# PEPFAR Country/Regional Operational Plan (COP/ROP) Guidance 2017

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U.S. DEPARTMENT OF STATE

# Table of Contents

**1.0 COP BASICS** ..... **10**

1.1 Executive Summary ..... 11
1.2 What is a COP? ..... 14
1.3 Which Programs Prepare a COP? ..... 15
1.4 COP Timeline ..... 16
1.5 Required COP Elements Checklist ..... 21

**2.0 PEPFAR'S APPROACH TO PROGRAM PLANNING AND DECISION-MAKING** ..... **22**

2.1 Global Overview and Context ..... 23
*2.1.1 PEPFAR's Role and Response* ..... *26*
2.2 Defining Program Goals to Accelerate Epidemic Control ..... 28
2.3 Coordination and Strategic Communication with External Partners during COP Planning ..... 32
*2.3.1 Host Country Governments* ..... *32*
*2.3.2 Multilateral and Private Sector Partner Engagement* ..... *33*
*2.3.3 Active Engagement with Community and Civil Society* ..... *36*
*2.3.4 Stigma, Discrimination, Violence and Human Rights* ..... *40*
*2.3.5 Coordination among U.S. Government Agencies* ..... *41*

**3.0 PLANNING STEPS FOR STANDARD PROCESS AND STAR PROCESS** ..... **43**

3.1 Overview of the Planning Steps for Standard Process and STAR Process ..... 44
3.2 Modular Planning Steps ..... 44

**4.0 TECHNICAL CONSIDERATIONS SUMMARY** ..... **48**

**APPENDICES** ..... **53**

**APPENDIX A: STANDARD PROCESS PLANNING STEPS** ..... **54**

Appendix A.1 Modular Planning Steps ..... 55
Appendix A.2 Order of Planning Steps and Activities ..... 55
*Appendix A.2.1 Planning Step 1: Understand the Current Program Context* ..... *56*
*Appendix A.2.2 Planning Step 2: Assess Alignment of Current PEPFAR Investments to Epidemic Profile, Partner Performance and Results* ..... *60*
*Appendix A.2.3 Planning Step 3: Determine Priority Locations and Populations for Epidemic Control and Set Targets* ..... *60*
*Appendix A.2.4 Planning Step 4: Determine Program Support and System-Level Interventions in which PEPFAR will invest to Achieve Epidemic Control* ..... *73*
*Appendix A.2.5 Planning Step 5: Determine the Package to Sustain Services and Support in Other Locations and Populations and Expected Volume* ..... *76*
*Appendix A.2.6 Planning Step 6: Project Total PEPFAR Resources Required to Implement Strategic Plan and Reconcile with Planned Funding Level* ..... *81*
*Appendix A.2.7 Planning Step 7: Set Site, Geographic and Mechanism Targets* ..... *84*
*Appendix A.2.8 Planning Step 8: Determine monitoring strategy for planned activities in accordance with requirements and assess staff capacity* ..... *87*
*Appendix A.2.9 Methods* ..... *91*
*Appendix A.2.9.1 Site Yield and Volume Analysis* ..... *91*
*Appendix A.2.10 Outlier Analysis* ..... *98*

**APPENDIX B: STAR PROCESS PLANNING STEPS ..... 101**

Appendix B.1 Executive Summary ..... 102
Appendix B.2 Key Components of STAR COP17 Development, Review, and Oversight Process - What Is New? ..... 102
Appendix B.3 Background and Goals ..... 103
Appendix B.4 Key Elements of the STAR Process ..... 104
Appendix B.5 Core Steps for STAR COP/ROP Process Submission ..... 106
*Appendix B.5.1 Core Steps Discussion ..... 106*
*Appendix B.5.2 How will countries submitting via the STAR process be evaluated? ..... 114*
Appendix B.6 Two Year Budget Review and Approval ..... 114
Appendix B.7 Completion of the Focused Outcome and Impact Table ..... 115
*Appendix B.7.1 Completion of the FOIT Activity Tab ..... 115*
*Appendix B.7.2 Completion of the FOIT Budget Tab ..... 117*
*Appendix B.7.3 Completion of the FOIT Central Funding Tab ..... 118*

**APPENDIX C: TECHNICAL CONSIDERATIONS ..... 119**

Appendix C.1 Executive Summary ..... 120
Appendix C.2 Introduction ..... 121
Appendix C.3 Section One: Preventing and Treating New Infections among Adolescents and Young Adults <30 Years Old ..... 124
*Appendix C.3.1 Background ..... 124*
*Appendix C.3.2 Priority Strategies & Interventions for COP17 ..... 127*
*Appendix C.3.3 Country Examples of Priority Interventions ..... 134*
Appendix C.4 Targeted Testing and Improving Testing Yield for Populations ..... 138
*Appendix C.4.1 Background ..... 138*
*Appendix C.4.2 Priority Strategies & Interventions for COP17 ..... 143*
*Appendix C.4.3 Country Examples of Priority Interventions ..... 151*
Appendix C.5 Retention and Viral Load Suppression ..... 153
*Appendix C.5.1 Background ..... 153*
*Appendix C.5.2 Priority Strategies & Interventions for COP17 ..... 157*
*Appendix C.5.3 Country Examples of Priority Interventions ..... 162*
Appendix C.6 Access to Quality, Sustainable HIV Services ..... 167
*Appendix C.6.1 Considerations of Utilizing Health Care Workers in HIV Delivery Models ..... 168*
*Appendix C.6.1.1 Background ..... 168*
*Appendix C.6.1.2 Priority Strategies & Interventions for COP17 ..... 170*
*Appendix C.6.3 Country Examples of Priority Interventions ..... 172*
*Appendix C.6.4 The Role of Civil Society Organizations ..... 174*
*Appendix C.6.4.1 Background ..... 174*
*Appendix C.6.4.2 Priority Strategies & Interventions for COP17 ..... 177*
*Appendix C.6.4.3 Country Examples of Priority Interventions ..... 178*
*Appendix C.6.5 Stigma, Discrimination, Violence, and Human Rights ..... 180*
*Appendix C.6.5.1 Background ..... 180*
*Appendix C.6.5.3 Country Examples of Priority Interventions ..... 183*
Appendix C.7 Summary ..... 184
Appendix C.8 New Guidelines about Technical Updates ..... 185
Appendix C.9 Program Quality and TWG Contacts ..... 189

**Appendix C.10 PEPFAR Combination Prevention Trials Technical Consultation: Meeting Summary ..... 191**

**Appendix D: COP ELEMENTS ..... 213**

Appendix D.1 Chief of Mission Submission Letter ..... 214
Appendix D.2 Strategic Direction Summary ..... 214
Appendix D.3 Indicators and Targets ..... 215
*Appendix D.3.1 Site and Sub-national Level Targets ..... 216*
*Appendix D.3.2 Implementing Mechanism Level Indicators and Targets: Required for all IMs ..... 216*
*Appendix D.3.3 PEPFAR Technical Area Summary Indicators and Targets ..... 217*
*Appendix D.3.4 National-level Indicators and Targets ..... 217*
Appendix D.4 Implementing Mechanism Information ..... 218
*Appendix D.4.1 Prime Partner Name ..... 219*
*Appendix D.4.2 Mechanism Details ..... 220*
*Appendix D.4.3 Government to Government Partnerships ..... 221*
*Appendix D.4.4 Funding Agency ..... 222*
*Appendix D.4.5 Procurement Type ..... 224*
*Appendix D.4.6 Implementing Mechanism Name ..... 225*
*Appendix D.4.7 HQ Mechanism ID, Legacy Mechanism ID, and Field Tracking Number ..... 225*
*Appendix D.4.8 Agreement Timeframe ..... 226*
*Appendix D.4.9 TBD Mechanisms ..... 226*
*Appendix D.4.10 New Mechanism ..... 226*
*Appendix D.4.11 Construction/Renovation ..... 227*
*Appendix D.4.12 Motor Vehicles ..... 227*
*Appendix D.4.13 Prime Partners ..... 228*
*Appendix D.4.14 Definitions ..... 229*
*Appendix D.4.15 Subdivisions of an Organization ..... 230*
*Appendix D.4.16 Funding Sources / Accounts ..... 230*
*Appendix D.4.17 Cross-Cutting Budget Attributions ..... 232*
*Appendix D.4.17.1Cross-Cutting Attributions and Definitions ..... 233*
*Appendix D.4.18 Activity Table ..... 244*
*Appendix D.4.19 Public Private Partnerships ..... 244*

**APPENDIX E: Budgetary and Reporting Requirements ..... 247**

Appendix E.1 COP Planning Levels, Applied Pipeline and Financial Supplemental Document ..... 248
*Appendix E.1.1 COP Planning Levels ..... 248*
*Appendix E.1.2 Applied Pipeline ..... 249*
*Appendix E.1.3 Financial Supplemental Workbook ..... 250*
Appendix E.2 Budget Code Definitions ..... 252
*Appendix E.2.1 MTCT- Prevention of Mother to Child Transmission ..... 252*
*Appendix E.2.2 HVAB- Abstinence/Be Faithful ..... 253*
*Appendix E.2.3 HVOP – Other Sexual Prevention ..... 254*
*Appendix E.2.4 HMBL- Blood Safety ..... 255*
*Appendix E.2.5 HMIN- Injection Safety ..... 255*
*Appendix E.2.6 IDUP- Injecting and Non Injecting Drug Use ..... 256*
*Appendix E.2.7 CIRC- Voluntary Medical Male Circumcision ..... 256*
*Appendix E.2.8 HVCT- HIV Testing Services ..... 258*
*Appendix E.2.9 HBHC- Adult Care and Support ..... 258*

*Appendix E.2.10 HKID- Orphans and Vulnerable Children* ..... 260
*Appendix E.2.11 HVTB- TB/HIV* ..... 261
*Appendix E.2.12 PDCS- Pediatric Care and Support* ..... 262
*Appendix E.2.13 HTXD- ARV Drugs* ..... 263
*Appendix E.2.14 HTXS- Adult Treatment* ..... 264
*Appendix E.2.15 PDTX- Pediatric Treatment* ..... 265
*Appendix E.2.16 OHSS- Health Systems Strengthening* ..... 266
*Appendix E.2.17 HLAB- Laboratory Infrastructure* ..... 267
*Appendix E.2.18 HVSI- Strategic Information* ..... 268
Appendix E.3 Mandatory Earmarks ..... 268
*Appendix E.3.1 Orphans and Vulnerable Children* ..... 268
*Appendix E.3.2 Care and Treatment Budgetary Requirements and Considerations* ..... 269
Appendix E.4 Other Budgetary Considerations ..... 269
*Appendix E.4.1 Water and Gender-Based Violence (GBV)* ..... 270
*Appendix E.4.2 Tuberculosis* ..... 270
*Appendix E.4.3 Food and Nutrition* ..... 271
*Appendix E.4.4 Abstinence and Be Faithful Reporting Requirement* ..... 272
*Appendix E.4.5 Strategic Information* ..... 272
Appendix E.5 Single Partner Funding Limit ..... 273
*Appendix E.5.1 Exceptions to the Single Partner Funding Limit* ..... 273
*Appendix E.5.2 Umbrella Award Definition* ..... 274
*Appendix E.5.3 Single Partner Limit Justifications* ..... 276
Appendix E.6 Justifications ..... 276

**APPENDIX F: U.S. GOVERNMENT MANAGEMENT AND OPERATIONS (M&O) ..... 277**

Appendix F.1 Interagency M&O ..... 278
*Appendix F.1.1 PEPFAR Staffing Footprint and Organizational Structure Analysis, Expectations and Recommendations* ..... 278
*Appendix F.1.2 SDS Requirements* ..... 281
Appendix F.2 Staffing and Level of Effort Data ..... 283
*Appendix F.2.1 Who to Include in the Database* ..... 283
*Appendix F.2.2 Staffing Data Field Instructions and Definitions* ..... 286
*Appendix F.2.3 Capturing Staff Time Instructions* ..... 290
*Appendix F.2.4 Attribution of Staffing-Related CODB to Technical Areas* ..... 293
Appendix F.3 OU Functional and Agency Management Charts ..... 294
Appendix F.4 Cost of Doing Business Worksheet ..... 295
*Appendix F.4.1 Cost of Doing Business Categories* ..... 296
Appendix F.5 U.S. Government Office Space and Housing Renovation ..... 303
Appendix F.6 Peace Corps Volunteers ..... 304

**APPENDIX G: TEMPLATES, TOOLS, AND COP SUBMISSION ..... 305**

Appendix G.1 Tools and Templates ..... 306
Appendix G.2 COP/ROP Submission ..... 308
*Appendix G.2.1 FACTS Info Templates for Data Entry* ..... 309
*Appendix G.2.2 Checking Your Work and Highlights of Key Reports* ..... 310

**APPENDIX H: OTHER ELEMENTS ..... 312**

Appendix H.1 Acronyms and Abbreviations ..... 313

Appendix H.2 Small Grants Program ..... 318
*Appendix H.2.1 Proposed Parameters and Application Process* ..... *318*
Appendix H.3 Construction and Renovation of Laboratories ..... 323
Appendix H.4 Technical Assistance Available for Global Fund Activities ..... 324
Appendix H.5 Pepfar.net Contacts and Help Information ..... 324
Appendix H.6 Public Private Partnership within the COP ..... 326
Appendix H.7 Long-term Strategy (LTS), Targeted Assistance (TA) and Technical Collaboration (TC) PEPFAR Operating Unit Assignments ..... 329
Appendix H.8 Inventory of PEPFAR Funded Evaluations ..... 330

**APPENDIX I: SUPPLEMENT DOCUMENTS CHECKLIST ..... 332**

**APPENDIX J: CASE EXAMPLES OF BEST PRACTICES FOR PEPFAR PROGRAMS ..... 335**

Appendix J.1 Preventing and Treating New Infections among Adolescents and Young Adults <30 Years Old ..... 336
*Appendix J.1.1 Prevention in Adolescent Girls and Young Women (AGYW), DREAMS & OVC* ..... *336*
*Appendix J.1.1.1 DREAMS Malawi – Mapping Female Sex Worker Hot Spots for Targeted HIV Testing & Outreach* ..... *336*
*Appendix J.1.1.2 Partner Layering & Coordination for Success in Adolescent Girl and Young Women Prevention in Uganda* ..... *337*
*Appendix J.1.1.3 Psychological and Behavioral Interventions to Reduce HIV Risk: Evidence from a Randomized Control Trial among Orphaned and Vulnerable Adolescents in South Africa* ..... *337*
*Appendix J.1.1.4 Enhancing Financial Literacy, HIV/AIDS Skills, and Safe Social Spaces among Vulnerable South African Youth* ..... *338*
*Appendix J.1.1.5 Family Economic Strengthening and Parenting Stress among Caregivers of AIDS-Orphaned Children: Results from a Cluster Randomized Trial in Uganda* ..... *340*
*Appendix J.1.1.6 Sexual Behavior among Young Carers in the Context of a Kenyan Empowerment Program Combining Cash-Transfer, Psychosocial Support, and Entrepreneurship* ..... *341*
*Appendix J.1.1.7 Support for Adolescents and Young Women in PMTCT* ..... *342*
*Appendix J.1.2 VMMC* ..... *343*
*Appendix J.1.2.1 Voluntary Medical Male Circumcision Demand Creation* ..... *343*
*Appendix J.1.2.2 VMMC Modeling for Prioritizing Sub-Populations by Age and Geography* ..... *344*
*Appendix J.1.2.3 VMMC Devices* ..... *344*
*Appendix J.1.3 Key Populations* ..... *345*
*Appendix J.1.3.1 Linking Online Demand Creation to Real World Results for KP Prevention in Thailand* ..... *345*
*Appendix J.1.3.2 Sisters with a Voice – Zimbabwe's National Sex Workers Program: Sharpening Targets to Reach Younger and Higher Risk Sex Workers* ..... *346*
*Appendix J.1.4 Testing & Treatment* ..... *347*
*Appendix J.1.4.1. Introduction and Roll-Out of the Adolescent Package of Services to Improve the Adolescent 90-90-90 in Kenya* ..... *347*
*Appendix J.1.4.2 Community-based ART Program Targeting Men in DREAMS Zimbabwe* ..... *348*
Appendix J.2 Targeted Testing and Improving Testing Yield ..... 349
*Appendix J.2.1 HTS Quality* ..... *349*
*Appendix J.2.1.1 HIV Rapid Testing Continuous Quality Improvement (RT-CQI formally referred to as RTQII)* ..... *349*
*Appendix J.2.1.2 Optimizing Provider-Initiated Testing and Counseling Using Quality Improvement Techniques in Tanzania* ..... *351*
*Appendix J.2.2 Self-Testing* ..... *353*

*Appendix J.2.2.1 Promoting Male Partner Testing and Safer Sexual Decision Making through Self-Testing in Kenya* ..... 353
*Appendix J.2.2.2 Increasing HTS Coverage through Assisted Self-Testing among People who Inject Drugs in Ukraine* ..... 354
*Appendix J.2.2.3 Using Peer Educators to Scale-up HIV Oral Self-Testing among Female Sex Workers in Kenya* ..... 355
*Appendix J.2.3 Sexual and High Risk Networks* ..... 356
*Appendix J.2.3.Building Quality Approaches for MSM and Transgender Women in Thailand* ..... 356
*Appendix J.2.3.2 Social Network Outreach Using Virtual Platforms for HIV Testing in Central America* ..... 356
*Appendix J.2.3.3 Peer-Driven Intervention (PDI) to Increase Uptake of HIV Services among Hard-to-Reach Key Populations in Vietnam* ..... 357
*Appendix J.2.3.4 Utilizing Social Network Referrals and Peer Navigation for Key Populations in Central America* ..... 358
*Appendix J.2.3.5 Expanding HIV Testing Approaches and Linkage to Care among Men who have Sex with Men in Curitiba, Brazil* ..... 360
*Appendix J.2.4 Children & Adolescents* ..... 360
*Appendix J.2.4.1 Optimized HTS Strategy in High-Burden Counties with the National Program's Rapid Results Initiative in Kenya* ..... 360
*Appendix J.2.4.2 Promoting Uptake of Child HIV Testing: An Evaluation of the Role of a Home Visiting Program for Orphans and Vulnerable Children in South Africa* ..... 361
*Appendix J.2.4.3 Optimizing Case Finding, Targeting Testing, Identifying High Yield Sites, and Index Case Tracking among Children Orphaned and Made Vulnerable by HIV and AIDS in Zimbabwe* ..... 362
*Appendix J.2.4.4 New Testing Strategies for Specific Populations (Pediatric and Adolescents)* ..... 364
*Appendix J.2.4.5 Effect of a Congregation-Based Intervention on Uptake of HIV Testing and Linkage to Care in Pregnant Women (Baby Shower): Results from a Cluster Randomized trial in Nigeria* ..... 365
*Appendix J.2.5 Early Infant Diagnosis (EID)* ..... 366
*Appendix J.2.5.1 Field Performance of Point-of-Care HIV Testing for Early Infant Diagnosis: Pooled Analysis from Six Countries from the EID Consortium* ..... 366
*Appendix J.2.5.2 Using a Web-Based HIV Infant Tracking System to Improve Early Infant Diagnosis* ..... 368
*Appendix J.2.5.3 Maximizing Early Infant Diagnosis (EID) of HIV-Exposed Infants through Quality Improvement* ..... 368
*Appendix J.2.6 Tuberculosis/HTS Linkage* ..... 369
*Appendix J.2.6.1 HIV Testing of Presumptive TB Patients in India* ..... 369
*Appendix J.2.6.2 HIV Testing of Presumptive TB Patients in Malawi* ..... 370
*Appendix J.2.6.3 Xpert MTB/RIF Network Optimization for Improved TB Detection among PLHIV in Kenya* ..... 370
Appendix J.3 Retention and Viral Load Suppression ..... 372
*Appendix J.3.1 Adherence & Retention* ..... 372
*Appendix J.3.1.1 Expansion of the Adherence Club Model for Stable Antiretroviral Therapy Patients* ..... 372
*Appendix J.3.1.2 Reducing Loss to Follow Up and Attrition through Decentralization of ART Services: The Swaziland Hub-and-Spoke Model* ..... 372
*Appendix J.3.1.3 Improving Isoniazid Preventive Therapy Delivery Models among People Living with HIV (PLHIV) in Swaziland* ..... 373

*Appendix J.3.1.4 EQUIP Best Practice: Bringing Pre-ART Clients for early ART initiation under Test and Start in Malawi* ..... 374
*Appendix J.3.2 Viral Load & Lab Considerations* ..... 376
*Appendix J.3.2.1 Reducing Lab Costs With Reagant Rental"* ..... 376
*Appendix J.3.2.2 Dried Blood Spots for Viral Load Monitoring: Feasible and Effective* ..... 377
*Appendix J.3.2.3 Application of Recent HIV infection Assays for Enhanced HIV Case-Based Surveillance and Targeted Prevention in PEPFAR-Supported Settings* ..... 378
*Appendix J.3.2.4 Use of Viral Load Scorecard to Identify Gaps and Measure Improvement for Viral Load Scale-up* ..... 380
*Appendix J.3.3 Pregnant and Breastfeeding Women* ..... 381
*Appendix J.3.3.1 Viral Load Monitoring in Pregnant and Breastfeeding Women as a Priority Population* ..... 381
*Appendix J.3.3.2 Use of mHealth Technologies to Support PMTCT Service Delivery* ..... 382
*Appendix J.3.3.3 Women's Needs and Preferences in PMTCT Services* ..... 382
*Appendix J.3.4 Children and Adolescents* ..... 383
*Appendix J.3.4.1 Characterizing Viral Load Testing and Suppression in Pregnant and Post-partum Women, Children, and Adolescents through a Service Quality Assessment in Kenya* ..... 383
*Appendix J.3.4.2 The Impacts of Economic Strengthening Interventions on Retention and Adherence to HIV Care and Treatment and Practicing Risky Behaviors: Quantitative and Qualitative* .... 384
*Appendix J.3.4.3 Promoting Strategies for Linking Community/Facility Providers to Support Children in Uganda* ..... 385
*Appendix J.3.4.4 Birth Cohort Monitoring to Evaluate Retention and Care of HIV-Exposed Infants* 386
*Appendix J.3.5 Key Populations* ..... 387
*Appendix J.3.5.1 Suppressing Viral Load among Sex Workers (Zimbabwe Sisters with a Voice)* ..... 387
*Appendix J.3.5.2 Building Quality Approaches for MSM and Transgender Women in Thailand: Investments in Innovative Information Systems* ..... 388
*Appendix J.3.5.3 Most at Risk Populations Initiative: MARPI Clinic - ART Scale Up Models for Key Populations* ..... 389
*Appendix J.3.5.4 LINKAGES, India - Dashboard for Monitoring Programmatic Data on Cascade Performance* ..... 390
*Appendix J.3.5.5 An Integrated Model for Scaling up ART among Key and Priority Populations in Kenya* ..... 391
*Appendix J.3.5.6 Cameroon Joint PEPFAR/Global Fund KP HIV Cascade Assessment* ..... 392
Appendix J.4 Considerations for Utilizing Health Care Workers in HIV Service Delivery Models ..... 393
*Appendix J.4.1 Adaptation of the Project ECHO model™ To Strengthen Workforce Capacity in PEPFAR-Supported HIV Programs* ..... 393
*Appendix J.4.2 Home Visiting Programs for HIV-Affected Families: A Comparison of Service Quality between Community-Based or Lay Cadres in Malawi* ..... 394
*Appendix J.4.3 Volunteer-Driven and Paraprofessional Models* ..... 395
*Appendix J.4.4 Bridging the Gap: The Impact of Home Visiting Programs for Orphans and Vulnerable Children on Social Grant Uptake in South Africa* ..... 397
*Appendix J.4.5 Integrating Wellness/Stable Patient Delivery Systems* ..... 398
*Appendix J.4.6 Addressing Retention through HRH in Uganda* ..... 399
*Appendix J.4.7 Zimbabwe: Utilization of a Cadre of Community Adolescent Treatment Supporters to Improve Linkage, Retention and Adherence in Adolescents and Young Adults Living with HIV* ..... 400
*Appendix J.4.8 Expansion of Package of Services Provided by Mothers to Mothers to Enhance Service Uptake by Families and Adolescents in Lesotho* ..... 401

Appendix J.5 Access to Quality, Sustainable HIV Services – Civil Society Organizations.....401
*Appendix J.5.1 Comprehensive Care* ..... *401*
*Appendix J.5.1.1 Towards Eliminating Infectious HIV in Sex Work in Zimbabwe*..... *401*
*Appendix J.5.2 Monitoring ARV Stock Outs* ..... *403*
*Appendix J.5.2.1 Partnering with CSOs to Monitor ARV Stock Outs in South Africa & Mozambique* *403*
*Appendix J.5.3 Creating Provider Treatment Care Teams and Linking Community/Facility Providers* ..... *404*
*Appendix J.5.3.1 Creating Provider Treatment Care Teams and Linking Community/Facility Providers in Thailand*..... *404*
*Appendix J.5.3.2 Using a Twinning Model with NGOs and the Public Sector in the Dominican Republic* ..... *405*
Appendix J.6 Stigma, Discrimination, Violence, and Human Rights.....406
*Appendix J.6.1 Reducing and Responding to GBV against Key Populations in Cameroon*..... *406*
*Appendix J.6.2 Mapping Violence Response Services in the Dominican Republic* ..... *408*
*Appendix J.6.3 Ghana HIV-related Stigma & Discrimination Reporting and Redress System*..... *409*
*Appendix J.6.4 Thai MOH Stigma Monitoring Systems* ..... *409*
*Appendix J.6.5 Health Facility Stigma & Discrimination-Reduction Programming* ..... *410*

# 1.0 COP BASICS

# 1.1 Executive Summary

PEPFAR's focus on gaining sustainable control of the HIV epidemic made possible the announcement of bold PEPFAR HIV prevention and treatment targets for 2017 and 2018 at the 2016 Sustainable Development Goals Summit and the 2016 United Nations General Assembly. The focus on sustainable epidemic control began in 2014, when PEPFAR programs began pivoting to a data-driven approach that strategically targets geographic areas and populations where HIV/AIDS is most prevalent, and in which PEPFAR, in collaboration with host country governments, can achieve the greatest impact. With the focus of scaling HIV services in the highest disease burdened areas now being implemented, the streamlined Country Operational Plan (COP) for Fiscal Year (FY) 2017 focuses on impact and performance.

For the first time, we have evidence that PEPFAR program implementation can change the course of the epidemic evidenced by the impact assessments recently completed in Zambia, Zimbabwe, and Malawi. Controlling the HIV pandemic is possible. For COP 17, all PEPFAR teams will continue to progress toward sustainable control of the HIV epidemic by using data to validate strategic approaches developed in COP 2016. Teams will also identify additional areas for saturation by examining opportunities for increased efficiency and effectiveness in investment approaches and service delivery models. In addition, PEPFAR teams will amplify their consultation and engagement with external stakeholders (i.e., civil society, multilateral organizations, and partner governments) to strengthen and enhance dialogue and input on PEPFAR-funded activities and services.

Specifically, COP 2017 responds to stakeholder and Ambassador feedback on COP 2016 guidance and offers a clearer, more transparent, streamlined strategic planning process that will be completed in a significantly reduced period of time. **Key modifications include:**

- Introduction of two distinct strategic planning processes that respond to the different approaches of PEPFAR involvement and investment in national HIV responses and better align with the programs and priorities of the diverse array of global PEPFAR programs (See Section 3).
    - The **Standard Process** will be used by PEPFAR programs in countries with comprehensive strategies to continue to advance epidemic control through increased focus on impact and sustainability. This process builds on the approach PEPFAR has

developed over the past three years and is designed for PEPFAR programs whose primary impact on the national program involves significant site-level investments. The Standard Process results are monitored throughout the year by quarterly PEPFAR Oversight and Accountability Results Team (POART) consultations using data to for real-time improvement for program impact. (See Appendix A)

- The **Strategic and Technical Alignment for Results (STAR) process** will be used by regional and bilateral PEPFAR programs which primarily provide technical assistance/technical collaboration programs to optimize the impact of PEPFAR resources, support control of the HIV pandemic, and enhance the sustainability of national HIV responses through the promotion of innovations that address key challenges and underserved populations. The STAR process will result in a two-year strategic plan supported by POART monitoring every six months. This approach better aligns with the time horizon in which tangible results to the national cascade are expected. Annual review processes will occur to ensure goals are achieved and investments are impactful. (See Appendix B)

- Introduction of a new tier of support ("Attained") for those scale-up subnational units (SNU) expected to have achieved 81% ART coverage by the 2017 Annual Progress Report (APR17) in adult males and females in all age/sex bands. (See Appendix A.2.3)
- Enhanced use of the annual target setting and budgeting approach for achieving sustained epidemic control, including Implementing Mechanism (IM)-level targets and budgets. COP 17 emphasizes the review of partner performance, quality, and financial data at the partner IM-level, site level, district level, and national level to ensure that resources are being allocated where they are most needed. Targets and budgets must be clearly linked to the PEPFAR Budget Allocation Calculator (PBAC). Routine program monitoring through the POART consultations will enable PEPFAR teams to track closely progress at all levels and flexibly adjust programs and budgets as required. An optional tool will be released to help teams develop site-level targets required for Data for Accountability, Transparency, and Impact Monitoring (DATIM) data entry. (See Appendix A)
- The PEPFAR Technical Considerations, now a part of this COP guidance (see Technical Considerations in Section 4 and Appendix C), has been restructured to focus on new solutions and innovations and to improve impact and accountability. COP 17 encourages teams to review policies, service delivery modalities, and implementation processes to ensure they reflect best practices and new technologies, and that HIV testing strategies have evolved to reach those who were not diagnosed through earlier strategies.

- Targeted investment in above-site activities to specifically overcome key system barriers that impede achievement of sustainable epidemic control and show demonstrable outcomes and improvements over the next 12 months.
    - Programs using the Standard Process are expected to **continue to support** those three-year systems activities identified and initiated in COP 16 after first validating that the identified barriers and outcomes are still relevant and on track to achieve proposed outcomes. These programs will provide a narrative on an updated Table 6 to describe progress made toward year one benchmarks and any factors limiting progress (see Appendix A.2.4).
    - Programs using the STAR process will adopt a new approach that builds on systems work in COP 16 to ensure that site-level and above-site investments work together and are complementary to support epidemic control. These programs will describe planned outcomes through completion of the Focused Outcome and Impact Table (FOIT), an expanded Table 6 that combines site and above-site activities. The FOIT will represent the major COP 17 submission for these country programs (see Appendix B.7).
- The Sustainability Index and Dashboard (SID) will not be required for COP 17; beginning in COP 18, the SID will be completed every two years. This longer timeframe will allow for a better analysis of trends in sustainability over time, recognizing that progress towards sustainability may not be measurable in one calendar year. The new SID timeline will also allow for harmonization with UNAIDS' National Commitments and Policies Instrument (NCPI), which will be implemented in SID off years.
- Integration of respect for human rights and efforts to eliminate stigma and discrimination into all PEPFAR-supported activities.
- Expanded meaningful engagement with external stakeholders and multilateral organizations (see Section 2.3.1, Section 2.3.2 and Section 2.3.3) to strengthen and enhance input on PEPFAR-funded activities and services.
- Teams are no longer required to submit documentation of core, near-core, and non-core assessments; however, the expectation is that all PEPFAR-supported activities will be aligned with these principles.

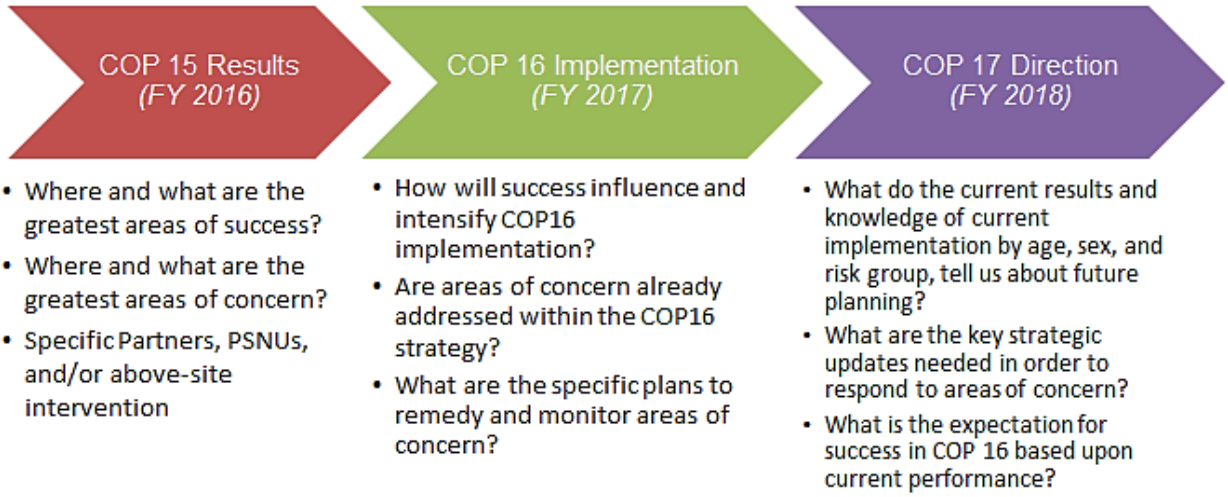
As the COP 17 process is implemented, comments and suggestions for how to further improve our program and approaches continue to be most welcome and encouraged.

# 1.2 What is a COP?

The COP[1] documents U.S. government (USG) annual investments and anticipated results in the global fight against HIV/AIDS. It is the basis for approval of annual USG bilateral HIV/AIDS funding in most partner countries. The COP also serves as the basis for Congressional notification, allocation, and tracking of budget and targets and as an annual work plan for the USG activities in global HIV/AIDS. Data from the COP are essential to complying with PEPFAR's commitment to transparency and accountability to all stakeholders.

For the past three years, PEPFAR COPs have focused on using data to inform decisions that resulted in more focused programs leading to sustained epidemic control. In COP 17 it is assumed that those pivots are now being implemented and that further major geographic shift in programming are not required. The focus of COP 17 is therefore on using ongoing analysis of implementation results to enhance impact and sustainability, including age and sex disaggregation to ensure all at risk groups are being reached.

**Figure 1.2.1**



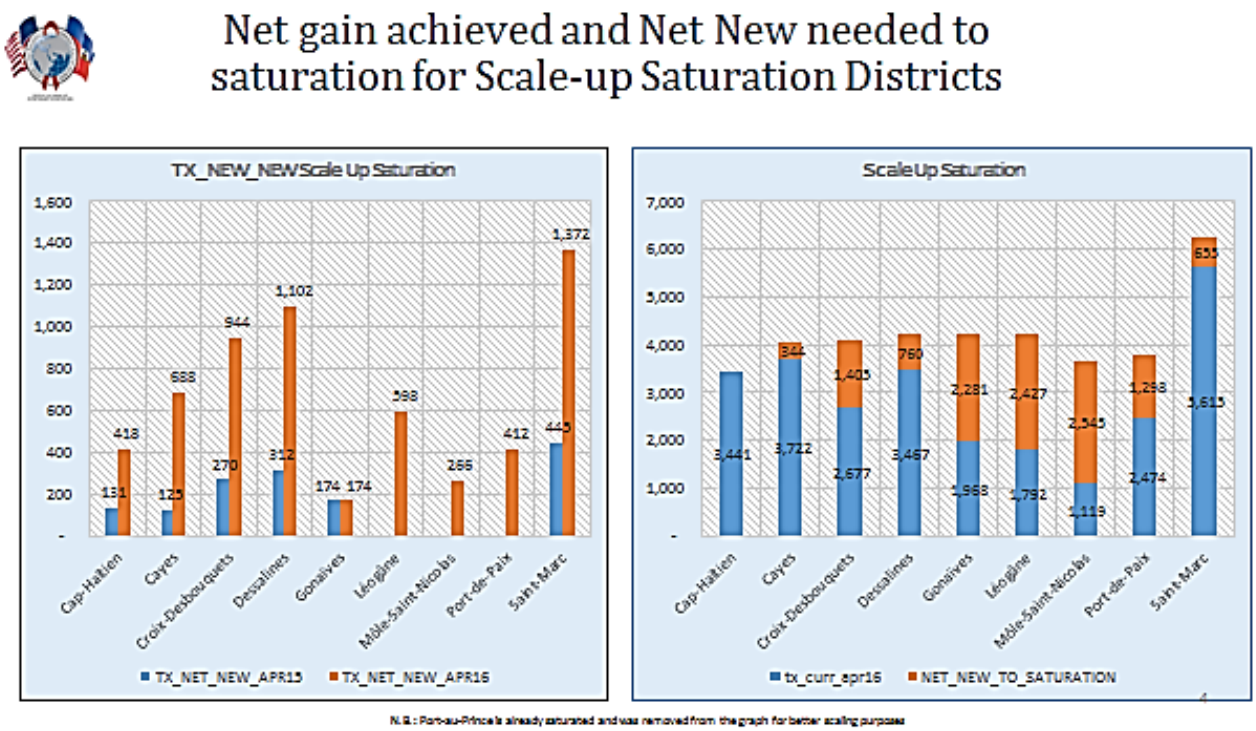

As illustrated in Figure 1.2.1, plans proposed in COP 17 will be guided by a thorough understanding of *current* results and *current* implementation. Information coming out of the FY 16 annual results report and POART monitoring consultations will be coupled with stakeholder input

[1] Throughout this document, the term 'COP(s)' includes Regional Operating Plans (ROPs) except as specified, and the term 'country teams' includes regional teams for programs completing a ROP.

and data from SIMS, PBAC, and other tools to identify areas of greatest success and areas of concern at both the programmatic and partner level. Based on this knowledge of *current* partner and program performance, COP 17 will propose key strategic updates to expand successes, including expanding to new areas identified for saturation, as well as updates needed to respond to areas of concern.

As illustrated below, in Figure 1.2.2, the PEPFAR Haiti program has successfully used this data analysis process to adopt current best practices, intensify partner monitoring, increase impact, and set future targets for epidemic control.

**Figure 1.2.2**




# 1.3 Which Programs Prepare a COP?

PEPFAR teams receiving $5 million in annual combined PEPFAR funding will prepare a FY 17 COP or ROP using either the Standard Process or STAR Process.

Bilateral programs required to complete a FY 17 COP using the Standard Process include:

Botswana, Burundi, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Haiti, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, South Sudan, Swaziland, Tanzania, Uganda, Ukraine, Vietnam, Zambia and Zimbabwe.

Regional and bilateral programs required to complete a FY 17 ROP or COP using the STAR Process include:

Regional Programs: Asia Regional Program (China, Laos, Thailand), and Caribbean (Bahamas, Barbados, Guyana, Jamaica, Suriname, Trinidad & Tobago), Central America (El Salvador, Guatemala, Honduras, Nicaragua and Panama) and Central Asia (Kazakhstan, Kyrgyz Republic, Republic of Tajikistan).

Bilateral Programs: Angola, Burma, Cambodia, Dominican Republic, Ghana, India, Indonesia and Papua New Guinea

PEPFAR programs receiving less than $5 million in PEPFAR funding are not required to complete a COP or ROP. These programs will account for PEPFAR resources through the preparation of a Foreign Assistance Operational Plan (FOP). The Office of U.S. Foreign Assistance Resources (F) at the Department of State coordinates the development of the FOP. The U.S. Centers for Disease Control (CDC) programs in countries/regions that do not prepare COPs will account for their resources through CDC Country or Regional Assistance Plans.

## 1.4 COP Timeline

The COP 17 Standard and STAR processes have been streamlined significantly and will be completed by the end of April 2017 and the middle of March 2017, respectively, providing PEPFAR country teams with more time to focus on execution and implementation of planned activities. That said, strategic planning is not a one-time activity. As illustrated in Figure 1.2.1 above, COP 17 plans are to be built on monitoring and analysis of data that takes place throughout the year, with the POART consultations a key tool in this process.

All COP 17 planning materials will be released on January 18, 2017. This includes the COP Guidance, the Technical Considerations, and each country's COP Planning Letter. COP Planning Letters will contain not only country-specific funding levels, but also country-specific

technical direction based on current performance. All COP 17 planning materials, including COP Planning Letters, will be posted on PEPFAR.gov; country teams are encouraged to make certain their stakeholders have timely access to these materials.

Post-Quarter 4 POART Consultation and Release of COP 17 Planning Materials

Following the December 2016 POART consultation and the January 2017 release of COP planning materials, country teams should intensify their ongoing dialogue about current implementation and the strategic direction for COP 17 to include:

- Review and discuss the Standard or STAR processes, as appropriate, to ensure that all are familiar with expectations and requirements.
- Discuss and reach consensus on how to address concerns raised in the Q4 Corrective Action Summary (CAS).
- Review and discuss the implications of the country-specific directions included in the COP Planning Letter.
- Review the Technical Considerations and identify current solutions that could be applied in country.
- Review the national context, highlighting any major changes since COP 16.

Internal PEPFAR Planning

The week of January 23, 2017, all PEPFAR programs are expected to host an interagency strategic planning retreat to analyze data, discuss options, and reach consensus on a proposed COP 17 direction. Key elements of the retreat include:

- Analyzing the current geographic and population priorities to determine whether these should be reviewed (e.g. based upon new data) and expanded to new areas/populations for saturation.
- Performing sex and age band analysis to understand gaps in services.
- Using an analysis of current performance and financial data at the national, district, and partner levels to propose COP 17 national, district, and partner level targets and budgets.
- Ensuring the geographic and population priority sites are aligned with the IMs.
- Validating system investments and analyzing progress toward three year outcomes and one year benchmarks.

Implementing Partner Engagement

In coordination with the internal planning session, PEPFAR teams should dialogue with their partners to:

- Review each partner's performance and discuss successes and challenges, including partner's insight on current population and geographic priorities, innovative and emerging trends in implementation, and risk behavior.
- Review expenditure and other financial data.

External Engagement

In coordination with the internal planning session, PEPFAR teams should engage in stakeholder consultations that include:

- A review of Q4 FY 16 and APR 16 program results and the Corrective Action Summary (CAS).
- A presentation of the preliminary conclusions and proposed direction for COP 17 from the internal planning session.
- A solicitation of stakeholder input on the proposed COP 17 direction.

Key dates for COP 17 vary for Standard Process and STAR Process, as illustrated in the following tables:

## Table 1.4.1 COP17 – Standard COP Process

| COP17 STANDARD COP PROCESS | |
|---|---|
| **Key Milestone** | **Dates** |
| Standard COP Kickoff Webinar | January 10, 2017 |
| Release final COP 17 guidance and tools (including country-specific COP guidance) | January 18, 2017 |
| In-Country Strategic Retreat | January 23 – 27, 2017 |
| DC DREAMS/OVC/ACT pre-meeting | February 4-5, 2017 (Johannesburg Group 1)<br>February 18-19, 2017 (Johannesburg Group 2) |
| DC Management Meeting | February 6-10, 2017 (Johannesburg Group 1)<br>February 20-24, 2017 (Johannesburg Group 2)<br>March 7-10, 2017 (Johannesburg Group 3) |
| COPs due | March 2, 2017 (Johannesburg Group 1)<br>March 16, 2017 (Johannesburg Group 2)<br>March 30, 2017 (Johannesburg Group 3) |
| In-person COP reviews | April 19-21, 2017 (Johannesburg 1)<br>April 24-26, 2017 (Johannesburg 2)<br>April 27-29, 2017 (Johannesburg 3) |

Regarding the "COPs Due" dates indicated in Table 1.4.1, all materials are to be also shared with external stakeholders.

## Table 1.4.2 COP17 – STAR Process

| COP 17 STAR PROCESS | |
|---|---|
| **Key Milestone** | **Dates** |
| STAR Kickoff Webinar | January 11, 2017 |
| Release final COP 17 guidance and tools (including country-specific COP guidance) | January 18, 2017 |
| Weekly structured check-ins with HQ | January 19 – February 10, 2017 |
| In-Country Strategic Retreat | January 23-27, 2017 |
| Weekly Structured Calls with HQ and Field Team | Weeks of January 30, February 6, 13, 2017 |
| COPs and ROPs due | February 16, 2017 |
| In-person COP reviews | February 28-March 2, 2017 (Bangkok)<br>March 13-15, 2017 (Washington, DC) |

# 1.5 Required COP Elements Checklist

Table 1.5.1 below outlines which elements are required for the FY 17 COP/ROP. For a full list of required supplements, templates, and instructions, see Appendix I.

**Figure 1.5.1**

**Required COP 17 Elements Checklist**

| COP Element | STANDARD Process | STAR Process |
|---|---|---|
| Strategic Direction Summary (SDS) | Required | Required |
| Data Pack | Required | Not Required |
| PBAC | Required | Not Required |
| Targets in DATIM | Required | Not Required* |
| FOIT | Not Required | Required |
| Implementing Mechanism Details in FACTS Info | Required | Required |
| Management & Operations in FACTS Info | Required | Required |
| Financial Supplemental Workbook | Required | Required |
| Chief of Mission Letter | Required | Required |
| COP 17 CSO Matrix Update | Required | Required |
| FY18 SIMS Site Visit Planning Table | Required | Required** |
| Laboratory Construction or Renovation Project Plan Supplemental | Required for BSL-3 and enhanced BSL-2 laboratory projects | Required for BSL-3 and enhanced BSL-2 laboratory projects |
| Justification for partner funding | Required if partner exceeds 8 percent of budget | Required if partner exceeds 8 percent of budget |
| Evaluation Inventory | Required for all programs that fund evaluations | Required for all programs that fund evaluations |

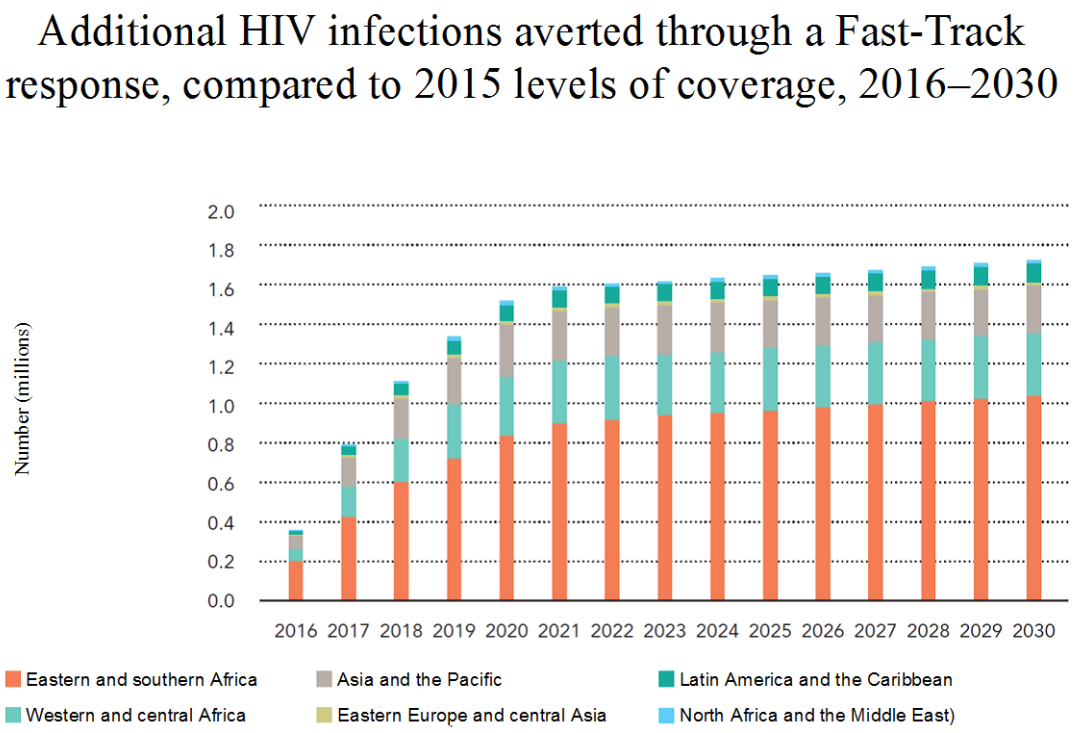
* If countries submitting under the STAR process will have site-level targets, those targets are entered into DATIM.
** SIMS Site Visit Planning Table required for all countries that have site or above-site investments that fall under the SIMS definition

# 2.0 PEPFAR'S APPROACH TO PROGRAM PLANNING AND DECISION-MAKING

# 2.1 Global Overview and Context

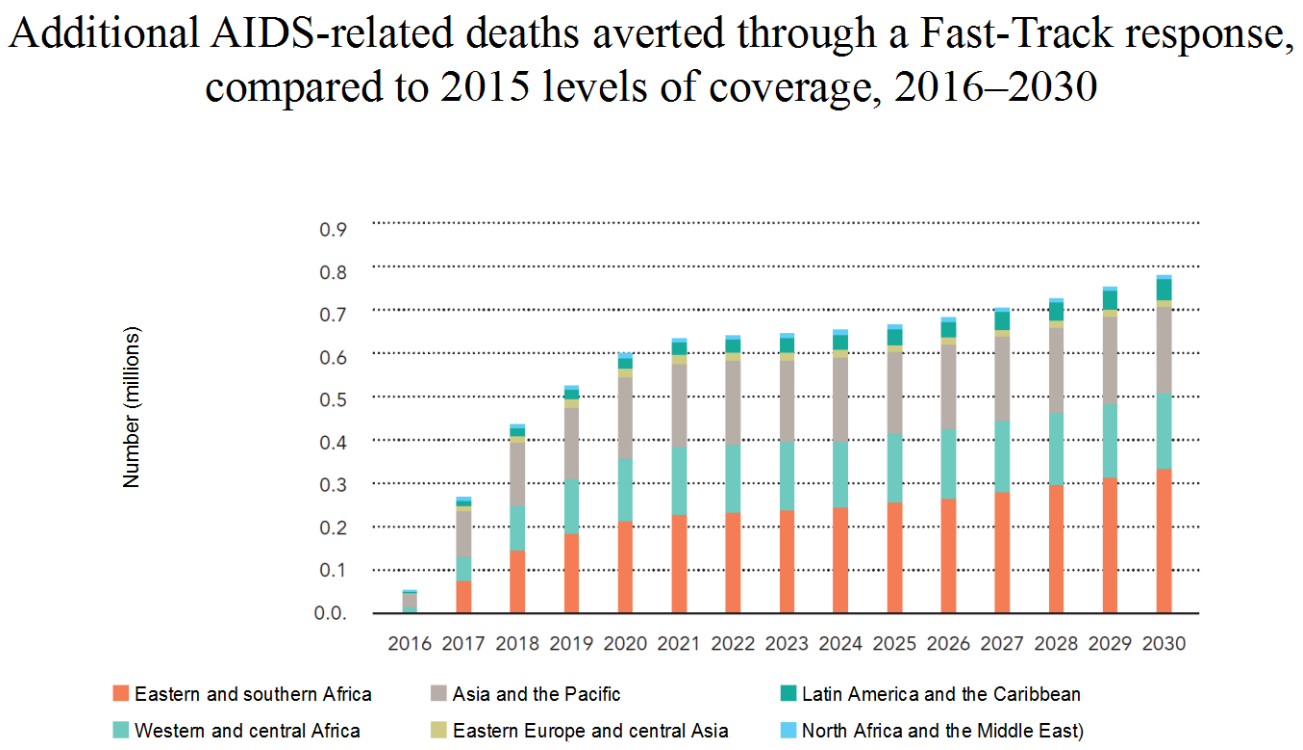
The Joint United Nations Programme on HIV/AIDS' (UNAIDS) December 2016 ***Get on the Fast-Track – The life-cycle approach to HIV*** report announced that the Fast-Track response is working. Globally, 18.2 million people now have access to HIV treatment and increasing treatment coverage has reduced AIDS-related deaths among adults and children by 45% since its peak in 2005. As demonstrated in the graphs below (Figures 2.1.1 and 2.1.2), continuing the Fast-Track response will avert over 1 million new infections annually in 2018 and beyond, dramatically reduce AIDS-related deaths, and critically reach budget neutrality.

**Figure 2.1.1**




Source: Lamontagne E, Over M, Stover J et al. The economic returns of ending the AIDS epidemic by 2030. 2016, in press.

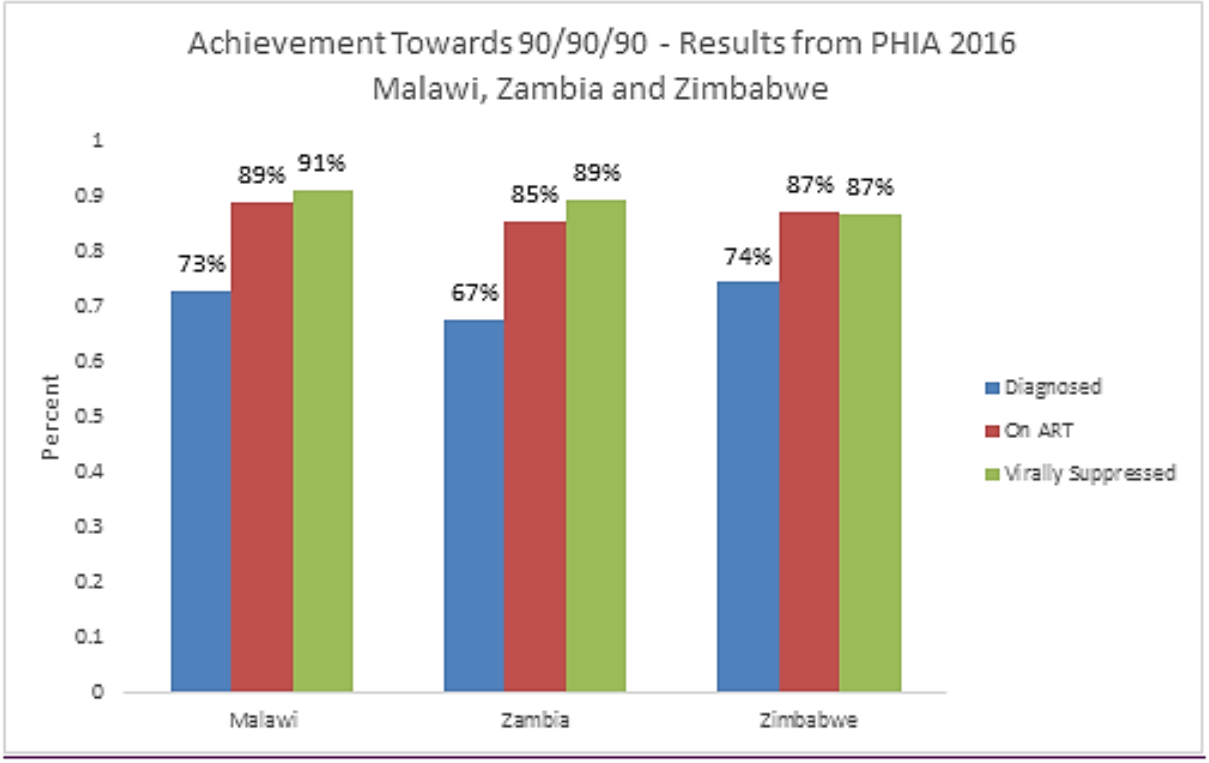
**Figure 2.1.2**




Source: Lamontagne E, Over M, Stover J et al. The economic returns of ending the AIDS epidemic by 2030. 2016, in press.

The preliminary findings from the three recent population based HIV-impact assessments (PHIA) in Malawi, Zambia, and Zimbabwe reaffirm that the 90-90-90 goals are attainable and that HIV incidence levels are reduced in all three countries. The PHIA also showed that all are rapidly moving towards epidemic control and budget neutrality, if focus and impact are sustained and if careful age group analysis are used to improve control in all risk groups.

**Figure 2.1.3**




The three PHIAs also provide critical information to inform future programming. In Malawi, Zambia and Zimbabwe, HIV incidence among young people, particularly women, remains unacceptably high. In particular, HIV prevalence increases significantly in the 20-24 year age group, indicating that renewed focus on reaching youth with prevention programming is imperative for epidemic control.

Viral suppression among all people living with HIV (PLHIV) is high across these countries that have over 60% of PLHIV on antiretroviral treatment (ART). However, there is some variation across provinces, and the factors relating to this should be understood as to reach the UNAIDS viral suppression goals.

**Figure 2.1.4** Viral Load Suppression Among HIV-Positive Individuals by Province, Zimbabwe

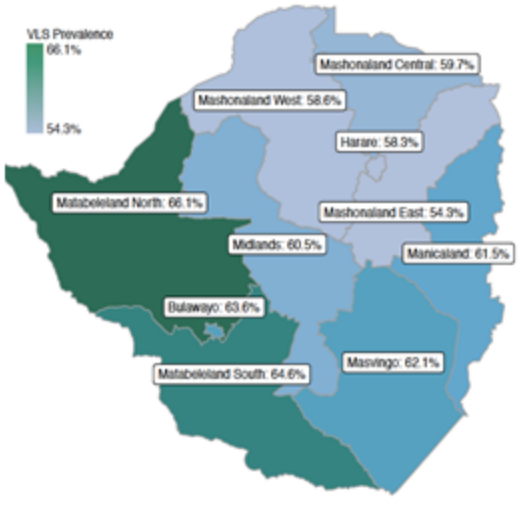
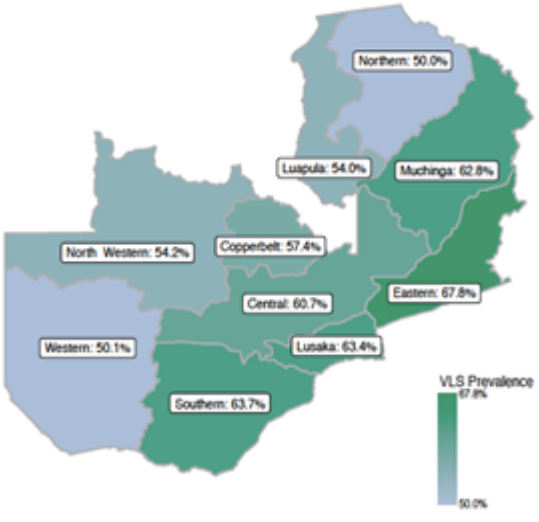



**Figure 2.1.5** Viral Load Suppression Among HIV-Positive Individuals by Province, Zambia




## 2.1.1 PEPFAR's Role and Response

For COP 17, the goal for PEPFAR is to sustain the pivots identified in previous COPs to accelerate epidemic control through greater impact, accountability, and sustainability. Teams will accelerate momentum to advance sustainable control of the HIV epidemic and ultimately achieve an AIDS-free generation by implementing *current solutions to current problems in the current epidemic*. We need fresh and innovative responses to help us address today's challenges, including age and sex group analysis to ensure prevention and treatment programs are ensuring coverage to all genders and ages.

PEPFAR's success will be measured by how effectively we target and tailor our efforts in an effective manner, together with our partners, toward sustainable control of the epidemic and, ultimately, achievement of an AIDS-free generation. Teams should refer to *PEPFAR 3.0 – Controlling the Epidemic: Delivering on the Promise of an AIDS-free Generation,* which describes how PEPFAR can best support sustainable control of the epidemic by pivoting to a data-driven approach that strategically targets geographic areas and populations where HIV/AIDS is most

prevalent, and in which we can achieve the greatest impact for our investments.[2] The report outlines PEPFAR's five action agendas that advance the five core principles of the *PEPFAR Blueprint,* support achievement of PEPFAR's new HIV prevention and treatment targets, and provide a pathway toward sustainable control of the epidemic:

- **Impact Action Agenda** – Do the right things, in the right places, right now, in the right way.
- **Efficiency Action Agenda** – Increase transparency, oversight, and accountability across PEPFAR and its interagency partners.
- **Sustainability Action Agenda** – As services are expanded to reach epidemic control, ensure that the factors required to sustain control are in place.
- **Partnership Action Agenda** – Share responsibility with our partners to achieve an AIDS-free generation.
- **Human Rights Action Agenda** – Respect human rights and address the human rights challenges faced by those living with and affected by HIV/AIDS.

In addition, teams should refer to the December 2016 PEPFAR Sustainability Position Paper, which describes concrete actions for immediately building sustainability into all PEPFAR programming, and to the 2017 PEPFAR Technical Considerations, which present current solutions to current problems and provide effective interventions to support the 90-90-90 goal.

To continue PEPFAR's data-centered business model and identify areas for the next tier of saturation, for COP 17 PEPFAR teams will conduct a solutions-oriented review that includes a series of enhanced data analysis and interpretation steps. This approach will enable teams to examine what is known epidemiologically and technically. Teams will then validate that PEPFAR programs are optimally focused to accelerate the scale-up of combination prevention interventions in prioritized populations and geographic areas. Importantly, the analysis and interpretation process will provide teams with the information needed to ensure that **PEPFAR programs remain focused within countries on the <u>locations</u> and <u>populations</u> with the highest burden of HIV disease.**

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[2] The Office of the U.S. Global AIDS Coordinator. (2014). *PEPFAR 3.0 – Controlling the Epidemic: Delivering on the Promise of an AIDS-free Generation. Retrieved from* *http://www.pepfar.gov/documents/organization/234744.pdf*

# 2.2 Defining Program Goals to Accelerate Epidemic Control

**Goal 1: Focus programming to achieve epidemic control.** PEPFAR defines epidemic control in standard epidemiologic terminology: *The point at which the number of new HIV infections is less than the total number of deaths regardless of cause among individuals infected with HIV.* Modeling studies suggest that achieving and sustaining epidemic control will stem the global pandemic, reduce the disease burden on communities and health systems, decrease the future costs of care and treatment, and enhance economic stability in resource-constrained settings by increasing the productive potential of people living in these areas.

Given the non-random distribution of HIV within a population, the UNAIDS 90-90-90 framework recommends maximizing the epidemiological impact of finite resources by allocating them to geographic areas and population groups with the highest prevalence.[3] Thus, PEPFAR field teams are urged to follow the epidemiologic data at the lowest sub-national unit available when setting targets and designing program activities to achieve countries' 90-90-90 targets and among all ages, gender and risk groups.

**Goal 2: Scale-up proven combination prevention and treatment interventions.** Achieving epidemic control requires investments in both prevention and treatment. Evidence indicates that increases in the number of people on HIV treatment are already having an impact on reducing HIV incidence. But, as the UNAIDS "*Get on the Fast-Track*" reports, progress on HIV prevention among adults must increase.[4] For this reason, since 2014, PEPFAR has launched the Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe (DREAMS) program for adolescents girls and young women, and provided additional funding to voluntary medical male circumcision (VMMC).

This reality highlights the importance of analyzing age and sex disaggregated data to scale up prevention and treatment interventions and approaches where they will have the greatest impact.

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[3] UNAIDS *90-90-90 – An Ambitious Treatment Target to Help End the AIDS Epidemic,* 2014. http://www.unaids.org/en/resources/documents/2014/90-90-90

[4] UNAIDS "*Get on the Fast-Track" 2016,* http://www.unaids.org/sites/default/files/media_asset/Get-on-the-Fast-Track_en.pdf , page 7

For example, the UNAIDS report points out that efforts to prevent HIV infections in young people need to be strengthened through expanding DREAMS and ensuring full VMMC coverage. Hitting the 2020 target will require a 74% reduction in new infections among young women between 2015 and 2020[5]. Clearly, for many countries, innovative solutions to break the cycle of transmission from older men to younger women must be implemented urgently.

**Figure 2.2.1**

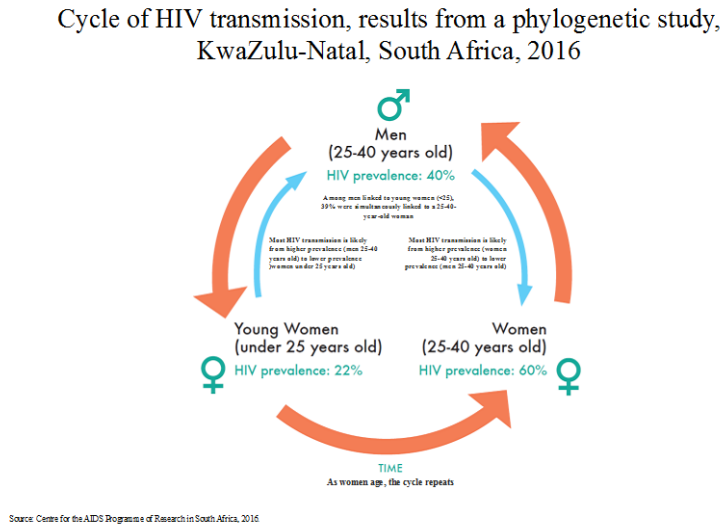
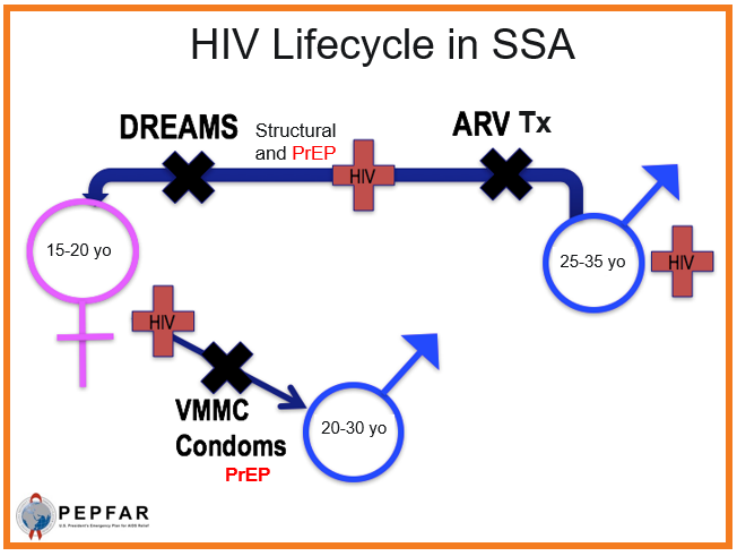



**Figure 2.2.2 HIV Lifecycle in Sub-Saharan Africa (SSA)**




[5] UNAIDS "*Get on the Fast-Track" 2016,* [http://www.unaids.org/sites/default/files/media_asset/Get-on-the-Fast-Track_en.pdf](http://www.unaids.org/sites/default/files/media_asset/Get-on-the-Fast-Track_en.pdf), page 30

Similarly, data indicate new infections appear to be rising among people who inject drugs, transgender persons, and men who have sex with men. Comprehensive HIV programs tailored to the needs of these key populations can reduce new infections if proven interventions are appropriately targeted.

The COP 17 Technical Considerations provide country teams with information on proven interventions and lessons learned to improve impact in both prevention and treatment.

**Goal 3: Ensure the availability and use of high quality data.** The availability and routine use of high quality data is a critical component of epidemic control. HIV incidence, prevalence, and AIDS-associated mortality among people living with HIV, and other key indicators are essential for monitoring national responses to the epidemic. Using PEPFAR and national program data, in combination with published impact studies and survey and surveillance data, is key.

Improving data use will ensure better understanding of programs and results, improve sustainable financing (through national buy-in), as well as program monitoring and accountability. Data use is to be reflected through regular national reporting and publishing granular results in a user-friendly and publically accessible means.

To address these issues and build sustainable structures, PEPFAR is working with host country governments and other stakeholders to improve the frequency and quality of survey and surveillance data. However, this requires more planning and alignment of resources to ensure high-quality data. HIV Impact Assessments provide necessary data to monitor coverage and impact of programs and are valuable in understanding the gaps to reaching epidemic control. The Assessments have been fully funded, with completion expected in 11 countries in the next 24 months.

Within PEPFAR, teams are asked to assess populations and geographies, to design activities, and to set targets aimed at accelerating epidemic control. To enhance the systematic gathering, analysis, synthesis, and interpretation of program data for routinely measuring progress, PEPFAR has defined a core set of program indicators that are collected and reviewed at least quarterly. PEPFAR teams are also asked to increase linkages between PEPFAR program data and national health monitoring systems and to support national capacity-strengthening efforts in publishing, promoting, and advocating more frequent use of programmatic data in public forums and platforms. In addition, PEPFAR adopted the **UNAIDS 90-90-90** global targets for “breaking” the AIDS epidemic by 2020 as a framework for program planning.

PEPFAR recognizes that the speed at which countries achieve epidemic control may vary considerably; as countries achieve control, resources need to stabilize. As such, PEPFAR teams are asked to mobilize all available data in order to systematically engage with the host country government and key stakeholders, to comprehensively outline the national/regional context for the HIV response, and to define tailored targets for accelerating epidemic control in the coming years. Specifically, PEPFAR teams are expected to submit COPs that are strategic and include targets that will assist host country governments to reach 81% coverage of PLHIV in a continuous manner, starting with the highest disease burden areas.

**Goal 4: Promote shared responsibility.** National contributions to the HIV response are critical in assuring progress toward sustainable epidemic control. For PEPFAR, these national contributions, or shared responsibility, are more than fiscal co-investment. National contributions also include the enabling environment, HIV services, and the systems required to effectively and efficiently control and monitor the HIV/AIDS epidemic.

As elaborated in the PEPFAR Sustainability Position Paper[6], the enabling environment reflects the political will to address the epidemic, ensure key policies are adopted and implemented quickly, and establish the legal framework within which all systems, services, and financing function. The Position Paper also stated HIV services must meet the HIV prevention and treatment needs of everyone in the populace, and that health systems are needed to ensure quality, efficient, and effective HIV services. Additionally, the enabling environment provides the financial, human, and organizational capital required to keep systems and services operating [7].

FY 17 COPs are expected to reflect activities that strengthen national contributions toward sustained epidemic control including rapid adoption of all key World Health Organization (WHO) policies.

**Goal 5: Partner Performance Management and Quality Assurance.** All country teams are expected to develop Partner Performance Management (PPM) operating procedures, and tools, to monitor the performance of partner achievements, at the site and above-site level. In addition, the PPM

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[6] PEPFAR *Sustainable HIV Epidemic Control: PEPFAR Position Paper.* November 2016. https://www.pepfar.gov/documents/organization/264884.pdf

[7] PEPFAR *Sustainable HIV Epidemic Control: PEPFAR Position Paper.* November 2016. https://www.pepfar.gov/documents/organization/264884.pdf

will establish clear and reasonable processes to address issues of underperformance. The PPM should include the range of indicators, including SIMS, MER, and above-site annual benchmarks used to monitor and manage progress of partners. Approaches to developing a remediation plan to address underperformance should be included in the PPM.

Quality Assurance will be conducted by all teams at two levels: PEPFAR-supported sites and activities and in areas that PEPFAR has supported in the past. Quality improvement data include a range of PEPFAR indicators, including SIMS, MER, above-site annual benchmarks, among others, and should be triangulated to understand the complex nature of program quality monitoring and management. To continue to ensure epidemiologic impact across the country, PEPFAR teams should assist local institutions and governments in monitoring site-level results across the country. This means that PEPFAR teams will work with districts to monitor results and outcome.

## 2.3 Coordination and Strategic Communication with External Partners during COP Planning

To achieve sustained control of the HIV/AIDS epidemic and, ultimately, an AIDS-free generation, it is essential that PEPFAR teams actively and routinely coordinate and communicate with their external partners, who can provide valuable insights that improve the impact and accountability of programs. External stakeholders include host country governments, multilateral organizations, bilateral donors, private sector, civil society, and faith-based organizations.

For COP 17, teams are expected to actively engage external partners in all aspects of the strategic planning, including strategic retreat the week of January 23, 2017. External partners should have the timely opportunity to discuss the Q4 POART results and have input into the strategic direction of COP 17.

Following COP submission, teams are expected to plan for continued engagement with external stakeholders through routine sharing of POART data.

### 2.3.1 Host Country Governments

PEPFAR is committed to strengthening and maintaining its partnership with host country governments to ensure alignment between PEPFAR contributions and national priorities and

investments. Collaborative planning between PEPFAR and host country governments is critical to ensuring that prioritized interventions are pursued, geographic priorities are shared, and that all available resources for HIV/AIDS in the country are utilized optimally. Country teams should regularly consult and communicate with the Ministry of Health (at various levels), the National AIDS Control Authority (or its equivalent), the Ministry of Finance, other relevant Line Ministries, and relevant government leaders, e.g., Office of the President and/or Prime Minister. This engagement is critical to ensure that PEPFAR's role in the national response, including the strategic focus on technical programming, efficiency, costing, and policies for achieving and sustaining epidemic control, is well understood.

### 2.3.2 Multilateral and Private Sector Partner Engagement

#### *Multilateral Partners*

Multilateral partners, including the Global Fund to Fight AIDS, Tuberculosis, and Malaria, UNAIDS, WHO, the United Nations Children's Fund (UNICEF), the World Bank and others, play a critical role in supporting our mutual goal of HIV epidemic control and an AIDS-free generation. They often have core competencies which differ from PEPFAR and other bilateral donors, and can play a significant role in influencing host government policy and program decisions, addressing implementation challenges, and coordinating and aligning efforts across the partners. Country teams should proactively engage multilateral stakeholders from the earliest phase of the COP and ROP planning.

In December 2016, the Global Fund will launch its funding request cycle for Allocation Period 2017-2019 (Implementation Period 2018-2020) and inform countries of allocation decisions for HIV/AIDS, Tuberculosis, Malaria and Resilient and Sustainable Systems for Health (RSSH). **In many PEPFAR countries, planning for the Global Fund funding request will overlap with COP17 planning. This overlap provides an opportunity for countries to consider all resources at one time and plan holistically using shared epidemiologic data, program results, expenditures, and planning levels to ensure cost effectiveness of all HIV dollars.** Building off the Q4 POART data analysis for HIV and TB/HIV co-infection, the availability of trend data across OU's, SID analysis and the Global Fund Principal Recipient data, country teams should support the government to convene relevant stakeholders in order to review the PEPFAR Country Specific direction. In addition, teams can use this joint planning process as an opportunity to identify country-specific uses for Global Fund technical assistance that is funded

through the 5% set aside. Teams may find resources related to the Global Fund's next funding request cycle on PEPFAR.net. Teams should remember the USG is one third of all Global Fund dollars, and should ensure PEPFAR, host country and Global Fund dollars are aligned and strategic for maximum impact.

UNAIDS, including its Secretariat at the global and country levels and co-sponsoring agencies (WHO, UNICEF, the United Nations Population Fund [UNFPA], etc.), can be an effective partner in working with countries to advance PEPFAR's and UNAIDS's shared goal of achieving epidemic control, and ending the AIDS epidemic by 2030. The 90-90-90 targets are taken directly from the UNAIDS Fast Track approach. UNAIDS works with national and subnational governments on a host of issues, including political advocacy, strategic planning, sustainability and resource mobilization, human rights, key populations, civil society engagement, modeling epidemic trends, and improving the quality of strategic information. UNAIDS, both the Secretariat and joint United Nations teams in countries, can help build support for PEPFAR's approaches and its alignment and harmonization with government-supported, Global Fund-supported and other programs. PEPFAR country teams, UNAIDS counterparts, and joint UN teams should collaborate early in the process to solicit each other's input and support.

During the COP development process, teams should continue to coordinate with other multilateral partners, especially UNAIDS and its co-sponsors, to ensure alignment between their investments and PEPFAR investments to achieve the shared vision of 90-90-90 by 2020. In particularly, data regarding the current epidemiology and response must reflect a shared and consistent understanding that reflects total national response. Any differences in this understanding of the epidemic should be resolved before COP finalization.

External partners will be invited to participate fully throughout the in-country COP preparation process and during the COP Review/Approval in-person meeting. As with COP 2016, PEPFAR teams should work with multilateral organizations to identify in-country representatives to attend their COP Review meeting. PEPFAR country teams should also engage multilateral partners at other stages in the PEPFAR operating model, including before and after POART calls, during the organization of site visits, and technical assistance visits.

Section 2.3.3 includes best practices to ensure engagement with multilateral partners and civil society organizations is meaningful.

## *Private Sector Partners*

No one government or entity can address the HIV epidemic alone. Success relies on building meaningful and wide-ranging partnerships with the private sector at the global and local levels. Scalability and sustainability of programs is more likely to be achieved with support and collaboration of the private sector. In addition, partnerships with the private sector offer opportunities for pursuing innovative strategies that can later be replicated. Teams are encouraged to build partnerships with a diverse set of private sector stakeholders, including private sector health delivery systems, as well as private for-profit institutions.

Private Sector Engagement (PSE) strategies and Public-Private Partnerships (PPPs) are enablers that leverage resources (in-kind, cash, or other) and ideas to achieve epidemic control. PEPFAR defines PPPs as collaborative endeavors that coordinate resources from the public sector with resources from the private sector (financial or in-kind) to accomplish HIV/AIDS prevention, care, and treatment goals. It is essential to align PPPs with core programmatic goals and work collaboratively with other technical areas to include sustainability, domestic resource mobilization (DRM), human resources for heath (HRH), program quality, etc. to accelerate outcomes and results.

All country teams are strongly encouraged to engage private sector stakeholders as early as possible during the COP process to help explore strategies, resource commitments, and the possibility of aligning proposed co-investments with core and near-core priorities.

Accountability of PPPs is essential and integrated within the routinized processes for reporting of results for PEPFAR programs. Entering into non-binding Memorandum of Understanding (MOU) is a critical tool in which all partners are expected to outline in detail roles, responsibilities, as well as procedures for addressing ongoing PPP activities throughout the life cycle of the partnership. For PPPs and their respective proposed MOUs that involve the State Department, S/GAC, and other State Department offices, has additional oversight responsibilities. **Therefore, S/GAC must be consulted on all such proposed PPPs (including any proposed MOUs) to ensure appropriate State Department approval**.

Please see Appendix 7 for more details on the available PPP toolkit to help support country teams with private sector engagement and PPP development during the COP.

## 2.3.3 Active Engagement with Community and Civil Society

The full participation of civil society in every stage of PEPFAR programming and planning, from their advocacy to service delivery, is critical to the success and sustainability of PEPFAR and the global effort to combat HIV[8]. Civil society has been a leading force in the response to HIV since the beginning of the epidemic, providing expertise and relationships with local communities that non-indigenous organizations often struggle to achieve. It is key to ensure that community and civil society engagement have a voice at the decision-making table commensurate with the burden of disease in a district or province. Civil society organizations (CSOs) provide services that are crucial to realizing donor strategies, advocating on behalf of beneficiary populations, promoting human rights to combat stigma and discrimination, identifying challenges to and gaps in health care delivery, collecting data, providing independent oversight of programming and processes, and promoting transparency. It is ethically imperative that affected populations have a voice in how the programs that serve them are designed and implemented. Therefore, meaningful engagement with community and CSO's remains a requirement of the PEPFAR program.

In 2016, civil society played a critical role throughout the COP development and implementation process. As part of our After Action Review of COP/ROP 16, a list of recommendations from CSO's to PEPFAR highlighted the shared value in bringing together civil society and country teams in PEPFAR processes. The full list can be found on PEPFAR.net.

### *Who to Engage?*

The community and CSOs that are engaged in the COP process should reflect the HIV disease burden of the country and the full range of populations affected by HIV. Establishing linkages with networks and coalitions is important to achieving broader civil society representation. Vital to success is the inclusion of key population-led CSOs and recognizing "Greater Involvement of People living with HIV/AIDS (GIPA)" principles, a detailed plan for engaging individuals at the center of HIV epidemics.

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[8]UNAIDS & Stop AIDS Alliance. Communities Deliver: The Critical Role of Communities in Reaching Global Targets to End the AIDS Epidemic. Geneva and Hove: 2017. Available from http://www.unaids.org/en/resources/documents/2017/JC2725_communities_deliver.

Civil society organizations may include: traditional health practitioners, community elders and leaders; local and international non-governmental organizations; networks/coalitions; religious and faith-based groups; professional associations; activist and advocacy groups, including those representing key and priority populations; organizations representing people living with HIV/AIDS; human rights groups; women's rights groups; youth organizations; access to justice and rule of law groups; groups representing other populations highly affected by the epidemic, such as persons with disabilities and woman and girls; PEPFAR program beneficiaries or end users; community associations; and not-for-profit organizations at national, district, and local levels.

In addition to engaging implementing partners who are vital to the process, country teams are required to engage smaller, local, KP-led civil society and community groups to gather community input and feedback. PEPFAR teams should seek the inclusion of a diverse range of CSO's in consultations, taking into account that this process requires proactive outreach to ensure all affected populations are represented. Additionally, PEPFAR teams should include organizations from outside of the capital (e.g., by phone and internet) to ensure that both rural and urban interests are represented. Strong consideration should be given to hosting the quarterly POART consultations remotely (i.e. by phone or webinar, as is outlined below) to allow maximum participation.

In 2017, external partners will be invited to fully participate throughout the in-country COP preparation process and during the COP Review/Approval in-person meeting. For representation at the Review meetings, PEPFAR teams are required to ask in-country civil society to select at least two representatives to attend their COP Review meeting, using management funds, the Ambassador's small grants program, or existing implementing mechanisms to support the costs associated with supporting civil society participation at all levels of COP planning and writing. For all countries, at least one of these of the CSO representatives must be a PLHIV; and for concentrated epidemic countries, at least one of the CSO representatives must represent a key population community representing the burden of disease in the country. Gender of these participants should also be taken into consideration, working to have representation that reflects the burden of disease in each country.

## *Ensuring Continued Meaningful Engagement*

For COP 17, PEPFAR teams are expected to continue to expand their successful COP 16 collaborations with local civil society, including activists, advocacy groups, and service delivery organizations. PEPFAR teams should proactively solicit input from civil society regarding their goals, priorities, targets, and budgets in drafting their COP as outlined below. Particular attention should be given to including civil society and activist groups that are not funded directly by PEPFAR. Civil society partners should be invited to share candid feedback to improve PEPFAR programming without fear of losing access to PEPFAR processes or resources. PEPFAR teams are also encouraged to establish terms of reference for the engagement of their local partners, inclusive of conflict-of-interest guidelines.

As national governments assume greater ownership of their HIV responses, the sustainability of this ownership will rely heavily on civil society partners to adequately address the health needs of their citizens. Meaningful engagement with PEPFAR can model this partnership and build the capacity of local CSOs to meet this challenge, better preparing them to play a leadership role now and in the future with host governments.

These are the tools that stakeholders should review for COP:

- Q4 data from Spotlight
- Country slides from the Q4 analysis and follow-up actions from POART Call
- Outcomes from SIMS
- Country Specific Direction (available January 18)
- COP Guidance including Technical Considerations

Based on reviews, civil society should identify areas where PEPFAR can increase impact in FY 18.

1. Engage in strategic planning retreat with USG to confirm proposed COP17 direction
    a. Provide written feedback
2. Review agreements coming out of DCMM and provide feedback prior to COP submission
3. Review SDS prior to in-country Ambassador Review

**Figure 2.3.3.1**

| PEPFAR Team Action | Stakeholder Action | Dates |
|---|---|---|
| **A. Distribute critical data and COP17 materials**<br>• Draft COP Guidance<br>• COP16 SDS<br>• Access to Q4 results via "Spotlight"<br>• Country Specific COP17 guidance letter<br>• Q4 POART Overview slides | Analyze materials to prepare for COP17 planning discussion at Strategic retreat; **identify areas of successful performance that can be leveraged going into COP17 and identify if there are activities that should not continue (site level and above site investments)** | December 30-January 18 |
| **B. USG invites and reviews materials with stakeholders at the strategic planning retreat.** | **Provide USG with recommendation** for COP17 focus and direction based on analysis of Q4 results and observations of in-country performance. | Starting January 23 |
| **C. Provide summary of DCMM agreements** | Provide **written input and feedback** on country goals, targets and changes from COP 16 prior to the COP Review meetings. | PEPFAR team provides summary no later than 3 days following DCMM; Stakeholders provide response within 4 days of receipt |
| **D. Provide draft SDS no later than 48-72 hours before submitting to in-country Ambassador** | Provide **written feedback** | 48 hours prior to submission to in-country ambassador |
| **E. Provide SDS, Data Pack and Focused Outcome and Impact Table (FOIT) (as applicable)** | **Review** all materials in preparation for COP review | Immediately following submission to OGAC |
| **F. In-person Approval Meeting** | Civil society and government representatives **attend in-person approval meeting** | Various |

All PEPFAR OUs are required to create a country-specific calendar of events which detail when documents will be shared and when meetings will be conducted so CSOs are able to plan and effectively support COP development

## *Civil Society Engagement Requirement*

Each country will receive an analysis of the CSO matrix they completed for COP 16 and guidance to enhance community engagement in COP 17 via the country-specific Planning Letter. Building on the COP 16 matrix, an updated COP 17 matrix must be completed and submitted.

## 2.3.4 Stigma, Discrimination, Violence and Human Rights

### *Stigma, Discrimination and Violence*

Stigma, discrimination, and violence, as well as harmful laws and policies, reduce access to and use of essential health services and undermine efforts towards effective responses to HIV/AIDS. PEPFAR is committed to joining others to end stigma, discrimination, and violence and increasing access to, and uptake of, HIV prevention, treatment, and care services for all persons infected and affected by HIV/AIDS, including: vulnerable, especially adolescents and young women and key populations such as men who have sex with men (MSM), transgender persons, sex workers, people who inject drugs and people in prisons and other closed settings.

To control the epidemic and, ultimately, achieve an AIDS-free generation, it is imperative that we identify and understand the often complex dynamics driving stigma, discrimination, and violence, and implement innovative evidence-based, community-led approaches to address the specific types of stigma (experienced, perceived, anticipated, internalized, compound or layered, and secondary). Additionally, there is a need to address the structural- and policy-level barriers that perpetuate discrimination. While stigma, discrimination, and violence is most often targeted at PLHIV, others being reached by or involved in HIV efforts such as individuals from key populations, women and girls, nurses and other health care workers, supportive community and political leaders, and other key stakeholders also suffer from the effects of stigma, discrimination, and violence.

While each of the actions outlined in this guidance is discrete, they are all part of a framework to promote human rights and eliminate stigma, discrimination, and violence by creating an enabling environment (e.g., structural) that amplifies the successful implementation of prevention, treatment, and care.

### *Human Rights*

PEPFAR's human rights guiding principles include securing, protecting, and promoting human rights and creating an enabling environment that sustainably addresses the epidemic.

The following are requirements for PEPFAR countries to support a sustainable enabling environment:

1. In coordination with regular CSO engagement and relevant existing working groups, including PEPFAR interagency, other U.S. Mission sections, U.S. Department of State Bureaus, and community representatives, PEPFAR countries will develop a plan, timeline, and resource allocations to measure, document, and mitigate stigma, discrimination, and violence. Please see Technical Considerations for additional resources relating to assessments and interventions.
2. Trainings on Non-Discrimination and Gender & Sexual Diversity Trainings will include a section on the inclusion of non-discrimination policies in the design or administration of programs in all PEPFAR trainings. These include, but are not limited to, trainings held for implementing partners and other direct service providers receiving PEPFAR funds. Please see Technical Considerations for an example of a non-discrimination policy.
3. Teams will establish an in-country, interagency point-of-contact (POC) whose responsibility will be the oversight of Gender and Sexual Diversity Training (GSD). Each new staff member will complete the online version of the GSD within two to six months of hire date, once it is available; this will be documented. In addition, once a year the GSD POC will convene a panel(s) to discuss PEPFAR's engagement around GSD, inclusive of LGBTI activities, and adolescent girls and young women. Please see Technical Considerations for options to implement the GSD refresher trainings.
4. Legal Environment Assessment (LEA) identify legal and policy barriers to accessing prevention, treatment, care and support services, and inform action to overcome these barriers, with a focus on access to justice and the reduction of stigma, discrimination, and violence. Country teams will be provided feedback on their LEA in their country-specific guidance

### 2.3.5 Coordination among U.S. Government Agencies

A key feature of PEPFAR is its whole-of-government approach that rests on a robust and productive U.S. government interagency response. All agencies working in a country or region are expected to work together to gather and analyze all available programmatic, epidemiologic, and financial data, which will include partner work plans, and partner- and site-level data. PEPFAR Country Coordinators are uniquely positioned to ensure that all available data are used to help inform planning and implementation of a unified country program as one U.S. government

team. **It is essential that all U.S. government agencies working on HIV/AIDS programs in a country participate in COP discussions, even if remotely.**

Country programs may have several sources of U.S. government HIV/AIDS funding (e.g. State, USAID, GAP funds). However, all HIV/AIDS programming decisions are to be made as an interagency U.S. government team with final coordination and approval by S/GAC. For example, it is a recommended best practice, and it is expected, that draft scopes of work for any new/renewed procurements will be carefully reviewed in an interagency manner at the country level before being included in the COP and/or submitted into official agency acquisition and award processes.

The quarterly reviews and data analyses with the interagency POART teams at headquarters require routine interagency discussion, facilitating a unified U.S. government approach that will ensure a well-vetted COP is reached prior to submission. POART activities represent an ongoing dialogue throughout the year that routinizes data sharing and transparency, which is critical to a successful COP process. Evidence-based solutions to implementation challenges generated by POART reviews should directly inform COP development. If any agency does not have staff or activities in-country, the country team may still draw on the agency through the POART and COP processes to solicit that needed expertise.

In preparing the COP and throughout the year, PEPFAR programmatic staff should consult with relevant non-program offices in all agencies, such as human resources, management, financial, general services, scientific review, acquisition, grants, general counsel, and policy officials at the appropriate levels to ensure that there is sufficient administrative and management support to facilitate PEPFAR activities. For example, the Embassy Management and Human Resources Offices are key partners in evaluating current and planned staffing for program management, oversight, and accountability. Similarly, all procurement and assistance actions must be coordinated with the appropriate agency's procurement office prior to COP approval and during implementation. Each agency must utilize any established agency financial forecasting systems during COP implementation. It is the onus of the agency to ensure approved COP activities can be funded and implemented in accordance with their own agencies' timelines.

# 3.0 PLANNING STEPS FOR STANDARD PROCESS AND STAR PROCESS

# 3.1 Overview of the Planning Steps for Standard Process and STAR Process

The tables below provide a broad overview of key planning steps for both STAR Process and Standard Process development, summarizing the steps and expected outcomes for each step. Detailed instructions for the Standard Process are available in Appendix A; detailed instructions for the STAR process are available in Appendix B.

# 3.2 Modular Planning Steps

Successful implementation of the Standard Process strategic planning depends upon a series of key analyses and decision points that require meaningful engagement across technical areas. This section offers guidance to countries following the Standard Process on key steps countries can take to meet planning requirements and draft a technically strong Strategic Direction Summary.

**Figure 3.2.1 STANDARD PROCESS:** The table below presents expected outcomes for each step of the planning for the Standard Process:

| Planning Steps | Outcomes for the Standard Process Planning Analysis | Tools / Analyses |
|---|---|---|
| Step 1: Understand the current program context | Updates in demographic, epidemiologic, programmatic, and country context identified | New Spectrum files, recent surveillance and demographic information; latest programmatic data |
| Step 2: Assess alignment of current PEPFAR investments and program focus | Areas not aligned with PEPFAR resources and program focus identified | Expenditure analysis and budget |
| Step 3: Determine priority locations and populations for epidemic control to set targets and prioritize activities | Revised tiers of support for FY17 identified:<br>• Attained<br>• Scale-up (saturation and aggressive)<br>• Sustained<br>• Central support | Datapack and related tools |
| Step 4: Determine program support and system-level interventions in which PEPFAR will invest to achieve epidemic control | Table 6 updated | SID 2016 and Table 6 |
| Step 5: Determine the package of services and support in other locations and populations and target accordingly | Packages of services for FY18 and FY19 defined for each of the following tiers:<br>• Attained<br>• Scale-up (saturation and aggressive)<br>• Sustained<br>• Central support | Datapack and related tools; technical considerations and COP guidance |

| | | |
|---|---|---|
| Step 6: Project total PEPFAR resources required to implement strategic plan and reconcile with planned funding level | Planned budget by IM reconciled with planned funding level | PBAC |
| Step 7: Set SNU and IM targets and budgets; then develop site-level targets | Targets at all levels agreed upon | Datapack and related tools; site-level target tool (optional); PBAC |
| Step 8: Determine monitoring strategy for planned activities in accordance with requirements and assess staff capacity | Monitoring plan for site level results set | SIMS<br>Table 6<br>POART |

**Figure 3.2.2 below illustrates a recommended order to carrying out the various steps of the Standard Process.**

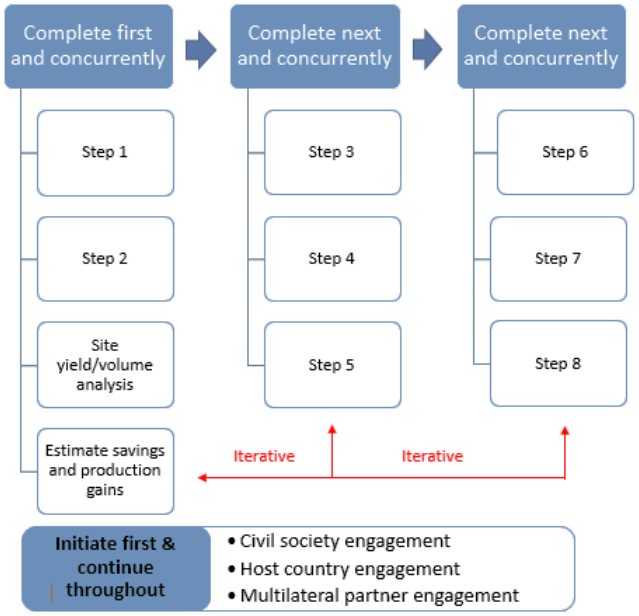


**Figure 3.2.3 STAR Process:** The table below presents expected outcomes for each step of the planning for the STAR process:

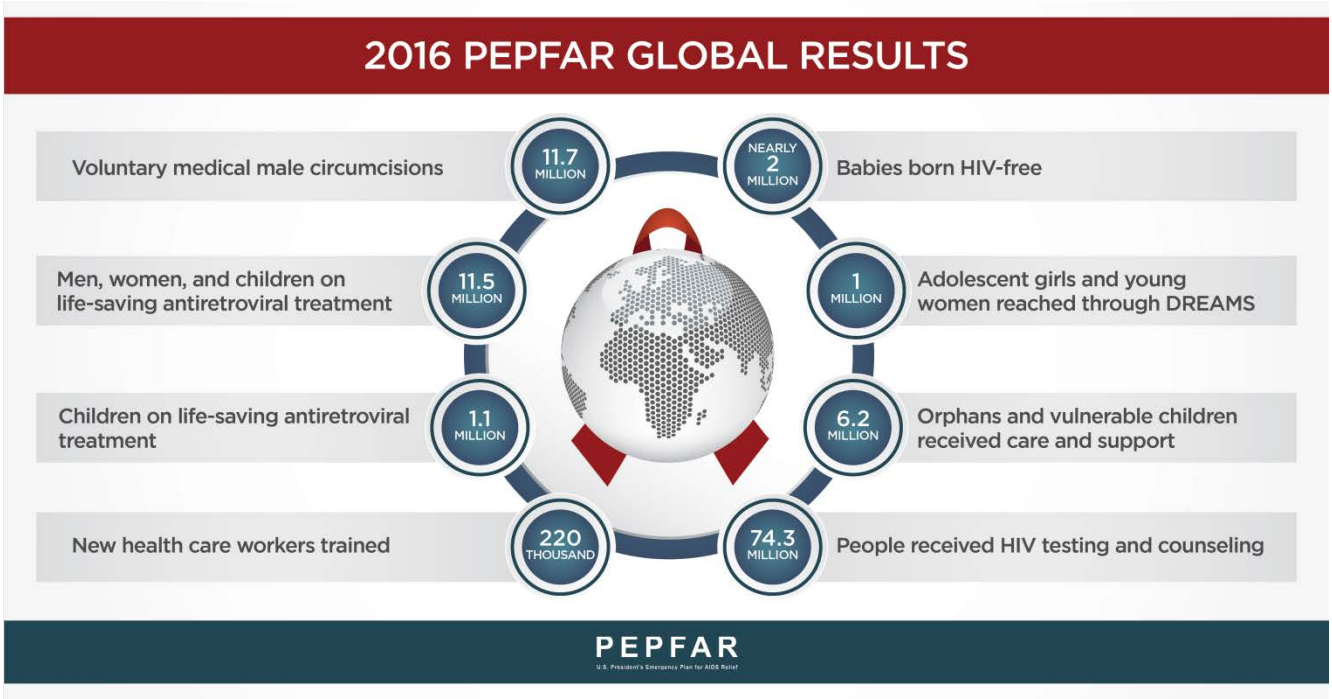
| Planning Steps | Outcomes for the STAR Planning Analysis | Tools/Analyses |
|---|---|---|
| Step 1: Understand the current national/regional context | Updates in epidemiologic, programmatic, country context and partner performance identified | • Recent survey and program data (PEPFAR and national)<br>• COP16 SID<br>• POART analyses, including partner performance<br>• Program investment profile<br>• Global Fund allocation letter<br>• Centrally-funded initiatives<br>• Stakeholder consultations |
| Step 2: Gap analysis | • Update barriers to the 3 90s<br>• Highest priorities for PEPFAR investments determined<br>• What is needed to support a sustainable national response | Country/region-specific guidance<br><br>POART discussions<br><br>COP16 Table 6 |
| Step 3: Identify priority outcomes and propose core activities | • Focused Outcomes and Impact Table (FOIT) completed<br>• Ensure alignment of site-level and above site investments<br>• SDS and other COP17 elements completed | COP16 Table 6 |

# 4.0 TECHNICAL CONSIDERATIONS SUMMARY

**(Details in Appendix C)**

PEPFAR, in collaboration with host governments, communities, multilateral organizations, and other global organizations, has made substantial achievements in combatting the global HIV/AIDS epidemic. As announced on World AIDS Day 2016 PEPFAR is supporting 11.5 million men, women and children to access life-saving antiretroviral treatment (ART), has completed 11.7 million voluntary medical male circumcisions (VMMC), performed 74.3 million HIV tests in FY 16, and provided services to 6.2 million orphans and vulnerable children (OVC) and their caregivers as of September 30, 2016 (Figure 4.1). Bold targets have also been set for PEPFAR's future achievements, including goals of supporting 12.9 million people on treatment, 13 million VMMCs, and reducing HIV incidence in adolescent girls and young women (AGYW) by 40% by the end of fiscal year 2017.

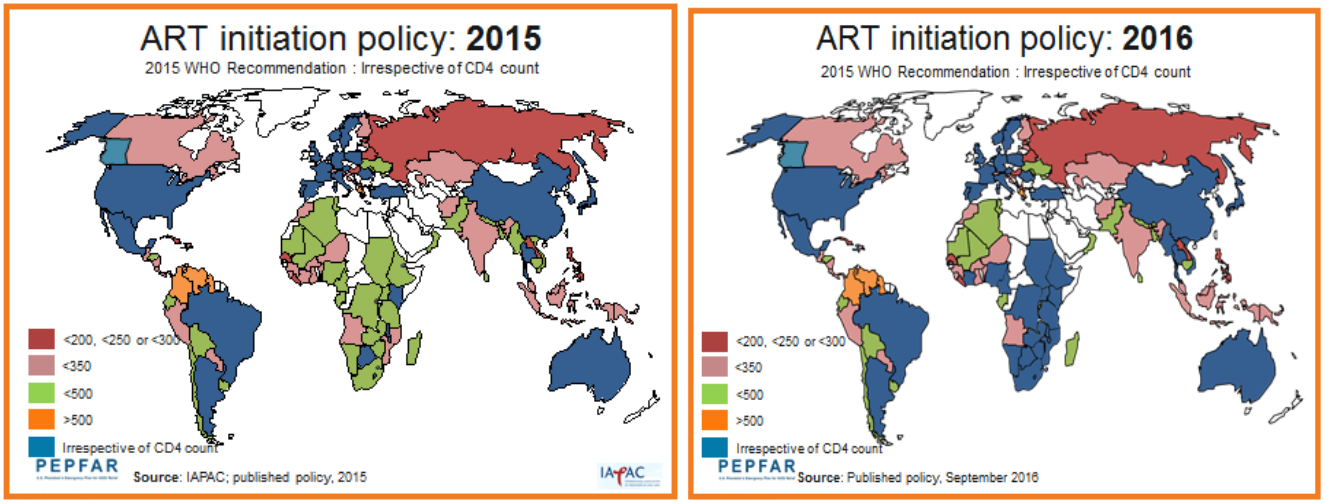
**Figure 4.1**




As we continue to work towards the 90-90-90 goals set out by UNAIDS in 2014, PEPFAR programs must continue to dive deep into programmatic and epidemiologic data to identify country, regional, and site-level successes and challenges to ensure every dollar is optimally invested. This will reveal areas for quality improvement and programmatic course correction. For example, global data from 2015 reveal that HIV testing results are highest for persons with tuberculosis (TB), sexually transmitted infections (STI), and those located in inpatient wards. However, these sources will not identify large numbers of untreated persons living with HIV.

