



# HIVCore HIGHLIGHTS

DECEMBER 2012

## HIVCORE AND OPERATIONS RESEARCH

### A LETTER FROM THE DIRECTOR

Over the past decade, unprecedented progress has been made in the scale-up of HIV treatment, care and support, and prevention of mother-to-child transmission (PMTCT) programs. Yet substantial coverage gaps remain. Many patients are not receiving the recommended standard of care; and resources are increasingly constrained. Operations research (OR) and program evaluation can play a significant role in ensuring efficient and effective service delivery, scaling up to reach more clients on a broader geographical scope, enhancing quality of care, and improving the health outcomes and health systems in developing country settings. With funding from the U.S. Agency for International Development (USAID), the Population Council in partnership with the Futures Group, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), and the University of Washington (UW) are responding to these critical service delivery issues through HIVCore. Our multidisciplinary central HIVCore team includes staff from the Council and its three partners (see Box 1 on page 2 for more details).



*Samuel Kalibala (second from right), HIVCore Project Director, oversees the operations research project.*

#### INSIDE

HIVCore’s Approach to OR and Program Evaluation .....	5
Focus Topic: PMTCT in the Era of Option B+ .....	8

## BOX I HIVCORE TEAM MEMBERS

Team Member	Organization	Role
<b>Samuel Kalibala</b>	<b>Population Council</b>	<b>Project Director</b>
Karen Foreit	Futures Group	Senior Advisor for Operations Research, Analysis & Utilization
Stephen Gloyd	UW	Technical Advisor
Sherry Hutchinson	Population Council	Knowledge Management Specialist
Nrupa Jani	Population Council	Research Coordinator
Naomi Rutenberg	Population Council	Technical Advisor
Deborah Weiss	Population Council	Project Manager
Godfrey Woelk	EGPAF	Technical Advisor

### WHAT IS HIVCORE?

HIVCore, a Task Order under USAID's Project SEARCH, seeks to improve the efficiency, effectiveness, scale, and quality of HIV and AIDS treatment, care and support, and PMTCT programs by conducting OR and program evaluation, promoting utilization of results, and building local capacity to conduct this work.

### WHAT IS OPERATIONS RESEARCH?

OR identifies service delivery problems and tests new programmatic solutions to overcome them through the application of systematic research methods. "HIV-Core's approach to operations research and program evaluation" on page 5 provides more details on OR and how it is used.

### WHY HIVCORE NOW?

The President's Emergency Plan for AIDS Relief (PEPFAR) started in 2004 and has supported rapid scale up of services. PEPFAR is now moving out of the emergency mode and into the stage of consolidation to achieve optimal program effectiveness and efficiency. It is also focusing on integration and coordination with other health areas to respond to the comprehensive needs of populations affected by HIV. There are many lessons that can be learned from past, present, and

future PEPFAR activities to inform the development of more effective, efficient, and integrated HIV programming.

Treatment, care and support, and PMTCT services still have many gaps that need to be addressed. Considerable proportions of people testing HIV positive do not seek care in a timely manner. Those who do enroll into care may not receive CD4 testing to assess their eligibility for ART in a timely manner and some eligible

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*There are many lessons that can be learned from past, present, and future PEPFAR activities to inform the development of more effective, efficient, and integrated HIV programming.*

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people may not be started on HAART. In addition, retention on HAART is not well documented. The adoption of the World Health Organization's new PMTCT guidelines has raised a host of questions related to cost, infrastructure requirements, implementation challenges, and the potential for population-level prevention impact (for more on this topic, see page 8).

OR can address these challenges in PMTCT and HAART programming by analyzing routine service statistics, conducting special program evaluations to

document best practices, and designing studies to test various service approaches.

