

Discovery

The Newsletter of
the Institute of
Human Virology

FROM LABORATORY TO CLINIC

Headlines and Happenings from Nigeria



Dr. Gallo officially inaugurated IHV's 60-person Nigerian satellite office and participated as the Nigerian government launched IHV's Asokoro Laboratory Training Center. Dr. Gallo and IHV staff were hosted to a state dinner by Plateau State Governor Joshua Dariye; spoke to Nigerian scientists at the Plateau State Virological Research Centre, which is named in honor of Dr. Gallo; and visited the Faith Alive Hospital, which is supported by IHV.

ROBERT C. GALLO, M.D.
Director of
the Institute



Since January of 2005, the IHV's sister institute, IHV-Nigeria, in Abuja, Nigeria, has been carrying out its mission: enhancing Nigeria's capacity to meet the care and treatment needs of millions of HIV/AIDS victims, and promoting HIV research and training.

Spearheading this project is William Blattner, Associate Director of the IHV, head of the Epidemiology and Prevention Division, and principal investigator (PI). Nigerian-born IHV virologist, Alash'le Abimiku, is co-PI. "Our major goal," says Blattner, "is to promote the capacity of IHV-Nigeria to respond, in a frontline way, to the greatest public health crisis in the history of man-

kind—the HIV epidemic."

Crucial to this mission is the establishment of an infrastructure that enables and facilitates HIV care and treatment. Currently, there are seven sites across Nigeria that, under the auspices of ACTION/PEPFAR, have been upgraded to provide clinical and laboratory support. "IHV-Nigeria's most important role has been in providing a high level of technical assistance in HIV/AIDS diagnosis, treatment and support," says Abimiku.

Kathleen Kennedy Townsend, IHV Board of Advisors Chair, in a week-long visit to Nigeria in December 2005, visited a clinical laboratory, as well as two hospitals. "My most vivid memory is of an HIV-positive father telling me that before he received antiretroviral treatment he couldn't even play ball with his son, and now he can," she stated. "It's one thing to say I'm proud of what the IHV and

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Molecular Detective Joins IHV as Faculty

New IHV faculty member, Jean Carr, Associate Professor and head of the new Molecular Epidemiology Laboratory, enjoys her role as a viral molecular detective. Carr, who determines the genetic makeup of the human immunodeficiency virus, HIV-1, and traces its journey through human populations around the world, is a self-described "gumshoe epidemiologist." "I always loved puzzles and mysteries," she states, "and HIV is full of surprises."

Carr arrives at the IHV after 16 years with the U.S. Military HIV Research Program in Rockville, Maryland. She and her former mentor, Francine McCutchan, worked primarily to determine how HIV was being spread in various countries within Africa, Southeast Asia, and South America, and the extent to which it has genetically altered into new viral forms over time.

Genetic analyses have helped classify HIV-1 into three broad groups, based on their extent of shared genetic similarity. These groups have been further delineated into numerous subtypes. It is at this level of viral identification that related HIV infections, or full-blown epidemics, can be identified within and between human populations, and even tracked across geographical and national boundaries.

"It's not a simple process," says Carr, "because different parts of the world

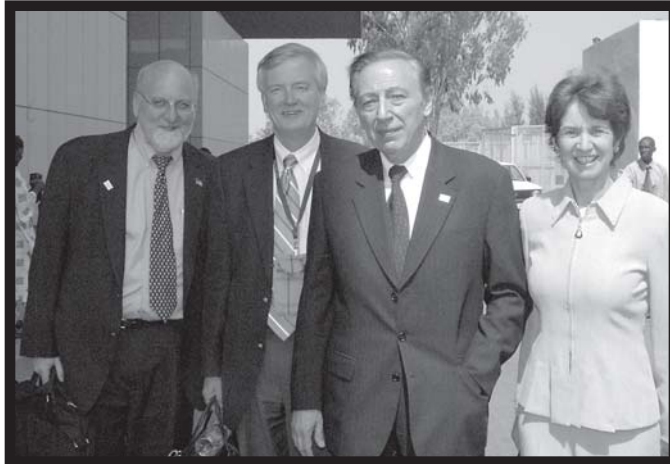
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NIGERIA, December 7-12: Dr. Gallo delivered a keynote address at the 14th International Conference on AIDS and Sexually Transmitted Infections in Africa. Along with IHV Board of Advisors Chair Kathleen Kennedy Townsend and IHV Associate Directors William A. Blattner and Robert R. Redfield, he also met with Nigeria's Minister of Health and successfully lobbied the minister to begin providing anti-retroviral medications at no cost to HIV-positive Nigerians.

