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Clinton calls for evidence-based efforts to defeat AIDS

In a speech at NIH marking 30 years of the fight against HIV/AIDS, Secretary of State Hillary Clinton called for a renewed push for an “AIDS-free generation” by the United States and other countries, using scientific advances to stem the pandemic.

“We need to let science guide our efforts,” she told the capacity crowd of scientists and research administrators. “Success depends on deploying our tools based on the best available evidence.” Using a variety of methods in a “combination prevention” strategy is the most effective way to combat HIV/AIDS, Clinton asserted. The focus should be on three key interventions: ending mother to child transmission, expanding voluntary medical male circumcision and scaling up treatment of people living with HIV/AIDS. She noted recent NIH-funded research shows that early treatment with antiretrovirals can reduce transmission of the HIV virus by 96 percent.

In addition to relying on science, Clinton urged more emphasis on country ownership of AIDS prevention programs and called on other donor nations to support the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Photo by Emie Branson



“The goal of an AIDS-free generation is ambitious, but it is possible,” Clinton said.

America must also continue its leadership role in global health, she said. “Our efforts advance our national interests. They help make other countries more stable and the United States more secure. And they are an expression of our values—of who we are as a people.”

NIH Common Fund supports bioethics study, training

All NIH-funded research involving human subjects must be conducted ethically and responsibly, yet there are few resources to advance bioethics studies or train scientists in these practices, particularly in low-resource countries.

To address this critical need, Fogarty recently issued 15 bioethics awards totaling nearly \$755,000. Much of the funding for the one-year supplements came from the NIH Common Fund, which supports strategic, high-impact, trans-NIH initiatives. The awards will provide additional resources to scientists already supported under various

Fogarty programs that advance bioethics issues or support

training in the responsible conduct of research. The grantee project sites are located in 23 developing countries across four continents.

“These awards will help ensure clinical research conducted in international settings will adhere to ethical standards and protect human subjects,” said Fogarty director Dr. Roger I. Glass. “By training scientists who will provide leadership in this field, we hope to have a lasting impact.”

RESOURCES

Complete list of awards at: <http://bit.ly/usyTuA>



- Ethical research in the age of globalization
- Transforming a barren ethics landscape in Nigeria
- Trainee to teacher: Leveraging learning in India

Sparking a career combating HIV/AIDS in Cambodia

By Steve Goldstein

Spotting leadership potential among budding researchers is more an art than a science. But when Fogarty grantee Dr. Roger Detels first met a young Cambodian epidemiologist named Chhorvann Chhea, his gut instincts told him Chhorvann had what it takes.

“You can tell when someone has ambition, drive and the commitment to do well,” said Detels, who leads Fogarty’s AIDS International Training and Research Program grant at University of California, Los Angeles. “I look for that little spark that tells me they will end up being leaders.”

The “little spark” ignited a dynamic career for Dr. Chhorvann, as he’s known in his home country. Since receiving his Ph.D. at UCLA with Fogarty support in 2009, he’s become chief of Cambodia’s national HIV/AIDS surveillance unit. He also was recently named director of the National School of Public Health, where he teaches epidemiology and biostatistics.

The Fogarty program, launched in 1988, supports HIV/AIDS-related research training for promising low- and middle-income country researchers. With Detels at the helm of UCLA’s grant, about 60 researchers have earned advanced degrees, with more than 100 others receiving short-term instruction. Under the program, trainees study their countries’ most pressing questions as part of their learning experience and are required to return home at its conclusion. Chhorvann earned his Ph.D. in epidemiology, with his thesis on the effects of voluntary counseling and testing on the behavior of discordant HIV/AIDS couples in Cambodia.

“Fogarty’s programs are very responsive to the individual needs of the countries and allow flexibility to accommodate changing circumstances,” Chhorvann observed.

Although Cambodia has seen the prevalence of HIV/AIDS infection drop, the disease continues to be a serious health burden. The number of adults and children living with HIV/AIDS declined to 75,000 in 2007 from 120,000 in 2001, according to WHO estimates, but the disease prevalence increased among children.

Projecting the course of HIV/AIDS transmission in Cambodia is vital to controlling the spread of the disease, Chhorvann stressed. As head of the surveillance unit, he

Photo courtesy of Dr. Chhorvann Chhea



Dr. Chhorvann Chhea, who received his Ph.D. with Fogarty support, has become a leader in the fight against HIV/AIDS in his native Cambodia.

oversees HIV prevalence surveys among different so-called sentinel groups—including sex workers and intravenous drug users—and develops national HIV/AIDS projections for use by policymakers and other organizations working to combat the disease.

His UCLA mentors not only gave him the scientific knowledge for these critical tasks, he said, but also motivated him to help train the next generation of Cambodian scientists. He’s currently developing a master’s degree program, so his students can benefit from a curriculum that’s specially tailored to their country’s unique disease priorities and health systems infrastructure.

“You can tell when someone has ambition, drive and the commitment to do well,” said Dr. Roger Detels.

Chhorvann, 38, already has an impressive list of publications to his credit on disease prevalence, changing behavioral patterns among Cambodian sex workers and early warning indicators of HIV drug resistance, among other topics. One of his papers advises countries with limited resources how to use proxies for HIV incidence “since the true incidence is too expensive to measure correctly,” Chhorvann said.

Most recently, he used his training to report on the long-run cost and financing for HIV/AIDS in his country. This project presents different scenarios that the Cambodian government could employ for controlling the spread of the disease.

Chhorvann is also interested in developing the capacity for more research projects in Cambodia, including the potential to compete for NIH funding, and he’s expressed a desire to develop a Cambodia Fogarty alumni network. “Besides my technical knowledge, I have established links with my friends and other UCLA alumni from other countries in the region,” he said in an interview. “With my Fogarty friends, I always feel at ease to consult with them when I have any questions.”

RESOURCES

Publication: <http://bit.ly/mZ5lvP>

Examining the connections between climate change and diarrheal disease

By Jeff Gray

Rainfall, temperature and other climatic factors affect the transmission of diarrheal disease, which causes about two million deaths each year, mostly among children. Fogarty is funding a new project in Ecuador to study the complex relationship between climatic exposures on health and the extent to which social and infrastructure factors can mediate the impact.