## WHO IS HIVCORE?

Each member of the HIVCore consortium provides global technical leadership in HIV and AIDS OR and program evaluation, service delivery, and strategic information. The Population Council is devoted to slowing the spread of the HIV epidemic as well as enabling people to reduce the negative impact of HIV on their lives by conducting OR and evaluations to strengthen HIV and AIDS and reproductive health services throughout the world. Futures Group has

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*...HIVCore will reach a wide audience; encourage the use of research results and practical tools; and impact treatment, care and support, and PMTCT activities at the global, country, and program levels.*

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fostered the field in using data for decision making in international development and public health, including HIV and AIDS, and has developed innovative information and communication technology solutions for HIV programs in resource-poor settings. EGPAF has conducted extensive research, advocacy, capacity building, and strengthening health systems for the delivery of comprehensive HIV services to women, children, and their families throughout the world with the ultimate goal of eliminating pediatric HIV infection. UW and its affiliated institutions have developed interdisciplinary HIV and AIDS research, education, and service programs in most regions of the developing world.

## WHAT DO WE HAVE PLANNED?

HIVCore is undertaking three sets of activities. We are conducting secondary analysis of existing site and client data from treatment, PMTCT, and pediatric HIV services in select PEPFAR countries, which will offer insights into the operational and client behaviors that have contributed to the success and gaps in the uptake and effectiveness of services. For example, in Cote d'Ivoire we are analyzing PMTCT "cascade" data to identify the bottlenecks and obstacles to effective out-

comes. Data will be used to improve loss to follow up and ensure that mothers and newborns receive timely treatment and prophylaxis.

We are also conducting original research studies in select PEPFAR countries addressing the quality, accessibility and effectiveness of treatment, PMTCT, and care and support programs. In, Uganda, for instance, we are examining different models of task shifting for delivering ART at the community level. Findings will provide a basis for scale up of effective models to increase access to treatment. For a complete list of HIVCore activities, please see page 4.

Finally, through various media including policy briefs, newsletters, presentations, and peer-reviewed publications, HIVCore will reach a wide audience; encourage the use of research results and practical tools; and impact treatment, care, and support, and PMTCT activities at the global, country, and program levels.

All HIVCore studies will engage local researchers and program managers from inception through dissemination to build capacity and foster utilization of results.

We will be sure to keep you updated of the progress of our activities through this newsletter. This first issue of *HIVCore Highlights* focuses on describing HIVCore, our approach to OR and program evaluation (page 5), and the newsletter's first focus topic, PMTCT in the era of Option B+, and highlights the possible knowledge gaps and operational questions that each country will need to consider for successful implementation (page 8). Later editions of our newsletter will focus on the service delivery challenges and OR questions related to treatment and care and support as well as updates and findings from our activities.

To ensure you are among the first to know the latest from HIVCore, or if you have any questions, please contact us at [info@hivcore.org](mailto:info@hivcore.org).

Sincerely,



Samuel Kalibala, HIVCore Project Director

## WHAT IS HIVCORE DOING NOW?

HIVCore is initiating a range of operations research and program evaluations addressing HIV treatment, care and support, and PMTCT. The following studies are in various phases of development. To learn more please contact us at [info@hivcore.org](mailto:info@hivcore.org).

Country	Study Synopsis
<b>PMTCT</b>	
Cote d'Ivoire	Identify reasons for delays and loss to follow-up among each step of the PMTCT cascade and potential interventions to improve program effectiveness.
Cote d'Ivoire	Test the operational efficacy of the WHO Option B approach compared to standard PMTCT practice.
Kenya, Malawi, Rwanda, Swaziland	Assess retention across the PMTCT cascade in countries implementing WHO Option A, B, and B+.
Zambia	Evaluate the effectiveness of the PMTCT program in reducing newborn infection rates and improving child survival.
<b>Care and Support</b>	
Ethiopia	Determine whether a psychosocial intervention for marginalized young people improves their responsiveness to HIV programs.
Ghana, Uganda, Zambia	Describe and identify factors affecting access to and use of HIV services for persons with disabilities as well as determine the gaps and opportunities within these services.
Kenya	Evaluate a computerized alert and reminder system for medical providers to improve tuberculosis case finding and therapy for adults living with HIV.
Mozambique	Identify facilitators and barriers to linking HIV-positive patients to care, and evaluate interventions to address these barriers.
Global	Develop an interactive tool to assess care and support practices in facility and community settings.
<b>Treatment</b>	
Kenya	Determine whether a cell-phone based counseling intervention can increase early initiation of and adherence to HAART among HIV-positive pregnant women.
Uganda	Compare different models of task shifting for delivering ART at the community level in terms of efficiency, patient satisfaction, knowledge, retention, and cost.
TBD	Conduct secondary analyses of patient-level data on operational factors and client behaviors that contribute to the uptake and effectiveness of HIV treatment services.
<b>Pediatric</b>	
Tanzania	Determine whether SMS reminders and notifications to mothers increase the proportion of HIV exposed infants tested for HIV.