Increased testing is needed for those under age 30 who are at highest risk for undiagnosed HIV infection. Analyzing this data at a site level is important to determine and overcome current barriers in identifying HIV infected persons and increasing testing yield and volume. Furthermore, prevention, testing, treatment, and retention strategies must be assessed for their effectiveness and appropriateness for specific age, gender, and risk groups in order to have the most impact. As well, a core premise of PEPFAR is respect for human rights in programming and the engagement of those most impacted by HIV/AIDS (e.g. PLHIV and members of key population communities) in the planning, implementation, and analysis of PEPFAR programs.

**Figure 4.2**




In working towards these goals, it is critical that PEPFAR provide support to national and local governments and institutions in a manner that builds a sustainable national HIV response. PEPFAR country teams must work with governments on national policies such as Test and START, differentiated service delivery models, programs integrated with human rights advocacy, and policies affecting stigma, discrimination, violence, and access to HIV services for key populations (KPs). Shared partnerships—financial and programmatic—are essential in establishing and sustaining epidemic control and responding to new and future challenges. COP 17 must include direct and meaningful dialogue with implementing partners and other key stakeholders, commitments from governments, and support from civil society.

The role of the Ambassadors and Deputy Chiefs of Mission have been critical in moving the essential policy agenda forward, resulting in a much more effective program. In 2016, country teams were able to work in partnership to ensure treatment starts before the immune system is

substantially damaged and transmission can be interrupted (Figure 4.2). Similar emphasis must be placed on policies to ensure access to services for 15-24 year olds, key populations, and service delivery that is more cost effective and client-friendly.

In order to reach PEPFAR's goals and accelerate impact to achieve the 90-90-90 targets, it is essential that COP17 continues the focus on epidemic control begun in COP15 by focusing on comprehensive implementation of evidence-based interventions. Collectively PEPFAR has been successful at focusing geographically. This COP17 we need to focus in the same detail on populations by risk, gender, and age to ensure we are focused for maximum impact. Of equal importance is the continuation of a human-rights based approach, emphasizing the need to engage, reach, and serve all individuals, especially those at highest risk for HIV. Teams should assess their ongoing work in geographic areas of high prevalence and incidence, and in key and priority populations, in order to evaluate the success and need for change and/or expansion in current focus. In addition, the COP17 Technical Considerations emphasize four key areas of impact that all country and regional teams should focus on during their planning. Each section of the Technical Considerations will provide a brief background on the importance of the focus area, highlight the key interventions country teams should implement, and provide country examples and best practices. The appendices at the end of this document will provide references to relevant guidance documents, further country examples, and contact information for technical leads.

1. Preventing and Treating New Infections among Adolescents and Young Adults <30 Years Old
   **Continuing to focus prevention on adolescents and young adults under 30 years old in Sub-Saharan Africa**. Prevention activities should be evidence-based, such as pre-exposure prophylaxis (PrEP) for those at high risk of HIV acquisition, condom distribution, for HIV-negative young men, and HIV treatment for all adolescents and young adults identified as HIV-positive. Special attention should be paid to pregnant and breastfeeding women <30 including adolescents, sex workers and adolescents engaged in transactional sex, men who have sex with men (MSM), transgender persons, orphans and vulnerable children (OVC), and 18-24 year old active duty military personnel.

2. Targeted Testing and Improving Testing Yield for Populations
   **Implementing a strategic mix of HIV testing modalities to improve testing coverage (especially among young men and women), yield, and efficiency of HIV testing services**. HIV testing is the gateway to accessing critical prevention and treatment

services. The challenges inherent in this service delivery differ greatly by country, and require detailed knowledge of the epidemic and who remain undiagnosed. Strategies to optimize case-finding, such as the determination and testing of sexual networks, and to ensure high quality testing services, including self-testing, are essential.

3. Retention and Viral Load Suppression

   **Retaining clients on ART and care to achieve viral suppression.** Retention on treatment and virologic suppression are critical to reducing HIV-related morbidity and mortality and preventing transmission. Strategies that improve adherence to treatment, prevent TB and other life-threatening diseases, and enhance access to viral load testing are needed to attain retention and viral suppression targets. Innovative service delivery models should focus on populations that have difficulty with retention, such as children, young adults and men, pregnant women, and key populations.

4. Access to Quality, Sustainable HIV Services

   **Ensuring access to non-discriminatory quality HIV services and a sustainable HIV delivery system**. From advocacy to delivering services, those affected by HIV play an important role in responding to the epidemic in ways the public sector cannot. Stigma, discrimination, and violence as well as harmful laws and policies reduce access to and use of essential health services and undermine efforts towards effective responses to HIV/AIDS. Community empowerment needs to be integrated into all aspects of health and HIV programming. Public and private sector facility and community-based health services, including those services delivered by KP-led organizations, need to be supported and funded appropriately. As the number of people on treatment increases, programs need to sustainably expand capacity, utilizing strategies such as community-based lay workers, prioritization and task-shifting, provider networks, and stable patient delivery systems. Retention of human resources should be a key objective for programs.

# APPENDICES

# APPENDIX A:

# STANDARD PROCESS PLANNING STEPS

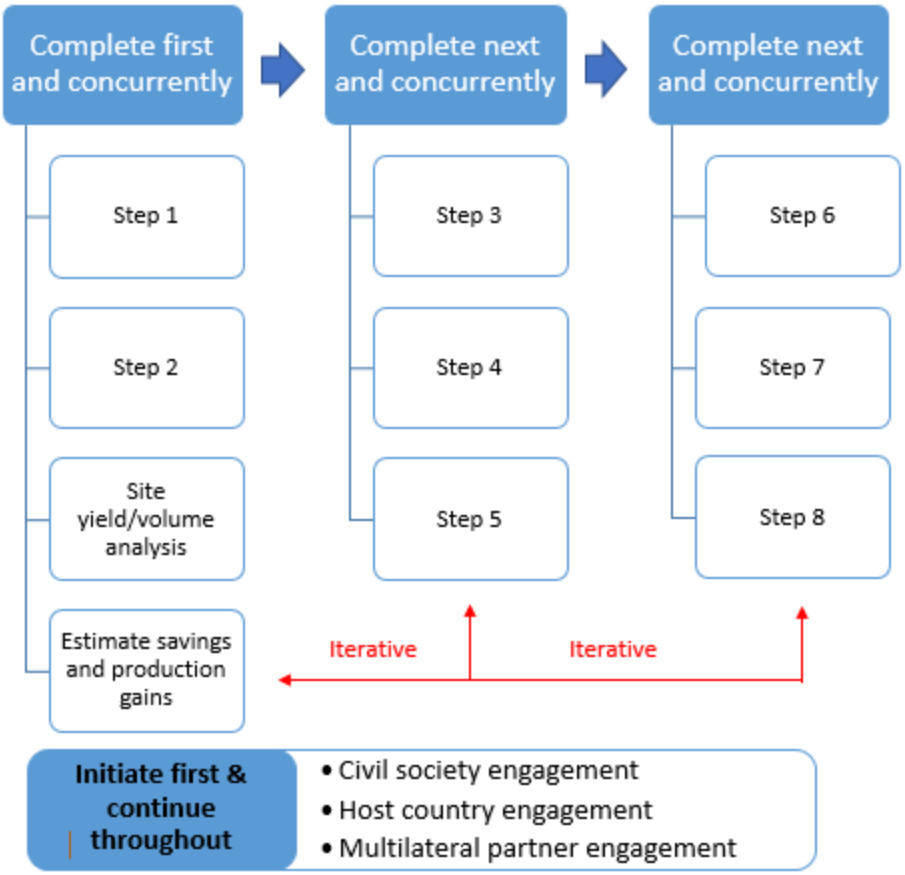
# Appendix A.1 Modular Planning Steps

Successful implementation of the Standard Process strategic planning process depends upon a series of key analyses and decision points that requires meaningful engagement across technical areas. This section offers guidance to countries following the Standard Process on key steps countries can take to meet planning requirements and draft a technically strong Strategic Direction Summary (SDS).

# Appendix A.2 Order of Planning Steps and Activities

The COP 17 Standard Process utilizes a flexible modular planning approach for developing an innovative HIV prevention and treatment strategy, specific to the country context, to accelerate progress toward achieving the country's 90-90-90 targets. As described below, each key planning module requires review of essential data and specific analysis techniques. The recommended order for these steps is illustrated in Figure A.2.1 below.

**Figure A.2.1**




As noted elsewhere in the COP 17 guidance, country teams are strongly encouraged to engage civil society, host governments, and external partners early and often in the development, implementation, and monitoring of the COP, as doing so will help to ensure a collaborative process as defined by meaningful partner engagement.

## Appendix A.2.1 Planning Step 1: Understand the Current Program Context

To determine how PEPFAR should optimally invest to maximize impact, PEPFAR teams must:

- Review demographic, epidemiologic, PEPFAR program data, and national/regional program data to the lowest sub-national unit (SNU) possible as well as age and sex disaggregated data.
- Review and update how the national response is funded and implemented, including Global Fund Principal Recipient(s) and host country government.

- Review the COP 16 Sustainability Index and Dashboard (SID) and identify any updates occurring within the country context.

These reviews were first conducted by OUs for COP 15 and were updated for COP 16. For COP 17, the assessments should be updated again, incorporating new data and analyses. The results of these assessments should be described in the SDS, Sections 2.1-2.3. Additional detail on each critical element in this step is described below.

*Review Demographic, Epidemiologic and Program Data*

PEPFAR teams are asked to update, gather, review and present key data describing the national and sub-national burden of HIV, including the number and percent of individuals testing HIV-positive at the site and SNU levels, and current program performance.

The purpose of this activity is to better understand the magnitude of the epidemic and current progress towards achieving adequate coverage of combination prevention and treatment to achieve epidemic control both in targeted SNUs, and nationally. Significant effort was made in COP 2015 planning to establish SNUs of focus for scale-up to saturation by the end of FY 17. Reviewing key epidemiologic and program data is important to understand if course corrections are needed, to determine whether acceleration to program saturation is happening at a faster or slower pace than anticipated with particular attention to age and sex bands and subgroups that may lag in reaching epidemic control, and to identify the next set of SNUs that could be the focus of future program scale-up should resources from COP 17 funds become available through efficiencies. Two standard tables in the SDS should be populated with key data to provide context for planning decisions.

Standard Table 2.1.1 outlines demographic and epidemiologic data for the national/regional context in which each PEPFAR OU operates. The table is organized to capture the key data points that should, at minimum, be reviewed prior to making program decisions. The data are disaggregated by age and sex (*note that data on female sex workers do not require age disaggregation*). This disaggregation is increasingly critical as evidence mounts regarding age and gender disparities in access to HIV services and the importance of focusing HIV activities on the populations with the highest HIV burden and unmet need, and therefore the highest likelihood of transmitting or acquiring HIV.[9] Further, these populations will vary by country and region, and PEPFAR field teams should make every effort to

[9] UNAIDS. (2014, September). *The Gap Report*. Retrieved from http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/gapreport

populate this table in its entirety using any data available of reasonable quality. Cells indicated in grey do not require information to be entered. *It is understood that not all countries will be able to populate every cell in the table; however, this exercise is also designed to highlight the areas where significant data gaps exist and where PEPFAR may need to invest to fill these gaps to better measure progress towards epidemic control.*

Every PEPFAR country should, to the extent it is safe, collect data on prevalence within key populations and estimate the size of those populations. Data for four groups are required for all PEPFAR countries: men who have sex with men (MSM), female sex workers (FSW), transgender persons (TG), and people who inject drugs (PWID). Weaknesses in these data should be noted in planning and data collection methods planned to address these weaknesses should be in included in the COP. See UNAIDS (2016) Guidance: The Privacy, Confidentiality and Security Assessment Tool[10].

Field teams are also asked to identify specific priority populations on which they will focus in the coming cycle, and include an additional row for total size estimate *and* an additional row for HIV prevalence within each population listed.

NOTE: *For each priority population selected for targeting in the coming cycle and identified in Section 3 of the SDS, an associated size estimate and HIV prevalence value is expected in Table 2.1.1.*

Standard Table 2.1.2 provides data on the cascade for HIV prevention, diagnosis, care and treatment for the most recent 12-month period available. The purpose of this information is to better understand in a standardized fashion how effectively different populations are reached with combination prevention services, diagnosed, linked and retained in ART, and ultimately, achieve and maintain virologic suppression. Identifying critical gaps in the clinical cascade can help PEPFAR and national/regional programs tailor activities to more effectively respond to unmet need and implementation realities.[11] Monitoring these data over time establishes a critical feedback loop informing planners if program choices are moving the country or region closer to the goal of 90-90-90 by 2020 or if course corrections are needed. Table 2.1.2 will be populated in the Datapack using data submitted for APR16 (e.g.

[10] UNAIDS. (2016). *The Privacy, Confidentiality and Security Assessment Tool*. Retrieved from http://www.unaids.org/sites/default/files/media_asset/confidentiality_security_tool_user_manual_en.pdf

[11] World Health Organization. (September 2015). *Consolidated strategic information guidelines for HIV in the health sector*. Retrieved from: http://apps.who.int/iris/bitstream/10665/164716/1/9789241508759_eng.pdf?ua=1&ua=1

PLHIV). If countries have more recent data from the most recent 12-month period available, this data should be incorporated into the Datapack and used in Table 2.1.2.

Cascade data in Standard Table 2.1.2 are disaggregated by population, necessary to effectively target based on burden of disease. The first row, "Total Population," should be inclusive of all subsequent rows and represents summary national cascade information across all populations.

*Update the Program Investment Profile*

Regardless of program type or size of investment, the success of PEPFAR programs are dependent on the resources, management, and support contributed by the host country government and other key stakeholders in the HIV response (e.g., the Global Fund). To minimize duplication across funders/implementers, increase allocative and technical efficiency, and maximize impact on the epidemic, PEPFAR must have a clear understanding of how the current program is being funded and potential dependencies on other partners for success in achieving the stated goal for epidemic control. This includes, at minimum, data describing total investment by key program area and source of support, as well as data describing how critical commodities are procured. Country teams are expected to provide information describing and referencing as necessary other existing workplans for how central initiatives such as ACT, DREAMS, DREAMS Test and Start, DREAMS Innovation, VMMC, and viral load, as well as other partnerships (e.g., Saving Mothers, Giving Life (SMGL), Pink Ribbon Red Ribbon) are aligned with the priority questions to be addressed in these sections, including transition planning expected by the conclusion of the initiative.

Two tables are provided in the SDS template to assist field teams with presenting these data (which are also a key inputs into the Sustainability Index) and are described in more detail below. Financial information should align with the appropriate designations within the investment portfolio section of Standard Tables 2.2.3 and 2.2.4 as well as in the program area (2.2.1) and procurement profile (2.2.2) summary to fully describe activities, targets, results.

Once Standard Tables 2.2.2, 2.2.3 and 2.2.4 have been populated, the PEPFAR team should concisely communicate key findings in the narrative portion of the SDS, Section 2.2. Given these data represent a static point in time, teams should use the narrative to contextualize the information provided and identify any potential changes or risks that may need to be addressed in the planning process. Specifically, teams should report in the narrative the year of the commodity expenditure data reported, any changes that have occurred in the country since these data were collected, and any planned changes in which funder(s) will be supplying each commodity in the next 1-3 years. This is particularly

important for commodities, as a stable supply of ARVs and other drugs and supplies for combination prevention is necessary to sustain existing programs and a pre-requisite for any planned expansion.

*Review the Sustainability Agenda*

Country teams should review their COP 16 SID, noting any changes in the country context that might impact the investment portfolio proposed in COP 17.

## Appendix A.2.2 Planning Step 2: Assess Alignment of Current PEPFAR Investments to Epidemic Profile, Partner Performance and Results

- In COP 15 and COP 16, PEFPAR teams compared PEPFAR expenditure data by lowest SNU available to burden of disease, as measured by total PLHIV, to determine if the PEPFAR program was most effectively aligned to reach the areas and populations with the highest number of HIV infections. To reassess or verify priority locations and populations for epidemic control selected in COP 17, PEPFAR teams must understand how current investments are aligned to the epidemic profile. This task again involves comparing the most recent PEPFAR expenditure data by lowest SNU available to burden of disease, as measured by total PLHIV. In which SNUs is PEPFAR expanding resources? Are these aligned with the areas that PEPFAR is seeking to have impact?

## Appendix A.2.3 Planning Step 3: Determine Priority Locations and Populations for Epidemic Control and Set Targets

FY 15-16 COPs ranked districts or SNUs according to HIV disease burden and classified them according to several tiers of PEPFAR support. Further, as part of the approach to epidemic impact, PEPFAR urged target setting in a manner that achieved accelerated coverage to 8% of PLHIV by the end of USG fiscal year 2017 for key and priority populations with the highest HIV prevalence.

Because many of the scale-up SNUs will have achieved or approached saturation by the end of FY17, COP 17 guidance requires PEPFAR teams to use the available epidemiological and expenditure data to reassess which SNUs, and population groups within them will be prioritized for scale-up activities by the end of FY 18.

**Scale-up: Saturation and Aggressive Scale-Up SNUs:** Geographic areas with the highest HIV prevalence nationally that have not yet achieved 81% coverage, particularly among local population groups experiencing the greatest burden of disease.

- Scale-Up: Saturation SNUs receive intensive PEPFAR support with a target of reaching 81% of all people at all ages, gender and risk groups, living with HIV (PLHIV) on ART by 2017 and 2018.

- Scale-Up Aggressive SNUs receive intensive PEPFAR support with an overall goal of an increased rate of 'new on ART,' but are not expected to reach 81% of PLHIV by 2017 or 2018.

Scale-Up SNUs will receive a package of PEPFAR-supported services designed to accelerate achievement of epidemic control. DREAMS, VMMC, and ACT-like activities should be prioritized for implementation in these areas.

Prioritized scale-up activities include:

Prevention and Treatment

- Facility- and community-based prevention and treatment activities, including demand generation.
- Facility-based testing, treatment, adherence and retention, as well as site, district, and national level quality monitoring.
- Support for quality monitoring at the site, district, and national levels.
- Support for surveillance systems to monitor programs by geography and age and sex disaggregated populations.
- Continued efforts for laboratory scaling to ensure monitoring of viral suppression.

**Figure A.2.3.1**

## Refreshing SNU Prioritization for Epidemic Control

| COP 16 SNU Prioritization | Potential COP 17 SNU Prioritization |
|---|---|
| **Scale-up: Saturation** | **Attained** (if > 80% ART coverage is expected to be achieved among both males and females living with HIV by APR17)<br>**Scale-up: Saturation** (if ART coverage of >80% is not expected to be reached for both males and females living with HIV by APR17) |
| **Scale-up: Aggressive** | **Scale-up: Saturation** (if 80% target is achievable by APR18)<br>**Scale-up: Aggressive** (if 80% target is not achievable by APR18) |
| **Sustained*** | **Scale-up: Saturation** (if the SNU is prioritized based on PLHIV for the next tranche of scale-up, and a target of 80% is achievable by APR18)<br>**Scale-up: Aggressive** (if the SNU is prioritized based on PLHIV for the next tranche of scale-up, but a target of 80% is not achievable by APR18)<br>**Sustained** (if the SNU is not prioritized based on PLHIV for the next tranche of scale-up) |
| **Central Support** | **Central Support** (by default)<br>**Sustained or scale-up** (if a compelling case can be made to prioritize the SNU for scale-up or sustained support based on HIV burden) |

* In rare cases where the "Sustained" category was applied to priority SNUs with very high levels of coverage, an SNU *may* transition from "Sustained" to "Attained", as long as it meets the definition for "Attained".

As described above, the FY 17 COP development process provides a platform for OUs to review progress toward the FY 17 goals and to reevaluate which sites or SNUs will be designated for saturation or aggressive scale-up in FY 2018. Figure A.2.3.2 shows the continuous nature of prioritization at the SNU level.

In this example, SNU 1, 2 and 3 were prioritized in COP 15 to get 81% ART coverage (saturation) by APR17. In COP 16, new ART slots should be allocated to SNU1, 2 and 3 to be able to reach 81% coverage by APR 2017. The next districts should be identified for saturation by APR 2018. SNUs that were identified as Aggressive Scale-up in COP 15 should be revisited to see which ones can become saturated by APR2018. In the example prioritization, SNU 4 and 5 were Aggressive Scale-Up in COP 15 and there are enough new ART slots to be able to saturate these districts in COP 16.

**Figure A.2.3.2: Example of ART Coverage Prioritization**

| SNU | COP15 Prioritization | APR16 Achievement | COP16 Prioritization | Expected Achievement By APR17 | COP17 Prioritization | COP17 Target: (APR18) |
|---|---|---|---|---|---|---|
| **SNU 1** | Scale-up: Saturation | 50% | Scale-up: Saturation | 81% among males & 84% among females | Attained | 85% among males & 85% among females |
| **SNU 2** | Scale-up: Saturation | 30% | Scale-up: Saturation | 60% | Scale-up: Saturation | 80% |
| **SNU 3** | Scale-up: Aggressive | 30% | Scale-up: Aggressive | 50% | Scale-up: Saturation | 80% |
| **SNU 4** | Scale-up: Aggressive | 15% | Scale-up: Aggressive | 45% | Scale-up: Aggressive | 60% |
| **SNU 5** | Sustained | 60% | Sustained | 60% | Scale-up: Saturation | 80% |
| **SNU 6** | Sustained | 40% | Sustained | 40% | Scale-up: Aggressive | 65% |
| **SNU 7** | Sustained | 35% | Sustained | 35% | Sustained | 35% |
| **SNU 8** | Central Support | | Central Support | | Central Support | 25% or no target |

Note: : The *Datapack* is available to assist teams with importing and organizing their epidemiologic and national/regional district program data using the methods described below.

Process for Prioritizing Locations and Populations for COP 17

As a first step in prioritizing locations and populations, teams should gather the following key data elements and potential data sources.

**Figure A.2.3.3**

| Key Data Elements and Potential Sources | |
|---|---|
| **Data element(s)** | **Potential Sources** |
| Total population<br>HIV prevalence and trends<br>Total number of PLHIV<br>Site-level positive yield data from PEPFAR PMTCT and HTC programs | Ministry of Health surveillance, Estimates from UNAIDS Spectrum and Subnational Estimates of HIV Prevalence Report, Surveillance Studies supported by PEPFAR<br>Central Statistics Agency, U.S. Bureau of Census |

Once these data elements have been assembled, the teams should rank SNUs as follows:

1. Sort SNUs by total number of PLHIV from largest to smallest
2. Calculate percentage of total (national/regional) PLHIV in each SNU
3. Calculate the cumulative burden by SNU by summing and recording the percent of total PLHIV for each SNU entry
4. Sort SNUs largest to smallest by positive yield based on PEPFAR PMTCT and HTC data; calculate estimated PLHIV based on PEPFAR program data and compare the ranking of SNUs to the ranking in step 1 above.

*If using the **Datapack**, steps 2-4 will be calculated automatically*

Next, teams should include current national or regional coverage data to calculate unmet need for comprehensive prevention and treatment services, including ART, PMTCT, and VMMC, particularly for key and priority populations.

ART coverage should be represented as a percentage for each SNU. Unmet need should be calculated using ***total PLHIV*** as the denominator. Although the number currently eligible has been an important factor in some countries to consider in operationalizing plans for scale-up, initial estimates of unmet need and program focus for epidemic control should be based on **total burden**, as measured by number of PLHIV. Countries will continue to integrate these new WHO guidelines into their own definitions of treatment eligibility.

*If using the **Datapack**, unmet need will be calculated automatically.*

Teams should calculate the **net new patient slots** required to achieve 81% ART coverage for PLHIV by SNU by end of APR 2018. In determining these targets, PEPFAR teams should adjust for scale-rate and expected loss to follow-up (LTFU). OUs should also provide 81% coverage targets for scale-up sites or SNUs to be addressed in APR 2018. Scale-rate and LTFU should be based on performance and new interactions that would improve case-finding, linking and retaining.

*Prioritizing locations and populations for program focus*

Multiple data sources and a number of program/contextual factors must be considered when PEPFAR teams prioritize geographic areas and populations groups for COP 17. **The goal of this analysis is to optimize resource allocation for maximum epidemiological impact.**

With currently available data, it is not always apparent which information should take precedence, what thresholds should be applied, and what weight should be given to each individual criterion. Teams must use the best available data to refine their operational plans, including: HIV prevalence, population size, total number of PLHIV, coverage of prevention and treatment services, and estimated key and priority population sizes within high prevalence SNUs.

Each country context will be different and one method or standard selection criteria should not be applied across the board; however, there are key considerations PEPFAR teams should consider when prioritizing SNUs for tiered support:

1. Prioritize **across** SNUs to give precedence to high disease burden geographic areas nationally.
   Because the distribution of HIV within a population is driven by factors that cause it to be non-random, it is important to examine the epidemiological data across geographic areas. A ranking of SNUs based on HIV prevalence will enable country teams to identify highest priority areas for the provision of evidence-based combination prevention services (HTS, PMTCT, ART, VMMC, condoms, and other targeted prevention for key and priority populations).
2. Prioritize **within** high-prevalence SNUs to focus resources on the highest prevalence areas *and* population groups at the local level.
   Once high burden SNUs are identified, further analysis within those bounded areas may be needed to refine the geographic targeting, as new infections may not be distributed randomly or evenly throughout the SNU. Furthermore, teams are urged to focus not just

on localized "hotspots" within SNUs but to utilize the available data to identify the population groups shouldering the greatest burden of disease within those bounded areas. Data analyses should clarify whether key population groups (e.g., MSM, PWID, CSW) or other population groups, such as 15 – 24 years old girls and women, account for the largest attributable fraction of new infections and teams should target prevention and treatment resources accordingly. Other sources of data (e.g., program, ANC surveillance) may help to inform resource optimization in the absence of population-based epidemiologic estimates.

Finally, if a site within a lower-prevalence, sustained SNU meets criteria for a microepidemic with the a high volume of new infections, the SNU in which it is located should be categorized as a scale-up SNU but only the hotspot site(s) within the SNU receive scale-up targets. In these cases, the number of PLHIV in the hotspot is needed to estimate current and target coverage levels. Teams should explain the need for a unique focus on these micro-epidemics and detail plans to achieve 81% ART coverage and accelerated coverage of combination prevention in the hotspot(s) within the SNU. Teams can provide the additional data in the narrative of Section 4.1 or as a footnote in Standard in Section 4.

3. **Strive for attained status and saturation within prioritized SNUs**

To reach countries' 90-90-90 targets, PEPFAR teams are urged to design programs using available population size estimates and set complementary prevention and treatment targets necessary to saturate geographic areas and key or priority population groups. Saturation is defined as achieving 81 percent coverage of prevention or treatment services in those population groups within SNUs needing them.

Finally if ART has exceeded saturation in an SNU (defined as >81% ART coverage among both males and females living with HIV), that SNU should be designated as **attained** and relevant programs should be designated. The aim then is to achieve saturation levels of ALL core interventions relevant to the populations within the SNU in order to curb HIV transmission and improve health outcomes for PLHIV. Even after achieving attained or saturation status, the SNU should remain a priority SNU and continue to scale other core interventions, as resources permit and as dictated by epidemiologic need.

*Setting targets for accelerated epidemic control in priority locations and populations*

PEPFAR field teams are urged to set targets for combination prevention interventions that assist host country governments achieve epidemic control as rapidly as possible in prioritized, high HIV prevalence geographic areas and population groups. Generally, targets should:

- Align with the OUs stated goal for epidemic control and specify how PEPFAR investments will translate into expected increases in coverage in the COP 17 implementation period and beyond[12].
- Rapidly saturate priority geographic areas and population groups with combination prevention interventions (ART, PMTCT, VMMC, and condoms).
- Be tailored to prioritize geographic areas and population groups with intervention packages selected based on their strong evidence, feasibility, relevance, and cost effectiveness.
- Preventing and Treating New Infections among Adolescents and Young Adults <30 Years Old
- Targeted Testing and Improving Testing Yield for Populations
- Retention and Viral Load Suppression
- Access to Quality, Sustainable HIV Services

*This section is **not** intended to provide comprehensive guidance on how to set targets for every indicator measured by PEPFAR.* Rather, the guiding principles and instructions below pertain to targets highlighted in the SDS that provide a snapshot of how field teams have prioritized locations, populations, and interventions for epidemic control. **Standard process country teams should utilize the Datapack and related tools for target setting. Detailed guidance on target-setting with Datapack is provided in the Datapack User's Guide. STAR process country teams may also request a Datapack if appropriate to the PEPFAR response and helpful for planning.**

PEPFAR teams should use this guidance to inform program choices and subsequently document targeting decisions in Sections 3 and 4 and Appendix A of the SDS,. Each table is described below in the context of the related combination prevention or support intervention.

Tables in Section 4 of the SDS should be generated from DATIM, and "COP 17 Target Table Favorites" will be available.

In setting targets to accelerate epidemic control and in completing the relevant section in the SDS, team should keep several factors in mind:

1. Targets for epidemic control are distinct and mutually exclusive of expected volume to sustain support in other locations and populations.

   In Section 4 of the SDS, PEPFAR teams will present targets across all scale-up areas in the standard tables. In many OUs, we expect PEPFAR resources dedicated to scale-up to shift to scale-up areas and interventions; however, PEPFAR teams will need to budget for continued support to existing ART and PMTCT patients and OVC beneficiaries in other locations and programs: To determine the required resources to support sites in other locations, PEPFAR teams should use program data to calculate the expected volume of beneficiaries in those areas should be recorded in relevant in Section 4 of the SDS. Methods for this analysis are described in section A.2.5 below.

   *The sum of targets included in both Sections 4 of the SDS should equal the technical area target*[13] *for each indicator*. For example, a PEPFAR team has determined the program can support 300,000 current on ART by APR 2018 in selected scale-up areas. This figure should be recorded in Standard Tables in Section 4. The team has also calculated there would be an expected volume of 200,000 current on ART by APR 2018 in other areas as programs are transitioned. This figure would be entered in the tables in Section 4. The total current on ART expected for APR 2018 would then equal the current on ART in priority areas (300,000), *plus* the current on ART in other areas (200,000). In this example, the summary technical area target for APR 2018 is 500,000.

2. Target timeframe should be framed by goals beyond implementation in COP 17.

   Strategic planning requires PEPFAR teams to think beyond the implementation year associated with COP 17 (FY 18). In this COP the Datapack will support calculating two-year strategic targets (e.g. APR 2018 and APR 2019), however teams are *not* expected to submit site-level targets beyond what will be achieved by APR 2018.

   In COP 15, for ART coverage specifically, teams were requested to select priority locations and populations in which coverage of 81 percent is possible by the end of FY 17. Since areas have already been identified for 81 percent coverage in FY 16 and FY

[13] See section 5.4 on target definitions.

17, in COP 17 teams should identify the areas for 81 percent coverage by FY 2018 or FY 2019. This timeframe is intended to provide a near-term goal post for PEPFAR teams to guide decisions as they set targets to accelerate ART coverage in priority areas.

For other combination prevention and support targets defined in Section 4 of the SDS, teams must estimate coverage by APR 2017 and APR 2018 in the Standard Tables, but are not expected to set targets that for key or priority populations if not achievable during this time frame.

3. Program costs and trade-offs should be taken into account when setting targets for priority locations and populations.

   Achieving targets outlined in Section 4 of SDS represents a cost to PEPFAR programs. In determining targets for ART, combination prevention activities, and OVC, teams should use actual costing data allocate resources within the available funding envelope (see section 3.3.6 on resource projections). Teams should also keep in mind that achieving targets in one technical area (e.g., ART) has an impact on funding available to achieve targets in another technical area (e.g., VMMC). There is no specific guidance applicable to all PEPFAR OUs on the most appropriate percentage of funds to allocate to combination prevention and support activities; however, teams are expected to meet legislated budget code earmarks (see Appendix E); consider any central funding that may be available to assist with achieving targets in specific technical areas, and consider the type and magnitude of support provided by the host country government and other stakeholders. The goal is to achieve epidemic control in prioritized geographic areas and populations as quickly possible. The mix of combination prevention interventions will vary by epidemiological context; teams should use any data available to optimize these allocations.

### *Setting Targets for ART in Priority Locations and Populations*

PEPFAR teams are requested to set targets for ART that will assist the host country government achieve ART saturation for PLHIV by the end of USG fiscal year 2018/19 (September 30, 2018/19). Given finite USG and other resources, PEPFAR teams will need to identify geographic areas where the attainment of 81 percent ART coverage is possible in two years. Teams should record proposed ART targets for priority locations and populations.

**In addition to setting targets for current on ART and ART enrollment (newly initiated) by SNU, PEPFAR teams should outline in Standard Table 4.1.1 how they will meet the**

**enrollment target proposed by entry stream for ART. At minimum, 4 entry streams should be considered and included as rows in Standard Table 4.1.1:**

1. **Initiate ART for all previously diagnosed and clinical care patients living with HIV infection**

   One very efficient way to increase enrollment for ART programs is to initiate clinical care patients living with HIV on ART, as is consistent with WHO treatment recommendations.

2. **TB-HIV patients not on ART**

   Teams should initiate ART in TB patients diagnosed with HIV. PEPFAR teams should estimate how many individuals currently receiving TB treatment and prophylaxis at TB sites will receive HIV testing and be linked effectively to ART sites as newly initiating ART patients.

3. **HIV-positive pregnant women and HIV-exposed infants**

   HIV-positive pregnant women receiving care through PMTCT sites will initiate or continue ART over the period. Teams should estimate the number of women newly initiated on ART through PMTCT programs as a key entry stream for ART enrollment targets. Early infant diagnosis (EID) of HIV-exposed infants is another important opportunity for case finding and pediatric ART initiation.

4. **Other priority and key populations**

   Improve linkage to ART services for PLHIV diagnosed through existing HTS programs. Strategic testing of high-yield populations through provider initiated testing and counseling (PITC), partner notification, and index-based testing are also important opportunities for case finding, linkage, and ART initiation. PEPFAR teams should be able to describe with data how many newly initiating ART patients can be expected from each of the entry streams above, and determine PMTCT and HTS testing targets accordingly.

### *Setting Targets for VMMC in Priority Locations and Populations*

Modeling tools can assist countries estimate unmet need for VMMC for adolescent boys and men, particularly for those age 15 - 29 years. Countries should aim to achieve VMMC saturation

in high burden SNUs/micro-epidemics and, within those SNUs, among males in the highest priority age bands. Geographic areas and age groups with higher levels of unmet need should be prioritized within the overall strategy, i.e., between SNUs of equivalent HIV burden, the SNU with lower circumcision prevalence should be prioritized (similar for age bands). PEPFAR teams are asked to present targeting decisions by VMMC in in Standard Table 4.1.2 of the SDS.

If targets have been set for areas outside of those selected for program focus, teams will need to explicitly state their rationale in the narrative portion of Section 4.

### *Setting Targets for Prevention Interventions in Priority Locations and Populations*

Once teams have identified key and priority populations in the selected SNUs, they should develop best-possible estimates of population size. See the indicator reference sheet for PP_Prev and KP_Prev in the MER 2.0 Indicator Guidance and the 2011 Guidance for Prevention of Sexually Transmitted HIV Infections for more information on size estimation. Teams should then develop a basic package of interventions for each population based on existing guidance from the above documents, and set coverage targets for each population based on an evidence-based hypothesis about the levels of coverage necessary to achieve population-wide reductions in incidence. For best practices on prevention for females age 15 – 24 years, please see Appendix J

PEPFAR teams are asked to present targeting decisions by priority and key populations in Standard Table 4.1.3 of the SDS.

Cascades are helpful tools to monitor program coverage for prevention and clinical services. The Scientific Advisory Board has been asked to develop Optimized Prevention Cascades to that PEPFAR can use to monitor prevention programs for specific populations.

### *Setting Targets for OVC*

Based on a comparison of current PEPFAR OVC coverage and estimates of the OVC population and inputs such as situational analyses, PEPFAR teams should describe/map the OVC situation, select locations and populations for program focus; and using the definitions provided in the indicator reference sheets set targets for OVC_SERV in the Datapack. Teams should provide a brief description of the data sources used and assumptions made.

While setting OVC targets, teams should focus on providing a comprehensive package of prevention and treatment services and supports to OVCs ages 10-17 years, particularly

adolescent girls in high HIV burden areas. Many programs have exceeded targets in OVCs under age 10 and should now shift to address the particular needs of adolescent OVCs. In areas with high HIV burden in adolescent populations, particularly East and Southern Africa, adolescent girls should be prioritized as they bear a disproportionate risk for HIV acquisition compared to their male peers.

PEPFAR teams are asked to present targeting decisions for OVCs in Standard Table 4.1.4 of the SDS.

**Population Data for OVC: Country teams should use these assumptions to calculate the denominator for OVC population data.**

**Orphans and other vulnerable children**, as a distinct population, is defined in PEPFAR's legislation as "children who have lost a parent to HIV/AIDS, who are otherwise directly affected by the disease, or who live in areas of high HIV prevalence and may be vulnerable to the disease or its socioeconomic effects". Calculating that total may be done in a number of ways depending on country context and data sources. Orphans (maternal/paternal/double) have a standard definition, which is further discussed below. Defining "other vulnerable children" may focus on the characteristics of their parents or caregivers, which raise risks for poor child outcomes, or the actual risks or vulnerabilities faced by children across multiple domains. DHS and MICS typically identify the percentage of children who have a very sick parent or live in a household where an adult has been very sick or died in the past 12 months, which they label "vulnerable children." National OVC situation assessments and other surveillance methods may use different definitions of vulnerability, commensurate with national policies, to estimate prevalence or population size or may be linked to rates of adult HIV prevalence and household size. Where these data are available and of sufficient quality, they should be used in program planning because they align most closely with PEPFAR's legislative definition cited above.

**Orphans (maternal/paternal/double)** refer to children (aged 0-17) whose mother, father, or both parents have died. Orphan prevalence rates (at both national and sub-national levels) are typically available through both DHS and MICS, which can be combined with child population figures from the national census or other sources to estimate the orphan population. Orphaning has been strongly correlated with HIV prevalence in the generalized epidemics common in sub-Saharan Africa, even when the actual cause of parental death is undetermined. Because these data are widely available from population-based surveys, they are important proxies for

estimating the size and distribution of OVC populations for PEPFAR program planning, though orphaning is only a partial subset of all children affected by HIV/AIDS.

**AIDS orphans** are defined as the estimated number of living children age 0 - 17 years who have lost one or both parents to AIDS. National estimates are only available through UNAIDS models based on demographic and epidemiological data; sub-national disaggregations are not usually available. The scope and quality of these data may make them less useful for PEPFAR program planning. However, this is one of the only standardized population level indicators relevant to calculating the total number of orphans and other vulnerable children due to HIV/AIDS systematically reported globally (by UNAIDS and MDG 6).

## Appendix A.2.4 Planning Step 4: Determine Program Support and System-Level Interventions in which PEPFAR will invest to Achieve Epidemic Control

As an emergency response to the AIDS pandemic, PEPFAR has made immense achievements in the past ten years. For PEPFAR 3.0, accelerating progress towards epidemic control and ensuring that the program's achievements and gains are consolidated and sustained remain major areas of focus. Thus, sustainability remains a key dimension of PEPFAR's business model. PEPFAR teams, in-country stakeholders (government and civil society), and multilateral partners (UNAIDS and Global Fund, etc.) must ensure their agendas are aligned to efficiently remove barriers to epidemic control. Through better coordination and accelerated impact with a focus on sustainability, PEPFAR can influence technical gains in country, and foster greater accountability, transparency, and use of evidence to accelerate progress towards epidemic control.

As country teams apply a sustainability lens to their 2017 investment planning, they should seek to advance several objectives:

- Ensure effective and efficient practices are adopted (including Test and START, reduced clinical visits and multi-month ARV scripting, task-shifting and new testing strategies) to improve client services and reduce the cost of delivery.
- Ensure that prioritized systems-support investments are aligned with sustainability vulnerabilities identified during the COP 2016 SID implementation process, and have validated outcomes and annual benchmarks to monitor progress.
- Increase local partner capacity, and leveraging funding mechanisms and approaches that increase ownership and accountability for results through local systems.

- Seek opportunities to improve national monitoring of service delivery and other PEPFAR activity costs given evolving service delivery models and the need to generate efficient systems. Identify opportunities for better data on what service delivery cost should be given evolving service delivery models.

- Support discussions and actions with Ministries of Finance and Health to increase domestic resource mobilization for HIV and to be partners and advocates for efficiency of current spending.

In COP 17, efficient and effective systems investments continue to be an essential component of achieving PEPFAR's goals, including identification and remediation of key gaps in the clinical cascade and shifting the national policies necessary to achieve countries' 90-90-90 targets. In COP 17, Table 6 is informed by the COP 16 Systems and Budget Optimization Review (SBOR) exercise to define key barriers to addressing shortfalls to achieving 90-90-90 targets and three year outcomes. Based on the SBOR, teams identified:

- Three to five systems barriers that impede closure of programmatic gaps

- Barriers to adoption of Test and START and alternative service delivery models

- Quantifiable three-year outcomes and corrective activities to achieve the outcomes

In line with the broader principles of streamlining in COP 17, Section 6.0 of the COP 17 SDS stays the course and refines, as needed, the three-year focused systems investments and outcomes defined in COP 16. The results of the 2016 SBOR exercise should continue to inform strategic programmatic priorities for COP 17. The focus for this year will be to revalidate the identified barriers and three-year outcomes from COP 16 and further define benchmarks to reach those outcomes. This is an important step forward for not only PEPFAR, but also for illustrating to non-PEPFAR programs how to build transparency and accountability for systems-related outcomes.

More specifically, in COP 17, the completion of Table 6 involves three stages which build upon the work country teams completed in the SBOR process in COP/ROP 2016. The completion of Table 6 should be led by the PEPFAR Coordinator and completed in the interagency space. Additionally, country teams should continue dialogue throughout the process with the host country government, the Global Fund, UNAIDS, and other partners to ensure that resources can

be leveraged as part of an ongoing overall strategy to address programmatic gaps and systems barriers. The three stages are as follows:

1. **Validate defined barriers and outcomes from COP 2016.** Country teams should use the following questions to examine each barrier and outcome entered in the COP 2016 SDS.
    a. Does the identified system barrier continue to be one of the most critical barriers to closing each programmatic gap?
    b. Do the prioritized systems investments continue to align with sustainability elements in which the country scored in the yellow or red range on the COP 2016 Sustainability Index and Dashboard (SID)?
    c. Are the defined three-year outcomes and related annual benchmarks quantifiable and measurable, and the most appropriate for the outcome?
    d. Are the proposed activities the most relevant/appropriate to support change in the barrier?
    e. For barriers toward which limited progress has been achieved (i.e., year one annual benchmark/s have not been met), should activities be funded in COP 2017 at the same level as in COP 2016?

2. **Evaluation of progress toward closing systems barriers.** Teams should write a brief narrative that addresses the following points. Additionally, country teams should be prepared to discuss the interagency process used for validating outcomes and annual benchmarks during the DC Management Meetings.
    a. Identify areas of significant and limited progress, and, if applicable, outside factors influencing annual benchmark achievement. Reference newly identified annual benchmarks that provide evidence for significant or limited progress. We recognize that COP 2016 annual benchmarks are being defined shortly before the COP planning cycle begins and only limited activity implementation will have occurred. Country teams should give their best estimate of the feasibility of the benchmark being met in the narrative in this section, identifying any known issues.
    b. Changes from COP 2016 identified barriers are not encouraged, as teams should build upon analysis from last year, unless the barrier is no longer relevant. However, if changes are being proposed, provide a justification for why the proposed changes are now more relevant than what was identified in COP 2016.
    c. Justify any modified or discontinued systems activities.

3. **Complete tables.** Country teams should complete the tables in the Section 6 Tables Excel tool, which will be done by updating the existing information in the COP 2016 SDS Section 6.0. A detailed column-by-column description of table inputs is located in the SDS template and in the Instructions tab of the Excel tool**. Teams should also consult the Illustrative Examples of Systems Investments Outcomes and Benchmarks document available on PEPFAR.net in the COP17 folder. The document provides illustrative examples to guide country teams in defining and refining country-specific outcomes and benchmarks**. The completed tables should be PDF'ed and attached as an appendix to the final SDS.

A successfully completed SDS Section 6 will include:

a. A brief narrative describing progress made toward year one benchmarks, as well as any factors limiting progress.
b. A brief summary of the rationale for revalidating the programmatic gaps and systems barriers.
c. Completed tables including annual benchmarks and progress updates.

**Note: See Appendix H.8 for required elements of Evaluation Standards of Practice and Evaluation Inventory**

After validating above-site activities planned, key programmatic evaluations should also be identified in Section 6 of the SDS. The required evaluation inventory (comprehensive list of all types of evaluations) should be a living document that plans ongoing and completed evaluations. In line with COP15 and COP16 analyses and execution, COP17 should also follow the path of resources in the areas with highest disease burden, and continue to saturate in areas by rank of order.

## Appendix A.2.5 Planning Step 5: Determine the Package to Sustain Services and Support in Other Locations and Populations and Expected Volume

This step outlines considerations for activities in Attained, Sustained and Central Support areas. Activities for each of these types of supported areas requires a different approach given disease burden, ART coverage and site level activities.

The following revised definitions of PEPFAR tiered support should be used for this prioritization:

**Attained SNUs:** SNUs that have achieved at least 81% coverage of ART among all adult males and females by the end of FY 2017. The emphasis for these SNUs is to sustain high coverage

levels and increase viral load suppression rates to achieve at least 90% suppression rate in all PLHIV on treatment.

Prioritized activities for Attained SNUs include:

Surveillance and Laboratory

- Real-time surveillance should identify populations that need prevention services.
- Surveillance should be conducted in a case-finding, outbreak investigation method to identify networks with on-going or new transmission; prevention and clinical services should be targeted to break the transmission.
- Program monitoring should include quality assurances mechanisms to ensure gains made in treatment and prevention services are maintained.
- Lab systems should support real-time surveillance and clinical monitoring of patients for 73% of patients virally suppressed.

Clinical Services

- Maintain clinical services and sites for 81% ART cohort coverage (substantial site expansion is not expected).
- To maintain current retention levels, assure clinical services consider current retention rates plus passive HIV diagnosis and linkages to maintain 80% coverage [Current Retention + (Passive HTC_POS * Linkage)]/PLHIV = 81%.
- Implement customized supportive ART retention services based on specific age, sex, and HIV risk factors related to the variable use of prevention and treatment services.

Prevention

- Aggressive demand creation is not expected for the general population.
- HIV-negative prevention programs should target those who continue to be at risk based on surveillance and epidemiologic data.

Key populations

- Continue outreach, prevention, testing, clinical services for key populations since these populations may not have 81% ART coverage

PEPFAR is obligated to ensure that standards of care are upheld for the patients we support with life-saving care, treatment and support services. In the current environment there is an urgent need to shift program resources to the locations and populations where most new HIV infections are likely to occur.

However, redirecting resources to enhance program focus must be accomplished through careful financial and program planning in partnership with the host country government and other stakeholders to preserve continuity of treatment while reallocating finite resources for maximal epidemic impact. In COP 17, PEPFAR teams are expected to define a package of services needed to sustain support for locations and populations that have not already attained epidemic control and that are not prioritized for accelerated epidemic control.

Guiding principles:

1. PEPFAR should no longer support sites with HTS services with less than four PLHIV diagnosed in the last 12 months and those sites should be carefully evaluated by the Host government to determine optimal support that the USG provides through investments identified in Table 6. As countries urbanize, an analysis of best options for service delivery must be explored for rural areas.

2. In addition to discontinuation of PEPFAR-supported HIV testing at sites with less than four positives identified in the last 12 months, PEPFAR teams with site-level indicator data are expected to complete a full site yield analysis for HTS, including testing conducted at PMTCT sites. The purpose of this analysis is to determine where the majority of positives are identified and quantify potential cost savings or increases in yield that result from enhanced program focus on high-burden areas and populations. A full description of methods to conduct a site yield analysis can be found in section 1.3.

Site yield Analysis is available through Panorama and Spotlight.

3. PEPFAR should work with the host country government and other stakeholders to transition support for low-volume ART sites and refer current patients to higher volume sites to improve quality of care.

   PEPFAR-supported ART sites that provide services to a low volume of ART patients may not be able to provide the same quality of care as sites with higher volume and greater capacity. If resources for scale-up are to be focused in high-burden locations and populations, PEPFAR teams will need to determine which treatment sites in other locations PEPFAR will continue to support with a core package of services (see next subsection) and which sites will be selected for transition.

PEPFAR teams with site-level data are expected to conduct an analysis for ART to identify low-volume sites and determine the cost savings or additional patient slots that could be supported if PEPFAR resources were redirected to higher volume sites. A full description of methods to conduct a site volume analysis can be found in Appendix A.2.9.1.

PEPFAR should jointly monitor these sites with host country governments to ensure quality services provided at these sites.

4. Program costs and trade-offs should be taken into account when determining sustained support for other locations and populations.

   Continuation of support to sites in areas not prioritized or de-prioritized in COP 17 consumes valuable resources that might be applied elsewhere for accelerated epidemic control and should be strongly justified.

   After the site yield and volume analysis are conducted and interagency decisions are made about which sites will continue to receive PEPFAR support in the coming cycle, teams will need to estimate the required resources necessary to sustain support of the program (i.e., sites/program activities outside of the selected priority locations). To the extent possible, this should be driven by program data, expenditure data, and the expected volume of beneficiaries. For PEPFAR-supported ART sites, teams should factor in an estimate of passive enrollment and continuation of care for current patients supported with clinical care and ART.

   Resources needed to support the current volume of beneficiaries in *scale up*, plus the resources needed to support the current volume of beneficiaries in *other locations* that will be sustained in COP 17, represent the total dollars required to sustain the current program, or the 'carrying costs.' Given a finite budget, this carrying cost will affect the resources available for other program activities and the magnitude of scale-up that can be achieved in priority locations. Appendix A.2.6 describes methods for resource projections that can be applied to assist with estimating this resource requirement.

**Note:** The *PEPFAR Budget Allocation Calculator (PBAC)* is a resource projection tool that PEPFAR teams are required to use to estimate and document the required resources to fund program activities based on historical expenditure or cost data.

When projecting resources, teams should consider changes in costs if patients are picking up drugs every 6 months, versus every three months, and the reduced need for lab services and doctor visits.

Review defined packaged of services for areas that have attained 81% ART coverage.

### *Review Defined package of services to sustain support for other locations and populations*

In COP 16, Country teams developed a package of services provided at PEPFAR-supported facilities and service outlets in other locations and for populations not prioritized for scale-up. For COP 17, PEPFAR teams should review this package of services and agree on any needed changes. The components of this package should be based on the host country's minimum/standard package of services for PLHIV and focused on essential HIV-related services and commodities. The components of this package will not be the same in every country and will depend on services provided by the host country government and other stakeholders. Essential components to be considered for a minimum package of services for other locations and populations include:

- HIV testing and counseling on request by a presenting client or as indicated by clinical symptomatology or identified risk behaviors.
- Treatment services including routine clinic visits, ARVs, adherence and retention support, and care package.
- Other HIV Care services for PLHIV, including provision of cotrimoxazole prophylaxis, screening for TB and other opportunistic infections, provision of fluconazole prophylaxis, treatment of latent TB infection (including INH prophylaxis), condoms, Positive Health, Dignity and Prevention PHDP package, etc. depending on the country context.
- Essential laboratory services for PLHIV – capacity for HIV testing, EID, viral load, molecular and routine diagnosis of TB (including Xpert MTB/Rif) and CD4 testing.

While PEPFAR programs phase out of active counseling and testing and new ART enrolment, PEPFAR service or technical support for other programs must be done as well through careful transition planning to ensure that harmful consequences are avoided. For OVC programs in central support and sustained SNUs, countries should use evidence-based models to set benchmarks for phased graduation and transition planning. PEPFAR teams should communicate early and comprehensively with other USG health programs, the Global Fund and government to

identify a clear transition plan that may include: uptake of services by the government or referral of clients to service delivery points in prioritized locations.

The sustained package of services and transition activities will have an impact on the resources required to support programs in areas outside of those selected for prioritization in COP 17. This package should be taken into account in estimating the budget needed to continue support in other locations and populations (see planning Step 6 below). As concisely as possible, PEPFAR teams should describe the package of sustained services in Section 5 of the SDS.

*Outline plans for sites and programs that will receive central support*

**After teams successfully complete the site yield and volume analyses, define a core package of services, and interagency decisions are made about which sites will be supported with the core package in the coming cycle, plans for sites or other PEPFAR supported programs to transition to central support should be documented in Appendix A, Table A.2 of the SDS.**

## Appendix A.2.6 Planning Step 6: Project Total PEPFAR Resources Required to Implement Strategic Plan and Reconcile with Planned Funding Level

PEPFAR teams are expected to estimate the resources required to achieve desired targets and program deliverables in the next fiscal year and verify this amount *does not exceed the planned funding level for COP 17.* Resource projections should also be used to guide program decisions regarding priority locations and populations chosen for scale-up; sustained packages for service delivery; and proposed targets. Generally, there is paucity of cost data at the field level that can be utilized to better inform program decisions and feed into budget projections. As in past years, PEPFAR will use data gathered through the Expenditure Analysis (EA) Initiative as a starting point for estimating the required resources for the PEPFAR program in the next fiscal year.

A strategic approach to empirically-based budgeting is described in detail in the methods portion of this section. When implementing this approach during COP planning, there are several guiding principles teams should consider:

1. Carrying costs to PEPFAR of current program activities should be calculated first.

As described in the section on sustained support above, PEPFAR will continue to support current PLHIV receiving clinical care and ART services in all sites until referral, consolidation or transition of site support to other stakeholders can be accomplished without compromising patients'

health. For sustained sites (i.e., in areas not prioritized for epidemic control), PEPFAR teams should allocate sufficient funds to support the current cohort of patients enrolled in care and treatment, consistent with the sustained package of clinical services defined. For low-volume and central support sites, the expected volume of beneficiaries should be adjusted to account for transition of patients to support by other stakeholders. In addition, teams should determine the expected number of new patients that will be enrolled in the implementation year in sustaining sites as a result of PITC and diagnosis. Calculating this carrying cost provides a sense of how much of the COP 17 budget should be set aside prior to planning for any other activities or scale-up to meet PEPFAR obligations and maintain clinical standards of care.

As teams calculate carrying costs and target-based budgeting, the length of time enrolled should be taken into account. Resource projection must adjust for the length of time a patient is receiving care over the implementation year—i.e., the cost-per-patient of a person initiated on ART in January will be different than the cost-per-patient of a person initiated on ART in July. Using the USG fiscal year as the discreet time period, the first patient would receive nine months of ART, whereas the second patient would receive three months, resulting in very different annual costs for each.

To correct for this time component, teams should use simple patient year calculations to determine the *equivalent number of patient-years* that would be expected given the number of patients enrolled at the start of the period, scale-up rate during the cycle, and the expected LTFU.

2. <u>Target-based budgeting and commodities budgeting should be prioritized over activity-based budgeting.</u>
   After calculating the costs of carrying current patients, all other target-based and commodities based budgeting should be completed to estimate the remaining available resources for activity-based budgeting (formerly lump-sum budgeting). If remaining resources are insufficient for site-level and above-site level activities not tied to targets or commodity procurement, prioritization and ranking of activities will need to be examined along with whether activities can be completed with reduced budgets.

3. <u>Remember not all costs increase with each additional patient added.</u>
   Training of staff members, construction or renovation of buildings, supportive or mentoring visits to a site, and site personnel are examples of costs that do not change for each additional patient, client or beneficiary Identifying which costs are 'fixed' over the fiscal year and which costs are variable according to the number of patients served is a first step to accurately planning for required

resources. For COP17, fixed costs that are expected to increase by site, e.g. the cost of a package of supportive visits to a site should be budgeted for at a site level rather than by patient.

4. Adjust Unit Budgets, as Necessary. While the starting point for budgeting is the prior year's unit expenditure, adjustments can and should be made to increase or decrease unit budgets appropriately. Increases should be balanced with decreases so as to maintain an overall national average in line with available resources.

- *Adjustments for program focus*

Based on the results of the site yield and volume analysis and selection of scale-up, sustained and central support sites, teams should adjust the unit budget for sites or for patients based on the implementing mechanisms and sites that will be responsible for achieving targets in the implementation year. Costs vary across geographic areas, targeted populations, service modalities, and implementing partners. Adjustments should be documented and may need to be explained if result in outliers for the budget.

- *Adjustments for expected changes to program components or costs*

The prior year's national average UE may include expenditures that will not be expected in the coming fiscal year (e.g., purchase of a fleet of vehicles). Conversely, the UE may not include investments that are expected in the coming fiscal year (e.g., improvements to retention through enhanced provider training programs). These differences can be quantified and should be used to adjust inputs to resource projections. The same principle applies to adjustments based on expected changes in contribution of other sources of support (e.g., Global Fund).

**Note:** The ***PEPFAR Budget Allocation Calculator (PBAC)*** is the budgeting tool that PEPFAR teams are required to use to estimate resources required for achievement of targets and other activities. The PBAC brings together prior year expenditure data and targets as set in the Datapack. Additionally, the IM-level target based budget allocation tool has been developed to assist with applying the same principles for target-based budget allocation to the implementing mechanism level. PEPFAR teams must provide clear documentation and the data on which they make adjustments to budgets for IMs; the IM-level tool used should be uploaded alongside the PBAC. PBAC outputs for the FSW should align with the FSW submitted. The final version of the PBAC should be saved with COP documents on pepfar.net for reference.

## Appendix A.2.7 Planning Step 7: Set Site, Geographic and Mechanism Targets

COP 17 will include five types of targets, all of which will be set for FY 18 results. FY 17 targets will not be restated in COP 17.

1. Site Level Targets – Site level target setting allows for implementing partners to clearly articulate and set expectations for achievements at each PEPFAR-supported site based on supported activities and in alignment with geographic, population, and intervention-based prioritization efforts for scale-up or sustained support.

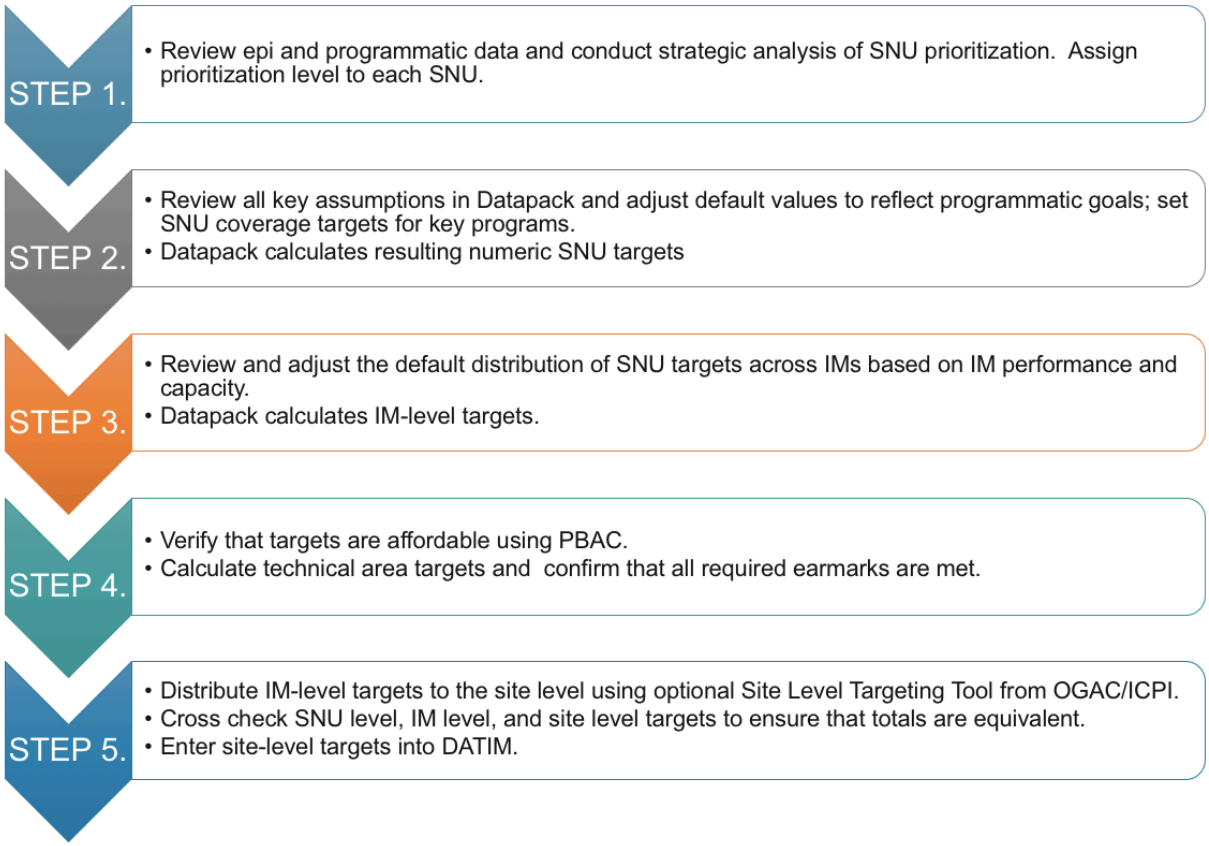
2. Sub-national (i.e., District) Level Targets – Sub-national level target setting strategically demonstrates geographic prioritization of efforts towards the 90:90:90 by 2020 UNAIDS target in alignment with the distribution of the burden of disease in a country.

3. Implementing Mechanism Level Targets – Implementing Mechanism (IM) targets represent expected accomplishments for the implementing partner based on available funding and agreed upon activities. Target setting is important for in-country partner management as well as routine planning and monitoring, and is aligned with agency-specific requirements.

4. Technical Area Summary Level Targets – The PEPFAR Technical Area Summary Targets are an aggregated reflection of total expected achievements in a country based on the collective work of all PEPFAR partners, and should represent PEPFAR's contributions to the national program. These targets should reflect scale up for epidemic control in high disease burden areas and sustain support of programs in other areas.

5. National Targets – National data represent the collective achievements of all contributors to a program area, including PEPFAR (i.e., partner country government, donors, or civil society organizations).

**Figure A.2.7.1** Steps in target-setting process for COP17




*Recommended Process for Establishing and Entering Targets*

- Country teams notify partners of priority areas and population groups by SNU and work with partners to set relevant site-level targets
- Partners enter site-level targets into DATIM or other identified format
- Activity managers and project officers review and approve partner targets at the agency-level and confirm budgets
- Interagency PEPFAR team reviews and approves site, mechanism, and geographic targets

After teams have completed the geographic and efficiency analysis and set programmatic targets for priority areas and populations, these will need to be distributed to sites (facility and community). The

strategic analysis conducted in Steps 1 - 6 now need to be operationalized by assigning site-level targets, and calculating mechanism level targets and budgets.

*Implementing Mechanism Level Targets*

**Implementing mechanism targets are produced in the Datapack. See Datapack User's Guide for detailed instructions.** Where more than one partner may reach the same individuals at a given site, country teams should take the opportunity to rationalize partners for increased efficiency.

*Distribution of SNU targets to sites for scale-up and sustained support*

In Step 3, scale-up and sustained support targets by SNU for all indicators were determined. These targets need to be distributed to sites. **OGAC and ICPI will release an optional Site Level Targeting Tool in February to support teams in distributing targets to the site level.**

*Distribution of scale-up targets by SNU to sites*

1. Distribution of SNU targets across sites need to take into account the following considerations:
    - New ART treatment slots should be prioritized for sites within SNUs identified as Scale-Up to Saturation districts and *then* should be assigned to sites in Aggressive Scale-Up districts
    - Past performance of partners at sites and capacity to expand site volume
    - Site yield for testing and volume for other services
    - The need to establish additional sites in catchment areas within a geographic region to meet the target
2. If additional sites are needed, then look at current partner's capacity to expand to additional sites.
3. Relevant site support should be determined by assessing site needs for commodities, human resources, or relevant technical support for expansion of services. This will determine the appropriate categorization of targets by DSD or TA-SDI support to the site.
4. If several partners are working across the continuum at facility and community sites, it is imperative that the partners coordinate to ensure no patients are lost across the continuum.

*Distribution of sustained support targets by SNU to sites*

1. Resources need to be allocated to sites to maintain patients on ART, taking into consideration other critical programmatic areas of support such as OVC.

2. As described in Step 6, PEPFAR will continue to support current PLHIV receiving ART services in all sites until referral or transition of site support to other stakeholders can be accomplished without compromising patients' health. For sustained sites (i.e., in areas not prioritized for epidemic control), PEPFAR teams should allocate sufficient funds to support the current cohort of patients enrolled in care and treatment, consistent with the sustained package of clinical services defined. For low-volume and transition sites, the expected volume of beneficiaries should be adjusted to account for transition of patients to support by other stakeholders. In addition, teams should determine the expected number of new patients will be enrolled in the implementation year in sustained sites as a result of passive HIV testing and diagnosis.

3. Relevant site support should be determined by assessing site needs for commodities, human resources, or relevant technical support for expansion of services. This will determine the appropriate categorization of targets by DSD or TA-SDI support to the site.

*Technical Area Summary Targets*

Technical area summary targets are a de-duplicated sum of the Implementing Mechanism targets. Cascade analysis of targets will need to occur at a subnational level as opposed to the technical area level, to verify or update COP 17 planning targets.

## Appendix A.2.8 Planning Step 8: Determine monitoring strategy for planned activities in accordance with requirements and assess staff capacity

PEPFAR must continue to enhance oversight of and accountability for programs and ensure that PEPFAR-supported beneficiaries are receiving quality services and accounting for US taxpayer dollars. Teams should consider how information from all data streams available to country teams will be used routinely throughout the year to monitor progress, ensure compliance with strategic plans outlined in the SDS, and course-correct where needed. PEPFAR teams should assess the current skills and time commitments of program staff to ensure sufficient capacity is available to meet monitoring requirements. Methods and tools to assess current staff time allocation and cost of doing business (CODB) can be found in Appendix F of this guidance. In addition, site monitoring requirements for all PEPFAR OUs need to be specifically addressed in COP 17 development.

PEPFAR's standards-based quality assurance Site Improvement through Monitoring System (SIMS) aims to: (1) facilitate improvement in the quality of PEPFAR-supported services and technical assistance, (2) ensure accountability of USG investments, and (3) maximize impact on the HIV epidemic.

Consistent with these goals, SIMS promotes compliance with global and national service delivery standards by facilitating program improvement. SIMS data will be used to: (1) demonstrate the quality of services and TA at each site, (2) demonstrate accountability of USG investments by showing that quality is being monitored and improved where needed, and (3) prioritize quality improvement of core interventions where most important for epidemic control and impact.

SIMS assessment results confirm compliance to minimum PEPFAR quality assurance standards and identify areas where improvements in PEPFAR-supported programs can be made. These standards are assessed in PEPFAR-supported entities, in communities, and above-site institutions that guide and support service delivery

Teams demonstrated accountability of USG investment by systematically monitoring the quality of service delivery across all PEPFAR implementing agencies and partners. As of the issuance of this document, over 12,000 SIMS assessments have been conducted in facilities, communities and above-site entities by all PEPFAR-funded agencies across PEPFAR's 36 Operating Units (OU). Additionally, use of SIMS data to facilitate program improvement is being embedded in PEPFAR business processes including PEPFAR Oversight and Accountability Review Team (POART) calls.

In FY 17, OU teams committed to SIMS site visit targets aligned with geographic and programmatic pivots made as part of COP 15. These commitments to scale up SIMS assessment coverage are critical to demonstrate USG investments toward standards of care to achieve HIV epidemic control. Access to PEPFAR resources for COP 17 will be contingent upon approved plans for SIMS assessment visits for FY2018. For FY18 there are no changes to SIMS implementation criteria and methodology.

For FY18 there are no significant changes in SIMS implementation criteria and methodology. However, to align SIMS with programmatic pivots and geographic/population prioritization, the following requirements apply:

1. <u>SIMS Coverage</u>

1.1. All PEPFAR-supported sites (facility or community) or entities that guide and support service delivery (at the above-site level) must receive at least an initial SIMS assessment during the life of an Implementing Mechanism funding agreement.

1.2. All newly-supported sites or entities must be visited in the first year of the agreement. A site or entity is considered "new" when it is supported through a new contract/agreement or a new Implementing Partner. A site or entity is not considered "new" if it was operational under a previous contract/agreement and is supported by the same partner/sub-partner.

2. Prioritization of SIMS Assessments

a) High volume sites in all areas (facility or community) must receive a SIMS assessment annually. An agreed upon definition of high-volume facility and community sites should be established. This definition will be reviewed and approved by S/GAC at the DC Management Meeting. The high-volume definition for facility should be determined using MER indicators applicable to a given Implementing Mechanism (i.e., HTC_TST,, HTC_POS, TX_NET_NEW, TX_CURR, PMTCT_STAT, PMTCT_STAT_POS, PMTCT_ARV, and VMMC_CIRC). The high-volume definition for community should be determined using MER indicators applicable to a given Implementing Mechanism (i.e., HTC_TST, HTC_POS, OVC_SERV, PP_PREV and KP_PREV or KP_MAT for certain STAR process countries).

b) Based on MER data, under performing sites in Attained and Scale-up areas should be prioritized in USG staff engagement, both timing and comprehensiveness of visit, to understand potential quality issues associated with underperformance. Other context related to performance should also be assessed according to areas of underperformance. SIMS assessments across all SIMS tools should be geographically prioritized (e.g., Scale-Up to Saturation and Aggressive Scale-Up districts) to focus on areas in which the majority of beneficiaries are receiving services supported by PEPFAR.

c) Above-site entities must be visited annually. Specifically, all national-level above-site entities supported by a given IM should be assessed annually, and at least one entity at each sub-national level supported by a given IM should be assessed annually.

3. Partner Performance Management and Program Quality Improvement

All country teams are expected to develop Partner Performance Management (PPM) operating procedures, and tools, to monitor the performance of Partner achievements, at the site and above site level, and establish clear and reasonable processes to address issues of under-performance. The PPM

should include the range of indicators, including SIMS, MER, and above site annual benchmarks, used to monitor and manage progress of partners. Approaches to developing a remediation plan to address underperformance should be included in the PPM.

There are no changes in the 25/50 rule criteria for USG and implementing partners from FY17. For all PEPFAR-funded CEEs that score yellow or red at an assessment, the IP is expected to have an action plan in place and have taken steps towards remediation within three months. Plans for improvement should be made between the IP and the USG activity manager, with monitoring of improvement tracked via routine partner management and oversight meetings with USG activity managers.

Any CEEs scoring yellow or red on an initial or annually required assessment trigger a rescore and, in certain cases, a re-visit. All CEEs scoring yellow or red should be re-scored by the IP within six (6) months of the assessment that triggered the rescore, with the rescore reported to the agency activity manager. IP-reported rescores should be entered into agency-specific data systems and sent to USG HQ by the next available reporting cycle.

<u>Two approaches for program quality assurance and management within PEPFAR</u>

A. Quality Assurance will be conducted by PEPFAR Implementing Agencies and S/GAC. Quality improvement data include a range of PEPFAR indicators, including SIMS, MER, above site annual benchmarks, and others, and should be triangulated to understand the complex nature of program quality monitoring and management. Implementing Agencies will be responsible for ensuring the quality and consistency of implementation using agency-specific standardized procedures. All PEPFAR Implementing Agencies must conduct Quality Assurance (QA) activities and report on their QA structures and process to S/GAC on an annual basis. All site-, partner-, agency- and country-identified data will be exchanged into a secure location (DATIM). Data exchange and security attributes and guidance on reporting to S/GAC will be provided through DATIM deployment and its user guide

B. Quality assurance and management in areas that PEPFAR has supported

   To continue to ensure epidemiologic impact across the country, PEPFAR teams should assist local institutions and governments in monitoring site level results within all geographies across the country. This means that PEPFAR teams will work with districts to monitor results and outcome within districts, interpret results to identify quality barriers, and establish QA strategies at the facility and geographic level t to ensure the gains jointly achieved are not lost. Teams will

be expected to have access to these activities and outcomes in order to monitor progress and any unexpected changes in access or quality of treatment services. These data should be reported in DATIM on an annual basis in the fourth quarter to inform Q4 and Q1.

4. Agency-specific considerations

Results from DoD SIMS assessments conducted at military sites are reported at the national level by IM, not at the site level. Site-level data from military sites will not be publically available. Military site-level planning information related to SIMS will be reviewed internally at DoD and is not required for submission to S/GAC. Results from DoD civilian SIMS assessments conducted at civilian sites will be reported at the site level. Refer to agency-specific guidance for more detailed information

## Appendix A.2.9 Methods

The sections below provide guidelines for completing activities and analyses necessary to successfully implement the modular planning steps in Appendix A and generate a comprehensive SDS.

## Appendix A.2.9.1 Site Yield and Volume Analysis

While a site yield and volume analysis was done in COP16, this exercise should be conducted on the sites reporting results in APR16. With the emphasis on case-finding to reach the 1st 90 and a fixed resource envelope smaller than the resource gap, tough decisions will need to be made in most countries about where PEPFAR provides services or support. Sites with low-volume, and particularly, low-yield should be critically assessed to determine if operations resources could be directed towards other sites or interventions to get a higher net program output and/or epidemic impact. To answer this critical question, operational definitions must be established for 'low-volume' and 'low-yield.' There is not a single definition that can be applied across countries and PEPFAR program areas and the threshold used to define low volume and yield should be driven by historical data and epidemiologic context.

**Note:** The *Datapack* is provided to field teams to assist with data organization and completing yield and volume analyses (see descriptions in text below).

*HIV Testing and Counseling Yield Analysis (HTS and PMTCT sites)*

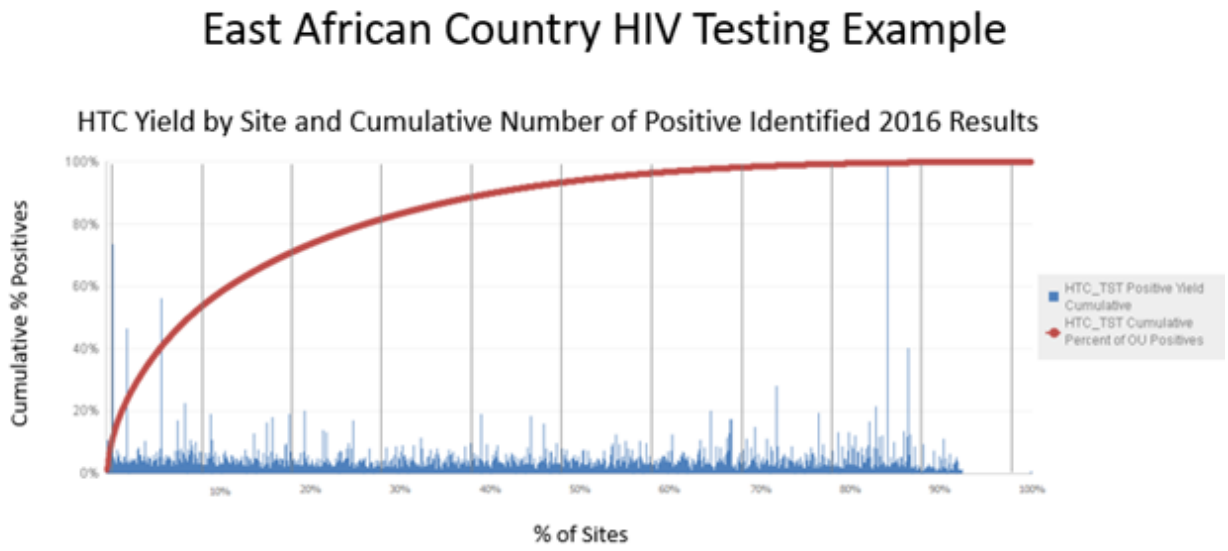
*All PEPFAR teams with site-level results are expected to complete a yield analysis for HTS sites, including testing for pregnant women through PMTCT sites and a volume analysis for ART sites.*

The purpose of this exercise is to quantify the number and percentage of sites where the most HIV-positive individuals are identified, and conversely, the number and percentage of sites where the fewest number of HIV-positive individuals are identified relative to others. The results of this analysis should guide program decisions about where PEPFAR will invest to maximize program output. To effectively complete this analysis, the following three data elements are critical to review:

1. The absolute number of positives by site
2. The positivity rate by site (numerator and denominator)
3. The cumulative number and cumulative percent of positives at any specific point in the distribution

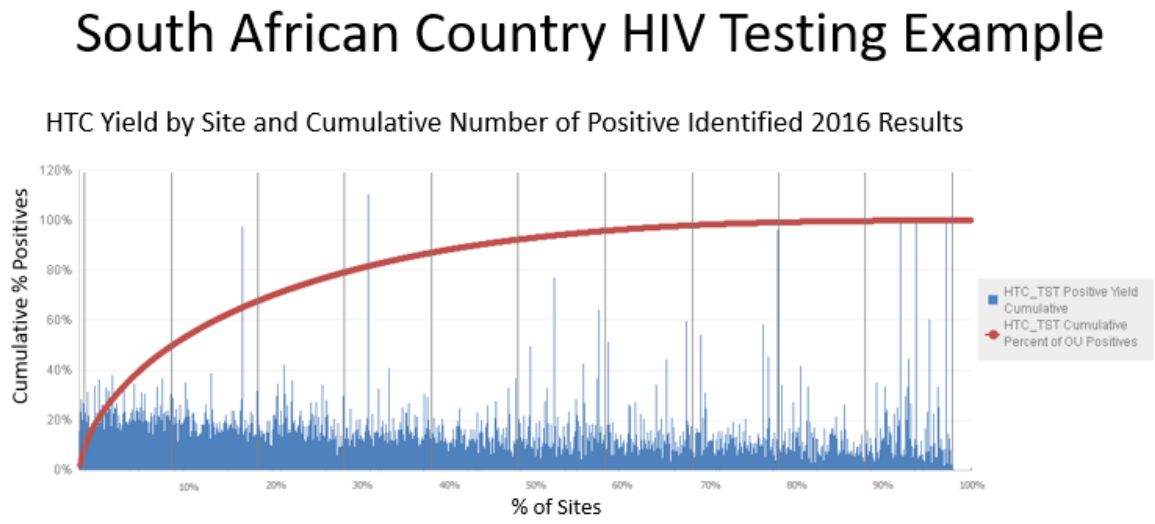
In the following graphs, Figure A.2.9.1.1, Figure A.2.9.1.2 and Figure A.2.9.1.3 are examples of HIV testing yield by site. The HIV testing yield is analyzed in two ways (1) HIV yield across all HIV counseling and testing sites and (2) HIV yield across sites testing pregnant women. Examples from countries in East Africa, Southern Africa and West Africa are included to show variability across the different epidemic types, HIV program coverage and HIV disease burden.

**Figure A.2.9.1.1**



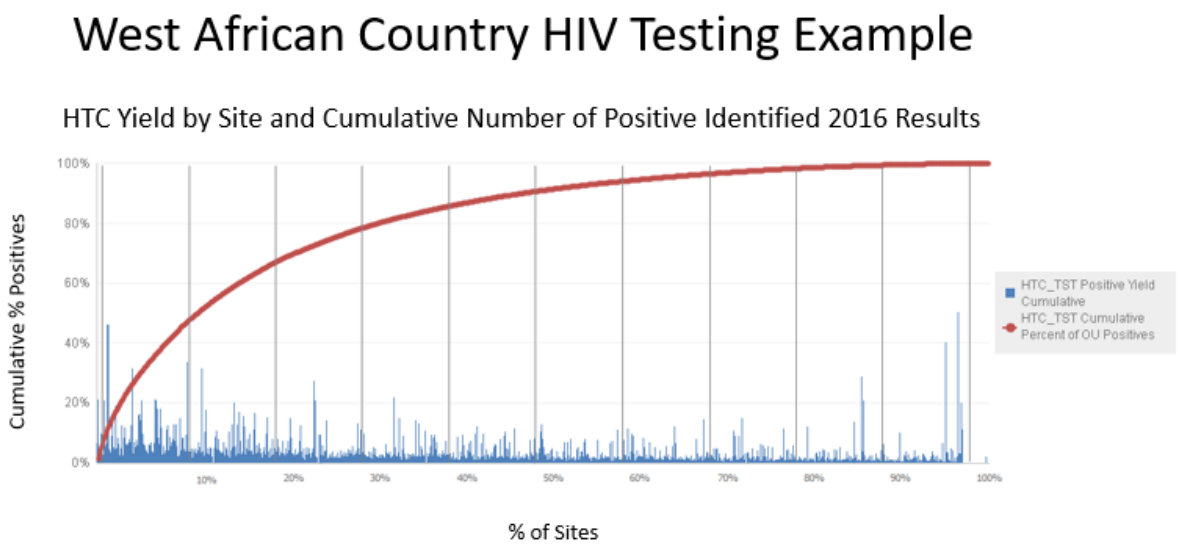

| Sites (Across four quarters) | Positives | Sites with 0 Positives | Sites with 1-4 positives |
|---|---|---|---|
| 4,103 | 239,054 | 265 | 579 |

**Figure A.2.9.1.2**




| Sites (Across four quarters) | Positives | Sites with 0 Positives | Sites with 1-4 positives |
|---|---|---|---|
| 3,754 | 989,419 | 65 | 190 |

**Figure A.2.9.1.3**




| Sites (Across four quarters) | Positives | Sites with 0 Positives | Sites with 1-4 positives |
|---|---|---|---|
| 850 | 55,055 | 24 | 56 |

PEPFAR teams are expected to summarize their findings in the corresponding sections in the SDS—in Panorama, "HTS yield" and "PMTCT yield" are provided to assist field teams organize site-level data and summarize their results in standard figures that can be inserted directly into the SDS.

Field teams are also expected to summarize the results in terms of high and low yield classification. As stated above, 'high' and 'low' yield must be operationally defined by the PEPFAR team and the threshold used to classify sites should be reflective of the distribution. For example, identifying sites as 'low yield' where fewer than 10 HIV-positive individuals are identified in the last year may not be reflective of the distribution if 95 percent of all supported sites identified more than 10 positive individuals. As a starting point for this investigation and identifying appropriate thresholds, teams may use one of the methods described below. This exercise will likely be iterative as the results are tied to resources (see section A.2.8.2 below) and considered in decision making.

*Method 1: "80/20 rule"*

Country teams can use the Panorama to classify sites as low-volume or low-yield using the "80/20 split test" to focus attention on sites with relatively lower performance (as measured by yield.) Specifically, the question to answer is: *What percentage of sites account for 80 percent of program yield?* Once the

data are sorted largest to smallest by number of positive individuals identified at each site, the point in the distribution where the cumulative percentage of positive individuals equals 80 percent will indicate the percentage of sites that account for those positive individuals. This method will also allow users to identify the number of HIV-positive individuals per year, per site that would establish the threshold for being classified 'low yield.'

*Method 2: "(X) times greater UE"*

The EA results can be a useful resource in identifying sites with relatively low performance and may help identify a threshold number of positives per year, per site used to classify sites as 'low' and 'high' yield. Though site-specific data are not currently available, unit expenditures (UEs) have been calculated for each partner working in each SNU (one level below national). Often "outliers"—those observations with higher than expected UEs—are driven by lower relative volume or yield or less efficient models of service delivery. To focus attention on sites with relatively lower performance (as measured by UE), country teams can set an acceptable range for UE and review outliers using the *EA Data Navigation Tool* (see Outlier Analysis in section 3.3.5 below). The outer bound of this range would be defined as (X) times greater than the average across all partner and SNUs for a specific UE. This allows teams to focus on partners, SNUs or sites where resources may not be utilized as efficiently as possible, resulting in lower relative yield and impact than could otherwise be achieved.

Other methods may be considered, but teams should complete an analysis that identifies low-yield sites using objective criteria. Identifying a site as low-yield does not necessarily result in discontinuation of services/support, especially if the site operates in a geographical focus area; however, the analysis will highlight areas where a performance improvement plan may be needed and help determine if additional investments in the site are sensible.

*ART Site Volume Analysis*

In addition to the yield analysis described above, PEPFAR teams with site-level ART data are expected to conduct a site volume analysis for ART. Two data elements are critical to effectively complete this analysis:

1. The absolute number of current on ART by site
2. The cumulative number and cumulative percent of current on ART at any specific point in the distribution

The following graphs are examples of ART volume analysis by site. Examples from countries in East Africa, Southern Africa and West Africa are included to show variability across the different epidemic types, HIV program coverage and HIV disease burden.

PEPFAR teams are expected to summarize their findings in the corresponding section in the SDS in Section 4. In addition to this analysis, teams are expected to classify sites as 'low' and 'high' volume as described in the yield section above. Both the *80/20 split* method and *(X) times greater* method are useful as starting points for the site volume analysis.

*Using the Results of Yield and Volume Analysis*

The HIV testing site yield analysis and ART site volume analysis should be used in conjunction with the efficiency analysis results; geographic and population prioritization; and core, near-core, and non-core determination to make decisions about which PEPFAR-supported sites will be prioritized for scale-up and which sites will be maintained or transitioned in the implementation year. *These decisions should be succinctly described in the SDS in the corresponding sections for HTS, PMTCT and ART*.

*Teams are also required to include in the Goal Statement narrative of the SDS the total number of sites that are assigned to each of the following categories:*

1. *Scale-Up Sites* are sites most often located in a Scale-up District (i.e., Scale-Up to Saturation or Aggressive Scale-Up.). However, Scale-Up sites can also be located in Sustained Districts if they are located in a "hot spot" and/or are targeting a key/priority population in order to leave no one behind.

2. *Sustained S*ites can be in Scale-Up or Sustained Districts and are characterized by ongoing PEPFAR-supported passive enrollment services and activities.

3. *Centrally_Supported Sites* can be in Scale-Up, Sustained, Attained or Central Support Districts, and represent sites that either transition to government or other support.

Sites prioritized for scale-up should generally be 'high' yield/volume per the operational definitions assigned by the country team. Additionally, sites defined as 'low' yield should generally be classified as 'sustained' or 'centrally supported' and not prioritized for scale-up. Further, analysis results across HTS, PMTCT and ART sites should be triangulated prior to making decisions about site classification. There is no step by step guide to how to accomplish this task, and the process will be iterative, likely requiring multiple rounds of data review and interpretation. Additionally, this information will need to be

considered within the local context; for example, epidemiologic data describing the size, location and HIV burden in key and priority populations, roll out of test and start, the current status of the national B+ implementation plan and the current HRH and HSS challenges will all be important to consider.

For each program area, (ART, HTS, and PMTCT) there are three broad categories of information that should be used to decide which group to place a PEPFAR supported site within:

1. Estimate of unmet need within the sub-national unit should be used to inform programs where additional support is needed and be consistent with geographic and population prioritization decisions

2. Location of sites in relation to each other (i.e., are ART, HTS and/or PMTCT sites co-located in the same facility and/or located in the same sub-national unit) should be used to ensure that prioritization decisions are consistent and integrated across all program areas.

3. Location and size of key and priority populations and the services targeted to these populations should be used to ensure hot spots are prioritized.

Further, there are a number of guiding principles teams should consider prior to making decisions about which sites will be prioritized for increased resources and program scale-up:

1. PEPFAR should no longer provide site-level support where four or fewer HIV-positives have been identified in the last 12 months.

For robust methods for case finding to reach 90-90-90, PEPFAR programs should stop site-level support of HIV testing at HTS and PMTCT sites that have identified four or fewer HIV-positives during the last 12-month APR reporting period. For PMTCT, teams should also consider if these sites provide Option B+ ART to pregnant women. If so, the results of the volume analysis of ART sites should be triangulated prior to making decisions regarding discontinuation of PEPFAR support.

2. Analysis should be completed first on the entire data set, and then adjusted for geographic focus.

Teams should conduct the site yield and volume analyses described above on the full data set—i.e., including all sites with data over the last reporting cycle—and present/describe summary results for HTS, PMTCT, and ART using the total sites reporting in APR 2016 as the denominator. Once the yield/volume in each of these program areas has been characterized for the existing program, the team

should determine how the sites classified as 'low' and 'high' yield align with geographic and population prioritization decisions.

3. Analysis should be based on empirical data, not what is "expected."

Consistent with guiding principle two above, actual results should be used to conduct site yield and volume analyses. Teams should not impute what the expected positivity rate would be in the future as a basis for decision making, unless there is strong empirical evidence that suggests otherwise. If any data are imputed, it must be clearly stated in the SDS in the relevant sub-sections of Section 4.0 (HTS, PMTCT, and Adult ART).

4. Low-yield sites in focus areas require additional scrutiny.

Sites classified as 'low' yield that operate in areas prioritized for scale-up should be highly scrutinized to determine if support to these sites can be discontinued without interrupting services for priority populations, and/or if quality issues are impeding the ability of the sites to scale at a pace required for attaining the stated goal for epidemic control.

5. The number of sustained or centrally supported sites should be de-duplicated when counting PEPFAR sites.

It is likely the site yield and volume analysis across HTS, PMTCT and ART programs will produce overlapping results—i.e., the same sites will be identified as 'low' yield in each program area analysis. Teams should look across platforms to consider co-location of services and how this impacts the total number of sites the team is reporting that will enter a sustained state, and the total number of sites PEPFAR will no longer support and will be centrally supported in the implementation period. In reporting the total number of sites classified as scale-up, sustained or centrally supported in the Goal Statement, teams should not count the same sites more than once.

## Appendix A.2.10 Outlier Analysis

There are a number of ways that analyzing outliers can assist with COP development, including identifying key cost-drivers and highlighting areas to focus attention for maximizing efficiency gains and program output. For the purposes of EA, an "outlier" is used to describe a unit expenditure (UE) that is a certain amount above or below the average UE for all observations in a distribution. An "observation" is a UE representing a combination of mechanism and location or the national UE for a mechanism. For example, if 10 PEPFAR implementing partners provide ART to adults in two provinces each, and

have reported *both* expenditures and indicators for the same time period, there would be 20 (10X2) unique unit expenditure observations in the distribution for adult ART.

The threshold for identifying an outlier is not prescribed and should be tailored to the indicator and program context. While the threshold for identifying an outlier should be tailored to the indicator and program context, a recommended cutoff is five times the average mechanism UE. PEPFAR teams should identify and pay close attention to EA 2016 outliers that were also outliers in 2015 and 2014.

While variation in the mechanism UEs is expected, PEPFAR teams should consider 1.) Why the unit expenditure is high (contextual factors, potential inefficiencies, or data quality concerns, 2.) Addressing any concerns identified and/or look for efficiency gains across partners and SNUs where similar expenditures and outputs are expected, and 3.) Determining whether or not the IM or IM-SNU combination will be funded for the same activities in COP17 with rationale as to why.

We recognize that partners have different models of service delivery, reach different populations, or may be providing different types of support even though they count the same indicator. It is also important to remember that the calculated UE is a combination of expenditure and result data. Often outliers are identified because the volume is disproportionate to the expenditure (i.e., incredibly low or high). In this respect, the outlier analysis can identify low performing or high cost SNUs and quantify efficiency gains from enhanced program focus.

In the context of COP refinement, we recommend country teams use the *EA Data Navigation* tool to address the following questions:

- What's an acceptable outlier threshold for each distribution?
- Which program areas have the greatest number of outliers?
- Which SNUs have the greatest number of outliers?
- Which partners/mechanisms have the greatest number of outliers?
- For extreme outliers (very top and bottom of distribution), does the volume or expenditure appear to be driving the UE? Is there reason to believe these data aren't accurate, and is it worth getting clarification from the reporting IP?

- What percentage of total expenditures for a specific intervention do the outliers account for? What percentage of total volume of beneficiaries do the outliers account for? Is this acceptable when compared?

- Given your knowledge of the program context and partner activities, can the outlier be explained *using quantitative data*? For example, if it's thought a partner has a higher UE due to serving a hard to reach population, can you demonstrate the partner spends more on travel/transport, vehicles, etc. than the average across all partners? Is this acceptable and in alignment with program prioritization?

This type of investigation may help teams identify common themes that will have broader implications for program output and efficiency, such as specific models of service delivery or geographic areas that are clear cost drivers and may need adjustment. It is important to note that UEs do not consider quality of the support provided. Other data, such as retention and linkage information and SIMS results, should be considered in tandem to assessing acceptability of outliers based on program quality considerations.

# APPENDIX B: STAR PROCESS PLANNING STEPS

# Appendix B.1 Executive Summary

For COP17, 12 operating units (OUs) have been selected to participate in a modified COP development, review and oversight process that will better align to the specific needs and strategies of these OUs. OUs eligible for this "Strategic and Technical Alignment for Results" (STAR) process will engage in a new approach that will not only streamline COP development, but is designed to better align with the types of programming and priorities of these OUs. Key characteristics of the COP process for OUs selected for the STAR process includes: development of a strategy that covers a two-year period, a shorter and more streamlined development process and tools, and a monitoring POART review every six months as opposed to quarterly.

# Appendix B.2 Key Components of STAR COP17 Development, Review, and Oversight Process - What Is New?

In recognition of the unique features of regional programs and countries that have been identified as being primarily a Technical Assistance (TA) or Technical Collaboration (TC) model, a new, streamlined planning, submission and review process, structured to be more aligned with the configuration of these programs, is being launched. Twelve TA or TC operating units (OUs) have been selected to join the inaugural cohort of STAR process countries. This process differs from the COP16 process these OUs engaged in and also differs from that which will be required from other countries for COP 17. Key differences in the STAR process include:

- A shortened COP17 submission timeline with modified required elements
- COP17 development will be guided by country-specific guidance, weekly check-ins with Headquarters that are guided by clear benchmarks towards completion
- COP17 submission will be due **February 16, 2017**
- The COP17 submission will cover a one + one year implementation period
- Alignment of site-level and above site-level activities to ensure that site-level activities contribute to a sustained national response
- POART reviews will occur every six months, unless significant issues require additional check-ins

- A budget review will occur after year one to confirm year two budgets and activities based upon year one performance

# Appendix B.3 Background and Goals

As with all PEPFAR countries, the ultimate goal for countries who are using the STAR process is to achieve epidemic control, with PEPFAR investments that support a demonstrable increase in, and sustainability of, coverage of testing, treatment and HIV prevention services. In these settings, PEPFAR is generally not directly paying for the majority of these services, but supporting their achievement through above-site level activities and innovative models. Site level activities fill critical service gaps and promote the development and adoption of best practice models.

The overall goal of the STAR process in COP 17 is to establish a modified planning, review, implementation and monitoring strategy to:

1. Optimize the impact of PEPFAR resources in achieving HIV epidemic control
2. Promote innovative strategies that can be brought to scale to address key challenges and underserved populations in a sustainable manner

**Figure B.3.1** COP17 STAR Process Timelines

Please see below for key dates for the COP17 development and review process for countries following the STAR process:

| COP 17 STAR PROCESS | |
|---|---|
| **Key Milestone** | **Dates** |
| STAR Kickoff Webinar | January 11, 2017 |
| Release final COP 17 guidance and tools (including country-specific COP guidance) | January 18, 2017 |
| Weekly structured check-ins with HQ | January 19 – February 10, 2017 |
| In-Country Strategic Retreat | January 23-27, 2017 |
| Weekly Structured Calls with HQ and Field Team | Weeks of January 30, February 6, 13, 2017 |
| COPs and ROPs due | February 16, 2017 |
| In-person COP reviews | February 28-March 2, 2017 (Bangkok)<br>March 13-15, 2017 (Washington, DC) |

# Appendix B.4 Key Elements of the STAR Process

**Coordination and Strategic Communication with Partners**

- Close collaboration with host governments, civil society and other national stakeholders and multilateral and other partners is essential to the success of all PEPFAR programs. Please see instructions in the overall COP17 guidance for this component.

**Coordination among USG agencies (including regional programs)**

- PEPFAR uses a whole-of-government approach, and this is no different for OUs that will be completing the COP through the STAR process. Regional programs require extra effort to ensure that PEPFAR staff, agencies and activities are well coordinated.

**Framing, Process & Submission Steps**

- OUs participating in the STAR process will follow a distinctive COP17 development and submission process. One important component of the overall strategy behind the analysis for these countries is to ensure that above-site and any site-level investments are well aligned for the greatest impact. Figure B.4.1., below, describes three general categories of PEPFAR investments, and provides a useful lens for framing the above-site and site-level investments.

