

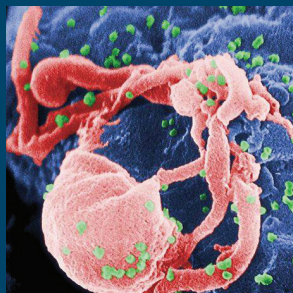
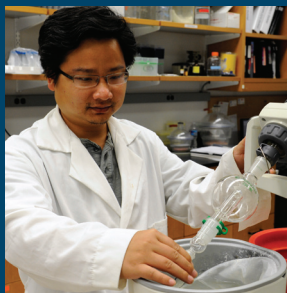


2011

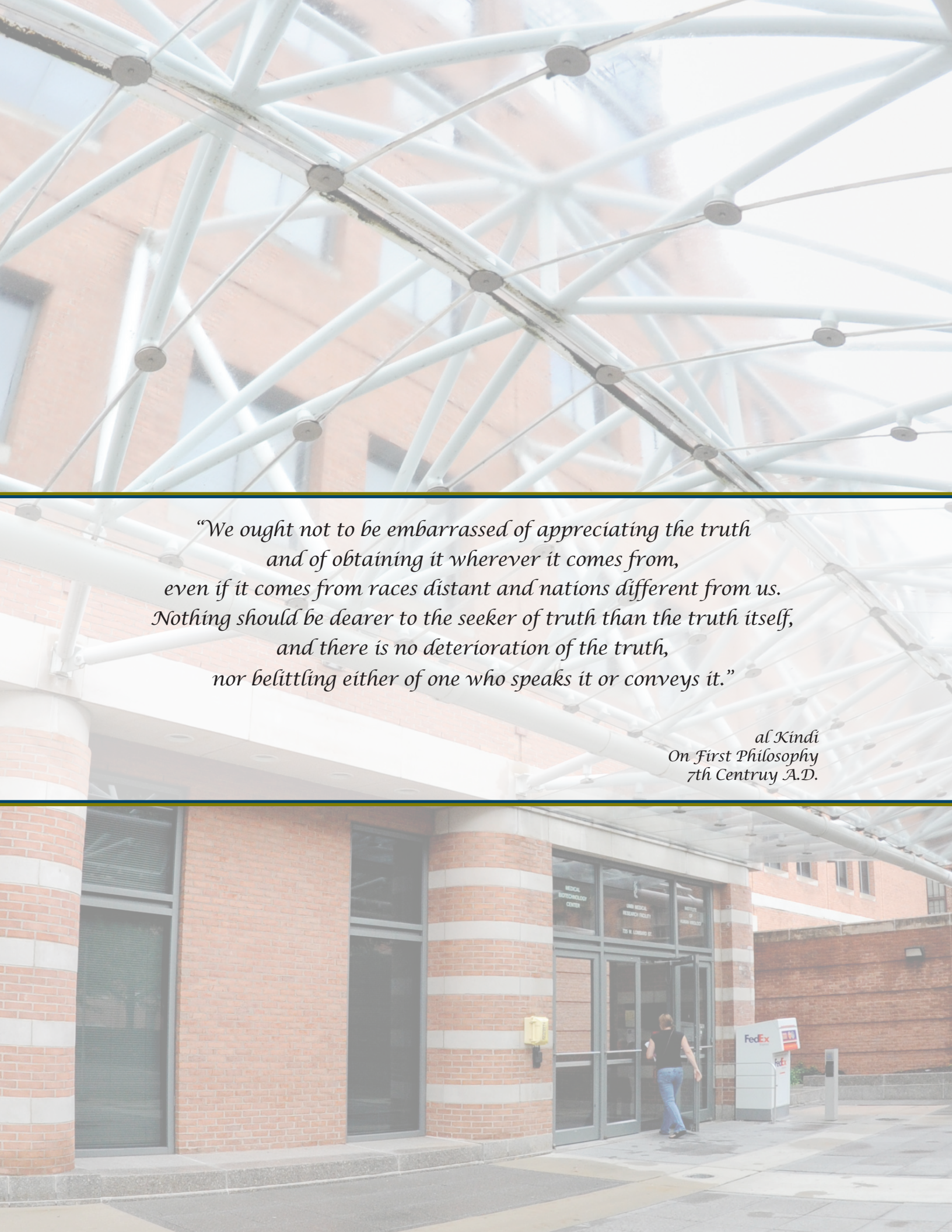
ANNUAL REPORT



Global Leadership in Research, Therapy, and Prevention



UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE



*“We ought not to be embarrassed of appreciating the truth
and of obtaining it wherever it comes from,
even if it comes from races distant and nations different from us.
Nothing should be dearer to the seeker of truth than the truth itself,
and there is no deterioration of the truth,
nor belittling either of one who speaks it or conveys it.”*

*al Kindī
On First Philosophy
7th Century A.D.*





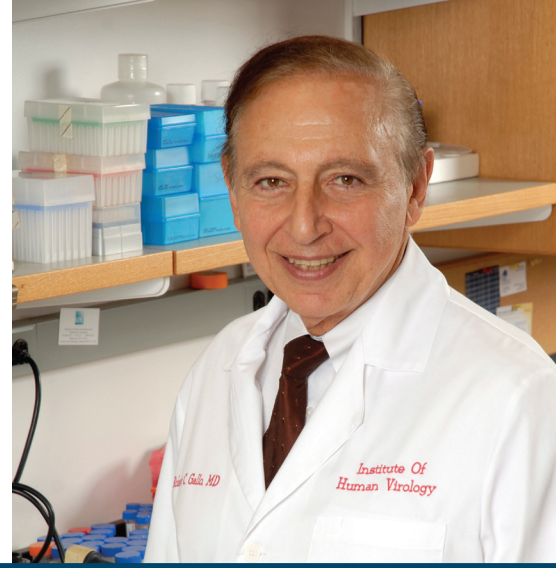
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12th Annual IHV International Meeting attendees.