# HIVCORE'S APPROACH TO OPERATIONS RESEARCH AND PROGRAM EVALUATION

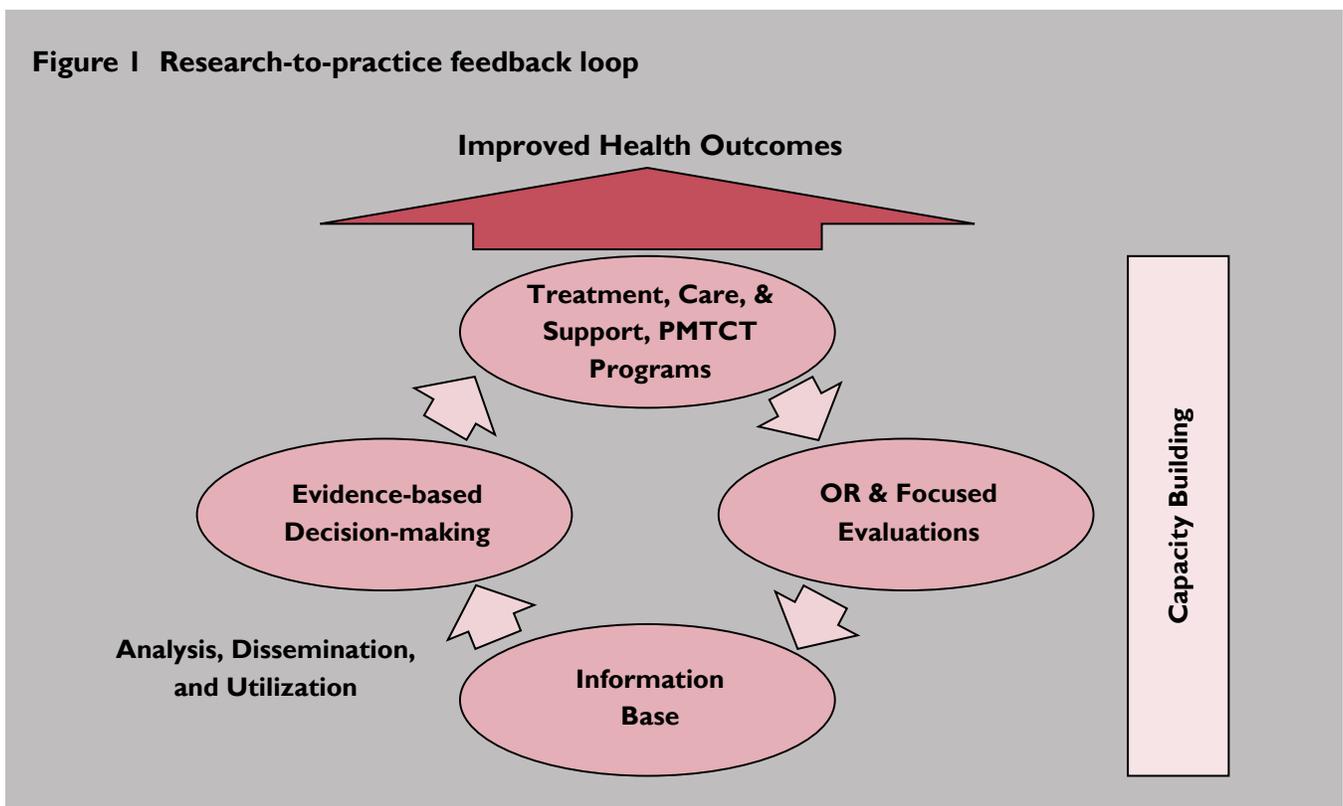
**H**IVCore is working with program managers, policymakers, and researchers to identify program successes and gaps and to design and test approaches to improve services. To achieve this, we are implementing a diverse portfolio of operations research (OR) and program evaluations that integrates capacity building and research utilization, as shown in Figure 1.

