



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

Fogarty launches plan to meet new global health needs

Global health research and training efforts should focus on combatting the growing epidemic of noncommunicable diseases (NCDs), better incorporating information technology into research projects and training tools, and more effectively converting scientific discoveries into practice in low-resource settings. These are among the goals detailed in Fogarty's new strategic plan, developed with input from the global health research community and in consultation with its many partners and grantees.

As research discoveries and aid efforts have reduced the death toll from HIV/AIDS, aging populations in the developing world are increasingly suffering from NCDs—heart disease, cancer, diabetes, mental illness and others. "It is critical that we leverage the HIV research and care delivery platform to build the capacity needed to stem the tide of these new disease epidemics," said Dr. Roger I. Glass, who leads Fogarty and also serves as the NIH Associate Director for Global Health Research. "We must focus our attention on these pressing problems, which



also plague us at home in the U.S., and discover new ways to prevent and treat them," Glass suggested. "Today, global health and local health are becoming one and the same and research anywhere can help people everywhere."

Fogarty plans to reinvigorate its efforts to train more developing-country scientists in these new areas of global health, where the field is

moving and where the most interesting discoveries are yet to be made, Glass said.

"Our concept of investing in training outstanding young investigators, both U.S. and foreign, and linking them

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NIH celebrates a decade of brain disorders research

Scientists gathered at NIH recently to explore frontiers in neuroscience for global health and to mark the 10th anniversary of Fogarty's brain disorders program, which is designed to focus attention and resources on this neglected area.

"There is no health without mental health," observed Dr. Thomas Insel, Director of the National Institute of Mental Health, who said it is "critical" this profound public health need is addressed as efforts are made to improve health care globally.

Yet an "unconscionable" gap remains between the care available for neurological conditions for people living in

wealthy countries as compared to populations living in low-resource settings, said Dr. Steven Hyman of Massachusetts Institute of Technology and Harvard University. This brings "huge societal costs," not only for patients but also for their caretakers and communities, he said. "It degrades human capital formation."

Research is key to improving patient care and must be conducted in-country to be viable and effective, said Dr. Gwen Collman, a director at the National Institute of Environmental Health Sciences. With community engagement and involvement, she noted, "you can translate the results more quickly."

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FOCUS



FOCUS on biomedical technology transfer

- NIH and its partners work together to spur biomedical technology development
- Low-resource populations more quickly gain access to affordable vaccines, drugs
- NIH provides training on global technology transfer and intellectual property

Read more on pages 8 - 9

NIH celebrates a decade of brain disorders research . . . continued from p. 1

Recognizing this research need, in 2003 Fogarty launched its program, Brain Disorders in the Developing World: Research Across the Lifespan. With broad support across NIH, the initiative has provided at least \$85 million to fund more than 150 projects that investigate conditions afflicting populations in low-resource countries. The disorders range from neurodevelopmental problems, such as autism, to neurodegenerative diseases, such as Alzheimer's, to neuropsychiatric conditions, as in depression.

One grantee who collaborates with researchers on different continents is Dr. Richard Guerrant at the University of Virginia. His projects in Brazil and South Africa have shown how child malnutrition impairs cognition and can be prevented by low-cost interventions such as zinc supplementation and reducing the incidence of diarrhea. Research evidence such as this, Guerrant noted, is essential for "driving future policy decisions."

Indeed, this is what happened in Barbados when researchers, starting in the 1960s, amassed records on malnutrition and child mortality. "We worked very hard with the government of Barbados to make malnutrition a reportable disease," said Dr. Janina Galler of Harvard. The government adopted a comprehensive nutrition program to age 12, and malnutrition was eliminated by 1980.

"All children should have the chance to achieve their full potential," said Dr. Alan Guttmacher, Director of the National Institute of Child Health and Human Development. He added this means protecting cognitive development not only prenatally and in the first months of life, but also "well beyond."

Fogarty's brain program covers conditions that strike at all ages, including adult onset neurodegenerative disorders and dementias. National Institute on Aging Director Dr. Richard Hodes noted about 15 percent of the world's population will be over 65 in a few years. "The challenges are going to be absolutely enormous, in particular those posed by age-related diseases," Hodes said. To maximize progress, he urged researchers to share their data widely and in interpretable forms.

One new arena for brain researchers is HIV/AIDS, where antiretrovirals have dramatically extended patients' lives but little is known about the long-term neurological impact of either the virus or the drugs. Fogarty brain program projects include studies of cognition in children exposed to HIV at birth, and the link between HIV and cerebral malaria.

The knowledge gleaned from global health research can bring insight into health everywhere, noted Dr. Story Landis, Director of the National Institute of Neurological Disorders and Stroke. She cited a Peruvian study of a tape-

worm disease transmitted from pigs to people and noted in one U.S. public hospital, a third of patients with epilepsy had eaten infected pork. "So it's not just a developing country issue," she said. "It's also an issue in this country."