Nigeria are accomplishing, but another to see it close up. The people at the IHV are doing a fantastic job, helping individual patients and helping raise the bar of high professionalism in the health care field across Nigeria.”

At Townsend's meetings with the Nigerian Minister of Health and physicians at sites she visited, all parties realized they must work “to make it less onerous for HIV patients to receive therapy,” she summarized. Often an HIV diagnosis leads to loss of family and social support as well as becoming ostracized. “Her visit has immediate benefits for Nigeria,” says Abimiku, “particularly because the

stigmatization has already claimed many lives. It is very important for the Minister of Health to hear a seasoned politician's thoughts on the program and the support from the IHV.”

In addition to HIV care and treatment, another IHV program designed to train Nigerian physicians to perform high quality, ethical, clinical research in compliance with federal and international stan-

dards, got underway in January 2006.

The training program was conceived by Blattner, who realized the need to establish a future Nigerian Institutional Review Board (IRB), a committee that provides review and oversight of research studies involving human subjects. “The ultimate purpose,” says Blattner, “is to enable testing of experimental vaccines and therapies, to target a worldwide epidemic.” In Abimiku's eyes, it also “ensures that best (clinical) practices are sustainable by Nigerians.”

Sponsored by the IHV Fogarty AIDS International Research Training Program, and evolving as a cooperative

effort between the IHV and the School of Medicine at University of Maryland, Baltimore, two concurrent courses were offered: Introduction to Research Coordination, and Clinical Research: Ethics, Regulations, and Oversight. Attendees were primarily physicians from across Ni-

geria, solicited for their potential future roles in critical clinical research or as IRB or National Ethics Committee members.

Susan Buskirk, Executive Director of the Human Research Protections Program, and Sue Hines, Director of Clinical Research Operations at the Center for Clinical Trials, both from the School of Medicine, were the primary course organizers and teachers. School of Medicine Professor and Ethicist, Henry Silverman, and Clement Adebamowo, a Nigerian Ethicist, were catalysts and advocates for their efforts, and three staff members provided on-site support.

“A huge amount of information was packed into five days,” says Buskirk, who taught the Ethics course, “and we altered the program dramatically, to fit the evolving needs we saw.” Buskirk was struck most by the “hunger for knowledge, and the openness to learning” of the attendees, as well as the incredible phenomenon she witnessed, namely, “the dynamic, real-time feedback between the attendees, the Nigerian National Ethics Committee, and Clement. You could literally see ideas forming.”

For Hines, teaching Research Coordination, the experience was “very interactive, comprehensive, and intensive” and she, too, perceived the “attendees were

IHV-Nigeria is funded by the U.S. Center for Disease Control (CDC) and USAID, as part of a \$15 billion U.S. initiative to turn the tide of HIV in 15 target countries around the world, known as the President's Emergency Plan for AIDS Relief (PEPFAR). The specific care and treatment mandates of PEPFAR are implemented through IHV's Project ACTION (AIDS Care and Treatment in Nigeria).

eager to learn, felt privileged to be chosen for a new initiative, and were anxious to contribute to new clinical knowledge.” As for herself, Hines said she felt “humbled and amazed by what the IHV is accomplishing” and was excited to feel “part of a global solution for HIV.”

For Blattner, the fruits of the Clinical Research and Ethics Courses make him confident that they can soon “take the ethics to the next level, and implement more complex interventions, such as vaccines and treatments, within an experimental study.”

Discovery is a quarterly newsletter of the Institute of Human Virology. Copies are available upon request. Please send comments to:

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IHV Brainchild Company, Profectus Biosciences, Hits its Stride Running

In little over one year since its official inception, the IHV spin-off company, Profectus BioSciences, Inc. has made great strides from infancy toward childhood. A private company whose name implies “to advance or improve,” Profectus was founded by IHV Director Robert Gallo, Associate Director and head of the Epidemiology and Prevention Division, William Blattner, and Robert Redfield, head of the Clinical Division. True to the spirit of the IHV, Profectus is geared primarily toward rapid advancement of vaccines and therapeutics for prevention and treatment of HIV/AIDS.

In the short term, Profectus has a three-pronged approach. First, compounds known as cell cycle agents are being further tested for their ability to reverse the loss of effective antiretroviral drugs stemming from HIV drug resistance and/or dose-related toxicity. Secondly, antibody-based viral entry inhibitors, which block infection of host cells, are being developed for preventive and therapeutic uses, either alone or with cell cycle agents. The third approach aims to prevent and treat HIV infection via a novel vaccine, already demonstrated in monkeys to have advantages over existing vaccine candidates.

