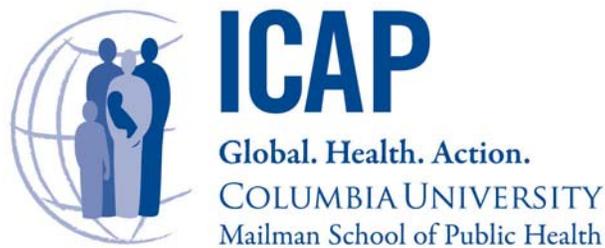


UNIVERSITY TECHNICAL ASSISTANCE PROJECTS
IN SUPPORT OF THE GLOBAL AIDS PROGRAM
(UTAP)

FINAL PROGRESS REPORT



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ACRONYMS IN THIS DOCUMENT AND IN COMMON USE

ACRONYM	MEANING
ACM	Atelier Central de Maintenance (Rwanda)
AFB	acid-fast bacteria
AIDS	acquired immune deficiency syndrome
ANC	antenatal care
APSS	adherence and psychosocial support
ARCC	at-risk child consultations
ART	antiretroviral therapy
ARV	antiretroviral
AZT	zidovudine
BCC	behavior change communication
CBO	community-based organization
CDC	Centers for Disease Control and Prevention
CHAI	CLINTON HIV/AIDS INITIATIVE
CHUB	Butare University Teaching Hospital (Rwanda).
CHUK	Kigali University Teaching Hospital (Rwanda)
CMAM	Center for Drug and Medical Commodity Procurement (Mozambique)
CMC	clinical male circumcision
CNLS	National AIDS Commission (Rwanda)
COP	country operational plan
CP	combination prevention
CPT	cotrimoxazole preventive therapy
COI	continuous quality improvement
CSM	Clinical Systems Mentorship
CTC	care and treatment centers
CTX	cotrimoxazole
CXR	chest x-ray
DBS	dried blood spot
DHT	district health teams (Rwanda)
DOH	Department of Health (South Africa)
DOTS	directly observed treatment, short course
DPS	provincial department of health (Mozambique)
EID	early infant diagnosis
EPTB	extrapulmonary tuberculosis
FBO	faith-based organization
FP	family planning
FxB	Association François-Xavier Bagnoud (FXB) (Zambia)
FY	fiscal year
GAP	Global AIDS Program
GOM	Government of Mozambique
GOR	Government of Rwanda
GOT	Government of Tanzania
HAS	HIV/AIDS/STI Unit of TRAC-Plus (Rwanda)

ACRONYM	MEANING
HBC	home-based care
HC	health center
HCT	HIV counseling and testing
HCW	health care workers
HEI	HIV-exposed infants
HF	health facility
HIV	human immunodeficiency virus
HMIS	health management information system
ICF	intensified case finding
ICT	information communication technology
IEC	information, education, and communication
INH	isoniazid
IPT	isoniazid preventive therapy
IRB	institutional review board
I-TECH	International Training & Education Center for Health
KHI	Kigali Health Institute (Rwanda)
L&D	labor and delivery
LPN	licensed practical nurse
M&E	monitoring and evaluation
MC	male circumcision
MCAP	Multicountry Columbia Antiretroviral Program
MCH	maternal-child health
MDG	Millennium Development Goal
Mdm	Médecins du Monde
MDR	multidrug resistant
MOC	model of care
MOH	ministry of health
MOHSW	ministry of health and social welfare
MOU	memorandum of understanding
MSM	men who have sex with men
MSPH	Mailman School of Public Health at Columbia University
MTCT	mother-to-child transmission
NGO	nongovernmental organization
NHLS	National Health Laboratory Service (South Africa)
NRL	National Reference Laboratory (Rwanda)
NVP	nevirapine
OGAC	Office of U.S. Global AIDS Coordinator
OI	opportunistic infection
ORCI	Ocean Road Cancer Institute (Tanzania)
PCOE	pediatric center of excellence (Zambia)
PCR	polymerase chain reaction
PE	peer educator

ACRONYM	MEANING
PEPFAR	United States President's Emergency Plan for AIDS Relief
PHASO	Partnership in HIV/AIDS Support Organizations
PHC	primary health care
PHE	public health evaluation
PICT/ PITC	provider initiated HIV counseling and testing (<i>acronym varies by country</i>)
PLWHA	people living with HIV
PMTCT	prevention of mother-to-child transmission
PWP	prevention with positives
PY	project year
QA	quality assurance
QC	quality control
QI	quality improvement
RCH	reproductive and child health
RH	reproductive health
RPR	rapid plasma regain
RRP+	Rwandan Network of PLWHA
RTC	Regional Training Center (South Africa)
SD-NVP	Single-dose nevirapine
SGBV	sexual gender-based violence
SMS	short message system
SOC	standard of care
SOP	standard operating procedure
STI	sexually transmitted infection
TB	tuberculosis
TMC	traditional male circumcision
TOR	terms of reference
TOT	training of trainers
TRAC-Plus	Treatment and Research of AIDS Center-Plus (Rwanda)
TWG	Technical Working Group
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session on HIV and AIDS
USAID	U.S. Agency for International Development
USG	United States Government
UTAP	University Technical Assistance Projects
UTH	University Teaching Hospital (Zambia)
VCT	voluntary counseling and testing
VL	viral load
WHO	World Health Organization
XDR	extensively drug-resistant
ZMOHSW	Zanzibar Ministry of Health and Social Welfare

BACKGROUND

In September 2002, the Mailman School of Public Health (MSPH) at Columbia University (CU) entered into a Cooperative Agreement with the Centers for Disease Control (CDC) for the University Technical Assistance Projects (UTAP) in Support of the Global HIV/AIDS Program. Originally envisioned as a single-country program for the provision of technical assistance, UTAP rapidly grew to include long-term and short-term technical and administrative assistance to the national responses to HIV/AIDS in five countries: Mozambique, Rwanda, South Africa, Tanzania, and Zambia. In close coordination with the local CDC in-country offices, CU successfully partnered with key Ministry of Health agencies charged with rollout of national HIV prevention, care, and treatment programs as well as public sector clinical facilities implementing key aspects of the national HIV/AIDS agendas.

Situated within ICAP, a center in the school of public health, UTAP directly supported scale-up of HIV prevention, care, and treatment programs in resource-limited settings. ICAP's approach to technical assistance through UTAP emphasized knowledge and skills transfer to government partners to ensure long-term impact. The infrastructure established through UTAP support in diverse areas of technical expertise, training, and monitoring and evaluation resulted in technical support at national, provincial, and site levels.

This report is a comprehensive summary of all of ICAP's UTAP-related activities from 2002 through 2011. Activities supported by UTAP provided essential technical assistance and made available resources that complemented the HIV prevention, care, and treatment programs that ICAP supports, especially those funded through the PEPFAR Track 1.0 program.

ICAP's approach is grounded in an appreciation of the HIV pandemic's broad impact on individuals, families, communities, and societies, and in an understanding of the connection between HIV/AIDS, childhood mortality and other health threats, including tuberculosis, malaria, malnutrition, and limited access to reproductive health services. Working with host countries and other partners, ICAP supports HIV programs at the national, regional, facility, and community levels, building on local strengths and resources and providing a very broad range of implementation and technical assistance.

ICAP in Mozambique provided assistance to the Government of Mozambique (GOM)¹ in the provision of comprehensive HIV prevention, care and treatment services with the overarching goal of increased capacity building. ICAP began working in Mozambique in September 2004. This work included infrastructure development, training of various staff members, ongoing intensive mentoring to clinical staff, training of new cadres of providers, and establishment of supportive services to enhance enrollment, follow-up and adherence.

ICAP provided support for the scale-up of the national HIV care and treatment program in the city of Maputo and in five other provinces: Maputo, Gaza, Inhambane, Zambézia, and Nampula. In addition to HIV care and treatment of adults and children, ICAP provided technical assistance in training, adherence and psychosocial support, prevention of mother to child transmission, integration of tuberculosis screening and care in HIV care settings, and monitoring and evaluation. ICAP also worked with the Ministries of Defence and Interior to provide support to HIV care and treatment at their affiliated sites.

Between 2004 and 2010, UTAP funds enabled ICAP to expand and enrich the GOM's capacity for HIV care and treatment in specific technical areas: laboratory renovations, enhancement of PMTCT activities, integration of TB/HIV programs, and palliative care.

PMTCT

Since February 2005, ICAP has been working in close collaboration with the MOH with the objectives of supporting the scaling up of the PMTCT program based on the PMTCT-Plus Initiative. Fundamental components of the initiative include:

- A comprehensive approach to **family-centered** care to families.
- Emphasis on the provision of **continuity and continuum of care**.
- Drawing services from a **multidisciplinary team of care providers**.
- A focus on **integration** with other important programs, such as reproductive health care.
- A focus on **psycho-social support** and interventions to promote **treatment adherence** through client-centered counseling.
- Attention to **long-term retention of patients** in care.
- Linking service delivery programs to their local communities through intensive **outreach activities**.

In order to implement the PMTCT-Plus initiative, MSPH assisted initially with the establishment of two PMTCT model centers in two provinces selected in collaboration with the Ministry of Health and CDC/GAP, Maputo city and Nampula province, and expanded support to three additional provinces and

¹ In this document, acronyms that may be unfamiliar to readers are expanded in text on first use as well as in the acronym list that follows the table of contents; all others are expanded only in the acronym list.

health facilities following the MOH PMTCT expansion strategy in Inhambane province in 2006, and to Zambézia and Gaza provinces in 2009.

The model centers have provided a standard of comprehensive care and up-to-date PMTCT service delivery by providing evidence-based PMTCT interventions. The overall goals of these centers are to support the MOH in its scale up efforts of the development, expansion, and implementation of activities regarding PMTCT and to develop the centers as resources for regional and national training programs. The strategies piloted at model centers have been scaled up to all ICAP-supported sites and include integration of routine counseling and testing into ANC and maternity settings, group pre- test counseling, integration of blood collection for CD4 testing for all women identified as HIV positive performed on the same day of their HIV test results, shift in prevention regimens from provision of sd-NVP to that of AZT + sd-NVP for mother and baby, integration of HIV care and treatment in MCH sector to support ART initiation for women with CD4 count <350 or strengthening linkages between MCH and ART care and treatment services. The model centers are also supporting infant feeding and mother support groups, with health education sessions held in conjunction with demonstration infant feeding sessions as well as information/training on income generating techniques such as sewing. In an attempt to engage families in care, letters of invitation for partner participation are provided at all ICAP health facilities to all pregnant women attending the PMTCT program, irrespective of HIV status.

Capacity building has also been a critical component of the PMTCT program. At model centers, the PMTCT Clinical Mentorship Initiative was launched in 2006 and was designed to develop and implement strategies to enhance provider skills, promote task-shifting, and empower non-traditional cadres to provide high-quality HIV/AIDS care and treatment. The goal is to support and progressively improve the quality of PMTCT-related capacity building in MCH nurses, with an emphasis on providing high quality care to pregnant women. ICAP has also intensively promoted the health providers capacity building supporting provincial trainings on MCH/PMTCT.

The emphasis of activities supported during FY07 were on scaling up the implementation of PMTCT services to 133 health facilities, on increasing the proportion of HIV positive pregnant women initiating ART for their own health, on increasing the number of infants identified as HIV exposed and/or infected through introduction of early infant HIV diagnosis (1160 expected children), on improving quality of follow-up for HIV exposed infants through 'at risk consultations' and enhancing referral to care and treatment by strengthening linkages between services, retention and adherence to care and treatment.

Technical Assistance to the MOH

- Since the inception of PMTCT support in Mozambique, ICAP has provided extensive technical assistance to the PMTCT program within the MOH at the central level. ICAP supported the national PMTCT program by recruiting a PMTCT M&E technical advisor to support the national PMTCT monitoring and evaluation system, to support the development and implementation of a national PMTCT information system database. ICAP also supported the recruitment and staffing of a data entry clerk to help with national PMTCT program monitoring and data entry, as well as, an administrative assistance to facilitate national PMTCT program coordination and communication with various partners and program implementers.

Implementation of the Clinical System Mentorship Initiative to Improve Quality of Care

- Since 2007, ICAP has been working closely with the provinces to implement the Clinical Systems Mentorship (CSM) approach, which relies on site assessment, team building, monitoring and evaluation to build a continuous quality improvement cycle that will ultimately enhance the PMTCT program. Tools includes Model of Care (MOC) for site assessment, facility-based reports and standards of care (SOC) for quality measures and follow up

Monitoring and Evaluation

M&E systems were developed and/or adapted consistent with national PMTCT, care and treatment, and/or more general HIV-related HMIS systems. In the development of new M&E tools for MCH/PMTCT and reproductive health, technical assistance for training and training capacity development consisted of:

- Development, adaptation and pilot testing of training materials for both PMTCT and MTCT-Plus
- Adaption and combination of CDC/WHO PMTCT training manual with Columbia's MTCT-Plus training materials for the Mozambique context
- Development and update of training material following new PMTCT recommendations in collaboration with other partners
- Finance and facilitation of national or regional TOT
- Provision of broad support to the MOH's national training effort in PMTCT and MTCT-Plus
- Dissemination of new protocols to provincial departments of health (DPS)
- In collaboration with the MOH and I-TECH, establishment of a formal mentorship program with practical for nurses to conduct a two-week rotation through the model centers to build their clinical capacity
- Training and mentoring of health care providers in MCH/PMTCT model centers and at all provincial level, including in drug management and M&E

ICAP supported provincial level PMTCT trainings thereby increased the number of MCH staff trained in PMTCT, counseling and testing, pediatric HIV diagnosis, and infant follow-up. With technical assistance provided by the CDC, the MOH developed a training curriculum and PMTCT manual for health care providers. A PMTCT workshop organized in collaboration between Columbia University and Ministry of Health took place in March 2005 to address treatment controversies.

A successful strategy to increasing the quality of services provided at the model centers has been the coordination of PMTCT retreats with model center staff. This enabled the site staff from the various program areas—ANC, maternity, at-risk child consultations (ARCC), and ART clinic—to discuss approaches to enhancing patient services and the quality of care that is delivered, with a special focus on pregnant women and infants.

Renovations of MCH/PMTCT Facilities

- Support included initial assessments of facilities, renovations and improvements to the overall patient flow of services. Funds were used for rehabilitation of space to improve privacy for provision of PMTCT services, training of MCH staff at these sites in PMTCT and infant follow-up, and technical support to establish linkages and referral between services. Additional funds were used to cover the costs of training materials, clinic supplies, medical equipment and furniture for these areas.

Psychosocial Support, Support to Long-Term Retention in Care and Adherence to Care and Treatment

- In FY06, ICAP had a subcontract with CARE who worked in Nampula with trained "activists" to support HIV care and treatment, and enhance community involvement in PMTCT. At the end of this subcontract, ICAP recruited a community outreach coordinator to continue supporting linkages with the community and increasing the number of peer educators involved in PMTCT activities.
- Implemented a PE/expert patients program at MCH/PMTCT to conduct counseling activities at MCH/PMTCT as well as outreach activities.
- Implemented mother support groups.

HIV Care

ICAP supported the Ministry of Health OI Program by purchasing additional OI medicines. These medicines were used to treat adult HIV-infected patients diagnosed with OI and drugs for prophylaxis and/or treatment of OI for HIV-infected infants and children at Columbia University-supported sites and other sites as needed. The list of purchased medications was developed in collaboration with the Center for Drug and Medical Commodity Procurement (CMAM) of the Government of Mozambique, input from leading clinical experts in the country and USG-supported agencies currently involved in drug procurement system development (e.g.: John Snow Incorporated). Drugs included in this list were those needed to treat the most common OI affecting HIV infected adults and children in Mozambique.

TB/HIV

The TB/HIV component of the ICAP program in Mozambique began in July 2006. ICAP collaborated with the MOH to support TB/HIV linkages and treatment service expansion by implementing a package of integrated TB/HIV activities according to WHO recommended TB/HIV collaborative activities, endorsed by the Mozambican MOH. This package is also in line with the Mozambican National TB Strategic Plan.

The package includes (but is not limited to): TB screening among HIV patients; CTX prophylaxis and regular follow-up of co-infected patients, strengthening and expansion of standardized M&E systems and medical records to capture TB/HIV information; evaluation for INH prophylaxis for HIV-eligible patients, IEC with special attention to co-infected patients' family and children, and promotion of basic measure for the prevention of TB infection transmission. Capacity building is a critical component for the program's implementation: periodic workshops on how to implement and strengthen the package are offered to staff and continuous technical assistance, mentoring and supervision are provided.

At ART facilities, a TB screening questionnaire was designed and implemented with a double objective: identifying HIV patients suspected of having TB who are then evaluated according to the diagnostic capacities of each site, and identifying patients not suspected of TB, who can be further evaluated to rule out TB for INH prophylaxis. This tool was piloted at the Mavalane TB/HIV Model Center and further implemented in another 61 locations. The TB screening tool developed by ICAP was then adapted for and adopted by the National TB Program at the MOH in early 2008 and implemented nationwide. ICAP continued the expansion of the TB screening activities in the supported sites. Furthermore ICAP supported provincial training on TB/HIV collaborative activities in the supported Provinces – these included TB screening and IPT, as well as management of TB/HIV co-infection and appropriate M&E of TB/HIV activities.

ICAP provided assistance to TB clinics near HIV/AIDS facilities, which are more closely linked to the ART clinics. Counseling and testing for HIV is currently available at most TB clinics and the activity is funded and managed by the MOH. Columbia University supported some Provincial training in VCT for TB nurses.

