



INSTITUTE OF
HUMAN VIROLOGY



*Extending the Frontiers of Science and Health:
Research, Care, and Prevention in Action*



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SCHOOL OF MEDICINE

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ANNUAL REPORT



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Photo above: Maria Salvato, PhD, Professor, Division of Basic Science and Vaccine Development, Institute of Human Virology and Department of Medicine, University of Maryland School of Medicine and Igor Lukashevich, MD, PhD, Associate Professor, Division of Basic Science and Vaccine Development, Institute of Human Virology and Department of Medicine, University of Maryland School of Medicine





Robert C. Gallo, MD, Director,
Institute of Human Virology and Professor,
Departments of Medicine and Microbiology
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DIRECTOR'S MESSAGE

The Institute of Human Virology (IHV) at the University of Maryland School of Medicine had a prosperous and eventful year in FY10. In the Basic Science and Vaccine Development Division led by Dr. George Lewis and me, IHV's preventative HIV vaccine candidate research continued to make progress with our colleague Dr. Tony DeVico through funding by the Bill and Melinda Gates Foundation and the National Institutes of Health. The next phase of funding would include researching the vaccine candidate through clinical trials next year. Also in the BSVD Division, IHV researchers including Dr. David Pauza continued to study the rise of HIV-related cancers as a growing public health concern in the United States and worldwide. As you may know, those infected with HIV have a much higher risk of developing cancer. In the past year, IHV has expanded our research with The University of Maryland Marlene and Stewart Greenebaum Cancer Center on HIV-related malignancies and in other areas, such as cancer vaccine development.

IHV Associate Director and Director of the Epidemiology and Prevention Division, Dr. William Blattner, continued to lead the Institute of Human Virology, Nigeria successfully with the opening of Africa's very first modular Biosafety Level Three (BSL-3) laboratory. Nigeria is ranked fourth in the world for TB and second for HIV -- a recipe for the multi-drug resistant form of tuberculosis (MDR-TB), an airborne disease that has emerged in South Africa. The level of MDR-TB is not known in West Africa because of the lack of suitable diagnostic facilities. With the leadership of IHV researchers such as Drs. William Blattner and Alash'le Abimiku the new laboratory provides a means of determining the prevalence of MDR-TB and a safe environment for detecting the more severe form of extremely drug resistant TB (XDRTB). XDRTB is untreatable but can only be

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“Since 2004, in partnership with Catholic Relief Services and through the President’s Emergency Plan for AIDS Relief (PEPFAR), IHV has been providing care and treatment to 30% of Haiti’s HIV/AIDS patients. ”

Robert R. Redfield, MD



Dr. Guesly Delva checks on a woman whose leg was amputated. Dr. Delva, an infectious disease fellow from the IHV team treats the injured at St. Francois de Sales, one of Haiti’s oldest hospitals. As a native of Haiti, he felt compelled to return to his homeland to help. After looking at the injured in Port au Prince and working with patients, he said: “I feel a sense of desperation. There’s so much to do. I know probably we’re not going to have enough time or resources to relieve all of the pain or suffering.”



detected in a laboratory of the type implemented in this U.S. Centers for Disease Control—IHV partnership with the government of Nigeria.

Dr. Robert Redfield, IHV Associate Director and Director of the Clinical Care and Research Division, helped lead the University's response to the devastating earthquake in Haiti on January 12, 2010. Since 2004, in partnership with Catholic Relief Services and through the President's Emergency Plan for AIDS Relief (PEPFAR), IHV has been providing care and treatment to 30% of Haiti's HIV/AIDS patients. Through the years, IHV has trained and employed 18 national Haitians to diagnose and treat HIV/AIDS patients, educate the public on the pandemic, and implement other important public health initiatives based upon IHV's programs and mission. After touring devastated IHV-AIDS Relief clinics in Port-au-Prince, the team developed a response plan that led to the deployment of weekly medical teams starting January 28. Due in large part to IHV's existing relationships in country, a collaborative team of 22 health care professionals from the University of Maryland School of Medicine/IHV and University of Maryland Shock Trauma Medical Center were one of the first teams of relief workers sent from America to Haiti.

In 2010, IHV continued its extraordinary growth driven by Baltimore based research and international HIV treatment programs. Our research portfolio was enhanced by increased funding on our HIV vaccine candidate by the Bill and Melinda Gates Foundation and NIH stimulus funding. International treatment programs increased again, although we envision unavoidable decreases in funding amounts in these programs in subsequent years as the US government transitions PEPFAR (President's Emergency Plan for AIDS Relief) programs to indigenous organizations. However, we do have reason to believe that our traditional basic and vaccine research base will increase in coming years.

“The JACQUES Initiative at the IHV helped save my life. Now, being the first person that people see when they walk through our clinic’s doors, I can give back to others and share my story of living well with HIV.”

