
<td>To key populations and high prevalence geographic areas</td>
<td>To key populations and remote areas</td>
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<tr>
<td><strong>Community-based</strong></td>
<td></td>
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<tr>
<td>Outreach and mobile</td>
<td>To key populations and high prevalence geographic areas</td>
<td>To key populations and remote areas</td>
</tr>
<tr>
<td>Home-based door-to-door</td>
<td>Where other HTC is lacking or women cannot leave home</td>
<td>Where other HTC is lacking or women cannot leave home</td>
</tr>
<tr>
<td>Home-based index</td>
<td>To households of those known or suspected to have HIV or TB</td>
<td>To households of those known or suspected to have HIV or TB</td>
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<tr>
<td>Events</td>
<td>For general population; can reach men, youth (e.g. sports events)</td>
<td>For general population; can reach men, youth (e.g. sports events)</td>
</tr>
<tr>
<td>Campaigns</td>
<td>Can address general population or specific audiences—e.g., couples, men, young people</td>
<td>For working people and students whose visits do not allow clinic visits</td>
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<tr>
<td>Workplaces, schools</td>
<td></td>
<td></td>
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<tr>
<td>Couples/partner testing</td>
<td>Couples HTC for partners of those testing HIV-positive</td>
<td>Couples HTC offered to all</td>
</tr>
</tbody>
</table>

Source: WHO (2012)(179)

2.1.2.1 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%, including KP such as SW, MSM, TG, and PWID; and
- **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;
  - PITC for *all patients* accessing health care services since the likelihood of exposure to HIV is high in countries with generalized epidemics. Special emphasis should be placed on PITC for children, pregnant and breastfeeding women, and their partners(189);
  - Home-based HTC (HB HTC) for *partners and families of PLHIV or TB* (index patient model); and communities with high population density and *high HIV*
prevalence or low numbers of people tested (door-to-door model). HB HTC has been found to be a highly acceptable approach in many sub-Saharan African countries. With the consent of the index patient, approaching their partner(s) and family members may have high yield for identifying HIV-infected individuals and discordant couples. A door-to-door approach may be most effective for reaching large numbers of people in areas with high population density. To achieve program goals, communities with high HIV prevalence or low numbers of people previously tested (or tested in the last year) should be targeted with the door-to-door approach;

- Mobile and Outreach HTC for communities with high HIV prevalence, low numbers of people tested, or that are hard-to-reach (e.g., children and adolescents, KP, other populations with high prevalence such as miners and fishing communities); and
- Stand-alone and integrated 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.

2.1.2.2 Mixed Epidemics

- **Target population for HTC:** all patients (adults, pregnant and breastfeeding women, and children) in health-care settings where HIV prevalence exceeds 1%, all partners and family members of PLHIV, and all residents or members of communities in which estimated HIV prevalence exceeds 5%, percent, including KP such as SW, MSM, and PWID; and

- **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;
  - Decisions about how to implement PITC in mixed generalized epidemics should be guided by an assessment of the epidemiological context at the sub-national level. Typically, some regions or districts will have very high prevalence within the general population, while others will have much lower prevalence. HTC strategies should take these sub-national level differences into account, with care to concentrate resources where prevalence is highest.
    - Where prevalence equals or exceeds 1% at the sub-national level, PITC for all patients including pregnant and breastfeeding women, and children accessing health care services in health facilities; and
    - Where prevalence is less than 1%, PITC for all patients in TB or STI clinics, or with opportunistic infections or other signs and symptoms suggestive of HIV infection and children known to be exposed to HIV perinatally. Consideration should also be given to PITC in ANC settings based on setting/population prevalence as well as for KP1.
Mobile and Outreach HTC for targeted sub-populations, including KP and other populations at elevated prevalence;

Home-based HTC (HB HTC) for partners and families of PLHIV or TB (index patient model); a door-to-door model may be indicated for communities with high population density and high (>5%) HIV prevalence; and

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 KP and hard-to-reach populations in mixed epidemics, particularly if they specifically target these populations and provide KP-friendly services.

### 2.1.2.3 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 KP (men who have sex with men (MSM), sex workers (SW) and people who inject drugs (PWID)); and

- **HTC Approaches:** The following HTC approaches should be prioritized based on the order below 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;

  - VCT sites for targeted sub-populations including KP. 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 KP. VCT may also be an effective approach for reaching KP through drop-in centers or fixed sites that provide KP-friendly services;

  - Mobile and outreach HTC for targeted sub-populations including KP (i.e., SW, MSM, PWID). Since many KP 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 KP feel comfortable. Examples may include drop-in centers, mobile unit, or organized testing event for KP. 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;

  - PITC is recommended for all adults, adolescents, and children who present to health facilities with signs and symptoms suggestive of underlying HIV infection, including TB and other opportunistic infections, and children known to have been exposed perinatally to HIV;
o PITC may be considered for sexually transmitted infection (STI) patients, KP, ANC and TB patients. Decisions about how to implement PITC in concentrated epidemics should be guided by an assessment of the epidemiological context; and

o 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.

2.1.3 Priority Populations

The decision to prioritize a population for HTC services should always be based on data about HIV prevalence in that population. Key populations (men who have sex with men (MSM) and transgendered persons (TG), sex workers (SW) and people who inject drugs (PWID)) should be a prioritized population for HTC in all epidemic settings. Other setting-specific populations where HIV prevalence may be higher than the general population include sexually active adolescents, uniformed/military personnel, migrant populations, truck drivers, and fishing communities. HTC services should prioritize identification of PLHIV and discordant couples within high prevalence populations, by focusing on those at disproportionate risk for HIV infection. This includes sexual partners and children of PLHIV, pregnant women in antenatal care (ANC) clinics, HIV-exposed infants and children, TB and STI patients.

2.1.3.1 Partners of PLHIV

All sexual partners of PLHIV should be offered voluntary HTC with support for mutual disclosure. Couples and partner HTC will be critical elements of emerging interventions promoting the use of ART to prevent HIV transmission between serodiscordant couples. WHO’s 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) and the 2013 WHO Consolidated ARV guidelines (190) emphasize the importance of HTC for couples and universal ART for all HIV positive partners with a serodiscordant partner for prevention purposes.

2.1.3.2 Children

Children (here defined as people aged zero through nine years) are frequently overlooked populations for HTC programs. Currently, only an estimated 15% of HIV-exposed infants needing testing are tested in the first two months of life(191). For a variety of reasons, most HIV-infected children are not identified through early infant diagnosis (EID). WHO now recommends immediate initiation of ART in children under five years testing positive for HIV, without waiting for clinical or immunological disease progression. Therefore early diagnostic testing should be performed with the aim of identifying as many HIV-infected infants as early as possible. Delays in initiation of ART in children are associated with a host of negative developmental sequelae including cognitive and metabolic impairments. Recent evidence suggests that more children than originally believed may be surviving perinatal infection and
reaching adolescence undiagnosed (192)(193). These children often present at primary healthcare clinics with symptoms of respiratory or other infection.

WHO recommends universal (“opt-out”) PITC to any infant 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). In high-burden settings, PITC for children should be universal in all clinical settings (e.g., inpatient pediatric wards, malnutrition clinics, TB clinics, immunization clinics, and other outpatient settings). PITC should be offered for siblings of these children, as well. HIV virological testing should be used to diagnose HIV infection in children < 18 months of age. The timing of any repeat testing should consider breastfeeding practices, as the risk of acquiring HIV infection from mothers continues throughout the breastfeeding period.

2.1.3.3 Adolescents

Two factors are leading to a growing population of adolescents living with HIV (ALHIV). The first is the “aging up” of children perinatally infected in the 1990s and early 2000s. The second is a population boom in sub-Saharan Africa during that same period which has led to the largest generation of adolescents and young people in history; even where incidence among these adolescents is low, the growth in population size has increased the absolute numbers of ALHIV. The UN estimates that 40% of new HIV infections occur in people aged 15 to 24, with 80% of those infections occurring in sub-Saharan Africa (194).

ALHIV may learn of their HIV status through HTC regardless of how they acquired HIV. Many perinatally infected adolescents do not know their status because their parents or caregivers have chosen not to disclose. These ALHIV often discover their status through testing. Evidence suggests that adolescents are not accessing HTC, care or treatment in numbers commensurate with their population.
For those who test positive, the period immediately after HIV diagnosis may require specific, targeted, psychosocial and mental health services tailored to both the situation in which infection happened and the developmental age of the individual (195). The period after HIV testing is a time for ALHIV to work with counselors to develop individualized plans to disclose their HIV status and engage their families and peers in providing support for the ALHIV, understanding the family environment (196)(197).

Adolescents’ access to HTC and linkage to ongoing clinical care may be hindered by age-specific barriers. Among these, varying legal ages of consent across countries may prohibit or otherwise reduce service access or have implications for disclosure and confidentiality (e.g., where providers must disclose a minor’s status to their parents or guardians) (198).

In 2013, PEPFAR will release special Adolescent Technical Considerations which will address the needs of ALHIV. PEPFAR teams and implementing partners should review this document for a more detailed discussion of HTC for this population.

Coverage may be insufficient
WHO recommends universal (“opt-out”) PITC 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).
Where epidemiologically appropriate, programs should work to support coverage and uptake of child and youth-friendly HTC services. In high-burden settings, universal (100%) PITC in inpatient pediatric wards, as well as in malnutrition clinics, TB clinics, and other outpatient settings should be prioritized. Other novel approaches may also reach infants, children and adolescents (e.g., immunization clinics, school-based HTC) and may warrant further study (199).

**Barriers to HTC service delivery for children and adolescents**

Staff may not be comfortable or lack skills in providing HTC to these populations. Family-centered approaches to HIV testing and counseling may be particularly important in index patient testing models, e.g., in home-based testing, and in HIV care and treatment settings and PMTCT clinics where routine PITC is offered to children of HIV-infected adults and siblings of HIV-infected children. Additional and appropriate training may be necessary; contact the HTC TWG for resources in this area.

Acceptability of HTC by or for children and adolescents may not be optimal (200) for the following reasons which PEPFAR teams and partners should strive to address:

- **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) should be updated to address children and adolescents specifically;
- **Disclosure** remains a concern. Fear, stigma, and lack of provider skills all contribute to inhibiting disclosure and the provision of guidance on disclosure to children and adolescents. Many of these disclosure issues likely need to be addressed at a country level and are grounded in the culture and legal frameworks of a given country. WHO guidelines endorsing age-appropriate disclosure are also available, and training materials to address the programmatic “how-to” are in development;
- **Linkage** from diagnosis to care and treatment has not been well-studied in these populations. However, the WHO 2013 Consolidated ARV Guidelines recommend ART initiation for young children (up to age five, five to nine years old) and adolescents (ages 10-19) ([http://www.who.int/hiv/pub/guidelines/arv2013/intro/rag/en/index2.html](http://www.who.int/hiv/pub/guidelines/arv2013/intro/rag/en/index2.html)); and
- Among HIV-infected children and adolescents, there’s a need to distinguish and recognize vertically vs. horizontally infected; these distinct populations will have some overlapping and some different needs related to disclosure and counseling.

See sub-section 6 (Additional Resources) of this Section for additional guidance providing programmatic support for adolescents.

### 2.1.3.4 Key populations

Key populations are defined by WHO and PEPFAR as MSM, TG, SW (male, female and transgender) and PWID. These populations tend to have very high rates of HIV infection, yet are typically underserved by HIV services. This may be because service providers in mainstream
settings are perceived to be or are insensitive and stigmatizing to KP. KP may be a risk of arrest because their behaviors are criminalized, and this can also undermine provision and uptake of services. Offering HTC through mobile or outreach services can be an effective way to reach KP. Many SW successfully access HTC through SW-friendly clinics that specialize in providing STI treatment and family planning. On-site rapid HIV testing with same-day results is an essential component of all KP-friendly HIV testing services. HTC services for KP are often offered as a package of HIV prevention services, which may increase uptake and may reinforce counseling messages. See Section 1.2 of the Technical Considerations (Prevention of Sexually Transmitted HIV Infections) for more information on effective HTC programs for KP.

2.1.4 Combination Approaches to Linkage to Care and Treatment

WHO’s 2012 Strategic HTC Programme Framework and 2013 Consolidated ARV Guidelines emphasize the importance of ensuring linkage between HTC programs and prevention, treatment, care and support services. In 2013, PEPFAR is releasing a Linkage, Engagement and Retention Strategy, aimed at helping country programs strengthen this aspect of their programs. Many PEPFAR programs and partners are already developing innovative approaches to strengthening LTC from HTC, including strategies such as telephone follow-up systems (Zambia), paper-based referral and tracking (Zimbabwe), community support structures and cadres (Malawi), and provision of ART clinic appointments at diagnosis (Zambia)(201). Other strategies include assistance with transport, involvement of community outreach workers to identify those lost to follow-up; support from peers or “expert patients” and use of reminders via mobile phone text message. These strategies have yet to be evaluated.

The following are illustrative examples that are either being implemented in some countries currently, or that countries may wish to pilot. However, at present the evidence base for the effectiveness of these interventions is limited. These and other innovative linkage strategies warrant further exploration and outcome evaluation to determine effectiveness; successful linkage approaches should be documented and expanded.

- Note that under updated WHO guidelines, all HIV-positive pregnant women, children under the age of five, patients with TB, and PLHIV with a seronegative partner are immediately eligible for ART. To the extent that these guidelines are consistent with national policies, enacting them will potentially reduce loss to follow-up by eliminating barriers to care such as the need for CD4 testing;
- Consider developing LTC-related policies, frameworks, and/or standard operating procedures collaboratively with key stakeholders from HIV care and treatment, HIV testing and counseling and community-based outreach and care programs. Consider impacts of laws and policies on confidentiality of HIV test results that preclude active follow up by health system staff or community workers;
- Develop systems and/or standard operating procedures for confirming that persons diagnosed with HIV have enrolled in care and treatment services; and
• Explore multi-level LTC strategies which address multiple barriers to linkage at the same time (healthcare system, individual/community and structural). A 2013 systematic review of interventions to promote linkage to HIV medical care among PLHIV identified the following successful strategies:
  o An active care coordinator who assists the patient to access HIV care;
  o Offering information and education about HIV care during the post-test counseling session;
  o Providing motivational or strengths-based counseling (or case management);
  o Accompanying clients to medical appointments; and
  o Helping with appointment coordination (186).

The findings of additional linkage studies are consistent with the findings of the review (186)(202)(183). There is also growing evidence of the positive impact of targeted healthcare system interventions such as integration of HTC and HIV clinical care services, and on-site or immediate CD4 testing with same-day results (203)(204) (205)(206). A 2012 systematic review that quantified losses along the continuum of HIV care identified point-of-care CD4 count testing, more efficient referral systems, and transport vouchers as effective strategies to reduce losses after diagnosis (204);

• Coordinate efforts and follow-up activities between key stakeholders and programs focused on HIV prevention, HTC, and HIV care and treatment services to ensure that efforts are complementary and increase impact. HTC and ART programs can work together to explore locally relevant systems for reducing the number of PLHIV who do not enroll in care, including linkage from TB treatment sites where ART is not provided. Costs of coordination should be factored in;

• Develop fora that enable PLHIV to offer feedback on the most effective LTC approaches, as well as on ways to improve HTC programs; and

• HTC programs can be monitored through a range of program-level indicators and special studies, generating program data that can help to support continuous improvement of LTC interventions. See new HTC indicators in PEPFAR’s forthcoming MER Guidance.

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 could consider integrating screening and referral for other HIV prevention and health services as available, such as:

• TB screening, prevention, and referral services;
• Family Planning counseling and referral;
• Alcohol screening and referral;
• STI screening and referral;
• Gender-based violence screening and referral; and
• Voluntary medical male circumcision (VMMC) screening and referral.
In the fourteen countries where VMMC is being scaled-up, all HTC programs should provide active referrals for HIV-negative boys and men to VMMC services, particularly HIV-negative men in discordant sexual relationships.

HTC programs should ensure that appropriate referrals and linkages are in place for any additional screening incorporated into the HTC counseling session.

Likewise, integrating HTC into other existing platforms, especially existing family planning services, should also be considered in countries with a high burden of HIV (see Section 3.10 of the Technical Considerations (HIV and Family Planning Integration)).

2.2 Emerging Approaches to HTC—a need for more evidence

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

2.2.1 HIV Self-testing

WHO’s working definition of HIV self-testing is using a test that is “collected, performed and interpreted in private by an individual who wants to know about their HIV status.” HIV self-testing (HIVST) does not confer ‘knowledge of status’ or provide a definitive diagnosis. HIVST involves a screening test that provides an individual with information upon which to base further action; this approach is often labeled “self-testing,” however a single test result is insufficient for diagnosis (207). Use of HIV tests for self-testing may or may not be accompanied by limited training. While this is occurring in some countries informally and with little or no regulation in the private sector (208), there have also been recent pilot trials exploring HIVST as an intervention. To date, these trials have used only single rapid HIV tests without immediate confirmatory testing. Furthermore, outside of the USA, there have been no HIV test kits developed and indicated specifically for self-testing use by the general public. HIVST has been investigated among health care workers in Kenya and MSM in developed countries (209)(207).

In general, there are both concerns and opportunities with this HTC approach. Reports on the field accuracy of HIVST have been mixed; ensuring quality test kits, accurate and reliable test results ⁴ and access to counseling and linkage to confirmatory testing pose challenges to this approach. Nevertheless, HIVST may also provide opportunities to dramatically increase coverage of under-tested populations and access to HIV testing if implemented in a way that is accurate, acceptable and feasible. Further policy and regulatory analysis and programmatic research are needed to determine how to strategically position HIVST and prepare for its introduction. The HTC TWG will be initiating these efforts in the coming year, and welcomes inputs from PEPFAR teams interested in participating.

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⁴ In the USA, preliminary studies of the recently FDA-approved, over-the-counter OraQuick rapid test showed 92% sensitivity—meaning one out of 12 positive tests would be false negative (386).
2.2.1.1 Partner notification and 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 PLHIV to HTC (210)(211). This pilot achieved high yield; 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 home-based HTC (212). Partner notification approaches are used in some home-based care models (index patient testing) and have also been used in the US for a number of years. In the US, a Disease Intervention Specialist (DIS) follows up the sexual partners of individuals with certain STIs; HIV was recently added to this subset (213). PEPFAR countries could explore the feasibility and potential cost efficiency of such programs.

2.2.1.2 Pre-exposure Prophylaxis

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 would be needed to identify new infections. Optimal intervals for retesting those on PrEP have yet to be determined.

2.3 Standards in HIV Testing and Counseling

2.3.1 Rapid HIV Testing and Updated HIV Testing Strategies

WHO has recently updated its recommended testing strategies for HIV diagnosis in both high- and low-prevalence settings. Because the positive predictive value of rapid testing declines with HIV prevalence, it is critical that country testing strategies be carefully chosen on the basis of prevalence to avoid misdiagnosis. PEPFAR programs should advocate for alignment of national testing strategies with this guidance:

- Testing strategies are based on the prevalence of the population to be tested (i.e., ≥5% or <5%).
- In high prevalence settings (≥5%), patients with reactive screening and confirmatory tests are diagnosed as positive;
- In low prevalence settings (<5%), patients with reactive screening and confirmatory tests should also be tested with a third assay. Only patients with reactive results on all three tests should receive a positive diagnosis. If the third assay is non-reactive, results should be reported as inconclusive (with A1+, A2+, A3-) and the client retested after 14 days; and
- In both high and low prevalence settings 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 repeat screening and confirmatory tests are discrepant:

- In *high-prevalence settings*: a third assay should be used. If reactive, results should be reported as inconclusive (with A1+, A2-, A3+) and the client retested after 14 days. If the tiebreaker test is negative, the patient should be reported as negative (with A1+, A2-, A3-); and

- In *low-prevalence settings*: If screening and confirmation tests are still discrepant results should be reported as negative, unless the screening test is antigen/antibody based and the confirmatory test is antibody only, then the result should be reported as inconclusive. The client should be retested after 14 days if results are inconclusive.


### 2.3.2 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...” (214) Most people who test HIV-negative do not need to be re-tested, and providers may need additional training to change outdated standard messages that encourage re-testing after the “window period”. Re-testing is important for persons with ongoing risk of infection, such as KP, pregnant women, and the HIV-negative partner in a serodiscordant couple. Recommendations on re-testing are available in WHO guidance referenced below, and PEPFAR teams should work to align messages in post-test counseling with this guidance, to more accurately target re-testing and reduce unnecessary re-testing among low-risk HIV-negative persons.

### 2.3.3 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. Section 3.11 of the Technical Considerations (Supply Chain Management) provides detailed information about HTC activities and interventions—along with cross-cutting supply chain management technical considerations—that country teams should consider to avoid potential supply chain disruptions.

### 2.3.4 Task-shifting

WHO guidance supports the use of lay counselors to perform HTC; shifting HTC to lower-level cadres can 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 morale. PEPFAR teams should work with partner governments to develop rational strategies for use of lay counselors in HTC and other HIV settings. See Section 3.4 of the Technical Considerations (Human Resources for Health) for more information.

2.3.5 Quality Assurance (QA) and Quality Improvement (QI)

Ensuring the quality of HTC service delivery is essential for both testing and counseling processes. Quality assurance and improvement activities for HTC are especially imperative for programs adopting Option B+ or any other “Test and Treat” approach to ensure correct diagnoses for treatment initiation. Key quality indicators may be established to help partner governments and PEPFAR programs assess and improve the quality of their services over time. In some PEPFAR programs, 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.

The Rapid Testing Quality Improvement Initiative is a new centrally funded initiative to help countries strengthen their quality assurance systems for rapid testing. Additional information is available in Section 3.1 of the Technical Considerations (Laboratory Infrastructure). PEPFAR is also in the process of developing a Quality Strategy, to set out high-level standards for all clinical programs and guide PEPFAR teams and implementing partners in developing quality assurance and improvement processes.

3 Gender Considerations

Gender norms and inequities affect men and women's access to and uptake of HTC services. As priority populations are identified for HTC, PEPFAR teams should assess any specific gender issues that might shape that population’s uptake of HTC and develop targeted interventions to address them. For example, many men avoid HTC because they feel uncomfortable in healthcare facilities where most patients are female or because they are unable or unwilling to take time off from work. Mobile testing marketed to men can be an effective way to overcome these barriers.

Data suggest that women with violent partners are more likely to acquire HIV, because men who engage in violent behaviors tend to also have riskier sexual behaviors and more partners. Emphasis should be placed on training providers on how to counsel and refer men and women who report being subject to intimate partner violence (IPV) or GBV. Programs may consider screening for GBV within HTC services if providers have been adequately trained. HTC services that screen for GBV should strengthen referrals/linkages to GBV services for those who screen positive. 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.

4 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.

5 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.

PEPFAR’s 2014 Monitoring, Evaluation and Reporting Guidance includes new indicators for monitoring HTC services and linkages of HIV positive persons to care and treatment services. Programs should review the new guidance and work with partners to modify or develop HTC registers and other data collection tools in order to capture the required and recommended information. The aforementioned WHO guidance on M&E for HTC programs is another useful guide 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.

6 Additional Resources

- WHO Consolidated ARV guidelines, June 2013
- Service delivery approaches to HIV testing and counseling: a strategic HTC programme framework: [http://apps.who.int/iris/bitstream/10665/75206/1/9789241593877_eng.pdf](http://apps.who.int/iris/bitstream/10665/75206/1/9789241593877_eng.pdf)

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• Planning, implementing and monitoring home-based HIV testing and counselling: http://apps.who.int/iris/bitstream/10665/75366/1/9789241504317_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
• WHO guidelines on HIV testing and counselling for adolescents and care for adolescents living with HIV: http://www.who.int/hiv/pub/posters/iaspost_htc/en/index.html
• Policy requirements for HIV testing and counseling of infants and young children in health facilities: http://whqlibdoc.who.int/publications/2010/9789241599092_eng.pdf
1.5 Positive Health, Dignity and Prevention for People Living with HIV

1. Introduction

In 2013, UNAIDS and the Global Network of People Living with HIV (GNP+) jointly issued a framework describing the range of health and prevention needs of people living with HIV (PLHIV) (215). This framework expands upon previous guidelines issued by the World Health Organization (WHO) (216) and the Centers for Disease Control (CDC) (217). Where earlier guidelines focused more narrowly on the imperative to prevent forward transmission, the Positive Health, Dignity and Prevention (PHDP) framework sets prevention activities for PLHIV within a context of holistic health promotion. PEPFAR recognizes PHDP activities as a core prevention intervention to be prioritized in PEPFAR-funded programs (215). Central to all these guidelines is the integration of HIV prevention and self-care services into the routine care and treatment offered to PLHIV (215) in both facility and community settings.

The PHDP strategy relies on two main goals: (1) to provide a minimum package of prevention services to all PLHIV, and (2) to develop and support linkages across services (e.g., prevention, care, treatment, PMTCT) and between facility and community settings. PHDP services comprise behavioral, biomedical, and structural activities aimed at reducing the morbidity and mortality experienced by HIV-positive individuals, reducing the risk of transmission to HIV-negative partner(s) and infants, and improving the quality of life. PHDP services may also help retain people in care by addressing their multiple prevention needs (215). Evidence indicates that these services can effectively reduce sexual risk behavior (218)(219)(220), STI incidence (221)(222), and unintended pregnancies among PLHIV (223) and that these services are cost-effective (224). PHDP services can be effectively delivered by health care providers in health facilities (225)(218)(226), by lay or peer counselors in clinic and community settings (227)(228)(229), and by community and home-based care (CHBC) providers (230).

1.1 What’s new in 2014?

PEPFAR’s 2014 Monitoring, Evaluation, and Reporting (MER) Guidance includes a revised indicator for measuring PHDP services. Due to the difficulties associated with providing all six elements of the minimum package of PHDP services at one clinical/community visit, the numerator has been expanded from services delivered at the last clinic visit to include services received in the past 3 months. Similarly, the denominator for this indicator has been revised and is now the age-disaggregated required indicator for Care and Support (i.e., the number of HIV-positive adults over the age of 15 years who received a minimum of one clinical service in the past 12-months). The forthcoming MER guidance on PHDP also describes indicators from other program areas (e.g., HIV Testing and Counseling (HTC), Adult Care and Support, and Health Systems Strengthening) that can be used to monitor elements of the PHDP package. This
includes indicators on linkage to and retention in HIV care, family planning (FP)-HIV integration, and representation of PLHIV on national technical and/or policy bodies.

1.2 PEPFAR Blueprint

The PEPFAR Blueprint: Creating an AIDS-Free Generation identifies the need to partner with PLHIV in the design, management, and implementation of HIV programs that are responsive to their needs (157). A top priority for the PHDP Task Force is to ensure that PLHIV have the ability and opportunity to represent their own views, concerns, and interests and take part in making decisions on issues that pertain to their health and well-being, rather than have others speak for them. A key component of PHDP services, therefore, is building the capacity of PLHIV to be active participants in the HIV response including in the delivery of prevention and support services in facility and community settings (e.g., peer counselors, expert patients), and through participation on national level technical working groups. Another aspect of capacity building is the strengthening of PLHIV organizations to represent the voice of PLHIV on national, regional, and local platforms including the Country Coordinating Mechanisms for the Global Fund to Fight AIDS, Tuberculosis, and Malaria and other policy making bodies.

In addition, offering prevention services to PLHIV can help achieve the goals outlined in the Blueprint’s Road Map for Saving Lives. Specifically, providing ongoing adherence counseling and support to PLHIV as part of their routine care maximizes the care and prevention benefits of anti-retroviral treatment (ART) by supporting optimal adherence among patients on treatment. These adherence interventions can help support goal 2, “increasing the coverage of HIV treatment”. Similarly, integrating PHDP interventions into all clinic and community settings providing care and support services to PLHIV can help achieve goal 4 “increasing access to, and uptake of, HIV testing and counseling, condoms and other evidence-based appropriately-targeted prevention interventions” by ensuring PLHIV have access to a number of prevention services including partner testing, risk reduction counseling, condom education and distribution, and family planning counseling and services.

2 Components of Effective PHDP Programs

2.1 HIV Prevention Messages and Services Should Be Integrated into all Clinic and Community Settings Providing Care and Treatment to 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, 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 and breastfeeding women to bring their partner(s) and other children to the clinic for HIV testing and counseling, offering support for disclosure and, where possible, home-based testing. STI treatment clinics, in settings where they exist as stand-alone services, are also important venues for identifying HIV-positive individuals and discordant couples/partnerships and for delivering HIV prevention messages.

Community programs that serve individuals, couples, and families living with HIV also offer opportunities for providing and reinforcing prevention messages and commodities, as well as provision of care and treatment services. These programs are especially important for targeting PLHIV who know their HIV status but are not yet eligible for (ART as these patients may not be accessing regular care or services in 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.

2.2 **PLHIV Should Be Offered a Comprehensive Package of HIV Prevention Services as Part of Their Routine Care**

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:

2.2.1 **Assessment of sexual activity and provision of condoms (and lubricant) and risk reduction counseling (if indicated)**

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). Offering skills development (e.g., condom negotiation, correct condom use) and other behavioral interventions that encourage safer sex are a critical component of risk reduction counseling and can be delivered by lay or peer counselors in facility settings. In addition, PLHIV support group facilitators, peer educators, expert patients and community care providers who 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 both at clinics and outside of the clinic/facility.
All clinic- and community-based programs should 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. Engaging and enlisting the support of peer educators, who are themselves HIV-positive, is particularly effective for promoting and distributing condoms and condom-compatible lubricants (228), especially with high-risk populations (e.g., men who have sex with men, male sex workers and transgender persons, people who inject drugs, female 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. For more information on condom programming, please sub-section 6.1.3 (Condom and condom-compatible lubricant promotion and distribution) of Section 1.2 of the Technical Considerations (Prevention of Sexually Transmitted HIV Infections).

2.2.2 Assessment of HIV serostatus disclosure to sex partners and family members and support of safe disclosure (if indicated)

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 sometimes lead to support from partner(s) and/or family, which improves uptake of, and retention in HIV care and treatment programs, as well as adherence to ART. In some studies, women living with HIV have cited fear of gender-based violence (GBV) (231) and fear of being abandoned by a partner as reasons not to disclose to their partners. While data do not indicate an enhanced risk of GBV following disclosure (232), women’s fears to the contrary may prevent them from disclosing. HTC programs should be responsive to these fears, as well as to other possible negative consequences of disclosure, and offer appropriate support to PLHIV and couples to help mitigate these potential consequences. 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. Participation in peer support programs should be encouraged to help facilitate and promote safe disclosure.

For children and adolescents, the issues of disclosure are complex. Many perinatally infected children don’t know their HIV status, and parents may need support to disclose to them. Adolescents infected with HIV also need to tailored support to help them develop skills for safe disclosure among peers and other family members. Section 1.4 (HIV Testing and Counseling) and Section 2.3 of the Technical Considerations (Pediatric Testing, Care and Treatment) include more information on disclosure and young people.
2.2.3 Assessment of partner status and (if indicated) provision of partner testing or referral for partner testing

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 (233). Integrating partner and couples HTC (CHTC) and other forms of index-patient testing into routine clinic- and community-based services can identify infected partners and family members in need of HIV care and treatment, and HIV-negative partners who are unknowingly in a serodiscordant relationship and may benefit from additional prevention services.

Providers should regularly ask PLHIV if their partner(s) have 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 in serodiscordant couples. 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.

2.2.4 Assessment for STIs and (if indicated) provision of or referral for STI treatment and partner treatment

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 (216). Some STIs may be more complicated and difficult to treat in HIV-infected individuals (234). 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 (234). In addition, many STIs (e.g., syphilis, gonorrhea) 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. STIs may also be markers 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 a 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 appropriate information and training on the symptoms of common STIs and be able to refer PLHIV with STI symptoms to an appropriate health care provider. In addition, they should have the capacity to provide basic education and ongoing counseling on STI prevention. This will enable community workers and peer educations to provide early referral of their clients and peers for STI treatment.
2.2.5 Assessment of family planning needs and (if indicated) provision of contraception or safer pregnancy counseling or referral for family planning services

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 (235). This highlights the critical need to offer FP counseling and services 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. PEPFAR-funded clinics providing family planning must ensure that all USG requirements for compliance, monitoring and reporting are met. For more information on integrating FP and HIV services, see Section 3.10 of the Technical Considerations (HIV and Family Planning Integration).

PLHIV who desire children should be offered, safer pregnancy counseling on methods to reduce the risk of HIV transmission to uninfected partners, as both women (12) and men (13) 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 ensure that women living with HIV are linked to and regularly attending antenatal and PMTCT services.

2.2.6 Assessment of adherence and (if indicated) support or referral for adherence counseling

Adherence counseling and support should be offered to both HIV-positive individuals and serodiscordant couples, as anti-retroviral treatment (ART), when taken as prescribed, leads to viral suppression (236), reduces the morbidity and mortality experienced by PLHIV (236) (237), and reduces the risk of HIV transmission to sex partners by 96% (17). To maintain optimal treatment efficacy, PEPFAR-funded programs should include interventions that increase adherence to prophylactic medications (e.g., cotrimoxazole) and ART as part of PHDP activities. 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 (238). Adherence support interventions can be successfully delivered in an ongoing manner at clinical, community, or home settings.
2.2.7 Assessment of alcohol use and provision of alcohol reduction counseling (if indicated)

Alcohol use is associated with both increased risky sexual behavior (239)(240) and reduced adherence to ARVs (241), which leads to inadequate viral suppression, accelerated disease progression and poorer health outcomes (242)(243), as well as increased levels of depression (243). Although the rate of alcohol use in many HIV-positive persons in sub-Saharan Africa is high, assessment of alcohol use and its impact on the health and behavior of PLHIV as part of patients’ care is lacking. Health care providers and counselors in facility and community settings should assess alcohol use in HIV-positive persons and encourage abstinence from alcohol or reduction in use. Moreover, patients with substance (i.e., cocaine, marijuana, and/or injecting drugs) and/or alcohol problems should be linked to substance abuse treatment programs where available, but at a minimum should be offered risk reduction counseling by a health care provider. While these technical considerations focus on preventing sexual transmission of HIV, the PHDP 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 sub-section 3 (Injecting Drug Use) of Section 1.3 of the Technical Considerations (Biomedical Prevention). 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.

2.2.8 Assessment of need and enrollment of PLHIV in community-based programs

Between clinical visits, many patients and their partners may benefit from support to maintain the motivation to achieve their health and prevention goals, including adherence to their ART and regularly attending their clinic visits. This support can be provided through community-based programs or through support groups at clinics. Facilitators of such individual and/or group programs should be well trained, possess excellent interpersonal communication (IPC) skills, and have the capacity to ensure that the prevention messages and services described above are integrated into their support 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. Clinical (e.g., ANC, ART and TB) and community programs should have strong bidirectional linkages and provide timely referrals to ensure access to critical prevention, care, support and treatment services. Functional linkages to relevant non-clinical services are critical for supporting the physical, mental, social, and economic well-being of PLHIV, their partner(s), and family.
2.3 PLHIV in Serodiscordant Couples May Need Additional Prevention Services to Reduce the Risk of HIV Transmission to the Negative Partner

PLHIV in serodiscordant couples should be offered the full range of HIV prevention messages and services described above as well as additional services to meet their unique prevention needs. Offering these services to HIV serodiscordant couples can substantially reduce the risk of HIV transmission to negative sex partner(s) and during pregnancy to the fetus, and ensure that HIV-positive partners receive the care and treatment services they need to remain healthy. These services include:

2.3.1 Antiretroviral treatment (ART) for the HIV-positive partner

ART can reduce the risk of heterosexual transmission by 96% (17) and reduce the morbidity and mortality experienced by the HIV-positive partner (244)(245)(246). To maximize the prevention, care, and treatment benefits of ART among serodiscordant couples, and in keeping with WHO normative guidelines, PEPFAR programs should offer treatment to all HIV-positive partners in serodiscordant relationships regardless of CD4 count (190).

2.3.2 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 (247)(248)(249), other studies have not found this association (250) (251) (252) (253). 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 sexual relationships, who choose 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 (254).

2.3.3 Voluntary medical male circumcision (VMMC) for HIV-negative male partners

VMMC can reduce men’s risk of acquiring HIV by 60% (255). All HIV-negative male partners in a serodiscordant couple should be counseled on the benefits of VMMC and referred to VMMC services, as desired.

2.3.4 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 (214).
2.4 PLHIV at Highest Risk of Transmitting HIV Should be Prioritized 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 PLHIV who are not yet eligible for ART, PLHIV on ART that have poor adherence with treatment and/or inadequate viral suppression, patients with substance abuse issues, and/or those patients in a serodiscordant couple.

2.5 Task Shifting Provision of PHDP Services to Lay or Peer Counselors

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, expert patients, and other PLHIV volunteers can assist health care providers to deliver HIV prevention messages and services by providing ongoing counseling and support to HIV-positive patients in clinical settings. Lay counselors can successfully provide ART adherence counseling (229), sexual risk reduction counseling (227)(225)(228), and HTC in HIV clinics. With appropriate supportive supervision from health care providers, incorporating lay counselors 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. Where feasible, these counselors should be identified from amongst capable and willing PLHIV.

2.6 PHDP Services Can Help Diagnose, Link, and Retain PLHIV in HIV Care and Treatment Services

Although access to HTC has rapidly expanded, only about 40% of PLHIV are aware of their status (256) and even fewer know their partner’s HIV status (233)(257) or presumably the status of their children. Ongoing HTC efforts must place greater priority on identifying HIV-positive individuals, including children and adolescents, as well as 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 and that of their family members. These include provider-initiated HIV testing and counseling (PITC), client-initiated testing and counseling (CITC) in clinic and community (e.g., home-based) settings, as well as different models of index patient testing (see Section 1.4 of the Technical Considerations (HIV Testing and Counseling)).

Approximately half of individuals newly diagnosed with HIV do not enroll in HIV care and treatment services (258)(259), making it imperative that HTC programs work with care and treatment providers to actively link newly diagnosed PLHIV with services. Several strategies can
facilitate linkage and enrollment. 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 (e.g., for testing and treatment, TB and HIV treatment, PMTCT), 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 (260)(261)(258). 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 (261) and are at higher risk for transmitting HIV to their partner(s) and child(ren) compared to patients on ART and with suppressed viral loads (17). Patients who are retained in pre-ART programs do show better health outcomes, including higher CD4 counts at ART initiation. 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 used 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 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.

2.7 Expansion of PHDP Services Requires National Coordination and Leadership

Integrating HIV prevention into the routine care offered to PLHIV 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 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 PHDP services 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.
PEPFAR teams should work with the Ministry of Health and National AIDS Program to ensure that PHDP activities are included in national guidelines and policies (e.g., Care and Treatment, the National Prevention Strategy) and to address implementation and monitoring issues. PEPFAR teams should have clearly described plans for integrating PHDP activities into relevant technical programs (prevention, treatment, care, PMTCT, etc.) across both clinic and community settings. These plans should include clear and measurable objectives addressing integration of PHDP, national plans for training facility and community-based service providers, methods for documenting and reporting PHDP service provision, and ensuring PHDP services are implemented with high quality and fidelity.

3 Monitoring and Evaluation of PHDP Services

The PHDP Task Force, in collaboration with the Strategic Information (SI) TWG, has defined a required 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. This indicator allows programs to assess the reach and coverage of prevention services for PLHIV. Because of the difficulties in providing all elements of the package at one clinical/community visit, the numerator for this indicator has been expanded from receiving all services during the last visit to receiving all services within the past three months. The forthcoming PEPFAR Monitoring, Evaluation and Reporting (MER) Guidance includes additional information on the indicator and how it is measured.

Programs should ensure that there are systems in place to document PHDP service delivery in both clinic and community settings. Monitoring PHDP service delivery can be challenging. Many existing medical records and patient forms lack space to document prevention services. Because these services may be provided in different settings and at different times, it can be difficult to determine whether a given patient has received all services in a three month period. Data collection tools and forms may not be designed to aggregate patient-level service delivery making it difficult to generate overall estimates of PLHIV reached with these services. Ideally the components of the PHDP indicator would be incorporated into existing systems used to document services provided to PLHIV, such as individual patient care cards and community health information systems. If existing systems are not available, then other documentation systems will need to be developed and implemented to collect data for this indicator.

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 PHDP program improvement. Countries may wish to align particular elements of the 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 (see Section 1.4 of the Technical Considerations (HIV Testing and Counseling)) and disaggregated by mode of testing and site of testing.
4 Contextual Considerations, Linkages, and Wraparounds

PEPFAR 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 should be developed and strengthened to increase PLHIVs’ access to PHDP messages and services.

In many countries, PHDP services for members of key populations (sex workers, people who inject drugs, men who have sex with men and transgender women) are lacking. PEPFAR teams are encouraged to expand the materials, messages, and intervention strategies to include these key populations, using the best available evidence on key population size and location to guide implementation. Services for uniformed personnel and their families and spouses are encouraged, along with services for other groups with high HIV prevalence, including migrant workers, miners, transport workers, and fisherfolk. For more information on the prevention needs of these populations, see sub-section 6.2.4 (Programming for Military Personnel, National Police, Wildlife Officials and other Federal and State Forces) of this Section.

Any program or activity that provides services to PLHIV 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 and risk reduction counseling to all clients, with active linkage to HIV care and treatment for those individuals identified as HIV-positive and their families.

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 actively 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 where available. 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. This population should be a high priority for HIV prevention messages and services including HTC and risk reduction counseling.
2 Care and Treatment

2.1 Adult Care and Support

1 Introduction

As more programs move 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 (defined here as all periods prior to actually initiating Art) and Art periods to ensure timely initiation and maintenance on Art); 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.

1.1 What’s New in 2014

To assist country teams in prioritizing care and support interventions in the current PEPFAR era, the Adult Care and Support Technical Working Group (TWG) is conducting a review of the evidence regarding the various interventions PEPFAR supports, examining the impact of each intervention on five outcomes: mortality, morbidity, quality of life, retention in HIV care, and prevention of ongoing HIV transmission. Following review of the literature and consultation with experts and stakeholders, new guidance will be drafted to assist PEPFAR country teams in prioritizing care and support interventions (guidance will be available in late 2013). PEPFAR country teams should be aware of this forthcoming guidance and use it to guide planning for Care and Support activities in the FY2014 Country Operational Plan (COP).

As programs mature from an emergency to a sustained response, PEPFAR teams and implementing partners should be increasing their focus on quality and continuous quality improvement. This year, PEPFAR launched a PEPFAR Quality Strategy (PQS), first focusing on HIV Clinical Services. The PQS provides country teams with guidance and tools to develop, implement and/or strengthen quality in HIV clinical services with partner governments through a Quality Management, Quality Assurance, and Quality Improvement approach. Technical assistance will also be available from headquarters to support implementation.

This year PEPFAR also launched the PEPFAR Linkage & Retention Strategy, complementing the model and the principles outlined in the PQS. The strategy sets expectations for retention outcomes in PEPFAR supported programs and provides guidance, best practices and specific tools for implementation.
1.2 PEPFAR Blueprint

Care programs provide a package of services that focus on saving lives and preventing new infections for PLHIV in the pre-ART and ART phases of care.

1.3 Technical Background

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 six to 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 People Living with HIV (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 that 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. PEPFAR programs, in consultation with ministries of health, 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, such as women, adolescents, or key populations. Additional considerations for selected populations are discussed later in this Section (see sub-section 4 (Special Populations)).

Programs are encouraged to profile their communities to determine priority care and support activities. Figure 3, below, indicates the potential range of care and support services. 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.
The WHO 2013 Consolidated ARV Treatment Guidelines (190) includes a brief section on non-ART services that summarizes prior guidance and does not provide new recommendations. However, these services are applicable across all countries, and apply to most adolescent and adult PLHIV, and are still generally felt to be the most important to implement for HIV-infected persons in care. The evidence review process described above, and the forthcoming guidance on care and support activities, will provide additional critical information to assist PEPFAR country teams in prioritizing care and support interventions.

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. 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

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Footnote:
55 Rosen, synthesizing available data from sub-Saharan Africa, reported that up to two-thirds of patients may be lost to follow up (LTFU) between HIV testing and initiation of ART (239), with many of these lost during this “ART-ineligible” phase. Fox, in a meta-analysis of 33 studies from sub-Saharan Africa, reported retention on ART at 36 months of 72% (Fox & Rosen, 2010).
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, yet 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 tuberculosis (TB) interventions), and to provide key HIV prevention interventions [i.e., prevention for PLHIV/Positive Health, Dignity and Prevention (PHDP) services]). Though some clients lost to follow up may be receiving care in other sites, or may re-engage in care later, the scope of the problem is still extremely concerning.

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. Uptake of ART in PMTCT Option A for the nearly 50% of women expected to be eligible was poor, only partly because of lack of access to CD4.

Women’s preferences for service location are expected to be an important factor in retention in HIV care in the B+ era and should be a consideration in planning and evaluating strategies in transition to B+ ART service delivery.

If women on B+ ART are still reproductively active but are referred to a Treatment Clinic it will be important to ensure their ongoing access to family planning services and their access to other services normally delivered in the MNCH clinics such as immunizations, EID, and infant/young child feeding support.

2.1 Improving linkage and retention in care

There are many factors that may contribute to low rates of linkage and retention in care; these may vary across different regions and populations. Table 2, below, lists a number of factors which may affect linkage and retention in care.
Table 2. Factors affecting linkage and retention in care

<table>
<thead>
<tr>
<th>Factors affecting linkage and retention in care</th>
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<tbody>
<tr>
<td>Personal Characteristics</td>
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<tr>
<td>---------------------------</td>
</tr>
<tr>
<td>Risk factors for patient loss</td>
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<tr>
<td>Protective factors – may favor retention</td>
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</table>

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. 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. 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.