ICAP monitored HIV counseling and testing performed at TB clinics, as well as CTX prophylaxis and other activities which are usually performed at TB sites, with the support of additional TB/HIV staff. ICAP supported the National TB Program at the MOH to develop tools to improve the referral of co-infected patients between TB and HIV clinics (TB/HIV referral form)

ICAP has a close partnership with the MOH: in addition to participating in the TB/HIV National Task Force and its activities, ICAP provided technical assistance to the National TB Program to develop a National TB Strategic Plan 2008-2012 and write proposals for Rounds 7 and 10 of the Global Fund. Furthermore, in 2008, ICAP supported the National TB Program to conduct a National assessment of TB/HIV collaborative activities implemented in the previous year. ICAP also provided technical assistance to analyze data and to develop three abstracts for international conferences. ICAP provided TA to the MOH to revise TB/HIV guidelines on IPT and ICF and to analyze national data to develop other abstracts for international meetings in 2011.

ICAP focused on the expansion and consolidation of TB/HIV collaborative activities by increasing support to more sites and entry points of possible co-infected patients. ICAP allocated funds to provide HIV test kits, cotrimoxazole, registers and referral forms at TB facilities. ICAP also funded the renovation of a TB culture laboratory in Nampula to increase accessibility to culture and drug susceptibility TB diagnostic services in compliance with safety guidelines and standards. This activity complements the renovation activities for the Nampula Central Hospital Laboratory.

During FY07, the TB/HIV M&E system was strengthened to improve both the recording and reporting of information about TB/HIV co-infected patients as well as the quality of those data.

Given that most patients who receive care through ICAP-supported sites live in extreme poverty and thus face serious obstacles to attending regular clinical and pharmacy appointments and to adhering to treatment, ICAP allocated additional funds to develop and implement strategies to support TB/HIV co-infected patients. In the case of TB/HIV co-infection, a double risk of infection transmission exists, as well as a double risk of weak adherence to both TB and ARV treatment. Irregular treatment increases the risk of developing resistance to drugs and persistence of infectiveness, with increased risk of infection transmission.

ICAP staff coordinated groups of volunteers patients trained as peer educators to work on enhancing counseling, promoting better linkages between services and monitoring patients' clinical, diagnostic and pharmacy appointments. Through home visiting, these groups:

- Help strengthen case finding and investigation of family contacts of patients with active TB (with special attention to children),
- Implement a patient tracking system for prompt identification of patients who do not adhere to and subsequently abandon treatment,
- Identify of patients lost to follow up in a timely way,
- Educate patients in treatment and prevention of infection transmission.

Activities were carried out to enhance linkages between HIV and TB programs at the point of service in order to improve the identification of dually infected patients as a component of comprehensive care and treatment services. The main component of these TB/HIV integration activities through this funding were to ensure that TB patients identified HIV positive had access to HIV care and treatment, as well as that HIV patients diagnosed with TB had prompt access to TB treatment. Another component of TB/HIV integration was to offer cotrimoxazole prophylaxis to all TB/HIV co-infected patients through DOT clinics located in the vicinity of ICAP-supported ART facilities.

ICAP provided support to:

- Establish stocking, procurement, distribution and administration systems for cotrimoxazole prophylaxis for HIV-infected TB patients at DOTS clinics.
- Develop a referral system to HIV services for continuation of cotrimoxazole after TB treatment is complete.
- Provide monitoring and evaluation support to evaluate program feasibility and monitor adverse events.

Finally, ICAP also worked with the MOH to strengthen the pediatric component of HIV/TB program integration. These activities included:

- Developing and evaluating TB screening and diagnostic tools for children.
- Introducing a package of TB care and treatment for HIV exposed and infected children at CU-supported ART facilities.
- Implementing HIV testing for children with TB.
- Improving the detection of TB in children of HIV/TB dually infected adults.

Laboratory

ICAP, in collaboration with CDC Mozambique, was integrally involved in building the capacity of national laboratories to support the national HIV prevention (PMTCT and counseling and testing), care and treatment program utilizing UTAP funding. These laboratories function as a resource for the entire Mozambican national roll out of HIV care and treatment, including sites supported by Columbia University through MCAP. The laboratory scaling up program involved the establishment of five level-three reference laboratories in four different urban centers: Maputo City (Mavalane and Jose Macamo General Hospitals), Xai-Xai, Quelimane, and Nampula. All five laboratories benefited from rehabilitation of the physical infrastructure. These labs were equipped with working station tables, benches, cabinets and some furniture. ICAP purchased some few reagents but only in rare cases for stockouts.

Rehabilitation work began at the Mavalane General Hospital laboratory in Maputo City. For the five reference laboratories rehabilitation work included the establishment of rooms with the following functions: waiting area, reception, specimen collection, microbiology, immunology (including CD4 counting), parasitology, general laboratory (including hematology and clinical chemistry), storage room, and washing/sterilization unit. The Quelimane laboratory, in addition to the above mentioned rooms, comprises three distinct areas for molecular biology techniques (including PCR and viral load) and a library/study room. For all five laboratories the electricity, water and sewage systems were replaced. Besides the five reference laboratories, ICAP supported eight other lab rehabilitations in the five supported provinces.

The other lab infrastructure interventions were geared toward improving physical space, functionalizing and optimizing work space. Work flows and patient flows were reviewed and improved at all the sites.

A subagreement with the National Institute of Health (NIH) covered the following support:

- HR staffing: 1 staff person for lab data collection
- Purchase of lab equipment and reagents
- Support to QA for CD4, viral load, and infant diagnosis
- Training staff for CD4
- Development of capacity for viral load testing and infant diagnosis

ICAP designed and initiated training program for laboratory technicians soon after the rehabilitation of the Mavalane and Maputo Military Hospitals laboratories were completed. The training program comprises the organization of wet-workshops and on-the-job training of laboratory technicians and supervisors on general and specific laboratory techniques, biosafety and good laboratory practices. A quality assurance program for CD4 counting was launched in 2005 once clinical laboratories begin their activities in this field. CD4 lab was supported both rollout and ongoing implementation at the Maputo Military Hospital Lab.

Infrastructure Support

As part of its program of assistance to the Ministry of Health and related institutions in Mozambique, the CDC Global AIDS Program country office in Mozambique (CDC Mozambique) requested that MSPH resources be made available to fund renovation of laboratories to support delivery of HIV care and treatment services and other interventions that amplified PMTCT areas at health facilities. MSPH provided funding in accordance with national needs and subject to CDC approval.

ICAP supported 36 infrastructure interventions, carried out in the five provinces supported by ICAP MZ. Among these interventions, 13 occurred at laboratories (Central, Provincial, General and Rural Hospitals, and at health facilities). Among the remaining 23, most occurred at health facilities, all supporting PMTCT services. Of the 36, 14 facilities were improved through procurement of prefabricated units, among these 2 Labs and 12 PMTCT. All infrastructure interventions have improved the physical space, functionalizing and optimizing work space. Patient flow charts were reviewed and improved at all the sites together with the provincial, district and health facility teams.

TABLE 1: INFRASTRUCTURE INTERVENTIONS AT ICAP SITES IN MOZAMBIQUE

	PROVINCE/SITE	FACILITY
MAPUTO CITY		
1	Mavalane General Hospital	Laboratory
2	Maputo Military Hospital	Laboratory
3	Jose Macamo General Hospital	Laboratory
4	Jose Macamo Health Center	PMTCT
5	Magoanine Mini Centro Health Center	PMTCT
6	Magoanine Tendas Health Center	PMTCT
7	Inhagoia Health Center	PMTCT
8	Zimpeto Health Center	PMTCT (prefab)

	PROVINCE/SITE	FACILITY
9	Bagamoio Health Center	PMTCT (prefab)
10	Romão Health Center	PMTCT (prefab)
GAZA PROVINCE		
11	Xai Xai Provincial Hospital	Laboratory
12	Marien Ngouabi Health Center	PMTCT (prefab)
13	Chokwe Health Center	PMTCT (prefab)
14	Manjacaze Health Center	PMTCT (prefab)
15	Guijá Health Center	PMTCT (prefab)
INHAMBANE PROVINCE		
16	Inhambane Provincial Hospital	Laboratory (prefab)
17	Maxixe Health Center	PMTCT (prefab)
18	Massinga Health Center	PMTCT (prefab)
19	Inharrime Health Center	PMTCT (prefab)
ZAMBÉZIA PROVINCE		
20	Quelimane Provincial Hospital	Laboratory
21	17 Setembro Health Center	Laboratory
22	Milange Health Center**	Laboratory (prefab)
23	24 Julho Health Center	PMTCT
24	24 de Julho Health Center	PMTCT (prefab)
25	Coalane Health Center	PMTCT (prefab)
NAMPULA PROVINCE		
26	Nampula Central Hospital	Laboratory
27	Nacala Rural Hospital	Laboratory
28	Malema Health Center	Laboratory
29	Ribaue Health Center	Laboratory
30	Anchilo Health Center	Laboratory
31	Nampula Military Hospital	PMTCT
32	25 Setembro Health Center	PMTCT
33	Psychiatric Health Center	PMTCT
34	Namicopo Health Center	PMTCT
35	1º Maio Health Center	PMTCT
36	Namutequeliua Health Center	PMTCT

** The DPS *Zambézia* later requested this prefab in Milange to be transferred to 17 Setembro Health Center in Quelimane City where it is now positioned.

In collaboration with the Ministry of Health and CDC/GAP, five reference laboratories were identified for renovation. Funds covered renovation of the physical infrastructure as needed including the following:

- Space — including floors, walls, ceilings, entrance ways, windows, roofs, waiting areas, offices, staff rest areas, laboratory rooms, consultation rooms, confidential space for counseling and testing, restrooms, closets, and storage areas.
- Function —including plumbing, gas, electricity, drainage, and ventilation.

23 infrastructure interventions were carried out to improve the physical space for PMTCT services during with UTAP funding: 12 prefab and 11 rehabilitations.

Public Health Evaluations

UTAP Year 3 Carryover funds and UTAP Year 4 funds were awarded to conduct the public health evaluation (PHE), *Assessing Enablers and Barriers to the Implementation of More Efficacious PMTCT Regimens During Pregnancy in Mozambique*, which is examining a prospective cohort of 1,140 patients at 10 PMTCT sites in Maputo and Nampula using routinely collected data from medical records and interviews with women as well as an assessment of contextual characteristics that might impact regimen uptake. Using less effective PMTCT ARV and inadequate adherence to PMTCT regimens and can severely impair the effectiveness of the national scale up of PMTCT interventions. This PHE is expected to provide important data on rates of initiation of more efficacious PMTCT regimens and to advance our understanding of the barriers and enablers for women and their babies initiation of and adherence to more efficacious PMTCT regimens. The results of this PHE will be used to improve the uptake of PMTCT services. A no-cost extension was requested to ensure sufficient time and funds to secure an adequate sample size for the PHE and post-partum follow-up of enrolled women.

Preliminary activities (developing the study protocols and draft data collection tools) were completed in Year 5 (the second budget year of funding). The key achievement during the program year was that study protocol was approved by the Mozambican MOH Ethical Review Committee and the Minister of Health, the OGAC PHE Evaluation team and GAP ADS, and by the Columbia University Internal Review Board. Of note, the OGAC PHE Evaluation Team required substantial changes in the design and sample size of the protocol and PMTCT guidelines and policies changed during the course of protocol development. All ethical and scientific approvals were received as of January 21, 2010 and ICAP requested release of restricted funds from CDC. SOPs were developed, hiring and training were completed, study procedures tested in August 2010 and tools fine-tuned in September 2010. Data collection began at Maputo sites in October 2010 and in Nampula sites in February 2011.

By the end of May 2011, 292 (25%) of the target sample of women had been recruited and 8 women have completed the entire follow-up period. Some of the challenges observed with the rate of recruitment include a less than expected number of HIV pregnant women at the study sites, a number of women not meeting the inclusion criteria, and interruptions as we sought IRB approval of protocol amendments. However, with the amendment to have 4 additional sites included in the study now approved, ICAP anticipates completing data collection about February, 2012 and funds from the Track 1.0 award have been allocated to support those activities. ICAP plans to request other funds to continue supporting the completion of PHE activities conducted after March 1, 2012.

Please note that the PHE listed above is being conducted among African patients and therefore the designation of minority subjects does not apply. Women and children were included as subjects per the study design and inclusion criteria of each PHE, and research materials, such as cell lines, DNA probes, and animal models did not result from the research. The PHE protocols and resulting data will be available to other investigators through the MOH.

Partnerships and Collaborations

PMTCT Program

CARE International: ICAP carried out a subagreement with CARE International. The agreement aligned with the project goal and objectives of CARE’s APPLE program to prevent future HIV/AIDS infections and mitigate the impact of HIV/AIDS on those infected and affected (in the Nacala Corridor area of northern Mozambique and southern Malawi and in the northern part of the Maputo Corridor of southern Mozambique). The scope of work included the following objectives:

Objective 1: Increased supply of quality health services for people living with HIV/AIDS in 25 Setembro VCT and day clinic

Objective 2: Increased BCC activities focusing on access to health services and on treatment literacy

Objective 3: Increased community-based capacity to provide quality prevention, care and support services

Lab

National Institute for Health: ICAP elaborated and executed a subagreement with NIH. Activities supported the MOH to install, implement and ensure quality for CD4, viral load and early infant diagnostics.

Progress During the Life of the Project

TABLE 2. PROGRESS TOWARDS ACHIEVING ORIGINAL AIMS

PROJECT PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS (FROM 2005 - 2009 UNLESS OTHERWISE NOTED)
PMTCT	Establish two PMTCT Reference Centers at José Macamo in Maputo City and 25 de Setembro Health Center in Nampula	Pilot innovative strategies to inform the MOH; implement the PMTCT clinical Mentoring program; support the implementation of more complex PMTCT regimen	<ul style="list-style-type: none"> • 34,816 HIV positive pregnant women received ARV prophylaxis • 2,729 HIV positive pregnant women initiated ARV triple therapy
PMTCT	Expand access of PMTCT services to peripheral health posts/centers that refer women to the PMTCT Reference Centers for delivery		By the end of March 2009, ICAP supported PMTCT services at 164 health facilities, including 134 maternities
PMTCT	Integration of PMTCT services to include pediatric care and treatment to maximize on prevention of mother to child transmission interventions	Reactivation of at-risk child consultations (ARCC)	<ul style="list-style-type: none"> • By the end of March 2009, ICAP supported the reactivation of the ARCC at 135 health facilities • 25,010 HEI initiated CTX from 2005-2009 • 19,106 HEI tested for HIV via PCR

PROJECT PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS (FROM 2005 - 2009 UNLESS OTHERWISE NOTED)
PMTCT	Implement testing and counseling services (T&C) within ANC and Maternity settings	Training and mentoring of health providers	<ul style="list-style-type: none"> • 393,068 pregnant women tested in ANC • 47,654 pregnant women tested in maternity settings • 34,816 HIV pregnant women receiving ARV prophylaxis in ANC • 26,880 HIV-positive women received ARV prophylaxis at L&D • 31,324 HIV-exposed infants received ARV prophylaxis
PMTCT	Support the implementation of the PMTCT clinical mentoring program at the two PMTCT model centers	<ul style="list-style-type: none"> • Training material development in collaboration with ITECH • Implementation of the program in the two PMTCT model centers 	148 MCH nurses trained as mentors (includes initial trainings and refresher trainings) at three mentoring sites
PMTCT	Support provincial-level PMTCT trainings	Technical and financial support, and facilitation during training	Over 2829 health providers trained in MCH/PMTCT
HIV Care	Purchase medications for opportunistic infections (OI) for patients at peripheral health centers		Purchased medications for OI prophylaxis and/or treatment for 400 HIV-infected patients
HIV Care	Expand access for OI management at peripheral health centers		As of the end of March 2009, ICAP supported HIV clinical services, including OI management, at 65 health facilities (cumulative total of 71)
HIV Care	Support provincial-level OI trainings	Technical and financial support, and facilitation during trainings	779 health providers trained in OI management from 2007 through 2009
HIV Care	Support development of national guidelines on OI and HIV Treatment	Technical support for the development of the national guidelines	National guidelines on HIV and OI treatment completed and distributed
TB/HIV	Introduce and expand TB screening for all HIV patients at HIV facilities	<ul style="list-style-type: none"> • Development of a TB screening tool, later adopted by the MOH 	61 HIV supported facilities screening HIV patients for TB through the TB questionnaire and reporting regular data