Judith Shaw



Judith Shaw, Office Clerk II,
JACQUES Initiative



OUR MISSION

The Institute of Human Virology was established to create and develop a world-class center of excellence focusing on chronic viral diseases, especially HIV/AIDS, and virally-linked cancers. The IHV is dedicated to the discovery, research, treatment and prevention of these diseases. Its unique structure seeks to connect cohesive, multi-disciplinary research and clinical programs so that new treatments are streamlined from discovery to patient. The IHV serves patients locally and the scientific community globally.

IHV LEADERSHIP



Robert C. Gallo, MD

Director, Co-Director, Division of Basic Science and Vaccine Research, Institute of Human Virology and Professor, Medicine and Professor, Microbiology and Immunology, University of Maryland School of Medicine



William A. Blattner, MD

Associate Director, Director, Division of Epidemiology and Prevention, Institute of Human Virology and Professor, Medicine, University of Maryland School of Medicine



Robert R. Redfield, MD

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C. David Pauza, PhD

Associate Director, Institute of Human Virology and Professor, Medicine, University of Maryland School of Medicine



George K. Lewis, PhD

Co-Director, Division of Basic Science and Vaccine Research, Institute of Human Virology and Professor of Microbiology and Immunology, University of Maryland School of Medicine



Joseph L. Bryant, DVM

Director, Division of Animal Models, Institute of Human Virology and Professor, Medicine, University of Maryland School of Medicine



Dave Wilkins

Chief Operating Officer
Institute of Human Virology
University of Maryland School of Medicine



About IHV

The Institute of Human Virology (IHV) is the first center in the United States—perhaps the world—to combine the disciplines of basic science, epidemiology and clinical research in a concerted effort to speed the discovery of diagnostics and therapeutics for a wide variety of chronic and deadly viral and immune disorders - most notably HIV, the cause of AIDS.

Formed in 1996 as a partnership between the State of Maryland, the City of Baltimore, the University System of Maryland and the University of Maryland Medical System, IHV is an institute of the University of Maryland School of Medicine and is home to some of the most globally-recognized and world-renowned experts in the field of human virology.

The Institute, with its various laboratory and patient care facilities, is uniquely housed in a 100,000-square-foot building located in the center of Baltimore and our nation's HIV/AIDS pandemic. IHV creates an environment where multidisciplinary research, education and clinical programs work closely together to expedite the scientific understanding of HIV/AIDS pathogenesis and to develop therapeutic interventions to make AIDS and virally-caused cancers manageable, if not curable, diseases.

A particular focus of IHV includes learning how to utilize the body's natural chemistry for its own therapeutic potential and pursuing biologically-based treatment approaches that are less toxic to the body and, often, less costly to the patient and public. IHV also pursues the development of effective therapeutic and preventative vaccines, science's greatest hope in putting an end to the AIDS pandemic.

IHV's more than 300 employees include 73 faculty whose research efforts are focused in the area of chronic human viral infection and disease. At present, more than 75 percent of the Institute's clinical and research effort is targeted at HIV infection, but also includes the Hepatitis C virus, herpes viruses and cancer research.

The Institute is divided into four major divisions: Basic Science and Vaccine Development, Clinical Care and Research, Epidemiology and Prevention, and Animal Models. To learn more about the Institute and its initiatives, visit www.ihv.org or contact IHV's Director of Public Relations, Nora Grannell at ngrannell@ihv.umaryland.edu.

“At IHV we can now see a pathway toward an HIV preventative vaccine. We have obtained the most interesting results in the past three or four years, and I am hoping we will be in clinical trials soon. I can say that our approach is logical, and based on scientific results.” – Robert C. Gallo, MD



DIVISION OF BASIC SCIENCE AND VACCINE DEVELOPMENT

Dr. Robert C. Gallo, director of the Institute of Human Virology (IHV) and co-director of the Basic Science and Vaccine Development division states that, "the division has had a clear-cut, productive year, with the most compelling science right now related to the candidate vaccine from this Institute."

Once HIV has infected a person, it maintains itself by the integration of its genes into the DNA of the infected cell. The IHV's vaccine candidate has shown in animal models to greatly reduce the virus gaining entry into cells (see sidebar for more information). IHV continues to pursue funding for further pre-clinical trial development of the vaccine candidate. The advancement of this work is due in large part to the generosity of the Bill and Melinda Gates Foundation, which, in 2007, awarded a \$15 million grant to IHV's research.

"The contribution of the Gates Foundation goes beyond the financial, which is obviously greatly appreciated by the scientific community," states Gallo. "It's the way they fund. They identify particular problems that need to be solved and provide money for people to focus their efforts in finding solutions to those problems. And their administrative people are extremely dedicated, unselfish, and capable."