A number of potential interventions to improve linkage and retention are listed below (this is not meant to be a comprehensive listing). While data on effectiveness of these interventions are limited, supporting evidence is referenced to provide information for countries as they consider strategies.
2.2 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 (205);
- 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; and
- Utilizing community-based programs such as home-based care to follow newly diagnosed PLHIV and facilitate clinic enrollment.

Please see Section 1.4 of the Technical Considerations (HIV Testing and Counseling), for more detailed discussion and recommendations concerning linkage to care.

2.3 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 (262); some may even distribute ART and monitor adherence (263);
- Community/home-based care – use of community health workers or HBC providers to monitor PLHIV, provide services/support, and promote retention in care (264);
- Patient tracing (physical +/- phone) (265);
- Mobile phone interventions (266)(65); and
- Provide valued commodities/services which may increase uptake of care (e.g., cotrimoxazole, possibly other components of “preventive care package” or nutritional support (267)).

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 on strategies to improve retention in care is listed in sub-section 9 (Additional Resources) of this Section.

3 Interventions

Evidence supporting specific Care and Support interventions and their potential public health impact, particularly regarding morbidity and mortality, are presented below (as in Figure 3, services are not listed in a particular order).

3.1 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. Currently, six- to 12-month mortality—early mortality that should be considered preventable—in persons initiating ART in PEPFAR countries is 6% to 10%. 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 are essential services which all programs should provide and will directly contribute to PEPFAR’s goal of increasing the number of HIV-infected persons on ART.

3.2 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. Because of the universal importance of CTX prophylaxis and its documented impact on morbidity and mortality, CTX prophylaxis is an essential service which all programs should provide. 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.

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 (268)(269). 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 two, three, or four, 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 (270).
3.3 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 is an essential service which all programs should provide (see also Section 2.4 of the Technical Considerations (TB/HIV)). TB services should include:

- **Intensified case-finding:** Every patient should have a documented four-question screen for TB [link](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; and

- **Infection control:** All HIV clinics should ensure that basic administrative and environmental infection control practices are in place to protect patients and staff.

See sub-section 9 (Additional Resources) of this Section for WHO Guidance on intensified case-finding and IPT.

3.4 Prevention interventions

Prevention interventions supporting HIV-positive persons are an essential part of comprehensive HIV prevention, care and treatment services. Defined by WHO as a core component of the Positive Prevention, Health and Dignity (PHDP) approach to care for people living with HIV (PLHIV), these interventions improve the health and quality of life for patients, and can reduce the risk of HIV transmission to uninfected partners and children, as well as improving identification of previously undiagnosed HIV-infected persons.

Essential prevention interventions for PLHIV include:

- Adherence counseling and support for ARV treatment regimens;
- Risk reduction information and coaching
- Promotion and provision of condoms with a minimum distribution of thirty condoms per monthly visit;
- Information and support for reducing alcohol consumption;
- Support for safe disclosure of HIV status to partners;
• Encouragement for family members and sexual partners and needle-sharing partners to test for HIV (index patient testing);
• Linkage to care for PLHIV identified through index-patient testing with immediate linkage to ART for PLHIV in serodiscordant relationships;
• Family planning or safer pregnancy counseling; and
• Assessment, diagnosis, and management of STIs as part of routine HIV care.

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. Many elements of the package can be delivered effectively by expert patients and other lower cadres of health care workers, reducing burden on overstretched clinical staff. However, where resources are limited, programs are encouraged to prioritize patients who are at high risk for transmitting HIV. 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 become LTFU and are at higher risk for transmitting HIV compared to patients with suppressed viral loads (261)(17). 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 serodiscordant partnerships.

In addressing PHDP, countries should aim for SMART (specific, measurable, achievable, realistic and time-bound) plans to support full integration of the PHDP principles into platforms of care and support. Further guidance on these interventions can be found in Section 1.5 of the Technical Considerations (Positive Health, Dignity and Prevention for People Living with HIV).

### 3.5 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 (271). Persons with CD4 counts <100 cells/mL are at highest risk. A recently available lateral flow assay (LFA) for Cryptococcal Antigen (a predecessor of CM in blood) has made it possible to inexpensively screen patients for Cryptococcal infection, and subsequently treat those who test positive with anti-fungal therapy (oral fluconazole), should be considered prior to ART initiation in settings with high prevalence of CrAg.

See sub-section 9 (Additional Resources) of this Section for additional information on CM.
3.6 Diagnosis, prevention and management of viral hepatitis in HIV-infected persons

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% to 17% (273). The prevalence of hepatitis C (HCV) co-infection among PLHIV from key populations ranges from 4% to 8% in HIV-positive MSM to an estimated 60% to 90% in HIV-positive injecting drug users. While data on HIV-HCV co-infection in sub-Saharan Africa are sparse and often of very poor quality, the prevalence of HCV among those with HIV is estimated to be highest in west and central Africa (1% to 24%) and lower in east and southern Africa (0% to 9%) (274).

Co-infection involving HIV and HBV and/or HCV is linked with more rapid progression of liver disease, including cirrhosis, end-stage liver disease, hepatocellular carcinoma and mortality (275)(276). There is also some evidence, although inconclusive, that infection with HBV and HCV may accelerate the progression of HIV (277)(278).

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 (279)(280)(281)(282)(283)(284). 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.

As countries move towards adopting and implementing national guidelines based on the WHO 2013 Consolidated HIV Treatment Guidelines², this will expand access to ART for many individuals co-infected with HBV and/or HCV, as the Guidelines recommend ART for all HIV-infected adults with CD4 counts <500 cells/mL. Further, currently recommended ARV regimens contain two HBV-active drugs (TDF plus 3TC or FTC), providing treatment for both HIV and Hepatitis B infection. For individuals who do not otherwise qualify for ART, the guidelines recommend initiating ART regardless of CD4 count for individuals co-infected with HIV and HBV with severe chronic liver disease (defined as those with cirrhosis and end-stage liver disease).

The WHO 2013 Consolidated HIV Treatment Guidelines do not formally address other aspects of hepatitis infection, such as prevention, screening for hepatitis B and C, hepatitis B vaccination, or specific management of hepatitis B and C infection, although they do suggest a broad, comprehensive approach to care of individuals co-infected with HIV and hepatitis B or C (190).
PEPFAR country teams should follow national guidelines for the diagnosis of HBV and HCV in HIV Care and Treatment programs, as epidemiologically appropriate. However, initiation of ART at CD4 >500 for those co-infected with HBV or HCV should not be supported, unless there is evidence of chronic HBV-related liver disease. Patients who meet these criteria should be treated with ART including at least 2 drugs active against HBV. PEPFAR funds should not be used to support treatment of HBV mono-infection. See sub-section 9 (Additional Resources) of this Section for more information on the treatment of known HIV-HBV co-infection. 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.

3.7 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 (see also sub-section 8.8 (Linkages and Wraparounds) of this Section).

3.8 Safe water, sanitation and hygiene

Diarrhea is an important cause of morbidity and mortality in PLHIV. Diarrheal illness in PLHIV may compromise the absorption of ARV drugs, reduce the absorption of essential nutrients, and reduce the impact of food supplements (285). Because safe water interventions have been shown to reduce the incidence of diarrhea in HIV-infected persons, 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.

Technologies for treating water in the home include 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 preventing both human and animal fecal contamination of water supplies and food are critical to reduce the spread of disease.

PEPFAR can provide support for construction of water/sanitation facilities associated with health care facilities subject to PEPFAR guidance for construction and renovation and require specific review and approval (see FY2013 COP Guidance and Appendices, sections on Construction and...
Renovation). See sub-section 9 (Additional Resources) of this Section for more information on safe water, sanitation and hygiene.

3.9 Nutritional assessment, counseling and support

Weight loss and wasting are associated with a significantly elevated risk of disease 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.

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 3.7 of the Technical Considerations (Nutrition and HIV/AIDS).

3.10 Prevention of cervical cancer

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. PEPFAR can provide support for screening and treatment to prevent cervical cancer in HIV+ women. As ART does not appear to reduce the risk of cervical cancer, screening and treatment to prevent cervical cancer remain important regardless of whether or not a woman is on ART.

PEPFAR teams should work collaboratively with host country leadership, WHO, and other key partners in planning and program implementation. 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. A sub-group of the Care and Support Technical Working Group, the Cervical Cancer Taskforce, can provide technical assistance and should be kept informed about country plans and experience.

PEPFAR-supported cervical cancer prevention programs should be guided by the following considerations:

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

3.11 Mental Health

Mental disorders are common co-morbid conditions affecting PLHIV and may affect access to and adherence to medication and retention in HIV care and treatment programs (286)(287). 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) and increase vulnerability to sexual exploitation or impair judgment required to engage in safe sexual practices (288)(289)(290)(291)(239). Mental health services may also be needed to treat conditions such as depression or anxiety that may reduce adherence to HIV treatment, or to address neuro-psychiatric complications of HIV disease or medication side effects (292)(293)(294)(295).

PEPFAR teams are encouraged to identify potential opportunities to support and strengthen mental health services. 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. These services can be captured under the scope of clinical, psychological or social services based on the specific aims of the intervention—such as psychiatric care given under the direct care of a clinician, drug rehabilitation services provided by a trained social worker, or peer support group
or family counseling provided by trained community care providers. 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.

3.12 Pain management

While the need for pain management has diminished with the wide-scale implementation of ART, 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 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.

3.13 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.

4 Special Populations

4.1 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 issues for care and treatment programs are described below. See sub-section 3 (Injecting Drug Use) of Section 1.3 of the Technical Considerations (Biomedical Prevention) and sub-section 9 (Additional Resources) of this Section for WHO guidance regarding recommended interventions for PWID.

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6 The term “palliative care,” in the PEPFAR context, refers to pain and symptom management and end-of-life care.
4.1.1 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.

4.1.2 Viral Hepatitis

PLHIV who inject drugs are at very high risk for hepatitis B and C; please see sub-section 3.6 (Diagnosis, prevention and management of viral hepatitis in HIV-infected persons) of this Section for more information on viral hepatitis. WHO guidance is available at http://www.who.int/hiv/pub/guidelines/hepatitis/en/index.html

4.1.3 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.

4.1.4 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.

4.2 Adolescents

While adolescents infected perinatally or vertically have different clinical needs, 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 issues to address among ALHIV include particularly complex clinical and psycho-social/mental health (including substance abuse) issues. Please refer to Section 2.3 of the Technical Considerations (Pediatric Testing, Care and Treatment) for guidance on how to provide multi-disciplinary care and support services to meet the needs of adolescents.

4.3 Aging populations

Diagnosis of HIV or AIDS at older ages presents new challenges for HIV medical care and service providers, as well as prevention and treatment strategies which formerly focused solely on younger age groups. Older persons are less knowledgeable about HIV/AIDS and condom use and 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. 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.

5 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/imal/PatientGuide/en/).

5.1 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; and
• 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.

6 Country Contextual Considerations

Country teams should be sure to use existing epidemiologic data to plan programs, including recent Demographic and Health Surveys (DHS), AIDS-Indicators Surveys (AIS), TB prevalence surveys, Key Populations (KPs) size estimation surveys and antenatal care sentinel surveys. Countries may also use mapping and Geographic Information Systems (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).

7 Partner Performance Considerations

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.

8 Cross-cutting, Linkages and Wraparounds

8.1 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. Use of Expenditure Analysis (EA) to examine actual program costs across geographic regions and partners can help to identify possible efficiencies and rationalize spending (see Section 3.9 of the Technical Considerations (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 sub-section 1.3 (Technical Background) of this Section); 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; and Support for transition of program implementation from international partners to local partners and ministries of health, including building capacity of governments and local partners.

8.2 Assuring quality care

PEPFAR Care programs need to prioritize assuring quality care throughout the continuum of care, whether provided in a facility-, community-, or home-based care setting. As indicated above, this year PEPFAR launched a Quality Strategy for Clinical services focusing on quality assurance and quality improvement across PEPFAR Clinical Programs. Specific 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 should 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/).

8.3 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. 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. 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.

PEPFAR teams are strongly encouraged to examine the benefits of community-level service delivery 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 where appropriate 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. Programs should 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 some 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. In all cases, programs should take into account features of the health system that will affect the scalability and sustainability of optimization of existing service delivery models (e.g., degree of functional decentralization or institutionalization of community-based cadres in the national health system) and engage Health Systems Strengthening/Human Resources for Health Advisors in program planning.

8.4 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, and other services.

8.5 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:

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

See Section 3.5 of the Technical Considerations (Gender) for more detailed information.

### 8.6 Human Resources for Health 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) 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. See Section 3.4 of the Technical Considerations (Human Resources for Health) for more information on Human Resources for Health considerations.

### 8.7 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. Section 3.11 of the Technical Considerations (Supply Chain Management) provides detailed information about care and support activities and interventions—along with cross-cutting supply chain management technical considerations—that country teams should consider to avoid potential supply chain disruptions.

### 8.8 Linkages and Wraparounds

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.

9 Additional Resources

Improving retention in care


Detection and treatment of TB:


Cryptococcal Meningitis:


Treatment of known HIV-HBV co-infection:


People Who Inject Drugs:

2.2 ADULT TREATMENT

1 Introduction

PEPFAR was launched in 2003 to combat the global HIV/AIDS epidemic and make life-saving antiretroviral treatment (ART) available to people who otherwise could not afford it. From 2004 to present, the effort to scale up adult treatment under PEPFAR has been remarkably successful. As of September 2012, nearly 5.1 million people were on ART as a result of PEPFAR support, increased from 1.7 million in 2008.

Supporting national treatment programs to increase access to treatment remains a central tenet of the PEPFAR program, while maintaining priority for the sickest persons in need of treatment. The World Health Organization’s (WHO) normative guidelines for provision of anti-retroviral treatment remain the definitive source of technical information for all PEPFAR-supported treatment programs. These technical considerations provide further information on best practices and recommendations for PEPFAR programs on the implementation of those guidelines, as well as on PEPFAR-specific approaches for ensuring quality. The technical considerations for adult treatment have been revised to present priorities for ongoing scale-up of ART in accordance with recent changes to WHO’s normative guidelines. These priorities are summarized in three categories: 1) Access, Expanding Coverage, and Integration of Services, 2) Quality and Oversight, and 3) Sustainability and Efficiency.

1.1 What’s New in 2014

1.1.1 Updated PEPFAR Treatment Goals

Rapidly and strategically increasing coverage of HIV treatment for all eligible PLHIV, both to reduce AIDS-related mortality and to enhance HIV prevention, is a cornerstone of the PEPFAR strategy to achieve an AIDS-free generation. In addition to saving lives, rapid scale up of treatment as a key component of a combination prevention strategy has the potential to reduce long-term resource needs and support sustainability, as outlined in the PEPFAR Blueprint.

Rapid increase in ART coverage reduces infectivity, making it possible to bring the number of annual new HIV infections below the annual increase in patients on ART—achieving what many have called a programmatic “tipping point” in the epidemic response. The tipping point is a metric of progress in meeting the needs of the epidemic in addition to treatment coverage. Scale-up of treatment programs to increase coverage and achieve a tipping point ratio of less than 1.0 is the goal of PEPFAR’s treatment response. This is further detailed in the Section 3.1 of FY2014 COP Guidance (Increase Treatment Coverage for All Eligible PLHIV).
1.1.2 WHO 2013 Consolidated Antiretroviral Guidelines

The WHO recently released the 2013 Consolidated Guidelines on the Use of Antiretrovirals for the Treatment and Prevention of HIV Infection, which significantly expand eligibility for ART. Key recommendations include:

<table>
<thead>
<tr>
<th>Highlights of the WHO 2013 Consolidated ARV Guidelines Related to Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) ART should be initiated in all individuals with HIV with CD4 count ≤ 500 cells/mm³ regardless of WHO clinical stage, as well as in HIV+ partners (at any CD4 count) in a serodiscordant partnership. However, ART should be prioritized for all individuals with advanced HIV clinical disease (WHO clinical stage 3 or 4) and individuals with CD4 count ≤350 cells/mm³.</td>
</tr>
<tr>
<td>2) TDF/XTC/EFV (tenofovir, emtricitabine or lamivudine, and efavirenz) as a fixed-dose combination is recommended as the preferred option for initiation of ART.</td>
</tr>
<tr>
<td>3) ART should be initiated in all HIV-infected children below five years of age, regardless of WHO clinical stage or CD4 count.</td>
</tr>
<tr>
<td>4) All pregnant and breastfeeding women with HIV should initiate triple ARVs. ART should be maintained for the duration of mother-to-child transmission risk at minimum. Women meeting treatment eligibility criteria should continue lifelong ART. For programmatic and operational reasons, particularly in generalized epidemics, all pregnant and breastfeeding women with HIV should initiate ART as lifelong treatment (“Option B+”).</td>
</tr>
<tr>
<td>5) Viral load is recommended as the preferred monitoring approach to diagnose and confirm ARV treatment failure.</td>
</tr>
</tbody>
</table>

Further discussion of these guidelines can be found in PEPFAR’s Country Operational Plan (COP) FY2014 Guidance. The WHO guidelines can be accessed at: http://apps.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf.

1.1.3 Treatment/Cascade Calculator

All teams with treatment portfolios are expected to complete the Treatment Budget Calculator and Cascade Calculators, found in the FY 2014 COP Guidance Appendices. These tools will ensure adherence to COP treatment funding guidance and that both country teams and headquarters staff understand the planned year-to-year treatment targets (including pregnant and breastfeeding women on life-long ART in PMTCT programs) along the continuum of care, as well as the relationship to budget allocations in the context of other available resources, including the Global Fund.

1.1.4 PEPFAR Quality Strategy

In 2013, PEPFAR is launching a PEPFAR Quality Strategy (PQS), focusing on HIV Clinical Services. The PQS provides country teams with guidance and tools to develop implement and/or strengthen quality in HIV clinical services with partner governments through a Quality Management, Quality Assurance, and Quality Improvement approach. This is an important focus as PEPFAR continues to shift from an emergency response to a sustainable one.
In particular, teams are encouraged to consider these specific areas related to quality assurance for support:

- National plans to ensure and measure quality of clinical services as governments and local partners take on increasing financial and clinical management of the HIV response;
- National framework for support and supervision of ART programs under the umbrella of the national HIV and/or health quality strategy;
- Harmonized quality management (QM) and quality improvement (QI) activities among country teams and implementing partners, which are in alignment with national, Ministry-led, quality plans and initiatives;
- Routinely collected program indicator data to guide QI activities at all levels;
- Standardized, periodic supportive site supervision and regular program reviews as an integral part of USG-supported ART programs;
- Geographic alignment processes to focus service provision in areas with highest concentration of HIV transmission, prevalence, and numbers of people in need of services;
- Efficient and effective algorithms for treatment failure monitoring;
- Surveys for HIV drug resistance; and
- National pharmacovigilance systems.

Additional information can be found in COP FY 2014 Guidance.

1.1.5 PEPFAR Linkage, Engagement and Retention Strategy

PEPFAR will also launch the PEPFAR Linkage, Engagement and Retention Strategy (PLERS), complementing the model and the principles outlined in the PQS. The strategy sets expectations for retention outcomes in PEPFAR supported programs and provides guidance, best practices, and specific tools for implementation.

Linkage between services and retention in care and on lifelong ART are critical for improving patient outcomes, but the clinical care cascade is imperfect and there are gaps, including many patients being lost to follow-up. Patients must be successfully linked to HIV clinical services (including treatment, per national guidelines) after receiving a positive HIV diagnosis. Further, they must be successfully retained in care and, after initiation, retained on and adherent to ART in order for treatment programs to be effective. The PLERS will help to define PEPFAR’s programmatic approach to addressing the gaps and challenges within linkage and retention, including for specific populations, such as pregnant mothers, infants and children, key populations, and patients co-infected with TB, who often have lower rates of retention in treatment and across the continuum of care and treatment.
1.1.6 Sustainability Strategy

In 2013, PEPFAR is launching a Country Ownership and Sustainability Operational Guidance to ensure the sustainability of programs as countries begin to transition to country-led HIV programs, management, and financing. While there are important variations in country contexts, every PEPFAR team supporting direct service provision should establish short- and long-term goals to further increase and scale up high-impact HIV prevention, care, and treatment services and to ensure quality as national governments and local partners take on more financial and managerial leadership. The Sustainability Guidance provides country teams with a list of key questions to consider and methods to monitor and evaluate these issues, as well as country-level country ownership assessment tools for program planning.

1.1.7 MER Update

PEPFAR’s new Monitoring, Evaluation, and Reporting (MER) Guidance provides a Strategic Information (SI) framework for the global HIV response, from specifics on key technical areas, such as treatment, to broader health system questions. The aim of the MER is to enable PEPFAR to systematically monitor, evaluate, and report the impact and quality of their programs.

The Treatment section of the MER provides guidance on M&E and reporting of outputs and outcomes, and impacts to measure the quality and success of treatment programs, such as coverage, scale-up, special considerations for different settings and populations, linkages and retention, HIV drug resistance, pharmacovigilance, and health system strengthening.

1.2 PEPFAR Blueprint

The PEPFAR Blueprint: Creating an AIDS-free Generation, released on World AIDS Day 2012, highlights the importance of treatment as prevention for achieving an AIDS-free generation.

Highlights of the Blueprint discussed in this Section include:

- Increasing eligibility for ART, while continuing to prioritize the sickest patients;
- Emphasis on ensuring adherence, retention and quality of programs;
- Supporting treatment for HIV-positive partners in serodiscordant partnerships regardless of immune status;
- Supporting transition to PMTCT Option B or B+ for pregnant and breastfeeding women;
- Support for key populations: In accordance with each national epidemiological context, working with countries to prioritize key populations (e.g., Men who have Sex with Men (MSM) and transgendered persons (TG), Sex Workers (SW), People Who Inject Drugs (PWID)) for ART, ensuring ART programs support a non-stigmatizing clinical environment that affords all individuals meaningful access to treatment services, including both facility and community-based care and support;
- Using the epidemiologic profile of each country to inform treatment scale-up, and working with countries to ensure that treatment programs are adapted to, and aligned with, their respective needs;
- Supporting HIV drug resistance (HIVDR) surveillance activities and stepping up pharmacovigilance efforts to ensure optimized long-term outcomes, particularly as the treatment programs mature and patients are initiated on ART earlier and are on therapy for longer periods of time; and
- Supporting scale-up of integrated TB/HIV services.

2 Access, Expanding Coverage, and Integration of Services

2.1 Increasing Access and Treatment Coverage for all Eligible PLHIV

The WHO recently released the 2013 Consolidated Guidelines on the Use of Antiretrovirals for the Treatment and Prevention of HIV Infection. These guidelines significantly expand eligibility for ART and promote simplified treatment regimens. The new guidelines recommend increasing CD4 eligibility criteria to ≤ 500 cells/mm³ for ART initiation regardless of WHO clinical stage. In addition, ART is recommended for HIV-infected partners in serodiscordant partnerships regardless of CD4 count, all PLHIV co-infected with TB, all HIV-infected children below five years of age and all HIV-positive pregnant and breastfeeding women (Option B or B+, see Section 1.1 of the Technical Considerations (Prevention of Mother to Child Transmission)).

There are numerous benefits to starting patients on ART earlier (with CD4 counts ≤ 500 cells/mm³) in the absence of other indications, including reduced rates of HIV-related morbidity and mortality, reduced maternal to child transmission, potential reductions in the incidence and severity of non-AIDS-defining chronic conditions (e.g., cardiovascular disease, kidney disease, liver disease, certain cancers, and neurocognitive disorders), and reduction in infectious complications (e.g., tuberculosis) (296)(297)(298)(299)(300). Furthermore, ART substantially reduces sexual transmission, and reducing the waiting time for ART initiation may also improve retention in care (17).

Nevertheless, while there are strong clinical reasons for increasing the CD4 eligibility threshold, the decision needs to be placed within the context of each country’s current response to the epidemic, available resources, other health priorities, and existing health system constraints (Box 1). The decision to increase CD4 eligibility criteria to ≤ 500 cells/mm³ for ART initiation should be made as part of an overall national strategy. WHO and PEPFAR continue to support prioritization of the sickest patients (WHO clinical stage 3 or 4, or CD4 ≤350 cells/mm³) for ART initiation. In settings where adoption of a CD4 threshold of 500 would divert resources away from large numbers of patients with lower CD4 counts, a more gradual transition towards expansion of ART coverage should be considered.

Box 1. Factors to Consider when deciding to implement the new WHO Guidelines
PEPFAR country teams should continue to support Ministries of Health, national HIV/AIDS control programs, and other key stakeholders in revising and implementing national ART guidance to reflect the 2013 WHO Consolidated ARV Guidelines. Specifically, support should include encouraging policies and guidelines that promote increased but equitable access, simplified clinical decision-making and treatment regimens, and streamlined and cost-efficient procurement.

Specific commodity-related issues are discussed below and in Section 3.11 of the Technical Considerations (Supply Chain Management).

The PEPFAR Adult Treatment TWG, working with several other TWGs, including Pediatrics/PMTCT, Care and Support, Strategic Information (SI), and Economic Analysis, can help countries develop a strategic approach to supporting the national program and implementation of the new guidelines in a rational, phased approach.

Additional information can be found in the WHO 2013 Consolidated ARV Guidelines.

2.2 Optimizing Commodity Management

Optimizing commodity management within adult treatment programming shares many features with strengthening supply chain management across multiple PEPFAR technical areas. In addition to the considerations provided below, Section 3.11 of the Technical Considerations (Supply Chain Management) provides cross-cutting supply chain management technical considerations that country teams should consider to avoid potential supply chain disruptions.

2.2.1 General Principles

Country teams are expected to forecast and budget appropriately to meet PEPFAR treatment targets in the context of all available funding streams and when considering implementation of the new WHO guidelines. 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 set by other donors); government budgetary shortfalls; transition to the new funding model; or issues related to in-country procurement processes. PEPFAR and Global Fund coordination is essential in order to ensure sufficient commodity stocks. PEPFAR teams should be vigilant for potential disruptions of supplies of essential commodities (particularly from other funders), and should actively engage PEPFAR teams and other stakeholders early and intently to avert these stock-outs. PEPFAR teams should adequately budget for buffer stocks, and intervene where Global Fund and/or country systems have broken down (or are experiencing challenges).

PEPFAR teams should work with other stakeholders to budget realistically to ensure that commodities for all PEPFAR treatment targets are available. The Office of the Global AIDS Coordinator (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. Headquarters staff can often assist with elevating Global Fund-related issues via technical and diplomatic channels, as well as obtaining commodities data for responsible forecasting; teams should not hesitate to engage the TWGs via their PEPFAR Coordinator and Country Support Team Lead (CSTL).

At the same time, country programs should continue to identify and implement strategies that 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.

2.2.2 ARV Regimen Selection

The WHO 2013 Consolidated ARV Guidelines recommend TDF/XTC/EFV (tenofovir, emtricitabine or lamivudine, and efavirenz) as a fixed-dose combination (FDC) regimen for most patients. This regimen is recommended as first-line therapy unless it is not available in-country or is contraindicated for an individual patient. Although this approach simplifies treatment and regimen choice, there are several important issues to consider:

- While adoption of a TDF/XTC/EFV fixed-drug combination as the preferred national first-line regimen is recommended, a gradual transition scheme is absolutely essential given the significant existing supply constraints for TDF- and EFV-containing regimens;
- When possible, PEPFAR-supported programs should use existing stocks of ARVs already purchased and available in country. This will ease the transition to TDF regimens, avoid waste of valuable resources, and eliminate the need for destruction of existing stocks;
- Reducing the number of ARV regimens in-country will simplify ARV options and reduce the complexity of procurement and supply chain logistics;
• Supply planning must incorporate anticipated increases in procurement lead times for FDC treatment regimens. Orders should be placed as far in advance as possible (at least 8 months);

• While country-specific stock, consumption, and forecasting data (taking into account expected lead-times for TDF/XTC/EFV procurements) may impact the transition scheme, consider the following phased approach:
  o Place patients newly initiating ART on a TDF-based regimen;
  o When beginning transition of patients already on ART, switch those patients currently receiving stavudine (d4T)-based regimens first; and
  o Phase in the transition of AZT and NVP-containing regimens to TDF-based regimens to mitigate potential stock-outs or shortages. Based on current projections, a phase in time frame from mid-2013 through mid-2015 will allow the market to “catch-up” with the increased demand. A phase-in approach, that transitions more patients later in 2014, will best support a smooth transition.

• Timelines and details of the phase-in plan can be determined based on country-specific data. It will be important not to modify existing procurement orders for ARVs (e.g., switching AZT orders to TDF), as this may lead to delays in receiving orders in country.

2.3 Understanding and Predicting Costs

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 allocative and technical efficiency of HIV funding portfolios and improve collaboration with host country governments, Global Fund, WHO, and other international stakeholders. Where available, expenditure analysis (EA) data are a valuable tool that can be used to manage the PEPFAR portfolio, prepare budgets, set targets, and improve operational efficiency. Within the treatment program area, both costing studies and EA 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
2.4 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.

2.4.1 Adult Care and Support Services

Section 2.1 of the Technical Considerations (Adult Care and Support) 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 (CTX) prophylaxis; and diagnosis, prevention, and management of TB); and core prevention services for PLHIV (Positive Health, Dignity and Prevention, or PHDP).

In addition to these core services, many other services are also important, but the need for these latter services may vary across geographic regions or patient populations. The Care and Support TWG is currently reviewing activities within the Care and Support portfolio and available evidence on the public health impact of these activities. Following review of the literature and consultation with stakeholders, new guidance will be drafted to assist countries in determining priority care and support activities. This will be available in late 2013.

The community plays a key role in providing critical support for many or all of these services, including key support for linkage and retention. PEPFAR programs should work with Ministries of Health, key stakeholders, networks of PLHIV and communities to assess barriers and facilitators, and to develop strategies to improve 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, including the use of opportunities where community and clinical stakeholders meet to discuss issues related to treatment, care and support of PLHIV and their families. Additional information can be found in the PEPFAR Linkage, Engagement and Retention Strategy (PLERS).

2.4.2 Tuberculosis (TB)

TB remains the most common cause of death among people living with HIV in sub-Saharan Africa. PEPFAR treatment programs should intensify efforts to identify co-infected individuals and link them to care and treatment to reach the goal of starting 100% of TB/HIV co-infected persons on ART. Efforts to improve linkages between TB and HIV programs should include:

- All PLHIV should be screened for TB and all TB patients should be tested for HIV;
• Referral to ART and/or TB clinics if both services are not provided at the same site, with the ultimate goal to fully integrate ART services and TB treatment at both TB clinics and ART sites; and
• Within ART sites, all patients should receive:
  o Intensified case-finding: Every patient should have a documented 4-question screen for TB 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;
  o At ART sites where TB diagnostic capabilities are not available, patients should be referred to TB clinics or a TB diagnostic facility for appropriate testing (e.g., sputum smear microscopy, chest x-ray, Xpert MTB/RIF, sputum culture). Results should be documented in the patients record for linkage to ART records and vice versa;
  o Patients with active TB should be treated promptly for TB and should also be started on ART immediately regardless of CD4 count. If CD4 test results are available, patients with CD4 <50 cells/mm³ should be started on ART within two weeks of starting TB treatment (except in cases of TB meningitis). All other patients should be started as soon as possible, ideally within eight weeks (301)(302)(303) (190);
  o 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;
  o Infection control: All ART clinics should ensure that basic administrative and environmental infection control practices are in place to protect patients and staff; and
  o Ensure that children and other vulnerable populations (e.g., people in prisons, miners, people who abuse alcohol) are included in all TB/HIV program components.

See sub-section 6 (Additional Resources) of this Section for further information on intensified case-finding and IPT and Section 2.4 of the Technical Considerations (TB/HIV) for additional information on TB/HIV co-infection.

2.4.3 Maternal Child Health (MCH)

Given the risk of MTCT during pregnancy and breastfeeding, all HIV positive pregnant and breastfeeding (BF) women should be placed on triple ARVs (ART) as soon as possible after identification (Option B or B+). ART must be maintained at a minimum for the duration of the pregnancy and breastfeeding period. Eligibility for lifelong ART for pregnant and breastfeeding women will depend on national guidelines. However, the new WHO 2013 Consolidated ARV guidelines recommend that for programmatic and operational reasons, particularly in generalized epidemics, all pregnant and breastfeeding women with HIV should initiate ART as lifelong treatment (Option B+) for their own health. PEPFAR programs should work closely with Ministries of Health and other partners to determine how best to assist with planning and transitioning to option B or B+ in their countries.
Initiating and retaining women on ART and in long-term HIV care and treatment will require strengthened linkages between PMTCT and ART programs and will become increasingly critical as more countries shift to Option B+ and services are decentralized to lower-level health care facilities. Efforts to enhance linkage between HIV Treatment programs, MCH, and primary health care services could include the following key components:

- HIV testing and counseling (HTC), and ART services should also be made available to adults and children in MCH clinics as part of a family centered approach, which has the potential to expand overall treatment access and improve retention;
- Mother-infant pairs should receive their HIV services, including ART, at the same facility;
- Integration of ART services and MNCH services, including PMTCT and family planning;
- Implementation of effective strategies to ensure enrollment, linkage and retention in HIV clinical care (e.g., physical escorts to the HIV clinic, mentor mothers, expert patients), accompanied by ongoing case management by dedicated linkage staff (PEPFAR HRH advisors should be engaged when considering such strategies to ensure that sustainability questions of these strategies are adequately addressed);
- As B+ ART becomes decentralized and delivered in PMTCT clinics within MCH, ongoing ART services must be delivered with appropriate arrangements to enhance retention and ART adherence while ensuring the high-impact survival related services normally delivered in MCH clinics. These include EID, Family Planning, immunizations, and infant/young child feeding support. Linkages and referrals should be understood in this light;
- Children and adolescent HIV services should have linkages with schools and community-based programs (e.g., OVC programs, nutritional support programs, immunization campaigns);
- Implementation of strategies to ensure that adolescents transition from childhood regimens to adult regimens; and
- Instituting tracking systems to identify women, children, and adolescents who fail to enroll in ART services either during pregnancy or post-partum or who are lost to follow-up.
- The M&E framework should be adapted as necessary to include tools for tracking HIV infected mothers and their infants through MCH and ART services.

2.4.4 Key Populations (KP)

Key populations (SW, MSM, TG, and PWID) typically have higher HIV prevalence than the general population and account for a large proportion of new infections in most of the world. Given the presence of key populations in every country, the scaling up of ART should include much stronger efforts to support access to treatment and care for key populations. Reaching key
populations with treatment is a high priority for PEPFAR, and country teams should strive for full coverage.

The following are important considerations related to KP:

- When no reliable population size estimate is available, teams are encouraged to determine appropriate KP treatment targets based on best available data (304); minimum target for number of KPs on ART = Size estimate of KP * HIV prevalence of KP * 80% (80% is assumed to be the proportion of KP who meet the criteria for treatment);
- ART programs should support a non-stigmatizing clinical environment that enables KP to have consistent and safe access to treatment services, including both facility and community-based care and support. Self-report by clinic staff that they provide such an environment is insufficient. Supportive supervision and monitoring is necessary in most sites to ensure clinical staff are providing appropriate care;
- Specific strategies should be employed to reach, test, link, treat, and retain KP in care and treatment services (305). These strategies should include monitored linkages between KP outreach programs and HTC, as well as between HTC and care and treatment;
- Peer outreach workers, patient navigators, and case managers can facilitate access to and uptake of ART by KP. Training health workers on clinically appropriate and non-stigmatizing care for KP is critical to developing an environment that enables key populations to access and adhere to treatment (PEPFAR HRH advisors should be engaged when considering such strategies to ensure that sustainability of these strategies are adequately addressed); and
- Teams are encouraged to use innovative strategies such as evening hours and/or co-location of ART services with KP-specific services such as MAT, HTC, or STI screening and treatment.

### 2.4.5 Other Clinic-Based Care Services

- Ensure linkages with laboratory services needed to diagnose and monitor HIV status, opportunistic infections (OI), especially TB, and ARV drug toxicity (e.g., serum creatinine, hemoglobin, liver function tests);
- All patients should be provided with the minimum package of PHDP services, see Section 1.5 of the Technical Considerations (Positive Health, Dignity and Prevention for People Living with HIV) for more information;
- 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. This should include pregnant and breastfeeding women who receive ARVs for PMTCT (Option B or B+);
- 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, TB screening and IPT);
• 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:
  o HIV testing and counseling, especially of partner(s) and children of PLHIV (please refer to Section 1.4 of the Technical Considerations (HIV Testing and Counseling) for more on index patient testing);
  o HIV primary care;
  o Management of OIs and STIs;
  o TB treatment or IPT;
  o Family planning (FP) and reproductive health (RH) planning;
  o Routine adherence counseling;
  o Nutritional counseling; and
  o Linkages with home-based care, positive/secondary prevention, OVC programs, key populations, and other supportive social services.
• Interventions to support linkage and retention in care.

2.4.6 Community Services
• Community programs that serve individuals, couples, and families living with HIV, including OVCs 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 PLHIV. Community-based treatment programs should include a care package for PLHIV. Additional information can be found in Section 2.1 of the Technical Considerations (Adult Care and Support).

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

• Include both didactic training and follow-up preceptorship and mentoring to ensure appropriate application of skills to the clinical setting. Where possible, use 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;
• Advocate for policy changes where policies preclude the use of non-physician staff for ART (i.e., task shifting/sharing);
• Promote activities designed to retain existing workers in the system; and
• Task shift/share delivery of HTC services and other HIV prevention services (i.e., sexual risk reduction counseling, adherence counseling and support, condom provision) 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 mobile and migrant populations, populations that may be underrepresented on treatment platforms, such as adult men, pregnant and breastfeeding women, HIV/TB co-infected patients, and key populations), 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 an effective means of expanding treatment access.

3 Quality and Oversight

3.1 Highlights

In 2013, PEPFAR is launching a PEPFAR Quality Strategy (PQS) and the PEPFAR Retention & Linkage Strategy, as highlighted above. The following describe quality considerations for successful ART scale-up and sustainability, while achieving and maintaining a high quality of patient care and retention in care.

3.1.1 Monitoring and Improving HIV Clinical Programs

Support for harmonized QM and QI plans and activities for all HIV clinical services supported by PEPFAR among country teams and implementing partners should be aligned with national, Ministry-led, quality plans and initiatives. PEPFAR-supported treatment programs should strive to provide:

• Facility-based Quality Improvement:
  o Performance measurement data used for improvement at the system and site levels, with monitoring and reporting of results; and
  o Support for a learning agenda to share and spread successful improvements.

• Supportive Supervision: Each program should have a standardized and routine supportive supervision system for site, district, and national levels, which is complementary to and consistent with the country MOH strategy. Some of the benefits of periodic site supervision include:
  o Identifying problem areas to guide QI interventions;
  o Improving collection and reporting of high-quality performance data; and
  o Building capacity among staff at the site level through training, mentoring and problem-solving activities.
• **Quality Management:**
  o USG teams and MOH counterparts should strive to conduct regular program reviews and reviews of performance measures and indicators with the goal of maximizing the ability of treatment programs to meet the needs of the population;

• **Support for Retention and Adherence:** Lifelong retention in care and ART adherence require facility-based approaches to monitor and improve both retention and adherence, which are detailed in PEPFAR Retention & Linkage Strategy. Highlights to consider:
  o Successful retention and adherence rely upon routine monitoring of performance measurement and quality improvement, when performance gaps are identified;
  o All programs should have a system to optimize enrollment and linkage, and retention in care and treatment services after HIV diagnosis. These may be specific to different program areas (i.e., PMTCT, TB/HIV) or common across the continuum of care;
  o 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; and
  o 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).

### 3.1.2 ART Program-Specific Quality and Oversight

In addition to the approach to quality services listed above and detailed in the PQS, some ART program-specific factors should be considered in the design and implementation of ART programs, including:

- **Commodities:** Support for reliable supply of commodities (i.e., rapid test kits, ARVs) to prevent delay in diagnosis, treatment initiation, and/or treatment interruption. This is detailed in the sub-section 2.2 (Optimizing Commodity Management) of this Section and Section 3.11 of the Technical Considerations (Supply Chain Management);
- **Geographic alignment of ART services:** Service provision should be focused on areas with highest concentration of HIV transmission, prevalence, and numbers of people in need of services;
- **Monitoring for treatment failure:** Please see sub-section 3.2 (Monitoring Patients for Treatment Failure) of this Section for further discussion;
- **Surveys for HIV drug resistance:** Please see sub-section 3.2.3 (HIV Drug Resistance) of this Section for further discussion; and
- **Pharmacovigilance:** Please see sub-section 3.2.4 (Pharmacovigilance) of this Section for further discussion.
3.2 Monitoring Patients for Treatment Failure

As ART coverage in resource-limited settings grows, but routine viral load (VL) monitoring does not, clinical experts are raising concerns about a range of issues related to treatment failure. These include the development of resistance to first-line ART regimens, poor 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 rise in CD4 count or clinical factors (i.e., weight loss), are poor predictors, and their use in decisions about regimens is not optimal. The following are considerations for PEPFAR programs on the use of CD4 versus viral load testing.

3.2.1 CD4 testing

CD4 testing continues to be used in many settings to determine eligibility for ART, OI prophylaxis, and monitoring on treatment. However, the 2013 Consolidated ARV Guidelines include recommendations for universal coverage in certain circumstances (e.g., Option B/B+, serodiscordant couples, children < five years), which will likely contribute towards decreased use of CD4 testing as the new guidelines are adopted. Furthermore, there may be little additional clinical benefit in performing CD4 and VL together, especially in stable patients. This is supported by the fact that in patients with suppressed VL, a poor immunologic response is not an indication to change an ARV regimen (i.e., in the setting of VL suppression, CD4 results will not prompt a change in management). However, in patients with a low CD4 count, OI prophylaxis may be warranted, even if VL is undetectable.

A recent study that evaluated CD4 change in patients with VL suppression showed that patients with CD4 counts >300 cells/mm$^3$ and VL suppression had a 97.1% likelihood of maintaining a durable CD4 >200 cells/ mm$^3$ for four years, suggesting that frequent monitoring of CD4 count in the setting of VL suppression may be unnecessary (162) and decreasing monitoring frequency may help save costs that can be reallocated towards VL testing. This has led even high-income countries, such as the U.S., to recommend less frequent CD4 monitoring (every six to 12 months) (306).

However, CD4 testing remains an essential component of management for newly diagnosed non-pregnant adults and children > five years of age and will remain an important diagnostic tool as countries gradually implement the updated guidelines. In addition, point-of-care CD4 testing has been shown to:

- Improve linkage to ART (307)(205);
- Determine need for initiation or discontinuation of CTX in countries without universal CTX recommendations and prophylaxis for Mycobacterium avium complex (MAC) in patients who are severely immunocompromised; and
- Provide a baseline assessment of immune status and risk for OIs.

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3.2.2 Viral load monitoring

Successful HIV treatment is dependent on high levels of sustained virologic suppression over time. While many PEPFAR-supported ART programs track clinical progression, measure CD4 counts to monitor for treatment failure, and monitor patient retention as a measure of the quality of ART programs, measurement of HIV VL remains the most reliable predictor of adherence, as well as transmission and disease progression. Immunologic and clinical criteria have not been demonstrated to be reliable predictors of virologic suppression, leading to both unnecessary regimen switches and missed virologic failure and resulting in accumulation of HIV drug resistance mutations (308). The 2013 WHO Consolidated ARV Guidelines recommend VL monitoring as the preferred monitoring approach to diagnose and confirm ARV treatment failure. Virologic testing is considered important for:

- Patient monitoring of treatment adherence and virologic response (at six months, 12 months, and then yearly and/or in cases of suspected virologic failure). Early detection of viremia can allow for targeted adherence interventions before HIVDR and treatment failure ensues. This also helps avoid unnecessary switches to second- or third-line regimens, which are more costly and inconvenient;
- Determining treatment failure and potential for development of HIV resistance mutations; and
- Measuring the quality of ART programs.

A transition towards routine VL monitoring should be part of a long-term plan to maximize the success of PEPFAR-supported ART programs. However, VL testing should be expanded in a highly controlled, rational, and phased manner to avoid compromising the continued scale-up of ART services to those currently eligible. Country teams should work with Ministries of Health and other key stakeholders to carefully consider the impact of different machines, placement, and clinical monitoring protocols (e.g., targeted vs. routine) on cost and feasibility.

The Adult and Pediatric Treatment TWGs, Laboratory TWG, and Supply Chain/Logistics Advisors at Headquarters are currently developing a strategy for scale-up of VL testing, and more guidance will be forthcoming. This process will likely encourage a phased approach to expand VL monitoring, informed by cost projections, existing laboratory infrastructure, and the success of the HIV treatment program. Approaches to introduce VL monitoring could include a focus on priority populations (e.g., pregnant women, postpartum mothers, patients with seronegative partners, those with immunologic or clinical signs of failure) before widespread access. Clinical algorithms for VL testing should be developed in-country with careful consideration of current capacity, geographic considerations, and cost.

