www.fic.nih.gov

GLOBAL HEALTH MATTERS

SEPT/OCT 2019

Inside this issue

FOGARTY INTERNATIONAL CENTER • NATIONAL INSTITUTES OF HEALTH • DEPARTMENT OF HEALTH AND HUMAN SERVICES

Innovative mHealth projects receive $5M from NIH

Fogarty and its partners from across NIH plan to award $5 million over two years to support innovative exploratory and developmental mobile health research in low- and middle-income countries (LMICs). The 13 new awards are made through Fogarty's mHealth program, which aims to catalyze innovation through multidisciplinary research, while strengthening LMIC mHealth capacity. Recipients will use mobile and wireless devices such as smartphones and tablets to improve health outcomes, health care services and health research.

A majority of the awards will support projects in sub-Saharan Africa, with many related to the diagnosis and treatment of infectious diseases. Researchers with the Boston University Medical

. . . continued on p. 2

Photo by Dr. Bill Tierney

Fogarty's mobile health research program aims to catalyze innovation in low- and middle-income countries by supporting multidisciplinary projects using wireless devices to improve health.

$9M awarded to establish independent research careers

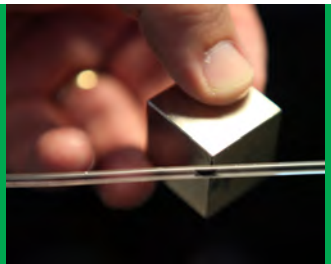
To bolster promising global health research careers, Fogarty and its partners are awarding up to $9.2 million over five years through two career development programs. The grants will help ensure that advanced postdoctoral scientists and junior faculty have a pathway to independence, with protected time for research activities under the guidance of experienced mentors in developing countries and in the U.S.

Recipients of 14 Emerging Global Leader Awards hold junior faculty positions and research scientist appointments at institutions in Bangladesh and India, and across Africa—in Ghana, Mali, Nigeria, South Africa and Tanzania. Four additional U.S. scientists supported through the International Research Scientist Development Award (IRSDA) will be conducting studies in China, Malawi and South Africa, with a majority of their supported time spent at institutions in low- and middle-income countries (LMICs).

The programs fund research relevant to the health priorities of the host countries, covering all health-related disciplines. Projects addressing women's health will explore perinatal depression in adolescents, hypertension during pregnancy and improving cervical cancer detection. Many will investigate solutions in the field of HIV and related infections, for instance working to better understand and treat HIV-related pain, identify biomarkers for Kaposi's sarcoma, reduce HIV transmission for young women, improve home-based ART interventions and explore treatments for HIV-associated Multicentric Castleman disease. They

. . . continued on p. 2

FOCUS



Fogarty grantees boost biomedical engineering in Africa

- Open-access book details case studies, lessons learned
- Bioengineers can advance frugal design, mobile health
- Africa ripe for technology innovation, entrepreneurship

Read more on pages 6 – 9

Innovative mHealth projects receive $5M from NIH

. . . continued from p.1

Campus will focus on screening children for pneumonia in Zambia, comparing traditional x-rays to cellphones with ultrasound transponders. Tulane University scientists will develop a cellphone microscope platform to rapidly screen children in Kenya for tuberculosis, while making improvements to the storage and transport of screening materials. University of Georgia investigators will adapt video directly observed therapy in Uganda to improve adherence of tuberculosis treatment, leveraging input on perceived barriers from patients and providers.

In the area of injury research, University of Texas Southwestern Medical Center will build mobile tools to report road traffic injuries in Nigeria, with the goals of reducing transport time for victims and improving information provided to first-responders.

A number of projects in the sub-Saharan African region will focus on improving health outcomes for people with noncommunicable diseases. The Sloan Kettering Institute will train radiologists in Nigeria to perform mobile ultrasound-guided breast biopsies, building capacity for point-of-care breast cancer diagnosis. Through an existing partnership in Lesotho, another team from Boston University Medical Campus will adapt an animated online tool that identifies and mitigates health risks for women before pregnancy. In Kenya, researchers with Michigan State University will bring together public health professionals and software developers to create a mobile application to help adolescents manage Type 1 diabetes. To improve self-care for heart failure patients in Uganda, scientists with Yale University will implement a scalable, locally relevant patient application that runs on low-cost feature phones, with an associated dashboard for clinicians.

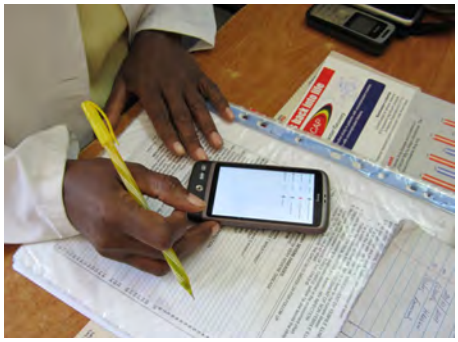


Photo courtesy of Dr. Marc Mitchell

Projects throughout Asia will also explore ways to leverage mobile health to treat chronic diseases. Rutgers Biomedical and Health Sciences School of Health Professions will create a smartphone app for self-management of gestational diabetes in Nepal, while helping deliver relevant information to clinicians. Also in Nepal, researchers with the University of California San Francisco will develop a mobile application to provide ongoing training to community health workers to improve depression treatment.