Researching ways to control and eliminate the AIDS virus, IHV's Dr. Fiorenza Cocchi (in collaboration with IHV Drs. Gallo, Alfredo Garzino-Demo and Tony Devico) has focused on the role of soluble factors in virus suppression. IHV's researchers have discovered a complex mixture of molecules secreted by human cells that act against X4 strains of HIV. The identification of these soluble factors provides researchers with an understanding of how the immune system defends itself against these types of HIV, which could ultimately lead to the development of new therapies. Much earlier, the IHV scientists had discovered natural suppressors of R5 HIV stains (i.e., those that use CCR5 as a co-receptor), identifying them as beta chemokines.

Meanwhile, Dr. Lai-Xi Wang's laboratory continues the adventures in glycobiology with a focus on structure and function of glycoproteins. His lab has developed a new chemoenzymatic approach for protein glycosylation engineering that allows precise glycan modification on monoclonal antibodies for enhancing their anti-cancer and anti-inflammatory activities. In collaboration with Dr. Markus Aebi at ETH, Dr. Wang's lab has also developed a novel method for producing homogeneous human glycoproteins by combining E. coli protein expression with in vitro enzymatic glycosylation remodeling.

HIV Vaccine Candidate

Research conducted at IHV has produced a unique immunogen that stops HIV from gaining the foothold it requires to become systemic in the body's cells, negating the need to anticipate the viruses variability. The IHV preventative vaccine candidate for HIV has proved effective in animal models and is now on a path to clinical trial through collaboration of IHV with Profectus Biosciences and Dr. Nelson Michael and his colleagues at the U.S. Military HIV Research Program.

This research effort was made possible in large part to generous funding from the National Institutes of Health and the Bill and Melinda Gates Foundation. The value of the IHV candidate is not only in its potential to greatly diminish HIV, but the approach may also be applicable to other viruses.

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Mohammed Amin, PhD,
Postdoctoral Fellow,
Division of Basic Science and
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The work was recently reported in *Nature Chemical Biology* (2010, 6, 264) and attracted attention.

One line of research in Dr. Wuyun Lu's laboratory centers on the development of peptide based anticancer therapeutics. His team has recently discovered several D-peptide antagonists of MDM2, an oncoprotein that negatively regulates the activity and stability of the tumor suppressor p53. These protease-resistant D-peptide antagonists efficiently inhibit tumor growth in cell cultures and experimental animals by reactivating the p53 pathway. Dr. Marzena Pazgier determines the atomic structures for MDM2, p53 and new tumor inhibitors. Knowledge about molecular structures confirms the mechanism of action for tumor inhibitors and guides the development of new and improved drugs. Drug design, structural analysis and functional testing are combined in this unique cancer biology project. Lu's laboratory is currently evaluating therapeutic potential of these antitumor peptides in preclinical models for cancer.

Research in the laboratory of Dr. David Pauza focuses on the impact of HIV infection on natural mechanisms for tumor immunity. HIV disease is associated with severe depletion of gamma delta T cells, which are important for killing tumors and are most potent against lymphoma, a common tumor in persons with HIV/AIDS. The small fraction of patients with HIV who achieve natural control over virus growth and disease, a cohort defined at IHV by Drs. Robert Redfield and Mohammad Sajadi, were studied by Dr. David Riedel in the Pauza laboratory, who reported that this group of patients was unique in its capacity to recover these cells after initial infection, and recovery was related to virus suppression and lack of overt disease. We continue our efforts to understand how gamma delta T cells are depleted and to test innovative approaches for reconstituting their activity in patients with HIV.

Within the field of vaccine research, IHV continues to move forward with a novel vaccine against Lassa Fever virus infection, a hemorrhagic fever that infects nearly 300,000 people a year and kills about 5,000.



Olga Latinovic, PhD, Assistant Professor, Division of Basic Science and Vaccine Development, Institute of Human Virology and Department of Microbiology, University of Maryland School of Medicine

Drugs currently available to combat the virus are expensive and limited in their efficacy depending upon the timing the Lassa Fever is diagnosed. To effectively control this virus outbreak, affected regions must have access to an effective, inexpensive vaccine.

Drs. Igor Lukashevich and Maria Salvato are developing several vaccine candidate platforms against Lassa Fever, the most promising of which was found safe and effective in animal models, even those that were immune-suppressed. Given the high incidence of both HIV and Lassa Fever in areas such as West Africa, it is vital that Lassa vaccines are safe for those with compromised immune systems. The IHV is seeking funding to produce the vaccine and move it toward a Phase I clinical trial.

The breadth of research and talent at the IHV is a powerful recruitment tool as evidenced by the arrival of Dr. Suzanne Gartner and her colleagues, Drs. Yiling Liu and Senthilkumar Natesan, who arrived from Johns Hopkins University to found the Stem Cell Biology section at IHV. According to Gartner, the opportunity to collaborate with world-class virologists and immunologists under Dr. Gallo's leadership was instrumental in her decision to move to the institution.

The section is working in a burgeoning field, utilizing a previously undiscovered human cell in its research, a cell that mimics stem-cell properties. The cells have many advantages. For example, because the cells are created from a blood sample, their study can take place unimpeded by ethical concerns surrounding embryonic stem cells. Their susceptibility to infection makes them an ideal host for the study of latent viral infection and the establishment of virus persistence.

