



FAMILY HEALTH INTERNATIONAL'S SITE IDENTIFICATION AND DEVELOPMENT INITIATIVE (SIDI)

KEY POINTS

- *Eight new sites in Africa and Asia will be ready for HIV prevention research by 2010. The sites are currently conducting innovative HIV incidence studies and behavioral studies on multiple and concurrent partnerships.*
- *Each site has clinical research facilities equipped to international standards and local staff who are fully trained in clinical research methods.*
- *Partnerships are in place with community members and stakeholders who understand and embrace the goals of HIV prevention research. Each site can identify, recruit, and enroll people at higher risk of HIV infection.*

A worldwide research effort is under way to address the huge, unmet need for HIV prevention. Three main biomedical strategies are being pursued to prevent HIV acquisition: (1) orally delivered antiretroviral agents, (2) HIV prophylactic vaccines, and (3) vaginal microbicides (i.e., gels or other topically applied products to stop sexual transmission of HIV). To date, research has eliminated some products from the pipeline of possibilities and identified others that look promising. Much research remains to be done to confirm the effectiveness of new products.

The successful conduct of this wide array of HIV prevention research requires the participation of tens of thousands of women and men at risk for HIV infection. Ultimately, success hinges on the development of multiple international research sites that must:

- Be able to identify, access, recruit, and follow study populations at high risk of HIV infection
- Have trained staff who adhere to Good Clinical Practice (GCP), Good Clinical Laboratory Practice (GCLP), and other international and biomedical standards
- Contain up-to-date clinical, laboratory, and data management facilities
- Collaborate with community members and stakeholders who understand and embrace the goals of an HIV prevention research project

To increase the number and readiness of sites for HIV prevention research, Family Health International (FHI) began the Site Identification and Development Initiative (SIDI) in July 2006, with funding from the U.S. Agency for International Development (USAID). The project will continue at least until April 2010, when the initial USAID grant is set to close.

WHAT SIDI HAS ACCOMPLISHED

Goals

Two primary goals have given SIDI its shape and direction.

- *First, to prepare at least five new sites for HIV prevention research.* Rather than link the initiative to a specific clinical trial or new product, FHI is focusing on working with sites to build the capacity and infrastructure needed for HIV prevention research to go forward. Much of this effort lays the groundwork for other types of public health research, as well.
- *Second, to create a multidisciplinary best practices curriculum and technical toolkit.* The content will be a synthesis of the lessons learned at each site and in all phases of SIDI. This material will be a fundamental resource to guide the work of site identification and development in the future.

Scope

SIDI has progressed through three phases:

- *Site identification* involved systematic, literature-based research, networking, and e-mail communication in order to identify communities that met initial criteria. We looked for places with a high percentage of people infected with HIV who were living near a clinical research facility that was not yet conducting HIV research or were living in an area where a clinical research facility might reasonably be created. We identified nearly 20 sites with these characteristics.
- *Site assessment* involved fieldwork to identify the places most promising for in-depth evaluation. During this phase, FHI staff traveled to 13 sites in nine African and

Asian countries in order to gain an accurate view of the current status of the HIV epidemic, identify gaps in the readiness for research at select sites, and determine what would be required to bring those sites up to international research standards. To meet SIDI's goal of capturing best practices, we also developed reporting and evaluation templates to compare sites.

- *Site development* began in 2008, when FHI gave priority to nine sites in seven countries: Addis Ababa (Ethiopia), Maseru (Lesotho), Beira and Chokwe (Mozambique), Rustenburg and Bloemfontein (South Africa), Tabora (Tanzania), Ho Chi Minh City (Vietnam), and Ndola (Zambia). At each site, FHI is working alongside collaborating organizations to conduct HIV incidence and behavioral studies and community engagement activities. In this way, local staff gain experience in engaging local stakeholders, identifying people who have a high risk of becoming infected with HIV, recruiting them for a research study, and retaining them in the study. This is also an effective and productive way for local staff to learn the precepts of data collection, study documentation, and data management.

Site development encompasses renovating clinic and laboratory facilities; procuring equipment; introducing data management tools and other components of a strong research infrastructure; and hiring local staff and training them in a variety of skills, including proper research methodology.

FHI's development work will ultimately identify whether a community's HIV incidence is

sufficiently high and its willingness to participate in HIV prevention research is sufficiently strong to support future HIV prevention trials.

WHAT THESE SITES PROMISE FOR RESEARCH

Development is proceeding now at the sites in Ethiopia, Mozambique, South Africa, Tanzania, Vietnam, and Zambia. In addition to bringing clinics and laboratories into readiness, FHI is training people in both clinical and qualitative research methods. For example, most of the sites are conducting HIV incidence studies to test the accuracy of new ways to measure incidence and new ways to detect acute HIV infections. Furthermore, qualitative studies on multiple and concurrent partners (MCP) began in early 2008 with co-funding by USAID, the Joint United Nations Programme on HIV/AIDS (UNAIDS), and others, offering local staff hands-on experience conducting behavioral research. Additional studies could begin with or without FHI's assistance in 2010, at sites with facilities that are equipped to international standards and local staff who are fully trained.

FHI has worked to build collaborations and capacity so these sites can be effective partners not only with FHI but also with researchers, sponsors, and funders worldwide. Indeed, partnership with the HIV prevention research community is essential to sustain the sites and to fulfill their promise as leaders in the global effort to halt the HIV epidemic.

For more information, please contact:
Paul Feldblum (pfeldblum@fhi.org) or
Connie Sexton (csexton@fhi.org)
Telephone: 1.919.544.7040
Fax: 1.919.544.7261