In Thailand, investigators with Massachusetts General Hospital will enhance a smartphone application for homebased monitoring of patients with chronic kidney diseases, comparing patient outcomes to those of patients using handwritten logs. An interdisciplinary team of U.S. and Chinese investigators led by the University of Pennsylvania will use a smartphone app to analyze biopsy results and transmit data to doctors, health records systems and surveillance teams to improve cancer therapy in low-resource areas.

In the Dominican Republic, researchers with Northern Illinois University will measure the effectiveness of a mobile application that delivers mental health treatment provided by community health workers.

Fogarty's mHealth program, which has funded more than 60 projects since it launched in 2014, has attracted interest from Institutes and Centers across NIH. The program, which initially provided up to two years of funding, now offers two to five years of support.

RESOURCES

Awards: http://bit.ly/mhealth-lmics
Apply: http://bit.ly/NIHmhealth

$9M awarded to establish independent research careers

. . . continued from p.1

will also study treatments for HIV-associated tuberculous meningitis, detection of multidrug-resistant TB, interactions between antiretroviral and tuberculosis drugs, and sex differences in immune response and risk for developing TB.

The new investigators will be researching chronic conditions, such as locally relevant innovations in cardiovascular disease care, and building a mobile application to help detect lung cancer. Some grantees will look into issues unique to their regions, countries and communities—sickle cell disease in infants, the role of genetics in craniofacial and dental anomalies, treatment for Guillain-Barré syndrome and causes of *Shigella flexneri* infections.

RESOURCE

Awards: http://bit.ly/careerdevawards

Scientists in Madagascar study novel methods to predict disease spread

Zoonotic diseases—infectious diseases that spread from animals to humans—are a major health threat in Madagascar. To understand why some people become conduits for these diseases, and whether farming practices or socioeconomic factors might influence transmission, a team of Fogarty-funded researchers will apply new analytical approaches for predicting infection. The grant to Duke University, totaling nearly $2.4 million over five years, recently was awarded through the Ecology and Evolution of Infectious Diseases program, a joint initiative between the NIH and the National Science Foundation.

"Most of the work in ecology, evolution and infectious disease has focused on the community composition and the abundance of different animal and human hosts. And we're really trying to model how hosts are coming into contact with one another, or how they're sharing habitats, and using that to generate a mathematical representation of disease transmission," said Dr. Charles Nunn, an ecologist and professor at Duke University who is the principal investigator on the project.

Nunn has assembled an interdisciplinary team of scientists with expertise in ecology, mathematics, sociology, evolutionary medicine, anthropology and environmental economics. Investigators will work in four villages around Marojejy National Park in the northeastern part of the country. They will collect biological samples and location data from about 250 residents from each location, as well as from small animals such as rodents and bats, and domestic animals including dogs, cows and pigs. The villagers and their domestic animals will be equipped with GPS devices to track to their movements. People will also be surveyed about their household size, education and other demographics, their health, social network, agriculture and other economic activity, land-use decisions and conservation attitudes.

Using innovative mathematical frameworks, those pieces of information will be brought together to generate networks representing interactions between people and animals. The team will then assess whether the transmission models they generate actually predict patterns of infection.

Zoonotic diseases in Madagascar that will be studied include the plague—which is typically spread to humans through flea bites—and leptospirosis—which people can get when they come in contact with water contaminated by urine from an infected animal. While those diseases may not be common in other countries, the research could have broad implications.

A new Fogarty-funded project in Madagascar will support researchers like Tamby Ranaivoson to develop and apply new frameworks for predicting the spread of zoonotic diseases.

Photo courtesy of Dr. Charles Nunn/Duke University

"Emerging diseases are still an issue. We see that with Ebola in the Democratic Republic of Congo and West Africa, or other outbreaks of infectious diseases, many of which come from wildlife or domesticated animals," Nunn said. "We hope the general principles and methods we're using in Madagascar will apply more generally to other locations in the world."

While this is Nunn's first Fogarty grant, he has years of experience working in Madagascar. The island country off the coast of East Africa provides an interesting environment for the research, according to Nunn. It is one of the world's poorest countries, but it is rich in biodiversity, with many species that are unique to the island. The population is growing and people are now encroaching on forests. In addition, land use is changing as some communities shift from subsistence farming to growing vanilla as a cash crop.

This project, like others Nunn has led, has a training component with Duke students working alongside Malagasy trainees doing field work in remote areas. In addition to research skills, Nunn says he facilitates cultural exchange, with trainees eating at the same table and learning each other's language and culture.

"Our work is at the nexus of human health, conservation, ecology and evolutionary biology. There's so much potential for that kind of research, including in the United States," Nunn said. "I really hope we're going to provide some new frameworks for investigating these questions, improving health and also helping conserve biodiversity."

RESOURCES

http://bit.ly/EEIDaward2019

PROFILE

Fogarty Fellow uses legal skills to study human rights and HIV/AIDS in Kenya

Neiloy R. Sircar, J.D., LL.M.

Fogarty Fellow:	2018-2019
U.S. Institution:	University of Washington
Foreign Institution:	Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN)
Research topic:	Human rights and HIV

As the first lawyer to participate in Fogarty's Global Health Fellows and Scholars program, Neiloy Sircar examined human rights and HIV in Kenya. The country has been encouraging testing and notification of partners and children who may be at risk as part of its strategy to control HIV and link more people with treatment. Sircar and the research team wanted to know if those practices and policies are effectively using what's known as a rights-based approach, especially when it comes to consent, privacy and confidentiality.