Several important considerations for PEPFAR support for the scale-up of VL testing include:
“Do No Harm”: The cost of scaling-up VL monitoring should not jeopardize scale-up of ART services to those currently eligible. This will need to take into account levels of ART coverage and existing guidelines. It is not expected that all countries will move towards adoption at the same rate. Additionally, the introduction of VL testing should not detract from roll-out of early infant diagnosis (EID) testing;

Minimize Impact on PEPFAR Budgets: A transition towards VL monitoring should have as little impact on PEPFAR laboratory and treatment budgets as possible. This will involve careful consideration of a variety of trade-offs involving clinical monitoring protocols, choice of technology, and instrument placement. Understanding that initial investments in the technology will be substantial, analyses of the costs (and potential benefits) should encompass multi-year time frames;

Optimize Platforms and Markets: The introduction of new laboratory technologies should take place in a rational manner. An optimal market will likely favor no more than two to four specific platforms in-country, and procurements through partners should be standardized to optimize the efficiencies gained through pooled procurement, while also allowing for competition. While initially cost-prohibitive, prices for VL technologies have fallen significantly in recent months. Furthermore, VL point-of-care platforms are expected in the near future, potentially placing further downward pressure on prices and removing some barriers to further VL expansion (e.g., need for cold chain, ability to perform with less training, use of dried blood spots to simplify transportation of specimens);

Quality Assurance: The platforms, testing algorithms, and lab systems set up for VL testing should be embedded within an appropriate system for quality assurance; and

Feasibility: Selection of regions/sites to roll-out VL testing should depend on the feasibility to implement VL testing at the sites. Certain factors, such as distance to the lab, lab infrastructure (e.g., availability of refrigerators, centrifuges), cold chain, electrical supply, and capacity of the clinicians to properly use the VL results should be considered.

3.2.3 HIV Drug Resistance

As ART is scaled-up to achieve universal access targets, there remains ongoing concern about the potential for increasing HIVDR. In most PEPFAR-supported countries, routine HIVDR surveillance is not yet considered an integral part of national ART programs. To help address the gap, PEPFAR supports robust monitoring of ART programs to ensure maximal virologic suppression and retention in care in order to minimize development of HIVDR.

The WHO, in collaboration with PEPFAR, continues to update guidance for an HIVDR surveillance strategy and methodologies. The WHO Global Strategy for the Surveillance and Monitoring of HIV Drug Resistance is available at: http://apps.who.int/iris/bitstream/10665/77349/1/9789241504768_eng.pdf.
• PEPFAR continues to support HIVDR surveillance activities that are relatively simple to implement, while successfully informing public health policy. This updated framework has five elements:
  o Cross-sectional survey of baseline HIVDR in adults initiating ART at representative sites;
  o Cross-sectional survey of acquired HIVDR in adults and children on ART for >12 months at sentinel sites;
  o Survey of HIVDR in children <18 months of age newly diagnosed with HIV;
  o Survey of transmitted drug resistance (TDR) in recently infected populations; and
  o Monitoring of HIVDR Early Warning Indicators (EWIs). EWIs include: ART prescribing practices, drug supply continuity, adherence to ARV drug regimens as measured by on-time pick-up of ARV drugs, retention in care, and viral load suppression (see WHO 2013 Consolidated ARV guidelines for further information).

• 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:
  o Is the prevalence of transmitted HIVDR high enough to potentially impact the efficacy of empiric first-line ART?
  o 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; and

• While other sources of funding for HIVDR surveillance activities may exist, PEPFAR program implementation funds should be allocated to fill any identified gaps.

3.2.4 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 (e.g., serum creatinine monitoring with tenofovir (TDF) use, hemoglobin measurement with AZT use).

The new WHO 2013 Consolidated ARV guidelines recommend TDF-based regimens for first line therapy in adults and pregnant women. There are many advantages to using a TDF-based regimen, including the ease of administration as a once-daily regimen and overall simplification of regimens. However, TDF has also been associated with the development of renal toxicity (19) and changes in bone density (20), and many studies highlighting the efficacy of TDF have been performed in settings where screening for kidney dysfunction (usually through a blood test for creatinine and/or creatinine clearance calculation) is possible. HIV infection itself has been identified as a risk factor for kidney dysfunction, and in some cases ARVs, including TDF, can help treat HIV-related kidney disease.
3.2.4.1 Risk of renal disease in persons living with HIV (PLHIV)

- PLHIV have an increased risk of renal disease when compared to HIV-uninfected individuals. Based on a recent meta-analysis, the relative risk of renal disease is 3.87 times greater than in HIV-uninfected people. PLHIV with more advanced immunosuppression are 3.32 times more likely than patients with earlier stages of infection to have renal disease (21). Older age and other underlying conditions, including diabetes and hypertension, also increase the risk of developing renal disease.
- Chronic kidney disease is relatively common in PLHIV. In patients of African descent, this is predominantly caused by HIV-associated nephropathy (HIVAN). (22)
- However, the relative risk of renal disease among PLHIV on ART is 46% lower than treatment-naïve PLHIV, which is due, in part, to reduction in the direct damage to the kidney from the HIV(22).

3.2.4.2 Risk of TDF-associated Nephrotoxicity in PLHIV:

- Use of TDF has been associated with renal dysfunction when compared to other antiretroviral medications, though it remains a relatively uncommon side effect (20) (22)(309);
- Several risk factors have been shown to increase the risk of TDF-associated nephrotoxicity, including: (a) age over 50 years, (b) low body weight, (c) concomitant use of nephrotoxic drugs, (d) pre-existing kidney dysfunction, (e) low CD4 count and advanced immunosuppression, and (f) hepatitis C co-infection (310) (311) (20); and
- Post-marketing surveillance studies conducted by pharmaceutical companies have demonstrated a < 0.2% risk of severe renal failure over an estimated 400,000 person-years of TDF exposure (312); however, a retrospective cohort study of over 1,000 HIV-infected individuals receiving TDF-containing ART suggested a risk closer to 1% (313). A meta-analysis of 17 studies published in 2010 found a slightly (0.7%) higher risk of acute renal failure with TDF, but no significant differences in rates of chronic kidney failure or end-stage kidney failure (314) (315).

Given the low risk of TDF-associated renal dysfunction and demonstrated benefits of ART for HIV-associated renal disease, TDF can be used as first-line ART in patients with low-risk of renal disease. Furthermore, current data do not show a risk of teratogenicity from any ARV. The benefits of early initiation of ART (reduced MTCT, improved maternal health), using a simple, once-daily TDF-based FDC likely outweigh any potential risk in pregnant women. Additional information about the risk of TDF, EFV and other ARVs is discussed in Section 1.1 of the Technical Considerations (Prevention of Mother to Child Transmission).

Birth defect surveillance is expensive and must be done correctly to yield useful data, so it should not be implemented everywhere routinely. TDF/XTC/EFV regimens can be implemented (e.g. PMTCT Option B or B+) without birth defect surveillance, as the risk of birth defects is far
outweighed by benefits to maternal health with ART. Birth defect surveillance could be considered in a country, if all births (livebirths and stillbirths) at selected sites can be examined and outcomes can be linked to drug exposures in early pregnancy, and if numbers are adequate to provide meaningful estimates of birth defect rates. If a country is interested in developing a birth defects surveillance program, PEPFAR Headquarters staff can assist with development of an appropriate program.

4 Sustainability and Efficiency

4.1 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) PEPFAR support to country ART programs is aligned with national HIV and ART plans and strategies, 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.

4.1.1 Transition of PEPFAR-Supported ART Programs to Sustainable, Country-led Programs

This year, PEPFAR is launching a Country Ownership and Sustainability Operational Guidance to ensure the sustainability of programs as countries begin to transition to country-led HIV programs, management, and financing.

In line with PEPFAR goal of fostering a sustainable, country-led HIV response, mature PEPFAR-supported treatment programs should work towards gradually transitioning support for treatment services to MOH and in-country actors. This will involve the following key elements:

- **Transition of Direct Service Delivery from International Partners to Local Partners:** A transition from international partners to local partners may reduce the cost of providing care and can build local leadership for HIV response. When applicable, this transition process should be 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; and

- **Transition from Direct Service Delivery to more targeted Technical Assistance (TA):** As treatment programs mature and governments assume greater responsibility for funding the treatment response, the type of support that PEPFAR provides needs to change too. This can involve both a transition from direct HRH support at facilities to supervisory support as well as moving towards support at the district and higher levels. Activities falling under TA for ART include:
- Support for the development, implementation and evaluation of a national supportive supervision system;
- Support for periodic revision of national ART treatment guidelines and their dissemination;
- Support for ancillary services for HIV treatment, such as supply chain management and laboratory monitoring;
- Support for national M&E systems to guide ART programs;
- Support for HRH workforce development for the provision of ART services, including training of MOH staff at the national and regional levels in mentoring/supporting of site-level staff and training of trainers; and
- Support for national, regional, and/or facility-based quality improvement plans and initiatives.

In the context of USG’s shift from a service delivery model to a TA model, the release of the MER guidance will move PEPFAR closer to being able to measure TA and community-based activities, outputs, and outcomes and the quality of interventions in the HIV continuum. 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.

These concepts are not necessarily sequential or exclusive. In order for this transition to be successful, careful planning needs to occur to minimize treatment disruptions and to avert potential degradations in program quality. The Sustainability Guidance provides country teams with a list of key questions to consider and methods to monitor and evaluate these questions, as well as country-level country ownership assessments for program planning.

Refer to Section 3.9 of the Technical Considerations (Finance and Economics) for further details.

4.1.2 Creating Efficiency Within PEPFAR Treatment Programs

Given the importance of treatment programs to curtailing the HIV-epidemic and the resource-intensive nature of ongoing, lifelong HIV treatment services, country teams should proactively analyze PEPFAR-supported treatment portfolios to see how additional efficiencies can be achieved. Potential examples 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 international partner;
Safely rationalizing the use of laboratory monitoring; and

Standardizing packages of PEPFAR support for ART Services. Developing a standard package of PEPFAR support for 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. Standardizing the type of support that PEPFAR implementing partners provide should not serve as a limit on what services get provided at site level, but rather as a complement to other inputs from Ministries of Health and other international stakeholders (such as the Global Fund and the Clinton Health Access Initiative (CHAI)) that are designed to maximize the impact of the HIV treatment program nationally.

5 Cross-cutting Content, Linkages and Wraparounds

5.1 Country Contextual Considerations

Country teams should be using and, where necessary, generating epidemiological data to plan programs, including recent DHS surveys, AIS surveys, and antenatal-care sentinel surveys. 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).

5.1.1 Strategic Information and Monitoring, Evaluation and Reporting

PEPFAR treatment and SI programs should work together to ensure that key treatment SI needs are addressed and integrated within the larger SI framework.

PEPFAR’s new MER Guidance provides a framework for the global HIV response, from specifics on key technical areas, such as treatment, to broader health system questions. The Treatment section of the MER provides details on the specific and broad areas critical to the success of treatment programs, including:

- PLHIV receiving care and support services (e.g. CTX, TB screening);
- Treatment coverage for adults, children and adolescents, pregnant and breast-feeding women, and key populations;
- Treatment scale-up;
- Retention in care and treatment (across continuum of care);
- HIV drug resistance;
- Health system strengthening services (e.g., laboratory services and accreditation, number of facilities providing ART, task shifting); and
- Overall 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. Data quality assessments should be undertaken by USG teams on a routine basis for the treatment program level data.

5.1.2 Wraparound Services

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, HTC programs must increase their effectiveness in identifying PLHIV and linking them to services.

In all countries and settings, regardless of epidemic type, HTC should be offered to all sexual partners and family members of PLHIV. Couples and partners HTC has been shown to increase uptake of ART among pregnant women (316)(5), reduce HIV transmission (317), increase condom use, and reduce the frequency of sex acts with outside partners within serodiscordant couples (14)(318)(3)(176). Testing of children of PLHIV in care and treatment has been shown to increase identification of young PLHIV. 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. See Section 1.4 of the Technical Considerations (HIV Testing and Counseling) for more information on effective approaches to partner and index patient testing.

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. Additional efforts to link healthcare facilities and community-based programs for HTC, Care and Support, and treatment services is essential to improve linkage and retention in care and treatment services. Again, see Section 1.4 of the Technical Considerations (HIV Testing and Counseling) for more information on effective linkage of patients from HTC to care and treatment.

Further detail on linkage and retention across the continuum of care is also available in PEPFAR’s PLERS.

5.1.2.1 Prevention

Secondary HIV prevention activities should be integrated into routine care for all PLHIV as 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 of the Technical Considerations (Positive Health, Dignity and Prevention for People Living with HIV)).

A comprehensive package of prevention messages includes:

- Counseling for safe disclosure of HIV status to sex partner(s) and other family members;
Support for and provision of HIV testing and counseling of sex partner(s) and children;
Safer sex counseling (e.g., mutual monogamy to a partner of known HIV status, reduction of sexual partners, and correct and consistent use of male and female condoms);
Counseling on how to incorporate correct and consistent condom (and lubricant) use into their work for SWs (e.g., condom negotiation skills, eliciting support from managers);
Alcohol assessment and counseling on reduction or abstinence;
Medically assisted therapy (MAT) and syringe services (as wraparound programs) for PWID;
Condom (and lubricant, where appropriate) promotion, distribution, and training on correct use;
Assessment, diagnosis, and management of STIs as part of routine HIV care;
Voluntary family planning and safer pregnancy counseling for HIV-infected women;
Adherence counseling and support for both prophylaxis and treatment regimens; and
Ongoing counseling and support for HIV serodiscordant couples, which includes all of the activities listed above in addition to:
  o ART for HIV-positive partners, which can reduce the risk of heterosexual transmission by 96% (165)(17);
  o Voluntary medical male circumcision (VMMC) for HIV-negative male partners, which can reduce the man’s risk of acquiring HIV by at least 60% (255);
  o 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 (254) contraception increase her risk of acquiring HIV (254); and
  o Safer pregnancy counseling for couples who desire a pregnancy.

Prevention for PLHIV should be integrated into care and treatment clinics and delivered during routine clinic visits as well as within community programs. Services at ART clinics should include referrals to community-based programs and community programs should be actively referring PLHIV to facilities. These bi-directional linkages can enhance patient retention, strengthen prevention messaging and build a platform for patient advocacy. See Section 1.5 of the Technical Considerations (Positive Health, Dignity and Prevention for People Living with HIV) for more detailed information.

5.1.2.2 Family-centered Services

PEPFAR teams should work with national programs to ensure that PMTCT and ART programs, guidance, and M&E systems are integrated as PMTCT becomes increasingly based on ART. As treatment services for pregnant and breastfeeding women are decentralized to lower-level health care facilities, ART services should also be made available to adults, children, and adolescents in
these clinics as part of a family centered approach, which has the potential to expand overall treatment access and improve retention.

5.1.2.3 HIV Services and ART Provision for Key Populations

An effective HIV response requires an understanding of the country’s epidemic and context and the provision of ART to populations at highest risk for HIV infection. Considerations in programming for ART provision to key populations (SW, TG, MSM and PWID), and other priority populations should include service delivery locations that are patient friendly, convenient, provide a confidential, non-stigmatizing environment and minimize barriers for patient adherence to care and treatment. Alternative models of ART service delivery such as mobile ART, ART delivery in non-traditional venues (i.e., drug treatment sites, drop in center, other community-based programs), or late hours of service delivery, may be necessary to achieve acceptable access, uptake, and retention. Programs for key populations tend to be more nascent in countries with generalized epidemics, while countries with concentrated epidemics such as India, Thailand and China have more mature, successful programs. As teams in the generalized epidemic countries move to strengthen ART for key populations, they should look to these countries for examples of strong programs, and consider learning visits, as appropriate.

6 Additional Resources

- PEPFAR Quality Strategy (PQS)
- PEPFAR Linkage, Engagement and Retention Strategy (PLERS)
- Treatment /Cascade Calculator


## 2.3 Pediatric Testing, Care and Treatment

### 1 Introduction

In 2012, the WHO reported that over eight million people had been initiated on ART worldwide, representing approximately 57% of adults in need of treatment. However, global pediatric HIV treatment coverage remains disparately low. Within the 22 priority countries participating in the Global Plan—countries that account for 90% of HIV-infected pregnant women and a similar amount for infants—only 34% of children in need of ART are receiving it. To close this gap pediatric treatment programs must focus on identifying and enrolling children already infected with HIV and those that are newly infected.

### 1.1 What’s new in 2014

The 2014 Pediatric Testing, Care and Treatment Technical Considerations reflect several critical new developments related to pediatric populations living with HIV:

1. **Expanded eligibility for children under five:** The 2013 WHO Consolidated Guidelines expand and simplify pediatric treatment eligibility, recommending universal initiation of antiretroviral therapy (ART) for children under five years of age immediately after documentation of HIV infection, without additional prerequisite lab tests. Expanding pediatric testing and treatment is critical to improving child survival and closing the gap in pediatric treatment coverage. PEPFAR programs should prioritize support to adopt and implement these new guidelines ([http://www.who.int/hiv/pub/guidelines/arv2013/download/en/index.html](http://www.who.int/hiv/pub/guidelines/arv2013/download/en/index.html)).

2. **Pediatric regimen rationalization:** The 2013 WHO Consolidated Guidelines offer an updated list of recommended pediatric formulations of antiretroviral regimens (ARVs).

3. **Earlier identification & treatment for children:** A growing body of scientific evidence supports earlier ART initiation for children, particularly among children under two years of age who are least likely to survive without ART. Early treatment requires expanding and improving early infant diagnosis (EID) services, aggressive pediatric testing targets, and increased support for pediatric case finding.

4. **Linkage & retention:** Renewed focus on the pediatric care and treatment cascade is needed to improve linkage and retention. Portions of the cascade known to be at especially high risk of attrition include the period immediately following early infant diagnosis, the period at the end of breastfeeding, and the cessation of scheduled routine immunizations (typically age five).

5. **Adolescents living with HIV:** PEPFAR and UNICEF have both emphasized the need to strengthen the HIV response for adolescents. In the context of pediatric care and treatment, this means tailoring HIV care and treatment programs to best fit the need of adolescents, and
facilitating the transition from pediatric to adult care and treatment. Please consult the forthcoming Adolescent Programmatic Considerations for comprehensive guidance on this important and often neglected population.

1.2 Opportunities to Expand Pediatric Care & Treatment

Recent developments present a unique opportunity to greatly expand and improve pediatric HIV services:

- **More children are eligible for treatment:** The new WHO guidelines expand eligibility to include all children under age five. Many national guidelines are now adopting this change, or expanding pediatric ART eligibility further (universal eligibility for children under age 15);

- **Expansion of EID and family-centered approaches to ART service delivery:** The WHO endorsement of initiating all HIV-infected pregnant women on ART will result in the expansion and decentralization of HIV care and treatment services. As lower-level facilities develop family-centered approaches to HIV care and treatment, a simultaneous expansion of access to EID services and pediatric treatment should also occur; and

- **Political will and momentum:** There is great global interest in expanding treatment and prevention services that impact children. This momentum is due in large part to the *Global Plan towards Elimination of New Pediatric HIV Infections by 2015 and Keeping their Mothers Alive*, the PEPFAR World AIDS Day Target of reaching six million people with ART, and the UNAIDS Treatment 2.0 initiative to treat 15 million people by 2015. Country teams should take advantage of this political will to mobilize support for necessary policy changes.

1.3 PEPFAR Blueprint

The PEPFAR Blueprint highlighted the U.S. Government’s commitment to expanding and improving infant, child, and adolescent HIV treatment, and realizing these goals remains a top priority in achieving an AIDS-free generation. In keeping with the Blueprint, PEPFAR teams should capitalize on opportunities to expand pediatric testing, care, and HIV services. Specifically:

- Set ambitious testing targets for pediatric populations and employ strategies to increase the positive yield of pediatric testing (e.g. PITC of pediatric inpatients or malnourished children, and targeted testing for children of adult TB, PMTCT or ART clients);

- Work to ensure that scale-up of PMTCT services includes a concomitant expansion of treatment for eligible pregnant women, and early infant diagnosis (EID) for all HIV-exposed infants as well as ART for all infants identified as HIV-infected;

- Explore public-private partnership opportunities to support the development of age-appropriate pediatric formulations, including fixed dose combinations of ARVs (first-,
second-, and third-line) and TB drugs (first- and second-line), particularly for infants and young children at the highest risk of dying without treatment; and

- Support the transition of adolescents from pediatric to adult HIV care and treatment services.

2 Priorities

2.1 Pediatric Case Finding

2.1.1 HIV testing of children for early identification

Without ART, more than half of infants infected through perinatal transmission die within 12 months after birth; early ART initiation substantially improves survival (319) (320). However, missed opportunities for HIV testing of infants and children are common and result in delays in ART initiation, which can be fatal. Expansion and improvement of EID programs is critical, including DNA or RNA PCR testing and follow-up of all HIV-exposed and HIV-infected infants. Successful national EID programs require coordinated program development and planning, such as expanded laboratory capacity for PCR testing and the training of lab and clinical care providers. Other essential components of a well-coordinated EID cascade include the decentralized collection of dried blood spot (DBS) specimens, reliable and rapid DBS specimen transport to the laboratory, rapid processing and return of results to families, and effective completed linkage to clinical care and treatment.

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, have been shown to improve follow-up (321).

Lack of PCR capacity should not prohibit early testing of infants with HIV antibody tests to assess HIV exposure. Clear guidelines and algorithms should be developed before presumptive diagnosis of HIV so that early treatment can be still prioritized for all children, even in the absence of PCR capacity. 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 nine, 12 and/or 18 months of age.

In generalized epidemics where (prevalence >1%), routine opt-out PITC should be provided to any infant or child with an unknown HIV exposure or infection status who presents at a health facility. Testing requirements for infants and children are further described in the WHO guidance on HIV testing and counseling for children

Key strategies for early identification of HIV exposure and infection highlighted in the WHO 2013 Consolidated ARV guidelines include:
• Ensuring that pediatric HIV testing and counseling policies, algorithms, guidelines, and implementation plans are consistent with recent WHO guidance and are widely available (see link above);
• Ensuring that national programs and supported partners train health care providers to test infants and children for HIV;
• Establishing and documenting HIV exposure status of all infants at first contact with the health system, ideally at birth or before six weeks of age. National programs should use mother/child health cards that document HIV exposure status;
• Scaling-up of HIV virologic testing (PCR testing of DBS or plasma) at four to six weeks of age and return of results for HIV-exposed infants;
• When PCR is not available, providers should use algorithms based on serology, clinical exam, history, and WHO guidance (see link above) for early HIV diagnosis, with the aid of CD4 count and total lymphocyte count (TLC) as available;
• Adopting guidelines that recommend repeat testing for:
  o Infants who test negative but have ongoing HIV exposure through breastfeeding;
  o Infants who test positive by antibody test before 18 months of age;
  o Infants or children who present with signs or symptoms that may be related to HIV infection;
  o Children who seroconvert after two years of age (e.g. due to BF), or who are missed because of gaps in PMTCT service coverage, or lost-to-follow-up (LTFU) for other reasons; and
  o Pediatric and adolescent survivors of sexual abuse in the context of a broader package of victim care and support.
• Ensuring pediatric testing beyond EID. When HIV-infected infants are not identified through EID or subsequently lost to follow up, they may present later with childhood diseases as manifestations of HIV infection. In countries where HIV prevalence and rates of vertical transmission are high, universal opt-out PITC in all inpatient pediatric wards, malnutrition clinics, TB clinics, OVC programs and other outpatient settings with increased HIV prevalence is an effective way to identify these children and link them to care (see Section 1.4 of the Technical Considerations (HIV Testing and Counseling) for more information on PITC). Whenever women or men are diagnosed with HIV, all of their children should be offered HTC and the issue should be readdressed at all subsequent visits until all appropriate follow-up is complete (see Section 1.4 of the Technical Considerations (HIV Testing and Counseling) for more information on index-patient testing). Integrating routine opt-out HIV testing in pediatric wards in Zambia and Malawi has shown high caregiver uptake, identification of high-risk patients in need of treatment, and successful linkage to ongoing ART. These successful models established HIV testing as a routine feature of the pediatric health package that is essential to provide appropriate therapy. Barriers such as requiring physician or nurse orders for an HIV test were removed and use of patient escorts increased testing uptake (322)(323)(324);
• Implementing and monitoring family-centered or index patient approaches to HIV testing in HIV care and treatment settings and PMTCT clinics, with routine PITC for children of HIV-infected adults and siblings of HIV-infected children; and
• Investing in cross referral mechanisms between orphans and vulnerable children (OVC) programs and HIV care centers to ensure that all children enrolled in OVC programs access HIV testing and HIV-related services, and all HIV-infected and exposed children are referred for OVC support.

In many countries the Clinton Health Access Initiative (CHAI), 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. PEPFAR headquarters can offer assistance to country teams in negotiating this transition.

### 2.1.2 PITC & Disclosure – Children and Adolescents

Many countries are experiencing an increasing number of newly identified older children and adolescents living with HIV.

Many adolescents do not yet know their status because of a parent or caregiver’s failure to disclose. They may learn of their positive HIV status through HTC regardless of how they acquired HIV. Adolescents who test negative should be connected with peer support programs, prevention programs, and condom distribution programs. When needed, they should be counseled and supported about disclosure.

Disclosure of HIV status can be challenging for children, parents, and healthcare workers, especially for young children. Disclosure is often a bottleneck for testing, and lack of disclosure may affect the well-being of both the caregiver and the child and may also have a detrimental effect on access to care and treatment, adherence, and long-term retention (325). 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 six to 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/). Adolescents should be counseled about the potential benefits and risks of disclosure of their HIV status and empowered to determine if, when, and how to disclose, and to whom (63).

Many perinatally HIV-infected children reach adolescence without knowing the nature of their disease. This has important consequences on adherence and may delay transitioning of otherwise ready adolescents into more appropriate care settings. Failure to disclose HIV status 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 can benefit from support to develop guidance for...
disclosure for children. Routine documentation of the disclosure process is recommended to remind health care workers of this important treatment intervention.

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.

2.2 Treatment of HIV-infected infants, children, and adolescents

2.2.1 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 that are equipped to diagnose and treat HIV in children within a supportive health systems structure. Strengthening pediatric diagnostic services and follow-up and referral systems within an expansion of trained health care workers is critical (see sub-section 2.3 (Pediatric care and support) and sub-section 2.4 (Human Resources for Health) of this Section). The updated 2013 WHO Guidelines simplify pediatric ART eligibility criteria, as well as support task sharing and decentralizing care and treatment in order to improve coverage. Plans for increasing pediatric coverage should include:

- Increasing testing for pregnant and breastfeeding women, and aggressive follow-up in HIV-exposed infants to identify infected children;
- Implementing PITC for children and adolescents;
- Improving access to early infant diagnosis;
- Expanding the pool of health care workers who can initiate and monitor children on treatment;
- Implementing task-sharing approaches for pediatric HIV treatment as services are decentralized, ideally within a family-centered approach (where applicable);
- Collaborating with the MOH, District or Regional Health teams, key stakeholders, and clinical staff at sites to improve pediatric treatment services at all levels of the health care system;
- Working with national programs to develop policies, training, and ongoing mentoring for nurses to initiate and maintain children on ART, with periodic supervision by a pediatrician or other qualified medical doctor; and
- Reviewing the pediatric “cascade” from identification to adequate follow-up on ART to identify and address drop-offs.

2.2.2 Implementation of 2013 WHO Guidelines

Updated ART eligibility criteria expand pediatric HIV treatment eligibility while simplifying programmatic implementation by no longer requiring CD4 testing for ART initiation in children under the age of five. The revised guidelines also align CD4 thresholds for children five years and older with adults (see Table 3).
Table 3. Timing to initiate ART in children

<table>
<thead>
<tr>
<th>Age</th>
<th>When you start</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants (&lt;one year)</td>
<td>Treat all individuals</td>
</tr>
<tr>
<td>One year to less than five years</td>
<td>Treat all individuals &lt;br&gt; (Prioritize children ≤two years and those with WHO stage 3 or 4 or CD4 count ≤750 cells/mm$^3$ or &lt;25%)</td>
</tr>
<tr>
<td>Five years and above</td>
<td>WHO stage 3 or 4 or CD4 ≤500 cells/mm$^3$ &lt;br&gt; (Prioritize CD4 ≤350 cells/mm$^3$)</td>
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Over the past few years the number of HIV-infected children transitioning into adolescence has greatly increased. This group of older 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.

2.2.3 Country pediatric ARV formularies and cost of pediatric ARVs

The number of pediatric ARV formulations has increased since 2003, making individual client-focused treatment choices more complex (for more details, see below and the updated recommendations for ARV treatment for children in the 2013 WHO Consolidated Guidelines). The number of different ARV formulations for children often results in smaller orders of pediatric ARV drugs, which in turn can make it difficult to maintain ARV supplies. Manufacturers typically wait until a minimum number of orders are reached before producing a batch of ARVs. This makes pediatric ARV production irregular and procurement in any given country difficult. WHO recommends the creation of a national “essential medicines” list of formulations that cover the regimen needs of the county’s children ([http://www.who.int/hiv/pub/meetingreports/paediatric_working_group/en/index.html](http://www.who.int/hiv/pub/meetingreports/paediatric_working_group/en/index.html)). 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 rationalizing the national pediatric ARV formulary to a limited number of drugs and formulations that meet the needs of the majority of children and align with nationally recommended regimens (see Section 3.11 of the Technical Considerations (Supply Chain Management)).
Key strategies for maintaining an adequate supply of pediatric ARVs for PEPFAR-supported programs should include:

- Ensuring that progress toward a national pediatric ARV formulary occurs;
- Assisting countries to streamline pediatric formulations to reduce redundancies and facilitate forecasting; and
- 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 over the course of 2013/2014, these changes may present both commodities challenges as well as further entry points for PEPFAR and Global Fund coordination to ensure sufficient commodity stocks.

In this context, PEPFAR teams should work with other stakeholders to budget realistically and to ensure that commodities for all PEPFAR treatment targets are available. *OGAC headquarters should be made aware immediately 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 their Country Coordination Mechanisms (CCM), Local Fund Agents (LFA), GF liaisons, and GF implementing partners in-country. PEPFAR teams should work with SCMS commodities and logistics experts to share information on commodities and evaluate how Global Fund resources and performance should shape PEPFAR forecasting and budgeting. Any critical commodities stockouts affecting continuation of children on ART should be reported immediately to the CSTL. 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). In some cases, this may involve procuring a greater proportion of ARV drugs 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.
2.2.4 New antiretroviral drugs and formulations for children

Compared to the prior year, relatively few new FDA approvals for pediatric ARV use have occurred over the past year:

- An expanded indication for efavirenz to include children over three months old (326); and
- Once-daily dosing of darunavir in treatment-naïve children three years and older (327).

Current WHO guidelines recommend a lopinavir/ritonavir-containing regimen for children less than three years of age, so the expanded use of efavirenz may not be of widespread program significance.

2.2.5 Pediatric and Adolescent 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. Although many national programs are not yet collecting disaggregated data, the Pediatric /PMTCT TWG and SI Liaisons are available to assist with strategic planning and development to encourage this modification.

In order to effectively monitor the provision of care and treatment to children, country programs and USG-supported partners will need to gather and analyze more highly age-disaggregated data than currently exists for these populations. There are challenges with upper age limits for adolescents, which can lead to poor alignment between data collected by medical, legal and social services. Additionally, the age of consent may vary across these programs, contributing to data conflicts. Country programs should engage pertinent technical working groups to resolve discrepancies and develop consensus.

Countries that are not reaching treatment targets for children should ensure that HIV testing services for children are being implemented systematically and aggressively for all ages, including for adolescents. Working with the MOH and USG-supported partners to gather information on testing practices and positivity rates among children in various high-yield entry points and in settings where large numbers of children and adolescents access health services can inform the roll-out of counseling and testing and treatment services. Such informed decision-making is critical to improving uptake of HIV services for children. Routine opt-out PITC for patients remains a priority. Pediatric in-patient wards, out-patient acute care services, TB and malnutrition clinics, and MNCH clinics are key areas where systematic testing approaches must be implemented.

2.2.6 Adherence support

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. Decentralizing pediatric care to reduce patient travel distance to treatment centers is critical to improving both access and adherence.

In older children and adolescents, efforts to support adherence are of particular importance and should be a component of all programs. Adolescents are a high-risk group for treatment default (328). Care and treatment delivery models that support adolescent psychosocial needs as individuals transition into adulthood can improve adherence, thereby improving treatment success.

### 2.2.7 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; and
- Monitor adherence or development of resistance.

**Laboratory monitoring of response to ART:** Providing access to CD4 percentages and counts remains important 1) at baseline, 2) at regular intervals for children >two years not yet eligible for ART, 3) to monitor response to treatment, and 4) to identify treatment failure. However, regarding treatment failure, CD4 decline may not be as helpful as viral load determinations, where available.

**Viral load monitoring:** Access to viral load testing is still limited in most settings. Nonetheless, the 2013 WHO guidelines urge expansion of viral load monitoring for routine patient monitoring. It is critical that children be incorporated in any country-level planning for expanded viral load capacity. The use of DBS for quantification of viral load (VL) is being evaluated and gradually introduced in countries. 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 basic clinical laboratory assays can be informed by the drugs included in first- and second-line regimens. Recent data suggest NNRTI and NRTI-based ART can be administered to pediatric patients without routine laboratory toxicity monitoring (329), but 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.

### 2.2.8 Surveillance for HIV Drug Resistance:

Select reports from resource-limited settings have described multi-class drug resistance in HIV-infected infants exposed to ARVs in utero and/or postnatally through infant prophylaxis or through ARVs in breast milk of women on ART (330). In most PEPFAR-supported countries, routine HIVDR surveillance is not yet considered an integral part of national ART programs; however, countries should work with ministries of health and other partners to implement surveys for monitoring of HIVDR in pediatric patients. The WHO Global Strategy for the Surveillance and Monitoring of HIV Drug Resistance is available at [http://apps.who.int/iris/bitstream/10665/77349/1/9789241504768_eng.pdf](http://apps.who.int/iris/bitstream/10665/77349/1/9789241504768_eng.pdf).

PEPFAR continues to support HIVDR surveillance activities that are relatively simple to implement while successfully informing public health policy. The WHO framework calls for HIVDR surveillance activities to simultaneously include adult and pediatric populations. This updated framework has the following elements relevant for pediatric populations:

- Surveys of HIVDR in children <18 months of age newly diagnosed with HIV using leftover DBS samples (331);
- Cross-sectional surveys of acquired HIVDR in children and adolescents on ART for >12 months at sentinel sites;
- Surveys of transmitted drug resistance (TDR) in recently-infected populations;
- Acquired and/or transmitted HIV DR studies in specific populations (e.g. pregnant women, adolescents); and
- Monitoring of HIVDR Early Warning Indicators (EWIs).

For additional information on HIVDR surveillance, please see Section 2.2 of the Technical Considerations (Adult Treatment) and The WHO Global Strategy for the Surveillance and Monitoring of HIV Drug Resistance. While other sources of funding for HIVDR surveillance activities may exist, PEPFAR funds can be allocated to fill any identified gaps for both adult and pediatric HIVDR activities.

### 2.3 Pediatric care and support

#### 2.3.1 Cotrimoxazole (CTX) prophylaxis for HIV-exposed and -infected children

At an estimated cost of US $0.03 per child per day or US $10/year, provision of CTX to HIV-exposed or -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 children, especially those 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 guidance on CTX prophylaxis for HIV-exposed and HIV-infected infants and children (http://www.who.int/hiv/pub/plhiv/ctx/en/index.html) and the 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection (http://www.who.int/hiv/pub/guidelines/arv2013/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 four to six weeks of age and continuing until HIV is excluded;
- All children less than five years of age diagnosed with HIV receiving CTX and continuing until at least five years of age if WHO immunologic and clinical criteria are met;
- Children older than five years of age diagnosed with HIV receiving CTX in accordance with current national pediatric and adult guidelines; and
- The integration of CTX with MNCH services, and inclusion of HIV exposure status and receipt of CTX in the child health card.

### 2.3.2 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 Figure 4, 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 the following.

2.3.2.1 Nutritional assessment, counseling, and support (NACS)

Nutrition status plays a crucial role in the health and development of infants and children infected with or affected by HIV. Most nutrient requirements are the same for HIV-infected and -uninfected infants and children, although documentation shows that children born to HIV-
infected parents are at 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;
- Promotion of good breastfeeding practice, from exclusive breastfeeding in first six months of life through long-term breastfeeding;
- Provision of complementary feeding support for all infants from six months through 24 months of age, and therapeutic or supplementary feeding support for children meeting criteria for malnutrition or undernutrition; and
- Nutrition surveillance, referral, and tracking systems for children in nutritional assessment, counseling, and support (NACS) and care and treatment programs.

For additional detail, see Section 1.1 (Prevention of Mother to Child Transmission) and Section 3.7 of the Technical Considerations (Nutrition and HIV/AIDS).

2.3.2.2 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).

2.3.2.3 Malaria prevention and treatment

- Distribution and use of Insecticide-treated nets (ITNs) in households of persons with HIV, pregnant women, and children less than five years of age; and
- Malaria screening, testing if symptomatic, and treatment as part of routine child health care.

2.3.2.4 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.

2.3.2.5 Prevention, diagnosis, and management of tuberculosis (TB)

Children living with HIV have a higher risk of developing primary TB, as well as more rapid progression and poorer outcomes than children not infected with HIV. Confirming the diagnosis of TB is more difficult in children than adults, especially among those living with HIV. Priority should be given to the following activities:

- Intensified case finding for TB by routinely screening HIV-infected children with a standardized screening algorithm, such as the one recommended by WHO:
  - Fever, current cough, contact history with a TB case, or poor weight gain (defined as reported weight loss, or very low weight [weight-for-age less than –3 z-score], or underweight [weight-for-age less than –2 z-score], or confirmed weight loss (>5%) since the last visit, or growth curve flattening).
  - Any child with one or more symptom should be evaluated for TB (332);
- Active case finding for HIV-exposed or -infected children with household TB contacts by asking all adults with infectious TB about children in their home;
- Working with the pediatric and TBHIV TWGs to assure integration of Xpert RIF/MTB into national guidelines for diagnosis of TB in children (pending dissemination of forthcoming WHO guidance);
- Ensuring that all children with TB receive HIV testing; and
- Scaling up isoniazid preventive therapy for HIV-infected infants and children with known TB contact and for HIV-infected children age 12 months and older, regardless of TB contact status after active TB disease has been excluded by symptom screen.

For more information on TB, see Section 2.4 (TB/HIV) and sub-section 4.2 (Prevention and treatment of tuberculosis) of Section 1.1 of the Technical Considerations (Prevention of Mother to Child Transmission).

2.3.2.6 Other opportunistic infections

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. In 2010, WHO published guidance on the management of diarrhea and pneumonia in HIV-infected infants and children (http://www.who.int/maternal_child_adolescent/documents/9789241548083/en/index.html).

2.3.2.7 Sexual and Reproductive Health (SRH) services for adolescents

All adolescents need access to HTC, SRH, psychosocial support, HIV prevention, and PMTCT services. Some services may need to be tailored to address factors affected by how they acquired their HIV. Regardless of the HIV transmission route, all ALHIV need prevention with positives
and positive health dignity and prevention programs, support regarding disclosure (to themselves and others), assistance to address stigma (both internal and external), and adherence and retention support. Most healthcare providers have not had training in providing services to adolescents and may inadvertently discourage them from seeking and remaining in care. Training and supportive supervision of health care providers in specific adolescent SRH issues, including issues specific to adolescent key populations (MSM, TG, SW, and PWID) can improve adolescent outcomes by increasing retention and adherence.

**2.3.3 Community services: 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 delivered by skilled providers through a continuum of service networks (e.g., care, routine immunization, OVC and nutrition services) and through effective linkages between facility-, school-, community-, and home-based care programs.

- Linkages and collaboration between health facilities and community/home services and schools build and strengthen bi-directional referrals. These programs increase access to HIV care services and improve retention of HIV-exposed/infected children in care;
- Community-based services that provide critical non-clinical components of care and support;
- Peer counselors, community health workers, and other community-based health professionals who support home caregivers to provide the needed care and support in the home;
- Community programs that serve mothers referring infected mothers and their HIV-exposed infants to health facilities for counseling, early HIV diagnosis, disclosure counseling, and cotrimoxazole prophylaxis; and
- Particularly for adolescents, community services such as mental health, peer support, and HIV positive groups help families with HIV-infected children to overcome stigma, promote adherence, and provide linkage to HIV care.

**2.3.4 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.
2.3.5 Retention of HIV-infected children in care (i.e. continuity of care in pre-ART services)

The WHO 2013 guidelines for initiation of ART have significantly increased the number of children eligible for treatment by recommending a “test and treat” approach for children under 5 years of age. These children will still require routine follow-up visits and laboratory monitoring, and programs will need to institute services to ensure that they are retained in care. Older children diagnosed with HIV, especially those not yet eligible for treatment, also need significant support to be retained in care.

Key strategies to ensure retention and strengthen the continuum of care for HIV-infected children and adolescents 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; and
- Linkage of all HIV-infected adolescents to facility-and community-based PWP/PHDP services that provide additional care and support.

2.3.6 Pediatric care and support targets

The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 states that USG-supported programs must “provide care and treatment services to children with HIV commensurate to their representation in a country's overall epidemic”. To establish country-based targets, accurate pediatric data must be obtained using modeling that accounts for incidence and prevalence estimates of pediatric HIV as well as estimates of care and treatment needs. Baseline estimates of children in need of care and treatment by country are available in the Children and AIDS Fifth Stocktaking Report, 2010, available at 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 FY2014 should use that growth level as their minimum target for the year.

2.4 Human Resources for Health

A critical barrier to the expansion and scale-up of pediatric HIV programs is the lack of sufficient numbers of health care providers with both competence and confidence in the provision of HIV services for infants, children, and adolescents. Task sharing allows nurses and cadres of health providers other than medical doctors to provide pediatric HIV services. These services include counseling and testing as well as ART initiation and management, all of which are essential to ensure adequate access to care. Continued mentoring and supervision of these
providers, coupled with access to higher level technical assistance when needed, increases confidence in providing pediatric services.

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 and should include training, provision of needed resource materials, ongoing mentoring, and supportive supervision. At the country level, programs will therefore need to:

- Ensure all health care workers caring for children or mentoring them are up to date on the latest national guidelines for pediatric treatment. This is particularly important given the new WHO guidelines recommending treatment for all children less than five years of age, regardless of WHO clinical stage or CD4 cell count;
- Adopt task-sharing to providers other than medical doctors. The task-shifting process should include the revision of national guidelines and regulations to legally expand the scope of practice for these cadres; training health care providers on the initiation and management of ART and needed care interventions for pediatric clients such as cotrimoxazole prophylaxis; and the implementation of an effective supervision and mentoring plan for these cadres;
- Work with national stakeholders (Nursing Councils, ARC) to ensure data-driven workforce planning that provides for adequate staffing at clinical sites to support the expansion of pediatric services;
- Improve the capacity of existing and new health care providers to deliver comprehensive health care services to infants, children, and adolescents. This should include 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. This includes not only exposed infants identified through PMTCT programs, but also children identified 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 infants, children, and adolescents;
o Increase availability and capacity to provide care and treatment services for adolescents;
  o Plan for psychosocial and mental health support services that bridge facility-, school-, and community-based programs; and
  o 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.

3 Strategic Information, Evaluation and Monitoring Technical Considerations

PEPFAR Pediatric Care and Treatment (Peds) and SI programs should work together to ensure that key pediatric SI needs are addressed and integrated within the larger SI framework are in accordance with PEPFAR’s new Monitoring, Evaluation and Reporting (MER) Guidance.

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.
5. Building M&E capacity.

There are many opportunities for pediatrics and M&E priorities to support each other in COP 2014. The priority activities for Pediatric Care, Support and Treatment M&E in COP 2014 are as follows below:

3.1 Routine program monitoring

Sub-section 2.3.6 (Pediatric care and support targets) of this Section includes an overview of routine program monitoring. To be consistent with UN conventions (http://www.unaids.org/en/media/unaids/contentassets/documents/document/2013/GARPR_2013_guidelines_en.pdf), countries are required by the new MER guidance to capture data on service provision to children and young adults in the age disaggregations mentioned below. These are critical for tracking and improving the uptake, retention, and adherence of young people within the continuum of care. This change will require significant advocacy and technical assistance in
most PEPFAR countries. SI advisors will work with each operating unit to develop an appropriate, phased approach to collecting and reporting on these data.

The Pediatric Care and Treatment program should use PEPFAR indicators to describe program performance and identify gaps in services. At a minimum, countries should be collecting and reporting on the indicators listed in PEPFAR’s forthcoming Monitoring, Evaluation and Reporting Strategy.

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 children newly initiated on ART, the Pediatric, SI, and 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 the clinical care indicator so that it reflects the cascade of care and treatment. See also sub-section 2.3.6 (Pediatric care and support targets) of this Section.

3.2 Data Quality and Use

High-quality data are crucial for monitoring the ability to meet program goals in realizing an AIDS-Free Generation. High-quality data mean that the data are accurate, reliable, complete, sufficiently precise, and collected/reported in a timely fashion with integrity. PEPFAR Pediatric and SI teams should develop a data quality management plan that describes how the team will systematically assess and improve program data in harmony with national protocols. At a minimum, a data quality management plan should include:

- Steps for validating or verifying indicators;
- A process for de-duplication; and
- A strategy for ongoing data quality improvement that is supportive of program goals.

USG teams should support systems for the use of routinely-collected data for evidence-based program planning and to guide implementation.

Additional details can be found in PEPFAR’s forthcoming Monitoring, Evaluation and Reporting Strategy.