## WHAT IS OPERATIONS RESEARCH?

Through the application of systematic research methods, OR increases the efficiency, effectiveness, and

quality of services delivered by providers and the availability, accessibility, and acceptability of services to users.<sup>1,2</sup> OR informs and enhances planning, coordination, training, and evaluation and provides managers, administrators, and policymakers with needed information to improve or scale up existing activities and to plan future ones. (See Box 1 for examples of how HIVCore partners have used OR to improve HIV programs in a variety of contexts.)

OR is a process, a way of identifying and solving program problems. As currently applied in many health and development fields, OR can be defined as a continuous process with five basic steps:



1. Problem identification and diagnosis
2. Strategy selection
3. Strategy testing and evaluation
4. Information dissemination
5. Information utilization<sup>1</sup>

HIV and AIDS OR focuses on the day-to-day activities or “operations” of programs. These operations are under the control of managers and administrators working in the public and private sectors. Examples include training, hospital and clinic activities, community- and home-based care, and community mobilization activities.

HIVCore’s application of OR not only links research to practice, but also practice to research. We begin by determining whether a particular problem can be

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*OR identifies service delivery problems and tests new programmatic solutions to overcome them.*

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solved through common sense or experience, through the application of lessons learned from past OR studies or reanalysis of existing data. Only after these alternatives have been explored do we design studies involving new data collection.

## WHAT IS PROGRAM EVALUATION?

Evaluation asks the “so what” question: did the program accomplish what it intended to accomplish?

HIVCore focuses on program evaluation, which is the systematic assessment of the processes and/or outcomes of a program with the intent of furthering its development and improvement. Program evaluation seeks to answer questions related to program design, management, and operational decision making such as: how it is being implemented; how it is perceived and valued; what the program has achieved; what its unintended consequences are (whether positive or negative); and whether expected performance benchmarks are being met.

## BOX 1 HOW OPERATIONS RESEARCH CAN IMPROVE HIV PROGRAMS

### **Time to ART initiation reduced in Mozambique.**

University of Washington assisted the National Health Institute to pilot test point-of-care CD4 testing in seven sites across Mozambique, reducing the complexity of patient flow, improving access to CD4 results by 63 percent, and cutting time from enrollment to ART by 50 percent.<sup>3</sup>

### **Adherence to antiretroviral medication.**

The Population Council implemented some of the first intervention studies on adherence to ART medication, determining that provision of and adherence to ART regimens in India, Kenya, Thailand, and Zambia were hindered by a lack of knowledge among providers and communities, a lack of linkages between services, and stigma surrounding HIV. These studies have contributed to the design, strengthening, and expansion of ART services.<sup>4</sup>

### **Increased identification of HIV infection in maternity units in Swaziland.**

Elizabeth Glaser Pediatric AIDS Foundation conducted OR to evaluate the introduction of a nurse-midwife targeted on-site training intervention at selected maternity units in Swaziland, determining that the intervention significantly increased the identification of HIV infection and maximized the provision of PMTCT interventions.<sup>5</sup>

## METHODS, INDICATORS, AND DATA SOURCES

HIVCore is using secondary analyses of existing data sets (e.g., clinical records, program registers) as well as primary data collection. To maximize efficiency of research efforts, preference will be given to

*HIVCore is testing promising service delivery approaches to enhance pediatric HIV testing and treatment.*



utilizing existing program data collection procedures whenever possible. Where these data are inaccessible, incomplete, or problematic for other reasons, we will look for quick and low-cost data collection methods—for example, client intercept surveys—to supplement.