"Are these programs actually protecting, promoting and fulfilling the human rights of those people who are benefitting from the programs? And if they are, how are they doing it? And if they aren't, let's identify ways to improve," Sircar said of the rationale for his fellowship project, which was supported by Fogarty and the Afya Bora fellowship program.

He was hosted by a prominent NGO known as KELIN—the Kenya Legal and Ethical Issues Network on HIV and AIDS—and was mentored by its director, along with faculty from the University of Washington. Sircar studied human rights and global health law at Georgetown University.

He worked with KELIN's lawyers and its partner community groups to conduct qualitative research. They wanted to learn what health care providers and at-risk populations know about legal and human rights and to identify barriers that might keep people from getting tested. The research focused on four key populations at risk of HIV, stigma and discrimination—young women, men who have sex with men, sex workers and injection drug users. The activities of the last three groups are illegal in Kenya.

Sircar wrote the guidelines for in-depth interviews and focus group discussions. He also designed a series of predominantly open-ended questions including: "Many people in your group are not testing for HIV. Why do you feel that is?" "Are you familiar with your legal and human rights?" "Do you feel there are any risks disclosing or sharing HIV status?" Questions for health care providers aimed to assess their understanding of human rights and whether they've received sensitivity training or any other related instruction.

The interviewers were Kenyans from the community organizations that work with the key populations. Sircar intentionally was not part of that process. "Seeing a foreigner in the room might affect how people answer questions," he said. "What was important to me was that the people who were giving us candid, honest answers felt safe."

The research team is just beginning to analyze the information collected. Sircar said his experience in Kenya taught him how to navigate the Institutional Review Board process, conduct qualitative research, do data analysis and manage a team. He credits the Fogarty fellowship with leading him to his current position as a postdoctoral scholar at the University of California, San Francisco and sees his career path heading to a U.S. institution focused on public and global health and human rights.

Sircar said colleagues have been excited to hear about his fellowship and how skills in law, policy, governance and regulation can complement or bring a new perspective to their research projects.

"There are a range of questions at all levels of public health and global health where having a legal background or a legal person on the team can be very helpful," said Sircar, who wants to raise awareness among both the health and legal communities. "We are still seen as a fish out of water, the odd person in the room. But it doesn't take much to articulate what it is that you can do to help this work along, to help achieve something good."

Q&A

SIMANI GASEITSIWE, PH.D.

Dr. Simani Gaseitsiwe began his research career nearly 20 years ago at the height of Botswana's AIDS epidemic. He took a job as a lab assistant for the Botswana Harvard Partnership (BHP), a research and training collaboration between the government and Harvard University, led by pioneering Harvard AIDS researcher and longtime NIH and Fogarty grantee, Dr. Myron "Max" Essex. Today, Gaseitsiwe directs BHP's laboratory in Botswana, trains young scientists and is among the accomplished researchers contributing to the NIH-funded Human Heredity and Health in Africa (H3Africa) project.

What Fogarty training did you receive?

Professor Max Essex has been my mentor throughout my career. When he started the lab in Botswana in 2000, I was recruited, having just completed my undergraduate degree. In the beginning, the lab was focused on very basic HIV clinical laboratory work, doing CD4 counts to check disease progression, viral loads and patient monitoring. At the time, the epidemic was really bad because that was before the advent of antiretroviral therapy in places like Botswana. After a year, I had the opportunity with Fogarty support to go to Max's lab in Boston to do more advanced molecular biology training, to do genotyping or sequencing the HIV strains that are circulating in Botswana. It was more hands-on training, which was very important at the time because we didn't have the capacity to do that kind of work here. It was a very cosmopolitan environment in Boston, with scientists from all over working together. Coming from my country, where there was basically no one doing HIV research, to train in such a prestigious institution like Harvard was very inspirational and motivated me to pursue further studies including a Ph.D.

How has your career progressed?

I have gone from being one of three lab assistants in a new operation capable of only doing basic HIV clinical lab work, to now being the director of 50 staff and a sophisticated, three-story facility with an expanded clinical laboratory, a million-sample repository, a research lab, sequencing facility and training space. Today, we have a number of students who are training at master's, Ph.D. and postdoctoral levels, and we attract students not only from the region but also internationally. From the humble beginnings to now, it's been really great to watch the lab develop over the past 18 years.

What research topics are you studying?

I've spent a lot of time trying to diversify the research agenda of BHP because most of the focus had been on HIV, but the situation is not as bad as it used to be. I've diversified the research portfolio to include viral hepatitis, which is under-researched in Botswana although it is highly prevalent here and in other sub-Saharan Africa countries. We've had a few projects looking at the TB incidence in patients who are on antiretroviral therapy because TB co-infection in HIV-infected individuals is the main type of TB in Botswana. Almost 60-70% of the TB patients are also HIV-infected, so I think there is a need to study the two infections together. The research that's happening here is a byproduct of my Fogarty training. So, you can multiply that by a factor of 10 or 20 because that's how many of us have had the opportunity for substantial training.

Why is local research capacity important?