Robert C. Gallo, MD, Director,
Institute of Human Virology and Professor,
Departments of Medicine and Microbiology
and Immunology,
University of Maryland School of Medicine



Director's Message

The Institute of Human Virology (IHV) at the University of Maryland School of Medicine had another flourishing and pivotal year in FY11. For the first time, the Annual IHV International Meeting was held outside the Washington, D.C./Baltimore region and uniquely hosted in the ancient region of Calabria, Tropea, Italy. The 12th Annual Meeting attracted approximately 300 scientists, clinicians and pharmaceutical representatives from around the world to explore the latest developments in the fight against HIV/AIDS, viral oncology and other infectious diseases. Prior to the IHV Annual meeting, IHV faculty voted for the prestigious Lifetime Achievement Award in Public Service and Lifetime Achievement Award for Scientific Contributions. Additionally, uniquely for this one and only year, the Institute's faculty unanimously voted to bestow a Lifetime Achievement Award in Teaching and Education. The esteemed winners included:

IHV Board Member Harry Huge, 2010 recipient of the IHV Lifetime Achievement Award in Public Service: For his distinguished law career with, among others, American labor unions and the country of Estonia and philanthropic work providing American students continued education scholarships.

Dr. Rino Rappuoli of Novartis Vaccines, 2010 recipient of the IHV Lifetime Achievement Award for Scientific Contributions: For his leadership in the research and development of vaccines, particularly for the first recombinant bacterial vaccine (against pertussis) and a conjugate vaccine against meningococcus C.

Dr. Michele LaPlaca, 2010 recipient of the Lifetime Achievement Award in Teaching and Education: For his writing career, long dedication to research and teaching, his production of the invaluable manual, "Principles of Medical Microbiology," (Esculapio, Bologna, Italy) - the most widely used textbook of microbiology in the medical schools of Italian universities, which is currently in its 12th edition - and for his ability to captivate and motivate students into the field of microbiology.

The science presented at the meeting was exciting and thought-provoking. Leading virologists discussed their work on continuing to understand HIV disease mechanisms; noteworthy findings from clinical studies; continued basic research in finding an HIV preventative vaccine candidate (particularly results from the U.S. Army's RV-144 Thai trial);

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Furthering IHV's outreach internationally we have been working to establish the Global Virus Network (GVN), a global authority and resource for the identification, investigation, and control of viral diseases posing threats to mankind.



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epidemiology on cancer in patients living with HIV; attempts to cure HIV infection; surprising new research in cancer; and, an opportunity to learn, discuss and argue about endogenous retroviral elements.

Furthering IHV's international outreach, since last year, my colleagues and I at IHV and throughout the world have been working to establish the Global Virus Network (GVN), a global authority and resource for the identification, investigation, and control of viral diseases posing threats to mankind. The inaugural meeting of the GVN was held March 1-3 at the Embassy of Italy in Washington. The GVN fulfills a goal of mine since the early 1980's following the immediate HIV/AIDS outbreak to effectuate the need for global collaboration to overcome gaps in research during the earliest phases of viral epidemics and to ensure that sufficient numbers of medical virologists are trained to meet these challenges.

A few of our highlights of the year are as follows:

In the Basic Science and Vaccine Development (BSVD) Division, led by Dr. George Lewis and me, Maryland Governor Martin O'Malley announced that IHV received \$23.4 million from a consortium of funding sources to support the next phase of research into a promising HIV/AIDS preventive vaccine candidate. The IHV vaccine program grants include \$16.8 million from the Bill & Melinda Gates Foundation, \$2.2 million from the U.S. Army's Military HIV Research Program (MHRP), and other research funding from a variety of sources including the U.S. National Institutes of Health (NIH). This has been the focus of Drs. Lewis and Tony DeVico, and the research area of my own major interest. Additionally in the Division, among other interesting research, scientists such as IHV Associate Director Dr. David Pauza continue 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. IHV's close working relationship with the University of Maryland Marlene and Stewart Greenebaum Cancer Center enhances our studies in 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 (IHVN) through funding from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Since PEPFAR's inception, the program's aim has been to provide on-the-ground training, education and clinical care to locals in targeted developing countries via American university collaborations, so that one day that country is in a position to prevent and care for its HIV/AIDS and associated diseases epidemics. Additionally, the Division's Fogarty sponsored AIDS International Training and Research Program grant continued to provide one of IHV's mechanisms



Drs. Michele LaPlaca and Rino Rappuoli



Dr. Robert Gallo and Harry Hogue



in support and engagement of IHVN faculty and staff as well as partners from IHV-Nigeria's network of academic and research institution partners.

Dr. Robert Redfield, IHV Associate Director and Director of the Clinical Care and Research Division, reported another successful year, particularly as his team continued to build upon their PEPFAR programs in seven African and two Caribbean nations, their presence in Malawi and their local outreach here in Baltimore. Particularly, the Division continues to help Haiti recover from their devastating January 2010 earthquake by providing ongoing care and treatment to approximately 10,000 Haitians living with HIV/AIDS and training and employing more than 20 Haitian nationals to diagnose, treat and educate others about the virus. The Division also provides care and treatment to more than 5,000 Baltimoreans – teaching them how they can live “well” with HIV.

IHV Associate Professor and Animal Models Division head, Dr. Joseph Bryant, saw growth in research and grants this past year. The Division will support BSVD and IHV's HIV preventative vaccine candidate research by studying and hopefully overcoming one of the greatest stumbling blocks to an effective vaccine, namely the sustainability of effective humoral immunity achieved by a candidate vaccine in the face of repeated challenge. The Division is also supporting a study to investigate the safety, efficacy, and mechanisms of action of Korean Wild Ginseng cambial meristematic cells (DMCs) in the treatment of HIV/AIDS. We believe this technology, in collaboration with Korea's Unhwa Bio Corporation, could contain one or several anti-HIV compounds that can be used alone or in combination with anti-retroviral drug therapy that acts against HIV directly or indirectly. Dr. Bryant is also collaborating with Dr. Davide Zella and me on the role of a new Mycoplasma isolated at IHV and the role it plays in Lymphoma, especially in AIDS patients.

In 2011, IHV achieved solid growth in its primary mission areas of basic science and vaccine development research, most notably from Bill & Melinda Gates Foundation and National Institutes of Health (NIH) grant pursuit efforts. At the same time, we began to see the effects of the long expected transition of the PEPFAR funding from U.S. based Universities to indigenous organizations. In aggregate, this left IHV's overall revenue generation for FY11 at nearly the same level as FY10. In the next several years, we can expect to see that while some international programs will be maintained directly through the Institute, others will have been transitioned to in-country organizations (this transition decision is driven by U.S. government policy). The net effect will be a decrease in IHV's overall revenue. However, since the indirect funds generated are realized on a one year lag, IHV won't see a negative effect on discretionary funding for some time.