The study, led by Dr. Karen Levy of Emory University, is one of nine initial projects funded by NIH's Human Health Impacts of Climate Change program. The new research initiative is administered by the National Institute of Environmental Health Sciences and is designed to explore how climate change will directly and indirectly affect human health risks.

Levy's study will bring together U.S. and Ecuadorian scientists with expertise in environmental epidemiology, modeling and prediction, tropical medicine and health impacts of climate change. The team will employ a novel approach, correlating data from five years of surveillance of diarrheal disease in 4,000 people living in 21 villages in rural Ecuador, weather pattern data for the same region



A new Fogarty-funded study in Ecuador examines the link between climatic exposures and health, and whether social and infrastructure factors can mediate the impact.

dating back to 1965, and datasets on social and infrastructure conditions in the villages.

The third data component of the team's approach will be crucial, as the communities being studied vary greatly in terms of infrastructure and social conditions while the overall climate across the region is similar. According to Levy, flooded latrines from excessive rainfall can be one factor in spreading diarrheal disease pathogens. Infrastructure features such as piped water systems and sanitation coverage can all lessen the impact of rainfall and other climatic drivers of waterborne disease. The social circumstances and human responses of each community also play a critical but little-studied role in disease transmission.

"Rather than treating social conditions as noise in the analysis, we look to explain the uncertainty in climate-disease relationships by examining villages under the same climatic regime with differing social and infrastructure conditions, which we refer to as the social vulnerability

of a community," said Levy. "Our approach provides a more complete understanding of the many ways—physiological, social and institutional—that climate affects disease incidence in communities."

The project will assess the studied communities' social vulnerability through existing ethnographic data—including interviews and observations collected over seven years—and additional fieldwork in the 21 villages. The resulting findings will allow Levy and her team to gauge their ability of the villages to adapt to both current and future climate change scenarios. The study outcomes will also be useful in determining the importance of social variables versus climate-related variables in the prevention of gastrointestinal disease, helping to shape effective health intervention strategies.

RESOURCES

For more information on the Emory program, see: <http://bit.ly/w2UJia>

For more information on the NIH Climate Change program, please visit: <http://1.usa.gov/w0hFSA>

CDC combats global infectious disease threats



CDC Director, Dr. Thomas Frieden

“CDC is the 911 for the world,” an African ambassador once told Dr. Thomas R. Frieden, director of the Centers for Disease Control and Prevention, who recounted the quote as he delivered an impressive argument for why supporting global health is in the interests of the United States.

Using U.S. aid and technical assistance to advance global health “protects Americans from health threats, promotes stability in key countries, advances U.S. economic interests by preserving productivity and markets, and helps to detect and control emerging and re-emerging threats,” Frieden told an audience of senior researchers and scientists at NIH.

Supporting global health generates knowledge as well as “a glow of goodwill,” Frieden said, adding that it is also “the right thing to do and what a great country does.” CDC’s strategy is to translate the agency’s domestic public health approaches on a global front. Such approaches may include technical assistance, direct funding, applied epidemiology and lab capacity development, embedding staff in health care organizations and improving lab quality. “Most of the world does not have the same confidence in their labs that we do,” said Frieden. “We’re working to change that.”

Promoting tobacco control and preventing motor vehicle injury are two of the key priorities for the CDC in global health. Others are achieving and sustaining global immunization initiatives, including polio eradication; substantially reducing mother to child HIV transmission and congenital syphilis; and eliminating lymphatic filariasis in the Americas.

To buttress the “911” reputation, Frieden noted that the agency had conducted 41 field epidemiology training programs in the last 30 years and had established seven Global Disease Detection Centers.

From 1992 to 1996, Frieden led efforts in New York City to control TB and, in his lecture, used the disease to illustrate the efficacy of U.S. assistance in eliminating the disease worldwide. Globally, there were 8.8 million cases of TB and 1.4 million deaths in 2010, according to the WHO. Cases have been falling worldwide since 2006, incidence rates have been down since 2002 and mortality rates have fallen by one-third since 1990.

“But we don’t have effective tools to control TB where HIV

prevalence is high,” Frieden said, “and this is an enormous challenge.”

Frieden was named CDC Director in June 2009. His address, titled “A Public Health Approach to Infectious Disease Prevention and Control for the 21st Century,” was this year’s Kinyoun Lecture.

The lecture honors Dr. Joseph J. Kinyoun, who in 1887 founded the Laboratory of Hygiene, the forerunner of NIH, to study infectious diseases.

RESOURCES

Videocast: <http://bit.ly/sPxCoE>

Photos by Bill Bronson/NIH



CDC Director Dr. Thomas Frieden described his agency’s global health efforts to NIH leadership and staff during a recent visit.

Congressman Fogarty’s widow dies

Photo courtesy of the Fogarty family



The widow of Congressman John E. Fogarty, Luise Rohland Fogarty, has died at the age of 96. After the Congressman’s death in 1967, she worked to realize her husband’s goal of establishing a center for international health at NIH. The John E. Fogarty International Center began operation in 1968, in memory of the Congressman and his long support for health research, as well as his interest in promoting world peace through health.

The Congressman and his wife are survived by their daughter, Mary Fogarty McAndrew, of Providence, R.I., shown here with her parents.

MENAFRIVAC™

NIH aids effort to produce meningitis vaccine for Africa

In the so-called “meningitis belt” of sub-Saharan Africa, the disease spreads during the dry season and millions of the afflicted await the “rains of hope” that curb that year’s epidemic. Now, an innovative, groundbreaking partnership has become its own rainmaker, producing a safe, inexpensive, long-lasting vaccine that offers hope to end Group A meningococcal epidemics.

The story of the development of the new vaccine, MenAfriVac™, was related in stirring detail during a presentation at NIH by Dr. F. Marc LaForce, director of the Meningitis Vaccine Project (MVP), a partnership between PATH and the WHO. Within a few short years, the vaccine was developed, approved and introduced at a cost of less than 50 cents a dose, a perhaps unprecedented achievement.

Bacterial meningitis is an infection of the thin lining surrounding the brain and spinal cord. In the 25 countries of the African meningitis belt, which stretches from Senegal in the west to Ethiopia in the east, more than 400 million people are at risk of brain damage, profound hearing loss or death. As many as 10 percent of those infected will die and one in four survivors has severe hearing impairment or mental deficiencies.