PROJECT PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS (FROM 2005 - 2009 UNLESS OTHERWISE NOTED)
		<ul style="list-style-type: none"> • Training, mentoring and supervision of health staff to proper use of the TB screening tool 	
TB/HIV	Offer a package of TB/HIV care to TB/HIV co-infected patients (including Cotrimoxazol Prophylaxis-CPT)	Training, mentoring and supervision of health staff to proper management of co-infected patients and CPT use	<ul style="list-style-type: none"> • Technical meetings regularly done at each facility by ICAP staff and TB/HIV patients regularly managed at HIV facilities • TB/HIV patients receiving CPT at TB services while patients are treating TB according national recommendations
TB/HIV	Introduce and expand IPT to HIV patients with no TB at HIV facilities	Training, mentoring and supervision of health staff to rule out TB before IPT and to implement IPT among HIV patients	Progressive increase of the number of sites doing IPT and number of patients enrolled on IPT
TB/HIV	Strengthen linkages between TB and HIV services and integrated approach to co-infected patients	Training, mentoring and supervision of health staff to link services and follow up patients among services (including the use of s'tool to facilitate the track of patients)	Patients co-infected regularly followed between TB and HIV services by ICAP TB provincial staff who eventually help the health staff of the facilities to track patients and to collect integrated information on co-infected patients
TB/HIV	Offer HIV counseling and testing to all TB patients at TB clinics linked to supported HIV facilities	Training, mentoring and supervision of health staff (TB services linked to HIV supported services) to offer HIV C&T to TB patients and to regularly collect their data in the TB registers	<ul style="list-style-type: none"> • Progressive increase in the number of TB patients tested for HIV at TB clinics, reaching 73% by 2009 • Good completeness of data in TB registers
TB/HIV	Strengthen screening of children in contact with adults with active TB	<ul style="list-style-type: none"> • Develop strategies to increase children evaluations • Training, mentoring and supervision of health staff to 	TB services are using simple strategies to increase the evaluation of children contacts of adults with TB using the existing national tools (PNCT 10 forms attached to TB cases treatment forms)

PROJECT PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS (FROM 2005 - 2009 UNLESS OTHERWISE NOTED)
		screen children in contact with adults with active TB	
TB/HIV	Offer technical assistance to the National TB Program at MOH and Enhance TB/HIV collaboration at all levels	Regular Technical assistance and participation to meetings at NTP-MOH	<ul style="list-style-type: none"> Regular active participation to meetings of the TB/HIV working groups at NTP-MOH (IPT-ICF subgroup, infection control and MDR-TB subgroup, pediatric TB sub-group, M&E TB/HIV subgroup) Assistance to write Global Fund Proposal, guidelines and TB/HIV tools, abstract and presentations
Laboratory	Support lab infrastructure to create conditions for HIV Prevention, Care and Treatment programs	Agree and carry out plans in coordination with MOH for lab infrastructure support.	13 laboratories infrastructure interventions (Central, Provincial, General and Rural Hospitals, and at health facilities)
Laboratory	Technical assistance for installation, implementation, and quality assurance for HIV Prevention, Care and Treatment programs	Support to Quality Assurance for CD4, Viral Load and Infant Diagnosis	In 2009, subagreement executed with NIH and all objectives achieved among goals
Infrastructure Support	Improving work conditions and increase the number of rooms in the existing MCH sector in 25 de Setembro HC in Nampula and in Jose Macamo in Maputo city to create an appropriate infrastructure to enable the establishment of two MCH/PMTCT model centers in 25 de Setembro model center in Nampula and in Jose Macamo model center in Maputo city	<ul style="list-style-type: none"> Rehabilitation of the existing MCH/PMTCT infrastructure in 25 de Setembro HC in Nampula and in Jose Macamo in Maputo city Building two MCH/PMTCT model centers (25 de Setembro model center in Nampula and in Jose Macamo model center in Maputo city) 	<ul style="list-style-type: none"> Rehabilitation concluded in Feb. 2008 for 25 de Setembro HC in Nampula Renovation and construction concluded in Sept. 2009 at Jose Macamo model center in Maputo city

PROJECT PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS (FROM 2005 - 2009 UNLESS OTHERWISE NOTED)
Public Health Evaluations	Set up and start the "Assessing Enablers and Barriers to the Implementation of More Efficacious PMTCT Regimens During Pregnancy in Mozambique" study	All ethical and scientific approvals were received as of January 21, 2010 and ICAP requested release of restricted funds from CDC. SOPs were developed, hiring and training were completed, study procedures tested in August 2010 and tools fine-tuned in September 2010. Data collection began at Maputo sites in October 2010 and in Nampula sites in February 2011	By the end of May 2011, 292 women (25% of the target sample) had been recruited and 8 women have completed the entire follow-up period

Significant Results

The indicators below do not represent a cascade from one complete cohort. Instead they come from overlapping but different cohorts of women and infants. For example, a woman testing HIV-positive at an ICAP-supported ANC clinic may go to a non-ICAP supported L&D site to deliver and therefore data on her ARV use and on follow-up of the baby would not be included.

TABLE 3: SIGNIFICANT RESULTS

PROJECT PROGRAM AREA	INDICATORS	PY1	PY2	PY3	PY4	PY5	PY6
		APRIL 2003-MARCH 2004 ²	APRIL 2004-MARCH 2005	APRIL 2005-MARCH 2006	APRIL 2006-MARCH 2007	APRIL 2007-MARCH 08	APRIL 2008-MARCH 2009
PMTCT	# of ICAP supported facilities offering PMTCT services	n/a	n/a	18	25	41	43
	# of pregnant women counseled and tested at ANC	n/a	n/a	2400	1373	55988	68378
	# of pregnant women testing HIV positive at ANC	n/a	n/a	435	140	6301	7195
	# of HIV positive pregnant women receiving ARV prophylaxis	n/a	n/a	151	812	3799	6589
	# of HIV positive pregnant women initiating ARV triple therapy	n/a	n/a	3	60	279	412
	# of HIV positive pregnant women having CD4 done	n/a	n/a	125	362	1743	2453
	# of male partners tested for HIV at ANC	n/a	n/a	0	10	329	823
	# of pregnant women counseled and tested at L&D	n/a	n/a	0	225	4534	8574
	# of pregnant women testing HIV positive at L&D	n/a	n/a	0	95	2989	6011
	# of HIV positive women receiving ARV prophylaxis at L&D	n/a	n/a	0	86	2500	5291
	# of HIV-exposed infant receiving ARV prophylaxis at L&D	n/a	n/a	0	87	2429	5772
# of HIV-exposed infant receiving CTZ	n/a	n/a	0	33	1979	4274	

² Data not collected consistently in PY1 and PY2 due to set up delay.

PROJECT PROGRAM AREA	INDICATORS	PY1	PY2	PY3	PY4	PY5	PY6
		APRIL 2003–MARCH 2004 ²	APRIL 2004–MARCH 2005	APRIL 2005–MARCH 2006	APRIL 2006–MARCH 2007	APRIL 2007–MARCH 08	APRIL 2008–MARCH 2009
	# of HIV-exposed infant tested with PCR-DNA	n/a	n/a	0	6	541	2986
TB/HIV	#HIV patients screened for TB at enrollment	n/a	n/a	n/a	587	11157	19910
	#HIV patients diagnosed with TB	n/a	n/a	n/a	39	452	765
	# of HIV patients initiated on IPT	n/a	n/a	n/a	n/a	70	304
	# TB patients tested for HIV	n/a	n/a	n/a	n/a	41	3273
	#TB patients identified HIV positive	n/a	n/a	n/a	n/a	27	1312
	#TB patients HIV positive referred to and enrolled at HIV clinics	n/a	n/a	n/a	n/a	26	1181
	#TB/HIV patients on CPT	n/a	n/a	n/a	n/a	25	1123

Presentations and Publications

PMTCT

Presentations

Development, planning, and implementation of two model PMTCT centers in Mozambique. Fatima Tsiouris, Poster presentation at PEPFAR HIV/AIDS Implementers' Meeting, Cape Town, 2006. Ivonne Butler, Judite Langa, Renata Schumacher, Irene Benech, Josue Lima, Jessica Justman, Denis Nash and Wafaa El-Sadr.

Follow the Paper Trail: Simple Assessment of PMTCT Program Operational Effectiveness. Poster presentation at PEPFAR HIV/AIDS Implementers' Meeting, June 2009; Windhoek, Namibia. Oliveira-Tsiouris F, Carter RJ, Yersin I, Tsague L, Abrams EJ.

Clinical Mentoring [poster presentation]. Presented at PEPFAR HIV/AIDS Implementers' Meeting; June 2009; Windhoek, Namibia. Also presented at: *Jornadas de Saúde*, 2009, Maputo, Mozambique; and 2nd Mozambican Pediatric Conference, 2010, Maputo, Mozambique. Yersin I, Estaleva A, Wate F, Matsinhe M-B, Mello M, Porto F, Mujacarama MLD, Lima J, Trotter D, Oliveira-Tsiouris F.

Integration of HIV-Exposed Child Care into Mother and Child Services to Maximize Prevention of Mother-to-Child Transmission Interventions in Mozambique [oral presentation]. Presented at PEPFAR HIV/AIDS Implementers' Meeting, 2008, Kampala, Uganda. Isabelle Yersin; Fatima Tsiouris; Matthew Rosenthal; Dorace Trotter; Denise Arakaki; Elaine J. Abrams.

Successful Scale-Up of AZT plus Single-Dose Nevirapine for Prevention of Mother-to-Child Transmission at Rural and Urban Primary Health Facilities in Mozambique [poster presentation]. Presented at PEPFAR HIV/AIDS Implementers' Meeting, 2008, Kampala, Uganda. Isabelle Yersin, Lilia Jamisse, Elsa Jacinto, Fatima Oliveira-Tsiouris, Daniel Shodell, Dorace Trotter, Mie Okamura, Matthew Rosenthal, Elaine J. Abrams.

Moving from Single-Dose Nevirapine (sd-NVP) to More Complex Regimens in PMTCT Programs. Mozambique, 2007 [oral presentation]. Presented at PEPFAR HIV/AIDS Implementers' Meeting, 2007, Kigali, Rwanda. Yersin, Isabelle; Langa, Judite; Langa, Marta, Tsiouris, Fatima; Adriano, Helena, Arakaki, Denise, Trotter, Dorace.

Challenges in Introducing Infant Diagnosis of HIV Using Dried Blood Spots for DNA PCR in Primary Health Care Settings [poster presentation]. Presented at PEPFAR HIV/AIDS Implementers' Meeting, 2007,

Kigali, Rwanda. Jani, Illesh; Vaz, Paula; Judite, Langa, Yersin, Isabelle, Oliveira Tsiouris, Fátima, Da Silva, Zulmira; Benech, Irene.

Provision of Pre-Selection Services (CD4 Test, HIV Staging) in ANC as a Means to Increase the Number of HIV Positive Pregnant Women on ARV Treatment [poster presentation]. Presented at PEPFAR HIV/AIDS Implementers' Meeting, 2006, Durban, South Africa. Langa J, Yersin I, Oliveira-Tsiouris F, Lima J, Justman J, El-Sadr W.

Group Pretest Counselling—A Strategy to Increase HIV Rapid Test Uptake among Pregnant Women Attending Antenatal Clinics (ANC) [poster presentation]. Presented at: PEPFAR HIV/AIDS Implementers' Meeting, 2006, Durban, South Africa. Yersin I, Oliveira-Tsiouris F, Langa J, Lima J, Justman J, El-Sadr W.

Increasing Partner Involvement in Antenatal Care Settings: Comparing Two Approaches [poster presentation]. Presented at PEPFAR HIV/AIDS Implementers' Meeting, 2006, Durban, South Africa, and IV International AIDS Society Conference, 2007, Sydney, Australia. Adriano H, Langa M, Langa O, Rurane O, Yersin I, Langa J, Oliveira Tsiouris F.

Training Material, Curriculum

Collaboration with I-TECH to develop the national PMTCT clinical mentoring training material. August 2008.

Mozambican Ministry of Health and multi-partners working group in charge of developing the “Integrated package of services and on the job training in the domain of reproductive health, maternal, child, neonatal health and youth and adolescent health. February 2011. (Pacotes Integrados de Serviços e de Formação Contínua na Área de Saúde Reprodutiva/Materna, Neonatal, Infantil e do Adolescente & Jovem).

Mozambican Ministry of Health and multi-partners working group in charge of developing the 'Training of trainers' material on PMTCT new WHO 2009 protocol. February 2011.

Mozambican Ministry of Health and multi-partners working group in charge of developing the “Family Planning and Contraceptives Strategy”. August 2010. (*Estratégia de Planeamento Familiar e Contraceção 2010 – 2015* (2020). August 2010.

TB/HIV

Presentations

E.Langa, A.Scardigli, Z.Cuna “Strategies for scaling-up TB/HIV collaborative activities at HIV facilities in Mozambique”, (accepted as oral presentation at UNION Conference, Lille, October 2011)

Langa E, Cuna Z, Scardigli A, “The TB services' contribution in the scaling up of TB-HIV collaborative activities in Mozambique” (accepted as poster discussion at UNION Conference, Lille, October 2011)

Scardigli A, Reid M, Langa E, Fernandes R, Lima J; “Expansion of Isoniazid Preventive Therapy at supported sites in Mozambique: successes and challenges” (accepted as e-poster at IAS, Rome, July 2011)

Suzue Saito, Mike Reid, Andrea Howard, Batya Elu, Denis Nash, Anna Scardigli and other TB diagnostic capacity in sub-Saharan African HIV care settings (accepted as poster at IAS, Rome, July 2011)

Prasso J, Scardigli A, El-Sadr A, Lima J, Justman J, Sultane R, Howard A; “Intensified Case Finding for Active Tuberculosis among Adults Enrolled in HIV Care and Treatment at an Urban Hospital in Mozambique”; CROI, San Francisco, February 2010.

Scardigli A., Samo Gudo P., Brower M., Coordination between TB and HIV services for the co-infected TB patient: a real challenge. UNION World TB Conference, Cancun, Mexico, December 2009.

Scardigli A, Langa J, Lima J, Vicente G, Mahomed Couto A, Rodriguez AP, Matsinhe MB, Silva Z Samo Gudo P; “Responding to the challenge of Patients’ adherence to Isoniazid Preventive Therapy: the experience of a urban ART Facility in Mozambique”; PEPFAR Implementing Meeting, June 2009, Namibia.

Scardigli A, Lima J, Fernandes R, Rodriguez AP, Nurbai C, Wate F, Samo Gudo P, Howard A; “Use of a TB Screening Tool at ART Facilities Improves TB Case Finding and Management of Co-infected Patients” PEPFAR Implementing Meeting, June 2009, Namibia.

Howard A, Flam R, Elul B, Scardigli A, Oyelendum B, Cunningham A, Hoos D, El-Sadr W. “On-site Location of TB Services Is Associated with TB Screening of HIV-infected Patients at Enrollment in HIV Care Programs in 6 Sub-Saharan African Countries”; CROI, Vancouver 2009

Scardigli A, Howard, A, Justman, J, Lobo, EC, Silva, JS, Arakaki-Sanchez, D, Fulano, R, Bento, J, Tonela, A, Samo Gudo, P: “Integration Between HIV Services and TB Services: The Experience of a Rural Health Centre in Mozambique” PEPFAR Implementing Meeting, Uganda, June 2008.

Other

Publications

Peter Young, Batya Elul, Cathy Mulsby, Dina Winchell, Brigida Mavie, Rufino Fernandes, Americo Rafi Assan, Sarah Gorrell and Denis Nash. Medical record completeness and accuracy at an HIV clinic in Mozambique, 2005-2006. J Health Inform Dev Countries 2010; 4(2):1-10.

In Rwanda, ICAP has supported the GOR to scale up HIV prevention, care, and treatment services since 2002 starting with the MTCT-Plus program. In 2003, Columbia University (CU) received CDC/GAP funding through the University Technical Assistance Program (UTAP)³ to support the Rwandan Ministry of Health (MOH) Treatment and Research of AIDS Center-Plus (TRAC-Plus) to scale up HIV care and treatment services and to support the development of HIV care and treatment protocols and training. The UTAP program further expanded to include a range of technical support to the MOH, including TB/HIV program integration, HIV-related laboratory services strengthening, expanding pediatric HIV care and treatment services, strengthening the capacity of Rwandan nurses to treat PLWHA, and public health evaluations.

These activities have supported and complemented Columbia's Multicountry Antiretroviral Program (MCAP), a PEPFAR Track 1.0-funded HIV care and treatment service delivery program, funded by CDC since 2004. MCAP now supports more than 53,937 people in care at 48 sites in nine districts, including 32,136 who have initiated ART.

ICAP's work in Rwanda is notable for its breadth, depth, and quality. As one of PEPFAR's largest implementing partners, ICAP was supporting nearly one-third of ART patients at Rwanda HIV service sites by the end of 2010 sites, and has robust hands-on experience supporting comprehensive, family-focused service delivery at the community, health facility, and district levels. ICAP has placed special emphasis on building the capacity of district health teams (DHT) to mentor, monitor, evaluate, and enhance HIV services, and has pioneered district approaches to HIV care and treatment programs. A strong focus on access, adherence, retention, patient tracking and outreach has helped to optimize the uptake of services.

In addition to supporting the delivery of clinical services, ICAP provides wide-reaching support for Rwanda's health system, from education, training, and task-shifting, to laboratory services, pharmacy services, and health facility infrastructure, to patient tracking, program monitoring, evaluation and operational research. ICAP has also been a source of programmatic innovation, piloting key approaches and initiatives, including the "MTCT-Plus" approach, successful continuous quality improvement (CQI) strategies based on ICAP's Models of Care and Standards of Care approach, TB/HIV integration, the integration of HIV and family planning services and of HIV and mental health services, and the care and treatment of prisoners, men who have sex with men (MSM), and survivors of sexual and gender-based violence (SGBV), as well as highly effective health systems-strengthening initiatives. ICAP's innovations in policy and technical areas are typically followed by the development of implementation systems—such as mentoring, M&E, and management approaches—and the subsequent scaling-up of decentralized services.

In close coordination with the CDC Rwanda office, CU has successfully partnered with some of the key Ministry of Health agencies charged with HIV/AIDS care and treatment and related services. Partners include TRAC-Plus, HIV/AIDS/STI and Tuberculosis Units, the National Reference Laboratory (NRL), the Kigali and Butare University Teaching Hospitals and Kigali Health Institute. Columbia's approach emphasized knowledge and skills transfer to government partners to ensure long term impact.