Using these cells to forward a greater understanding of viral behaviors could ultimately lead to strategies for their eradication from the human body. Currently the Stem Cell Biology section is in its infancy, furthering the characterization of these novel cells. In the future, the hope is to expand the research into the development of therapeutic approaches for the treatment of chronic viral infections and cancers.

The threat of a global pandemic does not come from infection alone, but how the medical scientific community responds to it. The number of trained medical virologists is dwindling, which could inhibit the ability to respond to viral epidemics in the future. In an effort to foster scientific collaboration across borders, IHV is



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building the Global Virus Network (GVN) to link together Centers of Excellence in Virology around the world. Twenty-one centers have already joined the GVN representing countries including China, Australia, Germany and Russia, among many others.

“This has excited medical virologists and inspired people to become a part of it,” says Gallo. “We are collecting people who we think are best in their field of medical virology and are responsive to virology problems.” Dr. Gallo is assisted in this effort by Dr. Salvato, a co-director of the IHV GVN effort, and a committee including Drs. David Pauza, Robert Redfield, Marv Reitz, Igor Lukashevich and Yongjun Guan, who meet weekly to help organize this important project.

The GVN will allow the scientific community to proactively tackle known, emerging, and undiscovered viruses. It will also assist in educational exchange programs and facilitate training for scientists in the field. With funding, which is currently being sought, the GVN will become a repository of the most knowledgeable medical virologists in the world, making it a resource that government and international agencies can consult regarding the appropriate responses to viral threats.

The IHV remains focused on a global approach to the study of virology and the exchange of ideas. In addition to the ongoing work of IHV on the GVN, China’s Shandong Academy of Medical Sciences established the Shandong Gallo Institute of Virology. This institute will promote the basic science of virology, especially in the field of HIV/AIDS and emerging viruses, to facilitate translational research and clinical trials. As government and scientific leaders develop a deeper understanding of the global nature of infectious diseases, IHV’s pioneering work in both basic science and scientific collaboration will become increasingly relevant.

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The development of IHV’s vaccine is the result of years of collaborative study led by Drs. Robert Gallo, Anthony DeVico, and George Lewis. Gallo emphasizes the conceptual contributions of both. According to Lewis, who has conducted vaccine research since 1987, the structure of IHV is uniquely suited to this type of multi-disciplinary research. “What the Institute has done, which is terrific, is put everything we need within four walls,” he explains. “There’s a level of ease and synergy that’s created when you can walk down a hall instead of picking up a phone or getting on a plane to share information.”

HIV-Associated Lymphoma

A person living with HIV is susceptible to many different malignancies, even those patients whose virus is effectively suppressed with anti-retroviral therapy (HAART). Scientists found that patients who develop cancer despite successful suppression may have a persisting level of the protein p17, a structural HIV protein. In some patients, p17 may be more than a component of HIV; it may trigger the dangerous release of c-Myc, which is activated in many AIDS-related Non-Hodgkin’s lymphomas, causing B cells to become malignant. Explains IHV Dr. Fabio Romerio, “What we have is a number of pieces to a puzzle suggesting that the persistence of p17 in HIV patients may induce B cells to become malignant, despite HAART.” Currently, IHV researchers are developing animal models to learn more about the possible correlation between p17 and B cell malignancy. With better understanding of the basic biology, there is hope that therapeutic interventions will be developed to impede the incidence and voracity of AIDS-related cancers.

CLINICAL CARE AND RESEARCH

“I don’t use the words international or domestic; those words separate us. They represent boundaries. I always try to use the word ‘global’ as it takes boundaries away and unites us.”

Robert R. Redfield, MD

The spread of infectious disease indiscriminately without heed of borders is proof of the global nature of society. Under the auspices of the Clinical Care and Research division, there exist several major activities: clinical care to persons in the mid-Atlantic region living with HIV and Hepatitis; clinical research predominantly focused on the examination of therapeutic treatment options for HIV and Hepatitis C; and the global program that provides medical education and targeted research to improve therapeutic strategies around the world. Although clinical care may be administered locally through the University of Maryland Medical Center and international initiatives may take place in far-flung nations such as Zambia, the efforts weave together into a continuum that respects that

boundary-free nature of disease in today’s world, and the importance of multinational partnerships to halt it.

Perhaps the greatest contribution to the global fight against the spread of infectious disease is the President’s Emergency Plan for AIDS Relief (PEPFAR). When the Institute of Human Virology (IHV) began working with PEPFAR in 2004, the program was in its early phases, focused on establishing and scaling up prevention, care and treatment programs in order to reduce HIV/AIDS mortality and new infections predominantly in Africa and the Caribbean. In 2005, Robert R. Redfield, M.D., director of the clinical care and research division, was a member of the Presidential Advisory Council on HIV/AIDS and in 2007 became Chairman of its international subcommittee under the presidency of George W. Bush. He can recall how, through application of medical advancements, the probability of living a natural lifetime with HIV was increased in the United States while it remained appallingly low in developing nations due to inequities in access to healthcare, including life saving medicine to treat HIV infections. Through PEPFAR, some of that inequality has been mitigated, and today there are persons with HIV living longer, fuller lives, able to work, to parent and to participate in their community.