Researchers seeking low-cost interventions in developing countries have produced novel, inexpensive approaches relevant for developed countries as well. Dr. Benjamin Warf, a current Fogarty grantee, in earlier research in Uganda devised a minimally invasive procedure for treating hydrocephalus. The procedure, now also adopted in the U.S., has greatly reduced the number of patients receiving brain shunts, which carry a higher infection risk. In another example of two-way benefit, a study in Latin

Photo by Ernie Baranson/NIH



NIH leaders discussed a number of significant accomplishments of Fogarty's brain disorders program, which receives broad support across the Institutes and Centers.

America compared treatment of traumatic brain injury using the expensive high-tech equipment common in the U.S. with its own practice of clinician monitoring, and found no difference in patient outcome. "It has caused us to rethink our care and ask what really, truly is important," said Dr. Randall Chesnut of the University of Washington. "By corroborating across borders, we can come to a better understanding of what we do."

As well as producing science to expand knowledge about brain disorders and ways to diagnose, prevent and treat them, a key aspect of Fogarty's brain program has been to provide significant training for more than 140 developing country researchers to expand capacity in their countries.

Chesnut's traumatic brain injury project, for example, involves 13 intensive care units in Latin America where many former trainees are conducting their own research and training programs. With Fogarty brain program grants, "you're making researchers as you're doing research," he said. "It's a bit like building the bridge as you're driving across it. We need to integrate the idea that research is not what you read in a journal, it's what you do in the educational process and in the machinery of medicine."

NIH research shows hookahs pose risks

By Cathy Kristiansen

Puffing tobacco through waterpipes, a Middle Eastern tradition, is exploding in global popularity, including among American college students. Many assume these gadgets, also known as hookahs, provide a safer, cleaner way of using tobacco. Yet NIH-funded researchers have determined the smoke from these pipes contains an array of harmful chemicals, including 10 times more carbon monoxide than the smoke from a single cigarette. Hookah smokers take an average of about 100 puffs per session, with each one delivering approximately the same amount of smoke typically consumed from a single cigarette, studies show.

“Now hookahs are the number two way of using tobacco on campus, it’s becoming a craze,” said Fogarty grantee Dr. Wasim Maziak of both the Syrian Center for Tobacco Studies and Florida International University. He added, “We have been beating the drums about the dangers of hookah smoking—including nicotine addiction, and the risk of cancer and cardiovascular disease—but the spread of waterpipe use continues unabated. This calls for more a comprehensive approach involving policy and regulatory oversight.”

There is little or no regulation of hookahs and many factors attract new people to waterpipes, including the misperception that the water in the bowl cleanses away the toxicants. Smokers are also drawn by novelty flavors, such as melon and mint-rose, and to the communal aspects of smoking a waterpipe in a café.

Yet, smoke from both the tobacco and the charcoal used to heat it produce a toxic soup at least as dangerous to health as cigarettes, researchers report. Studies have compared the smoke from each form and found many similar harmful compounds, although in varying quantities. Waterpipes, for instance, produce not only much more carbon dioxide, but also three to five times the amount of volatile aldehydes, such as formaldehyde, which are linked to a variety of disorders including pulmonary disease. Waterpipe smoke also contains triple the level of phenols—compounds thought to promote DNA mutations and cardiovascular disease—and high concentrations of benzene, a leukemia trigger.

Both waterpipes and cigarettes expose the smoker to ultrafine particles, which are not easily removed from the body or environment, polyaromatic hydrocarbons that

Photos by Cathy Kristiansen



NIH-funded researchers have shown waterpipe smoking, popular among U.S. college students, carries serious health risks.

are contained in “tar” that is present in the smoke, and enough nicotine to cause dependence. In sum, both users and bystanders breathe in compounds that cause lung inflammation, oxidative stress, higher counts of immune cells and other precursors to cancers, chronic obstructive pulmonary disease and cardiac dysfunction.



Researchers funded by Fogarty’s tobacco program were among the first to sound the alarm about waterpipes a decade ago. There are signs policymakers are starting to pay attention. “I’m getting calls right and left from regulators wanting to know more,” Maziak said. Ideally, he added, all U.S. regulations for cigarettes would be extended to cover waterpipes as well. Currently, the U.S. has about 2,000 smoke-free laws, but very few include waterpipes. The Campaign for Tobacco-Free Kids notes although the FDA regulates cigarettes and some other tobacco products, it has no jurisdiction over hookahs.

“People say, ‘There’s no warning label on the packet so it must be safe.’ We need the same kind of restrictions worldwide that are presently getting in place for cigarette smoking,” said NIH grantee Dr. Thomas Eissenberg of Virginia Commonwealth University.

In addition to Fogarty, several other NIH components support waterpipe research, including the National Cancer Institute; National Heart, Lung and Blood Institute; National Institute of Nursing Research; National Institute on Alcohol Abuse and Alcoholism, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Child Health and Human Development, and National Institute on Drug Abuse. Since the mid-2000s, NIH-funded researchers have produced more than 100 articles in peer-reviewed journals.