To demonstrate the effect or value of program interventions, HIVCore will include indicators of service delivery and/or client outcomes. These will generally be measured on a broad, programmatic level, for

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*HIVCore's application of OR not only links research to practice, but also practice to research.*

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example, obtaining a key service such as HIV or CD4 testing, initiating pre-treatment care, initiating treatment, and retention on treatment. Unless the data are readily available, HIVCore studies will not attempt to measure or evaluate clinical outcomes such as a fall in viral load, rise in CD4 count, or gain in body weight.

By implementing focused, high-quality OR and program evaluation, building local capacity to identify operational issues and conduct appropriate research to answer them, and widely disseminating the findings of

our work, HIVCore will help program managers and policymakers decide between alternative courses of action, identify and take advantage of opportunities, and find solutions to service-delivery problems that limit program effectiveness and efficiency.

## ENDNOTES

<sup>1</sup>Andrew A. Fisher, and James R. Foreit. (2002) *Designing HIV/AIDS Intervention Studies: An Operations Research Handbook*. New York: Population Council. Available at: <http://www.popcouncil.org/pdfs/horizons/orhivaidshndbk.pdf>.

<sup>2</sup>Nancy Padian et al. (2011) "Implementation science for the U.S. President's Emergency Plan for AIDS Relief (PEPFAR)," *Journal of Acquired Immune Deficiency Syndromes* 56(3):199–203.

<sup>3</sup>Ilesh Jani et al. (2011) "Effect of point-of-care CD4 cell count tests on retention of patients and rates of antiretroviral therapy initiation in primary health clinics: an observational cohort study," *Lancet* 378: 1572–1579.

<sup>4</sup>Avina Sarna and Scott Kellerman. (2010) "Access to antiretroviral therapy for adults and children with HIV infection in developing countries: Horizons studies, 2002–2008," *Public Health Reports* 125(2): 305–315.

<sup>5</sup>Mary P. Kieffer et al. (2011) "Improved detection of incident HIV infection and uptake of PMTCT services in labor and delivery in a high HIV prevalence setting," *Journal of Acquired Immune Deficiency Syndromes* 57(4): e85–91.

## FOCUS TOPIC

# PMTCT OPERATIONS RESEARCH IN THE ERA OF OPTIONS B AND B+

In 2010, the World Health Organization (WHO) released new guidelines for the prevention of mother-to-child transmission (PMTCT) of HIV. The guidelines emphasize providing antiretroviral therapy (ART) to all HIV-positive pregnant women who are eligible for treatment<sup>1</sup> for their own health. They also include two antiretroviral (ARV) prophylaxis regimens (Option A and Option B) for women who do not meet these criteria, as well as for their infants, during pregnancy and a limited time postpartum. Since then a new option, Option B+, has emerged and proposes a universal regimen for all HIV-infected pregnant women regardless of their CD4 count for the duration of their pregnancy and continuing ART for life postpartum. All three options, if implemented appropriately, are efficacious in PMTCT.<sup>2</sup> However, they involve notable differences in cost, infrastructure requirements, implementation, and the potential for population-level prevention impact (see Table 1).

To date, of the 22 focus countries of the UNAIDS Global Plan for 2015<sup>3</sup>, 15 have chosen Option A, 5 have chosen Option B, and 1 has chosen Option B+<sup>4</sup> (one country, Angola, has not adopted any options yet; see Table 2, page 10). The situation however is changing rapidly, as currently there are eight more countries planning to implement or considering Option B+.

In April 2012, WHO advocated the widespread adoption of Option B+ over the other options.<sup>5</sup> Option B+ simplifies the decisions around the PMTCT regimen



*Retention in PMTCT is one key area HIVCore is investigating. Analysis of existing data will identify barriers to facilitators of retention, and this information will be rapidly disseminated so that findings can be utilized by program managers to strengthen service delivery as soon as possible.*

(e.g., same regimen can be used for every HIV-infected woman throughout pregnancy), reduces the need for CD4 testing, may provide health benefits to the mother (e.g., decreases risk of contracting an opportunistic infection such as tuberculosis, which may reduce HIV-related deaths), and may reduce