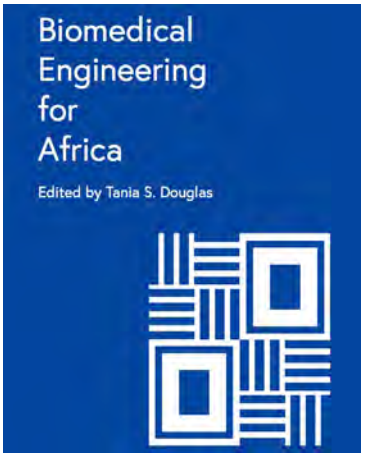
It's something I've always had a passion for, especially learning from what Max has done in Botswana. There is a dire need for individuals who are trained to the Ph.D. level to conduct research in places like this. By the time we really began to appreciate the magnitude of the HIV epidemic in my country, it had already reached levels where it was difficult to manage. I think we learned that there was a need to respond to outbreaks in a more timely manner. We need to develop human capacity first of all, because those are the people who will drive the programs to control the epidemics. It's not only HIV, we are also seeing Ebola and other diseases spreading in nearby countries. I think Fogarty in its nature was, and continues to be, very instrumental in supporting the training of people from a resource-limited setting to go to more developed countries to train, and then come back home and be able to be the drivers of the research, ultimately trying to control the epidemics there.

What is your approach to mentoring?

My approach is to get young people to come into the lab and, to a great extent, allow them some freedom. I learn from all these graduate students that I have, because they are younger, they tend to look at things in a different way and question concepts that we take for granted. I also have come to appreciate diversity. So, whenever possible I always try to attract people from different backgrounds into the lab. You don't want a homogenous group because your approach, your solutions will be similar. But if you take a group from different backgrounds, then the approach and the solution will be more holistic.

Fogarty grantees publish book to boost biomedical engineering in Africa

Africa's unique context and health care challenges would benefit from specially tailored technology solutions, rather than its current reliance on imports from industrialized nations. Appropriately designed technologies can be used in the prevention, diagnosis, monitoring and treatment of disease, which can save lives as well as money. To meet that need, the continent must develop its own biomedical engineers who are familiar with local needs and resource constraints, according to a book published recently by Fogarty grantees and collaborators.



Published with Fogarty support, the 22-chapter book is freely available at http://bit.ly/BioEng_Africa.

"The field of biomedical engineering is central to health technology innovation," the authors suggested. "Transplanting healthcare systems and technologies from high-income countries to resource-limited settings is slow and expensive, and in many instances, challenging if not impossible." Developing new healthcare delivery methods and devices tailored to LMIC environments and conditions is a faster, better and more cost-effective alternative, they said.

Grounded in the African context, the 22-chapter open-access volume is intended as a resource for practitioners, academics, students and university leaders planning to establish new biomedical engineering programs. Although focused on Africa, the publication is relevant to other low- and middle-income country (LMIC) settings and provides insights to guide global health initiatives focused ontechnology innovation. The book was produced with support from Fogarty and Northwestern University (NU) in Chicago, and was published by the University of Cape Town (UCT) Libraries. Nearly 90 authors from NU

Biomedical engineers are needed in Africa to develop locally relevant technologies and applications to improve health.

Photo courtesy of Dr. Omar Siddiqi

Africa contributed to the volume, which was edited by Dr. Tania S. Douglas, a biomedical engineering professor at UCT. A Fogarty Framework Innovation grant to NU helped establish departments of biomedical engineering at the Universities of Ibadan and Lagos in Nigeria, and facilitated collaboration with biomedical engineers at UCT.

> "The field of biomedical engineering is central to health technology innovation."
>
> – BIOMEDICAL ENGINEERING FOR AFRICA

In Africa, economic growth, increasing healthcare expenditure, the availability of digital technologies, and young populations provide opportunities for the development of robust health technology innovation systems, according to the book's authors. For local innovation to become the norm across the continent, capabilities must be developed to conduct needs assessments, market analyses, product design, prototyping and testing, manufacturing, distribution and management. To produce products that are actually used, biomedical engineers must develop an in-depth understanding of the social factors that impact technology adoption.

Resource: http://bit.ly/BioEng_Africa

Stronger linkage with clinicians needed

Creating technologies suitable for LMICs is not the only engineering need. More than half of medical equipment in developing countries is defective, according to WHO estimates, which causes delays in diagnosis and treatment, higher costs and sometimes loss of life. One book chapter makes the case for closer collaboration between engineers and clinicians to improve maintenance capability, as well as advance engineers' understanding of the technologies needed to improve patient care. For instance, in hospitals lacking incubators, engineers could develop low-cost baby warmers to reduce newborn deaths. However, identifying the problem is only the first step. A needs assessment should be performed, the authors suggested, noting the WHO recommends customization of the process according to the specific circumstances.

Best practices might include:

- Having both groups of personnel agree on the unified goal of establishing good patient outcomes.
- Fostering mutual understanding and respect for the unique roles and skills each group brings in working towards achieving the common goal.
- Ensuring good communication in problem-solving activities related to patient care.
- Raising awareness with hospital management and health system administrators of the benefits of clinician–biomedical engineer cooperation in order to garner their support.