PEPFAR has since moved into a mature phase of capacity building, working with host nations to develop the in-country talent and infrastructure needed to maintain long-term progress. IHV has capitalized on its legacy of partnership with PEPFAR to be a leader in this process. What began with sending American-trained physicians to Africa to facilitate skill transfer has grown such that IHV has overseen the training of African-born healthcare providers – physicians,



Dr. Robert Redfield, Associate Director of the Institute of Human Virology, and Catholic Relief Services Chief of Party, Anna Van Rooyen, look over a patient’s x-ray at the St. Francois de Sales hospital in Port-au-Prince, Haiti.



Jeffrey Weaver, MMS, a physician assistant with the JACQUES Initiative, meets with his client.

nurses and laboratory specialists – in the United States and assisted in repatriating those skilled medical practitioners into their home countries. In addition, IHV has created a seven year track that gives gifted African and Caribbean doctors the opportunity to work at IHV and enter an American residency program followed by an infectious disease fellowship before returning to their country of origin. In July of 2010, the first two participants on this path repatriated to Zambia, bringing unprecedented expertise to that country. The result of these ongoing efforts is that programs that began under the leadership of Americans in Africa and the Caribbean have become largely populated by nationals with ties to IHV.

As part of the growing web of capacity building, IHV obtained three noteworthy grants that will help build strategic alliances with academic and medical institutions within PEPFAR countries as well as partnerships with their Ministries of Health. The Partnership in Advanced Clinical Education (PACE), for example, is revitalizing HIV medical education for Kenya through a partnership with the University of Nairobi. An additional grant creates The Center of Excellence, also with the University of Nairobi, which provides for the overhaul of three Kenyan hospitals into centers of excellence for HIV care and treatment. These

West Africa to West Baltimore

IHV's extensive clinical care program has grown from treating approximately 200 patients with HIV/AIDS to over 5,000 through out-patient programs. Certainly much of that growth relates to the maturation of the virus in the regional area; in March 2009 a report from the Washington, D.C. Health Department revealed that Washington, D.C., has a higher rate of HIV than many areas in West Africa with 3% prevalence.

Just as IHV has worked to build capacity in its global programs, there has been a parallel effort here at home. Starting in 1996, clinics have been built or updated in Baltimore to preserve patient privacy and dignity. Through Federal grants, funds have been raised to allow the uninsured access to quality care. As IHV grew its quality of care and its non-judgmental infrastructure, the number of patients grew commensurately.

Despite the volume of patients, studies indicated that patients were still failing in their treatment.

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“Patients living with HIV go on therapy and need to take it every day for the rest of their lives,” says Derek E. Spencer, MS, CRNP, Executive Director of IHV’s JACQUES Initiative. “They make that commitment often without community support because of the stigma and discrimination associated with HIV.”

In 2003, IHV began the JACQUES Initiative (J.I.) to help patients improve their adherence to medical treatment through a holistic approach to care that draws on existing support structures, such as family and friends, as well as treatment coaches and healthcare providers. Since its inception, J.I. has expanded its scope to include HIV testing, primary care, case management, even housing and food assistance and mental health referrals.

As with all IHV’s efforts here and abroad, partnerships have proven valuable. Inspired by a Centers for Disease Control

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grants are instrumental in building capacity within local institutions so they can carry out the functions of advanced clinical education needed to continue equalizing the lifespan outcomes of HIV-infected individuals in resource-challenged countries.

Strategic development of healthcare workers and infrastructure is most effective when it is holistic and invites all partners into the process. IHV has routinely demonstrated an ability to effectively work with local Ministries of Health to develop long-range programs. The third of its recent grants, called The Partnership in Advanced Clinical Treatment (PACT), joins IHV’s efforts with those of the Ministry of Health of Kenya to provide mentorship in Nairobi’s public hospitals.

The importance of partnerships with Ministry of Health officials was underscored this year after the earthquake in Haiti. Haiti is one of two Caribbean nations where IHV is active through PEPFAR in a consortium with Catholic Relief Services. Under the program, IHV has provided care and treatment to approximately 10,000 Haitians living with HIV/AIDS and has trained and employed nearly 20 nationals to diagnose, treat and educate others about the virus. Recently, IHV entered into an agreement with the Ministry of Health, the University of Notre Dame of Haiti/School of Medicine and Health Science, and the St. Françoise Hospital in the capital, Port au Prince, to provide medical education in infectious diseases at the undergraduate and graduate levels. The program mirrors one IHV successfully implemented in Zambia. The Haitian project was in the process of launching when the magnitude 7.0 earthquake shook its foundation.