“There’s an enormous amount of disease caused by this pathogen,” said LaForce, who added that 90 percent of the world’s disease burden of serogroup A meningitis occurs in these countries. An outbreak in 1996-97 infected 250,000 people and more than 25,000 died.

In an effort to produce a serogroup A conjugate vaccine, the public-private partnership called MVP was established, with support from the Bill and Melinda Gates Foundation. The Serum Institute of India, agreed to produce the new vaccine for less than 50 cents. SyncoBioPartners in the Netherlands and the Serum Institute provided raw materials for the vaccine.

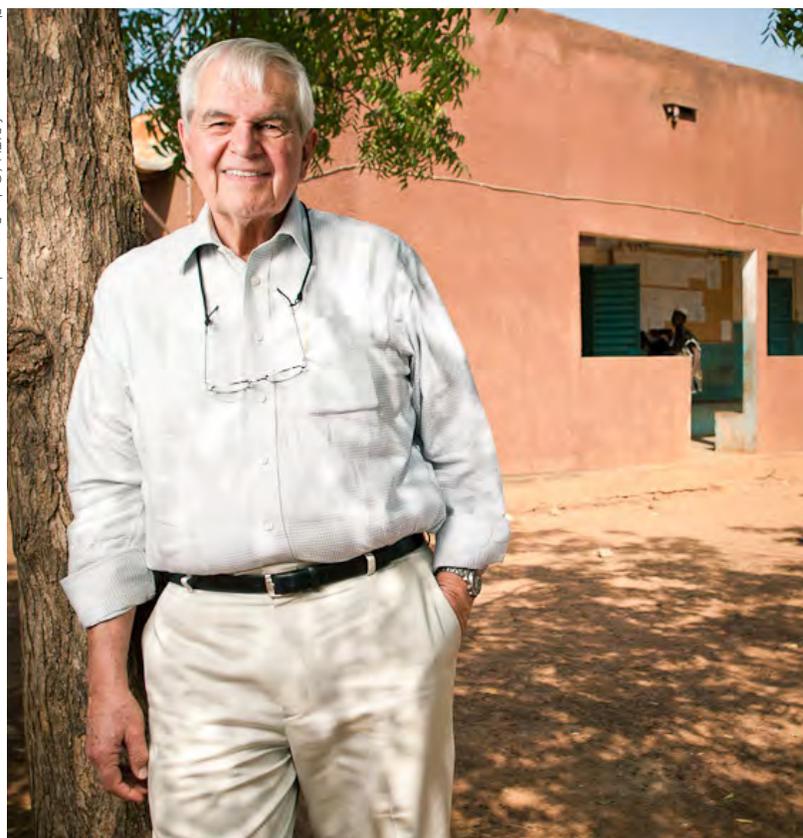
The NIH helped transfer the conjugation technology, developed by the FDA, to the Serum Institute at almost no cost—a sensitive proposition as it involved the transfer of intellectual property, LaForce noted.

Overall, the new vaccine, MenAfriVac™, cost a fraction of the \$500 million usually required to manufacture and bring a new vaccine to market. The drug was cleared by India in

Dec. 2009 and qualified by WHO in June 2010. And then the real miracle occurred.

On Dec. 6, 2010, in Burkina Faso, Mali and Niger, children and young adults—the disease strikes those mainly under 29 years of age—began being vaccinated. “We have an opportunity to change the health of the country,” the president of Burkina Faso said at a ceremony marking the occasion. Within 10 days, 10.8 million persons were immunized. “This was utterly remarkable,” said LaForce. Six months after introduction, Burkina Faso, Mali and Niger report the lowest number of confirmed meningitis A cases recorded during an epidemic season. There were 2,624 cases reported in Burkina Faso in 2011, compared with 26,878 in 2007.

Photo courtesy of PATH/Gabe Bienzajski



Dr. Marc LaForce, director of the Meningitis Vaccine Project, worked with NIH and other partners for nearly a decade to produce and distribute a cost-effective vaccine in Africa.

LaForce said the vaccine “proved to be therapeutic and greatly shortened the carriage rate”—the amount of time the pathogen is harbored within the body.

WHO and PATH are working to build support for sustaining the immunization effort and expanding it by 2016 to the 22 countries where people have yet to receive the vaccine. If successful, the “rains of hope” may become a footnote—not a fix—for the disease.

RESOURCES

More info: www.path.org/menafriovac/index.php

A passage to India paves a career path

By Steve Goldstein

It was a long way from identifying bird calls as her first high school research project in Manhattan, to listening to the heart sounds of a young schoolboy in the dusty southern Indian city of Vellore. For Lucy Horton, it was a culmination of sorts of her love of research and a year that clarified her desire to pursue a career in infectious disease.

As a Fogarty International Clinical Research Scholar, Horton spent the past year investigating the alarmingly high rate of chronic kidney disease that is affecting young children in Vellore. Since the Fogarty program began, more than 500 advanced health science students and post-doctoral fellows have had the opportunity to participate in mentored clinical research at NIH-funded centers in developing countries. Horton, who will graduate next spring with both an M.D. and a master's in public health from Tufts University, said she relished the unique experience.

"It was a great research opportunity because I was there for a length of time, as opposed to doing it during breaks at medical school or during summer vacations," said Horton. "I was able to work through various stages—creating a research plan, going through an Institutional Review Board, organizing a field team—as well as coordinating with a lab."

Based at Vellore's Christian Medical College (CMC), Horton worked with Dr. Madhumathi Rao, a CMC alumnus and Tufts professor, and was mentored by Dr. Gagandeep Kang, CMC's head of Gastrointestinal Science. They worked together to test a hypothesis that recurring diarrhea and resulting dehydration during infancy—coupled with

Horton screened study participants for evidence of kidney damage.



Photo by Louise Borst



Photo by M. Thiyagarajan

Fogarty Scholar Lucy Horton, left, said her experience in India helped her decide to pursue a career in international infectious diseases.

chronic low birth weight, malnutrition and immunological disorders—may play a significant role in early development of renal disease.

Horton spent much of her time in a small urban health clinic in a slum roughly five miles outside Vellore where she managed a team of field workers. "They gave me the clinic for the second half of each day so I could work on my study," she explained. "One field worker would go out to homes to recruit patients and the other worked with me partly as a translator."