Fogarty grant helps spur biomedical engineering in Nigeria

Nigeria's University of Ibadan began its graduate program in biomedical engineering in 2017, partly with support from Fogarty. It provides students with a broad and flexible education in engineering, biological science and medically-related fields; and develops skills in innovation, creativity, adaptability and critical thinking to solve problems in the biomedical industry. Students can pursue a one-semester certificate, two-semester diploma or four-semester master's degree. The program is intended to attract students from across Africa.

The University of Lagos has a longer tradition of biomedical engineering, with a unit having been established in 1974. Now an academic department, it trains students at all levels in biomedical engineering. Fogarty funding helped the university develop a more robust interdisciplinary collaborative research culture.

Africa is ripe for entrepreneurship

Africa has received global attention in the 21st century as the continent of growth and opportunities. One of the book's chapters explores its current climate for innovation, noting there has been considerable debate on how African governments can create jobs and develop home-grown business leaders able to access global markets and propel growth. That is partly dependent on the capacity and willingness of African countries to create an environment conducive to the emergence of entrepreneurship in the public and private sectors, the authors said.

There have already been a number of successful products developed by Africans, for use in Africa, which are described in the text. The Cardio-Pad, created by Cameroonian Arthur Zang, is used to detect cardiovascular disease in patients who live in remote areas by providing wireless data transmission to a cardiologist. Deaftronics, a company in Botswana, built a prototype charger for solar power hearing aid batteries that last for three years and can be used with many hearing aids available on the market. It was developed for the hearing impaired in developing countries who are unable to access electricity. In South Africa, Power Free Education Technology produced a wind-up Doppler ultrasound fetal heart rate monitor to detect fetal distress for use in rural areas.

The book contains several chapters detailing the process used to develop technologies in Africa including an innovative approach to improve burn wound treatment, an infant warming device and a needle disposal machine.

Future successes will depend, in part, on the "robustness" of higher education to train and develop biomedical engineers, the authors said. "The challenge in developing an African entrepreneurial biomedical engineering environment is not only the lack of infrastructure but also the lack of innovative capacity and ecosystems that support innovation, as well as a fragile healthcare system on the continent."

There are few biomedical engineering (BME) programs in Africa prepared to meet these needs, the publication noted. In 2008, only 12 universities in six African countries offered BME programs, compared with nearly 230 universities in North America. In 2012, a group of African universities founded the African Biomedical Engineering Consortium (ABEC) with the goal of increasing engineering capacity and nurturing entrepreneurial and innovative skills across the continent. It has developed a standard undergraduate BME curriculum that has been adopted by some of the participating universities.

Developing frugal design for low-resource settings

Frugal Biodesign—a unique approach to medical device design that is suited specifically to developing countries—is examined in one book chapter. The course, developed at UCT in South Africa, is aimed at stimulating postgraduate students studying BME to devise inexpensive and, more importantly, innovative solutions to medical problems. It recognizes the limitations that South Africa and other developing countries experience in terms of human, financial and physical resources. The medical devices that the students work on during this course are informed by clinicians. The course adopts a cyclical and dynamic approach that involves the constant exchange of information between multiple stakeholders.

The stages of the Frugal Biodesign approach.

Image from *Biomedical Engineering in Africa*

The two-semester, 10-month curriculum is intended to fast-track the process of ideation, which begins with identifying a need and continues until proof of concept is achieved. The course prepares students to develop medical devices that are appropriate to needs, at low cost. It takes into consideration the constraints which hinder technological development in low-income settings such as lack of funding, skilled personnel and infrastructure. By leveraging the talents of a pool of students drawn from different engineering backgrounds and the insights from clinical partners, an interdisciplinary approach is applied to the problems being addressed.

One UCT success has been the adoption of 3D printing to produce medical devices, such as a crutch that attaches to spectacles to elevate the upper eyelid in patients with *myasthenia gravis*, a condition that can cause eyelids to droop and for which treatment options are limited in low-resource settings. UCT released the design as an open source innovation that can be downloaded at no cost.

Mobile health is powerful platform for healthcare

With the ubiquity of cellphones in much of Africa, mobile health holds tremendous potential for extending healthcare services to remote areas and poor people in Africa. One section of the text is devoted to exploring these opportunities. Many disease outbreaks in Africa have been caused by lack of, or late, reporting. While most countries have implemented successful surveillance systems that include training for healthcare workers, many are still paper-based. The high penetration rates and increasing adoption of mobile devices in Africa has the potential to enhance the development of effective disease surveillance systems.

The main drivers for mHealth in Africa include high mobile penetration, increasing cellphone subscriptions and the high burden of disease, the authors said. There are opportunities for mHealth projects to provide health education and create awareness, deliver personalized and remote patient monitoring, conduct disease surveillance and build clinical decision support systems. Possible challenges include low health literacy levels; poor network, power supply and hospital infrastructures; socio-cultural barriers; and lack of political will by governments to support mHealth projects. To build scalable and sustainable mHealth systems, there is need to foster strong public-private partnerships, develop mHealth systems that can be easily integrated into existing healthcare systems, and produce health information systems that ensure the security, integrity and privacy of patient data.