Regulators can use this evidence to justify waterpipe controls and unwitting smokers should listen to the facts about their habit, Eissenberg said, concluding, “We need to get the word out to waterpipe smokers themselves that they are exposed to many of the same toxins that are in cigarette smoke.”

RESOURCE

More information: <http://bit.ly/hookahresearch>

Fogarty launches plan to meet new global health needs

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early in their careers in research partnerships between their institutions has been a winning strategy that has had a major impact on the research enterprise for global engagement.” Fogarty trainees have participated in research studies that have resulted in key discoveries to improve care and reduce the spread of HIV/AIDS. These include determining that populations in low-resource settings can adhere to complicated treatment regimens and that antiretroviral drugs and circumcision are effective at preventing disease transmission.

To capitalize on the upsurge of interest in global health on U.S. campuses, Fogarty intends to boost efforts to recruit investigators with diverse specialties including cardiology, oncology, bioengineering, neurology and mental health, and other topics that in the past were not considered in the realm of global health. “In order to solve the increasingly complex global health problems, we must also transform our programs to spur innovative solutions created by multidisciplinary teams with skills not traditionally related to health, such as engineering, business, economics and law,” Glass observed.

Another priority under the new plan is to intensify efforts to incorporate information and communication technology (ICT) into the Center’s research and training programs. “Our grantees and partners are producing novel teaching tools and electronic resources that make knowledge about disease and prevention freely available to all,” Glass noted. The Center recently requested proposals to develop innovative educational approaches that would enhance research capacity in low- and middle-income countries (LMICs). “E-learning is a powerful way to enable physicians and medical personnel at all levels to gain access to the ever-expanding and changing knowledge base that can

Fogarty’s new strategic plan stresses the importance of intensifying efforts to incorporate information communication technology into its research and training programs.

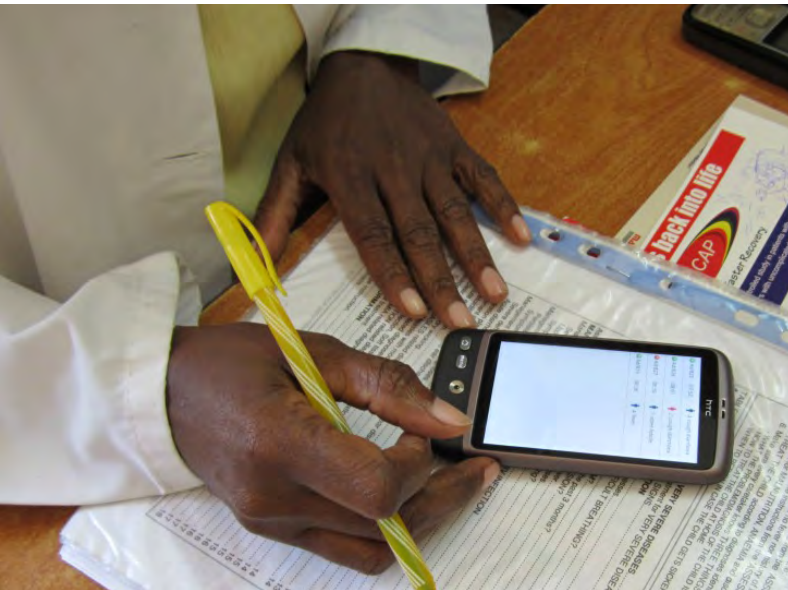


Photo by Curt Cornemark/World Bank



One of Fogarty’s new goals is to focus on research and training to address the rising tide of chronic, noncommunicable diseases in low-resource settings.

keep them up-to-date throughout their careers,” Glass explained. “Now that more people in LMICs have cellphones than toilets, we see growing opportunities to adapt mobile applications to improve access to populations for research and provision of care.” It will be critical that these projects are carefully monitored and evaluated to ensure they are effectively integrated into the practice of medicine, public health and research, he said.

Implementation science remains a high priority for the Center under the new plan, so that proven interventions are quickly adapted for use in low-resource settings and are actually delivered there and scaled up effectively. Increased efforts are needed to catalyze partnerships and improve communication between the scientific community and program implementers and decision-makers, so that science informs program and policy, and research is responsive to program and policy needs, according to the plan.

Fogarty’s new strategic vision is intended to advance the global health research agenda by building on past and current Fogarty investments and successes in a way that responds to the changed landscape in global health. Specific goals and priorities are outlined in five main areas: building research capacity to meet current and future global health challenges; stimulating innovation in the development and evaluation of technologies to address global health problems; supporting research and research training in implementation science; advancing research on prevention and control of communicable and noncommunicable diseases and disability; and building partnerships to advance global health research and research capacity.

Photo courtesy of Dr. Marc Mitchell

“By taking science to where the problems are, and by supporting research and research training in areas where the burden of disease is greatest, Fogarty investments will continue to build the health research workforce of the future while bringing scientific inquiry to bear on some of the world’s most complex health problems affecting populations both at home and abroad,” Glass concluded.