Dr. Gallo inaugurates a new scientific high school in Calabria

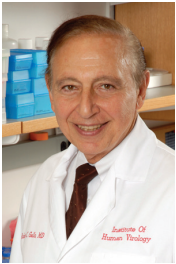




Our Mission

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



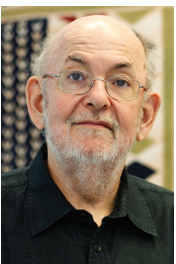
Robert R. Redfield, MD

Associate Director, Director, Division of Clinical Care and Research, Institute of Human Virology and Professor, Medicine and Professor, Microbiology and Immunology, University of Maryland School of Medicine



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 R. 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 approximately 300 employees includes more than 70 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.

“Our vaccine candidate induces antibodies that are sufficiently broad enough to make effective interactions with a variety of HIV strains, so we think there is progress on the problem of virus and envelope protein variability, and not from IHV alone but from many in the field.”

Dr. Robert Gallo



Division of Basic Science and Vaccine Development

After decades of working to understand HIV and develop a vaccine to stop the virus's deadly spread, Dr. Robert C. Gallo has built a collaboration to put a novel HIV vaccine candidate to the test. "The funding and consortium is there," says Gallo, speaking of the \$23.4 million in grants received this year in support for preclinical and Phase I/II trials.

Gallo, who co-discovered HIV, founded the Institute of Human Virology (IHV) at the University of Maryland School of Medicine to discover, research, treat, and prevent such chronic viral diseases. Now the IHV leads a collaboration of The Bill & Melinda Gates Foundation, U.S. Army's Military Research Program, National Institutes of Health, pharmaceutical company Sanofi-aventis, and Profectus Biosciences, which was co-founded by Gallo for bench-to-bedside medicine. "It's a true collaboration in every sense of the word," says Gallo, "because the Gates Foundation and the Army contributed ideas and criticisms as well."

Collaborators' ideas and criticisms are needed because previous HIV vaccine candidates have been far from effective. The difficulty, says Gallo, is in doing something that has never been done before in vaccinology: "We want the vaccine to work right at the beginning of the infectious process, so that we have a chance for complete blockage of viral entry and viral infection."

Past vaccine candidates have failed for two reasons. The first reason is that HIV envelope protein is highly variable and past candidates have only been protective against viruses carrying the same envelope protein which was used to make vaccine in the first place. Because of this variability, and because there are many different strains of the virus, IHV elicited an approach which primes the immune system with a novel molecule made up of gp120 fused to CD4—the primary receptor of HIV—a protein expressed on the surface of the immune system's T cells. Gallo explains, "In the moment that gp120 binds to the CD4 surface molecule on a target cell, gp120 goes through a dramatic change in shape," exposing a region of the envelope protein that is evolutionarily conserved. This shape-change allows gp120 to use another of the cell's receptors, CCR5, to enter and infect the cell. Says Gallo, "Normally the region of the envelope gp120 that interacts with CCR5 is well hidden. That vital region is only exposed to our immune system for a short period of time," which normally prevents the development of effective anti-virus antibodies. Without antibodies that completely block cell infection, HIV establishes a permanent infection within one day due to its capacity to integrate its genes into the target cells of an infected person. "The vaccine-induced immune response must be present immediately and it must be durable. This demands sterilizing immunity or close to it."

There are cases, however, of people whose immune systems naturally suppress HIV replication to undetectable levels. Research done at the Institute on these "natural virus suppressors" showed they have an immunological memory of antibodies capable of binding the fused gp120-CD4 molecule—called the Full-Length Single Chain (FLSC)—suggesting a similarity between natural control of HIV and what could be achieved by the IHV vaccine. "Those people," says Gallo, speaking of natural virus suppressors, "had only low levels of antibodies in their blood, unlike monkeys" actively infected with simian immunodeficiency virus, which

Focus on Cancer

There are two foci in the Institute of Human Virology's viral cancer research program, which is part of the University of Maryland's Greenebaum Cancer Center: investigate microbial roles in the origin of human cancer, and basic research on in vitro transformation with animal model tumor viruses and p53—the protein that signals cells to die when DNA mutations are detected. "In almost all human cancers," says Wuyuan Lu, a peptide chemist at IHV, "there's something wrong with the p53 protein due to mutations, so the protein is not active or it is blocked by another peptide." One of those blocker peptides is MDM2, which is produced naturally in the body and keeps the amount of p53 in check: if there's too much p53, the body produces more MDM2. However, if there's too much mbm2 (or too little p53), there is a positive feedback loop that further reduces the amount of p53 and allows cancers to grow.

"Now, in unpublished work," says Lu, "we have a lead compound with binds to MDM2 [allowing p53 levels to recover]. This year, we spent a lot of time trying to optimize this activity; we succeeded and just patented this. So we have roughly 200 picomolar binding affinity, which is very strong, and we have a plan to develop this particular compound as a potential therapeutic agent and test it in animal models of cancer to see where it goes.

The beauty about this approach is that it can benefit 25-30% of all cancer patients." While clinical trials are the ultimate goal, Lu says he is "realistic, though cautiously optimistic" the approach will work.

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To the other focus of IHV's viral cancer research program, it's already well established that HIV infections put patients at increased risk for cancer, but the mechanism is not clear. "We're accustomed to thinking," says IHV's David Pauza, "about Epstein Barr lymphoma, where the virus is in the lymphoma, or human papilloma virus infection, where the virus is in the cervical cancer. We have lots of examples like that; we feel comfortable with those. But when the virus massively elevates the rates of cancer and it doesn't appear in the tumor, this raises very significant, very substantial scientific questions."

