

USAID'S IMPLEMENTATION SCIENCE INVESTMENT

Improving HIV and AIDS Programming through the Translation of Research to Practice

PEPFAR's Approach to Promoting Evidence-Based Programming

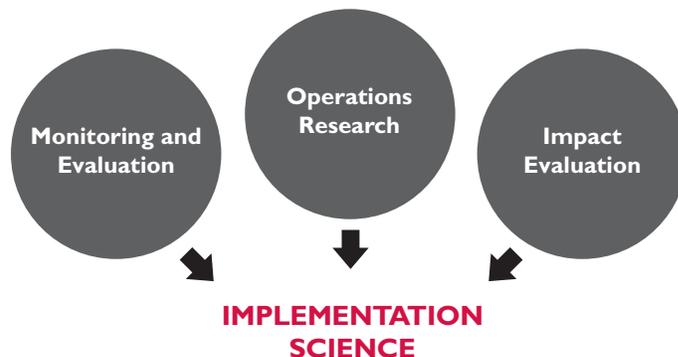
The first phase of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) focused on reducing HIV mortality and morbidity as quickly as possible. While basic infrastructure for monitoring and evaluation of programs existed, the main priority of the emergency response was rapid scale-up of service delivery programs. To ensure long-standing, locally owned approaches to sustaining the monumental increases in the availability of HIV and AIDS services enabled by PEPFAR's first phase, the second phase of PEPFAR focuses on increasing the sustainability, cost-effectiveness and impact of HIV and AIDS programs in those countries hardest hit by the epidemic.

In order to accomplish these goals, PEPFAR embraces an "implementation science" framework. Implementation science focuses on how to improve the uptake, translation and implementation of research into common practices. PEPFAR announced awards for a 3-year, \$60 million initiative, with potential for additional funding, to support implementation science research and evaluation of programs implemented under PEPFAR. These evaluations, funded in collaboration with the U.S. Centers for Disease Control and Prevention (CDC), the National Institutes of Health and the U.S. Agency for International Development (USAID), will contribute to the evidence base for HIV programs and maximize the impact of their investments in programs around the world. Data gathered will help partner countries strengthen their efforts to prevent new infections and save lives.

USAID's Implementation Science Investment and Partnerships

USAID released the Annual Program Statement (APS) "Implementation Science Research to Support Programs under PEPFAR" to support the PEPFAR investment in implementation science. The scope of the APS encourages studies that address HIV technical-area-specific program areas, as well as how to strengthen the integration of programs across the prevention, care and treatment continuum. USAID currently supports 10 studies in 9 countries throughout southern, eastern and western Africa under the APS.

PEPFAR's Implementation Science Framework



Cooperative Agreement Prime Partner: Futures Group International

- **Title:** Evaluating the Impact of a Community Savings and Loan Group Model on Child and Household Well-Being
- **Subpartners:** Institute of Economic and Social Research at the University of Zambia, Catholic Relief Services and World Vision
- **Country of Implementation:** Zambia
- **Principal Investigators:** Dr. Jenifer Chapman, Futures Group International; Dr. Karen Foreit, Futures Group International