For nearly five hours a day, Horton was on her own, dealing with small crises. "Research always comes with bumps along the way, but when you do it in India, it gets magnified because there are so many idiosyncrasies about the ways things work," she said. "It forced me to think creatively and to problem solve—like how to get the urine samples to the lab on time when the refrigerator disappeared and the motorcycle driver was out of gas but hadn't gotten his paycheck to be able to buy gas."

Yet Horton said the small frustrations did not detract from the big picture, which is that "each day of fieldwork can contribute to something," she said. "In the end I was able to follow almost the entire 300-child cohort in the study, and that was very rewarding."

In November, Horton presented her abstract detailing how gastrointestinal infections are a risk factor for chronic childhood kidney disease at the American Society of Nephrology Annual Conference in Philadelphia.

The Manhattan native said she is grateful for the support from Fogarty and Vanderbilt University's Institute for Global Health, which helped administer the program. Her fellowship experience helped her decide on a career in international infectious disease that combines both her interest in clinical work and her passion for research. After India, she said, "I was completely sure about my next steps in residency applications and what programs I'm interested in."

DR. WILLIAM COLGLAZIER



Dr. E. William Colglazier was appointed in July 2011 as the fourth Science and Technology Adviser to the Secretary of State. The mission of the Office of the Science and Technology Adviser to the Secretary (STAS) is to provide scientific and technical expertise and advice in support of the development and implementation of U.S. foreign policy. From 1994 to 2011, Dr. Colglazier served as Executive Officer of the National Academy of Sciences and the National Research Council.

What role do you think science and technology should play in supporting U.S. foreign policy?

America's scientific and technical capabilities support our foreign policy by addressing challenging problems facing the world. In addition, scientists speak a common language that transcends political systems and cultures, which can create channels of communication even when governmental relations are difficult. This "science diplomacy" can be of enormous benefit, especially when opportunities emerge for improved political relations. During the height of the Cold War, American and Soviet scientists met to discuss issues related to nuclear arms control. Today, U.S. academies and scientific societies have continued to build bridges to a number of countries where governmental dialogue is strained or nonexistent.

What would you like to accomplish during your tenure as science and technology adviser?

First, I want to ensure that our office continues to be a good steward of three outstanding fellowship programs that bring scientifically-trained people to work at State and USAID—the American Association for the Advancement of Science fellowship program, which is the largest and generally for younger scientists; the Jefferson Fellows program, which is for tenured faculty; and the Institute of Electrical and Electronics Engineers, which includes fellows from the private sector. Former fellows have permeated the department and greatly added to its scientific expertise. I also want to serve as a strong proponent of global scientific engagement. Nearly every country, regardless of its politics, respects America's scientific and technological enterprise; many want to engage with it for their own national interests, especially for stimulating innovation and economic growth. In addition to assisting the functional and regional bureaus at State and the science units in other U.S. agencies, our office is providing information about U.S. scientists who can serve in public diplomacy events overseas and promoting programs that facilitate bringing bright individuals to the

U.S. for education and training in science, engineering and health fields. I also want to encourage other governments to seek independent, objective advice from their scientific communities.

How do you plan to engage the other U.S. government agencies that work in the areas of global health and biomedical research?

These agencies—especially NIH and CDC—are the "crown jewels" of our scientific enterprise and they are fully engaged internationally. The ability of Fogarty to fund foreign scientists is very important for advancing science as well as building relationships with other countries. My goal is to help ensure that these great assets for American science and diplomacy are fully known at the State Department, and that American diplomats are available to help NIH and CDC when needed. The administration's Global Health Initiative illustrates what can be accomplished by an interagency partnership contributing to science, diplomacy and development goals.

What opportunities for scientific collaboration in the Middle East do you envision as a result of the so-called 'Arab Spring'?

The opportunities for engagement and their potential benefits for accelerating economic development, addressing regional needs, and building stable democratic societies have increased significantly. The State Department and USAID are pursuing a wide range of programs in these countries, including the "Global Innovation through Science and Technology" initiative, the U.S. Science Envoy Program, the Arab-American Frontiers of Science, the new Partnerships for Enhanced Engagement in Research program between USAID and NSF, the U.S.-Egypt Joint Science Fund, a new "center of excellence" for addressing water issues and a proposed program for young women to obtain undergraduate science degrees at U.S. women's colleges.

Bioethics: protecting lives in service to research

A young African woman, pregnant with her first child, lives in a small village with only a traditional healer to provide care. She suspects her husband died of HIV/AIDS but he was not tested. Some scientists visit her village and ask its leader for permission to study any women who are about to give birth, so they can test drugs that might protect the babies from HIV. The village elder agrees. When the researchers approach the woman, she is afraid to receive drugs that might harm her baby. But she is also terrified her baby will die if she doesn't accept treatment. She doesn't want to antagonize her leader, so she goes along with the trial. Although she is illiterate and didn't understand the researcher's description of the study, she marks an "X" on the form and agrees to participate.

Scenarios such as this one pose a number of thorny ethics questions for researchers attempting studies in settings with severe poverty, sex inequality and little access to basic health care. How can scientists ensure consent is freely given, and that the subject understands the proposed clinical trial and any risks? Is the possibility of access to treatment an unfair inducement? What obligation, if any, does the researcher have to treat the woman if she is found to be HIV positive? How can the woman's privacy be preserved in her small community? What benefits should the village receive from the results of the study?

Bioethics and the protection of human subjects are the foundation that enables clinical research. The combination of the globalization of the biomedical industry, outsourcing of clinical trials to developing countries to cut costs and avoid regulation, and the surge in research activity to address HIV and malaria has been overwhelming, given

the lack of developing country researchers with formal training in bioethics and the scant infrastructure to provide oversight.

"In order to preserve the health of society and its overall humanity, it's important that research be conducted in an ethical fashion," according to Nigerian scientist, Dr. Clement Adebamowo, who directs the Fogarty bioethics program at the University of Ibadan. "Invariably some participants will go before others in helping us to understand diseases, the treatments and the impact of those treatments. So, we owe those participants a debt of gratitude and we have a duty to protect them."

Concern for research subjects grew from the horror of the Nazi experiments on humans, spurring an effort to lay out ethical guidelines in the Nuremberg Code in 1947, followed by the World Medical Association's Declaration of Helsinki in 1964. The field of bioethics was largely the domain of philosophers and theologians until 1970s, when the tremendous growth of biomedical science expanded it to a multidisciplinary endeavor involving anthropologists, policy makers, physicians, sociologists and the public at large.