**Figure B.4.1** Framing Categories for Core STAR Process Activities

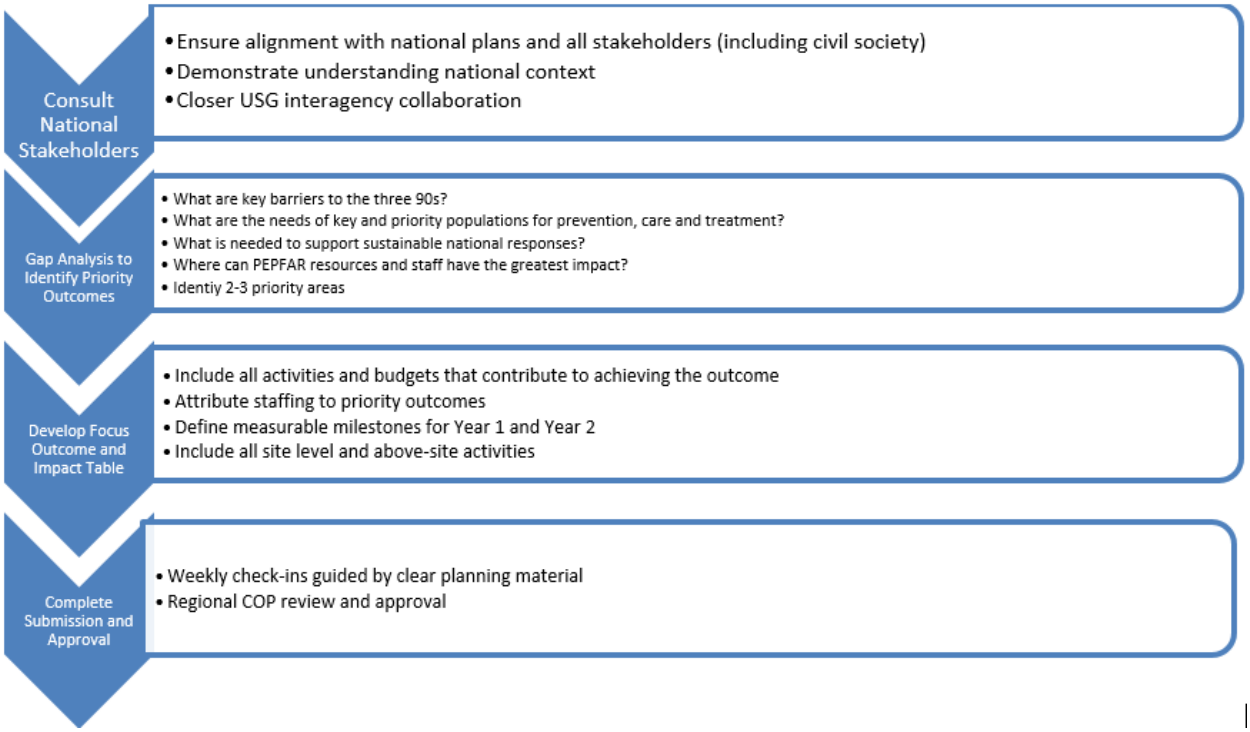
| |
|---|
| **Above-site activities:** Focused technical partnership with the national program to strengthen key systems to optimize quality, effectiveness and efficiency; build capacity for sustained epidemic control; use data to improve impact; and promote an enabling environment for effective programs. |
| **Site Level: Catalytic models and innovations designed for national impact.** Applying implementation science approaches for piloting new interventions with the understanding that host-country governments will scale them up if proven effective. Sharing findings with other country programs to extend impact. |
| **Site Level: Filling gaps in clinical cascade in under-served populations.** Support for facility and community service delivery for specific populations (e.g., key populations) that are underserved yet critical for sustained epidemic control. Note that the clinical cascade should include prevention activities (including testing and PrEP where indicated) |

All OUs following this process will be asked to follow the Core Steps described in the next section. Some steps will be very similar to COP16 and to the COP17 process for non-STAR OUs, while others will be significantly different. Each step is discussed in more detail, following the graphic. One key change for the STAR process is the completion of a Focused Outcome and Impact Table (FOIT) that will include all site-level and above-site investments as well as a summary of centrally funded activities. The FOIT Table is an outgrowth (and should build upon)

Table 6 from COP16, but has a different format and goal. Potential FOIT outcomes suggestions have been provided in your country-specific guarantee letter.

# Appendix B.5 Core Steps for STAR COP/ROP Process Submission

**Figure B.5.1:** Core Steps for STAR COP Process




## Appendix B.5.1 Core Steps Discussion

The approved COP16 proposal and program activities serve as the foundation for the COP17 proposal. The analysis should build on POART discussions, data previously shared during quarterly POART calls, any new epidemiological data, and country context. The STAR process is meant to further refine the strategic focus and alignment of PEPFAR resources to optimize impact and pilot new solutions.

Step 1: Consult National Stakeholders and analyze national and sub-national context to update the epidemiologic, policy, programmatic and funding landscape.

To determine how PEPFAR should optimally invest to maximize impact, PEPFAR teams must:

**Update understanding of national context**: Review demographic, epidemiologic, PEPFAR program data, and national/regional program data to the lowest sub-national unit (SNU) possible as well as age and sex disaggregated data. PEPFAR planning starts with a thorough understanding of the national (or regional) epidemiologic and programmatic context. This must include an understanding of prevalence (and estimated incidence) down to the lowest subnational unit (SNU available) and include data on key populations, including men who have sex with men (MSM), transgender persons (TG), sex workers (SWs), people who inject drugs (PWID), and prisoners. Where epidemiologic data suggest that other priority (or vulnerable) populations, including military, are important, these data should also be shared. National and SNU data on coverage are critical components of the cascade (prevention programming, testing, antiretroviral treatment (ART) and virologic suppression). Regional programs should include key epidemiologic and programmatic data (in a table format) for all countries (with data presented by country) in which PEPFAR is planning to invest COP/ROP17 resources.

- **Review and update how the national response is funded and implemented**, including Global Fund Principal Recipient(s) and host country government. PEPFAR teams should update the Program Investment Profile and review the COP 16 Sustainability Index and Dashboard (SID) and identify any updates occurring within the country context.

  PEPFAR teams should review and update COP16 activities regarding current status of a national strategic plan (and other key planning documents) and adoption and implementation of key policies (such as Test and START, PrEP, HIV self-testing), any HIV or HIV/TB Global Fund grants (and anticipated timeline) as well as key national fora or engagement with civil society organizations. Regional programs should document key data in a table format for all countries in which PEPFAR is planning to invest COP/ROP 17 resources. It is essential to consult with key stakeholders (including national governments, civil society, multilateral partners and other donors) during this step.

- As PEPFAR moves forward in its drive to be more efficient and transparent, PEPFAR country teams will continue to expand their collaboration with local civil society, including activists,

advocacy groups, and service delivery organizations, to ensure that they are actively engaged in PEPFAR processes and in the country-level HIV/AIDS response. To reiterate, the full participation of civil society should occur in every stage of our programming and planning, from their advocacy to service delivery which is critical to the success and sustainability of PEPFAR and the global effort to combat HIV. In addition, OUs participating in the STAR process are also required to promote human rights and structural barriers such as stigma and discrimination. These should be mitigated through planning specific programmatic activities. For further instructions on civil society and human rights requirements, please refer to Section 2.**Assess partner performance and results and program quality improvement:** PEPFAR teams should review each partner's performance through an analysis of any MER data, SIMS data, other performance data (e.g. achievement of benchmarks) and pipeline data. Corrective action steps that will be required to improve partner performance, or to seek alternate strategies, should be identified.

The results of this analysis should be described briefly in the SDS.

Step 2: Update Gap Analysis

In order to determine where current PEPFAR investments are optimally focused, the team is expected to engage in a structured discussion process to review the key questions listed below. As this is a critical planning process for a two-year strategy, all PEPFAR staff and USG agencies should plan to participate fully. Note that this should include consideration of existing investments or investments planned in COP16 as well as any pre-existing investments from prior years and the historic contributions of those investments.

- Are modifications needed to key barriers to the three 90s described in COP16?
- What is needed of key and priority populations for prevention, treatment, and care and are there any changes from COP16?
- What is needed to support a sustainable national response, and are there any changes from Table 6, COP16?
- Based on expected government contributions, how can PEPFAR staff and investments have the greatest impact?

Many programs have focused PEPFAR investments during COP15 and COP16. During COP17 development, PEPFAR teams should re-review epidemiologic data and

programmatic results, and determine whether existing geographic and population focus still makes sense or needs to be revised.

- Where can PEPFAR resources and staff have the greatest impact? PEPFAR teams should carefully review the Country- or Regional-specific guidance provided in their planning level letter, along with other specific guidance from headquarters. Based on knowledge of the country context (Step 1) and completion of the gap analysis (Step 2), PEPFAR teams should determine which areas are the highest priorities for PEPFAR investments from COP16. STAR programs should define 2-3 priority outcomes around which PEPFAR activities will focus.

Step 3: Identify Priority Outcomes and Propose Core Activities

• Include all activities and budgets that contribute to achieving the outcome

• Attribute USG staffing to priority outcomes

• Define measurable benchmarks for year 1 and year 2 for each activity

**Justification of site-level investments:** Please include all proposed site-level investments in the Focused Outcome and Impact Table (FOIT). In addition, for each site-level activity, please include a short narrative in the Strategic Direction Summary that describes: (1) the purpose of site level investment, (2) what the PEPFAR investments will cover at site level (e.g., staffing, equipment, commodities), and (3) how this site level investment will contribute to epidemic control.

**Scaling catalytic and innovative site-level activities:** One key goal of PEPFAR's investment in site-level activities is the identification of new innovations that should be taken to scale, often with government or other non-PEPFAR resources. Such activities often start out as small-scale pilots. Pilot activities are common in PEPFAR and piloting new interventions is a key component of STAR programs. However, some pilot activities have been implemented as just small stand-alone activities, without emphasizing or tracking factors that are critical to learning and scaling up for broader impact.

The STAR process should be used to maximize these activities as catalysts leading to national policy/practice change, adoption and implementation of best practices, and broader impact. Programs should determine which proposed activities are site-level

activities that are catalytic/innovative and discuss how they can be used for learning and scaled up (see below).

**Figure B.5.1.1: Process linking pilot activities to scaled-up impact**

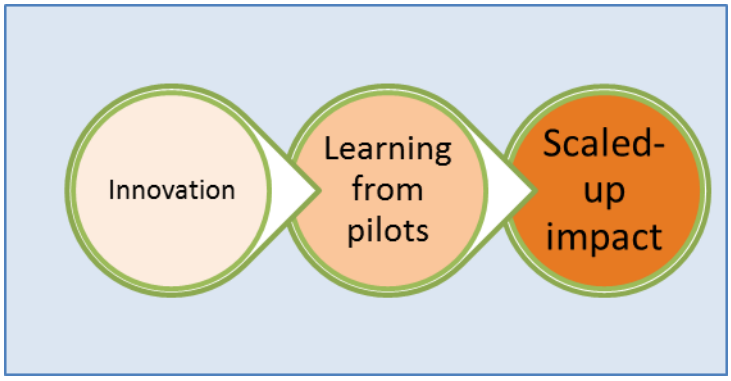
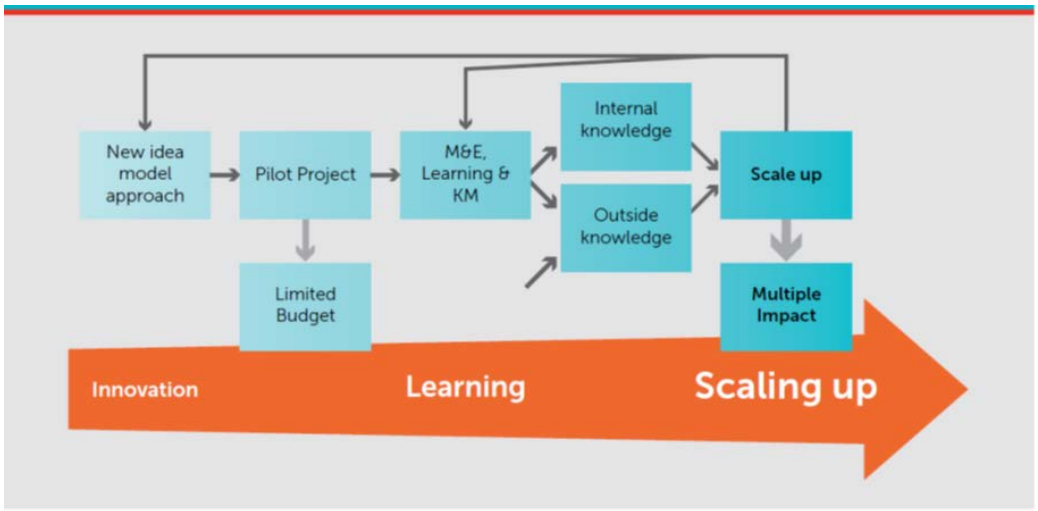



**Figure B.5.1.2**




Source: Linn

**Figure B.5.1.3: Development of a structured plan for site-level pilots:** PEPFAR programs in the STAR process who have site-level pilot activities should develop a structured plan for 1-2 of these pilots as follows:

**Core elements of a structured plan for pilots**

- Description: What are specific objectives of pilot activity and provide a brief description of activity itself
- What is stakeholder engagement plan?
- What capacity-building elements will be developed?
- What is pathway to scale? How will key enablers and barriers be addressed?
- Briefly describe learning plan and how pilot and scale up will be monitored and evaluated?
- If pilot is identified as a best practice and taken to scale, what would be expected impact following scale up?

**Possible elements to monitor and evaluate pilots**

- Impact:
  - effectiveness
  - cost
  - unanticipated results
- Documentation of:
  - implementation process
  - policy change/stakeholder support
  - capacity built
  - learning processes

**Completion of the FOIT:** STAR programs are required to submit a FOIT that reflects all PEPFAR funding proposed in COP17, including (1) above site activities (similar to Table 6 in COP16), (2) all site-level activities, and (3) any central funding that will be programmed during COP17. Each component is essential to achieving a full picture of proposed PEPFAR investments, including staffing.

**Identify up to three strategic objectives for PEPFAR support**: Key objectives were identified in each country/regional-specific guidance. Each strategic objective should contribute to a measurable impact on the epidemic through (1) a reduction in new HIV infections, (2) a reduction in morbidity or mortality, or (3) some other measurable impact. These 3 outcomes should form the basis for PEPFAR support and allow for an assessment of impact over time.

Please see Appendix B.7 for complete instructions for the FOIT table.

Step 4: Finalizing Submission

Please see Appendices D- I for further information on the COP elements and submission processes. Where the process is different for STAR process countries, this will be clearly noted.

**Weekly check-ins guided by clear planning milestones:** In order to maximize the period of COP preparation, the PEPFAR Headquarters team will arrange weekly check-in calls that are guided by clear planning milestones. These will be specific calls with each OU and the HQ team, and will be tailored to focus on specific issues that need to be resolved to support a successful COP review. OUs will not be expected to develop separate materials for these calls, but rather to engage in a discussion, and where relevant, to share drafts of materials that will be required for submission.

**Figure B.5.1.4: Milestones for Structured Check-Ins**

| Week | Goal | Deliverable |
|---|---|---|
| (1) January 23-27 | **In-Country Strategic Retreat**, including<br>(1) Consult national stakeholders:<br>• Demonstrate understanding of national context<br>• Ensure alignment with national plans and all stakeholders (including civil society)<br>• Closer USG interagency dialogue<br>(2) Perform structured gap analysis:<br>• What are key barriers to the three 90s?<br>• What are needs of key and priority populations for prevention, care and treatment?<br>• What is needed to support a sustainable national response?<br>• Where is PEPFAR best positioned to contribute? This should include an analysis of geographic focus and whether this should be reviewed (e.g. based on new data) This should include analysis of site-level activities as well as above site activities. This should also include a clear rationale for any site level work. | -Finalize planning calendar<br>- Develop Customized Data Slide Deck for Country Retreat<br>-Draft goal statement and Section 1.0 of SDS<br>-Validate 3 overarching strategic objectives<br>*Please note that retreat should include national stakeholders |
| (3) January 30-February 3 | Complete Focused Outcome and Impact Table (FOIT) | FOIT drafted |
| (4) February 6-10 | Finalize SDS narrative, targets, PBAC, and all required documents | Finalize SDS<br>Finalize Customized Data Slide Deck<br>Finalize FOIT<br>Finalize PBAC<br>Finalize SIMS Action Planner<br>Enter targets into DATIM and narratives into FACTSinfo |
| (4) February 13-16 | Finalize and upload all required documents and complete data entry into FACTSinfo and DATIM | All documents finalized |
| (5) February 16 | Submit COP | All required documents completed and uploaded |

**COP Review Process**

Regional COP review and approvals will be held on the following dates:

(1) **February 28-March 2 (Bangkok):** Asia Regional Program, Burma, Cambodia, Central Asia Regional Program, India, Indonesia, Papua New Guinea

(2) **March 13-15 (Washington, DC):** Angola, Caribbean Regional Program, Central America Regional Program, Dominican Republic, Ghana

## Appendix B.5.2 How will countries submitting via the STAR process be evaluated?

In order to recommend approval, the evaluation team, led by the S/GAC Chair, will explore the following seven questions:

1. Data - What was the underlying **data analysis** that was used to drive the COP decision making process?
2. Context - What critical **contextual** issues were taken into consideration in the development of the COP?
3. Strategy - Given the data and context, is the team's **overall approach** the most impactful use of resources? Does the approach align with national priorities?
4. Activity Descriptions - Are the individual **activities** the team is proposing well designed to achieve the program's goals?
5. Budget - Is the proposed **budget** the best use of financial resources to achieve the program's goals?
6. Targets - Will the proposed activity **targets and other measurable outcomes** result in a significant impact?
7. Program Management - Is the team organized to provide robust **monitoring and oversight** to ensure the program's success?

# Appendix B.6 Two Year Budget Review and Approval

At the FY 17 Quarter 4 POART, the field teams will have an opportunity to request minor modifications to their 2nd year budget, based on progress or other contextual changes in country. In addition, during this POART call, the Chair will review the progress. If there are no changes

requested from the field team, and achievements are on target, the field team will be able to immediately enter their COP18 data into the systems, and the chair will submit a memo to the Global AIDS Coordinator recommending approval of the 2nd year of funds. If the team does have minor changes, the Chair may incorporate these changes in the recommendation letter. In either case, there will be no need to attend any COP 18 planning or review meetings. The team is expected to continue implementation as planned.

However, if the team is significantly under- performing, or there have been major changes in the context in country, the team may be required to submit revised documents and may need to attend COP 18 planning and/or review meetings, depending upon the complexity of the changes required.

# Appendix B.7 Completion of the Focused Outcome and Impact Table

STAR programs are required to submit a FOIT that reflects all PEPFAR funding proposed in COP17, including (1) above site activities (similar to Table 6 in COP16), (2) all site-level activities, (3) Full-time technical staff and (4) any central funding that will be programmed during COP17. This table should cover the two-year period (e.g. FY18 and FY19). Each component is essential to achieving a full picture of proposed PEPFAR investments, including staffing.

Define up to three strategic outcomes for PEPFAR support

Key strategic outcomes were identified by OGAC within each country/regional-specific guidance document. Each outcome should contribute to a measurable impact on the epidemic through (1) a reduction in new HIV infections, (2) a reduction in morbidity or mortality, or (3) some other measurable impact. These 3 outcomes should form the basis for PEPFAR investments and allow for an assessment of impact over time.

## Appendix B.7.1 Completion of the FOIT Activity Tab

**Column A**: Describe all PEPFAR-funded activities (site level and above site) and group according to area of intervention.

**Column B:** Area of intervention - Proposed activities should be grouped in sections so that they can easily be reviewed together. Please see the drop down menu for category choices. If a

proposed activity does not fit into an existing category, please select other and specify this in the activity description.

**Column C**: Activity - Each proposed activity should be listed only once. Please include a brief description of the activity. This will be used to pre-populate other tabs in the spreadsheet. If an implementing mechanism contains both above site and site-level activities, these should be listed as two separate lines. Please estimate the budget attribution to the above site and site level components.

**Column D:** Activity code - Each activity line should have a unique code. All items under Strategic Objective 1 should start with 1.x. For example, the third activity under Objective 2 would be labeled 2.03.

**Column E**: Level - If an activity occurs both at site-level and above site, it may be listed twice; in column E, one line should indicate "site level", while the other line should indicate "above site".

**Columns F and G:** Specify the agency and prime partner for this activity.

**Columns H and I**: Include Implementing Mechanism information. Please list partner implementing mechanism ID number name, and the relevant agency. The table should include any TBD activities that are being proposed.

**Column J:** Direct technical support staff. In many countries, USG staff plays a critical role in providing direct technical assistance towards achieving PEPFAR results, such as serving as a seconded advisor to a national Ministry of Health. If a technical advisor supports a number of activities, please provide an activity description that best characterizes the nature of their work. Please note that this should not include staff time as an activity manager (COTR, Project Officer, etc.) for an implementing partner, but rather when a USG staff member is providing direct technical support for the implementation of a specific activity. Please list the Agency supporting this position. Please select “not applicable” for implementing mechanism information.

**Columns K and L**: Identify one- and two-year benchmarks for each activity. For each activity, PEPFAR teams must identify Year 1 and Year 2 benchmarks that will be used to determine whether a specific activity is on track or off track. These benchmarks may include deliverables (such as completion of a policy document). These benchmarks should be measured by PEPFAR indicators if they involve site-level activities. They can also be measured by other indicators where appropriate (columns O and P). Please note that all activities should have benchmarks,

though not all will have PEPFAR or other indicators. Please see additional guidance which includes examples of well-crafted benchmarks (add link).

**Column M:** Transition plan - For each activity, please describe whether the activity is (1) one-time, (2) continuing, or (3) whether the activity will be replaced by another activity. Please see illustrative examples in the draft FOIT table.

**Columns N, O, and P**: For activities that can be monitored by PEPFAR indicators, please include relevant indicators. Actual targets for activities should be entered into DATIM. If a proposed activity can be measured by other indicators (instead of or in addition to PEPFAR indicators), please select the category in drop down menu (Column O). Choices include a national indicator (generally defined at the global level or in a national strategic plan), a SIMS indicator (to assess quality of services provided), or a program indicator (which is typically defined in a grant agreement with an implementing partner and may be more specific that what is captured through PEPFAR indicators. If an activity (such as an above site activity) is best measured only by benchmarks, e.g. completion of a one-time evaluation or policy document, these columns related to additional indicators can be left blank.

## Appendix B.7.2 Completion of the FOIT Budget Tab

After entering the activities, the activities will populate the budget tab. Set the 2-year COP budget amount (column G). Enter a proportion of the 2-yr COP budget that is for the first year (COP17) (column H); the YR1 COP total budget will be calculated (column I).

For each activity & mechanism combination (row) with COP17 planned funding, please indicate the applicable budget code(s) and the proportion of the YR1 COP budget to allocate to that budget code. You may allocate up to 5 budget codes for each row. If one row needs more than 5 budget codes, you would need to split the activity on the FOIT table into 2 x rows.

**Column T** checks that you have allocated 100% of the COP17 funding; if it is red and you had planned funding for COP17, please check that your % allocations add to 100% (note that rounding errors may lead to what looks to be 100% to show red if it is 100.31%, etc).

Once your budget table has been completed, please check the PBAC output tab. No data entry is necessary on this page. This tab has been formatted in the same order as the input tab within PBAC, so you would be able to select, copy & paste your data into the PBAC tab. When copying and pasting into PBAC, please paste the number values rather than the formulas.

## Appendix B.7.3 Completion of the FOIT Central Funding Tab

All programs completing the FOIT should complete the Central Funding tab and include any current funding or current activities supported with central funding. These should be grouped according to strategic outcome and provide the information in the requested tabs.

**Column G and H**: Please provide the date which this activity started and the expected completion date.

**Column I:** If centrally funded activities are linked to a COP activity, please provide a brief description and activity code (column D on the FOIT tab).

# APPENDIX C: TECHNICAL CONSIDERATIONS

# Appendix C.1 Executive Summary

PEPFAR has made substantial progress toward the 90-90-90 targets, and there is clear evidence that high investment countries with major epidemics are beginning to control the epidemic; however, much remains to be done to achieve or sustain control. Recent gains need to be consolidated by focusing on the right populations and the most impactful, evidence-based interventions. In addition to ongoing work in geographic areas of high prevalence and incidence and in key and priority populations, the COP17 Technical Considerations emphasize the following four key areas to alleviate bottlenecks across the spectrum of care:

1. **Continuing to focus prevention and treatment on adolescents and young adults under 30 years old in Sub-Saharan Africa**. Prevention activities should be evidence-based, such as pre-exposure prophylaxis (PrEP) for those at high risk of HIV acquisition, condom distribution, voluntary male medical circumcision (VMMC) for HIV-negative young men, and HIV treatment for all adolescents and young adults identified as HIV-positive. Special attention should be paid to pregnant and breastfeeding adolescents, sex workers and adolescents engaged in transactional sex, adolescents living on the street, married adolescent girls, men who have sex with men (MSM), transgender persons, orphans and vulnerable children (OVC), and 18-29 year old active duty military personnel.
2. **Implementing a strategic mix of HIV testing modalities to improve testing coverage (especially among young men and women), yield, and efficiency of HIV testing services**. HIV testing is the gateway to accessing critical prevention and treatment services. The challenges inherent in this service delivery differ greatly by country, and require detailed knowledge of the epidemic and who remains undiagnosed. Strategies to optimize case-finding, such as the determination and testing of sexual networks, and to ensure high quality testing services, including self-testing, are essential.
3. **Retaining clients on antiretroviral treatment (ART) and care to achieve viral suppression.** Retention on treatment and virologic suppression are critical to reducing HIV-related morbidity and mortality and preventing transmission. Strategies that improve adherence to treatment, prevent TB and other life-threatening diseases, and enhance access to viral load testing are needed to attain retention and viral suppression targets. Innovative service delivery models should focus on populations that have difficulty with retention, such as children, young adults and men, pregnant women, and key populations.

4. **Ensuring access to quality, sustainable HIV delivery systems**. From advocacy to delivering services, those affected by HIV play an important role in responding to the epidemic in ways the public sector cannot. Stigma, discrimination, and violence as well as harmful laws and policies reduce access to and use of essential health services and undermine efforts towards effective responses to HIV/AIDS. Community empowerment needs to be integrated into all aspects of health and HIV programming. As the number of people on treatment increases, programs need to sustainably expand capacity, utilizing strategies such as community-based lay workers, prioritization and task-shifting, provider networks, and stable patient delivery systems; retention of human resource should be a key objective for programs.

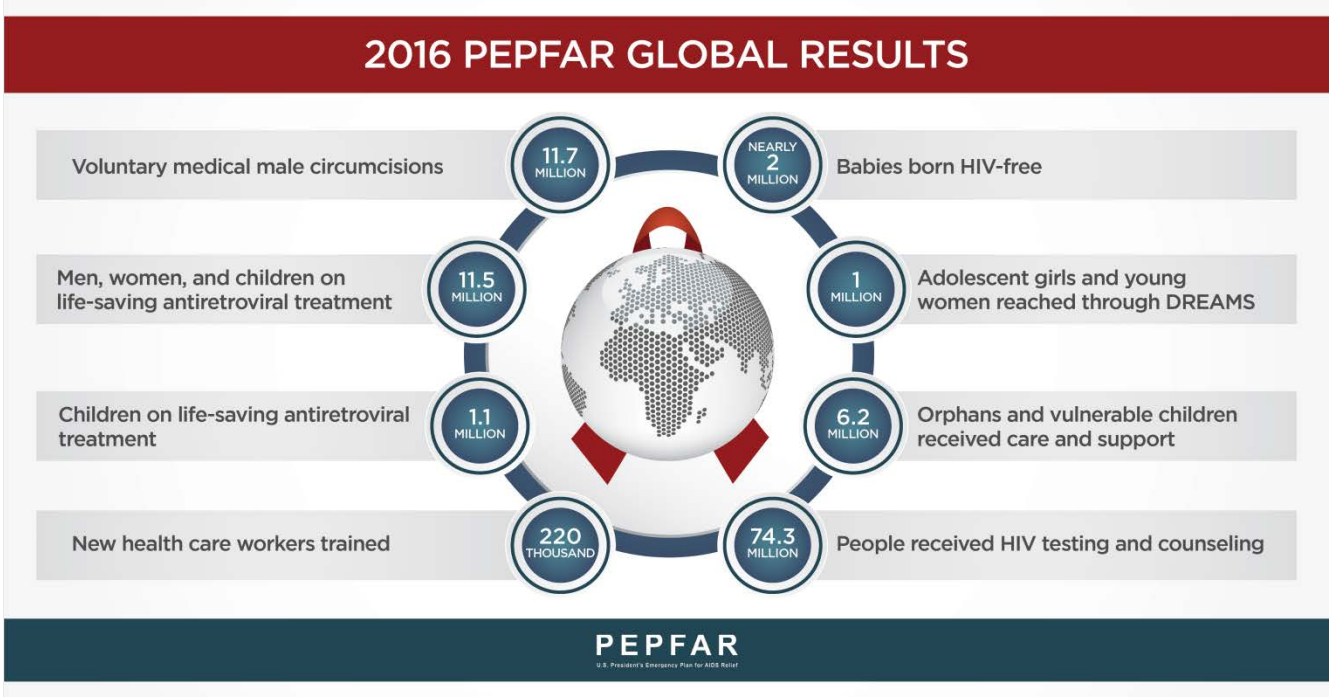
LATE BREAKER: In January 2017, S/GAC hosted a one-day, technical consultation with the principal investigators of three, multi-million dollar combination prevention trials that together seek to test the impact of packages of interventions to avert new HIV infections in Sub-Saharan Africa. The goal of the meeting was to facilitate the rapid transfer of lessons learned that address high priority, implementation challenges to accelerating epidemic control in countries supported by PEPFAR especially HIV case finding in men and men and women under 30 years old. A summary of the meeting is included in Appendix C.10. The meeting highlighted research-informed strategies to close gaps in the HIV prevention - treatment continuum, including HIV testing, linkage to HIV medical care and rapid initiation of antiretroviral treatment (ART), retention and re-engagement in medical care, and achievement of virologic suppression. A final segment highlighted opportunities for establishing effective models of integrated, health services.

# Appendix C.2 Introduction

PEPFAR, in collaboration with host governments, communities, multilateral organizations, and other global organizations, has made substantial achievements in combatting the global HIV/AIDS epidemic. Recent evidence from the Population-Based HIV Impact Assessment (PHIA) surveys show that certain countries with major epidemics have made substantial progress in controlling the epidemic. As announced on World AIDS Day 2016 PEPFAR is supporting 11.5 million men, women and children to access life-saving antiretroviral treatment (ART), completed 11.7 million voluntary medical male circumcisions (VMMC), performed 74.3 million HIV tests in FY 2016, and provided services to 6.2 million orphans and vulnerable children (OVC) and their caregivers as of September 30, 2016 (Figure C.2.1). Bold targets have also been set for

PEPFAR's future achievements, including goals of supporting 12.9 million people on treatment, 13 million VMMCs, and reducing HIV incidence in adolescent girls and young women (AGYW) by 40 percent by the end of fiscal year 2017.

**Figure C.2.1**



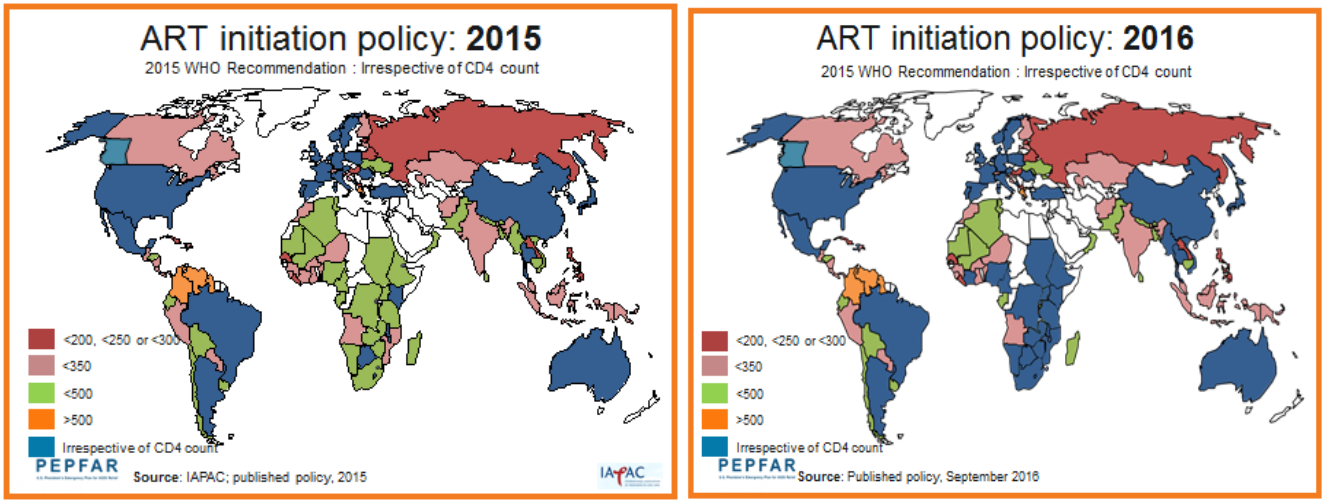

As we continue to work towards the 90-90-90 goals set out by UNAIDS in 2014, PEPFAR programs must continue to dive deep into programmatic and epidemiologic data to identify country, regional, and site-level successes and challenges to ensure every dollar is optimally invested. This will reveal areas for improvement and programmatic course correction. For example, global data from 2015 reveal that HIV testing results are highest for persons with tuberculosis (TB) and sexually transmitted infections (STI) and in inpatient wards. However, these sources will not identify large numbers of untreated persons living with HIV. Broader testing is needed for those under age 30 who are at highest risk for undiagnosed HIV infection and will require new strategies. Analyzing this data at a site level is important to determine and overcome current barriers in identifying HIV infected persons and increasing testing yield and volume. Furthermore, prevention, testing, treatment, and retention strategies must be assessed for their effectiveness and appropriateness for specific age, gender, and risk groups in order to have the most impact. As well, a core premise of PEPFAR is the inherent emphasis on respect for human rights in programming, and the engagement of those most impacted by HIV/AIDS

(e.g. PLHIV and members of key population communities) in the planning, implementation and analysis of PEPFAR programs.

In working towards these goals, it is critical that PEPFAR provide support to national and local governments and local institutions in a manner that builds a sustainable national HIV response. PEPFAR country teams must work with governments on national policies such as Test and START (Figure C.2.2), differentiated service delivery models, programs integrated with human rights advocacy, and policies affecting stigma, discrimination, violence, and access to HIV services for key populations (KPs). Shared partnerships—financial and programmatic—are essential in establishing and sustaining epidemic control and responding to new and future challenges. Country Operational Plans for 2017 (COP17) must include direct and meaningful dialogue with implementing partners and other key stakeholders, commitments from governments, and support from civil society.

The role of the Ambassadors and Deputy Chiefs of Mission have been critical in moving the key policy agenda forward, resulting in a much more effective program. In 2016, country teams were able to work in partnership to ensure treatment starts before the immune system is substantially damaged and transmission can be interrupted. Similar emphasis must be placed on policies to ensure access to services for 15-24 year olds, key populations, and service delivery that is more cost effective and client-friendly.

**Figure C.2.2**




In order to reach PEPFAR's goals and accelerate impact to achieve the 90-90-90 targets, it is essential that COP17 continues the focus on epidemic control begun in COP15 by focusing on

comprehensive implementation of evidence-based interventions. Collectively PEPFAR has been successful at focusing geographically; this COP17 we need to focus in the same detail on populations by risk, gender, and age to ensure we are focused for maximal impact. Of equal importance is the continuation of respect for human rights, emphasizing the need to engage, reach and serve all individuals, especially those at highest risk for HIV. Teams should continue their ongoing work in geographic areas of high prevalence and incidence and in key and priority populations. In addition, the COP17 Technical Considerations emphasize four key areas of impact that all country and regional teams should focus on during their planning:

- Continuing to shift prevention to focus on adolescents and young adults under 30 years old in Sub-Saharan Africa, utilizing all budget codes and partners;
- Implementing a strategic mix of HIV testing modalities to improve testing coverage (especially among young men and women), yield, and efficiency of HIV testing services;
- Retaining clients on antiretroviral treatment (ART) and care to achieve viral suppression; and
- Ensuring access to quality, sustainable HIV delivery systems.

Each section of the Technical Considerations will provide a brief background on the importance of the focus area, highlight the key interventions country teams should implement, and provide country examples and best practices. The appendices at the end of this document will provide references to relevant guidance documents, further country examples, and contact information.

# Appendix C.3 Section One: Preventing and Treating New Infections among Adolescents and Young Adults <30 Years Old

## Appendix C.3.1 Background

Continuing high fertility along with the successes of the Millennium Development Goals (MDGs), achievements in prevention of mother-to-child HIV transmission (PMTCT), and of child survival programs, have contributed to demographic shifts in sub-Saharan African, resulting in twice as many 15 to 24 year olds over the next decade than at the start of the AIDS epidemic (Figure C.3.1.1). This younger population is less likely to know their HIV status, and, have lower basic HIV knowledge levels, while remaining at high risk for HIV infection. Recent data from PEPFAR's

Population-based HIV Impact Assessments (PHIAs) in Malawi, Zambia, and Zimbabwe have shown the success of meeting the 90-90-90 goals in decreasing HIV incidence in the adult population by 76%, 51%, and 67% respectively (Figure 3.1.3)[14]. Unfortunately, these successes are not shown in PHIA data from 15-24 year olds where only 40-50% of individuals surveyed knew their HIV status, leading to lower rates of adolescents and young adults on treatment and being virally suppressed (Figure C.3.1.2). To control the epidemic and reach the 90-90-90 goals for all age groups, it is essential that PEPFAR country programs evolve to focus prevention, testing, and treatment services on individuals less than 30 years old while balancing continued achievement in adults over 30. This recommendation is aligned with the *Start Free, Stay Free, AIDS Free* targets, which are essential to ending the AIDS epidemic among children, adolescents and young women by 2020[15].

**Figure C.3.1.1**

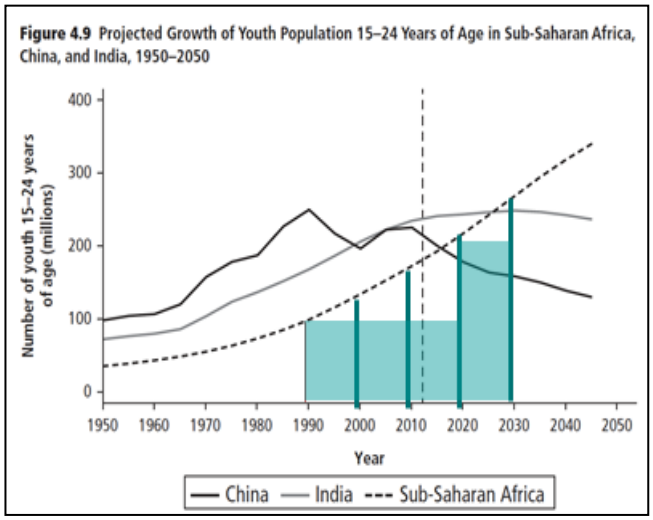
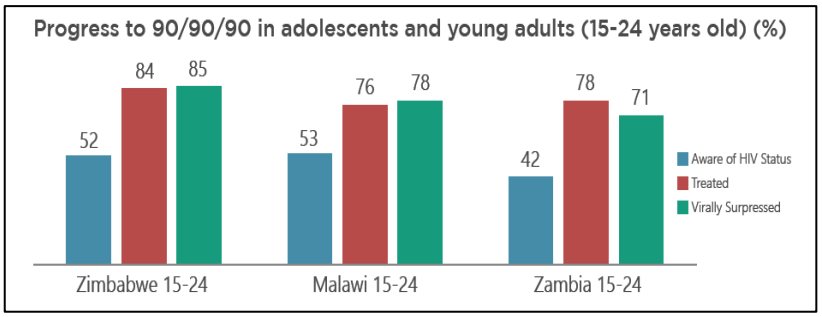


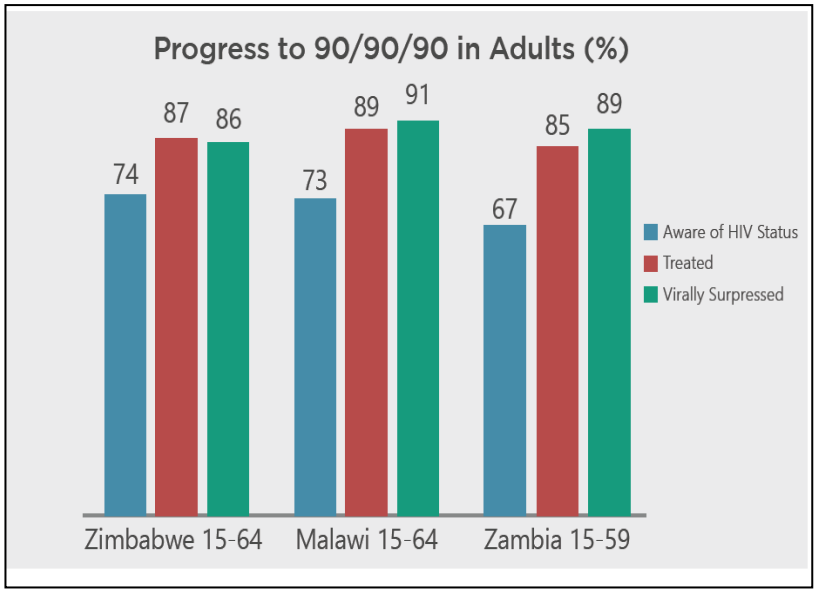

**Figure C.3.1.2**




[14] http://phia.icap.columbia.edu/

[15] http://www.unaids.org/en/resources/documents/2016/20160926_startfree_vision

**Figure C.3.1.3**




Among youth under 25 years of age, adolescent girls and young women (AGYW) in southern and eastern Africa carry the highest burden of HIV/AIDS and are more than twice as likely as their male counterparts to be newly infected with HIV[16]. Every year, 390,000 AGYW are infected with HIV, and in sub-Saharan Africa, girls account for 75% of new annual HIV infections among adolescents[17]. Young men who have sex with men (MSM) are also at high risk of infection and often also have sex with women, putting them at risk as well. Even less is known about young transgender women, however, data indicate increased risk as well.

In much of sub-Saharan Africa, the path of HIV transmission is through young women. AGYW often acquire HIV from men ages 23-35, with AGYW often remaining unaware of their HIV-positive status for years. These adolescents and young girls then transmit the virus to their similar-aged sexual partners as they grow older. These infected young men, in turn, reach their mid-to-late 20s and frequently begin the cycle again (Figure C.3.1.4). To disrupt this pattern of HIV infection, PEPFAR teams must reach sexual partners of AGYW with HIV testing, prevention and treatment services, as appropriate.

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[16] http://www.unaids.org/en/resources/presscentre/featurestories/2016/june/20160610_panel5

[17] http://www.unaids.org/en/resources/documents/2016/prevention-gap

**Figure C.3.1.4**

Adapted from: Dellar R, Tanser F, Abdool Karim Q, et al. Manuscript in preparation. / Abdool Karim Q. *HIV infection in young women in Africa: An overview.* Presentation at AIDS 2016. *http://programme.aids2016.org/Programme/Session/1257.*

## Appendix C.3.2 Priority Strategies & Interventions for COP17

In COP17, generalized epidemic countries should increase focus on country-specific data and ensuring a balanced portfolio that emphasizes HIV prevention and treatment of adolescents and young adults, both men and women, under the age of 30 in scale-up districts, where the HIV burden is the greatest. Country teams should continuously analyze their epidemic and program data, including incidence and prevalence, to ensure the needs of individuals less than 30 are met while also ensuring that achievements made in adults over 30 are not lost. These activities should include a combination of evidence-based prevention interventions including behavioral and structural interventions, pre-exposure prophylaxis (PrEP) for those at high risk of HIV acquisition, HIV testing services (HTS), VMMC for HIV-negative young men, and HIV treatment

for all adolescents and young adults identified as HIV-positive. Special attention should be paid to particularly vulnerable sub-groups of adolescents including HIV-uninfected and HIV-infected pregnant and breastfeeding adolescents, sex workers and adolescents engaged in transactional sex, those living on the streets, married adolescent girls, MSM, transgender persons, OVC, and 18-24 year old active duty military.

**Prevention in Adolescent Girls & Young Women**

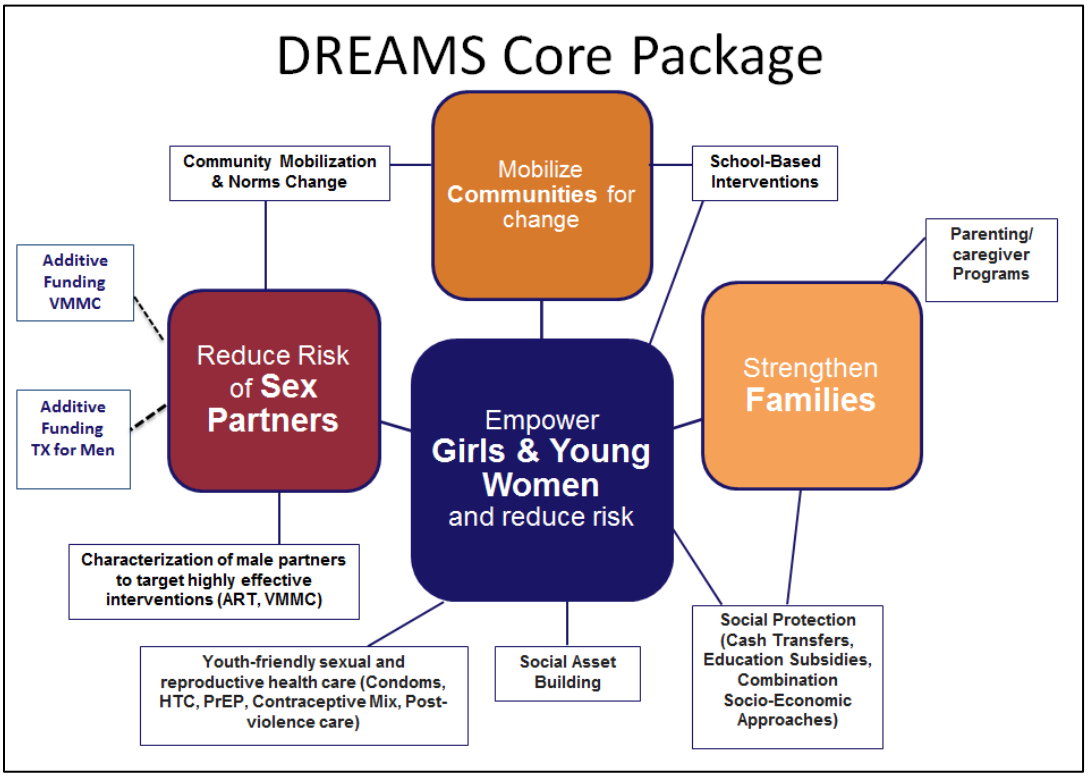
The Determined, Resilient, AIDS-Free, Mentored, and Safe (DREAMS) Partnership focuses on the reduction of HIV incidence in AGYW by delivering a core package of interventions that combines evidence-based approaches to address the individual, community, and structural factors that directly and indirectly increase girls' HIV risk, including poverty, gender inequality, gender-based violence, and a lack of education (Figure C.3.2.1). In COP17 and moving forward, DREAMS activities will be funded and managed through the COP process instead of centrally. OVC partners should fully engage in DREAMS-like activities for young women younger than 18 years. In COP17, countries currently implementing DREAMS should assess the progress of each component of the core package and determine if any course correction or redirection of resources to other components or other partners should be made to maximize impact. For example, if a country is having difficulty getting traction with community mobilization activities, resources could be redirected to an intervention that is more directly and immediately linked to reducing HIV acquisition such as PrEP and condoms. One exception to making changes to the investments in the DREAMS core package components is that resources should not be moved from an activity that has the potential for a direct impact on HIV (e.g. PrEP, condoms) to an activity that would have a more distal effect.

In COP: 17 countries should consider broadening geographic coverage beyond the original DREAMS SNUs to all prioritized SNUs using DREAMS and OVC funds to maximize AGYW-focused prevention activities. Selection of DREAMS activities for geographic expansion and any course correction within the current DREAMS program should be made by each country team in consultation with their DREAMS technical assistance (TA) and Monitoring and Evaluation (M&E) leads from headquarters. Factors such as potential for impact, cost, and acceptability should be considered when making decisions regarding shifting resources and/or expanding DREAMS activities. Countries should strive to ensure that the DREAMS package will have maximal impact and address the needs expressed by the beneficiary population. When conducting DREAMS

programming, teams should ensure the program is using a systematic method to identify vulnerable girls.

Countries not implementing DREAMS should examine HIV incidence and prevalence in AGYW ages 10-24 to ensure they are dedicating resources to prevention in high risk populations, especially in geographic areas with the highest HIV prevalence. Interventions that should be prioritized for this population include education subsidies, post-violence care, effective youth-friendly sexual and reproductive health services, characterizing male sex partners and linking them to prevention and treatment services as appropriate, and PrEP. Sites providing post violence care must provide the minimum package of services including post exposure prophylaxis and emergency contraception (see MER indicator). These interventions will not only impact HIV incidence in adolescents and young adults, but will address intermediate outcomes such as poverty, early pregnancy, child marriage, rape, violence, and educational attainment. Layering of multiple interventions that are tailored to the needs of the highest-risk AGYW is critical to maximize impact and ensure that the interventions reach vulnerable AGYW, their families, and their communities. PEPFAR funded programs should prioritize the engagement of AGYW in planning, implementing, monitoring, and evaluating the activities targeting these girls/young women to ensure their needs, perspectives, and experiences are appropriately addressed. For more information, examples, and resources detailing the evidence-based interventions described above, please refer to the full DREAMS guidance on pepfar.net.

**Figure C.3.2.1**




OVC platforms in particular should be leveraged to enable girls and adolescents, aged 10-17, to access a comprehensive package of prevention and treatment services. OVC focus should be directed to accelerating achievement of OVC_SERV targets among 10-17 year olds, especially where younger age bands (0-9) have been met or exceeded. In addition, the antenatal care (ANC) platform should be leveraged to provide enhanced prevention interventions and link at risk HIV-uninfected AGYW to available services. Finally, countries should leverage HIV testing, VMMC, and treatment platforms to ensure the right men are reached with appropriate HIV services to help break the cycle of transmission to their sex partners and ensure that all genders can thrive.

**Condoms and Lubricants**

When used correctly and consistently, male condoms are estimated to be 90% effective in reducing HIV transmission[18] and female condoms are 94% effective[19]. Condom programming is estimated to have averted up to 45 million new HIV infections[20]. In COP17, condom programming should focus on accessibility to adolescents and young adults under 25 years old, males aged 25-35 with younger partners, and key populations. All PEPFAR OUs are eligible for central funding for the procurement of male and female condoms and lubricant products in support of HIV programming. In COP17, condoms and lubricants will be procured through USAID's supply chain project and do not have to be budgeted in COP[21]. COP budgets should include distribution and programming support to make condoms available, accessible, and attractive to young people and other people at risk.

**Pre-Exposure Prophylaxis (PrEP)**

The use of tenofovir-based ART has been shown to reduce the risk of HIV acquisition by over 70% when taken consistently by heterosexual men and women, MSM, and people who inject drugs (PWID)[22]. World Health Organization (WHO) Guidelines recommend offering PrEP to those at substantial risk of infection, defined by population groups with HIV incidence at or above 3%[23]. In many settings, the uninfected partner in discordant couples, MSM, transgender persons, sex workers, military (in parts of southern Africa), and PWID will have risks above this threshold. In high prevalence settings, AGYW, including pregnant and breastfeeding women, may also have a risk of HIV acquisition above this level. Risk scoring systems have been developed to

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[18] Weller S., Davis K. Condom Effectiveness in Reducing Heterosexual HIV Transmission. Cochrane Database Systemic Review. 2002;(1).

[19] Trussel J., Sturgen K., Strickler J.,Dominick R. Comparative Contraceptive Efficacy of the Female Condom and Other Barrier Methods. Family Planning Perspectives. 1994;26(2):66-72.

[20] http://www.unaids.org/en/resources/presscentre/featurestories/2016/october/20161003_condoms

[21] https://www.pepfarii.net/OGAC-HQ/OGAC/CS/Shared%20Documents/Forms/AllItems.aspx?RootFolder=%2FOGAC%2DHQ%2FOGAC%2FCS%2FShared%20Documents%2FCOP17%20Technical%20Considerations&FolderCTID=0x0120001801439AC67EB64EA6DCD48CA6B3C92D00EF59E3C3FB6B364B99C9405D3EF08C55&View={2640B296-3106-45A1-98F9-84A64C1097CF}&InitialTabId=Ribbon%2EDocument&VisibilityContext=WSSTabPersistence

[22] http://www.who.int/hiv/pub/guidelines/keypopulations-2016/en/

[23] http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/

identify those at highest risk and can be incorporated into clinical settings[24]. PEPFAR teams should consider making PrEP available during comprehensive health services and health education as well as in a range of settings, including mobile and drop-in centers targeting key populations, family planning clinics, maternal child health clinics, and primary care settings based on expected incidence in the groups served. A recent comprehensive review has confirmed a lack of significant effects on fertility, pregnancy outcomes, and infant growth with use of tenofovir-regimens in pregnant and breastfeeding women. Use of COP funds to procure ARVs for PrEP is permitted in countries where Test and START policies have been initiated, viral load testing policies call for testing at least annually, and multi-month ARV provision is available for stable clients.

**Voluntary Medical Male Circumcision (VMMC)**

VMMC reduces the risk of heterosexual HIV acquisition for men by at least 60 percent and helps to break the cycle of transmission to future sexual partners as the preventive effect remains strong throughout aging. To have the most impact, VMMC programs should be implemented in scale-up districts with a high HIV burden and low coverage of male circumcision services in the fourteen priority countries (Botswana, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe).

In COP17, programs should continue to prioritize clients aged 15–29 years, especially those at high risk such as STI clients and partners in serodiscordant couples, for immediate impact. As prioritized areas approach saturation in this population group (e.g., 80% or more among males 15-29 years in select geographic areas are circumcised), programs are urged to extend the prevention benefit to adolescent boys 10–14 years of age and to begin policy discussions with governments about neonatal circumcision. Teams must also ensure that PEPFAR-supported VMMC programs include the WHO-recommended minimum package of accompanying services, including the offer of HIV testing, risk reduction counseling, condoms, and STI screening and

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[24] Balkus JE, et al. An empiric risk scoring tool to predict HIV-1 acquisition in African women. J Acquir Immun Defic Syndr 2016;72:333-43.

[9] Irungu E et al. Use of a risk scoring tool to identify higher risk HIV-1 serodiscordant couples for an antiretroviral-based HIV-1 prevention intervention. BMC Infect Dis 2016;16;571-6.

[10] Mofenson LM. Tenofovir Disoproxil Fumarate Safety for Women and their Infants during Pregnancy and Breastfeeding: Systematic Review. AIDS 2016;Nov 7 epub ahead of print.

treatment or referral. HIV testing services should be offered only on request, and not routinely, to boys and adolescents who have not yet had sexual debut, given low rates of HIV infection in these populations. In addition, WHO recommendations on tetanus immunization and the clean care approach for all circumcisions must be followed[25] [26].

**Testing & Treatment**

To make a more immediate impact on HIV acquisition and transmission among adolescents and young adults under 30 in generalized epidemic countries, PEPFAR country teams must ensure that all implementing partners offer HIV testing services either directly or through referral and then link individuals to services based on their serostatus. HIV-negative individuals should be linked to prevention services (e.g. VMMC, condoms, PrEP if indicated), while HIV-positive individuals should be linked immediately to ART initiation and treatment services.

Since HIV testing is a key element in HIV prevention activities, including PrEP implementation among young people, increased testing in this age group is expected to be associated with lower yields than in older age groups. It is especially important to target young men ages 15-35 in settings such as sexually transmitted disease clinics as they are a key part of the HIV transmission cycle as described in Figure C.3.1.4. Greater engagement of men in prevention and treatment services is indicated as they have higher rates of undiagnosed HIV infection, are more likely to seek treatment at a later stage of disease, and experience more HIV-related morbidity and mortality than women due to late presentation. Young men in military service are also especially important to target because of these same shared risk factors. Each country should use their demographic and surveillance data to understand as much as possible about HIV transmission dynamics for at-risk AGYW and their sexual partners in order to ensure that the right men are being appropriately targeted for HIV testing, treatment, and prevention to have the most impact. Additionally, ANC services provide a window of opportunity to identify HIV-uninfected AGYW who are sexually active and who should be prioritized for HIV prevention interventions as well as HIV-positive AGYW for whom rapid ART initiation can prevent HIV transmission to their infants and their partners.

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[25] http://www.who.int/hiv/pub/malecircumcision/tetanus-vmmc-report/en/

[26] 16 STATE 127820

## Appendix C.3.3 Country Examples of Priority Interventions

For a full list of country examples, please refer to the "Case Examples of Best Practices for PEPFAR Programs" document located in Appendix J.

### Combination Social Protection for Reducing HIV-Risk Behavior among Adolescents in South Africa[27]

Social protection (e.g. cash transfers, free schools, parental support) has potential for adolescent HIV prevention. In this study, child-focused grants, free schooling, school feeding, teacher support, and parental monitoring were independently associated with reduced HIV-risk behavior incidence (odds ratio: 0.10– 0.69). Strong effects of combination social protection were shown, with cumulative reductions in HIV-risk behaviors. For example, girls' past-year incidence of economically driven sex dropped from 11% with no interventions to 2% among those with a child grant, free school, and good parental monitoring. Similarly, girls' incidence of unprotected/casual sex or multiple partners dropped from 15% with no interventions to 10% with either parental monitoring or school feeding, and to 7% with both interventions. These findings show that specific social protection interventions in three domains, cash, psychosocial support, and education, independently reduce specific HIV-risk behaviors among adolescent boys and girls. Second, findings demonstrate that combination social protection interventions can have strong effects on HIV-risk behavior reduction, independently of sociodemographic cofactors and baseline HIV-risk.

### Determining HIV Risk for Pre-exposure Prophylaxis (PrEP)[28,29]

In many settings, AGYW are at increased risk of HIV acquisition, but determining which AGYW are at significant risk and would benefit from PrEP can be difficult. Investigators combined data on more than 9,400 women from three prevention studies conducted in Southern and Eastern Africa to identify risk factors for HIV acquisition. The scoring system included categories of risk based on age (<25 versus 25+), marriage/cohabitation, alcohol use, partner providing material

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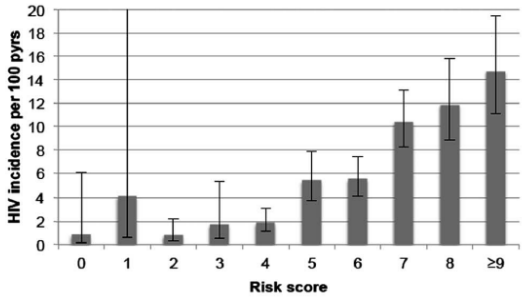
[27] http://www.socialserviceworkforce.org/system/files/resource/files/Combination_Social_Protection.pdf

[28] Balkus JE, et al. An empiric risk scoring tool to predict HIV-1 acquisition in African women. J Acquir Immun Defic Syndr 2016;72:333-43

[29] Pintye J, et al. A risk assessment tool for identifying pregnant and postpartum women who may benefit from pre-exposure prophylaxis (PrEP). Clin Infect Dis In press

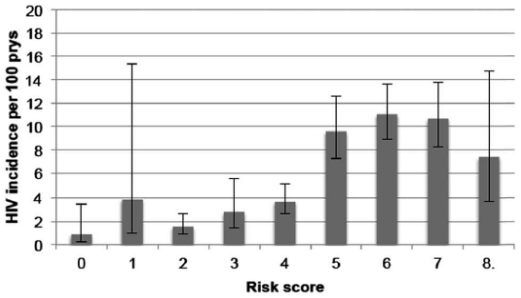
support, partner having other known partners, curable STI, and HSV2 seropositive or negative. The risks associated with increasing scores are illustrated in figure C.3.3.1. A similar risk assessment was performed in a cohort of pregnant women in Kenya and found that unknown partner HIV status, more than one lifetime partner, and having syphilis all conferred increased risk of HIV acquisition during pregnancy.

**Figure C.3.3.1**




| Risk score | # of HIV infections | Total # of women | HIV incidence 95% CI |
|---|---|---|---|
| 0 | 1 | 125 | 0.85 (0.12, 6.05) |
| 1 | 1 | 27 | 4.14 (0.58, 29.40) |
| 2 | 4 | 532 | 0.81 (0.30, 2.15) |
| 3 | 3 | 196 | 1.72 (0.55, 5.32) |
| 4 | 15 | 879 | 1.85 (1.11, 3.08) |
| 5 | 27 | 548 | 5.41 (3.71, 7.89) |
| 6 | 45 | 911 | 5.53 (4.13, 7.41) |
| 7 | 72 | 787 | 10.39 (8.25, 13.09) |
| 8 | 46 | 443 | 11.85 (8.88, 15.82) |
| ≥9 | 49 | 386 | 14.72 (11.12, 19.47) |

A




| Risk score | # of HIV infections | Total # of women | HIV incidence 95% CI |
|---|---|---|---|
| 0 | 2 | 248 | 0.86 (0.22, 3.44) |
| 1 | 2 | 57 | 3.84 (0.96, 15.37) |
| 2 | 13 | 928 | 1.52 (0.88, 2.62) |
| 3 | 8 | 316 | 2.78 (1.39, 5.55) |
| 4 | 35 | 1,056 | 3.66 (2.63, 5.10) |
| 5 | 51 | 603 | 9.58 (7.28, 12.61) |
| 6 | 86 | 889 | 11.04 (8.93, 13.64) |
| 7 | 58 | 611 | 10.67 (8.25, 13.81) |
| 8 | 8 | 126 | 7.39 (3.69, 14.77) |

B

1. HIV incidence and 95% CIs by risk score using the full risk score (A) and modified risk score that excludes variables for any curable STI at baseline and HSV-2 serostatus (B).

## Mobile SRH and HIV service delivery to reach AGYW and Men in Swaziland

Population Services International (PSI) in Swaziland is using vans branded for AGYW and men to provide comprehensive sexual and reproductive health (SRH) and HIV services in 17 Tinkhundla (districts). The state-of-the-art vans are visually appealing, staffed by young providers, and were branded in consultation with the targeted populations. “DREAMS on Wheels” provides comprehensive services for AGYW, including: HIV testing and counseling; access to a range of contraceptives with an emphasis on dual protection; condom promotion and distribution; syndromic screening and treatment of STIs; TB screening; and emergency contraception. The van that serves men (“Esangweni”) provides HIV testing within a broader package of men’s sexual health and wellness services to avoid stigmatizing men who access services. Anecdotal reports suggest the van serving males attracts many first-time testers and that roughly 10% of clients test HIV-positive.

Since this project began in June 2016, the DREAMS on Wheels vans have reached 2,755 girls with services. Between Q1 and Q4 of FY16, the number of HIV tests offered to AGYW ages 10-24 increased by 4,908 and by 3,529 for boys and young men ages 10-24. Additionally, the PP_PREV results in DREAMS districts from FY15 to FY16 increased by 19,697 for AGYW 10-24.This increase in testing and prevention services can in part be contributed to DREAMS projects like the PSI vans reaching more vulnerable, hard-to-reach AGYW and their communities.

**Figure C.3.3.2**

**<u>Community Mobilization & Norms Change Targeting Men in Lesotho</u>**

PSI in Lesotho has reached over 5,000 men since starting to implement a 10 hour Stepping Stones curriculum with men. The program targets men ages 20-49 for gender and social norm change, and links them to HIV testing at the end of their week-long training through PSI's mobile testing. Participants are recruited through soccer clubs, local chiefs, and at construction sites, taxi ranks, or other workplaces. When asked what they value about the Stepping Stones sessions, participants said they especially enjoy learning about ways to control anger and protect partners without resorting to violence. PSI reports that men are asking for the program to include their partners so as to better re-inforce their new learnings.

PSI reached 46,580 more individuals in the DREAMS districts of Berea and Maseru in FY16 than in FY15 with HIV testing, part of which can be contributed to DREAMS programming linking men and male partners of AGYW to HTS. Overall in Lesotho's DREAMS districts, PSI has reached 12,597 individuals with GEND_NORM activities in the past year.

**VMMC Demand Creation through Grassroots Soccer Program in Zimbabwe**[30,31]

A recently published study has reported on the success of creating demand for VMMC in secondary school males age 14-20 years through a Grassroots Soccer-based program known as Make-The-Cut-Plus (MTC+). In the school program, a trained, recently circumcised young male 'coach' led a one hour soccer-themed session in school. For participants with interest in VMMC, transport to a VMMC clinic was then arranged with the 'coach' sometimes accompanying the young male. Twenty-six schools in Bulawayo, Zimbabwe, were randomized to either receive MTC+ at the start or end of a 4-month period in 2014. The MTC+ intervention increased the odds of VMMC uptake by approximately 2.5 fold. Restricting to participants who did not report being already circumcised at baseline, MTC+ increased VMMC uptake by 7.6%. The number of participants who would need to be exposed to the demand creation intervention to yield one additional VMMC client was 22.7 (or 13.2 reporting not already being circumcised). This translated to approximately $49 per additional VMMC client yielded.

This follows an earlier trial of the program in adult men in which the proportion accepting VMMC was 4.8% compared with 0.5% in the control arm. Following the Zimbabwe studies in adult and adolescent males, Grassroots soccer has started working with partners outside of Zimbabwe including the Uganda Virus Research Institute and London School of Hygiene and Tropical Medicine, CHAPS Swaziland other partners in South Africa, Zambia, Kenya, and Botswana.

**The Tanzania Social Marketing Project**[32]

The Tanzania Social Marketing Project (TSMP) was a USAID-funded project (2010-2016) with a main purpose to engage key stakeholders from the public and private sectors to improve market segmentation, subsidy strategies, and distribution systems to engage the public, social marketing, and commercial marketing sectors in a total market approach (TMA) aimed at increasing sustained access to and use of condoms. A balanced TMA approach cultivated a marketplace where all segments of society have access to high-quality products and services based on their ability to purchase the products.

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[30] http://journals.lww.com/jaids/toc/2016/10012

[31] https://sciencenow.unaids.org/post/combination-prevention-12

[32] Field-Nguer, M, Kennedy, M, Fritz Matee, N, et. al. *The Tanzania Social Marketing Project: A Performance Evaluation*. June 2015. Accessed November 30, 2016. http://pdf.usaid.gov/pdf_docs/PA00KRJF.pdf

The TSMP focused on HIV prevention and family planning, distributing male and female condoms and FP products nationwide, with focused marketing and behavior change interventions in districts with high-HIV prevalence. Activities focused on shaping national markets for condoms and OCs, particularly aligning complementary targeting, positioning, and pricing between various brands. For instance, while Dume condoms were priced and targeted towards urban and peri-urban men with moderate socioeconomic status, Salama condoms were positioned to target rural men and men of lower socioeconomic status. This increases the cost-recovery of the products and sustainability of condom programming in Tanzania.

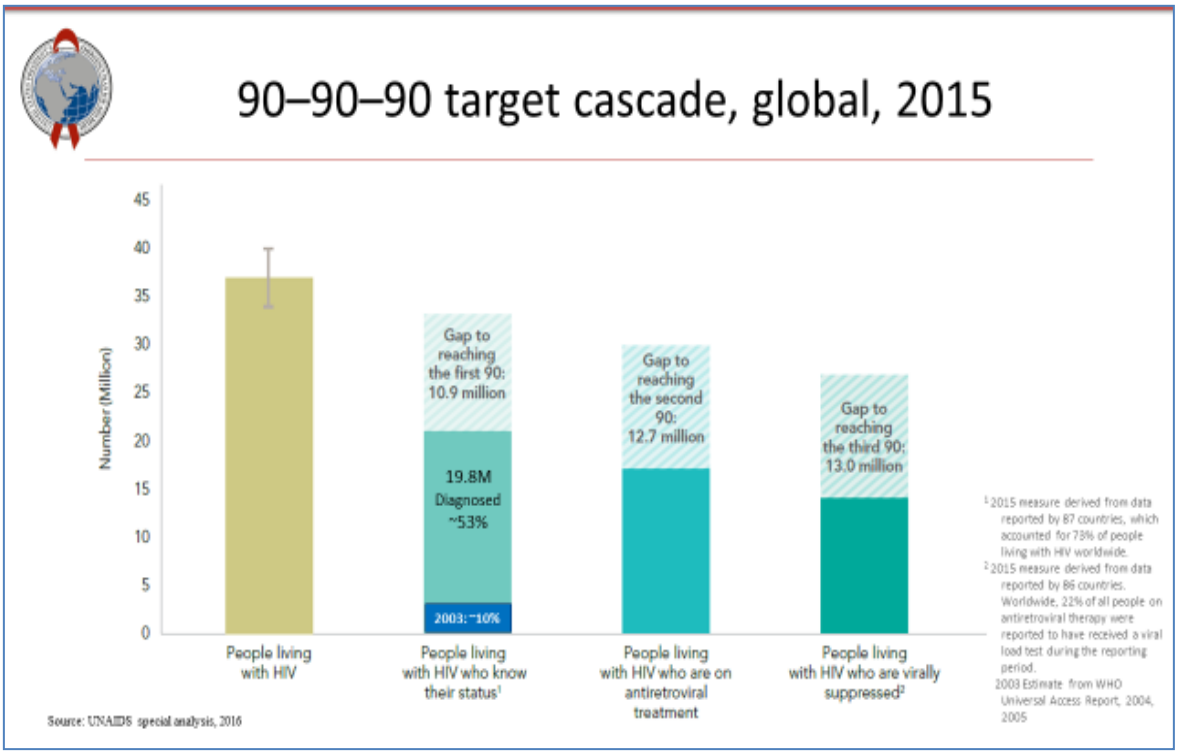
Stakeholders convened to coordinate a TMA approach to social marketing, and local capacity-building activities were implemented to sustain and strengthen social marketing activities. A mixed-methods performance evaluation showed that the TMA is progressing, though there was still more work to be done. TSMP has expanded condom availability and played a key role in providing availability and accessibility of low-priced contraceptive methods; it also contributed to improved water treatment for PLHIV.

# Appendix C.4 Targeted Testing and Improving Testing Yield for Populations

## Appendix C.4.1 Background

HIV testing is an important gateway to accessing critical prevention services for those testing HIV-negative and also in providing treatment for those testing HIV-positive. There are currently an estimated 10.9 million people living with HIV (PLHIV) who need to be identified in order to meet the UNAIDS first 90 goal of ensuring 90% of all PLHIV know their HIV status (Figure C.4.1.1). The identification and diagnosis of these undiagnosed individuals is essential in breaking the cycle of transmitting HIV to partners, families, and social and sexual networks. In addition, linkage of newly identified positives to same day treatment initiation is an important component of HIV-testing programs that supports efficiency in treatment.

**Figure C.4.1.1**




The challenges with identifying and linking PLHIV to treatment services differ greatly by country, type of epidemic, populations at risk, and current country progress toward reaching each of the 90-90-90 goals. Understanding the epidemic and who remains undiagnosed will help country teams tailor HIV testing services to their populations. In many locations, extra effort is required to test key populations, young men, and adolescents. The closer a country is to reaching 90-90-90, the more challenging it is to identify previously undiagnosed PLHIV, and more creative and targeted case identification efforts are needed (Figure C.4.1.2). In addition, directly linking HIV-positives into treatment is imperative for the health of the individual and their partners (Figure C.4.1.3). To facilitate strong linkages between HIV testing sites and treatment programs able to provide same day initiation of treatment, up to 30% of the HVCT budget code may be applied to the Care and Treatment earmark as it supports rapid treatment initiation.

**Figure C.4.1.2**

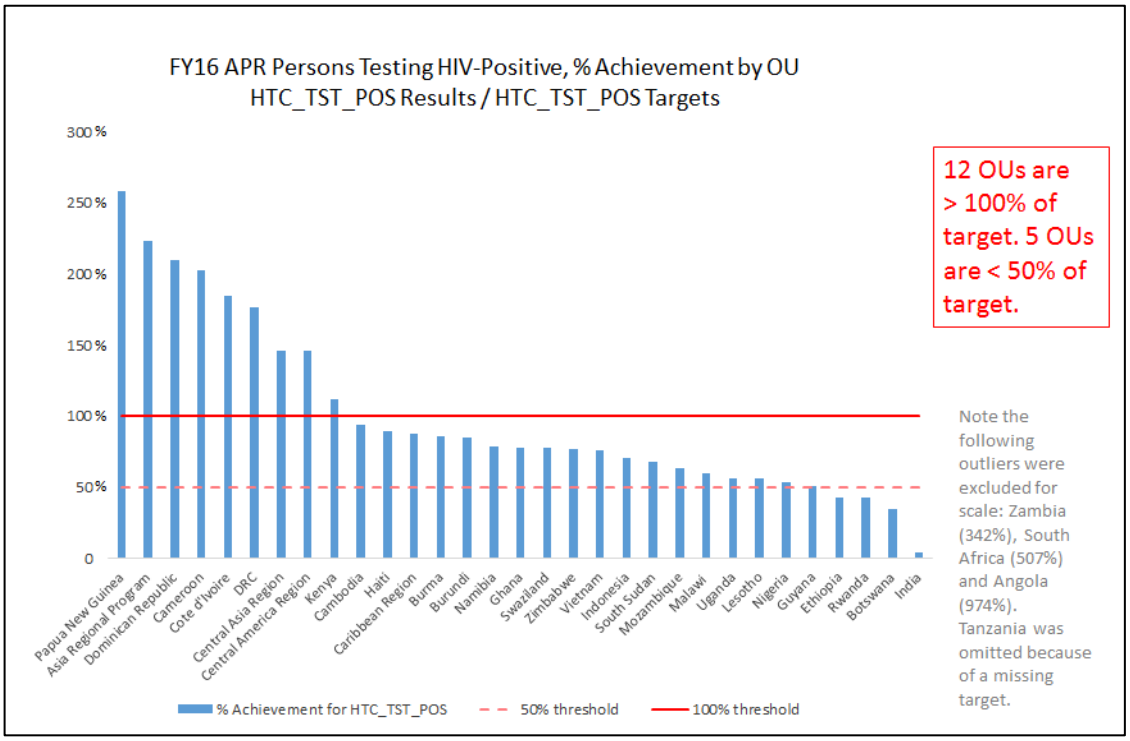
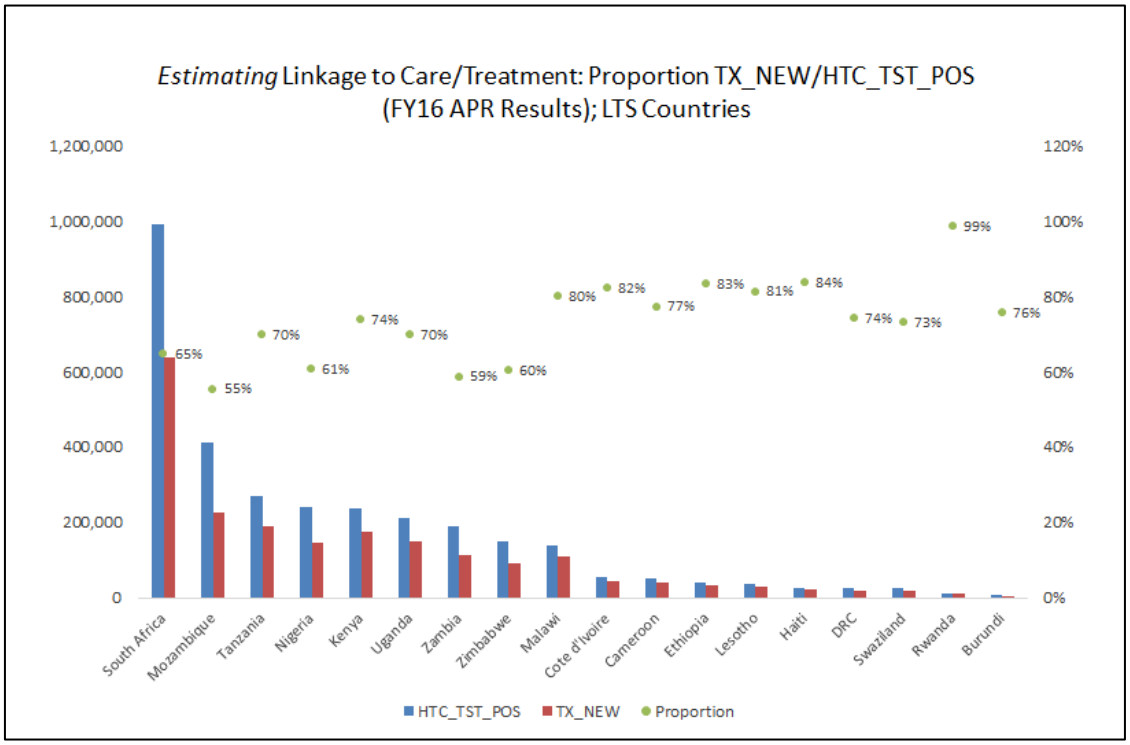
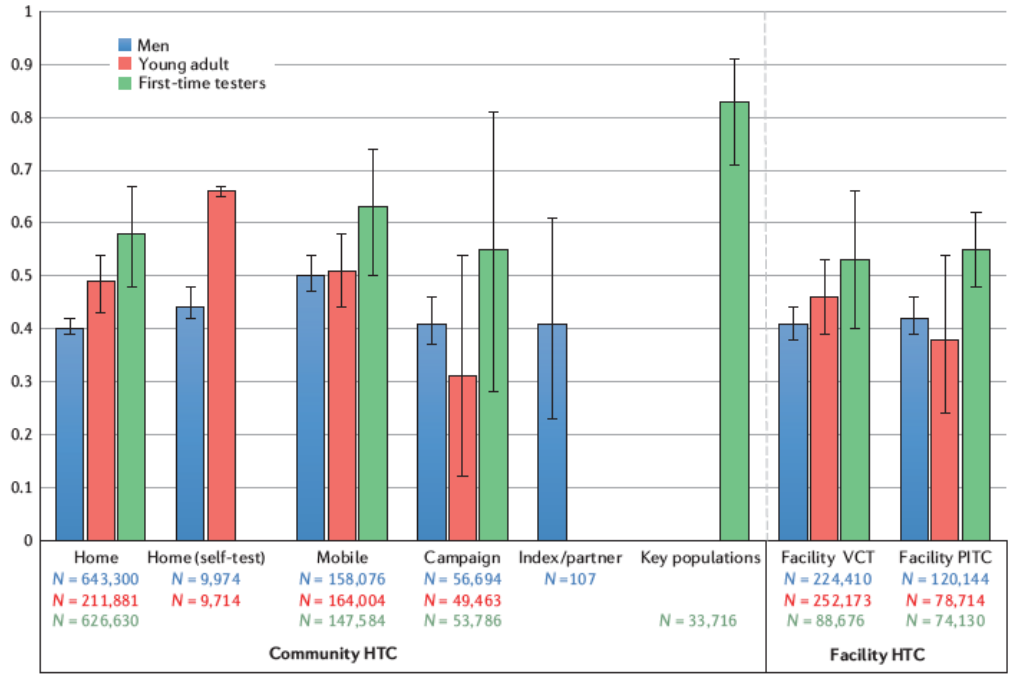



**Figure C.4.1.3**



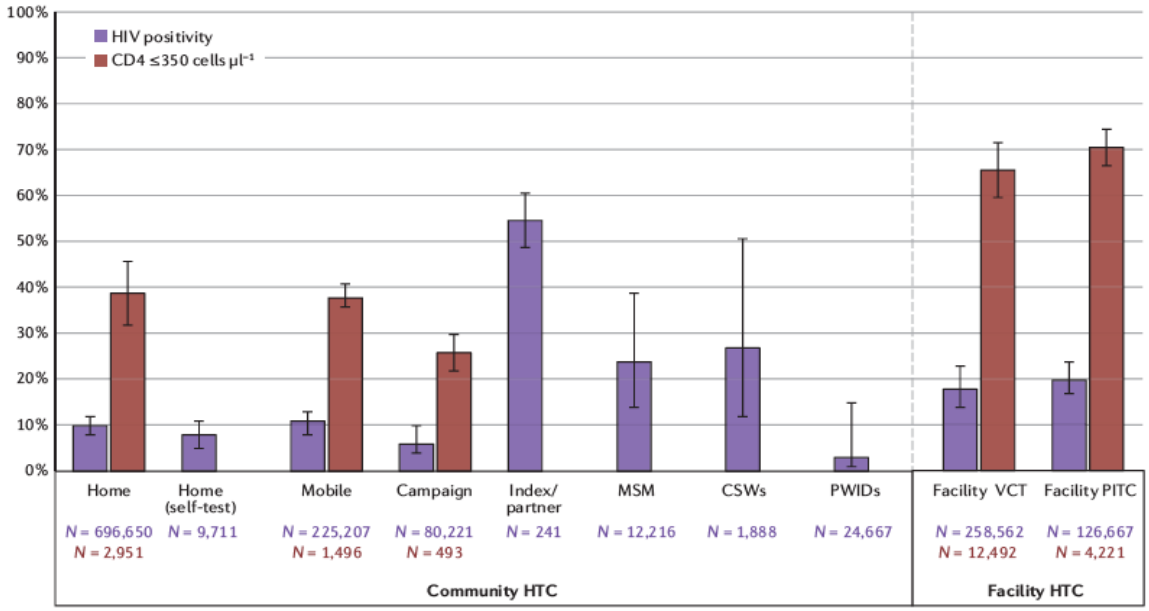
In generalized and mixed epidemics, facility based HTS in some settings has achieved high levels of coverage (e.g. ANC and TB), however outpatient departments and inpatient wards may require additional screening of patients based on country data. Community-based HIV testing approaches remain a critical avenue for achieving early diagnosis and reaching those not accessing the health system, first-time testers and asymptomatic PLHIV, which can include males, key populations, and other priority populations[33]. As noted in Figures C.4.1.4 and C.4.1.5, home- and mobile-based HIV testing campaigns resulted in an increased uptake among males of all ages with higher CD4 cell counts than facility-based testing, resulting in the identification of healthier HIV-positive males.

**Figure C.4.1.4**




[33] Sharma 2015 and Suthar 2013

**Figure C.4.1.5**



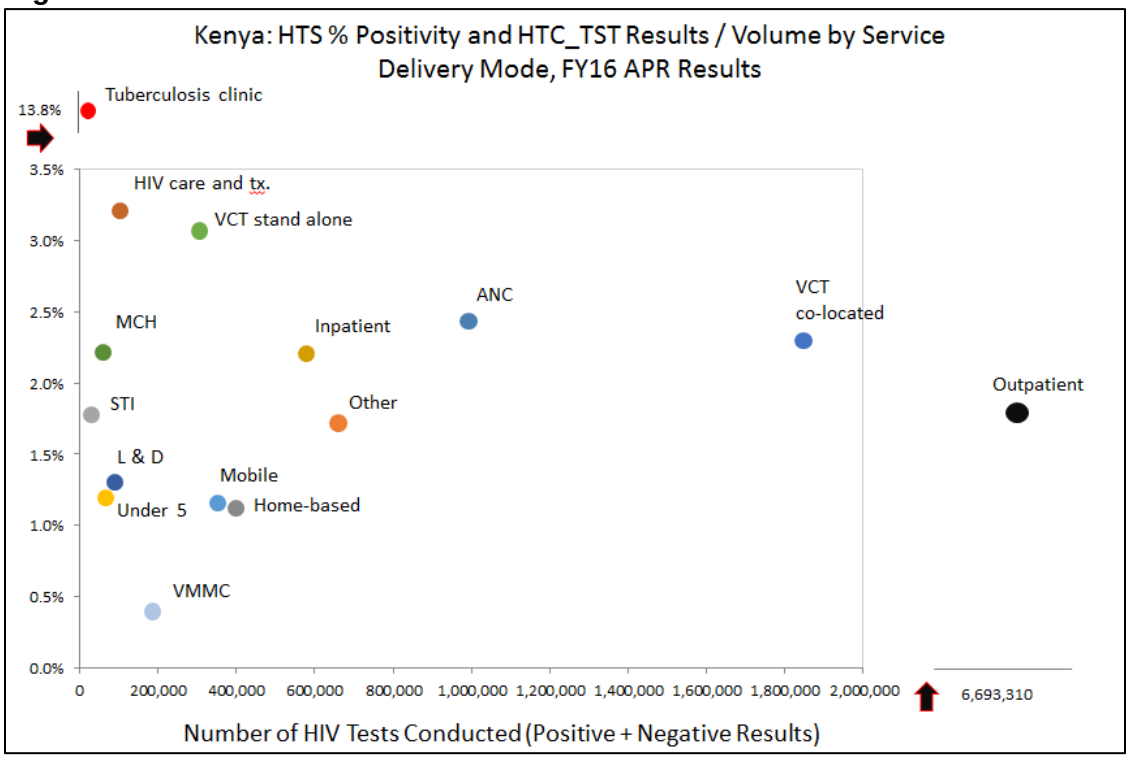

Ensuring linkage to treatment services is critical for achieving the second and third 90 goals. While a large proportion of newly diagnosed individuals are enrolled in treatment, a significant proportion of PLHIV do not link to treatment. Country teams must continue to address the country-specific issues and barriers faced when linking clients to treatment and prevention programs. Same day initiation of ART will support linkage and reduce loss between testing and treatment initiation. Activities under HVCT that support linkage and rapid treatment initiation can be counted as part of the Care and Treatment earmark, estimated to be 30% of the costs. To better understand and address gaps in achieving treatment targets, country teams should work with PLHIV and key population organizations/networks, implementing partners, host country governments, and other stakeholders to strengthen coordination and the tracking of PLHIV.. When analyzing their HTS program, country teams should consider: the unique needs and barriers of adolescents and KPs, including population friendly and competent providers, community-based and KP-led service delivery, strategies to reach hard-to-reach adolescents and KPs, stigma, discrimination, and violence; program capacity for case management; structural barriers preventing linkage to treatment, including the completion of a barriers assessment among clients; and treatment literacy.

# Appendix C.4.2 Priority Strategies & Interventions for COP17

## Optimizing HIV Case Finding

Country teams should review programmatic data, including yield and coverage data, at least monthly with implementing partners to assess achievement towards annual targets, to understand trends over time, identify where and which modalities are leading to high volumes of diagnoses, and to proactively identify underperforming sites and implement quality improvement approaches as needed (Figure C.4.2.1). Weekly monitoring is recommended for partners who may be implementing new HTS approaches to improve HIV case finding or who are conducting community-based HTS where the population or location may be not be fixed. Frequent reviews will also highlight innovative approaches (e.g. use of incentives, screening tools, etc.) and modalities that are effective at identifying PLHIV that may need to be scaled-up, as well as identifying populations not accessing testing services that may need additional targeting. These reviews should also address keeping partners of priority populations negative, condom availability, and appropriate prevention messages.

**Figure C.4.2.1**

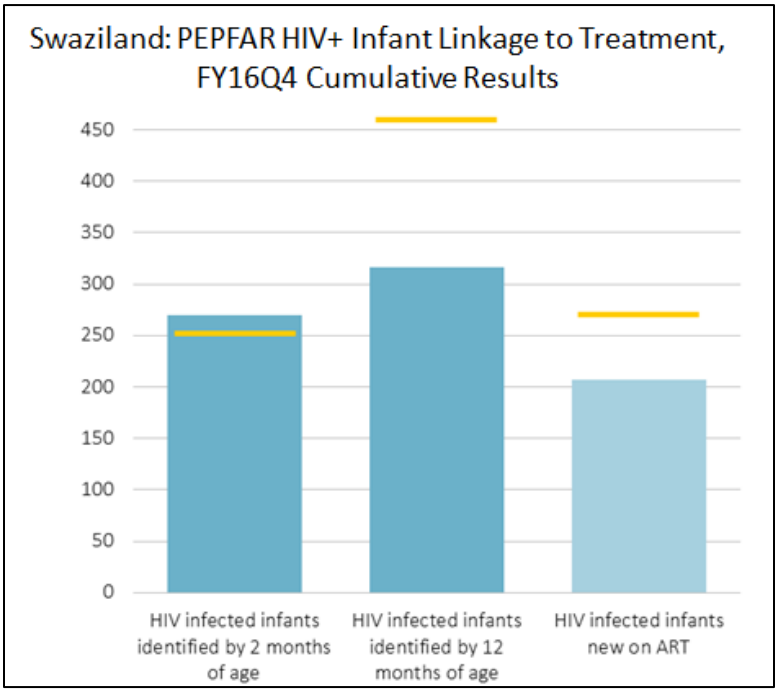


Country teams should work with partners to understand the reasons for low achievement and create an action plan for improving future performance; high-performing partners should be analyzed for best practices that could be shared among other implementing partners to optimize their program.

As HTS is increasingly integrated into clinical services, where appropriate and yielding high positivity, country teams should universally adopt opt-out or provider-initiated testing and counseling (PITC) at key entry points within health facilities based on country data. IPs should routinely monitor and use program data to target testing within key service delivery points (e.g. ANC, TB clinics, inpatient wards, outpatient departments, Family Planning (FP) and Sexually Transmitted Infections (STI) clinics, and HIV clinics) and among at-risk populations (e.g. partners of PLHIV, infants/children of an HIV-positive mother, TB patients, persons with presumptive TB suspects, STI patients, and key populations). Targeted testing remains crucial in diagnosing HIV-positive children not identified through EID programs. In addition to ensuring that adults in HIV care have testing offered to all of their children, programs should provide routine (opt-out) testing to all children and adolescents in TB clinics (TB cases and persons with presumptive TB), malnutrition services, and/or admitted to the hospital (for reasons other than trauma/surgery). PITC, screening-based, or other selective approaches may be more appropriate for determining need for testing among children presenting to outpatient departments for illness care. Children in OVC programs should also undergo routine assessment for HIV risk and need for testing.

Country teams should analyze their HIV testing data to determine the absolute number of new HIV diagnoses identified, the testing yield, and the estimated cost per positive case identified for each modality and service delivery point to determine the optimal mix of testing strategies. Access to virologic testing by age 4-6 weeks with systematic follow-up and determination of final HIV status at the end of breastfeeding is critical for early identification and improved linkage to treatment for HIV-infected infants and children, such as in the Swaziland example below (Figure C.4.2.2).

**Figure C.4.2.2**




**Ensuring HTS Quality**

To ensure the quality of HIV Testing Services, country teams should employ the following quality assurance approaches: (1) new lot verification and post-marketing surveillance; (2) external quality assurance (proficiency testing and retesting HIV-positives for verification prior to ART initiation); (3) programmatic use by program managers of a standardized logbook or electronic monitoring to track discrepant results or other errors; (4) training and certification of HIV testing providers; (5) supportive supervision; and (6) inventory management.

Programs should minimize risks of misdiagnosis. One Mozambique study estimated between 0.43-0.74% misdiagnoses rates in one district[34]. Therefore, WHO recommends verification testing in which all newly diagnosed HIV-positive clients be retested with a second specimen and a second tester prior to ART initiation. In addition to retesting, countries should also consider utilizing a recency test which can be beneficial in determining recent infections for better contact tracing, sexual network identification, and prevention targeting.

[34] Nelson, 2016

Every effort should be made to avoid stock outs of HIV rapid test kits and other HIV testing associated commodities through systems for forecasting, ordering, and distribution. Country teams should consider test kit storage requirements and ensure they align with the manufacturer's recommended storage temperature. SIMS data should be used to identify sites where quality of HTS may be a problem and where remediation is needed, including HTS policies and algorithms, use of lay providers, and rapid testing for key and priority populations.

Counseling content should be updated to reflect current international guidelines. Many HTS providers still recommend that people who test HIV-negative return for retesting to rule out acute infection (e.g. window period retesting). Such retesting is recommended only for HIV-negative individuals who report recent or ongoing risk of HIV exposure. Window period retesting is not otherwise recommended and may waste resources and dilute seropositivity. HTS providers should include behavioral risk screening in order to provide appropriate retesting recommendations and inform referrals for additional services (e.g. PrEP, PEP, condom distribution) for individuals who report recent or ongoing risk. If this is not a hotspot or a key population, do not recommend retesting in 3 months. HTS demand creation and counseling messages also need to be updated to address treatment literacy. Communities must be made aware that Test & START policies will now make ART available to all PLHIV upon diagnosis, which may encourage more people to seek HTS and enroll in treatment services.

**Uncovering Sexual and High Risk Networks and Improving Coverage among High Risk Populations**

Passive referral for partner and couples testing has been the standard of care for many years and has had minimal success in getting partners tested for HIV. PLHIV are typically advised to disclose their HIV status to intimate partners but IPs do not systematically elicit the names of current or previous partners of index clients, nor do they actively follow-up to ensure that partners received an HIV test. Several recent evaluations have shown that testing sexual and needle-sharing partners of index clients or using index clients to refer social network members is a more efficient way to identify undiagnosed PLHIV. To improve HIV case finding, country teams should work with all stakeholders (including PLHIV) to implement more effective and innovative strategies for testing sex and drug use partners and locating sexual and other high-risk networks.

Several recent studies have demonstrated that Partner Notification Services (PNS) are an effective way to identify PLHIV who do not know their status, with yields ranging from 35-54%.

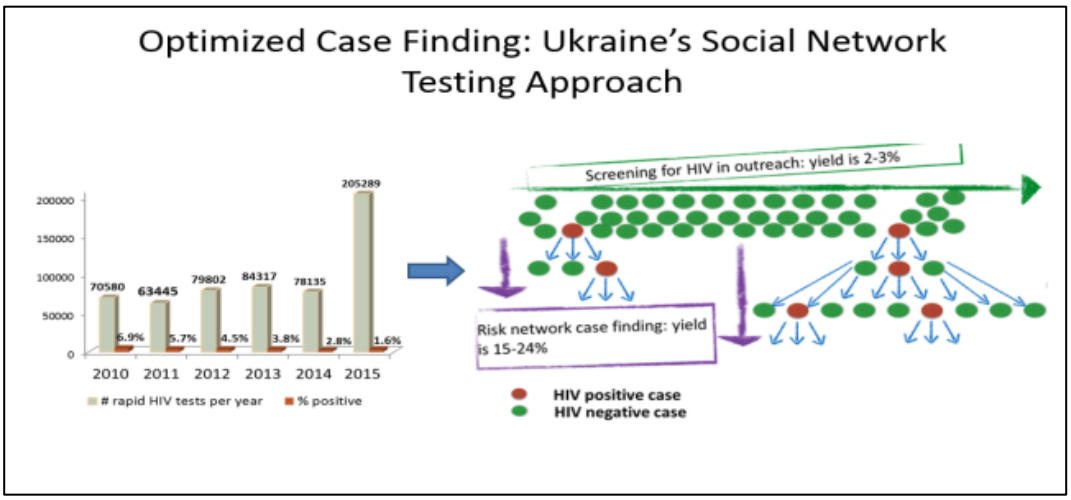
Active and contact referral programs have been very successful and should be used to the full extent possible by HTS and clinical staff in both facility and community settings. Country teams should work with IPs to ensure they are collecting partner and family information from newly diagnosed PLHIV and PLHIV already in care, as well as tracking whether all partners and children have been tested. Partner tracking should continue for all contacts who test HIV-positive. Where disclosure is a barrier, approaches to anonymous notification should be considered. HIV-negative partners in serodiscordant couples should be offered annual retesting and offered PrEP when indicated. In addition, all PLHIV enrolled in treatment services should be screened for new partners at least annually.

*AGYW and Their Partners:* As illustrated in Figure C.3.1.2, it is critical to target AGYW (15-24) and their male partners (25-35) with HTS in order to interrupt the transmission cycle. Country teams need to work with IPs to address barriers to testing adolescents, such as providing adolescent-friendly HTS in community- and facility-based settings and advocating for policies that lower age of consent. Social network testing and using index clients are some approaches to improve HIV case finding among AGYW and their male partners. Further, HTS should ensure adolescents have access to adolescent-friendly SRH services, condoms, and other prevention strategies such as PrEP and VMMC. Country teams should routinely examine if IPs are effectively reaching AGYW and their partners with HTS and adjust their programs accordingly. In VMMC settings, HIV testing and counseling is no longer recommended for pre-sexual boys. HTS should only be provided to pre-sexual boys upon request due to very low HIV prevalence rates in this population, although prevention messages and counseling should always be offered. Lastly, teams should implement aggressive case finding strategies using a variety of methods to identify OVC populations in need of HTS.

*Key Populations:* Coverage of HTS among KPs including MSM, transgender persons, sex workers (SW) and their clients, and PWID remains low in many settings. For KP with ongoing behavioral risk, extending HIV testing to social networks of those testing both HIV-positive and HIV-negative may identify others at high risk of contracting HIV. Key to any strategy, however, rests with engaging KP community leaders and advocates to promote, support and implement such efforts throughout their communities while ensuring confidentiality of all individuals involved. An established technique for peer outreach to those unaware of but at risk for HIV infection is through social or sexual network connections. Members of KPs, in particular those who are HIV-positive, are highly qualified to refer HIV-positive network members who are unaware of their infection for HTS. An example is Ukraine's approach to social network testing outlined in figure

C.4.2.3 suggests a seven-fold greater yield when compared to HTS outreach testing approaches (15-24% versus 2-3%).

**Figure C.4.2.3**




*Infants:* Recently published WHO recommendations include consideration of a nucleic acid test (NAT) at birth and introduction of point-of-care (POC) or near-POC NAT tests for HIV-exposed infants. These new testing strategies will address some barriers to achieving high testing coverage, but implementation experience is limited. PEPFAR does not support birth testing of HIV-exposed infants unless coverage of testing by two months of age is at or above 80% of infants born to women receiving ART in PMTCT programs, and immediate treatment regimens are available for newborns. POC NAT has the capacity to dramatically reduce turn-around-times so that diagnosis and ART initiation can occur on the same day. Careful consideration needs to be given to placement strategies, patient and geographical prioritization, quality assurance, M&E requirements, and confirmatory testing for all initial positive results. Country teams should continue to strengthen the current services for care and testing of HIV-exposed infants using conventional platforms and testing algorithms.

**HIV Self-Testing (HIVST)**

HIVST is an emerging approach for expanding access to HTS among underserved, vulnerable, or disenfranchised populations. Evidence from multiple countries indicate potentially high accuracy, especially when combined with assisted approaches, in addition to levels of acceptability for HIVST ranging from 74-96% among couples, young women, adolescents, key

populations, and health care workers[35]. HIVST is a screening test and should not be used to provide a definitive HIV diagnosis and linkage to confirmatory testing by an HTS provider is critical. No self-test kits have been included on the PEPFAR waiver list or are WHO pre-qualified at this time, however, a number of products are in the pipeline (WHO, UNITAID, 2016). While WHO Guidelines were released in November 2016, few national policies currently support widespread programmatic application of HIVST. HIV self-test kits can currently be purchased as investigational devices for pilots and other formative research and will hopefully be available for routine programmatic use (beyond a pilot) in the few months. For many countries, HIVST should be part of the HTS portfolio and strongly considered with AGYW and their partners, sex workers, MSM and other key and priority populations (young men and at risk males) that face high levels of stigma and discrimination. Following self-testing, facility referral and the regular diagnostic algorithm can be used according to national standards. It is vital to engage community groups to advocate for, design, implement, and analyze the success of HIVST.

[35] Pant Pai et al., 2013

**Figure C.4.2.4**

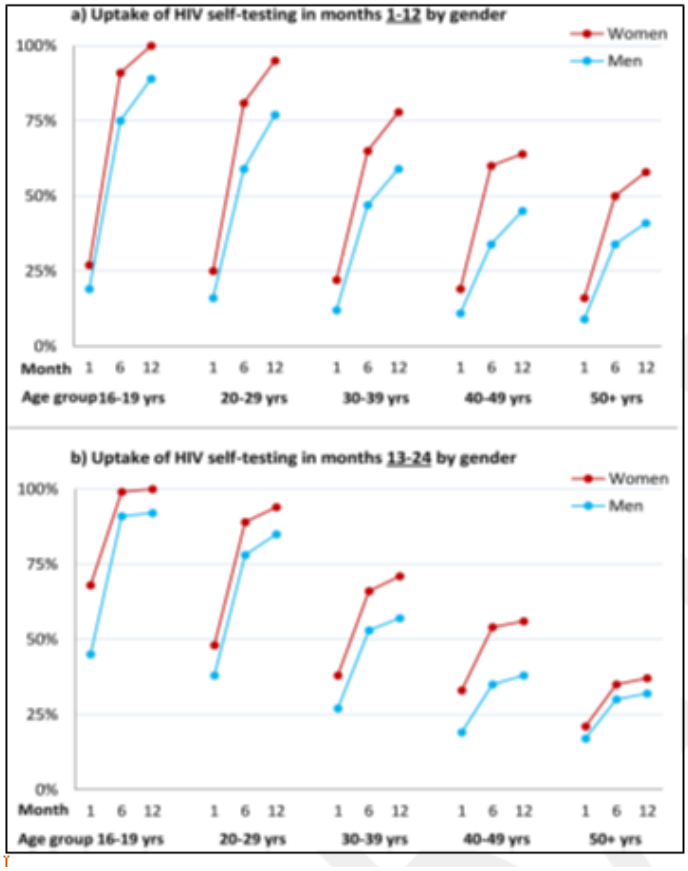



Figure C.4.2.4: Cumulative uptake of HIV self-testing by sex, age group, and time point. (A) Cumulative uptake of HIVST during the first 12 months of availability among all HIVST cluster residents by age and time point among men and women. HIVST uptake increased with time, rising to close to 100% by 12 months in adolescents (age group 16–19 y); uptake for men was lower than for women at every time point. (B) Cumulative uptake of HIVST during months 13–24 of HIVST availability among all cluster residents by age and time point. Uptake defined as an individual having collected an HIVST kit from a community counsellor. Since crude uptake of HIVST exceeded 100% in some age-sex-neighborhood subgroups, likely explained by migration, revised estimates were calculated where uptake in any single age-sex-neighborhood subgroup was censored at 100%; study census data were used for denominators.