3.3 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.*

Understanding the ability of systems to link HIV-infected children from testing to care and treatment is increasingly important, particularly with the goal of achieving an AIDS-Free Generation. Conducting an evaluation of patient monitoring systems, tools, and the ways in
which they support linkages of newly identified HIV-infected children from testing to treatment is a priority. The SI and PMTCT/Peds TWG have resources available to support this effort.

3.4 Assessing M&E tools and systems to support linkage and retention

The pediatric care and treatment cascade consists of multiple care services that can be delivered in facilities and communities, and that are reflected in registers or other data collection tools. Ensuring that HIV-exposed infants and HIV-infected infants, children, and adolescents are successfully linked to services is critical to the success of all programs that serve pediatric populations. As many pediatric programs are currently reviewing and revising their national guidelines, the Pediatric Care and Treatment TWG recommends that programs review their data collection tools and systems to assess whether or not the structures and capacity exist to link individuals among available services. Examples of these structures include defaulter tracking, village health workers, peer mothers, and teen clubs.

Where possible, adolescents should be involved in program design, management, and evaluation. Their client perspective will help ensure adolescent-friendly services that meet the WHO criteria are designed.

3.5 Quality Management and Quality Improvement

PEPFAR has prioritized quality management and quality improvement in all clinical programs we support. For pediatric care and treatment programs, the same broad concepts apply and certain specific factors should be additionally addressed. Most quality measures, including ART coverage for eligible patients, show much lower rates of service delivery for children than adults across the majority of PEPFAR-supported countries, and interventions specific to children’s services are needed in order to address this gap in services.

3.6 Monitoring and Improving HIV Clinical Programs

PEPFAR offices should continue to support harmonized quality management (QM) and quality improvement (QI) plans and activities for all HIV clinical services provided by PEPFAR implementing partners, which are in alignment with national (Ministry-led) quality plans and initiatives.

- Quality Assurance:
  - Standardized, periodic supportive site supervision and regular program reviews are an integral part of USG-supported ART programs, with regular review of performance data; and
  - For pediatric patients, this requires addressing of basic competency in pediatric HIV services, which can be a concern at sites with low-volume pediatric populations. Areas of focus are delineated throughout the pediatric section of these technical considerations. The entire spectrum of care and treatment (e.g., case identification,
testing protocols, care services, ART initiation, monitoring, adherence, retention) should be evaluated for quality of pediatric services.

- Quality Improvement:
  - Performance measurement data are used for improvement at the system and site levels, with monitoring and reporting of results;
  - Support for a learning agenda, such as breakthrough series collaboratives, can be used to share and spread successful improvements; and
  - Benchmarks for concern of poor performance can be used to direct these activities where most needed. For instance, loss to follow-up is reported to be highest prior to ART initiation, and if >20% of patients in these registers are not retained in services then specific programs can be established.

3.7 Pediatric ART Program-Specific Quality and Oversight

- Support aggressive approaches at the system, site, and patient level to improve both adherence and retention of patients on ART;
- Support for reliable supply of commodities to prevent treatment interruption;
- Support for efficient and effective algorithms for treatment failure monitoring;
- Distinguish adult and pediatric populations to determine areas where pediatric quality may be categorically lower (e.g., TB screening, growth monitoring, laboratory monitoring); and
- Surveys for HIV drug resistance.
3.8 Select Scientific Abstracts on Quality & Pediatric Programming

- Youngleson, Nkurunziza, Jennings, Arendse, & Mate, 2010(334):
  - BACKGROUND: Health systems that deliver prevention of mother to child transmission (PMTCT) services in low and middle income countries continue to underperform, resulting in thousands of unnecessary HIV infections of newborns each year. We used a combination of approaches to health systems strengthening to reduce transmission of HIV from mother to infant in a multi-facility public health system in South Africa.
  - METHODOLOGY/PRINCIPAL FINDINGS: All primary care sites and specialized birthing centers in a resource constrained sub-district of Cape Metro District, South Africa, were enrolled in a quality improvement (QI) programme. All pregnant women receiving antenatal, intrapartum and postnatal infant care in the sub-district between January 2006 and March 2009 were included in the intervention that had a prototype-innovation phase and a rapid spread phase. System changes were introduced to help frontline healthcare workers to identify and improve performance gaps at each step of the PMTCT pathway. Improvement was facilitated and spread through the use of a Breakthrough Series Collaborative that accelerated learning and the spread of successful changes. Protocol changes and additional resources were introduced by provincial and municipal government. The proportion of HIV-exposed infants testing positive declined from 7.6% to 5%. Key intermediate PMTCT processes improved
(antenatal AZT increased from 74% to 86%, PMTCT clients on HAART at the time of labour increased from 10% to 25%, intrapartum AZT increased from 43% to 84%, and postnatal HIV testing from 79% to 95%) compared to baseline.

CONCLUSIONS/SIGNIFICANCE: System improvement methods, protocol changes and addition/reallocation of resources contributed to improved PMTCT processes and outcomes in a resource constrained setting. The intervention requires a clear design, leadership buy-in, building local capacity to use systems improvement methods, and a reliable data system. A systems improvement approach offers a much needed approach to rapidly improve under-performing PMTCT implementation programmes at scale in sub-Saharan Africa.

- Webster, Sibanyoni, Malekutu, Mate, & Venter, 2012(335):
  - INTRODUCTION: The authors report on a health systems strengthening intervention using quality improvement (QI) methods at the subdistrict level to accelerate highly active antiretroviral treatment (HAART) initiation in South Africa.
  - METHODS: Using a phased scale-up design between August 2006 and November 2009, 14 primary healthcare clinics, one community health centre, one district hospital and one tertiary hospital in a subdistrict were recruited into a 'learning network' using QI methods to facilitate cross-facility learning/mentorship/support. Clinic teams consisting of nurses, counsellors, clerks and/or doctors set collective and individual performance targets, analysed their care systems using 'real-time' data feedback, and designed/implemented a set of simple changes to improve HIV testing and HAART initiation rates across the region.
  - DATA ANALYSIS: Primary clinic data were used to measure HAART initiation rates (primary outcome) and HIV testing (secondary outcome). We analysed data variation/trends using an interrupted time series design. Logistic regression analysis was applied to examine trends in HAART initiation during the intervention phases.
  - RESULTS: Clinics in the learning network increased HIV testing by 301.8% from 891/month (SD=94.2) to 3580/month (SD=327.7) (p<0.0001). Monthly HAART initiations increased by 185.5% from 179/month (SD=17.22) to 511/month (SD=44.93) (p<0.0001). During the pilot (phase I), the monthly rate of HAART initiations increased by 3.6 patients. In the prototype collaborative (phase II), there was no acceleration in the rate of increase (3.3/month, p=0.92). Significant acceleration was observed in the rate of increase during the QI scale up (phase III) (10.1/month, p<0.001). The proportion of estimated need for HAART met in the region increased from 35.8% to 72.4% at a time of rapid population growth.
  - CONCLUSION: A QI approach, using learning networks to teach simple data-driven methods for addressing system failures, with increased training and resource inputs, can assist districts to quickly reach universal coverage targets.
5. **Additional Resources**

- WHO 2013 Consolidated Guidelines
- WHO Policy Brief on commodity issues
- PEPFAR Quality Strategy
- PEPFAR Linkage, Engagement and Retention Strategy (PLERS)
- Adolescent Technical Brief
2.4 TB/HIV

1 Introduction

1.1 What’s new in 2014

1.1.1 Support integration of TB/HIV care and treatment to ensure linkage and retention

In FY2014, PEPFAR will also launch a Linkage, Engagement and Retention Strategy (PLERS), complementing the model and the principles outlined in the PEPFAR Quality Strategy. The strategy sets expectations for retention outcomes in PEPFAR supported programs and provides guidance, best practices, and specific tools for implementation.

The PLERS will define PEPFAR’s programmatic approach to addressing the gaps and challenges within linkage and retention. Further, PEPFAR will propose expected outcomes on key metrics, provide clearer guidance on linkage and retention approaches to measurement, identify existing tools to increase linkage and retention, and enable countries to identify barriers and plans for improvement based on country specific contexts. Additionally, it will address special considerations, challenges and approaches for specific populations, such as pregnant and breastfeeding women, infants and children, key populations, and persons co-infected with TB, who often have lower rates of retention in treatment and across the continuum of care.

Integration of TB and HIV services is often sub-optimal. Programs should support expansion of TB screening and case finding in settings where co-infected individuals are likely to seek services such as PMTCT, antenatal clinics, HTC settings, and ART sites. There are many challenges to retaining clients across the TB/HIV cascade. Many of these are similar to challenges across the platform of clinical services while others are exacerbated given the inherent complexities of transition and establishing effective linkages between services (i.e., HIV testing and counseling to enrollment in care) and across programs (i.e., TB and HIV as well as PMTCT and ANC services).

1.1.2 TB/HIV activities highlighted as a smart investment in the Blueprint

Tuberculosis (TB)/HIV activities contribute to an AIDS-free generation and are featured in the PEPFAR Blueprint: Creating an AIDS Free Generation. PEPFAR support has been instrumental in expanding HIV testing for persons diagnosed with TB. This effort has revealed that in many PEPFAR supported countries, especially in Sub-Saharan Africa, HIV prevalence among people with TB is alarmingly high, ranging from 40% to 80% (336). In 2009 WHO revised its antiretroviral therapy (ART) guidelines to recommend that all persons co-infected with TB and HIV, regardless of CD4 count, be initiated on ART, which is further supported in the WHO 2013 Consolidated ARV guidelines (http://apps.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf).
As a package of activities with a strong evidence-base for population-level impact, TB/HIV interventions should be scaled up. Ending HIV-associated TB among People Living with HIV (PLHIV) is possible through a combination of widespread ART coverage, early identification and treatment of TB, isoniazid preventive therapy (IPT), and infection control activities. These high-impact interventions will be critical to achieving an AIDS-free generation and are integral to PEPFAR planning and program implementation.

1.1.3 Scale-up rapid initiation of ART for HIV-positive TB patients

All PLHIV diagnosed with TB need to start ART as early as possible to reduce mortality; however, many programs are falling short (190)(301) (302)(303). Current WHO ARV guidelines recommend starting ART in all HIV-positive patients with active TB, regardless of CD4 count. TB treatment should be started first, followed by ART as soon possible within the first eight weeks of treatment. Among patients with severe immunodeficiency (CD4 <50 cells/mm³), ART should be started immediately within the first two weeks of initiating TB treatment. Figure 6, below, demonstrates the proportion of HIV-positive TB patients receiving ART in 17 PEPFAR-supported countries. PEPFAR treatment programs should intensify efforts to identify HIV-positive patients with TB who are not yet receiving ART and link them to care and treatment services, with the goal of 100% coverage.

Figure 6. Attention needed to close gaps in ART coverage for TB/HIV patients

Source: (336)

1.1.4 Renewed focus on children and maternal child health settings

Despite international guidelines, TB/HIV activities have not been integrated into most PMTCT settings. The PMTCT/Pediatric HIV Technical Working Group recommends that TB/HIV activities, especially intensified TB case finding, be implemented in all PMTCT programs.
Screening for TB among pregnant women and children living with HIV, using an evidence-based clinical algorithm, is the first step in the prevention, diagnosis, and treatment of TB. This approach is well described in the 2011 World Health Organization (WHO) guidelines on intensified TB case finding and isoniazid preventive therapy (IPT) for people living with HIV (337) and the 2011 PEPFAR PMTCT/Maternal-Child Health/Pediatric HIV Integration Guidance. Implementation of TB intensified case finding (ICF) and appropriate TB treatment, coupled with early initiation of antiretroviral therapy (ART), appropriate use of IPT, and TB infection control in PMTCT and MNCH settings, has been shown to be the most effective strategy for reducing TB/HIV-related morbidity and mortality among HIV-infected pregnant women and their infants and children. This is especially relevant as countries adopt and implement option B+ for pregnant women.

1.1.5 PEPFAR Quality Strategy

In 2013, PEPFAR is launching a PEPFAR Quality Strategy (PQS), focusing on HIV Clinical Services. The PQS provides country teams with guidance and tools to develop implement and/or strengthen quality in HIV clinical services with partner governments through a Quality Management, Quality Assurance, and Quality Improvement approach. This is an important focus as PEPFAR continues to shift from an emergency response to a sustainable one.

Specific programs related to quality assurance that should be strongly considered include:

- National plans to ensure and measure quality for clinical services as governments and local partners take on increasing financial and clinical management of the HIV response. Harmonized quality management (QM) and quality improvement (QI) activities among country teams and implementing partners, which are in alignment with national, Ministry-led, quality plans and initiatives; and
- Performance measurement data used for quality improvement at the site level such as screening for TB and successful referral/counter-referral across programs, timely initiation of ART among persons with TB and HIV and retention of these patients on treatment, and implementation of TB infection control. Standardized, periodic supportive site supervision and regular program reviews as an integral part of USG-supported ART programs.

Additional information can be found in PEPFAR’s Country Operational Plan (COP) FY2014 Guidance.

1.1.6 Scale-up of Xpert MTB/RIF

PEPFAR support for the introduction of Xpert MTB/RIF has significantly increased since the WHO recommended this new diagnostic test. Efforts to scale-up Xpert MTB/RIF should accelerate according to 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

1.2 PEPFAR Blueprint

A growing body of evidence clearly indicates that initiating ART soon after starting TB treatment significantly increases survival among co-infected persons. TB clinics are therefore high yield sites for identifying PLHIV eligible for ART. However, in 2011, despite WHO recommendations, only 46% of HIV-positive TB patients were initiated on ART (336). This translates into a missed opportunity to avert preventable deaths and improve quality of life.

Improving early uptake of ART among co-infected PLHIV will substantially contribute to PEPFAR’s goals of ensuring an AIDS-free generation and initiating ART for six million PLHIV by end of FY 2013.

Countries should assess the current level of ART coverage among HIV-positive TB patients and set country specific targets for ART initiation among HIV-positive TB patients to improve patient outcomes and help meet PEPFAR goals. Country programs should identify barriers to initiating ART for HIV-positive TB patients and develop and scale-up successful models of service delivery to achieve these targets. Approaches might include integrating the provision of ART in TB clinics or primary health care settings or establishing strong referral systems between TB and HIV programs, along with strengthened M & E systems to ensure follow-up of persons referred for and receiving TB diagnostic and treatment services.

Achieving PEPFAR’s new goals also calls for improving survival of PLHIV in care and treatment by reducing HIV-associated morbidity and mortality. 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 PEPFAR has made in rapidly 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.

1.3 Technical Background

Tuberculosis remains the most common infectious cause of death among PLHIV in sub-Saharan Africa. The PEPFAR Five Year Strategy and the Blueprint recognize 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.

In our current resource-constrained environment, 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 initiation of 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 already on ART, particularly in the first six months of therapy. Thus screening and treatment for TB is important throughout the continuum of care, and is particularly critical for PLHIV 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 2011, 1.1 million (13%) of the 8.7 million people who developed TB worldwide were HIV-positive; 79% of these HIV-positive TB cases were in the African Region. There were 400,000 estimated deaths from TB among PLHIV. These estimates are thought to be a more accurate reflection of TB/HIV associated morbidity and mortality than previous estimates, as they are derived from direct measurements of TB/HIV co-infection in a much larger patient population due, in large part, to rapid expansion of provider-initiated testing and counseling (PITC) in TB settings.

According to the 2012 WHO Global TB Report, the percentage of persons diagnosed with TB with a documented HIV test result in the African Region increased from 59% in 2010 to 69% in 2011 (336). Among persons diagnosed with TB, 46% of those tested were HIV-positive, ranging from 8% in Ethiopia to 77% in Swaziland. Worldwide, 40% of persons diagnosed with TB notified in 2011 had a documented HIV test result, up from 34% in 2010 and more than ten times the level of 2004. Among persons with TB known to be HIV-positive worldwide, 79% were provided with cotrimoxazole prevention therapy (CPT) and 48% were started on ART, similar to levels achieved in 2010. The coverage of ART for HIV-positive TB patients needs to be substantially improved, which is further emphasized in WHO’s recommendations (http://apps.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf). In 2011, 3.2 million people enrolled in HIV care were screened for TB, increased from 2.3 million in 2010. Of those without active TB disease, 0.45 million were provided with IPT, which is more than double the
level achieved in 2010, mostly due to progress in South Africa. The scale-up of collaborative TB/HIV activities saved a cumulative total of 1.3 million lives between 2005 and the end of 2011 (336).

2 Technical Considerations

2.1 Early initiation of ART among HIV-positive TB patients 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 among HIV-positive TB patients reduced mortality by 56% (301). In 2009, WHO revised its ARV 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-positive 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.

2.2 ART reduces TB incidence among PLHIV

ART dramatically reduces TB incidence, as demonstrated by a 67% reduction in TB incidence rates in nine observational cohort studies in which 37,879 persons were enrolled (338). However, TB rates still remain high among PLHIV established on long term ART, further emphasizing the importance of early ART initiation combined with a 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.

2.3 Screening for TB and case detection among PLHIV 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 four symptom screening tool (337)) and act rapidly to diagnose and treat the disease in those with both classic and non-specific symptoms, and provide IPT to those who screen negative for these symptoms (337). 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, HIV testing and counseling (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 (339). 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:

### 2.3.1 Ensure HIV testing for TB patients and immediate access to ART for HIV-positive TB patients

Support the development of national policies, training, infrastructure, procurement of HIV rapid test kits, development of referral/tracking systems for PLHIV diagnosed with TB, and provision of HIV treatment in TB clinics. Specifically, support the adoption of the revised WHO 2013 ARV Consolidated 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 persons with TB. Programs should assess the current level of ART uptake among PLHIV with TB and set achievable targets for percentage of HIV-infected persons with TB initiating ART (this should be 100% according to WHO ART guidelines), Country programs should assess the barriers to initiation of ART among HIV-infected persons with TB and develop models or scale-up existing models of service delivery to achieve these targets. 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 HTC as outlined in the 2007 WHO PITC Guidance including External Quality Assurance (EQA) for both counseling and testing processes (189) (For more information HTC, see Section 1.4 of the Technical Considerations (HIV Testing and Counseling));
- Consider supporting “one-stop” models that provide integrated TB and HIV services (e.g., CPT and ART in TB clinics); and
• Develop and pilot Positive Health, Dignity and Prevention (PHDP) prevention interventions for PLHIV in TB clinical settings with a special emphasis on HIV testing for partners and family members of persons with TB. Generic 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.

2.3.2 Implement, track and report TB screening of PLHIV and provide isoniazid preventive therapy (IPT) for PLHIV who do not have active TB disease

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, and/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 and breastfeeding women and their 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) (340);
• 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 clients 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 to improve identification of TB and MDR TB disease, including point of care placement where appropriate and integration of Xpert® MTB/RIF into existing reporting systems and algorithms. Refer to implementation and technical approach guidance documents for USG-funded Xpert® MTB/RIF activities here:
• Consider diagnostic “fast tracking” of PLHIV with TB symptoms to promote timely treatment initiation and reduce the risk of nosocomial transmission to susceptible individuals (both those receiving care and their providers). This should also include a “retrieval” or back-referral system to help ensure that individuals with TB continue to access HIV care;

• Strengthen the HIV patient monitoring system (suggest adaptation and use of the WHO IMAI HIV care/ART patient monitoring system) to monitor and document TB screening, TB status, and TB treatment of PLHIV. Expand ICF activities to include high-risk contacts of PLHIV with TB, including children and mothers in high TB prevalence areas; and

• Support expansion of TB screening and case finding while addressing prevention of mother-to-child HIV transmission (PMTCT) in antenatal clinics, HTC, and ART clinical settings.

IPT for TB can safely be given to PLHIV without active 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 six months of IPT for children and adults, including pregnant women, PLHIV not yet on ART, PLHIV 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 HIV/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; and

• Components of the roll-out should include development of policies and operational guidance for IPT that address issues such as supply chain management, training and supervision, patient monitoring and follow-up, and monitoring and evaluation.
2.3.3 Support TB infection control measures to prevent transmission of TB in healthcare and community settings

Nosocomial (hospital) transmission of multi-drug resistant (MDR) and extensively drug resistant (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. Despite existing policies and activities listed to implement TBIC in the past COPs, progress is very limited in actual implementation. Countries need to focus on specific activities for scale-up of TBIC including specific budget allocation for TB IC. 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 (341). 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, which should 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 at the national level and down to the facility level to minimize the risk of infection with TB to both patients and health care workers;
- Support the development of policies and plans (including training tools for health care workers) to implement and monitor IC measures in adult and maternal and child health facilities. USG should consider funding a TB IC coordinator (s) at the national and/or lower levels to assist countries with implementing and monitoring TB IC activities and identifying areas that need more support; and
- Include TB IC in plans to renovate health facilities to maximize TB IC (refer to the WHO Policy on TB Infection Control in Health Care Settings, Congregate Setting, and Households) and document specifics of renovations. 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. Documentation of trainings and follow-up evaluations should be done to ensure adoption of best practices.
2.3.4 Expand interventions to improve early diagnosis and treatment of TB among PLHIV

Efforts to improve early diagnosis and treatment of TB among PLHIV include supporting TB diagnostic capacity as part of overall lab strengthening, as well as scale-up of Xpert® MTB/RIF assay.

- 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 to 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 (regional) laboratories to provide quality assured mycobacterial culture, and TB drug susceptibility testing (DST), as appropriate;
- Support development, implementation, and strengthening of external quality assessment (EQA) for smear microscopy, Xpert® MTB/RIF, culture, DST, and other rapid diagnostic methods throughout the laboratory network;
- 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 (including TB/HIV co-infection, extrapulmonary, and pediatric TB);
- Focus on improving quality as well as access to TB laboratory services for PLHIV through a spectrum of activities including integrating rapid TB diagnostic testing into laboratories co-located with ART clinics; and supporting national integrated specimen transport, result reporting, and laboratory information management systems;
- Surveillance and management of multi-drug resistant TB (MDR TB); and
- Strengthening general TB control (DOTS).

2.3.5 Strengthen TB/HIV program monitoring and evaluation (M&E)

Collecting accurate and complete information to monitor PEPFAR-supported TB/HIV interventions is critical to meeting the priorities outlined in the PEPFAR Blueprint. PEPFAR TB/HIV and Strategic Information (SI) staff should continue to collaborate to ensure that key TB/HIV SI needs are addressed and integrated within the larger SI framework and reflect updated PEPFAR Monitoring, Evaluation and Reporting (MER) operational guidance.
The following are priority activities for TB/HIV M&E:

1. M&E tools and systems’ capacity to monitor programs, linkage and retention.
   - 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 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 implementation of the revised TB/HIV indicators and reporting formats defined in the recent MER process both across the cascade among registered TB cases (typically originating in TB services) and the cascade among PLHIV making an HIV clinical visit (typically originating in an HIV care or treatment facility); and
   - Support capacity to monitor the implementation and performance of near point of care TB diagnostics (such as Xpert® MTB/RIF).

2. Support planning and data use.
   - 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; and
   - Ensure that every partner planning to implement a TB/HIV related activity has a plan for monitoring and evaluating that activity.

3. Routine monitoring of program outputs, linkage and quality: PEPFAR-funded programs should continue to use indicators to describe program performance and identify gaps in services. In addition, the delivery of TB/HIV clinical services is frequently inseparable from successful program linkages, and the monitoring of TB/HIV service outputs is substantially the monitoring of program linkages. The monitoring of these linkages is therefore crucial for tracking progress toward the TB/HIV objectives described in the PEPFAR Blueprint. See the MER Operational Guidance for a listing of TB indicators.

4. Target setting: Work with partners to ensure rationalized target setting processes for TB/HIV indicators, taking into account: international guidance, local capacity, history of program performance, evolving programs, and national norms of care.
5. Data Quality: To ensure that the routine monitoring data collected and reported are accurate, data quality assurance systems should be in place and data quality assessments should be conducted on a routine basis.

6. Evaluation: Evaluations that measure effectiveness of TB/HIV interventions and outcomes are crucial in describing program goals and performance. Further, many key quality and outcome measures are difficult to capture through routine monitoring of national indicators. For this reason, the following periodic special studies or evaluations are recommended:

- 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 persons with TB who are diagnosed with HIV in TB clinics;
- Evaluation of TB/HIV service cascade among registered TB cases, including what services are delivered, the quality and timeliness of services and linkages, and patient outcomes;
- Evaluation of TB/HIV service cascade among PLHIV making an HIV clinical visit, including what services are delivered, the quality and timeliness of services and linkages, and patient outcomes; and
- Evaluation of TB infection control measures in HIV service facilities. Key quality TB infection control elements to be monitored include the implementation of administrative, environmental, and personal-protection infection control activities in accordance with international standards.

2.3.6 Ensure that children and other vulnerable populations (e.g., people in prisons, miners, people who abuse alcohol) are included in all TB/HIV program components

- 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; and
- Within the context of prevention for PLHIV in TB clinical settings- 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).
2.3.7 Stepwise approach to scale-up of TB/HIV collaborative activities

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 one to five as they relate to PITC among persons diagnosed with TB, and therefore, for COP FY 2014, 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 2014. 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 are generally useful for planning TB/HIV activities include:

- HIV prevalence in the general population (stratified by geographic area);
- HIV prevalence among persons diagnosed with TB (stratified by geographic area), age (two 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 (two age groups for children: 0-4 years old and 5-14 years old), and gender;
- Estimated MDR-TB prevalence;
- Geographic mapping of partner coverage of TB/HIV activities; and
• Data on the current level of scale-up of key activities by geographic area/site.

3 Linkages and Wraparounds

PEPFAR teams should ensure that USG and other donor TB resources (e.g., Global Fund, Bill & Melinda Gates Foundation) 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). TA is available to facilitate this strategic process.

TB/HIV activities should be closely linked to other relevant technical areas including laboratory strengthening, HIV testing and counseling, sexual prevention (including PWID), adult/pediatric care and treatment, health systems strengthening, and strategic information. Additional information on specific opportunities for effective linkages across HIV and TB services are described in previous sections. 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).
2.5 ORPHANS AND VULNERABLE CHILDREN

1 Introduction

1.1 PEPFAR Blueprint

The PEPFAR Blueprint highlights the importance of reaching orphans and vulnerable children (OVC) affected by AIDS, and supporting programs that help them develop to their full potential. To achieve this goal, the Blueprint outlines key strategies to strengthen family, community and governmental capacity to attend to children’s socio-economic needs. OVC commits to continuing to take a leadership role in strengthening community responses for children and families. Strategic interventions include household economic strengthening and social protection programs that promote family stability and help facilitate children's access to education, health and nutrition services. The Blueprint also stresses interventions that strengthen child welfare systems responsible for preventing and responding to child maltreatment, and importantly for ensuring children grow up in safe, nurturing families.

2 Technical Considerations

The new PEPFAR 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). The purpose of this guidance is to help PEPFAR country teams and implementing partners develop country operational plans (COPs) and design programs that support vulnerable children in their contexts, align with known best practice, and incorporate potential innovation. It seeks to aid teams in identifying and implementing appropriate, evidence-based, and cost-effective activities that will maximize improvement in the well-being of vulnerable children in the epidemic and close gaps in past programming efforts. Importantly, the guidance clearly places the OVC programming within the HIV/AIDS continuum of response at the country level.

2.1 Guidance Programming Principles

The PEPFAR Guidance for Orphans and Vulnerable Children mirrors principles found in the Framework for the Protection, Care and Support of Orphans and Vulnerable Children Living in a World with HIV/AIDS (The Global Framework) as well as those found in the UNAIDS Investment Framework for HIV/AIDS. The principles are also aligned with the objectives included in the U.S. Government (USG) Action Plan for Children in Adversity: A Framework for U.S. Government Foreign Assistance, which was developed under the auspices of the USG Secretariat for Children in Adversity (PL 109-95).

The following principles included in the new Guidance undergird all PEPFAR OVC programming:

- Strengthening families as primary caregivers of children;
• Strengthening systems to support country ownership, including community ownership;
• Ensuring prioritized and focused interventions that address children’s most critical care needs; and
• Working within the continuum of response to achieve an AIDS-free generation.

Stable, caring families and communities and strong child welfare systems are the best defenses against the effects of HIV AIDS in the lives of children. Nurturing families are critical to children’s lifelong health and well-being, including their prospects for living HIV-free, or positively with HIV. The PEPFAR approach to children in the epidemic is based on a social-ecological model that considers the child, family, community, and country contexts and recognizes the unique yet interdependent contributions of actors at all levels of society to the well-being of children affected by HIV/AIDS.

Families, communities, and governments share responsibility to protect children from HIV infection and to ensure children thrive despite the impacts of HIV/AIDS. Meeting the needs of children made vulnerable by HIV/AIDS provides a unique opportunity for collective action on individual, local, and national levels. No single government, civil society organization, or community can do it alone, and each of these has an important role to play in improving the lives and futures of all children affected by HIV/AIDS.

As shown in Figure 7, children and families and the communities that surround them are at the center of PEPFAR efforts. Governments and nongovernmental organizations (NGOs) working from national to local levels also play a critical role in the response to children. The following sections discuss each of these actors in terms of their role and contribution as partners in PEPFAR’s response to children in the epidemic.
2.2 Important Key Themes in this OVC Programming Guidance

The PEPFAR Guidance for Orphans and Vulnerable Children builds on past programming and guidance, with new emphasis on key points such as:

- While programs must continue to improve child outcomes, the primary strategy for achieving this is strengthening parents and caregivers so they can provide for their children’s basic needs;
- Sustainability through capacity building and transfer of program responsibility to promote country ownership are imperative and must be balanced with careful monitoring to ensure children’s immediate needs are also met;
- There is a growing evidence base for OVC programming reflected in the document. Programs should build interventions on evidence-based practice; and
- Programs should allocate at least 10 percent of project funding to monitoring and evaluation (M&E) to ensure that the evidence base continues to grow and to inform better practice.
2.3 Technical Sectors included in the OVC Programming Guidance

Addressing OVC issues entails a multi-sectoral approach that assesses the complexities of vulnerability at the individual level while understanding contextual and collective effects. Detailed descriptions of the evidence-base of each of the sectors reflected below as well as outlined priority interventions are included in the Guidance for OVC Programming.

2.3.1 Education

PEPFAR OVC programs should support efforts to reduce educational disparities and barriers to access among school-age children through sustainable “systemic” interventions (for example, school block grants) and by:

- Ensuring children have a safe school environment and complete their primary education
- Promoting access to early childhood development (ECD) programs;
- Ensuring personnel create child-friendly and HIV/AIDS- and gender-sensitive classrooms;
- Strengthening community-school relationships, including partnering with out-of-school programming;
- Consider supporting post-primary school programming and especially the transition for girls from primary to secondary school; and
- Implementing market-driven vocational training only when previous lessons learned are integrated into intervention designs.

2.3.2 Psychosocial Care and Support

PEPFAR OVC programs should prioritize psychosocial interventions that build on existing resources and place and maintain children in stable and affectionate environments through:

- Parents and family support programs;
- Peer and social group interventions;
- Mentorship programs; and
- Community caregiver support.

2.3.3 Household Economic Strengthening (HES)

HES aims to reduce the economic vulnerability of families and empower them to provide for the essential needs of the children in their care through:

- Money management interventions for savings, access to consumer credit, and fostering knowledge and behaviors for better family financial management;
- Integration of HES activities with complementary interventions, such as parenting skills; and
• Income promotion using low-risk activities to diversify and stimulate growth in household income.

2.3.4 Social Protection
PEPFAR support for social protection aims to reduce vulnerability and risks, foster human capital development, and interrupt the transmission of poverty from one generation to the next through supporting host-country governments to initiate, expand, or be innovative in their social protection initiatives at both the policy and operational levels.

2.3.5 Health and Nutrition
PEPFAR OVC programs aim to improve children’s and families’ access to health and nutritional services through:

• A child-focused, family-centered approach to health and nutrition through ECD and school-based programs;
• Effective integration with existing or planned child-focused community- and home-based activities, including PMTCT, treatment, the President’s Malaria Initiative (PMI), and child survival;
• Reducing access barriers to health services through HES and social protection schemes, such as health insurance opportunities; and
• Establishing linkages and referral systems between community- and clinic-based programs.

2.3.6 Child Protection
PEPFAR OVC programs aim to develop appropriate strategies for preventing and responding to child abuse, exploitation, violence, and family separation through:

• Implementing child safeguarding policies;
• Integrating child protection activities;
• Supporting communities to prevent and respond to child protection issues;
• Strengthening linkages between the formal and informal child protection systems; and
• Building government capacity to carry out and improve child protection responses.

2.3.7 Legal Protection
PEPFAR OVC programs aim to develop strategies to ensure basic legal rights, birth registration, and inheritance rights to improve access to essential services and opportunities through:

• Raising awareness about birth registration and succession planning;
• Linking birth registration and succession planning to other essential services; and
• Improving government birth registration systems and legal mechanisms for enforcing fair and equitable inheritance laws and guardianship.

2.3.8 Capacity Building

PEPFAR programs should prioritize within their country context the following capacity-building and systems-strengthening interventions:

• Investing in efforts to build strong leadership and governance;
• Pursuing strategies to strengthen the social service workforce;
• Supporting strategies to improve financing for social service systems;
• Strengthening information management and accountability mechanisms of the social service system; and
• Supporting coordination and networking within the social service system.

2.4 Strategic Portfolio Development Guidance

The PEPFAR Guidance for Orphans and Vulnerable Children also includes guidance for country teams and partners on developing a strategic portfolio that includes prioritized and focused interventions that address children’s most critical care needs. Strategic portfolio development is predicated on having an evidenced-based understanding of the unique challenges and opportunities faced by children and families within a specific country context as well as an informed perspective of the existing and potential capacity of partners to respond. In a world of limited resources and a multitude of children in need, prioritization and focus are critical. Building on the “four knows” outlined in the PEPFAR sexual prevention guidance, the evidence required by programs to inform an effective plan of support is outlined in detail and includes an additional “fifth know” which speaks to the need for clarity on child risk factors that often underlie and impact HIV specific effects.

2.5 Monitoring and Evaluating OVC Programs

The PEPFAR Guidance for Orphans and Vulnerable Children includes guidance for building strong M&E systems, which are the essential foundation to improving the effectiveness of OVC programs. Quality monitoring (routine tracking of inputs, activities, and outputs) and evaluation (using data to assess effectiveness, relevance, and impact of achieving program goals) provide the evidence and essential information for strategic planning, program improvement, accountability of funds and effort, and advocacy.

Components that are particularly critical to improving the quality of OVC M&E systems:

• Allocate sufficient funds;
• Link with national M&E systems;
• Develop M&E capacity; and
• Promote quality assessment and improvement.
Well-designed program evaluations are needed to confirm that OVC programs are achieving the desired results and that those results can be associated with the interventions. Additional avenues for enhancing program evaluations include:

- Base evaluation design on theory;
- Develop M&E plans in tandem with program plans;
- Qualitative and/or Quantitative;
- Indicator choices;
- Next generation indicators;
- Rigorous design;
- Comparison and controlled groups; and
- Conduct baseline assessment.

In addition, please refer to the OVC Program Evaluation Toolkit (http://www.cpc.unc.edu/measure/our-work/ovc/ovc-program-evaluation-tool-kit ) and the new MER Operational Guidance and indicators when planning for the use of the M&E portion of the funding.
3 Cross-cutting

3.1 LABORATORY INFRASTRUCTURE

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. Strengthening key elements of a country’s health systems, including the workforce and laboratories, is critical to meeting the PEPFAR’s goal of promoting sustainability, efficiency, and effectiveness of PEPFAR programs. United States Government (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 country-owned and -led 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 and improving accessibility to patients. Cumulatively, these local networks provide the support structures for a country’s national network of tiered laboratory services, and an efficient mechanism for referral of complex testing and validation of new technologies and 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.

1.1 What’s New in 2014

1.1.1 Rapid Testing Quality Improvement Initiative
This year, PEPFAR has launched the Rapid Testing Quality Improvement Initiative (RTQII), which aims to ensure the quality of HIV rapid testing and expand upon current in-country HIV rapid testing quality improvement work. The RTQII is comprised of the following five key action areas:

1. Policy engagement
2. Human resource development through training and certification.
3. Proficiency testing.
4. Logbook use for quality assurance (QA) purposes.
5. Rapid test (RT) lot-release testing for RT post-marketing surveillance.
The RTQII will be implemented in a phased approach beginning this year. Additional information is available in sub-section 2.1.1 (Quality Management Systems) of this Section.

1.1.2 Development of National Laboratory Policies

The Laboratory Technical Working Group has been quite successful in helping countries to develop National Laboratory Strategic Plans (NLSP) in all countries where PEPFAR has worked on laboratory strengthening. Given the importance of national laboratory policy for overall laboratory system strengthening, countries will now be requested to integrate their NLSP into national policy and report on this policy development. This will achieve the following goals: (1) improve the quality and consistency of policy and strategic planning data reported to PEPFAR; (2) improve the usefulness of the data reported for PEPFAR and country governments; and (3) facilitate cross-country comparisons of progress on key reforms.

1.2 PEPFAR Blueprint

The *PEPFAR Blueprint: Creating an AIDS-free Generation*, released on World AIDS Day 2012, emphasizes the importance of supporting laboratory system strengthening as part of a comprehensive approach for achieving an AIDS-free generation. The Blueprint’s Roadmap to Saving Lives and Road Map for Driving Results with Science highlight key laboratory strengthening efforts, which are discussed further in this Section:

- Support the deployment of suitable technology for measurement of viral load, both through tiered laboratory networks and point-of-care (POC) tests as they become available;
- Build capacity to ensure HIV diagnostics and ART for children are scaled-up, including Early Infant Diagnostic (EID) and age-appropriate pediatric formulations of ARVs, particularly for infants and young children at highest risk of dying without treatment;
- Support HIV drug resistance (HIVDR) surveillance activities;
- Assist countries in adopting breakthrough new technologies with proven impact, such as new, molecular-based TB tests that have dramatically reduced diagnosis and treatment time for people living with TB and HIV;
- Support quality assurance of laboratory services and laboratory capacity strengthening, including provision of POC diagnostic machines (e.g. CD4 testing) or specimen transport systems, to enhance retention in PMTCT programs and other care and treatment services; and
- Support for the African Society for Laboratory Medicine (ASLM).
2 Technical Considerations

2.1 Framework for Laboratory System Strengthening

It is helpful to visualize laboratory services as being nested in a pyramidal system. At the base of the system are services offered at the community level (e.g. rapid test kits, POC diagnostics), and at the top are complex testing strategies. At each level of the system, PEPFAR programs are working to adopt new technologies and serve patients at all tiers of a laboratory network (community, district, regional, central). In order to accomplish this, essential laboratory strengthening services should include: (1) training and mentorship, (2) quality assurance (QA) and proficiency testing (PT), (3) quality management systems leading to accreditation, (4) development of host-country partnerships, and (5) working with national and international partners and the private sector in the development of public private partnerships (PPPs). This strategy will promote a mature and enduring concept of laboratory systems and network development, one that strengthens laboratories to provide quality services for all diseases of public health importance (see Figure 8). The key components of this framework are:

- Quality Management Systems;
- Laboratory Workforce;
- Equipment Maintenance Systems and Biosafety;
- Supply Chain Management Systems;
- Laboratory Information and Data Management Systems;
- Sample Referral Systems;
- Point-of-care Systems; and
- Institutions and Policies.
2.1.1 Quality Management Systems

To ensure that laboratory systems are strengthened as part of overall health systems, the developmental focus of Quality Management Systems (QMS) should be directed towards achieving international accreditation of testing laboratories. Accreditation is an indicator of the quality of a laboratory. 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 national, regional, or international accreditation bodies, 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

Adapted from Nkengasong (2011)(342)
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 applying for full accreditation based on their audit score.

Each country should have a Quality Assurance (QA) program to promote and support a laboratory’s quality management system (QMS). This is vital to ensure that laboratory testing, including HIV rapid testing, is available, accurate, reliable and timely. The national QA system should encompass 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. Functional QA programs for laboratory testing are critical to ensure access to testing that is accurate and reliable to support quality patient care.

As HIV rapid testing continues to expand, sustainable improvement of the quality of HIV rapid testing will require high-level policy engagement with Ministries of Health (MOH). Currently, most PEPFAR countries lack national quality assurance (QA) policies for HIV rapid testing. In support of efforts to ensure the accuracy of HIV testing, the Laboratory, HIV Testing and Counseling (HTC) and Prevention of Mother to Child Transmission (PMTCT) Technical Working Groups (TWGs) collectively proposed a HIV Rapid Testing Quality Improvement Initiative (RT QII). In order to ensure the quality of HIV rapid testing and expand upon current in-country HIV rapid testing quality improvement work, key quality assurance components will be implemented as a part of the RT QII:

1. Policy engagement to address supply chain, regulatory and national policy issues that will strengthen the quality and monitoring of HIV RTs and testing.

2. Human resource development through training and certification and the creation of a network of HIV rapid testers at various levels.

3. Use of dried tube specimen (DTS) technology for proficiency testing program and quality control (QC) materials.

4. Rollout of the standardized logbook for the purposes of quality assurance of HIV rapid testing.
5. Establishment of new rapid test kit (RTK) lot verification and post-marketing surveillance

2.1.2 Laboratory Workforce: Training and Retention Systems

PEPFAR’s reauthorization legislation mandates the training of 140,000 new health care workers. As it relates to Laboratory Systems, the intent is 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. The top priorities for laboratory workforce development should include: a) short-term training for 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.

Pre-service training should engage local university and other partners (e.g., Ministry of Education, Ministry of Health) to promote sustainability of the pre-service training initiative and to ensure the training adequately meets the needs of the country. Emphasis should be placed on the rollout of comprehensive training tools that have been developed centrally, including the WHO/CDC HIV Rapid Test training and the Laboratory Management training packages. Adequate training for performance and reporting of rapid tests are critically important since these assays are often performed by non-laboratory staff. In addition, management training for laboratory managers and supervisors is essential for effective service provision, given that leadership and an effective laboratory management is often lacking. Ideally, this will incorporate regional training venues and should include information suitable for laboratory managers/directors and senior supervisory technicians in their local setting.

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 have prioritized short-term, hands-on essential courses offered for laboratory staff from PEPFAR and Division of Global HIV/AIDS (DGHA) at the African Centre for Integrated Laboratory Training (ACILT), in Johannesburg, or other local laboratory training institutions. PPPs have also played a role in strengthening laboratory systems and training institutions. Examples include establishment of a training center in South Africa (Roche) to support courses that Stepwise Laboratory Quality Improvement Towards Accreditation (SLIPTA) and development of curriculum and training courses for strengthening of phlebotomy services (BD).

PEPFAR HRH advisors should be engaged when developing pre-service initiatives for Laboratory workers.
2.1.3 Equipment Maintenance Systems and Biosafety

2.1.3.1 Equipment Maintenance Systems

Among the most important factors that influence decision-making about laboratory equipment are those that concern equipment maintenance requirements. In general, two types of maintenance are required: laboratory-initiated and manufacturer or 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 testing venues are often distant from major cities. Obtaining manufacturer or 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. The 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, the purchaser or purchasing organization should consider including extended manufacturer/service provider maintenance clauses in the purchasing contracts, where possible.

Consistent with the guidance recommendations agreed upon at the Maputo Consensus Conference(344), service contracts should be:

1. Negotiated at the time of equipment procurement;
2. Contain reagent rental agreements with bundled service and reagents; and
3. For a minimum of three years and renewable, with no cost increase.

Service contracts (after-sale maintenance contracts) should also include, at a minimum, the following items:

- Response time (ideally within 48 hours);
- Defined number of preventative maintenance visits, as required by the manufacturer;
- Training of local service engineers and users;
- Availability of routine/emergency service; and
- List or identification of costs that may be incurred outside of the contract, such as when additional service requests are made.

Additional service contract recommendations include:

- Penalties in the contracts for failure to meet the conditions of the agreements;
- Periodic contract review process to determine compliance;
- Certification of local service providers by the manufacturer;
- Provision for backup support (loaners) within 72 hour and access to spare parts; and
- Contingency plan for returning equipment for service if repairs cannot be performed in-country; and
- In-country support should be guaranteed.

See the “Consultation on Technical and Operational Recommendations for Clinical Laboratory Testing Harmonization and Standardization” for more detailed information (http://www.who.int/diagnostics_laboratory/3by5/Maputo_Meeting_Report_7_7_08.pdf).

2.1.3.2 Biosafety

Overall laboratory safety programs are necessary to ensure quality in laboratory operations and test results, prevent employee exposure and occupational acquired infections, minimize the release hazardous/infectious agents to the environment, and protect biological agents from loss, theft, or misuse (biosecurity).

Consistent with international guidance(140), laboratory safety programs should include the following: (1) safety regulatory and business programs; (2) annual laboratory review and identifications of hazards; (3) safety equipment, maintenance programs, and personal protective equipment (PPE); (4) facility/building review and maintenance programs; (5) employee occupational health programs; (6) waste management programs; (7) chemical management programs; (8) emergency preparedness and response programs; (9) agent biosecurity program; and (10) safe packaging and transport of biological agents. Items 3-7 are critical to the SLIPTA process and may require additional allocation of resources.

2.1.4 Supply Chain Management Systems

The supply chain management plan for laboratory commodities should be coordinated among the MOH and all partners and should identify responsible persons/contacts that can be reached in event of difficulties or unexpected needs at each level of the procurement and distribution chain. 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, supplies, and reagents based on service needs. Additional information on laboratory-related supply chain management issues can be found in Section 3.11 of the Technical Considerations (Supply Chain Management).