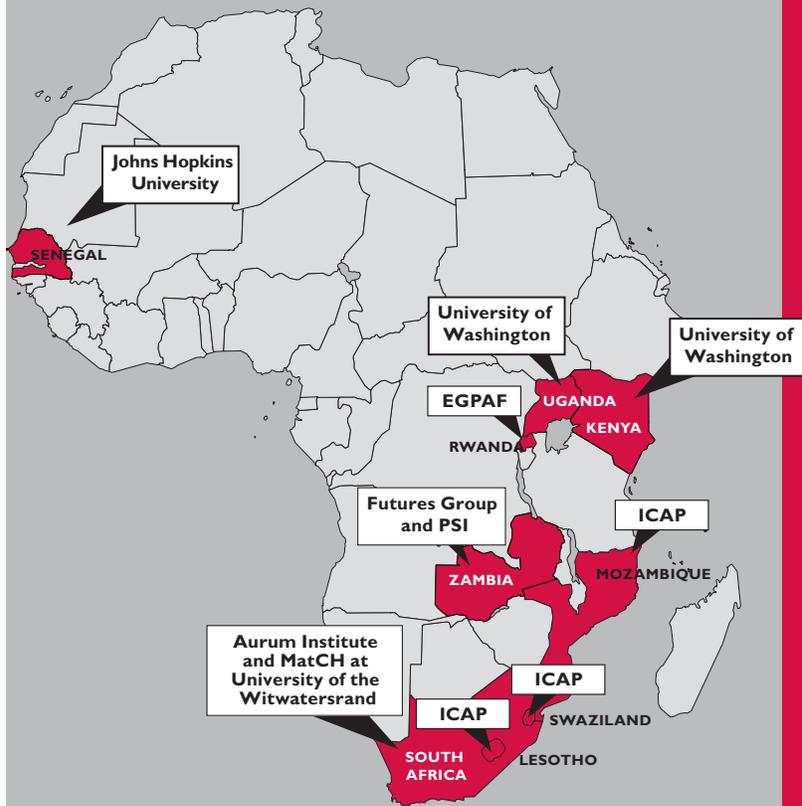
Study Synopsis

Zambia has one of the highest HIV prevalence rates in the world. As in other countries with high HIV prevalence, Zambia faces high poverty rates, high food insecurity and high child malnutrition. To address these critical health challenges, this study will examine a Zambian community savings model, known as savings and internal lending communities (SILC). Evidence suggests community saving models such as SILC can improve child and household well-being, but much is to be learned about how to make such programs work best. The study will contribute to the evidence base by evaluating the impact of caregivers' participation in SILC on children's food security and how participation in SILC changes household decision-making dynamics, children's nutritional status, access to health and school services and household expenditures. The

Definition of Implementation Science

PEPFAR embraces an "implementation science" framework. Implementation science takes innovative approaches to addressing critical HIV and AIDS program barriers – those that have demonstrated success in a research setting – and translates them into efficient and effective program practices for real world application.

USAID HIV and AIDS Implementation Science Study Partnerships



- Futures Group International: Institute of Economic and Social Research at the University of Zambia, Catholic Relief Services and World Vision
- University of Washington: Harvard Medical School, Imperial College, Kenyatta National Hospital, Makerere University Kampala and Kabwohe Clinical Research Center
- ICAP at Columbia University: National University of Lesotho, Lesotho's Ministry of Health and Social Welfare, Lesotho Red Cross and Christian Health Association of Lesotho
- EGPAF: National University of Rwanda, School of Public Health and Rwanda Ministry of Health
- Population Services International-Zambia: Society for Family Health and Population Council
- The Aurum Institute: South African Department of Health
- ICAP at Columbia University: Swaziland Ministry of Health and Social Welfare, University of Cape Town, National Emergency Response Council on HIV/AIDS and Elizabeth Glaser Pediatric AIDS Foundation
- ICAP at Columbia University: Eduardo Mondlane University, Mozambique's Ministry of Health, Mozambican National Institute of Health and Center for Collaboration in Health
- Johns Hopkins University: Enda Santé
- MatCH at University of the Witwatersrand: HIV Center for Clinical and Behavioral Studies, New York State Psychiatric Institute and Columbia University

study will identify effective approaches to implementing savings and loan group models, a key tool to promote economic security for orphans and vulnerable children households, and improve children's access to health care, education and nutrition.

Cooperative Agreement Prime Partner: University of Washington

- **Title:** Evaluating Antiretroviral (ARV)-based Prevention in HIV-1 Serodiscordant Couples in Kenya and Uganda
- **Subpartners:** Harvard Medical School, Imperial College, Kenyatta National Hospital, Makerere University Kampala and Kabwohe Clinical Research Center
- **Countries of Implementation:** Kenya and Uganda
- **Principal Investigator:** Dr. Connie Celum, University of Washington

Study Synopsis

Safe and effective approaches to preventing new HIV infections are urgently needed. In Africa, couples where one person has HIV and the other does not (often called "discordant couples") account for a substantial proportion of new HIV infections. Antiretroviral treatment (ART) and pre-exposure prophylaxis (PrEP), are two of the most powerful tools for preventing HIV transmission within discordant couples and other high HIV risk groups. Outside of clinical trial settings, however, not much is known about how to effectively incorporate these tools into large-scale public health programs. This study will examine whether providing PrEP to an HIV-negative partner as a "bridge" (i.e., until their HIV-positive partner starts ART) reduces HIV infection in the HIV-uninfected partner. The study is enrolling high-risk couples to measure uptake of PrEP and ART, sustained adherence to PrEP and ART and the

cost-effectiveness of the "bridging" strategy. The findings will inform ongoing policy discussions about how to best incorporate PrEP and ART into HIV prevention strategies.