Incorporating bioethics into innovation

Biomedical engineering is unique as an engineering specialty, in that it is a synthesis of engineering principles and medical practice, the authors noted. The unique professional identity of biomedical engineering requires ethical frameworks that are sensitive to both medical and engineering standards. While engineering ethics is narrowly focused on safety, and medical ethics on patient care, biomedical engineering ethics is at the intersection of safety and patient care, beginning at scientific experimentation and design, and extending through medical practice and administration. Understanding the history of engineering ethics and biomedical ethics is essential to understanding the evolution and future of modern biomedical engineering ethics, according to the authors.

A 3D-printed device attaches to spectacles to elevate the upper eyelid in patients with myasthenia gravis, *a condition for which treatment options are limited in low-resource settings.*

Photo from *Biomedical Engineering in Africa*

Protecting intellectual property

Developing novel biomedical products including drugs, devices, assays and equipment is a lengthy, and possibly expensive, process that starts with an innovative idea that potentially meets a critical medical need. Intellectual property protection may be needed to prevent the concept from being used or even marketed by another party, the authors said in a chapter devoted to the topic. Trademarks, patents, copyright and trade secrets are some issues that may be considered. Commercialization paths such as licensing and establishing spin-off companies may also be relevant. In addition, biomedical engineers must obtain regulatory approval to bring their products to market. After proving the safety and efficacy of their invention, they then will need to convince clinicians to adopt it, which can be time consuming.

Research universities may play a role in the process, ranging from educating the innovators to developing prototypes. Universities may even assist in licensing and start-up activities. A robust development pipeline involves identification and protection of the intellectual property and a clear, well-defined partnership between the institution and its inventors.

Regulating medical devices in Africa

The book also contains an overview of medical device regulation in 10 African countries, noting they have a strong focus on imports, which is not surprising given their heavy reliance on medical devices from developed countries. For example, South Africa, Nigeria and Egypt—considered to be the largest markets and economies in Africa—continue to be dominated by the supply of orthopedics, prosthetics, patient aids and consumables from the U.S. The regulatory approval process for medical devices in Africa is lengthy, not transparent and skewed toward controlling entry into the market of substandard imports that pose a health risk, the authors reported. None of the ten countries discussed has specific regulations or regulatory bodies dedicated solely to medical devices, which can cause difficulties and delays in the process.

Photo courtesy of Dr. Ayeesha Kamal

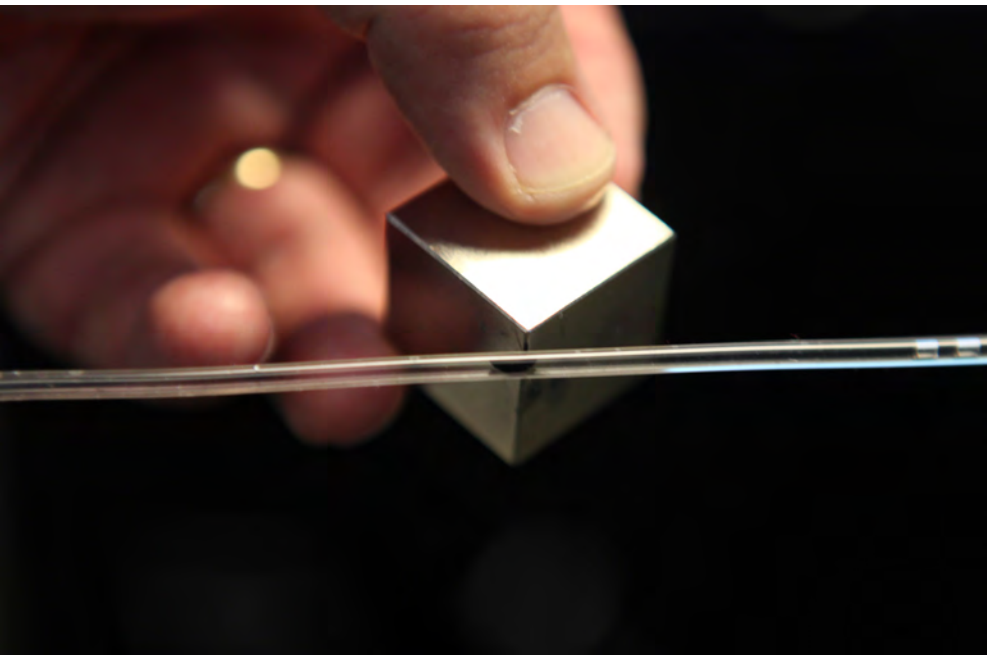
Mobile health solutions hold much potential to improve health in low-resource settings.

However, medical device regulations in Africa are designed along the framework of models used in developed countries. For example, the requirements for importation and exportation of medical devices in South Africa, Algeria, Kenya and Ethiopia are similar to the internationally recognized regulatory programs in Europe, the U.S. and Australia. This is important in that it aligns African countries with a harmonized framework for medical device regulation. In an era of globalization, this facilitates cooperation among regulators and the industry.

Beyond regulations, much could be done to promote the development of medical device industries in African countries. In Ethiopia, Ghana, Kenya and Tanzania, a WHO framework for local production and access to essential medical products is being implemented to stimulate innovation and provide technical assistance. National policymakers can also establish preferential procurement of domestically manufactured medical devices to increase demand for home-grown products.

"African governments can play a leading role in encouraging the development of their domestic medical device industries," the authors said, "not only by establishing medical device regulations and providing adequate resources for their implementation, but also through broader policy considerations."