2.1.5 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 a 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.

### 2.1.6 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, a reliable transportation system for samples and result reporting, and to support QA programs 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.

### 2.1.7 Point-of-Care Diagnostics

Worldwide there has been a trend for more POC diagnostics, as they provide an opportunity to increase access to laboratory testing at sites where laboratories do not exist or with poor infrastructure and technical expertise to support traditional laboratory testing. POC diagnostics can also be used when timing for laboratory results are critical for patient retention and care. It has been recognized that in order to ensure quality of these POC diagnostics, proper quality management and laboratory support is essential for accurate and useful results. There must be a continuous evaluation of the quality of these POC assays to provide valuable input for the appropriate use for patient care. Plans must promote standards, guidelines and policy for the quality management and monitoring of POC assays, as well for all other laboratory testing.
High-burden countries funded by PEPFAR have expanded laboratory CD4 testing supported by trainings, mentoring, quality assurance programs, and procurement of instruments, supplies and training provided by international public and private partners. In order to expand access to CD4 testing, the need for new technologies (that would allow point-of-care testing) is driving evaluations of innovative instruments and assays currently ongoing in several countries. These point-of-care CD4 testing needs the same support as laboratory base CD4 testing in order to ensure quality and reliable results.

As countries scale up viral load (VL) testing for monitoring HIV patients, POC testing will play a critical role to expand access to many more patients, particularly those without access to laboratory facilities. Current VL test technologies require costly, sophisticated laboratory infrastructure, including a dust-free, temperature-controlled environment with stable electricity, complex instrumentation and well-trained operators, which are only available at reference laboratories in large urban areas. Technologies that extend the reach of laboratories to decentralized patient populations are needed, such as dried blood spot samples, sample collection and preservation devices, and pooling of plasma samples are being explored to provide equitable access to persons living in non-urban areas. As innovative technologies become available, such as POC tests, their performance and utility will need to be validated and cost-effective models for deployment that balances their use with laboratory-based test platforms will be compulsory. Long-term planning will be needed to ensure appropriate investment in technologies that still enables new, improved platforms to be introduced in future. These new technologies have the potential to transform the HIV diagnostic landscape, bringing VL testing closer to the patient, reducing test turn-around time and patient loss to follow-up, and expanding access to testing in many new geographic areas.

### 2.1.8 Institutions and 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 the clinical cascade and provision of quality clinical services. 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 program areas (including Adult and Pediatric Treatment, Palliative Care, TB/HIV, PMTCT, Testing and Counseling, Strategic Information, and Blood Safety). For this comprehensive approach to be synergistic, the laboratory programs should:

- 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.

The national laboratory policy and strategic plan should address the laboratory-related PEPFAR indicators to support the country specific health plan to ensure that adequate numbers of quality-
assured laboratories, testing sites, and workforce are available to perform testing for HIV/AIDS diagnostics, and care and treatment services. Laboratory policies are essential for developing a harmonized approach to implementing laboratory strengthening activities. Countries are encouraged to have or develop national laboratory policies and monitor and evaluate their implementation. As a pathway towards country ownership, countries are also encouraged to support the development and/or strengthening of local indigenous capacity and regional institutions, such as ASLM.

3 Cross-cutting, Linkages and Wraparounds

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 POC testing facilities and referral laboratories. 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 POC testing services are available along the newly built roads.

PEPFAR-related laboratory activities should not happen in a vacuum but rather be fully integrated into clinical laboratory support activities. The “best laboratory practices” and quality assurance measures should be applied holistically in improving access to quality laboratory services with the goal of increasing HIV diagnosis, enrolment, linkage, and retention in care and treatment services. The most frequently cited examples of this are HIV rapid testing, CD4 testing, EID services and diagnosis of opportunistic infections (e.g., malaria, TB, cryptococcus). The development of new viral load technologies, and the need to increase access VL testing to monitor for virologic failure and potential HIVDR, provides a unique opportunity for further integration of clinical and laboratory services. It will also require additional collaboration with MOHs, other partners and technical areas to ensure strategic placement of diagnostics and clinical services and to develop plans for rational and strategic scale-up of HIV diagnostics to support clinical service needs.

PEPFAR staff should work with partners to ensure that effective linkages exist between clinic- or community-based HIV testing sites, TB clinics, and antenatal clinics with ART sites to ensure that newly diagnosed patients are linked with appropriate services.

To ensure harmonization of key activities, improved programming, and strategic use of resources, working collaboratively with other working groups to advise on activities, trainings, programs, development of public and private partnerships, or projects that may impact laboratory activities will be mutually beneficial. The importance of linkages between the clinical and laboratory interface as well as across the laboratory tiered structure cannot be overemphasized. For instance, it ensures that problems at the clinic due to specimen type or quality can be quickly corrected. Such communications can improve clinical services as well as strengthen requests for
human resources for health. Coordination of training efforts with established programs would be mutual beneficial and the laboratory component of the training further developed to better meet the needs of the country or region.

3.1 Partner Performance Considerations

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., complete blood count with differential, creatinine, ALT, kidney function, CD4 count, viral load, and drug resistance). 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 2014 COP Guidance Appendix 11 for more information on how PEPFAR funds may be used for renovation.

4 Monitoring, Evaluation and Reporting

PEPFAR’s new Monitoring, Evaluation and Reporting (MER) Guidance provides a framework for the global HIV response, from specifics on key technical areas, to broader health system questions, including laboratory strengthening activities. In addition to the two existing laboratory indicators, two additional indicators have been included to better capture PEPFAR laboratory strengthening efforts (for a total of four indicators. Additional information on these indicators can be found in the PEPFAR MER Strategy.

5 Additional Resources

- WHO-AFRO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) program;

Biosafety Resources:


ISO 15189 Medical Laboratories—Particular Requirements for Quality and Competence, 2007;

ISO 15190: Medical Laboratories—Requirements for Safety, 2003;


CEN Workshop Agreement CWA #16393:2012–Laboratory Biorisk Management - Guidelines for the Implementation of CWA 15793:2008:


3.2 Strategic Information

1 Introduction

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 is an important driver in creating an AIDS-free generation as outlined in PEPFAR’s Blueprint: Creating an AIDS-free Generation (157).

Data use continues to be of great significance, given the need to accomplish much more work under more limited funding. In FY 2013, the Monitoring, Reporting, and Evaluation (MER) Operational Guidance is being developed to carefully outline key priorities and considerations for PEPFAR in using data to strategically answer planning, programming, and technical questions. This guidance document, along with the PEPFAR Data Quality Standards of Practice and the PEPFAR Evaluation Standards of Practice will be instrumental in advancing SI priorities described throughout the SI Technical Considerations.

1.1 What’s new in 2014

- Data Quality: In support of PEPFAR’s long-standing commitment to data quality and in response to PEPFAR’s emphasis on strengthening partner government systems, a new PEPFAR Data Quality Standards of Practice guidance is forthcoming (estimated release date December, 2013). The new guidance emphasizes a unified, coordinated USG approach to strengthen the capacity of national governments and local institutions to establish standards, processes, and protocols for DQ activities.
- Evaluation: The forthcoming PEPFAR Evaluation Standards of Practice guidance will articulate a set of evaluation standards that can be applied to strengthen quality and accountability during all phases of evaluations of PEPFAR-funded programs, consistent with recommendations from the Institute of Medicine (IOM) and Government Accountability Office (GAO).

1.2 PEPFAR Blueprint

At its core, the success of the PEPFAR Blueprint rests on the contributions of strategic information. The breadth of work represented provides information ranging from epidemic characteristics, to monitoring program performance, to documenting population impacts, to evaluating program effectiveness, and to building national systems to orchestrate and manage all of these types of activities, among others. Additionally, the Blueprint recognizes that building capacities in use of strategic information is a shared responsibility, involving other donors and stakeholders.
1.3 Technical Background

SI is the composite of three distinct, highly integrated, technical areas: Monitoring and Evaluation (M&E), Health Information Systems (HIS), and Surveillance and Surveys (S&S). HIS pertains to 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 relates to the generation of data that flow in this system and the systematic collection of data to determine whether or not programs are meeting their goals and objectives. M&E also focuses on strengthening data quality, analysis, interpretation, and use. S&S pertains to systematic data collection, analysis, and interpretation, by specifically sampling data from national populations, service populations, risk populations, and service delivery locations, among others.

2 General Principles of SI programming

PEPFAR has been transitioning from an “emergency” program to a routine public health service delivery and development program. SI supports this transition with:

- 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
- Support for the development of national SI coordinating mechanisms for improved collaboration, reduced redundancy and improved system efficiencies.

2.1 SI framework

As countries build and strengthen the capacity of national SI systems, consideration should be given to how the different SI components (M&E, HIS, and S&S) are integrated into a larger whole to improve SI functioning at all levels. The international community has reached general agreement on the overall purpose and components of an SI system, defining 12 such components in this larger framework (345):

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.

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.

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 towards SI implementation throughout the year.

6. **SI Advocacy, Communications, and Culture** - Ensure knowledge of and commitment to SI and the SI system among policymakers, program managers, program staff, and other stakeholders.

7. **Routine Monitoring** - Produce timely and high quality routine program monitoring data.

8. **Surveys and Surveillance** - Produce timely and high quality data from surveys and surveillance.

9. **Database** - Develop and maintain national and sub-national health information systems 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.

These 12 components constitute the elements of a fully functional, national SI system. The USG team should work in collaboration with national partners to identify these key components within the national context, to establish priorities for building greater capacities, and to utilize PEPFAR resources to support the national plans and implementation efforts. This formulation of a National SI Strategic Plan is vital to the successful achievement of a national system, and it is important that PEPFAR play a supportive role in its development. There are implications for this planning support in each of the three sections of SI considered below.

### 2.2 National or Sub-National HIV/AIDS SI Strategic Plan

Development of a national SI strategic plan represents two of the 12 components of a comprehensive framework. The plan itself is one key milestone (#4), while having an
accompanying costed work plan constitutes a second (#5). Both components are required for coherent planning, and both need to address independently and in aggregate the M&E, HIS, and S&S areas of interest. The aggregate planning will require careful consideration, given its complexities, but basing this approach on the themes of data quality and data use will facilitate this step in the process. The MER Strategy is built on these same principles.

A well-developed National HIV/AIDS SI Strategic Plan ensures that the national strategy and major components of SI receive adequate attention while permitting evaluation of emerging issues. Strategic planning—a fundamental activity led by national counterparts that results in a national or sub-national SI plan—focuses on completing the circle of epidemic understanding, program planning, implementation, monitoring, evaluation and using results for decision-making. The strategic planning process should be characterized by systematic collaboration among stakeholders to incorporate national goals and objectives to address key epidemic drivers and national priorities reflected in the national strategy.

Planning processes for each of the M&E, HIS, and S&S areas should follow a similar pattern, and these results incorporated into a single, comprehensive SI strategic plan. As a model for all three areas of interest, while supporting the national M&E planning process, the USG team should:

- Participate actively in the national HIV M&E technical working group/ committee coordinated by MOH;
- Assist in the development and implementation of a national M&E assessment that will enable stakeholders to identify strengths, weaknesses and recommend actions to inform the strategic planning process;
- Address key questions for national program management and improvement:
  - Are we doing the right things?
  - Are we doing them correctly?
  - Are we doing them on a large enough scale to make a difference?
- Prioritize M&E activities that will build one national M&E system;
- Ensure that the national M&E plan is fully funded and that there is an M&E unit with the adequate number of qualified staff at all levels of the health system; and
- Contribute to the evaluation of national M&E plan implementation to determine whether activities have advanced stated program goals.

In addition to supporting the development and implementation of the national M&E plan, the USG needs to have an M&E plan for its own internal coordination, performance measurement and accountability, and be aligned with both the national strategy and the National M&E Plan. Toward this end, the USG team should:
• Revise the USG M&E plan annually and ensure that it is continually supporting national M&E efforts; and
• Ensure accountability for the full range of USG-supported work and activities.

The National HIV SI Strategic Plan should make explicit references to data 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. In this instance, it is critical to determine the balance between the public health and the patient-centric perspectives, including any reference to the ongoing role of paper-based systems. The HIS strategic plan may explicitly focus on eHealth initiatives, in which case, some effort must be made to account for the short- and long-term thinking regarding paper-based systems. PEPAR-related HIS activities must be carefully developed to support these national strategic documents.

Similarly, the National HIV SI Strategic Plan should include a five-year HIV/AIDS surveillance 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. In addition, plans for building in-country capacity to implement and sustain surveillance activities and operations should be a priority component of this strategic thinking. Once the surveillance strategic plan has been established, countries should routinely evaluate the surveillance activities being implemented. PEPAR planning should take into account the priorities for surveillance and survey implementation, as well as the associated efforts to build country capacities in this area. A listing of surveillance guidance documents can be found on the WHO website: http://www.who.int/hiv/pub/surveillance/en/.

2.3 Building in-country capacity for SI and data use

PEPFAR supports partner governments in their work to integrate PEPFAR SI systems and partner systems into the overall national system and emphasizes 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.

The following are the key goals for building country capacity across all SI areas:

• Improve integration and collaboration of HIS, M&E efforts, and S&S at all levels of the national system;
• Build national capacity to collect high-quality data, and manage, analyze, and use data for better decision-making and policy formulation; and
• Increase coordination with other international donors and agencies.

The 2012 PEPFAR Capacity Building and Strengthening Framework (346) emphasizes three components of capacity building to ensure overall successful performance of the HIV response: individual, organizational, and system-wide. When planning SI activities, capacity building
should be considered at all three levels with the recognition that improving capacity at one level may require concurrent interventions at another level. USG should cultivate linkages with in-country higher learning institutions to support training of M&E professionals. Individual and organizational capacity is essential to 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.

Across the SI system, USG should promote a culture of data use for decision making. Correct data interpretation and use is critical to planning, assessing, strategizing, and determining next steps in public health programs.

When designing capacity building strategies with national partners, it is essential that these three levels are addressed adequately. Also critical is to remain cognizant that requirements for M&E, HIS, and S&S—while all components of an integrated SI system—require very specific attention when designing and supporting capacity building approaches. USG teams should support the national plans, which may require a formal assessment of current capabilities, and in this process should consider a variety of activities to fund in each of the three levels. For example, activities targeting individual capabilities frequently rely on different forms of training or mentoring. This work may occur in academic settings, in work settings, or even in on-line settings. All of these modalities, and others, have important roles in the development and strengthening of individual skills. Activities at an organizational level might include definition of relevant job descriptions, career paths for particular job classifications, career development opportunities, recruitment retention strategies, professional certifications, management development, strengthening of government or other entities responsible for SI work, etc. At a system level, support might be useful for policy development, strengthening data use practices, strategic planning for health and other sectors, university programming and curricula, standards development, and implementation coordination, among others. However the USG determines to support the national capacity building effort, it is imperative that these activities are consistent with national priorities and contribute to the fulfillment of the national agenda.

3 Monitoring and Evaluation (M&E)

This sub-section addresses the M&E components of the SI framework and highlights the complexities of a fully functional, unified, national M&E system to support:

- 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
- Response to donor and country reporting requirements and needs through unified coordinated monitoring systems.
See sub-section 8 (Additional Resources) of this Section for additional resources on M&E.

### 3.1 Program Monitoring

#### 3.1.1 Strengthen national HIV M&E systems

The goal of routine program monitoring systems is to produce timely and high-quality data to improve programs and inform decision-making. 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 patient monitoring systems for prevention, care, and treatment services continue to need strengthening. In particular there should be a focus on monitoring standards and tools that cover the continuum of prevention to care and treatment, especially in the context of the expansion of option B+ in PMTCT. Facility-based M&E systems should also address provider-initiated counseling and testing and HIV interventions integrated with other disease areas, such as TB and voluntary family planning (FP). M&E for referrals of facility-based prevention, care and treatment services continue to need strengthening in many countries. In addition, processes to track referrals and linkages, as well as retention and adherence, are increasingly important as programs mature and care and treatment systems become more complex.

Community-based M&E systems, such as programs including community-based prevention, home-based care, and OVC activities, need to be developed, strengthened and integrated into national information systems. 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.

#### 3.1.2 Improve M&E for integrated health services

HIV programs increasingly go beyond the traditional boundaries of HIV prevention, care, and treatment to better mitigate the impact of the epidemic. 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. More generally, 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.

### 3.2 Data Quality

PEPFAR’s forthcoming *Data Quality Standards of Practice* provides a template for planning data quality assessments (DQAs), includes an inventory of DQA resources and will provide
concrete ways to work with national governments to strengthen their data quality strategy, infrastructure, and processes. USG SI teams should collaborate with host country partners and other key stakeholders with this new guidance to renew their commitment to improving the quality of programmatic data at all levels of the system.

3.3 Evaluation

Evaluation refers to studies that systematically guide program and policy improvement and development, and focuses on how a program is implemented and its effects and impact on the target populations. Different forms of evaluation include:

- Process, outcome, and impact evaluations. Process and outcome evaluations should be used to measure implementation fidelity (i.e., ascertain if and to what extent the intervention was implemented as planned) and to determine the short-intermediate term effectiveness of programs, respectively, for the country and for donors, including PEPFAR. Impact evaluations are used to measure changes in outcomes attributed to a particular intervention. Results from evaluations inform health providers, decision-makers, and program planners on facilitators, barriers, and best practices of HIV/AIDS programs; and

- Operations research: focused 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 evaluation or implementation science). Operations research provides answers to program problems, providing program managers and policy makers with the necessary information to improve program delivery. Operations research can also be used to answer special questions, scenarios arising from the programmatic environment.

As PEPFAR moves into its third phase, there is an increased emphasis on conducting high quality, independent evaluations, driven by host country needs and engagement, and with results that are communicated to relevant stakeholders and decision makers in a clear and transparent manner(347)(348). Operating Units and Implementing Partners should collaborate closely with host country governments to strengthen national capacity to develop evaluation plans, conduct evaluations and use findings in a timely manner for program and policy improvement. Additional information and support is available in the forthcoming PEPFAR Evaluation Standards of Practice document.

3.3.1 Developing an Evaluation Strategy

Evaluation strategies should be developed in collaboration with national stakeholders, to ensure all relevant parties have consensus on the purpose, use, and users of evaluation results. This helps ensure timely access to evaluation findings, as well as higher quality implementation. As prevention, care, and treatment programs continue to increase country sustainability and to scale up efforts to achieve an AIDS-Free Generation, evaluation is a crucial component of evidence-based decision making and accountability. Therefore, the USG team should collaborate with
national partners in the development of a national evaluation strategic plan, and align USG support for evaluation with those priorities. Additional guidance on the components of an evaluation plan is forthcoming.

3.4 Data Dissemination and Use

Correct data interpretation and use are critical to planning, assessing, strategizing, and determining next steps in public health programs. Population-level data sources can be used at the national level to strategize and reprioritize activities, while routine monitoring data can feed into sub-national and community-based programs to support strategic planning, program improvement, evaluation design, and management of prevention, care, and treatment programs. While much effort is expended to collect population-level, community-based, and facility-based data, implementers commonly note that the information is not used effectively, if at all, for decision making.

To address these limitations in data dissemination and use, a country’s SI portfolio should include a specific data use plan, developed by the partner country that explains how data will be more effectively used to improve programs at the national, sub-national, and community levels. Interventions intended to facilitate data use need to be implemented as part of country SI plans.

Further information and guidance for data dissemination and use are forthcoming in the Monitoring, Evaluation, and Reporting Guidance materials. For questions about any of the content in this section, please contact the M&E Technical Work Group (TWG).

4 Health Information Systems

The Health Information Systems Technical Working Group (HIS TWG) has developed a six-step HIS strategy to ensure that PEPFAR Country Teams work with partner governments to generate and analyze the 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 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 the vision, principles and standards that guide the Ministry’s purchase and deployment of technology and use this “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 recommends that Country Teams operationalize this strategy with a two-part assessment:

- 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.

### 4.1 The evolving role of HIS in large-scale HIV focused health programs

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. Efforts to strengthen HIS 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. 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 in the Mechanism Overview or Budget Code Narrative in the COP.

The emergence of the concept of eHealth (349), 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 (350) is a suggested starting point for articulating a coherent eHealth strategy. 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, and even mixed-method 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.

4.2 Strengthen National Health Information Systems Framework

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 a minimum, 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; and
  - 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)

4.3 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 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), 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.

4.4 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 UN 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; and
• 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.

4.5 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.

4.6 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.

5 Geographic Mapping, Spatial Data and Geospatial Tools

National plans for increasing the efficiency and coverage of programs should be developed in a geographic context, with resources aligned to the location of people who need them. The inclusion of geography in a standardized approach to describing and analyzing facility- and community-based programs will also facilitate reporting requirements. Geography allows us to link program, epidemic, demographic, service, human resource, finance, logistic, and other types of data to answer important program questions (351), such as:

• What is the geographic distribution of HIV prevalence, incidence, and numbers of infected people in relation to HIV/AIDS service delivery points?
• Do PEPFAR-supported services duplicate or complement services supported by other funders or the private or public sectors in the same local area?
• Is there a geographic pattern to stock-outs?
• How many people live within the catchment areas of facilities that offer a service?
• Where is PEPFAR supporting services in relation to other priority health programs?
• Where will the expansion of a service likely increase coverage or equity?
To leverage geographic analysis to improve programs it is necessary to integrate spatial data collection, management, and use into M&E, surveillance and surveys, and health information systems strategic plans.

5.1 Geography of facility-based services

Master Facility Lists (MFL) are standardized, authoritative ways of uniquely identifying health facilities and serve many functions in an HIS. Health facility latitude, longitude, and other geographic identifiers that describe facilities (e.g., district name) should be managed as data elements in a MFL. WHO guidance on creating a master facility list describes various methods for obtaining geographic coordinates for health facilities, such as Global Positioning System or satellite imagery, as well as the process for the maintenance of these data over time. Countries with MFL initiatives should support the integration of latitude, longitude and other geographic identifiers into these authoritative facility lists. Countries without MFL initiatives should develop facility lists according to WHO MFL guidance in anticipation of country-owned MFL development. In either case, the lack of latitude and longitude should not delay the development of MFL.

5.2 Geography of community-based services

The geography of community-based services can vary substantially. Some services may occur in a precise location such as a school or a bar while others, such as a behavior change communication activity, may have a more diffuse geography. Partner government institutions such as a Central Statistical Agency or National Mapping Agency likely have a responsibility to manage standardized spatial data sets on populated place locations that include latitude, longitude, and standardized place spellings. Countries should seek out and to the greatest extent possible, align community-level spatial data to these authoritative national spatial data systems.

5.3 Geography of prevalence and burden

Programs should strategically align service provision location with the best geographically defined estimate of need at the most granular level possible. Population-based surveys may provide province-level estimates of HIV prevalence, but prevalence alone in not sufficient for geographic targeting of services to increase population coverage. Key inputs to subnational analysis for many countries can be found at http://hivspatialdata.net. Programs should support partner government estimation of populations in need as well as prevalence at subnational levels through modeling approaches such as Spectrum/Estimation and Projection Package (EPP).

5.4 Spatial Data and the Preservation of Confidentiality

Spatial data can uniquely identify individuals, especially when multiple sources of spatial data are linked. For example, the issue of confidentiality and spatially explicit data arises in population based surveys such as Demographic and Health Surveys (DHS). In DHS methodology, sample cluster latitude and longitude are displaced with random error specifically
to prevent the identification of survey respondents. Special care should be taken with maps in which key populations are a subject. If such maps are programmatical essential, they should employ geographic masking techniques as feasible and not be circulated any more widely than necessary.

5.5 Geospatial Tools

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 (GIS). Technical assistance on geospatial tools and the acquisition, management, and use of spatial data is available from OGAC.

6 Surveillance and Surveys

6.1 General considerations

_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 of the Technical Considerations (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 five to fourteen 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 (GHI).

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.** 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 partners. 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 three to five years. This is generally a cost-free exercise involving only staff time. Guidelines, such as those issued by the CDC, can be found in the report: *Updated Guidelines for Evaluating Public Health Surveillance Systems* (353).

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

6.2  Surveillance and Survey Activities

6.2.1  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](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 findings should be reported along with HIV prevalence estimates. Partner governments should be encouraged to include other routinely available ANC data, such as those related to maternal and child health, as feasible, to help address GHI information needs.

6.2.2  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; and
- 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.

Guidelines for assessing the utility of PMTCT program data for surveillance can be found at: [http://www.who.int/hiv/pub/guidelines/assessing_mtc_data/en/index.html](http://www.who.int/hiv/pub/guidelines/assessing_mtc_data/en/index.html). 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. Prospectively capture information about PMTCT HIV acceptance and testing among pregnant women sampled by ANC SS onto the ANC SS form. 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 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; and
   - 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.
6.2.3 Behavioral and Biologic Surveillance among Key populations and higher risk populations

All countries, whether facing generalized, mixed or concentrated HIV epidemics, harbor key populations (e.g., men who have sex with men (MSM), transgender persons, (TG), sex workers (SW), and people who inject drugs (PWID), migrant workers, truck drivers, members of the military, fishermen, etc.)\(^7\) that are at increased risk of HIV infection. All countries should therefore conduct periodic behavioral surveillance activities among (relevant) key populations and their clients.

Behavioral surveillance is often termed 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). This survey method 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 (164). Whenever possible, biomarkers (HIV, other sexually transmitted infections (STIs) depending on their prevalence) 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 (see also sub-section 6.2.5 (Surveillance among pediatric populations) of this Section for further information on surveillance and research studies involving children and adolescents).

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 they will make the most difference. Therefore, each behavioral surveillance cycle should include a formative assessment phase to plan appropriately in order to avoid making mistakes that will

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\(^7\) S&S for KP is distinct from other sub-populations at higher risk because KP behavior is usually criminalized and often hidden, and they experience significant stigma and discrimination, which inhibits access to and uptake of HIV services and may make it more difficult to recruit them for surveillance and other data collection activities.
cost time and money and to 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*(354).

Partner governments are responsible for ensuring such surveys among relevant groups are conducted every two to three years, depending on the specific epidemic conditions. 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 (http://www.pepfar.gov/reports/guidance/171094.htm).

### 6.2.4 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.


### 6.2.5 Surveillance among pediatric populations

The recommended approach for pediatric surveillance is the use of 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 case surveillance would utilize 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.
Additional approaches for pediatric surveillance include household surveys including children, immunization clinic surveys, mortality surveillance, in-school youth surveys, and other special surveys. The UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance has produced guidelines on this topic: *Pediatric HIV surveillance among infants and children less than 18 years of age* (355).

PEPFAR supports a variety of surveillance and research studies that include children and adolescents. When conducting such studies, it is important to note that the U.S. Government is a signatory on the UN Convention on the Rights of the Child, which defines a child as anyone under the age of 18. Therefore, anyone under 18 who participates in PEPFAR-supported surveillance and research studies needs to receive special consideration, keeping in mind the best interest of the child. This is particularly important for surveillance and research that examines experiences of violence, as well as ongoing surveillance efforts that include 15-17 year olds grouped together with adults (over the age of 18). Sub-section 8 (Additional Resources) of this Section for resources in ensuring that the protection and well being of children is of primary concern in any attempt to gather information from them.

### 6.2.6 Population-based household surveys

Population-based surveys, such as AIDS Indicator Surveys (AIS) or Demographic and Health Surveys with HIV biomarkers (DHS+) are important components of HIV surveillance systems that provide nationally-representative HIV-related indicators. These surveys provide critical data on behavioral and programmatic parameters and can inform assessment of impact of HIV services and interventions. HIV testing, along with viral load and CD4 cell count determinations should be considered for all population-based surveys in countries with generalized or mixed epidemics. Typically such surveys should be conducted every three to five years. Countries with high HIV prevalence or rapidly expanding HIV programs may consider conducting AIS more frequently in order to measure program impact and the current state of a country’s epidemic. These population surveys may also provide large enough sample sizes to allow for cross-sectional HIV recency testing for HIV incidence estimation and viral load measurements to provide further information for program monitoring and strategic planning.

Conducting population-based HIV-focused surveys is a priority for PEPFAR as a means of monitoring epidemics, program progress and HIV program impact. PEPFAR should help support AIS and DHS+ though coordination with other donors. USG teams may use new or old FY funds to ensure that routine surveys are conducted and sample sizes are large enough for significant findings to be measured. The Kenya AIS can serve as an example that can be adapted to other country contexts.

Careful consideration should be given before using population-based surveys to collect blood samples from children to measure uptake of PMTCT services. The sample size required to adequately measure HIV prevalence among children is usually very large, resulting in high
survey cost and additional burden on survey logistics. In additional, human rights protections are of critical concern in these same circumstances.

Further guidance on HIV testing in surveys is provided by UNAIDS (http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/20101207_HIVtesting_in_surveys_WG_en.pdf).

6.2.7 TB/HIV surveillance

Tuberculosis (TB) is a leading cause of death amongst PLHIV, and reducing the TB associated mortality and morbidity amongst PLHIV is a PEPFAR priority. Strong TB/HIV information systems allow programs to track patients as they move through the HIV and TB service cascades, from screening/diagnosis to treatment, both within and across TB and HIV services’ platforms. Furthermore, effective TB/HIV surveillance allows the estimation of the incidence and prevalence of TB/HIV, providing data that can be used to guide public health decision making and target setting as well as measuring the impact of programmatic activities to control TB/HIV.

Sustainable and effective surveillance systems for TB/HIV must be based on data collected during routine clinical services and recorded in individual patient records and/or clinical registers in both TB and HIV clinical settings. Efforts to strengthen TB/HIV surveillance should focus on improving the recording and reporting of routine clinical data in both TB and HIV clinical settings. Also, programs must ensure that data elements that capture important clinical activities are included in data collection tools and that systems to track referrals and counter-referrals between TB and HIV services are in place. Finally, since TB/HIV surveillance is based on data collected during clinical service delivery, strengthening of programmatic services will correspondingly strengthen TB/HIV surveillance.

6.2.8 Recent HIV infections

To describe current HIV transmission dynamics, HIV incidence or recentness 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 repeated surveys; or approximated by measuring HIV prevalence among young adults or other recent initiators of high risk behavior; and estimated with the help of laboratory assays.

The field of laboratory assay-based incidence estimation is particularly dynamic with the development of new, improved tests for recent infection. Countries should contact OGAC 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 (LAg)-Avidity EIA), and may be used to test serum or plasma specimens. Kits for testing dried blood spot specimens are currently being evaluated and may soon be commercially available. Estimating HIV incidence through the use of laboratory
assays on cross-sectional samples usually requires very large sample sizes, such as those obtained in AIS or DHS+, 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, including requirements for correcting results for false recency, and relevant guidance as outlined in the report *When and how to use assays for recent infection to estimate HIV incidence at a population level* (356).

### 6.2.9 HIV 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 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 and can be used to monitor the clinical cascade of services.

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 more than once, regardless of where s/he is tested or reported.

In late 2006, WHO released a new HIV case definition using four stages of HIV infection (357), offering 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).

### 6.2.10 HIV drug resistance (HIVDR)

As ART scale-up to achieve an AIDS-free generation 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 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; and
- Monitoring of HIVDR early warning indicators.

Given their cost and logistic challenges, prospective cohort methods are no longer recommended for monitoring for acquired HIVDR. To leverage existing resources and reduce costs, programs may consider using samples collected during other surveillance activities (e.g., ANC surveillance, incidence testing, key population surveys) to generate estimates for HIVDR amongst certain populations or those recently infected with HIV.

6.2.11 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.
6.2.12 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.

6.2.13 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.

6.3 Other Activities

6.3.1 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 on the UNAIDS website:
6.3.2 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 (pop.ipc.hiv@census.gov).

6.3.3 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 Surveillance and Surveys Technical Work Group.

7 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, many of the programs supported through PEPFAR are interlinked 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.

In any given country, SI supports the overall PEPFAR mission while simultaneously strengthening national health systems. Consequently, deliberations are necessary to determine what level of funding should be assigned to these different activities. At the national health system level, PEPFAR recommends SI funding at the 5-10% range of all program resources to support this system effort. At the program level to support program M&E and HIS activities, PEPFAR recommends a 5-10% range, calculated by and drawn from associated program funding. International standards suggest this same range of a program budget should be dedicated to M&E of the program. Regardless of the exact percentages, SI effort and funding needs to target the national system, as well as the routine M&E integral to all PEPFAR programs.
8 Additional Resources

Monitoring and Evaluation:


Capacity building assessments and implementation plans:

- “Making Monitoring and Evaluation Systems Work”
- UNAIDS 12 Components Monitoring and Evaluation System Strengthening Tool (361)
- UNAIDS HIV M&E Capability Building Guidance (362)

Evaluation:

- A National Evaluation Agenda for HIV. (360)
- Department of State Program Evaluation Policy: [http://www.state.gov/s/d/rm/rls/evaluation/2012/184556.htm](http://www.state.gov/s/d/rm/rls/evaluation/2012/184556.htm)
- USAID Evaluation Policy, Learning from Experience (363)

Research and surveillance with children and adolescents:

3.3 Health Systems Strengthening

1 Introduction

A recent multi-year evaluation of the PEPFAR program by the Institutes of Medicine recommended that PEPFAR continue to implement Health Systems Strengthening (HSS) activities as part of the “sustainable management of the HIV response” (364). Achieving an AIDS-free generation depends on health systems that are capable of sustainably organizing and providing HIV/AIDS services to those in need. The following provides guidance to assist country teams to plan and integrate HSS activities into PEPFAR programming.

1.1 What’s new in 2014

This year’s Section on health systems strengthening builds on guidance from previous years while taking into account evolving PEPFAR program priorities and strategies. In particular, this year’s Section on health systems strengthening:

- Provides teams with a clear investment framework tool to describe, map out and align health systems strengthening interventions with PEPFAR priorities (e.g., Blueprint commitments) and strategic directions (e.g., country ownership);
- Provides considerations for strategically investing PEPFAR resources in health systems and developing a health systems strengthening strategy;
- Updates examples of what are and are not considered health systems strengthening investments across the health system building blocks; and
- Further articulates links between health systems strengthening investments and selected PEPFAR program priorities, including integration of services, capacity building and country ownership.

1.2 HSS Commitments from the PEPFAR Blueprint

Health systems strengthening within PEPFAR takes place in the context of broader program priorities, including Blueprint commitments and country ownership. PEPFAR’s Blueprint for achieving an AIDS-free generation makes several HSS-related commitments. Examples include:

- Prevention of Mother to Child Transmission (PMTCT): laboratory strengthening, human resources for health, strategic information, and decentralized/integrated models of care;
- Voluntary Medical Male Circumcision (VMMC): integrated, long-term early infant male circumcision (EIMC) program;

To increase system-wide integration of services, the Blueprint makes HSS commitments to integrating HIV with both family planning and tuberculosis (TB) services. To realize operational efficiencies, Blueprint commitments include those related to task shifting, regulation systems,
financing, strengthening procurement systems, strategic information, and private sector engagement.

Strengthened health systems are also critical inputs into country ownership embodied by country-led and -managed responses to the HIV response. By definition, a durable and effective national HIV response will be delivered through a national health system. Achieving and sustaining an AIDS-free generation requires health systems capable of effectively providing HIV/AIDS services to those in need, through government, civil society and the private sector. Investments in the health system should be aligned with and support countries in making progress on all four dimensions of country ownership (i.e., political ownership/stewardship, institutional ownership, capabilities and mutual accountability). Sub-section 2.2 (HSS and Country Ownership) of this Section provides teams further guidance on aligning health systems strengthening investments with country ownership.

1.3 Technical Background – Definitions

1.3.1 Health Systems

The health system includes all the individuals and organizations that focus primarily on ensuring health outcomes. This spans those focused on public health – including laboratory systems – to those providing clinical goods and services to individuals. Health systems are formed and operate at multiple levels of aggregation, including national, state/provincial, district and community. They also encompass a myriad of stakeholders, including policymakers, health care workers, civil society (e.g., non-governmental organizations, faith-based organizations, and the private commercial sector), as well as communities.

Health systems carry out a number of key functions. While multiple typologies exist to characterize those functions (365), the World Health Organization’s (WHO) health systems building blocks framework (366) provides a framework that is relevant to PEPFAR programs. Following the WHO’s building block framework and as illustrated in Figure 9, key functions of the health system from a PEPFAR perspective include:

- Leadership and Governance, including health policy development and implementation, regulation, strategy development, management and accountability;
- Financing, including the mobilizing of funds, organizing risk pools for funds, allocating funds to programs, and planning for long-term sustainability;
- Human Resources for Health (HRH), including planning, production and management, deployment, retention, and performance management (for further information about each of these functions, see the Section 3.4 of the Technical Considerations (Human Resources for Health));
- Medical Products, Vaccines, and Technologies, including, in particular, supply chain functions (commodities selection, forecasting, procurement, distribution, use,
accountability and inventory management) and laboratory systems (including a national integrated quality-assured network of tiered laboratory services);

- 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
- Service Delivery, including its quality, efficiency, equity, accessibility, patient-centeredness, and safety.

The ways in which health systems carry out these functions affects performance and, ultimately, achievement of health systems goals. Underlying health system inputs and resources include human resources for health, strategic information (encompassing health information systems, monitoring and evaluation, and surveillance and surveys), essential medicines (including supply chains), and laboratory systems. Critical enablers (governance/leadership and finance) transform these inputs into delivery of health goods and services. Together these inputs and critical enablers contribute to the delivery of core HIV prevention, care and treatment interventions, services with close links to HIV/AIDS (e.g., family planning, maternal and child health, TB) and the broader array of health goods and services. Interactions between health systems functions (i.e., “components” or “building blocks”) influence performance including: coverage of and access to health services; the efficiency, quality and safety with which services are provided; and the degree to which services are equitably provided. The overall performance of health systems along these dimensions significantly influences health system outcomes such as improved health (including decreased HIV mortality, morbidity and infections), protection from financial risk, and responsiveness to consumer needs and expectations. Interactions between communities and patients at various entry points into health system also affect performance and achievement of health systems goals.
The above-described health systems framework can be utilized by country teams to formulate, organize and describe PEPFAR investments to strengthen health systems. The building blocks typology provides an internationally recognized reference point by which to characterize country teams’ HSS strategies and activities. It has served as a basis for tools and methodologies external to PEPFAR that can be of use to country teams to assess, monitor and evaluate components of the health system in need of strengthening (see sub-section 7 (Additional Resources) of this Section for a listing of additional resources). The building blocks framework referenced here is also harmonized with health systems frameworks adopted by both PEPFAR’s Monitoring, Evaluation and Reporting (MER) and Expenditure Analysis methodologies to capture health systems strengthening investments.

However, country teams are encouraged to extend, integrate into or harmonize this framework with other health systems investment frameworks when developing HSS programming according to country-level needs. As highlighted by others, the descriptive nature of the building blocks framework is limited in capturing pathways between programs, policies or activities and improved health systems performance (365). Focusing on health system building blocks, for example, may be a necessary but not sufficient step in designing programs that lead or support changes to incentives, regulations, provider payment systems, models of service delivery, etc. that are likely to result in better service delivery performance. The above-reference building blocks framework is also limited in capturing how the dynamic nature of health systems, such as linkages, interactions and feedback loops between health system building blocks, will impact

(Adapted from: (367))
PEPFAR strategies and programs. Other health systems frameworks exist (322) and may be of use to country teams.

### 1.3.2 Health Systems Strengthening

Health systems strengthening encompasses all actions focused on improving “health system building blocks and managing their interactions in ways that achieve more equitable and sustained improvements across health services and health outcomes” (366). PEPFAR’s HSS activities fall along a continuum. At one end are those activities which are primarily HIV/AIDS-specific such as strengthening anti-retroviral (ARV) supply chains. There are also interventions that leverage the HIV/AIDS platform to benefit other specific diseases or health priorities (e.g., supporting development of integrated HIV and FP models of service delivery). At the other end of the continuum are those activities that are intended to broadly improve health systems and outcomes (e.g., development and use of a human resources information system).

### 2 Strategically Investing in HSS

PEPFAR investments in health systems strengthening are a means to support the sustained achievement of an AIDS-free generation and, more broadly, improved health outcomes. HSS represents a potentially 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. However, not all health systems issues can be addressed in a given funding cycle, and many health systems issues cannot be addressed by PEPFAR alone. Given PEPFAR’s mandate and resource constraints, the scope of PEPFAR’s involvement in HSS should be strategic and well-aligned with national investments in HIV/AIDS and health systems, as well as with other USG and international partner efforts (particularly those of the Global Fund).

Developing strategic, smart investment strategies to strengthen health systems is challenging for many reasons and has resulted in an under-developed evidence base linking HSS interventions to health systems performance and health outcomes. It is therefore especially important that country teams rely, as much as possible, on the existing evidence base to prioritize health system investments, and work to strengthen that evidence base. PEPFAR teams should be guided by three main principles to strategically plan HSS investments.

1. Demonstrated relationship of HSS programming to national strategic HIV and health sector plans and PEPFAR goals—including Blueprint priorities and country-level prevention, care and treatment goals (including health outcomes).

2. Health systems strengthening investments that are aligned with country ownership principles by striking an appropriate balance between short- to medium-term measures of support for inputs and medium- to long-term measures to strengthen institutions and processes.
3. Health systems strengthening investments that are aligned with, support and leverage other HSS and disease-focused programs and policies, including those from other USG initiatives, donors (particularly the Global Fund), and countries.

Teams are encouraged to develop a written HSS strategy. Content of the HSS strategy may vary by country context (i.e., epidemiologic needs, organization of the health system, scope of PEPFAR, level of other donor engagement, and country ownership classification). However, it would be useful for all country teams to utilize a similar approach and format. To this end, an illustrative HSS strategy outline is included in sub-section 8 (Annex – Illustrative HSS Strategy Outline) of this Section.

2.1 Relationship between HSS Investments and PEPFAR Goals

HSS investments should clearly support achievement of Blueprint priorities and country-level goals that have been articulated for individual PEPFAR countries, and national priorities. In developing a PEPFAR HSS program of strategic investments, teams are encouraged to work backward by identifying the health goals to be achieved, analyzing systems-level bottlenecks in achieving those goals, and determining which system-level constraints should be targeted to facilitate scaling up of effective HIV/AIDS interventions (368). This is best done through an iterative process involving other programmatic areas. For example, in countries rolling out Option B+, it is likely that a significant portion of the HSS strategy will be to support expansion of treatment to pregnant women (e.g., ensuring appropriate task-shifting policies are in place and supply chains are able to deliver commodities at lower levels of the system). At the same time, the design of PEPFAR treatment programs in support of Option B+ will be informed by the health system constraints to scaling up ART (e.g., timeframe for expansion of services may depend on health systems constraints). In this way, HSS investments surrounding Option B+ both follow from investments by other programmatic areas and informs the nature of those investments.

HSS programming should include an evidence-based mapping process that links together: 1) specific health goals to be achieved (i.e., PEPFAR and/or national prevention, care and treatment targets); 2) systems-level bottlenecks to achieving those goals (and resulting impacts); and 3) system-level responses that can facilitate scaling up of effective HIV/AIDS interventions. As an example, reducing HIV transmission among key populations requires a portfolio of cost-effective and evidence-based preventive and curative interventions, based on a good understanding of the dynamics of HIV transmission and epidemiology (e.g., characteristics and risk factors that drive transmission). Strategically investing in HSS involves a determination of health system requirements - and the system-level bottlenecks that will need to be overcome - for effectively delivering those interventions.

To undertake evidence-based mapping, PEPFAR country teams are encouraged to develop a conceptual logic model that links health goals by building block to each HSS intervention. To the
extent possible, the logic model should be supported by data collected about the current status of the health system (see sub-section 8 (Annex – Illustrative HSS Strategy Outline) of this Section). This should include data from various sources (e.g., health system or human resources for health assessments). Where health system data are lacking, the HSS strategy should identify gaps in knowledge and, in the context of those gaps, qualitatively justify choice of HSS priorities and/or interventions.

2.2 HSS and Country Ownership

PEPFAR countries are categorized into country ownership categories that broadly define the current vision for U.S. engagement and level of investment. PEPFAR’s approach to HSS investment will differ slightly for each category. The following outlines strategies and considerations about strategic approaches country teams should consider in their respective settings.

Across PEPFAR programs, HSS interventions fall into two categories. The first are a mix of input-focused investments to support health systems in the short- to medium-term. The second are investments in strengthening institutions, health system apparatuses and processes in the medium- to long-term. As an example, PEPFAR investments in equipment for health facilities (e.g., generators) is short-term support-focused. This infrastructure input may be critical for scaling up delivery of HIV/AIDS services in the context of prevention, care and treatment programming, but is limited in sustaining scale-up over time. By contrast, longer-term actions, that focus on strengthening the system, might include assistance in implementing regular inventory surveys of equipment while working with national health planning authorities to ensure the budget includes funding for equipment maintenance and replacement. These actions are better positioned to sustain scale-up over time, but immediate impact on scale-up of HIV/AIDS services are limited (369). As a second example, seconding PEPFAR-supported personnel to fill gaps in and provide technical assistance to the national MOH office (in policy development, creation of guidelines, program management skills, etc.) is a HSS intervention that supports needs in the short-term. By contrast, seconding PEPFAR-supported personnel to help the MOH to plan, cost and implement staffing structure changes to take on those responsibilities would be a longer-term institutional strengthening focused HSS intervention.