RESOURCE

Website: <http://bit.ly/FogartySP>

STRATEGIC PLAN GOALS

GOAL 1

Build research capacity through INDIVIDUALS, INSTITUTIONS and NETWORKS to meet future and evolving global health challenges

► **Strategic Priorities**

- Support training of INDIVIDUALS to build future research leaders in the U.S. and low- and middle-income countries (LMICs).
- Invest in INSTITUTIONS as sustainable platforms for research in LMICs.
- Promote research NETWORKS.
- Stimulate linkages among disciplines to address complex global health problems.

GOAL 2

Stimulate innovation in the development and implementation of technologies and other locally relevant solutions to address global health problems

► **Strategic Priorities**

- Support the enhanced use of information and communication technologies to facilitate and improve health research education.
- Encourage innovation in the development and implementation of mobile and other technologies, systems, and policies to address global health problems.

GOAL 3

Support research and research training in implementation science

► **Strategic Priorities**

- Expand investment in research and research training in implementation science across programs.
- Catalyze interaction between researchers, policymakers and program implementers to promote uptake of evidence into global health policy and practice.

GOAL 4

Advance research on prevention and control of the dual burden of communicable and noncommunicable diseases and disabilities

► **Strategic Priorities**

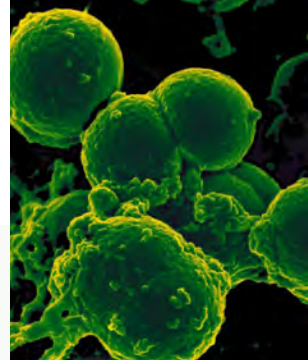
- Support research and research training in clinical, behavioral and population sciences.
- Identify ways to leverage investments in communicable diseases, including HIV, to better address the dual burden of disease.

GOAL 5

Build and strengthen partnerships to advance global health research and research capacity

► **Strategic Priorities**

- Engage and support the NIH Institutes and Centers to advance their research agendas for global health.
- Forge partnerships at home and abroad to leverage complementary interests and strengths.
- Convene global experts to address priority research questions and catalyze new areas of science.



PROFILE

Fogarty Scholar helps improve speed of disease diagnoses

By Arthur Allen

As a medical student on a Fogarty Fellowship in Dar es Salaam, Tanzania in 2005, Paul Drain watched AIDS patients die because they couldn't afford needed medicines. After each day's rounds, Drain would spend hours writing in a journal just to keep from feeling totally powerless.

Eight years later, on his second Fogarty-sponsored research experience, in South Africa, the drugs are there—at least for HIV patients—thanks to global initiatives. But keeping patients alive after diagnosis still involves hurdles. The focus of his work today is developing easy, cheap ways around them.

“My group at Harvard has done several studies showing that when these patients leave the clinic, around 40 percent never come back,” Drain says. Many of those told to return for the results of tuberculosis tests, or CD4 counts that indicate the seriousness of HIV infection, never do.

Drain used his two-year award from the Fogarty's Global Health Program for Fellows and Scholars to assess point-of-care diagnostics that can short-circuit such delays. One is a urine test for TB that resembles a home pregnancy kit; the second a modular CD4 cell counter. Both provide results in 20 minutes.

“This way, the patient is still there and we can start treatment right away. We don't have to send samples to the lab, to pay for transportation and processing,” he says. “Also, nurses aren't exposed to the risk of TB by getting patients to cough for sputum samples.”

Drain is continuing his research at the KwaZulu-Natal Province clinic, where 40 people are tested each day. About a third are found to be HIV-positive, and about 20 percent of the HIV patients are also positive for tuberculosis, including extreme drug-resistant strains. The intersection of the two has just been devastating. Doctors will not start patients on a regimen of HIV medications until they can exclude a TB diagnosis, because TB must be brought under control before a patient can take antiviral drugs that will strengthen



Paul Drain, M.D., M.P.H.

Fogarty Scholar:	2011-2013
Fellowship at:	Durban, South Africa
U.S. partner:	Harvard University
Research topic:	Point-of-care diagnostics for TB and HIV
Website:	http://bit.ly/PDrain

his or her immune system. The faster it all happens, the better the results—for the patient and public health—since untreated diseases spread to others in the community.

Drain first got interested in public health as a Peace Corps volunteer in Morocco in 1997. He had nothing more than a freshly printed bachelor's degree in microbiology. With no doctor or nurse in his village, Drain became a kind of de facto public health administrator, helping to build bathhouses and set up an immunization program.

After returning to the United States, Drain earned both a master's in public health and a medical diploma at the University of Washington, Seattle. After his third year in medical school, he spent a year in Tanzania as a Fogarty Fellow, working under Dr. Wafaie Fawzi, professor of nutrition and epidemiology at the Harvard School of Public Health.