### Linkage to Care and Other Services

Country teams should continue to work with IPs to ensure that HIV-negative individuals are linked to prevention services such as condoms, VMMC, counseling, and PrEP as appropriate, and that HIV-positive individuals are linked to HIV treatment services. HIV-negative KP members should be linked to social, violence prevention, or legal support as appropriate. A package of support interventions should be offered to newly diagnosed PLHIV to ensure timely linkage to treatment; country teams should also work to improve systems for documenting and monitoring referrals and linkage to care. .Several evidence-based practices are summarized in figure C.4.2.5. To support Test and START initiatives, HTS programs should move toward same day ART initiation whenever feasible, including immediate ART initiation for infants who test HIV-positive while confirmatory results are pending and use of ART starter packs while baseline blood work is being analyzed.

**Figure C.4.2.5**

**Strategies for Facilitating Linkage to HIV Prevention and Treatment Services (WHO 2016)**

- Co-located or integrated services where HIV testing, prevention, and treatment as well as TB and STI screening and treatment are provided together at the same facility (one roof) or in same exam room (one room)
- SMS text reminders
- Community-based distribution of ART
- Providing HIV serostatus disclosure counseling and support
- Instituting a system to track referrals to ensure clients keep their appointments
- Follow-up tracing for individuals who fail to keep an appointment offered through phone calls and/or home visits
- Enhanced post-test counseling to emphasize the importance of early treatment
- Dedicated case management teams (especially important for individuals having difficulty lining to care)
- Peer escorts or navigators
- Supportive cessation programs for substance abusers
- Using data to improve linkage through a quality improvement approach
- Development of youth-friendly service sites

## Appendix C.4.3 Country Examples of Priority Interventions

For a full list of country examples, please refer to the "Case Examples of Best Practices for PEPFAR Programs" document located in Appendix J.

**Key Intervention Elements of Tanzania JHPIEGO Pilot, 2015**

A JHPIEGO pilot tested three approaches toward partner notification and referral of newly HIV-diagnosed men and women. All partner notification was voluntary and consensual. Index clients were requested to list all partners within past 24 months; all partner notification was voluntary and consensual. Intimate partner violence (IPV) screening took place during the initial interview with the index partner and at partner listing. Those at risk were excluded.

- Three methods of sexual partner notification and referral were offered to index clients:
  - Passive referral: Index client notifies/refers partner(s) to HTS.
  - Provider referral: Health care provider anonymously notifies/refers partner(s) to HTS.

- Contract referral: Index client attempts notification/ referral of partner(s) to HTS with agreement that health care provider will contact partner if index is not able to bring in partner by an agreed-upon date.

92% of clients chose the passive referral approach. The notification method for provider and contract approaches was limited to mobile phone contact, which kept costs down.

**Enhanced Peer Mobilizers in Thailand**[36]

The Enhanced Peer Mobilizer program, implemented by the LINKAGES Project, focuses on: 1) targeted, one-on-one interpersonal communications between clients and trained, salaried community-based supporters; and 2) an informal network of incentivized peer mobilizers who recruit clients from within their social and sexual networks. The enhanced peer mobilizers are not paid staff, but receive a small incentive for each eligible client they successfully link to an HIV test. By following recruitment chains, the project can identify mobilizers that are most successful and follow up with them. LINKAGES project data demonstrates that peer mobilizers are more successful at recruiting clients than community based supporters. Additionally, the clients recruited by peer mobilizers were more than twice as likely to be positive and more likely to initiate HIV treatment. This approach, first piloted in Chiang Mai, has resulted in significant increases in uptake of HTS and appears effective at identifying individuals not previously tested and linking them into care. This model is now being rolled out in other African and Caribbean countries (adapted for local context).

[36] https://www.fhi360.org/sites/default/files/media/documents/linkages-success-story-testing-model-thailand-april-2016.pdf

**Figure C.4.3.1**

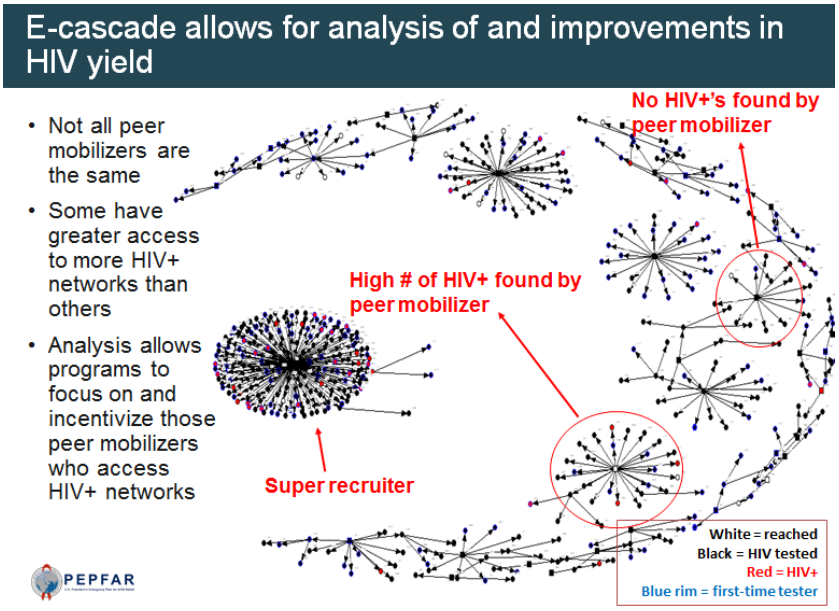



**Figure C.4.3.2** Partner Notification Testing

| Country | Tanzania | Mozambique | Kenya |
|---|---|---|---|
| # Index Enrolled | 390 | 206 | 550 |
| # Partners Notified | 248 | 266 | 620 |
| # Partners Tested | 238 (96%) | 192 (72%) | 388 (63%) |
| # Partners Positive | 93 (39%) | 103 (54%) | 136 (35%) |

# Appendix C.5 Retention and Viral Load Suppression

## Appendix C.5.1 Background

HIV virologic suppression is critical to reducing HIV-related morbidity and mortality in those already infected and preventing the continued transmission HIV infections. Recent Population-Based HIV Impact Assessment (PHIA) results show that the proportion of patients self-reporting ART is 88.6% in Malawi, 85.4% in Zambia, and 86.8% in Zimbabwe. Of those self-reporting ART, the proportion of virologic suppression was 91% in Malawi, 89% in Zambia, and 87% in Zimbabwe (Figure C.5.1.2) with an average of 65% community viral load (VL) suppression

among HIV-positive adults, nearing the 73% UNAIDS target[37]. These data suggest substantial durability of first line treatment, high adherence, and high retention. Despite these successes, men, younger adults, and children continue to have lower rates of VL suppression and gaps remain in scale-up and access to VL testing.

PEPFAR data on ART retention at 12 months suggest that many countries still fail to achieve high retention rates, with significant challenges among children under 15 years of age (Figure C.5.1.1). Analysis of routine PMTCT program data highlight higher losses to follow-up of pregnant and breastfeeding women in Option B+ (Test and START) programs[38,39,40]. Patients who are not retained are considered to have died or to have been lost to follow-up; however, our understanding of retention is hampered by incomplete reporting, limited data on sub-populations, and difficulty tracking longitudinal outcomes. The PHIA data demonstrate that treatment coverage and retention rates may be higher than PEPFAR data suggests[41]. In particular, PEPFAR data may be categorizing “silent transfers” (in which ART patients seek care and ART at a different facility or location without the original facility being aware) as lost to care, potentially leading to underestimates of treatment coverage and retention. Programs may still be developing accurate methods to capture transition of ART to delivery through newer models of care such as community-based delivery, less frequent (3-6 month) intervals for drug refills, and use of programs such as community adherence groups (CAGs) in which one patient collects medications refills for multiple patients. While we must continue to make every effort to reduce mortality and the number of patients who are lost to follow up, understanding and tracking of retention on treatment will become increasingly essential.

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37 PEPFAR is saving lives and sharing the course of the epidemic. December 1, 2016. Accessed at http://www.pepfar.gov/press/releases/264672.htm

38 Tenthani L, Haas AD, Tweya H, et al. Retention in care under universal antiretroviral therapy for HIV-infected pregnant and breastfeeding women ('Option B+') in Malawi. AIDS 2014; 28: 589-98.

39 Domercant JW, Puttkammer N, Lu L, et al. Attrition from antiretroviral treatment services among pregnant and non-pregnant patients following adoption of Option B+ in Haiti [Abstract]. Abstract Book 8th IAS Conference on HIV Pathogenesis, Treatment & Prevention; 2015:148.

40 Abrams EJ et al. Impact of Option B+ on ART Uptake and Retention in Swaziland: A Stepped-Wedge Trial. CROI 2016, Abstract 34.

41 New findings from the PHIA project show significant progress against HIV in Africa. December 1, 2016. Accessed at http://phia.icap.columbia.edu/new-findings-from-the-phia-project-show-significant-progress-against-hiv-in-africa/

**Figure C.5.1.1**

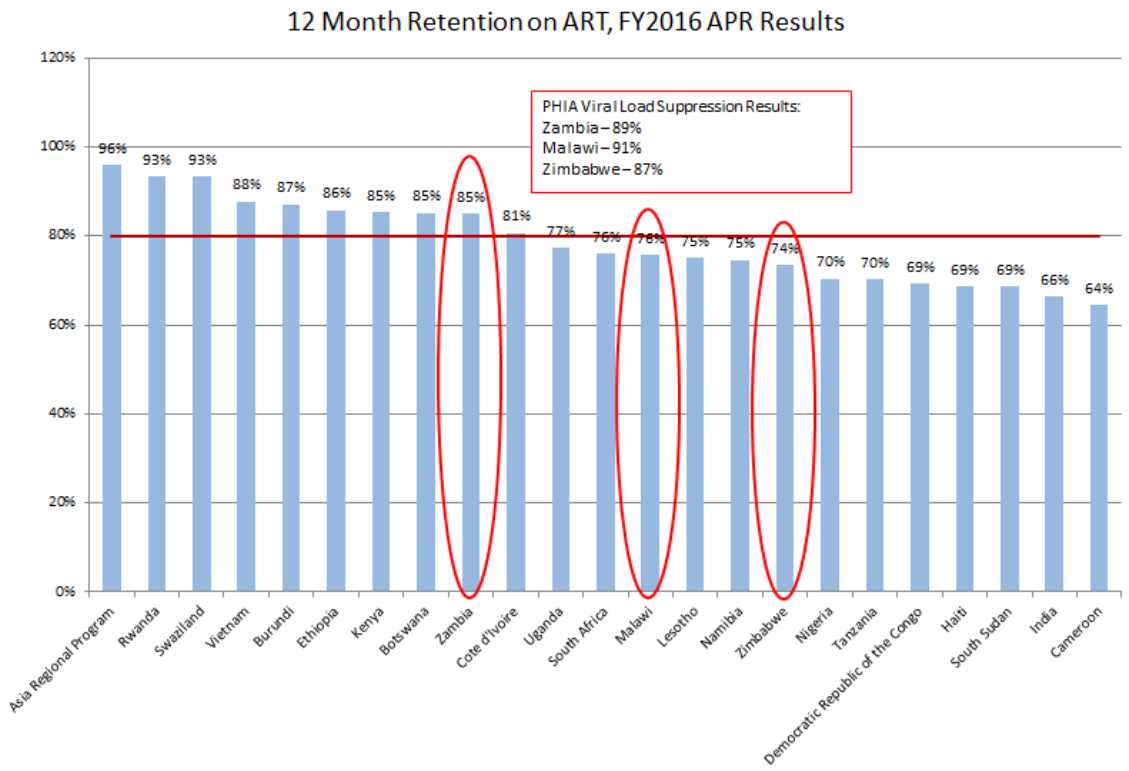

12 Month Retention on ART, FY2016 APR Results
120%
100%
80%
60%
40%
20%
0%
PHIA Viral Load Suppression Results:
Zambia – 89%
Malawi – 91%
Zimbabwe – 87%
96%
93%
93%
88%
87%
86%
85%
85%
85%
81%
77%
76%
78%
75%
75%
74%
70%
70%
69%
69%
69%
66%
64%
Asia Regional Program
Rwanda
Swaziland
Vietnam
Burundi
Ethiopia
Kenya
Botswana
Zambia
Cote d'Ivoire
Uganda
South Africa
Malawi
Lesotho
Namibia
Zimbabwe
Nigeria
Tanzania
Democratic Republic of the Congo
Haiti
South Sudan
India
Cameroon

**Figure C.5.1.2**

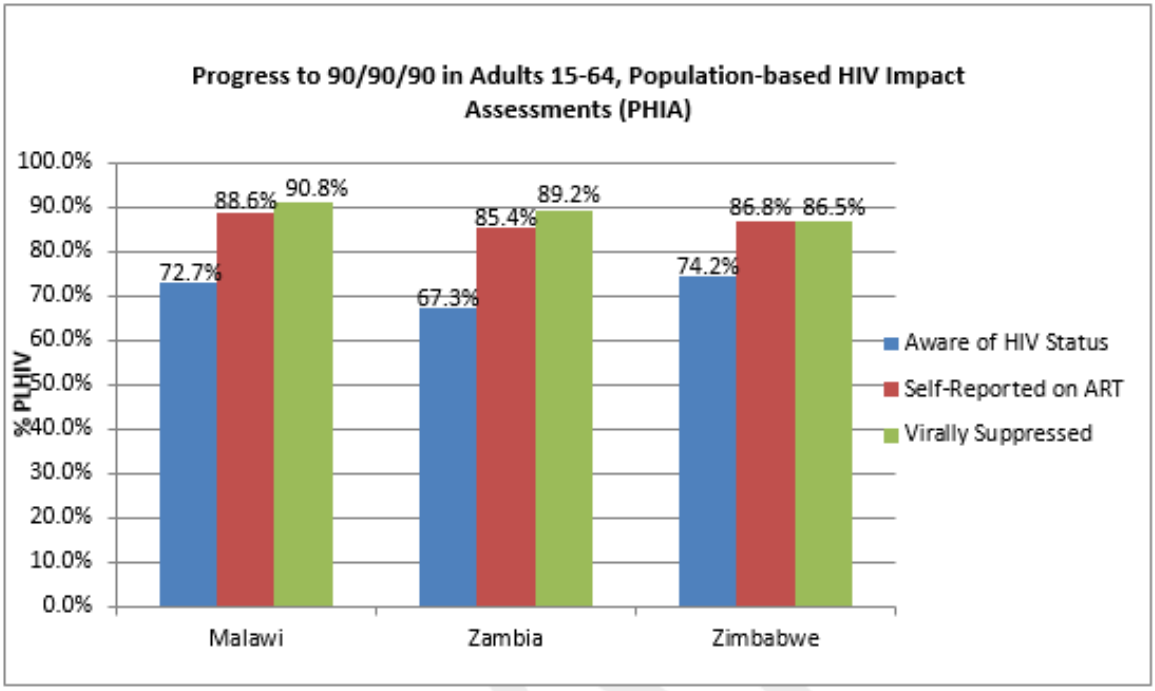
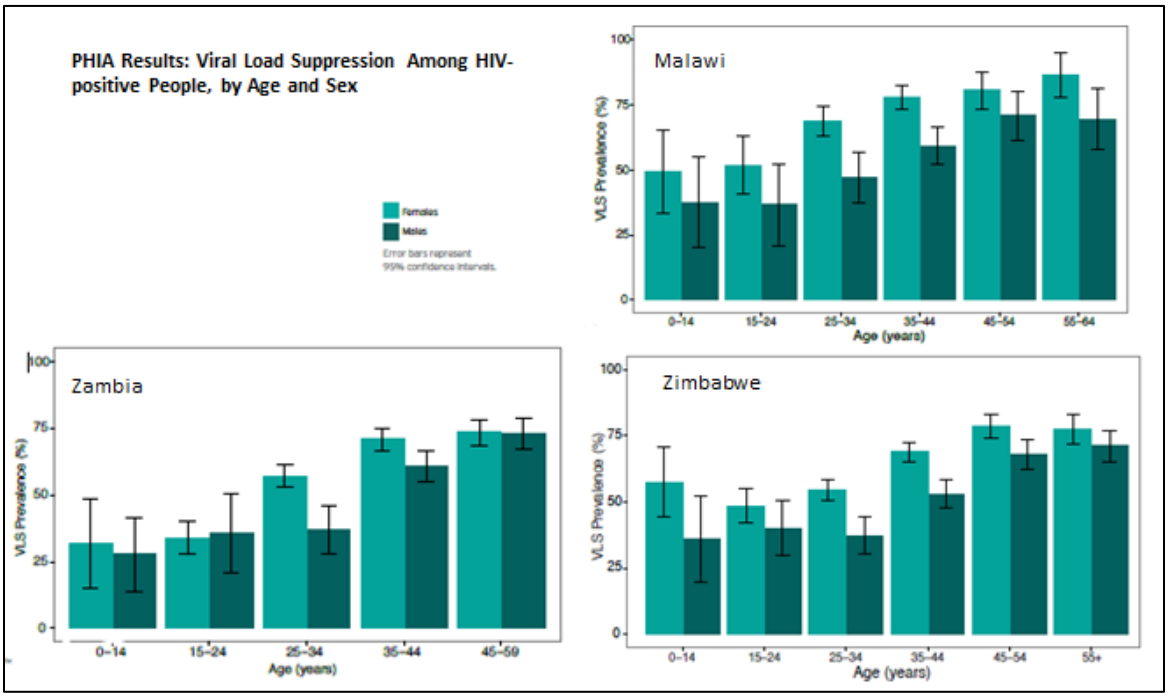



**Figure C.5.1.3**



# Appendix C.5.2 Priority Strategies & Interventions for COP17

## Population Specific Approaches to Improving Retention and Viral Load Suppression

Strategies that focus on the needs of specific populations to improve retention on treatment and access to viral load testing will be key to attaining VL suppression targets. Achieving these targets will enhance health outcomes for PLHIV, limit the need for more costly, less well-tolerated second-line ART regimens, and reduce the risk of horizontal and vertical HIV transmission.

PHIA data highlight gaps remaining in achieving VL suppression between populations, and specifically lower VL suppression rates for males compared to females across all age groups and a lower VL suppression rate of 42% (range= 34.4-47.9) among younger adults (age=15-25 years) (Figure C.5.1.3). Rates varied by geographical region in each country. Data such as these should be utilized to determine specific needs and develop targeted interventions.

Potent, first-line ART regimens enable PLHIV to achieve virologic suppression but greater effort is needed to ensure that all PLHIV – especially young children – are receiving the most appropriate and effective regimens. Once-daily and single-pill, co-formulated regimens enable PLHIV to achieve higher levels of adherence. Other interventions that have demonstrated improved adherence and viral suppression include use of peer counselors, mobile phone text messages, reminder devices, cognitive-behavioral therapy, behavioral skills training and medication adherence training[42]. Studies have shown many patients (chiefly non-pregnant adults) on first-line ART who have a first high viral load will re-suppress following an adherence intervention. Hence targeted enhanced adherence counseling is strongly suggested to improve viral suppression, particularly following virologic failure.

Differentiated models of ART delivery are designed to provide quality, client-centered treatment that reflect the preferences and expectations of specific PLHIV populations, while reducing unnecessary burdens on the health system[43]. Innovative approaches to service delivery, with reduced frequency of clinic visits, multi-month drug pick-ups for stable patients, and increased availability of services in the community encourage improved retention while also reducing wait times. Decisions related to design and selection of differentiated models of care should consider

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[42] WHO 2016 *Consolidated Guidelines on HIV*

[43] www.differentiatedcare.org

clinic characteristics, sub-populations, and context, such as current ART data, policies, and delivery methods[44][45].

Innovative service delivery models should focus on improving retention and VL suppression among young adults and men, as well as other populations in which treatment gaps often remain, such as children, pregnant women, and key populations. Programs should consider designs that reduce transport needs, frequent clinic visits, stigma, long wait times, fees, unwelcoming clinic and staff environments, and concerns of confidentiality. To better address the needs of younger adults, WHO recommends a package of youth-friendly services offered at the facility- and community-level, including high quality comprehensive services addressing youth needs and priorities (e.g. SRH, psychosocial support), offered in a dedicated setting with flexible hours to accommodate school attendance, with a strong focus on peer-based interventions[46]. Specific services that enhance care delivery to key populations are necessary, such as mobile and community-based services, peer-led service provision, targeted on-line messaging and use of social media, peer and community ART support groups, and provision of opioid replacement therapy to injection drug users[47].

Retention rates of HIV-infected women who initiate ART during pregnancy remain below the level of ART retention rates for adult populations; substantial early loss is often found within the first one to three months after ART initiation and loss continues among mother-baby pairs in the post-partum period, raising the risk of poor health outcomes for the mother and increasing likelihood of transmission of HIV to the infant. Interventions which have shown to improve retention include use of mHealth technologies such as web-based HIV infant tracking systems and phone calls or SMS text messaging, implementation of cohort monitoring systems, use of district-level focal points, active patient tracing, support for transportation, use of community health workers, and community-based interventions such as peer support (e.g. mothers to mothers programs), integration of ANC/PMTCT and HIV-exposed infant care into ART services,

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[44] International AIDS Society. Differentiated Care for HIV: A decision framework for antiretroviral care delivery. 2016 Accessed at: www.differentiatedcare.org

[45] The Global Fund. A Toolkit for Health Facilities: Differentiated Care for HIV and Tuberculosis. November 2015.

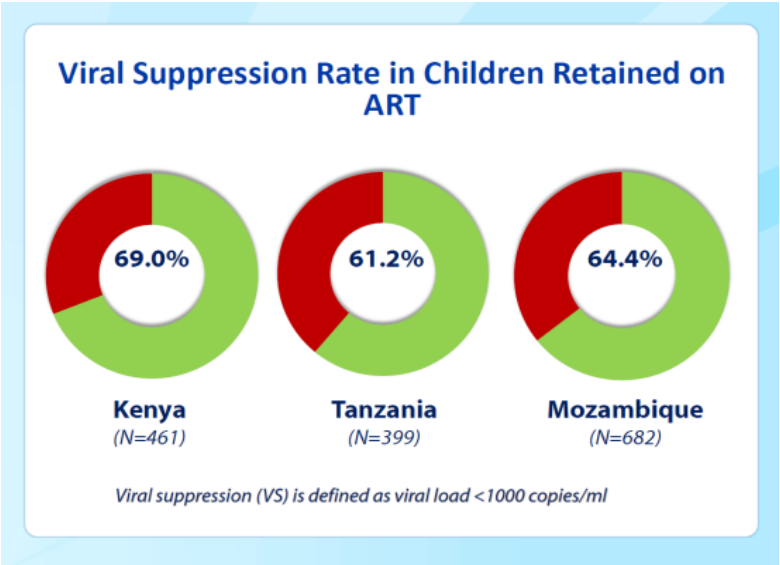
[46] *See section 6.11 in WHO Consolidated Treatment Guidelines, "Delivering HIV services to adolescents"*

[47] *See chapter 6 in WHO Consolidated Guidelines on HIV prevention, diagnosis, treatment and care for key populations*

and structured client-centered counseling. Adolescent-friendly ANC and PMTCT services are critical to improve the currently poor engagement of adolescents in antenatal care.

Virologic suppression remains a particular challenge among children (Figure C.5.2.1)[48] who have unique adherence challenges and an increased risk for resistance. Effective ART regimens are essential to achieving VL suppression and persistently poor uptake of recommended first-line lopinavir/ritonavir-based regimens (and continued use of inferior nevirapine-based regimens) in infants and young children remains a major factor contributing to poor suppression rates in these children. For children, caregiver engagement is key: WHO recommends supporting caregivers to attend regular clinic visits all while reinforcing the importance of age-appropriate disclosure to children. The OVC platform can be leveraged to contribute support to retention of children, adolescents, and their caregivers on treatment, as well as viral load uptake. Community-based OVC workers and volunteers should be utilized to provide case management services that support access to comprehensive services and to provide regular follow up and monitoring at the household level.

**Figure C.5.2.1**




Retention is also enhanced by lowering mortality; therefore in addition to ensuring that all PLHIV are put on effective antiretroviral therapy, programs need to ensure that life-saving interventions

[48] Beard, S. 2015 ACT Regional Workshop.

are provided to all eligible PLHIV. Routine, standardized assessment for TB, coupled with early, adequate treatment, is critically important[49]. Disease prevention with cotrimoxazole and TB preventive therapy is a part of routine care, and is one of the most impactful ways to reduce mortality. Given the importance of TB preventive therapy, reporting will now be mandatory and semi-annual[50]. Country teams will need to set targets, budget accordingly, and plan for programmatic scale-up.

**Access to Viral Load**

Access to VL remains a challenge in some countries. A recent review of seven PEPFAR countries demonstrated that three of the seven did not have the capacity to test all persons on ART once a year and in four of the countries ≤ 25% of persons on ART had received at least one VL test (Figure C.5.2.2)[51]. Effective planning for and implementation of VL monitoring scale-up requires projecting the number of PLHIV in need of VL; adequate VL platform capacity/placement along with coordinated planning with EID testing; forecasting and procurement of lab reagents and other commodities; ensuring availability of systems for specimen collection, transportation, testing, and results reporting; training and systems improvements to ensure appropriate patient management actions are undertaken based on results; and patient engagement and understanding of the test value and process. The use of dried blood spots (DBS) to facilitate sample transportation and improve testing coverage should also be encouraged. All country teams should have a well-developed plan for scaling up VL testing and results actioning with systems in place to monitor progress, identify implementation gaps, and improvement strategies along the testing cascade. Strong demand creation with clinicians, patients, and communities, together with coordinated laboratory/clinical interface, will be necessary to improve testing coverage and prompt patient management of test results.

Plans for VL monitoring and evaluation should be developed, utilizing data from lab and clinical information systems. Through tools such as unique identifiers, efforts should be made to track individuals and their VL test results over time.

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[49] http://www.who.int/tb/areas-of-work/tb-hiv/algorithms_for_diagnosis_and_management_of_hiv-associated_tb.pdf

[50] PEPFAR Operational Policy for TB Prevention

[51] Lecher S, Williams J, Fonjungo PN, et al. Progress with Scale-Up of HIV Viral Load Monitoring — Seven Sub-Saharan African Countries, January 2015–June 2016. MMWR Morb Mortal Wkly Rep 2016;65:1332–1335. DOI: http://dx.doi.org/10.15585/mmwr.mm6547a2.

**Figure C.5.2.2**

| HIV treatment monitoring indicators, January 2015-June 2016 | | | | | | |
|---|---|---|---|---|---|---|
| | Total # ART patients | | % ART patients with >=1 viral load test | | % viral load tests with viral suppression | |
| Country | 2015 | 2016 | 2015 | 2016 | 2015 | 2016 |
| Cote d'Ivoire | 147,947 | 160,561 | 10 | 11 | 78 | 66 |
| Kenya | 860,297 | 923,000 | 76 | 49 | 83 | 84 |
| Malawi | 595,186 | 606,673 | 19 | 19 | 82 | 89 |
| Namibia | 143,805 | 148,940 | 91 | 43 | 87 | 87 |
| South Africa | 3,318,384 | 3,422,724 | 87 | 91 | 83 | 83 |
| Tanzania | 758,344 | 769,527 | 5 | 9 | 88 | 72 |
| Uganda | 1,066,519 | 1,213,091 | 23 | 22 | 91 | 92 |

## Unique Identifiers[52]

The existence of national health identifiers (NHIDs) ensures that each patient has one unique identity within the health system. This facilitates the development of longitudinal medical records and allows users to be tracked across health-care sectors. Such a system is particularly helpful for tracking individual patients who transfer care to new sites, seek care at multiple sites, and/or who receive care through newer differentiated models of care. Improved tracking through use of NHIDs can dramatically improve delivery of care and dramatically improve HIV program information about treatment coverage, retention, viral suppression, and other care outcomes. Establishing and implementing a NHID policy framework is a complex process that requires strategic planning and coordination among key stakeholders. PEPFAR programs are strongly encouraged to work closely with host country government partners and technical experts to develop plans for NHIDs in COP17.

Governments and others who hold personally identifiable data, whether for clinical, surveillance, or research purposes, must implement appropriate technical and organizational measures to protect data against accidental or unauthorized access, alteration, destruction, loss, use or disclosure, whether these data are collected and stored in paper or electronic format. The level of security measures must be appropriate to the risks and the nature of the data to be protected, taking into account the state of the art and the costs of their implementation. In particular, sensitive information, raising higher risks of stigmatization or discrimination for individuals and

[52] http://www.unaids.org/en/resources/documents/2014/national_health_identifiers

communities, should be subject to specific—and especially rigorous—security safeguards. Policies and procedures must be developed or adapted and should describe how data concerning PLHIV will be protected during collection, access, transfer, storage, and use in order to prevent unauthorized disclosure of personally identifiable information. Security procedures should be independently assessed to assure effectiveness. All persons involved in the case surveillance system at all levels should be trained on these policies, providing them with the skills and knowledge needed to maintain data security and confidentiality.

## Appendix C.5.3 Country Examples of Priority Interventions

For a full list of country examples, please refer to the "Case Examples of Best Practices for PEPFAR Programs" document located in Appendix J.

### Use of Biometric Coding (Unique Identifier) to Monitor and Improve Case Finding and Retention Along the HIV Clinical Cascade: Haiti Experience

Biometric Coding (BC) was implemented in Haiti in 2015, when local implementers acquired the capacity to link the technology to existing medical records. BC allows the addition of digital biometric codes to patients' demographic and clinical data captured on the electronic medical records (EMRs) and the HIV case-based surveillance system, SALVH "Suivi Actif Longitudinal du VIH en Haïti," formerly known as HASS: HIV/AIDS Surveillance System.

BC has enabled the ongoing development of a National Master Patient Index (MPI) that will ensure in the future that every patient is represented only once and with constant demographic identification at facilities supported by the program.

The BC technology has been rolled out to 75 sites providing ART services (representing ~ 59% of the total ART sites). At supported facilities, BC data collection is not limited to only HIV patients only, but it is extended to all patients attending these facilities to the extent possible. The BC data are collected at the site through biometric readers linked to the EMR infrastructure. Sites involved are able to retrieve more easily their patients' files. The facility level BC data are replicated regularly on the national server to feed the MPI. Although BC has not yet been implemented at all supported sites, the MPI currently provides the possibility to uniquely identify patients across the implementing sites and can generate a list of all treating facilities at which these patients have received services. Figure C.5.3.1 below illustrates the case of a patient that

has sought services at 9 different facilities and for whom the manual algorithm would have turned a match in only three cases.

**Figure C.5.3.1** "Medical Shopping": Example of a unique patient identification allowed by the biometric code: a patient changing their personal information and receiving services at nine (9) different facilities.

| FACILITIES | Name* | Year of Birth# | Last Contact with facility | Mother's first name* | Phone Number |
|---|---|---|---|---|---|
| HUEH | Carla | 1970 | 9/23/2016 | Emma | Same Number |
| Clinique Communautaire de Martissant | Sandra | 1982 | 9/15/2016 | Stephany | Same Number |
| Centre Hospitalier d'Arcachon 32 | Jessy | 1970 | 8/31/2016 | Martha | Same Number |
| HCH | Carla | 1976 | 9/12/2016 | Emma | Same Number |
| FAME PEREO | Carla | 1971 | 11/22/2016 | Emma | Same Number |
| Maternité Isaie Jeanty\| | Carla | 1970 | 6/28/2016 | Emma | Same Number |
| Hôpital Universitaire la Paix | Judith | 1962 | 8/29/2016 | Karen | Same Number |
| Centre de Santé Portail Léogâne | Angela | 1977 | 10/28/2016 | Rita | Same Number |

**Names do not represent the real patient names or patient's mother's name, these are included for illustration purposes.*

*#Year of birth also does not reflect the real dates of the patient.*

A total of 34,000 BC data have been collected among HIV patients; but so far 27,333 BC data have been transferred to the MPI server. Preliminary analyses of these data show that Biometric Coding is an added value to the deduplication process by:

- Identifying duplicates that the current algorithm based de-duplication system would not have been able to identify, especially when patients intentionally change their personal and demographic information.
- Giving more insights into the Losses To Follow-Up and other challenges the program faces such as silent transfers and medical shopping .

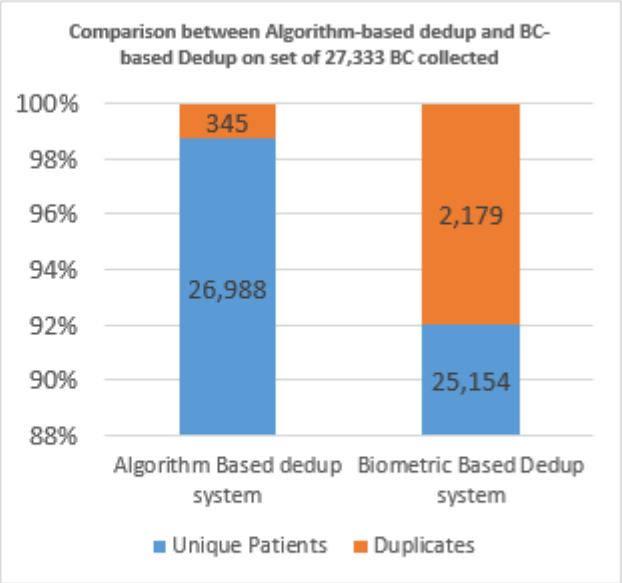
The following graphs show the results of the preliminary analysis performed on this batch of 27,333 BC data stored in the Master Patient Index

**Figure C.5.3.2**

Using both the Algorithm-Based (AB) deduplication, and the Biometric Code based (BC) deduplication on the set of 27,333 Biometric codes collected it was found that BC deduplication identified 5 times more duplicate cases than the AB deduplication.

26,988 cases out of the 27,333 (99%) were identified as unique cases with the AB Deduplication

Using the biometric code for deduplication, only 25,154 (92%) of cases turn out to be true unique patients



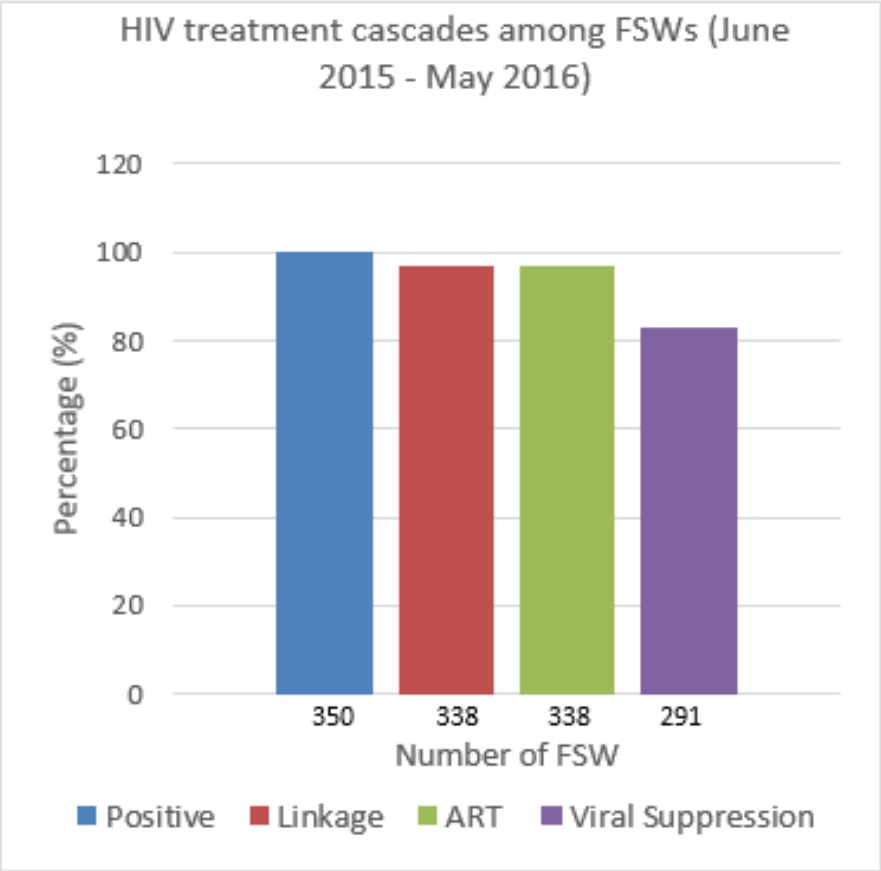

## A Model for Scaling up ART Among Key and Priority Populations in Uganda

Reach Out Mbuya (ROM) has provided services for female sex workers (FSW), fisher folk (FF), uniformed men, truckers (TR), people who inject drugs (PWID), and MSM since 2012. These

populations are reached through static and outreach clinics offering HIV testing and are then fast tracked for ART. Between 2012 and 2015, the number of PLHIV in care increased from 60 to 751, representing a 12-fold increase.

From June 2015 to May 2016, 5670 individuals belonging to different key and priority population groups were tested and a total of 525 HIV-positives were identified. Figure C.5.3.3, below, shows the HIV treatment cascade. The program has high linkage and ART initiation rates for FSW, FF, and TR but ongoing challenges remain with MSM and PWID. Among those on ART, adherence is reported to be at 88% and retention at 90.6%. This model has successfully used peers to mobilize KP for testing, same day CD4 testing, and use of different ART delivery models that included a roving clinician for timely ART initiation, peer ART drug pick-ups, and individualized appointments.

**Figure C.5.3.3**



**Zvandiri Model of Differentiated HIV Service Delivery for Children, Adolescents and Young People in Zimbabwe**

Africaid is a non-governmental organization based in Harare, Zimbabwe. Through its Zvandiri ('As I am') program, Africaid provides community-based treatment, care, support, and prevention services, which complement clinic-based care for children, adolescents, and young people living with HIV.

The Zvandiri program was launched in 2004 and now offers a combined package of differentiated services for children, adolescents, and young people with HIV. Services are primarily led by adolescents and young people with HIV who are trained and mentored as Community Adolescent Treatment Supporters (CATS). CATS work in their own communities with children and young people living with HIV (0-24 yrs) with the aim of improving the uptake of HIV testing services, linkage, retention, and adherence, as well as mental health and sexual reproductive health outcomes. CATS provide:

- ART counseling and monitoring in the homes and health facilities
- Identification and referral of those who are unwell or require further investigations for non-adherence, potential treatment failure, child protection issues, mental health disorders, or sexual and reproductive health issues
- Index case finding, through the identification and referral of children and adolescents in the homes of children on ART
- Community Support Groups
- Capacity strengthening for health care workers, social workers, communities and families

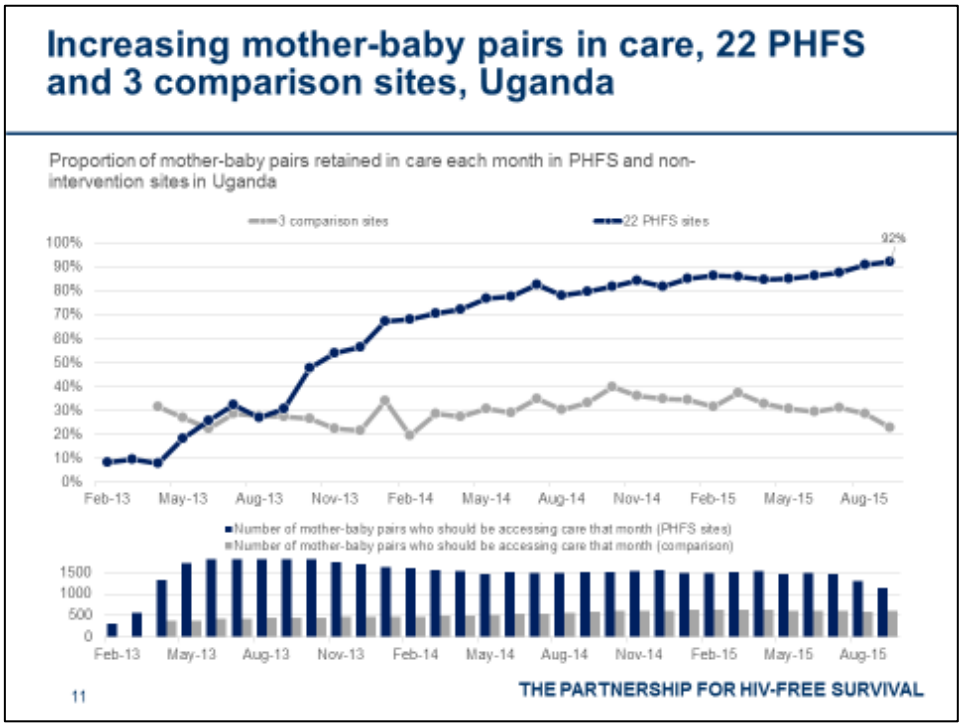
In 2015, operations research and programmatic data confirmed improved retention, adherence and psychosocial well-being among children, adolescents and young people engaged with Zvandiri. In 2014, Zvandiri reported a 90% retention rate among clients served by CATS. Zvandiri is currently being scaled up under the Ministry of Health and Child Care into 36 priority districts of Zimbabwe.

**Increasing the Engagement and Retention of Mother-Baby Pairs in Care and Reducing Mother-to-Child Transmission Rates through Quality Improvement**

Significant improvement in HIV-positive mothers and their exposed infants accessing and retained in care were achieved through the application of quality improvement within clinical services (see figure C.5.3.4). The increase in mother-baby pairs kept in care (see C.5.3.4) was

achieved through: (1) consolidating all services for mother and infant within single appointments; (2) merging EID and PMTCT/ART services into one service point for mother and baby; (3) pairing mother and baby health cards; (4) peer counseling of mothers; and (5) writing next appointment dates on medicine bottles and calling to remind mother of upcoming appointments. Using quality improvement methods, Partnership for HIV-Free Survival (PHFS) countries have shown the benefits of integrating PMTCT, MNCH, and nutrition services through achieving a MTCT rate of 2.2%, within the 5% level set by WHO towards elimination of new pediatric HIV infections in breastfeeding populations in the 22 initial PHFS demonstration sites in Uganda.

**Figure C.5.3.4**




# Appendix C.6 Access to Quality, Sustainable HIV Services

PEPFAR's work must effectively and meaningfully engage communities and civil society if it is to make a sustainable impact in controlling the HIV/AIDS epidemic. From advocacy to service-delivery, those affected by HIV play an important role in responding to the epidemic in ways the public sector cannot. Civil society organizations (CSOs) and community leaders can work with PEPFAR programs and local governments to ensure strong referral and adherence services that address barriers across the prevention and treatment clinical cascades, ensure stock outs are

prevented or shortened in duration, and enhance the ability of public health facilities and health care workers to mobilize and address the needs of the communities in which they work.

Along with advocacy and providing a voice and support for populations affected by HIV, community plays an important role in delivering HIV services. Community-based or lay cadres have been essential in helping countries address human resource challenges and in advancing HIV services. Multiple studies have shown that community-based services achieve results and increase access to HIV treatment and prevention services (Figure C6.1.1.1). If PEPFAR is to be successful in reaching its goals and in helping countries achieve 90-90-90, we must work closely with CSOs, community-based or lay cadres, faith-based organizations, and community leaders to ensure that barriers to HIV prevention, treatment, and adherence are addressed in the communities where we work. Lay cadre and community health workers should be recognized for their contribution through incentives and/or financial remuneration.

## Appendix C.6.1 Considerations of Utilizing Health Care Workers in HIV Delivery Models

### Appendix C.6.1.1 Background

Successful roll out of Test & START and meeting the 90-90-90 targets will introduce more patients into care. Simultaneously, the successful expansion of TB preventive therapy, which should be offered to all PLHIV who are not diagnosed with TB disease, will require diligent screening as well as monitoring for adherence and adverse events. These additions to the current volume of clinical work require implementation of innovative service delivery models. This in turn necessitates that PEPFAR programs continue to address the large human resource challenges they face. Task-shifting and utilization of community-based or lay cadres have been integral to advancing HIV services. For example, in Malawi, one out of every three health workers supporting HIV services falls under the lay cadre category across surveyed sites[53]. Across sites surveyed in Zambia, lay health workers are allocated to every single HIV service delivery task, including patient consultation and clinical assessment and ARV initiation; and on average, 41% of task allocation to lay workers is to manage high patient volumes and 39% is to

[53] PEPFAR Malawi Site-Level HRH Assessment, 2016

compensate for health worker shortages[54]. Many advances have been made in formalizing task-shifting that allow midwives, nurses, and community health care workers to provide HIV counseling and testing, initiation and ongoing monitoring of ARVs, and community level dispensing. However, only slightly less than half of PEPFAR countries have task-shifting polices in place[55]. Even less is known about the extent of implementation of these task-shifting policies and utilization of community-based or lay cadres in HIV.

**Figure C.6.1.1.1**

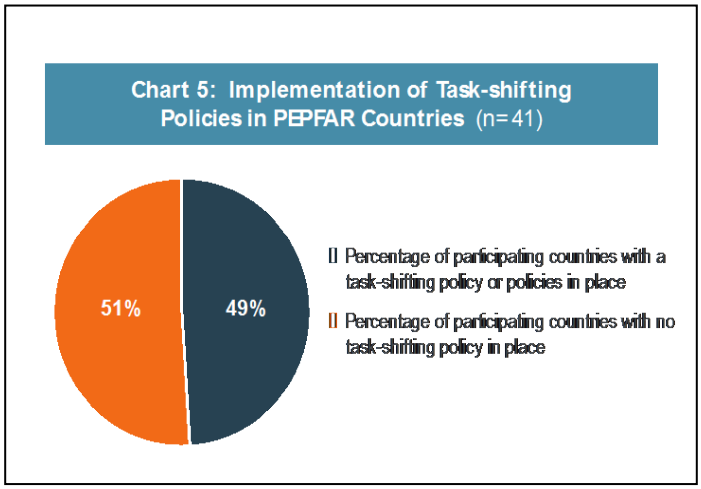
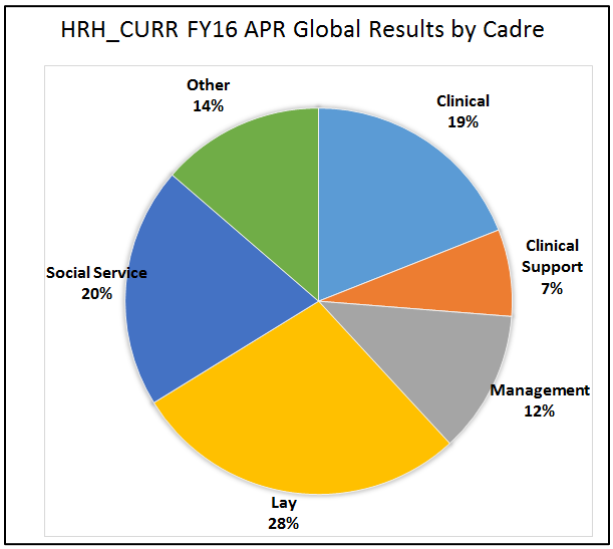



**Figure C.6.1.1.2**




While there are numerous efforts to develop national community health worker programs across countries, there are many community-based or lay workers supporting HIV who are dependent on donor support and are not formally recognized by country governments. As a result, data availability on this workforce and the workload that it supports is limited. PEPFAR historically has provided significant support to health workers in the delivery of HIV service. From data captured last year, 36% of these workers (total reported 55.7 thousand) fall into the lay cadre category. As the role of community-based or lay cadres increases for HIV, it is anticipated that PEPFAR support of these workers will increase to support transfer of HIV services to the community. This places priority on better understanding the composition of this workforce and how it is being utilized to support HIV.

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[54] PEPFAR Zambia Site-Level HRH Assessment, 2016

[55] *PEPFAR Sustainability Briefer*, 2016

## Appendix C.6.1.2 Priority Strategies & Interventions for COP17

In COP17, all countries should focus on human resources for health (HRH) considerations including appropriate composition, utilization, and performance/productivity of providers to facilitate the alternative service delivery models and decrease facility visits to only once per year. These activities should include a combination of: use of community-based or lay cadres; continued implementation of task shifting; creating provider care teams and networks; integrating wellness/stable patient delivery systems; and addressing retention. Additional information can be found in the *PEPFAR Human Resources for Health Strategy document*[56].

### Community-Based or Lay Cadres

Across countries there are a wide range of community-based or lay cadres supporting HIV. These include workers who are formally recognized as government cadres (such as health surveillance assistants in Malawi or community health extension workers in Ethiopia) and those that are not formally recognized and are dependent upon donor support. Greater country-level coordination and partnership to strengthen the accountability, effectiveness, and sustainability of this workforce in HIV is critical for optimizing and sustaining the role of these cadres in new HIV service delivery models.

In COP17, country teams should gather data to better understand the supply, workload, and existing linkages with facility and community based human resources. Using this data, country teams should focus on coordinating the different community-based cadre programs in order to reduce duplication, gaps, and fragmentation to achieve greater efficiency and impact. Linkages between community-based workers and facility-based counterparts should be strengthened with special consideration given to strengthening linkages with social service workforce also working in the community, such as family-based approaches. Activities that focus on 15-24 year olds should look at different models that promote youth-friendly services.

### Task Shifting

Many countries face critical staffing imbalances and deficits in the numbers and skills of cadres needed to provide HIV services. Countries have utilized different methods to increase their pool of skilled health care workers including task shifting where the delegation of tasks is moved,

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[56] *PEPFAR Human Resources for Health Strategy*, 2015, https://www.pepfar.gov/documents/organization/237389.pdf

where appropriate, to less specialized health workers. Task shifting from physician to nurse, as has been the case with nurse-initiated and managed ART care (NIMART), has expanded the role of nurses and increased availability of HIV services at facilities. In order to increase retention and to expand HIV services into communities closer to where people live, task shifting to lay cadres has strengthened the facility-community service delivery links.

With new service delivery models implemented, it is now necessary to create reliable systems of care that link a facility to its community. Clinical tasks, such as screening for TB or other diseases, and adherence monitoring of ART and therapy for TB disease or latent infection are critical for good patient care and will require special attention if they are shifted to the community. As tasks are shifted, it is paramount to have effective systems for preparing cadres for new tasks and to have ongoing support for maintaining high quality service delivery that extends into communities. In COP17, country teams should ensure that task shifting for both pediatric and adult treatment activities: are strategically implemented to avoid fragmented implementation of task shifting; systematically track progress of implementation; and consistently offer initial preparation (pre-service or in-service) for new tasks performed by receiving cadre and activities focused on ensuring quality.

**Creating Provider Care Teams and Networks**

Meeting the needs of PLHIV, their caregivers, and their family members requires the collective effort of many facilities and organizations, both clinic and community-based. It also requires appropriate policies, supportive social attitudes, and community support systems. Strengthening access to a range of HIV-related services for those in need and promoting communication among service providers requires a formalized referral network of providers including nurses, lay workers, and social service providers. This is even more important as service delivery is increasingly decentralized to the community level requiring increased communication and collaboration amongst providers at the facility and community level. In COP17 country teams should focus on ensuring these provider care teams and networks are established and well-functioning. As the clinical team continues expanding to include lay health workers and tasks are shared amongst all the available members of the clinical team, it is vital that ongoing support and mentorship are provided to all who are asked to take on additional responsibilities.

**Integrating Wellness/Stable Patient Delivery Systems**

The HIV epidemic has strained the healthcare system at all levels of care and with the continued implementation of Test and START, additional patients will burden healthcare systems. PEPFAR teams must now address how to best utilize limited human resources to increase coverage across the diverse epidemiologic and programmatic landscape. Innovative service delivery models providing wellness care for stable patients will help ensure they are retained and will help to decongest facilities. Some 80% of patients can follow less expensive, differentiated service delivery follow-up and yearly viral load tests. In COP17 country teams should focus on how health workers are being utilized and how to enable quality performance and productivity. This will require evaluating the number, location, types of health care workers available, and any gaps that need to be filled.

**Addressing HRH Retention**

PEPFAR has supported multiple interventions to address health worker shortages. Many countries fund salaries and remuneration of health workers to support immediate delivery of HIV services. Teams should track the level of these investments across sites and should also incorporate plans for transition to support retention of critical health worker posts. PEPFAR's extensive investments in re-service training have supported expansion of the health and social workforce, but it is both costly and time intensive. Given the level of investment, it is essential that newly minted workers are absorbed into the delivery system and efforts are in place to support their retention over time. In addition, with the introduction of community based service delivery models, lay cadres are becoming increasingly important. Retaining these workers will require special attention and focus to ensure they do not burn out, have opportunities for career growth, and receive adequate support from the facilities with which they are linked. In addition, as many of these cadres are not currently officially recognized by the health system, country teams should increase consideration for retention and sustainability of these cadres for HIV services in COP17.

## Appendix C.6.3 Country Examples of Priority Interventions

For a full list of country examples, please refer to the "Case Examples of Best Practices for PEPFAR Programs" document located in Appendix J.

**Task Shifting in Kenya**

A community-randomized control trial in Kenya evaluated the clinical outcomes of task shifting patient assessment and ART distribution from facility-based nurses and clinical officers/physicians to PLHIV trained as Community Care Coordinators (CCCs). The CCCs were trained to use Personal Digital Assistants (PDAs) to collect medical and psychosocial information during monthly home visits, and pre-programmed decision alerts triggered CCCs to either dispense a one-month pre-packaged ART supply or refer the patient to clinical care. The intervention group required half as many clinic visits as the control group and there were no significant differences in clinical and laboratory outcomes. Lessons learned for task shifting HIV care to lay persons include: 1) decide appropriate lay worker eligibility requirements considering the recruitment supply and intended role in the intervention; 2) determine adequate job aides to engage lay individuals in needed interventions while ensuring medical decisions are made by trained clinical providers; and 3) ensure effective linkages to facility-based clinical providers to guarantee coordinated care that is responsive to patient needs. As demonstrated by the study, task shifting to appropriately recruited and prepared community-based health or lay workers appears promising to expand coverage of ART treatment without compromising clinical outcomes[57].

**Creating provider care teams and networks in Uganda[58]**

At the Reach Out Mbuya Parish HIV/AIDS Initiative, an ART program in Kampala, Uganda, instead of increasing the staff to meet growing service demands and patient wait times, they reconfigured the work flow to increase efficiency. Over the course of 1 year, the clinic went from seeing 3,400 to 3,625 patients, with a higher proportion on ART (1951 to 2293), and nine clinicians at the start of the year to eight by the end (one nurse resigned and was not replaced). The total time all health workers spent with a single patient was cut in half. Provider teams who examine areas to increase productivity and revisit how patients move through services can create avenues for increases in care coverage.

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[57] Selke, H. M., Kimaiyo, S., Sidle, J. E., Vedanthan, R., Tierney, W. M., Shen, C., ... & Wools-Kaloustian, K. (2010). Task-shifting of antiretroviral delivery from health care workers to persons living with HIV/AIDS: clinical outcomes of a community-based program in Kenya. *JAIDS Journal of Acquired Immune Deficiency Syndromes*, *55*(4), 483-490.

[58] Alamo ST, Wagner GJ, Ouma J, et al. Strategies for Optimizing Clinic Efficiency in a Community-Based Antiretroviral Treatment Programme in Uganda. AIDS and behavior. 2013;17(1):10.1007/s10461-012-0199-9. doi:10.1007/s10461-012-01999. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3887144/

**Community health worker (CHW) support for PMTCT care and Early Infant Diagnosis in Malawi[59]**

Lay health workers are increasingly providing HIV testing services, client follow-up and tracing, and health education and counseling. The Tingathe program in Malawi evaluated enrollment of HIV-exposed infants, HIV-infected children, and pregnant women into HIV care during three phases of their program: Phase I: Clinical mentorship only (Tingathe-MO), Phase II: Clinical mentorship and CHW-delivered HIV testing and counseling (Tingathe-Basic), and Phase III: Tingathe-Basic plus CHW-delivered case management for pregnant women and mother-infant pairs in PMTCT (Tingathe-PMTCT). Providing CHW support for HIV testing and linkage to care [Phase II (Tingathe-Basic)] resulted in a six-fold increase in the average number of HIV-infected children enrolled per month when compared to clinical mentorship only [Phase I (Tingathe-MO)] (19.8 vs. 3.2 HIV-infected children enrolled per month). Providing CHW support of HIV-positive pregnant women from diagnosis at antenatal clinic through final HIV status determination for her infant [Phase III (Tingathe-PMTCT)] resulted in a seven-fold increase in the average number of HIV-exposed infants enrolled per month (from 9.5 to 70 patients per month) and younger median age at enrollment (from 5.2 to 2.5 months; $p<0.001$) in comparison to CHW support for HIV testing and counseling only (Tingathe-Basic). Lay health workers such as community health workers may provide valuable support for enrollment and retention in PMTCT services and linkage of HIC to care.

## Appendix C.6.4 The Role of Civil Society Organizations

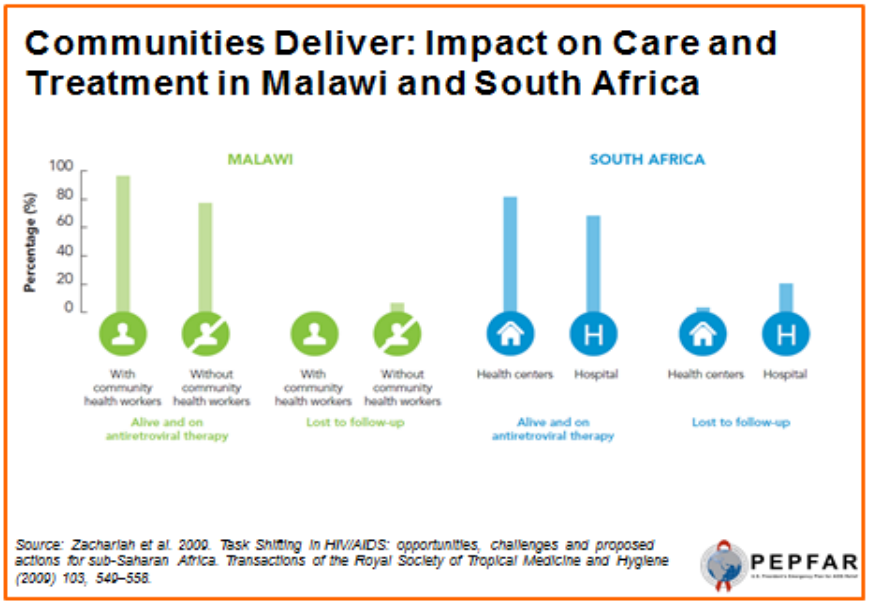
### Appendix C.6.4.1 Background

Throughout the HIV response civil society engagement has been an essential component for the delivery of effective HIV services. When public health systems struggled to address the spread of HIV, key population communities throughout the world have taken initiative to keep their communities healthy. Today we know that public sector responses to HIV cannot always provide

[59] Ahmed S, et al. Improved identification and enrolment into care of HIV-exposed and –infected infants and children following a community health worker intervention in Lilongwe, Malawi. JAIDS 2015, 18: 19305.

the continuum of care needed for all populations. In fact, investing in CSO empowerment is not only the right thing to do but makes good sense[60].

**Figure C.6.4.1.1**




For example, among sex workers (female, male and transgender), whose occupation and lived realities increase their likelihood of them living with HIV by 12-fold[61], strategies such as peer-led education and control of STIs are more effective and sustainable when conducted within a community empowerment framework. Consequently, community-led organizations of sex workers has resulted in improved reach, access, service quality, service uptake, condom use and engagement by sex workers in national policies and programs. Scaling up comprehensive, community empowerment-based HIV interventions helps prevent significant numbers of new HIV infections, particularly in settings with high rates of HIV.

Community empowerment is more than a set of activities; it is an approach that should be integrated into all aspects of health and HIV programming. It is the cornerstone of an inclusive and non-discriminatory approach to addressing HIV.

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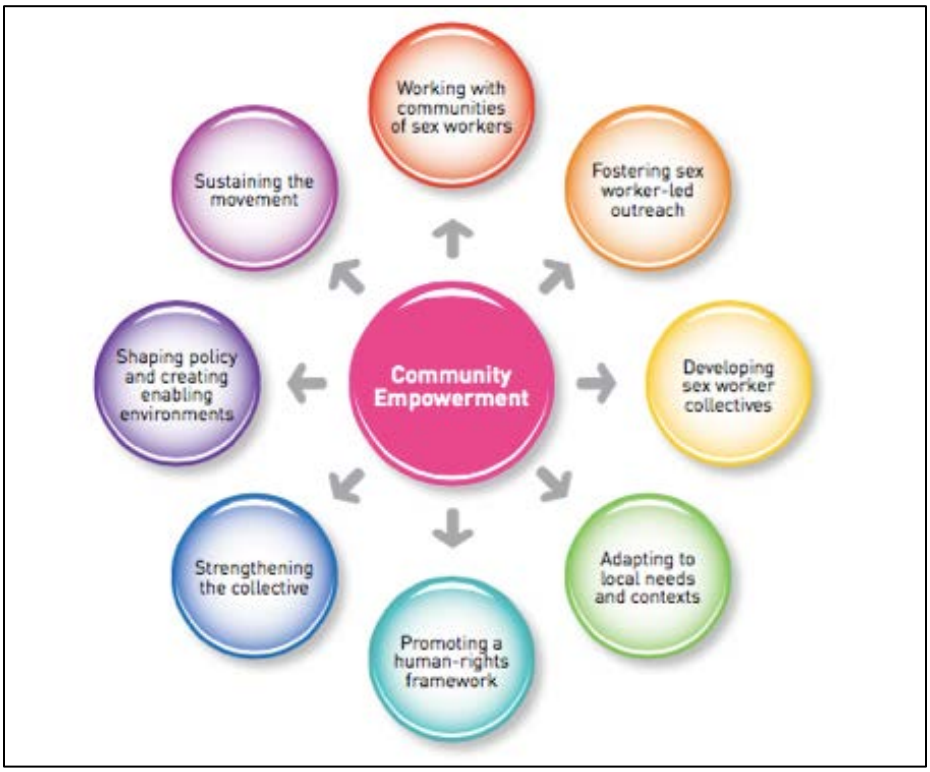
[60] World Health Organization, United Nations Population Fund, Joint United Nations Programme on HIV/AIDS, Global Network of Sex Work Projects, The World Bank. Implementing comprehensive HIV/STI programmes with sex workers: practical approaches from collaborative interventions. Geneva, World Health Organization, 2013.

[61] Baral, S et al (2012) Burden of HIV among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. The Lancet 12(17):538-549

**Figure C.6.4.1.2**




Community empowerment means (Figure C.6.4.1.2):

- Community members coming together for mutual assistance;
- Removing barriers to full participation, including travel allowances to attend meetings;
- Strengthening partnerships among community members, government, other civil society and local allies;
- Addressing collective needs in a supportive environment;
- Leading the process: Communities (especially key population communities) know best how to identify their priorities and the context-appropriate strategies to address those priorities;
- Meaningful participation of community CSOs in all aspects of program design, implementation, management and evaluation; and
- Providing money and resources directly to CSOs, which become responsible for determining priorities, activities, staffing, and the nature and content of service provision. Ultimately, CSOs may become the employers of relevant staff (doctors, nurses, social

workers, outreach workers), rather than community members being solely volunteers, community outreach workers or employees.

## Appendix C.6.4.2 Priority Strategies & Interventions for COP17

**Comprehensive Care**

While it is important that country teams work with communities to get people tested for HIV, testing alone is insufficient. For those who test negative and are at risk of infection, they must be engaged in preventive services. It is critical that those who test positive are linked to treatment, initiated on ART, and retained in treatment. Country teams can identify CSOs and community leaders to work with them to ensure that referral systems and adherence support are strong and address any barriers along the prevention or treatment clinical cascades.

**ARV Commodities**

Introduction of newer, more potent and less costly ART regimens, such as Dolutegravir (DTG) based regimens should be considered. DTG is now an alternative to Efavirenz (EFV) for first-line regimens for adults in the WHO guidelines; however, evidence gaps remain for persons with TB and pregnant women. Programs should consider timelines and steps to introduce new regimens, including the necessary regulatory approvals, updates to national guideline, ensuring drug availability from manufacturers.

Drug stock outs remain a key operational barrier in the delivery of effective HIV healthcare around the globe. The main consequences are unnecessary suffering, drug resistance, and, in the worst cases, death. In the long run, stock outs also reduce confidence and trust in communities which will negatively impact program support and referrals to services. By partnering with CSOs dedicated to the timely monitoring of stock levels and who can participate in quantification and forecasting exercises, country teams can ensure that stock outs are prevented or, at minimum, shortened in duration. Additionally, CSOs can be strong proponents of policy change toward multi-month scripting.

**Creating Provider Treatment Care Teams and Linking Community/Facility Providers**

Public health facilities are sometimes perceived as less welcoming to HIV affected communities and infected individuals. When CSOs twin with public health facilities, they can: Enhance the ability of health care workers to address the needs of these communities and individuals; bring additional knowledge and outreach resources to the facility; increase levels of accountability of

and trust in the public sector; mobilize their constituents to go to these facilities; and help make the facilities more welcoming and accessible to all. Public facilities can benefit from these twinning relationships by enhancing their HIV services, increasing demand for their services, and ultimately, improving the health of the community they serve.

## Appendix C.6.4.3 Country Examples of Priority Interventions

For a full list of country examples, please refer to the "Case Examples of Best Practices for PEPFAR Programs" document located in Appendix J.

**Partnering with Civil Society to Strengthen Stock Monitoring in Cameroon**

In Cameroon, PEPFAR through the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) project partnered with a local civil society organization called Positive Generation to enhance stock monitoring at facility level. Positive Generation has created a mechanism called Treatment Access Watch (TAW), where anonymous informers can report experiences accessing HIV services (HTC, CD4, and ARVs) in 71 health facilities.

In 2015 and 2016, SIAPS partnered with Positive Generation to monitor supply chain indicators (e.g. availability of ARVs, RTKs, and lab reagents for CD4) in order to increase transparency on information related to availability of HIV commodities at health facility level and overall improve patient outcomes. By comparing formal stock reports from health facilities with experiences reported through the TAW mechanism, PEPFAR Cameroon was able to develop a comprehensive picture on availability and accessibility of HIV/AIDS services and commodities and therefore develop remediation plans in cases of significant discrepancies. Through SIAPS organized regional meetings, Positive Generation presented findings affecting access to HIV treatment services to health facility managers resulting in price reductions in certain health facilities.

The outcome of this partnership resulted in the reduction of health facilities experiencing stock-outs due to close follow-up and technical assistance provided by PEPFAR. Furthermore, this improved knowledge and understanding of barriers identified by patients that helped prioritize governance and technical interventions

**Figure 6.4.3.1**: *Trend of stock out of ARVs as observed by SIAPS from 2014 to 2016*

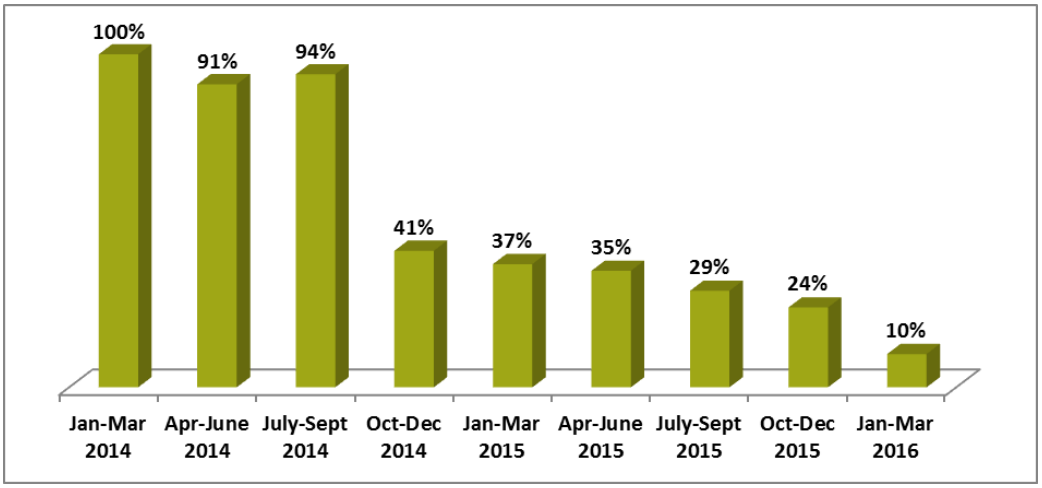
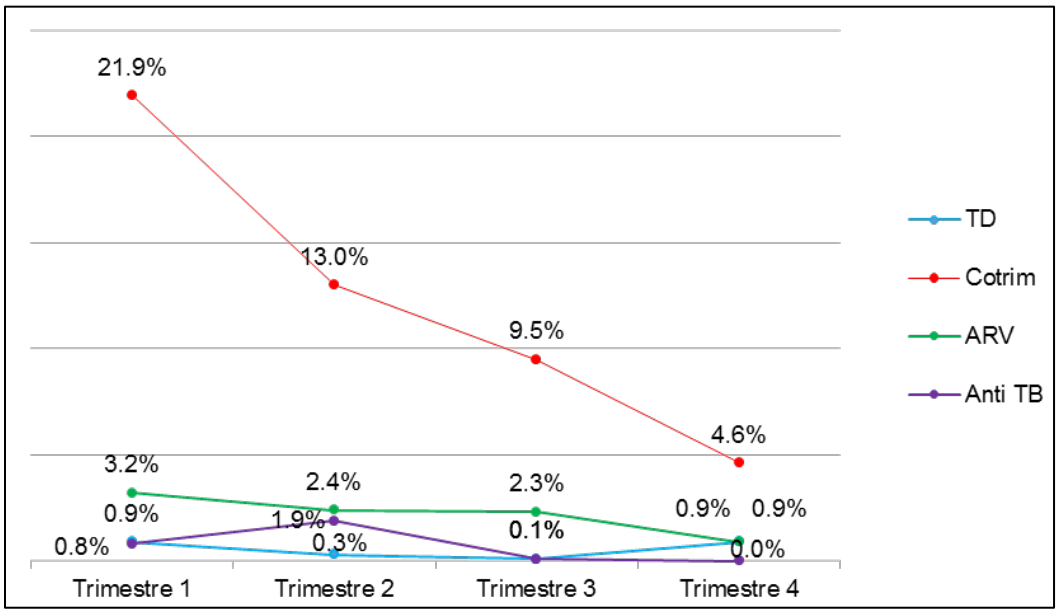



**Figure *6.4.3.2***: *Trend of Stock out of Rapid Test kits (TD), Cotrimazole (Cotrim), Antiretroverals (ARV) and Anti-tuberculosis medicines in 2015 as observed by Positive Generation*




## iMonitor+ in Indonesia

iMonitor+, developed by Dure Technologies, is a smartphone application that provides real-time data directly from grassroots communities and serves as a dynamic link between community members and project activities, empowering communities and driving public accountability. Whereas it has often proved difficult to create dialogue between members of targeted communities and project staff, iMonitor leverages technology to enable monitoring, recording and

reporting on the state of healthcare services by members of the public themselves, for instance a stock outage of ART medications at a clinic; instances of intimidation or violence; unsupportive health staff.

In Indonesia, iMonitor+ is being piloted by the Indonesian AIDS Coalition (IAC) and UNAIDS to conduct community-based logistics monitoring for stocks of ARV, condoms and lubricant, needles and methadone. The system is currently running in Bandung (West Java), Garut (West Java), Surabaya (East Java), and Jakarta, where there are approximately 90 registered users who send in reports if they encounter difficulty accessing services. The reports are fielded by specific "community champion" IAC staff who can serve to address, facilitate or investigate situations or escalate to appropriate agencies. The system has already seen preliminary successes such as identifying stock-outs at the clinic level which were not reflected in the national logistics monitoring system. Based on these successes, iMonitor+ has been adopted by the MOH and National AIDS Commission and has been included as one of the activities in the 2015-2019 Indonesia National HIV Prevention Strategy.

## Appendix C.6.5 Stigma, Discrimination, Violence, and Human Rights

### Appendix C.6.5.1 Background

Reaching the goal of an AIDS Free Generation not only requires robust clinical interventions, but simultaneously requires addressing social, cultural, legal, and policy barriers that result in hostile environments creating barriers to equal access to health services for all people living with and affected by HIV. This requires not only the training of those at all levels of service delivery to reduce stigma and discrimination but also strengthening the capacity of civil society organizations, engaging host country governments, and working in concert with our multilateral and other bilateral partners to advance an enabling environment. Further, the Greater Involvement of People Living with and affected by HIV (GIPA) principle have been effective in the US response to HIV and PEPFAR implementing agencies are encouraged to incorporate GIPA principles into their project design, management, evaluation, and country engagement and sustainability strategies. PEPFAR is committed to supporting a focused programmatic response that reduces structural barriers and demonstrates increased access to justice, reduced stigma and discrimination and improved satisfaction with the quality and appropriateness of HIV services. Throughout all of our programs, PEPFAR is committed to ensuring that grantees

receiving PEPFAR funds implement their programs in a way that supports promotion, protection, and respect for human rights.

Stigma is a social process that occurs within the context of power and undermines three key determinates of health: access to resources, access to social support, and psychological and behavioral responses. UNAIDS defines discrimination as any form of arbitrary distinction, exclusion or restriction affecting a person, usually (but not only) because of an inherent personal characteristic or perceived membership of a particular group. In the case of HIV, this can be a person's confirmed or suspected HIV-positive status, irrespective of whether or not there is any justification for these measures. Discrimination is the unfair and unjust action toward an individual or group on the basis of real or perceived status or attributes. Discrimination is often considered something that is legally actionable while enacted stigma may not be legally actionable.

Within the PEPFAR human rights action agenda and the frameworks of the Sustainable Development Goals (SDGs), we strive to reach all affected populations with core HIV services without discrimination, even when facing difficult cultural contexts, severe stigma, or challenging security environments. SDG 5 (Gender Equality), SDG 10 (Reduced Inequalities), and SDG 16 (Peace, Justice and Strong Institutions) provide PEPFAR with important frameworks to mitigate stigma, discrimination, and violence and advance human rights. The guiding principles of respecting and promoting human rights should be part of all PEPFAR programming.

Stigma, discrimination, and violence as well as harmful laws and policies reduce access to and use of essential health services and undermine efforts towards effective responses to HIV/AIDS. PEPFAR is committed to joining others to end stigma, discrimination, and violence and increasing access to, and uptake of, HIV prevention, treatment, and care services for all people infected and affected by HIV/AIDS, including: vulnerable and key populations such as men who have sex with men (MSM), transgender persons, sex workers, people who inject drugs and people in prisons and other closed settings , and individuals who serve those who are infected and affected (i.e. health care workers who experience secondary stigma because of their work). Research in the stigmatization process has identified specific domains and note that specific interventions have been developed to tackle them including:

(1) Drivers: Individual-level factors including lack of awareness; fear of infection; prejudice and stereotypes towards PLHIV and people at high risk of HIV infection;

(2) Facilitators: Societal-level factors including protective or punitive laws; redress availability; structural barriers at the public policy level' gender and cultural norms; availability of supports for those who experience the manifestation of stigma;

(3) Intersecting stigmas (also called layered or compound stigma): Refers to multiple stigmas that people face due to HIV status, gender, profession, migrancy, drug use, poverty, marital status, sexual and gender orientation; and

(4) Manifestations of stigma: The immediate results of stigma being applied to individuals or groups including: i) Anticipated stigma (fear of experiencing stigma if HIV status is known); ii) Perceived stigma (perceptions about how PLHIV are treated); iii) Internalized stigma; iv) Shame; v) Experienced or enacted stigma (experiencing stigma outside the law); vi) Discrimination (experiencing stigma within the law); vii) Resilience (ability to overcome threats to health after stigma is experienced

**Figure C.6.5.2.1**

| Name of Scale | Author of scale and reference | Type of stigma measured | Population |
|---|---|---|---|
| Parallel Scales to measure Stigma | Visser, M.J., Kershaw, T., Makin, J.D., & Forsyth, B.W.C. (2008). Development of parallel scales to measure HIV-related stigma. AIDS Behav, 12(5): 759-771 | Three Scales:<br>- Personal views of stigma (for general population and PLHIV)<br>- Stigma attributed to others (general population and PLHIV)<br>- Internalized stigma (PLHIV) | General population and PLHIV |
| HIV/AIDS Related Stigma | Genberg, B.L., Kawachai, S., Chingono, A. et al. (2008) Assessing HIV/AIDS stigma and discrimination in developing countries. AIDS Behav. 12:772-780. | Three subscales:<br>- Shame, blame, & social isolation<br>- Perceived discrimination<br>- Equity | General population |

# Appendix C.6.5.3 Country Examples of Priority Interventions

## Positive Health Dignity and Prevention (PHDP) in Jamaica

The Jamaican Network of Seropositives (JN+)—with support from the Jamaican Ministry of Health's National HIV/STI Program (GIPA Unit) and the USAID- and PEPFAR-funded Health Policy Project—created a capacity-building curriculum led by people living with HIV (PLHIV). The curriculum aims to implement and advocate for Positive Health, Dignity, and Prevention (PHDP) and promote community leadership at the country level. PHDP—a global policy framework authored by the Global Network of People Living with HIV (GNP+) and UNAIDS in 2011—advances a holistic framework for PLHIV to manage their health, advocate for high-quality HIV services, and prevent onward HIV transmission. PHDP provides a concrete framework and road map that is especially relevant to meeting current global and national care and treatment goals for HIV—and to making combination prevention a reality. The Jamaican curriculum is adaptable across countries and provides an easy-to-use set of resources (combining structure and flexibility) that permit PLHIV to adapt PHDP to specific communities and stakeholders.

## Providing Key Population-Friendly Services: A Sensitivity Training for Health Care Workers (HCWs)

Despite recent progress in scaling HIV programming for key populations (KP) in PEPFAR, high HIV prevalence and low HIV service utilization among most KP persist. Perceived stigma from health care workers, discrimination within health care settings, and receipt of services that are unresponsive to their unique needs are commonly reported barriers to HIV care among KP. KPs report fear of seeking care, avoiding care, and poor treatment after disclosing behaviors to HCWs. This training was developed to enable HCWs to provide HIV testing, treatment, and related HIV services to all clients, particularly KPs, in a competent and non-stigmatizing manner, thereby reducing barriers to care for KPs. HCWs who currently provide clinical- or community-based HIV and related services (e.g. STI, TB, family planning), and all staff members working in the settings, are encouraged to participate to create a friendlier, more accepting environment for all clients. The 10-hour training has been conducted in 10 OUs, all providing positive feedback on its utility and future use. Recent examples include: Rwanda MOH's adoption into their national training curriculum resulting in over 100 HCWs trained across 50 facilities; and in Zambia a training of trainers (ToT) was conducted for 28 providers who will go on to disseminate the training for additional HCWs. Training materials are available to interested field teams and partners, can be adapted to fit context-specific needs (e.g. addresses relevant KP groups and

stigmatizing views), and can be delivered directly to HCWs or as a ToT to capacitate cadres of trainers. An evaluation of the training is currently underway in Burma to assess effect on service uptake and acceptability by KPs and HCW knowledge and acceptability of providing services to KPs. All materials are currently available in English, French, and Spanish, with Portuguese and Russian pending..

**Ensuring Key Population Friendly Services through LINKAGES in Kenya**

Kenya has some of the most advanced key population programming in the world, including work with KP peers to detect violence and provide crisis assistance in the case of violence. LINKAGES conducted a gender analysis in Kenya regarding access to HIV services that meet KP community members' needs and learned that health care workers (HCWs) involved in HIV prevention, care and treatment for KPs did not consider violence detection or response to be part of their remit. The gender analysis also found that KP community members wanted violence detection and response to be part of the care offered through HIV testing, care and treatment. As a result of these findings, NASCOP requested that LINKAGES provide training in violence detection and response to HCWs using a curriculum developed by the LINKAGES Project. This curriculum was subsequently adapted and adopted as part of the national trainings for HCWs that serve KPs across Kenya. The training is being rolled out under NASCOP's National Advocacy Strategy to Address Barriers to Access to Services for Key Populations in Kenya (October 2016 – September 2017).

# Appendix C.7 Summary

PEPFAR, in collaboration with host governments, communities, multilateral organizations, and other global organizations, has made substantial achievements in combatting the global HIV/AIDS epidemic. The PEPFAR program has used data to focus efforts on geographic areas with the highest prevalence and incidence of infection. Now additional focus is required on testing, prevention, and treatment for young people and key populations to reach the 90-90-90 goals and turn the tide on the epidemic. Testing strategies must be honed based on program data, and innovative service delivery models used to maximize retention and viral suppression. Increased engagement of communities and civil society will promote improved quality of care and sustainability of the response. Together, we must work to end the epidemic.

# Appendix C.8 New Guidelines about Technical Updates

For more country examples on the interventions detailed in the COP17 Technical Considerations, see Appendix J.

1. WHO Guidelines and Updates:
    a. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Recommendations for a public health approach – Second edition http://www.who.int/hiv/pub/arv/arv-2016/en/
    b. Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV http://apps.who.int/iris/bitstream/10665/186275/1/9789241509565_eng.pdf.
        i. Please note that implementation of birth testing for HIV -exposed infants is included here as a conditional recommendation. Birth testing is not supported by PEPFAR unless testing rates at 4-6 weeks exceed 80% of PMTCT_STAT_POS and appropriate drugs are available for treatment of neonates identified as positive for HIV infection.
    c. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations 2016 update http://www.who.int/hiv/pub/guidelines/keypopulations-2016/en/
    d. WHO 2015 Consolidated guidelines on HIV testing services http://apps.who.int/iris/bitstream/10665/179870/1/9789241508926_eng.pdf?ua=1
    e. WHO Links to HIV Self-Testing Guidelines & Policy Briefs: http://www.who.int/hiv/pub/vct/hiv-self-testing-guidelines/en/
    f. Expert opinions on new guidelines: http://www.who.int/hiv/mediacentre/news/hiv-self-testing-guidelines-quotes/en/
    g. HIV Self Testing Infographics: http://www.who.int/campaigns/aids-day/2016/infographics/en/
    h. WHO's Q&A video on HIV self-testing : https://www.youtube.com/watch?v=BA5E9wsEbPw
    i. Improving the quality of HIV-related point-of-care testing: ensuring the reliability and accuracy of test results Handbook WHO http://apps.who.int/iris/bitstream/10665/199799/1/9789241508179_eng.pdf

j. Handbook for improving HIV testing and counselling services
http://whqlibdoc.who.int/publications/2010/9789241500463_eng.pdf

k. WHO Global examples of HTS
http://apps.who.int/iris/bitstream/10665/180212/1/WHO_HIV_2015.22_eng.pdf

l. Landscape for HIV rapid diagnostic tests for HIV self-testing - Second edition
http://unitaid.org/images/marketdynamics/publications/UNITAID_HIV_rapid_diagnostic_tests_for_self-testing.pdf

m. HIV and adolescents: Guidance for HIV testing and counselling and care for adolescents living with HIV. Guidance document
http://www.who.int/hiv/pub/guidelines/adolescents/en/

n. Global tuberculosis report 2016
http://www.who.int/tb/publications/global_report/en/

o. Intensified tuberculosis case-finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings. WHO guidelines 2011
http://www.who.int/hiv/pub/tb/9789241500708/en/

p. Recommendation on 36 months isoniazid preventative therapy to adults and adolescents living with HIV in resource-constrained and high TB and HIV-prevalence settings: 2015 update
http://www.who.int/tb/publications/2015_ipt_update/en/

q. Algorithm for managing people living with HIV who are suspected of having TB (ambulatory)
http://www.who.int/tb/areas-of-work/tb-hiv/algorithms_for_diagnosis_and_management_of_hiv-associated_tb.pdf

r. Technical and operational considerations for implementing HIV viral load testing: Interim technical update
http://www.who.int/hiv/pub/arv/viral-load-testing-technical-update/en/

s. Male circumcision for HIV prevention: WHO informal consultation on tetanus and voluntary medical male circumcision. Meeting report
http://apps.who.int/iris/bitstream/10665/181812/1/9789241509237_eng.pdf?ua=1&ua=1

t. Tetanus and voluntary medical male circumcision: risk to circumcision method and risk mitigation. Report of the WHO Technical Advisory Group on Innovations in Male Circumcision – consultative review of additional information, 12 August 2016
http://apps.who.int/iris/bitstream/10665/250146/1/WHO-HIV-2016.19-eng.pdf

2. MSF Guidelines and Updates:
    a. Making Viral Load Routine: Successes and challenges in the implementation of routine HIV viral load monitoring http://www.msfaccess.org/content/report-making-viral-load-routine
3. Additional References for Key Populations:
    a. Implementing Comprehensive HIV and STI Programmes with Transgender People: Practical Guidance for Collaborative Interventions (TRANSIT) http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/implementing-comprehensivehiv-and-sti-programmes-with-transgend.html
    b. Implementing Comprehensive HIV and STI Programmes with Men Who Have Sex with Men (MSMIT) http://www.unfpa.org/publications/implementing-comprehensive-hiv-and-stiprogrammes-men-who-have-sex-men
    c. Implementing comprehensive HIV/STI Programmes with sex workers: practical approaches from collaborative interventions (SWIT) http://www.who.int/hiv/pub/sti/sex_worker_implementation/en/
    d. Measuring HIV Stigma and Discrimination Among Health Facility Staff
    e. Integrating collaborative TB and HIV services within a comprehensive package of care for people who inject drugs. Consolidated guidelines, 2016. http://www.who.int/tb/publications/integrating-collaborative-tb-and-hiv_services_for_pwid/en/
    f. Services for people in prisons and other closed settings. http://www.unaids.org/sites/default/files/media_asset/2014_guidance_servicesprisonsettings_en.pdf
    g. HIV prevention, treatment and care in prisons and other closed settings: a comprehensive package of interventions. http://www.unodc.org/documents/hiv-aids/HIV_comprehensive_package_prison_2013_eBook.pdf
    h. PLHIV Stigma Index (will be available in December 2017)
    i. PEPFAR Environmental Scan (in process)

4. Additional References:

a. Suthar et al. 2013 Towards Universal Voluntary HIV Testing and Counselling: A Systematic Review and Meta-Analysis of Community-Based Approaches http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001496
b. Nelson et al. 2016. Low prevalence of false prior HIV diagnoses in Chokwe District, Mozambique. *CROI 2016 Abstract 516* http://www.croiconference.org/sessions/low-prevalence-false-prior-hiv-diagnoses-chokwe-district-mozambique
c. PLOS Collection: Voluntary Medical Male Circumcision for HIV Prevention: New Mathematical Models for Prioritizing Sub-Populations by Age and Geography http://collections.plos.org/vmmc2016
d. "An innovation in public health: devices for voluntary medical male circumcision" JAIDS http://journals.lww.com/jaids/toc/2016/06011
e. "Interventions to drive uptake of voluntary medical male circumcision" JAIDS http://journals.lww.com/jaids/toc/2016/10012
f. DoD HIV/AIDS Prevention Program Guidance for Targeting Military Populations Pepfar.net
g. COP17 Policy Brief: Condom Commodity Fund for Procurement of Male and Female Condoms and Lubricants Pepfar.net
h. Condom and lubricant programming in high HIV prevalence countries http://www.unaids.org/sites/default/files/media_asset/condoms_guidancenote_en.pdf
i. HIV prevention among adolescent girls and young women http://www.unaids.org/sites/default/files/media_asset/UNAIDS_HIV_prevention_among_adolescent_girls_and_young_women.pdf
j. Fast-Tracking Combination Prevention
k. http://www.unaids.org/sites/default/files/media_asset/20151019_JC2766_Fast-tracking_combination_prevention.pdfPEPFAR_Human_Resources_for_Health_Strategy https://www.pepfar.gov/documents/organization/237389.pdf
l. Operational Policy for TB Preventive Therapy for People Living with HIV in PEPFAR-Supported Programs: PEPFAR Operational Policy for TB Prevention

# Appendix C.9 Program Quality and TWG Contacts

| TWG Co-Chairs & Ex Officios | | | |
|---|---|---|---|
| **TWG** | **Co-Chair Name** | **Agency** | **Email** |
| Care and Treatment | Tedd Ellerbrock | CDC | tve1@cdc.gov |
| | Tom Minior | USAID | tminior@usaid.gov |
| S/GAC Ex-Officio | Suzy Jed | | Sjed@hrsa.gov |
| | Sean Cavanaugh | | hgi7@cdc.gov |
| Commodities | Bill Coggin | CDC | Wlc1@cdc.gov |
| | John Crowley | USAID | jcrowley@usaid.gov |
| S/GAC Ex Officio | George Siberry | | SiberryGK@state.gov |
| Finance & Economics | Elan Reuben | USAID | ereuben@usaid.gov |
| | Nalinee Sangrujee | CDC | nks9@cdc.gov |
| S/GAC Ex Officio | Kate Bistline | | bistlineks@state.gov |
| Gender & Adolescent Girls | Janet Saul | CDC | jsh3@cdc.gov |
| | Amelia Peltz | USAID | apeltz@usaid.gov |
| S/GAC Ex-Officio | Nora Toiv | | ToivN@state.gov |
| HIS and M&E | John Aberle Grasse | CDC | joa7@cdc.gov |
| | Rachel Lucas | USAID | rlucas@usaid.gov |
| S/GAC Ex-Officio | Mark DeZalia | | mvd5@cdc.gov |
| HRH | Diana Frymus | USAID | dfrymus@usaid.gov |
| | Cate McKinney | CDC | ckm6@cdc.gov |
| S/GAC Ex-Officio | Adrienne Hurst | | ahurst@usaid.gov |
| HTS and Linkages | Vincent Wong | USAID | vwong@usaid.gov |
| | Margo Sloan | DOD | margo.l.sloan.ctr@mail.mil |
| S/GAC Ex Officio | Mike Grillo | | michael.p.grillo2.civ@mail.mil |
| Key Populations | Sasha Mital | CDC | ggu4@cdc.gov |
| | Tisha Wheeler | USAID | twheeler@usaid.gov |

| TWG Co-Chairs & Ex Officios (continued) | | | |
|---|---|---|---|
| **TWG** | **Co-Chair Name** | **Agency** | **Email** |
| S/GAC Ex Officio | Kent Klindera | | kklindera@usaid.gov |
| Lab | Joel Kuritsky | USAID | jkuritsky@usaid.gov |
| | Heather Alexander | CDC | drz5@cdc.gov |
| S/GAC Ex-Officio | George Alemnji | | ikv3@cdc.gov |
| OVC | Maury Mendenhall | USAID | mmendenhall@usaid.gov |
| | Molly Rivadeneira | CDC | ehr3@cdc.gov |
| S/GAC Ex-Officio | Gretchen Bachman | | gbachman@usaid.gov |
| Pediatrics and Adolescents | Anouk Amzel | USAID | aamzel@usaid.gov |
| | Laura Broyles | CDC | zjt5@cdc.gov |
| S/GAC Ex-Officio | George Siberry | | SiberryGK@state.gov |
| Pregnant & Breast Feeding Women | Surbhi Modi | CDC | bkt1@cdc.gov |
| | Ryan Phelps | USAID | bphelps@usaid.gov |
| S/GAC Ex-Officio | Heather Watts | | wattsdh@state.gov |
| Prevention | Tim Mah | USAID | tmah@usaid.gov |
| | Linda Wright-DeAguero | CDC | Lkw1@cdc.gov |
| S/GAC Ex-Officio | Anne Sanicki | | sanickia@state.gov |
| Surveys & Surveillance | Noah Bartlett | USAID | nbartlett@usaid.gov |
| | Mahesh Swaminathan | CDC | mswaminathan@cdc.gov |
| S/GAC Ex-Officio | Parviez Hosseini | | HosseiniPR@state.gov |
| Sustainability | Jin Park | OGA/HHS | Jin.Park@hhs.gov |
| | Debbie Kaliel | USAID | dkaliel@usaid.gov |
| S/GAC Ex-Officio | Janis Timberlake | | timberlakej@state.gov |
| VMMC | Naomi Bock | CDC | Neb2@cdc.gov |
| | Anne Thomas | DOD | Anne.g.thomas.ctr@mail.mil |
| S/GAC Ex-Officio | Renee Ridzon | | reneeridzon@gmail.com |
| OTHER | | | |
| Private Sector Interest Group | Jeff Blander | SGAC | blanderjm@state.gov |

# Appendix C.10 PEPFAR Combination Prevention Trials Technical Consultation: Meeting Summary

**Background**

On January 11 2017, S/GAC hosted a one-day, technical consultation with the principal investigators of three, multi-million dollar combination prevention trials that together seek to test the impact of packages of interventions to avert new HIV infections in Sub-Saharan Africa. The goal of the meeting was to facilitate the rapid transfer of lessons learned that address high priority, implementation challenges to accelerating epidemic control in countries supported by PEPFAR, *especially HIV case finding in men and men and women under 30 years old*. This summary highlights research-informed strategies to close gaps in the HIV prevention - treatment continuum, including HIV testing, linkage to HIV medical care and rapid initiation of antiretroviral treatment (ART), retention and re-engagement in medical care, and achievement of virologic suppression. A final segment highlighted opportunities for establishing effective models of integrated, health services and complements other examples in the COP 17 Technical Considerations.

**HIV Prevention and Testing**

The studies endeavored to address challenges to reaching the first target of the UNAIDS 90/90/90 strategy – viz., achieving 90% awareness of HIV diagnosis in all persons living with HIV infection (PLHIV). In addition to innovations in HIV case finding, investigators were asked to describe lessons for linking people to prevention services (e.g., voluntary medical male circumcision [VMMC]). Although each of the trials demonstrates progress toward achieving a 90% diagnosis rate in PLHIV, tremendous challenges remain in terms of age- and sex-related disparities in HIV testing (**see Figures C.10.1 andC.10. 2**) and awareness of infection (**see Figure C.10.3**). Specifically, higher rates of undiagnosed HIV infection were reported in adolescents and adults 30 years or younger (**see Figures C.10.4 and C.10.5**), mobile and urbanizing subsets of the population, and employed men with non-traditional hours (e.g., taxi drivers, fishermen; **see Figure C.10.6**).

Promising strategies for improving HIV testing and linkage to prevention services for those underserved groups included:

Men and internal migration

- Instituting year-round, continuous HIV testing campaigns in communities with seasonal or other sources of churn within the population associated with mobility and in or out migration.
- Extending clinic hours to increase service availability to early morning, evening hours, or weekend access.
- Bundling HIV testing services into multi-disease community programming or clinic services (e.g., urgent care tents, safe zones for youth) that may better meet the needs of hard to reach subsets of the population who may underutilize HIV prevention and treatment services.
- Increasing work place HIV testing and prevention and encouraging self- and index-partner testing for HIV infection.
- Collaborating with communities and local government leaders to design health campaigns informed by implicit knowledge of community needs and motivations for care seeking behaviors (e.g., screening for hypertension or diabetes in men).

Youth and young men and women

- Routinizing HIV testing in outpatient clinical care, particularly in high prevalence areas, and establishing age-appropriate and sensitive school-based (or proximal) services for adolescents and young adults.
- Optimizing community health worker outreach to provide both HIV testing as well as active referral to other health services, including sexual and reproductive health, condoms, antenatal care access, and voluntary medical male circumcision (VMMC).
- Utilizing age-tailored strategies such as social activities or specific training for community health work that may assist in reaching and testing adolescents.
- Providing transportation services to increase the number of men accepting referrals to existing VMMC services.

**Linkage and ART Initiation**

The studies also explored strategies for expediting linkage to HIV medical treatment and initiation of ART in order to achieve the second target of the UNAIDS 90/90/90 strategy – viz., ensuring that 90% of all persons with diagnosed HIV infection are on ART regardless of CD4 count. Barriers to successful linkage and immediate treatment initiation in the CPTs were common and included such factors as: limited access to same-day ART initiation services (**see Figures C.10.7 ; C.10.8; and C.10.9**); lack of co-located testing and treatment sites; persistent disparities by age and sex (**see Figures C.10.10 and C.10.11**), marital status, education, and employment in ART

initiation, even when eligible; and HIV-associated stigma and discrimination associated with clinics, clinic staff beliefs and attitudes, and treatment access. A consistent finding is that the attrition or loss-to-follow-up (LTFU) increased in proportion to the delay in successful linkage to HIV medical treatment.

Promising strategies, based on documented increases in linkage and ART initiation, include:

- Implementing change management processes that include provider and clinic staff training about universal treatment guidelines, maintaining a patient-centered practice, importance and meaning of undetectable VL and reducing barriers to engagement and retention in treatment.
- Initiating same-day ART initiation can have a dramatic effect on clinical outcomes; policy adoption of same day initiation and scale up should be an urgent priority.
- Allowing community health workers to distribute ART starter packs to the community newly diagnosed clients or for treatment to be initiated immediately following an HIV diagnoses without waiting for the return of initial labs improved treatment outcomes.
- Eliminating or minimizing lab testing (and repeat visits to obtain lab results) prior to ART initiation reduced delay and loss-to-follow-up, as directed by the latest treatment guidance.[62]
- Implementing fast-track strategies for newly diagnosed patients that ensure immediate linkage and treatment initiation (e.g., RapIT[63], RAPID[64]).
- Streamlining clinic operations to minimize wait times, improving training and supervision with all staff to identify and remediate discriminatory behaviors by any member of clinic staff, and establishing a welcoming environment and a warm handoff between testers and clinic staff, particularly for underserved groups (e.g., youth, men) may increase retention and treatment outcomes.
- Acknowledging that most PLHIV link successfully to medical care with minimal intervention and linkage services should meet the level of need, starting with the least to most intensive strategies.
- Utilizing ART initiation as an opportunity to facilitate disclosure and encourage index partner testing.

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[62] https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0/

[63] http://www.croiconference.org/sessions/rapid-art-initiation-reduces-loss-between-hiv-testing-and-treatment-rapit-trial

[64] http://www.aidsmap.com/Same-day-start-to-antiretroviral-treatment-leads-to-faster-HIV-suppression-in-San-Francisco/page/2987355/

- Addressing treatment support needs, particularly for underserved groups, including transportation vouchers, hotlines for questions and missed appointments.

**Retention, Re-engagement, and Virologic Suppression**

The studies also sought to improve retention and re-engagement in care, and achieving virologic suppression in order to achieve the third target of the UNAIDS 90/90/90 strategy – i.e., achieving viral suppression in 90% of all persons on ART. Although each of the CPTs has demonstrated that high rates of retention on ART and virologic suppression are feasible (**see Figures 12 - 15**) and lead to favorable patient outcomes, considerable health system and other challenges remain. As noted, many priority subnational units are characterized by high rates of mobility and unrecognized patient transfers to health facilities in nearby areas, both of which may increase apparent attrition rates. Other known challenges include disparities in retention by age, sex, and education; suboptimal clinic operations and workflows; higher rates of viremia in men; young adults; and reaching post-partum women. In the context of test and start policy, the lack of virologic control at the population level is due to undiagnosed HIV infection in the population, not treatment failure.