Photo by Susan Urmy/Vanderbilt University



Tiny magnets and plastic tubing are being developed by Fogarty grantees to provide a low-cost method of diagnosing malaria.

OPINION

By Dr. Roger I. Glass, Director, Fogarty International Center

Celebrating 30 years of capacity building in Rakai

A paper published by a group of Ugandan researchers in October 1985 described a mysterious illness, called "slim disease," which had killed 100 people in the country's Rakai district. It was a seminal moment that awoke the world to the looming HIV/AIDS crisis. The investigations begun then have grown into the Rakai Health Sciences Program, which is marking its 30th anniversary this year. For Fogarty, it's a wonderful opportunity to celebrate three decades of research capacity building that have resulted in numerous groundbreaking scientific discoveries.

The idea that our small center could play a vital role in preparing low- and middle-income country scientists for the battle against HIV/AIDS came from Fogarty's Dr. Ken Bridbord. As co-chair of the third International Conference on AIDS, held in Washington D.C. in 1987, it became clear to him that a dramatic response was required that should include a rapid scaling up of scientific capacity in Africa and other places where the death toll was quickly rising. Ken conceived an innovative program consisting of mentored research projects, in addition to formal coursework. The result was the AIDS International Training and Research Program, which supported training for more than 2,000 scientists and clinicians in more than 100 developing countries. The initiative was revised to meet evolving needs and continues today as the Fogarty HIV Research Training Program.

In Rakai, the early years of the epidemic were devastating. An HIV diagnosis was a virtual death sentence, with those effected wandering around listlessly with open sores, being shunned by all. Witnessing such suffering gave researcher Fred Nalugoda chills and he thought he could not go back. Now field director and a principal investigator in Rakai, Nalugoda says public awareness and the availability of treatment have dramatically improved the situation. Another Fogarty alum, Dr. Elioda Tumwesigye, is now Uganda's minister of science and technology. He says without the opportunity to receive advanced training funded by Fogarty, he simply wouldn't be who he is today. That support helped him reach significant career milestones such as starting the first standing committee on HIV in any African parliament and being selected for his current position.

Virtually the entire leadership team at Rakai has benefited from Fogarty training or research funding. In partnership with Johns Hopkins University, training conducted has run the gamut from lab methodology and bioethics to epidemiology, biostatistics and pathology. That laid the groundwork for this small but mighty team to make scientific contributions detailed in a whopping 573 publications, on the implications of circumcision on HIV transmission prevention and numerous other important issues. Those articles have been cited more than 20,000 times, clearly demonstrating the findings' significance.

Today, Rakai is engaged in about a dozen NIH-funded research projects, devoted to pressing issues such as how to improve prevention and treatment among adolescents, and ways to make better use of mobile technologies. But even as we review these incredible accomplishments, we must not rest on our laurels. Much still remains to be done. For instance, it is my hope that the Rakai grants, which are managed by Hopkins, will someday transition to directly fund the Ugandan research leaders themselves. A trove of data and specimens have been collected. We must make sure it is thoroughly mined so we can all learn from these decades-long studies of this population that was so greatly impacted by the epidemic. Over the next decade, it's my hope that the Rakai team will not only continue to gain control of the epidemic and improve treatment for those living with HIV, but will also continue to branch out to other pressing issues such as noncommunicable diseases, and maternal and child health. They must carry on strengthening training resources so they can adequately prepare the next generation of scientists. By bringing in new partners, they may expand south-south partnerships and ensure sustainability of all that has been achieved.

We owe this small community of committed researchers a debt of gratitude for all the knowledge they have given us, from their post on the front lines of this terrible scourge. Paraphrasing Sir Winston Churchill, never was so much owed by so many to so few!

PEOPLE

Former NLM Director Lindberg dies

Dr. Donald A.B. Lindberg, who directed NIH's National Library of Medicine (NLM) for 31 years until his retirement in 2015, has died. A pioneer in computers and medicine, Lindberg's tenure included the creation of NLM's National Center for Biotechnology Information and launch of online resources such as PubMed, ClinicalTrials.gov and MedlinePlus.

Environmental health director Birnbaum retiring

Dr. Linda S. Birnbaum is retiring after nearly 40 years as a federal scientist, the last 10 leading NIH's National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program. Birnbaum is the first board-certified toxicologist and the first woman to direct NIEHS.

Tucci to lead deafness institute

Dr. Debara L. Tucci has been selected to lead the NIH's National Institute on Deafness and Other Communication Disorders (NIDCD). Previously, she was surgery professor and director of the cochlear implant program at Duke University. Tucci will remain co-chair of the Lancet Commission on Global Hearing Loss.

New global health head for NIH neurological institute

NIH's National Institute of Neurological Disorders and Stroke (NINDS) has tapped Dr. Richard Benson as director of its Office of Global Health and Health Disparities. Benson was an associate medical director at Medstar Washington Hospital Center and faculty member of the NIH vascular neurology fellowship program.

Byanyima chosen to lead UNAIDS

Winnie Byanyima is the new executive director of the Joint United Nations Programme on HIV/AIDS (UNAIDS). She previously led Oxfam International, the global organization addressing the injustice of poverty. Trained as an aeronautical engineer, Byanyima's experience as a champion for women and marginalized communities began 30 years ago as member of Uganda's parliament.

