

Kara Palamountain, executive director of the Kellogg School's Global Health Initiative, discusses the infant-HIV strip test with a group of healthcare workers in Africa.

Photo courtesy Kara Palamountain

Designed for Life

A DECADE IN THE MAKING, LOW-COST INFANT-HIV TEST NEARS CLINICAL USE



Kara Palamountain awakens to a rooster's crow. It's already warm at 6 a.m., and the tropical sun has just begun its daily ascent.

She is 8,000 miles from her office at Northwestern's Kellogg School of Management, working among the scattered homesteads of Macha, Zambia (shown on map, left). More than 125,000 people live here, and one in seven has the virus that causes AIDS. In neighboring Botswana, the statistics are even worse. Palamountain and her Northwestern colleagues are trying to slow the epidemic by harnessing the power of management, medicine, and biomedical design.

"The people of Macha have worked hard to improve health within their community, and they are seeing the fruits of their labor," says Palamountain, executive director of the Kellogg School's Global Health Initiative, after returning from her mid-March trip. "In the past 20 years, Macha has reduced new malaria cases by 90 percent. In the past five years, they have reduced the percentage of babies contracting HIV from their mothers by about half. Seeing this progress really motivates me, although there is still much work to be done."

Every day, about 300 infants the majority of them in Africa die because their HIV-infected conditions went undiagnosed. This tragedy occurs for multiple reasons.

For example, common antibody tests don't work in infants. That's because all babies of mothers infected with HIV are born with their mother's HIV antibodies, though not necessarily the virus itself. Then there are logistical and economic challenges. Parents often must travel long distances and at great expense to get their children tested. The average income for a person living near Macha is about \$1 a day; a bus trip to the nearest town can cost five times that much.

More troubling from a healthcare perspective is that even when a person makes the journey and undergoes the tests, reaching patients with the results often takes weeks or months. In some parts of Africa, up to 50 percent of those results never make it back to the patient.

Designing a Lifesaving Solution

At Northwestern the plan to combat such challenges began in 2003, when Palamountain and **David Kelso**, biomedical engineering, launched an initiative to design and produce affordable HIV diagnostics for the developing world. The project gained additional momentum in 2006 thanks to a \$5 million grant from the Bill & Melinda Gates Foundation, funding that created the Center for Innovation in Global Health Technologies (CIGHT pronounced "sight").

Today Palamountain and Kelso are part of a team that includes **Sally McFall**, **Mark Fisher**, and CIGHT director **Matthew Glucksberg**, all biomedical engineering. Contributing faculty also include **Robert Murphy**, medicine: infectious diseases, who has played a significant role in the President's Emergency Plan for AIDS Relief, a U.S. government initiative started by George W. Bush to manage multimillion-dollar grants.









Kara Palamountain, executive director of Kellogg's Global Health Initiative

Left: Matthew Glucksberg, biomedical engineering and director of CIGHT

Right: Robert Murphy, MD, the John Philip Phair Professor of Infectious Diseases and director of Feinberg's Center for Global Health

How the Infant HIV Test Works

Responding to the need for affordable HIV tests and rapid diagnoses, CIGHT laboratories have developed a low-cost device that yields a result in less than 45 minutes. The easy-to-use test can detect very low levels of the protein p24, which is part of the virus itself.

To administer the test, a doctor or nurse places a drop of blood on a plastic membrane and then inserts the membrane into a processor about the size of a small toaster. If the virus is detected, the clinician will see two black lines on the test strip.

Harnessing the combined thought leadership of faculty from Kellogg, the McCormick School of Engineering and Applied Science, and the Feinberg School of Medicine means CIGHT has accomplished what few academic global health organizations can do: develop and achieve commercialization of innovative medical technologies.

Marketing New Ideas

Palamountain plays a critical role in developing each new CIGHT device, and so do students in her Kellogg course Medical Technologies in Developing Countries. Together they conduct the crucial market research to identify community needs and then work with end users to pursue optimal designs, closely assessing any functionality tradeoffs. For instance, a small design tweak may require more manual steps to obtain test results, or a change could require electricity, a resource not universally or reliably available in some locations. Palamountain collaborates with in-country healthcare providers to determine whether such modifications are acceptable.

In her Evanston office, she sets out an early prototype of an infant HIV test kit. It's not much bigger than a deck of cards and has no functionality.

"The first time I brought this to Africa, it was difficult to have a real conversation while holding foam core," she recalls. "But when you return and show them how we've improved the design, how we are making progress, and how their suggestions helped advance this project, the dialogue becomes much easier."