Drain's enthusiasm for the work led him in 2008 to publish a practical reference guide for students, called *Caring for the World: A Guidebook to Global Health Opportunities*. He's currently working on two related books, and spends several weeks every three months conducting research at King Edward Hospital and the Ithembalabantu People's Hope Clinic in Durban, South Africa.

There are more opportunities than ever before to participate in global health and they're easier to access, notes Drain. “Young people are thinking more globally than generations before. They want to diversify their training, see different types of diseases,” Drain concluded. “Fogarty's support has allowed me and many other people to continue doing global work. Without their support a lot of this wouldn't be possible.”

SALIM ABDOOL KARIM, M.D., PH.D.

Dr. Salim Abdool Karim is a clinical infectious disease epidemiologist and world expert in HIV prevention and treatment research. He directs the Center for the AIDS Program of Research in South Africa (CAPRISA) and is a grantee of the National Institute of Allergy and Infectious Diseases and Fogarty. He recently stepped down as President of the South African Medical Research Council to focus more on his research. His academic affiliations include the University of KwaZulu-Natal, Columbia, Cornell, MIT and Harvard. Below are excerpts from his recent lecture at NIH.



What progress has been made against HIV?

What we are seeing now is a different phase of the HIV epidemic than the first 25 years. We've seen a huge push and increase in resources to fight AIDS. Several countries are systematically closing the gap between those who should be on treatment and those who actually are on treatment. If we look at the expenditure by each of the key countries, we see rapid growth in local expenditure in the last several years at the country level. So now we are no longer seeing the same level of dependence on international assistance, we are seeing countries rising to the challenge of treating their people with local financial resources. We have seen antiretroviral treatment having a dramatic impact at the community level, increasing life expectancy by as much as 20 percent in some instances. There's no other intervention in history I can think of—maybe the steam engine, introduction of clean water and sanitation or the agricultural revolution—that led to such enormous increases of life expectancy. And at the same time, we're seeing the benefits of prevention. But we still have much work to do.

What are the biggest challenges?

We already have 35 million people living with HIV with no cure in sight, so AIDS is not going away anytime soon. Even as we start talking about the end of AIDS, it's a substantial existing problem affecting almost every region of the world. We have not yet controlled HIV globally due to a range of obstacles, with three of them being key. The first is dysfunctional health systems. While we have new efficacious tools to fight HIV, we have not been always able to convert them into prevention interventions with maximum effectiveness. Second, although the number of new infections is going down globally, HIV continues to grow in several key populations such as young women in Africa, men who have sex with men, transgender persons and injecting drug users. And then the third is stigma and discrimination, which remain major obstacles to both treatment and prevention access.

What role should research play?

A key step on the path to ending AIDS is what I call epidemic control—that point at which AIDS no longer

represents a public health threat. We're not going to get there unless we really know our local epidemic, the key populations and the detail of the local epidemiology that defines where the pockets of populations with ongoing high HIV incidence continue to exist. We cannot deal with the problem of high HIV rates in sex workers if sex work is illegal and driven underground. We cannot deal with the challenges of implementing HIV prevention tools in men who have sex with men in Uganda if imprisonment is what they face. It's going to take the kind of global solidarity that raised billions of dollars to fund the anti-AIDS effort to now also deal with these kinds of legal, social and structural obstacles to HIV prevention and treatment.

What innovations are needed most?

To reach the goal of scaling up antiretroviral treatment to everyone with HIV, we need a new paradigm for the way in which these services are provided. In a country like South Africa, with six million people living with HIV, if we are to make treatment available by the current approach—where patients have to take a tablet every day and come to the hospital or clinic regularly to get their blood tested—I think we are in a situation where the already overburdened health system will simply not cope. I foresee a day where HIV patients who have undetectable viral loads could be switched to four injections a year with new long-acting antiretroviral drugs that are currently being tested. Also, we're going to have to find new diagnostics for primary HIV infection. This remains an ongoing problem, where we are putting patients on treatment several years after they've become infected and have already spread the virus.

We risk losing the momentum against AIDS if we miss this historic tipping point created by an amazing amount of research we've seen in the last four years. Achieving epidemic control depends on doing what we know works. We can't simply be doing great science to find and discover new tools. We're going to have to do great science to figure out how to get those tools to the people who need them so that we see their impact. I don't believe we're going to end AIDS tomorrow, but I do believe that objective has to be part of our long-term vision.

NIH tech transfer office speeds global health products

NIH and its partners are pursuing creative new ways to move biomedical innovations more quickly from publicly-funded laboratories to developers to factories. Their goal is to ensure new products such as vaccines and more affordable HIV/AIDS treatments reach those who need them most in low-resource countries.

“We want to have an impact where we can, in areas of the world where the disease burden is heavy,” said Steven Ferguson, Deputy Director of Licensing and Entrepreneurship in NIH’s Office of Technology Transfer (OTT). “Diseases know no national boundaries and with the globalization of living styles, we just have to have a global approach.” The OTT was established in 1989 to centrally manage technological innovations made by intramural scientists at the NIH and the FDA, including the licensing, patents and royalties.