The St. Françoise Hospital was almost entirely destroyed by the quake, and IHV’s staff (Haitian and American) shifted from the care of HIV/AIDS patients to the immediacy of life-saving rescue and emergency medical treatment in a makeshift “hospital” constructed in an open courtyard. However, within a week, all IHV’s HIV/AIDS patients were re-engaged with their care regimen. Also in that time, IHV leveraged its partnerships and connections with the University of Maryland Health System to bring five surgical teams from the University of Maryland Medical Center to care for the high number of trauma cases. In the aftermath of the quake, not only has the advanced degree program in infectious diseases been funded, it has been expanded to include nursing, orthopedic and trauma management. Just as the nature of infectious disease knows not geographical boundaries or ethnic differences, the efforts of IHV demonstrate that successful research, treatment and education are only effective in collaborations that embrace a global society.



JACQUES Initiative Executive Director, Derek Spencer, MS, CRNP speaks of Project Shalem during the July press conference.

report that underscored the importance of complete community engagement in fighting disease, IHV formalized its existing community-based programs in July 2009 with the launch of Project Shalem. Shalem is a term common across many faiths, which means “a safe place.” Fittingly, the program engages churches, mosques and synagogues as satellite centers for HIV testing.

Project Shalem kicked-off with an event where 900 people were tested for HIV. One year later, in July 2010, 1,050 people were tested in one day. Testing is largely conducted by volunteers trained under the umbrella of J.I. The volunteers come from diverse backgrounds and include suburban housewives and urban religious leaders.

“To change the city, you must engage the city,” Spencer explains. The testing helps identify new HIV positive individuals -- or those who know they are positive but have fallen out of treatment -- and links them to care.

According to Spencer, diagnosis and management of HIV is important because in treatment, “People can live well in their lives and be productive in society.” He continues that, “When someone’s virus is suppressed, you can see people get out of the cycle of being sick in the ER only to wind up back in the acute care setting within weeks or months.” From a public health perspective, those in treatment whose virus is suppressed are less likely to engage in high-risk behavior and have a lower risk of mother-to-child pre-natal transmission of the virus.

“We must have a presence in the community beyond the academic environment,” says Spencer of the importance of efforts like Project Shalem. “A typical work week for us is not Monday through Friday. It includes Saturday and Sunday, whenever people are worshipping or will give us an invitation to engage and share what’s going on in our city related to HIV and how they can make a difference.”

EPIDEMIOLOGY AND PREVENTION

“The University and IHV-Nigeria are focused on helping indigenous hospitals to implement quality medical care. Our programs are about working with existing healthcare infrastructures to improve them, to move them to a new level of excellence.”

William A. Blattner, MD, Associate Director, Institute of Human Virology

In 2004, the Institute of Human Virology—Nigeria (IHV-Nigeria) was established under the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR). The goal was to implement growth of the PEPFAR program and conduct research and training to promote quality, evidence-based health system strengthening in Nigeria. When it began, it was little more than a single hotel room. Over its six years in existence, IHV-Nigeria, one of the largest activities of the Institute of Human Virology of the University of Maryland School of Medicine’s Epidemiology and Prevention Division, has engaged approximately 160,000 HIV-positive people into care and 90,000 in treatment. It supports 139 health care sites. Of the 230 staff members, 95% are Nigerian. IHV-Nigeria has grown to exemplify IHV’s commitment to combating infectious disease through effective training partnerships with other nations in a spirit of collaboration.

IHV’s grant-garnering work is intensely focused on these capacity building efforts, a concentration that has taken on new relevance as PEPFAR monies are increasingly devoted to infrastructure support inside the host country and outside of the United States. Through programs such as The University of Maryland, Institute of Human Virology AIDS International Training and Research Program (UM-IHV AITRP) funded by the John E. Fogarty International Center, IHV has supported pre- and post-doctoral research training as well as workshops and short-term training for specialists



in partner institutions outside the United States. The Fogarty Training has impacted more than 1,250 scientists in Jamaica, Trinidad, Tobago, Brazil, Mali, and Nigeria. This year, that grant (which has been held by IHV since 1998), was competitively renewed, ensuring the continuity of the Fogarty Training program for another five years. Through the Fogarty Scholars, the Institute affirms its global participation in long-range infrastructure building.

Below depicts registration for a short-term course sponsored by NIH Fogarty International AIDS Training and Research Program. The Statistical Methods in Epidemiology short-term course in this picture introduces epidemiology, emphasizing its methodology and statistical approaches and applications in research and public health, to 25 Nigerian researchers each year. The best performing students are invited to apply for long-term Fogarty Scholar positions.





In 2004, the Nigerian government presented IHV-Nigeria "The Robert Gallo House," a state-of-the-art clinical and research laboratory located at Plateau State Human Virology Research Center in Jos, Nigeria.