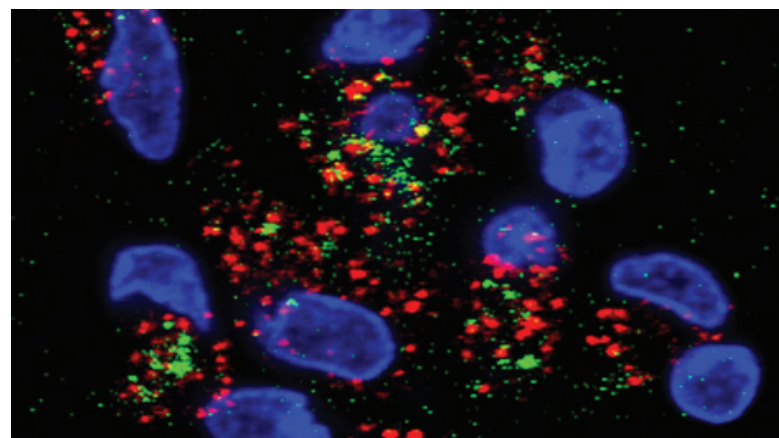
Such indirect effects of HIV infection may be linked to the depletion of gamma-delta T cells, "which don't express CD4 and so are never infectable by HIV," Pauza says, who has been studying and describing the depletion of these cells as far back as 1995. An important function of gamma-delta T cells is in natural control of cancer. The team has looked at large clinical populations in collaboration with Dr. Redfield and IHV's Clinical Care and Research Division, which were available partly because gamma-delta T cells are also very important to the immune system's response to tuberculosis, malaria, and the control of tumors. "One of the most important breakthroughs of the last year is that we finally uncovered the mechanism by which these cells are killed in patients with HIV."

"Now," says Pauza, "we are tracking down all other cell types that might be damaged or depleted through the same mechanism, and we think this is going to be an important explanation for what happens during the very early events in HIV infection and eventually increases the risk for cancer." And for patients that have both HIV and cancer, a new clinic at the University of Maryland's Greenebaum Cancer Center will focus on the particular issues that come about because HIV and cancer often require two very different and demanding treatment approaches that are not easy to use together. "It's an entirely new set of challenges in clinical medicine," says Pauza, reflecting on the initiative of IHV's Dr. Robert Redfield together with clinical faculty member David Riedel and Carla Alexander to create the center, "and I think we are very fortunate to have people willing to take on those challenges. I think they will make a very big difference in helping patients with these two difficult diseases."

maintained high antibodies that failed to control the virus. "Then," continues Gallo, "it occurred to George to look at memory B cells from natural virus suppressors." Together with IHV colleague Yongjun Guan, PhD the researchers figured out technologies to single-cell clone and expand these memory B cells, inducing them to produce antibodies which represented an earlier response to the infection. "And lo and behold," summarizes Gallo, "more than a third of the total antibodies they make are of the kind we think are important ones induced by the Full-Length Single Chain vaccine..., namely antibodies against the envelope protein, gp120, but only after it has interacted with CD4."

"Our hypothesis," says Gallo, "is those antibodies existed early on [in natural virus suppressors], and blunted early infection, which is why the patients were able to control virus growth." The original idea of linking gp120 with CD4, says Gallo, "goes back two decades to Franco Celada, who's appreciative that this idea has been pursued, and was then actively pursued at IHV, notably and first by Tony DeVico and then Lewis and Tim Fouts, who is now with Profectus. And a decade ago, we were pretty convinced that this would be an important pathway to a HIV vaccine. Now, we can do it—Gates has been a godsend for the field [with the Gates Foundation contributing over 70% of the \$23.4 million grant funds supporting the collaborative project]."

"Our vaccine candidate induces antibodies that are sufficiently broad so that we can have effective interactions with a variety of HIV strains," says Gallo, "so there has been progress on the problem of virus and envelope protein variability."



But before IHV Associate Director Robert Redfield, MD, starts Phase 1 clinical trials in Baltimore, Gallo says a little more preclinical development is needed: “I think we’ll get interesting results in clinical trials. But we need our antibodies to last longer than they do. Antibodies can be short-lived or long-lived. These [FLSC-induced antibodies] are not surviving long enough for a feasible vaccine—we would have to be boosting every three or four months. So that’s a problem, scientifically, that we have to solve, and the way we approach that is with different adjuvants, or non-specific stimulants to the immune system.”

Complementary research is being carried out by IHV’s Lai-Xi Wang, who studies glycosylation, or how carbohydrates attach to proteins. “Once you understand how the envelope protein [gp120] is glycosylated,” says Wang, “you can study the structure/activity relationships—so if you attach a different carbohydrate, it changes the immunogenicity and other biological functions. You can use that information to design a better vaccine candidate.” In other words, the target for immune system recognition is still the regions exposed after the binding of gp120 and CD4, with Wang’s work helping to optimize the immune system’s recognition of gp120. Says Gallo, “Lai-Xi’s work has broad implications for vaccine and cancer. In studies with the [University of Maryland’s] Medical Center on cancer, he is modifying monoclonal antibodies with carbohydrates in the Fc region. These improved antibodies attack cancer cells on two fronts: one end finds something odd on the cancer cell surface—or something you vaccinated against—the other “Fc” end brings bridges to Natural Killer cells, which help to kill the tumor.”

Of course, vaccine has little effect on people where already infected: with HIV, the virus remains integrated within the host cells’ DNA. While anti-retroviral therapies keep HIV/AIDS in check for some patients, eradicating the virus means killing those reservoirs of latently infected cells. “We’re talking about a cure,” says IHV’s Fabio Romerio, who, along with Gallo, thinks current cure strategies of reactivating latently infected cells and then treating them with anti-retroviral drugs will be ineffective. “There’s always a chance,” says Romerio, “that [implementing such a strategy] you will seed new reservoirs or that not all the latently infected cells



Dr. George Lewis

will die. So we need to develop a whole new class of drugs that are specifically targeting latently-infected cells.” To do that, Romerio and his team are working to identify what if any proteins are uniquely expressed on the surface of latently infected cells and whether they can be therapeutic targets.

“Now, there are different types of cellular reservoirs,” says Romerio. “Every cell that can be infected by HIV can—one way or another—become part of a viral reservoir.” So Romerio is focused first on the type of cells that make up what appears to be the largest such reservoir in the body: CD4+ T-cells. “We’re reasoning that the infection by HIV might have induced the expression of specific cellular proteins in these [latently infected] cells that are different from their uninfected counterparts,” Romerio says, providing a target for a potential therapy. Having received a separate grant this year from the Gates Foundation, Romerio and his team are using a model developed earlier for culturing latently infected CD4+ T-cells in vitro and comparing them with uninfected cells. “We also need to demonstrate that any difference we see with our in vitro system reflects differences in vivo—in patients—because there is a possibility that our model may not perfectly reflect the situation in vivo.”

With funding secured for Romerio’s work and with HIV-vaccine development well underway, Gallo also has increased his focus on cancer and its causes (see sidebar), specifically, Human T-Lymphotropic Virus (HTLV)—a retrovirus Gallo first identified and the only known virus which causes human leukemia. Joining



Dr. David Pauza (right) oversees research in his lab.

him in this study and joining the Institute this year is Yutaka Tagaya, who first studied HTLV in graduate school and has since become an expert in signaling molecules—cytokines—important for immunology and T-cell leukemia.