In the context of Long-Term Strategy (LTS) countries, PEPFAR programs vary widely in scope. As a result HSS investments will therefore depend greatly on each country’s context and on the features of its health system. Additionally, LTS countries’ HSS strategies may appropriately contain an array of health system activities that continue to directly support service delivery and rapid scale-up of HIV/AIDS services.

In the context of Targeted Assistance (TA) countries, certain health system building blocks are often more relevant to both the scope of PEPFAR programming and sustainability (e.g., addressing regulatory barriers to access to HIV/AIDS services by key populations). Additionally, TA countries are often further along the country ownership continuum. HSS programming in
these countries is expected to consist predominately of strengthening rather than support activities.

2.3 HSS Alignment, Support and Leveraging

While PEPFAR HSS investments should further national HIV responses, there are many opportunities to leverage the HIV platform to amplify improvements in other disease areas and to strengthen health systems more broadly. PEPFAR country teams should leverage HSS activities to amplify the impact on health systems and outcomes. As part of the Global Health Initiative (GHI), PEPFAR teams should continue to expand their collaboration with other USG global health programs to establish a coordinated USG approach for HSS. Within the global response to HIV/AIDS, PEPFAR teams should leverage other development programs and partners, such as the Global Fund, when opportunities exist to jointly address HSS investments that have an HIV/AIDS link (for example, improvement of national supply chain management system).

As discussed earlier, HSS investments lie along a continuum that ranges from HIV-focused interventions to broader investments likely to have spillover effects into other diseases. For example, developing information systems to improve ARV delivery, an HIV-focused HSS investment, addresses health system gaps specific to the achievement of PEPFAR and national HIV/AIDS goals. Integration of HIV with other focused health programs (such as family planning or maternal and child health) can and will have spillover effects by benefitting non-HIV/AIDS elements of the health system at no (or very low) additional cost to the USG. At the far end of the continuum, in the context of decentralized delivery of HIV/AIDS services, building the leadership capacity of district-level health management teams in planning, budgeting, and resource management can be expected to positively impact both HIV/AIDS services and the broader range of health services that fall under the responsibility of district-level health authorities. PEPFAR resources may be used for all HSS investments along the continuum, as long as those investments are guided by the three previously-cited HSS principles.

3 What are HSS Interventions?

In the context of PEPFAR budget codes, HSS work is captured in three main budget codes: OHSS (related broadly to HSS); HLAB (related to Laboratory Systems); and HVSI (related to strategic information). The following provides guidance on what constitutes HSS activities regardless of what budget code or technical area they fall under.

3.1 Leadership and Governance

Leadership and governance involves ensuring that strategic policy frameworks exist and are combined with effective oversight, coalition building, the provision of appropriate regulations

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8 Guidance on determining which laboratory and SI activities should be programmed under HLAB and HVSI, respectively, versus OHSS, is provided in the Appendices to COP FY14 guidance.
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; strengthens management structures and capacity; and enables substantive engagement of civil society in a continuing fashion. Examples include:

- 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;
- 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;
- Development of leadership and management skills for strategic planning, monitoring and supervision, and ongoing decision making of appropriate government offices and civil society organizations at national and sub-national level;
- Strengthening the capacity of civil society organizations as implementing partners in the HIV/AIDS response;
- 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 investments through its implementing mechanisms, or fulfills management functions on behalf of host-country governments or other governance structures. Examples include:

- 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; and
- Seconding staff to positions for management, strategic planning, and related functions.

3.2 Medicines and Technologies (including Drugs, Treatment, and Laboratory Systems)

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. Examples include:

- Improving the efficiency and effectiveness of existing procurement systems to ensure timely and cost-effective purchase and distribution;
- Parallel acquisition and distribution systems when these systems are implemented *through formally established host-country entities* that will continue beyond PEPFAR support;
- Development of sound warehousing and distribution practices to be implemented by country counterparts, ensuring that related processes are efficient;
- Establishing nationally-owned regulatory and quality assurance systems which function across the public and private sectors;
- Leveraging of skills from private and public sector partners to increase competition, share lessons learned, and further develop the national supply chain; and
- Developing mechanisms to reduce pilferage and leakage through the system and better accountability.

HSS is *not* spending to acquire, distribute and use medical commodities. Examples include:

- 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; and
- Direct training that targets only PEPFAR-supported lab sites or commodity systems, or other subsets of the national health system.

### 3.3 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. While health finance was not traditionally addressed under PEPFAR’s initial phase, resource mobilization, cost-effectiveness, and efficient resource allocation have subsequently received greater emphasis. See Section 3.9 of the Technical Considerations (Finance and Economics) for more information on promising activities to strengthen the health finance function.

HSS is spending that improves the efficiency, responsiveness and accountability in the host government’s financial systems for health, including financial management. Examples include:

- 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;
• 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.;
• Support to develop models of performance-based financing and linkages to HRH financing; and
• Health financing systems or mechanisms and insurance schemes to increase access to HIV/AIDS services.

HSS is not spending intended to improve the management and accountability of PEPFAR funds. Examples include:

• 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; and
• Audits or other examinations of financial management processes designed to determine compliance with USG regulations.

3.4 Information (including Strategic Information)

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. Examples include:

• Work to identify and resolve bottlenecks in information flows through the national health management information system (HMIS);
• 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;
• Building local capacity to interpret research and employ research results in policy dialogue; and
• Ensure civil society and private sector partners have the capacity and are feeding information into national systems.
HSS is not spending intended to improve monitoring, evaluation and reporting for PEPFAR. Examples include:

- 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; and
- Evaluation and research to inform PEPFAR strategies that have not been adopted by host countries;

3.5 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. Examples include:

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 Human Resource Information System (HRIS), managed by local entities on a continuing basis;
- Development and implementation of policy and guidelines for task-shifting and supportive supervision; and
- Development/strengthening of community health workers and community-based organizations to provide HIV/AIDS counseling and referral services.

HSS is not spending for human resources that meets only PEPFAR implementation needs, or does not enhance local capacity to further training. Examples include:

- Seconding staff to line positions for PEPFAR-specific program implementation;
- Direct training that does not include development of training systems and capacity; and
- Development and implementation of human resources policies that apply only to PEPFAR-supported staff.

3.6 Service Delivery (including Care, Treatment and 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 and other key stakeholders, such as civil society or private sector, at any or all levels (i.e., national, provincial, district, local). Examples include:

- Policy work that facilitates the quality, safety, and/or relevance of services;
- Development and 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 or strengthening 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. Examples include:

- Direct provision of services, including expansion and salaries;
- Direct in-service training that does not build capacity for training; and
- Policy or guidelines that target only PEPFAR-supported sites.

4 Linkages between Health System Building Blocks

HSS investments strengthen not only individual building blocks, but many activities strengthen multiple building blocks and enhance the interactions between the building blocks. PEPFAR country teams’ HSS strategies should take advantage of these interactions to optimize linkages and feedback loops between building blocks. Examples include of this are listed below.

- Strengthening SI and Health Information Systems requires capacitated cadres of HRH to support improvements in information infrastructure. HSS investments in SI human resources need to consider whether and how new SI cadres integrate into national strategic plans and staffing establishments, as well as what complementary HSS investments are required to ensure longer-term sustainability of these investments.
- Strengthening community-based adherence efforts may involve: policy changes to allow community health workers (CHWs) to do adherence counseling (governance); training programs for CHWs and strengthened supervisory skills of clinic staff to ensure quality of services (HRH); and increasing linkages between CHWs and clinic staff (service delivery).
- Implementing the new WHO treatment guidelines will involve: costing and funding of increased number of patients on ART (finance); policy change or revision to address
changes in recommended CD4 levels and drug regimens (governance); and may require changes to the supply chain (medicines and technologies).

- Task shifting, such as permitting lower-level cadres to administer rapid test kits or nurses to initiate and manage ART, can improve coverage of/access to HIV services and increase operational level efficiencies. However, complementary investments in supply chain and/or laboratory systems may be necessary to ensure that these health care workers have the supplies and commodities necessary to realize those system-level improvements.

5 Monitoring and Evaluation

As highlighted in sub-section 2 (Strategically Investing in HSS) of this Section, strategically investing in HSS requires an understanding of health system gaps and bottlenecks hindering the provision of HIV services, as well as linking HSS interventions to service delivery or health outcomes. HSS portfolio development 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 country teams should carefully monitor and evaluate their HSS strategy in terms of its effectiveness, cost-efficiencies, and long-term sustainability. PEPFAR’s MER operational guidance provides several new approaches and indicators for monitoring HSS investments.

6 Linkages and Wraparounds

6.1 Integration of Services

Integration of health services is a core principle of the GHI, and is consistent with leveraging the HIV service platform to create positive spillover effects for other health diseases, conditions and needs (see sub-section 2.3 (HSS Alignment, Support and Leveraging) of this Section). Integration of services also requires health systems strengthening along all building blocks. For example, integration of PMTCT, pediatric HIV and MCH may require: policy reforms to create an enabling environment (e.g., revisions to scopes of practice to permit nurse initiation and management of pediatric HIV treatment); organizational changes at the policy, program and facility levels; changes to curricula at the pre- and in-service levels; harmonized PMTCT, adult treatment and MCH information systems; heightened resource coordination with development partners; and restructuring of supply chain systems to support integrated service delivery. For more detail see PEPFAR Guidance on Integrating Prevention of Mother to Child Transmission of HIV, Maternal, Neonatal, and Child Health and Pediatric HIV Services (http://www.pepfar.gov/documents/organization/158963.pdf).

These technical considerations provide scope within which to benefit the broader health system through intentional spillovers and targeted leveraging. Well-designed HSS 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 GHI. As such, country teams are encouraged to work 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.

6.2 Capacity Building

PEPFAR defines capacity building as an “evidence-driven process of strengthening the abilities of individuals, organizations, and systems to perform core functions sustainably, and to continue to improve and develop over time” (346). Many HSS interventions are intended to build systems-level capacities to provide HIV/AIDS and broader health services through strengthening health system building blocks and their interactions. However, there are also other capacity building interventions do not necessarily strengthen health systems or their performance. When considering HSS investments in capacity building, country teams should take into account two important considerations.

First, because health systems are composed of individuals and institutions, teams need to consider which complementary capacities at the individual and organizational levels require targeting to result in strengthened health systems. For example, with task shifting, national-level capacity building of the MOH that results in revisions to national scopes of practice is, in itself, unlikely to improve supply of and access to HIV services. Capacity building interventions at the organizational level are also necessary components that could include: improving capacity of a district health office to plan and manage its health activities and helping civil society organizations to better link with each other and government services. Interventions are also needed at the individual-level and could include providing training in nurse-initiated and managed ART or helping CHWs to better support ART adherence counseling and referrals. Ensuring capacity throughout the system is a necessary component of an effective HSS strategy that achieves health system objectives described in Figure 9.

Second, particularly in the context of decentralization, capacity building needs are likely to vary by level of the health system. Many PEPFAR countries are or have undergone a process of decentralization which has resulted in the decentralized delivery of HIV/AIDS services. In the decentralized context, building leadership capacity of provincial or regional governments to manage local health system HIV responses, as well as building national capacity to formulate policies and regulations will both be necessary components for country ownership. With the decentralized delivery of services, ensuring adequate planning and budgeting capacity of District Health Management Teams will be as important as national-level technical leadership. For all PEPFAR countries, strengthening of both national and sub-national capacity is equally important and the focus of capacity building interventions will differ according to level of the health system.

6.3 Community System Strengthening

As with health system strengthening, strengthening community systems is a comprehensive approach requiring individual, organizational and system-level capacity building. *Community*
systems are defined as community-led structures and mechanisms through which members, organizations, and groups interact, coordinate and deliver their responses to the challenges and needs affecting their communities. Community systems may be defined geographically or by similar interests, such as PLHIV groups (370). Community systems strengthening (CSS) is an approach that promotes the development of informed, capable and coordinated communities, as well as community-based organizations, groups and structures (371).

CSS involves a broad range of community actors, enabling them to contribute as equal partners alongside other actors to the long-term sustainability of health and other interventions at the community level. This includes creation of an enabling and responsive environment in which these contributions can be effective. There are many dimensions along which community systems may be strengthened including: enabling environments and advocacy; community networks, linkages, partnerships and coordination; resources and capacity building; community activities and service delivery; organizational and leadership strengthening; and monitoring and evaluation and planning (371). The goal of CSS is to achieve improved health outcomes by developing the role of key affected populations, communities, and community-based organizations in the design, delivery, monitoring and evaluation of health services.

According to country context, investments in CSS may support a country team’s overall HSS strategy. Examples of CSS investments that align with HSS include: building managerial and technical capacities of civil society organizations to manage and provide HIV/AIDS programs and services; developing linkages among community actors, including government and the private sector, to generate demand for services; strengthening the advocacy role of media institutions or other civil society organizations; and leveraging local and indigenous organizations to establish continuous quality improvement systems. Country programs are encouraged to understand systems-level implications and interventions when implementing community-level activities.

6.4 Gender

Gender norms and inequities impact health system performance and achievement of health goals. For example, the quality of health services suffers if health providers stigmatize and/or discriminate against female and male members of key population groups, or there is an absence of policies, laws and regulations addressing gender workplace discrimination. The ability to monitor all dimensions of health systems performance suffers when gender-disaggregated strategic information is lacking.

PEPFAR teams should mainstream gender considerations into HSS strategies and programming. Examples of gender mainstreaming are listed below.

- Leadership/Governance and Financing: ensuring that gender considerations are integrated into national strategic plans and operational budgets; working towards laws, regulations and policies that address gender-based violence or stigma and discrimination of key
populations; capacity building of District Health Management Teams in planning, allocation of resources and monitoring of gender-responsive approaches;
- Service Delivery: addressing barriers different groups of men and women may face to access services under decentralized models of HIV service provision: ensuring male- and female-friendly and LGBT-friendly facility environments;
- HRH: ensuring gender dimensions of health integrated into pre- and in-service training curricula, such as awareness of gender-based violence or diminishing provider stigma and discrimination towards men who have sex with men;
- SI: ensuring availability of gender-disaggregated data; and
- Medical Products: ensuring equitable provision of HIV commodities to men, women and key populations.

7 **Additional Resources**

8 **Annex – Illustrative HSS Strategy Outline**

1. **Country Context**
   - Epidemiological context (burden/distribution of disease)
   - Health systems overview (including bottlenecks/challenges faced by the host government)
   - Country progress on country ownership and transition (see PEPFAR’s Monitoring, Evaluation and Reporting guidance for indicators of Country Ownership (1))
   - Strategic priorities of national health authority in strategic plans (e.g., Health, HIV/AIDS)
   - Existence of a Health Systems Assessment (HSA) or other assessments to inform HSS investments

2. **Current Support**
   - How PEPFAR’s HSS investments align with, support and leverage HSS activities of countries (e.g., HSS activities/national plans of the host country government) and other stakeholders, including those from other USG initiatives, donors (particularly the Global Fund)
   - Alignment with partner country HSS goals

3. **Planned focus areas – multi-year year strategic plan**
   - Priority areas: describe the criteria/guiding principles for prioritizing of HSS activities (e.g., building on current investments that are strongest; filling in gaps in other donors/governments activities; etc)
   - By HSS building block (as appropriate for the portfolio) describe health goals (i.e., health systems performance outcomes from the PEPFAR HSS Framework (access, coverage, efficiency etc), the bottlenecks and systems responses/activities (see table at end of this illustrative outline)
   - Use all available evidence and identify where there are gaps in knowledge and programming
   - Describe how PEPFAR proposed activities leverage those of other stakeholders
   - Describe how activities contribute to country ownership and transition
   - Broader linkages to GHI/other health areas

4. **M&E**
   - Discuss how activities will be monitored and evaluated (including links to health outcomes)
   - Develop M&E framework linked with PEPFAR indicator reporting
   - Describe how will/can the evidence base be increased
## HSS mapping examples

<table>
<thead>
<tr>
<th>PEPFAR Prevention, Care and/or Treatment Goal</th>
<th>Health Systems Building Block</th>
<th>Bottleneck(s)</th>
<th>Outcome(s)</th>
<th>System Strengthening Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased use of HIV/AIDS services by key populations</td>
<td>Governance/Leadership</td>
<td>Laws prohibit anal intercourse and prostitution</td>
<td>Inhibits MSM and SW access to health care</td>
<td>Legal reform/legislation supporting interventions for key populations</td>
</tr>
<tr>
<td></td>
<td>Human Resources for Health</td>
<td>Inadequately trained peer educators and service providers</td>
<td>Prevention intervention will not be implemented correctly, effectively and with efficacy</td>
<td>Development of national pre- and in-service training strategies for peer educators/service providers</td>
</tr>
<tr>
<td></td>
<td>Medical Supplies, Vaccines, Technologies</td>
<td>Weak supply and distribution system for condoms and lubricants to target populations</td>
<td>Failure of 100% condom policy</td>
<td>Supply chain strengthening</td>
</tr>
<tr>
<td>Option B+/pediatric treatment scale-up</td>
<td>Governance/Leadership</td>
<td>Scopes of practice do not allow non-physician clinicians to perform key ART initiation/management functions</td>
<td>Regulatory bottlenecks on HRH prevent scale up of ART</td>
<td>Legal/policy reform supporting Nurse Initiated and Managed ART</td>
</tr>
<tr>
<td></td>
<td>Human Resources for Health</td>
<td>Lack of: facility-based providers capacitated in initiating pediatric treatment; community-based HRH to follow up pediatric patients</td>
<td>Low pediatric treatment initiation/adherence; high loss-to-follow-up</td>
<td>Development of pediatric care and treatment modules for integration into national pre- and in-service curricula; formalization of CHWs in continuum of response for pediatric patients</td>
</tr>
<tr>
<td></td>
<td>Medical Supplies, Vaccines, Technologies</td>
<td>Weak supply and distribution system at lower-levels of the health system</td>
<td>Unavailability of ARTs to mothers and children</td>
<td>Supply chain strengthening</td>
</tr>
<tr>
<td></td>
<td>Strategic Information</td>
<td>Non-integrated HIV M&amp;E systems (ART, PMTCT, pediatric)</td>
<td>Inability to track HIV status over lifespan/across mother-infant pairs</td>
<td>Harmonize national patient tracking M&amp;E systems</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>PEPFAR Prevention, Care and/or Treatment Goal</th>
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<th>Outcome (s)</th>
<th>System Strengthening Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Scale-up</td>
<td>Policy/Governance</td>
<td>Policies on treatment and retention guidelines require updating and government endorsement</td>
<td>Lack of government clarity on directions of future programs and/or ownership</td>
<td>Update policies; revise national strategic plans to support scale-up plans. Link policies with financial requirements.</td>
</tr>
<tr>
<td></td>
<td>Finance</td>
<td>Ensuring short-term and longer term financing of treatment scale-up programs</td>
<td>Rate of treatment scale-up impacted</td>
<td>Costing of programmatic components for treatment and retention, and development of financing schemes to support program short-term and long-term program goals.</td>
</tr>
<tr>
<td></td>
<td>Human Resources for Health</td>
<td>Inadequate staffing, including distribution and retention of HCWs; reliance on donor supported staff.</td>
<td>Rate of treatment scale-up impacted; uneven availability of services, particularly in rural or underserved areas. Loss to follow-up.</td>
<td>Increase staffing and transition of HRH from donor-funded staff; develop and implement recruitment, retention and distribution plans; operationalize at sub-national levels.</td>
</tr>
<tr>
<td></td>
<td>Medical Supplies, Vaccines, Technologies</td>
<td>Weak supply chain systems, including for management and logistics capacity. Poor transparency; ensuring drug/commodity quality.</td>
<td>Uneven distribution of drugs and lack of system reliability; quality assurance compromised.</td>
<td>Supply chain strengthening to meet country needs, including for management and logistics capacity. Supply chain information system; adequate financing and reduced reliance on donor management and funding.</td>
</tr>
</tbody>
</table>
Introduction

What’s new in 2014

This year’s section on human resources for health builds on guidance from previous years while taking into account evolving PEPFAR program priorities and strategies. In particular, this year’s section:

- Provides teams with a clear investment framework for human resources for health as a tool to describe, map out and align health systems strengthening interventions with PEPFAR priorities (e.g., Blueprint commitments) and strategic directions (e.g., Country Ownership).
- Provides teams guidance on aligning investments in human resources for health with Country Ownership principles.
- Highlights the cross-cutting importance of national human resources for health leadership.

PEPFAR Blueprint

PEPFAR’s Blueprint for achieving an AIDS-free generation makes several commitments related to Human Resources for Health. These include support for task-shifting and -sharing – such as within the PMTCT and treatment platforms – as well as integration of health services – such as with tuberculosis treatment.

Technical Background

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 directed 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, with chronic problems of attrition facing many PEPFAR countries, investments in training alone will not lead to sustained workforce improvements and those efforts must be coupled with investments in supporting the recruitment, retention, and more efficient use of health workers within countries health systems. 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 working lifespan approach of the health worker (from education and credentialing, through recruitment, retention, and retirement) (372). The health
workforce system in this approach includes the public, private, and voluntary sectors. 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.

As highlighted by PEPFAR’s Blueprint, investing in HRH is an essential part of supporting HIV service delivery. HRH investments are needed for expansion of HIV services through scale-up of Antiretroviral Therapy (ART), Prevention of Mother-to-Child Transmission (PMTCT)—including Option B+—and Voluntary Medical Male Circumcision (VMMC), as these programs require new health worker competencies and increased service volume. HRH investments are also needed to facilitate integration of services, such as HIV and TB, family planning, maternal and child health, and malaria. According to country context, HRH activities should be planned in conjunction with these key PEPFAR program areas. Investing in HRH is also critical to PEPFAR’s goal to foster country ownership of the national HIV response. The capability of countries to sustain their HIV response will depend on the capacity of the health workforce-spanning preventive, curative, public health, and administrative positions. PEPFAR should invest in the systems of training, credentialing, planning, management, recruitment and retention, so that countries have capacity to sustain improvements to their health workforce even as PEPFAR’s role evolves or diminishes.

2 PEPFAR HRH objectives

Investing in HRH represents a potentially broad scope of work to improve health workforce functioning and provision of HIV/AIDS services. As illustrated in Figure 10, improving HRH outcomes—overall numbers, distribution (e.g., geographic, skills, gender), and performance (e.g., quality, productivity)—involves addressing several inter-related dimensions, including Human Resource Management systems, policies, leadership and finance, educational systems and partnerships. As an example, supporting PMTCT Acceleration Plans and rolling out of Option B+ is likely to require a combination of pre-service education investments to increase HRH production (often of non-physician clinicians), an enabling policy and regulatory environment (e.g., sanctioned task sharing), increased financial resources to retain providers delivering PMTCT services, and private sector health providers partnering with non-governmental organizations to integrate new cadres (e.g., peer educators) into the continuum of response and national health systems, and a robust Human Resources Information Management System to target supply of HRH to needs for PMTCT services.
The above-referenced framework is a useful reference point in considering strategic entry points for HRH investments. In the absence of a national HRH strategic plan, the framework can serve as a basis by which teams and national stakeholders can diagnose HRH weaknesses that impact countries’ HIV/AIDS response. For countries with HRH strategic plans, it can help teams and stakeholders identify which HRH dimensions are being addressed, and which gaps PEPFAR investments may be able to fill.

Not all HRH bottlenecks to scaling up HIV/AIDS services issues can be addressed by PEPFAR in a given funding cycle, nor can they be addressed by PEPFAR alone. To help PEPFAR country teams prioritize HRH investments, the HRH Technical Working Group (TWG) developed “Priority Areas of PEPFAR HRH interventions”, in the January, 2009 “State of the Program Area”. 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 to strengthen and foster sustainability of the overall health workforce system. The objectives also serve as a reference point from which country teams should develop a country-level PEPFAR HRH strategy, bearing the following principles in mind. First, HRH interventions should be aligned with and in support of a national HRH strategy, focusing on interventions that are expected to have the greatest impact on strengthening the national HIV response. Interventions should be targeted at health workers that provide HIV/AIDS services, but can also leverage the HIV platform to improve the overall health workforce (e.g., supporting pre-service education of cadres that will apply HIV competencies when delivering services). Second, in the context of the Global Health Initiative (GHI), it is important to identify opportunities where PEPFAR can also coordinate with and leverage other non-PEPFAR United States Government (USG) HRH investments, as well as with other donors and the private sector. Third, HRH activities should be evidence-based where possible, and based on an understanding of health workforce dynamics (i.e. supply, demand, and outmigration) in the country. In following these principles, country teams are encouraged to actively participate in National HRH TWGs, HRH Observatories, and Country Coordination Mechanisms (CCMs). Additionally, as a priority of PEPFAR, country teams should work to build in-country capacity, ownership, and sustainability of HRH interventions within both the public and private health sectors.

3. HRH investments and Country Ownership

HRH investments are one of the main drivers of recurrent costs of PEPFAR programs and national health systems. As PEPFAR works with countries to increasingly lead, manage and finance national HIV responses, national ownership of investments in HRH in terms of interventions and personnel will take on increasing importance. PEPFAR countries are categorized into Country Ownership categories that broadly define the current vision for U.S. engagement and level of investment. PEPFAR’s approach to HRH investment will differ slightly for each category. The following outlines strategies and considerations about strategic
approaches country teams should take in their respective settings. Country teams are encouraged to follow-up with the PEPFAR headquarters HRH Technical Working Group for further assistance.

3.1 HRH investments by country classification

3.1.1 Long-term Support

HRH investments are intensive, comprehensive and directly support PEPFAR program scale-up and sustainability goals. Support for salaries, scholarships, equipment and supplies, infrastructure, and direct implementation of HRH activities by PEPFAR funded organizations may be necessary in this context. As part of broader planning for sustainability of PEPFAR programs, country teams are encouraged to develop multi-year plans for how the implementation of these HRH activities will be increasingly managed and financed by host country institutions over time. These plans should include how health care workers on PEPFAR-supported salaries will be transitioned to host-country institutions A focus on helping to define cost-effective staffing models for key HIV services, in partnership with professional associations and other national leadership, is encouraged in this context.

3.1.2 Targeted Assistance

HRH investments are focused to directly support the priority program areas for the country program, such as key populations or PMTCT. HRH investments are focused on increasing country ownership of HRH interventions. PEPFAR HRH support is shifting away from intensive, comprehensive, and direct implementation and funding, towards technical guidance and support, such as through training, mentorship, and technical assistance. In this context, local institutions are the primary implementers of HRH interventions, with PEPFAR funded organizations increasingly serving in a technical advisory capacity. This transition may require an increased level of HRH investments in the short-term, such as to accommodate any shifts in the PEPFAR program portfolio (e.g., towards key populations) or to ramp up capacity of local institutions that will be taking over increased ownership of HRH interventions. A special focus on cadres needed for public health or clinical service delivery to key populations is also encouraged in this context.

3.1.3 Technical Collaboration

HRH interventions are mostly technical in nature (as opposed to financial or implementation support) and are focused on ensuring the sustainability of the national HIV response. Investments support the ongoing technical engagement of subject experts from the U.S. and other countries with professionals from host country institutions to strengthen HRH approaches. Activities largely comprise training, mentorship, collaboration on HRH policies or strategies, and other forms of technical assistance. Direct funding to host country institutions is modest and does not typically support salaries or other recurring costs.
3.2 PEPFAR health worker support

Applicable to all country categories is ensuring the appropriate absorption of PEPFAR supported health worker positions into the public sector system (or by voluntary or private sector employers) over time. As part of its effort to expand access to HIV/AIDS services, PEPFAR has been partially or wholly subsidizing the wage bill of large numbers of health workers in over 30 countries. Country team members should refer to agency-specific guidance to determine acceptable forms of salary support, as well as other financial/non-financial s.

In the context of Country Ownership, PEPFAR is increasingly emphasizing more sustainable approaches to meeting HRH needs for the long term. PEPFAR teams should work with partner governments to plan for the eventual integration of affected cadres into national health systems, including the eventual assumption of functions, management and wage bill by governments or other national entities. While the pace of and entry points for this transition will differ by Country Ownership country category, health worker transition must be accomplished without interruption or significant changes to quality of services offered by the health workers currently being supported by PEPFAR, and therefore, should be approached with careful planning by country teams. To assist country teams in health worker transition, the HRH Transition Resource Guide (available on pepfarii.net) is available on pepfarii.net to facilitate planning, implementing and monitoring transition of health worker support. This interactive resource is a newly developed reference for all categories of PEPFAR countries that can help guide thinking and planning of transitioning of PEPFAR supported health worker positions. It aims to capture lessons learned from PEPFAR countries that have experience with transition of PEPFAR supported health workers. Transition of all PEPFAR supported cadres should be considered and not limited to more formal cadres.

4 Interventions to support PEPFAR HRH Objectives

4.1 Interventions to support: national HRH planning and management

4.1.1 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. As illustrated in Figure 10, 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 (both public and private) 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 an HRH assessment or an Human Resource Information System—to project the supply and demand for health workers in the country over several years (usually five to 10);
identifies approaches, including necessary financial resources, 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 (374).

PEPFAR-supported HRH activities should align with this national plan, where one exists and is implemented as an integral component of the national health strategy. 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 in planning expanded recruitment, the deployment of public sector staff, or the integration of private health providers supporting public health services. 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 implement the national HRH plan and achieve health goals. In particular, PEPFAR teams planning to support the scale-up of ART, PMTCT, VMMC, and other service delivery 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 (see sub-section 6 (Additional Resources) of this Section).

### 4.1.2 Human Resource Information System

An Human Resource Information System (HRIS) is a systematic means by which to acquire, store, manipulate, analyze, retrieve, and distribute relevant information about the health workforce, including workforce demographics and capacity, training needs, and migration patterns. An 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. An 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 human resources data in a sustainable manner.
An HRIS ideally encompasses each stage of a health worker’s 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) (375). An HRIS enables 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. An 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, an HRIS contain routine reports on key information required by decision makers that can easily be disseminated. Given the varying levels of Information Technology (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 an HRIS is developing a clear understanding of the information needs of the end user(375). 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), other MOH decision-makers, and private health sector association participation. WHO-supported national health workforce observatories can be a resource for improving the strategic use of HR data in your country.

4.2 Interventions to support: strengthening pre-service education institutions to improve the quality, output and relevance of graduates

To meet the PEPFAR’s Congressional target of 140,000 new health workers, PEPFAR is supporting the production of new graduates from pre-service educational institutions. Pre-service education (PSE) 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 and achieve improved health outcomes. 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.

Strengthening pre-service institutions requires the involvement of multiple stakeholders across the public and private sectors—including the MOH, public and private educational institutions, workforce planning bodies, public and private professional associations, regulatory bodies, local organizations and communities—and is necessary for building ownership and sustainability of PSE investments. Country teams should carefully consider with the MOH and other stakeholders how PEPFAR can best support pre-service education in each country. Pre-service investments also provide an opportunity to strengthen other HRH activities. For example, if there is an
emphasis on HRH in rural areas, retention strategies can be coordinated with pre-service investments, such as preceptor training. 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. Additionally, pre-service investments can and should be integrated and linked to in-service training systems, such as via preceptorships for new graduates, agreement of job competencies, and sharing of curricula (see also sub-section 5.2 (The Medical and Nursing Partnership Initiatives) for further information on leveraging central-level investments in pre-service education).

PEPFAR supports PSE towards achieving the 140,000 production target in a variety of ways. 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. 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 to be published in 2013 and can serve as a reference for addressing new and emerging issues in health professional education.

Different aspects of country ownership can 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; and
- 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.

Country teams considering the use of PEPFAR funds to strengthen pre-service education should contact the PEPFAR HRH TWG for further guidance on investments that contribute to the 140,000 HRH target. This guidance includes information on eligibility criteria (e.g., training duration, eligible cadres) and attribution methodologies.
4.3 Interventions to support: ensuring the standardization, quality, and coordination of in-service training

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 public and private 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.

4.3.1 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 their 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 include:

- **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; and
- **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.

### 4.3.2 Performance Assessment and Quality Improvement

PEPFAR country HRH teams should coordinate with other HIV technical areas teams in supporting appropriate government and private sector entities to design and institutionalize approaches and standardized tools that are used to assess and improve quality of care provided by health workers in the workplace. For example, supporting the development of systems that employ continuous quality improvement (CQI) methodologies, which include building HRH knowledge, skills, and capacity for ongoing problem identification and problem-solving. This may also include 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, Uganda, and Tanzania this approach has also been integrated with performance management techniques and has demonstrated impact on both HRH performance and service delivery outcomes. Approaches have also been successfully utilized at the community level to support improved Community Health Worker (CHW) performance.

### 4.3.3 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; private health sector associations and
entities; 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, palliative care, information technology, 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.

4.4 Interventions to support: advancing innovative and cost effective models of service delivery and skill mix

4.4.1 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”.10

In January 2008, the WHO, with PEPFAR support, released Global Recommendations and Guidelines for Task Shifting for HIV/AIDS (376). 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/-sharing 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, 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(35). Nurses and other non-physicians clinicians 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.

10 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 (12). Both aim to improve the efficiency and effectiveness of service delivery by maximizing the performance of health workers.
Task-shifting/-sharing to community health workers 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 health system (public and private sectors). 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.

### 4.4.2 Integration of Community Health Workers into Continuum of Response

Utilization of community health workers is also an important strategy in addresses HRH capacity constraints and in expanding coverage of key health promotive, disease preventive, and curative interventions. Within the HIV context, CHWs are integral for strengthening the HIV continuum or response. As many countries are scaling-up their national CHW programs, PEPFAR partners CHW efforts (which may include a variety of HIV community-based cadres) should be within the context of a country’s strategy for CHWs, supporting their performance and where applicable integration into the overall health system (public and private sectors). This may include establishment of mechanisms for collaboration between CHWs and their more formal cadre counterparts. Strategies for supporting CHW performance include standardization of competencies and tasks, initial training and periodic retraining, and support which may include supervision, teamwork, and financial and non-financial incentives from both the health system and communities in which CHWs work. Recommendations for supporting CHW performance can be found in the 2012 USG CHW Evidence Summit final report (377).

### 4.5 Interventions to support: investigating and applying recruitment and retention strategies

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 (see also sub-section 5.2 (The Medical and Nursing Partnership Initiatives) for further information on leveraging central-level investments in pre-service education). 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 (325), areas of intervention to be considered are: education, regulation, financial incentives, and 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 workers’ 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 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. 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) are encouraged. Costing of retention interventions is encouraged.

4.6 Interventions to support: advancing health worker regulation and policy

Regulatory bodies and professional associations representing both the public and private health sectors 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 (378)(379):

- 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); and
- 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 training, especially in the context of a continuing professional development program), or by improving their skills in policy, advocacy, and coalition building.

5 Cross-cutting interventions and considerations

5.1 HRH Leadership and Management 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. Interventions to support the development of leadership and management skills should take place at all levels of the health system, including within the Ministry of Health (MOH), private health sector, and within important non-governmental service delivery providers. Leadership and management skills building interventions should also take place at all stages of the HRH lifespan, from
integrating management skills-building in pre-service educational programs to strengthening local management training institutions to provide training for practicing HRH.

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 across both the public and private health sectors. 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.

5.2 The Medical and Nursing Partnership Initiatives

The centrally-supported Medical and Nursing Partnership Initiatives (MEPI (see www.mepinetwork.org) and NEPI (see http://www.pepfar.gov/partnerships/initiatives/nepi/), respectively) provide platforms upon which to amplify, optimize and anchor PEPFAR investments in HRH. There many ways that country teams can coordinate with and leverage these initiatives which are focused on the second priority HRH objective—strengthening pre-service education institutions. For HRH investments focused on pre-service education, MEPI/NEPI networks and institutions are a resource for technical collaboration, particularly in terms of training and mentorship. NEPI institutions in particular may be a technical resource to draw upon in terms of nursing leadership and management development. More broadly, in many countries the MEPI and NEPI networks has forged close connections with the Ministry of Health and may be able to serve as a resource to country teams in support of broader HRH efforts. For example, MEPI and NEPI programs are often linked closely to governmental HRH planning processes and can provide an entry point for country teams considering workforce planning interventions. Country teams are encouraged to consider investments in HRH activities that leverage the MEPI and NEPI platforms.

5.3 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 with HRH investments, such as 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 (e.g., training, equipment, management) that
provide quantitative and qualitative data for monitoring and evaluating the progress and impact of HRH interventions within both the public and private health sectors. Additionally, where possible, investment in HRH research is encouraged.

5.4 Gender

Attention to women, girls, and gender equality is a core principle of PEPFAR and the GHI, and should be considered in the development of a PEPFAR HRH strategy. PEPFAR gender guidance being issued in 2013 requires country teams to re-assess and formulate a new gender strategy. This is an opportune time for PEPFAR HRH advisors to work with their colleagues to identify health workforce interventions necessary to support the overall PEPFAR gender strategy. Examples include: promoting pre-/in-service training and mentoring on gender issues for relevant professions (e.g., community-based workers and health care personnel, including informal health workers) such as recognizing signs of gender-based violence, reducing stigma and discrimination against female sex workers, and making PMTCT/ANC settings more welcoming to men; training of local law enforcement and members of the judiciary on laws that promote gender equality and protect women, girls and LGBT rights (PEPFAR Gender Guidance, 2013). Additionally, gender issues within the health workforce should also be considered. This may include understanding how gender issues may impact health worker team dynamics (such as the relationship of doctors and nurses in a task-shifted environment); and addressing gender inequities that may impact recruitment and retention in pre-service and in-service education, training, and career advancement.

6 Additional Resources

*Human resources for health (HRH) tools and guidelines:*
http://www.who.int/hrh/tools/planning/en/index.html

*Global Recommendations and Guidelines for Task Shifting for HIV/AIDS:*
3.5 Gender

1 Introduction

1.1 What’s New in 2014

Teams should refer to new PEPFAR Gender Guidance—forthcoming in late 2013—for incorporating gender considerations into PEPFAR programming.

1.2 Gender and HIV: Why, Who, What and How?

1.2.1 Why is integrating gender into HIV programs important?

Integrating gender into HIV programs is critical because:

- Gender norms, relations, and inequities affect health outcomes for everyone;
- Understanding the unique needs of men and women, boys and girls, and other gender identities helps identify target populations and dedicate resources where they are most needed;
- Ignoring gender-related barriers, such as norms and expectations and gender-based violence can negatively affect service utilization, treatment adherence, and health outcomes for everyone; and
- Responding to the unique needs of men and boys, women and girls, and other gender identities may improve program outcomes and enhance sustainability.

1.2.2 Who benefits from gender integration in HIV programs?

Among low- and middle-income countries worldwide, HIV is the leading cause of death and disease in women of reproductive age. In sub-Saharan Africa, 60% of people living with HIV are women. In some countries, prevalence among young women aged 15-24 years is on average three times higher than men of the same age.

Men and boys are affected by gender expectations that may encourage risk-taking behavior, discourage accessing health services, and narrowly define their roles as partners and family members. On average, rates of HIV testing and treatment are lower among men than women. Gender norms around masculinity and sexuality also put men who have sex with men (MSM) at increased risk for HIV. Globally, MSM are 19 times more likely to be HIV-positive compared to the general population.

Finally, norms around gender identity and sex put transgender populations at greater risk for both GBV and HIV. Transgender women are 48 times more likely to have HIV compared to others of reproductive age.
These disparities are the result of biological, structural, and cultural conditions, as well as stigma and discrimination that affect men and women, boys and girls, and other gender identities differently and impede access to resources that can prevent and mitigate HIV.

1.2.3 **What does it mean to integrate gender into HIV prevention, care, and treatment?**

Integrating gender into HIV programs means responding to the unique men and women, boys and girls, and other gender identities so they are equally able to:

- Access and utilize HIV prevention, care and treatment services initiate and practice healthy behaviors;
- Improve their health outcomes; and
- Live lives free from violence, stigma and discrimination.

1.2.4 **How can the PEPFAR Gender Framework be applied to PEPFAR-supported programming?**

Gender should be integrated into each step of the program cycle.

2 **Additional Resources**

- What Works for Women and Girls?: [www.whatworksforwomen.org](http://www.whatworksforwomen.org)
- Integrating Multiple PEPFAR Gender Strategies to Improve HIV Interventions: Recommendations from Five Case Studies from Programs in Africa: [http://www.aidstar-one.com/focus_areas/gender/resources/compendium_africa](http://www.aidstar-one.com/focus_areas/gender/resources/compendium_africa)
- IGWG Gender and Health Toolkit: [http://www.k4health.org/toolkits/igwg-gender](http://www.k4health.org/toolkits/igwg-gender)

[^11]: The Compendium of indicators covers programmatic areas vital to the intersection of gender and HIV. Each of these programmatic areas includes a number of indicators that may be used at national, regional or programmatic levels.
• AIDSTAR-One. Gender Technical Area Resources: [http://www.aidstar-one.com/focus_areas/gender_technical_area](http://www.aidstar-one.com/focus_areas/gender_technical_area)


• Addressing violence against women in the context of HIV and AIDS: A programming tool. WHO. (Forthcoming)

• UNAIDS Gender Assessment Tool (Forthcoming)

• Resources for the Clinical Management of Children and Adolescents Who Have Experienced Sexual Violence [http://aidstar-one.com/focus_areas/gender/resources/prc_technical_considerations](http://aidstar-one.com/focus_areas/gender/resources/prc_technical_considerations)
3.6 Private Sector Engagement and Public-Private Partnerships

1 Introduction
Private sector engagement (PSE) and public-private partnerships (PPPs) play a critical role in strengthening and extending the principle of shared responsibility in the PEPFAR Blueprint to achieve an AIDS-free generation. The ultimate goal of each PPP is to allow more people to benefit due to the additional resources—whether monetary or technical—brought to the partnership by the private sector organization. Doing so can increase efficiency, increase effectiveness and harness the comparative advantages of all partners. It can also be a tool to build capacity of local country partners.

1.1 PEPFAR Blueprint
Key PSE PEPFAR Blueprint strategies include:

- Maintain and expand current partnerships, as well develop new partnerships that enhance country ownership and shared responsibility;
- Create collaborations around private health sector delivery of services to expand coverage and quality of care;
- Support reporting and evaluation of private sector engagement to assess impact and share lessons learned; and
- Actively seek and apply the core competencies of the private sector in strengthening the global HIV/AIDS response at every level, including local, regional, and global.

1.2 Technical Background
PEPFAR defines Public Private Partnerships (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. By leveraging private sector resources (financial and expertise), PPPs enable the U.S. government and private sector entities to enhance their efforts. PPPs are characterized by jointly defined objectives, program design and implementation, and the sharing of resources, risks, and results.

Country teams are encouraged to build and support local PPPs within the Country Operational Plan (COP) that draw on a diverse set of stakeholders from the private sector. These private sector stakeholders may include 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 responsibility 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 utilizing the management, marketing and core business expertise that private business enterprises bring to bear.

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 (TWG). PPP models, technical assistance opportunities, and information on multi-country PPPs are also available upon request. Key areas for technical assistance include, but not limited to: a) Strategic planning and private sector landscape analysis, b) Convening and dialogue of local and global PPP stakeholders, c) PPP Policy development at the national and local levels, and d) Design of demonstration to scale programs. Country teams are encouraged to contact the Private Sector Engagement Office of the Office of the Global AIDS Coordinator (OGAC) through their Country Support Team Lead (CSTL) to assist during this process.

2 Technical Considerations

2.1 Defining features 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 that a private sector partner must be contributing resources. PPPs are activities where both parties invest new resources toward a common purpose. Examples of partnerships that are not PPPs include: a contract with a private company or private health sector that directly pays for the delivery of services; an activity that will build off an existing investment but with no new financial resources or in-kind contributions towards the partnership activity. If in doubt, ask yourself, “Is the partner giving something of real value to the partnership?” Also please consult with the PPP TWG through your CSTL.

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:

- Coherence with country strategy and PEPFAR goals in prevention, care and treatment and orphans and vulnerable children: 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 required 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.

### 2.2 Partner Determination

USG country teams may consider new partnerships with private entities in a variety of sectors with diverse core competencies. 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.

Because private entities are diverse and have different motivations, country teams are responsible for vetting potential partners to ensure their suitability. 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, APS processes, grants, etc.) and due diligence protocols should be used. However, 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.

### 2.3 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 are recommendations for narrative reporting on PPPs within the COP and Annual Performance Results (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; and

- **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 or the Interagency TWG 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.

### 2.4 Country Contextual Considerations

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, adhere to 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, Ethiopia, 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. PEPFAR’s PSE Team and PPP TWG strongly encourage country teams to communicate opportunities and seek additional support to help develop and implement successful PPP projects and strategies.
3 Linkages and Wraparounds

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. Examples include private sector engagement to increase access to PMTCT services and B+ rollout, and global partnerships to improve laboratory and health systems strengthening.
3.7 NUTRITION AND HIV/AIDS

1 Introduction

HIV and malnutrition interact in a vicious cycle. HIV and associated opportunistic infections can cause or aggravate malnutrition by reducing appetite, increasing energy needs, impairing nutrient absorption and causing nutrient losses through frequent and persistent diarrhea. Malnutrition can also hasten the progression of HIV to AIDS, further weakening the immune system, increasing susceptibility to opportunistic infections (OIs) (e.g., tuberculosis (TB)) and reducing the effectiveness of both anti-retroviral therapy (ART) and the treatment of OIs. Even with ART, chronic HIV disease requires continued nutrition management and support to mitigate the increased risks of arteriosclerosis, diabetes, anemia and osteoporosis associated with HIV and ART. In addition, food insecurity and malnutrition are endemic in most PEPFAR countries, particularly in sub-Saharan Africa.