Several promising strategies were discussed that included:

- Prioritizing training of all clinic staff to ensure that comprehensive understandings of the benefits of ART, importance and meaning of viral load monitoring, and benefits of adhering to medications and clinic appointments.
- Reviewing retention data and problem-solving with community health workers and clinic staff helps to identify LFTU and initiate tiered tracking and re-engagement services.
- Providing active outreach immediately following or within one week of missed appointments improves retention.
- Integrating HIV treatment into a health center and wellness approach, where patients benefit from medical care that goes beyond HIV alone.
- Implementing alternative service delivery models that meet the needs of patient populations, including home ART delivery, adherence clubs, six month ART supplies, decongested clinics, extended hours, and bundled health services provision.
- Establishing a chronic care model that addresses both HIV and key non-communicable diseases to increase the efficiency of patient visits, improve patient satisfaction, provide additional supports (e.g., transport vouchers, telephone hotline, SMS reminders) lowers barriers to adherence and viral suppression.

- Streamlining viral load monitoring, including less frequent monitoring for stable patients, prioritizing the return of lab results by priority population (e.g., young men and women) or viremic control (e.g., un/suppressed) and initiating a rapid response mechanism to engage those not fully suppressed.
- Facilitating timely provision of viral load results and viral load counseling provides a tool for adherence assessment and retention support.
- Permitting task-shifting of critical adherence, counseling, and retention support services to community cadres in order to reserve provider resources for more patients with more acute needs.
- Developing an acceptable, confidential system for tracking retention if electronic health records are unavailable, such as the use of finger-coding technology, and then accelerate follow-up within one week of a missed appointment.

**Service Integration for Epidemic Control**

The final session for the meeting explored models for integrating health services for common HIV-comorbidities, including non-communicable diseases (NCDs; e.g., hypertension and other cardiovascular disease, diabetes, cervical cancer), mental health and alcohol use disorders, and other communicable diseases (e.g., sexually transmitted infections, tuberculosis (TB)). BCPP integrated site support and community liaisons into the clinics to enhance data tracking and increase community engagement. The trial also introduced rapid HIV testing counselors (RHT) into the ANC, TB and STI clinical settings resulting in a doubling in the number of HIV tests administered. PopART endorses the use of CHWs as critical components of successful multi-service integration, as they can offer services to include concurrent HIV testing with TB screening, STI and PMTCT screening during home visits and referral to local clinics for confirmatory testing and subsequent treatment if results were positive. Trial investigators also stressed the cost-effectiveness of a CHIPs model. With input from community members and leaders, country advisory boards and the NCD MoH, SEARCH increased the number of services offered at community health campaigns for multiple diseases. These services included those pertaining to men's health, urgent care, TB and diabetes testing, VMMC, reproductive health (RH) and cervical cancer screening. Such approaches were popular with community leaders and men, and very well accepted. Some of the final comments from members of SEARCH include that successful elimination of HIV requires higher-quality care by integrating HIV services into TB, family planning, NCD services, STI screening and other programs. HIV and TB program integration is especially important, as TB is the most common cause of mortality in HIV-infected

persons. Members also suggested an increased public health focus on mental health. Service integration can improve care and reduce missed opportunities for key interventions such as HIV testing, provision of ART and adherence support.

**Summary**

Findings from the three CPTs presented at the meeting offer important lessons for accelerating HIV epidemic control by addressing gaps in the HIV prevention-treatment continuum. Priorities for program implementation and ongoing research include strategies to reach adolescents and adults under age 30 with prevention, testing and linkage services as well as to reach other sub-populations left behind. Same-day ART initiation, which yields tremendous clinical and public health benefit and minimizes costs associated with tracking and re-engagement, must be prioritized. Moreover, expanded use of differentiated treatment and alternative service delivery models may help to focus finite clinical and personnel resources where they are needed most and harness innovative, community-driven approaches to reducing community viral loads. Given high LTFU rates, attention to clinic environments is clearly indicated in order to minimize stigmatizing and discriminatory behaviors by any clinic staff, streamline operations, and provide greater flexibility in meeting the needs of underserved subsets of the population. More data are needed on strategies to reach and retain young men and to address mental health and substance use (especially alcohol). Programs should not miss opportunities to link persons testing negative to prevention interventions including VMMC and PrEP for persons at high risk. Taken together, these and other innovations suggest approaches for PEPFAR-supported country programs that may accelerate achievement of the 90/90/90 targets for both sexes and all age-bands.

**Background – Combination Prevention Trial (CPT) Studies**

Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART; HIV Prevention Trials Network Protocol 071) is a three-arm, cluster-randomized trial implemented in 21 communities in Zambia and South Africa. The primary objective of the study is to measure the impact of the two intervention packages on HIV incidence by enrolling and following a random sample of adults in the trial communities for 3 years. The Botswana Combination Prevention Project (BCPP) is an unprecedented collaboration between the Botswana Ministry of Health, U.S. and Botswana Centers for Disease Control and Prevention, local implementing partners, Botswana Harvard AIDS Institute Partnership and the Harvard School of Public Health. The over-arching goal of this pair-matched community-randomized trial is to implement the combination

prevention intervention package in combination prevention communities and describe uptake of these interventions (expanded HIV Testing and Counseling, strengthened Male Circumcision, expanded HIV Care and Treatment, and strengthened PMTCT services), which will be completed over the course of approximately 4 years. The Sustainable East Africa Research in Community Health (SEARCH) is a cluster randomized community trial aimed to quantify the health, economic and educational impact of a) early HIV diagnosis and immediate ART using a streamlined care delivery system in rural communities in Kenya and Uganda (Phase I) and b) targeted Pre-Exposure Prophylaxis (PrEP), targeted HIV testing and targeted care interventions on top of universal treatment and streamlined care (Phase II). The study intervention is designed to improve the entire continuum of care, to reduce structural barriers for all populations including those most “at risk” and build upon evidence based prevention interventions including adult male circumcision. The meeting was attended by CPT principal investigators, agency representatives (CDC, HRSA, NIH, Peace Corps, USAID), Ambassador Deborah Birx and other S/GAC staff from the offices of the Chief Medical Officer, Research and Science, and Program Quality.

**Figure C.10.1: PopART - First 90 estimates for Zambia Round 1 vs. Round 2 of study; adults age ≥18 years at time of annual round visit**

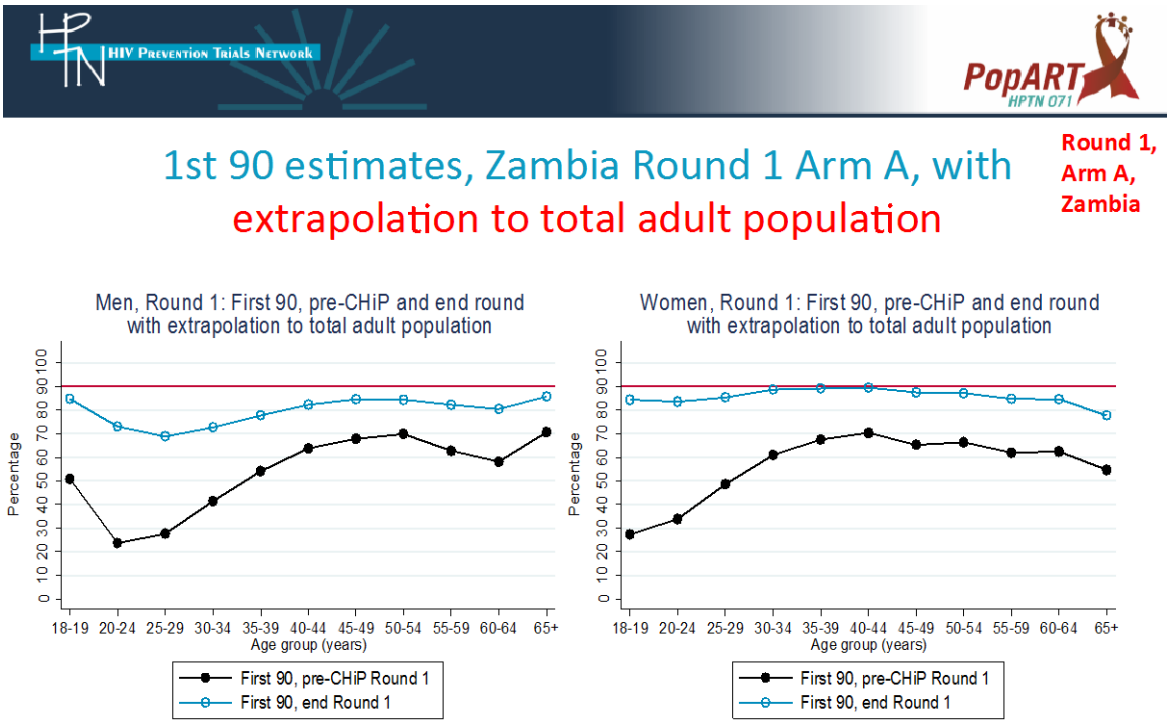


**Figure C.10.2: BCPP – Newly Identified HIV+ by gender and age**

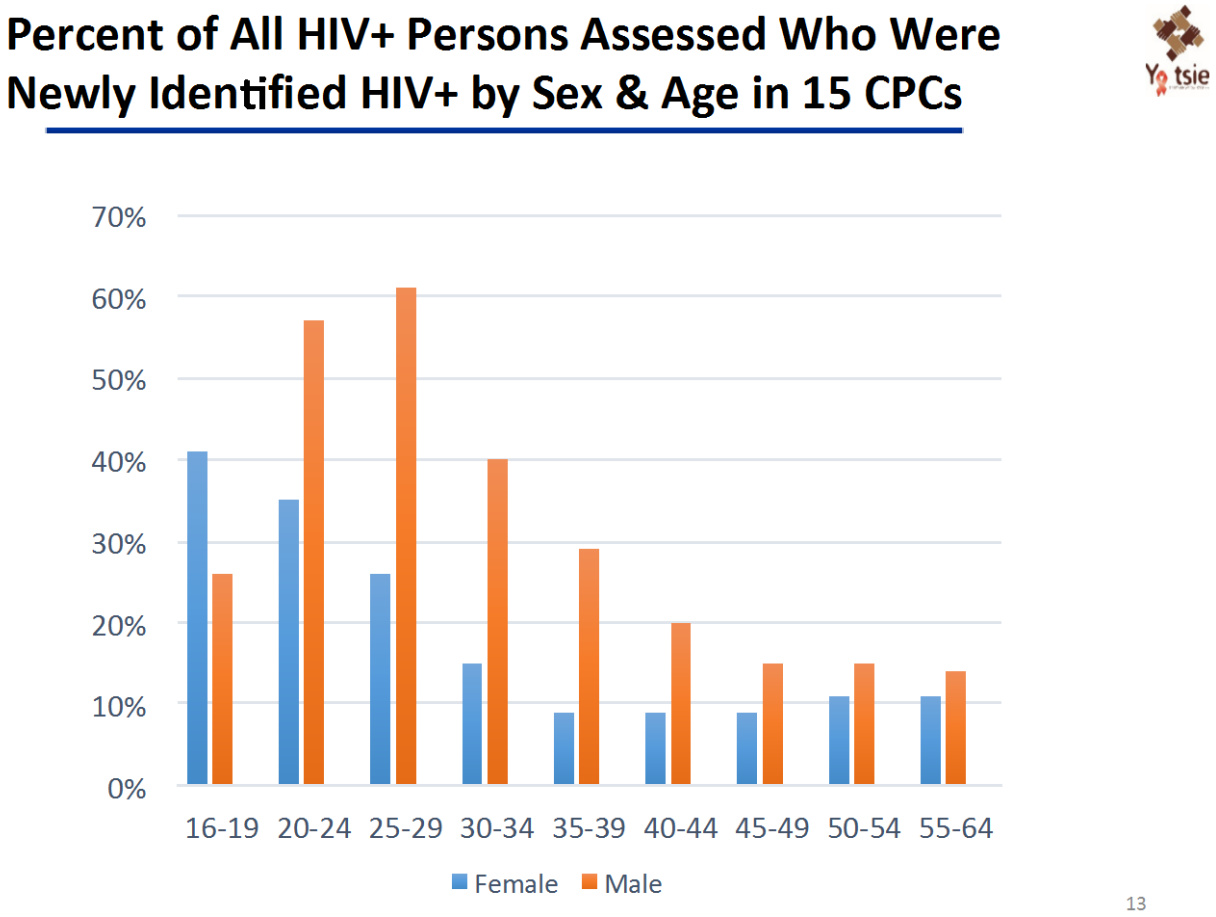


**Figure C.10.3: SEARCH – Reduction in unknown HIV Sero-status: 3 communities over time**

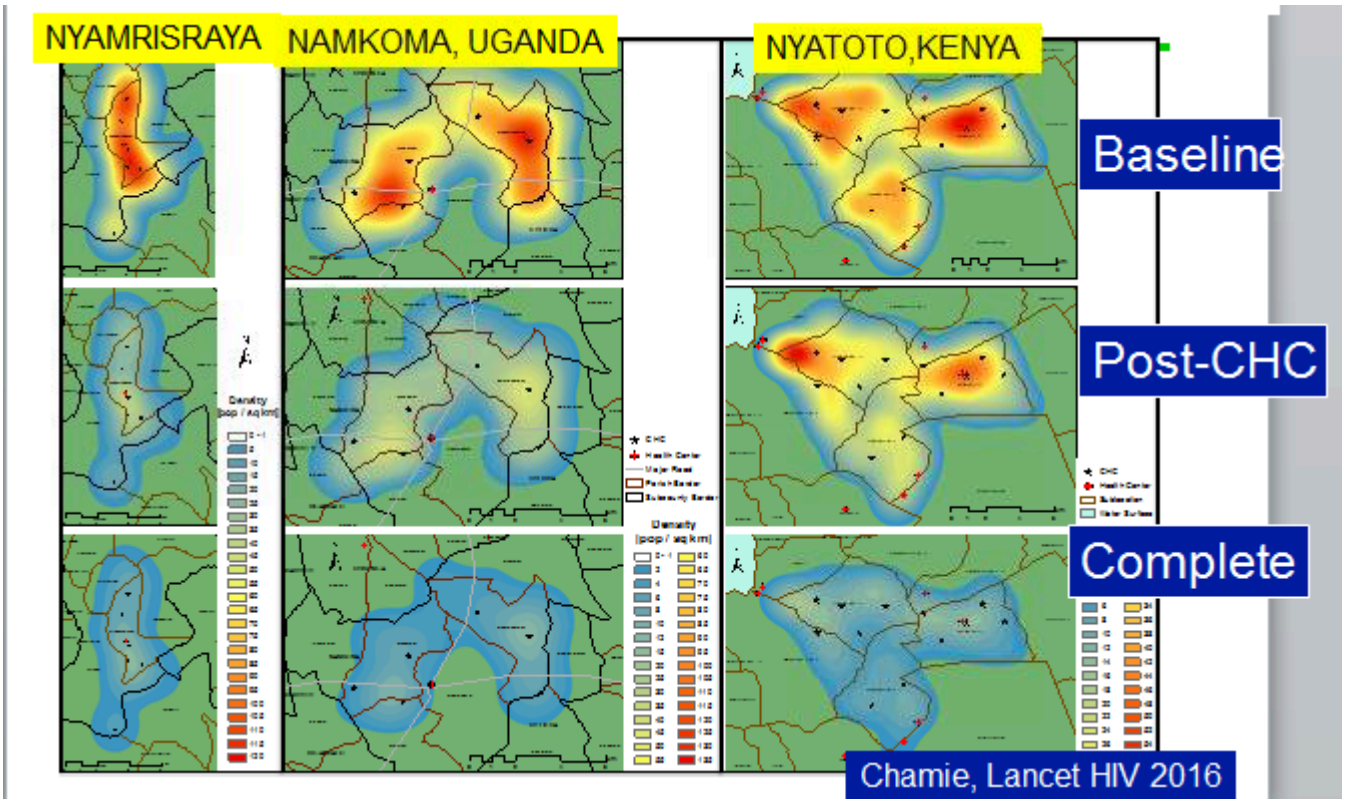
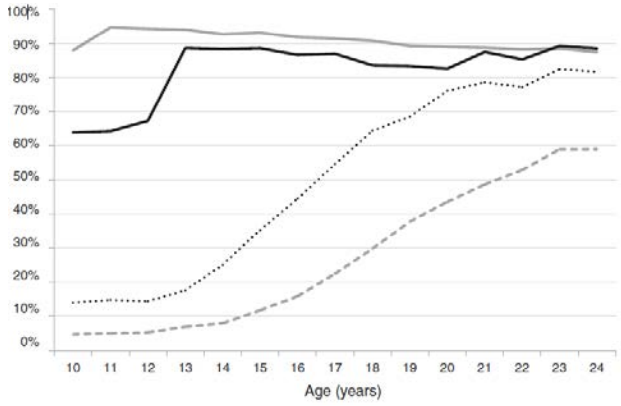


**Figure C.10.4: SEARCH – Testing coverage among adolescents and adults 30 years and younger**

# Project SEARCH Result: Adolescent testing coverage 88%




s of HIV+ with no prior testing: Male, Uganda, unmarried

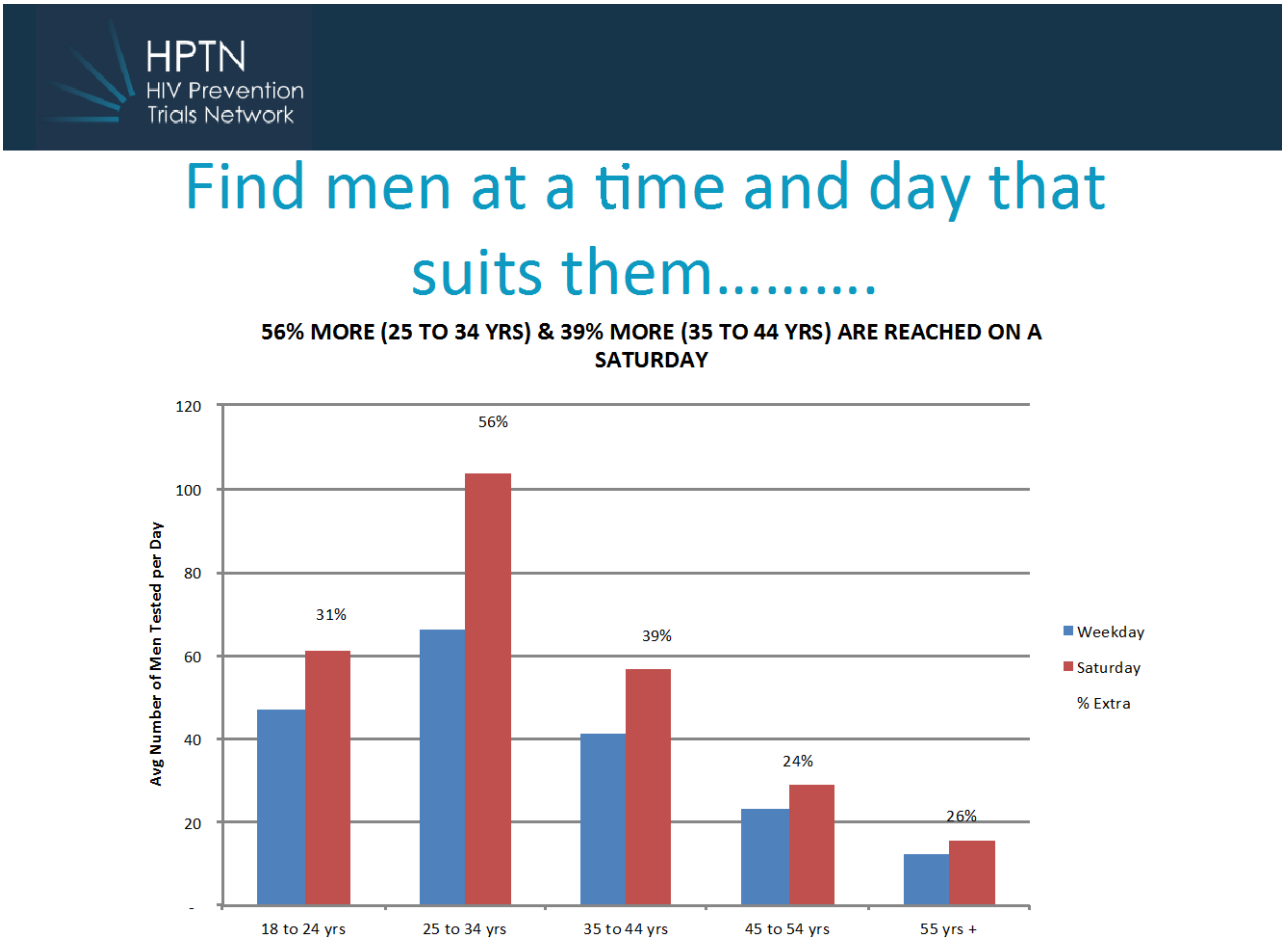
**Figure C.10.5: BCPP – Testing coverage among adolescents and adults 30 years and younger**

## HIV Testing Campaign: Persons Identified as HIV+ through BCPP Compared to Population Estimates by Sex & Age – Round 1 CPCs 1-15

| | Total 16-64 | Females 16-24 | Males 16-24 | Females >24 | Males >24 |
|---|---|---|---|---|---|
| **Population Estimates** | 52,522 | 7,650 | 5,727 | 25,722 | 13,423 |
| **Estimated HIV+ Population** | 13,634 | 851 | 298 | 7,979 | 4,506 |
| **HIV+ persons identified/ estimated** | 9,586/13,634 (70%) | 544/851 (64%) | 156/298 (52%) | 6,115/7,979 (77%) | 2,771/4,506 (61%) |
| **1st 90** | 12,271 | 766 | 268 | 7,181 | 4,055 |

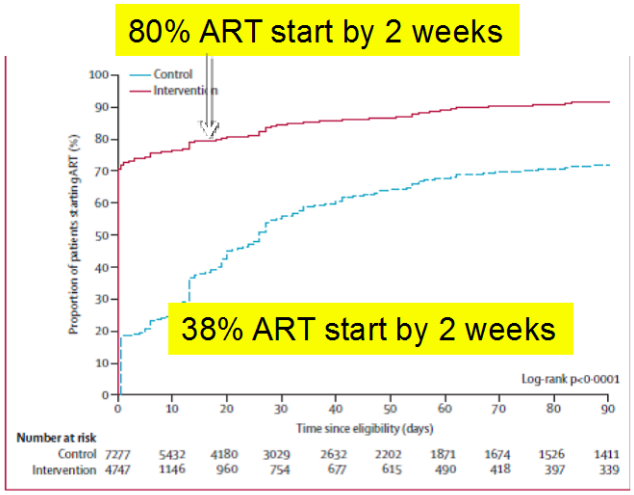
12

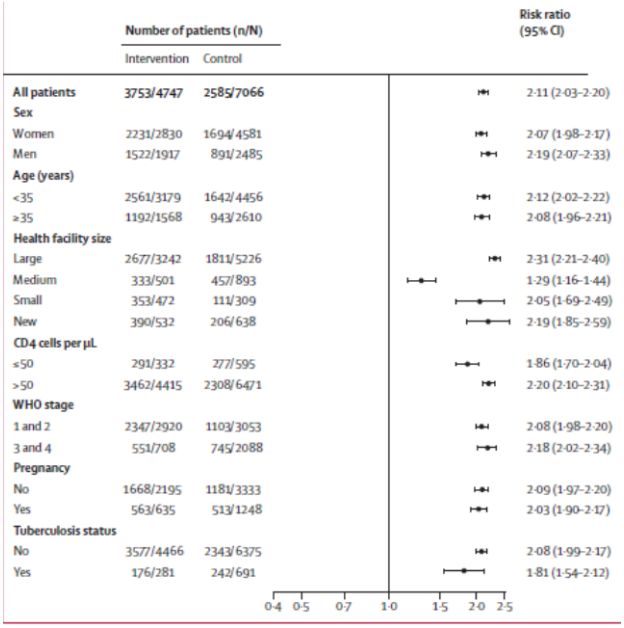
**Figure C.10.6: PopART – Testing coverage among men**



**Figures C.10.7: SEARCH – Same day ART initiation**

# STARTS ( Uganda) Double the number of patients in rapid ART started by 2 weeks




Amanyire, Lancet HIV, 2016

**Figure C.10.8: BCPP – ART Initiation by time and by age and gender**

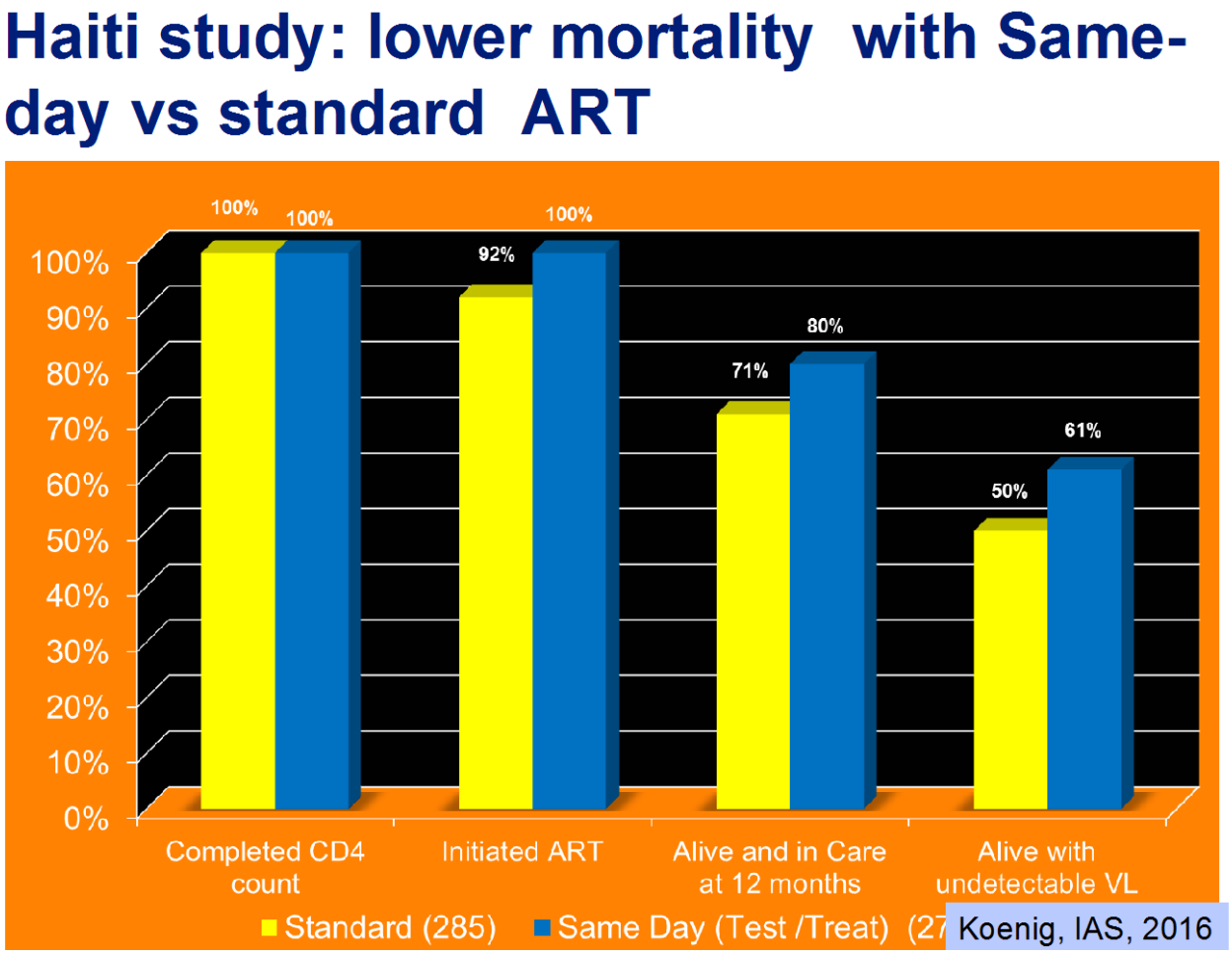
## BCPP ART Initiations by Time: Pre-UTT vs. Post-UTT

| ART Initiation | Same Day | 1-7 Days | 8-14 Days | 15-30 Days | > 30 Days |
|---|---|---|---|---|---|
| Pre-UTT N= 1,359* | 0 (0%) | 79 (6%) | 171 (14%) | 321 (26%) | 682 (54%) |
| Post-UTT N=818** (Jun-Aug 2016) | 629 (85%) | 80 (11%) | 16 (2%) | 10 (1%) | 8(1%) |

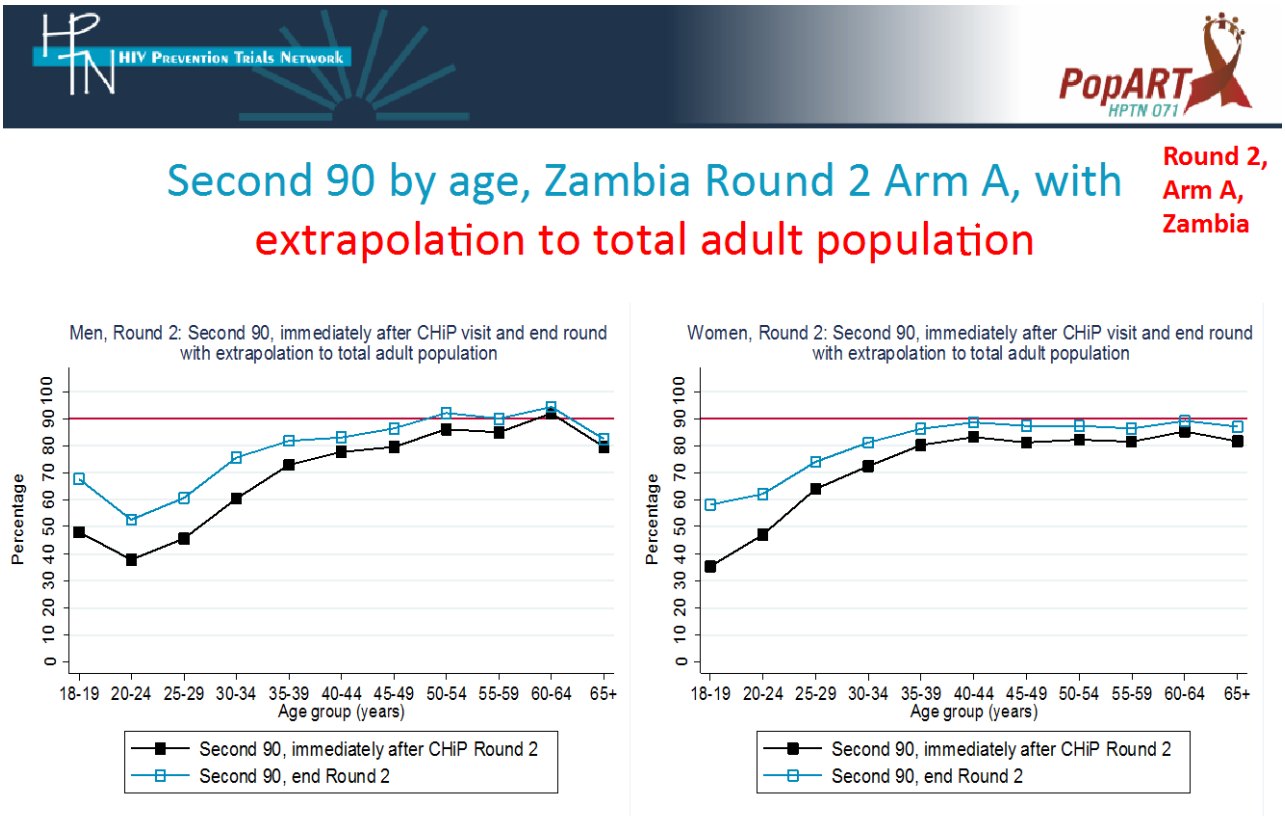
*Pre-UTT – ART timing missing in 106 (8%) of the 1379 ART Initiations
** Post-UTT – ART timing missing in 75 (9%) of 818 ART Initiations

16

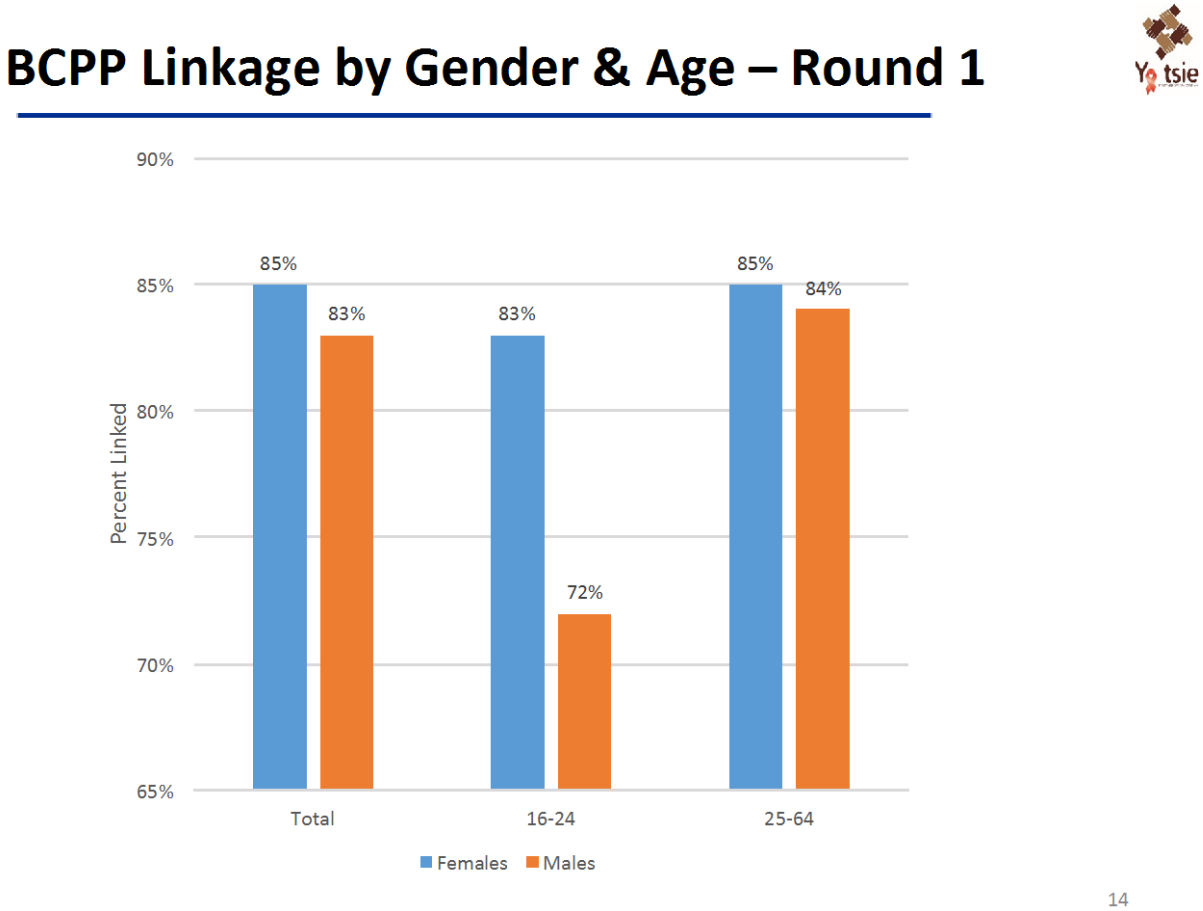
**Figure C.10.9: Other studies also reporting positive results on same day ART Initiation**



**Figures C.10.10: PopART - Second 90 estimates for Zambia Round 2 of study; adults age ≥18 years at time of annual round visit**



**Figures C.10.11: BCPP - Second 90 by age and gender**



**Figures C.10.12: PopART – Retention on ART and Adherence by age and gender**

HIV Prevention Trials Network

PopART HPTN 071

## Retention on ART and adherence to ART by age and gender (self-report)

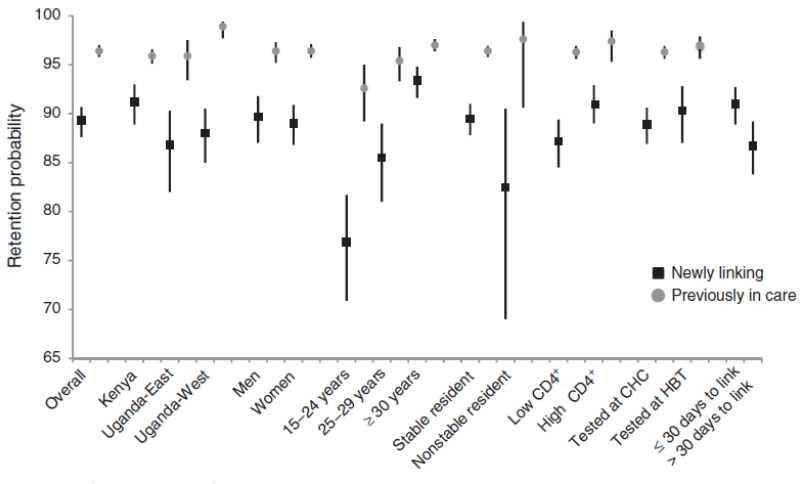
**Round 2, Arm A & B**

| | Zambia | | SA | |
|---|---|---|---|---|
| **Adults started ART 2014 or 2015** | **Male** | **Female** | **Male** | **Female** |
| 15-17 years | 93% | 94% | 100% | 100% |
| **18-19 years** | **100% (n=7)** | **91% (n=75)** | **75% (n=4)** | **80% (n=30)** |
| **20-24 years** | **86% (n=66)** | **91% (n=736)** | **85% (n=20)** | **88% (n=245)** |
| 25-54 years | 92% | 94% | 91% | 92% |
| ≥≥ 55 years | 94% | 98% | 89% | 92% |
| **Adults started ART before 2014** | | | | |
| 15-17 years | 100% | 96% | 87% | 100% |
| **18-19 years** | **90% (n=31)** | **88% (n=49)** | **100% (n=5)** | **100% (n=7)** |
| **20-24 years** | **86% (n=35)** | **93% (n=275)** | **80% (n=10)** | **93% (n=99)** |
| 25-54 years | 95% | 96% | 93% | 94% |
| ≥≥ 55 years | 94% | 97% | 92% | 93% |

**Numerator: Currently on ART, and 0 pills missed last 3 days**
**Denominator: Adults who participated in Round 2, and have ever reported (in Round 1 and/or Round 2) to CHiPs that they have taken ART**

**Figures C.10.13: SEARCH – Retention in care**

# Retention in care




**a mong newly linking**

- **Taking >30 days to link**

Brown, AIDS, 2016

**Figures C.10.14: SEARCH – Virologic suppression by age**

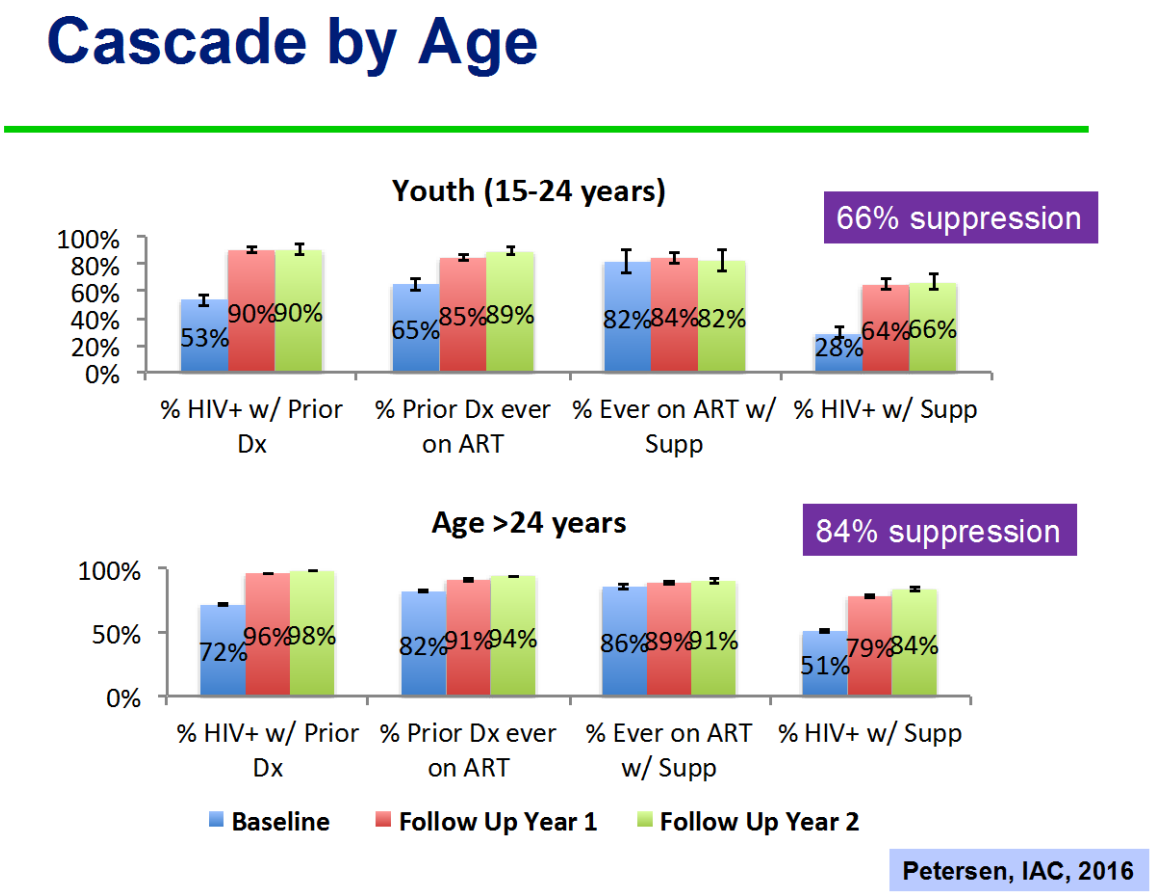
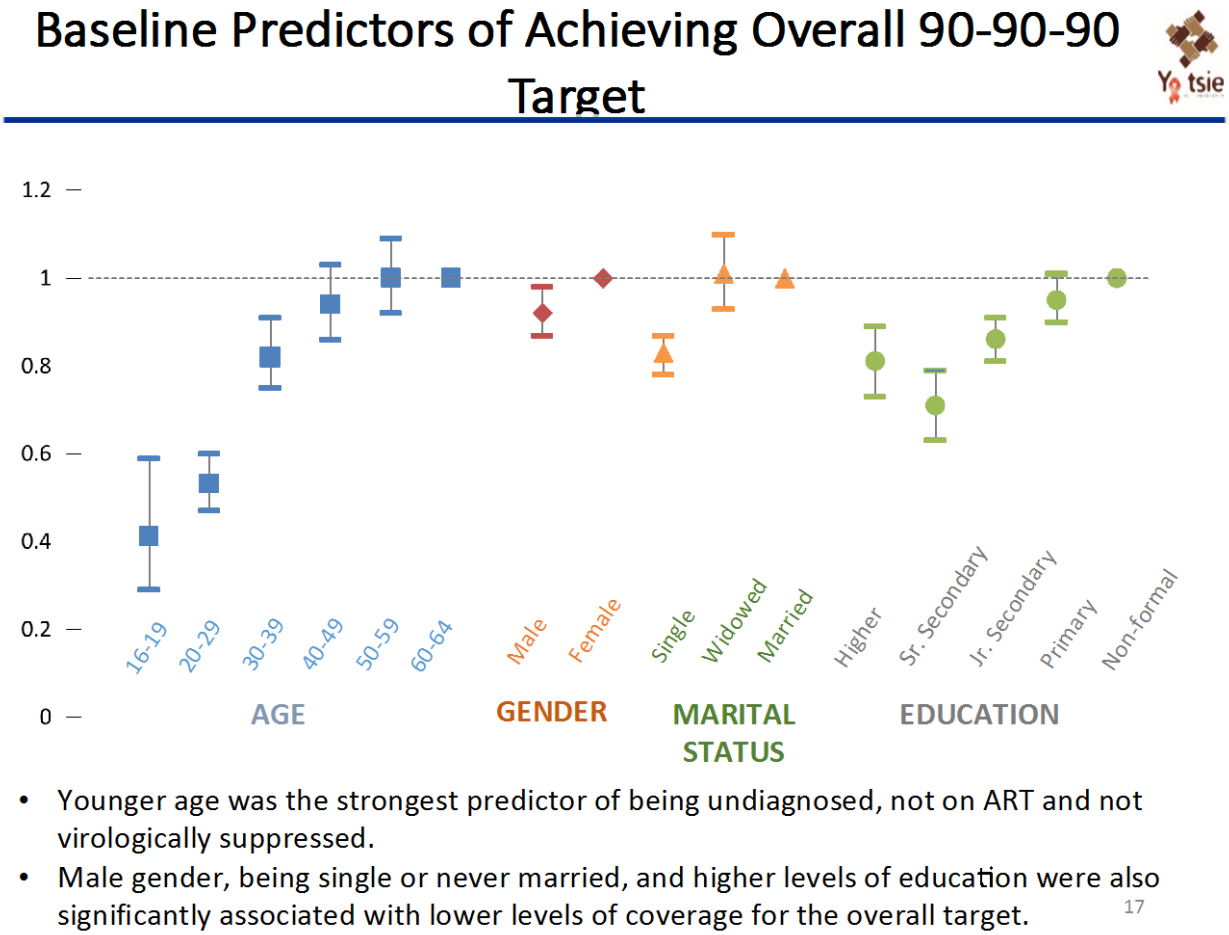


**Figure C.10.15: BCPP - Baseline predictors of diagnosis, on ART and virologic suppression**



# Appendix D: COP ELEMENTS

# Appendix D.1 Chief of Mission Submission Letter

As in past COP cycles, PEPFAR teams are encouraged to include a letter in their COP submission from the Chief of Mission (COM) to the Ambassador-At-Large and Coordinator of U.S. Government Activities to Combat HIV/AIDS and U.S. Special Representative for Global Health Diplomacy. The purpose of the letter is to articulate at a high-level major changes that are being proposed, assumptions that the team has made about factors required to successfully meet the 2017 COP goals, objectives and targets, and identified concerns or barriers. Recognizing that each operating environment is unique and that there are significant contextual factors that influence the PEPFAR program, the COM letter is a place to articulate these issues and their impact on the team's success and plans.

# Appendix D.2 Strategic Direction Summary

**The SDS outlines key data and analysis results concentrating on changes between COP 16 and COP 17, the strategic plan for the coming year, and the monitoring framework that will be used to measure progress**. The SDS is submitted in FACTS Info as a supplemental document. Separate templates for the Standard Process and STAR Process have been provided to assist country teams prepare a comprehensive SDS.

PEPFAR teams should use the guiding questions and adhere to the required tables and figures in the SDS templates to successfully meet this COP 2017 requirement.

The SDS templates may be downloaded on the pepfar.net COP 17 website.

**Note:** *The COP17 SDS is a public document, to be shared with stakeholders during development and prior to submission, and published on pepfar.gov upon approval. All data tables, graphics, figures and language contained in the SDS should be drafted with this knowledge.*

*In the event that sensitive information must be included in the SDS to provide for robust planning and discussion, it will be reviewed collaboratively with HQ and field teams to identify any sensitivity prior to being distributed outside of PEPFAR implementing agencies/partners and released into public domain. Elements that may be useful for internal program planning, but not yet cleared by external owners (e.g., unpublished data provided by host country governments) will be redacted if approval is not granted.*

*Data that are likely to put certain populations at risk if published (e.g., geographic data on key populations) will also be redacted.*

# Appendix D.3 Indicators and Targets

In COP 2017, all teams are expected to report on targets for required indicators that are applicable to the program's funded activities. These targets reflect expected accomplishments that will be directly supported by PEPFAR. PEPFAR recognizes that 'direct support' in the form of 'direct service delivery' or 'technical assistance for service delivery improvement' support[65] is provided within the context of partner country national programs, as a contribution to or a share of those programs, which may also receive financial and other support from the host country and other donors such as the Global Fund. As such, these targets should feed into the national program goals set through a strategic planning process led by the partner government and supported by key stakeholders.

PEPFAR will consider five types of targets that serve different purposes when reviewed at different levels of aggregation.

1. **Site Level Targets** – Site level target setting allows for implementing partners to clearly articulate and set expectations for achievements at each PEPFAR-supported site based on supported activities and in alignment with geographic, population, and intervention-based prioritization efforts for scale-up or sustained support.

2. **Sub-national unit (i.e. District) Level Targets** – Sub-national unit (SNU) level target setting strategically demonstrates geographic prioritization of efforts towards the 90:90:90 by 2020 UNAIDS target in alignment with the distribution of the burden of disease in a country.

3. **Implementing Mechanism Level Targets –** Implementing Mechanism (IM) targets represent expected accomplishments for each implementing partner based on available funding and agreed upon activities. Target setting is important for in-country partner

[65] Please refer to PEPFAR's *MER Indicator Reference Guide v2* for more guidance on required indicators and reporting, including detailed information on what constitutes PEPFAR direct service delivery and technical assistance for service delivery improvement.

management as well as routine planning and monitoring, and is aligned with agency-specific requirements.

4. **Technical Area Summary Level Targets** – The PEPFAR Technical Area Summary Targets are an aggregated reflection of total expected achievements in a country based on the collective work of all PEPFAR partners, and should represent PEPFAR's contributions to the national program. These targets should reflect scale up for epidemic control in high disease burden areas and sustained support programs in other areas.

5. **National Targets** – National data represent the collective achievements of all contributors to a program area, including PEPFAR (i.e., host country government, donors, or civil society organizations).

Each type of target, starting at the site-level, builds upon the other. In other words, site-level targets should aggregate into sub-national level targets. Together, these should inform implementing mechanism target totals which feed into aggregate technical area summary level totals for each operating unit. Appropriate deduplication of the targets need to be taken into account at each level of aggregation.

PEPFAR teams are required to provide FY 18 targets (October 1st to September 30th of each fiscal year). FY 18 targets represent expected accomplishments with COP 17 funds by September 30, 2018.

## Appendix D.3.1 Site and Sub-national Level Targets

Please reference Section 3 of the COP Guidance for information on the strategic approach for targeting.

## Appendix D.3.2 Implementing Mechanism Level Indicators and Targets: Required for all IMs

Implementing Mechanism (IM) target setting is important for in-country partner management as well as routine planning and monitoring, and is aligned with agency-specific requirements. Each Implementing Mechanism's indicator set should represent a comprehensive set of measurements that provide the information needed by the partner and the PEPFAR team to manage the program activities. Minimally, partners will be expected (by the country team) to set targets for all required indicators that are applicable to the work they are doing (reference the MER Guidance for reporting requirements). If there

are no applicable indicators, and none otherwise identified by the OU (such as a custom indicator), no IM target submission is necessary.

Target Justification Narratives (2250 characters) should follow the same guidance as provided below (as applicable) for the technical area indicator narratives.

## Appendix D.3.3 PEPFAR Technical Area Summary Indicators and Targets

The PEPFAR Technical Area Summary Targets are based on the collective work of all PEPFAR partners, and should represent PEPFAR's contributions to the national program. These targets should reflect scale up for epidemic control in high disease burden areas and sustaining programs in other areas.

The FY 18 targets should reflect geographic and population-based prioritization and targeting efforts. Technical area summary are a duplicated sum of site/implementing mechanism level targets.

**Target Justification Narratives (2250 characters)**

Target justification narratives should be specific to each indicator and should describe:

- the methods used to calculate the indicator
- the strategic focus for implementation in that area and what type of activities are supported by U.S. government
- any changes in the focus of the work and/or in the IP landscape
- related national policies that may influence expected achievements (including policy issues related to registers / site-level data collection)
- any successes or challenges to implementing or monitoring the program (i.e. in a way that the targets are higher/lower than might be expected for the fiscal year)
- any de-duplication methods that were utilized

## Appendix D.3.4 National-level Indicators and Targets

All operating units (countries and regions) will report national level data on a small core subset of indicators, where applicable. National targets are the expected national achievements inclusive

of all stakeholders in a country, and are based on a reporting timeframe defined by the partner national government. These are required for submission to headquarters for selected indicators. All Operating Unit teams must work with partner governments to set and review the annual targets for 2017 and 2018, at a minimum. As in previous COP cycles, PEPFAR teams should have already identified the timeframe for which the national targets are set (e.g., Jan – Dec or Oct – Sept).

In light of recent legislation extending the authorities of the PEPFAR authorization, national targets will continue as a requirement of all COP submissions for selected program areas. These requirements are consistent with PEPFAR practices throughout the recent phase of the initiative. PEPFAR teams will report national targets for seven national output indicators. For the COP 17, the required targets are in the areas of treatment, PMTCT, voluntary medical male circumcision, key populations, and country ownership. The MER 2.0 Indicator Reference Sheets revised for FY 17 based on feedback from the last year of implementation, outline the specific indicators that should be used for target setting and the reference sheets that will inform the target setting process. Although these indicator labels and reference sheets primarily describe PEPFAR-supported programming, OUs are being asked to expand the utility of these indicators to the national context.

# Appendix D.4 Implementing Mechanism Information

An implementing mechanism (IM) is a grant, cooperative agreement, or contract in which a discrete dollar amount is passed through a prime partner entity and for which the prime partner is held fiscally accountable for a specific scope of work. Examples of implementing mechanisms are bilateral contracts, bilateral grants, field support (USAID) to a HQ-managed project/entity, cooperative agreements, etc.

Each U.S. government implementing partner will have a separate mechanism. One prime partner will need to have multiple mechanisms only if:

- A partner is funded by more than one agency; or

1. A partner has multiple projects that are administered through separate procurement instruments. These will need to be entered as two separate partners and implementing mechanisms.

**Note:** *You do not need a separate "funding mechanism" entry for each funding source that a partner is receiving.*

All costs associated with institutional contractors providing support to the country team should be entered in the M&O section.

## Appendix D.4.1 Prime Partner Name

The prime partner name for a mechanism, regardless of prime partner type, will be selected from a list of pre-existing partner names that currently exist within the FACTS Info – PEPFAR Module system. If the partner is new, and does not already appear as a prime partner within the FACTS Info system, you will select "New Partner" as the partner name. To request the addition of a new partner, country teams will need to submit a "New Partner Form" to your CL. The New Partner form can be downloaded from within the FACTS Info system's Document Library, under the "Help Documents" section.

Once the partner form is received, the new partner name is validated and loaded into FACTS Info. You will be notified that the "New Partner" prime partner entry can be changed in the system to the actual partner name (note, this update will not be possible via templates).

### *Global Health Supply Chain Program (GHSC)*

The Global Health Supply Chain Program (GHSC) is USAID's flagship health commodity procurement and supply chain assistance program. All PEPFAR Global Health Supply Chain Program COP funds go through the Working Capital Fund (WCF) managed by GH/OHA/SCH.

**To ensure funds are allocated correctly, teams should choose *Global Health Supply Chain Program* as the prime partner in FACTS Info from the drop-down, and enter Global Health Supply Chain Program as the mechanism.** This will ensure that these funds are correctly routed to the WCF. The GHSC COR in Washington will work with PEPFAR teams to ensure funds are disbursed from the WCF to the appropriate supply chain project, including GHSC-PSM, GHSC-QA, GHSC-RTK and GHSC-TA.

As in prior years, once funding is deposited to the WCF, it cannot be transferred out of this account and allocated back to USAID Missions. In addition, GHSC cannot accept PEPFAR funds that have been obligated but not sub-obligated by USAID Missions (i.e. field support), except in special circumstances. Therefore, it is important that teams carefully plan the amount budgeted for GHSC in COP 17.

Funding for condom and lubricant procurement is now provided centrally for all countries via the USAID Commodity Fund. If countries elect not to utilize the Commodity Fund and to fund condom procurement with COP funds, COP-funded condom procurement costs should be allocated to the Global Health Supply Chain Program. However, please note that funds for distribution and programming to ensure that condoms and lubricants are available, accessible, and attractive to users are not centrally funded and must be programmed with COP funds.

If you have questions, please contact Amanda Paust (apaust@usaid.gov) Venera Barsaku (vbarsaku@usaid.gov).

## Appendix D.4.2 Mechanism Details

The following information regarding an implementing mechanism will be submitted on the "Mechanism Details" tab of the Implementing Mechanisms section of the COP. In general, these implementing mechanism details should not change from one cycle to the next (i.e., the data remains static over time):

- Prime Partner Name
- G2G ( and Managing Agency)
- Funding Agency
- Procurement Type
- Implementing Mechanism Name
- HQ Mechanism ID (system assigned)
- Legacy Mechanism ID
- Field Tracking Number (optional)
- Agreement Timeframe (may change if there are no-cost extensions)
- Benefitting Country(ies) (only required for Regional OU programs)

The following implementing mechanism details must be reviewed and if necessary updated by country teams for the current FY 17 COP. While some items may stay the same from cycle to cycle, others must be updated for the current submission in order to respond to revised guidance and/or reflect current data.

- TBD mechanism (a mechanism that was TBD in prior cycles may be named in COP 17)
- New Mechanism (A mechanism can only be listed as "new" during its first COP cycle)
- Global Fund/Multilateral Engagement

- Construction/Renovation Projects
- Motor Vehicle data

## Appendix D.4.3 Government to Government Partnerships

The Department of State cable released 05 September 2012 serves as the guidance document to be followed when establishing and executing new government-to-government (G2G) agreements in the FY 17 COP and is posted on the COP17 site of pepfar.net.

Direct G2G assistance includes **"Funding which is provided to a Host Government Ministry or Agency (including parastatal organizations and public health institutions) for the expenditure and disbursement of those funds by that government entity".**

The tick box designating the mechanism as G2G must be checked in FACTS Info if the mechanism represents an intention to provide direct G2G assistance from the U.S. government to any entity as defined above. Teams should **not** check the box if fund transfers to the government will be through a non-governmental implementing partner.

Upon selecting the G2G tick box, you must also indicate the "Managing Agency" for this mechanism, i.e. which agency will be managing the relationship with the government and the project. This may be the same agency or a different agency from the one listed in the implementing agency box.

If you have any questions about whether planned assistance to a partner falls under the G2G definition (i.e. whether your partner is a parastatal), or regarding the managing agency for a mechanism, please contact your CL.

Upon submission of a G2G request, S/GAC will conduct a review process to approve all newly planned G2G agreements under PEPFAR. This includes activities using FY 17 PEPFAR planned funds, prior-year funds and anticipated out year funds for the life of the project. To fully evaluate the proposed G2G mechanism, country teams need to provide supporting documentation on the government entity that will hold the agreement and execute the activities, the agency-specific risk assessments conducted or planned, as well as the intended fund transfer mechanism (i.e. Fixed Amount Reimbursement Agreement (FARA), direct transfer, cooperative agreement, etc.…).

To initiate the G2G review process the following information is required:

- Proposed grantee name (e.g. specific ministry)

- Annual funding for project
- Life of project funding
- Fiscal year of funds to be used
- Anticipated start and end dates
- Type of risk assessment to be done or already done for each agency

The merit of a G2G request will be evaluated during the technical and programmatic FY 17 COP reviews. S/GAC will conduct a final review and approve which proposals can advance through a G2G agreement.

In COP 2017 an "Activity Table" must be submitted for all G2G mechanisms, new and continuing. See Appendix D.4.18 for more details.

## Appendix D.4.4 Funding Agency

It is critical that teams identify the correct USG agency in the Funding Agency field; the agency or Operating Division selected will receive the funding from S/GAC.

**Figure D.4.4.1**

**USG Funding Agencies**

- **DoD (Department of Defense)**
- **DOL (Department of Labor)**
- **Department of State**
  - AF (African Affairs)
  - EAP (East Asian and Pacific Affairs)
  - EUR (European and Eurasian Affairs)
  - INR (Intelligence and Research)
  - NEA (Near Eastern Affairs)
  - S/GAC (Office of the U.S. Global AIDS Coordinator)
  - PM (Political-Military Affairs)
  - PRM (Population, Refugees, and Migration)
  - SCA (South and Central Asian Affairs)
  - WHA (Western Hemisphere Affairs)
- **HHS (Health and Human Services)**
  - CDC (Centers for Disease Control and Prevention)
  - HRSA (Health Resources and Services Administration)
  - NIH (National Institutes of Health)
  - OGA (Office of Global Affairs)
  - SAMHSA (Substance Abuse and Mental Health Services Administration)
- **Peace Corps**
- **USAID (United States Agency for International Development)**
- **U.S. Treasury**

- **HHS/NIH:** Field teams should ensure that they are familiar with the scope of HIV-related clinical or other research that NIH (and potentially other U.S. government agencies) currently fund in

country to determine whether or not there are non-research activities appropriate for inclusion in the COP that may be logically "appended" to these research efforts. If there are opportunities to provide country/regional PEPFAR funding to add a service component to an NIH study, country funding for the additional service component *only* would be put into the COP. The NIH study would NOT be included. You can also include support for training through NIH via Fogarty International Center (FIC) research training grants that support the strengthening of human capacity in strategic information: surveillance, HIS, targeted and public health evaluations, program monitoring and evaluation, modeling, and bioethics. Operating Unit teams should be in contact with the FIC research training program officer or directly with the grantee and their in-country collaborators to discuss capacity building needs (see research training websites at www.fic.nih.gov for contact info for AIDS International Training and Research Program, International Clinical, Operations and Health Services Research Training Award for AIDS and TB, and International Research Ethics Education And Curriculum Development Award). As with all agencies, NIH should be listed as the Funding Agency, and the Prime Partner who will eventually receive the funding should be listed as the Prime Partner.

- Please identify HRSA for all mechanisms where HRSA is the Funding Agency. Current mechanisms/prime partners include ITECH/University of Washington, the Twinning Center/American International Health Alliance (AIHA), Quality Improvement Capacity Project for Impact/New York AIDS Institute (HIVQUAL) and Columbia University (ICAP) and the Global Nurse Capacity Building Program/Columbia University (ICAP).
- **Peace Corps:** Funding going to the Peace Corps should be identified with Peace Corps as the Funding Agency. Peace Corps should never appear as another USG Agency's prime partner. The Implementing Mechanism section of the COP should only be used to capture Peace Corps programming outside of Peace Corps Volunteer costs.
- **Department of Labor:** Funding going to the Department of Labor should be identified with Department of Labor as the Funding Agency. Department of Labor should never appear as another U.S. government Agency's prime partner.
- **State:** Please identify the State Department Bureau for all mechanisms where the Department of State is the Funding Agency. Any project using State's Regional Procurement Support Offices (RPSO) for construction or renovation, must list the relevant State regional bureau as the Funding Agency. For more information on construction or renovation as an implementing mechanism, see Section 5.5.11.

- **Treasury:** Treasury's Office of Technical Assistance (OTA), which provides advisors with expertise in public financial management to government ministries, was included in PEPFAR's most recent authorization. Depending on country context, Operating Unit teams may wish to incorporate this element into their broader health systems strengthening portfolio. For these mechanisms, please identify Treasury as the Funding Agency and as the Prime Partner.

## Appendix D.4.5 Procurement Type

PEPFAR utilizes the following types of procurement:

- Contract **-** A mutually binding legal instrument in which the principal purpose is the acquisition by purchase, lease, or barter of property or services for the direct benefit or use of the Federal government or in the case of a host country contract, the partner government agency that is a principal signatory party to the instrument. Note: IQCs should be listed as contracts.
- Cooperative Agreement **-** A legal instrument used where the principal purpose is the transfer of money, property, services, or anything of value to the recipient in order to accomplish a public purpose of support or stimulation authorized by Federal statute and where substantial involvement by the USG is anticipated. Note: PASAs should be listed as cooperative agreements.
- Grant - A legal instrument where the principal purpose is the transfer of money, property, services or anything of value to the recipient in order to accomplish a public purpose of support or stimulation authorized by Federal statute and where substantial involvement by USG is *not* anticipated.
- Umbrella Award – An umbrella award is a grant or cooperative agreement in which the prime partner does not focus on direct implementation of program activities, but rather acts as a grants-management partner to identify and mentor sub-recipients, which in turn carry out the assistance programs.
- Inter-agency Agreement (IAA) **-** An Inter-Agency Agreement is a mechanism that may be used to transfer funding between agencies. If the USG team decides that one agency has a comparative advantage and is better placed to implement an activity with either GHP-USAID or CDC GAP funding, the USG team may have the option of requesting to transfer money from one agency to another through an IAA. This may not be the most efficient way of providing funds from one agency to another. However, one example of an appropriate use of an IAA is agency buy-in for census bureau (BUCEN) services.

## Appendix D.4.6 Implementing Mechanism Name

The mechanism name is a tool to identify unique mechanisms. We have seen the following mechanism naming conventions:

- Partner Acronym: AIHA; CHAZ
- Project Name: Support to RDF; Sun Hotel PPP; GHAIN, If this is a HQ buy-in implementing mechanism then you must put the name of the HQ project in the implementing mechanism name field. For example, if you are using the CTRU Project or UTAP, you should use these names in the implementing mechanism name field.
- Unique Agency Identifier: A grant/cooperative agreement or contract number.

Other than the HQ buy-in Implementing Mechanism requirement above, there are no limitations on mechanism name; we recommend that country teams choose unique values for the mechanism name.

The Implementing Mechanism name is not the same as the Prime Partner name, although in some cases the fields may hold the same values. The table below provides several examples of the difference between implementing mechanism name and prime partner name.

**Figure D.4.6.1:** Examples of Implementing Mechanism and Prime Partner names are below:

| Implementing Mechanism Name | Prime Partner Name |
|---|---|
| Together We Can | American Red Cross |
| Twinning | American International Health Alliance |
| MEASURE/DHS | Macro International |
| Network RFP | To Be Determined |
| GH000642 | Elizabeth Glaser Foundation |

## Appendix D.4.7 HQ Mechanism ID, Legacy Mechanism ID, and Field Tracking Number

The **HQ Mechanism ID** will be assigned by the FACTS Info – PEPFAR Module system when the mechanism is saved in the system (either through a template upload or on-screen). New FY 17 mechanisms will be assigned HQ Mechanism IDs by the FACTS Info – PEPFAR Module system when they are saved to the system.

The **Legacy Mechanism ID** refers to the historical mechanism ID that was used either in COPRS I or Plan B. Country teams should reference the following Legacy Mechanism ID types:

- For mechanisms that existed in the FY 2009 COP in the COPRS I system, Operating Unit teams should use the COPRS I "mechanism system ID."

- For mechanisms that were created in the FY 2010 or 2011 COP or using the "Plan B" system, country teams should use the mechanism ID from that system. For example, if the file name included "new017" in the name, the mechanism ID would be "17."

The **Field Tracking Number** is not a required field. It is intended for country use only to assist with internal tracking systems or syncing COP data with country-based "shadow systems." Examples of possible field tracking numbers include:

- Contract / cooperative agreement number
- Vendor ID
- COPRS shadow system ID

## Appendix D.4.8 Agreement Timeframe

The Agreement Start Date and Agreement End Date fields are a month-year stamp that field teams use to indicate the agreement timeframe. This time stamp will serve as an indication of where a mechanism is in its lifecycle. An actual time stamp is not required for TBD mechanisms.

## Appendix D.4.9 TBD Mechanisms

If the mechanism prime partner is TBD, the tick box "TBD Mechanism" must be checked and FACTS Info will automatically populate the Prime Partner field with "TBD." When using Implementing Mechanism templates, if you indicate that the mechanism is TBD, please ensure the Prime Partner is listed as "TBD" only.

Upon checking the TBD tick box, or when completing an IM template for a TBD, a new tab will appear in FACTS Info requesting the user to enter details regarding the status and history of the TBD, projected award date, and any other information that would be helpful for a reviewer.

## Appendix D.4.10 New Mechanism

Upon the creation of a new mechanism in FACTS Info, the "New Mechanism" tick box will be checked automatically.

In COP 2017 an "Activity Table" must be submitted for all new mechanisms. See Section 5.5.19 for detailed guidance.

## Appendix D.4.11 Construction/Renovation

This tick box in FACTS Info is used to identify mechanisms that contain funding for construction and/or renovation projects. Checking this box will then open a separate tab in the IM where country teams should complete required information on the projects.

A Construction/Renovation tab will appear requesting the user to enter each proposed project. All fields on the Construction/Renovation Project Plan form must be completed. There is no minimum or maximum limit on the amount of funds allocated to a construction/renovation project for it to be subject to inclusion in the COP submission i.e., all projects, regardless of amount, need to be submitted for approval. Cross-cutting attributions for construction and renovation for each IM should match the total of all IM project plans.

## Appendix D.4.12 Motor Vehicles

This tick box is used to identify mechanisms that have purchased and/or leased motor vehicles over the timeframe of the IM/agreement. This tick box must be used in order to report on the FY 17 request for the purchase and/or lease of motor vehicles as well as to report on the number of previously PEPFAR purchased or leased that are in use at the time of COP submission. A Motor Vehicle tab is where country teams should enter the data on new FY 17 funding and provide the current size of the PEPFAR fleet under this mechanism.

- At the top of the tab, enter the total number of motor vehicles previously PEPFAR purchased or leased under this mechanism that are currently in use (i.e. from the start of the mechanism through COP submission).
- The main section of the tab requires OUs to provide specific information on each motor vehicle request. Upon clicking the "add" button, you will be required to provide:
    - The type of vehicle requested (boat, truck, car, ambulance, etc.)
    - The acquisition method for the requested vehicle (leased or purchased)
    - The total number/amount of this particular type of vehicle being requested
    - The new FY 17 funding being requested for the group of vehicles that are batched in this entry.
        - NOTE: Any vehicles that are being funded out of the applied pipeline should be listed as zero-funded.

Only new FY 17 funding requested for motor vehicles should be entered in the appropriate cross-cutting attributions ("Motor Vehicle: Purchased" and "Motor Vehicle: Leased.") The totals for these attributions must equal the new funding requested in the motor vehicles tab. Teams are encouraged to utilize the Motor Vehicles IM Summary Report, found in the Budget Section of FACTS Info to check their planned allocations and requests to ensure accuracy.

Any USG related motor vehicle planned expense must be captured in the appropriate agency and cost category of CODB.

## Appendix D.4.13 Prime Partners

**Definition:** A prime partner is an organization that receives funding directly from, and has a direct legal relationship (contract, cooperative agreement, grant, etc.) with, a USG agency.

There can be only one prime partner per implementing mechanism. When implementing mechanisms are awarded to a joint venture/consortium, the lead partner is the prime, and any other partners in the consortium should be identified as sub-partners. With the exception of the prime partner, you will only need to enter those members of the joint venture/consortium that are active in your country.

As noted above, the prime partner name for a mechanism, regardless of prime partner type, will be selected from a list of pre-existing partner names that currently exist within the FACTS Info – PEPFAR Module system. If the partner is new, and does not already appear as a prime partner within the FACTS Info system, you will select "New Partner" as the partner name. In order to request the addition of a new partner, country teams will need to submit a "New Partner Form" to your CL. The New Partner form can be found within FACTS Info's Document Library "Help Document" Section. Once the partner form is received, the new partner name validated, and the partner information loaded into FACTS Info, you will be notified that the "New Partner" prime partner entry can be changed in the system to the actual partner name (note, this update will not be possible via templates).

Maximizing Efficiencies:

1) **In order to maximize efficiencies in administrative costs, countries should have no shared prime implementing partners with multiple agency agreements, including with partner governments** (see cable entitled: MESSAGE FROM SECRETARY CLINTON ON GOVERNMENT-TO-GOVERNMENT MECHANISMS FOR PEPFAR). If you feel that this is necessary in your country's context, you will be expected to submit a request for a waiver of this requirement.

2) In order to avoid duplication in program implementation by partner, agency, program area and geography, country teams are not allowed to fund different partners that are working in the same program area in the same facilities or geographic locale – independent of whether or not they are currently funded by one agency or different agencies. The following is allowed however:
    - Different partners; same program area; same agency; distinct geographic locales
    - Different partners; same program area; different agency; different locale
    - Different partners; different program area; different agency
    - Partners working in multiple geographic areas on technical assistance only

As above, if you feel that funding multiple partners is necessary in your country's context, you will be expected to submit a request for a waiver of this requirement.

**Do not** name a partner as a prime or sub under an implementing mechanism until it has been formally selected through normal Acquisition & Assistance processes, such as Annual Program Statements, Requests for Application, Funding Opportunity Announcement, or Requests for Proposals. If a partner has not been formally selected, list the prime partner for the implementing mechanism as TBD.

For all direct programming to be implemented by a USG, the agency should have an implementing mechanism with itself named as the prime partner. Note that all of the costs associated with a USG agency's footprint in country, i.e., costs of doing PEPFAR business or "Management and Operations" costs (including staffing to support TA), will be entered in the M&O section. Technical staff salaries will be attributed to the applicable budget code through the M&O section, not through implementing mechanisms.

## Appendix D.4.14 Definitions

**Sub-Partner:** An entity that receives a sub-award from a prime partner or another sub-partner under an award of financial assistance or contract and is accountable to the prime partner or other sub-partner for the use of the Federal funds provided by the sub-award or sub-contract. **Sub-Award:** Financial assistance in the form of money, or property in lieu of money, provided under an award by a recipient to an eligible sub-partner (or by an eligible sub-partner to a lower-tier sub-partner). The term includes financial assistance when provided by any legal agreement, even if the agreement is called a contract but does not include either procurement of goods or services or, for purposes of this policy statement, any form of assistance other than grants and cooperative agreements. The term includes consortium agreements.

## Appendix D.4.15 Subdivisions of an Organization

If an organization has one or more subdivisions or sub-offices that are receiving funding, you should not enter each subdivision or sub-office. You would only enter the subdivision or sub-office if it is receiving the funding directly from a USG agency prime partner, independently of the parent organization.

*Examples:*

1. If you are funding the national Red Cross in your country, you would not list each subdivision of the Red Cross as a sub-partner if it is receiving its funding from the national headquarters office. You should only list local chapters of the Red Cross as sub-partners if they are receiving funds directly without it first going through the national headquarters office.
2. If you are funding the national MOH in your country, you should only list the district level health ministries as sub-partners if they are receiving funds directly from a prime partner without going first through a national level headquarters.

## Appendix D.4.16 Funding Sources / Accounts

The funding sources tab is the space for OUs to indicate the total funding that will be used for the implementation of FY 17 COP, and provide details of the breakdown across funding accounts and new vs. prior FY year funds. Country teams are encouraged to think about new planned FY 17 resources and available pipeline funding as one funding envelope for the mechanism. A strong COP submission will reflect a strategic application of pipeline and allocation of new funds.

<u>FY 17 Resources</u>

For new FY 17 funds, there are as many as three accounts (GHP-State, GHP-USAID and GAP) available to country teams for programming. FACTS Info will be programmed with the available budgets for these three accounts, and not all OUs will have all accounts available to them.

Please note: there are firm parameters as to how the three accounts can be allocated across agencies. The funding source choices for each agency are:

**Figure D.4.16.1**

| U.S. government Agency | FY 17 COP Funding Source Categories for New Planned Funding |
|---|---|
| USAID | GHP (State)<br>GHP (USAID)* |
| HHS/CDC | GAP**<br>GHP (State) |
| HHS/HRSA | GHP (State) |
| HHS/OGA | GHP (State) |
| DoD | GHP (State) |
| DoL | GHP (State) |
| State | GHP (State) |
| Peace Corps | GHP (State) |
| ALL OTHERS | GHP (State) |

** The GHP-USAID account is the account appropriated directly to USAID, formerly the Child Survival and Health (CSH) Account (FYs 2007 and prior), and the Global Health and Child Survival (GHCS) Account (FY 2008-FY 2011) and is applicable for USAID activities only.*

*** The GAP account was formerly called "Base (GAP Account)," and is applicable for HHS/CDC activities only.*

As noted elsewhere, please ensure that you are coordinating as a USG Team in determining funding decisions and that **all** USG HIV/AIDS funding is being programmed as an interagency country team. Please also ensure that your programming is consistent with your budget controls in order to ensure a smooth submission.

At the top of the Funding Source tab, country teams have the opportunity to enter an amount of "**Applied Pipeline Funding**," which the system will auto-sum with the new FY 17 funding requested, by funding account. This applied pipeline data will reflect the amount of PEPFAR pipeline funding, from all accounts, that will be applied to the mechanism for the FY 17 COP implementation. The applied pipeline is the amount of money you project will not be expended by September 30th, 2017 and can be used in the FY 17 COP (i.e. FY 18).

# Appendix D.4.17 Cross-Cutting Budget Attributions

## *Overview*

The importance of cross-cutting budget attributions cannot be over-emphasized. Each represents areas of PEPFAR programming with great potential to contribute to PEPFAR by more consciously seeking opportunities for integration and synergy across program areas. Cross-cutting attributions also reflect areas in which there is continuing stakeholder interest, including earmarks for water and GBV activities. Similar to other earmarks and budgetary considerations, only new FY 17 planned funding can be reflected in cross-cutting attributions (i.e. applied pipeline does not get reflected).

Correct identification of cross-cutting attributions and key issues are **critical** to minimize data calls in the future.

All mechanisms that are applying new FY 17 planned funding for work in any of the cross-cutting attributions (HRH, Construction/Renovation, Motor Vehicles, Food and Nutrition, Economic Strengthening, Education, Water, Condoms, Gender-based Violence, or Gender Equality) **must** have the cross-cutting budget attributions identified and accurately quantified; if you need assistance in developing standard approaches to quantifying cross-cutting attributions, please contact your CL. It is critical that you estimate these attributions and submit with your COP; it is not acceptable to skip this process. For definitions of cross-cutting attributions, please see Appendix 2.

In FY 17, we will be capturing FY 17 funding information for sixteen system-level areas, which are listed below and defined in Appendix 2. Individual attributions should not total more than the FY 17 mechanism planned funding (new FY 17 funds only), but the sum of all cross-cutting attributions may exceed the FY 17 mechanism total planned funding. For example, if a partner is being funded at $1,000,000, the planned funding for each attribution cannot be more than $1,000,000. A single activity can often have more than one system-level attribution (e.g., service training on safe water would be split between both HRH and Water), and together these attributions could exceed $1,000,000 in funding. Attributions should be identified for all relevant mechanisms, even in the case of TBD mechanisms. In these cases, country teams should estimate the amount of funding for each of the cross-cutting budget categories.

# Appendix D.4.17.1Cross-Cutting Attributions and Definitions

For each implementing mechanism, countries must estimate the amount of funding that is attributable to the following programming:

1. **Human Resources for Health (HRH)**

   HRH attribution includes the following:

   - Workforce Planning
   - Human Resource Information Systems (HRIS)
   - In-Service Training
   - Pre-Service Education
   - Task shifting
   - Performance Assessment/Quality Improvement
   - Retention
   - Management and Leadership Development
   - Strengthening Health Professional Regulatory Bodies and Associations
   - Twinning and Volunteers
   - Salary Support

2. **Construction or Renovation (two separate attributions)**

   These attributions are meant to capture construction and renovation costs. Construction refers to projects to build new facilities, such as a health clinic, laboratory, or hospital annex or to expand an already existing facility (i.e. adds on a new structure or expands the outside walls). Renovation refers to projects with existing facilities intended to accommodate a change in use, technical capacity, or other infrastructure improvements. PEPFAR-funded construction projects should serve foreign assistance purposes, will involve facilities that are provided to the partner government (or potentially to another implementing partner) as a form of foreign assistance, and are considered necessary to the delivery of HIV/AIDS-related services. Note, any funding attributed to these codes must have a corresponding should be identified in a Construction/Renovation Project Plan completed directly in FACTS Info. For more information about project plans and details concerning the "bundling" of renovation requests, please consult Appendix 4.11.

   For U.S. government-occupied rented or owned properties, the cost of renovating should be captured in the Agency Cost of Doing Business (CODB). None of these costs should be captured in budget attributions within Implementing Mechanisms.

3. **Motor Vehicles: Purchased or Leased (two separate attributions)**

   Countries need to provide the total amount of funding by Implementing Mechanism, which can be attributed to the purchase and/or lease of motor vehicle (s) under an implementing mechanism. The term Motor Vehicle refers to motorcycles, cars, trucks, vans, ambulances, mopeds, buses, boats, etc. that are used to support a PEPFAR Implementing Mechanism overseas.

4. **Key Populations: Men who have sex with Men (MSM) and Transgender Persons (TG)**

   This budget attribution is meant to capture activities that focus on gay men, other men who have sex with men including male sex workers, and those who do not conform to male gender norms and may identify as a third gender or transgender (TG). Broader definitions can be found in Section 3.1.1. These activities may include 1) implementation of core HIV prevention interventions for MSM and TG that are consistent with the current PEPFAR technical guidance; 2) training of health workers and community outreach workers; 3) collection and use of strategic information; 4) conducting Epidemiologic, social science, and operational research among MSM and TG and their sex partners; 5) monitoring and evaluation of MSM and TG programs; and 6) procurement of condoms, lubricants, and other commodities essential to core HIV services for MSM and TG.

   Activities marked as Key Population: MSM and TG will now be required to provide additional information on activities. Teams should select all that apply and must select at least one tick-box if there is funding in this crosscutting attribution.

   Please include the amount of the budget allocated to MSM and TG activities and check all of the following boxes that apply:

   - Implementation of core HIV prevention interventions for MSM and TG that are consistent with the current PEPFAR technical guidance
   - Training of health workers and community outreach workers
   - Collection and use of strategic information
   - Conducting Epidemiologic, social science, and operational research among MSM andTG and their sex partners
   - Monitoring and evaluation of MSM and TG programs
   - Procurement of condoms, lubricants, and other commodities essential to core HIV services for MSM and TG

**5. Key Populations: Sex Workers (SW)**

This budget attribution is meant to capture activities that focus on sex workers. Relevant activities include: 1) implementation of core HIV prevention interventions for SWs consistent with PEPFAR guidance on sexual prevention; 2) training of health workers and community outreach workers; 3) collection and use of SI on SWs and clients; 4) conducting Epidemiologic, social science, and operational research among SWs, their partners, and clients; 5) monitoring and evaluation of SW programs; and 6) procurement of condoms, lubricants, and other commodities essential to core HIV services for SWs.

Activities marked as Key Population: SW will now be required to provide additional information on activities. Teams should select all that apply and must select at least one tick-box if there is funding in this crosscutting attribution

Please include the amount of the budget allocated to SW activities and check all of the following boxes that apply:

- Implementation of core HIV prevention interventions for SWs consistent with PEPFAR guidance on sexual prevention
- Training of health workers and community outreach workers
- Collection and use of SI on SWs and clients
- Conducting Epidemiologic, social science, and operational research among SWs, their partners, and clients
- Monitoring and evaluation of SW programs
- Procurement of condoms, lubricants, and other commodities essential to core HIV services for SWs

**6. Key populations: People Who Inject Drugs (PWID)**

Investments in programs for this key population are captured in the IDUP budget code.

**7. Food and Nutrition: Policy, Tools, and Service Delivery**

This secondary budget attribution should capture all activities with the following components:

- Development and/or Adaptation of Food and Nutrition Policies and Guidelines – The cost of developing or adapting guidelines that provide a framework for integrating food and nutrition activities within the care and support of people infected and affected by HIV/AIDS, including OVC. This includes policies and guidelines that foster linkages with "wraparound" programs

that address food security and livelihood assistance needs in the targeted population. This also includes activities that improve quality assurance and control for production and distribution of therapeutic and fortified foods for use in food and nutrition activities.

- Training and Curricula Development – The cost of training for health care workers, home-based care providers, peer counselors, and others to enhance their ability to carry out nutritional assessment and counseling. This includes developing appropriate nutrition-related curricula for inclusion in pre- and post-service training programs and development of appropriate job aids for health care workers.
- Nutritional Assessment and Counseling – The cost of providing anthropometric, symptom, and dietary assessment to support clinical management of HIV-positive individuals before and during ART as well as exposed infants and young children. This includes nutrition education and counseling to maintain or improve nutritional status, prevent and manage food- and water-borne illnesses, manage dietary complications related to HIV infection and ART, and promote safe infant and young child feeding practices. It also includes nutritional assessment, counseling and referral linked to home-based care support.
- Equipment – The cost of procurement of adult and pediatric weighing scales, stadiometers, MUAC tapes, and other equipment required to carry out effective nutritional assessment. This also includes more general procurement, logistics and inventory control costs.

**8. Food and Nutrition: Commodities**

This secondary budget attribution is meant to capture the provision of food commodities through food by prescription, social marketing, school feeding, OVC, PMTCT or other programs, including:

- Micronutrient Supplementation – The cost of micronutrient supplement provision according to WHO guidance or where individual assessment determines a likelihood of inadequate dietary intake of a diverse diet to meet basic vitamin and mineral requirements.
- Therapeutic, Supplementary, and Supplemental Feeding – The cost of facility- and community-based food support for nutritional rehabilitation of severely and moderately malnourished PLWHA, as well as supplemental feeding of mothers in PMTCT programs and OVC.
- Replacement Feeding and Support – The cost of antenatal, peri- and postpartum counseling and support to HIV-positive mothers concerning infant feeding options and vertical transmission; on-going nutritional and clinical assessment of exposed infants; replacement feeding support, including limited provision of infant formula where warranted;

and associated counseling and program support through at least the first year of life, per national policies and guidelines.

Please note that "safe water" is NOT included in this definition of food and nutrition. It is addressed separately, in the definition for Water.

**9. Economic Strengthening**

Countries should estimate the amount of funding for each activity that is attributable to economic strengthening activities, including:

- Economic Strengthening - The portfolio of strategies and interventions that supply, protect, and/or grow physical, natural, financial, human and social assets. For PEPFAR generally, this refers to programs targeting HIV-infected individuals in care and treatment programs, OVC, and their caregivers. These activities can include a variety of microfinance, micro-enterprise and market development interventions For OVC programs, these activities should focus on families and the household as direct beneficiaries, with success measured by a family's ability to invest in the education, nutrition, and health of its children.
- Microfinance - The range of financial products and services, tailored to meet the needs and demands of low-income or otherwise vulnerable populations. This includes group and individual lending, savings, insurance, and other financial products. Microfinance is distinguished from mainstream finance by its outreach to isolated and poor populations and its efforts to make financial services accessible and approachable to them, in terms of product design and delivery systems.
- Microenterprise - A very small-scale, informally organized business activity undertaken by poor people. Generally refers to enterprises with 10 or fewer workers, including the micro-entrepreneur and any unpaid family workers; many income generating activities fall into this category.
- Microcredit - A form of lending which involves very small sums of capital targeted towards micro-entrepreneurs and poor households. Microcredit can take the form of individual or group loans, and have varying terms, interest rates and degrees of formality. Microcredit is a *type* of microfinance.
- Market Development - A fundamental approach to economic development that recognizes and takes advantage of the fact that products and services are most efficiently and sustainably delivered through commercial systems. Market

development encompasses more targeted strategies such as microfinance and microenterprise development.

**10. Education**

Efforts to promote effective, accountable and sustainable formal and non-formal education systems should be included in this secondary budget attribution. In particular, activities focused on basic education, which is defined as activities to improve early childhood education, program area education and secondary education delivered in formal or non-formal settings. It includes literacy, numeracy and other basic skills programs for youth and adults. Activities related to life skills training and HIV prevention education within the context of education programs or settings should also be included in this budget attribution.

**11. Water**

Countries should estimate the total amount of funding from their country budgets, not including central funds, which can be attributed to safe water. Activities include support for availability, access, and use of products to treat and properly store drinking water at the household level or other point-of-use, and promotion of hand washing with soap.

**12. Condoms: Policy, Tools, and Service Delivery**

This secondary budget attribution should capture all activities with the following components:

- Development and/or Adaptation of National Condom Policies and Guidelines – The cost of developing or adapting national guidelines for condom procurement, distribution and promotion. This also includes activities that improve forecasting, procurement and distribution systems.
- Training and Curricula Development – The cost of training for health care workers, HIV prevention program staff, peer educators, and others to enhance their ability to promote and distribute condoms effectively and efficiently. This includes developing appropriate condom-related curricula for inclusion in pre- and post-service training programs and development of appropriate job aids.
- Condom promotion, distribution and provision – The cost of programs that promote, distribute and provide condoms (but not the cost of procuring condoms – this should be captured in the Condoms: Commodities cross-cutting budget attribution). This includes programs nested within existing clinical and community programs, such as programs for HIV-positive individuals or PMTCT programs, as well as costs for programs that focus

exclusively on condom promotion. Condom social marketing programs should be attributed to this cross-cutting attribution.

- Equipment – The cost of procurement of any tools or equipment necessary to carry out condom programs, such as distribution boxes or dispensing machines, display stands, etc. This also includes more general procurement, logistics and inventory control costs.

**13. Condoms: Commodities**

This secondary cross-cutting budget attribution is meant to capture the cost condoms **procured using bilateral funds** including:

- Condoms for free distribution – The cost of condoms procured with bilateral funds for free distribution in clinical, community or other settings.
- Socially marketed condoms – The cost of condoms procured with bilateral funds for socially marketed condoms clinical, community or other settings.

Please note: most PEPFAR OUs order condoms through USAID's Commodity Fund (CF) and do NOT pay for condoms using bilateral funds. Only those few OUs that are not eligible to order condoms through the CF and are therefore purchasing condoms with bilateral funds should be reporting through this secondary cross-cutting budget attribution.

**14. Gender: Preventing and Responding to Gender-based Violence (GBV)**

This secondary cross-cutting attribution should capture all activities aimed at preventing and responding to GBV. For PEPFAR, GBV is defined as any form of violence that is directed at an individual based on his or her biological sex, gender identity or expression, or his or her perceived adherence to socially-defined expectations of what it means to be a man or woman, boy or girl. It includes physical, sexual, and psychological abuse; threats; coercion; arbitrary deprivation of liberty; and economic deprivation, whether occurring in public or private life. GBV is rooted in gender-related power differences, including social, economic and political inequalities. It is characterized by the use and abuse of physical, emotional, or financial power and control. GBV takes on many forms and can occur across childhood, adolescence, reproductive years, and old age. It can affect women and girls, men and boys, and other gender identities. Women, girls, including men who have sex with men and transgendered persons are often at increased risk for GBV. While GBV encompasses a wide range of behaviors, because of the links with HIV, PEPFAR is most likely to address physical and sexual intimate partner violence, including marital rape; sexual assault or rape; female genital cutting/mutilation; sexual violence against children and adolescents; and child marriage.

Examples of activities for "Preventing and Responding to Gender-Based Violence" include:

- Collection and Use of Gender-related Strategic Information: assess differences in power and gender norms that perpetuate GBV as well as gender and societal norms that may facilitate protective actions against GBV and changes in attitude and behaviors; analysis of existing data on different types of GBV disaggregated by sex, age and geography, and in relation the HIV epidemiology in order to identify priority interventions and focus in the context of PEPFAR programs; analysis of treatment, care and referral services data by sex and age to ensure the unique needs of actual and potential victims are being met; employ rapid assessment, situational analyses and other quantitative and qualitative methods to understand norms and inequalities perpetuating GBV
- Implementation: Screening and counseling for gender-based violence (GBV) within HIV/AIDS prevention, care, and treatment programs; strengthening referrals from HIV/AIDS services to GBV services and vice-versa; strengthening post-rape care services, including the provision of HIV PEP; interventions aimed at preventing GBV, including interpersonal communication, community mobilization and mass media activities; programs that address societal and community norms that perpetuate violence against women and girls and other marginalized populations; that promote gender equality; and that build conflict resolution skills; strengthening linkages between health, legal, law enforcement, and judicial services and programs to prevent and mitigate gender-based violence; interventions that seek to reduce gender-based violence directed at children and related child protection programs; support for review, revision, and enforcement of laws and for legal services relating to gender-based violence, including strategies to more effectively protect young victims and punish perpetrators
- Capacity building: capacity building for U.S. government staff and implementing partners on how to integrate GBV into HIV prevention, care and treatment programs; capacity building for Ministry of Women's Affairs, Ministry of Health or other in-line Ministries to strengthen national GBV programs and guidelines; pre and in-service training on the identification, response to and referral for cases of intimate-partner violence, sexual violence and other types of GBV; assist in development and implementation of agency-, government-, or portfolio-wide GBV strategy
- Monitoring and Evaluation: strengthening national and district monitoring and reporting systems to capture information on provision of GBV programs and services, including HIV PEP within health facilities

- Operation Research: to better understand the associations and pathways between GBV and HIV/AIDS; identify promising practices in training and protocol for the effective delivery of GBV screening and services and of GBV prevention programs; evaluate the impact of comprehensive GBV programming on HIV and GBV outcomes of interest

Activities marked as GBV will now be required to provide additional information on specific activities supported. Upon ticking the GBV crosscutting attribution box a drop-down menu of activities will appear. Teams should select **all** that apply.

- GBV Prevention
  - Collection and Use of Gender-related Strategic Information
  - Implementation
  - Capacity building
  - Monitoring and Evaluation
  - Operation Research

- GBV Care
  - Collection and Use of Gender-related Strategic Information
  - Implementation
  - Capacity building
  - Monitoring and Evaluation
  - Operation Research

**15. Gender: Gender Equality**

This secondary cross-cutting attribution should capture all activities aimed at ensuring that men and women are treated without discrimination and have equal access to healthcare, contribute to health development and benefit from the results by taking specific measures to reduce gender inequities within HIV prevention, care and treatment programs. This would consist of all activities to integrate gender into HIV prevention, care, and treatment and activities that fall under PEPFAR's gender strategic focus areas:

- Working to change harmful gender norms and promoting nondiscrimination
- Promoting gender-related policies and laws that increase legal protection
- Increase nondiscriminatory access to income and productive resources, including education
- Nondiscrimination in HIV prevention, care, treatment and support

Examples of these activities include:

- Collection and use of Gender-related Strategic Information: Analysis of existing HIV prevention, care, and treatment portfolios and/or individual programs to understand and ensure appropriate response to: gender norms, relations and inequities that affect health outcomes; variation across populations and population subsets (by sex and age) in terms of gender norms, roles and resource needs; differences in power that affect access to and control over resources between women and men, girls and boys, which are relevant to health objectives; key gaps and successful programs in gender integration across HIV prevention, care and treatment; analysis of access and adherence to treatment includes analysis of data by sex and age and assessment of barriers to service by men and women; employ rapid assessment, situational analyses and other quantitative and qualitative methods to understand gender norms and inequalities in the context of HIV prevalence and programming

- Implementation of: HIV prevention interventions redressing identified gender inequalities; Legal, financial or health literacy programs for women and girls; programs designed to reduce HIV that addresses the biological, cultural, and social factors that disproportionately impact the vulnerability of women, men or transgender persons to the disease, depending of the setting and type of epidemic; a PMTCT or HTS program that implement interventions to increase men's meaningful participation in and use of services; specific programming for out-of-school adolescent and pre-adolescents who are often the most vulnerable, including males and married adolescent girls; male circumcision programs that include efforts to reach female partners, mothers and other women in the community and incorporate messages around gender norms in pre and post counseling

- Capacity building: assist in development and implementation of agency-, government-, or portfolio-wide gender strategy; conduct training for U.S. government staff and implementing partners on women, girls, and gender equality issues, as well as capacity building on how to integrate gender into HIV prevention, care and treatment programs; capacity building for Ministry of Women's Affairs or the Gender Unit within a Ministry of Health; capacity building interventions for HIV-positive women to assume leadership roles in the community and programs; training for health service providers

on unique needs and risks of specific sub-populations such as adolescent girls and older, sexually-active men

- Operational Research: to better understand gender-related barriers and facilitators to HIV prevention, care and treatment programs; identify HIV-related needs and risks specific to adolescent girls and young women; promote constructive male engagement strategies to increase uptake of male circumcision, other prevention strategies, HTS, treatment, and care among adult men

- Monitoring and Evaluation: of programs and services through the use of standardized indicators and strengthening monitoring systems be able to document and report on accessibility, availability, quality, coverage and impact of gender equality activities; ensure that data is disaggregated by sex and age

Activities marked as GBV will now be required to provide additional information as part of a drop-down menu. Teams should select all that apply.

- Working to change harmful gender norms and promoting nondiscrimination
  - Collection and Use of Gender-related Strategic Information
  - Implementation
  - Capacity building
  - Monitoring and Evaluation
  - Operation Research
- Promoting gender-related policies and laws that increase legal protection
  - Collection and Use of Gender-related Strategic Information
  - Implementation
  - Capacity building
  - Monitoring and Evaluation
  - Operation Research
- Increase nondiscriminatory access to income and productive resources, including education
  - Collection and Use of Gender-related Strategic Information
  - Implementation
  - Capacity building
  - Monitoring and Evaluation
  - Operation Research

- Nondiscrimination in HIV prevention, care, treatment and support
  - Collection and Use of Gender-related Strategic Information
  - Implementation
  - Capacity building
  - Monitoring and Evaluation
  - Operation Research

## Appendix D.4.18 Activity Table

In COP 2017, an ***Activity Table*** will be required for all new mechanisms and all G2G mechanisms (new or continuing), and is entered within a tab in FACTS Info. The Activity Table tab provides additional detail on these mechanisms, including a brief statement on the overall mechanism purpose, and brief description, including outcomes and relevant budget codes, for the intended activities within each mechanism. In COP 2017, activity tables for continuing, non-G2G mechanisms are *not* required.

## Appendix D.4.19 Public Private Partnerships

PEPFAR defines Public Private Partnerships (PPPs) as collaborative endeavors that coordinate programs funded by resources from the public sector with resources from the private sector to accomplish HIV/AIDS prevention, care, and treatment goals. PEPFAR has three types of Public Private Partnerships (PPP), based on the origin of the funding for the PPP Program:

1. **Global:** Global PPPs are initiated and managed at the central (HQ) level. They are typically funded on the U.S. Government side by central funds through the Headquarters Operational Plan (HOP) process, although they can also be jointly funded with combined central and country funds. These PPPs typically span multiple countries with multiple partners, and are reviewed by the Technical Working Group (TWG) and Deputy Principals (DPs).
2. **Country-Based:** Country-Based PPPs are initiated and managed at the country level. They are funded on the U.S. Government side by the country teams through the Country Operational Plan (COP) process. Countries are responsible for reporting on these programs in the COP and Annual Program Results (APR).
3. **Incentive Fund:** Incentive Fund PPPs are a combination of the two previous types of PPPs. They are initiated and managed by the country teams and reported on in the COP and APR. Incentive Fund PPPs are funded on the U.S. Government side solely through central (HQ) funds or through a combination of country funds and central (HQ) funds.

For any of the above types of PPPs that involve the State Department, S/GAC must be consulted to ensure appropriate State Department approval.

Country teams should incorporate country-based PPPs into the COP planning process. To strategically develop high-impact partnerships, country teams should prioritize alignment with core and near-core activities and geographic high yield/burden sub-national localities. New ideas and opportunities to scale and expand best practices should be regularly reviewed and discussed interactively with partners.

All PPPs should be considered when planning the COP and be part of the COP submission, in the same way as any other implementing mechanisms are planned for and reported;

- Country-based and Incentive Fund PPPs must be associated with an Implementing Mechanism and reported in FACTS Info.
- Global PPPs and Central Initiatives should also be fully aligned with the modular planning steps outlined within Appendix B including geographic alignment and reported in FACTS Info.