Profectus Chief Executive Officer Joseph Berardino, former CEO of Andersen Worldwide, a global accounting and consulting firm, brings vast expertise in corporate governance, financial reporting, and negotiation and management of corporate partnerships. “My role is to assemble a strong management team, provide a disciplined business approach, and pull together incredibly valuable science, talented people, and investment money,” he says, “so we can form partnerships and help ‘finish the job’ with HIV.”

Jeff Meshulam, former IHV Director of Corporate Development, now Chief Operations Officer of Profectus, believes the company’s greatest assets “derive from our strong intellectual property portfolio, ties to the IHV, serious commitment to the business of science, and ability

to quickly develop partnerships.” These traits are coupled with an ingenious “pull-push” strategy for product development and commercialization, wherein Profectus can ‘pull in’ early stage, clinical and pre-clinical research, improve and refine it, and then offer it (‘push it out’) to, or partner with, larger companies for final development and marketing.

Profectus has already obtained intellectual licenses for three HIV/AIDS technologies from the IHV, University of Maryland Biotechnology Institute (UMBI), and University of Maryland, Baltimore (UMB); created a development plan for its HIV-1 vaccine; submitted a multi-million dollar National Institutes of Health (NIH) proposal to take the vaccine through phase I clinical trials; brokered a vaccine option arrangement with a major U.S. pharmaceutical company; received over \$350,000 in research funds; and generated over \$325,000 in license fees, patent reimbursement payments, and grants for UMBI.

The fruit of IHV ties, foresight, business acumen, and a focus on HIV/AIDS is being borne out by performance. “I doubt you’ll find any other company who has delivered all that in one year,” Meshulam states proudly. Berardino sums it up best, stating “the potential I see for Profectus to bring some relief to mankind is staggering.”



Front row, left to right, Joe Berardino and Jeff Meshulam. Back row, left to right, Tim Fouts, Ilia Harris, Jennifer Presley, Antony Dimitrov and Kathryn Bobb

HIV/AIDS Molecular Detective Joins IHV as Faculty, *continued from page 1*

have different social and cultural practices, and different risk behaviors, such as commercial sex, multiple partners, and injection drug use," which makes tracking an epidemic a complex matter. In addition, several HIV subtypes can exist in an individual and ultimately recombine to produce new, hybrid subtypes that pass into populations as "circulating recombinant forms" (CRFs).

"Most HIV subtypes likely arose from recombination," Carr feels, "although we didn't see it happening." The rapid ability of HIV to recombine and mutate into new subtypes creates huge variability in its genetic makeup, adding layers of complexity and difficulty both to developing globally-applicable vaccines for prevention and to applying cocktail-like mixtures of therapeutics for treatment.

Currently, Carr is funded by a U.S. Military grant to assess the nature and extent of HIV's spread throughout Latin America, including South America, Central America, Mexico, and the Caribbean. Her primary objective is to generate "maps" of HIV subtypes for each country, before extensive use of antiretroviral therapeutics alters the natural distribution of parent viruses and precludes tracing the path of HIV and the associated risk factors.



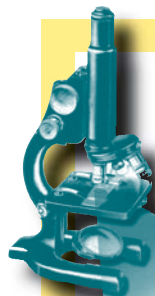
JEAN CARR
HIV Associate Professor

The potential of Carr's work for fighting HIV is two-fold. For the present, "once the risk factors are known, we can promote measures that alter risk behavior and slow or stop progression through the popu-

lation," Carr states. In the future, if a vaccine with a broad (non-subtype specific) potential is developed, Carr's viral maps will provide "groupings of countries or populations that can then be targeted in similar manners by similar vaccines," she says.

Carr intends to explore several avenues of collaborative opportunities at the IHV. "What I truly value here is the intellectual freedom and the openness toward sharing ideas," she comments. "Basically, if I can get funding, I can work on it. That's very refreshing."

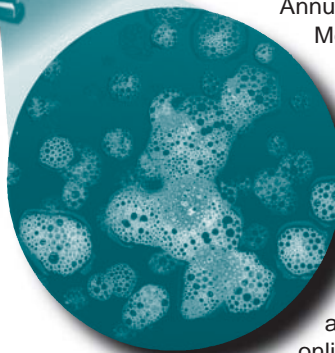
"I always loved puzzles and mysteries and HIV is full of surprises."



2006 Annual Meeting

The 2006 10th Anniversary Annual International Meeting of the Institute of Human Virology will be held Nov. 17 - Nov. 21 in Baltimore, MD.

Check www.ihv.org for more information in upcoming weeks and to register online.