Cooperative Agreement Prime Partner: ICAP at Columbia University

- **Title:** Combination Intervention Package to Enhance Antiretroviral Therapy Uptake and Retention during TB Treatment in Lesotho
- **Subpartners:** National University of Lesotho, Lesotho's Ministry of Health and Social Welfare, Lesotho Red Cross and Christian Health Association of Lesotho
- **Country of Implementation:** Lesotho
- **Principal Investigator:** Dr. Andrea Howard, ICAP at Columbia University

Study Synopsis

Tuberculosis (TB) morbidity and mortality among HIV-infected patients remains a major problem in Africa. In Lesotho, HIV prevalence is the world's third highest (23 percent), and the TB incidence rate is the world's fifth highest (632 cases per 100,000 population). Fortunately, effective treatments exist for individuals affected by both HIV and TB. Although providing HIV treatment – or ART – for those being treated for TB reduces mortality risk by 64 to 95 percent and is associated with a reduction in recurrent TB, implementation and uptake have been suboptimal. This study will evaluate the effectiveness, cost-effectiveness and acceptability of a combination intervention package to improve early ART initiation and retention during TB treatment, as well as TB treatment success among HIV-infected TB patients in Lesotho. This study will address

“ We seek to identify what works, what doesn’t, and why, and implement changes in our programs to optimize ... that information.”

– USAID Administrator Rajiv Shah –

the evidence-to-program gap to overcome barriers that prevent early ART implementation in high-burden, resource-limited settings.

**Cooperative Agreement Prime Partner:
Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)**

- **Title:** The Kabeho Study-Assessing the Implementation of Revised HIV and Infant Feeding Guidelines and the Effect on Nutrition, Growth and HIV-Free Survival among Children Born to HIV-Positive Mothers in Kigali, Rwanda
- **Subpartners:** National University of Rwanda, School of Public Health, and Rwanda Ministry of Health
- **Country of Implementation:** Rwanda
- **Principal Investigators:** Dr. Emily Bobrow, EGPAF; Dr. Anita Asimwe and Dr. Placidie Mugwaneza, Rwanda Ministry of Health

Study Synopsis

World Health Organization guidelines (2010) for the prevention of mother-to-child transmission of HIV (PMTCT) highlight effective infant feeding practices and emphasize the use of ARVs to make extended breast feeding a safe option for HIV-positive women and children. In Rwanda, the government initiated all HIV-positive women on lifetime ARV therapy (Option B+), in addition to infant feeding counseling and support programs, to reduce pediatric HIV infection and allow for safe breast feeding practices. However, multiple questions exist about how resource-limited countries like Rwanda can best carry out effective national PMTCT programs integrated within MNCH services. This prospective cohort study examines how to make universal ART for HIV-positive pregnant women, along with infant feeding counseling and food support, work. The results will contribute to PEPFAR’s understanding of how to achieve a key AIDS-Free Generation goal: ensuring HIV-free survival of HIV-exposed children through the effective scale up of ARV therapy and infant feeding counseling and support within PMTCT programs.

**Cooperative Agreement Prime Partner:
Population Services International-Zambia**

- **Title:** Randomized Evaluation of Family Planning and HIV Service Linkage and Integration Models for Implementation at Scale in Zambia
- **Subpartners:** Society for Family Health and Population Council
- **Country of Implementation:** Zambia
- **Principal Investigators:** Dr. Paul C. Hewett, Population Council; Mr. Nicholas Shiliya, Society for Family Health

Study Synopsis

In Zambia and other African countries, a fragmentation exists in the continuity of care between family planning and HIV services. Previous modeling has shown that in generalized HIV epidemics, integration of family planning and HIV services is critical and cost-

effective in controlling HIV transmission. Unfortunately, the service models between non-governmental organizations and government-sponsored public care are often disconnected, leading to missed opportunities for averting unintended pregnancies and new HIV infections, poor tracking and follow-up and a lower uptake of lifesaving HIV treatment and cost-effective prevention methods such as voluntary medical male circumcision. This study will compare the incremental costs and health service utilization of two models of family planning and HIV service linkage and integration. Results from this study will contribute to the evidence base used to inform family planning and HIV service integration programming.

Cooperative Agreement Prime Partner: The Aurum Institute

- **Title:** Accelerating Entry into Care Following HIV Diagnosis
- **Subpartner:** South African Department of Health
- **Country of Implementation:** South Africa
- **Principal Investigator:** Dr. Salome Charalambous, The Aurum Institute

Study Synopsis

Late initiation of HIV treatment, or ART, of newly diagnosed HIV-positive patients contributes to high HIV-associated mortality and new HIV infections in South Africa. One reason for late entry into treatment is the failure to connect people who test positive for HIV into immediate care. This study will examine how to increase the timely entry into care among people recently diagnosed as HIV-positive by examining four different strategies on entry into care. Each strategy tested addresses key barriers to timely initiation of ART, including health perceptions and personal and structural barriers. Other factors that will be examined include the time to initiate ART among those eligible, retention in care 6 months from entry, cost-effectiveness and impact on mortality and HIV transmission. The study findings will strengthen care and treatment programs by identifying effective approaches to reducing late initiation of HIV treatment.