Please remember that a PPP can be a program by itself, but it may also be added to an existing program or can be designed as part of a larger program to fill gaps as necessary. For instance the AstraZeneca partnership that was recently launched in Kenya is implemented by an existing PEPFAR-funded partner and adds a new component to their service delivery platform. Key Programmatic areas and Implementation Focal Areas for PSE and PPP development include:

- Improving and strengthening program quality, efficiency and sustainability through private sector engagement aligned with the scale up of core interventions
- Focusing private sector engagement efforts on geographic areas at sub-national levels with the highest disease burden
- Engaging private sector to play a vital role in getting ahead of and ultimately controlling the HIV/AIDS epidemic
- Engaging private sector on commitments for prevention investments for DREAMS, Test & Start for men in DREAMS districts, and VMMC
- Implementing the DREAMS Innovation Challenge for new partners to contribute new resources and ideas to spark innovation into the DREAMS partnership
- Reducing the impact of cervical cancer on HIV-positive and -vulnerable women
- Developing new partnerships and central initiatives in line with other Front Office priority areas

In COP 2017, PPPs are entered in the mechanism information section of FACTS Info. All PPPs should be linked to an existing or planned mechanism.

# APPENDIX E: Budgetary and Reporting Requirements

# Appendix E.1 COP Planning Levels, Applied Pipeline and Financial Supplemental Document

Countries or regions should fund their program based upon the COP 2017 planning level and earmark requirements as described in the official planning letter. **COP 2017 should be planned to the stated planning level in the letter, which equals the sum of requested new FY 18 resources and prior year available pipeline applied in support of COP 201 activities (applied pipeline).** The distribution between new and applied pipeline should be finalized based upon the amount of excessive pipeline available for implementation in COP 2017.

PEPFAR will continue to meet previously stipulated Congressional earmarks and fulfill the expectations around other key priority areas while S/GAC continues to communicate with Congress about their expectations and will make teams aware of any shifts for programmatic focus.

Please note: earmarks/budgetary considerations can only be satisfied via programming of current year (FY 17) funds. The application of pipeline cannot be counted towards a team's fulfillment of earmark requirements or other budgetary considerations.

## Appendix E.1.1 COP Planning Levels

The COP 2017 planning level represents the total resources (regardless of whether they are new FY 17 resources or prior year pipeline resources) that a country or region will outlay over a 12-month period in order to achieve the stated goals or targets of COP 2017.

The COP planning level is the sum of new FY 17 resources and pipeline applied to COP 2017 implementation (COP Planning Level = New Funding Request + Total Applied Pipeline). All outlays anticipated to occur during the COP 2017 implementation cycle must be included within the COP 2017 planning level.

As pipeline is applied to COP 2017 implementation, FY 17 new funds must be decreased in order to keep the entire COP request within the COP 2017 planning level.

**Contact your Country Lead prior to final COP submission within FACTS Info in order to ensure FY 17 funding account control levels are updated within FACTS Info, and the completed COP balances.** A COP cannot be submitted without these updates made at headquarters.

A COP may not include any "unallocated" funds within the COP Planning Level. If the total planning level exceeds the overall resource envelope required to achieve targets, or is determined to be greater than a country or region's actual ability to outlay within a 12-month period, teams are encouraged to submit a final COP requesting a lower COP 2017 planning level, rather than creating TBDs and/or overfunding mechanisms, or stating a higher spend-rate than is feasible. Some examples of instances in which this scenario may occur are as follows**:** transition, other available donor resources, etc**.**

Contact your Country Lead if this scenario seems likely during the COP planning process or for more information on expectations.

## Appendix E.1.2 Applied Pipeline

Applied pipeline should reflect the pipeline resources that have been deemed as "excessive pipeline," and are therefore available for implementation within COP 2017. The applied pipeline field should include any prior year (non-FY 17) COP funding that will continue to be implemented and expended during the COP 2017 cycle (i.e. construction funding programmed in a previous year that continues to outlay during COP 2017).

**It is expected that all agencies within all countries or regions will analyze their pipeline, ensuring that pipeline remains within an acceptable range, and adjust the new funding allocations as required to spend down excessive pipeline.** A submitted COP that does not address excessive pipeline may be subject to delays in approval.

Every PEPFAR program requires a certain amount of pipeline to ensure there is no disruption to services due to possible funding delays or other unanticipated issues. An acceptable level of pipeline is expected to be reflective of an additional 5 months of outlays beyond the current implementation cycle, unless a country is designated as "Special Notification" within the FY 17 appropriations bill. Countries designated as "Special Notification" should consider a pipeline that is reflective of 9 months of outlays as acceptable. Pipeline that is above this accepted level of 5 months (or 9 months for special notification) is considered "excessive." With the expectation that funds will arrive in the same fiscal year as the COP is approved, less excess pipeline is needed in reserve than previous years. Only "excessive" pipeline should be included in the COP 2017 request as applied pipeline, as this excessive amount must be spent down in order to reduce pipeline and bring it into an acceptable range.

As stated in Section 8 below, funding for Peace Corps Volunteers (PCVs) must cover the full 27-month period of service and thus, countries with PEPFAR-funded volunteers are exempt from the 3-6 months of pipeline rule.

In most instances, the pipeline applied to a mechanism (or CODB category), "applied pipeline," will be less than the total pipeline available to the mechanism, as the acceptable pipeline level must be maintained and should not be considered as available for application to COP 2017.

The applied pipeline field within COP 2017 should be considered a type of COP 2017 funding source (in addition to the GHP-State, GHP-USAID, and GAP accounts). The sum of these funding sources (new FY 17 funds + applied pipeline) will equal the total resources expected to be outlayed by an individual mechanism (or CODB category) over the 12-month COP 2017 implementation period. When all mechanism funding sources (new FY 17 funds + applied pipeline) and all M&O funding sources (new FY 17 funds + applied pipeline) are added together, this total is equal to the outlay level for COP 2017, i.e. to the COP planning level.

**Note:** *It is understood that many agencies follow a "first-in, first-out" approach to budget execution, requiring the full utilization of expiring funds and older funds before any new FY 17 funds are obligated and expended. Due to this budget execution approach, the actual fiscal year of funds that are outlayed in support of an approved COP 2017 activity may not match the approved COP 2017 applied/new funding breakdown.*

## Appendix E.1.3 Financial Supplemental Workbook

Each country or region must submit a financial supplemental workbook at COP/ROP submission, detailing the historic, current and projected financial performance of all mechanisms and CODB categories included within the COP/ROP. Each country or region must submit one workbook compiling the information for all agencies. Multiple workbooks (i.e., one for each agency) will not be accepted

The ***Financial Supplemental Workbook*** can be found on the pepfar.net COP 17 website.

The ***Financial Supplemental Workbook*** must be uploaded into the FACTS Info Document library upon submission. A COP/ROP submission will not be considered complete without the submission of this supplemental document. The information entered into the supplemental document must match your COP submission in FACTS Info, be free of errors and the current budget request information (new funds requested and applied pipeline) can be copied from a FACTS Info Standard COP Matrix Report.

The ***Financial Supplemental Workbook*** includes three tabs to be populated:

Tab 6: Mechanism Data

All mechanisms included in the COP 2017 submission must be represented in this tab. The final submitted Financial Supplemental Worksheet must combine all agencies into one submission, and the totals must match with the data entered into FACTS Info.

The Standard COP Matrix Report should be used as a resource for completing this Tab. It is the best source for a complete listing of all implementing mechanisms and data within that report should be copied and pasted into the worksheet.

The remaining required elements should be completed with assistance from agency field and headquarters financial staff.

Tab 7: CODB Data

See M&O section 8.0 for further details.

Tab 8: Certification Page

Provide the contact information for the personnel that compiled the workbook and the agencies' points of contact that cleared the workbook.

The totals reflected in this Tab must match with the total COP planning level and totals submitted within FACTS Info.

The **Financial Supplemental Workbook** includes three tabs to verify for data entry completeness

Tab 3: Summary

The summary tabs are automatically populated once the mechanism data and CODB tabs are completed. The totals reflected in this Tab must match with the total COP planning level and totals submitted within FACTS Info.

Tab 4: Summary Tables

Another summary tab but with pivot table functions to review information by specific categories.

Tab 5: BC_Earmarks

This summary tab verifies if funding levels reach the required earmark amounts. If earmark levels are not met, this tab will highlight that as an error. The funding levels must be adjusted so that earmark levels are met.

# Appendix E.2 Budget Code Definitions

## Appendix E.2.1 MTCT- Prevention of Mother to Child Transmission

MTCT – Includes activities aimed at preventing mother-to-child HIV transmission.

Activities that **should be** included in MTCT:

1. Services and support related to the initiation, adherence, retention, clinical monitoring (including labs), and Nutrition Assessment Counseling and Support (NACS) (including breastfeeding counseling) for HIV+ pregnant and breastfeeding women *newly initiating ARVs under option B+*.
2. HIV testing for all pregnant and breastfeeding women and their partner(s).
3. Salary support for CHWs that assist with PMTCT specific adherence and retention activities
4. Training for clinical and other personnel supporting PMTCT activities (e.g., lay counselors, mentor mother programs, data clerks)
5. Training for services for HIV-exposed infants (HEI)
6. Sample transport systems for specimens at the site level for clinical monitoring of PMTCT clients (VL and early infant diagnosis specimens)
7. Roll-out of B+ PMTCT program policy and implementation including:
    a. National/district level support for B+ roll-out
    b. Register revision/program reviews for B+ transition
    c. Evaluation of B+ implementation
8. Real-time PMTCT program monitoring and quality improvement
9. Activities on estimation of population transmission rates at national or subnational level
10. Activities supporting delivery of ARV prophylaxis for newborns

Activities that **should *NOT*** be included in MTCT (these costs should be accounted for in their respective budget codes):

1. Service delivery for B+; lifelong ART(HTXS)
2. ARV drugs, including for infant prophylaxis (HTXD)
3. Male and female condoms and lubricant (HVOP)
4. Community based activities focused on family strengthening (HKID)
5. Household and economic food security (HKID)
6. Social welfare (HKID/HBHC)
7. Lab reagents for CD4/VL/EID (care and treatment codes)
8. INH prophylaxis (HVTB)
9. TB screening and treatment for pregnant women (HVTB)
10. Women on their second pregnancy and are on ART from their previous pregnancy – service delivery (HTXS); ARVs (HTXD)

Activities that should NOT be included in MTCT as they are not currently supported by PEPFAR

1. Birth testing: implementation of birth testing for HIV -exposed infants is not supported unless testing rates at 4-6 weeks exceed 80% of PMTCT_STAT_POS and appropriate drugs are available for treatment of neonates identified as positive for HIV infection.

## Appendix E.2.2 HVAB- Abstinence/Be Faithful

Activities that **should** be included in HVAB:

1. All prevention activities that promote abstinence or fidelity
    a. School-based prevention programs that promote delay of sexual debut
    b. Sexuality education
    c. Parenting programs
2. Life Skills Programs
3. Mass Communication and media campaigns
4. Behavior change programs

Activities that **should *NOT*** be included in HVAB:

1. Prevention aimed at Key Populations (HVOP)
2. Condom procurement, distribution or marketing (HVOP)

## Appendix E.2.3 HVOP – Other Sexual Prevention

Activities that **should** be included in HVOP:

1. Services related to the procurement, distribution and marketing of male and female condoms and condom-compatible lubricant
2. Beginning in FY17, male and female condom and lubricant products will be procured with HOP funds through USAID's supply chain project and do not need to be budgeted for in COPs. COP budgets should include condom distribution and programming support that makes headquarter-procured condoms available, accessible, and attractive to young people. All sexual prevention programs targeted for key populations:
    a. Peer outreach
    b. Small group prevention activities
    c. Hotspot prevention activities
3. NGO Network building
4. PrEP implementation and demonstration projects (excluding procurement of ARVs)
5. Comprehensive care for survivors of sexual assault
6. Activities related to reducing alcohol related sexual disinhibition
7. Linkages to other services and platforms (i.e. VMMC, Care, Treatment)
8. Engagement with the government and civil society organizations to reduce criminalization of key populations
9. Training for providers for key populations considerations
10. Prevention targeting priority populations (i.e. military, adolescent girls)
    a. Adolescent friendly sexual and reproductive health services

Activities that **should *NOT*** in included in HVOP:

1. Activities for key populations living with HIV(These activities should be tracked using key populations budget attributions- KP : FSW or KP: MSM and TG- if possible):
    a. STI management for HIV+ in KP setting (HBHC)
    b. MAT/MMT for HIV+ PWIDs (HBHC)
    c. MAT/MMT for HIV- persons PWID (IDUP)
2. Community or facility clinical services for HIV+ KP clients (HTXS or HBHC)
3. All PwP or PHDP activities (HBHC)
4. Size estimation surveys or IBBS surveys (HVSI)

5. Procurement of drugs for Post-Exposure Prophylaxis (PEP) as part of care for survivors of sexual assault (HTXD)
6. Procurement of drugs for Pre-Exposure Prophylaxis (PrEP) (HTXD)

## Appendix E.2.4 HMBL- Blood Safety

Activities that **should** be included in HMBL:

1. Activities supporting a nationally-coordinated blood safety program to ensure accessible, safe and adequate blood supply
2. Infrastructure, training and policy
3. Donor-recruitment, blood collection, testing (transfusion-transmissible infections), and appropriate use.
4. Blood collection and blood testing (transfusion-transmissible infections)
5. Storage and distribution
6. Transfusion procedures and hemovigilance
7. Monitoring and evaluation for blood safety
8. Quality improvement, including accreditation of blood bank services and participation in external quality assessment (EQA) programs

## Appendix E.2.5 HMIN- Injection Safety

Activities that **should** be included in HMIN:

1. Programs, policies, training and advocacy to reduce medical transmission of HIV and other blood borne pathogens
2. Education of healthcare workers and the community on injection safety.
3. Strategies to reduce occupational exposure to blood borne pathogens.
4. Programs to reduce unnecessary injections and promote injection safety
5. Health care waste management programs
6. Management of needle sticks and occupational PEP
7. Safe phlebotomy
8. Infection prevention and control
    a. Single use syringes and needles
    b. Lancets and blood drawing equipment
    c. Safety boxes
    d. Gloves for safe phlebotomy

## Appendix E.2.6 IDUP- Injecting and Non Injecting Drug Use

IDUP- Prevention among people who inject drugs (PWID)

Activities that **should** be included in IDUP:

1. Policy reform around PWIDs
2. Needle and syringe access programs
3. Training and capacity building for providers, including the host government and NGOs
4. Procurement of methadone and other medical-assisted therapies (MAT) should be included ONLY if it is for HIV-negative PWIDs for prevention purposes (see HBHC for MMT/MAT for HIV-positive PWIDS)
5. Comprehensive programs for PWIDs included treatment of other drug addictions such as methamphetamine
6. Community mobilization and PWID Networks

Activities that **should *NOT*** be included in IDUP:

1. Prevention of sexually transmitted HIV infection among PWIDs (HVOP)
2. MMT/MAT for HIV-positive PWIDs (HBHC)
3. Continuum of care for HIV+ PWIDs (HBHC)
4. Non-injection drug prevention interventions (i.e., alcohol risk reduction) (HVOP)

## Appendix E.2.7 CIRC- Voluntary Medical Male Circumcision

Activities that **should** be included in CIRC:

1. Support the implementation of VMMC - This includes the minimum package of clinical and prevention services which MUST be included at every VMMC delivery point
    a. Age-appropriate sexual risk reduction counseling
    b. Counseling on the need to refrain from sexual activity or masturbation during the healing process after the procedure
    c. Circumcision by a medical method recognized by WHO (device or surgery)
    d. Post-surgery follow-up, including adverse event assessment and management
    e. Distribution of condoms
    f. Voluntary HIV testing prior to circumcision for all men and their partners (given low rates of HIV infection among males who have not yet had sexual debut, programs should consider whether HIV counseling and testing of this group should be routine or done only upon request rather than as a routine)

2. Circumcision supplies and commodities
    a. This includes emergency equipment such as tourniquet, IV and IV catheters, hydrocortisone, adrenaline, sphygmomanometer, stethoscope, and sodium chloride
    b. PrePex or other circumcision devises (only if they are WHO prequalified)
    c. Supplies for safety during the procedure: exam gloves, alcohol swabs, gauze, adhesive tape, syringes and needles
    d. Tetanus toxoid containing vaccine (TTCV) as needed to comply with WHO recommendations and MOH policy as part of tetanus mitigation.
    e. Prioritize use of reusable instruments instead of disposable kits given cost and waste management challenges of disposable instruments
3. Communication and demand creation
4. Training
    a. Adverse event and safety training
    b. Training to comply with mandatory reporting of defined notifiable adverse events to S/GAC within 24 hours of learning of adverse event
    c. In-service training for VMMC for either surgery or devices
    d. Curriculum creation
5. Linkages to treatment/ Care services for men who test HIV+
6. Case finding and linkages for high-risk men
    a. Establishing connections with settings that provide treatment for STIs and demand creation with referral systems to VMMC clinics
    b. Establishing connections with settings that identify HIV sero-discordant couples and demand creation with referral systems to VMMC clinics among HIV-negative male partners
    c. Targeted follow-up of men who present with STIs and receive treatment to ensure that they return for VMMC

Activities that **should *NOT*** be included in CIRC:

1. Circumcisions for clients between 61 days old up to age 10 years
2. Circumcisions that require general anesthesia or sedation

## Appendix E.2.8 HVCT- HIV Testing Services

Activities that **should** be included in HVCT:

1. The provision of HIV testing services (HTS, formerly HTC) across the range of community and facility-based settings (including client and provider- initiated approaches) and all associated programs for training and refresher training for counselors/testers
    a. HVCT should include budgets for HIV testing for PHDP, key populations, adult treatment, care and support, pediatric treatment, and for orphans and vulnerable children
2. Supply, provision and distribution of HIV RTKs (Rapid Test Kits)
3. Mobilization to support HTS demand creation
4. Linking HTS-users to the appropriate services (i.e. VMMC, Prevention, Treatment, Care) and tracking those linkages
5. Note that verification (for confirmation prior to ART initiation) in persons testing HIV-positive can be covered by HTS or by Adult Care and Support (HBHC, preferred budget code) or PDCS for ages < 15.
6. Linking HIV+ persons identified to treatment programs for same day initiation of ART. Includes counselors/navigators to take clinents to treatment sites, increased testing at facilities able to provide same day initiation, and innovative programs to allow counselors and other testing providers to provide immediate ART provision while linking clients to ongoing treatment. These activities can account for up to 30% of the budget code and can be applied to the Care and Treatment earmark.

Activities that **should *NOT*** be included in HVCT

1. Testing and counseling in the context of PMTCT (MTCT)
2. Early Infant Diagnosis (EID)(PDCS)
3. Testing and counseling in the context of TB (HVTB)
4. Testing and Counseling in the context of VMMC (CIRC)

## Appendix E.2.9 HBHC- Adult Care and Support

Activities that **should** be included in HBHC:

1. All services provided under the HBHC budget code apply to HIV+ adult clients (age 15 and older) only. Care and support interventions, including PHDP interventions, provided to HIV+ adult clients should be attributed to HBHC.

2. Procurement of cotrimoxazole and associated support (e.g. training, monitoring, oversight/mentoring, etc.)
3. Services related to prevention and treatment of OIs (excluding TB) and other HIV/AIDS-related complications including malaria, diarrhea, and Cryptococcal disease (including provision of commodities such as pharmaceuticals, insecticide-treated nets, safe water interventions and related laboratory services) to all HIV+ adults,
4. Pain and symptom relief
5. Screening and treatment to prevent cervical cancer in HIV-infected and vulnerable women, specifically screening with molecular diagnostic testing for the human papillomavirus and/or direct visual inspection with acetic acid, and treatment of pre-cancerous lesions with ablative treatment ( cryotherapy or thermal coagulation), or loop electrosurgical excision procedure (LEEP), in alignment with WHO guidelines (*WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention, 2013*), including procurement of associated supplies and equipment
6. Nutritional assessment, counseling, and support (NACS) for HIV+ adults
7. Procurement of monitoring commodities (CD4 and viral load) for adult PLHIV, along with costs associated with sample transport, testing and results return (HBHC or HTXS). Programs are encouraged to move towards routine VL monitoring for ongoing follow-up of PLHIV.
8. Medication Assisted Treatment (MAT – provision of methadone and associated services) can be proposed for inclusion in situations where country teams are able to track the portion of the MAT services provided to HIV-positive individuals.
9. Support for ongoing adherence and retention interventions for PLHIV - community and /or facility-based (HBHC or HTXS)
10. For HIV+ individuals, all services related to the prevention of onward transmission of HIV as well as maintaining health of the patient (PHDP services):
    1. Assessment of sexual activity and provision of condoms (and lubricant) and risk reduction counseling (if indicated).
    2. Assessment for STIs and provision of or referral for STI treatment and partner treatment if indicated.
    3. Assessment of family planning needs and (if indicated) offering contraception or safer pregnancy counseling or referral for family planning services.
    4. Assessment of adherence and (if indicated) support or referral for adherence counseling; assessment of need and (if indicated) referral or enrollment of PLHIV in

community-based programs such as home-based care, support groups, post-test-clubs, etc.

11. Repeat HIV testing(for confirmation prior to ART initiation) in persons testing HIV-positive can be covered by HTS (HVCT) or by Adult Care and Support (HBHC, preferred)

Activities that **should *NOT*** be included in HBHC:

1. ARVs (HTXD)
2. TB drugs and services, including TB screening, diagnostic testing and support for TB preventive therapy (HVTB)
3. Costs associated with testing partners and family members of PLHIV (HVCT or MTCT)
4. STI drugs used for broader populations (e.g. KPs seen in a general STI clinic) (HVOP)
5. Services provided more broadly to key populations of unknown or negative serostatus (HVOP)
6. All care interventions for HIV+ children (under age 15) (PDCS).
7. With regard to cervical cancer, PEPFAR does not provide funding for primary prevention (HPV vaccine), cytologic screening (Pap smears), or treatment for invasive cervical cancer.
8. PEPFAR does not procure contraceptives, with the exception of male and female condoms.

## Appendix E.2.10 HKID- Orphans and Vulnerable Children

HKID activities should prioritize adolescents ages 10-17 and particularly adolescent girls in areas with the highest HIV burden, especially where targets for younger children have been met or exceeded. Activities that **should** be included in the HKID budget code:

1. Support of vulnerable children and their households
    a. Promotion of Cash Transfers
    b. Household economic and food security
    c. Education subsidies
    d. Improve child and family relationships
    e. Protective services for children
    f. Keeping children in family structures
    g. Access to healthcare and health services
    h. Access to adolescent friendly services/ Reproductive health services, including post-rape care [N.B.: HKID can be used to help OVC beneficiaries *access* these services; provision of services is funded under HVOP].
    i. Early Childhood Development programs
    j. Strengthen growth monitoring for young children and linkages to nutrition programming

2. Support of the community with OVC
    a. Mobilizing child protection committees
    b. Strengthening the capacity of local NGOs and CBOs who work on OVC issues
    c. Building of social welfare and service networks including the social workforce

3. Linkages to other HIV related services
    a. Linkage and referral to facility and community-based services like HTS, pediatric care and treatment
4. M&E for intervention evaluations of OVC programming

Activities that **should *NOT*** be funded under HKID:

1. Pediatric drugs, diagnostics and services (HTXD, HVCT, PDCS, PDTX)
2. Pediatric care and support (PDCS)
3. HTS in OVC settings (HVCT)
4. Prevention services and commodity procurements for adolescent friendly/reproductive health/post-rape services (HVOP).
5.

**Note:** *Implementing Partners working to serve orphans and vulnerable children should be supported to offer comprehensive programs that include HTS and linkages to care and treatment from both community and facility sites; activities within these comprehensive programs must be coded to HTS and HKID accordingly as indicated in the budget code guidance as noted in sections 7.2.8 and 7.2.10*.

*Please refer to the 2012 PEPFAR OVC Guidance for more information on acceptable activities.

## Appendix E.2.11 HVTB- TB/HIV

Activities that **should** be included in HVTB:

1. All TB screening activities, including chest radiography among PLHIV, including women and children
2. TB preventive therapy for all PLHIV
3. Laboratory investments for TB/HIV, including GeneXpert equipment and MTB/RIF cartridges, determine TB LAM Ag urine dipstick tests and other TB-specific diagnostics and consumables (e.g., biosafety cabinets, supplies and equipment for AFB smear microscopy and culture, supplies for drug susceptibility testing)
4. Specimen transportation for diagnostic testing

5. Examinations, clinical monitoring (including related laboratory services), and treatment for TB and prevention of TB (including isoniazid and drugs for treating active TB)
6. Costs associated with adherence monitoring (including use of community health workers or text messaging)
7. Costs associated with contact tracing or household investigations
8. Testing of TB clinic clients for HIV (HIV testing), including fast-tracking/referral of PLHIV with TB for initiation of ART
9. Services that target TB/HIV activities in special populations such as pediatrics, prisons, and miners
10. Human resources to accelerate planning and implementation of collaborative TB/HIV activities, including site-level integration of TB and HIV activities
11. Efforts to improve monitoring, evaluation and reporting of collaborative TB/HIV activities
12. Efforts to increase public awareness and reduce stigma and discrimination of TB, including engaging community service organizations and social media campaigns

Activities that **should *NOT*** be included in HVTB:

1. Costs associated with ART treatment and monitoring of TB/HIV patients (HTXD, HTXS or PDTX)

## Appendix E.2.12 PDCS- Pediatric Care and Support

Activities that **should** be included in PDCS:

1. All HIV-related care services provided for children and adolescents living with HIV either in the community or in the facility
2. Facility based services for HIV-exposed infants (NACS, insecticide treated bed nets, safe water, clinical monitoring, pain and symptom relief, and nutritional assessment and support including food)
3. Early infant diagnosis (EID) services implemented at the site level
4. Cotrimoxazole (CTX) prophylaxis (commodities)
5. Sample transport and results return for pediatric specimens at the site level (VL/EID)
6. Activities to support the needs of adolescents with HIV (ALHIV) (PwP, support groups, support for transitioning into adult services, adherence support, reproductive health services, refer to the OVC program for educational support for in and out of school youth)
7. Activities promoting integration with routine pediatric care, nutrition services and maternal health services, malaria prevention and treatment.

8. Activities to ensure appropriate dispensation of CTX and Isoniazid (INH), prophylaxis in infants, children and adolescents.
9. Activities to address nutritional evaluation and care of malnutrition in HIV+ and exposed infants, children and youth.
10. Activities to address psychosocial support of children and adolescents, including disclosure, adherence counseling, and support groups. Where possible, countries should coordinate adherence and disclosure activities with the OVC program.
11. Activities that will increase direct linkages to the community to improve communication between facilities and community services for HIV+ children and youth.
12. Activities that support HTS to widen the access, utilization and uptake by families and adolescents
13. Activities that strengthen retention in care from infant to transition from adolescent to adult services

Activities that **should *NOT*** be included in PDCS:

1. Broader lab capacity, training and equipment, including activities to strengthen laboratory support and diagnostic services for pediatric patients (HLAB)
2. Services that target TB/HIV activities in pediatrics, including INH (HVTB)
3. Infrastructural and construction activities (OHSS)
4. Key prevention activities that address girls, young MSM, LGBT, substance users and youth involved in sexual exploitation (HVOP)
5. ARVs (HTXD)

## Appendix E.2.13 HTXD- ARV Drugs

Activities that **should** be included in HTXD:

1. All ARVs, including ARVs for adult treatment, pediatric treatment, and PMTCT (including ARVs for prophylaxis of HIV-exposed infants).
2. All antiretroviral Post-Exposure Prophylaxis procurement for rape victims and needle stick injuries
3. All antiretroviral Pre-exposure Prophylaxis (PrEP) commodities for prevention of HIV. PrEP can only be procured in countries where policies are in place supporting all of the following:
    - Test and START for all PLHIV
    - Routine viral load testing at least annually
    - Service delivery models allowing 3-6 months of ARV provision to PLHIV stable on ART.

ARV drug volumes and costs should be tied to targets and there must be clear presentation of how funding for ARVs is coordinated and accounted for across all funders, including at minimum:

- **PEPFAR**
- **Global Fund Principal Recipient(s) (GF)**
- **Host national government**

Activities that **should *NOT*** be included in HTXD:

1. Cost of distribution of ARVs to the site level - facility or community (HTXS)
2. Supply chain management advisors (OHSS)
3. Supply chain/logistics, pharmaceutical management and related systems strengthening inputs (OHSS)
4. Commodity storage costs or management of those storage costs related to distribution of ARVs (OHSS)
5. Rental costs or the tracking or equipment needed to move commodities inside a warehouse (OHSS)
6. Software or planning costs related to distribution of ARVs (OHSS)

## Appendix E.2.14 HTXS- Adult Treatment

Activities that **should** be included in HTXS:

1. Direct service provision as well as direct technical support to the site, including:
    a. Direct services for HIV+ adult patients (age 15 and over) related to adherence, retention, and clinical monitoring both at the facility and community-level (HBHC or HTXS)
    b. Procurement of CD4 and VL reagents, along with costs associated with sample transport, testing and results return for adult PLHIV (this can be coded in HTXS or HBHC but costs cannot be double-counted). For routine monitoring of PLHIV, CD4 testing should be replaced with viral load monitoring as rapidly as possible.
2. Service delivery for option B+, including support for clinic personnel
3. In-service training for clinicians and other providers to provide adult care
4. Sample transport and results return for adult specimens at the site level (CD4/VL)
5. Cost of distribution of ARVs to the site level (facility or community)

Activities that **should *NOT*** be included in HTXS:

1. Procurement of RTKs for initial testing (HVCT), Cost of retesting of initially positive persons before initiation of ART can be included in HBHC.
2. ARVs (HTXD)
3. Pre-service training (OHSS)
4. Laboratory services for counseling and testing (HLAB or HVCT)
5. TB screening (HVTB)
6. Pediatric care and treatment (PDCS or PDTX)
7. HIV drug resistance surveillance activities (HVSI)
8. Services and support related to the initiation, adherence, retention, clinical monitoring (including labs), and NACS (including breastfeeding counseling) for HIV+ pregnant and breastfeeding women *newly initiating ARVs under option B+*. (MTCT)

## Appendix E.2.15 PDTX- Pediatric Treatment

Activities that **should** be included in PDTX:

1. Costs associated with providing clinical services to HIV+ children
2. Costs associated with community support to HIV+ children
3. Support to the government to roll out updated pediatric treatment guidelines
4. In-service training for clinicians and other providers to provide pediatric care
5. Clinical and laboratory monitoring of children and adolescents on treatment (CD4/VL reagents)
6. Activities building capacity to monitor, supervise and implement uninterrupted HIV treatment services from infancy to adolescents (including transition to adult services)
7. Activities supporting adherence in pediatric and adolescent populations, improve overall retention on treatment and establish functional linkages between programs and with the community to reduce loss to follow up and improve long-term outcomes
8. Activities promoting case finding and integration of pediatric HIV treatment services into MCH platforms

Activities that **should *NOT*** be included in PDTX:

1. ARVs for children and adolescents (HTXD).
2. Development of capacity to provide laboratory services that escalate case finding for children/adolescents and detect treatment failure (HLAB)
3. Infrastructural and construction activities (OHSS)

4. Promoting integrated approaches to improve outcomes HIV drug resistance surveillance activities (HVSI)
5. Activities related to specialized curriculum development and pre-service training (OHSS)
6. Procurement of RTKs for initial testing (HVCT), Cost of retesting of initially positive children and adolescents before initiation of ART can be included in HBHC.
7. Broader lab capacity, training and equipment, including activities to strengthen laboratory support and diagnostic services for pediatric patients (HLAB)

8. Services that target TB/HIV activities in pediatrics, including INH (HVTB)
9. Activities supporting virologic diagnostic testing (EID) of infants and young children (PDCS)

## Appendix E.2.16 OHSS- Health Systems Strengthening

Activities that **should** be included in the OHSS budget code:

1. Activities that contribute to improvements in national-, regional- or district-level health systems (generally those that are implemented above the service delivery point (site) level and/or are not directly tied to patients, beneficiaries, facilities or communities)
2. Development and implementation of policy, advocacy, guidelines and tools (e.g., broad-based, such as development of Human Resources for Health Strategic Plan; related to specific technical areas, such as circular/guidelines/protocol development)
3. Technical assistance to improve system-level financial management systems
4. Pre-service training and curriculum development support for in-service trainings at regional training centers
5. An integrated package of activities focused on a range of health systems strengthening building blocks with a SI or lab component that does not constitute the majority of those activities
6. Support for supply chain at above-site level, including support to national and subnational levels for forecasting and warehousing of HIV-related commodities
7. Supporting supply chain systems through training and development of cadres with supply chain competencies
8. Capacity strengthening of civil society organizations that interact with the health system, such as local non-governmental, faith-based, and community-based organizations
9. Support to Global Fund programs and activities, and donor coordination

Activities that **should *NOT*** be included in the OHSS budget code:

1. Laboratory and SI activities that fall under the HLAB and HVSI budget codes, respectively

2. In-service training for care and treatment and should be coded under the relevant care and/or treatment budget code (MTCT, HTXS, HBHC, PDCS)
3. Cost of distribution of ARVs to the site level (facility or community) (HTXS)

## Appendix E.2.17 HLAB- Laboratory Infrastructure

Activities that **should** be included in the HLAB budget code:

1. Development and strengthening of tiered national laboratory networks to improve testing and coverage for viral load (VL), early infant diagnosis (EID) and HIV diagnosis and clinical monitoring (except site sample collection, packaging, and transportation)
2. Strengthening supply chain management systems to including inventory and forecasting and procurement of standardized and point of care (EID) instruments based on justified country needs.
3. Supporting Laboratory commodities/consumables (except reagents for CD4, EID and VL)
4. Supporting continuous laboratory/facility quality improvement initiatives, including accreditation, HIV rapid testing (RT), and participation in external quality assessment (EQA) programs for HIV, VL, EID, CD4, and TB
5. Supporting targeted laboratory staff training and other technical assistance to address gaps in scaling-up services for HIV RT, VL, EID, and TB.

Supporting Laboratory Information Systems (LIS) and other M&E tools to track progress and address gaps along the VL/EID and other related laboratory testing cascades

Activities that **should *NOT*** be included in the HLAB budget code:

1. An integrated package of activities focused on a range of health systems strengthening "building blocks" that has a lab component, but where laboratory activities does not constitute the majority of those activities (OHSS)
2. Lab reagents for the support of CD4, EID, and VL (HTXS, PDTX or PDCS)
3. GeneXpert machines and consumable (HVTB)
4. Service delivery costs, including costs associated with providing service to the patient such as phlebotomy or sample collection, packaging, and transport from the site (HTXS, HBHC)

### Appendix E.2.18 HVSI- Strategic Information

Activities that **should** be included in the HVSI budget code:

1. Activities that build capacity for and ensure the implementation of the collection, analysis and dissemination of HIV/AIDS behavioral and biological surveillance and monitoring information; Supporting capacity building efforts and the implementation of facility and other surveys; Build the capacity for the development of national program monitoring systems; Support the development of country-led processes to establish standard data collection methods; and
2. Support for the national health information system planning and development.
3. HIV Drug Resistant (HIVDR) surveys
4. HIV Impact Assessments (HIA)
5. Lab Management Information Systems (LMIS)
6. Integrated Bio-Behavioral Survey (IBBS)
7. Country wide electronic medical records

Activities that **should *NOT*** be included in the HVSI budget code:

1. Activities directly supporting one specific program area (e.g., B+ M&E framework);
2. Activities that are integral components of a prevention, care, or treatment funding mechanism;
3. An integrated package of activities focused on a range of health systems strengthening "building blocks" that have a SI component that does not constitute the majority of those activities (OHSS).

# Appendix E.3 Mandatory Earmarks

Planning for mandatory earmarks should be fully integrated into the COP planning process. This funding should complement and enhance the country program, reflect sound and effective allocations to partners with high outlay rates and associated results and ultimately allow for PEPFAR to continue meeting Congressional expectations.

### Appendix E.3.1 Orphans and Vulnerable Children

PEPFAR's authorizing legislation directs that 10 percent of PEPFAR's bilateral funds be used for Orphans and Vulnerable Children programming. The OVC earmark focuses on socio-economic

interventions critical to mitigating the impact of HIV and AIDS on children ages 0-17, prioritizing those which contribute to epidemic control, in line with the 2012 OVC Guidance.

For FY17, S/GAC will consult with Congress prior to determining the final OVC funding level. For the 2017 COP submissions, PEPFAR country teams will receive their HKID investment requirement in the COP 2017 planning level letter.

As described in the 2017 Technical Considerations and the 2012 Guidance for OVC Programming, activities should focus on OVC priority interventions in close proximity to other PEPFAR supported HIV and AIDS services and interventions and within PEPFAR defined geographically prioritized areas to the extent possible. OVC programs provide socio-economic services that mitigate the impact of AIDS on children ages 0-17 by reducing vulnerability, contributing to prevention goals (especially for adolescent girls), and supporting access to and retention in treatment (especially pediatric treatment).

### Appendix E.3.2 Care and Treatment Budgetary Requirements and Considerations

Globally, at least 50 percent of the total FY17 bilateral resources must be dedicated to treatment and care for PLHIV. In order to reach this global requirement, each country or region submitting a 2017 COP or ROP will be notified of their specific care and treatment requirement within the COP 17 country- or regional-specific planning level letter.

The care and treatment earmark is calculated according to the following formula:

$$\frac{Care\ \&\ Treatment\ for\ PLHIV\ (HBHC + HTXS + HTXD + PDCS + PDTX + HVTB + 0.3 * MTCT) + (0.3 * HVCT)}{\begin{array}{c}Total\ FY\ 2017\ PEPFAR\ Bilateral\ Resources \\ (minus\ funds\ to\ GF\ Multilateral, TB\ Bilateral, and\ NIH\ Research)\end{array}}$$

If upon submission of your COP/ROP, the above formula is not greater than or equal to the care and treatment requirement allocated to your team, your Country Lead will be in touch to discuss further how each COP/ROP can reach this mandatory earmark with FY 17 resources.

## Appendix E.4 Other Budgetary Considerations

While it does not rise to the level of "hard" earmarks in legislation, our partners in Congress may use the annual appropriations process to emphasize priorities from their unique perspectives and to indicate levels of funding for those priorities which they expect the program to achieve, sometimes

referred to as "soft" earmarks. It is vitally important that teams are responsive to these concerns. If any such provisions are enacted for FY 17 within the expected full year FY 17 appropriations bill, S/GAC and the implementing agencies will communicate any changing or new expectations for teams to incorporate such provisions in their planning processes.

## Appendix E.4.1 Water and Gender-Based Violence (GBV)

It is anticipated that in the FY 17 appropriation bill, investments in GBV and Water will be earmarks for all foreign assistance funding. PEPFAR has an obligation to meet its portion of the earmark by ensuring investments in these two areas are at the same level, or greater, than the FY 16 investments as captured by the cross-cutting allocations in COP 16.

For FY 17 COP submissions, PEPFAR country/regional teams will use the final FY 16 COP cross-cutting allocations for GBV and Water as the baseline planning level. The 2017 COP planning levels for GBV and Water can be above the COP 16 allocations; they **cannot** fall below it. Exact required investment levels will be reflected in the COP 17 planning level letter.

If, due to a pivotal change in COP 17, you will be unable to reach these levels of investments, please contact your Country Lead to discuss further.

## Appendix E.4.2 Tuberculosis

As tuberculosis (TB) remains the most common cause of death among people living with HIV in sub-Saharan Africa, responsible for more than a third of all HIV-related deaths. Implementation of the package of evidenced-based interventions is a smart and very high-impact investment of resources and is a priority for PEPFAR programming in areas with the greatest burden of co-infection.

Ending HIV-associated TB among PLHIV is possible through a combination of widespread ART coverage, early identification and treatment of TB, TB preventive therapy (for example, isoniazid preventive therapy, or IPT), and infection control activities. These high-impact interventions will be critical to achieving the goal of an AIDS-Free Generation and need to be integral to COP planning and program implementation.

However, progress on these interventions has been notably slower than in other areas of clinical care. There remain important gaps in screening for TB and HIV and assuring effective linkages across TB and HIV services and programs. Rates of ART for co-infected TB patients are lagging in many countries. Programming for TB preventive therapy, while recommended every year, is still very limited

across PEPFAR. Efforts to overcome barriers to effective service-level integration need ongoing attention as do efforts to explore and adapt models of integration that are country context-specific. Therefore, investment in TB/HIV should be maintained PEPFAR-wide.

The MER TB indicators have been enhanced for FY 17 to promote better integration of TB/HIV activities, more effective TB screening and diagnosis, and scale-up of TB preventive therapy. In addition to HIV testing, diagnosis, and initiation of ART among TB patients, countries will be required to report on TB screening of patients on ART, and the two mutually exclusive clinical decisions made from that screening: initiation of TB therapy and initiation and completion of TB preventive therapy. This reporting mandate is a deliberate attempt to drive programming. Countries are expected to increase the use of TB diagnostic testing within PEPFAR-supported HIV care and treatment facilities and promote the use of TB preventive therapy as a routine part of HIV care. Consequently, countries should have clear policies and/or guidelines for the use of TB preventive therapy and should plan for programmatic and clinical trainings, procurement and supply management, adequate diagnostic capacity (including specimen transportation), and development of appropriate data collection systems. In Global Fund high-impact countries implementing joint TB/HIV grants, PEPFAR teams also should seek opportunities to support effective joint program implementation.

## Appendix E.4.3 Food and Nutrition

Nutritional assessment and support are critical components of successful HIV/AIDS care and treatment. HIV and malnutrition often interact in a vicious cycle. For many PLHIV, particularly those with advanced or poorly controlled infection, HIV contributes to malnutrition through reduced food intake, increased energy needs, or poor nutrition absorption of nutrients. Malnutrition can hasten the progression of HIV and worsen its impact by weakening the immune system, increasing susceptibility to opportunistic infections, and reducing the effectiveness of treatment. Malnutrition and food insecurity remain highly prevalent in most countries where PEPFAR supports programs, particularly in sub-Saharan Africa. Thus, nutritional assessment and support remain critical elements of a comprehensive response to HIV/AIDS.

While the contributions of programs such as Feed the Future, Title II Food Programs, the World Food Program, and others cannot be counted toward PEPFAR's food and nutrition attribution, country teams are expected to closely coordinate with these key counterpart programs to ensure maximum complementarity and synergy of our respective investments.

## Appendix E.4.4 Abstinence and Be Faithful Reporting Requirement

*Field teams are reminded that the budgetary requirement ("hard earmark") for Abstinence and Be Faithful (AB) programs in the original PEPFAR authorizing legislation is no longer in place and has been superseded by a reporting requirement for countries with generalized epidemics.*

If AB-programmed activities do not reach a 50 percent threshold of all sexual prevention funding in any country with a generalized epidemic, S/GAC is required to report to the appropriate Congressional committees on the justification for the decision. In such cases, teams should provide brief justifications and explain the rationale for prevention programming decisions given the epidemiologic context, contributions of other donors, and other relevant factors. The written justifications should be uploaded as 'Budgetary Requirements Justification' to the document library of FACTS Info.

The Abstinence and Be Faithful reporting threshold for countries with generalized epidemics is calculated by dividing the total HVAB budget code funding by the sexual prevention funding (HVAB + HVOP):

$$\frac{\text{AB (HVAB)}}{\text{Sexual Prevention(HVAB + HVOP)}} \leq 50\%$$

## Appendix E.4.5 Strategic Information

### *Central Support for SI – HVSI Budget Code*

An important consideration when determining the overall COP planned budget is how much to allocate towards Strategic Information (SI). International standards suggest approximately 5-10 percent of the total budget should be dedicated to SI. Some exceptions may include countries with very large planned budgets, which may have a lower percentage in SI, while some technical assistance countries may have SI budgets that far exceed 5-10 percent. Activities supported by these resources have a more central or SI infrastructure focus, including, for example, support to national or district health information systems, government monitoring and evaluation or statistical units, surveillance/survey implementation, university centers of excellence, etc.

### *Program Budget Allocated for M&E*

In addition to the aforementioned overall support for SI activities in the country plan, further deliberations are necessary to determine what percentage of program-level funding should be set aside

for basic program monitoring and evaluation. International standards suggest approximately 5-10 percent of a program budget should be dedicated to monitoring and evaluation of the program. Regardless of the exact percentage, routine monitoring and evaluation should be integral to all PEPFAR programs. It is important to note that an outcome or impact evaluation may be considered in conjunction with a program, and these studies often require a higher level of funding. (Note that any such planned studies must also be identified in section 6.2b). In these instances, additional resources above the 5-10 percent range may be necessary.

# Appendix E.5 Single Partner Funding Limit

The single partner funding limit diversifies the PEPFAR partner portfolio and expands collaboration with local partners, all with the goal of promoting the long-term sustainability of HIV/AIDS programs in our partner countries. For FY 17, the limit on funding to a single partner is no more than eight percent of a country's PEPFAR budget excluding U.S. Government country team management and operations costs.

## Appendix E.5.1 Exceptions to the Single Partner Funding Limit

The limit applies only to grants and cooperative agreements; contracts are exempted. In addition, there are three blanket exceptions to the limit: drug/commodity procurers, government ministries and parastatal organizations, and umbrella awards. They are defined as follows:

A. **Drug/Commodity Procurers:** The exception will apply to all organizations that purchase drugs and commodities, including those that primarily provide technical assistance and services. All commodity/drug costs will be subtracted from the partners' total country funding applicable against the cap. The remaining awards and all overhead/management costs will be subject to the cap.

   When a country team notifies S/GAC that an awardee has been selected, it also should note whether the awardee purchases drugs and commodities and identify the amount spent on those drugs and commodities. The amount of funding for drug and commodity procurement should be included in the COP entry for the given partner.

B. **Government Ministries:** Awards to partner government ministries and parastatal organizations are excluded from the limit. A parastatal organization is defined as a fully or

partially state-owned corporation or government agency. Such state-run enterprises may function through a board of directors but ultimate control over the board rests with the government. Parastatal organizations are most often found in centrally planned economies.

C. **Umbrella Awards**[66]**:** The grants officer will determine, in consultation with the country team, whether an award is an umbrella for purposes of exception from the cap on an award-by-award basis. This determination may be made at the time the announcement is written based on the statement of work or at the time of award based on the applicant's work plan. The following criteria apply to decisions about umbrella status:

- Awards made with the intent that the organization sub-award at least 75 percent of the grant (with the remainder of the grant used for administrative expenses and technical assistance to sub-awardees) are umbrellas and exempted from the cap.
- Awards that include sub-awards as an activity under the grant but do not meet the above criteria are not exempt, and the full award will count against the cap.

Partners may have multiple PEPFAR awards in a country. Some of these awards may qualify as umbrellas that are exempt from the limit; others may not be umbrellas and thus count against the limit. When country teams notify S/GAC that the grants officer has selected an awardee, it also should note whether the award qualifies as an umbrella based on the above criteria and identify the amount of the award.

Where an award has characteristics of an umbrella award but administrative and technical assistance expenses exceed 25 percent, the country team may consider requesting an exception to the cap on a case-by-case basis.

## Appendix E.5.2 Umbrella Award Definition

An "**umbrella award"** is a grant or cooperative agreement that does not include direct implementation of program activities; rather, the awardee acts as an awards-management partner to identify and mentor sub-recipients, which in turn carry out the assistance programs. Thus, an umbrella award functions primarily as a sub-award-making instrument, although the awardee may also operate a small administrative program attendant to its award-making function. Typically, a relatively small percentage of the funds of the overall award is appropriate for use for administrative purposes. When a partner with

[66] See the definition of and additional guidance on umbrella awards below.

an umbrella award provides significant technical assistance and management support to its sub-recipients, it may reasonably devote a greater percentage of its overall funds to providing these services.

An umbrella award may be made to a local or international entity, but S/GAC strongly encourages teams to use local, indigenous organizations wherever possible. A basic goal should be to use the umbrella award recipient to develop indigenous capabilities to create a more sustainable program. Umbrella awards are not subject to the eight percent cap on single-partner funding.

The following are "best practices" for umbrella awards:

- Where local organizations are strong, umbrella award programs hire a strong local or international organization whose role is to run an award-making and -administration program that uses a relatively small percentage of the funds (usually around seven percent) in the overall award for these purposes.
- Where local organizations are weak, umbrella award programs include significant technical assistance, either as part of the responsibilities of the award-making organization or a separate organization. The best examples again spend a relatively small proportion of the overall grant (typically 20-30 percent) on these services and are quite specific as to the responsibilities of the prime awardee in strengthening local partners. Such awards must move to the seven percent level as the technical capacity of local partners' increases.
- To qualify for exemption from the single-partner funding cap, an umbrella award may not spend more than 25 percent of the overall award on administrative expenses and technical assistance. Where an award has characteristics of an umbrella award but administrative costs and technical assistance exceed 25 percent, the country team may consider requesting that S/GAC authorize an exception to the cap on a case-by-case basis.
- An organization that receives umbrella awards may have other awards through which it engages in direct program implementation activities. However, awards containing such activities are not considered umbrella awards and are subject to the eight percent single-partner cap. An award that includes both direct implementation and sub-award-making activities will not normally count as an umbrella award for the purposes of that award, but S/GAC may permit exceptions on a case-by-case basis.

## Appendix E.5.3 Single Partner Limit Justifications

You will be asked to submit a justification for any partner that exceeds the single-partner funding limit after excluding organizations (host country government organizations, parastatals) and funding (umbrella awards, drug and commodity purchases) exempted under the exceptions noted above. No justification is required for partners that would exceed the eight percent limit only if procured commodities were included; however, the dollar amount of funding the partner will use for commodity procurement should be included with the implementing mechanism information.

Teams can utilize the *Single Partner Funding Limit* report in the Budget Module of FACTS Info to help determine if a justification is required for any partners. Justifications should be uploaded to the FACTS Info document library as 'Budgetary Requirements Justification'.

# Appendix E.6 Justifications

All justifications should be uploaded into the FACTS Info document library as 'Budgetary Requirements Justification'. The *Single Partner Funding Limit* report will help teams to determine if justifications are required for the FY 17 COP.

Justifications are required in the following instances:

- Generalized epidemic countries not allocating 50 percent or more of their sexual prevention budget to Abstinence and Be Faithful programming
- Any country allocating more than eight percent of their program budget to one partner if this partner does not fall within one of the exceptions.

# APPENDIX F: U.S. GOVERNMENT MANAGEMENT AND OPERATIONS (M&O)

# Appendix F.1 Interagency M&O

For COP 17, the data elements in the Staffing tool within FACTS Info maintains the updates made from COP 16 for OU and HQ staffing analyses. The number of individual fields has been removed. As with COP 16, in COP 17, all staff fully or partially funded by PEPFAR should be included as individual entries. Other staff who work more than 30 percent on PEPFAR also should be included as individual entries.

PEPFAR's business model focusing on regular data analysis and use for decision-making requires that teams revisit and update their staffing footprints and organizational structures to maximize effectiveness and efficiency. With consideration given to intra-agency and mission-wide demands, as well as space constraints at virtually all embassies, teams should review how they are staffed and organized to complete regular and ad hoc tasks, perform core PEPFAR functions, oversee partner performance, and ensure achievement of goals and targets.

In COP 17, interagency M&O includes a short narrative in the SDS to summarize the team's staffing and organizational analysis, itemization of the personnel implementing the OU program in the FACTS Info staffing data, and allocation of the CODB that capture the costs inherent in running the program and having essential personnel. The CODB proposed funding levels are captured in FACTS Info and the Financial Supplemental Workbook.

COP 17 M&O Submission List:

- SDS Narrative
- Staffing Data
- Functional Staff Chart (as previously required but updated to reflect any footprint or organizational changes)
- Agency Management Charts (one per agency)
- ***Financial Supplemental Workbook*** – Cost of Doing Business Workbook

## Appendix F.1.1 PEPFAR Staffing Footprint and Organizational Structure Analysis, Expectations and Recommendations

Given legislative and budget constraints, OU teams should ensure that all management, operations, and staffing decisions are based on meeting PEPFAR programmatic goals and that non-PEPFAR needs are not driving organization decisions. Teams must be able to accomplish interagency tasks and

processes while simultaneously ensuring agency oversight and accountability over implementing partners. OU teams should be working in a complementary, non-redundant fashion (e.g., all technical staff working as a team, shared team responsibility for the entire U.S. government program rather than just one agency's portfolio, new technical staffing needs considered by the team rather than just one agency).

**Expectations**

For 2017, the minimum expectations for all OUs are that they complete an analysis of the existing staffing footprint and interagency organizational structure prior to the COP DC Management Meetings and identify any adjustments that need to be implemented to successfully manage business process. Teams should have made recommendations on any adjustments to their staffing footprints and CODB ahead of the DC Management Meetings as these decisions have an impact on the amount of funding available for program implementation and earmarks.

The focus of reviewing the OU's footprint and organizational structure for COP 17 should be on how staff are organized and funded to meet key tasks and core functions and deliver results. While OU footprints should follow rightsizing and good position management principles, the emphasis is not simply on the number of staff or vacancies vis-à-vis overall footprint. The focus should be on ensuring a balance of staff across interagency business process and coordination demands, agency partners' management and accountability, and external engagement. Further, the expectation is that staff funded partially or fully by PEPFAR are available and assigned to meet key interagency and intra-agency tasks throughout various PEPFAR business cycles (e.g., POART, COP, S/APR).

First, teams should consider the core competencies and functions needed to meet pivots. A first step will be to outline various PEPFAR-required (interagency and intra-agency) and agency-required (intra-agency) processes (e.g., COP, POART, SAPR, APR) and then use the staffing data to measure and ensure coverage of tasks and functions. The Level of Effort Workload Management Indicators have been introduced in 2017 to facilitate teams' assessments. Organizational structures may need to be shifted; for example, new teams may have to be created to manage each step of the COP process or TWGs may need to be collapsed to streamline them. Key questions include: how will the OU team handle key tasks during the year? Who is the lead? Who are the alternates and/or team members? OUs should consider how to de-duplicate current activities across the team to maximize efficiency.

Second, the OU should analyze the staffing data and review the staffing footprint to determine whether there is alignment with the core competencies and functions. What do the data tell you about how the

OU is managing the program and essential tasks? Are there missing skills identified during COP 16 development or post-pivot for which training is needed or new/revised positions might be required? Is there a need to repurpose or update existing positions (whether filled or vacant) to meet key competencies and accomplish tasks? If space is available, is there a need for new positions? In lieu of new positions, is there a plan to bring in TDY, WAE, or temporary hire assistance at certain times of the year? Teams should consider the trajectory, including funding, of the program in reviewing the staffing footprint and organizational strategy.

**Best Practices**

For 2017, teams should consider the following best practices:

- Consult with embassy and agency management support offices for help finding balance across the OU footprint.
- Create or update the interagency charter, SOPs, and/or manual to codify decisions made around core tasks and assignment of individuals and groups. As examples, OUs could consider including:
    - SOPs for each working group or task team
    - Principles for regularly scheduled in-person and phone meetings and ad hoc meetings and processes, for example:
        - General schedule
        - Process for scheduling ad hoc discussions
        - Principles for meeting minutes and action item follow-up
    - General communication principles
        - How and when information is shared
        - Direct and copied recipients on certain messages
    - How to handle conflict, seek consensus, and come to decisions
    - External engagement leads and principles
- Review all PEPFAR-related Position Descriptions (vacant and encumbered) to ensure they are updated for PEPFAR 3.0, e.g., include data analysis, interagency work, and SIMS site visits.
- Itemize training or other skill development needed across the team to achieve pivots and create a training schedule in partnership with S/GAC and agency headquarters.
- Identify for the Working Group on Issues Affecting LE Staff (LE Staff WG) any positions that would benefit from a Framework Job Description (standardized PD for mid- and senior-level common positions that can be used by any agency or OU). See pepfar.net for the currently available FJDs that can be used as is or as guides.
- Identify any additional HQ assistance needed to facilitate a staffing or organizational analysis, implement organizational changes, or provide training.

An addendum with helpful tips on how to utilize the staffing data and conduct a staffing and organizational assessment will be shared separately. In addition, the pepfar.net LE Staff WG page houses a repository of helpful guides, tips, and templates to assist teams.

## Appendix F.1.2 SDS Requirements

The SDS M&O narrative will:

1) Summarize the analysis conducted of its staffing footprint and interagency organizational structure in the SDS. The following key questions will help teams evaluate appropriate staffing and CODB levels:

- What changes did the team make to its USG staffing footprint and interagency organizational structure to maximize effectiveness and efficiency to achieve program pivots? How did you assess baseline Level of Effort of current staff to determine changes in staffing needs?
    - How has the team ensured balance between interagency business process coverage and intra-agency partner management and technical roles?
    - How will staff be utilized to meet SIMS requirements?
    - What additional action does the team want to take that has a timeline beyond COP submission?
- Were there missing skill sets or competencies identified? What steps are the teams taking to fill these (e.g., training, repurposing vacancies/encumbered positions)?
    - Did the team alter existing, unfilled positions to better align with the new PEPFAR business model and program priorities in Country/Region X?

2) Explain Vacant Positions

In the SDS, OUs should summarize the steps it is taking to fill vacancies of more than six months and what action it has taken to alter the scope of the position to balance interagency and intra-agency needs.

For each approved but vacant (as of March 1, 2017) position, the OU must explain the reason(s) it is vacant and describe the plan and timeline for filling the vacant position in the FACTS Info staffing data. If the position has been previously encumbered, please provide the date that the position became vacant and whether the position has been recruited yet. If recruitment has occurred but the team has been unable to fill it, please indicate why (e.g., lack of candidates, salary too low). Vacant position narratives should be no more than 500 characters and entered directly into the Comments field within

the Staffing section of the FACTS Info PEPFAR module. There should be one explanation for each staffing record marked as vacant.

Submitting this information will help identify program-wide recruitment and retention issues and skill and knowledge gaps.

3) Justify Proposed New Positions

In the SDS, OUs should summarize the interagency analysis and decision making that culminated in the agreement to request funding for a new position, including whether space for the position has been validated with the Embassy Management Officer and Chief of Mission. Teams should strongly justify why they are proposing new positions instead of repurposing an existing filled or vacant position. For positions that the team plans to fill with a U.S. citizen direct hire or PSC, indicate why this position cannot be hired locally. In addition, teams are encouraged to use term-limited appointments versus permanent mechanisms.

In the Comments field within the Staffing section of the FACTS Info PEPFAR module, OUs must describe how each proposed new position fits into the interagency and individual agency staffing footprints (e.g., meets changes in the program, addresses gaps, and complements the existing staff composition). New position narratives should be no more than 500 characters. All proposed positions (not previously approved in a COP) should be marked as planned in the staffing data.

In the COP 17 review process, all proposed new positions will be rigorously evaluated for relevance to new business process needs and alignment with programmatic priorities. Because the approval threshold for new positions will be high, wherever possible, country teams are advised to repurpose existing vacancies to fill new staffing priorities (particularly long-standing vacancies, i.e., those vacant for two or more COP cycles). Note that any proposed new positions should spend at least 50 percent of their time on PEPFAR activities.

4) Explain major changes to CODB

In the SDS, OUs should summarize any factors that may increase or decrease CODB in COP 17. Identify whether there are any trade-offs that will be required if the CODB request is not fully approved.

# Appendix F.2 Staffing and Level of Effort Data

OUs must update their staffing data annually within the FACTS Info PEPFAR Module (pre-populated with COP 16 staffing data).

The purpose of the staffing data is to assist each OU with strategic staffing assessments and decisions – during the COP planning process and throughout the year – by transparently organizing and managing the demographic information and staff time/LOE. The information should assist each team in assessing their current and proposed PEPFAR staff, from interagency and intra-agency functional perspectives, for the purposes of effective and efficient program design and oversight. Helpful tips on how to utilize the staffing data to assess staffing and functional balance will be disseminated separately.

The annual revision of staffing data should support each U.S. government agency in ensuring that sufficient staff are in place for effective fiscal management, partner oversight, SIMS implementation, and interagency collaboration. Staffing data should be integral to COP planning and reporting, staff planning, and position and program management. In both management and technical areas, review of staffing data may help to identify gaps (e.g., skill sets or functional area/business process coverage) and areas of overlap, as well as support Chiefs of Mission in managing the PEPFAR team while engaging in agency headquarters-driven management exercises such as "rightsizing" and "managing to budget."

To assist teams in best aligning their staff to operationalize the pivot and new targets, as well as continue to implement SIMS and quarterly data reviews, the FACTS Info staffing data has been updated for COP 17, e.g., integrating aspects of the COP 15 LOE staffing tool. Changed fields are noted with ***asterisks.

## Appendix F.2.1 Who to Include in the Database

- All fully or partially PEPFAR-funded (i.e., GHP, GAP, or other PEPFAR fund accounts) current, vacant (as of March 1, 2017,), and proposed positions working on PEPFAR planning, management, procurement, administrative support, technical, and/or programmatic oversight activities. Note that **all** PEPFAR-funded staff must be included in the staffing data. This is a change from previous years when there was a 10 percent threshold.

- Any non-PEPFAR funded current, vacant (as of March 1, 2017), and proposed positions that are involved in decision making for PEPFAR planning, management, procurement, and/or programmatic oversight activities.
- Any non-PEPFAR funded current, vacant (as of March 1, 2017), and proposed positions that will spend at least 30 percent of their time working on PEPFAR planning, management, procurement, administrative support, technical, and/or programmatic oversight activities.

Include all:

- U.S. Direct Hire (USDH) (includes CDC appointed staff, military, and public health commissioned corps),
- Internationally recruited Personal Services Contractors (PSCs),
- Personal Services Agreements (PSAs) (includes locally-recruited Eligible Family Members and Foreign Service Nationals),
- LE Staff (locally hired PSC or PSA host country nationals, Americans, and TCNs),
- Internationally recruited TCNs,
- Non-Personal Services Contractors (also known as commercial, third party, or institutional contractors)/Fellows, and
- Other employment mechanisms (for which there should be very few entries).

Any non-PSC/institutional contractor who is employed by an outside organization (e.g. CAMRIS, GH Pro, ITOPPS) who provides full-time, permanent support to field operations and sits imbedded with USG staff should be included in the staffing data if they are partially or fully paid for by PEPFAR and/or otherwise meet the inclusion criteria above. Do not include temporary or short-term staff. However, if the position slot is permanent and the incumbent rotates, please include the position and state "rotating" in the last and first name fields. The costs of these staff should be captured in the Institutional Contractor CODB field.

Temporary or seasonal hires should not be included but should be considered in overall footprints/organizational structures to achieve various business processes.

Peace Corps Volunteers should not be included in the staffing data as they are not U.S. government employees. However, Peace Corps staff should be included.

## *Notes*

**Program staff:** Those who work directly on PEPFAR programs or who provide leadership, technical, and/or management support for PEPFAR and program staff. Program staff includes the Ambassador, DCM, Mission Director, CDC Chief of Party, legal, contracts, financial, and Public Affairs/Public Diplomacy staff. Administrative staff who provide direct support to the program team also should be included.

**Non-Program staff:** Those who provide valuable administrative support to the PEPFAR team, including travel staff, drivers, and gardeners, but not direct program support.

**Aggregate Entries:** Country teams no longer have the option of including in the database an aggregate entry for program staff who individually contribute less than 30 percent of their average time on PEPFAR. Please create individual entries for all positions that meet the overall criteria for inclusion.

**Inclusion of non-PEPFAR-funded and non-program staff:** While optional, you may also elect to include in the database non-PEPFAR funded staff who work less than 30 percent of their average time on PEPFAR. However, do not include any staff that work on a temporary or seasonal basis, such as during the COP season. Do not include those working in ICASS-funded offices (e.g. motor pool, GSO, FMO, EX, HR, etc.); staff working in ICASS offices and paid by ICASS contributions should be removed from the staffing data.

**Inclusion of Global Fund Liaisons:** As in past years, Global Fund Liaison positions (whether centrally funded or cost-shared) should be included in Staff Information. For centrally funded Liaisons, enter the record into the staffing database as “Non-PEPFAR Funded” (i.e., centrally or non-COP funded). As Missions pick up the funding of the Liaison position (full or cost share), enter the record as “PEPFAR Funded” or “Partially PEPFAR Funded” as relevant. Please contact your CL with any questions about funding stream for this position.

As a part of the cleaning and review process, HQ will review the submission to ensure that positions are marked as non-PEPFAR funded where appropriate to avoid skewing staffing analyses. If a mission picks up the position, it can then be marked as either partially or fully PEPFAR-funded.

## Appendix F.2.2 Staffing Data Field Instructions and Definitions

OUs should update the staff demographic information in the following fields (data field definitions are included below) pre-populated from COP 16. Please note that there are new fields required in COP 17; they are labeled with ** and their titles are italicized.

**Operating Unit:** The appropriate OU will be pre-populated by the system to facilitate analysis across countries.

**Time Devoted to PEPFAR:** Refers to the annual staff time the person in the position spends on PEPFAR. This is one of the key fields in determining the position's PEPFAR-related FTE. Enter the average percentage (10-100 percent) in the data field.

**Staffing Status:** Refers to whether a position is currently staffed or not. Select whether the position is Filled, Vacant (previously approved in COP 16 or prior), or Planned:

- Filled refers to currently encumbered positions;
- Vacant refers to positions that have been previously approved in a COP, but are currently empty; or
- Planned (new requests) refers to positions that are new for COP 17 and have not been approved in previous COPs. A justification narrative must be entered into Appendix F.2.3.

**Last Name:** If desired and the position is filled, enter the staff member's last name.

**First Name:** If desired and the position is filled, enter the staff member's first name.

**Funding Agency:** Select from the drop-down menu the employing agency of the staff person. For contractors, select the agency that supports the position.

**Agency Position Title:** Country teams should use a detailed functional title appropriate for each position or use official titles. Choices are pre-populated, for example, "Senior Technical Advisor for PMTCT" or "M&E Advisor," or "Management and Program Analyst" and "Public Health Advisor." For LE Staff positions for which a Framework Job Description has been used, please use the associated official title.

**Type of Position:** Select the type of position from the following list. Please note that for positions within categories (a) and (b), all or part of the staff time/funding will likely be attributed to technical budget

codes; for positions within categories (c), (d), and (e), all of the staff time/funding will likely be attributed to the M&O budget code (HVMS).

a. Technical Leadership/Management includes positions that lead the health/HIV team within the agency, e.g., the head of the agency (for example, CDC Country Director), someone who oversees all U.S. government health activities and spends only part of the time on PEPFAR (e.g., USAID health office head), and a U.S. Direct Hire Foreign Service officer filling an HIV/AIDS advisor position and thereby leading an HIV/AIDS team. The PEPFAR Country Coordinator and Deputy Coordinator should be included in this category.
b. Technical and Programmatic Oversight and Support includes the technical staff within the health/HIV team who spend most of their time developing, implementing, or managing programs in technical areas, including Agreement Officer Technical Representatives (AOTRs), Project Officers (POs), and Public Health Advisors. Please also include here any entry and mid-level staff providing direct public health programmatic activities in this category (this is most relevant for CDC staff) and any programmatic support positions within the health/HIV team or non-health/non-HIV staff who provide support to the health/HIV team (e.g., Education, Reproductive Health, TB, Food & Nutrition). Contracting/Financial/Legal includes acquisition (contracts) and assistance (grants and cooperative agreements) officers and specialists and their support staff. A contracting officer represents the U.S. government through the exercise of his/her delegated authority to enter into, administer, and/or terminate contracts, grants, and cooperative agreements, and make related determinations and findings. Contracting officers and specialists usually support an entire agency in country or will support an entire regional portfolio. If an agency utilizes the contracting officer services of another agency, include the position only in the contractor's home agency. This category also includes the financial management officer or specialist for the agency who supports financial and budget analysis and financial operations functions. Legal includes staff who provide legal advice and support to PEPFAR. Do not include ICASS-supported positions.
c. Administrative and Logistics Support includes any secretarial, administrative, drivers, and other support positions.
d. U.S. Mission Leadership and Public Affairs/Public Diplomacy (PA/PD) include any non-health/HIV staff who provide management, leadership, and/or communications support to PEPFAR, such as the Ambassador, Deputy Chief of Mission, USAID Mission Director, Political or Economic Officers, and any PA/PD staff.

**Employee Citizenship: Select the citizenship of the staff member:**

a. U.S.-based American citizen: Direct hire (including military and public health commissioned corps), appointees (CDC), or PSCs hired in the U.S. for service overseas, often on rotational tours. They are paid on the U.S. Foreign Service or Civil Service pay scale or compensated in accordance with either scale. The U.S. government has a legal obligation to repatriate them at the end of their employment to either their country of citizenship or to the country from which they were recruited.
b. Locally Resident American Citizen: Ordinarily resident U.S. citizens who are legal residents of a host country with work permits or Eligible Family Member positions authorized to work in country and hired locally. U.S. government agencies recruit and employ them as LE Staff under Chief of Mission (COM) authority at Foreign Service (FS) posts abroad often as PSAs. They are compensated in accordance with the employing post's Local Compensation Plan (LCP).
c. Host Country National (or legal permanent resident): Citizens of the host country or ordinarily resident foreign nationals who are legal residents of the host country and hold work permits. They are employed as LE Staff at FS posts abroad and compensated in accordance with the LCP of the employing post.
d. Locally Hired Third Country Citizen: Foreign Service Nationals (FSNs) who are not citizens or permanent residents of either the host country or the United States and are hired locally in the country in which they are employed. They are compensated in accordance with the employing post's LCP.
e. Internationally Recruited Third Country Citizen: FSNs who are recruited from a foreign country other than where they are employed with whom the U.S. government has a legal obligation to repatriate them at the end of their employment to either their country of citizenship or to the country from which they were recruited.

**Employment Type:** Refers to the hiring authority by which the staff member is employed or engaged:

a. Direct Hire: A U.S. government position (AKA billet, slot, ceiling, etc.) authorized for filling by a Federal employee appointed under U.S. government personnel employment authority. A civilian direct-hire position generally requires the controlling agency to allocate an FTE resource. NOTE: Host country nationals that are appointed by a U.S. government agency should be listed as a Direct Hire.

b. Personal Services Contractor (PSC): An individual hired through U.S. government contracting authority that generally establishes an employer/employee relationship. Both USAID and Peace Corps use PSCs to obtain services from individuals.
c. Personal Services Agreement (PSA): An individual hired through specialized Department of State contracting authority that establishes an employer/employee relationship.
d. Non-Personal Services Contractor (non-PSC/PSA): An individual engaged through another contracting mechanism (e.g. institutional contractor) by a non-U.S. government organization (e.g. CAMRIS, GH Pro, ITOPPS) that does not establish an employer/employee relationship with the U.S. Government.

**Funding Type:** Select the appropriate choice for the position:

a. PEPFAR Funded: Any position fully funded by GHP-State, GHP-USAID, GAP, or other PEPFAR fund accounts.
b. Partially PEPFAR Funded: Any position partially funded by GHP State, GHP-USAID, GAP, or other PEPFAR fund accounts.
c. Non-PEPFAR Funded: Any position funded by agency core (State, Defense, and Peace Corps positions). CDC and USAID positions should be partially or fully PEPFAR funded.

**Schedule:** Refers to whether the position is a full-time or part-time position. It does NOT refer to how much time the position spends working on PEPFAR. Do not include any staff who work on PEPFAR on a temporary or seasonal basis, e.g., during the COP season.

a. Full-time: Considered to be ≥ 32 hours/week for FTE calculations.
b. Part-time: Considered to be <32 hours/week for FTE calculations.

**Note:** *The overall full time equivalent (FTE) box and budget code FTE boxes will auto-calculate based on the percentage of time entries. The position's overall PEPFAR-related FTE is calculated by multiple the Schedule entry by the Percent Time Devoted to PEPFAR:*

- Full-time (= 1) vs. Part-time (= .5),
- Percent Time Devoted to PEPFAR by Each Individual (40% = 0.4; 100% = 1).

**Other Roles:** Identifies additional responsibilities of staff engagement in the following categories:

a. Education

b. ES: Economic Strengthening
c. Food (and Nutrition)
d. HCD: Human Capacity Development
e. Water
f. Gender
g. CTO: CTO (Cognizant Technical Officer)/CTOR (Cognizant Technical Officer Representative)/Project Officer or Agency Equivalent
h. PPP: Public Private Partnership
i. Supervisor: Has official supervisory duties per position description
j. Financial Manager: Has official management duties per position description

**Note that PHE: Public Health Evaluations and NPI: New Partners Initiative have been eliminated as options.

**Gender:** If a staff member works on gender, indicate 'Yes' and include a numeric value of 25-100 indicating the percent of time the staff member spends on gender activities. The amount of time spent on gender will not impact the allocations made to the Program Areas or total percent of time spent on PEPFAR.

For example, an OVC Senior Technical Advisor may spend 30 percent of his/her time on gender issues. In the Staff Information tab, time spent on gender will be indicated with 'Yes' and a value of 30. In the Program Area tab, the budget code distribution will follow the division of time associated with the established budget codes (e.g., 80 percent OVC and 20 percent HVMS) with no reference to gender.

**Comments:** Country teams are required to provide additional details for specific vacant or planned records (Justify Vacant and Proposed New Positions). For existing positions, country teams may opt to add comments on an individual position that will aid in institutional memory for the team, such as the date a position is encumbered.

## Appendix F.2.3 Capturing Staff Time Instructions

There are two ways in which the staffing data assist teams in measuring a PEPFAR's contribution to PEPFAR and whether there is appropriate balance of workload for various business processes.

First, as it has since its introduction, the staffing data captures the amount of time (out of total 100 percent PEPFAR-related time – irrespective of total time dedicated to PEPFAR) the position spends working on different technical areas (i.e., budget codes). OU teams are expected to reflect staff time

across technical budget codes as appropriate. Technical area time allocation should be reserved for technical guidance and activities in a particular area; general program management, leadership, grants administration, communications, and external engagement (of a non-technical nature) should be captured under HVMS. For example:

- A PMTCT Senior Technical Advisor who is involved in technical direction of the eMTCT program but also provides technical advice regarding lab activities related to Option B+ implementation would be captured, for example, as 70 percent MTCT, 20 percent HLAB, and 10 percent HVMS. The 10 percent attributed to HVMS for this position reflects staff time spent on managerial responsibilities.
- A Finance Specialist's PEPFAR work would be captured wholly (100 percent) under HVMS. This position does not contribute to any technical areas and provides general administrative support.

The expanded LOE indicators, now incorporated directly into the Staffing tool in FACTS Info, better capture and provide a better understanding of what positions are doing that contribute to intra-agency, interagency, mission-wide, and external engagement activities and goals. These indicators build upon the concept introduced in the COP 15 LOE tool that accompanied the SIMS Action Plan, but have been expanded to cover a wider range of mutually exclusive activities. They can be used by OU teams to assess their staff balance across seven functional work streams.

OU teams should complete the following fields based on the average time spent by the position in an average quarter. The total should add up to 100 percent of the position's total PEPFAR-devoted time. While these fields are mutually exclusive from the technical area fields above, there should be harmony between the entries. The fields are:

- Intra-agency Administration, Training, Financial Management – this field captures time spent on agency-mandated or agency-focused activities, e.g. training requirements, administrative tasks. This field should <u>not</u> include any time spent directly managing or overseeing partners. Most admin staff will have 100% of their time captured in this field unless they are providing direct support to interagency groups, in which case that percentage of time would be reflected in Interagency Other.
- Intra-agency Partner Management/CoAg Admin/Site Visits – this field captures <u>all</u> time spent in the management and oversight of implementing partners including time spent in FOA

development and technical review, work plan development/oversight, COR/Activity Manager duties, and SIMS and non-SIMS site visits. Contracting Officers time should be reflected in this field.

- Interagency Leadership – this field captures time spent in the leadership role over an interagency team, such as member of an executive-level PEPFAR interagency committee, technical working group (TWG) chair, or head of a COP/APR planning task team.
- Interagency Other – this field captures all other interagency activity, e.g., TWG membership, participation in COP or other task teams, and participation in all hands meetings.
- Mission-wide Activities – this field captures participation in mission-wide activities, such as engagement with the Embassy Front Office, participation in Ambassador-led committees (e.g., senior staff, country team, interagency health team), or participation in subject-matter-focused mission-wide working groups (e.g., on human rights).
- External Engagement – Leadership – this field captures engagement with the host government, other donors, civil society, media, etc. at a senior- or policy-level. Activities reflected in this field include time spent in review of COP plans or APR results with senior Ministry of Health officials, participation on donor group committees or the Global Fund Country Coordinating Mechanism, or speeches to stakeholder groups. The engagement captured here reflects broader PEPFAR program goals vice a single technical area. This category is most appropriate for interagency PEPFAR leadership, Embassy/agency leadership, and communications staff.
- External Engagement Technical – this field captures technical advice and assistance given by the position to the host government or other stakeholders, participation in national TWGs. This category is most appropriate for technical and programmatic staff.

Please note that the FTE for each of the indicators will auto-calculate based on the position's overall PEPFAR-related FTE.

Coupled with an assessment of staff time needed to accomplish key interagency and intra-agency tasks, the updated LOE FTE can help teams understand whether they have balanced staff time well across the streams. For example, the team can look at the COP development step-by-step guide, quantify the amount of estimated staff time needed to complete the tasks, and assign responsible staff. Then looking at the allocation of staff time in the LOE indicators, they can assess whether there is a match or mismatch between the amount of time estimated to complete the tasks and the staff assigned to do it. The outcomes of this analysis can also inform changes to interagency organizational structures needed to facilitate work, identify missing skills that can be addressed through training or Position

Description updates, and provide a framework for interagency Standard Operating Procedures or an interagency manual.

In addition, the team can look at estimated SIMS travel and determine whether there is a good balance between a position's intra-agency and interagency responsibilities and the amount of time expected to be out of the office on SIMS visits. The new SIMS field captures the average number of business days each quarter a position is expected to be out of the office on SIMS visits. It does not capture days spent in the office on SIMS visit planning or data analysis. This field should align with the percentage of time allocated to Intra-agency Partner Management/CoAg Admin/Site Visits as well as to the SIMS Action Planner. Teams can use the aggregated data from an agency or interagency perspective to evaluate whether adequate time has been allocated to achieve the desired site visits itemized in the SIMS Action Planner.

A LOE tool populated with the new fields will be disseminated to teams after COP guidance dissemination to enable teams to enter and use the new data ahead of Facts Info being open for COP 17 entry.

## Appendix F.2.4 Attribution of Staffing-Related CODB to Technical Areas

Each position's entry should reflect the amount of time spent working on PEPFAR and whether the position is partially or fully PEPFAR-funded or non-PEPFAR-funded. The funded costs for all positions should be reflected in the U.S. government Salaries and Benefits CODB categories. New for 2017, there are separate CODB salary and benefit categories for:

- Internationally recruited staff, e.g., U.S. direct hire, U.S. PSC, and TCNs
- Locally recruited staff, e.g., host country national PSA staff, locally hired Americans and TCNs

Salary costs for Institutional Contractors should be entered in the appropriate CODB category for non-PSC/PSAs.

For U.S. government Staff Salaries and Benefits and Staff Program Travel, OU teams will update their staffing data and enter the top-line budget amount for each CODB category, by fund account (see CODB guidance below). Based on the calculated budget code FTE (for only those fully or partially funded PEPFAR positions) aggregated for each agency, a portion of the agency's top-line CODB budget amount will be attributed to relevant budget codes and to the M&O funding amounts. **New for COP 17, only the budget code FTE for partially and fully PEPFAR-funded positions will be applied to the CODB categories.**

For Institutional Contractors, country teams will enter the budget code planned funding amount for the appropriate technical areas, by fund account - i.e., the area(s) for which institutional contractors are providing personnel support on behalf of the U.S. government.

For Peace Corps staff in COP 17, country teams should attribute all PCV funding to Management and Operations (budget code HVMS).

# Appendix F.3 OU Functional and Agency Management Charts

OU teams are asked to submit charts reflecting their functional and management structures. The functional staff chart and agency management charts should be uploaded as required supplemental documents to COP 17.

The interagency chart should reflect the leadership and decision-making structures for the OU as well as permanent working groups or task teams involved in interagency program management and oversight and/or external engagement. Only leadership position and TWG titles should be included; do not include names of persons. Teams should update the chart as appropriate to reflect any organizational changes made based on its review of the staffing footprint and organizational structures to facilitate achieving the pivots and targets. Examples of functional management charts will be available on the LE Staff WG pepfar.net page.

Along with the functional staff chart, OU teams should also submit copies of each agency's existing country organizational chart that demonstrates the reporting structure within the agency. If not already indicated on those charts, please highlight the management positions within the agency organizations. One chart should be uploaded per each USG agency operating in country.

The functional staffing chart and agency management charts are not intended to replace or duplicate existing agency organizational charts depicting formal reporting relationships or existing administrative relationships between staff within agencies.

# Appendix F.4 Cost of Doing Business Worksheet

U.S. government Cost of Doing Business (CODB) includes all costs inherent in having the U.S. government footprint in country, i.e., the cost to have personnel in-country providing technical assistance and collaboration, management oversight, administrative support, and other program support to implement PEPFAR and to meet PEPFAR goals.

There are a number of cost drivers in FY 17 that S/GAC anticipates may cause teams to increase their CODB, including global U.S. Department of State increases in Capital Security Cost Sharing (CSCS), ICASS costs, and Locally Employed (LE) Staff pay increases. In addition, as new PEPFAR business processes come on-line, teams must ensure that they are staffed and supported to successfully implement SIMS, POART, and enhanced routine program planning with civil society, governments, and the Global Fund.

Again for COP 17, teams must submit a ***Financial Supplemental Workbook*** detailing the historic and projected financial performance of all CODB categories included within the 2017 COP/ROP. Each OU must submit one document compiling the information for all agencies, and the totals must match with the data entered into FACTS Info. The CODB worksheet can be found in the ***Financial Supplemental Workbook*** located on the pepfar.net COP 17 website.

- Teams should refer to the Agency CODB report to complete the worksheet. The data in this report should be copied and pasted into columns A-I of the worksheet.
- Column J requires information on CODB category pipeline as of 12/31/2016 and column K requires detailing the total funds spent per CODB category in FY 2016. These required elements should be completed with assistance from agency field and headquarters financial staff.
- Column L will auto-calculate the percent change in CODB, per cost category, from the FY 2016 actual expenditures to the FY 17 planned amount.
- Justifications for any increase or decrease from FY 17 COP CODB expenditures should be detailed in column M, the “Notes” section of the worksheet.

The completed Financial Supplemental Workbook must be uploaded into the FACTS Info Document Library. A COP/ROP submission will not be considered complete without submission of this supplemental document.

## Appendix F.4.1 Cost of Doing Business Categories

By capturing all CODB funding information in the M&O section, data are organized in one location, allowing for clear itemization and analysis of individual costs. In addition to providing greater detail to headquarters review teams and parity in the data requirements for field and headquarters management costs, the data provides greater transparency to Congress, OMB, and other stakeholders on each U.S. government agency's costs for managing and implementing the PEPFAR program.

If there is any funding requested for the following CODB categories, then you must complete the "Item Description" field associated with the category and planned amount.

- **Non-ICASS Administrative Costs:** Please provide a detailed cost breakout of the items included in this category and their associated planned funding (e.g., $1,000 for printing, $1,000 for supplies). The narrative should be no more than 500 characters.
- **Non-ICASS Motor Vehicles:** If a vehicle is necessary to the implementation of the PEPFAR program (not for implementing mechanisms) and will be used solely for that purpose, purchase or lease information needs to be justified and dollar amount specified. The narrative should be no more than 500 characters.
- **U.S. Government Renovation:** Describe and justify the requested project. Significant renovation of properties **not** owned by the U.S. government may be an ineffective use of PEPFAR resources, and costs for such projects will be closely scrutinized. The description should be no more than 1000 characters and include the following details:
    - The number of U.S. government PEPFAR personnel that will occupy the facility, the purpose for which the personnel will use the facility, and the duration of time the personnel are expected to occupy the facility.
    - A description of the renovation project and breakout of associated costs. Include a description of why alternatives – facilities that could be leased and occupied without renovation – are unavailable or inadequate to meet personnel needs.
    - The mechanism for carrying out the renovation project, e.g., Regional Procurement Support Office (RPSO).
    - The owner of the property.
    - The U.S. government agency which will implement the project, and to which the funds should be programmed upon approval. If the project will be implemented by DOS through RPSO, the funding agency should be the State Bureau (e.g., State/AF).

- **Institutional Contractors:** Describe the institutational contractor (IC) activities and why these activities will be conducted by an IC rather than a U.S. Direct Hire or PSC/PSA. Where possible, please provide the contracting company name and the technical area(s) which the IC(s) will support.

Once you have completed the steps for one agency, please repeat for all other agencies working in country.

There are eleven U.S. government CODB categories. The following list of CODB categories provides definitions and supporting guidance:

1. **U.S. Government Staff Salaries and Benefits:** The required costs of having a person in country, including housing costs not covered by ICASS, rest and relaxation (R&R) travel, relocation travel, home leave, and shipping household goods. This category includes the costs associated with technical, administrative, and other staff.
    a. PEPFAR program funds should be used to support the percentage of a staff person's salary and benefits associated with the percentage of time they work on PEPFAR. The direct costs of PEPFAR, specifically the costs of staff time spent on PEPFAR, need to be paid for by PEPFAR funding (e.g., GHCS, GAP). For example, if a staff person works 70 percent on PEPFAR, PEPFAR program funds should fund 70 percent of that person's salary and benefits. If the percentage worked on PEPFAR is 10 percent, then PEPFAR funds should fund 10 percent of the person's salary and benefits.
    b. For agencies that cannot split-fund staff with their agency appropriations (such as USAID's OE funds), multiple staff may be combined to form one FTE and one of the staff's full salary and benefits will be funded by PEPFAR. For example, if two staff each work 50 percent on PEPFAR, PEPFAR funds should be used to fund the salary and benefits of one of the positions. If three staff each work a third of their time on PEPFAR (33% + 33% + 33%), PEPFAR funds should be used to fund the salary and benefits of one of the positions. If multiple staff work on PEPFAR but not equally (such as 10% + 20% + 70% or 25% + 75%), the full salary and benefits of the person who works the most on PEPFAR (in the examples, either 70 percent or 75 percent) should be funded by PEPFAR. This split should be reflected in the staffing data.
    c. If the agency is paying for host country citizen fellowships and is going to only train the fellows, then the funding can remain in an implementing mechanism. If the agency will receive a work product from the fellows, then this cost should be counted in M&O.

Similarly, if agencies are paying for trainers who are U.S. government staff, then the costs associated with these staff should be reflected within M&O. If the mechanism is paying for the materials and costs of hosting training, then the funding should be reflected in an implementing mechanism.

New in COP 16, and continued in COP 17 – there are two categories of Salaries and Benefits:

d. Internationally Recruited Staff
e. Locally Recruited Staff

***2.*** **Staff Program Support Travel:** The discretionary costs of staff travel to support PEPFAR implementation and management does NOT include required relocation and R&R travel (those are included in U.S. government Salaries and Benefits).

This category includes the costs associated with technical staff travel and travel costs associated with the provision of technical assistance. All costs associated with technical staff time should be reflected within M&O; other TA funding (e.g., materials) should be reflecteded in an implementing mechanism.

Teams should include SIMS related travel costs in this category. Refer to your country SIMS action plan and ensure that the following costs are properly captured: driver travel, driver overtime, gas, lodging, and M&IE (GSA rate).

In FY 17, technical assistance-related travel costs of HHS/CDC HQ staff for trips of less than 3 weeks will be included in the PEPFAR Headquarters Operational Plan (HOP) and funded centrally. Under this model, costs for short-duration technical assistance travel by HHS/CDC staff should not be included in COPs.

***3.*** **ICASS (International Cooperative Administrative Support Services):**

a. ICASS is the system used in Embassies to:
   *i.* Provide <u>shared common</u> administrative support services; and
   *ii.* <u>Equitably distribute</u> the cost of services to agencies.
b. ICASS charges represent the cost to supply common administrative services such as human resources, financial management, general services, and other support,

supplies, equipment, and vehicles. It is generally a required cost for all agencies operating in country.

c. Each year, customer agencies and the service providers present in country update and sign the ICASS service "contract." The service contract reflects the projected workload burden of the customer agency on the service provision for the upcoming fiscal year. The workload assessment is generally done in April of each year. PEPFAR country teams should ensure that every agency's workload includes all approved PEPFAR positions.

   *i.* ICASS services are comprised of required cost centers and optional cost centers. Each agency must sign up for the required cost centers and has the option to sign up for any of the optional cost centers.

   *ii.* More information is available at http://www.state.gov/m/a/dir/regs/fah/c23257.htm.

d. ICASS charges must be planned and funded within the country/regional budget (COP). However, ICASS costs are typically paid by agency headquarters on behalf of the country team from their budgeted funding. Each implementing agency, including State, should request funding for PEPFAR-related ICASS costs within its M&O budget.

   *i.* It is important to coordinate this budget request with the Embassy Financial Management Officer, who can estimate FY 17 anticipated ICASS costs. This FY 17 ICASS cost estimate, by agency, should then be included as the planned ICASS funding.

   *ii.* It is important to request all funding for State ICASS costs in the original COP submission, as it is difficult to shift funds at a later date.

   *iii.* The Peace Corps subscribes to minimal ICASS services at post. Most GSO and all financial management work (except FSC disbursing) are carried out by Peace Corps field and HQ staff. In order to capture the associated expenses, Peace Corps will capture these costs within the indirect cost rate.

***4.*** **Non-ICASS Administrative Costs:** These are the direct charges to agencies for agency-specific items and services that are easy to price, mutually agreed to, and outside of the ICASS MOU for services. Such costs include rent/leases of U.S. government-occupied office space, vehicles, shipping, printing, telephone, driver overtime, security, supplies, and mission-levied head taxes.

In addition to completing the budget data field, teams are expected to explain the costs that compose the Non-ICASS Administrative costs request, including a dollar amount breakout by each cost category (e.g., $1,000 for printing, $1,000 for supplies) in the "Item Description" field.

5. **Non-ICASS Motor Vehicles:** If a vehicle is necessary to the implementation of the PEPFAR program (not for implementing mechanisms) and will be used solely for that purpose, purchase or lease information needs to be justified. For new requests in **FY 17** please explain the purpose of each vehicle(s) and associated cost(s) in the "Item Description" field. It is also a requirement that the total number of vehicles purchased and/or leased under Non-ICASS (Motor Vehicles) costs to date **(cumulative through COP 17)** are provided in this category. Teams should include new vehicle requests related to the completion of SIMS in this category.

6. **CSCS (Capital Security Cost Sharing):** Non-State Department agencies should include funding for CSCS, except where this is paid by the headquarters agency (e.g., USAID).
    a. The CSCS program requires all agencies with personnel overseas subject to Chief of Mission authority to provide funding in advance for their share of the cost of providing new, safe, secure diplomatic facilities (1) on the basis of the total overseas presence of each agency and (2) as determined annually by the Secretary of State in consultation with such agency.
    b. The State Department uses a portion of the CSCS amount for the Major Rehabilitation Program (MRP).
    c. It provides steady funding annually for multiple years to fund 150 secure New Embassy Compounds in the Capital Security Construction Program.
    d. More information is available at http://www.state.gov/obo/c30683.htm.
    e. Country teams should consult with agency headquarters for the appropriate amount to budget in the COP.

7. **Computers/IT Services:** Funding attributed to this category includes USAID's IRM tax and other agency computer fees not included in ICASS payments. If IT support is calculated as a head tax by agencies, the calculation should transparently reflect the number of FTEs multiplied by the amount of the head tax.
    a. CDC should include the IT support (ITSO) charges on HIV-program-funded positions; these costs will be calculated at CDC HQ and communicated to country teams for inclusion in the CODB.

b. USAID should include the IRM tax on HIV-program-funded positions.

***8.*** **Management Meetings/Professional Development:** Discretionary costs of country team meetings to support PEPFAR management and of providing training and professional development opportunities to staff. Please note that costs of technical meetings should be included in the relevant technical program area.

***9.*** **U.S. Government Renovation:**

a. Country teams should budget for and include costs associated with renovation of buildings owned/occupied by U.S. government PEPFAR personnel.
b. Costs for projects built on behalf of or by the partner government or other partners should be budgeted for and described as Implementing Mechanisms (see Sections 5.5.11 of the COP Guidance).

***10.*** **Institutional Contractors (non-PSC/non-PSA):**

a. Institutional and non-personal services contractors/agreements (non-PSC/non-PSA) includes organizations such as IAP Worldwide Services, COMFORCE, and all other contractors that do NOT have an employee-employer relationship with the U.S. government.
b. All institutional contractors providing M&O support to the country team should be entered in M&O, not as an Implementing Mechanism template.
c. *In addition to the budget information, country teams must provide a narrative to describe institutional contractor activities in the "Item Description" field*.
d. Costs associated with this category will be attributed to the appropriate technical program area within the FACTS Info PEPFAR Module.

***11.*** **Peace Corps Volunteer Costs (including training and support):**

a. Includes costs associated with Peace Corps Volunteers (PCV), Volunteer Extensions, and Peace Corps Response Volunteers (PCRVs) arriving at post between **October 1, 2017** and **September 30, 2018**.
    i. The costs included in this category are direct PCV costs, pre-service training, **Volunteer-focused** in-service training, medical support and safety and security support.

ii. The costs excluded from this category are: U.S. government staff salaries and benefits, staff travel, and other office costs such as non-ICASS administrative and computer costs, which are entered as separate CODB categories. Also excluded are activities that benefit the community directly, such as Volunteer Activities Support and Training (VAST) grants and **selected** training events where the number of host country nationals is greater than the number of PCVs participating. These types of activities should be entered directly into the appropriate program area budget code in an Implementing Mechanism template.

b. Funding for PCVs must cover the full 27-month period of service. For example:

iii. Volunteers arriving in June **2017** will have expenses in **2017, FY 18 and FY 2019**.

iv. Volunteers arriving in September **2017** will have expenses in FY 17**, FY 18, FY 2019, and FY 2020**.

c. PCV services are not contracted or outsourced. Costs are incurred before and throughout the Volunteer's 27-month period of service. Costs incurred by Peace Corps Washington and domestic offices, such as recruitment, placement and medical screening of Volunteers, are included in the Headquarters Operational Plan (HOP). Costs such as living allowance, training, and support will continue to be included in the COP.

*Inclusion of Global Fund Liaison Costs (where applicable):* For Global Fund Liaison positions that remain centrally-funded at this time, the funding should not be included in the CODB. As Missions pick up the funding of the Liaison position (full or cost share), the percentage of the position that is PEPFAR funded should be reflected in the COP and allocated to the above CODB categories. Please contact your CL with any questions about funding stream for this position.

# Appendix F.5 U.S. Government Office Space and Housing Renovation

Country teams may include support for U.S. government renovation in their CODB submission. All other construction and/or renovation should be included in the Implementing Mechanism section of the COP. The terms are defined as follows:

**Construction** – refers to projects that build new facilities, or expand the footprint of an already existing facility (i.e., adds on a new structure or expands the outside walls).

**Renovation** – refers to projects with existing facilities intended to accommodate a change in use, square footage, technical capacity, and or other infrastructure improvements.

All construction and renovation projects should be cleared by the Ambassador in country before submission to headquarters. The notes below outline how U.S. government renovation funds may be used.

*PEPFAR Funding May Not Be Used for New Construction of U.S. Government Office Space or Living Quarters*

Consistent with the foreign assistance purposes of PEPFAR appropriations, PEPFAR GHAI, GHCS, and GHP-State funding should not be used for the construction of office space or living quarters to be occupied by U.S. government staff. The Embassy Security, Construction, and Maintenance (ESCM) account in the State Operations budget provides funding for construction of buildings to be owned by the Department of State, and the Capital Investment Fund (CIF) is a similar account appropriating funds for USAID construction. Other agencies such as HHS/CDC and DOD have accounts that provide funding to construct U.S. government buildings, and implementing mechanisms may contribute to the ESCM account through the Capital Security Cost Sharing program.

*PEPFAR Funding May Be Used to Lease U.S. Government-Use Facilities*

Where essential office space or living quarters cannot be obtained through the Embassy or USAID Mission, a request to use PEPFAR funds may be made in the context of a Country or Regional Operational Plan (COP/ROP) to rent or lease such space for a term not to exceed 10 years, if necessary to implement PEPFAR programs.

*PEPFAR Funding for Renovation of U.S. Government-Owned and Occupied Properties*

Country teams may request the use of PEPFAR funds to renovate U.S. government-occupied facilities in exceptional circumstances. The justification for using PEPFAR funds to renovate U.S. government-occupied facilities must demonstrate that the renovation is a "necessary expense" that is essential to carrying out the foreign assistance purposes of the PEPFAR appropriation, and should show that the cost of renovation represents the best use of program funds. The justification should also explain why appropriate alternative sources of funding for renovation are not available. The country team must submit a comprehensive plan that includes an explanation of the unique circumstances around the request to renovate U.S. government-occupied facilities. The plan must have support from the Ambassador that justifies the renovation project. In addition to the "Item Description" narrative, country teams must provide the total costs associated with renovation of buildings owned/occupied by U.S. government PEPFAR personnel under the CODB section. Note, renovation of facilities owned by the U.S. government may require coordination with the State Department's Office of Overseas Buildings Operations (OBO) and other State Department bureaus, and may require the clearance of the State/Office of the Legal Advisor.

# Appendix F.6 Peace Corps Volunteers

For each OU and in aggregate, Peace Corps Washington will submit to S/GAC the number of PEPFAR-funded:

- Volunteers on board as of October 1, 2017;
- Volunteer Extensions on board as of October 1, 2017;
- Peace Corps Response Volunteers on board as of October 1, 2017;
- New Volunteers proposed in COP 17;
- Volunteer Extensions proposed in
- COP 17; and
- New Peace Corps Response Volunteers proposed in COP 17.
- Peace Corps Washington will obtain this information from Peace Corps country programs.

# APPENDIX G: TEMPLATES, TOOLS, AND COP SUBMISSION

# Appendix G.1 Tools and Templates

The following tools and templates are provided to PEPFAR teams to assist with the analysis and completion of COP17. Not all countries will need to use each tool and should review Section 1.5 and Appendix I for more details about which tools or templates are applicable.

***Datapack:*** The Datapack has been provided to country teams in Microsoft Excel format and is intended to be a template and analysis tool to assist PEPFAR field teams meet the requirements for successful target-setting in COP 17. The Datapack is also intended to assist reviewers to understand the data analysis completed by the country teams and limit the need for extensive verbal or written clarification around targets. The Datapack is submitted in FACTS Info as a supplemental document. Please note that the Datapack produces both SNU-level targets and IM level targets. The PBAC requires both SNU prioritization summary targets and IM-level targets; DATIM requires site-level targets. Teams will need to use tools outside of the Datapack to distribute across sites. OGAC and ICPI will release an optional Site Level Targeting Tool in February that can assist teams with this process. Please consult the Datapack User's Guide for detailed guidance on how to use the Datapack, an overview of major changes in the COP17 Datapack, and an overview of how to link the target-setting and budgeting processes.

The ***Datapack*** may be downloaded from each country's pepfar.net OU Collaboration page.

***Sustainability Index and Dashboard (SID):*** The SID is an excel-based tool that measures the current state of sustainability of the national HIV/AIDS response and tracks progress over time in PEPFAR countries among four key domains and fifteen elements essential for a sustainable HIV/AIDS response. In COP16, all PEPFAR teams submitted a completed SID which formed a baseline for the current state of sustainability and to inform the definition of above site investments (Table 6). While the SID is not required in COP17, its results should continue to inform contribution to sustained epidemic control as defined in Table 6 in section 4.