"Most countries around the world do not have laws or norms about research ethics locally," said bioethics professor and Fogarty grantee Dr. Nancy Kass, of Johns Hopkins University. "You can find many places where nobody has ever talked to researchers about the importance of asking permission before they do research. And nobody's talked to researchers about making sure a third party looks at their research before they go into the field. But in every country I've worked there are plenty of people who appreciate that it is very important to follow international standards of research ethics."

Bioethics guidelines are intended to protect all human research subjects, with special provisions for studies of illiterate populations and children.



Photo by Roy Wilkins/World Bank

The stories in the Focus: Bioethics section were researched and written by Steve Goldstein.



Photo by David Snyder for Fogarty/NIH

Fogarty's bioethics training program helps researchers communicate more clearly with potential study subjects so they understand what is involved and can give informed consent.

One reason is that, to receive NIH grants, research studies must be designed and implemented to conform to the same standards as U.S. clinical trials. In locations with little expertise in bioethics, that can be extremely challenging.

Began in 2000, Fogarty's bioethics program is designed to develop culturally relevant bioethics curricula for developing country scientists and support training to produce leaders who could advise on policy and help train the next generation. In the last decade, Fogarty has enabled more than 560 developing country scientists and administrators to complete master's level training in bioethics. Kass, who has run Fogarty-supported programs in Africa, said, "What Fogarty has created with minimal funding and the impact that these programs have had is remarkable."

To leverage the effort, Fogarty has partnered with other NIH Institutes and Centers to expand training efforts. Co-funders of the program include The National Institute of Allergy and Infectious Diseases, National Institute of Mental Health and the National Human Genome Research Institute. In addition, the NIH Clinical Research Center provides significant leadership and expertise, as well as online and in-person bioethics training courses geared to developing country researchers.

Some key bioethics issues for developing country researchers:

- Have subjects granted truly informed consent? Have they fully understood the information presented, including any possible risks?
- What's the appropriate standard of care for the study participants? If researchers discover in a malaria study that a participant has HIV, do they have a responsibility to treat that disease? What is their responsibility to provide care after the study is concluded?
- What measures are being taken to ensure the participants' medical information remains confidential?
- As genomics advances and DNA analysis is increasingly part of clinical trials, how can participants' samples be protected?
- How are the research priorities determined? How does the community benefit?

"The problem is that good ethical research requires a lot from top to bottom—from what questions to ask, how to design studies, how to do them, how to get them designed in a way that recognizes risks," said Dr. Christine Grady, acting chair of the bioethics department at the Clinical Center at NIH.

Many bioethicists agree that regulation is necessary but not sufficient to ensure ethical research. Examination by an ethics committee or an Institutional Review Board only goes so far. Training is geared to creating a culture of responsibility, so that it's accepted by investigators, the teams that work with them and institutions that host them. "You can still get an unethical result even if rules are followed," said Grady.

Changes to the IRB process are under discussion in the United States, much of them involving streamlining the process. Because the bureaucracy has been viewed by some as cumbersome and investigators regard it as a burden, they may try to avoid it, ignore or outsource it to a third party.

The review process is critical. "If the review is done incorrectly, you risk people getting harmed," said Dr. Joseph Millum, bioethicist at Fogarty. "If you do it inefficiently, you hold up the process of research." The IRB is further limited by its function, reviewing the protocol and the consent form, but not overseeing the actual research process.

Fogarty's program aims to produce bioethics leaders who can advise developing country institutions how to formulate and strengthen local bioethics guidelines, build well-informed review bodies capable of evaluating research proposals, and train others in the principles of ethical research conduct. Given the increasingly collaborative nature of research, it's also important to bring new voices with different perspectives to the global ethics conversation.

Fogarty's Dr. Barbara Sina, who has managed the program since its inception, said she's encouraged at the progress developing country trainees have made. "Our ultimate goal is to develop research ethics capacity and expertise so that countries can create their own ethical oversight processes and participate equally in the global dialogue on research ethics."

RESOURCES

Fogarty bioethics program:
<http://bit.ly/skSQmf>

FOCUS ON BIOETHICS

Transforming a barren ethics landscape in Nigeria

When he lectures on research ethics, Nigerian scientist and oncologist Dr. Clement Adebamowo begins by quoting German-born philosopher Hans Jonas, who said the loss of moral values due to a ruthless pursuit of scientific progress “would make its most dazzling triumphs not worth having.”

Examining the bioethics landscape in Nigeria today, it’s difficult to imagine how recently it was a barren plain. Adebamowo recalled a “perfect storm” of events that spurred him to develop the Fogarty-supported bioethics training program located at the University of Ibadan.

In 1996, a controversial drug trial conducted during a meningitis outbreak caused fatalities, triggering a backlash against researchers and creating suspicion of vaccines. This led to a resurgence of polio, which spread to neighboring countries. Meanwhile, Western organizations were gearing up efforts to combat HIV/AIDS and malaria in African countries, including Nigeria. Global outsourcing of clinical trials was growing in popularity, taking advantage of low-cost settings with little or no regulation. Finally, the “Out of Africa” theory of evolution was generating additional interest among researchers keen to conduct population studies in the continent that might determine the genetic basis of diseases.



Fogarty bioethics grantee Dr. Clement Adebamowo drafted Nigeria’s first national ethics code and has provided training for more than 1,000 West African researchers.

At the same time, Nigeria was going through political change, adopting a democratic government in 1999 that began engaging with civil society to improve conditions,

Photo by Curt Camerak/Wald Bank



Illiteracy, cultural traditions and religious beliefs make clinical research especially challenging for scientists in Nigeria.

including health, Adebamowo remembered. He convinced officials that research and bioethics should play an important role. “There was some sensitivity to research ethics but it was not formal, it was not large scale and it was not pervasive.”

Adebamowo began his bioethics training program with a Fogarty planning grant in 2004. He and his team developed web resources, conducted sensitivity and public awareness campaigns, and offered training to institutions to strengthen their research ethics committees. Once he received a full grant—funded by Fogarty and the National Human Genome Research Institute—he launched a master’s degree program designed to serve as a bioethics resource for all of West Africa. The first class of master’s students were drawn from nursing, biomedical research and public health. Coursework included classes on informed consent, research designs, philosophy of bioethics, religion and ethics, and qualitative and quantitative research methods.