Three key changes jolted the status quo in how biomedical inventions are handled: new U.S. technology transfer legislation, more favorable licensing agreement terms and the rise of global partnerships to steer products through development to low-resource markets.

NIH and partners are finding creative ways to steer new technologies from invention to development to delivery of vaccines and drugs to low-resource countries.

Developing a new compound usually costs hundreds of millions of dollars and is fraught with risk, Ferguson noted. He compared the typical path for an innovation born at a U.S. government laboratory to reach the bodies of humans with the three-stage launch of a rocket. In the initial stage, scientists come up with a new compound or technique, such as a chemical that kills the parasite responsible for river blindness or a protein that induces a strong immune response to an influenza virus, and they test it for safety in animals or even in a few dozen people.

In the second stage, a biotechnology company—often a startup or pharmaceutical firm—acquires permission to make its own products using the technology. It conducts development often up to phase 2 clinical trials in perhaps 200 people to test for efficacy and side effects. Although NIH intramural scientists may not commercialize products themselves due to conflict of interest rules, they may help others with the basic or clinical research as part of their official duties. NIH-funded recipients outside government, such as universities, own the technology they invent and may develop it themselves or transfer it.

Finally, the biotech company—or an interested pharmaceutical firm that acquires the technology rights, sometimes by purchasing the smaller company—conducts large phase 3 trials involving 1,000-3,000 people. These are costly and the product must demonstrate that the product is safe and improves health in order to garner regulatory approval.

“There’s developmental risk, financial risk and regulatory issues, particularly on novel approaches,” Ferguson said. Against all this, the developing and emerging country markets might be small and the price charged must be low enough to be affordable, he noted. “The risk, on top of something that perhaps doesn’t have a very strong market in Western countries, makes for a difficult overall proposition for development.”

But more economical biotechnology products are now finding their way to low-resource settings. “We are doing more and more licenses



Photo by Gabee Bienczynski/PATH

at non-U.S. companies,” Ferguson said. “It is a relatively small number of agreements, about 300 so far including those completed in non-U.S. Western countries, but they have a huge health impact. This will make a real difference from a global health perspective, especially for the several dozen to date, done directly in emerging or developing countries.”

The trigger for a proactive approach to technology transfer at NIH was a change in U.S. legislation. In the past, the government retained the rights to all technology produced by both NIH and NIH-funded scientists. But rather than attracting developers to make products and share the revenue with the government, most technology gathered proverbial dust on the shelf. So Congress passed legislation in 1980 to require the formation of formal technology transfer offices and programs at both federal labs like at NIH and at government-funded institutions. The Bayh-Dole Act allows extramural government-funded grantees to hold the rights to their innovations and the similar Stevenson-Wyndler Act enables agencies to own and manage their intramural innovations.

But even with more favorable conditions for transferring ideas out for development, a number of new products were still beyond the reach of many country budgets. So in recent years, NIH and other public and private organizations have partnered to bridge this gap, negotiating more favorable licensing and manufacturing agreements, raising funds to purchase vaccines and drugs, and securing government collaboration in developing countries.

This has triggered a surge in new products using technologies licensed by the OTT—more than 600 across all markets to date. One is the meningitis A vaccine. The NIH OTT licensed the vaccine conjugation technology developed intramurally at the FDA to the nonprofit PATH, which teamed up with the WHO to set in motion production of the vaccine at a prearranged price. In another case, OTT transferred vaccine technology to South Korea’s International Vaccine Institute for a typhoid vaccine produced in Indonesia and India for Asian populations. Also, the nonprofit GAVI Alliance was formed to bring low-cost vaccines to global populations via negotiations on technology transfer, manufacture and sale of these products. It garners funding from international organizations, donor governments, philanthropic groups and the pharmaceutical industry.

In another approach supported by the President’s Emergency Plan for AIDS Relief (PEPFAR), the FDA introduced a special licensing agreement for generic antiretrovirals to be produced and sold in developing countries, while upholding the brand-name drug’s patent protection at home. These cheaper drugs mean millions more patients can access lifesaving treatments.

Photo courtesy of NIAID



New laws, licensing terms and global partnerships are speeding translation of scientific discoveries into lifesaving biomedical products.

The changing face of technology transfer carries several risks from a corporate perspective, not least in opening up an alternative supply chain of drugs that could filter back into developed countries and threaten sales of pharmaceutical companies there, Ferguson noted. And enforcement of intellectual property rights is weak in some countries, eroding the willingness of a company to pour money into drug development if their findings might be snatched by another firm. But, he said, “That’s all been changing.”

For its part, NIH’s OTT and technology transfer staff in the Institutes and Centers are raising global awareness of intellectual property and technology transfer issues by sending trainers as part of NIH or other federal agency programs to a number of low- and middle-income countries. In addition, the OTT offers a mentoring program in technology transfer on the NIH campus for officials from foreign research institutes or government agencies.