³ Cooperative Agreement 5 U62 PS222407

ICAP's approach to strengthening national capacity is informed by the following key principles:

- Collaboration with the MOH at the national, district, and site levels to ensure that local priorities are addressed, systems are strengthened, and capacity-building is decentralized;
- Careful attention to the transfer of technical capacity; and
- Emphasis on simple, standardized and technically sound approaches to assuring quality services, utilizing the principles of family-centered care, a multidisciplinary approach to service delivery, and attention to linkages and coordinated services.

ICAP's central-level technical assistance is informed by its service delivery support program. ICAP's close connection to district and site staff provide insight into the challenges and opportunities at the facility and community level and enable the testing and refining of new and innovative approaches and tools.

Systems strengthening and the transfer of skills and competencies are central components of ICAP's activities. A variety of approaches ensures capacity-building at all levels:

- ICAP staff transfers capacity to the staff and institutions of TRAC-Plus, MOH, and partners via technical working groups, meetings, trainings and institutional support.
- Secondment of staff to MOH units for the purpose of building individual and institutional capacity, supporting sub-granting to districts and other partners, and providing training in USG grants management.
- Tools and best practices are shared with MOH and other partners including USG and non-USG funded institutions.
- The capacity of district health team (DHT) and health facility staff is strengthened via educational and training activities including on-site implementation workshops, supervision and mentoring, and support for evidence-based program and performance management, as well as off-site training to enhance knowledge and skills.

Main achievements of ICAP's UTAP-supported program include:

- While the Rwandan care and treatment program was taking shape, ICAP provided support for the development of national adult HIV care and treatment guidelines, and in the establishment of the national training program.
- Support to TRAC-Plus on TB/HIV integration has resulted in Rwanda becoming an international model in the TB/HIV arena. National TB/HIV policies have been approved and TB/HIV services are well integrated. For example, by the end of 2010, 97% of all TB patients in Rwanda were tested for HIV and more than 90% of all HIV patients newly enrolled at care and treatment sites were screened for TB.
- Established a Pediatric HIV Center of Excellence, supported the development of national pediatric HIV care and treatment guidelines and related training materials
- Significantly enhanced capacity of NRL as well as the entire national lab network. For example, in 2004, the national public health laboratory system had two CD4 machines and performed approximately 16,400 CD4 enumeration assays. By 2011, the CD4 network had 31 machines at the District Hospital level (FACSCount) and two at NRL (FACSCalibur) and performed an estimated 282,000 CD4 assays.
- Subcontracted Voxiva, Inc., to introduce TRACnet, an innovative real-time reporting system, and then to transfer capacity to TRAC-Plus for the management of TRACnet.
- Supported TRAC-Plus to implement several Public Health Evaluations to inform the national HIV/AIDS program and build capacity in research

HIV Care

Support to TRAC's Care and Treatment Unit through the Provision of Long-Term and Short-Term Advisors. Columbia University provided technical, planning and professional development support to the TRAC, the department within the MOH responsible for HIV/AIDS programs, including care and treatment. A main component of this support was the placement of a long-term Technical Advisor in the TRAC Care and Treatment Unit to enhance the capacity of the Government of Rwanda to plan and manage its National ART Program. This Advisor, who started in January 2004, focused on knowledge and skills transfer to with counterparts in TRAC. Columbia University staff and consultants also provided short-term technical support in HIV clinical care in the areas of training, policy and treatment protocols.

Specific activities included:

- Establishing and updating National HIV/AIDS care and treatment policy, norms, and training curricula in the areas of ART, OI and nutrition;
- Supporting the National HIV care and treatment trainings;
- Reviewing, revising and testing standard HIV care and treatment clinical forms, reporting tools and supervision tools;
- Supporting TRAC to facilitate National ARV Technical Advisory Committee;
- Improving the technical capacity of TRAC Care and Treatment Unit to implement programs through conferences, study tours, and the purchase of professional materials and publications;
- Supporting TRAC to conduct two evaluation studies on HIV care and treatment and to develop an annual report tracking progress of the national ART scale up.
- Technical support for adult learning techniques to strengthen the cadre of national expert HIV technical trainers
- Supporting TRAC to implement a referral system for women in PMTCT services to HIV care and treatment.

Support of Pediatric HIV Treatment and Care in Rwanda. Columbia University supported TRAC and other institutions to improve national capacity to provide appropriate care and treatment to HIV-infected infants and children. The initiative focused on establishing model centers of pediatric HIV care, formalizing national policies and norms in pediatric HIV care, training experienced HIV clinicians from around the country in pediatric care, and improving identification of pediatric cases and access to care. Columbia University has extensive experience with pediatric HIV care and treatment and provided technical and managerial support to all areas of the initiative through a combination of in-country staff and short term technical advisors.

Activities included support in the revision of pediatric clinical protocols and training materials. CU significantly increased the government's capacity to conduct pediatric diagnosis through the purchase of 450 diagnostic kits to screen HIV-exposed infants. ICAP also provided financial and technical support to the pediatric model centers to establish the HIV care and treatment program. CU supported renovations to house the model centers Kigali University Teaching Hospital (CHUK), the national referral hospital in Kigali, and University of Butare Hospital, both affiliated with the Medical School. In 2010, the project supported comprehensive care for 237 HIV-infected children including 180 who were initiated on antiretroviral treatment at CHUK and for 331 HIV-infected children including 200 who were initiated on ART at Butare

University Teaching Hospital (CHUB). These sites were used as practical training sites for health care workers from around the country being trained in pediatric HIV treatment and care. CU also supported the NRL to improve its PCR testing capacity starting in 2005. NRL is presently performing PCR HIV testing on Dry Blood Spot (DBS) samples collected from HIV-exposed and other infants in need at all HIV care and treatment sites in Rwanda. Columbia University staff and consultants provided ongoing management and technical support to Treatment and Research on Aids Center (TRAC), CHUK and CHUB to enhance their capacity to institutionalize pediatric HIV care and treatment in Rwanda, including providing clinical mentoring and supervision. CHUK and CHUB senior providers also travelled to 18 District Hospital ART sites in Rwanda to provide on-site pediatric care and treatment training and supervision. Finally, ICAP is working with the MOH and NRL to improve early infant diagnosis.

Columbia University/UTAP also provided support for a Pediatric HIV Treatment and Care Initiative. The initiative focused on establishing model centers of pediatric HIV care, formalizing national policies and norms, training experienced HIV clinicians from around the country, and improving identification of pediatric cases and access to care.

Specific activities included:

- Supporting TRAC to develop national policies and protocols related to HIV pediatric care and treatment
- Developing a national pediatric training curriculum and train 200 providers from all provinces
- Support model centers of pediatric HIV care and treatment at CHUK and CHUB including additional hospital staff and operating expenses
- Continuing ART for 200 children and treating 200 new children
- Conducting ongoing follow up training, clinical supervision and quality assurance at sites
- Supporting TRAC to develop a referral and follow up system to ensure appropriate referral of HIV positive infants from health centers to pediatric care
- Supporting a laboratory technician position at the National Reference Laboratory to manage PCR testing

As a result, pediatric HIV care and treatment guidelines were developed and are being used to guide pediatric HIV care practices in the country, composition and TOR of the national TWG and of its members were developed, and the pediatric service infrastructure at CHUK and CHUB was renovated. Additionally, a model of pediatric HIV care and treatment was developed and is being used to carry out decentralized training on pediatric care for multidisciplinary team members from district.

By March 2010, 305 staff (70 doctors, 200 nurses, and 35 social workers) from 58 health facilities had been trained. By September 2008, 160 HIV-infected children were enrolled including 116 who were initiated on ART at CHUK and 293 other ones were enrolled including 161 who were initiated on ART at CHUB. By September 2008, 3027 HIV-infected children were enrolled for care at the 18 district hospitals supervised by CHUK and CHUB including 1572 who were initiated on ART.

TB/HIV

Support to the TB Unit of TRAC-Plus. Since 2004, Columbia University provided technical and administrative support to the TB Unit of TRAC-Plus to ensure effective integration between HIV and TB programs. A major component of this support was the placement of a high level TB/HIV Technical Advisor within the TB Unit to assist the Director and other key staff with policy development, program design and

coordination with the HIV/AIDS/STI Unit (HAS) of TRAC-Plus, international donor partners and other relevant organizations working on TB/HIV integration in Rwanda. This advisor, who started in August 2004, focused on knowledge and skills transfer to counterparts within the TB and HAS units so as to strengthen their capacity to manage high quality integrated programs. Columbia University also provided short term technical advisors to support TRAC-Plus on specific discrete projects related to the integration of TB and HIV programs.

Specifically, long- and short-term advisors supported:

- Create a national TB/HIV working group to ensure national level coordination in planning and evaluation of TB/HIV integrated activities
- Revision of national policies and program guidelines related to the treatment and care of TB patients with HIV, including provider initiated testing for TB suspects and patients, initiation of cotrimoxazole preventive therapy and ART as well as the development of a standardized five question checklist to screen HIV-infected people for TB and effectively link those suspected of having TB to proper diagnosis and treatment.
- Development of training materials on treatment and care for TB patients with HIV and provision of financial, logistical and technical support for the training of health care workers at district and health center level and supervision of TB/HIV integrated activities at sites.
- Development and support of the implementation of monitoring and evaluation procedures for TB/HIV integrated services.
- Development and support of two model TB/HIV outpatient centers that served as centers of excellence for integrated TB and HIV services including antiretroviral therapy
- Evaluation and documentation of the rate of TB/HIV co infection, cotrimoxazole preventive therapy and ART provision in TB patients with HIV at districts and health facilities nationwide as well as documentation and reporting on TB screening in PLWHA
- Roll out and scale up of one-stop TB/HIV services for TB patients with HIV to all TB detection and treatment centers nationwide and TB screening activities to all HIV care and treatment clinics.
- Strengthened capacity of USG and non-USG partners in TB/HIV collaborative activities through practical training, field visits and exercises on TB/HIV integration data recording and reporting;

Because of these activities, a national TB/HIV policy was developed and approved. National TB/HIV training curriculum and training materials were developed and implemented nationwide with more than 1500 providers trained. Recording and reporting tools were revised and disseminated and national TB/HIV reporting system is now functional and accurate. Two TB/HIV model centers are functional as centers of excellence for service integration and promoting one-stop TB/HIV services. TB/HIV integrated services have been rolled out and scaled up nationally.

Laboratory

Support to the National Reference Laboratory. Since 2004 UTAP through Columbia University in partnership with CDC Rwanda managed a series of activities to build the capacity of the NRL and of the national laboratory network to better support the scale- up of TB and HIV diagnostic and treatment programs. The aim of this support has been mainly to upgrade the quality of laboratory services to insure patients care and treatment based on lab confirmed diagnosis. To accomplish this, CU negotiated a sub agreement directly with NRL to enhance their capacity to implement key activities. In addition, CU hired two

high level technical advisors to support NRL, one focusing on technical issues, the other on infrastructure and management. As a result of this support, the NRL and the national network of laboratories have seen significant improvement in both infrastructure and capacity. In 2008, strengthening the TB laboratory network for TB diagnosis and quality assurance were added to the UTAP program.

Facilities renovations have been carried out for all ICAP network supported labs from the Health Centers (HC) to the District Hospitals (DH). These renovations / rehabilitations have allowed improving basic bio-safety and environmental working conditions. The KHI (Kigali Health Institute) has benefited of lab section renovation to upgrade training conditions for the students. At NRL, from 2006 to 2010, renovations have been undertaken for the main units such as, immune-virology, microbiology with a P2 TB lab, clinical pathology, offices and reception areas. Lab floor plans redesigning to improve laboratory process and work flow have been addressed in addition to infection control. In CHUK the entire lab building rehabilitation has been undertaken with the creation of a TB P2 lab and a section set up for molecular biology.

Following renovations and in conjunction with designated PEPFAR specialized purchasing partners such as SCMS, lab supplies to equip the ICAP supported labs were purchased. A standardized list of equipment, reagents and consumables has been established for the HCs and DHs in order to harmonize testing procedures and simplify equipment maintenance. At KHI new lab equipment was installed for training. At NRL new TB specialized diagnostic equipment was purchased for liquid culture and DST 2nd line (MGIT 960, Becton Dickinson) and MDR TB rapid test using PCR (HAIN). ICAP supported advocacy for a national maintenance plan to be set up and driven by the “Atelier Central de Maintenance” (ACM).

Via UTAP, ICAP supported NRL to establish and sustain national external quality control programs for CD4 (proficiency testing or retesting for 30 DHs), HIV screening based on retesting (the entire lab network) and TB diagnosis by randomly controlling site smears quality and interpretation. Integrated supervision teams using a common standardized check list has been established to oversee lab management and testing process for HIV, TB and Malaria.

To support national standardization of policies and procedures ICAP has assist NRL for the redaction of the national strategic plan and other documents such as the “Norms and standards for HC and DH” to better define the minimum package of services by tiers level. ICAP working plans have also been regularly established and updated for NRL, CHUK and CHUB to build capacities at central levels.

Training

Support to TRAC to Implement an Innovative Information System. CU provided support to GOR to improve information systems through the development of a multi-site ART client information system known as TRACnet. In conjunction with project partners and stakeholders, Columbia University and Voxiva, Inc. designed, developed and initiated this system which uses telephone and Internet-based data collection and communication systems to report data on program indicators, ARV stock levels, and CD4 and viral load test results. The initial design and initiation phase occurred in Year 2 and the focus of Year 3 was scale-up of the system to all ARV sites in Rwanda.

This activity was a supplement to Columbia University MCAP Track 1.0 mechanism, to expand ART services to the health center level in two provinces, Butare and Cyangugu. In FY2003 and 2004, USG provided technical assistance to the TRAC (MAP) for ART service delivery at the hospital level in these two provinces. With this additional support, USG completed the network by linking health center, district hospital and

provincial hospital sites. By the end of FY05, 400 patients were treated with ART at six health centers in Butare and Cyangugu provinces.

Specific activities included:

- *Establishment of Six New Sites:* Columbia supported TRAC to establish six new sites in Butare and Cyangugu. Activities included site baseline assessments, site preparation (including renovation), hiring staff, and establishing relationships with local community based programs supporting PLWHA.
- *Training:* TRAC coordinated training for key staff from the new sites, and additional staff from year one sites as necessary. These individuals participated in the National HIV Care and Treatment training which is held every two months in Kigali. Following the training, and just prior to the initiation of services at a given site, staff participated in a two-week practicum training at an experienced HIV treatment site such as CHUK, Kicukiro Health Center or TRAC Clinic. When services were launched, a Columbia technical staff member along with counterparts from TRAC spent two or more weeks on site to provide mentorship and on-site training and technical assistance. Columbia also provided on-site training and support to laboratory staff at the six sites
- *Site Supervision:* Columbia technical advisors and TRAC staff members provided ongoing support to the sites through periodic supervisory site visits to advise on all technical and management aspects.

Columbia University and Voxiva, Inc., provided support to GOR for the expansion of the TRACNet pilot, a Web- and telephone-based ART client information system, to new sites. The pilot system consists of three modules—program indicators, ARV stock monitoring, and CD4 and viral load test results. In FY2005, Columbia and Voxiva:

- Conducted training on TRACNet 1.0 for 20 new sites and provide ongoing TA to the 20 sites launched in FY2004
- Conducted initial training for analyst-level users at TRAC, CAMERWA, NRL, SIS (Health Information System), CNLS.
- Conducted initial training at two sites for users of the lab results module.
- Began using all functions of TRACNet, including data collection, communication and analysis
- Completed ICT assessment, compiled and distributed results.
- Gathered feedback from all levels of users and stakeholders on TRACNet 1.0 for future versions.

Additional activities included:

- Transfer of capacity to the TRACNet management team within TRAC through ongoing training and guidance. This management team assumed ongoing management and operation of TRACNet.
- Coordination with national and international stakeholders and partners on cross-cutting issues affecting the use and management of TRACNet, such as program indicators, patient identification and drug supply management.
- Working closely with partners on the integration of TRACNet into the day-to-day management of key institutions.

Nursing School Training. Columbia provided technical assistance to TRAC to develop specialized training curricula for ART service provision for nurses and social workers. These curricula will be incorporated into the national bimonthly classroom training for ART service providers nationwide.

ICAP received FY05 “plus up” funds for a collaborative project with IntraHealth and the Rwanda MOH Department of Nursing to design, offer and evaluate a comprehensive, competency-based HIV/AIDS prevention, care and treatment curriculum for A1 nursing students (equivalent of US LPN level) and their instructors in the five schools of nursing in Rwanda. This project was requested by the GOR in recognition of the critical role of nurses in scaling up HIV services in the country. IntraHealth coordinated the project with ICAP focusing on the HIV care and treatment elements of the curriculum. This project was linked to a larger initiative to revise the standardized national nursing school curriculum to increase the skill level of nurses in Rwanda. As a result, the nursing HIV care and treatment curriculum was finalized and adopted by TRAC-Plus and the nursing curriculum development committee, 10 nursing school lecturers and mentors were trained in August 2007, on HIV/AIDS care and treatment using the new curriculum, about 20 field trainers were trained in February 2008. In addition, the nursing HIV/AIDS competencies framework was finalized and adopted. The competencies framework is being used by the nursing schools. CU supported also the selection process of the practical training sites for A1 nurses.