***PEPFAR Budget Allocation Calculator (PBAC):*** The PBAC tool will assist country teams with estimating appropriate allocations to target-based budget, commodity procurement, program management and routine strategic information for partners, and site-level and above-site level activities. The national envelope and a target unit budget are set for target-based budgeting, starting from prior year unit expenditures for key targets. Note that this national budget tool provides a starting point to assist teams and provides an objective basis for IM-level allocations, but is not intended to be a rigid

benchmark. For key targets, the same methodology of starting with prior year unit expenditures and then planning an appropriate unit budget should be applied for allocations to the IMs, using separate tools. All IM-level budgets, for target-based allocations, commodity procurement, program management and strategic information, and site-level and above-site level activities, should be documented in the PBAC. The summed budget across all IMs should be reviewed and discussed in terms of the country strategic direction.

The ***PBAC*** may be downloaded from pepfar.net. An additional users' manual is posted on the COP17 page on pepfar.net.

***EA Data Navigation Tool:*** This tool was designed to assist country teams and HQ support teams review expenditure data from the prior fiscal year. This Excel tool features multiple sheets with dropdown menus that allow users to select, summarize and visualize EA results by program area, sub-national unit, and cost category over multiple fiscal years. The tool also contains information on national UEs and mechanism specific UEs, as well as mechanism specific information by program area, cost category and SNU.

Pre-populated ***EA Data Navigation Tools*** may be downloaded from each country's PEPFAR OU Collaboration page on pepfar.net.

***Focused Outcome and Impact Table (FOIT)*****:** The FOIT template is provided to teams as an excel workbook, and is used to complete the SDS for those countries who are completing their COP using the STAR process. The FOIT reflects all PEPFAR funding proposed in COP 17, including above-site activities (similar to Table 6 in COP16), site-level activities and central funding in order to achieve a full picture of the proposed PEPFAR investments.

The ***FOIT template*** may be downloaded from the COP17 page on pepfar.net.

***Table 6 Excel Worksheet:*** In COP 17, country teams will complete all tables in Section 6 (Table 6.1.1, Table 6.1.2, Table 6.1.3, Table 6.2.1, Table 6.2.2, and Table 6.3) in an Excel worksheet which will be attached to the completed SDS as SDS Appendix C. The tables should be populated with the data entered last year in the COP 16 SDS tables and updated, per Appendix A.2.4 Planning Step 4 of the COP guidance... The tables should draw on the work done in the COP 16 SBOR exercise, as well as the results of the COP 16 SID. The work done in COP 16 should also inform the completion of the FOIT for STAR countries. A document containing illustrative examples of outcomes and annual

benchmarks has also been developed. Teams should consult this document for assistance in developing country-specific outcomes and annual benchmarks for both Table 6 and the FOIT.

The ***Table 6 Excel Worksheet*** and the ***Illustrative Examples of Systems Investments Outcomes and Benchmarks*** will be downloaded from the pepfar.net COP17 website.

***Financial Supplement Workbook:*** Each country or region must submit a ***Financial Supplemental Workbook*** at COP submission, detailing the historic, current and projected financial performance of all mechanisms and CODB categories included within the COP. Each PEPFAR team must submit one document compiling the information for all agencies.

The ***Financial Supplemental Workbook*** can be found on the pepfar.net COP 17 website.

***OP 17 CSO Matrix Update:*** Building on the successful engagement of many community and Civil Society Organizations in COP 16, the COP 17 CSO Engagement Matrix will serve as a tool to define civil society in each country/region and articulate how stakeholder engagement supports the development and implementation of your annual COP/ROP process to enhance impact. The mapping of CSO engagement in each country and region should align with the burden of disease in each OU. The updated CSO Engagement Matrix should be completed; both quantitative and qualitative components, addressing any specific CSO engagement feedback noted in your country specific guidance related to last year's matrix.

The analysis of each COP16 Matrix will be posted on each country's pepfar.net OU collaboration page for review and update.

***FY18 SIMS Site Visit Planning Table:*** Each country or region must submit a ***FY18 SIMS Site Visit Planning Table*** at COP submission, detailing the planned SIMS visits by quarter. This replaces the SIMS Action Planner (SAP) required in previous years. The ***FY18 SIMS Site Visit Planning Table*** can be found on the pepfar.net COP 17 website.

# Appendix G.2 COP/ROP Submission

The COP is comprised of four primary elements, using DATIM and Facts Info.

The **Strategic Direction Summary (SDS)** outlines key data and analysis results, the strategic plan for the coming year, and the monitoring framework that will be used to measure progress. The SDS is

submitted in FACTS Info as a supplemental document. Microsoft Word format is recommended and a template has been provided to assist country teams prepare a comprehensive SDS.

**Supplemental documents** as outlined in Appendix I are required and are to be submitted in FACTS Info.

This year, **targets** will be submitted through PEPFAR's data collection system DATIM. Targets are required at the site, geographic, mechanism and technical area levels.

The **budget**, **mechanism information** and **other required documentation** are submitted in FACTS Info by direct entry in the user interface.

Both DATIM and FACTS Info systems are accessible to field teams, and require users to set up accounts to access these systems. Please work with your CL to ensure your team has appropriate access.

## Appendix G.2.1 FACTS Info Templates for Data Entry

COP/ROP submission may be done using PEPFAR Module templates that teams can upload directly into FACTS Info, or via direct data entry using the screens in the PEPFAR Module. **Prepopulated templates for existing IMs, and blank templates for new IMs will be available at this time.** When the COP module is launched teams can export templates and share them with their partners for data. Please note that **blank templates must be used for entering new mechanisms only, and CANNOT be used for existing mechanisms**. Teams are required to use prepopulated templates for existing mechanisms in order to maintain the mechanism ID number and history.

**Figure G.2.1.1**

| Template Name | Function of Template | Where to find the template |
|---|---|---|
| **Blank Implementing Mechanism Template** | For new IMs created in FY 17 COP/ROP, has all elements that will be asked for in FACTS Info and is organized in a way that corresponds to the FACTS Info Tabs for each IM. When the full COP Module is open you can upload this template to FACTS Info to create a new IM rather than entering data directly on the screen in FACTS. | FACTS Info only |
| **Pre-populated Implementing Mechanism Template** | Format is similar to the Blank IM template but this is specifically for continuing IMs. This template is exported from FACTS Info under the IM search screen. Use this template to update existing IMs created in previous FYs. You can import this template to FACTS Info to pull a continuing IM into the current year COP or ROP rather than entering data directly into the screen in FACTS Info. | FACTS Info only |
| **Blank PPP Template** | For new PPPs created in FY 17 COP/ROP, this template has all elements that will be asked for in the PPP tab in FACTS Info. You can export this template, populate it, and import in to FACTS Info, within the appropriate IM, to create a new PPP entry rather than entering data directly into the FACTS Info screen. | FACTS Info only |
| **Pre-populated PPP Template** | Format is similar to the Blank PPP template but this is specifically for continuing PPPs. This template is 'exported from FACTs Info in the PPP tab or the IM search screen. Use to update existing PPPs created in previous FYs. When COP is open in FACTS Info, you can export this template, populate it, and import it in to FACTS Info, within the appropriate IM, to update an existing PPP rather than entering data directly into the FACTS Info screen. | FACTS Info only |
| **New Partner Template** | If you don't find a partner's name in the Partner List please fill out this form and submit to PEPFAR-Module-support@state.gov. | FACTS Info document library |

## Appendix G.2.2 Checking Your Work and Highlights of Key Reports

In addition to systems checks, the FACTS Info system offers multiple options for 'checking your work.' In many countries there are multiple U.S. government team members who enter data in FACTS Info and DATIM and even more that enter data into templates that are uploaded to FACTS Info that collectively become the COP or ROP. By utilizing key reports you can ensure the COP/ROP submission (i.e., what is in FACTS Info) is what the country team intended to submit. Checking your work can also lessen the need for extensive clarifications between S/GAC, Agency Headquarters, and

country teams after COP/ROP submission. We urge all teams to heavily utilize the reports available in both the Standard Reports section of the COP module and within the Budget section of FACTS Info in the 'ad-hoc' reports section where you can customize reports.

**Highlights of Key Reports**

- **Standard COP Matrix Report**- Shows all IMs along with Agency, Funding Source (including Applied Pipeline) and amounts, Budget Code Funding amounts, and crosscutting allocations. This report is the most useful snapshot of critical budget information entered into FACTS Info.
    - Available in the Standard Reports section of the COP Section of the PEPFAR Module and also through the Budget section of FACTS Info.
- **Summary of Planned Funding by Agency**- Shows the allocations of the full programmed COP budget by funding account, applied pipeline and implementing agency.
    - Available in the Standard Reports section of the COP Section of the PEPFAR Module and also through the Budget section of FACTS Info.

- **Summary of Planning Funding by Budget Code**- Shows the allocations of the full programmed COP budget by budget codes. This report can be filtered by implementing agency. Also, indicates the total budget code allocation "on hold" amount, if applicable.
    - Available in the Standard Reports section of the COP Section of the PEPFAR Module and also through the Budget section of FACTS Info.
- **Agency Cost of Doing Business (CODB)** - Shows the agency-specific allocations across the 11 CODB cost categories by funding source.
    - Available in the Standard Reports section of the COP Section of the PEPFAR Module and also through the Budget section of FACTS Info.

# APPENDIX H: OTHER ELEMENTS

# Appendix H.1 Acronyms and Abbreviations

A&A – Acquisition and Assistance

AB – abstinence and be faithful

ABC – abstain, be faithful, and, as appropriate, correct, and consistent use of condoms
– African Affairs (State Department Bureau)

AFG – AIDS-free Generation

AIDS – Acquired Immune Deficiency Syndrome

ANC – antenatal clinic

APR – Annual Program Results

APS – Annual Program Statement

ART – antiretroviral therapy

ARV – antiretroviral

CBO – community-based organization

CCM – country coordinating mechanism

CDC – Centers for Disease Control and Prevention (part of HHS)

CN – Congressional Notification

CODB – Costs of Doing the U.S. government's PEPFAR Business

COP – Country Operational Plan

CP – Combination Prevention

CQI – Continuous Quality Improvement

CSH – Child Survival & Health (USAID funding account; replaced by GHCS-USAID)

CL – Country Lead (formerly CSTL)

CSW/SW – Commercial Sex Worker

DFID – Department for International Development (UK)

DOD – U.S. Department of Defense

DOL – U.S. Department of Labor

DOS – U.S. Department of State

EA – Expenditure Analysis

EAP – East Asian and Pacific Affairs (State Department Bureau)

EID – early-infant diagnosis

EUM – End use monitoring

EUR – European and Eurasian Affairs (State Department Bureau)

F - The Office of U.S. Foreign Assistance Resources

FBO – faith-based organization

FDA – Food and Drug Administration (part of HHS)

FJD – Framework Job Description

FP – Family Planning

FSN – foreign service national

FSW – female sex workers

FTE – full-time equivalent

FY – fiscal year

GAP – Global AIDS Program (CDC)

GFATM – The Global Fund to Fight AIDS, Tuberculosis, and Malaria (also “Global Fund”)

GHAI – Global HIV/AIDS Initiative (funding account; replaced by GHCS-State)

GHCS – Global Health Child Survival funds (funding account)

GHI – Global Health Initiative

HCN – Host Country National

HCW – Health Care Workers

HHS – U.S. Department of Health and Human Services

HIV – Human Immunodeficiency Virus

HMIS – Health Management Information System

HQ - headquarters

HRSA – Health Resources and Services Administration (part of HHS)

HRH – Human Resources for Health

HTS – HIV Testing Services (formerly HIV Testing and Counseling – HTC)

ICASS – International Cooperative Administrative Support Services

ICF – Intensified Case Finding

ICPI – Interagency Cooperative for Program Improvement

INH - Isoniazid

INR – Intelligence and Research (State Department Bureau)

IPT - isoniazid preventive therapy

IRM – information resources management

LE – Locally Employed (Staff)

LCI – Local Capacity Initiative

LOE – Level of effort

LTFU – Lost to follow up

M&E – monitoring and evaluation

MER – Monitoring, Evaluation and Reporting

M&O – Management and Operations

MC – Male Circumcision

MOA – Memorandum of Agreement

MOU – Memorandum of Understanding

NACS - Nutrition Assessment Counseling and Support

NEA – Near Eastern Affairs (State)

NIH – National Institutes of Health (part of HHS)

OE – operating expense

OGA – Office of Global Affairs (part of HHS)

OMB – Office of Management and Budget

OS – Office of the Secretary (part of HHS)

OU – Operating Unit

OVC – orphans and vulnerable children

PASA – Participating Agency Service Agreement

PEPFAR – President's Emergency Plan for AIDS Relief

PLHIV/ PLWHA/PLWA – People Living with HIV/AIDS or People Living with AIDS

PM – Political-Military Affairs (State Department Bureau)

PMTCT – prevention of mother-to-child HIV transmission

POART - PEPFAR Oversight and Accountability Response

PPP – Public-Private Partnership

PR – Principal Recipient

PRH – Population and Reproductive Health

PRM – Population, Refugees, and Migration (State Department Bureau)

PSC – Personal Services Contract

PSE – Private Sector Engagement

PWID – People who inject drugs

QA – quality assurance

RCNF – Robert Carr civil society Networks Fund

RFA – Request for Application

RFC – Request for Contracts

RFP – Request for Proposal

ROP – Regional Operational Plan

SAPR – Semi-Annual Program Results

SAMHSA – Substance Abuse and Mental Health Services Administration (part of HHS)

SCA - South and Central Asian Affairs (State Department Bureau)

SCMS –Supply Chain Management System

SDS – Strategic Direction Summary

S/GAC and S/GAC – Office of the U.S. Global AIDS Coordinator (part of State)

SI – Strategic Information

SSDA—System Support Decision Algorithm
SIMS – Site Improvement through Monitoring System

TAN – Technical Area Narrative

TB –Tuberculosis

TBD – To Be Determined

TCN – Third Country National

TTFs – Tools, Templates and Frameworks

TWG – Technical Working Group

UNAIDS – Joint United Nations Program on HIV/AIDS

UNDP – United Nations Development Program

UNICEF – United Nations Children's Fund

USAID – U.S. Agency for International Development

USDA – U.S. Department of Agriculture

USDH – U.S. direct hire

USPSC – U.S. personal services contractor

UTAP – University Technical Assistance Project

VCT – voluntary counseling and testing

VL – viral load

WHA - Western Hemisphere Affairs (State Department Bureau)

WHO – World Health Organization

# Appendix H.2 Small Grants Program

Beginning in FY 2005, program funds were made available for all PEPFAR countries and regional programs to support the development of small, local partners. The program is known as the PEPFAR Small Grants Program, and replaced the Ambassador's Self-Help Funds program for those activities addressing HIV/AIDS. These grants provide an opportunity for country teams to address diverse issues specific to each country context. In prior years, grants have supported a wide range of activities, including but not limited to:

- Training for local press to effectively cover HIV/AIDS,
- Building capacity within civil society organizations to combat LGBTQ stigma and discrimination,
- Developing education and cultural programs for HIV prevention and awareness, including for key populations (PLHIV, MSM, PWID and prisoners),
- Providing job skills training for women and girls living with HIV, and
- Developing networks of PLHIV to increase retention in care.

S/GAC will release additional guidance and best practices for use of PEPFAR Small Grants later this year.

Country and regional programs should submit an entry for the PEPFAR Small Grants Program as part of their yearly operational plan (COP or F-OP). The total dollar amount of PEPFAR funds that can be dedicated to this program should not exceed $300,000 or 5 percent of the country allocation, whichever is the lower amount. This amount includes all costs associated with the program, including support and overhead to an institutional contract to oversee grant management if that is the preferred implementing mechanism.

## Appendix H.2.1 Proposed Parameters and Application Process

### *Eligibility Criteria*

- Any awardee must be an entirely local group.
- Awardees must reflect an emphasis on community-based groups, faith-based organizations and groups of persons living with HIV/AIDS.

- Small Grants Program funds should be allocated toward stigma and discrimination, democracy and governance (as related to the national HIV response), HIV prevention, care and support or capacity building. They should not be used for direct costs of treatment.
- When PEPFAR funds are allotted to Post for State to issue grant awards, the below clauses must be included in addition to the standard terms and conditions.

CONSCIENCE CLAUSE IMPLEMENTATION: An organization, including a faith-based organization, that is otherwise eligible to receive funds under this agreement for HIV/AIDS prevention, treatment, or care;

- (a) Shall not be required, as a condition of receiving such assistance—
    - (1) To endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or
    - (2) To endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection; and
- (b) Shall not be discriminated against in the solicitation or issuance of grants, contracts, or cooperative agreements for refusing to meet any requirement described in paragraph (a) above.

PROHIBITION ON THE PROMOTION OR ADVOCACY OF THE LEGALIZATION OR PRACTICE OF PROSTITUTION OR SEX TRAFFICKING:

- (a) The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence 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.
- (b)(1) Except as provided in (b)(2) and (b)(3), by accepting this award or any subaward, a non-governmental organization or public international organization awardee/subawardee agrees that it is opposed to the practices of prostitution and sex trafficking.

- (2) The following organizations are exempt from (b) (1): U.S. organizations; the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Health Organization; the International AIDS Vaccine Initiative; and any United Nations agency.
- (3) Contractors and subcontractors are exempt from (b)(1) if the contract or subcontract is for commercial items and services as defined in FAR 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding.
- (4) Notwithstanding section (b)(3), not exempt from (b)(1) are recipients, sub recipients, contractors, and subcontractors that implement HIV/AIDS programs under this assistance award, any sub award, or procurement contract or subcontract by:
    - (i) providing supplies or services directly to the final populations receiving such supplies or services in host countries;
    - (ii) providing technical assistance and training directly to host country individuals or entities on the provision of supplies or services to the final populations receiving such supplies and services; or
    - (iii) providing the types of services listed in FAR 37.203(b)(1)-(6) that involve giving advice about substantive policies of a recipient, giving advice regarding the activities referenced in (i) and (ii), or making decisions or functioning in a recipient's chain of command (e.g., providing managerial or supervisory services approving financial transactions, personnel actions).

The following definitions apply for purposes of this provision:

- Commercial sex act means any sex act on account of which anything of value is given to or received by any person.
- Prostitution means procuring or providing any commercial sex act and the ―practice of prostitution‖ has the same meaning.
- Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act.
- The recipient shall insert this provision, which is a standard provision, in all sub awards, procurement contracts or subcontracts.

*Accountability*

Programs must have definable objectives that contribute to sustainable epidemic control, including addressing stigma and discrimination, HIV/AIDS prevention, care and/or (indirectly) treatment.

- Objectives must be measurable.
- These will normally be one-time grants. Renewals are permitted only where the grants show significant quantifiable contributions toward meeting country targets.
- According to Department of State's Administration /Office of the Procurement Executive's (A/OPE) grant regulations, before any single/individual grant estimated over $25,000 can be signed by grants officers in the field, the grant documents going into the grant file must be reviewed for accuracy and completeness by the authorized program office in Washington, D.C.
    - At least four (4) weeks prior to award, posts planning to issue a grant with PEPFAR funds in the amount of $25,001 or more (for a single grant) must submit grant documents to the respective Country Lead for review via email.
        - Country Leads will review the following documents for PEPFAR program specific accuracy and completeness (also see the S/GAC-PEPFAR Grant Review Checklist):
            - DS-1909
            - Award Specifics
            - SF 424, 424-A, project and budget narratives
            - Reporting Plan
            - Monitoring Plan
            - Competition or Sole Source justification
- S/GAC strongly encourages Posts to minimize the number of grants exceeding $25,000 so that additional work and extended timelines are not required on behalf of both Post and S/GAC country POCs.

*Submission and Reporting*

Funds for the program should be included in the COP under the appropriate budget category.

- Individual awards are not to exceed $50,000 per organization per year; the approximate number of grants and dollar amount per grant should be included in the narrative. Grants should normally be in the range of $5,000 - $25,000. In a few cases, some grants may be funded at up to the $50,000 level for stronger applicants. The labor-intensive management requirements of administering each award should be taken into account.

- Once individual awards are made, the country or regional program will notify their SCL/CL of which partners are awarded and at what funding level. This information will be added in the sub-partner field for that activity.

- Successes and results from the Small Grants Program award should be included in the Annual Program Results and Semi-Annual Program Results due to S/GAC. These results should be listed as a line item, like all other COP activities, including a list of partners funded with the appropriate partner designation.

*Additional Requirements for Construction/Renovation*

- OU teams that have small grant applications for construction/renovation need to submit a ***Small Grants Program - Construction/Renovation Project Plan*** form for each construction/renovation project (under an already approved COP implementing mechanism) for review/approval throughout the year (there is no set time for submission, but is as needed based on the country's small grants award timeline).
- Please send the project plan form applications directly to your S/GAC SCL/CL (copy Latoya Cook from the Management and Budget team at PEPFAR-Construction-Renovation@state.gov) throughout the year during your small grant proposal review periods. Note, all form fields need to be completed.
- The form(s) will be uploaded into the **FACTS Info – PEPFAR Module Document Library** as part of the COP Submission after it is reviewed and approved.
- Once the OU receives confirmation from S/GAC that the small grant applications have been approved, the OU team needs to the upload the approved application forms (for construction/renovation only) into the **FACTS Info – PEPFAR Module Document Library** under the approved COP cycle (e.g., if the 'small grants program' implementing mechanism was approved in the FY 15 COP, then the S/GAC approved small grant applications need to be uploaded in the Facts Info Document Library under the FY 17 COP cycle).
- The ***Small Grants Program - Construction/Renovation Project Plan*** form template is located at pepfar.net within the COP 17 Planning and Reporting cycle folder.

# Appendix H.3 Construction and Renovation of Laboratories

This supplemental document is required for all new BSL-3 and BSL-2 enhanced laboratory construction or renovation projects. To submit, upload the completed template to the FACTS Info FY 17 COP document library as part of the COP submission. Please provide the following as a supplement to your project proposal:

- Receiving institution information:
  - Name of receiving institution
  - Address of receiving institution
  - A point of contact at the institution
- Purpose of proposed lab:
  - Expected containment level (BSL-2 enhanced or BSL-3)
    - If enhanced BSL-2, what specific enhancements are planned?
  - Rationale for why that containment level is required
    - Presentation of an analysis of alternatives, if appropriate, or plans to conduct one
  - List of Select Agents (if any) and toxins (if any) that the lab anticipates handling
- Proposed timeline:
  - Including additional planning, funding, design and construction
  - For transition to host country oversight

Sustainability:

- What Ministry/organization/institution will be responsible for the long term sustainability of the lab?
- Involvement of other domestic/international partners

# Appendix H.4 Technical Assistance Available for Global Fund Activities

Global Fund technical assistance resources are available to address key program issues in Global Fund grant implementation where countries are at risk of not achieving targets. For example, testing yield/identifying positives and retention across various ages and populations are two critical issues where countries need improvement. Another critical issue is saturation of ARV services in priority (high burden) SNUs. Needs can also be specific to systems – such as, coordinated and accelerated roll-out of district data systems and entrenching a culture of data use – and key populations (access to services, human rights infringements, tailored service delivery models). PEPFAR country teams are encouraged to identify needs through the joint planning process for COP17 and the Global Fund's next funding request cycle (see Section 2.3.2) and convey these needs to HQ to inform allocation of Global technical assistance resources.

In addition, a limited amount of funding is available

This support may be accessed through an online application. Applications are vetted and coordinated across USG agencies, other bilateral investments, the Global Fund Secretariat, and multilateral partners to ensure complementarity and non-duplication of support.

*Website: http://www.pepfar.gov/partnerships/coop/globalfund/ta/index.htm*

# Appendix H.5 Pepfar.net Contacts and Help Information

Templates and guidance documents for COP 16 development can be found on the Pepfar.net COP 16 website here: https://www.pepfar.net/Project-Pages/collab-48/SitePages/Home.aspx

For any questions related to access to or the use of pepfar.net in support of this year's COP process, please contact the pepfar.net help desk at help@pepfar.net.

**NOTE**: *The pepfar.net site is fully supported by the Microsoft Internet Explorer web browser ONLY. While other popular browsers, such as Google Chrome or Mozilla Firefox, may allow you to view pepfar.net, full site functionality cannot be guaranteed using those browsers.*

**Logging in to Pepfar.net (Users *with* existing Pepfar.net accounts):**

Please use this link to access https://www.pepfar.net.

Your user name and password are required to enter the site. For most users, your user name is **LastNameFirstInitial**

Users who have an account but have not yet logged into pepfar.net will need to create their own password upon logging in for the first time. To do so, navigate to pepfar.net and click "Forgot your password." For most users, your user name is **LastNameFirstInitial**. For example: the user name for John Smith is **SmithJ.** You will then need to follow the on-screen prompts to create your new password.

**Logging in to Pepfar.net (Users *needing* Pepfar.net accounts):**

Field Users:

First time field team users will need to have an account established by a designated representative at their location. Contact your country team's pepfar.net Power User (or PEPFAR Coordinator if the Power User is unknown or not yet established), who will contact the pepfar.net Help Desk by sending an email to help@pepfar.net to request an account. After your account has been established, you will receive an email with a temporary password and instructions for resetting your password.

Agency Headquarters Users:

If you are based at headquarters, you will need to send an email to the Help Desk at help@pepfar.net requesting access to the site. Please note: for HQ personnel, your request must include the name of an individual who can verify your involvement/role within the PEPFAR community, for example, a County Support Team Lead.

For any questions regarding access to or use of the site, email the Help Desk at help@pepfar.net. Users can also request training on using the new site by emailing the Help Desk. Training materials, as well as a calendar of upcoming live training sessions, are available under the Help section of PEFPAR.net (https://www.pepfar.net/help/SitePages/Home.aspx).

# Appendix H.6 Public Private Partnership within the COP

Beyond the development and launch of a partnership, it is essential to systematically document and provide timely information updates across all PPPs within the OUs portfolio.

- All Public-Private Partnerships (PPP), including country PPPs, ongoing Incentive Fund PPPs, and Global PPPs/Central Initiatives should be planned for and reported in the FACTS Info portion of the COP.
- Accurate financial information is critically important as it allows PSE to calculate the leverage (ratio of PEPFAR resources compared to private sector resources).
- Each data field collected is used for PPP tracking and reporting. PSE does not collect superfluous information.
- PPPs are entered in the Implementing Mechanism section of FACTS Info. All PPPs should be linked to an existing or planned mechanism.

Please contact the PSE Team if you have any questions with regards to completing the PPP portion of the COP: Lauren Marks: marksla@state.gov, Neeta Bhandari: bhandarin@state.gov and Gary Kraiss: kraissgp@state.gov

Public Private Partnership Toolkit:

To help improve process development and knowledge management for PPPs, a Community of Practice Toolkit has been developed to identify, create, and strengthen PPPs in your country. It is important to remember that an integral component of driving quality of partnerships within PEPFAR is through sharing of best practices.

- Country Teams are encouraged to make use of the Community of Practice on pepfar.net and Toolkit materials (Table 4.5.1), which were developed by S/GAC to assist PPP

practitioners with engaging with the private sector, opportunity identification, development, management, and reporting of PPPs. The PPP toolkit, in coordination with targeted TA assistance, can support country teams as they work through the various stages of PPP development process within their portfolios.

- The Toolkit is intended to assist PPP practitioners by engaging with the private sector in identifying opportunities, developing ideas, as well as the management, and reporting of PPPs.
- For all PPPs that involve the State Department, The Office of U.S. Global AIDS Coordinator and Health Diplomacy must be consulted to ensure appropriate State Department approval. Please visit The Secretary's Office of Global Partnerships for more information at http://www.state.gov/s/partnerships/.

**Figure H.6.1**

| Opportunity Identification | Idea Development | Management | Reporting |
|---|---|---|---|
| 1. ITT PPP Questionnaire Template | 6. Country Analysis Standard Operating Procedure (SOP) | 11. Country Team PPP TWG Charter Template | 16. Interagency PPP Valuation Handout |
| 2. Presenting PEPFAR to the Private Sector Best Practices | 7. Interagency PPP Funding Opportunities Guide | 12. Example PPP Analysis Templates | 17. PSE Monitoring & Evaluation Handout |
| 3. Private Sector Expression of Interest Form | 8. PPP Concept Note Example | 13. Implementation Timeline Templates | |
| 4. Private Sector Meeting Preparation Guides | 9. PPP Ranking Ideas Template | 14. PPP Meeting Notes Template | |
| 5. Sample PSE Stakeholder Agendas | 10. PPP Technical Assistance SOW Template | 15. PPP 101 Overview Presentation | |

The following represents suggested key steps for PPP development and fostering meaningful private sector stakeholder engagement:

- Step 1 Situational Gap Analysis: Use POART data to identify key programmatic and technical gaps ripe for partnership aligned with priorities identified by country teams within scale-up sub-national units (SNU's)

- Step 2 Private Sector Landscape Assessment: Conduct or review existing local and regional private stakeholder landscape analysis/assessment of companies and private providers likely to align with PEPFAR goals and geographic priorities.
- Step 3 Convening, Planning, and Conceptualization: Host convenings involving public, private, multilateral, civil society, and affected populations to advance partnership dialogue and submission of concept notes aligned to meet or extend core programmatic goals for inclusion into the COP for partnership consideration. For example the Accelerating Children's HIV/AIDS Treatment (ACT) initiative is supplementing COP planning in eligible countries through public private partnership to help support doubling the number of children on treatment. Private partners are coordinating funding and support through unified ACT plans aligned with the COP and established PEPFAR monitoring systems such as POART and DATIM respectively. Convenings are held with multi-sector stakeholders to jointly plan activities and develop engagement 'roadmaps' at the country level as well as to review results on a quarterly basis to formulate shared responsibility for corrective action planning.
- Step 4 Approval: The Office of U.S. Global AIDS Coordinator and Health Diplomacy should be consulted on all such proposed PPPs (including any proposed MOUs) involving the Department of State to ensure appropriate State Department approval.
- Step 5 Implementation and Tracking: Beyond the development and public affairs (PA) announcement launch of a partnership, it is essential to systematically document and provide timely information updates across all PPPs within the OUs portfolio.

# Appendix H.7 Long-term Strategy (LTS), Targeted Assistance (TA) and Technical Collaboration (TC) PEPFAR Operating Unit Assignments

| Long Term Strategy (LTS) | Targeted Assistance (TA) | Technical Collaboration (TC) |
|---|---|---|
| Burundi; Cameroon; Cote d'Ivoire; DRC; Ethiopia; Haiti; Kenya; Lesotho; Malawi; Mozambique; Rwanda; Swaziland; Tanzania; Uganda; Zambia; Zimbabwe | Asia Regional (China, Laos, Thailand); Cambodia; Caribbean Regional (Bahamas, Barbados, Guyana, Jamaica, Suriname, Trinidad &Tobago); Central America Region (El Salvador, Guatemala, Honduras, Nicaragua and Panama); Central Asian Republics (Kazakhstan, Kyrgyz Republic, Republic of Tajikistan); Dominican Republic; Ghana; Indonesia; Ukraine; Burma; Papua New Guinea; South Sudan | Asia Regional (China); Brazil; India |
| Co-Finance Sub-group of LTS Countries<br>Nigeria; South Africa | Co-Finance Sub-group of TA Countries<br>Angola; Botswana; Namibia; Vietnam | |

# Appendix H.8 Inventory of PEPFAR Funded Evaluations

This section details requirements for evaluation-related information that must be provided as part of the COP submission. PEPFAR defines evaluation as *"the systematic collection and analysis of information about the activities, characteristics, outcomes, and impacts of programs and projects."* Evaluation requirements for COP17 are linked directly to the Evaluation Standards of Practice (ESoP) Version 2.0, which was released in September 2015 (www.PEPFAR.gov). The goal of the ESoP is to improve evaluation planning, implementation, oversight, and quality across PEPFAR programs. In addition, the ESoP responds to recommendations by the Government Accountability Office (GAO) and the Institute of Medicine (IOM), and stipulations within the congressional reauthorization to expand the utility of evaluation processes and data across PEPFAR programming for greater accountability and transparency. The ESoP contains 11 standards to which all PEPFAR evaluations (i.e., process, outcome, impact, and economic evaluations) must adhere. Full definitions of these evaluation types can be found in ESoP Version 2.0.

**Starting in FY17, the Evaluation Inventory will be used to capture both planned evaluations during the COP planning process (previously the COP Planned Evaluation Inventory) and progress updates on all planned, newly commencing, ongoing, and completed evaluations during APR (previously the APR Evaluation Inventory).** Each planned evaluation should be directly linked to and attempt to answer at least one evaluation question in the COP17 OU Evaluation Plan, which is to be submitted in Q2 (additional guidance forthcoming). If a **planned** evaluation addresses any of the programmatic needs identified in Section 6 of the SDS, OUs are required to identify which gap(s) the evaluation addresses. There will be drop-down options in DATIM for OUs to select programmatic gap(s). For planned evaluations that do not link to any of the OU programmatic gaps, OUs should select N/A in DATIM.

OUs are required to enter information on each planned evaluation into DATIM within the Evaluation Inventory module. A template of the Evaluation Inventory fields will be available on pepfar.net to assist with data collection and facilitate entry into DATIM.

OUs are encouraged to keep the template for their records but do not need to upload the template into any data system.

**DC Management Meetings will include a discussion of the extent to which planned evaluations address the identified gaps in Section 6 of the SDS.** Planned evaluations will be confirmed at the conclusion of the COP review.

NOTE: For countries going through the STAR process, if a planned evaluation addresses any of the strategic outcomes identified in FOIT, OUs are required to identify which outcomes the evaluation addresses in DATIM.

Any questions regarding evaluation planning should be directed to one of the following:

- SGAC_EWG@state.gov
- esop@cdc.gov
- esop@usaid.gov

# APPENDIX I: SUPPLEMENT DOCUMENTS CHECKLIST

## Detailed COP 17 Elements and Supplemental Document* Checklist

| COP Element | Requirement | Template location / completion instructions |
|---|---|---|
| **Strategic Direction Summary (SDS)** | **STAR / Standard** | **PEPFAR.net, COP 17 page** |
| **Datapack** | **Standard** | **PEPFAR.net, OU page** |
| **PBAC** | **Standard** | **PEPFAR.net, OU page** |
| **Targets** | | |
| *National Level Indicators* | | |
| *Technical Level Indicators* | **Standard**** | **DATIM** |
| *Mechanism Level Indicators* | | |
| *Site-Level Indicators* | | |
| **FOIT** | **STAR** | **PEPFAR.net, COP 17 page** |
| **Implementing Mechanism Details:** | **STAR / Standard** | |
| *Partner Name* | *All IMs* | |
| *G2G check-box and managing agency* | *As Applicable* | |
| *Funding Agency* | *All IMs* | |
| *Procurement Type* | *All IMs* | |
| *IM Name* | *All IMs* | |
| *Mechanism ID* | *All IMs* | |
| *Agreement Timeframe* | *All IMs* | |
| *TBD check-box* | *All IMs* | |
| *New IM check-box* | *As applicable* | |
| *Construction/Renovation check-box and vehicle plans* | *As applicable* | **FACTS Info** |
| *Motor Vehicles check-box and numbers* | *As applicable* | |
| *Funding Source allocations, including applied pipeline* | *As applicable* | |
| *Budget Code allocations* | *All IMs* | |
| *Crosscutting Allocations* | *As Applicable* | |
| *Crosscutting Allocation: Gender Activity Checklist* | *Required if Gender-GBV or Gender Equality allocation* | |
| *Crosscutting Allocation: Key Populations Checklist* | *Required if Key Populations allocation* | |
| *Activity Table* | *All new IMs and all G2Gs* | |
| **Management & Operations:** | | |
| *Agency Cost of Doing Business, including total and applied pipeline figures* | **STAR / Standard** | **FACTS Info** |
| *FACTS Info Staffing Data Module* | | |
| *Agency functional staff charts* | | **No Template** |

| | | |
|---|---|---|
| **Financial Supplemental Workbook** | **STAR / Standard** | **PEPFAR.net, COP 17 page** |
| **Chief of Mission Letter** | **STAR / Standard** | **No Template** |
| **COP 17 CSO Matrix Update** | **STAR / Standard** | **PEPFAR.net, OU page** |
| **FY18 SIMS Site Visit Planning Table** | **STAR / Standard** | **PEPFAR.net, COP 17 page** |
| **Laboratory Construction or Renovation Project Plan Supplemental** | **STAR / Standard**<br>***Yes:*** *PEPFAR funding proposed for laboratory construction in COP 2017 at BSL-3 and BSL-2 lab*<br>***No:*** *PEPFAR not funding laboratory construction in COP 2017* | **No Template** |
| **Justification for partner funding** | **STAR / Standard**<br>***Yes:*** *Single partner budget exceeds 8 percent of PEPFAR budget*<br>***No:*** *No partner exceeds 8 percent of PEPFAR budget* | ***No Template*** |
| **Evaluation Inventory** | **STAR / Standard**<br>***Yes:*** *PEPFAR funding proposed to fund evaluations*<br>***No:*** *PEPFAR funding not funding evaluations* | **DATIM** |

** All supplemental documents are submitted in the Document Library of FACTS Info

* If countries submitting under the STAR process will have site-level targets, those targets are entered into DATIM.

# APPENDIX J:

# CASE EXAMPLES OF BEST PRACTICES FOR PEPFAR PROGRAMS

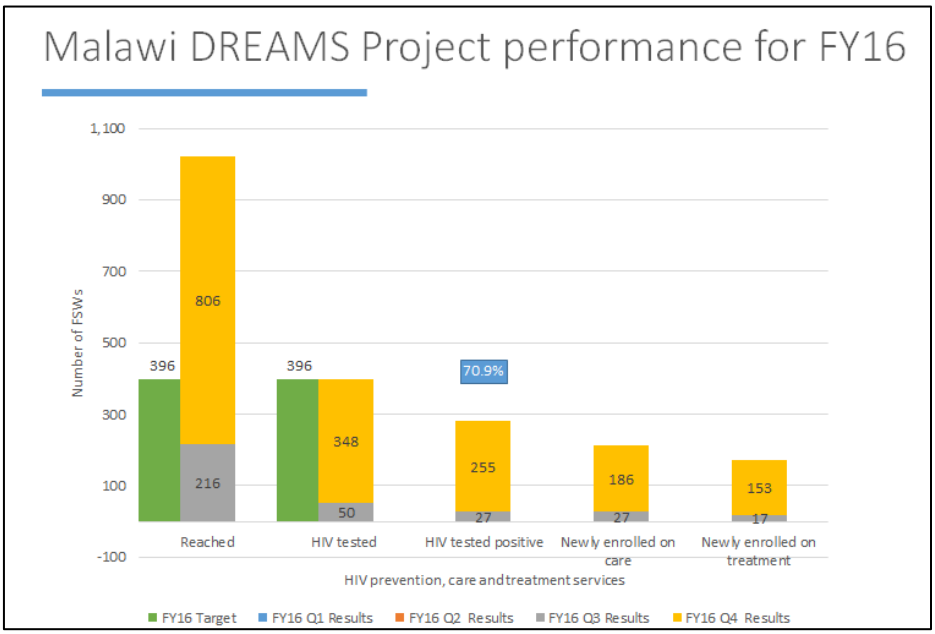
# Appendix J.1 Preventing and Treating New Infections among Adolescents and Young Adults <30 Years Old

## Appendix J.1.1 Prevention in Adolescent Girls and Young Women (AGYW), DREAMS & OVC

### Appendix J.1.1.1 DREAMS Malawi – Mapping Female Sex Worker Hot Spots for Targeted HIV Testing & Outreach

LINKAGES in Malawi conducted physical site-walks to map Female Sex Worker (FSW) hot spots, operating times, and total estimated number of FSWs to determine the location of drop-in centers, mobile outreach services, and proportion of peer educators/peer navigators needed. LINKAGES has a strong focus on the clinical cascade using trained Peer Navigators to follow-up with HIV-positive FSW. In FY16, 398 FSW tested for HIV in Zomba and Machinga through the DREAMS program, 282 were HIV-positive (70.9% yield), 213 were enrolled in clinical care, and 170 were initiated on treatment.

**Figure J.1.1.1.1**



## Appendix J.1.1.2 Partner Layering & Coordination for Success in Adolescent Girl and Young Women Prevention in Uganda

Uganda DREAMS hosts quarterly Implementing Partner (IP) meetings to review program progress and all IPs are asked to present on MER results and custom indicator results. IPs are encouraged to routinely review data and create visualizations for discussion and presentation. For example, Rakai Health Science Program (RHSP), a DREAMS IP, creates quarterly data visualizations in an effort to review program data routinely. RHSP has a database where all outputs from DREAMS monitoring tools are entered. There is a unique ID assigned to each AGYW and this ID is linked to the identified male partner. The stem for this ID is the DREAMS AGYW ID.

## Appendix J.1.1.3 Psychological and Behavioral Interventions to Reduce HIV Risk: Evidence from a Randomized Control Trial among Orphaned and Vulnerable Adolescents in South Africa[67]

Psychological distress is a key risk factor for poor sexual decision-making and is particularly salient for Orphans and vulnerable Children (OVC) given their well-documented higher risk for mental health problems. Findings from an OVC program in South Africa indicate that layering psychological and behavioral interventions was associated with risk-reduction behaviors, but the outcomes varied by gender: boys reported fewer risky sexual partnerships ($\beta = -.48$, $p = .05$) and girls reported more consistent condom use ($\beta = 1.37$, $p = .02$). There was no difference in the likelihood of sexual debut for either gender. Exposure to a single intervention did not impact behaviors. Furthermore, providing both psychological and behavioral interventions resulted in long-term changes in sexual behavior that were not present when either intervention was provided in isolation.

The PEPFAR OVC partner, World Vision South Africa, under their community-based OVC programming model, Networks of Hope provides a general package of support to HIV-affected children, including those who have lost a parent or are living with someone who is chronically ill. This package consists of home visits by trained volunteers who seek to improve the economic security of beneficiaries (e.g., helping them obtain social grants); support academic

[67] http://www.tandfonline.com/doi/full/10.1080/09540121.2016.1146213

achievement (e.g., providing uniforms and educational supplies); and provide referrals for health care and other social services. In addition to this package, the project randomly tested the impact of two additional interventions. The first intervention, Interpersonal Psychotherapy for Groups (IPTG), consists of 16 weekly 90-minute group sessions led by a trained lay adult community facilitator. The sessions are designed to provide participants with opportunities to learn and practice interpersonal skills for resolving distress, and to facilitate the provision of emotional support between group members. The second intervention, called Vhutshilo (meaning "Life" in Venda), is a curriculum-based behavioral intervention developed by a South African non-profit organization, Centre for the Support of Peer Education (CSPE). The Vhutshilo program was designed specifically for OVC aged 14 and older in South Africa, and addresses HIV risk factors and pathways considered particularly relevant for this population. It consists of 13 weekly 60 minute sessions covering topics including: alcohol and substance abuse; crime and sexual violence; HIV/AIDS; healthy sexual relationships; transactional sex; and condom use.

These results underscore the potential of incorporating psychological health interventions as part of a comprehensive strategy for mitigating HIV risk among OVC. Mediators between psychological distress and unhealthy sexual decision-making include high rates of substance use, low self-esteem, increased susceptibility to pressure to have sex, comfort seeking, and self-destructive attitudes.

## Appendix J.1.1.4 Enhancing Financial Literacy, HIV/AIDS Skills, and Safe Social Spaces among Vulnerable South African Youth[68]

The Population Council, in collaboration with the University of KwaZulu-Natal, Development Research Africa, and Tulane University, carried out a four-year longitudinal study of young people aged 14–24 in KwaZulu-Natal testing the impact of three evidence-based interventions.

Participants in the intervention group showed improvement in several important areas, including attitudinal and behavioral changes regarding self-esteem, financial matters, and protection from HIV. Recall of discussing key concepts increased after the intervention among participants, and the data showed that most non-participants did not discuss these topics. For example, 70

[68] https://assets.publishing.service.gov.uk/media/57a08c0ced915d3cfd00112c/brief4.pdf

percent of girls in the intervention—compared to 26 percent of those who did not participate—recalled discussing self-esteem in the last 12 months. Figures for boys were similar: 51 percent of participants recalled discussing self- esteem, while only 23 percent of non-participants did. Young people who participated in the intervention also reported having more exposure to messages in the media at a higher rate than non-participants. For example, the percentage of people who reported hearing HIV-related messages on the radio rose about 20 percent from baseline to end line among participants but did not increase at all among non-participants. Key financial behaviors were much better among young people who participated in the intervention than among those who didn't. Participants had higher rates of both talking about financial matters and acting on what they had learned, by taking actions such as starting to save money. Among young women, for example, 75 percent of participants had discussed financial decision-making, while only 21 percent of non-participants had (up from 27 percent and 6 percent, respectively, at baseline). Among young men, 56 percent of participants had discussed financial decision-making, but only 23 percent of the control group had (13 percent and 4 percent at baseline). Girls in the intervention group have also started saving money: up 50 percent from baseline, compared to almost no change among the control group. Young women participants also reported increased autonomy regarding decisions about how to spend their own money, up from 82 percent at baseline to 90 percent after the intervention.

Attitudes about their own lives and about other important issues also improved after the intervention. Nearly three-fourths of girls and 61 percent of boys who participated in the intervention groups said that participation had changed their views of themselves and their capabilities. Seventy percent of girls and 61 percent of boys said participation gave them the ability to better manage their lives. There are also indications that participation in the program was helpful in encouraging aspirations, goals, and ambitions among young people, and that the program contributed to the kinds of aspirations and visions young people developed. Parents of participants were also affected, expressing that the training had helped them as household heads to manage money better.

The intervention included three main components:

- Safe spaces and social networks that recognize age and gender-specific needs. Small groups of young people met regularly with community mentors. In addition to giving young people an identity beyond home and school, such networks may be a key element for HIV

prevention because they reduce social isolation, build positive social relationships, and encourage healthy behaviors among young people.

- Financial management. Young people were taught how to budget, save, plan for the future, identify safe and appropriate income-generating opportunities, and access social benefits.
- Awareness about HIV/AIDS. Sessions focused on HIV/AIDS, with the goal of dispelling myths, providing accurate information about how the disease is transmitted, teaching skills for avoiding infection, and coping with AIDS within the family and community.

## Appendix J.1.1.5 Family Economic Strengthening and Parenting Stress among Caregivers of AIDS-Orphaned Children: Results from a Cluster Randomized Trial in Uganda[69]

Parenting stress has been identified as a factor influencing parenting behavior and a determinant of dysfunctional parenting. Dysfunctional parenting has been associated with increased HIV infection among children, particularly at adolescence.

Using data from a 4-year (2008-2012) randomized controlled trial involving the Suubi-Maka project - program that involved matched child savings accounts (CSAs) and workshops on financial management and enterprise development for caregivers and children affected by HIV and AIDS, researchers found that participation in the intervention was associated with a significant decline in parenting stress in two domains of parent distress, such as caregiver's perception of own incompetence, role restrictions, and relationship problems ($\beta = -2.4$, 95%CI=−4.3, −.43, $p < .01$) and parent–child dysfunctional relationship, such as the quality of the current relationship ($\beta = -2.0$, 95%CI=−3.5, −.47, $p < .01$), suggesting that the intervention probably helped caregivers feel less stressed about meeting children's basic needs and school needs, and less stressed about their relationship with their children.

Institutional matched saving accounts are seen as a way to empower poor people by incentivizing them to save for future education or other career preparation expenses, linking them to formal financial institutions and potentially changing saving behaviors. Savings accounts seek to reduce poverty "through the promotion of asset ownership is grounded in the

[69] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4133737/

premise that access to assets, including savings, home ownership, education, and income generating activities, enhances people's capacities to make choices and pursue their life goals."

The authors note that though these findings are significant, their model explains only a small amount of the variance measured in parenting stress. That being said, they suggest that in communities where supports like counseling are not available, ES interventions may be helpful in reducing caregiver distress. A related study found that a similar intervention, coupled with mentorship by an adult, may have helped reduce depression in targeted adolescents, although the findings were not conclusive and the study did not tease out the effects of the different component parts of the program[70].

## Appendix J.1.1.6 Sexual Behavior among Young Carers in the Context of a Kenyan Empowerment Program Combining Cash-Transfer, Psychosocial Support, and Entrepreneurship[71]

This study examined associations between sexual initiation, unprotected sex, and having multiple sex partners in the past year with participation in a three-year empowerment program targeting OVC. A Kenya-based program combines community-conditioned cash transfer, psychosocial empowerment, health education, and microenterprise development. Program participants (n=1,060) were interviewed in a cross-sectional design. Analyses used gender-stratified hierarchical logit models to assess program participation and other potential predictors. Significant predictors of increased female sexual activity included less program exposure, higher age, younger age at most recent parental death, fewer years of schooling, higher food consumption, higher psychological resilience, and lower general self-efficacy. Significant predictors of increased male sexual activity included more program exposure, higher age, better food consumption, not having a living father, and literacy. Findings support a nuanced view of current cash transfer programs, where female sexual activity may be reduced through improved financial status but male sexual activity may increase. Targeting of OVC sexual risk behaviors would likely benefit from being tailored according to associations found in this study. Data

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[70] Ssewamala et al. 2012

[71] http://opensample.info/sexual-behavior-among-young-carers-in-the-context-of-a-kenyan-empowerment-program-combining-cash-transfer-psychosocial-support-and-entrepreneurship

suggest involving fathers in sexual education, targeting women who lost a parent at a younger age, and providing social support for female OVC may decrease risk of HIV transmission.

## Appendix J.1.1.7 Support for Adolescents and Young Women in PMTCT

Current evidence suggests that 'business as usual' within the PMTCT service cascade has not worked well for pregnant and breastfeeding adolescents and young women and that enhanced support for adolescents and young women in PMTCT settings is needed to improve outcomes for young HIV-infected mothers and their infants.

Recent data from Kenya has highlighted major gaps in adolescent engagement in antenatal care and PMTCT services. In the Kenya study, adolescents were less likely to have disclosed their HIV status (77.5% vs. 90.7%) ($p<0.01$), to attend >=4 ANC visits (35.2% vs. 45.6%, $p=0.002$), to receive maternal antiretroviral medications (ARVs) (65.0% vs. 85.8%, $p=0.01$), to have infants on ARVs (85.7% vs. 97.7%, $p=0.005$), or to be retained in care compared to their adult counter parts[72].

While there is limited information about interventions specifically designed to improve retention and outcomes for adolescents in PMTCT, interventions that have been shown to work for vulnerable adolescents in other settings should be considered. For example, implementation of a 'centering model' where pregnant adolescents and young women (aged 14 – 21 years) receive clinical, social, and mental health services in a youth-supportive environment in the United States has been shown to improve maternal health behaviors and outcomes[73][74].

Providing adolescent support groups as well as sexual and reproductive health services tailored to the needs of youth has also been shown to improve outcomes for HIV-infected adolescents and young women. In a multi-country cohort study utilizing routinely collected patient-level data from 160 HIV clinics in Kenya, Mozambique, Tanzania, and Rwanda, youth (15-24-year-old) attending clinics providing sexual and reproductive health services including condoms (AHR =

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[72] Ronen K et al, JAIDS; 2016.

[73] Jeannette R et al, Am J Public Health; 2016.

[74] Trotman et al. J Pediatr Adolesc Gynecol; 2015.

0.47, 95% CI: 0.32–0.70) and clinics offering adolescent support groups (AHR = 0.73, 95% CI: 0.52–1.0) experienced significantly lower attrition I year after ART initiation. In Rwanda, the sole country with sufficient heterogeneity in the availability of adolescent peer educators, attrition was substantially lower at clinics with this service (RR = 0.30, 95% CI: 0.07–1.3). Similarly, youth attending clinics offering adolescent support groups had lower attrition (RR = 0.73, 95% CI: 0.52–1.0)[75].

Peer counselling (which involves group counselling sessions where adolescent patients provided motivation and support to each, often facilitated by a clinic staff member or researcher) was investigated in one study of adolescents attending a hospital outpatient clinic in France. Groups were not randomly allocated to receive peer support or control interventions. After two years of follow-up, the proportion of participants achieving viral suppression was higher among adolescents who received peer counselling[76].

## Appendix J.1.2 VMMC

### Appendix J.1.2.1 Voluntary Medical Male Circumcision Demand Creation

In October, a second supplement, “Interventions to drive uptake of voluntary medical male circumcision” was published in JAIDS. This supplement included a collection of articles on Gates-funded research of various interventions aimed at increasing demand for MC[77]. Interventions that led to an increase in the uptake of MC included an intervention using soccer as an entry point for education around VMMC and use of fixed financial incentives to offset lost wages incurred as a result of MC.

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[75] Matthew R et al, AIDS; 2014.

[76] Funck-Brentano I. et al, AIDS; 2005.

[77] http://journals.lww.com/jaids/toc/2016/10012

## Appendix J.1.2.2 VMMC Modeling for Prioritizing Sub-Populations by Age and Geography

A PLOS Collection, "Voluntary Medical Male Circumcision for HIV Prevention: New Mathematical Models for Prioritizing Sub-Populations by Age and Geography"[78], developed in collaboration with USAID with PEPFAR funding, the World Bank, and the Bill and Melinda Gates Foundation, was launched in October. Data from this collection of articles was presented at the IAS meeting in July and in a webinar that was held in late October. The supplement presents results of several mathematical models examining

a) Effects of prioritizing specific subpopulations for VMMC services on program impact and cost-effectiveness, for example, by client age, HIV-positive status, risk group, and geographical location
b) Long-term sustainability strategies, such as adolescent and/or early infant male circumcision, to preserve VMMC coverage gains achieved during rapid scale-up
c) Impact and cost of scaling up VMMC in the context of UNAIDS 90-90-90 treatment targets
d) Impact and cost-effectiveness of targeting 20–29 year olds in Zimbabwe
e) Unit cost, cost drivers, and cost variances of providing VMMC within the health system and client out-of-pocket costs for being circumcised in South Africa

During the webinar, panelists from the Office of the Global AIDS Coordinator, the Centers for Disease Control and Prevention, UNICEF, Bill & Melinda Gates Foundation, Swaziland Ministry of Health, and Tanzania National AIDS Control Program discussed how the models have been used to inform their choices about where best to invest their resources to prevent HIV.

## Appendix J.1.2.3 VMMC Devices

In July, a supplement "An innovation in public health: devices for voluntary medical male circumcision", covering various studies on MC devices was published in JAIDS[79]. The supplement covered articles on both the PrePex and ShangRing devices with the majority on PrePex. The work published was conducted prior to WHO guidance on the need for

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[78] http://collections.plos.org/vmmc2016

[79] http://journals.lww.com/jaids/toc/2016/06011

immunization with tetanus toxoid-containing vaccines prior to the use of the PrePex device (described in the WHO Technical Advisory Group on Innovations in Male Circumcision in its report entitled Tetanus and voluntary medical male circumcision: risk according to circumcision method and risk mitigation, issued 21 September 2016, http://www.who.int/hiv/pub/malecircumcision/tetanus-vmmc-report/en ) so some of the acceptability data may not be not align with current programmatic requirements. Nonetheless, articles in the supplement include:

a) WHO process for prequalification of MC devices
b) Training issues
c) Clients' understanding of pre and post-operative counseling RE condom use, abstinence and wound care
d) Safety of use of fewer sizes of ShangRing
e) Safety of PrePex in adolescents
f) Results from pilot studies of PrePex
g) Use of PrePEx device in mobile services
h) Effect of devices on demand for MC
i) Cost of device introduction and implementation

## Appendix J.1.3 Key Populations

### Appendix J.1.3.1 Linking Online Demand Creation to Real World Results for KP Prevention in Thailand

Www.adamslove.org – a MSM-specific sexual health website linked to the Thai Red Cross AIDS Research Center and supported by various donors including USAID's LINKAGES Project, generated online demand for HIV prevention information, condoms and lubricants, HIV testing and other MSM-specific sexual health services. Adam's Love reached over 15,000 MSM from around Thailand and Southeast Asia visiting Bangkok during Thai New Year (Songkran) for the gCircuit festivities – dance parties targeted towards gay, bisexual, and other MSM. Beyond the online format, staff and volunteers from a consortium of partners including Rainbow Sky Association of Thailand, Asia Pacific Committee on Male Health (APCOM), and Sex Workers In

Group (SWING) distributed 9,000 bundled packages of condoms and lubricant during the gCircuit festivities.

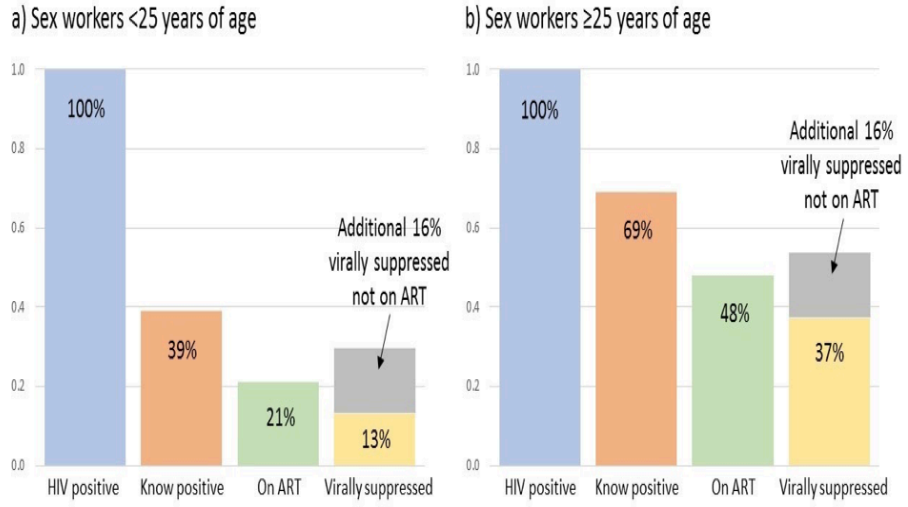
## Appendix J.1.3.2 Sisters with a Voice – Zimbabwe's National Sex Workers Program: Sharpening Targets to Reach Younger and Higher Risk Sex Workers

Zimbabwe's national sex workers program ('Sisters with a Voice'), supported by Ministry of Health and Child Care and National AIDS Council, has rapidly scaled-up since its inception in 2009 to approach national coverage reaching over 60,000 women in 36 priority locations along major transport routes where demand for sex work is high.

The Centre for Sexual Health and HIV AIDS Research (CeSHHAR) provides technical assistance with implementation support and research activities to evaluate and strengthen interventions and services. The intervention model includes peer-based outreach at hotspots with clinical services provided by fixed and mobile clinic teams, integrated with public services. Mapping and size estimation and RDS surveys conducted by CeSHHAR provide up-to-date information for planning, monitoring and evaluation. Current plans include extending outreach to new areas and populations in need including male and transgender sex workers.

Sisters with a Voice interventions are regularly assessed by monitoring routine programmatic data. CeSHHAR has also conducted several rounds of RDS studies to assess population-level data on key indicators including HIV burden, client numbers condom use, knowledge of HIV status, ART use, etc. Cascade analyses were stratified by age group and other risk factors to identify intervention gaps and guide future targeting.

**Figure J.1.3.1.1** Cascade outcomes for sex workers less than 25 compared to older sex *workers*



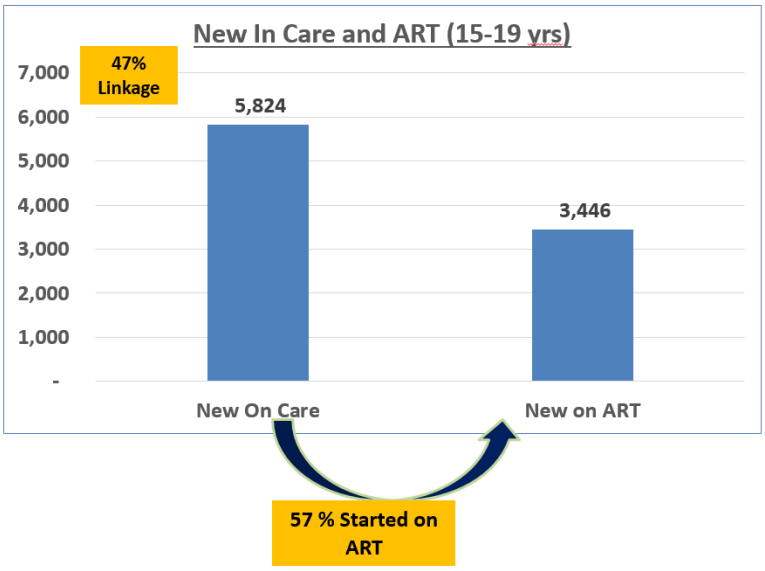
Based on the significantly poorer outcomes for younger sex workers as well as other data showing higher risk for sex workers with other measurable risk factors, outreach programs are currently being strengthened. CeSHHAR has developed specific materials for community mobilization based on stated priorities of young sex workers and has recruited, trained and supported younger women who sell sex aged 15-19 in order to meet their needs better. Peer educators are being trained as case care workers (lay child protection officers) in addition to paralegals so that they can provide tailored social protection to young women selling sex. This program has been extended to DREAMS districts as part of the DREAMS initiative. A recently awarded BMGF grant will support work on micro-planning (with risk assessment and risk-guided interventions) as well as a range of structural interventions to build financial and psychological resilience thereby reducing their vulnerability with the aim of further improving retention of sex workers in the program over time. Previous CeSHHAR experience conducting RDS surveys will inform operation research into supplemental methods of reaching deeper into sex work networks.

## Appendix J.1.4 Testing & Treatment

### Appendix J.1.4.1. Introduction and Roll-Out of the Adolescent Package of Services to Improve the Adolescent 90-90-90 in Kenya

Adolescents have poorer uptake of HIV testing and linkage services. Within Kenya, as of the end of fiscal year 2015, only 47% of adolescents 15-19 years old testing positive for HIV were thought to be linked to care compared to 76% of all PLHIV, and only 57% of adolescents linked to care were started on antiretroviral therapy compared to 90% of all PLHIV. The Kenya Ministry of Health had developed an Adolescent Package of Care with a focus on providing services to adolescents living with HIV, with the goal of improving HIV prevention, testing uptake, linkage to care and treatment, viral suppression and retention in care. This package of care along with training and basic health care worker tools has been implemented country-wide. In fiscal year 2016, age-disaggregated monitoring was introduced in PEPFAR-supported sites to document progress in improving adolescent service provision.

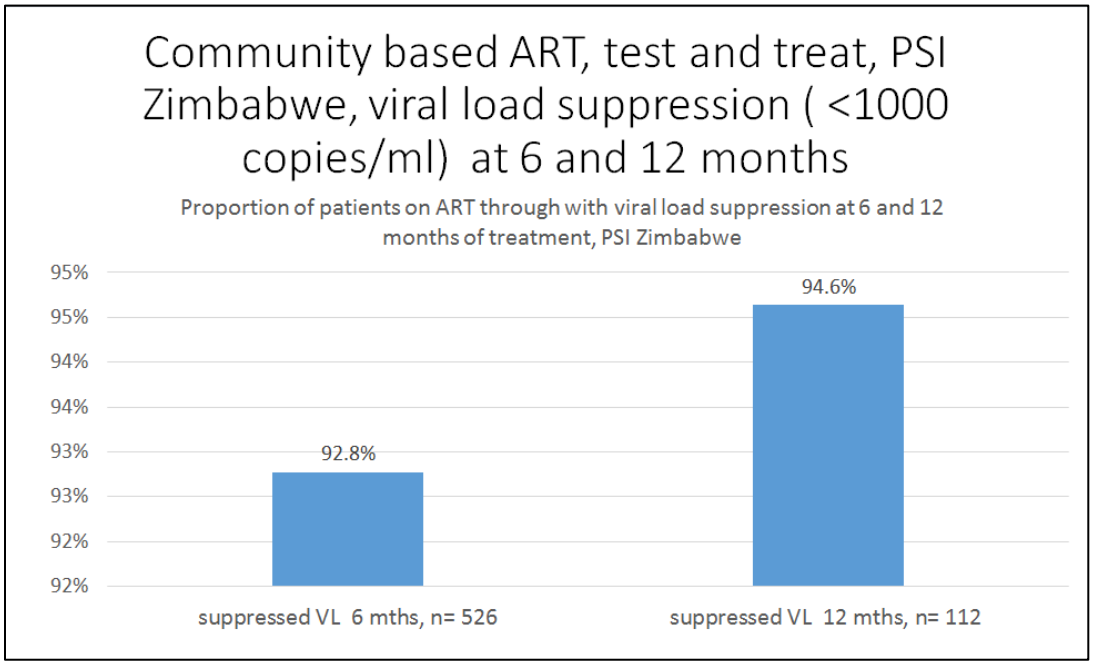
**Figure J.1.4.1.1**




## Appendix J.1.4.2 Community-based ART Program Targeting Men in DREAMS Zimbabwe

A community based ART program in three DREAMS Districts (Mutare, Makoni and Chipinge) in Manicaland Province, Zimbabwe specifically targets men for HIV testing with the offer of immediate ART initiation to all who test positive. Community outreach points are chosen in consultation with district health officers, and drugs are procured through the national drug supply chain. Uptake of ART by clients testing positive is over 95%. Follow-up visits and viral load testing by DBS were provided in the community until week 24 of treatment. At 6 months, 93% of patients are virally suppressed, at 12 months 95% of patients are virally suppressed. Stable and virally suppressed patients were linked to community ART groups with medication provision and monitoring and evaluation through the local clinic.

**Figure J.1.4.2.1**




# Appendix J.2 Targeted Testing and Improving Testing Yield

## Appendix J.2.1 HTS Quality

### Appendix J.2.1.1 HIV Rapid Testing Continuous Quality Improvement (RT-CQI formally referred to as RTQII)

The rapid expansion of HIV testing and counseling services has been driven by the implementation of HIV rapid diagnostic tests (RDT) performed by either health care workers or lay providers, the increasing need for HIV services, and the increased provision and demonstrated effectiveness of antiretroviral drugs to treat persons living with HIV and prevent further transmission (e.g., prevention of mother-to-child transmission (PMTCT), discordant couples, etc.). Considerable efforts and resources have focused on expanding and decentralizing HIV Testing Services (HTS), Prevention of HIV Mother to Child Transmission

(PMTCT) programs and HIV care and treatment services. However, complementary quality assurance program and quality improvement processes for HIV rapid diagnostic tests have not been adequately prioritized or implemented. WHO has supported the use of HIV rapid diagnostic tests, including their use by specifically trained and supervised lay providers, as part of the recommended testing algorithms and the scale-up of provider-initiated HIV testing and counseling (PITC) in health facilities. The WHO 2016 Consolidated Guidelines on the Use of Antiretrovirals for the Treatment and Prevention of HIV Infection (Consolidated ARV Guidelines) now recommends ART initiation based solely on the result of the HIV rapid tests for certain populations. In the area of “Test and Start”, increasing the access to accurate and reliable HIV test result is critical in order to meet the UNAIDS targets of diagnosing 90% of HIV infected persons by 2020. Therefore there is an urgent need to strengthen country capacity for robust continuous quality improvement processes.

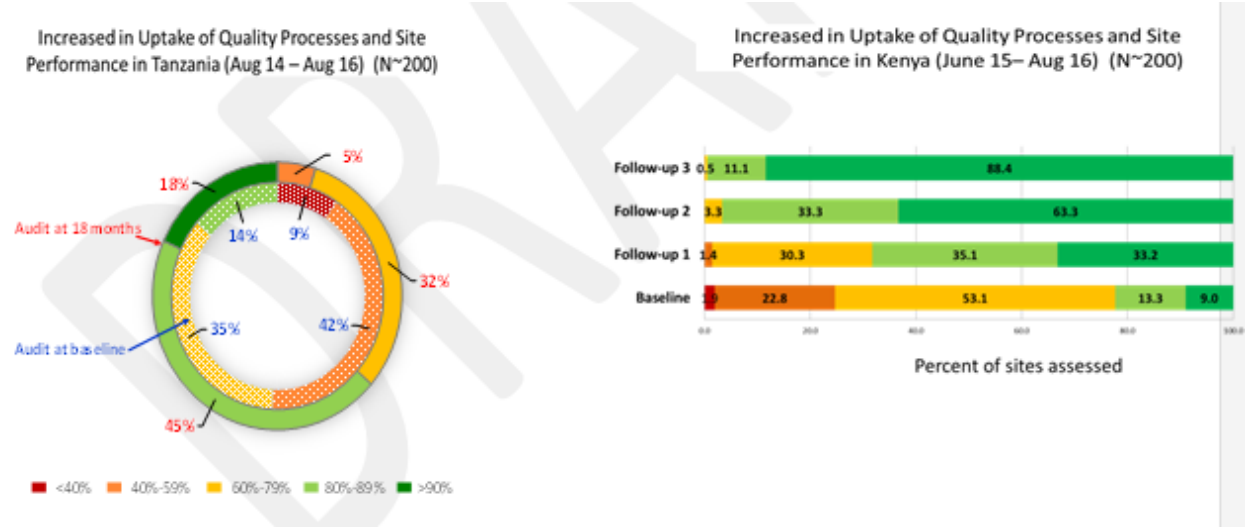
RT-CQI is a comprehensive package of quality assurance and improvement activities that have been piloted by seven PEPFAR supported countries and is now widely adopted as a continuum of integrated planned activities that supports and promotes effective rapid HIV testing – to ensure the accuracy and reliability of HIV test results. This package includes 1) Developing guidelines and policies on quality assurance and improvement 2) Establishing a certification program for testers and testing sites using innovative tools and approaches, 3) Scaling up their proficiency testing program, 4) Increasing the used of standardized testing logbook and finally 5) Strengthening their capacity to ensure the quality of test kits.

The 2015 WHO Handbook on QA for HIV rapid testing and POCT has been adopted and incorporated into several national HTS guidelines recently revised.

RT-CQI, has shown a significant increase in the implementation of best practices at site level in the pilot countries. For example, the implementation of the stepwise process for improving the quality of HIV rapid testing (SPI-RT) using a standardized checklist revealed a significant increase in the number of sites in Kenya and Tanzania with improved performance as well as (Figure J.2.1.1.1 below). In Malawi after 15 months of implementation, it was observed a 60% increase in the number of sites eligible for national certification. In Malawi, RT-CQI implementation has helped increase the proficiency testing (PT) performance by 62.5% increase after 4 PT rounds. Moreover, there was a significant increase in the return of PT

results resulting in 37.5% decrease in turnaround time for returning results and 90% of the sites receiving their PT scores and corrective actions within 6 weeks.

**Figure J.2.1.1.1**

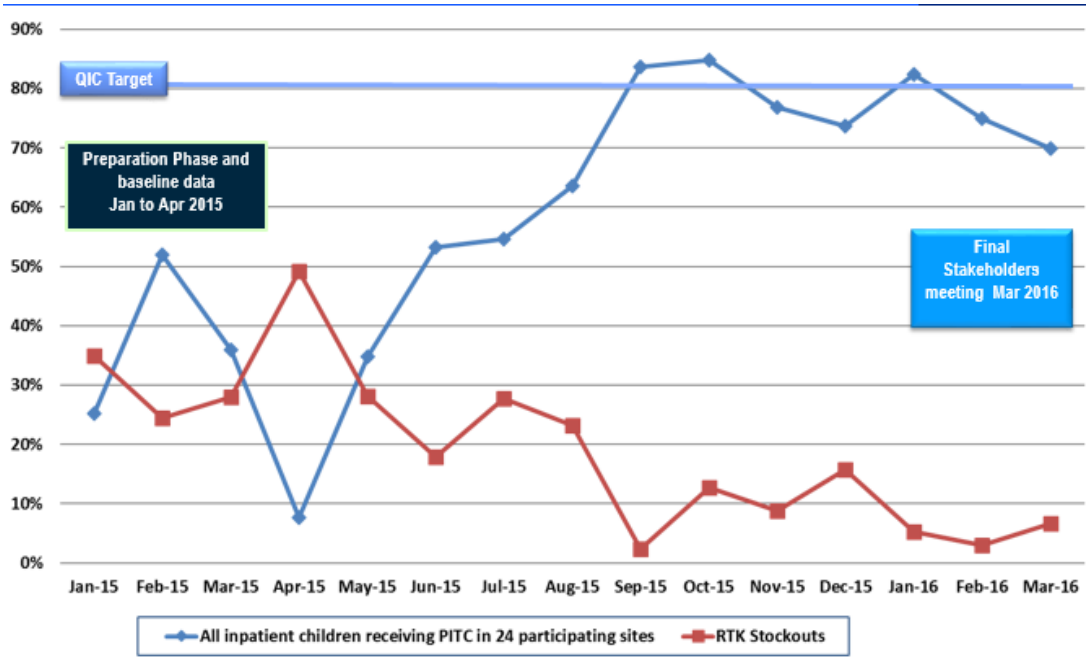



## Appendix J.2.1.2 Optimizing Provider-Initiated Testing and Counseling Using Quality Improvement Techniques in Tanzania [80]

Routine pediatric HIV testing at standard testing points was not maximized in Tanzania despite the National AIDS Control Program (NACP)'s national guidelines and training supporting HIV testing services for children, adolescents, and families in health facilities. A quality improvement learning collaborative methodology was introduced in pediatric facilities to address low provider-initiated testing and counselling (PITC) in Tanzania with the goal of achieving NACP's quality improvement goal to offer HIV testing to 80% of health facility attendees. NACP, along with local implementing partners - Christian Social Services Commission and the Ariel Glaser Pediatric AIDS Healthcare Initiative; ICAP; and the US Centers for Disease Control and Prevention, supported 24 health facilities in 2 regions of the country to implement basic change ideas including improvements in staff and client education, staffing, workflow, commodity management, documentation, and referrals to improve pediatric PITC. After 1 year of implementation the overall inpatient pediatric PITC coverage rose from an average of 25% from January to March 2015 to 70% in March 2016.

[80] IAS 2016 late breaker presentation

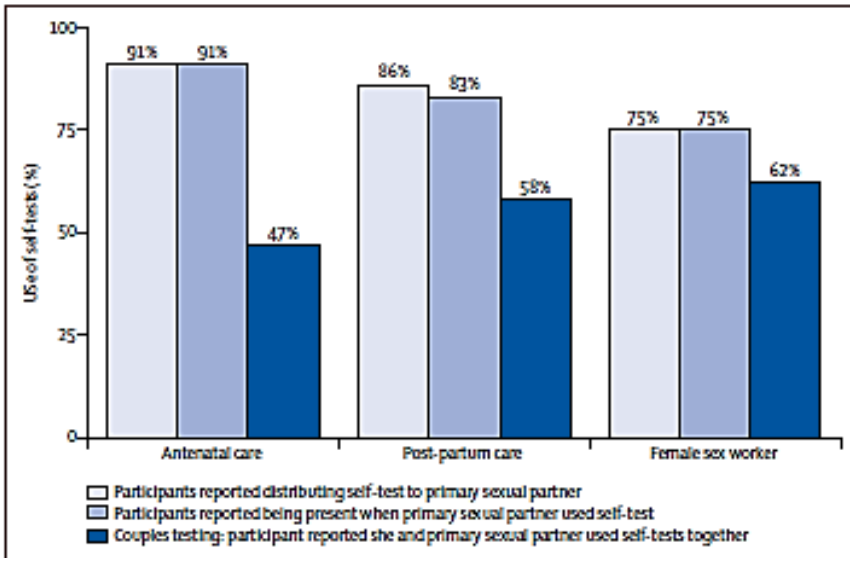
**Figure J.2.1.2.1.**



# Appendix J.2.2 Self-Testing

## Appendix J.2.2.1 Promoting Male Partner Testing and Safer Sexual Decision Making through Self-Testing in Kenya

**Figure J.2.2.1.1**




Increased testing in men is needed to optimize HIV prevention and treatment. In this pilot project in Kenya, women in antenatal care, postpartum care, or presenting to a drop in center for sex workers (SW) were given self-tests and instructions to provide to their sexual partners. As shown, uptake of testing by partners was high. 45 (10.2%) of 442 tests among the partners were positive, with the highest rate among partners of SW (14%). Condom use with partners testing positive was 100% after testing, compared to 44% after negative testing ($p < 0.001$). Linkage to care could be confirmed in 58% of those testing positive among partners or clients of sex workers. Four (1.9%) of women providing tests to partners reported intimate partner violence as a result of test distribution. Provision of self-tests to women to increase HIV testing in their partners appears promising to increase testing in men and decrease HIV risk in women.

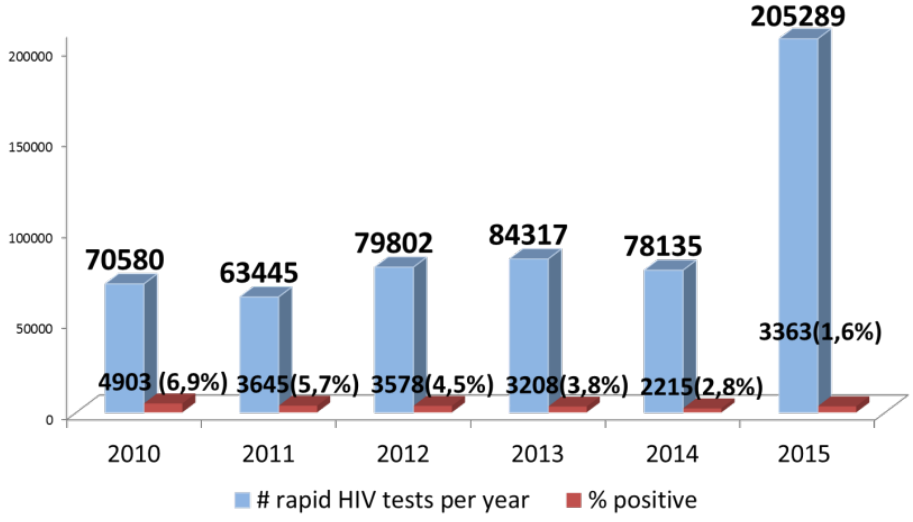
## Appendix J.2.2.2 Increasing HTS Coverage through Assisted Self-Testing among People who Inject Drugs in Ukraine

In 2015, Alliance for Public Health in Ukraine initiated a new strategy for HIV screening during community-based outreach called “assisted HIV testing.” Prior to 2015, due to national regulations, community-based HIV testing access was limited by the schedule when a healthcare provider was available to conduct HTS. In the majority of cases, doctors were only available 2-3 hours per day or every second day since these staff are often employed full-time at the AIDS center. Assisted HIV testing is a combination of HIV self-testing (HIVST) and testing performed by peer outreach workers. All outreach workers who participate in assisted self-testing are provided standardized training and are monitored by Alliance Ukraine to ensure their proficiency in assisting clients. Currently, assisted-self testing is not part of the national testing algorithm, thus all project clients who test positive are immediately referred to an AIDS center for diagnostic HIV testing and enrollment into HIV care.

According to the assisted self-testing model, peer outreach workers usually carry rapid HIV tests when they are visiting clients for the purpose of syringe or condom distribution. They offer clients the opportunity to test for HIV and they also assist them in testing, provide pre-test counselling, ensure the proper testing procedures, conduct post-test counselling, and follow-up on positive cases by linking them to HIV care services. Assisted self-testing has reduced the previous barriers to HIV testing while addressing potential shortcomings of self-testing such as user error, misinterpretation of results, and suboptimal linkage to HIV treatment among those who test HIV-positive.

While assisted self-testing has increased PWID access to testing, Alliance Ukraine has observed lower HIV-positive test yield in their outreach testing efforts. The absolute number of new cases, however, has increased because of the higher number of tests completed. Alliance Ukraine continues to innovate their testing approaches to increase positive test yield through complementary methods, such as Optimized Case Finding (OCF).

**Figure J.2.2.2.1**




## Appendix J.2.2.3 Using Peer Educators to Scale-up HIV Oral Self-Testing among Female Sex Workers in Kenya

To increase identification of HIV-infected FSW, a multi-site Kenyan team developed an HIV Oral Self-Testing (OST) strategy and applied an implementation science approach to assess user acceptability, competence, feasibility and impact on enrollment of FSW into ongoing HIV prevention and treatment programs. Four teams with ongoing FSW programs covering diverse geographic locations (Nairobi, Mombasa, Kisumu, and Migori) are using a quasi-experimental crossover design and baseline/end line qualitative interviews in eight sites to determine: FSW acceptance and competence in OST, feasibility of FSW peer educators (PE)-led OST distribution and the proportion of FSW who seek confirmatory HTS and linkage to care if positive. Those targeted for OST are FSW who have never or not recently (>6 months) sought HTS. Forty PE were trained to implement demand creation for OST among the targeted FSW, collect and interpret data to enhance program delivery.

Preliminary data show 99% (446/449) acceptance, 84% (324/385) confirming their HIV results, 100% (98/98) test result concurrence of FSW-initiated OST with facility-based confirmation, and enrollment of 98% (96/98) FSW into HIV treatment and prevention services. None of the PE declined addition of OST into their package of services.

Integrating OST into FSW services using PE is feasible, acceptable, gives accurate results and encourages enrollment into prevention and treatment programs. It is also convenient to FSW and improves access for HTS first-timers or infrequent testers.

## Appendix J.2.3 Sexual and High Risk Networks

## Appendix J.2.3.Building Quality Approaches for MSM and Transgender Women in Thailand

In FY2016, as a result of PEPFAR-supported efforts under the USAID LINKAGES Project, a program in Thailand and Laos sought to reduce HIV transmission and improve quality of life for men who have sex with men (MSM), male sex workers and transgender women. The main approaches included intensive case finding, HIV testing and the immediate offering of treatment, use of mobile technology in tracking and monitoring people across the HIV continuum of services, online outreach coupled with in-person mobilization and increasing the availability and access to PrEP. In FY16, 69,097 MSM and TW were reached with one-on-one or small-group prevention behavioral interventions, condoms and lubricant. HTC_POS results from LINKAGES were 1,223 of 12,595 tested for a 10 percent yield. This is in line with prevalence rates and led to 835 MSM and transgender persons new on treatment.

The results were achieved through a combination of approaches, including collaboration with community-based organizations, regional networks, and research institutions, and Thailand and Laos's national policy adoption of immediately offering HIV treatment upon diagnosis.

## Appendix J.2.3.2 Social Network Outreach Using Virtual Platforms for HIV Testing in Central America

In Central America, the USAID-funded Combination Prevention Program, implemented by Pan-American Social Marketing Association (PASMO), combines social network outreach with virtual platforms for HIV and STI testing referrals. In 2014 and 2015, this system resulted in reaching 22,444 MSM and transgender women with 6,475 of those being tested for HIV in six countries. The program has hired 20 online peer educators, or cyber educators, to engage men who have

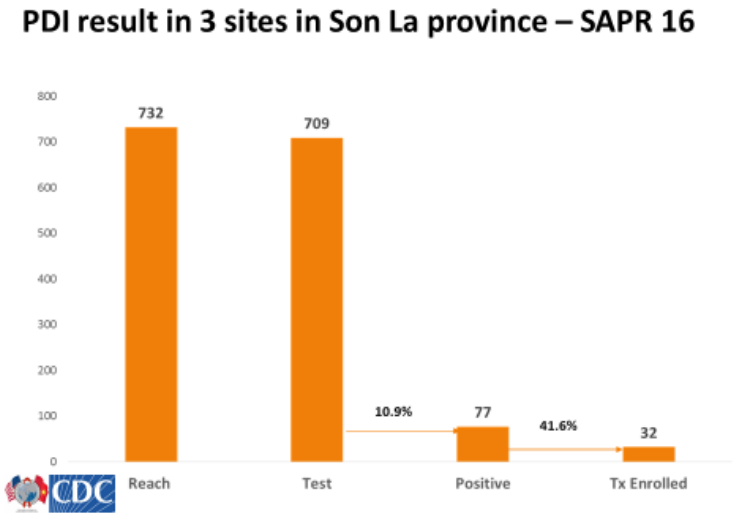
sex with men in chat rooms and other platforms in Guatemala, Belize, Panama, Nicaragua, El Salvador, Costa Rica. The cyber educators assist MSM in obtaining an online Unique Identifier Code voucher that is to be used at participating MSM-friendly testing sites. If the client desires, the cyber educator is encouraged to accompany the client, and their information (name, age, etc.) is never revealed in process unless the client chooses to disclose.

## Appendix J.2.3.3 Peer-Driven Intervention (PDI) to Increase Uptake of HIV Services among Hard-to-Reach Key Populations in Vietnam

In PEPFAR Vietnam's original PDI model, two well-trained outreach workers (OW) are deployed at HTS sites. OW are selected when they are associated with KP networks as peers (e.g., either active or former PWID), have good communication skills, and satisfy certain program management requirements. HTS-based OW, instead of reaching out to individual KP in the community for test referral, are responsible for recruiting "seeds" and guiding seeds on how to identify KPs among their network members and refer them to HTS. OW also link newly diagnosed individuals to out-patient clinics (OPC).

"Seeds" are selected by OW from communities or among clients of HTS, MAT and OPC services according to certain criteria (e.g., active PWID, FSW, MSM, PLHIV or sex partners of KP). Once a seed voluntarily agrees to recruit members of their networks for HIV testing, they receive a brief training on how to approach high-risk members of their associated networks, conveying HIV messages on the benefit of early HIV testing and entry into treatment, and refer these people to HTS with referral coupons and receive incentives per client successfully referred. Clients recruited through PDI present their coupon to the OW located at the HTS site. The OW will assess the client's risk to verify their eligibility as true PDI target clients. The eligible clients then go through the standard HTS procedure and receive a small monetary incentive for testing. Interested clients may also be recruited and trained to become new "seeds" for the next wave if they meet recruitment criteria. Incentive mechanisms are also being applied for seeds per OPC referral and for HIV-positive clients registered at OPC.

**Figure J.2.3.3.1**




## Appendix J.2.3.4 Utilizing Social Network Referrals and Peer Navigation for Key Populations in Central America

Through the Key Population Challenge Fund (KPCF) project, improving the HIV cascade for Key Populations – Utilizing Social Network Referrals and Peer Navigation in Central America, PEPFAR Central America improved their prevention reach (KP_PREV), HIV testing uptake, and testing yield among MSM and TG and FSW by implementing social network referrals and peer navigation. In Honduras, peer promoters were hired to develop and implement a promotional plan to increase awareness and attendance among MSM and TG and FSW to key population-friendly STI services established by MoH in VICITS clinics (comprehensive HIV and STI prevention clinics). Multiple strategies were implemented to raise awareness, including social media outreach, round tables on Gender Identity and Transsexualism, promotion of MoH-run services, KP-friendly HIV testing booths at diverse venues, and the development and distribution of promotional material to increase linkages to VICITS. The use of promoters, peer who were highly active and familiar with KP communities, resulted in significant increases in reaching, testing and finding HIV-positive KP.

**Figure J.2.3.4.1**

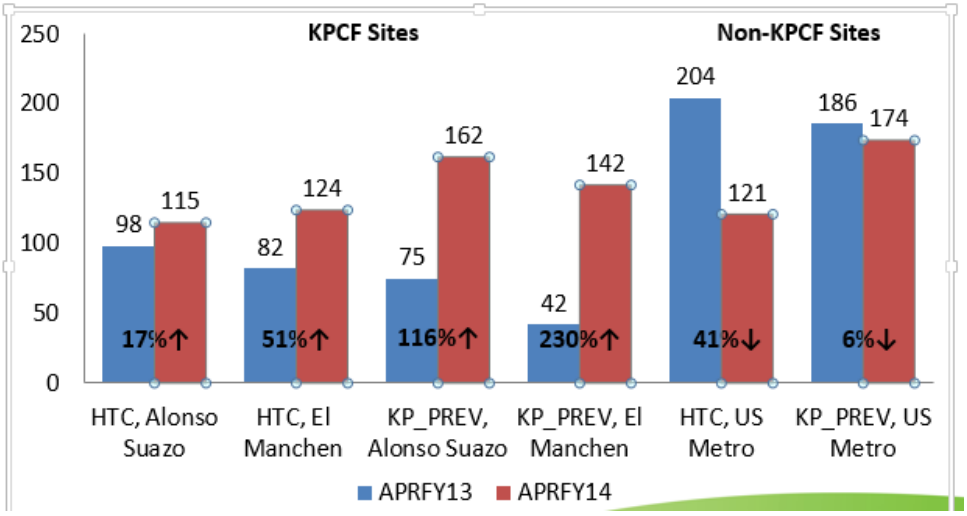



**Figure J.2.3.4.2**

## VICITS FY14 Results

| | Individuals reached through VICITS prevention services | Individuals who received HTC at VICITS clinics | Individuals who tested HIV positive |
|---|---|---|---|
| FSW | 1014 | 891 | 54 (6.1%) |
| MSM | 433 | 310 | 44 (14.2%) |
| Total | 1,447 | 1,201 | 98 |

Similarly, in Guatemala, three health navigators were trained to support recently diagnosed KP to enter care and develop a support network. Attention was placed on identifying patient's needs, facilitating access to medical care which included making patients' first medical appointment and accompanying them to their first and subsequent appointments, developing a follow-up plan towards care and treatment, building a supportive social network and connecting them to support groups, and helping with HIV disclosure. As part of Guatemala's project, 1,121 KP individuals were tested and 62 were found to be HIV-positive; 81% consented to be linked to

care through a health navigator and the average number of days to enroll in HIV clinical care services for this group was 4.

### Appendix J.2.3.5 Expanding HIV Testing Approaches and Linkage to Care among Men who have Sex with Men in Curitiba, Brazil

A multi-disciplinary team launched a community-wide intervention in 2015 to evaluate the acceptability and uptake of multiple HIV testing services (HTS), combined with linkage to HIV care, to determine the strategy that (a) was most acceptable to MSM and service providers; (b) resulted in highest number of new HIV diagnoses and highest proportion of MSM entering HIV care; and (c) had the lowest cost per output. MSM are offered HTS through a web-based HIV self-testing platform; rapid HTS within 2 mobile vans, a community LGBT organization, and a public health facility. Peer navigators ("linkadores") facilitate enrolment in HIV treatment (ART). The team analyzed program data collected between March 2015-16, including socio-demographics, number of MSM/people tested, number of HIV+ MSM, number of MSM referred to HIV care, and number of MSM who self-report linking to ART with support of linkage-to-care navigator.

Over 4,000 tests were delivered via the web-based platform to self-reported MSM, with 14% of MSM reporting test results; all 23 HIV-positive MSM accepted linkage services. Additionally, 4,913 individuals received HTS from the other four intervention outlets, of which, 74% (3,616/4,913) were male, 51% of those (1,861/3,616) self-reported MSM, 26% (493/1,861) testing for the first time. Considering first-time testers diagnosed HIV-positive, over two-thirds were between 18-29 years old. Among the 391 newly diagnosed HIV-positive, 200 were MSM, with 161/200 HIV-positive accepted linkage-to-care navigators.

## Appendix J.2.4 Children & Adolescents

### Appendix J.2.4.1 Optimized HTS Strategy in High-Burden Counties with the National Program's Rapid Results Initiative in Kenya

In order to improve testing coverage and yield, Kenya Ministry of Health (MOH) in collaboration with PEPFAR and its implementing partners carried out a rapid results initiative (RRI) with enhanced focus on pediatric identification and linkage in the period between April to July 2016.

There were enhanced efforts to increase testing coverage in 21 high burden counties that account for 80% of children living with HIV in Kenya. More importantly enhanced case identification strategies were implemented in 5 high burden counties that account for 46% of children living with HIV in Kenya. The main strategies were:

- Universal OPD and IPD HIV testing coverage especially in the 5 high-burden counties
- Universal testing for all children and adolescent of enrolled HIV infected index clients
- Universal HTS for all eligible at the MNCH /FP clinic
- Enhanced HEI identification in MNCH, OPD and IPD settings.

This optimized testing strategy included supporting complete testing coverage in high-yield entry points such as index family member testing; introducing tools to capture data on testing uptake, testing positivity, and linkage to care; and investing in additional testing counsellors.

A total of 5,905 children were identified during the RRI period. Of these, 80% were from 21 high-burden counties and 47% were from 5 high-burden counties. The 5,905 children identified in the 3-month period is higher than 5,600 children identified in the previous 6 months. These results demonstrate that targeted, intensified case identification efforts with geographic prioritization is important in scaling up pediatric ART.

## Appendix J.2.4.2 Promoting Uptake of Child HIV Testing: An Evaluation of the Role of a Home Visiting Program for Orphans and Vulnerable Children in South Africa[81]

HIV testing services (HTS) are critical for children in generalized epidemic settings, but significant shortfalls in coverage persist, notably among orphans and others at disproportionate risk of infection. Findings from a study investigating the impact of a PEPFAR funded home visiting program in South Africa on orphaned and vulnerable children's uptake of HTS found that children receiving home visits from trained community-based care workers were 97% more likely to be tested than children living in similar households that had not yet received home visits (OR = 1.97, 95% CI = 1.34–2.92). The home visitation program had an especially pronounced effect on orphans, more than doubling their odds of being tested (OR = 2.12, 95% CI = 1.00–4.47) compared to orphans living in similar households that did not receive home visits. Orphan

[81] http://www.tandfonline.com/doi/full/10.1080/09540121.2016.1176679

status alone had no effect on HTS independent of program exposure, suggesting that the program was uniquely able to increase testing in this subgroup.

Since 2001, the PEPFAR USAID partner Future Families has provided services to the families of children orphaned and made vulnerable by HIV and AIDS in three contiguous peri-urban townships (Mamelodi, Mamelodi East and Nellmapius) containing both formal and informal settlements northeast of Pretoria/Tshwane. The 2010 HIV rate among pregnant women in the greater Tshwane area was estimated at 26.1%: lower than the national prevalence rate, but among individuals in the lowest socioeconomic quintile, rates are expected to be much higher. Program services are targeted to households containing children who have lost one or both parents, chronically ill adults, and/or households in extreme poverty. Potential beneficiaries are visited in their homes by a care worker who collects detailed information about the family for eligibility determination. Households containing the most vulnerable children are prioritized for enrollment. Under the supervision of a qualified social worker, care workers who have completed secondary education and are recruited from the community receive ongoing training from Future Families and make regular home visits to beneficiary households. A customized action plan is developed to meet the needs of each family, including material support, counseling, and referral for a variety of health and social services. Training for care workers includes an emphasis on HIV prevention and workers are encouraged to promote HIV testing and connect families to HTS providers.

Results highlight the potential for increasing HTS access among children at high risk through targeted community-based initiatives.

## Appendix J.2.4.3 Optimizing Case Finding, Targeting Testing, Identifying High Yield Sites, and Index Case Tracking among Children Orphaned and Made Vulnerable by HIV and AIDS in Zimbabwe

The Expanded Integrated Management of Pediatric HIV and AIDS Care and Treatment Program (EIP), a model implemented by World Education Inc. Zimbabwe's Vana Bantwana Project, in close collaboration with the MoHCC, more than doubled their targets for testing OVC between October 2014 and September 2015. Through the collaborative efforts of the EIP and the MoHCC, a total of 113,104 children aged 0-19 years old were tested for HIV. Of these, 4,561

tested positive (a yield of just over 4% overall – however, in Harare and Chitungwiza, the yield exceeded 10%) and of those, 3,797 (83%) were successfully initiated on ART.

The EIP was designed to facilitate children's access to HIV counseling, testing, enrollment into care and treatment, adherence and retention services, by layering additional HIV and health services on top of a social service platform serving children orphaned and made vulnerable by HIV (OVC) and layering social services on top of an HIV and health platform. WEI receives support from ELMA Philanthropies to implement health systems strengthening interventions in support of Pediatric HIV Care and Treatment objectives.

The approach has identified a number of promising practices. (1) The EIP addressed siloed service provision challenges by creating a staff team that reflected the complementary skills sets of the two sectors, (2) The deliberate recruitment of "health" volunteers (Village Health Workers, Home-based Care providers, mentor mothers and male mobilizers) into the OVC volunteer workforce leveraged their years of HIV training, experience and relationships, expanding the scope of overall labor force and allowing for cross-fertilization of skills and practice, (3) Bringing HIV literacy to the social welfare (OVC) volunteer cadre ensured the swift identification and response to the combined vulnerabilities of child protection violations and HIV, (4) The EIP used three mutually-reinforcing strategies, Early Childhood Stimulation playgroups, Parenting Training and Integrated Savings and Lending groups, to encourage consistent engagement of mothers in PMTCT, (5) Working closely with the MoHCC, EIP developed and introduced two new Results Based Financing indicators, and these indicators along with community verifications and community incentives worked synergistically to ensure that health facilities understood the role and contributions of the social sector and incentivize child testing and treatment initiation, (6) To increase collaboration between facility- and community-based team members, IEP initiated case management meetings held at the health facility (rather than in the community), enabling the nurses to more easily attend, (7) HIV-positive case workers, or those who are caregivers of HIV-positive children, are able to use their own experiences to assist parents and caregivers to overcome fear and denial. The volunteer's carefully timed disclosure of HIV status and personal experiences provide a unique and sometimes critical brand of influence, (8) The EIP extended the reach of HTS services for children by partnering with the education sector to use school health assessments and adolescent health fairs as platforms to provide HIV testing services to children.

## Appendix J.2.4.4 New Testing Strategies for Specific Populations (Pediatric and Adolescents)

The coverage of antiretroviral therapy (ART) is disproportionately lower in children (30%) than in adults (43%) in sub-Saharan Africa, despite tremendous improvement in access to ART in the last 10 years[82]. The reason for the low coverage of ART is partially due to insufficient identification of those children who are HIV-positive. HIV Testing and counseling (HTC) is the critical entry point into HIV care and treatment services, and the World Health Organization (WHO) recommends provider-initiated HIV testing and counselling (PITC) for all individuals attending any health care facility in high HIV prevalence settings. However, in busy clinical settings, children and adolescents are not routinely being offered HIV testing, missing a critical opportunity to identify HIV-positive children and adolescents and linking them to ART services. In a pilot program in Zimbabwe from January 2013- December 2014, a 4 question tool, [the result of previous work in Zimbabwe] was evaluated to screen for risk of HIV infection in children (6-15 years). These children were attending primary healthcare facilities and the tool was administered by healthcare providers to determine which children should receive HIV testing. A total of 9568 children underwent HIV testing with a HIV prevalence of 1.4% among those scoring zero (answering no to all questions asked) to 63.6% among those children scoring four (yes to all questions asked). The improved overall HIV prevalence was 4.7%. The number of children needed to screen to identify one child living with HIV would drop from 22 to 10 if this screening tool was used at a national level, thereby decreasing the amount of HIV tests kits used and increasing the overall yield[83]. Uganda is now in the process of creating a screening tool for use in their country, with the assistance and guidance from the investigators of the Zimbabwe pilot. Adaption of this type of screening tool could increase targeted testing of children at risk of HIV infection and therefore increase the yield of HIV infections, and reduce the cost of HIV testing especially among an age-group where the burden of undiagnosed HIV infection is high but the overall prevalence is low.