For the past 15 years, ten of which he was in charge of his own group at the National Cancer Institute, Tagaya has been one of the frontrunners of the research of the cytokine interleukin-15 (IL-15), a critical growth factor for the immune system's Natural Killer and CD8 T cells, both of which participate in engaging invading pathogens. Having generated a transgenic mouse that overexpresses IL-15 and develops T-cell leukemia, Tagaya hopes to continue his study in the context of T-cell exhaustion, which, he says, "May explain why some viral infections are chronic," and he plans to collaborate with the IHV groups led by Maria Salvato and David Pauza to understand the signaling pathways and so attempt to revitalize T cells in engaging HIV. Of the overlap with Gallo's work on HTLV, Tagaya says "Although Adult T-cell Leukemia (ALT) is a CD4-type T-cell leukemia and my [transgenic] mice develop CD8-type leukemia, I expect there are common elements of transformation between them: I plan to compare my leukemic T cells with human ATL cell (Adult T-cell Leukemia, i.e. the leukemia caused by HTLV-1) lines to find this overlap."

Also joining the Institute this year is Eric Sundberg, a structural biologist formerly at the Boston Biomedical Research Institute. Says Gallo, "The structure that

is important to our vaccine division is the structure of antibodies, particularly antibodies capable of directing ADCC—antibody-dependent cellular toxicity. Eric is studying the structure of antibodies that have ADCC activity, which works not just against cancer, but ADCC's more common use is against virus-infected cells, and—as IHV's Roberta Kamin-Lewis recently discovered—against virions just as they begin to attach to cells."

"There are obvious interactions," Sundberg says, "between our group and many other groups here. For example, say, with Lai-Xi Wang's group—we're interested in some of the same questions about glycosylation—but we're also interested in combining our forces and asking questions that neither of us could ask alone."

That spirit of collaboration within IHV also extends globally, with 100 participants attending the Global Virus Network's (GVN) inaugural meeting this year. Established to fill the critical need for scientist-driven global health efforts, the GVN promotes medical virology research, international collaborations, rational response to viral threats, training for young medical virologists, and advice on viral disease control. Playing a principal role in GVN, says Gallo, is IHV's Maria Salvato: "Maria is my right and left arm in this because of her great breadth in virology. She's truly, I believe, the only broad virologist in the Institute."

"In the vaccine business," says Salvato, who in addition to her GVN duties continues to work on vaccines, including one for Lassa Fever, "which is now trying to optimize immune responses to DNA vaccines, you can tell by the blood changes whether the vaccine is working. And that's not just with the old, classical way. You can look at all the gene expression changes—the eight-thousand genes that usually go up or down in gene expression—when you alter the blood. And it's not just gene expression for genes that encode proteins now, but genes that are encoding control-RNAs, and that's pretty exciting, too."

In the end, it's that native excitement of IHV's researchers to reach a deeper understanding of the properties of chronic viral diseases that will help the broader scientific community develop preventative medicines and vaccinations. Gallo says there may be multiple treatments to many of these diseases. For important progress against HIV/AIDS this year, the FLSC vaccine candidate supported by \$23.4 million and an active research consortium is seen by Gallo as an important way forward.

Clinical Care and Research

“This year the Division continued to grow—from Zambia to our clinics in Baltimore—our faculty and staff now collectively treat close to one half a million people living with HIV”

Dr. Robert R. Redfield



Dr. Robert Redfield

Many exciting things are happening in the Division of Clinical Care and Research in the Institute of Human Virology (IHV) at the University of Maryland School of Medicine. The Division operates a domestic clinical care program which serves more than 5,000 people, as well as domestic and international research and education programs, connecting patients to care, researchers to training, resources to those who need them, and bringing countries together in collaborative caring for those with viral and infectious diseases.

Global Capacity Building

The Division of Clinical Care and Research is active in establishing strategic alliances with key in-country institutions and is focused on strengthening educational and research capacity globally. The division’s first successful program in post graduate medical educational capacity was established in Zambia four years ago, through a grant from the Zambian Ministry of Health and the University of Zambia, when IHV began a residency training program for Zambian doctors to improve their capacity to conduct care and treatment.

Devang Patel, M.D., assistant professor in the Division, states, “our approach was to provide mentored clinical training, similar to the United States model of residency training.”

This year, the Zambia program received a grant enabling it to be upgraded to a full Masters in Medicine, a 18 month program (increased from its previous, one year length) that will significantly improve the doctor’s knowledge and training, as well as their future job placement. The Zambia program has been highly successful and has garnered the attention of health advocates in Haiti who championed the initiation of a similar program for the island nation. Currently, six Haitian physicians have been identified and trained to become faculty in our partnership with the University of Notre Dame d’Haiti, located in Port au Prince. In the winter of 2011, the inaugural class was initially trained in Baltimore because their



JACQUES Initiative volunteers educate and test Baltimoreans for HIV and AIDS

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Dr. Devang Patel
(photo credit: Antonio Paterniti)

own hospital was destroyed in the 2010 earthquake. Since that time, IHV faculty have been on-site in Haiti to mentor the physicians in their final stage of faculty development, with the Haitian education program on target to enroll its first class in January 2012.

In September 2010, the Division of Clinical Care and Research was awarded two grants under the NIH funded Medical Education Partnership Initiative (MEPI). Eleven, five-year medical education-focused programmatic grants of up to \$2 million per year, and eight grants supported by the U.S. National Institutes of Health were awarded. These prestigious grants, made directly to IHV's African partner institutions, University of Nairobi and University of Zambia, will further international education and in-country workforce development opportunities.

Furthering Research

Meanwhile, important work is done every day in the domestic clinics operated by the Division of Clinical Care and Research in Baltimore. While serving more than 5,000 patients with HIV/AIDS, in addition to providing important care and treatment, the clinics are a place of advanced research and discovery. For example, this year researcher David Riedel, M.D., identified

a large number of HIV-infected patients with cancers through the clinics. This patient cohort will soon be part of a dedicated clinic to better manage the individual's care and treatment. "My work is focused on understanding the immunological background that affects the risk of cancer development, and exploring ways to augment the immune system in its fight against cancer," says Dr. Riedel, whose work is made possible by the Paul Calabresi Scholar Training Program of the Greenebaum Cancer Center. "We hope to advance the clinical care of HIV patients with cancer, to the point where their outcomes are no different from HIV negative patients with cancer."