Nutrition and HIV/AIDS, including nutrition assessment, counseling and support (NACS), economic strengthening, and livelihood and food security assistance, represents a critical component of comprehensive HIV programs to improve clinical outcomes and alleviate the impact of the HIV on individuals and families. It is critical to integrate this cascade—nutrition assessment, counseling, and support—starting with nutritional assessment for all people living with HIV and orphans and vulnerable children benefitting from PEPFAR clinical and community-based programs. Nutrition and HIV/AIDS has evolved 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.

1.1 What’s New in 2014

PEPFAR and WHO, under the umbrella of the PMTCT IATT, have launched The Partnership for HIV-Free Survival (PHFS) to assist national efforts to integrate PMTCT, MNCH and maternal/infant nutrition through the effective implementation at scale of the 2010 WHO PMTCT guidelines, including the Guidelines on HIV and Infant Feeding (the guidelines provide normative guidance on how the continuum of care can be strengthened and improved for HIV-infected mothers and their infants, countries are still working out how to effectively implement these guidelines at scale). Initially launched in six countries (Tanzania, Kenya, Uganda, Mozambique, Lesotho and South Africa), the PHFS supports linkages between PMTCT and NACS programs by emphasize integration and implementation through the use of Quality Improvement (QI) methods. The PHFS will particularly focus on postnatal retention and care establishing best practices in one or two districts of each country and then rapidly spread the implementation lessons throughout the country. The PHFS learning platform will also allow best practices to be shared among countries to drive implementation and scale-up. The PHFS is not limited to the initial six countries – interest in the PHFS should be directed to the NACS TWG.
2 Nutrition and HIV/AIDS Program Priorities

The Food & Nutrition Technical Working Group (F&N TWG) has identified four areas of programmatic focus:

1. NACS in the continuum of care.

2. Integration of PMTCT, MNCH & nutrition within 1,000 days of pregnancy and the first two years of life.

3. Economic strengthening, livelihood and food security (ES/L/FS) support targeted to vulnerable patients and families.

4. Monitoring and evaluating NACS activities along the continuum of response.

These four focus areas highlight critical elements for country teams to consider as they develop a nutrition portfolio within their Country Operational Plan (COP).

2.1 Nutrition Assessment, Counseling and Support in the Continuum of Care

Figure 11, below, depicts NACS from a patient perspective. Access to NACS services can be provided through multiple points of entry, including HIV Testing and Counseling (HTC) and HIV/tuberculosis (TB) clinical care, antenatal care (ANC)/Prevention of Mother to Child Transmission (PMTCT)/Maternal, Neonatal and Child Health (MNCH) care, and community referrals. Comprehensive nutrition assessment is critical to inform clinical management and counseling, as well as to determine appropriate support for individuals and families at both clinic and community levels.
The following are key components of NACS for individuals attending health clinics for HIV care and treatment.

### 2.1.1 Nutrition Assessment

#### 2.1.1.1 Prioritization of nutrition assessment within NACS

While food support is often the most visible nutrition intervention and attracts the greatest attention, nutrition assessment is a critical component of care and support for PLHIV and orphans and vulnerable children (OVC). Strong PEPFAR programs will ensure that nutrition assessment is 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.

Note that nutrition assessment, at a minimum, should include recording of measures of height and weight for adults, and for children, plotting of growth relative to a standard growth curve or use of mid-upper arm circumference measurements. Comprehensive nutrition assessment also includes evaluation of clinical and dietary factors, as well as referral to community level assessment of household economic and food security status.
2.1.2 Nutritional Counseling

2.1.2.1 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 is an integral component of NACS within care and treatment services at both the clinic and community levels.

2.1.2.2 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 economic strengthening, livelihood and food security assistance, as well as community health services (e.g. home-based care (HBC) providers and Community Health Workers (CHWs)).

In counseling, food security assessment for the individual and the family should be made to appropriately link services at the community level. These services may be wraparounds provided by other U.S. government programs or other development partners.

2.1.2.3 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. Consequently, a basic tenet of NACS is to support referral, retention and adherence to clinical health care to address the underlying health problems that contribute to malnutrition. It is well established that 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.

2.1.2.4 Addressing gender issues in the provision of NACS

Key activities include:

- Identifying and addressing barriers to women’s and girls’ access and adherence to quality nutrition services, including screening for gender-based violence and referrals to services;
- Designing and implementing 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;
• Integrating activities to increase women’s and girls’ access to income and productive resources as an essential component to ensure sustainability and address underlying gender inequalities contributing to HIV and malnutrition; and
• Addressing the gender norms that influence men’s and boys’ health-seeking behaviors and their willingness to use NACS services.

2.1.3 Nutritional Support

2.1.3.1 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 used 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 three to six months, on the basis of clear anthropometric entry and exit eligibility criteria or vulnerability (particularly infants six to 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.

2.1.3.2 Prioritization of NACS food support within and across sites based on relative vulnerability

Key activities include:

• Complementary food for all HIV-exposed infants from six months up to two years of age, irrespective of anthropometric status;
• Supplementary food to women in PMTCT programs who are underweight or fail to gain adequate weight in pregnancy or are underweight during lactation;
• 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 five to 19 years of age); and
• Therapeutic/supplementary food to adult HIV/AIDS patients w/ BMI < 18.5.

2.1.3.3 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 those under five, 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. Overall, the emphasis in NACS programs should be 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.

Figure 12, below, shows the NACS program from a patient perspective, nested within the policy and program environment that supports the most effective service delivery. On the left side of diagram, there is a list of key health systems components that should be in place and under consideration when developing NACS programs at the clinic and community levels, and on the bottom right are suggested programs for linkage that will improve the continuum of care; namely, the Global Health Initiative, Feed the Future, and Scaling-Up Nutrition (SUN)/1000 Days, which focuses on maternal/infant nutrition support beginning in pregnancy and extending through the first two years of life. The resources at the top right are critical elements for successful program implementation. PEPFAR country programs developing a strategy for integrating NACS within care and treatment services may use this framework as a checklist for program elements that serve to categorize and define key activities for funding and implementation.
2.2 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. Current WHO guidelines on PMTCT include recommendations for ARV interventions that can drastically reduce the risk of MTCT prenatally and postnatally. These include lifelong ART for all HIV-positive pregnant and breastfeeding women regardless of CD4 count or clinical stage (Option B+) or during the MTCT risk period, and then lifelong for women with CD4 count under 350 who are eligible for ART for their own health and account for more than 80% of total MTCT. MTCT is typically reduced to under 5% with ART – the goal of eMTCT – versus ~35% without ART.

The current 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 ARV adherence, infant feeding practices, nutrition and health. Special attention should be given to link counseling to early infant diagnosis to dissuade premature weaning (i.e. before 1 year of age) if the infant tests HIV-negative, and to counsel mothers to continue breastfeeding if the infant is HIV-positive. Regular assessment, counseling and support should be provided for the mother and infant, with an emphasis on encouraging exclusive breastfeeding for the first six months of life, providing appropriate complementary feeding beyond six months of age, and supporting pre/post-weaning during the second year of life.

Establishing a PMTCT *continuum of care*, including PMTCT longitudinal registries and at least quarterly clinical visits, should facilitate tracking of mother-infant pairs, a focus on improving maternal health and nutritional status, and provision of basic child survival interventions through the first 24 months of life. Programmatically, this translates into a number of priorities:

- Emphasis on ART with good adherence and retention for all PMTCT women who are eligible for treatment for their own health or initiate ART under Option B+, and ARV prophylaxis for the duration of breastfeeding if the mother is not yet initiated on ART.
- Provision of antenatal and postnatal counseling to support optimum infant feeding, nutrition and health;
- Promotion of exclusive breastfeeding for the first six months of life, adequate complementary feeding beyond six months of age and provision of complementary food if access is limited, and 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 or inappropriately weaned;
- Rapid referral of HIV-positive infants and children to ART and support to ensure adherence and retention;
- Promotion of improved pre- and postpartum maternal and infant nutritional and health status, including regular NACS support and supplementary feeding support if there is inadequate weight in pregnancy or the mother or infant is underweight as assessed by MUAC (when pregnant or up to six months postpartum) or Body Mass Index (BMI);
- Provision of the basic preventive care package for infant and young child survival, including routine immunizations, growth monitoring, micronutrient supplementation and regular clinic referral, assessment and treatment for infections; and
- Provision of family planning counseling and support in the antenatal and postnatal period, including lactational amenorrhea method (LAM) in conjunction with exclusive breastfeeding during the first 6 months of infancy and transition to a modern method of contraception.
2.3 Economic Strengthening, Livelihoods and Food Security

Care and treatment facilities assist in meeting the health needs of PLHIV, their families and OVC through the provision of NACS and other clinical services. However, these services are not able to address underlying economic and food insecurity issues that can compromise the success of care and treatment and the long-term survival of PLHIV; nor are they able to address the livelihood and food security needs of OVC and their caregivers. To mitigate those issues, NACS programs link patients to community services that provide economic strengthening, livelihood and food security (ES/L/FS) support. Priority interventions for ES/L/FS assistance include:

- 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 patients and their families, including OVC;
- Establishment of gender-specific approaches for ES/L/FS assessment, referral and support;
- Creation/fostering of linkages between NACS and Feed the Future, Title II and other ES/L/FS programs;
- Establishment of referral and tracking mechanisms for individuals in clinical care and their families to ES/L/FS services in their communities; and
- 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.

Figure 13 highlights the need for a community-based organization (CBO), local government or other entity to assess patients/families referred from clinical care for household resilience and food security, link them with appropriate community services, and track outcomes.
3 Monitoring and Evaluation

With the scale-up of NACS activities, monitoring and evaluation data are needed to assess the effectiveness of interventions, inform and improve program design, report results, identify successful and unsuccessful approaches, and plan and budget for expansion of activities as needed.

It is critical that each country develop a monitoring and evaluation framework and select indicators that will provide decision-makers and key stakeholders at all levels of the continuum of response with useful, feasible, and relevant data to help them manage and implement their country’s NACS response effectively. Indicators should be selected that will clearly demonstrate if desired results have been achieved in NACS programs and investments.

The NACS TWG has collaborated with international stakeholders to develop a set of harmonized nutrition and HIV indicators. All indicators in this set are included in the UNAIDS Indicator Registry (www.indicatorregistry.org). Some of the indicators are included in the PEPFAR Monitoring, Evaluation and Reporting (MER) Operational Guidance and the latest version of the Global Fund M&E Toolkit.

The set was designed to be a flexible resource for use by national governments and programs to enhance the monitoring and evaluation of their NACS response. The intention is that country teams will select those indicators from the set that are specifically applicable to the design and
status of their NACS programs. Collecting data for these indicators will provide necessary information needed to improve the effectiveness and quality of NACS services.

The harmonized nutrition and HIV indicator set (located in the annex of this document) provides suggested indicators for all three areas of NACS programmatic focus (nutrition care, PMTCT, ES/L/FS). Within these recommended indicators, there are a few indicators that form what is considered the core cascade for monitoring and evaluating the NACS response:

- Number and proportion of clients who receive a nutrition assessment (the denominator being the number that access care and support services at the facility or community level)
- Number and proportion of clients who are found to be undernourished (the denominator being the number that received a nutrition assessment);
- Number and proportion of clients who receive nutrition counseling; and
- Number and proportion of clients who are undernourished and receive therapeutic or supplementary feeding (the denominator being the number found to be undernourished).

Data generated from these indicators have typically been measured at facilities offering clinical services, but can also be measured at the community level as dictated by the national nutrition strategy and the capacity within the community to provide and document such services. Other aspects of nutrition programs can and should be measured and documented as relevant to the specific country program and context.

Technical support for developing a robust set of indicators that can assist in monitoring and evaluating the NACS response can be provided by the NACS TWG as needed.

4 Policies, Service Delivery and Commodities

PEPFAR support for NACS activities fall into three broad categories: Policies, Service Delivery, and Commodities.

4.1 Policies

PEPFAR support for policies include development and/or adaptation of food and nutrition policies and guidelines to provide a framework for integrating NACS into HIV care and support, as well as into 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.

4.2 Service Delivery

PEPFAR support for service delivery includes curriculum development, training, quality (specifically quality assurance and improvement (QA/QI)) and health system strengthening – to build and support the capacity of 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;
• Develop and conduct skill-based pre- and in-service training;
• Develop appropriate job aids and quality systems to integrate NACS within care and treatment and other clinical health services;
• Provide appropriate WASH and food hygiene practices at the clinic level itself, including adequate infrastructure to facilitate WASH practices by service providers and clients; and
• Provide nutrition assessment and counseling – anthropometric, clinical, dietary, food security and WASH (water/hygiene/sanitation) to:
  o Support care and treatment of PLHIV and their families, as well as OVC;
  o Provide nutrition counseling to maintain or improve nutritional status, prevent and manage food- and water-borne illnesses, manage dietary complications related to HIV and ART, and promote safe infant and young child feeding practices; and
  o Provide referral linked to community nutrition surveillance, home-based care support and community WASH services.

4.3 Commodities

PEPFAR does not support the 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 and other programs that provide direct household food assistance.

PEPFAR can support provision of:

• Micronutrient supplements: routine and clinically prescribed provision of vitamin and mineral supplements according to WHO guidance for children and adults, including multi-micronutrient supplements for infants six to 24 months of age, prenatal/postnatal women, and other children and adults whose diets are unlikely to meet vitamin and mineral requirements.;Specialized foods: competitive procurement of the following processed foods from local, regional or international companies that meet internationally recognized standards for safety and quality:
  o Therapeutic and supplementary foods: for the nutritional rehabilitation of severely and mild-to-moderately malnourished PLHIV and OVC, according to eligibility criteria and protocols for therapeutic and supplementary feeding based on WHO and national guidelines, as well as OGAC/PEPFAR policy guidance; and
  o Supplemental, complementary and replacement feeding: for the protection of nutritionally vulnerable women in PMTCT programs to improve birth outcomes and to support lactation, as well as complementary feeding (with breastfeeding beyond six months of age) and replacement feeding (post-weaning) support (infant formula provided on an emergency basis for individual infants where breastfeeding is not an option (e.g., due to maternal death or incapacitation)).
• Equipment and Supplies: procurement of adult and pediatric weighing scales, stadiometers, MUAC tapes, and other equipment and supplies required to conduct effective nutrition assessment.

5 Key Issues

5.1 Nutrition Assessment and Counseling
To ensure the smooth integration of NACS into HIV and other health care and treatment services, the equipment, materials, and human resource capacity needed for nutrition assessment and counseling must be present. Training should incorporate continuous quality improvement to ensure effective practice in clinical services, and a human resource plan that promotes hiring and retention of appropriate staff. Nutrition assessment and counseling should be extended to all clinical care and treatment sites as rapidly as possible, even where the procurement and distribution of therapeutic and supplementary food is currently limited, as well as at the community level through community health workers, peer counselors and support groups. Counseling needs to particularly emphasize retention and adherence to care and treatment regimens.

5.2 Interagency Coordination
An interagency approach to joint programming is underway in a number of countries to strengthen nutrition support within national HIV and AIDS programs. This joint effort will encourage U.S. government 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, their families and OVC. In addition, WHO and international partners have developed guidelines for the inclusion of food and nutrition support of PLHIV within Global Fund proposals, which should be encouraged and supported by PEPFAR country teams. At the same time, most of the 16 countries that have adopted NACS are now extending the NACS systems approach to provide nutrition support integrated within health services for the general population. Thus, it is critical to engage multiple international and national stakeholders and coordinate efforts and investments across initiatives, particularly Scaling-Up Nutrition (SUN)/1,000 Days, Feed the Future and the Global Health Initiative, including PEPFAR.

5.3 Quality Improvement and Other Programming for Quality
Clinic-based NACS is most effective and sustainable when fully integrated into existing HIV care and treatment and other health services, rather than it being established as a parallel system. However, 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 lack sufficient training in nutrition care or cannot execute that training because of organizational and operational constraints. Approaches that address quality, particularly
quality improvement, data quality assessments, site monitoring, partner performance monitoring, and quality assurance, are critical to achieving efficiencies that allow NACS to be successfully integrated within health services. Application of these approaches at the clinic level is critical to ensure the translation of training into practice and to achieve efficiencies that allow NACS to be successfully integrated into health services. This process involves helping health care providers to establish performance standards and self-improvement mechanisms, creating job aids, and improving patient management and information systems, task shifting, improving time allocation and establishing supervision systems and learning platforms with teams from different facilities to help scale up improvements. This necessitates a close working partnership among technical partners providing technical assistance for nutrition, quality improvement and clinical services, and each should include these joint activities in their respective work plans and budgets.

5.4 Links between Clinical and Community Services

Community services are important entry points for NACS. Community programs can offer services to address household resilience and food security needs, nutrition surveillance and growth monitoring and promotion (GMP), nutrition counseling linked to home-based care and support groups, and outreach and follow-up of PLHIV and mother/child pairs by community health workers. To optimize these services, PEPFAR programs should support reciprocal referral systems between communities and clinic services. The community aspect should further include the training of volunteers and health workers to do basic nutrition screening and supportive counseling, and to refer undernourished individuals to clinical services, particularly chronically ill individuals who do not know their HIV status, or those who previously tested positive, but were not yet eligible for ART. NACS patients and families identified to be in need of ES/L/FS support should be referred to community services for food production, employment, income-generation activities, micro-credit and savings programs and vocational training.

5.5 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 to ensure that nutrition care and support meets the unique needs of women and men, and boys and girls. Specific interventions that address the underlying structural factors that cause malnutrition, including gender inequality, access to income and productive resources, 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. Nutrition assessment and counseling can identify and address barriers to women’s and girls’ access and adherence to quality nutrition services. Nutrition counseling should engage partners and family members to ensure support for optimal infant feeding and other nutrition practices and address gender norms that influence utilization of NACS services. In addition, referral and support to address economic and food security should recognize and be appropriately responsive to differential needs and opportunities of men and women within their communities.
5.6 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 into HIV and health services. For further information about resources available to conduct costing assessment of NACS programs, please contact the NACS TWG through your CSTL.

5.7 Procurement of Specialized Food Products

Several options exist for PEPFAR procurement of therapeutic and supplementary foods. Section 3.11 of the Technical Considerations (Supply Chain Management) provides detailed information about those options—along with cross-cutting supply chain management technical considerations—that country teams should consider in NACS programming.

5.8 Global Health Initiative (GHI), PEPFAR, Feed the Future, and SUN/1,000 Days Integration

Recently, the Scaling-Up Nutrition (SUN) movement has been launched – 41 countries to date, most PEPFAR-supported, particularly in sub-Saharan Africa – to galvanize political commitment and bring together agencies and organizations across sectors to support national plans to scale up nutrition by helping to ensure that financial and technical resources are accessible and coordinated. The SUN movement focuses on promoting the implementation of evidenced-based nutrition interventions, as well as integrating nutrition goals into broader efforts in critical sectors such as, health, social protection, development and agriculture. NACS provides a unifying framework and systems approach to integrate nutrition and food security programming to meet the SUN goals, especially when linking GHI, PEPFAR and Feed the Future as a USG whole-of-government effort. Clinic and community programs should be strategically linked and complementary – Feed the Future 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.
3.8 Disability

1 Introduction

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.

1.1 Technical Background

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, often 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.

2 Technical Considerations

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).

The following provide examples across technical areas of integrating disability issues into programming.

2.1 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.

2.2 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.

2.3 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;
• 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;
• 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.

2.4 HIV 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.

2.5 **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;
• 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;
• 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.

2.6 **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.

2.7 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.

2.8 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.

2.9 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.

2.10 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 Linkages and Wraparounds
Linkages and Wraparounds for disability-related work include:
- Linkages and integration of gender-based violence (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.
3.9 **Finance and Economics**

1 **Introduction**

In the context of limited global HIV resources relative to program needs, treatment, care and prevention programs must be implemented in a way that focuses on prioritizing cost-effective interventions and provides transparency and accountability in the use of resources. These goals can be achieved with an improved understanding of program costs through expansion of expenditure analysis and other targeted costing activities. Transition to country ownership implies building and strengthening financial management, including identifying appropriate systems that link to and support implementation activities; program management; and monitoring and evaluation systems.

1.1 **What’s New in 2014**

- Description of the headquarters-based Finance and Economic Working Group (role, objectives, and governance structure)
- Description of PEPFAR’s Expenditure Analysis and strategies to use Expenditure Analysis to inform programming

1.2 **Technical Background**

Established in 2010, the Finance and Economics Work Group (FEWG) provides technical guidance to PEPFAR implementing agencies, field offices and implementing partners (IPs) to encourage and support informed financial planning, efficient and cost-effective use of resources, and sustainability and accountability of PEPFAR-supported programs. The FEWG provides expert technical assistance on finance and economic activities, oversees central economic reporting by PEPFAR teams, and serves as the liaison for PEPFAR with multilateral organizations related to economic activities. The FEWG works in coordination with the Health Systems Strengthening Steering Committee on activities related to systems and capacity building in this area.

The objectives of the FEWG are to:

- Encourage and support the collection and use of financial and other resource-use data for guiding financial and other resource planning efforts of PEPFAR teams and host country partners;
- Promote economic evaluations and studies, including cost and cost-effectiveness studies, in informing the optimal use of resources in PEPFAR-supported HIV prevention, care and treatment programs;
- Promote financial systems and expertise in resource management, planning and economic analysis to support goals of local management and long-term sustainability of HIV programs;
- Provide guidance and coordination support to OGAC, USG agencies and PEPFAR field teams in implementation of financial reporting and tracking activities undertaken by multilateral partners and partner country governments, including National AIDS Spending Assessments and National Health Accounts activities; and
- Support design and implementation of systems that encourage program efficiency and accountability through regular collection and analysis of program cost and expenditure data.

The work of the Finance and Economics Work Group is coordinated by three co-chairs, representing the Office of the Global AIDS Coordinator (OGAC), the United States Agency for International Development (USAID) and the Centers for Disease Control (CDC). The membership of FEWG will comprise representation from USG agencies supporting implementation of PEPFAR programs such as OGAC, USAID, CDC, Health and Human Services (HHS), Treasury, and the Department of Defense (DoD). Both the headquarters- and field-based representation from implementing agencies with expertise in these areas is encouraged. There is permanent representation from the Office of Management and Budget. These representatives should have expertise in finance and economic analysis. FEWG will also solicit technical input from non-USG experts in health economics and finance—from multilateral, technical and academic partners—to provide guidance into best practices; an annual consultation of external experts is proposed. FEWG will also solicit input from other USG representatives from other program areas and agencies on the implementation of best practices that encourage program efficiency and accountability.

2 Elements of a strategic finance and economics portfolio

Country teams need to consider both financing of PEPFAR activities and financing of the partner country’s health system. There are several types of economic analyses that can inform program planning, with each producing different information that is appropriate for different questions (several types are detailed below). The following describe types of economic analyses used to inform program planning.

2.1 Cost Studies

Targeted cost studies are designed to produce estimates of the unit cost of a particular service or a discrete set of services. For example, targeted costing studies help to estimate the cost per year on ART, the cost per client in PMTCT, or the cost per caretaker trained for OVC support. Because targeted costing studies also help to identify key cost drivers, they can 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.
2.2 Cost projection models
Cost projection models use unit cost calculations to estimate resource requirements over some future period, usually about five years. Cost project models inform questions of resource requirements for scale-up, gap analysis and sustainability. They are particularly useful to support planning, budgeting and resource mobilization. Cost project models that have been used for HIV/AIDS programs include the PEPFAR antiretroviral (ART) Costing Model (PACM), the HIV/AIDS Program Sustainability Analysis Tool (HAPSAT), and the SPECTRUM suite of models.

2.3 Cost-effectiveness analysis
Cost-effectiveness analysis compares costs and effectiveness of two or more alternative approaches to the same health problem, with effectiveness commonly measured as health outcomes. Cost-effectiveness analysis frequently used to compare new or promising technologies to current practice, and helps policy makers with the selection of service delivery model or program approach. Cost-effectiveness analysis is well suited to inform questions of productive efficiency (see sub-section 5.1 (Program efficiencies) of this Section).

2.4 Costing of national strategic plans
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.

2.5 Expenditure analysis (EA)
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 technical area and by partner, by cost category, by geographic area, and stratifications of these. EA is meant to supplement, not replace, the economic activities described above. EA is useful to promote portfolio management and accountability, and helps to identify potential sources of efficiency. In designing their finance and economics portfolio for the Country Operational Plan (COP), countries teams should delineate:

- Key priorities for economic and fiscal data at the national level (e.g., preparation of Global Fund applications, costing of a new national strategic plan);
- An inventory of U.S. government activities in support of in-country institutions related to health financing, expenditure tracking, costing, etc. Teams should describe how these
activities respond to in-country priorities and explain how they are coordinated across USG and with other donor-funded activities in this area;

- Ongoing or planned national expenditure tracking activities (e.g., National AIDS Spending Assessments) and, for countries completing expenditure analysis in 2013, processes for aligning these activities with the EA;
- How teams have reviewed and aligned proposed COP-funded finance and economics activities with any Headquarters Operational Plan (HOP) activities; and
- If the team has utilized input from the FEWG to ensure the proposed activities are appropriate to address the priorities above and have sufficient technical rigor.

3 Health Financing

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. While health finance was not traditionally addressed under PEPFAR’s initial phase, resource mobilization, cost-effectiveness, and efficient resource allocation have received greater emphasis under the second phase. Promising activities to strengthen the health finance function include:

- 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;
- Strengthening Ministries of Finance and Ministry of Health’s 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 and linkages to HRH;
- Public and private sector financial management trainings, though not just for management of USG grants;
- Health financing systems or mechanisms and insurance schemes to increase access to HIV/AIDS services;
- Promotion of policies that allow for increased efficiencies through outsourcing of select services to private sector or community organizations; and
- Resource mobilization through innovative public-private partnerships, equitable cost sharing strategies, etc.

In order to ensure activities are well-coordinated and take advantage of previous and ongoing work, country teams should engage with relevant headquarters working groups (e.g., the FEWG, the HSS Steering Committee, Private Sector Engagement) when planning economic and finance investments.
4 PEPFAR Expenditure Analysis Initiative

Informed by cost and financial data, PEPFAR continues to design efficient and sustainable models of service delivery and adapts to changing circumstances that have increased demand for services in the context of finite resources while maintaining service delivery quality. To achieve an AIDS-free generation, PEPFAR will work to realize efficiency gains to deliver greater results for its investments.

PEPFAR EA is an important tool to help understand where resources are going, what outputs are produced by these investments, and how to spend those resources efficiently. The data can be used in a variety of ways at various levels of management within HIV/AIDS programs. As PEPFAR institutionalizes its routine collection of EA data, the analyses will fall under three main categories:

1. **Internal PEPFAR partner management**: EA results help PEPFAR country teams to better understand the cost structures within their programs and to identify program outliers and areas to be improved. This information is a tool for ensuring more efficient program implementation, identifying efficient program models, and broadening these successes. EA is best evaluated in the country context, with knowledge of specifics of the local HIV epidemic, health system, and programs.

2. **PEPFAR Portfolio allocations and budget projections**: EA results help PEPFAR understand cost structures and areas of investment on a global scale across countries. With results-linked data, EA provides decision-makers the information on which interventions provide the greatest value-for-money compared to the outputs. These data provide evidence to underlie the longer-term budget projections and ensure that gains against HIV are sustainable even in uncertain fiscal times. As PEPFAR transitions from direct service provision to more technical assistance models, routine reporting for PEPFAR expenditures can track shifts in PEPFAR support and assist with country planning and budgeting and development of PEPFAR transition strategies.

3. **Country-level harmonization of expenditure tracking for governments**: Realistic and strategic planning of a national HIV/AIDS response requires accurate and reliable fiscal data on the interventions. Documenting national expenditures and understanding public sector spending can be a challenge in many countries. PEPFAR continues to work extensively with global stakeholders and national resource tracking initiatives on aligning definitions and expenditure categories with the goal of having a minimum data set containing HIV expenditures regardless of source available to the government and stakeholders. The rewards for this effort will be increased transparency of donor and partner nation funding; better data for financial planning and evaluation of programs, and a stronger, data-driven national HIV response.
5 Considerations for COP Planning

The PEPFAR Expenditure Analysis Initiative evolved from the recognized need for timely expenditure data to improve management and increase efficient operations of PEPFAR programs. By employing tools to quantify programs, improve accountability, and maximize smart investments, PEPFAR is achieving more with finite resources and taking greater strides towards an AIDS-Free Generation. Country teams are strongly encouraged to conduct further analyses and use EA data and other sources of data to increase value for money in PEPFAR investment and sustain PEPFAR impacts by reducing the program costs and working with country partners to increase domestic financing and efficiently mobilize financial resources.

5.1 Program efficiencies

Countries which have completed an expenditure analysis will, when preparing FY2014 COP budgets, need to illustrate how EA data and other empirical cost data were used in determining program allocations and specifically reference the unit cost estimates in setting budgets relating to achievement of country-level targets. These budget allocations should reflect attempts to achieve efficiency from a variety of perspectives:

- **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., down-time, wastage and loss are minimized). Technical efficiency typically can be realized over the short run with strong management processes that promote accountability and are informed by cost analyses;

- **Productive efficiency** requires optimization of the resource mix and production process for a specific type of service. Increases in productive efficiency, therefore, may require rethinking service delivery models to substitute less costly resources for more expensive ones, or to employ strategies that increase effectiveness with low marginal cost. Examples include task-shifting, strategic integration of services, and scaling up of new, highly effective interventions. Productive efficiency can be achieved over the medium term, as best practices are identified and disseminated; productive efficiency decisions are informed by cost-effectiveness analysis; and

- **Allocative efficiency** is achieved when the optimal distribution of resources is made across program areas to maximize their benefit. 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.
5.2 Portfolio Review and Partner Management

EA generates financial indicators to assist in identifying cost outliers and efficient program models, and to allow tracking of increased efficiencies over time within the PEPFAR portfolio. It is important to note that there could be outliers on the high and low side:

- Outliers on the high side are often an issue of efficiency and potential allocation of intervention questions (e.g., targeting a low prevalence area) or having a low efficiency service model; and
- Outliers on the low side are often a question of data quality and reporting (counting all people reached but maybe not full attribution of support or under reporting of expenditures or they are receiving support from another funder but counting all achievements to PEPFAR).

A reasonable first step is to look at the unit expenditure distribution by implementing partner mechanisms and identify the top 25% and the bottom 25% data points (it is important to note that unit expenditure is an index, not a benchmark). The next logical step would be to understand the context and structure of the programs that those implementing partners are conducting. Program scale and maturity can play a significant role in driving the expenditures in either direction. If the country team identifies two or more IP mechanisms supporting similar programs in the same regions with comparable program maturity but present a varied cost structure, country teams should further investigate the reasons for this difference. Discussions between program managers and IPs to understand their cost structure should focus on creating a plan that will strive for the partner to either reduce their expenditures or increase their targets in a given timeframe. Where relatively higher costs are due to issues which cannot be addressed through this approach, (e.g., high cost driven by high transport costs due to exceptionally poor road infrastructure) teams should quantify this higher cost per output and determine if this additional investment makes sense and is viable in their larger context.

5.3 Program and Strategic Planning

Optimal allocation of resources between programs and interventions is another way in which PEPFAR can improve effectiveness and efficiency. Allocative efficiency is achieved when policies and funding decisions are driven by evidence of impact and value, both within program areas, such as prevention, and between areas such as care and support and laboratory or health systems strengthening, based on the needs at the national and local level. With rapidly expanding availability of country-level and local data on areas of new infection, an increasing array of proven prevention interventions, and provisions in the PEPFAR reauthorization, PEPFAR is moving toward improving allocative efficiency within prevention to maximize program impact. Country teams can use the total expenditures by geographical area and program area to understand the spread of technical allocation mapping to the epidemic by asking the questions:
• Do the levels correspond to the epidemiologic context?
• Are high prevalence areas funded proportionate to their burden?
• Does the geographic distribution of funds seem aligned with government priorities and strategies?
• Are funds appropriate for areas/programs where there are key populations?

EA provides estimates of the mean and variability of the USG expenditure per beneficiary across a range of interventions, and further disaggregates these estimates by region, cost category and other key parameters. These financial indicators assist in identifying cost outliers and high efficiency models, and allow tracking of increased efficiencies over time within the PEPFAR portfolio. EA should be viewed in the context of target and performance data. The total expenditures reported by program area in a country will help country teams assess whether the program distribution reflects the PEPFAR country portfolio and matches COP priorities.

• Is this reasonable in the context of budget, priorities and strategies?
• Was there incomplete reporting or could this represent challenges with moving money?
• Is PEPFAR investment complementary with other donors (e.g., Global Fund) in country?

Country teams will also be able to look at the total expenditures by cost category to assess if the distribution is in alignment with the national strategy and priorities (e.g., does this distribution seem consistent with the status of transition and scale up in country? Are the recurrent site level costs consistent with transitioning from service delivery support to TA role?)

Teams should review the output indicators (volume) and unit expenditure by program area from EA and/or other fiscal data and document key issues:

• Are there any program areas where the budget-to-target was a concern last year or which demonstrate significant shifts from last year?
• How did the country team use EA and/or other fiscal data to determine its budget and check it against targets?
• Did the team use EA to verify that key programmatic outputs in COP, necessary for meeting targets, are adequately funded by comparison of proposed budget/target to EA unit expenditure result where possible?
• Did the team issue guidance to TWGs and/or AORs/Activity Managers for EA data use? Have they had or requested FEWG technical assistance for a dissemination session with partners?

During the COP FY2013 process, the FEWG created a list of questions to guide the TWGs and COP reviewers. It is important to note that partner-specific analysis is not appropriate for COP reviews, as COP reviewers may not possess the country-level knowledge required to contextualize such an analysis. HQ TWG participation in partner-specific analysis may be useful.
in the setting of portfolio review or in-depth TA visit; these conditions would be worked out with the country team. Cross-country comparisons are discouraged as these are not a technically sound application of the EA data.

In designing their COPs, country teams are strongly encouraged to consider the following questions:

- What metrics is the team using to assess and monitor efficiency within programs?
- How have the results of routine EA been used for COP planning?
- How EA has been used for portfolio management, including examples of how cost information has been used with individual partners to enhance efficiency?
- How EA has been useful in planning focused economic analyses (detailed costing studies) and supporting HIV/AIDS financing systems?
- Are any other economic studies needed for program planning and have those activities been reviewed with the FEWG to ensure technical rigor and appropriateness?

6 Resources for Country Teams on use of Expenditure Analysis

The FEWG has developed extensive resources for country teams to facilitate understanding and use of EA data. There was considerable feedback from Phase I of EA on the difficulty of translating EA results into the PEPFAR budget codes. A budgeting tool is in final development and will be available in late November. Teams enter or import key EA data and targets and the tool generates budget allocations that correspond to the traditional PEPFAR budget codes. An addendum to the Technical Considerations will accompany the budget tool. It should be noted that the budget tool provides an index value to assist teams and provide an objective basis for allocations, but does not provide rigid benchmarks. Budgets should be guided by fiscal data and determined in overall program context.
3.10 HIV AND FAMILY PLANNING INTEGRATION

1 Introduction

The global health community has set ambitious goals related to both HIV and voluntary family planning (FP). Among them is working towards an AIDS-free generation (157), keeping mothers alive (380), and enabling an additional 120 million women with an unmet need for family planning to obtain contraceptives by 2020 (381). The U.S. government (USG) is fully committed to reaching these targets, with the President’s Emergency Plan for AIDS Relief (PEPFAR) leading the U.S. global response to HIV/AIDS, and the U.S. Agency for International Development (USAID) leading the U.S. effort to strengthen and expand access to voluntary FP and related reproductive health information and services.

1.1 Background

As defined by the seminal 1994 International Conference on Population and Development (ICPD) Program of Action in Cairo, of which the U.S. government is a signatory, reproductive rights rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health. They also include the right of all to make decisions concerning reproduction free of discrimination, coercion and violence (382). As such, access to voluntary family planning (FP) services and information is critical for individuals to exercise their reproductive health rights and should be offered to all people, including people living with HIV (PLHIV) as part of their routine HIV care. In addition, FP services for PLHIV are directly linked to improved health outcomes. The U.S. government is committed to meeting the reproductive health needs of PLHIV and those at risk of HIV. This requires helping PLHIV to access family planning counseling and services and safe pregnancy counseling through the integration of FP services into all PEPFAR prevention, care, and treatment programs.

Ensuring PLHIV have access to FP services can impact several important health outcomes, including maternal mortality and vertical transmission of HIV. Women living with HIV (WLHIV) are at greater risk of adverse obstetrical or neonatal outcomes and are almost twice as likely to die in childbirth as HIV-negative women (383)(384)(385). Unfortunately, as a global community, we are far from ensuring that all WLHIV have access to family planning services, including contraceptives, and to safe pregnancy counseling. Among WLHIV, there is some evidence that they have less access to family planning and reproductive health services, in the face of great need and often higher vulnerability to morbidity and mortality. In one Ugandan study, 75% of PLHIV (men and women) reported an unmet need for contraception, compared to 33% of uninfected individuals (386). Rates of unintended pregnancy among WLHIV range from 51% to 91% in studies in three countries (386)(387)(388). Further data are needed to determine whether HIV status exacerbates the already high levels of unmet need in sub-Saharan Africa.
addition, some PLHIV who wish to have children face stigma and discrimination from their communities and health care providers. Challenges to FP service provision are numerous and include challenges in coordinating HIV and FP programs, inadequate forecasting and supply chain systems that lead to a lack of contraceptive commodities at health facilities, and a lack of adequate training for HIV care providers on FP service provision.

Effective and efficient integration of HIV and FP services makes use of diverse entry points, reduces organizational “silos”, and improves comprehensive care for clients. Strategic integration decisions require consideration of the country-specific context, especially the country’s HIV epidemic and its modern contraceptive prevalence rate. Specifics such as HIV incidence and prevalence, unmet need for FP, numbers of people served and cost-effectiveness are important factors to consider when making programmatic choices about integration. The use of multiple service delivery entry points to offer FP services—including through HIV prevention, care, and treatment programs—can have a great impact on the ability of PLHIV and those at risk of HIV to realize their reproductive rights, provide support for meeting women’s fertility choices, and increase the voluntary use of contraception to prevent unintended pregnancies.

1.2 What’s New in 2014

1.2.1 PEPFAR Blueprint

As outlined in the 2012 PEPFAR Blueprint, we are working to optimize PEPFAR as a platform to incorporate and integrate other essential health services for women, including the integration of HIV and voluntary FP services, aimed at safeguarding the rights of individuals living with HIV in reproductive decisions. PEPFAR supports teams to pursue the following activities, as appropriate:

- Provide counseling and/or referrals to voluntary family planning services for women and men in HIV prevention, treatment and care programs. Provide HIV prevention messaging and support, as well as HIV testing and counseling, within antenatal care, maternal and child health, and family planning programs for both men and women;
- Ensure access to a comprehensive range of contraceptive commodities for PLHIV who wish to delay or prevent pregnancy;
- Monitor enrollment and receipt of services when referrals are made to capture linkages and ensure uptake of high-quality services including FP, maternal, neonatal and child health (MNCH) and primary care;
- Develop and disseminate technical guidance materials related to HIV and FP integration;
- Strengthen the policy environment for appropriate integration of HIV and FP platforms and services;
- Evaluate the efficiency and effectiveness of integrated HIV and FP service delivery;
- Support quality assurance efforts to improve integrated HIV and FP services;
• Conduct operational or implementation science research on effective integration approaches;
• Strengthen public health and primary health care systems, including commodity procurement, information systems, and logistics and distribution systems designed to improve the availability of HIV and FP commodities within integrated programs;
• Ensure that HIV and FP integrated program activities respect a client’s right to make informed decisions about his or her reproductive life and that a full range of contraceptive options are available for those clients who wish to avoid pregnancy;
• Strengthen delivery of voluntary family planning services within PEPFAR programs to improve PLHIV’s access to these services; and
• Document successful and promising approaches to integrated HIV and FP programs.

1.2.2 U.S. Government FP/HIV Integration Task Force

In February of 2013, the PEPFAR Deputy Principals and the USAID Office of Population and Reproductive Health (PRH) approved the creation of a USG FP/HIV Integration Task Force (FP/HIV TF). The TF includes headquarters representation from OGAC, PEPFAR implementing agencies and USAID/PRH. It is co-chaired by OGAC and USAID/PRH. The FP/HIV TF is available to provide support and technical assistance to field teams.

2 Guiding Principles of the U.S. Government’s Response on HIV and FP Integration

For several years, USAID’s FP/RH program has prioritized the integration of HIV into FP services and special attention has been given to implementing smart integration practices across USAID’s FP/RH portfolio. Smart integration refers to integration where it makes technical, financial, epidemiological and cultural sense. As part of this effort, USAID’s FP/RH program has supported national level policies that create an enabling environment for integrated HIV and FP services and designed programs that address health systems barriers to integrated service delivery as part of its global health programs.

Similarly, PEPFAR, through its implementing agencies—including the U.S. Centers for Disease Control CDC (CDC), USAID, and U.S. Department of Defense (DoD)—has supported provision of voluntary family planning service, as part of the standard of care for PLHIV as well as through HIV prevention programs. As PEPFAR has evolved from an emergency plan towards a more long-term, sustainable response, the program has consistently incorporated emerging scientific evidence and lessons learned in the field into its guidance documents and strategies. This includes underscoring the importance of partnering with national governments, other bilateral donors and civil society to optimize the delivery of various health services within existing PEPFAR platforms.

Together, USAID’s FP/RH program and PEPFAR have agreed on three key principles that guide the U.S. government’s renewed HIV and FP integration efforts: (1) a focus on reproductive
rights through voluntarism and informed choice, (2) quality service provision through evidence-based programming, and (3) partnerships.

2.1 Reproductive Rights

As per the 1994 ICPD Cairo Program of Action, and reaffirmed in the more recent 2013 Resolution by the U.N. Commission on Population and Development (389), of which the U.S. government is a signatory, the United States Government (USG) is committed to upholding the reproductive rights of the populations it serves. The principles of voluntarism and informed choice are prerequisites to quality reproductive health care and form the basis of U.S. government-supported integrated HIV and FP programs. U.S. government-supported HIV and FP programs are also guided by U.S. legislative and policy requirements that govern the use of U.S. government foreign assistance funds.

In order to continue ensuring these rights are upheld, the USG has developed a comprehensive approach to strengthen its response. This approach includes:

- **Guiding Principles:** USAID’s FP/RH program and PEPFAR have worked together to develop a set of guiding principles for U.S. government-supported HIV and FP integration programs. These principles are included in the Fiscal Year (FY) 2013 and 2014 PEPFAR Country Operational Plan (COP) Guidance and focus on services to WLHIV, but can be applied to all individuals accessing services through the HIV platform. The principles that guide U.S. government-funded programs include:
  - PLHIV should be provided with comprehensive information on, and be able to exercise voluntary choices about their health, including their family planning choices;
  - All individuals have a right to choose, as a matter of principle, the number, timing, and spacing of their children, as well as decide on the use of family planning methods, regardless of their HIV 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 PLHIV 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 e.g., drug interactions); and
  - WLHIV who wish to have children should have access to safe and respectful pregnancy counseling, antenatal, and childbirth services.

- **Improving access to FP services in line with U.S. government Legislative and Policy Requirements:** Training materials have been developed for specific programmatic contexts to ensure all U.S. government-supported integrated HIV and FP service
activities uphold the highest standards of voluntary family planning and reproductive health care. Resources and processes have been developed to ensure compliance within project activities and to report instances of possible non-compliance if they arise. USAID’s expertise in voluntary FP approaches and ensuring compliance with applicable U.S. government requirements is being shared across PEPFAR implementing agencies.

### 2.2 Quality Service Provision

Evidence-based programming is essential to ensuring tailored, high quality family planning services, which have direct health impacts for PLHIV and their children. A recent review of evidence concluded that two key interventions have proven to be effective in increasing uptake of FP services by WLHIV: (1) promoting FP as a routine part of HIV services, particularly as part of treatment and care; and (2) early post-partum visits that include both HIV and FP services(390). USAID’s FP/RH program and PEPFAR have supported integrated HIV and FP services as part of care and treatment for PLHIV, as well as through antenatal care and MCH care platforms, including PMTCT. It is expected that future integrated program activities will expand on these and other promising interventions.

Integrated HIV and FP programming is promoted through the support of research studies, documentation of good and promising practices, and technical assistance to national programs to scale-up integration models. Integrating FP services into HIV clinical settings can expand access to FP service provision and offer potential increased synergy and efficiency across programs. There is no “one size fits all” approach to HIV and FP service integration and approaches 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 to consider when making decisions around integration.

Programs should also seek to address the structural and institutional barriers that often prevent women from accessing services. Such barriers include gender inequality, social norms, and stigma and discrimination(391). For example, people living with and affected by HIV may refrain from seeking FP services or safe pregnancy counseling for fear of 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 within U.S. government-supported programs. Furthermore, experience has shown that men’s dominance in reproductive health decision-making, and cultural expectations that encourage high fertility can lead to poor uptake of FP services by both HIV-positive and HIV-negative women. To address this issue, U.S. government-supported programs encourage constructive male participation and couples counseling within family planning services so that both partners can make shared decisions around future childbearing and contraception. Finally, the meaningful involvement of those who
utilize health services, including PLHIV, in the development, provision, and monitoring of integrated HIV and FP services is critical.

Comprehensive counseling is essential for maintaining high quality family planning programs and for ensuring PLHIV have all the information they need to make informed decisions around contraception and childbearing.