Infrastructure

The infrastructure support was provided as to the central level institutions as follows:

TABLE 1: INFRASTRUCTURE SUPPORT TO CENTRAL-LEVEL INSTITUTIONS

N	BUDGET YEAR	OWNERSHIP OF BUILDING	DESCRIPTION OF RENOVATION ACTIVITIES	AMOUNT IN \$	VENDOR	FUNDING SOURCE	FINAL HANDOVER
1	2006	National Reference Laboratory	To accommodate increased quality of testing by renovated molecular biology, serology and immunology and laboratory.	72,831	GECO INTER	UTAP	Completed April 24, 2007
2	2006	Kigali University Teaching Hospital	Pediatric Model Center at CHUK: The renovation will affect space critical to effective service delivery such as waiting areas, first treatment room, lab, pharmacy and training.	131,138	GECO	UTAP	Completed July 20, 2008
3	2006	Kigali University Teaching Hospital	Extension of Pediatric EMERGENCY at CHUK: The renovation will affect space critical to effective service delivery such as waiting areas, first treatment room, hospitalization areas and oxygen system.	67,225	ECOMIN	UTAP	Completed January 26, 2009
4	2006	Butare University Teaching Hospital	Pediatric Model Center at CHUB: The renovation will affect space critical to effective service delivery such as waiting areas, first treatment room, lab, pharmacy and training.	126,492	ECAR	UTAP	Completed February 11, 2011
5	2006	Rubilizi National Veterinary Laboratory	The renovation will support Avian Influenza Project.	10,113	GECO INTER	UTAP	Completed April 15, 2008

N	BUDGET YEAR	OWNERSHIP OF BUILDING	DESCRIPTION OF RENOVATION ACTIVITIES	AMOUNT IN \$	VENDOR	FUNDING SOURCE	FINAL HANDOVER
6	2007–2008	National Reference Laboratory	To accommodate increased quality of testing by renovated biology, hematology and the sample reception.	67,000	GECO INTER	UTAP	Completed April 24, 2008

Testing

Support to the TRAC PMTCT/VCT Unit. In FY04, CU received UTAP funding to support TRAC’s the PMTCT/VCT Unit to conduct PMTCT/VCT trainings of trainers, to design an evaluation of the PMTCT program, and to pilot test a referral system between PMTCT and HIV care and treatment sites.

Columbia University, in collaboration with CDC, piloted an innovative counseling and testing strategy to move HIV counseling and testing beyond health facilities. The pilot began in one province and made testing more readily available to family members of PLWHAs enrolled in treatment programs. Counseling and testing services were offered to these family members through a combination of referral and home-based CT. This strategy identified additional family members who require care and treatment and will provide counseling support to HIV-negative family members. ICAP worked closely with CDC, the Rwandan Network of PLWHA (RRP+), National AIDS Commission (CNLS) and the MOH to build consensus. The pilot was evaluated and rapidly expanded to other provinces. Home-based CT is one of several new innovative approaches in the USG plan to enhance Rwanda’s ability to rapidly identify HIV+ individuals and link them to services.

Public Health Evaluations

With carryover funds from Year 2, ICAP and consultants from the Institute of Tropical Medicine, Antwerp and the University of Butare in Rwanda worked with TRAC to design an evaluation of the National PMTCT program. The evaluation design received approval by the Rwandan ethical committee and Columbia University’s IRB, and was successfully implemented in collaboration with TRACPlus. The evaluation identified factors affecting HIV testing uptake among pregnant women and adherence to the PMTCT protocol among HIV-positive women at 12 PMTCT clinics in Rwanda, including breastfeeding practices, infant feeding and pregnancy desires. The final report was disseminated in February 2006, and findings have been used broadly to influence national policy on the prevention of mother to child transmission including designation of infant feeding guidelines, family planning and strategies to improve and enhance adherence.

The project also funded five other public health and basic program evaluations, including:

- Evaluation of adherence to antiretroviral therapy among HIV care and treatment patients in Rwanda
- Operating characteristics of a screening instrument for the detection of active tuberculosis in adult outpatients with HIV infection in Rwanda
- Evaluation of TB screening approaches for HIV-infected children in Rwanda.
- Evaluation of smear negative pulmonary (SNPTB) and extrapulmonary tuberculosis (EPTB) diagnosis and outcomes in Rwanda

- Evaluation of accessibility and acceptability of HIV testing in TB patients

The Evaluation of Adherence to Antiretroviral Therapy among HIV Care and Treatment Patients in Rwanda PHE. This PHE used a nationally representative cross-sectional design to identify patient-level factors that are associated with sub-optimal adherence to ART at six, 12, and 18 months after initiation; and to identify site-level and contextual factors that are associated with sub-optimal adherence at six, 12 and 18 months after initiation, after adjusting for patient-level factors. For a random subset of study participants, a single non-routine blood draw was done and used for viral load assessments.

Conducted in collaboration with TRAC-Plus and the Rwanda School of Public health, multistage sampling methods with stratification by time on ART (i.e., six, 12, or 18 months prior to study start) and type of site (i.e., public or faith-based) were used to randomly select a nationally representative sample of 1,798 adults ≥ 18 years of age across 20 sites. For simplicity, the time on ART strata are referred to as “study groups” in this report (e.g. six months on ART study group, 12 months on ART study group, etc). Four study assessments were done: a) a quantitative closed-ended patient questionnaire; b) abstraction of baseline and follow-up demographic and ART-treatment information from patient records; c) viral load assessments for a sub-sample of study participants; and d) a structured site assessment questionnaire that collected information about programmatic variation that could impact adherence at the patient level. Adherence was assessed using four key outcome measures: a) patient three-day recall, b) patient 30-day recall, c) CD4 change, and d) viral load.

The study successfully estimated adherence using multiple indirect and direct measures among a nationally representative sample of patients remaining on ART for six, 12 and 18 months in Rwanda; identified patient- and site-level predictors of sub-optimal adherence and virological failure which can be used to guide program and policy decisions; and for approximately half of the population, self-reported measures of adherence were compared against viral load, providing insights into the effectiveness of potential low-cost measures of adherence which can be incorporated into routine service delivery.

Very high levels of self-reported adherence and virological suppression were observed. When combined with the positive results from a previous evaluation of outcomes of the Rwandan national program that showed 92% and 93% of patients were retained on ART six and 12 months after ART initiation, this study provides further evidence of a successful national HIV treatment program. While time on ART was not significantly associated with self-reported adherence in multivariable analysis, there was substantial variability in the relationship between patient- and site-level determinants of adherence by time on ART, suggesting the need for evolving and targeted adherence support tools and strategies as patients gain experience with ART. Additionally, several modifiable patient- and site-level variables were associated with adherence, suggesting areas for potential intervention. While peer educator programs negatively associated with adherence and viral suppression, we cannot rule out selective implementation at sites with poorer adherence. Use of simple self-reported adherence measures had a high positive predictive value for detectable viral load, but there was significant lack of specificity, indicating further field testing and refinement of short adherence recall questions may be needed.

Evaluation of the Operating Characteristics of a Screening Instrument for the Detection of Active Tuberculosis in Adult Outpatients with HIV Infection in Rwanda. This PHE aimed to evaluate and validate an effective, easy to use and inexpensive TB screening questionnaire in routine clinical care of HIV-infected patients in resource limited settings in order to improve early detection of sub-clinical TB, promote early treatment of active TB and reduce duration of infectiousness and morbidity of TB in HIV-infected

persons. This evaluation is currently ongoing. By the end of May 2011, 1320 samples (75% of the sample size) were collected.

The Evaluation of TB Screening Approaches for HIV-Infected Children in Rwanda. This PHE used a 6-month cross-sectional design and focusing on children under 15 years of age to determine the highest yield and most practical way to screen HIV-infected children for TB in outpatient HIV care and treatment clinics in Rwanda, determined period prevalence of *M. tuberculosis* disease and infection among HIV-infected children, assessed the acceptability of isoniazid prophylaxis, determined the feasibility and utility of QuantiFERON (QFT) test for diagnosing LTBI and determined the feasibility and utility of abdominal ultrasound as aid in the diagnosis of TB disease.

Between March and June 2008, HIV-infected or HIV-exposed children who were younger than 15 years of age, in three HIV/AIDS outpatient care facilities in Rwanda were enrolled in a cross-sectional study. Standardized medical history and physical examination, tuberculin skin test (TST), Quantiferon Gold In-tube interferon-gamma release assay (QFT), chest radiography, abdominal ultrasound were conducted on all enrolled children. For children who were identified as TB suspects based on symptoms suggestive of TB and/or abnormal physical examination findings and/or abnormal chest radiography findings, consecutive sputum specimens or gastric aspirates were collected for microbiological testing, including AFB smear microscopy and culture for *Mycobacterium tuberculosis*. Children were categorized into one of the following clinical case definitions based on clinical, laboratory and radiologic results: 1) definite TB case for those laboratory confirmation of TB or presence of chest radiography findings highly suggestive of TB; 2) probable TB case based on standardized clinical case definition and expert review; 3) latent TB infection (LTBI) for those with a positive TST, but otherwise unremarkable TB screening findings; 4) high risk for developing TB without evidence of LTBI for those who were contacts of an adult with TB but had a negative TST and a negative diagnostic work-up; and 5) not TB for those not meeting any of the above criteria. The prevalence of TB disease and LTBI were calculated in a descriptive analysis and calculated sensitivity and specificity of TB screening approaches, assessing both individual indicators and a variety of combination of indicators, with the goal to identify a highly sensitive approach to identify children for further work-up and in order to reliably exclude active TB in children who screened negative

The study revealed that TB prevalence among children with HIV attending outpatient facilities in Rwanda is high; leading to the conclusion that routine TB screening would represent a high-yield program activity and could be implemented by introducing a standardized TB screening approach. It also showed that using a combination of indicators, including chronic symptoms and TST, is highly sensitive and could be used to identify children needing additional evaluation for TB disease. The approach would be feasible to implement in Rwanda and can also aid in the diagnosis of LTBI to identify children with HIV for IPT. Following selection of an appropriate algorithm by the Ministry of Health with consideration of resource availability and operational feasibility, a prospective validation of the chosen TB screening approach would be recommended. The results have been used to develop the new guidelines on the diagnosis, prophylaxis and treatment of TB amongst children in Rwanda, which include IPT using INH.

The Evaluation of Smear Negative Pulmonary (SNPTB) and Extra Pulmonary Tuberculosis (EPTB) Diagnosis and Outcomes in Rwanda. This PHE aimed at describing the diagnostic steps currently used to diagnose SNPTB and EPTB in a cohort of TB patients and estimates the delay in time from clinical presentation to TB diagnosis and treatment in patients diagnosed with SNPTB and EPTB. Treatment outcomes of SNPTB and EPTB were examined in order to inform the national policy on TB diagnosis and treatment.

The proportions of TB cases that are extrapulmonary or sputum smear negative are increasing in Rwanda and diagnosing these conditions remains problematic. Although most of the clinicians interviewed (14/17) reported that they knew the national diagnostic algorithm for extrapulmonary and smear negative TB, only eight physicians reported following this algorithm. Numerous barriers to following the algorithm were reported by the physicians and included: loss of follow-up with patients, patients present with advanced disease and severe illness, and cost of medical visits and medicine. Physicians reported that additional resources would help, including availability of tests free of charge to the patient, timely histology and pathology services, and rapid diagnostic tests. Physicians thought that additional trainings that focus on diagnosis of TB among persons living with HIV/AIDS would help improve the diagnostic capabilities of physicians in Rwanda.

As originally hypothesized, results from the patient record reviews indicate that patients with extrapulmonary disease are more likely to suffer from poor TB treatment outcomes than are patients with pulmonary TB disease. However, these analyses have many limitations which need to be considered before interpreting the results. First, data were collected from only three sites which were not randomly selected and therefore no generalizations should be made beyond the facilities from which the data were collected. The epidemiology of TB was particularly unique for these three selected sites. For example, in one site (CHK) 68% of the TB cases reported were SNPTB or EPTB in 2004. Second, the sample size was originally small and there were many missing data points making it difficult to properly address some of the objectives listed in the evaluation protocol. For example, no analytic assessment of the relation between sputum smear status and treatment outcome was possible because only one smear negative case had a good treatment outcome. Third, data for treatment outcomes, the main outcome variable for these analyses, was missing for greater than 30% of the sample. Because of limited data points on treatment outcome, we had to dichotomize the treatment outcome variable as a good or poor outcome to analyze. In doing so, a poor outcome included death, treatment failure and default. Since some of the persons recorded as default may have had positive outcomes, misclassification is possible. Despite these limitations, information from this evaluation can be used to support efforts such as physician trainings aimed at achieving better diagnostics and treatment outcomes for persons diagnosed with extrapulmonary TB disease in Rwanda.

Accessibility and Acceptability of HIV Testing in TB Patients. In October of 2005, the Rwandan Ministry of Health adopted a new policy that called for routine HIV counseling and testing for all patients with TB. Prior to full implementation of the policy, this evaluation was conducted to provide baseline data to support implementation and ongoing evaluation of the new policy. The evaluation was conducted from September through October of 2005 at a geographically representative non-probability sample of 23 TB clinics. The evaluation included three components: 1) patient interviews, 2) staff interviews, and 3) a review of clinic records. Multiple data sources were collected and used in order to compare and contrast what patients told us, what staff told us, and what was documented to strengthen findings and conclusions. The main findings include:

From the patient interviews

- When HIV counseling and testing was offered the majority of patients got tested.
- Among patients with TB offered a test, tested, and willing to disclose their status, 49% reported being HIV-infected.

From the staff interviews

- Need to improve staff awareness of the relationship between TB and HIV.

- Inconsistent offering of HIV counseling and testing to patients with TB.
- Under the Voluntary Counseling and Testing model staff needed more training, staff, and physical space to routinely provide HIV counseling and testing.

From the documentation

- No documented HIV test result for almost half of patients.
- Among patients with a documented HIV test result 42% were HIV-infected.
- No documentation of HIV care and treatment (i.e., CPT or ART) for the majority of patients with TB and HIV.
- Patients with a positive HIV test were more likely to die during TB treatment than patients with a negative HIV test result.

Patients reported a high acceptance and willingness to accept HIV testing. If fully implemented, the new policy should lead to a dramatic uptake of HIV counseling and testing among patients with TB. When HIV counseling and testing was offered the majority of patients got tested. Based on our interviews with patients the most common barrier to HIV counseling and testing was TB clinic staff not offering patients a test when they were diagnosed with TB. By simply offering HIV counseling and testing to all patients with TB we would expect a dramatic increase in HIV testing among patients with TB.

Please note that all of the PHE above were conducted among African patients, so the designation of minority subjects does not apply. Women and children were included as subjects per the study design and inclusion criteria of each PHE, and research materials, such as cell lines, DNA probes, and animal models did not result from the research. The PHE protocols and resulting data are available to other investigators and may be accessed through the MOH (TRAC).