Additionally, the Division of Clinical Care and Research has been involved with HIV/AIDS clinical trials for the past 12 years. "Our clinical care and clinical research faculty bring a long and experienced history of involvement in both basic sciences and clinical research," explains Charles Davis, M.D., the clinical research unit associate director at the IHV. "Some members of our group have over twenty five years of experience in clinical research, and have been pioneers in the evaluation and modifications of therapeutics to treat HIV."



Dr. Charles Davis
(photo credit: Antonio Paterniti)



A volunteer helps with HIV testing organized by the JACQUES Initiative.

As part of its ongoing work, the Division of Clinical Care and Research is an active participant in the Adult AIDS Clinical Trials Group (AACTG), a network of international experts in HIV/AIDS and co-morbidities, funded by the Department of Health and Human Services, National Institutes of Health through the National Institute of Allergy and Infectious Diseases. IHV has participated in numerous clinical trials and its clinics in Maryland play a key role in extrapolating challenges affecting the AACTG. Moving forward, the Division of Clinical Care and Research is positioned to assist the AACTG as it addresses preventative and therapeutic vaccines, end-organ disease and inflammation, and "HIV cure," focusing on viral eradication and HIV reservoirs.



JACQUES Initiative's Project SHALEM.

Clinical Programs Make a Difference

IHV has seen significant growth in its capacity to provide primary and specialty care for people with chronic viral diseases, particularly HIV and hepatitis, in the Baltimore-Washington community. Stephanie Pons, director of social work and case management, describes the evolution of IHV's domestic clinical work:

I started here 20 years ago in the hospital in the outpatient HIV clinic. It was a very small clinic and we had 200 patients who we saw in a trailer on a parking lot. Now we have five clinics as part of the IHV network. I primarily work at the Evelyn Jordan Center where we see 2,000 patients. We also have a clinic at Maryland General Hospital, two clinics at the VA hospital, and the JACQUES Initiative Clinic,

which also conducts community-based outreach.

Our patients receive outstanding HIV primary care services, which is usually the main reason someone comes for an appointment. However, because of the nature of the disease and the population that it tends to impact, the psycho-social needs of our patients are extremely challenging. People are dealing with substance abuse and homelessness, just to name a few. Over the years we've identified needs and added funding for services like housing assistance, support groups, drug abuse and mental illness services, we help people apply for social security, and we have legal services. We use the term "one-stop shop."

When people come in, we're not just treating them medically.

I'm now exploring the issue of intimate partner violence and we're getting ready to implement a new initiative in which we'll partner with an organization in South Africa that has a similar program which addresses partner violence in the HIV-positive population. We are also working now to help transition young people who were born HIV-positive and have lived to adulthood from pediatric AIDS clinics to the IHV's adult clinic environment.

Our model of care in the HIV clinic world is unique in that people come in regularly. Someone who may be quietly suffering or experiencing emotional or physical abuse is assigned to a dedicated team; over time, you have an opportunity to gain someone's trust and to provide that person the needed linkage to services.

Twenty years ago we helped people prepare to die; now, we help those same people re-enter the workforce and improve the quality of their lives. The whole course of the disease has changed so drastically that the focus of our work has also changed. We provide an intensive, caring network.



Stephanie Pons, director of social work and case management. (photo credit: Antonio Paterniti)

“The Division of Epidemiology and Prevention continues to tackle global health challenges from West Africa to West Baltimore through research on cancers affecting the underserved.”

Dr. William A. Blattner



Epidemiology and Prevention

The Division of Epidemiology and Prevention in the Institute of Human Virology (IHV) at the University of Maryland School of Medicine continues to implement a complex care, treatment, training and research agenda in HIV and Cancer Epidemiology from West Africa to West Baltimore. The division is actively engaged in four areas of research: Operations and Implementation Research; Clinical and Molecular Epidemiology; Cancer Epidemiology and Pathogenesis; and Vaccine Research, and is further developing capacity in international laboratory science, viral oncology, public health, international clinical trials, international Tuberculosis (TB) and HIV research, and epidemiological studies of marginalized, at risk groups.

This complex agenda has resulted in 11 active National Institutes of Health (NIH) and Centers for Disease Control (CDC) grants and subcontracts totaling \$27,365,533 committed this past year to further the division's work. As part of its commitment to an international, cooperative approach to care, treatment and scientific study IHV's African partner organization, IHV-Nigeria (IHVN) received \$8,163,056 in its own direct funds this year, monies from national and international funding sources that are only available to indigenous organizations.

Operations and Implementation Research

Nigeria ranks second in the world for HIV infection. Up to 30 percent of those who are HIV-positive are co-infected with TB. The mortality rate for co-infections is high due to the lack of adequate strategies for screening and diagnosis of TB in a setting where HIV is prevalent. The result: many cases of TB go undetected, perhaps as many as 20 percent. Many patients die before their TB can be diagnosed and treated.

Drs. Mary Ann Etiebet and William Blattner (associate director of the IHV and director of the division of epidemiology and prevention) are working together in Nigeria on Mobile Intensified Case Finding for TB and HIV. This research evaluates the impact of community-based, intensified case finding using mobile clinical units in an effort to determine cost-effective methods of identifying active TB in areas of high HIV infection. The prevalence of undetected TB and HIV among household contacts where an active TB patient is already known will also be studied. At present, 200 TB-positive cases are being followed in 800 households.

The division is also conducting research studying high-risk populations that are drivers of the HIV epidemic: Men having Sex with Men (MSM) and Female commercial Sex Workers (FSW). The prospective cohort study will evaluate an intervention that engages

Nigerian MSM and FSW and links these clients to an intensive combination of prevention interventions and ongoing, comprehensive clinical services delivered at community-trusted venues. This platform could potentially reinforce sustainable behavioral change. In addition, data gathered from different aspects of this study will help guide best practices for scalable service delivery to high-risk populations and future vaccine studies.