See sub-section 8 (Additional Resources) of this Section for examples of existing tools that assist with appropriate and effective services including counseling in service delivery settings.

2.3 Partnerships

In line with the GHI principles of country ownership, PEPFAR and USAID’s FP/RH program are committed to partner with and support Ministries of Health, bilateral and multilateral organizations, the private sector and civil society to ensure a strengthened national response for both HIV and FP programs.

One area where better integrated programming can have a significant impact is in strengthening commodity supply chain management systems to ensure access to contraceptive commodities and male and female condoms in HIV and FP platforms, and HIV commodities in FP settings. Another key area for integration is training of HIV care providers. Since the beginning of PEPFAR, family planning services, including safer pregnancy counseling, have been a key component of prevention interventions for PLHIV (also known as Positive Health, Dignity, and Prevention (PHDP)) in both facility and community care programs. PEPFAR support has enabled multiple countries to develop national guidelines and trainings for integrating FP services into facility-based HIV care for PLHIV. PEPFAR has also supported integration of FP into community care services including support groups and home-based care programs.

3 Contraceptive Security

In order for HIV and FP integration to be successful, contraceptive security must be considered. Contraceptive security exists when women and men can choose, obtain and use a wide range of high quality affordable contraceptive methods, including male and female condoms for sexually transmitted infections and HIV prevention. To achieve this, contraceptive security programs include: (1) financing supplies, systems, staff and facilities; (2) a commitment by local political and health leaders to ensure the long-term availability of contraceptives; (3) capacity of staff and systems to manage and report on products and services; and (4) coordination with global, regional, national and local stakeholders.

PEPFAR funds cannot be used to procure contraceptives other than male and female condoms. Contraceptives procured from other sources, including USAID’s FP/RH program, can be provided as part of all PEPFAR-supported facility and community-based programs. PEPFAR is committed to working with other HIV and FP donors to improve coordination and strengthen supply chains to ensure contraceptives are available in all PEFAR supported programs. It is
important to note that male and female condoms, which PEPFAR supports, are an important commodity for integrated HIV and FP services. As they are the only technology proven to prevent both HIV infection and unintended pregnancy, male and female condoms should be readily available in both HIV and FP service delivery points.

For over a decade now, USAID’s FP/RH program has been working with national governments, bilateral and multilateral donors, and other partners on establishing and strengthening national level contraceptive security committees. Such bodies are responsible for a number of commodity security components, including national-level forecasting and quantification of FP commodities as well as strengthening distribution systems. In coordination with the Global Fund for HIV, Tuberculosis and Malaria and others, PEPFAR supports similar national level committees for HIV commodities, including ARVs. In order for sustainable HIV and FP service integration to happen on a wide scale large scale, the contraceptive needs of HIV platforms must be considered during contraceptive security fora at the national and global levels. Both PEPFAR implementing agencies and USAID FP/RH programs at the country and headquarters level have an important role to play in ensuring that contraceptives reach the populations that need them, including condoms in FP programs and a broad range of contraceptive methods in HIV programs. The U.S. government will continue to improve coordination to ensure that this happens in a growing number of countries.

PLHIV opting for a primary contraceptive method other than condoms should be counseled on the importance of using condoms to prevent HIV acquisition and transmission to their sexual partners. This is particularly true for HIV-negative women using progestogen-only injectable contraceptives, since some, but not all, studies have suggested that risk of HIV acquisition and transmission may increase with use of these injectables(392). This is an area where continued research is critical. In addition, given gender inequities that fuel the spread of HIV it is important to consider HIV prevention and contraceptive alternatives that are woman-initiated.

4 HIV and Hormonal Contraception

In early 2012, 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 expert group at the technical consultation concluded that the WHO should continue to recommend no restriction 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(392) (393). Teams should also refer to the USG Technical Brief on Hormonal Contraception and HIV which summarizes the current evidence and implications for policies and programs. Additional detail is provided in three recently published systematic reviews which summarize the epidemiological evidence on hormonal contraception and HIV acquisition in women, HIV disease progression, and female-to-male HIV transmission(392)(393).

5 Opportunities for Programming

Integration of HIV and FP activities may be cost-effective and appropriate, depending on the country context, within PEPFAR-supported programs for prevention-of-mother-to-child transmission (PMTCT), care and treatment, services for key populations, and health systems strengthening. Below is a more detailed description of opportunities for programming within these program areas.

5.1 Care and Treatment

Integration of FP counseling and services into the routine care offered to PLHIV in clinic and community settings is a core component of comprehensive and integrated HIV prevention, as outlined by WHO(216) and PEPFAR’s Prevention Guidance(63). Many WLHIV in sub-Saharan Africa report an unmet need for contraception (235). Ensuring that PLHIV can access contraceptive services in order to prevent unintended pregnancy can also contribute to reductions in perinatal HIV.

For PLHIV who desire children, partner testing and safe conception and pregnancy counseling are essential to reduce the risk of HIV transmission to uninfected partners. Both women (12), and men(394) may potentially be at increased risk for acquiring HIV during women’s pregnancies. The most common reason cited for unprotected sex among serodiscordant couples is pregnancy desire(395). Safe 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. If the woman is the negative partner, she should be aware that 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(396; 397; 398). WLHIV should also be counseled on safe timing of pregnancies based on their health
status, and WLHIV who become pregnant should be linked to appropriate PMTCT programs. FP services that include fertility awareness methods, such as the Standard Days Method (SDM), can also help couples identify when they are most likely to conceive and thus limit unprotected sex to when they have the highest probability of achieving their pregnancy intentions.

HIV care and treatment settings offer routine services to PLHIV and are therefore well-positioned to integrate FP services. FP counseling and provision of contraceptive services should ideally be integrated within most HIV care and treatment settings serving PLHIV to increase both access 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.

5.2 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 maternal, newborn, and child health (MNCH) services, including antenatal care, 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 WLHIV and their 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, PLHIV 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 MNCH 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 U.S. government agencies, and bilateral or multilateral donors (399).

5.3 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 people who inject drugs (PWID), as well as other vulnerable groups such as the female partners of men who have sex with men, or partners of individuals 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 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 (400); and in another, 28 percent of sex workers in Cambodia reported having had abortions due to poor access to contraception (401). While the FP needs of females who inject drugs (FWID) are not well-documented, high rates of exchanging sex for drugs, housing or protection, and limited ability to negotiate condom use, puts them at high risk of both unintended pregnancy and HIV infection (150). It is important to note that females who exchange sex for money or goods often have high unmet need for effective FP services even when they report high levels of condom use during transactional sex.

PEPFAR encourages the integrated delivery of HIV 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, 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; and
- Close monitoring of referrals between sites serving key populations and FP service delivery sites to ensure uptake of services.

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; and
• Include dual method use messages (e.g., a condom plus a more highly effective contraceptive method) in all behavior change communications messages directed toward key populations.

Within generalized epidemic contexts, key population groups may not be reached by general population-focused MNCH 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.

5.4 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, Ministries of Health (MOHs) and other donors will help to prevent duplication, maximize efficiencies, and assess the appropriateness of harmonized national systems around integrated HIV and FP-related services. Some activities to support quality integration of HIV/AIDS and FP services include:

5.4.1 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; and
• Support mentorship and supervision for healthcare workers, focusing on skills and information needed for integration of HIV and FP services.

5.4.2 Information Systems
• Support development of or enhance existing integrated local health management information systems to ensure harmonized reporting of patient and program data; and
• Support development and implementation of patient tracking and follow-up tools, especially as they relate to referral for FP and other related services.
5.4.3 Financing

Given that PEPFAR funds may not be used to purchase FP commodities (with the exception of male and female condoms), 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 HIV integrated platforms; and
- 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.

5.4.4 Supply Chain Management

Shortages and stock-outs of drugs and contraceptive commodities can severely undermine the ability to effectively integrate HIV and FP services. Section 3.11 of the Technical Considerations (Supply Chain Management) provides detailed information about FP/HIV integration activities and interventions—along with cross-cutting supply chain management technical considerations—that country teams should consider to avoid potential supply chain disruptions.

6 USG FP Policy and Legislative Compliance Requirements

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 U.S. government foreign assistance funds and U.S. government FP assistance. As always, all other legislative and policy requirements that govern U.S. foreign assistance and PEPFAR funding must be complied with.

PEPFAR takes these requirements very seriously and expects compliance in all program activities. Each USG agency is responsible for its own compliance monitoring and training activities in their projects, and HIV teams should contact their respective compliance teams for assistance. Some examples of activities related to reducing vulnerabilities and preventing violations include holding trainings for agency staff on the requirements; training implementing partners and other key stakeholders; incorporating compliance monitoring into routine field visits; and developing or adapting existing monitoring tools to include specific observations or questions related to compliance with the requirements. Ongoing, active monitoring for compliance is an essential element to ensure good quality of care for the people that PEPFAR serves. 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](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; and
- 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; and
- 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. See USAID's *Family Planning Guiding Principles and U.S. Legislative and Policy Requirements* for additional information ([http://transition.usaid.gov/our_work/global_health/pop/policy.html](http://transition.usaid.gov/our_work/global_health/pop/policy.html)).

7 Monitoring and Evaluation

Monitoring and Evaluation and Research and Innovation are two of the seven Global Health Initiative (GHI) principles and deserve particular attention in the context of integrated HIV and
FP programs. Close monitoring of integrated HIV and FP integrated programs is necessary to ensure voluntarism, informed choice, and protection of human rights as well as to maximize quality of care, and assess program progress. U.S. government teams should consider how existing reporting systems can be used to monitor HIV and FP integration.

PEPFAR will include one required HIV and FP integration indicator to be reported to headquarters on a yearly basis: *Percentage of HIV service delivery points supported by PEPFAR that are directly providing integrated voluntary family planning services.* In addition to this indicator, USG and FP/RH teams are encouraged to identify appropriate country-specific programmatic indicators to measure impact related to the uptake of FP services, proportion of service delivery points that offer integration services, and other activities. The USG is engaged in international working groups that are helping to develop and share programmatic indicators. A compendium of global family planning indicators can be found here: http://www.cpc.unc.edu/measure/publications/ms-94-01. In addition, USAID’s RH/FP program has developed a list of standard indicators for measuring family planning services. Programs may also consider using these indicators, which are listed below:

- Couple Years Protection (CYP) in USG supported programs;
- Percent of USG-assisted service delivery points (SDP) that experience a stock out at any time during the reporting period of a contraceptive method that the SDP is expected to provide;
- Percent of USG-assisted service delivery sites providing family planning (FP) counseling and/or services;
- Number of USG-assisted community health workers (CHWs) providing family planning (FP) information and/or services; and
- Percent of audience who recall hearing or seeing a specific USG-supported FP/RH message.

Please contact the PEPFAR FP/HIV Integration Task Force if you would like more information on indicators.

Operational or implementation research supported with rigorous monitoring and evaluation and an emphasis on using data will also help identify critical problems and improvements, including (a) sustainable and cost-effective integrated service delivery approaches, (b) obstacles to rapid system scale-up and approaches to reduce such obstacles, and (c) strategies to help improve integrated health service delivery models. PEPFAR programs are encouraged to support these research activities.

While Cochrane reviews and other systematic studies have concluded that integration is feasible and can produce positive effects, the health field would benefit from more evidence of these effects and from more rigorous studies of integrated service delivery. The GHI *Principle Paper*
on Integration in the Health Sector (http://www.ghi.gov/documents/organization/195596.pdf) is a resource for additional information on integration, including measurement of integration.

8 Additional Resources

Appropriate and effective services including counseling in service delivery settings:

- The Balanced Counseling Strategy Plus (BCS+): A Toolkit for Family Planning Service Providers Working in High HIV/STI Prevalence Settings is a tool to improve the quality of family planning services and to strengthen the integration HIV prevention, detection, and care into family planning, including the risk assessment of STIs: http://www.k4health.org/toolkits/sdm/balanced-counseling-strategy-toolkit-family-planning-service-providers

- Family Planning Counseling: USAID e-learning course: http://www.globalhealthlearning.org/course/family-planning-counseling


- Reproductive Choices and Family Planning for People Living with HIV: Counseling Tool was developed by the World Health Organization to help health care workers counsel women and men living with HIV and their partners on sexual and reproductive choices and family planning: http://apps.who.int/iris/bitstream/10665/43609/1/9241595132_eng.pdf

- Family Planning and Safer Pregnancy Counseling for People Living with HIV/AIDS: A Tool for Health Care Providers in HIV Care and Treatment Settings was developed by the Prevention with Positives (PwP) Task Force to support FP-HIV integration within HIV care and treatment clinics. Programs can request access to these tools by contacting the PwP Task Force co-chairs (Mike Grillo at Michael.Grillo@med.navy.mil, Amy Medley at igm8@cdc.gov, and Ugo Amanyeie uamanyeie@usaid.gov)

3.11 Supply Chain Management

1 Introduction

Ensuring that the desired type and quantity of health commodities (e.g., medications, testing devices, and lab equipment) are received by health facilities is the responsibility of the supply chain and the professionals working within it. A supply chain is an interdependent system with a myriad of players at different levels of the system, tasked with diverse duties which are all necessary to ensure that health workers have the supplies needed to treat patients. A supply chain for HIV/AIDS commodities requires:

- Trained personnel throughout the supply chain who can ensure patient enrollment and availability of supplies;
- An ordering mechanism that allows for data flow and organized consumption/logistics data storage;
- Adequate warehousing facilities that can guarantee the safe storage of sensitive health commodities;
- Regularly maintained delivery trucks with drivers who can successfully deliver the health commodities to the health facility which ordered them;
- Staff that can utilize data from the ordering/distribution process to glean national consumption of each product and produce a demand-based forecast to account for future health commodity needs (examples of sources of data are Logistics Management Information System (LMIS), order forms, reporting forms, issues data from storage facilities, physical stock counts for levels of the supply chain, and demographic data can also be used in the forecast to project future needs);
- Procurement professionals who can use forecasting and supply planning methodologies to procure the commodities needed;
- A regulatory body to ensure that the commodities coming into the country are acceptable and aligned with nationally approved HIV/AIDS commodities or product list (e.g., ARV regimens, rapid test kits, point of care diagnostics);
- A group of technical authorities, who can engage in product selection, manage the disease program and help to manage the supply chain for HIV/AIDS commodities commodities to both public and private providers of services; and
- A political environment which allots resources to supply chain activities.

In order to achieve the aforementioned requirements for a robust supply chain, multiple activities must occur, as highlighted in the flowchart Figure 14, below. Furthermore, supply chain needs will differ for HIV-related services across the continuum of care. The supply chain needs for a PMTCT clinic will not be the same as the supply chain needs for a major hospital; therefore, supply chain activities must be tailored to suit the needs of each technical area(190).
2 General Supply Chain Considerations for all Technical Areas

2.1 Product Selection

Technical authorities should collaborate on product selection (see the right-side box in Figure 14) with new products added to nationally available product (essential medicines) list as programs mature and select new products. The essential medicines list should be shared with all stakeholders, from clinicians to implementing partners to the national regulatory authority.

2.2 Quantification and Procurement

The HIV/AIDS products on the essential medicines should be quantified annually, with quantification based on consumption data, demographics, stock on hand for each product and program targets. These data will help quantifiers produce a demand-based forecast for the HIV/AIDS products on the essential medicines list as well as a supply plan for each product (See lower box in Figure 14). As targets are revised, or population coverage changes, the forecast must be revised to agree with the new plans or targets and storage must be secured before scale-up can be implemented. On a quarterly basis the amount of a product consumed should be compared to the forecast and cross-checked with the stock available nationally as well as upcoming shipments to determine if demand was correctly forecast and if the planned supplies are sufficient. All partners should be made aware of over- or under-estimation situations, along
with sharing an updated supply plan reflecting this change. See Figure 15 below, for a diagram of quantification/forecasting and supply planning.

**Figure 15. Diagram of the Forecasting and Supply Planning Process**

![Diagram of the Forecasting and Supply Planning Process](image)

The forecast and supply plan should be shared with all procurement partners to ensure that any commodity gaps are made public and allow partners to help fill those gaps. Procurement partners use the publically available forecast and supply plan to: plan procurements; foster open collaboration and share information on planned procurements and expected delivery dates to avoid stock-outs and overstock with product wastage. Procurement partners should also follow the nationally accepted supply plan and adjust to any quarterly review of the forecast and supply plan that shows an over- or underestimation. Lastly, whenever commodity shortfalls threaten HIV 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.

### 2.3 Inventory Management

An acceptable, national, inventory management plan (Figure 14, left box) should be in place for all levels of the system. Best practices may be conveyed through training and standard operating procedures (SOPs). SOPs should include: information on proper storage; acceptable stock levels; buffer stock; proper ordering and reporting protocol; distribution practices; and guidance on
monitoring and supportive supervision. Job aids and other reminder/teaching equipment ought to be considered and, if available, distributed to health facilities. An example of this could be providing a poster which lists succinct information on best storage practices in each storage facility.

To ensure a steady supply of all HIV and AIDS commodities, a consistent, well-organized distribution system must be in place to get commodities through the established national supply chain to the health facilities. Distribution quantities should be based on orders from health facilities or data showing an anticipated demand. Vehicles for distribution should be well-maintained and have qualified drivers who are able to safely and efficiently transport commodities to health facilities.

In order to record that commodities are received at health facilities, proof of delivery forms should be signed by qualified staff and those commodities should be stocked in a timely fashion, adding the new quantity to a regularly updated stock card. As commodities are issued/consumed, the quantities should be subtracted on the stock cards.

Consumption quantities should be subsequently regularly reported to the restocking level within the supply system for national aggregation and use in decision-making. In addition to consumption data, data on product loss and transfer should also be reported to the restocking level. Reporting forms should be easily understood and completed.

A waste management protocol must be in place for all HIV/ AIDS diagnostic materials and other medical waste. SOPs for waste management should be available at all sites and waste management practices should be monitored continuously.

2.4 Continuous Quality Monitoring—throughout the Supply Chain

Monitoring should be designed to improve all elements of the supply chain, as shown in figure 1 and should occur at all levels of the system from central level actions like procurement to facility level inventory management and record-keeping. Regular monitoring will illustrate which areas require more assistance to improve the system as a whole, and may illustrate gaps.

All USG teams are strongly encouraged to use USAID mechanism Supply Chain Management Systems (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. The SCMS project also can obtain the lowest reported prices for all ARVs, generic or innovator, by leveraging the economies of scale created by USG pooled procurement. Furthermore, SCMS can assist with system monitoring as much or as little as needed, at the system level where it is needed.
Supply Chain considerations for specific Technical Areas

Supply chain needs differ from one HIV/AIDS activity to another, requiring that supply chain activities be tailored to suit the needs of each technical area. The supply chain needs for a PMTCT clinic, for example, will not be the same as the supply chain needs for a major hospital. The following sub-sections highlight supply chain management considerations that are unique and/or particularly relevant to different programmatic areas.

3.1 Supply Chain considerations for Prevention of Mother to Child Transmission

For effective delivery of PMTCT services, a regular supply of essential testing and treatment-related commodities should be available, including pediatric and adult formulations of ARVs and co-trimoxazole (CTX) and HIV testing equipment for adults and infants (e.g., RTKs, EID testing materials). As countries move towards provision of Option B or B+ (and away from Option A) and harmonization of ART regimens (e.g., to fixed-dose combination tablets for adults, children, and PMTCT), adjustments in forecasting and supply planning will be essential. Some of the commodities required for PMTCT activities may also be required at other clinical sites (e.g., ART clinic, hospital), so forecasting, supply planning and appropriate placement of these commodities to ensure adequate supplies are maintained for PMTCT sites is also essential. Therefore one consideration may be that commodities intended for PMTCT activities ought to be maintained and stored together in each clinic, ensuring that co-trimoxazole, ARVs, and other PMTCT-related commodities are used only for PMTCT. This principle of grouping PMTCT commodities may be maintained throughout the supply chain by distributing the commodities together, including them in the national or HIV/AIDS forecasting and supply planning activities, and organizing ordering and reporting forms in such a way that the commodities can be ordered and reported on together. Clear PMTCT policies must be in place to prevent misuse or waste of commodities, and supply chain personnel within PMTCT sites must be fluent in these policies. (Please see Section 1.1 of the Technical Considerations (Prevention of Mother to Child Transmission) for more information.)

3.2 Supply Chain considerations for Biomedical Prevention

3.2.1 Supply Chain considerations for Injection Safety

Supply chain considerations for injection safety can be complex. At a minimum, programs must provide appropriate injection safety and waste management practices within their existing programs. This may include reverse logistics to collect waste for incineration or the practices consistent with local guidelines. Furthermore, programs must ensure that availability of sufficient, appropriate, quality, single-use injection and safe phlebotomy supplies is sustainable.

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A national plan that includes the costs of single-dose vials/diluents as well as sharps containers and other waste management commodities should be factored into overall costs of commodities during supply planning and must be included in national commodity forecasts.

Source: CDC (2012) (404)

3.2.2 Supply Chain considerations for Voluntary Medical Male Circumcision

When a country is preparing to add or increase the coverage of an existing voluntary medical male circumcision (VMMC) program the supply chain must be considered during the earliest phases of planning. An uninterrupted supply of VMMC commodities as well as a sound methodology for waste management needs to be in place before activities can begin. A revision of a country’s current waste management policy may be needed to support VMMC activities, including additional logistics activities for the waste produced from VMMC. If facilities without an incinerator are expected to perform VMMC, then safe disposal of waste from the procedure is mandatory as well as regular transportation of this waste to a facility that does have an incinerator. The VMMC budget should include a waste disposal line item since VMMC waste disposal processes can double the cost of the procedure (405).

VMMC services are dependent on the availability of injectable anesthetics, which relates back to injection safety (see sub-sections 2 (Injection Safety) and 4 (Voluntary Medical Male Circumcision) of Section 1.3 of the Technical Considerations (Biomedical Prevention) for more information) and the availability of high-quality disposable items.

Nationally it is important for programs to anticipate the quantities of VMMC commodities that will be needed, consider the average monthly consumption (AMC) of VMMC disposable products, and plan timely procurements to avoid overstock as well as stock-outs situations. Overstocks of VMMC commodities are detrimental since VMMC kits require a great deal of
warehouse space and the disposable commodities used are also bulky. A country will need to ensure that warehouse space is sufficient before ordering VMMC products. For planning purposes, a 40-foot container is required to transport approximately 18,200 MC kits; therefore, equivalent warehouse space is required. Furthermore, there have been global shortages of qualified VMMC products, which resulted in an increased lead time of six months. This lead time should be built into program planning. Buffer stock for VMMC products has been funded by PEPFAR and procured through SCMS for the benefit of all PEPFAR VMMC programs.

Additionally, since PEPFAR funding may only be used to support products that have been pre-qualified by the WHO, this will also need to be considered when planning for procurement of medical devices for VMMC. A list of WHO pre-qualified products, including prequalified medical devices for VMMC, can be found on the WHO’s Diagnostics and Laboratory Technology webpage (http://www.who.int/diagnostics_laboratory/evaluations/prequalification_male_circumcision_devices/en/index.html).

3.3 Supply Chain considerations for HIV Testing and Counseling

A stockout of rapid HIV test kits (RTKs) is as serious and urgent as a stock-out of ARVs. HIV Testing and Counseling (HTC) services cannot be provided without an adequate supply of essential commodities, including 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 for a variety of reasons including, but not limited to, weaknesses in the local supply chain. Efforts to strengthen supply chain management systems need to be undertaken to ensure the commodity security of RTKs and related supplies. These efforts can include more timely and accurate reporting on test kit supply, usage, loss (if any), enhanced distribution to all HTC service delivery points, and ensuring adequate storage of kits. Additional consideration needs to be given to waste disposal as well. After a test is given, all sharps and other products used to hold blood must be properly disposed of. Guidance needs to be given to health facilities on the nationally accepted strategy to properly dispose of these products.

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

- Conduct country level assessments of the RTK supply chain;
- Conduct more frequent quantification of RTKs with forecast accuracy done regularly;
- Chronicle causes of stock-outs or expired supplies to help target TA, inform interventions, and advocate for improving these systems;
- Funding for emergency procurements of test kits and related supplies; and
- Collaborate and communicate with USG Supply Chain Advisors.
Country teams should make every effort to work proactively with government and donor counterparts to improve forecasting, procurement, storage and delivery processes to avoid stock-outs and shortages. In cases where these measures are insufficient and when teams anticipate a central level stock-out, HQ (OGAC and USAID) has mechanisms to provide assistance in procuring emergency supplies of RTKs if given sufficient lead-time (i.e., three to four months). The first point of contact for these requests should be the Country Support Team Lead. Please contact the HTC TWG for more information on communications from January, 2013 to the field on the Emergency Commodity Fund.

3.4 Supply Chain considerations for Care and Treatment

3.4.1 Adult Care and Treatment

Access to specific drugs and supplies on a regular and reliable basis is necessary for effective provision of HIV care and treatment services. Availability of cotrimoxazole for CPT, medications for management of opportunistic infections (OIs) and sexually transmitted infections (STIs), ARVs, and necessary diagnostic testing supplies are essential. Regular forecasting and supply planning for these commodities is necessary to avoid stock-outs to ensure that PLHIV are maintained on treatment. This is discussed in detail in sub-section 3.4.3 (Supply Chain considerations for ARV Drugs) of this Section and in Section 2.2 of the Technical Considerations (Adult Treatment). Other related medical supplies, including drug-dispensing equipment, gloves, HIV test kits, and sterile needles should also be maintained in adequate supply.

Where CD4 testing is available for determining ART eligibility, national programs and other key stakeholders should work to ensure that all supplies needed to perform CD4 tests are on national product lists, properly forecasted, and available within the country. Similar considerations should be made for countries scaling up viral load testing for monitoring patients on ART. Additional information is available in Section 3.1 of the Technical Considerations (Laboratory Infrastructure).

The WHO 2013 Consolidated ARV Guidelines recommend TDF/XTC/EFV (tenofovir, emtricitabine or lamivudine, and efavirenz) as a fixed-dose combination (FDC) regimen for most patients. This regimen is recommended as first-line therapy unless it is not available in-country or is contraindicated for an individual patient. As Tenofovir (TDF)-based regimens and/or FDC regimens is phased in as a preferred first-line treatment, countries will need to develop responsible, globally-aware procurement plans for these commodities. This includes:

- Development of a gradual transition scheme given the significant existing supply constraints for TDF- and EFV- containing regimens;

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Supply planning for anticipated increases in procurement lead times for FDC treatment regimens. Orders should be placed as far in advance as possible;

- When possible, programs should use existing stocks of ARVs already purchased and available in country. This will ease the transition to TDF regimens, avoid waste of valuable resources, and eliminate the need for destruction of existing stocks. Further guidance on d4T phase-out and use of AZT-based regimens during this transition can be found in Section 2.2 of the Technical Considerations (Adult Treatment);
- Reducing the number of ARV regimens in-country will simplify ARV options and reduce the complexity of procurement and supply chain logistics; and
- Priority should be given for transition of patients currently on d4T-based regimens to a TDF-based regimen, as this is no longer a recommended regimen based on WHO guidelines (406).

As a country is preparing to procure ARVs that country is encouraged to:

- Use a publically accessible database to facilitate access to information about prices and support competition; and
- Encourage pooled procurement through a common tender that can be implemented to save time and resources.

For more information please also refer to WHO guidelines(406).

3.4.2 Pediatric Testing, Care and Treatment

Supply chain needs for testing, care, and treatment of children are more complex than those for adults since more products are needed to fulfill needs from infancy to adolescence.

For Early Infant Diagnosis (EID), a country will need to define the preferred testing methodology, supplies needed to perform tests, testing algorithm for infants, and a procedure for proper waste disposal. Commodities for follow-up testing for infants who test negative on their first test should also be forecasted. When an infant tests positive for HIV, the health facility performing the test will need to report this information so that the child can be included in HIV commodity forecasting. WHO now recommends universal treatment for all HIV positive children 5 years or younger. Commodity forecasting and supply planning for this transition will be a multi-step process to ensure adequate supply of ARVs.

Finally, some pediatric ARVs require cold storage. Therefore, facilities providing pediatric ARVs must be able to maintain a cool storage facility. For these medications, a cold chain must be maintained from shipment of the drugs through to the treating facility. Where possible, the cold chain required for pediatric ARV formulations could be combined with local immunization programs where a cold chain may already be supported.
3.4.3 Supply Chain considerations for ARV Drugs

A number of factors, including variable funding flows, inadequate forecasting based on treatment targets, as well as procurement and supply management issues at the country level, can undermine the availability ARVs at the site and national level. To mitigate procurement issues (particularly for testing and treatment commodities) PEPFAR teams should work with other stakeholders to forecast product needs according to treatment targets, then utilize that forecast to produce a supply plan with realistic budgets for each needed product, which partners can then publically take responsibility for procuring (see sub-section 2.2 (Quantification and Procurement) of this Section for more information on forecasting).

Unanticipated “emergency” situations, such as natural disasters or conflict, can threaten the availability of ARVs in a country, despite the best forecast and supply plans. 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 and 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 of Health officials to ensure the availability of ARVs.

The cost savings to be found through greater procurement of generic ARVs rather than branded ARVs and through greater pooled procurement are substantial and should be encouraged whenever feasible. 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.

ARVs purchased with PEPFAR funding must have FDA-approval or FDA-tentative approval. 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.
Within the supply chain, acceptable storage conditions for ARVs must be maintained. ARVs often have short shelf lives, the practice of first to expire, first used must be implemented at all levels of the system to avoid costly expiries as well as sound storage practices (407).

3.5 Supply Chain considerations for TB/HIV

Updated WHO guidelines recommend that irrespective of CD4 count, an HIV positive patient who has active TB must be treated not only for TB, but should also be started on ART as early as possible. Although in general TB drugs are not provided with PEPFAR funds, PEPFAR teams need to ensure that forecasts for ARVs include anticipated quantities needed to treat co-infected patients and should liaise with national TB programs to share forecasts. Isonaizid will be required to scale up isoniazid preventive therapy (IPT). If this drug is unavailable via the TB program supply chain, it should be integrated into the HIV supply chain.

PEPFAR provides significant resources to improve TB diagnostic capacity and this necessitates supply chain coordination. TB diagnosis often requires diagnostic testing, such as sputum smear, Xpert MTB/RIF and sputum culture, each of which entail supply chain considerations for equipment, reagents and other consumables. Procurement needs to take into account readiness assessments that reflect training needs and assure optimal placement of instruments in settings serving large numbers of co-infected clients.

Each country will have its specific diagnostic algorithm which the supply chain will need to support. This should include a program for safe disposal of sharps and medical waste as well as regular distribution and safe storage of all the materials required to perform these diagnostic tests. Regular screening of HIV positive patients should happen, so there will be a regular use of and need for testing equipment.

3.6 Supply Chain considerations for Laboratory Infrastructure

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 from the Maputo Consensus Conference (408). 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, especially for laboratory products. In particular, the following parameters should be considered for lab needs:

- Defined inventory management systems should be operational in each laboratory;
- Reagent rental and standing orders for reagent delivery should be options if appropriate;
- Lot assurance should be provided by suppliers;

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• In procurement and distribution planning, 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;
• Countries should work toward a harmonized laboratory system to streamline the supply chain and improve laboratory efficiency;
• Service Maintenance contracts should be procured for all equipment; and
• 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.

Point-of-care (POC) diagnostic technologies are created for use in resource-limited settings by persons with little or no laboratory training. Currently, only the PIMA CD4 machine has been approved for use in PEPFAR programs. For longer term planning on the integration of POC CD4 and upcoming viral load devices, 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.

3.7 Supply Chain considerations for Sustainability

The development of a sustainable national supply chain management system with accountability is needed to increase service capacity to deliver effective care. Sustainability of ART programs in recent years has been greatly enhanced by achieving significant cost savings on 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. 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.

Costing the supply chain itself may prove to be infinitely helpful. This would involve creating a budget for a fully functioning supply chain using real costs for: proper storage space, salaries for supply chain professionals, maintenance and fuel costs, vehicles, and a reporting system. 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. Moreover, the act of costing the supply chain itself would give the country insight into the real costs required to maintain an adequate supply chain. These real costs may allow the country to assume greater responsibility for components of the supply chain or provide more funding for elements which are currently underfunded.

### 3.8 Supply Chain considerations for Nutritional Products and HIV/AIDS

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. Those standards will need to be incorporated into any procurement. If a vendor has not been approved then UNICEF and WFP will need to be engaged to assess that vendor for quality. UNICEF and WFP have established quality assurance and distribution systems for therapeutic and supplementary foods that offer a foundation and precedent for PEPFAR.

Systems are necessary for forecasting need, conducting competitive procurements, and then efficiently transporting, storing, and distributing food products in clinics. There are a number of options for PEPFAR procurement of therapeutic and supplementary foods, including: 1) the 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.

In most countries, these supplemental nutritional products will be available by prescription. This puts the treatment provider in the position of not only storing medical commodities, but also storing food. This increases the importance of maintaining a clean storage environment since an open or leaking container of this product will draw pests quickly. These products are also
susceptible to theft. They have immediate value on the open market since they may be consumed by anyone and provide nourishment. The threat of theft also increases the need for proper inventory management, if a stock card is not updated and a physical count is not often done, then theft may occur without the facility realizing it until there is an urgent need for the product. Finally, the shelf life of many of these products is short; therefore, higher level facilities will need to consider redistribution of products with little shelf life remaining to facilities that will immediately prescribe/consume them. Redistribution may increase the burden on the distribution system, but will decrease loss due to expiry.

3.9 Supply Chain considerations for Family Planning and HIV Integration

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).
3.12 IMPACT EVALUATION

PEPFAR has adopted an implementation science (IS) framework to improve the development and effectiveness of its programs at all levels (409). IS is the study of methods to improve the uptake, implementation, and translation of research findings into routine and common practices (the “know-do” or “evidence to program” gap) (409). Impact Evaluations (IE) are the evaluation tools that definitively establish “what works,” hence they are the fundamental backbone of IS. IEs permit causal attribution of changes in outcomes to a particular program by comparing observed changes to what would have happened had the program not been implemented (the counterfactual scenario). PEPFAR IEs assess the effectiveness, comparative effectiveness and/or cost-effectiveness of new or existing PEPFAR programs.

1 Why are these country-driven IEs reviewed at the headquarters level?

Recent reports from the Government Accountability Office and the Institute of Medicine(410)(411) have emphasized the need for PEPFAR to maintain a central inventory of completed and ongoing evaluations across programs and countries. The IE review process ensures that PEPFAR’s scientific portfolio is not just rigorous, but also balanced, appropriately representative of program areas and geographic regions, and free of excessive duplication of efforts. A centralized mechanism also permits tracking and reporting program-wide evaluations, and facilitates the translation of evaluation results into program implementation.

2 What kinds of IE may be funded through the COP?

The goal of this process is to fund IEs that contribute clearly and directly to the evidence base that supports PEPFAR funded and implemented activities. Other types of evaluations and impact evaluations that lack scientific rigor will not be accepted. Proposals for IE should be initiated by country and regional OUs and connected directly to activities funded through the COP/ROP.

3 Impact Evaluation Methods

The distinctive feature of an IE is the use of a counterfactual to control for factors (other than the intervention) that affect the outcome of interest. IEs generally use experimental (e.g. randomization) or quasi-experimental methods. Another hallmark of IEs is that they require interim analyses and permit mid-course corrections in the program while the evaluation is ongoing. IEs may be possible through slight changes in the program (e.g. adding a peer navigator to increase testing or adherence to randomly selected clinics) and/or by adding de novo data collection in order to examine clear outcomes. There is a large array of IE methods (for example, stepped wedge evaluations, cluster randomized trials, matching, difference in difference [pre-post differences in the intervention compared to pre-post differences in controls] as well as various analytic tools (propensity score matching, use of instrumental variables, as well as some mathematical modeling). A more complete description of the full array of IE methods can be found in Gertler et al. (2011)(412).
4 **Criteria for IE**

An evaluation activity may be classified as PEPFAR impact evaluation (IE) if it addresses *all* of the following four questions:

- Does the study measure the effectiveness of a PEPFAR intervention, using verifiable measures such as biological, clinical or other outcomes that can be externally validated?
- Is there a valid counterfactual comparison and related hypothesis?
- Do the methods of design and analyses permit attribution of outcomes to the program of interest?
- Are there plans for interim analyses and the ability to provide feedback to the program while it is being evaluated?

Note that randomized, controlled efficacy trials that evaluate the efficacy of a single or multiple drug regimens, medical device, or other similar type of pharmaceutical or medical intervention do not meet the criteria for IE. The interventions evaluated in an IE should have already been shown to be efficacious, and the purpose of the IE is to examine the effectiveness of the intervention at scale focusing on methods of delivery, or in a different setting.

5 **What funds may be used to pay for IE?**

Funds for this work should be drawn from country budgets. The requested total life of project budget for IEAs should not exceed 3% of annual COP budgets or $3 million USD. Countries should make a commitment to fund the IE through completion before applying, and ensure that this commitment is clearly articulated in their submitted concept note.

6 **Applying for an Impact Evaluation**

PEPFAR country and regional OUs proposing an IE in their FY 2014 COP should submit a concept note with the COP as a supplementary document in FACTS Info. Concept notes must be submitted according to the following guidance, and will be reviewed by an interagency technical review panel convened by S/GAC’s Office of Research and Science. **Please note** are no additional funds for IEAs. IEAs must be funded within a COP/ROP. OUs should make a commitment to fund the IE through completion before applying, and ensure that this commitment is clearly articulated in their concept sheet.

Once OUs receive notification that their concept note has been approved, they should begin to develop a protocol for the IE. The level of rigor in the review of the concepts obviates the need for central protocol evaluation. OUs should submit protocols through partner, agency, and host country technical and bioethical reviews as appropriate.

A brief progress summary will be required on an annual basis for all IEAs; this should include updates on protocol approvals for any ongoing IEAs. In addition, OUs must submit a final report and/or manuscript using standard PEPFAR attribution language (413) in all resulting publications.
so these can be added to the central inventory of PEPFAR funded evaluations. In order to proceed with the IE, a country team submitting a concept note in the FY14 COP must have an approved protocol by submission of the FY15 COP.

At any stage of IE concept planning, please email questions to PEPFAR_ORS@state.gov for technical assistance. Country OUs that are considering submitting a concept note this year are encouraged to begin discussion early with PEPFAR headquarters and S/GAC’s Office of Research and Science in conjunction with their Country Support Team Lead (CSTL).

In order to provide additional assistance if needed and prepare for the review, we ask that country OUs planning to submit a concept note alert their CSTL via email by January 23, 2014, and copy PEPFAR_ORS@state.gov. The email should indicate

1. The name and type of program to be evaluated.
2. The hypothesis.
3. The implementing mechanism.

S/GAC will use the above information to inform the composition of the IE review panel. Concept notes will be due with the COP on March 1, 2014.

7 Concept Note Submission Requirements
The FY 2014 IE concept note submission process will be for activities with a planned or existing implementing mechanism identified by the time of submission.

The concept note should be no more than 10 pages plus appendices, and include the following (suggested page lengths are in parentheses):

- Cover page (0.5 – 1 page):
  - IE title
  - Name of program or intervention being evaluated
  - Principal investigator
  - Country team contact
  - Implementing agency
  - Implementing partner
  - Implementing mechanism
  - Start and end dates of agreement for the IE implementing mechanism (to ensure no breaks in funding)

- Specific Aims (0.5 – 1 page): What is/are the main evaluation question (s) to be addressed by the proposed study? What is the goal of this evaluation? What hypothesis will be tested? What are the primary and secondary outcomes of interest?
• Background (justification) (0.5-1 page): Why is this question significant to your country program? How will this IE add to the evidence base for your existing or newly funded activities? Describe how the IE results will inform current or future program(s). What work has been done on this topic to date? (Cite relevant work).

• Evaluation design: (5 pages)
  o Outline the main features of the proposed evaluation design. The following must be addressed:
    ▪ description of the program, how exposure to the intervention “will be measured and anticipated measurement challenges (if any);
    ▪ description of the outcome measures and anticipated challenges (if any);
    ▪ expected relationship between “program exposure” and primary outcome measure;
    ▪ key confounding factors;
    ▪ selection bias;
    ▪ other sources of measurement error;
    ▪ spillover effects;
    ▪ contamination of comparison groups or inadequate programmatic exposure (e.g., effects of in and out migration between intervention and comparison area); and
    ▪ impact heterogeneity; specifically how might the results differ by beneficiary type (age, gender and other demographic factors) or context (urban, rural, type of habitation). Include methods for data management (including data collection and quality assurance) as well as the overall analytic framework (including proposed interim analyses). Discuss potential problems, alternative strategies, and the study milestones required to achieve the aims.

• Required Appendices
  o Budget and budget narrative. Cost per year itemized into standard major categories (personnel, ARVs, other commodities, travel, etc.) Please specify the total duration of the study (1-3 years) and the cost per year. IEs without budgets will not be reviewed.
  o Timeline: Specify the timeline for protocol development, submission, data collection and study end date.
  o Innovation (if applicable): Does the study challenge or seek to shift current programmatic, clinical practice, or evaluation paradigms? Does the study design include novel concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used? If so, describe them and explain any advantage over existing methodologies, instrumentation or intervention(s).
  o References: Cite relevant work and related other background information.

8 IE Submission through FACTS Info

To submit an IE concept with your COP, please go to the “Document Library” section of FACTS Info, select “Impact Evaluation” in the drop down menu, upload the concept sheet and the review
form with country information completed, and upload the IE documents. Use the following naming convention:

- IE_Country_Brief Title_Review Form
- IE_Country_Brief Title_Concept

IE concepts will be due on

**IE Concept Timeline:**

<table>
<thead>
<tr>
<th>10/01/2013</th>
<th>1/23/2014</th>
<th>03/01/2014</th>
<th>05/2014</th>
<th>07/2014</th>
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</thead>
<tbody>
<tr>
<td>FY 2013 IE Guidance and call for IE concepts released</td>
<td>E-mails to CSTLs and <a href="mailto:PEPFAR_ORS@state.gov">PEPFAR_ORS@state.gov</a> notifying intent to submit due</td>
<td>IE Concept submissions due through the COP</td>
<td>Scientific and programmatic reviews of IE concept notes</td>
<td>IE Decisions reported to country teams</td>
</tr>
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Appendix I

Technical Review Form and Checklist for IE Concept Sheets

To be completed by Country Team:

Country/Regional Program

____________________________________________________________

Primary Evaluation Contact

____________________________________________________________

PHE/IS Liaison in field office

____________________________________________________________

Technical Area ____________________________________________________________

Hypothesis___________________________________________________

____________________________________________________________

Program to be Evaluated (Provide clear linkage to PEPFAR Program and COP mechanism to be used)

____________________________________________________________

Have relevant stakeholders been part of designing this concept? If so, who have you briefed within the MOH, the national HIV Council/Commission and other local stakeholders? YES/NO

Comments___________________________________________________

Has the country team identified a planned or existing mechanism with sufficient funds and adequate length of agreement to complete the study?

____________________________________________________________

List IRBs or other relevant Ethical Review Panels that will be reviewing the protocol that emerges from this concept sheet:

____________________________________________________________
Has the AOTR/Project Officer verified that the activities are within the scope of the agreement? YES/NO

Comments

AOTR/Project Officer signature (if signoff confirmation, please attach email):

Signoff

To be completed by IE Reviewer(s):

IE Submission Number (OGAC will assign)

IE Reviewer (OGAC will assign)

Does this concept sheet meet the definition of Impact Evaluation based on the PEPFAR Guidance for Impact Evaluation? YES/NO

Comments

Is the scope realistic such that impact data will be available in less than 3 years from submission of concept? YES/NO

Comments

Does the concept allow for interim data analysis and a plan to feedback results to inform program planning? YES/NO

Comments

Is the study question related to a current knowledge gap? Is this an area of priority for PEPFAR? YES/NO

Comments

Is the PEPFAR program submitting the concept well positioned to address this question? YES/NO

Comments

Is the budget consistent with the scope of the study and has the country team drawn on local information to provide realistic cost estimates for the total study? YES/NO
Comments___________________________________________________

**Technical Review**

Methods (40 points): ________ points

Is the evaluation hypothesis driven? Is the study design rigorous and has there been adequate statistical/epidemiological inputs to ensure the sampling methodology and sample size are adequate to address the hypothesis? Is there a valid counterfactual comparison?

Can the question (s) proposed be answered through well-designed and conducted research? Do the methods permit attribution of outcomes to the program of interest? Does the study measure specific outcomes (impacts) of the intervention, preferably using validated and externally verifiable measures such as biological or clinical outcomes?

Are there plans for interim analyses and the ability to provide feedback to the program while it is being evaluated?

Comments___________________________________________________

Country ownership and capacity building (10 points): ________ points

Does the proposal respond to a country priority or strategy, especially as identified by the MOH and/or National AIDS Council? What would be the programmatic impact? Is there a commitment or plan to make use of the findings?

Does the proposal involve and strengthen an in-country institution’s evaluation/research capacity? Does the proposal involve in-country investigator (e.g., co-PI) participation? Is there participation by local governments or indigenous NGOs in a way that will strengthen the research capacity or research utilization capacity of those organizations?

Additional Reviewer Comments or special considerations?

___________________________________________

The Primary Reviewer recommends this concept sheet be approved YES/NO

___________________________________________

Signature of Primary Reviewer
The Secondary Reviewer recommends this concept sheet be approved YES/NO

_______________________________________
Signature of Secondary Reviewer
4 Works cited


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