**Table 1 Overview of PMTCT ARV options**

		<b>Woman receives:</b>		
		<b>Treatment (for CD4 count ≤350 cells/mm<sup>3</sup>)</b>	<b>Treatment (for CD4 count &gt;350 cells/mm<sup>3</sup>)</b>	<b>Infant receives</b>
Option A <sup>a</sup>	Triple ARVs starting as soon as diagnosed, <i>continued for life</i>	<i>Antepartum:</i> AZT starting as early as 14 weeks gestation <i>Intrapartum:</i> at onset of labour, single-dose NVP and first dose of AZT/3TC <i>Postpartum:</i> daily AZT/3TC through 7 days postpartum		Daily NVP from birth until 1 week after cessation of all breastfeeding; or, if not breastfeeding or if mother is on treatment, through age 4–6 weeks
Option B <sup>a</sup>	<i>Same initial ARVs for both<sup>b</sup>:</i>			Daily NVP or AZT from birth through age 4–6 weeks regardless of infant feeding method
	Triple ARVs starting as soon as diagnosed, <i>continued for life</i>	Triple ARVs starting as early as 14 weeks gestation and <i>continued intrapartum and through childbirth if not breastfeeding or until 1 week after cessation of all breastfeeding</i>		
Option B <sup>+</sup>	<i>Same for treatment and prophylaxis<sup>b</sup>:</i>			Daily NVP or AZT from birth through age 4–6 weeks regardless of infant feeding method
	Regardless of CD4 count, triple ARVs starting as soon as diagnosed, <sup>c</sup> <i>continued for life</i>			

Note: “Triple ARVs” refers to the use of one of the recommended 3-drug fully suppressive treatment options. For the drug abbreviations in the table: AZT (azidothymidine, zidovudine); NVP (nevirapine); 3TC (lamivudine).

<sup>a</sup>Recommended in WHO 2010 PMTCT guidelines.

<sup>b</sup>True only for EFV-based first-line ART; NVP-based ART not recommended for prophylaxis (CD4 >350).

<sup>c</sup>Formal recommendations for Option B+ have not been made, but presumably ART would start at diagnosis.

Source: WHO. (2012) “Use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: Programmatic update.” Geneva: WHO.

transmission to sexual partners.<sup>4</sup> Challenges with this option—and to some extent, with Option B—include the significantly higher costs against a flat or decreasing funding base; a limited number of facilities with ART services compared to PMTCT services; and shortages of qualified health personnel to deliver the regimen. Despite the recent adoption of the WHO-recommended regimens, there are limited operational data on their implementation and effectiveness outside of clinical trials, and no data from clinical trials or program implementation on the use of Option B+.

A major challenge in implementing PMTCT programs, regardless of regimen used, is ensuring access to services for all pregnant women. To reach the goal of virtual elimination of pediatric HIV infection, population coverage and uptake need to be over 90 percent.<sup>3</sup> Currently, global coverage of HIV-positive pregnant women receiving effective regimens for PMTCT (A, B, or B+) is only 57 percent.<sup>6</sup> Identification of effective strategies to reach all women is thus another critical need.

**Table 2 Global plan focus countries by options<sup>a</sup> (as of 30 September 2012)**

<b>Option A</b>	Cameroon <sup>b</sup>	Namibia <sup>f</sup>
	Democratic Republic of the Congo	Nigeria <sup>c</sup>
	Ethiopia	South Africa
	Ghana	Swaziland <sup>b</sup>
	Kenya <sup>d</sup>	Tanzania
	Lesotho	Zambia <sup>e</sup>
	Mozambique <sup>b</sup>	Zimbabwe
<b>Option B</b>	Botswana	Côte d'Ivoire
	Burundi	India <sup>g</sup>
	Chad	Nigeria <sup>c</sup>
<b>Option B+</b>	Malawi	Uganda <sup>h</sup>

<sup>a</sup>Angola has not fully adopted any of the options; <sup>b</sup>Conducting pilot studies; <sup>c</sup>Has adopted Option A and B; <sup>d</sup>Planning to implement Option B+; <sup>e</sup>Considering switching to Option B+; <sup>f</sup>Adopted Option A, but has plans to switch to Option B+; <sup>g</sup>Is currently shifting to Option B; <sup>h</sup>Launched Option B+ nationwide on 14 September 2012

Updated adaptation from Business Leadership Council and UNICEF, in collaboration with the Clinton Health Access Initiative, "A business case for options B and B+ to eliminate mother to child transmission of HIV by 2015," revised July 2012.