Clinical and Molecular Epidemiology

Collaborative research is a vital component of the work of IHV in Baltimore and IHVN. The prevention of mother to child transmission of HIV, for example, is an important scientific pursuit for the Division of Epidemiology and Prevention. In Nigeria, it is estimated that between 63,000 to 125,000 infants acquire HIV each year from their mothers either in-utero, intra-partum, or through breastfeeding. In an effort to control this spread, the Division of Epidemiology and Prevention is engaged in a study that will establish the incidence of HIV infection among pregnant women in Nigeria, characterize the natural history of HIV among pregnant women with acutely acquired HIV infection, measure the risk for mother-to-child transmission among mothers with acute HIV infection in the setting of standard antiretroviral prophylaxis, extend the knowledge of early host-virus interaction in the West African setting, and create a valuable biological repository of collected samples for future studies.

In the last year, the study enrolled 3,450 pregnant women, and enrollment continues to grow. The work is being conducted through a \$2.8 million grant from the National Institute of Allergies and Infectious Diseases (NIAID) under the direction of Dr. Man Charurat, associate professor.

According to Dr. Charurat, "it is important to recognize that despite advances in antiretroviral therapies for prevention, we still need to make an effort in repeat testing of seronegative [having a negative blood test for the disease] mothers in settings where the risk of HIV acquisition is high. More sensitive diagnostics that detect early infections and are easier to use in the field are needed."

Cancer Epidemiology

Researchers know there is a correlation between HIV infection and the prevalence of cancer incidence. However, studies continue to better understand this connection. Under the leadership of Dr. Clement Adebamowo, IHVN provides training and capacity building in clinical trials, epidemiology, and research ethics that will improve the ability of researchers in Nigeria to collaborate with University of Maryland faculty on AIDS-associated cancer research and in NIH-sponsored clinical trials.

The division is taking this work further with the creation of a program in cancer epidemiology in conjunction with the University of Maryland Greenebaum Cancer Center. The program will research HIV/AIDS-related cancers as well as cancers of disparity that disproportionately affect populations in West Baltimore and West Africa.

“We have high hopes for this research,” says Dr. Adebamowo. “We already have \$1.5 million in NIH funding for capacity development in AIDS-associated cancer research, which complements existing funding.”



IHVN & National Hospital, Abuja staff launch the cold coagulation procedure for cervical cancer screening

By connecting with the Greenebaum Cancer Center in its pursuit of understanding AIDS-associated cancers, faculty from Nigeria will undergo clinical observership and training in the conduct of clinical trials and, ultimately, extend the research opportunities in AIDS-associated malignancies in Nigeria.

Pathogenesis and Vaccine Research

Much of the IHV's efforts related to advancing the pathogenesis and vaccine research agenda for HIV/AIDS involves work from Drs. Blattner and Alash'le Abimiku. At present, the division is an effective implementer of HIV services in Nigeria, particularly through its PEPFAR program, which currently has 75,000 patients enrolled in treatment and approximately 120,000 in care. The Division of Epidemiology and Prevention is studying the effect of HIV on the central nervous system.

“HIV attacks the brain and causes impairment of brain function,” explains William Blattner, MD. “That brain function may affect adherence to therapy as well as have lifelong consequences for the person infected.”

This research involves partners from the University of Maryland Department of Neurology (Dr. Walter Royal) and the Division of Basic Science and Vaccine Development (Dr. Suzanne Gartner) working in partnership with scientists at the neuro-AIDS Center at University of California-San Diego, to develop a prospective cohort of untreated patients. The study will examine the infection of the brain, how the virus travels to the brain and whether it is possible to reverse the impact of HIV on brain function over time through treatment. NeuroAIDS has direct implementation impact as it affects patients' adherence to antiretroviral treatment. Currently, Dr. Alash'le Abimiku, Associate Professor in the Division, is partnered with Dr. Gary Garber, a Canadian HIV clinical researcher at University of Ottawa, to implement the creation of an internationally certified HIV clinical research site in Nigeria. The Nigerian Canadian Collaboration on AIDS Vaccine (NICCAV) is a four-year grant award totaling \$1.3 million.

Today, the grant is approaching the end of its first year. Under its auspices, meetings have taken place with the Nigerian government and other stakeholders, training is underway of Nigerian staff to support the study, and protocols have been developed and approved for the conduct of the study. Enrollment of volunteers into the study has commenced.

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Fogarty Fellows Train Tomorrow's Researchers

The Division of Epidemiology and Prevention continues to be a place of rigorous training and mentoring for Fogarty International Clinical Research Fellows. The program offers one-year mentored clinical research training experience to post-doctoral candidates who come from the U.S. and low- and middle-income countries (as defined by The World Bank). In the last year, the Division of Epidemiology and Prevention matriculated three PhD Fellows. Here, Fogarty Fellow Chuka Anude describes his experience in the Fogarty program at IHV:

From 2008 to 2011, I was fortunate to be awarded the Fogarty Fellowship, first as a Fellow and then a Post-Doctoral Fellow under the mentorship of Dr. William Blattner. For me, this was a dream come true as I have admired and respected Dr. Blattner and his unique contributions to HIV epidemiology and prevention and his ground-breaking work in Nigeria. Working directly with him and the world-class team at the IHV gave me a unique mentorship experience and opportunity for career development and research I could not have gotten anywhere else.

As a Fogarty fellow, Dr. Blattner and his team helped me to hone my research skills, develop a cohort of 2,600 adults, and lead an original research



Dr. William Blattner lectures health care professionals via video conference on Clinical Trials.



Dr. William Blattner

study looking at HIV treatment outcomes that I successfully defended for my PhD in epidemiology in May 2011. My time as a Fogarty Fellow is filled with memories of academic rigor, research accomplishments and a fruitful, collaborative relationship with the IHV team and with Dr. Blattner in particular.

I was able to complete my entire PhD program in under four years, in part because of the guidance I received from Dr. Blattner. In addition, I've developed a desire to mentor junior colleagues and give back some of what I received from Dr. Blattner and his team. In the future, I want to be a world class physician-scientist with expertise in HIV, HIV-TB co-infections and translational research in Africa, particularly Nigeria. I plan to work in Nigeria and lead national and regional efforts to improve the quality of research, train more scientists, build world-class research programs and facilities and help stem the tide of the HIV and TB epidemics. I want to impact lives by leading innovations in research and programs that meet the local needs of people and at the same time build bridges and collaborations across the countries of Africa and the West, particularly the United States.



IHVN Lab scientists at the PEPFAR lab, Asokoro District Hospital, Abuja.