Similarly, this year marked the opening of a national HIV Clinical Training Center at the University of Abuja Teaching Hospital in Nigeria. The center demonstrates a model of a functional clinical structure appropriate to Nigerian needs and accessible to Nigerian health care workers. The building includes 12 dedicated examination rooms, conference facilities and multidisciplinary HIV and HIV/tuberculosis care.

At the Center, doctors receive the same level of training they would receive in the United States without the expense of traveling abroad. In addition, working with the University of Maryland School of Nursing, IHV has funded a curriculum development activity to support HIV training for nurses in Nigeria. This educational component, when linked to the Clinical Training Center, will provide a model of task shifting instruction on how doctors and nurses can work together more effectively to meet the needs of patient care and treatment.

IHV-Nigeria has provided HIV counseling to over 500,000 individuals. Among them are 290,000 women seeking information related to mother-to-child transmission. IHV's scientists and epidemiologists place special emphasis on training Nigerian clinicians in strategies for the prevention of HIV transmission from mothers to newborns. A new grant gained this year will provide funding to study acute HIV infection in women during pregnancy and the impacts on the baby.

These research efforts illustrate how HIV infection is a community issue as much as one of public health. Whether it is a mother passing the virus to her child or a father who dies from AIDS and leaves a breadwinner position unfilled in a family, the societal ramifications of the virus are far-reaching. Another grant funded this year (in collaboration with the Department of Neurology) will examine the effect of HIV on neurological functions. Studies indicate that 20% of

Where Cancer and AIDS Meet

This year, the Epidemiology and Prevention Division received a Capacity Development for Research into HIV-Associated Malignancies (CADRE) training grant through the National Cancer Institute (NCI). To the untrained observer, this poses a logical question: How does cancer relate to IHV's expertise in HIV/AIDS? Clement Adebamowo, M.D., a Nigerian-born physician and member of the University faculty, received the grant and explains that HIV and cancer have always been linked since the HIV infection was first officially described.

"At that time, certain cancers were found to occur more frequently among people who are HIV positive," says Adebamowo, noting that some of those include cervical cancer and non-Hodgkin Lymphoma. "The CDC designated these cancers as "AIDS defining" cancers with the implication that any patient with these cancers should be tested for HIV."

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With the advent of better care and treatment for HIV, patients can live far longer than when HIV was first defined. However, this also makes these individuals vulnerable to cancers that Disease Control's original list, such that the compendium of malignancies possible is now referred to as AIDS-associated cancers. In the U.S. and Europe, cancer is the leading cause of death for persons living with HIV.

A major goal of the CADRE Nigeria grant is to build capacity for cancer research including the development of clinical trials of drugs that will be effective, affordable and available in the developing world. Through the grant, Adebamowo explains that IHV will develop clinical trial teams at leading teaching hospitals in Nigeria. The teams will learn multi-disciplinary approaches to cancer care and how to use this information to enhance case identification.

The project will enhance cancer registration in a country that currently does

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HIV-positive individuals have some cognitive problems, which can lead to serious medical problems due to non-adherence to therapy and have societal ramifications caused by impaired critical judgment for persons in positions of authority. The hope of the research, which is in its initial stages, is to develop an effective screening tool for the clinical diagnosis of cognitive impairment and effective interventions. In the future, the research holds promise to identify the domains of the brain affected by HIV and methods to block its entry.

The work of IHV is inextricably linked with HIV/AIDS, yet the Institute's work extends to a broad spectrum of infectious diseases. Nigeria, for example, ranks fourth in the world for incidence of tuberculosis. Coupled with its standing as the second highest rate of HIV infection, Nigeria is positioned to be a haven for a new wave of infectious disease: multi-drug resistant tuberculosis, or MDR-TB. In anticipation of the growing need for research in this area, IHV-Nigeria this year opened a modular Biosafety Level Three (BSL-3) laboratory to provide a means of determining the prevalence of MDR-TB and a safe environment for detecting extreme versions of drug resistant TB.





U.S. Centers for Disease Control (CDC) Director, Dr. Tom Frieden, visited the Nigerian National TB and Leprosy Training Center (NTBLTC) to tour a multimillion dollar laboratory complex established by the Institute of Human Virology-Nigeria.

The BSL-3 lab is the first of its kind in West Africa. This lab will be instrumental in helping Nigeria as well as its neighboring countries in the accurate diagnosis of TB in a completely safe environment. It will also create an established reporting mechanism for TB results. Dr. Alash'le Abimiku, an Assistant Professor at IHV who works in partnership with Dr. Blattner, is originally from Nigeria and was instrumental in the laboratory's creation has stated that it will play a major role in Nigeria's ability to monitor the spread of MDR-TB in the country for appropriate response, especially as the country plans the release of second line TB drugs.