Rotimi recognized for human genetics research

The American Society of Human Genetics has honored Dr. Charles Rotimi for his outstanding scientific achievements during the past decade. A genetic epidemiologist and senior investigator with NIH's National Human Genome Research Institute, Rotimi's lab discovered African-specific variants for diabetes, obesity, lipids and metabolic syndrome.

Ramsay among distinguished women researchers

Dr. Michele Ramsay received a 2019 South African Women in Science Award in the category of natural and engineering sciences. A professor of human genetics at the University of the Witwatersrand, Ramsay has held a Fogarty research training grant for noncommunicable diseases and is part of the NIH-supported Human Heredity and Health in Africa (H3Africa) initiative.

Global HEALTH Briefs

NIH Director publishes innovation forecast

Ten promising areas for biomedical innovation are highlighted in a book chapter authored by NIH Director Dr. Francis S. Collins. Part of the Global Innovation Index 2019 report, Collins describes the most exciting areas of science that might yield "striking progress" in the next decade.
Full report: http://bit.ly/NIHInnovation

Child Health launches strategic plan

Global health was one of five cross-cutting topics identified in the NIH's National Institute of Child Health and Human Development's new strategic plan. Priorities include research to improve health of at-risk mothers and children, and exploration of new technologies.
Full plan: http://bit.ly/NICHDplan

Mental Health unveils research toolbox

The NIH's National Institute of Mental Health (NIMH) recently developed a Clinical Research Toolbox designed to assist clinical investigators with the development of clinical research studies. It includes NIH and NIMH policy documents, sample forms and other resources.
Website: http://bit.ly/NIMHtools

WHO reports on HIV drug resistance

The rise in antimicrobial resistance—including the threat posed by drug-resistant HIV—is one of the greatest challenges in global health, according to the WHO. Its latest report shows that in 12 of the countries reporting data, pretreatment HIV drug resistance exceeded 10%.
Full report: http://bit.ly/WHO_HIV

Report says better nutrition saves lives

A stronger focus on improving global nutrition could save 3.7 million lives globally by 2025, according to a new WHO report. While childhood stunting has declined, the prevalence of obesity is on the rise in nearly every region and country. The Essential Nutrition Actions publication provides a tool for countries to improve their health policies.
Full report: http://bit.ly/nutrition_WHO

Global pandemic preparedness lacking

Despite the risk of widespread epidemics, many countries are not ready to respond in a crisis, according to the inaugural report of the Global Preparedness Monitoring Board. About 59 countries have action plans but none has been fully funded.
Full report: http://bit.ly/GlobalPMB

Funding Opportunity Announcement	Details	Deadline
Noncommunicable Diseases and Disorders Research Training Programs in LMICs D43 Clinical Trial Optional	http://bit.ly/NCDtrain	Nov 12, 2019
Reducing Stigma to Improve HIV/AIDS Prevention, Treatment and Care in LMICs R21 Clinical Trial Optional	http://bit.ly/NIHstigmahiv	Nov 12, 2019
Global Infectious Disease (GID) Research Training Program D71 Clinical Trials Not Allowed	http://bit.ly/IDtraining	Nov 12, 2019
Mobile Health: Technology and Outcomes in LMICs R21/R33 - Clinical Trial Optional – non-AIDS applications	http://bit.ly/NIHmhealth	Nov 19, 2019
Ecology and Evolution of Infectious Diseases Initiative (EEID) R01	http://bit.ly/EEIDNIH	Nov 20, 2019
African Postdoctoral Training Initiative (APTI)	http://bit.ly/NIHAfricanPostdoc	Dec 1, 2019
Mobile Health: Technology and Outcomes in LMICs R21/R33 - Clinical Trial Optional – AIDS applications	http://bit.ly/NIHmhealth	Dec 3, 2019
Heart, Lung, and Blood Comorbidities Implementation Models in People Living with HIV (HLB-SIMPLe) UG3/UH3 Clinical Trial Optional U24 Clinical Trial Not Allowed	http://bit.ly/hlbsimple http://bit.ly/hlbsimple-center	Dec 10, 2019
Global Noncommunicable Diseases and Injury Research R21 Clinical Trial Optional	http://bit.ly/NIHncds	Dec 13, 2019

For more information, visit **www.fic.nih.gov/funding**

Global Health Matters

September/October 2019

Volume 18, No. 5 ISSN: 1938-5935

Fogarty International Center
National Institutes of Health
Department of Health and Human Services

Managing editor: Ann Puderbaugh
Ann.Puderbaugh@nih.gov

Web manager: Anna Pruett Ellis
Anna.Ellis@nih.gov

Writer/editor: Shana Potash

Designer: Carla Conway

SUBSCRIBE:
www.fic.nih.gov/subscribe

WHO calls for more research into microplastics pollution

Plastic Ocean by Kevin Krejci CC BY 2.0

The WHO has released an assessment on microplastics in drinking water that suggests current levels aren't a human health risk but more studies are needed. The report examines the evidence related to the occurrence of microplastics in both tap and bottled drinking water, the potential health impacts, and the removal of microplastics during wastewater and drinking-water treatment.

Researchers should undertake targeted, well-designed and quality-controlled investigations to better understand the occurrence of microplastics in the water supply chain and their health effects under relevant exposure scenarios, according to the WHO.

RESOURCES

Full report: http://bit.ly/WHOplastics