The OTT currently holds rights to nearly 8,000 inventions and has licensed technology relevant to diseases such as HIV/AIDS, malaria, dengue, rotavirus, meningitis and typhoid fever. License negotiations are completed or ongoing with a growing number of public and private institutions in India, Mexico, Brazil, China, Korea, Egypt, Argentina and South Africa.

“We are finding a home for the technology where the real need is, where it can have a large public health impact,” Ferguson noted. “It has been really exciting to see this level of interest and activity, where 10 years ago we had almost none.”

RESOURCE

Website: www.ott.nih.gov

OPINION

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

Bioethics in research: strengthening the foundation



No research on human subjects can be conducted without an effective local system in place to ensure the protection of human subjects. And yet many low- and middle-income study sites lack the capacity to address this critical need. In recognition of this issue, Fogarty hosted the first Global Forum on Bioethics in Research in 1999. The following year the Center launched its International Research

Ethics Education and Curriculum Development program. Several other NIH institutes, which appreciated the value of this endeavor to their own programs, joined this initiative. Over the past decade, this program has grown to address the urgent need to train a cohort of bioethicists in low-resource settings where research is conducted and encourage them to build academic programs and national structures for biomedical review and research ethics.

I'm pleased this program is being featured in two sets of papers written by many of its principal investigators and published in the *Journal of Empirical Research on Human Research Ethics*. The timing of this series could not be better: 2014 will mark the fiftieth anniversary of the publication by the World Medical Association of the Declaration of Helsinki, the document that first outlined many of the central principles for the ethical conduct of biomedical research.

This collection on international research ethics education comes at a critical point for the global health community. The past decade has witnessed a major increase in funding for biomedical research globally and a clear shift toward the conduct of more clinical trials in low- and middle-income countries (LMICs). This shift recognizes that biomedical research anywhere can help people everywhere and that many health problems of global concern can best be addressed by conducting studies in countries where these problems are most prevalent.

For example, much of our understanding of the treatment and prevention of HIV/AIDS has come from research in countries where this problem is most devastating, especially in sub-Saharan Africa. The testing of new drugs and regimens, and the development of strategies to prevent transmission of the disease—prevention of mother-to-child transmission, circumcision, counseling of discordant

couples and treatment as prevention—have all benefited from extensive research conducted in areas where the disease has the greatest prevalence and the most devastating impact.

Major funding for these studies has come from international donors, which raises concerns about who controls the research agenda, who benefits from the research, and whether the pressure to achieve expeditious results might trump concerns for the safety and well-being of the populations being studied. Researchers also face unique challenges in low-resource settings, for example, creating a meaningful informed consent process among low-literacy populations and providing ancillary care to study participants who lack access to adequate health care. NIH-supported research, no matter where it takes place, must adhere to the same high ethical standards. Our ability to address many critical health concerns can only advance by globalizing our research agenda and extending our ability to assess and understand the underlying ethical issues. International training and research in research ethics is essential.

While many other research sponsors have recognized and joined the global effort to support training and research in research ethics in LMICs, funding and support have not kept pace with the growth of global health research. Consequently, these efforts at training and research in research ethics remain a critical need but an orphan child.

While this collection highlights some of the key features and findings of the Fogarty program, it also provides clear directions to advance research ethics education for the future. Unquestionably, as clinical research and trials increase in LMICs, the need for skilled local experts to independently assess and address thorny ethical issues will remain key. Fogarty, along with its many partners at NIH, is committed to being part of this continuing and essential process.

This is a condensed version of the editorial, "International Research Ethics Education," published by the Journal of Empirical Research on Human Research Ethics (JERHRE).

RESOURCE

JERHRE Papers: <http://bit.ly/Fbioethics>



Birx confirmed as new U.S. Global AIDS Coordinator

The U.S. Senate has approved the nomination of Dr. Deborah L. Birx to be U.S. Global AIDS Coordinator, a position previously held by Ambassador Eric Goosby. Birx is a veteran AIDS researcher who previously led the CDC's division of global HIV/AIDS.



Dr. Joseph C. Kolars

Fogarty adds three new advisory board members

Fogarty has announced the appointment of three new members to its advisory board. The panel is comprised of researchers, policymakers and others involved in global health who can provide strategic advice to Fogarty on its policies, programs and other matters.

Dr. Joseph C. Kolars, a Fogarty grantee, is Senior Associate Dean for Education and Global Initiatives and professor at the University of Michigan. He has consulted for the Medical Education Partnership Initiative and the Bill and Melinda Gates Foundation.



Dr. Wafaa M. El-Sadr

Dr. Wafaa M. El-Sadr, a Fogarty grantee, is professor of epidemiology and medicine at Columbia University. She founded the university's Mailman School of Public Health program that provides family-centered care and services to HIV/AIDS patients.