**Cooperative Agreement Prime Partner:
ICAP at Columbia University**

- **Title:** *Situkilwane Lesiphephile-Safe Generations: Improving Approaches to ARV Therapy for HIV+ Pregnant Women*
- **Subpartners:** Swaziland Ministry of Health and Social Welfare, University of Cape Town, National Emergency Response Council on HIV/AIDS and Elizabeth Glaser Pediatric AIDS Foundation
- **Country of Implementation:** Kingdom of Swaziland
- **Principal Investigator:** Dr. Elaine Abrams, ICAP at Columbia University

Study Synopsis

Mother-to-child transmission (MTCT) of HIV is attributable to 90 percent of new pediatric HIV infections worldwide, yet evidence

PEPFAR Support for Building the HIV and AIDS Evidence Base



shows that initiating HIV treatment during pregnancy can effectively reduce MTCT. However, many factors – from diagnosis of maternal HIV to initiation of HIV treatment – have prevented effective scaling up of prevention of mother-to-child transmission (PMTCT) programs. This study will evaluate the feasibility and cost-effectiveness of providing all HIV-positive pregnant women lifelong HIV treatment via triple ARV therapy, regardless of CD4 count, in the Kingdom of Swaziland. The goal of the study is to show that a single, streamlined approach to ARV therapy for HIV-positive pregnant women will lead to more effective PMTCT.

Cooperative Agreement Prime Partner: ICAP at Columbia University

- **Title:** Combination Intervention Strategies for Linkage and Retention
- **Subpartners:** Eduardo Mondlane University, Mozambique's Ministry of Health, Mozambican National Institute of Health and Center for Collaboration in Health
- **Country of Implementation:** Mozambique
- **Principal Investigator:** Dr. Batya Elul, ICAP at Columbia University

Study Synopsis

Ensuring effective linkages between HIV testing and care and retention in HIV care remains challenging throughout Africa. Available data suggest that less than one-third of individuals who test positive are successfully linked to and retained in HIV care 1 year after their initial diagnosis. This study will compare the effectiveness of a combination of interventions (point-of-care CD4 testing in HIV testing clinics, accelerated ART initiation for eligible individuals and SMS reminders for appointments and missed visits) versus the current standard of care on the linkage and retention of newly diagnosed HIV patients in Mozambique. The study also will examine the incremental effect of providing non-cash financial incentives with the combination of interventions compared to just the combination of interventions alone. The study aims to identify effective approaches to addressing the multiple barriers HIV-positive patients face when moving from diagnosis to treatment.

Cooperative Agreement Prime Partner: Johns Hopkins University

- **Title:** HIV Prevention 2.0 (HP2): Achieving an AIDS-Free Generation in Senegal

- **Subpartner:** Enda Santé
- **Country of Implementation:** Senegal
- **Principal Investigator:** Dr. Stefan Baral, Johns Hopkins University

Study Synopsis

In Senegal, as in many sub-Saharan African countries, there is a disproportionate burden of HIV among key populations, including female sex workers and men who have sex with men. The stigma affecting these populations limits the coverage of services by mitigating both the provision and uptake of effective HIV prevention, treatment and care programs. The HP2 study proposes to characterize metrics of stigma for key populations and implement stigma-reduction interventions evaluated with a combination of biological, behavioral and economic approaches. By assessing the benefit and cost-effectiveness of a scalable package of integrated stigma-mitigation interventions, the study will contribute to the understanding of what programs work best to reduce HIV acquisition and transmission risks in key populations.

Cooperative Agreement Prime Partner: MatCH at University of the Witwatersrand

- **Title:** Evaluation of the National South African Female Condom Program: Investigating Factors Associated with Uptake and Sustained Use
- **Subpartners:** HIV Center for Clinical and Behavioral Studies, New York State Psychiatric Institute and Columbia University
- **Country of Implementation:** South Africa
- **Principal Investigators:** Dr. Mags Beksinska and Prof. Jennifer Smit, MatCH Research, University of the Witwatersrand

Study Synopsis

Globally, female condoms are significantly under-used and under-distributed, despite their potential to expand choice in reproductive health and family planning programs. South Africa has one of the largest and best established female condom programs worldwide; however, no comprehensive evaluation of the program has been conducted. Critical information about the successes and gaps of South Africa's female condom program could benefit not only South Africa, but also inform global female condom program best practices and serve as a model for evaluating the introduction of new HIV prevention options. This study aims to strengthen the South African female condom program through the identification of strategies that are most likely to enhance its acceptability, effectiveness and efficiency and generate crucial information to refine implementation and guide future directions of female condom programs globally.

USAID's Ongoing Support for Implementation Science

USAID can award multiple rounds under the "Implementation Science Research to Support Programs under PEPFAR" APS. USAID encourages interested applicants to monitor www.grants.gov for information regarding future rounds of the implementation science APS.