Eight of his faculty obtained master’s degrees in bioethics through established Fogarty training programs in the U.S. and Canada. They in turn have provided instruction at Ibadan, mentoring 20 students through the master’s program and more than 1,000 West African researchers through the short course. The “multiplier effect” is huge, Adebamowo observed.

Photo courtesy of Dr. Clement Adebamowo

FOCUS ON BIOETHICS

“For us in Nigeria, the Fogarty funding for bioethics changed the entire landscape. What we have now would have been impossible without the Fogarty funding,” he said. Previously, individuals who received international training in bioethics would return to home “like being cast loose on an ocean, with no focus, no organizing principle and no idea of how they could continue to use that skill.”

Bioethics was also significant as the first-ever multidisciplinary degree program developed at Ibadan, involving faculty collaborators from 13 different departments, from philosophy and law, to sociology, psychology and nursing.

In concert with his training efforts, Adebamowo also helped the health ministry transform Nigeria’s national ethics system and drafted the country’s first formal code for research ethics. His trainees held or assumed positions in state and federal institutions, creating a framework and resource as the code was implemented. His NIH funding provided credibility, he said, which was helpful as he re-established and chaired the National Health Research Ethics Committee, created a web-based research protocol tracking system, and initiated or strengthened 25 Institutional Review Boards across the country.

The code lays out principles and guidelines for ethical behavior, such as research studies must have social and scientific value to the participants, be scientifically valid, minimize risks and maximize health benefits. In addition, proposed trials must be independently reviewed and must demonstrate the informed consent of participants. The code serves as a training tool for researchers who apply it in their institutions and use their experience to further develop and refine it.

Bioethics is the key to unlock research in a developing country like Nigeria, said Adebamowo. “Research is an imperative, a public health good,” he said. “Ethics capacity increases awareness of the need to respect our collective humanity and think even more about the most scientifically rigorous method of testing a hypothesis without research misconduct.”

Nigeria presents specific challenges to consent due to illiteracy and religious differences. A large segment of the population may not accept scientific explanations of diseases. Culture, education and religion play a major role in national identity, acceptance of what is wrong or right, and the level of privacy that is appropriate.

Currently, Adebamowo is exploring ethics research issues as applied by Nigerians of Muslim and other religious backgrounds, to see “how they grapple with research ethics and apply philosophies from those moral traditions to these issues,” he explained.

Photo courtesy of USAID



A controversial drug trial caused many Nigerians to fear vaccines, leading to a resurgence in polio. Religious leaders joined efforts to restore confidence in vaccines and evidence-based medicine.

The Nigerian educational system, like many in developing countries, is based on rote learning. “To make students walk away from that learning is quite a challenge,” Adebamowo said. “My goal is for them to take the tools they’ve been given and use them to engage with the ethical issues they come across. What we are trying to do is not just import Western concepts but to teach students in Nigeria the philosophical methods, the quantitative and qualitative research methods that they can use to grapple with the ethical issues that occur within their research environment.”

Similarly, Adebamowo said he’s built a flexible national ethics committee that will evolve over time. “It’s not a dormant committee but is functioning and responding to its environment.”

The cultural shift has been enormous and will have lasting impact, he said. “The most significant thing we’ve achieved is elevating the status of research ethics and helping researchers and Nigerians in general appreciate the value of ethical conduct of research,” said Adebamowo. “We have more people who know that there is a way of doing research that is both scientifically appropriate and ethically sound. Those people will pass this down to their trainees, so over time a better research culture will develop.”

Adebamowo ends his ethics lectures with a quote from Pope Pius XII, who said that “science is not the highest value to which all other orders of values ... should be subordinated.” Adebamowo wants trainees to understand that it is not so much what you do but how you do it. “We want to find the cure for HIV/AIDS,” he tells them, “but if we find the cure in an unethical manner, it will not be worth it.”

Trainee to teacher: Leveraging learning in India

India has become one of the world's preferred locations for clinical trials due to its low operating costs and well-educated workforce. The country's clinical trials business has exploded into a \$1.8 billion dollar a year industry involving more than 100 domestic and multinational organizations, according to an Indian trade association. This phenomenal growth has raised concerns about exploitation and patient safety and made it more urgent that India shore up its bioethics infrastructure.



Photo courtesy of USAID

India is a popular location for clinical trials due to its low costs and educated workforce. Fogarty's training program is helping to ensure biomedical research is performed in an ethical manner and vulnerable populations are protected.

Since 2000, Fogarty's bioethics program has been supporting efforts to increase local capacity in India and other low- and middle-income countries in this critical area by encouraging bioethics curriculum development and training activities. Indian scientist Dr. Nandini Kumar leapt at the chance to join the first class of trainees funded by the Fogarty program at the University of Toronto.

During the one-year master's course, Kumar and her developing country colleagues learned about philosophical and historical approaches to bioethics, regulatory codes and the multidisciplinary case study approach to research issues—taking into account the setting, population diversity and culture. As Assistant Director General of the Indian Council of Medical Research, Kumar was ideally placed to return home and help guide the development of

her country's bioethics framework and policies, then in their infancy.

Because Fogarty 'trainees' are prepared to become the 'trainers', the program has a multiplier effect, expanding the field of bioethics and better integrating it into the research enterprise globally. "Dr. Kumar is a great example of leveraging funding from Fogarty," noted her Toronto mentor, Dr. Peter Singer. "It's obviously more cost-effective and sustainable if the leadership for global health education is in low- and middle-income countries."

After completing the course in 2002, Kumar was encouraged by Singer to apply for Fogarty support to plan her own bioethics training program, specially tailored to India's unique culture and research environment. She was successful in her bid for a planning grant, and then received a full Fogarty award to implement her program in 2005.

Kumar's priorities were to create a national task force and advisory committees for bioethics, develop a centrally coordinated network of faculty prepared to train in the topic, implement the curriculum and evaluate the results. Her overall goal was to build capacity in bioethics education that is culturally sensitive—with special emphasis on research ethics related to genetics, drug development—including traditional medicine—and social sciences and international research ethics.

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India's bioethics guidelines are rooted in ancient philosophies of its traditional systems of medicine, which established that a physician's primary concern should be for the safety and best interests of the patient and conflicts of interest should be avoided. The traditions were formalized in India's Drugs and Cosmetics Act in 1982 and have been updated and revised numerous times since then.