Progress During the Life of the Project

TABLE 2. PROGRESS TOWARDS ACHIEVING OF ORIGINAL AIMS

PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS
Care and Treatment	Support to TRAC's Care and Treatment Unit	<ul style="list-style-type: none"> • Support the development of a national scale up plan; • Support development of national guidelines, tools and training curriculum. 	<ul style="list-style-type: none"> • HIV care and treatment national scale up plan developed. • National HIV care and treatment guidelines developed and approved. • A two-week national training curriculum for trainers developed and training sessions carried out.
	Support of Pediatric HIV Treatment and Care in Rwanda	<ul style="list-style-type: none"> • Providing support to TRAC Plus to develop pediatric HIV care and treatment guidelines. • Provide support to TRAC Plus to formalize the national pediatric technical working group (TWG). • Renovation of pediatric service infrastructure at CHUK and CHUB and, with CDC approval, construction of new pediatric clinic at CHUK. • Providing support to CHUK and CHUB to develop a pediatric model of pediatric HIV care to support the scaling up of pediatric care at district hospitals. • Training staff on children's HIV testing including by DBS/PCR. • Training CHUK and CHUB staff on ART 	<ul style="list-style-type: none"> • Pediatric HIV care and treatment guidelines were developed and are used to guide national pediatric HIV care practices. • Composition and TOR of the national TWG and of its members were developed. • The pediatric service infrastructure at CHUK and CHUB was renovated. • A model of pediatric HIV care and treatment was developed and is being used to carry out decentralized training on pediatric care for multidisciplinary team members from district hospitals and Health centers. By March 2010, 305 staff (70 MDs, 200 Nurses and 35 Social workers) from 58 health facilities had been trained. • By September 2008, 160 HIV-infected children were enrolled, including 116 who were initiated on ART at CHUK; 293 HIV-infected children were enrolled, including 161 who were initiated on ART, at CHUB • By September 2008, 3027 HIV-infected children were enrolled for care at the 18 district hospitals supervised by CHUK and CHUB including 1572 who were initiated on ART

PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS
		<p>prescription for children.</p> <ul style="list-style-type: none"> Supporting CHUK and CHUB to mentor 18 district hospitals staff on pediatric HIV care and treatment. 	
TB/HIV	Support to PNILT	<ul style="list-style-type: none"> Provide support to TRAC-Plus for TB/HIV program and service integration 	<ul style="list-style-type: none"> National TB/HIV policy developed and approved. National TB/HIV training curriculum and training materials developed and implemented nationwide with more than 1500 providers trained Recording and reporting tools revised, disseminated and in use, resulting in a functional and accurate national TB/HIV reporting system. Two TB/HIV model centers functional as centers of excellence for service integration, promoting one-stop TB/HIV services. TB/HIV integrated services rolled out and scaled-up nationally.
Laboratory	Support to the National Reference Laboratory	<ul style="list-style-type: none"> Strengthen laboratory diagnostic capacity for TB 	<ul style="list-style-type: none"> Renovated and equipped TB sections of CHUK, CHUB and NRL. Introduced new TB diagnostic techniques (Ziehl Neelsen for TB microscopy, liquid culture, drug sensitivity testing for second line drugs, PCR test for rapid diagnosis of MDR-TB. Revised QA/QC systems for TB section of NRL.
Building Capacity in Surveillance	Support to TRAC to implement an innovative information system	<ul style="list-style-type: none"> Develop, initiate and transfer capacity for a telephone and internet- based data collection and communication system for TRAC program indicators, on ARV stock levels, 	<ul style="list-style-type: none"> ICAP contracted Voxiva, Inc. to design and support roll out of the TRAC-net system to all ARV sites in Rwanda. TRACnet was initiated in a total of 84 clinical sites. CU and Voxiva trained and transferred capacity for management

PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS
		and CD4 and viral load test results.	of the TRACnet project to TRAC.
Infrastructure Support	Improved infrastructure where appropriate and approved	<ul style="list-style-type: none"> • Infrastructure renovation of pediatric centers of excellence at CHUK and CHUB and, with CDC approval, construction of new pediatric clinic at CHUK. • Infrastructure renovation of CHUK, CHUB and NRL TB laboratories 	<ul style="list-style-type: none"> • NRL: Accommodated increased quality of testing by renovated molecular biology, serology, hematology and immunology, sample reception, and laboratory. • Pediatric Model Center at CHUK, Extension of Pediatric EMERGENCY at CHUK and Pediatric Model Center at CHUB: renovation improved space critical to effective service delivery including waiting areas, first treatment room, lab, pharmacy and training area.
HIV Testing	Support to TRAC PMTCT/VCT Unit	<ul style="list-style-type: none"> • Support for the development of national guidelines on physician-initiated testing (PIT), and on testing of pregnant women and HIV-exposed infants 	<ul style="list-style-type: none"> • National guidelines developed.
Public Health Evaluations	Support to TRAC to build research capacity	<ul style="list-style-type: none"> • Support the development, approval, implementation and dissemination of results of PHEs relevant to HIV care and treatment scale-up 	<ul style="list-style-type: none"> • ICAP supported the conduct of six PHEs: • An evaluation of the national PMTCT program • An evaluation of adherence to antiretroviral therapy among HIV care and treatment patients in Rwanda • Operating characteristics of a screening instrument for the detection of active tuberculosis in adult outpatients with HIV infection in Rwanda • An evaluation of TB screening approaches for HIV-infected children in Rwanda. • An evaluation of smear-negative pulmonary and extra pulmonary tuberculosis diagnosis and outcomes in Rwanda

PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS
			<ul style="list-style-type: none"> <li data-bbox="1024 226 1398 323">• An evaluation of accessibility and acceptability of HIV testing in TB patients

Significant Results

TABLE 3: SIGNIFICANT RESULTS

PROJECT PROGRAM AREA	INDICATORS ⁴	BASELINE (2003)	TARGETS ACHIEVED DURING THE LIFE OF THE PROJECT (2010)
Care and Treatment	n/a	No national adult HIV care and treatment guidelines existed	ICAP provided support for the development of national adult HIV care and treatment guidelines, and in the establishment of the national training program.
	n/a	No Pediatric HIV Center of Excellence in existence	Established a Pediatric HIV Center of Excellence, supported the development of national pediatric HIV care and treatment guidelines and related training materials.
TB/HIV	HIV testing of TB patients	46%	97%
	TB/HIV patients on CPT	NA	92%
	TB/HIV patients on ART	NA	49%
	TB screening of PLWHA at enrollment in HIV care	NA	90%
	n/a	Little TB/HIV integration	Support to TRAC-Plus on TB/HIV integration has resulted in Rwanda becoming an international model in the TB/HIV arena. National TB/HIV policies have been approved and TB/HIV services are well integrated. For example, by the end of 2010, 97% of all TB patients in Rwanda were tested for HIV and more than 90% of all HIV patients newly enrolled at care and treatment sites were screened for TB.
Laboratory	n/a	Limited capacity at NRL	Significantly enhanced capacity of NRL as well as the entire national lab network. For example, in 2004, the national public health laboratory system had two CD4 machines and performed approximately 16,400 CD4 enumeration assays. By 2011, the CD4 network had 31 machines at the District Hospital level (FACSCount) and two at NRL (FACSCalibur) and performed an estimated 282,000 CD4 assays.
Training	n/a	Reduced reporting capabilities	Subcontracted Voxiva, Inc. to introduce TRACnet, an innovative real-time reporting system, and then to transfer capacity to TRAC-Plus for the management of TRACnet.
Public Health Evaluation	n/a	Need for data to inform national program	Supported TRAC-Plus to implement several Public Health Evaluations to inform the national HIV/AIDS program and build capacity in research

⁴ UTAP mainly focused on central support to MOH so ICAP didn't have any indicators to report on to CDC. This arrangement was mutually agreed upon with CDC.

Presentations and Publications

Adult and Pediatric HIV Care and Treatment

Presentations

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N. Muganga, G. Tene, C. Baribwira, L. Tuyisenge, B. Sangwayire, M. Mukaminega, A. Mwali, R. Awazi, J. Gato, C. Gacharasiye, P. Hitimana, P. Kambale, L. Tsague, G. Vandebriel, T. Hategekimana, R. Sahabo, P. Twyman, E.J. Abrams. Rolling out Providers Initiated HIV Testing (PIT) for Children in Kigali University Teaching Hospital (CHUK) Pediatric Admission Ward: Approach and Outcomes. Poster presentation at the 4th National Pediatric Conference November 19th–21st 2008, Kigali, Rwanda

N. Muganga, C. Baribwira, L. Tuyisenge, G. Tene, B. Sangwayire, M. Mukaminega, A. Mwali, R. Awazi, P. Kambale, E. Nkezabera, T. Hategekimana, R. Sahabo, P. Twyman, E. Abrams. Prise en charge des enfants VIH+ au Centre d'Excellence « MPORE » du Centre Universitaire de Kigali (CHUK). Poster presentation at the 4th National Pediatric Conference November 19th–21st 2008, Kigali, Rwanda

Gilbert Tene, Landry Tsague, Narcisse Muganga, Neniling-Ay Cwinya, Cedric Yambabayire, Veronica Mugisha, Greet Vandebriel, Ruben Sahabo, Peter Twyman, Elaine J Abrams. Clinical and Immunological Outcomes among Children Enrolled in a Decentralized Pediatric HIV Care and Treatment Program in

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C. Adje-Toure¹, L. Tsague¹, S. Koblavi¹, P Rugimbanya², G. Tene¹, J. Rusine², R. Clive², J C Uwimbabazi ², R Sahabo¹, P. Twyman³, E. Munyana⁴, E. Kayirangwa⁵, J. Gatabazi² Preliminary analysis of the scaling up of Early Infant Diagnosis (EID) of HIV in Rwanda . Poster presentation, 3rd Rwanda National pediatric conference December 2007, Kigali, Rwanda

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SOUTH AFRICA

FINAL PROGRESS REPORT SEPTEMBER 30, 2003–MARCH 31, 2011

The Eastern Cape and Kwazulu Natal Provinces in South Africa have been particularly hard-hit by HIV/AIDS with an increasing antenatal HIV prevalence from 12% in 1997 to 28.6% in 2006. Added to the high burden of HIV and TB, absolute poverty characterizes the province with the lowest household income/expenditure in South Africa.

Since 2004, ICAP in collaboration with South African government institutions and departments, has supported high-quality HIV and AIDS care and treatment programs in 37 care and treatment sites and 2 TB hospitals in Eastern Cape and KwaZulu Natal Provinces.

Each site is provided individualized support based on its unique contextual characteristics. However, in all ICAP sites there are three common areas of focus that guide ICAP's work in South Africa: service delivery, capacity building including training, and program monitoring and evaluation. ICAP's approach in South Africa is guided by five principles: partnerships with Departments of Health (DOH); support for comprehensive programs, family-focused services, with special emphasis on the needs of women and children; formation and utilization of multidisciplinary teams of healthcare providers; empowering PLHA and building linkages between them and their communities; and support for wide-ranging capacity-building activities.

Laboratory

Under UTAP, ICAP supported the National Health Laboratory Service (NHLS) with an infant diagnosis program in Eastern Cape Province. Support from ICAP in South Africa focused on initiation of sample collection at clinical sites; the NHLS also asked for ICAP support to the regional PCR laboratory at Mthatha. South Africa's NHLS, a quasi-governmental or parastatal organization, is responsible for the maintenance and infrastructure of all laboratories in the country. Thus, ICAP worked with NHLS to address infrastructural issues at reference laboratories. With UTAP funds, ICAP advanced the infant diagnosis program by providing training to health care staff (primarily nurses and doctors) on collecting blood samples from infants using DBS for PCR testing. ICAP also worked with NHLS to upgrade the only PCR laboratory in South Africa, which was in Mthatha at that time. UTAP funds were used to purchase laboratory equipment to facilitate PCR testing using the DBS method.

It was important to upgrade the laboratory to meet the increase in demand for this type of testing after training of health care staff was completed. During FY05 (April 1, 2005, to March 31, 2006), 102 nurses and 43 doctors were trained at ICAP-supported facilities on DBS collection. Staff at the Mthatha laboratory were trained by the ICAP Senior Regional Lab Advisor, Dr Amilcar Tanuri, on how to process DBS specimens utilizing the recently procured equipment.

At the end of FY05 and throughout FY06 (April 1, 2006, to March 31, 2007), ICAP discussed and planned with NHLS to upgrade another laboratory in East London to support the increase in demand in testing for PCR using the DBS method. During FY06, plans to upgrade the East London reference laboratory were underway. The East London laboratory now also supports analysis of DBS specimen.

Training

Under UTAP work in South Africa, there were two principal training objectives.

Objective #1: Provide technical assistance to enhance the development of HIV care and treatment programs and support HIV/TB linkages.

During Year 3, ICAP assisted the Regional Training Center (RTC) in a range of activities aimed at supporting the establishment of a center of excellence in HIV/AIDS care and treatment. UTAP funds were used to develop patient triage and work flow protocols; new clinical forms; and an HIV coordinating committee to monitor clinical treatment outcomes at Mthatha Clinic. As a result of clinical staff training (*see Objective #2, below*), HIV clinic sites began to screen and stage HIV-infected patients for ART as well as to provide treatment for HIV-related conditions and comorbid conditions (ie, OI, STI, and TB).

Objective #2: Provide technical assistance to assess training needs, and to develop and implement an HIV/AIDS training program for clinical staff, peer educators, and community health workers on a broad range of topics related to HIV/AIDS care and treatment (ie, PMTCT, ARV management).

In Year 3, UTAP funds supported training with the following activities:

- An assessment of training and staff development needs was conducted in nine clinics and two hospitals.
- Training and residential facilities were identified for use by training participants during training programs.
- A 36-bed training and residential facility was renovated. This facility has already been used for staff and community training events. For example, the Partnership in HIV/AIDS Support Organizations (PHASO) used the facility to conduct capacity building training activities, and the RTC ran ARV orientation workshops there. The PHASO training took place beginning on June 1, 2004, and again on August 31, 2004. Refresher and new training events were also held between June 1 and August 31, 2005.
- 1,394 persons in 38 sites participated in 38 training events offered by the RTC, which were directly supported by UTAP funds. These training events were directed at doctors, nurses, pharmacists, community health workers, social workers, counselors, dieticians, administrative staff, peer workers, and PLWHA. Training topics included: ARV orientation, community health worker activities, pharmacy activities, PMTCT model of care, ARV adherence, ART management, HBC, TB/HIV services, peer educator activities, CBO involvement, and ART and social work services. These trainings took place during FY04, April 1, 2004, through March 31, 2005.
- An automated program, TIMS—which tracks training—was installed at the RTC to facilitate collection of training data for accurate reporting.

A two-day course on TB management was held in September 2006 in East London. More than 100 health care professionals participated from the Buffalo City local service area PHC clinics, health centers, and hospitals as well as from the district office, including nurses, doctors, pharmacists, and pharmacy assistants. Facilitators were all from the local health care facilities as well and included consultant physicians and the pediatrician from each of the East London Hospital Complex sites as well as doctors from the Fort Hare University/ICAP program. The agenda covered a wide range of aspects of the TB control program, including systems issues and epidemiology as well as the clinical management of the different forms of TB.

A two-day training workshop in November 2006 was conducted for clinic staff and managers involved in the implementation of the TB/HIV integration policy for the East London Hospital Complex. The workshop gave a clinical update on TB management and TB/HIV integration and had a large practical focus on recording and how to use the DOH TB cards. There were also practical exercises in completing the TB register and the different TB cards.

Public Health Evaluations

Two TB-related PHE were funded in Year 4.

- **Barriers to HIV Testing Among TB Patients in the Eastern Cape, South Africa:** A cross-sectional quantitative and qualitative design based on registry data and interviews with patients and health care workers at TB clinical facilities was proposed. The evaluation aimed to assess the proportion of TB patients tested for HIV at TB clinical facilities, the degree of variation of testing across facilities, and barriers to HIV testing among patients undergoing treatment for TB. The evaluation was expected to take place over a 14-month period (including data collection, interviews, data analysis, and dissemination of results). Interviews were to be performed with between 100 and 120 patients (≥ 18 years of age) and between 30 and 40 health care workers across 10 TB clinical facilities.
- **Operating Characteristics and Effectiveness of a Screening Instrument for the Detection of Active Tuberculosis in Adult Outpatients with HIV Infection in the Eastern Cape, South Africa:** A cross-sectional design was used to validate a tuberculosis screening instrument that includes symptom questions and measured weight. A pre–post design was employed in a secondary analysis to assess the impact of implementation of the screening questionnaire on TB detection. The evaluation aimed to assess the operating characteristics of a province-implemented screening instrument designed to detect active TB in HIV-infected outpatients as measured against a gold standard diagnosis of TB based on chest radiograph, sputum microscopy, culture of *Mycobacterium tuberculosis*, and in the case of extrapulmonary TB, isolated acid-fast bacilli or other pathologic evidence of TB. In addition, the study team also proposed an evaluation of the effectiveness of implementing the screening tool through comparing TB case detection rates for newly enrolled HIV outpatients during the six months before implementation of the questionnaire and during six months after its initiation. The evaluation targeted patients ≥ 18 years of age enrolled in clinical care at two large outpatient HIV care and treatment centers in the Eastern Cape, South Africa. From the two sites, 1,200 patients are to be enrolled.

The protocols and tools for both these studies were submitted to in-country IRB in December 2006 and were approved in February 2008. A decision was made not to pursue the “Barriers to HIV Testing” PHE: because of the protracted waiting period required to obtain necessary approvals for the protocols and from IRB and OGAC, the program felt the evaluation questions were no longer relevant.

In September 2008, ICAP submitted the study protocol for a third PHE, “Operating Characteristics and Effectiveness of a Screening Instrument for the Detection of Active Tuberculosis in Adult Outpatients with HIV Infection in the Eastern Cape, South Africa,” to CDC South Africa GAP-ADS for review. Approval for the protocol was received in March 2009, at which time the protocol was submitted to the Office of the Global AIDS Coordinator’s PHE Committee for review. Approved by this committee on March 31, 2010, this PHE is now being supported through the Multicountry Columbia Antiretroviral Program (MCAP) mechanism, effective during FY2009.

Because of the lengthy approval process, ICAP requested a no-cost extension to continue the work begun on this PHE. The protocol was approved by the Columbia University IRB on June 9, 2010. Approval by CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) was obtained in July 2010. The protocol was approved by the Eastern Cape Department of Health (ECDOH) in August 2010, and the East London Hospital Complex in November 2010. Enrollment began on March 3, 2011. Upon completion of data collection, the ECDOH will have the opportunity to review analyses as well as the final report.

Please note that all of the PHEs listed above were conducted among African patients and therefore the designation of minority subjects does not apply. Women and children were included as subjects as per the study design and inclusion criteria of each PHE, and research materials, such as cell lines, DNA probes, and animal models did not result from the research. The PHE protocols and resulting data are available to other investigators and may be accessed through the ECDOH.