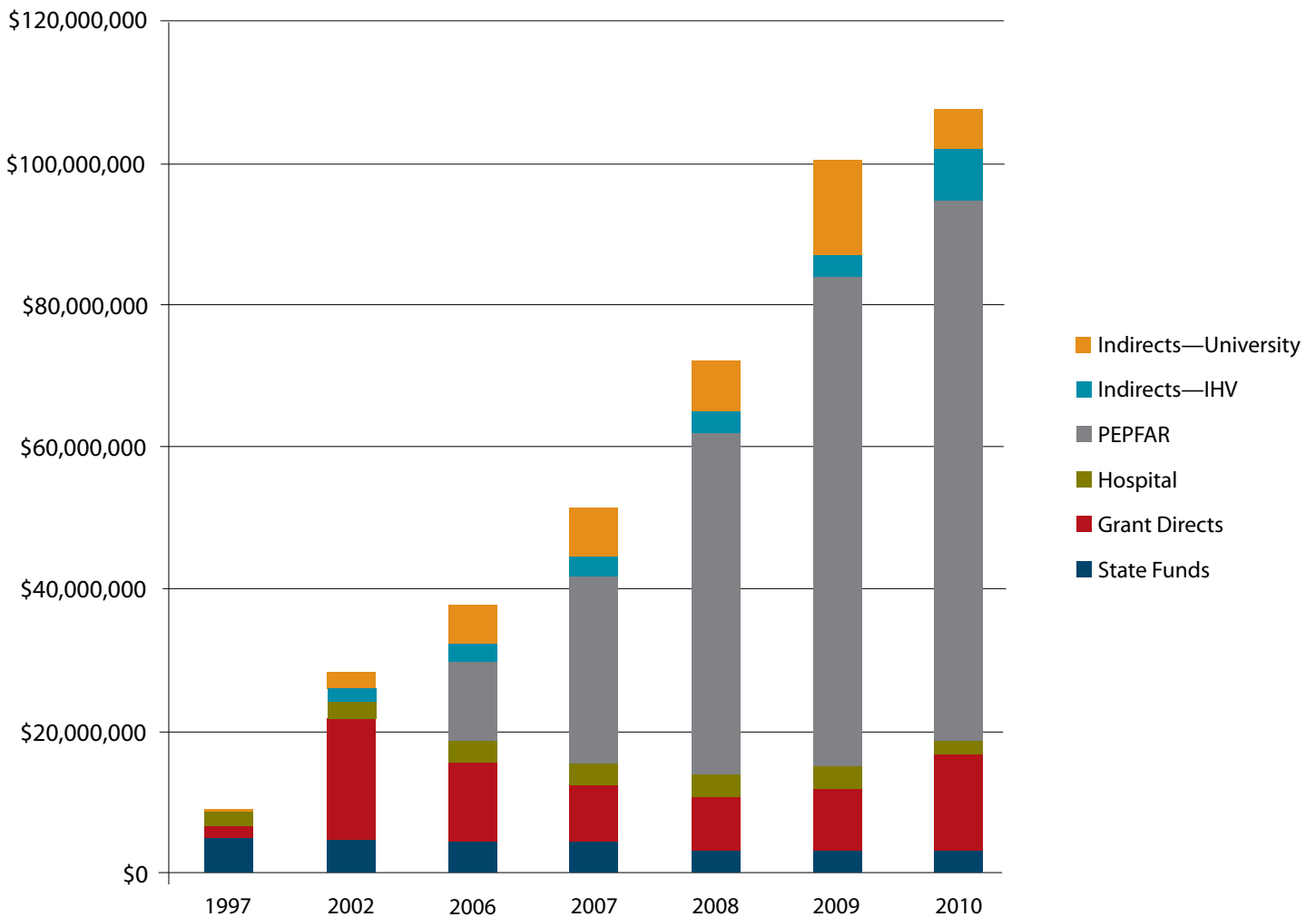
not have an effective means of enumerating cancer occurrence. This information will improve Nigeria's ability to garner resources for cancer management and to spot trends. It will also provide an effective research platform to study cancer causation including the search for new viruses associated with HIV cancers. In this way, IHV will continue the legacy of its director, Dr. Robert C. Gallo, as a leading virus hunter.

"This is a very exciting opportunity to link cancer prevention and care with the infrastructure and resources that have been put in place with HIV care and treatment in developing countries," says Adebamowo.

"We hope that at the end of the grant period we will have provided capacity building for institutions in Nigeria that will increase their ability to perform AIDS-associated cancer research with broad implications to cancer research in general."

Budgeted Revenues: Distribution by Funding Source

In 2010, IHV continued its extraordinary growth driven by Baltimore based research and international HIV treatment programs. Our research portfolio was enhanced by increased funding on our HIV vaccine candidate by the Bill and Melinda Gates Foundation and NIH stimulus funding. International treatment programs increased again, although we envision unavoidable decreases in funding amounts in these programs in subsequent years as the US government transitions PEPFAR (President’s Emergency Plan for AIDS Relief) programs to indigenous organizations. However, we do have reason to believe that our traditional basic and vaccine research base will increase in coming years.



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