With more than one billion people, India is the second most populous country in the world. Despite its burgeoning

FOCUS ON BIOETHICS

economy, the country faces significant health challenges including high rates of malnutrition, a continuing battle against infectious diseases, in addition to early onset of chronic diseases such as diabetes and hypertension. Research controversies include targeting illiterate populations and preying on drug-naïve populations without according them the benefits of a study.

When Kumar began her training program, bioethics was not uniformly required study in Indian medical schools and the country had only a handful of self-taught experts and health professionals with formal training in bioethics.

She began with three components: a sensitization program to create awareness beginning at the undergraduate level, a short-term course for trainers as well as longer more intensive curriculum. She later added distance learning diploma and master's degree courses through the Indira Gandhi National Open University. An online program is being planned that will be mandatory for all researchers and research ethics committee members in India.

Kumar organized the development of teaching materials covering historical background, ethical principles, informed consent, research on vulnerable populations, inducement for study participation, institutional ethics committee frameworks and operations, standards of care, post-trial benefits, stored tissue, intellectual property rights and conflicts of interest. In addition to adding to the bioethics expertise in India, her courses also attracted trainees from elsewhere in the region such as Bangladesh, Nepal, Pakistan and Sri Lanka.

With Fogarty support, Dr. Nandini Kumar (left) has built a bioethics program that has trained thousands of researchers in India and throughout the region.



Photo by Roy Wilkin/World Bank



Informed consent is a key component of ethical clinical research and included in the Indian Council of Medical Research training program.

Over the past seven years, Kumar's program has trained more than 2,000 scientists and health care workers. More than 50 of them completed the intensive course and two earned master's degrees. The program has hosted nearly 24 intensive workshops in 16 Indian cities. Its distance learning programs train as many as 50 each year.

Many of the graduates have published papers, prepared curriculum for bioethics instruction at their own institutions, presented papers at national and international conferences, served as evaluators and set up or become members of ethics committees. As the field has developed, Kumar has become not only a national leader in bioethics but also a member of international panels, including the U.S. Presidential Commission for the Study of Bioethical Issues.

In 2007, India launched a clinical trials registry to bring transparency and accountability to the research community, re-establish public trust and encourage the publication of information on failed trials. Registration of trials is required by the Indian government and the country's major scientific journals require registration in order for results to be published.

Despite paving the way for these and other successes, Kumar admitted India remains a challenging environment for research ethics. "There's much more work to be done," she said. She views bioethics at the nexus of research and human rights. Although violations persist, she noted, they "can at least be curtailed by insisting and mandating that ethical principles be observed whenever there is human involvement." Bioethics is more important in developing countries like her own "where the population is more vulnerable."

Photo by Roy Wilkin/World Bank

RESOURCES

More info about Dr. Kumar's Fogarty program:
<http://bit.ly/sUuEUO>

Indian Council of Medical Research Bioethics info:
<http://icmr.nic.in/bioethics.htm>

A research agenda for indoor air pollution



The problem of indoor air pollution has been around for decades but we have never viewed it as a single and critically important risk factor for poor health in the developing world. The challenge is immense because nearly 3 billion people worldwide use indoor cookstoves and are exposed daily to the pollution that this yields. This includes the products of incomplete and inefficient combustion of

biomass fuels such as wood, charcoal, dung and crop residues, which produces particulate matter, carbon monoxide and other toxic fumes.

We now recognize that the risks from indoor air pollution range widely from low birth weight of children to chronic conditions in the elderly and everything in between—acute respiratory disease, cancer, asthma, cardiovascular disease, eye disease, lung disease and chronic pulmonary obstructive lung disease. Women and children are mainly affected because they are at home much of the time. It's comparable to the long-term risks from smoking, except more concentrated.

Much research has been focused on developing cleaner cookstoves that use alternative sources of energy and burn more efficiently. Yet we really don't know how much cleaner the household environment has to be in order to achieve a better health impact. The WHO has estimated that about 2 million lives are lost per year from the problem of indoor air pollution and this is clearly a troubling estimate. We don't know how accurate this is or whether the introduction of clean cookstoves could make a major impact on this, so there's clearly a research agenda that needs to be pursued to address this fundamental question.

In an article recently published in *Science*, my co-authors and I conclude that although the problems of indoor air pollution are well established, there remains a critical research agenda to determine how much these emissions must be reduced by cleaner cookstoves and improved fuels to achieve substantial health benefits. This unresolved question has created some controversy over whether health benefits must be documented before new technologies

for cookstoves—already moving forward—should be implemented.

At Fogarty we've looked at this issue in the past through our International Training and Research in Environmental and Occupational Health (ITREOH) program. Investigators like Dr. Kirk Smith at Berkeley, who have been clear leaders in understanding and evaluating the health impact of cookstoves, have used grants for studies in Bangladesh, India and other locations where indoor air pollution is common.

We are transitioning ITREOH to a program we call Geo Health, and indoor air pollution will be included as a key topic. We also have a fellows and scholars program where we place young medical students and residents in different specialties in developing countries to pursue research. Some of them are working in the area of lung disease, child health and birth outcomes and we'd love to see the interventions of clean cookstoves become part of their research agenda.

This is a huge global problem to address, since to solve it, we must change the cooking habits of nearly half the women in the world. In many countries, the cookstove is the central hearth of the family and to replace a traditional stove with a cleaner device may be akin to taking out the heart of the home. We are actually attempting to change behavior.

Many groups are leading the introduction of clean cookstoves in developing countries. Pilar Nores, the former First Lady of Peru, writes in an editorial accompanying our article about her program to introduce these new cookstoves in the highlands of her country. A health evaluation impact could tell us whether this is really improving the health of recipients in a way that justifies the investment.

Clean air is clearly better for health. But while we believe the interventions we're promoting are highly effective, we really need to develop the evidence that will allow for the global investment as a major intervention project to improve the health of women and children.

RESOURCES

Science article: <http://bit.ly/nmXA35>



Mundel to lead Gates Global Health

Dr. Trevor Mundel, global head of development for Novartis Pharma AG, has been named president of the Global Health Program of the Bill & Melinda Gates Foundation.