As countries consider and implement their options, knowledge gaps and operational questions can be addressed through the collection and analysis of more complete and longitudinal patient- and facility-level

*A major challenge in implementing PMTCT programs, regardless of regimen used, is ensuring access to services for all pregnant women.*

data. These include acceptability of the regimens; drug adherence; retention in care; and health system capacity. Important operational research questions include:

- How will facilities with PMTCT programs but no ART services ensure functional linkages such that HIV-infected women will receive the drugs they need?
- To what extent will healthy young pregnant women, with no symptoms of illness, accept and adhere to ART drugs immediately upon diagnosis, throughout pregnancy, and then for life?
- What is the best way to measure adherence in routine practice, given rare access to viral load monitoring?
- How can the current staffing levels and configurations in the maternal and child health centers be organized to manage the additional tasks and workload involved in initiating all HIV-infected pregnant women on lifelong ART?
- What are innovative strategies at the health system, community, and individual levels that can increase retention and minimize loss to follow-up, which are particularly problematic during pregnancy and the postpartum period?
- How can women and their infants be tracked across services delivery sites (i.e., antenatal care, maternal and child health clinics, HIV clinics) and different locations over time to ensure they receive an uninterrupted continuum of care and services?
- Would the introduction of mobile clinics to remote and poorly-served areas be a feasible, efficacious, and cost-effective mechanism to deliver ART services to all HIV-infected pregnant women?



Currently, global coverage of HIV-positive pregnant women receiving effective regimens for PMTCT (A, B, or B+) is only 57 percent.<sup>7</sup> Identification of effective strategies to reach all women is critical.

- What is the effect of using Option B/B+ regimens on the stigma experienced by pregnant women?
- In the current environment of declining resources, how can equity in access to ART be achieved?

If implemented efficiently and effectively, Option B+ has the potential to accelerate the progress toward elimination of pediatric HIV infection and improve women's health. However, there are many critical questions that need high-quality, data-derived answers

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*As countries consider and implement their options, knowledge gaps and operational questions can be addressed through the collection and analysis of more complete and longitudinal patient- and facility-level data.*

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to support Ministries of Health to make informed decisions. HIVCore will provide answers to some of these questions through secondary analysis of data and original research studies in a variety of settings.

## ENDNOTES

<sup>1</sup>Defined as CD4 cell count of < 350 cell/mm<sup>2</sup> or clinical stage 3 or 4.

<sup>2</sup>World Health Organization (WHO). (2010) "Antiretroviral drugs for treating pregnant women and preventing HIV infections in infants: recommendations for a public health approach." Geneva: WHO. <http://www.who.int/hiv/pub/mctct/guidelines/en/> Accessed February 28, 2012.

<sup>3</sup>Joint United Nations Programme on HIV/AIDS (UNAIDS). (2011) "Countdown to zero: Global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive." Geneva: UNAIDS.

<sup>4</sup>Business Leadership Council and UNICEF, in collaboration with the Clinton Health Access Initiative. (Revised July 2012) "A business case for options B and B+ to eliminate mother to child transmission of HIV by 2015."

<sup>5</sup>WHO. (2012) "Programmatic update: Executive summary of the use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants." Geneva: WHO. [http://www.who.int/hiv/PMTCT\\_update.pdf](http://www.who.int/hiv/PMTCT_update.pdf). Accessed April 3, 2012.

<sup>6</sup>UNAIDS. (2012) "Together we will end AIDS" [http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/20120718\\_togetherwewillendaids\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/20120718_togetherwewillendaids_en.pdf). Accessed July 19, 2012.

## HIVCore HIGHLIGHTS

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