Dr. J. Stephen Morrison

Dr. J. Stephen Morrison is Senior Vice President and Director of the Global Health Policy Center at the nonprofit Center for Strategic and International Studies. He testifies before Congress, directs high-level task forces and commissions, and presents ideas in the media.



Gray to lead South Africa's research council

The South African Medical Research Council has selected Dr. Glenda Gray as its president. A former Fogarty trainee and longtime NIH grantee, Gray heads Witwatersrand University's Perinatal HIV Research Unit and directs the HIV Vaccine Trials Network's Africa programs.



US selects Kolker as senior global health diplomat

Ambassador Jimmy Kolker has been named the U.S. Department of Health and Human Services' Assistant Secretary for Global Affairs, following his role as principal deputy. He previously had a 30-year career at the State Department, including ambassadorships in Uganda and Burkina Faso.



Gates Foundation picks Desmond-Hellmann as CEO

The Bill and Melinda Gates Foundation has named Dr. Susan Desmond-Hellmann, an oncologist, as its new chief executive officer. Previously chancellor of the University of California, San Francisco, she is an expert in public health, drug development, regulatory innovation and health policy.

NIH gene database opens to researchers

Researchers can now access genetic data on 78,000 individuals of various ethnicities through NIH's Genotypes and Phenotypes database. The content can be used to identify genetic risks and influences on many health conditions, including those related to aging.

Website: www.ncbi.nlm.nih.gov/gap

NIH, WHO join on environmental health

To promote cooperation among environmental health research institutes around the world and raise awareness about emerging issues in the field, NIH's National Institute of Environmental Health Sciences has launched the NIEHS WHO Collaborating Center.

Website: <http://1.usa.gov/1jQsLI6>

CDC forms global public health division

The CDC recently established a new office to promote global public health capacity and ensure health security. The Division of Global Health Protection will work with countries to build core capacities to prevent disease, disability and death.

Website: <http://1.usa.gov/1IMVAV9>

Report assesses drug and vaccine safety

A new strategy to improve the post-market safety of pharmaceutical products in low-resource countries is described in "Drug and Vaccine Safety in Global Health." The Bill and Melinda Gates Foundation sponsored the research.

Full report: <http://on.cfr.org/1fmEyxk>

Researchers can access ethics training

A new, free online ethics training program for researchers has been launched by the Global Health Network. The comprehensive course, adapted from a WHO program, has 14 modules and includes access to a substantial resource library.

Website: <http://bit.ly/1eaiSVe>

Arab countries see more chronic disease

Although longevity in Arab countries has risen over the past two decades, so has chronic disease, according to the Institute for Health Metrics and Evaluation. This finding is reported in "The State of Health in the Arab World, 1990-2010," published in *The Lancet*.

Website: <http://bit.ly/1my4qMm>

Funding Opportunities

Funding Opportunity Announcement	Details	Deadline
Global Health Research and Research Training eCapacity Initiative (R25)	http://1.usa.gov/190BF4c	May 15, 2014
International Research Ethics Education and Curriculum Development Award (R25)	http://1.usa.gov/15jRbAB	May 22, 2014
Fogarty HIV Research Training Program (D43) (D71) (G11)	http://1.usa.gov/QFOauP http://1.usa.gov/NqFOVm http://1.usa.gov/NqFFkW	July 24, 2014 July 24, 2014 July 24, 2014
Mobile Health (mHealth): Technology and Outcomes in LMICs (R21)	http://bit.ly/ficmobile	Feb 19, 2015
Junior Research Scientists (IRSDA) (K01)	http://bit.ly/IRSDA15	Mar 4, 2015

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

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NIH leaders, grantees present at CUGH meeting

A number of NIH officials and grantees are participating in the fifth annual Consortium of Universities for Global Health conference at the Washington Hilton in Washington D.C. from May 9-12.

PRECONFERENCE ALL-DAY SESSIONS

May 9

- Global cancer: NIH's National Cancer Institute (NCI)
- Innovation and implementation: NIH's National Center for Advancing Translational Sciences (NCATS)

CONFERENCE SESSIONS

May 10

4:30-6:30 p.m.

Medical Education Partnership Initiative: new paradigm in capacity development

4:30-6:30 p.m.

Ethical practices in global health projects and collaborations

May 11

11:00 a.m.-12:30 p.m.

Implications of environmental change for global health practices

4:30-6:30 p.m.

NIH Fogarty Global Health Fellows: global health through multiple lenses

May 12

11 a.m.-12:30 p.m.

Perspectives from NIH directors: Fogarty's Director Dr. Roger I. Glass moderates; invited speakers are Dr. Anthony Fauci of the National Institute of Allergy and Infectious Diseases; Dr. Linda Birnbaum of the National Institute of Environmental Health Sciences; Dr. Harold Varmus of the National Cancer Institute; and Dr. Walter Koroschetz, Deputy Director at the National Institute of Neurological Disorders and Stroke.

Please note sessions are subject to change.

Full schedule available at: <http://bit.ly/1hZTC2L>