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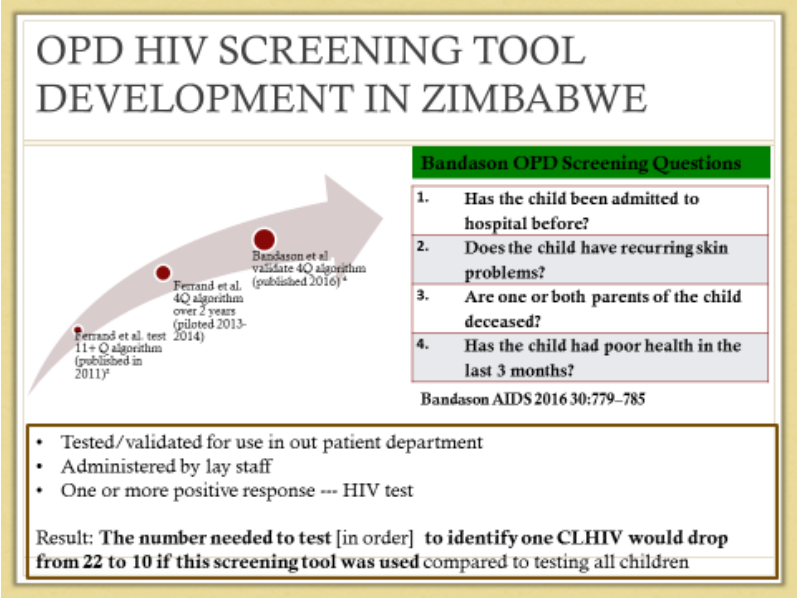
[82] UNAIDS. How AIDS Changed everything- MDG6: 15 years, 15 lessons of hope from the AIDs response. Geneva, Switzerland: UNAIDS; 2015. See www.unaids.org/sites/defualt/files/media_assest/MDG6Report_en.pdf

[83] Bandason T, McHugh G, Dauya E, Mungofa S, Ferrand R. Validation of a screening tool to identify older children living with HIV in primary care facilities in high HIV prevalence settings. AIDS 2016, (30): 779 – 785

**Figure J.2.4.4.1**




## Appendix J.2.4.5 Effect of a Congregation-Based Intervention on Uptake of HIV Testing and Linkage to Care in Pregnant Women (Baby Shower): Results from a Cluster Randomized trial in Nigeria[84][85]

Few effective community-based interventions exist to increase HIV testing and uptake of antiretroviral therapy (ART) in pregnant women in hard-to-reach resource-limited settings. Delivery of an HIV intervention through churches has been associated with increase uptake of HIV testing in pregnant women compared with standard health facility referral.

The Baby shower is a cluster randomized trial where self-identified pregnant women, aged 18 years and older who attended churches in southeast Nigeria were enrolled. The churches (clusters) were randomized to intervention or control groups and stratified by mean annual number of infant baptisms (<80 vs ≥80). The Healthy Beginning Initiative intervention included health education and on-site laboratory testing implemented during baby showers in intervention group churches, whereas participants in control group churches were referred to health facilities

[84] Lancet Glob Health 2015;3: e692–700

[85] AIDS and Behavior 2016; 1-10; DOI 10.1007/s10461-016-1626-0

as standard. Participants and investigators were aware of church allocation. The primary outcome was confirmed HIV testing in pregnancy. An important secondary outcome was the rate of HIV testing of male partners.

Between January 20, 2013, and August 31, 2014, a total of 3,002 participants at 40 churches (20 per group) were enrolled, and 1,309 (79%) of 1,647 women attended antenatal care in the intervention group compared with 1,080 (80%) of 1,355 in the control group. 1,514 women (92%) in the intervention group had an HIV test compared with 740 (55%) in the control group (adjusted odds ratio 11·2, 95% CI 8·77–14·25; p<0·0001).

As part of this study, male partners in the intervention group received the HBI intervention with their partners, including education and onsite HIV testing. 2,498 male partners enrolled, a participation rate of 88.9%, and results showed that male partners in the intervention group were 12 times more likely to have had an HIV test than male partners in the control group (CG = 37.71% vs. IG = 84.00%; adjusted odds ratio = 11.9; p\.01).

This randomized study tested a framework that identified pregnant women early, implemented an intervention with an integrated testing approach (HIV plus other conditions to reduce stigma associated with HIV-only test approaches), and used a systematic follow-up mechanism. The authors noted that a culturally adapted congregation-based approach delivered by trained volunteer health advisers can be used effectively to increase HIV testing in pregnant women.

## Appendix J.2.5 Early Infant Diagnosis (EID)

### Appendix J.2.5.1 Field Performance of Point-of-Care HIV Testing for Early Infant Diagnosis: Pooled Analysis from Six Countries from the EID Consortium

Identification and early initiation of treatment for HIV-infected infants in resource-limited settings (RLS) have been limited by access to appropriate diagnostic tools and logistical challenges in implementing early infant diagnosis (EID) programs. New technologies in the pipeline, including point-of-care (POC) and near-POC assays may enable on-site, same day testing in clinics, which in turn could result in immediate link to care. There is a need to evaluate such new technology before implementation and deployment for use in the field. Data from 9 independent field evaluations of Alere q HIV-1/2 Detect and Cepheid Xpert HIV-1 qual assays were pooled

from on-going studies in Kenya, Malawi, Mozambique, Tanzania, South Africa and Zimbabwe. A range of health professionals from nurses, laboratory technicians to medical doctors operated the devices. Specimens from HIV-exposed infants < 18 months old, were analyzed on Alere q HIV-1/2 Detect (n=1884) or Cepheid Xpert HIV-1 qual (n=2598) and compared to Roche HIV CAPCTM at all sites with the exception of Malawi which compared to Abbott HIV m2000. Alere q achieved a sensitivity of 99.07% (95% CI, 95.48-99.95%) and specificity of 99.94% (95% CI, 99.72-100.00%) with an overall error rate of 6.4%. Cepheid yielded a sensitivity of 96.88% (95% CI, 91.73-99.20%) and specificity of 99.92% (95% CI, 99.74-99.99%) with an overall error rate of 4.3%. The analysis shows good performance of both the Alere q HIV-1/2 Detect and Cepheid Xpert HIV-1 qual assays, suggesting that POC devices have the potential to complement the expansion of EID in the region[86].

**Figure J.2.5.1.1**

**Table 1:** Performance of Alere q HIV-1/2 Detect and Cepheid Xpert HIV-1 qual

**Alere q HIV-1/2 Detect**

| | Reference Assay | | |
|---|---|---|---|
| **Alere q** | Positive | Negative | Sum (n=) |
| Positive | 106 | 1 | 107 |
| Negative | 1 | 1776 | 1777 |
| Sum (n=) | 107 | 1777 | 1884 |

| | Point Estimate | Lower CI | Upper CI |
|---|---|---|---|
| **Sensitivity** | 99,07% | 95,48% | 99,95% |
| **Specificity** | 99,94% | 99,72% | 100,00% |

| Device Errors | total # | Rate |
|---|---|---|
| | 128 | 6,36% |

**Cepheid Xper HIV-1 qual**

| | Reference Assay | | |
|---|---|---|---|
| **Xpert** | Positive | Negative | Sum (n=) |
| Positive | 93 | 2 | 95 |
| Negative | 3 | 2500 | 2503 |
| Sum (n=) | 96 | 2502 | 2598 |

| | Point Estimate | Lower CI | Upper CI |
|---|---|---|---|
| **Sensitivity** | 96,88% | 91,73% | 99,20% |
| **Specificity** | 99,92% | 99,74% | 99,99% |

| Device Errors | total # | Rate |
|---|---|---|
| | 118 | 4,28% |

[86] Sergio Carmona, et al. AIDS2016

## Appendix J.2.5.2 Using a Web-Based HIV Infant Tracking System to Improve Early Infant Diagnosis[87]

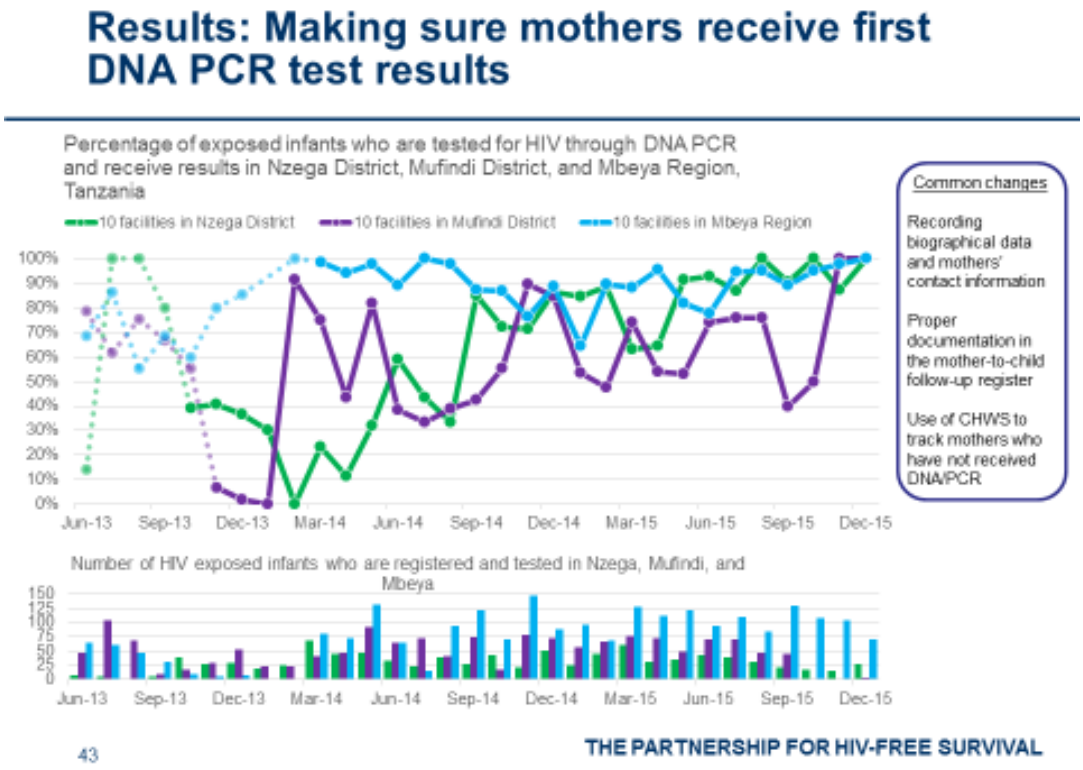
Significant challenges remain in Early Infant Diagnosis (EID) testing, including delayed or lost results and passive delivery of test results to caregivers. In order to address these challenges, sites in Kenya implemented the HITSystem, a web-based system that provides prospective tracking of HIV-exposed infants using automated alerts, connect clinicians submitting EID samples with lab technicians, and provides text message notifications to mothers when infant test results are ready. The HITSystem was initially piloted at 2 hospitals and then introduced in ten health facilities in Kenya. The average turn-around time (TAT) for infant DNA PCR at facilities using the HITSystem was 3.3 weeks, compared to an estimated average TAT of 7 weeks at health facilities in Kenya. At facilities using the HITSystem, 90.7% of eligible infants (118/130) were initiated on ART, and 86.7% of eligible infants were re-tested for HIV at 9 months. HITSystem implementation encountered minimal short-term technology challenges and low direct implementation costs. A key factor in success was stakeholder motivation, buy in and ownership of the system. System-level innovations that improve coordination and communication among EID stakeholders have potential to improve the EID process.

## Appendix J.2.5.3 Maximizing Early Infant Diagnosis (EID) of HIV-Exposed Infants through Quality Improvement

Quality improvement teams within 30 Partnership for HIV-Free Survival (PHFS) demonstrations sites in three districts in Tanzania increased 6-week DNA PCR (see figure J.2.5.3.1 below) through onsite mentorship of health care workers to consistently record mothers' biographical data, contact information and health data within registers, and the use of community health workers to track and follow-up with mothers who have not had brought their infant in for a DNA-PCR test.

[87] Finocchario-Kessler S, et al. Lessons learned from implementing the HIV infant tracking system (HITSystem): A web-based intervention to improve early infant diagnosis in Kenya. Healthcare 2015, 3: 190-195.

**Figure J.2.5.3.1**




## Appendix J.2.6 Tuberculosis/HTS Linkage

### Appendix J.2.6.1 HIV Testing of Presumptive TB Patients in India[88]

HIV testing yields are low and identifying and testing potentially high-yield populations are high priorities for PEPFAR. In this small study conducted between January-March 2012 in Karnataka State, South India (population 64 million, which accounts for 10% of India's HIV burden), the utility of testing presumptive TB patients for HIV within routine health care settings was examined. All presumptive TB patients attending public sector sputum microscopy centers state-wide were offered HIV testing by the laboratory technician, and referred to the nearest

[88] Kumar AM, Gupta D, Kumar A, Gupta RS, Kanchar A, Rao R, et al. (2016) HIV Testing among Patients with Presumptive Tuberculosis: How Do We Implement in a Routine Programmatic Setting? Results of a Large Operational Research from India. PLoS ONE 11(5): e0156487. doi:10.1371/journal.pone.0156487

public sector HIV counselling and testing services, usually within the same facility. Overall, 115,308 patients with presumptive TB were examined for sputum smear microscopy at 645 microscopy centers. Of these, HIV status was ascertained for 62,847 (55%), among whom 7,559 (12%) were HIV-positive, and of these, 3,034 (40%) were newly diagnosed. Reasons for non-testing were reported for 37,700 (72%) of the 52,461 patients without HIV testing; non-availability of testing services at site of sputum collection was cited by health staff in 54% of respondents. Only 4% of patients opted out of HIV testing.

### Appendix J.2.6.2 HIV Testing of Presumptive TB Patients in Malawi[89]

HIV testing yields are low and identifying and testing potentially high-yield populations are high priorities for PEPFAR. A small operational study was conducted between February and September 2013 in Malawi to determine 6-month outcomes (including HIV status) of adult outpatients who were registered in chronic cough registers in Zomba Central Hospital and Matawale peri-urban Health Center. Of 348 persons with chronic cough (i.e., those with presumptive TB), 154 (44%) were known HIV-positive, 34 (10%) HIV-negative (26 unconfirmed) and 160 (46%) had unknown HIV status; 104 (65%) patients with unknown/unconfirmed HIV status underwent HIV testing. At 6 months 191 (55%) were HIV-positive, 87 (25%) HIV-negative (26 unconfirmed) and 70 (20%) still had unknown HIV status; 37 out of 90 (41%) patients with unknown HIV status were found to be HIV-infected. One quarter was not HIV tested and mortality in this group was substantial (10%).

### Appendix J.2.6.3 Xpert MTB/RIF Network Optimization for Improved TB Detection among PLHIV in Kenya[90]

Undiagnosed and inappropriately-treated TB negatively impacts viral suppression and significantly contributes to TB-related morbidity and mortality among persons living with HIV (PLHIV). Xpert MTB/RIF is the most rapid and sensitive test for detection of TB and rifampicin resistance among PLHIV, but implementation of the assay has been plagued by low rates of

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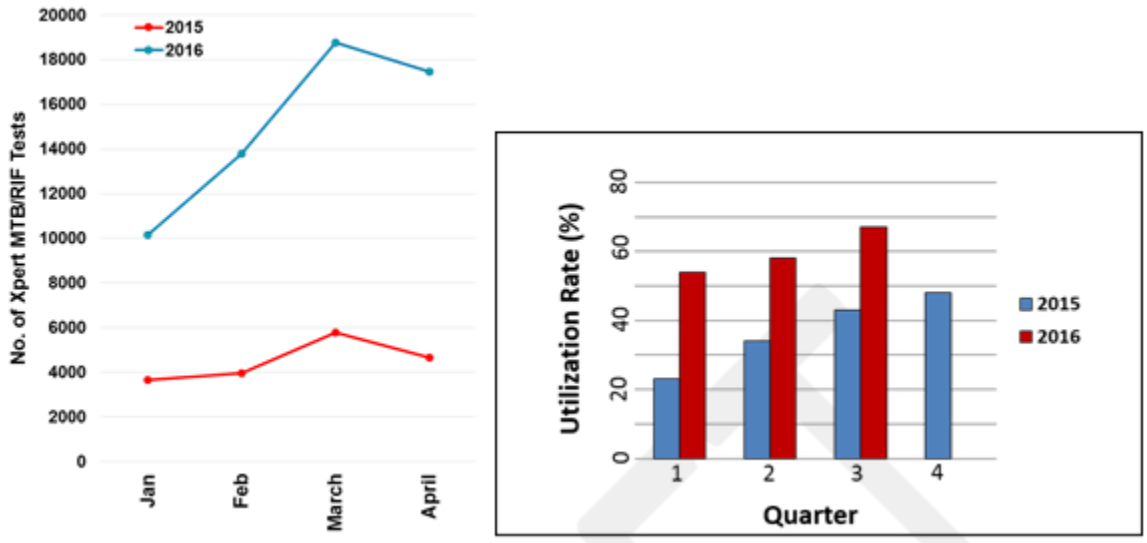
[89] Van Lettow M, Bedell R, Maosa S, Phiri K, Chan AK, Mwinjiwa E, et al. (2015) Outcomes and Diagnostic Processes in Outpatients with Presumptive Tuberculosis in Zomba District, Malawi. PLoS ONE 10(11): e0141414

[90] M. Mburu, PEPFAR Annual Meeting 2016; Kenya NTLP

testing among PLHIV and suboptimal instrument utilization rates. To optimize the Xpert MTB/RIF network for improved TB detection among PLHIV in Kenya, a multipronged intervention was implemented that utilized geospatial mapping, National TWG and PEPFAR partners' forum engagement, clinician trainings, and specimen referral network strengthening to improve TB and HIV patient access to testing services. Overall Xpert MTB/RIF testing volumes increased from >13,000 in Q1 2015 to >42,000 in Q1 2016. GeneXpert instrument utilization rates increased from an average of 33% in Q1-Q3 2015 to 60% in Q1-Q3 2016. Comprehensive approaches to strengthen existing TB diagnostic networks can lead to improved TB and HIV patient access to rapid Xpert MTB/RIF testing services for timely bacteriological confirmation of TB disease and initiation of appropriate therapies.

**Figure J.2.6.3.1**



# Appendix J.3 Retention and Viral Load Suppression

## Appendix J.3.1 Adherence & Retention

### Appendix J.3.1.1 Expansion of the Adherence Club Model for Stable Antiretroviral Therapy Patients[91]

Wilkinson et al report the feasibility of scale up of adherence clubs as a differentiated model of care in Cape Metro Health District. Between 2011 and 2015 the Western Cape and City Health Department expanded the adherence club (AC) program from 11,000 patients to 32 425 patients in 1308 adherence clubs in 55 facilities. During this period of scale up, the AC program expanded from providing ART from 7.3% of the ART cohort at the end of 2011 to 25.2% by March 2015. The number of facilities offering AC also increased from 16 to 55 during the same period. The overall ART program also grew from 53 facilities providing ART to 66 626 patients to 70 facilities providing ART to 128,697 patients. This study shows that expansion of the AC program is feasible. However patient's outcomes in the expanded program are yet to be reported.

### Appendix J.3.1.2 Reducing Loss to Follow Up and Attrition through Decentralization of ART Services: The Swaziland Hub-and-Spoke Model[92]

Rapid ART scale up can be facilitated in resource-limited settings by decentralizing ART services from hospitals to peripheral health clinics (PHCs). Retaining PLHIV on ART within these models is critical to achieve epidemic control. In 2007, Swaziland initiated a hub-and-spoke model for "hub" facilities with large patient loads. Of 31 hubs, 7 initiated this model from 2007-2010, linking with 59 PHCs that served as spokes. PHCs could only act as a spoke if they met select human resource infrastructure, data capture, and operational criteria. Patients could only be down-referred from a hub to a spoke if they had completed 3 months of ART,

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[91] Wilkinson L,et al. Expansion of the Adherence Club model for stable antiretroviral therapy patients in the Cape Metro, South Africa 2011-2015. Trop Med Int Health. 2016 Jun;21(6):743-9]

[92] Auld AF, Kamiru H, Azih C, et al. Evaluation of Swaziland Hub-and-Spoke Model for Decentralizing Access to Antiretroviral Therapy Services. J Acquir Immune Defic Syndr. 2015; 69(1): e1-12.

demonstrated good adherence, appeared clinically stable with an increase in CD4 count, and agreed to down-referral. In this nationally representative retrospective cohort study of 2,510 adult ART enrollees from 2004-2010, both down-referral from hubs and spoke-initiation of ART (as opposed to hub-initiation and hub-maintenance) were strongly protective against loss to follow up and attrition over 5,198 person-years of follow-up. Similar partial or full decentralization models could facilitate ART program expansion elsewhere.

**Figure J.3.1.2.1**

| | Death | LTFU | Attrition |
|---|---|---|---|
| Down-referral | | | |
| No | 1.00 | 1.00 | 1.00 |
| Yes | 1.84 (0.47-7.13) | 0.38 (0.29-0.50) | 0.50 (0.34-0.76) |
| Site of ART Initiation | | | |
| Hub-only | 1.00 | 1.00 | 1.00 |
| Hub with spokes | 0.70 (0.37-1.30) | 0.93 (0.59-1.45) | 0.90 (0.62-1.29) |
| Spoke | 0.50 (0.17-1.45) | 0.54 (0.35-0.84) | 0.54 (0.40-0.73) |

Adjusted for: Age, sex, marital status, calendar year, WHO stage, functional status, weight, CD4 count, hemoglobin, co-trimoxazole prescription, presence or absence of a treatment supporter at ART initiation.

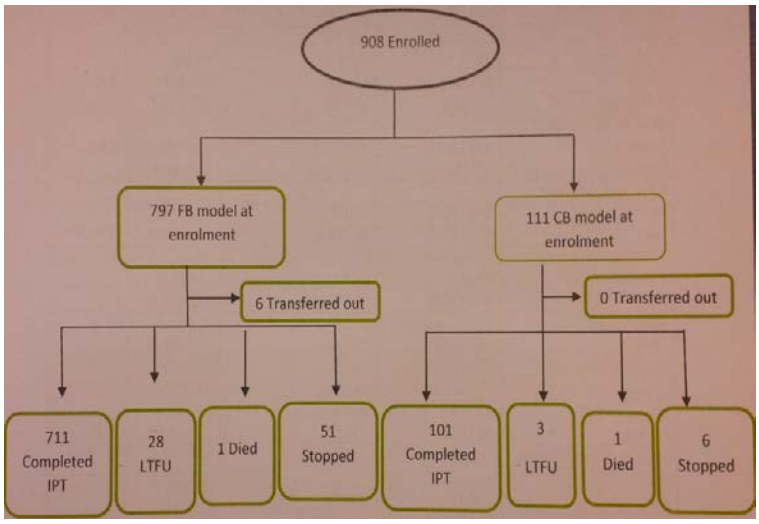
## Appendix J.3.1.3 Improving Isoniazid Preventive Therapy Delivery Models among People Living with HIV (PLHIV) in Swaziland[93]

World Health Organization and Swaziland national guidelines recommend provision of isoniazid preventive therapy (IPT) to all PLHIV without active TB. However uptake among eligible PLHIV in Swaziland (and globally) is low. The Swaziland Ministry of Health and partners conducted a prospective cohort study in 2015 to improve IPT uptake and assess feasibility of and patient preferences for different models of IPT delivery. Patients were offered one of 3 IPT delivery models: Routine facility-based (FB), community-based (CB) and peer/family-support (PS), and

[93] Pasipamire M, Mahlalela N, Adams LV, et al. Research and Evaluation report: Interventions to Improve Isoniazid Preventive Therapy Delivery Models and People Living with HIV in Swaziland. September 2016. Online publication pending.

were allowed to switch between models during the study period. IPT refills were aligned with ART refills for all models. Of 908 eligible participants, 797 chose initially to enroll in the FB model, 111 in the CB model, and none in the PS model. Adherence over 5,590 person-months of monthly patient follow up was 80-100% in 98% of people in the FB model, and 94% of people in the CB model. 93% of participants maintained their first IPT delivery model choice, and most switches were from the CB to FB models. 812 (89%) participants completed their course of IPT, 57 (6%) discontinued, 37 (4) were lost-to-follow-up, and 2 (0.2%) died. This study demonstrates that high levels of IPT adherence and treatment completion are achievable through providing choices of IPT delivery models to patients and integrating IPT with ART provision.

**Figure *J.3.1.3.1***




## Appendix J.3.1.4 EQUIP Best Practice: Bringing Pre-ART Clients for early ART initiation under Test and Start in Malawi

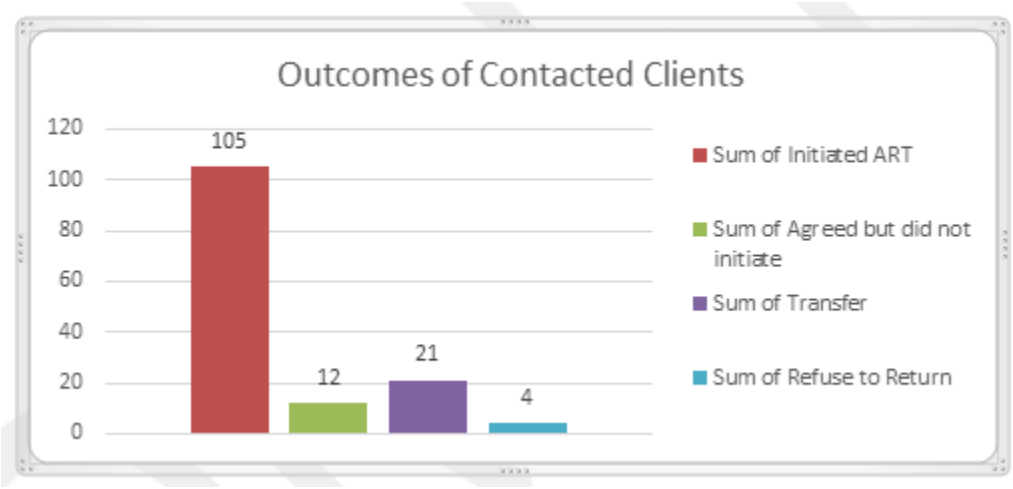
EQUIP implemented an active Pre-ART client contact and tracing program within 20 supported Ministry of Health (MOH) facilities utilizing existing clinic and community outreach staff. The intervention was implemented utilizing a training package developed by the EQUIP team; orientation of clinic staff by mentor team members, and through Swift Action Team (SWAT) punctual supervision to ensure activity progression. The objective of the intervention was to promote the cohort of known HIV+ clients to come to clinic and initiate ART as quickly as possible.

Utilizing the existing defaulter tracing mechanisms within facilities, a modified protocol was developed to identify and trace Pre-ART clients. Facilities were briefly oriented on the tracing protocol, provided a standardized 'script' as to what to say to Pre-ART clients successfully contacted, and supplied a client tracing register. Staff provided supportive supervision to ensure quality tracing was performed by 1-2 visits +/- phone call follow up and final data collection visit at the end of September. The intervention lasted for five weeks.

Of the 230 Pre-ART clients in which tracing was attempted, 88 (38.3%) were untraceable. Clients were defined as untraceable if they were unreachable by phone, unable to be located through home visits (minimum two attempts), or confirmed deceased.

Of the 142 clients successfully contacted, 117 verbally agreed to return to the facility and 105 actually returned and initiated ART (73.9%). 21 clients (14%) of those contacted stated they had transferred their care to a different facility so ART initiation is unknown. Only 4 clients (2.8%) refused to return to the clinic. Overall, active tracing resulted in the ART initiation of 105 clients across 20 clinics, while only 29 self-return clients would have initiated ART without this active intervention.

**Figure J.3.1.4.1**



## Appendix J.3.2 Viral Load & Lab Considerations

### Appendix J.3.2.1 Reducing Lab Costs With Reagant Rental[94,95,96,97]

South Africa, Kenya, Uganda, and Cote d'Ivoire all are taking advantage of reagent rental and/or a combination of reagent/service schemes. South Africa, Kenya and Uganda have all received replacement instruments at no cost at high burden testing sites. Cote d'Ivoire amortized their initial capital investment for VL instrument scale-up and service and maintenance within their reagent pricing scheme, offsetting initial scale-up costs and expanding instrument coverage, as well as ensuring complete service contract availability.

Calculated instrument viral load test capacity exceeds demand in many countries leading to low utilization. Reagent procurement, through USAID mechanisms, is approaching 35 million USD as of October 2016. Historically, instruments to perform viral load testing have been purchased with additional funding required to cover service contract mechanisms beyond initial warranty periods. This approach has a high initial capital cost, with many instruments lacking service contracts beyond the life of the initial warranty. In an effort to improve service delivery and cost efficiencies, the PEPFAR Laboratory TWG is recommending that countries consider reagent rental agreements for new instruments. The benefits of this strategy will enable countries to better align capacity with demand, transfer responsibility of maintaining the instrument to the manufacturer, and provide a mechanism for product upgrades at minimal cost. Initial per test costs will likely be higher than with procurement, but long term the strategy will be beneficial.

The PEPFAR Laboratory TWG also encourages countries to:

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[94] Edgil, D., Williams, J., Smith, P., Kuritsky, J. Optimising the laboratory supply chain: The key to effective laboratory services, African Journal for Laboratory Medicine, Vol 3, No 1, 2014.

[95] Habiyambere V., Ford, N., Low-Beer, D., Nkengasong, J., Sands, A., Pérez González, M., Fernandes, P., Milgotina, E., Availability and Use of HIV Monitoring and Early Infant Diagnosis Technologies in WHO Member States in 2011–2013: Analysis of Annual Surveys at the Facility| DOI:10.1371/journal.pmed.1002088, August 23, 2016

[96] Kilmarx, Peter H., Simbi, R., Progress and Challenges in Scaling Up Laboratory Monitoring of HIV Treatment | DOI:10.1371/journal.pmed.1002089, August 23, 2016

[97] Global Fund: Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool http://www.theglobalfund.org/documents/psm/PSM_ViralLoadEarlyInfantDiagnosis_Content_en/

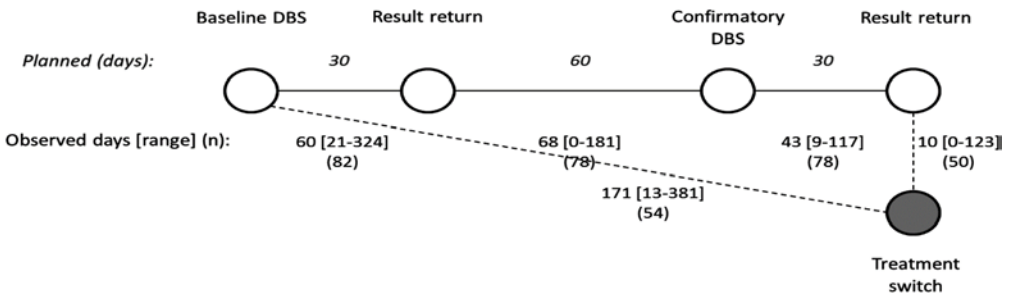
- Ensure competition at the country level. Countries should seek to introduce 2-3 VL instrument providers to promote a competitive market – driven by costs and service provision.
- Promote procurement coordination between Global Fund and PEPFAR. This would include network expansion (instrument deployments) and reagent procurements.
- Ensure that any future POC or near-POC implementation strategy complements the existing conventional VL network development strategy in an effort to protect initial investments and existing reagent pricing schemes.

## Appendix J.3.2.2 Dried Blood Spots for Viral Load Monitoring: Feasible and Effective[98]

Despite the benefits of VL monitoring, traditional VL tests used in developed countries are prohibitively expensive and complex for routine use in resource-limited settings because they require laboratory infrastructure for plasma processing, continuous cold-chain, and phlebotomy-trained providers. The use of dried blood spot (DBS) for specimen collection and subsequent transport to centralized testing laboratories is an appealing alternative to plasma-based VL testing. A study in Malawi evaluated the feasibility and effectiveness of dried blood spots (DBS) use for viral load (VL) monitoring, and described patient outcomes and programmatic challenges that are relevant for DBS implementation. Among 1,498 participants enrolled; 5.9% were failing at baseline. Median time from enrollment to receipt of results was 42 days; 79.6% of participants received results within 3 months. Among participants with confirmed elevated VL, 92.6% initiated second-line therapy; 90.7% were switched within 365 days of VL testing. Median period between enrollment and specimen testing was 23 days. DBS for VL monitoring is feasible and effective in real-world clinical settings. Centralized DBS testing may increase access to VL monitoring in remote settings. Programmatic outcomes are encouraging, especially proportion of eligible participants switched to second line therapy.

[98] PLOS ONE | DOI:10.1371/journal.pone.0124748 April 21, 2015

**Figure J.3.2.2.1**




## Appendix J.3.2.3 Application of Recent HIV infection Assays for Enhanced HIV Case-Based Surveillance and Targeted Prevention in PEPFAR-Supported Settings

As we enter the elimination phase of HIV, continuous assessment of the direction of the HIV epidemic through ongoing HIV case-based surveillance remains essential to ensure that interventions are efficiently and effectively targeted to those at highest risk of acquiring or transmitting HIV infection. The point of HIV infection is a sentinel event in the course of HIV disease that is difficult to capture in case surveillance systems without tools that can determine when infection occurred in the past. A recency assay that tests for antibody-based biomarkers of early HIV infection to distinguish established from recently acquired HIV infection can provide information on trends in recent infection to monitor acute changes to the epidemic to inform and re-direct prevention strategies. Moreover, interweaving effective strategies at the individual-level to locate the hard-to-reach HIV cases with recent infection and rapidly intervening to interrupt the chain of transmission will be the last step towards reaching the last case of HIV. Services that target the sexual and drug-using partners of persons with recent infection to get tested and linked to prevention and treatment services play a critical role in reaching these last cases.

Assisted partner services (APS) for newly diagnosed HIV cases has been proven to be feasible and effective in identifying undiagnosed HIV infection and linking HIV-positive partners to care[99].

[99] Aghaizu A, Murphy G, Tosswill J, et al. Recent infection testing algorithm (RITA) applied to new HIV diagnoses in England, Wales and Northern Ireland, 2009 to 2011. Euro Surveill. 2014;19(2):pll=20673

In Kenya, partners that were contacted through APS were 15 times more likely to have been tested for HIV for the first time, 5 times more likely to be HIV-positive, and 4 times more likely to be linked into HIV care compared to partners contacted through routine passive partner notification[100]. Because APS is costly and labor intensive, in lieu of limited resources, these services may have greatest public health impact when focused on HIV index cases with recent infection. Not only is their viral load and risk of transmission higher than cases with established infection, HIV cases with recent infection may have higher numbers of partners that can be named and reached for testing than cases with established infection. Beyond a few settings that have piloted the use of recency assays at the individual-level, the United Kingdom is the only setting that routinely tests newly diagnosed HIV cases for recent infection.

Based on data collected from 2009-2011, prevalence of recent infection was 8% among heterosexuals and 22% among men who have sex with men (MSM)[101]. A much higher prevalence of recent infection was noted in young persons with new HIV diagnoses, including 17% among heterosexuals and 31% among MSM aged 15-24 years. Given the ability of recency assays to rapidly identify sub-populations with high levels of recent infection and who are most likely to transmit the virus, methods that can expedite the return of results from recency testing through rapid point-of-care testing is optimal for successful prevention. The Asante rapid recency assay is a new point-of-care assay that can simultaneously diagnose HIV and distinguish recent from established infection using a single test device[102]. The assay is undergoing in-house evaluation at CDC to determine the accuracy of the test compared to validated tests for recent infection and will be commercially available in early 2017 for field validation and implementation in PEPFAR-supported countries.

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[100] Brown LB, Mimller WC, Kamaga G, et al. HIV partner notification is effective and feasible in sub-Saharan Africa: opportunities for HIV treatment and prevention. JAIDS 2011; 56(5):437-442).

[101] Cherutich P, Golden MR, Wamui B, et al. Effectiveness of partner services for HIV in Kenya: a cluster randomized trial. Presented to the National AIDS and STI Control Programme, Ministry of Health, Nairobi, Kenya, August 2016.

[102] Granade, TC, Workman, S., Kuehl, DS and Parekh, BS. Development of a novel rapid HIV test for simultaneous detection of recent or long-term HIV-1 infection using a single testing device. 2013. AIDS Research and Human Retroviruses, 29:61-67.

## Appendix J.3.2.4 Use of Viral Load Scorecard to Identify Gaps and Measure Improvement for Viral Load Scale-up

Several barriers have been identified within the viral load spectrum (pre-analytical, analytical and post analytical phase) that hinder testing and uptake of results for monitoring patients on ART for viral suppression. Efforts to scale up viral load testing and uptake of results are occurring in multiple countries. Tools are required to measure and monitor progress and improvement with these efforts. One such tool is the HIV viral load scorecard which helps define gaps and allows countries to improve and measure workflow efficiencies within the viral load cascade for viral load scale up over time. The scorecard categorizes laboratories into 5 levels based on overall points earned from 9 areas identified as essential for efficient scale-up of viral load. This scorecard has been successfully piloted in 25 laboratories in 5 PEPFAR-supported countries. Evaluation of laboratories with the scorecard identified gaps (Figure J.3.2.4.1) which helped program implementers to focus on gaps which need improvement. Two specific gaps (monitoring and evaluation and documents and records) required for efficient viral load scale-up were found to be challenging for majority of laboratories with only 5 labs scoring >85%. Several labs performed well in both internal quality audits/quality indicators and continuous improvement areas. A majority of laboratories scoring >85% were laboratories previously accredited or involved in continuous quality improvement and suggests that laboratories performing viral load testing services should be engaged in sustained continuous quality improvement efforts.

**Figure J.3.2.4.1** Preliminary results of viral load scorecard pilot in 25 laboratories in countries

| | Personnel | Physical Facility / Environment | Safety / Waste Management | Procurement / Inventory | Sample Management | Equipment | Process Controls | M&E Documents and Records | Internal Quality Audits / Quality Indicators / Continual Improvement | Lab Score |
|---|---|---|---|---|---|---|---|---|---|---|
| Cameroon | 63% | 70% | 34% | 50% | 50% | 67% | 50% | 65% | 21% | 54.6% |
| | 71% | 87% | 100% | 61% | 91% | 75% | 66% | 39% | 46% | 72.8% |
| | 79% | 97% | 98% | 89% | 100% | 92% | 86% | 85% | 83% | 89.2% |
| Cam mean | 71% | 84% | 83% | 67% | 80% | 78% | 67% | 70% | 50% | 72.2% |
| Ethiopia | 67% | 73% | 83% | 67% | 47% | 67% | 60% | 50% | 29% | 58.8% |
| Myanmar | 50% | 37% | 54% | 44% | 31% | 42% | 38% | 48% | 4% | 43.0% |
| South Africa | 100% | 100% | 100% | 100% | 97% | 100% | 100% | 78% | 100% | 95.8% |
| | 92% | 97% | 100% | 89% | 100% | 100% | 100% | 78% | 92% | 93.5% |
| | 92% | 100% | 100% | 89% | 94% | 100% | 92% | 76% | 96% | 91.5% |
| | 92% | 100% | 100% | 94% | 81% | 100% | 100% | 89% | 88% | 93.5% |
| | 96% | 97% | 100% | 94% | 97% | 100% | 100% | 74% | 100% | 93.8% |
| | 96% | 100% | 92% | 78% | 100% | 92% | 92% | 74% | 79% | 88.8% |
| | 88% | 93% | 83% | 89% | 84% | 100% | 92% | 72% | 83% | 85.8% |
| | 92% | 87% | 100% | 100% | 84% | 100% | 92% | 65% | 75% | 85.8% |
| | 100% | 100% | 100% | 94% | 94% | 100% | 100% | 78% | 96% | 94.6% |
| | 100% | 100% | 100% | 94% | 94% | 100% | 100% | 78% | 96% | 94.6% |
| | 100% | 100% | 100% | 94% | 94% | 100% | 100% | 78% | 96% | 94.6% |
| | 100% | 100% | 100% | 94% | 94% | 100% | 100% | 78% | 96% | 94.6% |
| | 100% | 100% | 100% | 94% | 94% | 100% | 100% | 78% | 96% | 94.6% |
| | 92% | 93% | 100% | 67% | 88% | 100% | 90% | 72% | 83% | 86.2% |
| | 79% | 87% | 100% | 89% | 81% | 100% | 80% | 67% | 54% | 79.6% |
| | 100% | 100% | 100% | 83% | 88% | 100% | 92% | 65% | 75% | 87.3% |
| | 92% | 100% | 100% | 100% | 97% | 100% | 100% | 87% | 100% | 96.5% |
| | 100% | 100% | 100% | 100% | 97% | 100% | 100% | 87% | 100% | 97.3% |
| SA mean | 95% | 97% | 99% | 91% | 92% | 100% | 96% | 76% | 89% | 92% |
| Tanzania | 88% | 87% | 67% | 94% | 94% | 75% | 96% | 50% | 92% | 81.5% |
| | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100.0% |
| TZ mean | 94% | 93% | 83% | 97% | 97% | 88% | 98% | 75% | 96% | 91% |

## Appendix J.3.3 Pregnant and Breastfeeding Women

### Appendix J.3.3.1 Viral Load Monitoring in Pregnant and Breastfeeding Women as a Priority Population

Pregnant and breastfeeding women on ART are critical populations for HIV viral load (VL) monitoring. Controlling VL in pregnant and breastfeeding women 1) improves maternal health, 2) reduces sexual transmission to partners, 3) improves long-term health of children and families, and 4) reduces vertical transmission[103][104][105]. The window of opportunity to intervene during pregnancy and breastfeeding is time-limited, so a rapid return of results and appropriate patient-level action are critical to prevent vertical transmissions of HIV. Maternal VL near the time of delivery is also one of the criteria for identifying "high-risk" infants who may benefit from enhanced antiretroviral prophylaxis to prevent HIV transmission.

Optimal timing and frequency of testing during pregnancy and breastfeeding are context-specific and influenced by effective turn-around-times (TATs), interventions available, and the gestational age of mother at presentation for care. A reasonable approach is to test a woman's VL at the point in time when it should be suppressed (based on her duration and adherence to appropriate ART) and re-test every 3-6 months during breastfeeding, ensuring that patient-level action is taken on any elevated result. To ensure critical information is available in time to initiate the appropriate patient-level action, it is important to improve effective TATs. This requires effective coordination among: 1) Clinics: Developing protocols and training staff in clinical testing, patient counseling, sample collection and storage, and patient re-engagement for action on elevated VL results; 2) Supply chain management: Ensuring that stock-outs do not occur; 3) Transportation: Ensuring reliable, effective, and timely transportation of samples and

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[103] Davis et al. Maternal and Breast Milk Viral Load: Impacts of Adherence on Peri-Partum HIV Infections Averted - the BAN Study. JAIDS, 2016

[104] Townsend, et al. Earlier initiation of ART and further decline in mother-to-child HIV transmission rates, 2000–2011. AIDS, 2014

[105] Tubiana et al. Factors Associated with Mother-to-Child Transmission of HIV-1 Despite a Maternal Viral Load <500 Copies/mL at Delivery: A Case-Control Study Nested in the French Perinatal Cohort (EPF-ANRS CO1). Clinical Infectious Disease, 2010

results; and 4) Laboratory: Ensuring that VL machines are strategically located and optimally-maintained and functioning, training staff on proper use of equipment and specimen acceptance/rejection protocols, and designing personnel schedules (potentially outside normal hours of operation) to maximize operational time for VL machines to process samples.

## Appendix J.3.3.2 Use of mHealth Technologies to Support PMTCT Service Delivery[106]

Mobile health technologies, text messaging, and phone follow ups have all been explored as tools to aid in health service delivery including PMTCT. The Millennium Villages Project (MVP) in western Kenya implemented a mobile health tool called the ANC/PMTCT Adherence System (APAS) that uses text messages to coordinate community health worker (CHW) activities around ANC and PMTCT. In structured interviews, CHWs reported that APAS helped them track pregnant women more efficiently than with paper forms, and women registered in APAS reported that CHWs reminded them of appointments more regularly than before APAS introduction. Women enrolled in the APAS program had an increased likelihood of attending more ANC visits and making the 6 recommended post-delivery baby follow-ups compared to women who were not registered in APAS. Women not registered in APAS had a 9% (3 out of 33) MTCT rate at 18 months compared to 0% (0 out of 20) transmission rate among women enrolled in APAS. This was an observational study with a small sample size for final infant outcome, however results are encouraging that use of mHealth technologies can improve patient tracking and communication and facilitate the desired outcomes of improved PMTCT retention and reduced MTCT of HIV.

## Appendix J.3.3.3 Women's Needs and Preferences in PMTCT Services[107]

Strategies are needed to retain women in PMTCT throughout pregnancy and breastfeeding. In order to better understand the needs and preferences of women attending PMTCT clinics, women in Ethiopia and Mozambique were surveyed using a discrete choice experiment study.

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[106] Mushamiri I, et al. Evaluation of the impact of a mobile health system on adherence to antenatal and postnatal care and prevention of mother-to-child transmission of HIV programs in Kenya. BMC Public Health 2015, 15: 102.

[107] Kruk ME, Riley PL, Palma AM, et al. How Can the Health System Retain Women in HIV Treatment for a Lifetime? A Discrete Choice Experiment in Ethiopia and Mozambique. Roy JK, ed. PLoS ONE. 2016;11(8):e0160764. doi:10.1371/journal.pone.0160764.

Study investigators conducted formative research to develop a list of attributes for Option B+ services that were thought to be both important to the women and realistic to implement. After selecting the final set of attributes, 1,013 women in Ethiopia and 1,077 women in Mozambique women were presented with 9 choice cards, each showing two health facilities. They were asked to select the option that described their preferred health facility to obtain ART care in PMTCT and ART clinics. Data from both countries showed that the two most important aspects of health facilities providing HIV care to HIV-positive women include: respectful care by providers and access to non-HIV health services in the same visit.

## Appendix J.3.4 Children and Adolescents

### Appendix J.3.4.1 Characterizing Viral Load Testing and Suppression in Pregnant and Post-partum Women, Children, and Adolescents through a Service Quality Assessment in Kenya

Since Kenya changed its national guidelines to include routine viral load testing for all persons on ART in 2014, viral load testing has been scaled up with 634,717 viral load tests done in 2015 compared to 51,850 tests in 2013, and 241,644 in 2014. In an effort to characterize viral load testing implementation in antiretroviral treatment facilities, an interagency USG team conducted a 1.5 week service quality assessment (SQA) of viral load implementation at 20 sites and included a specific focus on children and adolescents; populations known to have poorer viral suppression compared to adults.

Viral load SQA results show overall viral suppression of 77% in children and 83% in adolescents. Most (83%) of the SQA viral load (VL) results were routine tests for patients retained in care; this differs from the national VL database results that show VL suppression of 65% and 61% for children and adolescents respectively. The VL database combines routine VL and VL for clients with suspected treatment failure (targeted). Of 259 children and adolescents with an initial viral load done within 9 months of starting antiretroviral therapy, 71% had viral suppression. The SQA data are unpublished.

**Figure J.3.4.1.1**

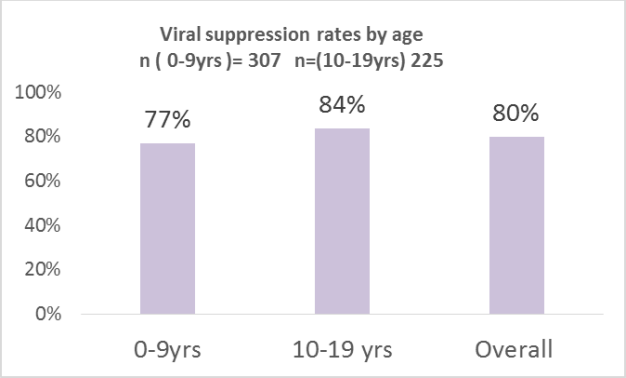
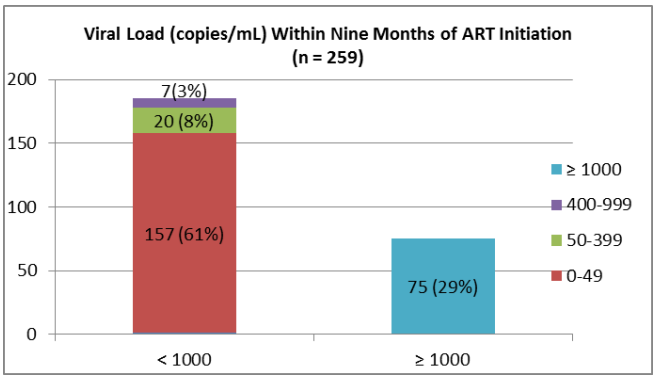



**Figure J.3.4.1.2**




## Appendix J.3.4.2 The Impacts of Economic Strengthening Interventions on Retention and Adherence to HIV Care and Treatment and Practicing Risky Behaviors: Quantitative and Qualitative

The economic strengthening (ES) scheme pursued by WFP comprises different economic strengthening interventions tailored for food insecure PLHIV caring for children orphaned and made vulnerable by HIV (OVC) in different economic categories. In a study comparing PLHIV enrolled in the WFP economic strengthening scheme against a control, nearly 98 percent of the respondents enrolled in the ES scheme reported HIV treatment adherence, defined as taking more than 95 percent of the prescribed pills in the four days before the survey. The corresponding value for the control group was 88 percent and the difference between the two groups was statistically significant (P=0.009). The difference between the ES group and control group in terms of ART adherence is even more discernible when taking into consideration the overall adherence in the past 30 days before the survey as perceived by the respondent. Among the ES participants 96.9 percent reported good adherence, as compared to 84.2 percent among the control group.

The ES interventions offered by WFP were offered in three packages to PLHIV depending on their level of economic vulnerability. For PLHIV categorized as food insecure with severe hunger or destitute, initially it provides food and assets in the form of short term and targeted financial

and/or physical assets (Provision) and increasingly assists to develop resilience. For food insecure PLHIV with moderate hunger the intervention focuses on building their capacities to enable them reduce risks or cope with shocks (protection). It involves assisting these households to smooth their income and consumption and manage cash flows. For better-off but still food insecure PLHIV households without hunger, the intervention is geared towards expanding their household income and assets through linkage to long term livelihoods opportunities to enable them meet the increasing expenses of basic needs, health and education (Promotion). ES participants from all the three categories are organized into Village Saving and Loan Associations (VSLAs) so that they can save from their sources, loan and invest in different business activities. A range of capacity building trainings and intensive technical support are provided for the first three years of engagement in ES activities.

## Appendix J.3.4.3 Promoting Strategies for Linking Community/Facility Providers to Support Children in Uganda[108]

An initiative intended to facilitate collaboration between HIV treatment and OVC partners in Uganda improved the success of both within a short period. The PEPFAR HIV treatment partner, STAR-EC, increased pediatric enrollment and retention (0-14yrs) from 4-5% (n=1,719 in 2012) to 7% (n=2,803 in 2014). The Bantwana Initiative, under the USAID/PEPFAR SUNRISE-OVC project, increased the success of referrals to social service and HIV/health services increased from as low as 50% in some settings to an average of 85%. In addition, more victims of defilement accessed free medical treatment, and healthcare staff and the local Community Development Officer worked together to support a young positives group to apply for and receive a Uganda-supported government grant to support entrepreneurial activity among young people through the Youth Leadership Program (YLP).

Bantwana hired and placed interns to serve as social welfare/health/HIV referral coordinators, often recent university graduates, at the health center to support referrals and linkages to the social welfare system. Other referral coordinator interns were placed at the office of local government Community Development Officers (CDO) to receive, document and or update the case management registers and ensure the referral loop between the health facility and

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108 http://www.crs.org/sites/default/files/tools-research/case-study-integrated-child-protection-and-care-and-treatement-programming.pdf

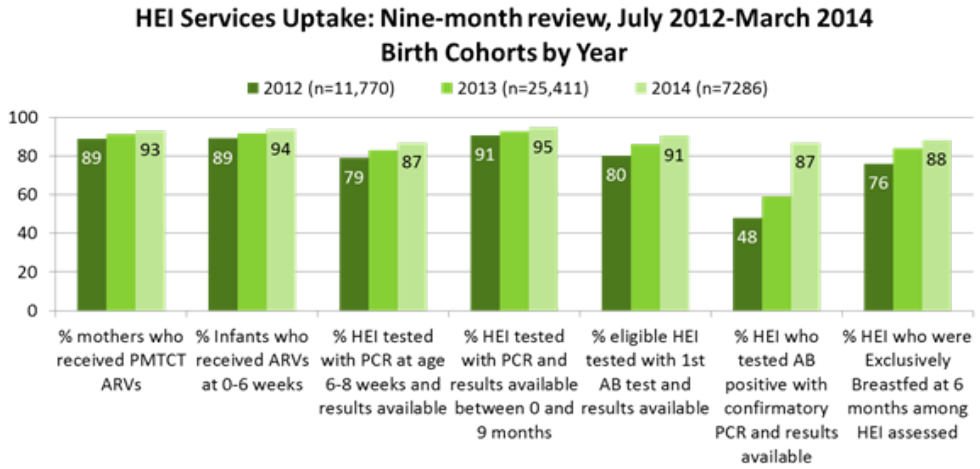
community social service was complete. Bantwana also supported relevant OVC service providers and affiliated community to meet once per month to review specific cases, discuss challenges, and enable the CDO to approve the closure of cases.

## Appendix J.3.4.4 Birth Cohort Monitoring to Evaluate Retention and Care of HIV-Exposed Infants[109]

Cohort monitoring allows measurement of key outcomes that demonstrate program impact. The cohort monitoring approach tracks a population of individuals with a designated shared event over time to measure an outcome of interest at a designated time point. For PMTCT programs, impact is measured by the final HIV status of the HIV-exposed infant after breastfeeding.

Longitudinal registers are required for cohort monitoring. Some countries have developed mother-infant pair registers. While these registers are useful for clinical and for tracking purposes, they are difficult to use for infant cohort monitoring because their organization does not allow easy identification of birth cohorts.

**Appendix J.3.4.4.1**




Kenya developed and employs a dedicated national HIV-exposed infant birth cohort register to monitor 9- and 18-month infant outcomes. Using a cohort monitoring approach and a dedicated HIV-exposed infant birth cohort register has substantially improved infant HIV testing coverage

[109] Program data, CDC-Kenya, Presented to CDC Maternal and Child Health Branch Learning Collaborative 6 September, 2016.

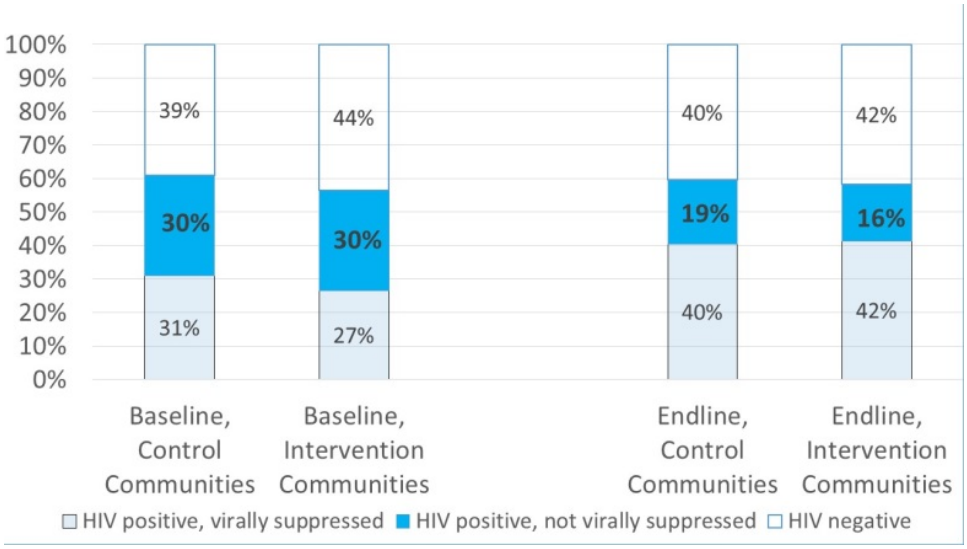
and follow-up and retention of HIV-exposed infants during the entire breastfeeding period. Prior to the register pilot project in 2012–2013, intensive training about the register and cohort monitoring was provided for nurses working in Maternal and Child Health sites, Health Records Information Officers, County and Sub-county AIDS and STI Coordinators, and implementing partner program officers. Between 2013 and 2015, DNA PCR testing uptake for early infant diagnosis improved, with the percentage of infants tested by 6–8 weeks increasing from 79% to 87%; during that same time, confirmatory DNA PCR testing for older infants testing HIV antibody positive improved dramatically (from 48% to 87%). In addition, retention of HIV-exposed infants at 9 and 18 months also improved between 2012 and 2014, from 77% to 85% at 9 months of age and from 68% to 72% at 18 months.

## Appendix J.3.5 Key Populations

### Appendix J.3.5.1 Suppressing Viral Load among Sex Workers (Zimbabwe Sisters with a Voice)

Between 2013 and 2016, the SAPPH-IRe trial was nested within the Sisters program to test the population level impact of strengthening demand, supply and adherence to ART based prevention and treatment among female sex workers. The Sisters program (standard of care) was compared against an enhanced Sisters program which included on site ART for HIV-positives, access to PrEP for HIV-negatives and enhanced community support for adherence (the SAPPH-IRe intervention) in a cluster randomized trial (seven matched pairs). In both arms, there was a dramatic decline in the proportion of female sex workers who had a viral load >1000 copies/ml (30% to 19% in the Sisters only arm and 30% to 16% in the SAPPH-Ire intervention arm) over the course of the trial.

**Figure J.3.5.1.1**




## Appendix J.3.5.2 Building Quality Approaches for MSM and Transgender Women in Thailand: Investments in Innovative Information Systems

CommCare (Dimagi) is a data collection tool using mobile phones to confidentially monitor and improve successful client referrals across community and clinical HIV partners and services via handheld technologies in real time. A version of this tool has been adapted for Thailand whereby community-based supporters and clinical sites are able to register and refer clients to services, send clients mobile-phone-based reminders and notifications, and collaborate with each other to assist in service provision and client retention. This innovative use of mobile technology has been rolled out in Chiang Mai, and is expected to be used in other MSM high prevalence areas, including Pattaya, Bangkok and Hat Yai.

Across PEPFAR KP programs are exploring new ways to use social media, Apps and digital tracking to ensure that they keep pace with how KP are reaching one another and would like to be reached. CommCare is just one method being used in LINKAGES. Others include DHIS2, Magpi, Open MRI and a combination of WhatsApp, Facebook and Excel.

## Appendix J.3.5.3 Most at Risk Populations Initiative: MARPI Clinic - ART Scale Up Models for Key Populations[110]

The Most At risk populations' initiative (MARPI), located at Mulago National Referral Hospital, Sexually Transmitted Infections (STI) unit, started providing services in February 2008. The Unit had previously provided facility based STI services only to high risk populations however, with support from PEPFAR through the Makerere University Joints AIDS Program (MJAP) and the Global Fund, additional services were added and fully integrated into the STI clinic. MARPI is known for its key populations friendly services culture and is often mentioned as the preferred provider by many KPs especially MSMs. These services were further expanded to the community.

The clinic offers the following:

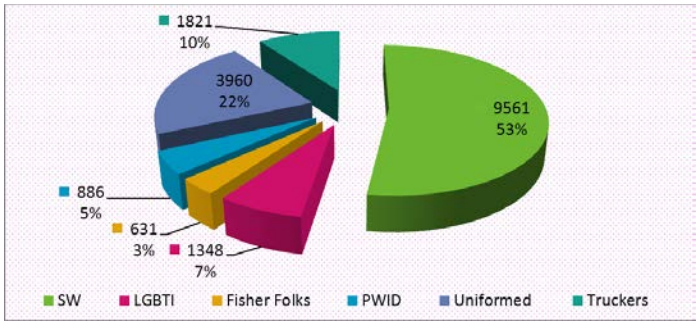
- Safe space and general clinic for KPs
- HIV Testing Services
- ART onsite for those who are HIV-positive
- Sexual and Reproductive Health (SRH) and Family Planning
- Treatment for STDs and skin conditions
- Cervical Cancer screening and Proctology
- Opportunities for trainees
- Family care (Spouses and children)

Clinic staff include peers who conduct outreach to hot spots and provide training and capacity building for other regional centers and facilities including Jinja, Mbarara and Gulu.

By the end of 2015, 800 of the 902 individuals in care were on ART. Of the 246 sex workers (11% male and 89% female) on ART, retention was over 95% in the majority and (82%) and 85.4% were virally suppressed.

[110] MARPI Website http://www.marpi.org/feedback.php Implementing Partner report: http://mjap.or.ug/wp-content/uploads/2016/02/MJAP-Annual-Report-2015.pdf

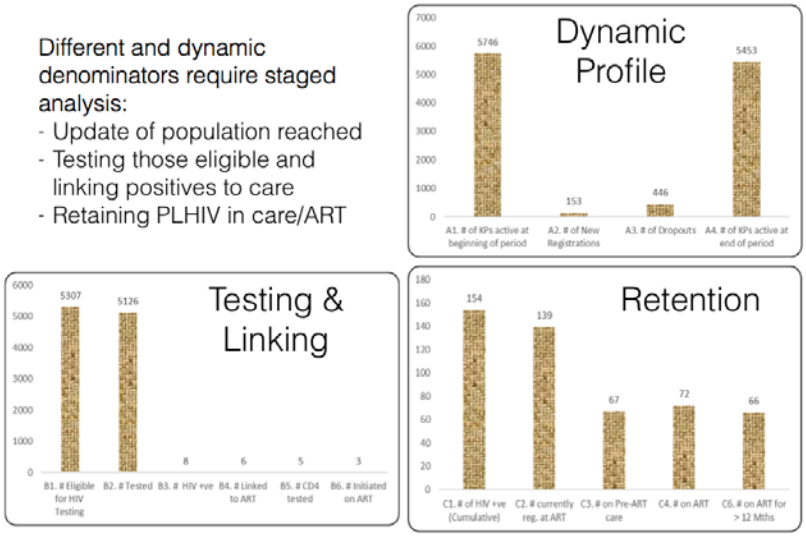
**Figure J.3.5.3.1** Different Key and Priority populations served through the initiative (Presented at the 2nd African Conference on Key Populations in the HIV Epidemic, December 16 - 18, 2015 Dar es Salaam, Tanzania)




## Appendix J.3.5.4 LINKAGES, India - Dashboard for Monitoring Programmatic Data on Cascade Performance

In PEPFAR India dashboard management of KP interventions using improved monitoring of programmatic data and analysis of cascade performance is allowing for site level management for results at government supported KP program sites. High mobility and shifting patterns of sex work and MSM hook ups into online formats create dynamic environments where new hotspots spring up, web based interface is needed and new entrants into sex work in existing hotspots need to be identified. By analyzing cascade data in real-time implementers can spot changes immediately, adjusting for new influx of populations, new online users, dropouts and newly registered. Those who are eligible for HIV testing form a denominator to inform targeted testing numbers, those with positive results are assigned a navigator and linked to government supported care/CD4/ART. High numbers of HIV+ were also found and they were linked again to supported care/CD4/ART. Retention in care/ART is then viewed as a separate dashboard panel with different denominators and data on relevant HIV services. Additional dashboard panels follow key indicators along the prevention arm of the cascade, high incidence in key populations requires regular outreach and regular medical checkups for STI screening and related services.

**Figure J.3.5.4.1** Cascade analysis dashboard, Pune, India – Female sex workers (6 months)




## Appendix J.3.5.5 An Integrated Model for Scaling up ART among Key and Priority Populations in Kenya

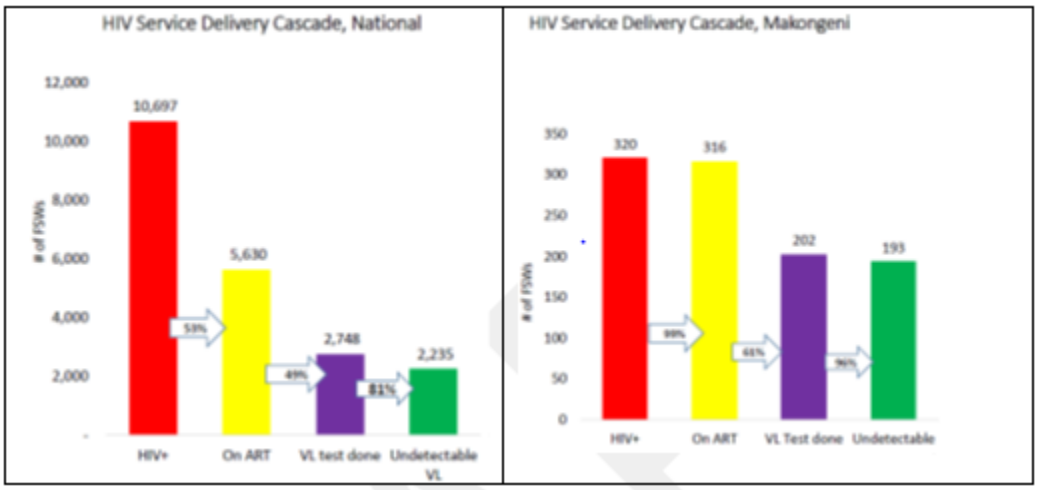
CDC Kenya in collaboration with the ministry of health has implemented several models to reach, test and initiate ART among key and priority models. The different models employed are; (1) a dedicated model and (ii) an integrated model. The dedicated model involve drop in center (DICE), that is conveniently located to allow the KPs easy access to services and an enabling environment to remain engaged in care. The DICE has dedicated staff and peer educators and operate as standalone facilities.

In the integrated models the KP services are provided in facilities that provide routine services to the general population. They can be partially integrated "co-located" or fully integrated.

An example of a fully-integrated model is the one implemented at Makongeni sub-county hospital in Homabay, the highest HIV burden area in Kenya. In this model both general population (GP) and sex workers receive services from the same providers. Success in this model of scaling up ART involved the EGPAF engaging with the local county government to get buy in, consultations with KP and hotspot mapping, sensitization of health care workers on working with KPs. The "Makongeni" integrated model shows superior linkage to ART and high

suppression rates. It has demonstrated that integration of KP and GP services are feasible and scalable and result in improved service coverage and clinical outcomes of for KP.

**Figure J.3.5.5.1**




## Appendix J.3.5.6 Cameroon Joint PEPFAR/Global Fund KP HIV Cascade Assessment

Recent research shows antiretroviral treatment for viral suppression reduces morbidity and mortality, and cuts the probability for transmission to almost zero. Key populations in Cameroon, namely men who have sex with men and female sex workers, carry a disproportionate HIV burden coupled with barriers along the HIV prevention-testing-treatment cascade. The U.S. President's Emergency Plan for AIDS Relief and Global Fund collaborated on a HIV cascade assessment in Cameroon to jointly identify barriers, align approaches, and harmonize efforts for coverage and scale for HIV prevention, treatment, and care services for key populations, inclusive of community engagement.

In April of 2016, these two donors, implementing agencies including U.S. Agency for International Development and the Centers for Disease Control and Prevention, and their local partners assessed the cascade of HIV prevention, care, and treatment among key populations in Cameroon. This assessment was the first such active cross-collaboration among donors and stakeholders in the country. The assessment team identified behavioral, programmatic, structural, technical, and administrative barriers. The partnership from this assessment produced synergistic effects – official agreements between donors on technical approaches,

harmonization of monitoring and reporting and government adoption of recommendations. Implementing partners for both donors immediately operationalized recommendations. The lessons learned in Cameroon demonstrate the power in combined donor efforts while ensuring that recommendations are operationalized post-assessment.

Cameroon is a prime example of how intensive, joint donor and interagency cascade assessments can have the potential to affect catalytic change. This assessment was a milestone for Cameroon's HIV key population response, and will result in an increase in quality, access, and availability for key populations along the HIV cascade. These lessons have the potential to be applied in contexts where there is more than one donor investing in the cascade of HIV services for key populations. In FY16 LINKAGES supported 5 cascade assessments like this one and in FY17 at least 7 more are being planned.

# Appendix J.4 Considerations for Utilizing Health Care Workers in HIV Service Delivery Models

## Appendix J.4.1 Adaptation of the Project ECHO model™ To Strengthen Workforce Capacity in PEPFAR-Supported HIV Programs

The Project ECHO® model is a distance clinical mentoring intervention that can help support PEPFAR's goal of HIV epidemic control, and:

- Provides accessible and cost-efficient clinical mentorship and continuing professional education
- Fosters the development of peer networks and communities of practice that increase provider satisfaction
- Trains healthcare workers while they remain at their posts, reducing costs related to travel and limiting time away from seeing patients
- Offers the opportunity to address operational and program priorities, including laboratory support and supply chain management

The first HIV ECHO in Africa was launched in November 2015, representing a consortium of stakeholders, centrally-funded by CDC, implemented by the Elizabeth Glazer Pediatric AIDS

Foundation, and led by the Namibia MOHSS. This pilot was completed in September 2016. Although 10 regional spokes were selected for weekly didactic content and case-based learning using a broad HIV curriculum, 10 more sites rapidly signed on for weekly sessions. 36 weekly sessions were held with an average of 72 participants per week (the majority of whom are nurses), representing more than 1600 training hours. An evaluation is underway. The PEPFAR Namibia and the Namibia MOHSS are committed to expansion in FY2017. To date, 4 additional African countries and the Central Asia Region are launching HIV ECHO's, 2 countries are initiating rapid HIV testing ECHO's through the support of CDC's International Lab Branch, and more are planning for FY 2107-2018.

Lessons Learned:

- Feasibility and success depends upon adequate IT capability, strong leadership, national ownership, and collaboration.
- The ECHO model and technology can be expanded beyond HIV care and treatment to address other diseases and chronic conditions.
- Use of distance clinical mentoring can be used to disseminate the latest guidelines, so that all clinicians have access to the same information and a large community of practice.
- Distance mentoring in Namibia has made it possible to expand nurse-initiated and -managed ART (NIMART), to routinely review cases of first-line ART failure and make treatment decisions, and to routinely review quality of care and supervision at the site level.

## Appendix J.4.2 Home Visiting Programs for HIV-Affected Families: A Comparison of Service Quality between Community-Based or Lay Cadres in Malawi

Alignment of community-based or lay cadres is needed to harmonize efforts to improve accessibility to HIV services despite bottlenecks caused by facility-based healthcare worker shortages. Malawi's community health worker program is a leading example of a national cadre (i.e., Health Surveillance Assistants) organized and supported by the MOH and supplemented by synchronized donor support to fill supply gaps (e.g., PEPFAR's Health Diagnostic

Assistants).[111] The growing reliance on these lay cadres and political emphasis on building synergies between various programs moved state and non-state stakeholders to create policy guidelines to regulate task shifting and ensure quality of services being provided.[112] Many of Malawi's CHWs live in the community they serve and provide support across health programs, thus positioning themselves as successful links between the community and formal health system.[113] The approach to support integration of community-based and lay cadres with national health systems is variable across countries, but evidence supports the need to formally recognize these workers, clearly define their roles and responsibilities, and coordinate an approach to optimize performance through quality improvement strategies.[114]

## Appendix J.4.3 Volunteer-Driven and Paraprofessional Models[115]

Home visiting is a popular component of programs for HIV-affected children in sub-Saharan Africa, but its implementation varies widely. While some home visitors are lay volunteers, other programs invest in more highly trained paraprofessional staff.

In South Africa, PEPFAR supports both models. Beneficiary children and caregivers at sites served by both partners in KwaZulu-Natal, South Africa were interviewed after 2 years of program enrollment and asked to report about their experiences with home visiting. Exposure varied substantially between program models: 75% of caregivers enrolled in paraprofessional programs reported having ever had a home visit versus only 34% in the volunteer-driven models. Just 58% of caregivers enrolled in paraprofessional staffed programs and 14% of those in volunteer-driven ones continued to receive visits into the second year. Among them, the reported frequency and duration of home visits were both significantly greater among paraprofessional program enrollees, with over 40% reporting that the home visitor came at least weekly and/or stayed over an hour. Assistance related to social grants was more common in the paraprofessional model programs: 18% of caregivers reported receiving assistance obtaining

[111] Mogedal S, Wynd S, Afzal MM. Community health workers and universal health coverage: A framework for partners' harmonized support. Global Health Workforce Alliance. October 2013.
[112] Government of Malawi Ministry of Health "Guidelines for the management of task shifting to health surveillance assistants in Malawi." (2014).
[113] Mogedal S, et al. October 2013.
[114] Mwai, G. W., et al. Role and outcomes of community health workers in HIV care in sub-Saharan Africa: a systematic review; Journal of the International AIDS Society. 2013;16.1

[115] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4205849/

the documents necessary to apply for grants and 28% reported help applying for a grant or pension. In volunteer-driven models this was 7% and 13%, respectively. Children enrolled in the paraprofessional programs were also significantly more likely to report that the home visitor spent time talking with them on some or all visits (84% versus 62%; $p < 0.001$) and covered a larger range of topics (4.2 versus 3.3 topics, $p < 0.001$). Similarly, home visitors in paraprofessional model programs communicated with the caregiver on a greater variety of topics during some or all visits (5.2 versus 4.3 topics, $p = 0.02$). Fifty-three percent of caregivers reported discussing their feelings or emotions with the care worker some or all of the time. Care workers also commonly discussed how to care for oneself or others when someone is sick (reported by 66% of caregivers), how to reduce HIV risk (62%), how to manage money (48%), and how to apply for grants or pensions (42%). Home visitors in paraprofessional model programs were also more likely than those in volunteer-driven programs to talk with caregivers about effective ways to communicate with children (75% compared to 56%; $p = 0.001$).

The PEPFAR supported Isibindi program, initiated in 2005 by the National Association of Child Care Workers (NACCW), has trained over 11,000 paraprofessionals (called Child and Youth Care Workers or CYCWs) over the past decade. CYCWs are full-time employees who undergo a regimen of nationally accredited training during their first 2 to 3 years of employment. They receive a stipend of R1000 (110 USD) per month alongside incentives such as Isibindi t-shirts and hats. NACCW also provides bicycles for work use to CYCWs. Alternatively, community-based organizations affiliated with the PEPFAR supported Heartbeat's Tswelopele initiative or the Children in Distress Network (CINDI), largely operate volunteer-driven programs, with minimal compensation and training for home visitors.

These results suggest that programs that invest in compensation and extensive training for home visitors are better able to serve and retain beneficiaries, and they support a move toward establishing a professional workforce of home visitors to support vulnerable children and families in South Africa.

## Appendix J.4.4 Bridging the Gap: The Impact of Home Visiting Programs for Orphans and Vulnerable Children on Social Grant Uptake in South Africa[116]

Cash transfer programs hold significant potential to mitigate the economic burdens resulting from the HIV epidemic and enhance the wellbeing of affected children. South Africa offers two cash transfers designed specifically to benefit children: the Child Support Grant, for low income families with children, and the Foster Child Grant, for children living outside of parental care.

Results from a quasi-experimental study examining differences in grant uptake over a two-year period show that OVC programs that are staffed with trained paraprofessionals who received training, compensation and other support were significantly more effective at linking families to social grants for children than volunteer-based programs. Notably, children in the paraprofessional programs were more likely to have received the highest grant they were eligible to receive, as compared to children in the volunteer-driven programs. Paraprofessional program enrollees receiving the highest possible grant rose from 44% to 66% between the study's two data collection rounds. The proportion of grant-eligible children receiving a FCG in particular increased from 36% to 54% among this group, as compared to only a 7% improvement among their counterparts in volunteer-driven programs. Access to the CSG rose more modestly for enrollees of both program models. After controlling for important covariates, participants in the paraprofessional model programs were nearly three times as likely to have access to the highest grant they were eligible to receive (AOR 2.92, p-value < 0.001).

Given the high proportion of HIV-affected children who qualify for these grants, increasing grant access among eligible families is a natural objective for many programs targeting orphans and vulnerable children. Grant receipt was also positively associated with household food security and children's obtainment of basic educational and material resources. Effective strategies for promoting social grant access among HIV-affected households therefore have the potential to yield significant improvements in wellbeing for orphans and vulnerable children.

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[116] http://www.sciencedirect.com/science/article/pii/S0190740914004149

## Appendix J.4.5 Integrating Wellness/Stable Patient Delivery Systems

The evidence about client retention after implementing multi month dispensing of ARVs and fast track refills is modest, but suggests potential gains considering these interventions require relatively few additional resources for the health facility and enables health workers to see more patients over time. In Uganda, health care workers in six public hospitals with poor patient adherence rates implemented an appointment system and triaging to enable experienced patients with refill only appointments to bypass the counselor and clinician[117]. In addition, clinicians were encouraged to give patients 2/3 monthly clinical visits and prescriptions if they reported adherence and were well. The results 11 months post the launch of the intervention were significant decreases in missed appointments and medication gaps of three or more days among cohorts of experienced patients. Considerations of health worker staffing, workflow, and factors contributing to productivity and performance should be incorporated into programing and M&E efforts to enable replication of successful models globally.

**Figure J.4.5.1**

| Changes in Adherence-based Indicators over time for Experienced Patients | | | | | |
|---|---|---|---|---|---|
| | Unadjusted percent during period | | | Adjusted intervention effects | |
| Outcome | Pre-intervention (%) | During intervention (%) | Post intervention (%) | Odds ratio (95% CI) | p |
| Any scheduled visits missed | 24.4 | 21.4 | 20.3 | 0.67 (0.59, 0.77) | <0.0001 |
| Patients with >30 days dispensed medication days | 4.3 | 8.0 | 9.3 | 2.35 (1.91, 2.89) | <0.0001 |
| Patients with ≥3 days medication gaps | 20.2 | 15.0 | 18.4 | 0.69 (0.60, 0.79) | <0.0001 |

[a]On ART at least 6 months prior to the index visit.

[117] Obua C, Kayiwa J, Waako P, Tomson G, Balidawa H, Chalker J, et al. Improving adherence to antiretroviral treatment in Uganda with a low-resource facility-based intervention. Global Health Action. 2014;7. http://www.globalhealthaction.net/index.php/gha/article/view/24198

## Appendix J.4.6 Addressing Retention through HRH in Uganda

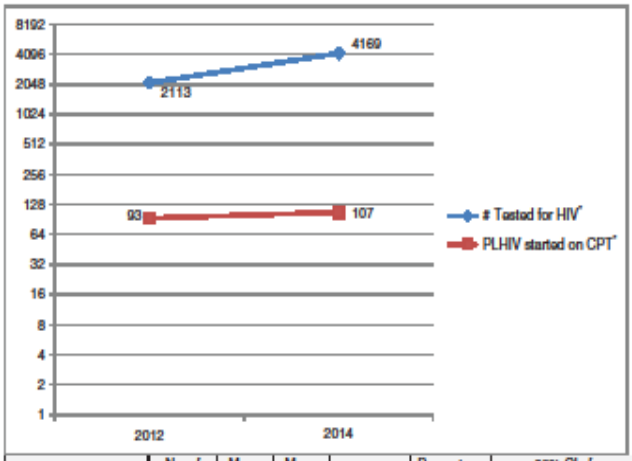
Appropriate distribution and retention of health workers is key for ensuring delivery of HIV services. In Uganda, a comprehensive package of human resources management support to strengthen utilization of data for HR planning, deployment, and management of health workers was directed for overcoming Uganda's shortage and inadequate distribution of workers[118]. As part of this package of support, tools utilizing discrete choice experiment methodology[119] were applied to determine health worker preferences to develop identify incentive packages to influence rural recruitment and retention. HRH preference data along with other data from the country's Human Resource Information system was used to successfully advocate for increased $20 million of government funding to address shortage, distribution, and retention issues. The increased funding was used to recruit new health workers and double the pay of medical doctors to attract and retain doctors to rural areas. In the following two years, the mean number of HIV persons tested for HIV doubled across facilities where additional health workers were deployed. Combined areas of intervention should be considered for addressing health worker's retention issues[120]. Health worker willingness to serve in rural and remote areas is an important factor to inform incentives.

[118] Uganda article: Jaskiewicz et al.: Investing in the health workforce to increase access to and use of HIV and AIDS services in Uganda. AIDS 2016 30:N21-N25. http://journals.lww.com/aidsonline/Citation/2016/08240/Investing_in_the_health_workforce_to_increase.1.aspx

[119] https://www.capacityplus.org/rapid-retention-survey-toolkit

[120] http://www.who.int/bulletin/volumes/91/11/13-119008/en/

**Figure J.4.6.1**




| Variable | No. of facilities | Mean (2012) | Mean (2014) | Difference | Percentage difference | 95% CI of differences |
|---|---|---|---|---|---|---|
| # Tested for HIV | 944 | 2113 | 4169 | 2056 | +97% | (–2538.40, –1574.50)* |
| PLHIV started on CPT† | 881 | 93 | 107 | 14 | +15% | (–21.52, –6.48)* |

**Fig. 2. Mean annual numbers receiving HIV services between 2012 and 2014 at health facilities with newly recruited health workers, by select HIV service.** *$P \leq 0.01$, †CPT =cotrimoxazole prophylaxis.

## Appendix J.4.7 Zimbabwe: Utilization of a Cadre of Community Adolescent Treatment Supporters to Improve Linkage, Retention and Adherence in Adolescents and Young Adults Living with HIV

Adolescents living with HIV have poorer outcomes across the HIV care cascade when compared with adults and younger children, and many countries have been developing services to target the unique needs within this population. Zvandiri was started in 2004 as a community-based, adolescent-led support group for adolescents living with HIV, and has developed into a community HIV prevention, treatment, care and support program for children, adolescents, and young adults aged 6-24 years. The program has strong linkages with health facilities using a cadre of young adults known as Community Adolescent Treatment Supporters (CATS). CATS are involved in mobilizing adolescents for HIV testing services, as well as index case finding. They assist adolescents with linkage to ART services and provide community adherence counseling, monitoring and support. Working closely with facilities, they actively trace adolescent clients that have defaulted, and serve as leaders within peer support groups and young mothers groups. A recent evaluation of the program was presented at the AIDS 2016 conference, comparing 50 adolescents on ART receiving standard of care with 50 receiving standard of care plus the support of CATS in rural Zimbabwe. Adolescents receiving the extra

support from CATS were 3.9 times more likely to have good adherence, as well as improved linkage and retention. The program is now being scaled up to 36 districts in Zimbabwe and is undergoing evaluation for the effect of the program on viral suppression.

### Appendix J.4.8 Expansion of Package of Services Provided by Mothers to Mothers to Enhance Service Uptake by Families and Adolescents in Lesotho

The impact of the mentor mother cadre on linkage to care, retention, and adherence to ART in pregnant HIV-infected women has been well demonstrated. Mothers 2 Mothers (M2M) Lesotho has expanded their service package from focused prevention of mother-to-child transmission (PMTCT) services to a more comprehensive family-centered approach, aiming to enhance community engagement and improve bidirectional community-facility linkages. Community mentor mothers conduct family-oriented household and community education sessions to demand uptake of HIV testing services. M2M Lesotho has also collaborated with clinical partners to establish 25 adolescent support groups to improve education on HIV and sexual and reproductive health (SRH) services, as well as to provide HIV testing services for adolescents attending these community group events. The expanded service package provided by M2M leverages relationships built with index clients as an entry point for service uptake for their entire family.

# Appendix J.5 Access to Quality, Sustainable HIV Services – Civil Society Organizations

## Appendix J.5.1 Comprehensive Care

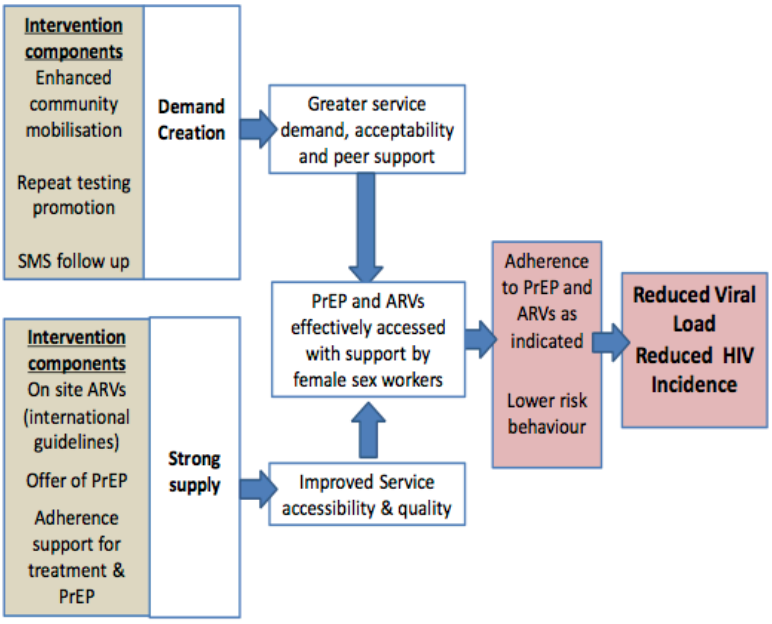
### Appendix J.5.1.1 Towards Eliminating Infectious HIV in Sex Work in Zimbabwe

The aim for Zimbabwe's National Sex Workers Program is to build on its success in scaling up and expanding coverage of effective interventions in order to eliminate infectious HIV in sex work. The main components of the Sisters program contributing to this outcome include:

- Enhanced community mobilization, guided by micro-planning, with risk-guided prevention, condoms/lubricant, promotion of clinical services and adherence support. Periodic remapping and RDS/snowball recruitment to identify new hotspots and unreached sex workers.
- Regular medical checkups, including STI screening/treatment, SRH services, violence prevention and management, designed to respond to sex workers' needs and encourage regular participation, reduce risk and detect changes in status.
- HIV services tailored to individual needs, with repeat HIV testing linked to immediate ART for positives and offer of pre-exposure prophylaxis (PrEP) for negatives. Adherence to ART and PrEP supported by peer workers and community groups. Testing for intimate partners and children.
- Structural interventions designed to reduce vulnerability of sex workers and their families as well as other minors living near sex work venues.

Close monitoring of programmatic data from micro-planning and clinical services are regularly monitored against mapping and size estimates during monthly and quarterly dashboard reviews to assess progress, identify problems and inform planning.

**Figure** **J.5.1.1.1**



## Appendix J.5.2 Monitoring ARV Stock Outs

### Appendix J.5.2.1 Partnering with CSOs to Monitor ARV Stock Outs in South Africa & Mozambique

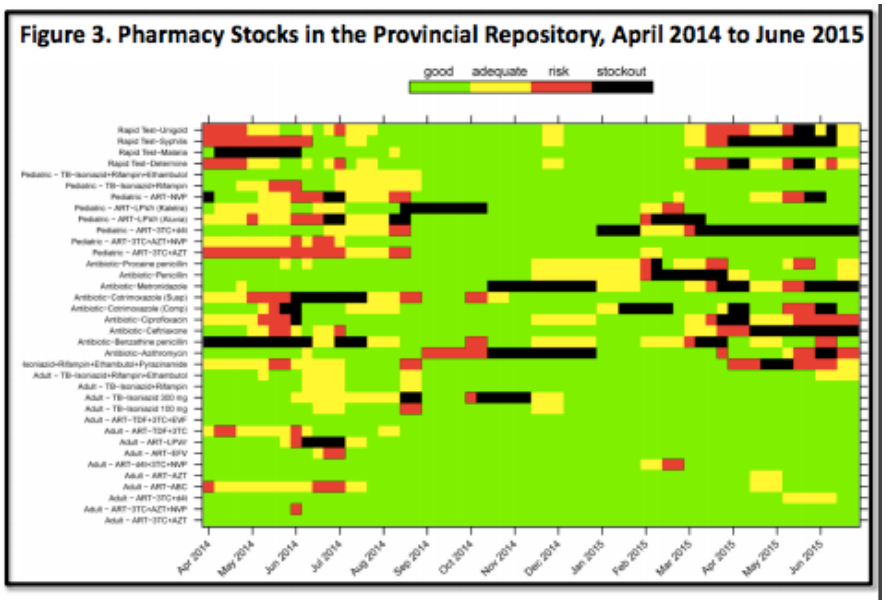
Recognized as a major challenge for HIV programming among all populations, CSOs can play a vital role in monitoring and advocating for the avoidance of ARV stock outs. In Mozambique, Friends in Global Health conducted a PEPFAR supported community-led research study to examine stock outs. Their findings showed among 2,160 weekly records, there were 166 (7.7%) stock outs and 150 (6.9%) imminent stock outs. Similarly, the Treatment Action Campaign, Médecins sans frontières and many other community-based partners in South Africa conducts similar reviews of facilities and found stock outs of ARV and/or TB drugs affect one in four facilities in South Africa. The extent and severity of the problem varies widely. A third of reported stock outs last one month or more, 41% between one to four weeks; and unfortunately, the most vulnerable patients are the most severely affected: patients who are failing the standard first line HIV treatment, children, pregnant women, and complicated tuberculosis cases. MSF did find that most stock outs are due to internal problems between the depots and facilities, while a minority of stock outs are due to national or international shortages.

## Appendix J.5.3 Creating Provider Treatment Care Teams and Linking Community/Facility Providers

## Appendix J.5.3.1 Creating Provider Treatment Care Teams and Linking Community/Facility Providers in Thailand

Sisters, a registered trans-led community organization, provides HIV, health and human-rights services to the trans woman community in Pattaya, Thailand. Sisters provides information on hormonal therapy including gender enhancement procedures as an entry point to increase uptake of HIV testing and STI screening services. The organization collaborates with owners of local nightclubs, beauty salons, live entertainment venues and other popular spots to organize mobile HTS in their spaces. HTS is also provided at the Sisters drop-in center. Trained trans counsellors provide confidential pre- and post-test counselling, and rapid HIV testing from venous and finger-prick blood samples are administered by certified trans counsellors, a professional nurse and a lab technician. Those who test HIV-positive are referred to local health-care and social-welfare facilities for care, support and treatment services. In 2015, 154 trans women received mobile on-site HTS and 435 received community-led HTS at the Sisters drop-in center. By making access to health information and services more convenient, Sisters has also helped greater numbers of trans women seek medical care in Sisters partner clinics.

**Figure J.5.2.1.1**

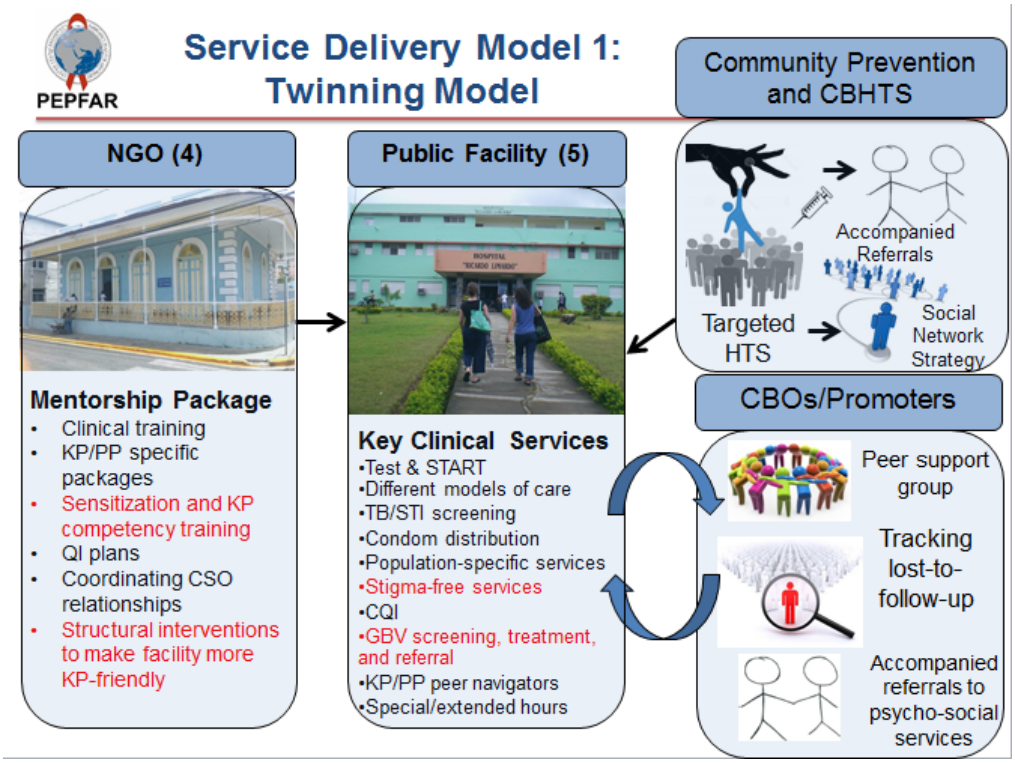


PEPFAR/DR proposes to use a twinning model, whereby a local non-governmental organization (NGO) HIV clinic is paired with a public-sector clinic to transfer expertise and capacity to appropriately serve the needs of KP/PP. There will be eleven supported HIV clinics situated in four provinces, selected for HIV burden and KP/PP size estimates. The four NGO clinics will become “centers of excellence” for KP/PP services, offering both clinical and community-based population-tailored interventions. The five public-sector clinics will be mentored to track and provide KP/PP-friendly services, consisting of a set of population-specific activities. In addition to these nine sites, two mobile clinics will target migrants in remote areas and will offer HIV testing and ART services.

## Appendix J.5.3.2 Using a Twinning Model with NGOs and the Public Sector in the Dominican Republic

In COP16, PEPFAR Dominican Republic will use a twinning model, whereby a local non-governmental organization (NGO) HIV clinic is paired with a public-sector clinic to transfer expertise and capacity to appropriately serve the needs of key and priority populations (KP/PP). There will be eleven supported HIV clinics situated in four provinces, selected for HIV burden and KP/PP size estimates. The four NGO clinics will become “centers of excellence” for KP/PP services, offering both clinical and community-based population-tailored interventions. The five public sector clinics will be mentored to track and provide KP/PP-friendly services, consisting of a set of population-specific activities. In addition to these nine sites, two mobile clinics will target migrants in remote areas and will offer HIV testing and ART services. Implementation has begun and data will be available in coming quarters.

**Figure J.5.3.2.1**




# Appendix J.6 Stigma, Discrimination, Violence, and Human Rights

## Appendix J.6.1 Reducing and Responding to GBV against Key Populations in Cameroon

LINKAGES is assisting the USAID-funded CHAMP project and government counterparts in Cameroon to reduce and respond to gender-based violence (GBV) against key populations (KPs) by providing technical assistance to community-based organizations (CBOs) and through advocacy at regional and national levels.

LINKAGES led a PEPFAR gender analysis that identified a number of structural barriers that sex workers and MSM face to HIV service uptake rooted in gender-based stigma,

discrimination, and violence. Building on these findings, LINKAGES then worked with CHAMP, the government, and seven CBO implementing partners to define a minimum package of services (MPS) for GBV response. At the conclusion of the process, the seven CBOs agreed to offer the MPS for GBV response to the KP communities they serve. The MPS consists of:

- Clinical services: evaluation and treatment of injuries; rapid HIV testing with referral to care and treatment as appropriate; post-exposure prophylaxis; STI screening, testing, and treatment (including prophylaxis); emergency contraception; mental health screening; mental health services from a psychologist; and forensic (medico-legal) examination
- Psychosocial services: counseling and support groups
- Legal services: statement-taking/documentation and legal counsel
- Information, education, and communication on GBV prevention and response

To ensure that all direct service providers are equipped to provide the MPS, LINKAGES and CHAMP developed standard operating procedures and tools based on global standards. The two projects have conducted capacity-building activities for peer educators, psychosocial counselors, social workers, and other service providers. These activities have focused on providing comprehensive first-line response skills to increase access to and quality of health services for GBV survivors. Training has also been provided on management procedures related to GBV services, including screening interventions to make timely and appropriate referrals.

The CBOs now feel they can address violence experienced by key population community members because they are 1) more informed of what violence is and how to detect it; 2) knowledgeable that violence is not the fault of key populations; and 3) better able to offer support such as first-line response and referrals to those who experience violence.

While these efforts are relatively new – we have found that CBOs are embracing the training they have received and have begun to educate their communities on what violence is and what support is available – particularly through screening, counselling, small group talks, and support group activities. The KP community is also responding positively. Early education and response efforts have led to increased disclosure of violence (general) to peer leaders via a case detection tool and increased disclosure of economic violence to counselors via a violence

screening tool. In some sites, we see that gatekeepers are even more willing than we had imagined to be involved in the process and are accompanying survivors to the DIC for support in cases of physical violence. This is promising as many of those brought to the DIC by gatekeepers are not those who normally frequent the DIC

## Appendix J.6.2 Mapping Violence Response Services in the Dominican Republic

In the Dominican Republic LINKAGES is partnering with a local community-based organization, CEPROSH (the Center for the Promotion of Human Rights and Solidarity) to ensure that members of key populations - men who have sex with men, sex workers, people living with HIV, and transgender persons – who experience violence have access to KP-friendly health, legal, and psychosocial support that are in line with global best practices. To ensure these services are available, CEPROSH led the mapping of local services for victims of violence, conducted advocacy with the Ministry of Women, the police, the District Attorney's office, the local public hospital, and public SAIs (Servicio de Atencion Integral – a clinic serving people living with HIV) in Puerto Plata, Dominican Republic. CEPROSH then conducted advocacy with these institutions and sensitized staff from each on the specific needs of KP victims of violence and how to meet those needs through existing services. At this time, peer educators from each key population and staff at the 3 SAIs in Puerto Plata are detecting cases of violence and ensuring linkages to appropriate care. At the same time, work with police is ensuring that fewer members of KPs experience violence and that those who come in to report violence will be treated with respect and care. Vanessa, a transgender peer educator with CEPROSH, had this to say about how she is helping to address violence in her community:

**Figure J.6.2.1**

"One of the root causes of gender-based violence is a lack of knowledge. Most victims don't know that they deserve better or they think violence is normal. Perpetrators also think it's normal. Especially for transgender people and gay people, violence starts within their own families because the victim's behavior is seen as bad based on gender norms. It is really important to end GBV, because many victims abandon or are abandoned by their families, partners and friends. They have nowhere to go, and experience terrible physical and mental health risks. Most of the suicides, homicides, and mistreatment that we see every day could be prevented if violence was not considered normal or deserved. With the

## Appendix J.6.3 Ghana HIV-related Stigma & Discrimination Reporting and Redress System

Drawing on lessons learned from other contexts, the Health Policy Project (HPP) collated international best practices, research on legal codes and systems in Ghana, and consultations with key stakeholders to determine approaches to monitoring discrimination. Using this information, the report describes internet- and text message-based platforms for reporting HIV-related discrimination to the Commission on Human Rights and Administrative Justice (CHRAJ), providing a mechanism for civil society organizations to report cases to CHRAJ, track case progress, and use data on stigma and discrimination to guide future advocacy on HIV- and other related policies in Ghana.

## Appendix J.6.4 Thai MOH Stigma Monitoring Systems

Having set "Zero Discrimination" as one of the top three priorities in its national strategic plan, in 2014 the Thai Ministry of Health (MOH) worked in partnership with UN agencies, universities, INGOs and national and local civil society organizations to develop three monitoring "systems" to track progress. 1) For the general population, six HIV stigma questions were added to the National Health Examination Survey in 2014, which is repeated every five years. 2) For health

facilities, a 14-question survey for health care workers and a 17-question survey clients of those same facilities was piloted and scaled up. 3) For key populations, 7-10 questions (depending on KP group being assessed) were developed and are now mandatory for any IBBS being conducted in Thailand. Each of these systems is now tracked to monitor progress in terms stigma and discrimination reduction, as well as data used to inform programming and future strategic planning. For its next phase, the MOH is developing an electronic tool for individuals to directly report stigma, discrimination and violence they witness.

## Appendix J.6.5 Health Facility Stigma & Discrimination-Reduction Programming

The HPP stigma-reduction package for health facilities is based on a globally validated measurement tool and a 'best of' set of participatory training materials based on experiences in nine countries in Africa, the Caribbean and South and South-East Asia. This total facility approach for reducing stigma and discrimination in health facilities covers all staff working in a health facility, from support staff through clinicians. Developed under the health policy project, this package brings together three key intervention elements: assessment, participatory training and a focus on facility policies and environment. This package has been adapted for use in multiple countries in the Caribbean and is the basis for Thailand's national roll-out of S&D-reduction programming.