South Africa honors Salim Abdool Karim

Fogarty grantee Dr. Salim Abdool Karim has been named Outstanding Senior African Scientist for 2011 by the European & Developing Countries Clinical Trials Partnership. He also received the Gold Medal for Science in Medicine from the South African Medical Association.



Curioso to head office in Peru's health ministry

Dr. Walter Curioso, a Fogarty grantee who has studied mobile health technologies in Peru, is the new General Director of the General Office of Statistics and Informatics in Peru's Ministry of Health.



Mechael new executive director of mHealth Alliance

Dr. Patricia Mechael is the new executive director of the mHealth Alliance, which is hosted by the United Nations Foundation. She previously was director for health-related mobile technology at Columbia University's Earth Institute.



New US health attaché to Brazil

Dr. Abraham Miranda is the new U.S. Health Attaché to Brazil. Miranda, a captain in the Commissioned Corps of the U.S. Public Health Service, has been with CDC's Global AIDS Program since 2004.



Trimble to direct NCI's Global Health Center

Dr. Ted Trimble is the new director of the National Cancer Institute's Center for Global Health. He previously was head of Gynecological Cancer Therapeutics in the Division of Cancer Treatment and Diagnosis.



Honors for Pettigrew

Dr. Roderic Pettigrew, director of the National Institute of Biomedical Imaging and Bioengineering, has been chosen to receive the 2011 Distinguished Achievement Award from the Biomedical Engineering Society.

WHO releases list of new, emerging technologies

A compendium of new and emerging technologies that address global health concerns has been released by the WHO. The list features technologies that could solve unmet medical needs in low-resource settings

Online: <http://bit.ly/ouHCN7>

Award for NIH Clinical Center

The NIH Clinical Center has won the 2011 Lasker-Bloomberg Public Service Award, which recognizes outstanding advances in medical research. The research hospital is being honored as a model institution that has transformed scientific advances into innovative therapies.

New edition of global health text

The third edition of the popular text *Global Health* has been published. Co-authors are Drs. Michael Merson of the Duke Global Health Institute, Robert Black of the Johns Hopkins Bloomberg School of Public Health and Anne Mills of the London School of Hygiene and Tropical Medicine. Black and Merson are longtime Fogarty grantees.

WHO Mental Health Atlas 2011 issued

The new edition of WHO's mental health survey indicates that one in four individuals will need such care in their lifetimes, but average global spending on mental health is less than \$3 per capita per year and as little as 25 cents per person annually in low-income countries.

Atlas: <http://bit.ly/rocBFH>

Global TB cases decline

Worldwide TB cases declined annually for the first time, according to the WHO. The number of people with TB in 2010 dropped to 8.8 million after peaking at 9 million in 2005 and the number of TB deaths fell to 1.4 million after peaking at 1.8 million in 2003.

Report: <http://bit.ly/nEIQ60>

Africa health statistics released

WHO has released the *2011 Atlas of Health Statistics for Africa*.

Atlas: <http://bit.ly/qFlv8W>

Journal revisits mental health issue

Four years after publishing a special series on global mental health, *The Lancet* revisits the issue, welcoming new initiatives to close the gap between rich and poor countries but concluding many challenges remain.

Journal: <http://bit.ly/nbJc0s>

Funding Opportunities

Program	Contact	Receipt Date	Eligibility
Framework Programs for Global Health Innovations (D43) PAR-12-003	Flora Katz, Ph.D. Flora.Katz@nih.gov	Dec. 15, 2011	U.S. and low- and middle-income country (LMIC) institutions are eligible; U.S. applicants are required to have LMIC collaborators.
Brain Disorders in the Developing World: Research Across the Lifespan (BRAIN)-Non-AIDS PAR-11-031 (R21) PAR-11-030 (R01)	Kathleen Michels, Ph.D. Kathleen.Michels@nih.gov	Jan. 10, 2012	Must have an LMIC collaborator, as defined by The World Bank. R01 applicants must have already had an R21 planning grant.
Fogarty International Research Collaboration-Basic Biomedical Research (FIRCA-BB)(R03) PAR-11-037 Behavioral & Social Sciences (FIRCA-BSS) (R03) PAR-11-036	Xingzhu Liu, M.D., Ph.D. Xingzhu.Liu@nih.gov	Jan. 10, 2012	Must have an LMIC collaborator, as defined by The World Bank. For this announcement, Hong Kong and Taiwan are considered high-income, thus not eligible.
Limited Competitions: Global Research Initiative Program, Basic Biomedical (GRIP-BB)-Non-AIDS (R01) PAR-10-278 Behavioral/Social Sciences (GRIP-BSS)-Non-AIDS (R01) PAR-10-280	Xingzhu Liu, M.D., Ph.D. Xingzhu.Liu@nih.gov	Jan. 10, 2012	Only LMIC institutions are eligible. For the purposes of this announcement, Hong Kong and Taiwan are considered high-income, thus not eligible.

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

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Former Fogarty Director remembered



Dr. Phillip E. Schambra

Family, friends and colleagues paid tribute to former Fogarty Director Dr. Phillip E. Schambra Nov. 2 at a memorial service held at NIH. Schambra, 76, died Sept. 11 in Rockville. The global health advocate and science diplomat was remembered as a creative, visionary administrator.

Under Schambra's leadership from 1988-98, the Center witnessed tremendous growth as its budget doubled and its research training portfolio dramatically expanded.

Fogarty's flagship AIDS International Training and Research Program (AITRP) grew substantially and, as a result, scores of scientists have been trained throughout the developing world, saving countless lives from HIV/AIDS and facilitating many breakthroughs in prevention, therapy and care. In addition, Schambra guided the development of five Fogarty extramural programs that encourage international collaborations, increase opportunities for minority scientists and build developing country expertise in environmental and occupational health science, population studies and emerging infectious diseases. Perhaps most importantly, he focused the Center's mission on building capacity in low- and middle-income countries.

"All of us here at Fogarty are grateful for the strong and creative leadership Phil provided to the Center during the critical decade he served at its helm," said Fogarty Director Roger I. Glass. "By having the vision to support and expand AITRP, he had a huge impact on the Center and on global health."

Born in Saginaw, Mich., Schambra received his bachelor's from Rice University and Ph.D. in biophysics from Yale. His government career spanned 30 years and included stints in the White House budget office overseeing research funding, at NIEHS coordinating interagency programs and at Fogarty as chief of the international relations division.

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