Partnerships and Collaborations

Primary partners for ICAP under UTAP were:

- **Partnership in HIV/AIDS Supporting Organizations (PHASO):** ICAP was instrumental in developing this group of HIV/AIDS support organizations and participated in monthly meetings while the group established its identity, mission, goals, and future work. One of PHASO's initial objectives was conducting capacity building training; PHASO worked closely with RTC to conduct training for a total of 1,394 health care staff in 38 DOH sites in the Eastern Cape. This early health systems strengthening work served as a model for support for improving health systems in South Africa. Although ICAP did not have a formal subagreement with PHASO, it participated in its training and general meeting activities throughout the UTAP funding period. In addition, ICAP worked with PHASO to develop its annual workplans and training needs assessments and to plan and implement training activities; ICAP also helped monitor and evaluate annual workplans and planned activities.
- **Regional Training Center:** During the contract period, the RTC was involved in a range of activities aimed at supporting the establishment of a center of excellence in HIV/AIDS care and treatment. UTAP funds were used to develop patient triage and work flow protocols; new clinical forms; and an HIV coordinating committee to monitor clinical treatment outcomes at the Mthatha Clinic. As a result of clinical staff training, the HIV clinic sites began screening and staging HIV-infected patients for ART as well as providing treatment for HIV-related conditions and comorbid conditions (ie, OI, STD, and TB).
- **Eastern Cape Department of Health:** The ECDOH was (and remains) an important partner for planning and implementing UTAP-funded activities. The PHE for a TB screening tool was made possible, in part, by the ECDOH's shared vision of the tool's value and department's agreement to pilot the TB screening tool in Eastern Cape facilities. ICAP signed a formal MOU with ECDOH for broad support to health care facilities within the Eastern Cape Province. UTAP funds resulted in broad reexamination of HIV-related guidelines—specifically, TB-related guidelines and protocols.
- **National Health Laboratory Services:** The NHLS was an important partner in helping ICAP upgrade the reference laboratory in Mthatha to support a greater demand for PCR testing of infants via DBS. ICAP worked closely with NHLS to coordinate training for laboratory staff and to procure necessary equipment for testing. NHLS and ICAP also worked closely to upgrade the reference laboratory in East London to support the greater demand for PCR testing and CD4 testing. As for the Mthatha lab, this

collaboration involved coordinating training of laboratory staff and advising on procurement of necessary equipment to support greater HIV testing.

Progress and Results

TABLE 1. PROGRESS TOWARDS ACHIEVING ORIGINAL AIMS

PROJECT PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS
Laboratory	<ul style="list-style-type: none"> Work with NHLS to upgrade Mthatha reference laboratory to support greater demand for PCR testing using the DBS method. 	<ul style="list-style-type: none"> Coordinate training of laboratory staff. Advise on procurement of necessary lab equipment to support PCR testing. Plan with NHLS on expansion of lab services to other reference labs in EC. 	<ul style="list-style-type: none"> 102 nurses and 43 medical doctors were trained on the DBS specimen collection method. All Mthatha laboratory technicians were trained to process DBS specimens. NHLS procured additional lab equipment to support greater ability to support higher volumes of PCR testing.
Training	<ul style="list-style-type: none"> Build health care staff capacity to provide high-quality HIV care and treatment services. 	<ul style="list-style-type: none"> Assist in coordinating and implementing training activities with RTC and PHASO Assist in monitoring and evaluating effectiveness of training and help conduct training needs assessments. 	<ul style="list-style-type: none"> During the first and second year of funding, more than 1,300 health care staff were trained in providing higher-quality HIV care and treatment services. Lab technicians were trained on processing HIV-related testing specimens (<i>see above</i>).
Public Health Evaluation	<ul style="list-style-type: none"> Carry out two PHE: Evaluating the Effectiveness of a TB Screening Tool and Identifying Barriers to HIV Testing Among TB Patients. 	<ul style="list-style-type: none"> Protocol development for the two PHE. Obtain IRB and OGAC approvals. Hire and train staff. Implement PHE. 	<ul style="list-style-type: none"> PHE to identify barriers to HIV testing among TB patients was cancelled with CDC approval. Protocol for TB screening PHE was developed and approved by IRB and OGAC.

TABLE 2: SIGNIFICANT RESULTS

PROJECT PROGRAM AREA	INDICATORS	BASELINE	TARGETS ACHIEVED DURING THE LIFE OF THE PROJECT
<p>Laboratory</p>	<ul style="list-style-type: none"> • Improved processing of HIV-related specimens. • Improved turnaround times for HIV-related tests. • Number of pieces of lab equipment available for HIV testing and analysis. 	<ul style="list-style-type: none"> • <100 HIV-related specimens tested and analyzed monthly. • 4 to 6 weeks turnaround time for processing CD4 tests and other HIV-related tests. • Mthatha laboratory had basic lab equipment to process and analyze only a limited amount of HIV-related tests. 	<ul style="list-style-type: none"> • Steady growth in testing over the life of the project. Currently more than 1,000 HIV-related tests are processed monthly. • Turnaround times, declining steadily over the life of the project, are now 1 to 2 weeks for results. Labs send results directly to health care personnel (doctors and nurses) via SMS text, e-mail, and fax. • Mthatha lab's equipment has been upgraded and increased to support greater demands for testing and analysis. This has decreased turnaround times as more equipment is available to process greater volumes of tests.

PROJECT PROGRAM AREA	INDICATORS	BASELINE	TARGETS ACHIEVED DURING THE LIFE OF THE PROJECT
Training	<ul style="list-style-type: none"> • Number of health care staff trained on HIV management of patients. • Number of lab technicians trained on processing HIV-related testing, including PCR testing. 	<ul style="list-style-type: none"> • < 50% of health care staff knew how to stage and treat HIV-infected patients at targeted facilities. • < 30% of lab technicians knew how to accurately process HIV-related tests in a timely fashion within the Mthatha reference laboratory. • < 10% of lab technicians knew how to process PCR tests using the DBS method within the Mthatha laboratory. 	<ul style="list-style-type: none"> • 100% of health care staff providing HIV care and treatment services are now provided with annual training, refresher courses, and mentorship on HIV patient management. • 100% of lab technicians assigned to process HIV-related tests are fully trained in all HIV-related tests. In addition, >80% of lab technicians not assigned to process HIV-related tests are trained to act as back-up in case demand increases. • 100% of lab technicians are trained to process PCR tests with the DBS method.
Public Health Evaluation	<ul style="list-style-type: none"> • IRB approval received. • OGAC approval received. • Discussion of analysis of results held. 	<ul style="list-style-type: none"> • Protocol for two PHE developed and reviewed within ICAP. 	<ul style="list-style-type: none"> • Protocol for one PHE (TB screening tool) was approved by IRB in South Africa and Columbia University and by OGAC. • As of March 2011, the PHE for the TB screening tool was underway, but funds for it was transferred to another funding mechanism (MCAP) to allow the PHE to be completed.

Presentations and Publications

Laboratory

PCR Testing Utilizing DBS Method/Processing Test and Analysis [training curriculum for laboratory technicians].

Training

Management of the HIV Positive Patient [training curriculum].

PCR Testing Utilizing the Dried Blood Spot Method [training curriculum].

Between 2003 and 2011, ICAP provided technical assistance to Tanzania’s Ministry of Health via the CDC-CU UTAP cooperative agreement. Through collaborative planning with CDC Tanzania and MOH, ICAP’s UTAP-supported activities evolved over the duration of the grant to match national needs and priorities, encompassing a wide range of activities designed to promote access to high-quality HIV/AIDS prevention, care, and treatment services in Tanzania.

Initially focusing on PMTCT-Plus services in Tanzania during Years 1 and 2, ICAP UTAP-supported activities expanded in Years 3 and 4 to include comprehensive family-focused care and treatment and the launching of a national pilot on early infant diagnosis of HIV. UTAP support also allowed the initiation of PMTCT services in Zanzibar, as well as family-focused HIV care and treatment programming. Year 5 marked two new national initiatives: the enhancement of palliative care services, with a focus on the management of HIV-related malignancies; and the establishment of a national program for early infant HIV diagnosis services. In Year 6 and then through several no cost extensions, ICAP helped MOH to conduct a public health evaluation on male circumcision.

PMTCT

In December 2004, ICAP staff presented at the National HIV/AIDS Care, Treatment and Support Conference, held in Arusha, Tanzania, on the experience of ICAP’s MTCT-Plus Program. This roundtable discussion provided a forum on the usefulness of a PMTCT-Plus model of care in Tanzania and the appropriate design of such a model in the local context. Technical experts from ICAP and from MTCT-Plus sites in Kenya gave presentations on the application of this model. Over 200 people attended the roundtable session and participated in discussion on such topics as pediatric care, acceptability of men receiving services, and ensuring quality services for pregnant women and their children within the context of care and treatment.

Tanzania

Initial support for PMTCT-Plus services focused heavily on the strengthening of PMTCT programming in Kagera and Mwanza regions. Major partners, Kagera Regional Hospital, and Bugando Medical Centre, served as two of the four original pilot PMTCT sites established in 2000. Other partners included Medecins du Monde (Mdm) who worked in partnership with Kagera Hospital staff on increasing facility capacity for HIV/AIDS services. Additionally, TADEPA, a local NGO that provides HIV/AIDS care in the region, supported a satellite clinic located on the Kagera hospital campus that offered voluntary counseling and testing (VCT) and HIV care. TADEPA has a trusted reputation in the community for providing high quality, confidential care to people living with HIV and, consequently, facilitated an ideal entry point for enhanced HIV/AIDS services.

Overall, ICAP supported infrastructure upgrade of the PMTCT clinics, training of personnel in VCT, PMTCT and ART, and establishing effective referral mechanisms between the ANC and HIV/AIDS clinic. ICAP also supported the establishment of PMTCT monitoring and evaluation systems at the clinics.

Zanzibar

In July 2004, ICAP technical advisors attended an official Zanzibar Ministry of Health and Social Welfare (ZMOHSW) planning session on a broad-based initiative of HIV/AIDS services for the islands. ICAP was designated as a partner with the ZMOHSW to assist with two main objectives: (1) to help develop a national infrastructure for the provision of PMTCT services and (2) to help establish and implement PMTCT programs. Joint discussions and assessments between ZMOHSW officials, CDC/Tanzania, and ICAP staff identified the need for technical assistance with design of technical guidelines, training curricula, and training materials and with establishment of steering and technical committees. With HIV/AIDS service delivery, ICAP staff assisted with designing infrastructure upgrades of planned PMTCT sites, training of staff in VCT and PMTCT care, and provision of clinical mentoring. At the request of ZMOHSW officials and CDC/Tanzania, ICAP also provided technical assistance on initial preparations for scaling-up PMTCT sites to include ARV provision for pregnant women and their family members.

Family-Focused HIV Care and Treatment Services

ICAP supported comprehensive HIV care and treatment activities at five sites under UTAP support—three in Tanzania: Kagera Regional Hospital,⁵Bugando Medical Centre, and Sekou Toure Regional Hospital;⁶ and two in Zanzibar: Chake Chake Hospital and Mnazi Mmoja Hospital. UTAP supported the implementation of expanded service delivery for HIV-infected pregnant women and their families, as well as for the general population of people living with HIV/AIDS. Program planning entailed the design of both a PMTCT-Plus model of care and a broader component tailored to other populations. UTAP funds were used to augment numerous aspects of site service delivery including: increasing the number of trained VCT hospital counselors, renovating existing infrastructure to house a HIV/AIDS clinic, upgrading TADEPA facilities to accommodate increased patient flow, training of clinical personnel and health workers, and strengthening capacity of community based workers to increase local awareness of expanded HIV/AIDS services and to provide home-based care. Activities also supported the referral and follow-up mechanisms of HIV-positive pregnant women and their family members for care and treatment.

Supportive supervision visits by ICAP staff, MOH, and ZMOHSW clinical advisors included clinical mentoring on HIV care and ART, support for the consistent use of cotrimoxazole prophylaxis among HIV-exposed infants and HIV-infected patients, particularly those diagnosed with TB, and troubleshooting of service delivery systems. Three hospitals received support for renovations in the care and treatment clinic, laboratory, and/or pharmacy. ICAP procured medical furniture, equipment and HIV medications. A strategic community mobilization plan for increased HIV counseling and testing was developed in Kagera region. Opt-out counseling and testing in adult and pediatric inpatient wards and diagnostic counseling and testing in the outpatient department were implemented. All five facilities implemented paper-based systems

⁵ In Year 4, support for care and treatment activities at Kagera Regional Hospital was transferred to MCAP. Data from KRH is included in this report because they reflect the work of Year 3 UTAP-supported activities as well as the contributions of senior level technical assistance in Year 4.

⁶ During Year 4, support for Sekou Toure Regional Hospital was transferred to other partners due to regionalization of USG ART partners.

for collection of national care and treatment indicators. Four hospitals were upgraded to electronic data collection systems for monthly reporting and monitoring of services.

While strengthening health worker skills in care and treatment service provision is important, increasing knowledge and capacity related to identifying HIV-infected individuals, retaining them in care, and monitoring their progress is also essential to maintaining a strong continuum of comprehensive HIV/AIDS services. ICAP supported formal didactic training using national curricula, as well as on-site clinical mentoring and supportive supervision in the areas of HIV counseling and testing, adherence to care and treatment, and use of computer-based patient tracking systems.

Laboratory

In Years 4-6, UTAP funds supported the development and implementation of a national pilot program on infant HIV diagnosis using dried blood spot sampling and DNA PCR. The success of the pilot encouraged the expansion of services throughout the country. While ICAP continued to support policy and guidelines development at the national level, early infant diagnosis services were strengthened under UTAP support in four major sites in the Lake Zone: Bugando Medical Centre, Sekou-Toure Hospital, Makongoro Health Centre, and Kagera Regional Hospital. These sites served as hubs for the collection of DBS samples at maternal child health clinics in the Lake Zone. ICAP's activities included:

- **Policy:** Consensus building with MOH and local facility partners was essential to establishing services. Standards and protocols for laboratory and clinical services were developed, implemented and revised based on pilot experience.
- **Laboratory support:** Bugando Medical Centre's laboratory was enhanced according to international standards for quality assurance of laboratory services. Renovations allowed for integration of three additional rooms within existing laboratory space to implement DNA PCR testing: 1) pre-PCR room; 2) DNA extraction room; and 3) post-PCR room. ICAP also provided the complete range of equipment necessary for DNA PCR testing: biosafety cabins, hematology mixer, PCR machine, microplate washer and reader, water distiller, and laminar flow PCR workstation.
- **Implementation support:** The implementation of early infant diagnosis required careful identification of all entry points for HIV-exposed infants at each facility, strengthening of referral linkages between these entry points and HIV testing services, support for HEI follow-up, design of HEI registers for monitoring and tracking, and development of protocols for parent counseling and support.
- **Training and clinical mentoring:** ICAP supported orientation, training, and clinical mentoring for clinicians at HEI entry points and pediatric care and treatment venues (inpatient and outpatient). Clinicians were trained in the specialized counseling required for early infant diagnosis, as well as in pediatric HIV/AIDS care and treatment, including ART.
- **Logistics:** Health workers were trained in collection, transportation and tracking of DBS specimens.

Following these preparatory stages, early infant diagnostic services were initiated in October 2006 and created a platform of support for expansion of EID services. As of March 2011, 6,194 HIV-exposed infants (HEI) had been cumulatively enrolled in care.

Palliative Care and Management of HIV-Related Malignancies

In Years 5-6, ICAP partnered with the Ocean Road Cancer Institute (ORCI) to support the management of HIV-related cancers and to lead the national strategy in scaling up palliative care services to the districts. ICAP supported the care and treatment of individuals with HIV-related malignancies in two ways: via clinical mentoring at ORCI and the provision of technical assistance for decentralization of HIV-related oncology services to Bugando Medical Centre. Dr. Donald Abrams, a clinical expert in HIV-related cancers including Kaposi's sarcoma, provided technical assistance as a consultant to ORCI on clinical co-management of HIV and malignancies. Linkages between oncology services and the HIV/AIDS care and treatment clinic were strengthened, and the lessons learned from these activities helped inform the basic program design for decentralized services in the country. Activities also supported the modification of national policy guidelines on management of HIV related Kaposi's sarcoma.

ICAP and ORCI convened an expert committee to support the development of national palliative care guidelines for HIV/AIDS. The existing multidisciplinary country palliative care team (a national body that includes representation from NACP) played a critical role in this process and formed the basis of the committee's deliberations. The committee built upon an existing proposal which included four basic elements: 1) incorporation of palliative care into the existing health care system; 2) training of health workers in pain management and palliative care; 3) providing for palliative care support in both the home and health facility; and 4) increasing facility capacity to offer appropriate specialist back-up support for home-based care services.

Following the design of service delivery tools, such as registration logs, patient assessment tools, medication charts, and monthly summary forms, ORCI led the expansion of services to include district-level training to increase integration of services within care and treatment programs. ICAP supported training-of-trainers for 27 individuals from ORCI and Council Health Management Teams who will implement additional trainings within their respective districts. The rollout of pain management and symptom control included training on handling and use of opiates and development of policy guidelines on use of morphine.

Public Health Evaluation: Situational Analysis of Male Circumcision

Adult male circumcision has been shown in clinical trials to reduce the risk of HIV infection among men by at least 50%. Prior to the introduction of male circumcision as an additional prevention strategy, the Ministry of Health in Tanzania requested a study of the acceptability and feasibility of male circumcision in selected areas of Tanzania. The findings from the situation analysis will inform the plans for introducing MC services in Tanzania.⁷

⁷ ICAP had a sub agreement funded by the U.S. Centers for Disease Control to support the Government of Tanzania's National Institute of Medical Research in Mwanza (NIMR) to conduct a public health evaluation regarding knowledge and attitudes about male circumcision. The protocol and six consent forms were first approved by the CU IRB in September 2008. Five consent forms for this study were then modified and approved by the CU IRB in October 2008. These were consent forms for male survey participants, female survey participants, key informants, health workers and heads of health facilities. The sixth consent form, to be used with focus group participants, was not modified from the initial version approved in September 2008. NIMR's Ethics Committee had already

Through individual and group interviews with populations living in selected areas, knowledge, attitudes, practices and cultural issues related to MC were investigated to evaluate the acceptability of MC as an additional HIV prevention strategy among men. A total of 601 individuals (mean age=36-45 years) were involved in the interview. Of the 601 respondents, 88.2% admitted that circumcision is a common practice among their communities; with 71.4% preferring traditional male circumcision (TMC). The most frequently mentioned reason for preference to traditional MC was that the respective boy receives advices on the role and responsibilities in the society and his responsibilities as a husband. A total of 253 (42.1%) of the respondents knew at least one advantage of clinical male circumcision (CMC). However, CMC was considered to be against tradition and culture and may results into respective boy being discriminated by the society. Only 228 (37.9%) of the respondents were aware of the occurrence of adverse events associated with TMC. A total of 405 (67.4%) of the respondents were of the view that it is important to create linkages between traditional and clinical male circumcisers.