Dr. Abimiku, a native of Nigeria who did her postdoctoral training in Dr. Gallo's laboratory at NIH, is passionate about a vaccine and the importance of global partnership. "I believe that an effective HIV vaccine is critical for ending the epidemic in Nigeria and the rest of the world," she explains.

"I have particularly enjoyed great support and mentorship from Dr. Gallo and Dr. Blattner and the Institute, which has led to great collaboration and cooperation between our two countries."

In addition to its work in vaccine development, IHVN has been selected as a site for the international trial known as START (Strategic Timing of AntiRetroviral Treatment), sponsored by the University of Minnesota and coordinated by the NIH-funded INSIGHT Trials Network. This global study examines the impact that early intervention with antiretroviral therapy has on reducing the occurrence of HIV morbidity and mortality. Patients will be accrued through IHVN-supported, comprehensive HIV/AIDS clinics at the National Hospital in Abuja and the University of Abuja Teaching Hospital.

Marlene and Stewart Greenebaum Lecture Series



Since 2004, Marlene and Stewart Greenebaum have sponsored an annual lecture series hosted by the Institute of Human Virology at the University of Maryland School of Medicine. Speakers are persons who have made substantial scientific contributions and focus on bettering the human condition. Each year, IHV faculty invite leaders in the field of human disease to present this prestigious lecture before IHV and campus leaders, students, faculty and staff. In FY11, IHV nominated Reinhard Kurth, MD—Emeritus Professor and Former Director, Robert Koch Institute, Berlin; Former Director, Paul Ehrlich Institute, Frankfurt; and, Co-founder, Global Virus Network—to present *“The Viruses in All of Us: Functions of Human Endogenous Retroviruses.”*

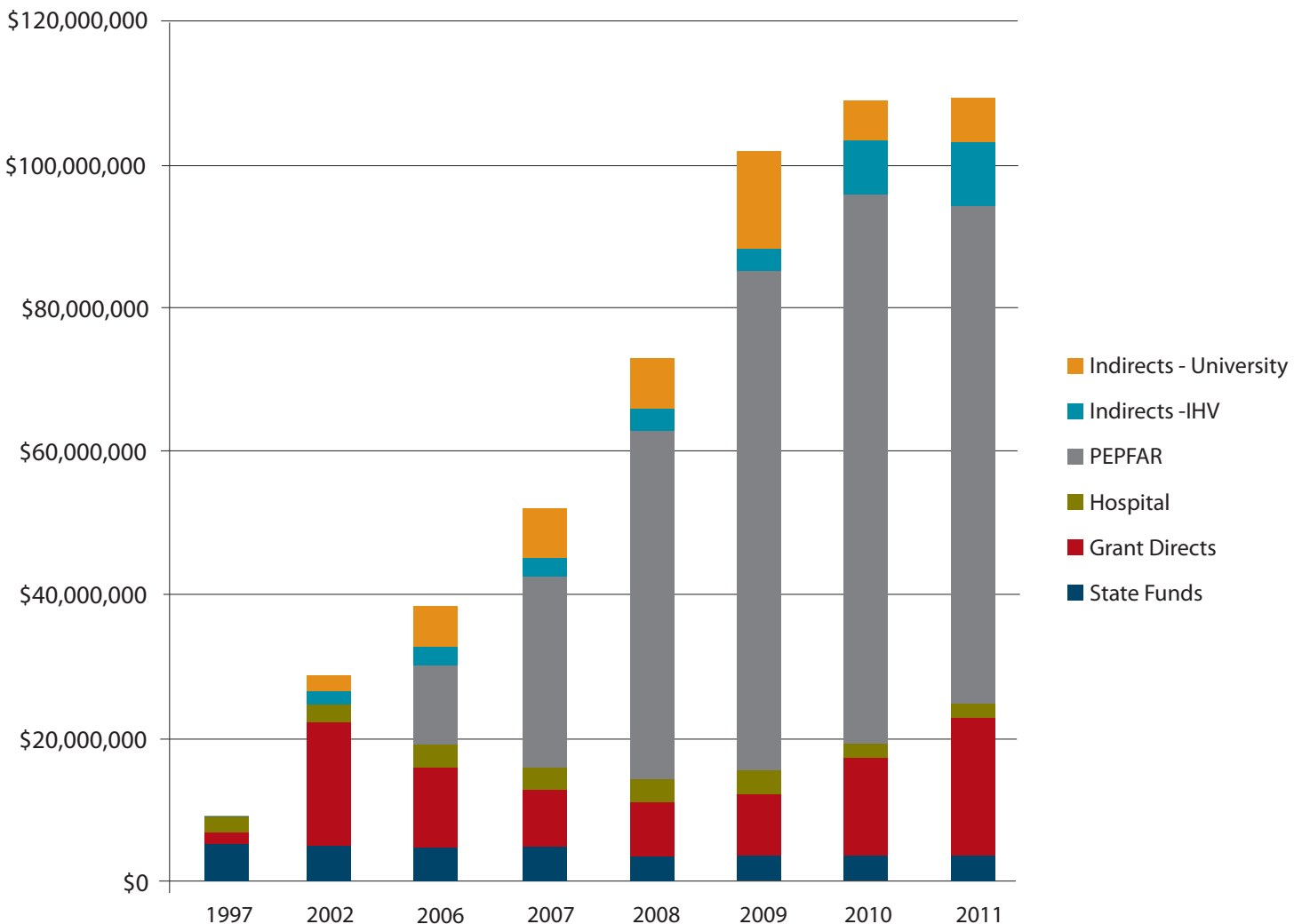


University of Maryland School of Medicine Dean E. Albert Reece and Drs. Kurth and Gallo.

Financials and Related Charts

Budgeted Revenues: Distribution by Funding Source

In 2011, IHV achieved solid growth in its primary mission areas of basic science and vaccine development research, most notably from Bill & Melinda Gates Foundation and National Institutes of Health (NIH) grant pursuit efforts. At the same time, we began to see the effects of the long expected transition of the President's Emergency Plan for AIDS Relief (PEPFAR) funding from U.S. based Universities to indigenous organizations. In aggregate, this left IHV's overall revenue generation for FY11 at nearly the same level as FY10. In the next several years, we can expect to see that while some international programs will be maintained directly through the Institute, others will have been transitioned to in-country organizations (this transition decision is driven by U.S. government policy). The net effect will be a decrease in IHV's overall revenue. However, since the indirect funds generated are realized on a one year lag, IHV won't see a negative effect on discretionary funding for some time.



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