After many iterations, the rudimentary model evolved into an advanced rendering and finally a working prototype. Today the basic strip test uses a small blood sample to provide an answer to a single question: Does this baby have HIV?

Results take about 45 minutes, and healthcare workers almost anywhere can be trained to conduct the test. Its use will allow parents to leave clinics armed with vital diagnostic insights and a medical plan.

"We are looking at what products should be made and also how they might need to be constructed to benefit a specific group of people," says Palamountain. "With 54 countries in Africa, our final hurdle will be getting the finished product approved and introduced into each healthcare market."

Thirteen students joined Palamountain on her recent trip to Zambia. Another 12 students visited Lesotho with course co-instructor **Robert Dintruff.** The teams each researched how and where they might place a second testing platform — a more expensive device that provides information on a patient's HIV viral load. Such testing is common for individuals living with HIV in the United States; results indicate viral strength based on the amount of HIV in the blood.

CIGHT is working with collaborators on this second testing platform, which can identify not only HIV viral load but also tuberculosis and many other diseases. Although each test is conducted differently, the core equipment adapts to provide accurate disease-specific results. Back in Evanston, engineers at CIGHT's laboratory space are working to finalize the TB-specific test technique; tuberculosis ranks second only to HIV/AIDS in deaths caused by a single infectious agent.

Advances in Engineering

While Palamountain was in Zambia, her colleagues Glucksberg and Murphy were 1,500 miles away in South Africa.

Since its inception, CIGHT has worked closely with the University of Cape Town to provide an academic framework for student-led innovation. This spring 16 students from Northwestern spent nearly three months working on projects that included a device to protect healthcare workers in TB clinics and a low-cost $\rm CO_2$ monitor to aid in placing endotracheal tubes while out in the field.

The team's ultimate goal is to sustainably design new devices for the developing world while also transforming current medical and manufacturing techniques. Tests that are expensive, take significant time to analyze, or require electricity present significant obstacles throughout Africa.

"CIGHT helps build platforms the machines that run the tests using well-understood technologies and developing the assays for specific diseases,"

Chief Macha, center, leader of the Tonga-speaking people in southern Zambia, with Northwestern students and representatives from the University of Lagos, the University of Ibadan, and diagnostics company Quidel after a March meeting in Zambia. Kara Palamountain, pictured far right, was part of the team. As the principle leader in Macha, the chief has been responsible for numerous sanitation and healthcare reforms in the region.



says Glucksberg. "In Africa we are looking at point-of-care diagnostics because we believe it's a critical need there. For example, during the process of sending tests to a lab, results frequently go missing."

Once the team assesses such market needs and solves related chemistry and engineering challenges, prototypes are tested in the field. Then CIGHT's HIV-testing devices move into the manufacturing stage.

"That is where we are right now with both projects the HIV strip test as well as the more complicated HIV viral load test. Figuring out how to translate a manmade device into a mass-produced one is something that universities don't traditionally do," Glucksberg explains. "We're finalizing the design and identifying a manufacturer, and will be working with Rob Murphy to ensure our introduction into clinics goes as well as possible."

Major Impact on Health

It's often said that Robert Murphy is the most traveled professor at Northwestern. Director of Feinberg's Center for Global Health, Murphy recently attended a conference in Seattle before heading to Lima, Peru. He then flew to Cape Town to watch students present their final CIGHT projects.

In the 1990s Murphy was already working in Africa as the AIDS epidemic there began to spread. An expert in viral infections, he has spent the past two decades exploring new antiretroviral drugs and vaccines for HIV and viral hepatitis. He's also worked to improve therapies for tuberculosis and AIDS.

"The perception by some is that global health involves getting on a plane and taking care of poor people in various stages of disease," says Murphy. "A big part of the way that our team thinks of global health revolves around doing things to decrease the health disparities that exist between nations. The only way to achieve that vision is by building strong relationships within these communities over time."

As Northwestern's infant-HIV test enters the marketplace — a development expected this year — Murphy will play a large role in its implementation.

"Africa is rife with applied engineering teams, groups that work to fix broken Western machines," he says. "What CIGHT has done is develop products relevant to Africans that clinicians and healthcare workers can use to improve the overall health of those around them. It's a model that's soon to make a major impact."

- Roger Anderson

Other CIGHT Projects

CIGHT currently has 10 ongoing projects in various stages of development. Student-led initiatives include an iPad application for training nurses in integrated management of childhood illness and a low-energy phototherapy blanket for treating jaundice in newborns.