The study recommended that traditional and clinical circumcision practices should be allowed to continue and operate as parallel systems that will complement each other; An Act to formally regulate traditional circumcision should be enacted; the government should develop clear guidelines on the referral linkages between traditional and clinical practitioners; traditional surgeons should be required by law to be registered; Government should make available to traditional surgeons surgical tool kits and appropriate medical supplies sustainably; Registered traditional practitioners should be trained on good circumcision practices; and the male circumcision should be voluntary and observe human rights and individual consent.

Please note that the PHE listed above was conducted among African patients and therefore the designation of minority subjects does not apply. Women and children were included as subjects; and research materials, such as cell lines, DNA probes, and animal models did not result from the research. The PHE protocols and resulting data will be available to other investigators through the MOH.

Partnerships and Collaborations

Tanzania – Kagera Region

- Regional Medical Officer's Office of Kagera
- Kagera Regional Hospital
- Medecins du Monde (Mdm)
- TADEPA

Tanzania – Mwanza Region

- Regional Medical Officer's Office of Mwanza
- Bugando Medical Center
- Sekou Toure Regional Hospital

approved the study in March 2008. Additional reviews by the CDC then followed, requesting minor revisions in the sample size, and clarifications about recruitment methods and approach to treating sexually transmitted infections prior to study implementation. These revisions were adopted and NIMR's Ethics Committee approved them in April 2009. ICAP planned to initiate the study in May or June 2009, as soon as the final version of the protocol and consent forms had been reviewed and approved by the CU IRB. In June 2009, ICAP learned that NIMR had begun data collection without informing ICAP and had completed approximately two thirds of data collection. ICAP verified that the participants signed consent forms that had been modified by NIMR. Despite this complication, the study was completed by NIMR.

- Makongoro Health Clinic
- TADEPA

Tanzania – Dar es Salaam Region

- Muhimbili National Hospital
- Ocean Road Cancer Institute

Zanzibar

- Ministry of Health and Social Welfare of Zanzibar
- Zanzibar AIDS Control Program
- Mnazi Mmoja Zonal Hospital
- Chake Chake Regional Hospital

Progress and Results

TABLE 1: PROGRESS TOWARDS ACHIEVING ORIGINAL AIMS

PROJECT PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS
PMTCT	To establish quality PMTCT services in 23 facilities in Pwani, Kagera and Kigoma regions	a. Develop district PMTCT plans in collaboration with Council Health Management Teams.	a. All 22 district and 15 Faith Based Organization sites have PMTCT district scale up and implementation plans. i
		b. Conduct training of PMTCT counselors in new national protocol and guidelines.	b. 67 trained in PMTCT as managers and 203 people trained as implementers.
		c. Initiate/strengthen partnerships with CBOs for tracing of patients lost to follow up.	c. 18 Family Support Groups and 23 Peer Educator Groups established in CTC and PMTCT sites to support adherence to care and follow up of clients.
		d. Ensure opt-out counseling and testing is conducted at PMTCT sites.	d. Opt out testing is the national guideline and over 95% of all women uptake VCT in PMTCT sites.
		e. Ensure provision of ARV prophylaxis, according to revised national guidelines, to all eligible HIV-positive pregnant women and their newborns.	e. 45 sites implemented the new efficacious regimen which became national policy by mid-2008.
		f. Ensure registration and follow-up of HIV-exposed infants.	f. 105 sites have EID tracking and follow up systems in place.
		g. Ensure male partner and family member testing is conducted.	g. 15,824 male partners tested. Multiple approaches are being used. Partner invitation letters are implemented at all sites.
		h. Strengthen referral networks between PMTCT and the Care and Treatment clinics.	h. Nurses/peer educators escort clients if CTC on site. PMTCT registers now record CTC number allowing for nurses to educate clients at every encounter.
		i. Ensure the HIV-positive pregnant mother and families receive adherence support.	. All HIV+ mothers receive adherence support and counseling through ANC, and where Family Support Groups are present mothers receive immediate connection with a Peer Mother and the family support group meeting monthly or bimonthly

PROJECT PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS
Early Infant Diagnosis	To support the national roll-out of EID programs at up to 27 facilities in ICAP-supported regions, as well as through design of national policies and tools and trainings.	a. Establish EID program in 27 centers	a. EID now implemented in more 160 sites .
		b. Training-of-trainers training technicians in DNA PCR and DBS methods for other USG partners and staff from zonal laboratories.	b. Over 600 people trained, including ToT for 23 USG implementing partner staff.
		c. Procurement of laboratory reagents and DBS consumables.	c. Completed. Leveraged Clinton Foundation to procure lab reagents for entire country.
		d. Lead development of National EID Guidelines	d. National EID Guidelines completed under ICAP leadership.
		e. Strengthening of monitoring and tracking system of blood samples and of patients.	e. ICAP has procured motorcycles to facilitate DBS sample transportation. Moreover, ICAP supports 22 districts to transport samples using travel vouchers.
		f. Conduct quality assurance of DBS samples.	f. External quality control program with CDC Atlanta is in place and ongoing each quarter. Retesting program in BMC is established and ongoing.
		g. Supervisory visits by nurse coordinator and senior CU staff.	g. Supervision is conducted quarterly by ICAP EID team in collaboration with the trainers and onsite mentoring with ICAP field officers.
		h. Joint meetings between ID, CTC and PMTCT centers.	h. EID is funded through agreements in all 22 district grants on mainland and ZACP on Zanzibar as well as all 15 faith based and private sites. The MOHWS also coordinates quarterly EID meetings with all key stakeholders at the national level including PMTCT, RCH, lab units and implementing partners.
		i. Quality assurance visits by CU New York staff.	i. Quarterly QA visits from Regional ICAP Lab Advisor and MOHSW PCR technician
Palliative Care	To assist the Ministry of Health and Ocean Road Cancer Institute with the decentralization of HIV care services for HIV-related malignancies, primarily Kaposi's sarcoma and cervical cancer.	a. Train HCWs in care and screening of HIV-related malignancies.	a. 27 people from the four referral hospitals received a two week training based on a palliative care and pain management training module supported by ICAP..
		b. Implement services at Bugando Medical Centre and other referral hospitals.	b. Palliative care teams formed at each of the referral hospitals and staff have been trained and equipped.
		c. Conduct quarterly supportive supervision.	c. Quarterly supervision conducted by ORCI and ICAP staff.
		d. Train TOTs in palliative care	d. 27 HCWs from 4 referral hospital were trained in palliative care and pain management.
		e. Expand training at regional and district levels.	e. 324 HCWs/community volunteers trained

PROJECT PROGRAM AREA	OBJECTIVES	KEY ACTIVITIES	SIGNIFICANT PROJECT ACHIEVEMENTS
Training	To enhance human resource capacity in the provision of HIV/AIDS care and treatment services through training.	a. Conduct training in adherence counseling.	a. 150 providers trained in adherence counseling.
		b. Conduct training in computer literacy for selected site personnel.	b. 40 trained in computer literacy as part of standard M&E training for site level staff.
		c. Conduct training in PICT.	c. 115 HCWs trained in PICT.

TABLE 2: SIGNIFICANT RESULTS

INDICATORS (2004-2008)	
PMTCT	
Number of women received PMTCT testing and counseling at antenatal clinic/labor and delivery	60,192
Number of HIV-infected mother-infant pairs received ARV prophylaxis	2,159
Number of providers trained in national PMTCT curriculum	554
Number of facilities providing PMTCT services	127
HIV EARLY INFANT DIAGNOSIS	
Number of HIV-exposed infants receive DNA PCR testing	1,178
Number of HIV-exposed infants receive cotrimoxazole prophylaxis at 4-6 weeks of age	1,161
Number of HIV-infected infants enrolled in care and treatment	499
Number of trainers trained on implementation of early infant diagnostics programming	23
Number of laboratory technicians trained in DNA PCR method using DBS technique	7
PALLIATIVE CARE	
Number of cumulative patients receiving palliative care services for HIV-related disease	1,208
health care workers trained as trainers on palliative care	27
Number of health care workers trained on screening and care of HIV-related malignancies	27
TRAINING	
Number of providers trained in adherence counseling as part of national ART training	150
Number of health care workers trained in computer literacy	40
Number of providers trained in national provider initiated counseling and testing curriculum (PICT)	115

Publications

Nuwagaba-Biribonwoha H, Werq-Semo B, Abdallah A, Cunningham A, Gamaliel JG, Mtunga S, Nankabirwa V, Malisa I, Gonzalez LF, Massambu C, Nash D, Justman J, and Abrams EJ. Introducing a multi-site program for early diagnosis of HIV infection among HIV-exposed infants in Tanzania. *BMC Pediatr.* 2010 Jun 17;10:44.

Mboera, L.E.G., Massaga, J.J., Senkoro, K.P., Kilima, S.P., Mayala, B.K., Msovela, J., Shayo, E.H. & Mwangi, J.R. (2009) *Challenges and Opportunities for the involvement of Traditional Practitioners in scaling up of Safe Male Circumcision in the Context of HIV Prevention in Tanzania.* National Institute for Medical Research, Dar es Salaam, Tanzania

Tanzania National Guidelines for Infant Diagnosis of HIV, 2008.

Zambia is one of the countries in sub-Saharan Africa most affected by the HIV/AIDS pandemic. Of its 12 million people, an estimated 1.1 million are living with HIV, and HIV prevalence is 15.2% in the 15–49 age group and 19.3% among pregnant women. In 2008, according to WHO/UNICEF estimations, 95,000 children aged 0–14 were living with HIV, 34,000 of them in need of ART; 18,040 (53%) of these children had initiated therapy.

In March 2005, ICAP began UTAP activities in Zambia with the aim of supporting the design, implementation, and evaluation of three pediatric Centers of Excellence (PCOE) in partnership and close collaboration with the Department of Pediatrics and Child Health at the University Teaching Hospital (UTH) in Lusaka Province, Livingstone General Hospital in Southern Province, and Ndola General Hospital in Copperbelt Province.

The UTH PCOE was the first such center in Zambia and now contains the most comprehensive program elements and organizational structure of any institution of this type, providing a comprehensive program for infants, children, and adolescents with HIV. Services include routine HIV testing for all inpatients, daily care and treatment clinics, an extensive adolescent HIV care program, neurodevelopmental assessment and treatment services, community outreach, and extensive laboratory services, including infant diagnosis using HIV DNA PCR, viral load and resistance testing, CD4 testing, and microbiology.

The goals of the PCOE are to serve as 1) model facilities to provide state-of-the-art comprehensive pediatric HIV care and treatment services; 2) referral centers for district clinics; and 3) training and dissemination centers for Zambia. ICAP supported PCOE design and implementation by serving as a technical assistance provider, supporting capacity building activities (including training and staff augmentation), renovating some facilities, and procuring limited, targeted items.

ICAP's objectives in supporting the PCOE through UTAP included:

- Increasing PCOE capacity to provide comprehensive HIV case management and pediatric care and treatment services.
- Ensuring that key services such as clinical care, OI prophylaxis, and adherence and nutritional counseling and support are integrated with ART provision.
- Identifying and engaging HIV-exposed infants into follow-up services.
- Conducting early diagnostic testing of HIV-exposed infants using PCR technology.
- Increasing antibody testing of children >18 months of age.
- Implementing routine provider-initiated HIV testing for hospitalized pediatric and neonatal patients.
- Instituting a comprehensive patient follow-up and defaulter tracing program.
- Linking and collaborating with community and faith-based organizations to support complementary and supportive services.

- Integrating child development and neurodevelopment assessments and interventions into routine care for HIV exposed and HIV-infected children.
- Improve the physical and emotional well-being of HIV-infected children and their caregivers and families.
- Supporting comprehensive, efficient, and effective monitoring and evaluation systems.
- Implementing training, supervision, and capacity building in pediatric HIV/AIDS management, including ART.
- Enhancing and expanding human capacity resources to support a multidisciplinary team of HIV pediatric and family care providers.
- Cooperating and collaborating with other HIV care and treatment activities in the respective PCOE provinces.
- Disseminating lessons learned, models, and best practices to multidisciplinary teams and sites implementing pediatric HIV/AIDS programs.

Progress and Results

ICAP has helped strengthen Zambia's PCOE pediatric HIV care and treatment activities with programs and activities initiated under the UTAP award: capacity building activities, including training and staff augmentation; by serving as a technical assistance provider; and by procuring targeted commodities. Throughout the project period, with technical support from ICAP, UTH PCOE has demonstrated best practices of care and treatment for HIV-infected and HIV-exposed children by successfully enhancing health care worker capacity to offer quality, comprehensive pediatric services. UTH PCOE continues to effectively deliver and coordinate pediatric HIV care and treatment services and will continue to serve as a national model site beyond March 31, 2011. In addition, UTH supported Livingstone to expand pediatric HIV activities after the model developed at UTH.

- Provided quality and comprehensive pediatric care and treatment service.

As of March 31, 2010, the PCOE have 14,210 HIV-infected children currently in care,⁸ with 6,573 children receiving ART and regularly attending clinic. From the start of funding in April 2005 through March 31, 2010, 4,563 children newly initiated ART, and a total of 60,884 children received HIV antibody testing—13,215 (21.7%) of them with positive test results. Since 2007, when the laboratory at PCOE began providing PCR testing, 7,580 HIV-exposed children < 18 months of age received virologic testing, and 2,700 (35.6%) had a positive PCR result.

- Served as a regional facility to initiate, stabilize, and provide ongoing care for children infected with HIV.
- Initiated and stabilized newly diagnosed children from the catchment area and refer to lower level facilities.
- Cared for complex and difficult pediatric cases, including cases involving treatment failure, cancers, and neurodevelopmental conditions.

⁸ These figures reflect children receiving services as of the end of data collection in March 2010. They are slightly different from the figures in Table 1, which reflect the cumulative number of children who ever received care during the entire period 2005–2010.

- Expanded the infant diagnosis program with PCR-based HIV testing for all children < 18 months of age identified in the inpatient testing program.
- Enhanced and strengthened pediatric the patient tracking and monitoring system via:
 - Development of M&E tools to capture necessary information for clinical decision making,
 - Linking and centralizing all databases and patient tracking systems to improve coordination.
 - Implementing appointment and follow-up systems to identify patients at risk of being lost to follow-up.
- Formalized PCOE linkages and relationships with adult ART facilities in PCOE catchment areas to enhance coordination and referral of care and treatment programs for caregivers and family members.
- Continued to enhance skills and capacity of PCOE teams by conducting regular implementation workshops to discuss new or existing PCOE program elements in need of enhancement and facilitating trainings to support program areas in need of strengthening.
- Instituted the first routine HIV testing program for pediatric inpatients, which became the national model, leading to guideline development.
- Worked with UTH to develop and publish national guidelines, develop a national training and train health care workers throughout the country so that PITC became the national norm for children.
- UTH Center also became a national training center for health workers on pediatric and General Hospital family centered HIV care.
- Many of the staff at UTH became national trainers.
- Work in Zambia became a model internationally influencing WHO guidance and many national policies (*see the paper below*). All documents developed for PITC guidance in Zambia are on the ICAP Web site.

TABLE 1: SIGNIFICANT RESULTS

INDICATORS (FOR OCTOBER 1, 2005–MARCH 31, 2010, UNLESS OTHERWISE INDICATED)	RESULT
Number of health care workers who successfully completed an in-service ART training program.	1042
Percent of health facilities that provide virological testing services for infant diagnosis for HIV-exposed infants, on site or via DBS.	100%
Number of individuals who received testing and counseling services for HIV and received their test results.	60,884
Cumulative number of eligible children provided with a minimum of one care service. ⁹	39,008
Cumulative number of HIV-infected children receiving a minimum of one clinical service.	27,033
Number of HIV-positive clinically malnourished clients who received therapeutic or supplementary food.*†	134
Percent of HIV-positive patients who were screened for TB in HIV care or treatment settings, as an average value for UTH PCOE (29%) and Livingstone PCOE (20%).*	24.5%
Percent of HIV-positive patients in HIV care or treatment (pre-ART or ART) who started TB treatment.*	13.5%
Cumulative number of children with advanced HIV infection newly enrolled on ART.	4,563
Cumulative number of children with advanced HIV infection ever receiving ART.	13,992

* PEPFAR indicators reported from October 1, 2009, to March 31, 2010, only.

† UTH only.

⁹ Reflects HEI plus HIV-infected children in care.

Publications

Kankasa, C, Carter RJ, Briggs N, Bulterys M, Chama E, Cooper ER, Costa C, Spielman E, Katepa-Bwalya, M'soke T, Chole K, Ou CY, Abrams EJ. Routine offering of HIV testing to hospitalized pediatric patients at University Teaching Hospital (UTH), Lusaka, Zambia: acceptability and feasibility. *J Acquir Immune Defic Syndr.* 2009;51(2):202–208. DOI:10.1097/QAI.0b013e31819c173f. PMID:19504732.

No further publications are anticipated.