Site features will include:

- Meeting information
- Session titles
- Speaker schedule
- Hotel information with online registration
- Guidelines for submitting abstracts
- Scholarship information
- Reception and banquet details

Important Deadline:

July 15, 2006
Abstract Submissions
Scholarship Submissions





Public Health Expert Joins IHV Board

IHV recently named public health expert Dr. Sue Bailey as its newest board member. A news analyst for NBC since 2001, Dr. Bailey has been at the forefront of challenges faced by the United States including national security, environmental safety and public health issues.

Dr. Bailey, a resident of Bethesda, MD., served from 1998-2000 as assistant secretary of defense for health affairs, where she headed

the \$17 billion military medical system coordinating the care for 8 million beneficiaries. She was responsible for health protection of

American military forces from combat casualties, disease, environmental hazards, and biochemical warfare.

“Dr. Bailey brings a vast wealth of experience and knowledge of health issues, both of which are invaluable assets to the Institute,” says Dr. Gallo.

Dr. Bailey is a board certified physician whose clinical and academic background includes a faculty position at Georgetown University Medical School. She has served on several professional boards, including the Board of Governors for the Armed Forces Institute of Pathology.

Dr. Bailey holds degrees from the University of Maryland and the Philadelphia College of Osteopathic Medicine. She completed her internship and residency at George Washington University and completed a medical post-graduate fellowship at Johns Hopkins University.

Dr. Gallo Ranked Among Top Scientists With Most Impact

Dr. Robert Gallo ranks among the top three international biological scientists according to the University of California’s newly developed h index.

Jorge E. Hirsch, professor of Physics at the University of California at San Diego, developed the h index to quantify an individual’s cumulative career impact and relevance of scientific research. This score is based on the highest number of scientific papers produced and the number of times these papers have been cited.

“The h index may provide a useful yardstick with which to compare, in an unbiased way, different individuals...” Hirsch said in his paper.

Hirsch suggests that for faculty at major research universities an h index of 12 might be a typical value for advancement to tenure

while memberships in the National Academy of Sciences of the United States of America may typically be associated with an h index of 45 or higher. Dr. Gallo’s h index is 154.

Dr. Gallo is the author of more than 1,100 scientific publications and published the book, “Virus Hunting - AIDS, Cancer & the Human Retrovirus: A Story of Scientific Discovery.”

Though best known for his co-discovery of HIV, Gallo and his team in the early 1980s also pioneered the development of the HIV blood test, which enabled health care workers for the first time to screen for the AIDS virus, leading to a more rapid diagnosis while simultaneously protecting patients receiving blood transfusions.

International Training Initiatives

The Institute of Human Virology in March hosted a two-week course to train top physicians from around the world in the Institute’s innovative model of HIV/AIDS research and treatment.

The visiting physicians represented China, Haiti, Nigeria, Tanzania and Uganda and spent time at each of IHV’s clinical sites in Baltimore where they learned about IHV’s unique treatment, education and support programs for people living with HIV/AIDS.

The visiting physicians are leading research experts in their own countries and together the group is responsible for treating tens of thousands of HIV patients.

The Chinese physicians were hand selected by the Chinese Center for Disease Control (CDC), which signed a partnership agreement with IHV in 2005.

Primary funding sources for the program are the Clinton Foundation, founded by former President Bill Clinton and the United States government through the President’s Emergency Plan for AIDS Relief (PEPFAR).

Severo Ochoa Award to Dr. Gallo

Dr. Gallo has been selected by the National Minority Health Month Foundation to receive its 2006 Severo Ochoa Award. Named after the 1959 Nobel Prize winner for medicine, the award recognizes Dr. Gallo’s contributions to the eradication of HIV/AIDS in minority communities. The Foundation has previously awarded Senator Bill Frist, former Health and Human Services Secretary Tommy Thompson and others. The award was presented to Dr. Gallo during a luncheon in Washington, D.C., on April 11th.

THE INSTITUTE OF HUMAN VIROLOGY (IHV) at the University of Maryland was established to create and develop a world-class center of excellence focusing on chronic diseases and virally linked cancers. The IHV is dedicated to discovery, research, treatment, and prevention of these diseases and cancers. Its unique structure seeks to connect cohesive, multidisciplinary 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 to Take Part in Research on GeoVax Product

By Dennis O'Brien, Baltimore Sun Staff

The University of Maryland's Institute of Human Virology is one of four research centers nationwide seeking volunteers to test an experimental HIV vaccine.

"We're accepting volunteers immediately," said Dr. William A. Blattner, director of the institute's Epidemiology and Prevention Division.

The vaccine was developed at Emory University in Atlanta, and is being marketed by GeoVax Inc., an Atlanta biotech company. Clinical trials also are being conducted at St. Louis University, Vanderbilt University and the University of Alabama at Birmingham.

The vaccine, which is designed to prevent HIV infection, will be given to volunteers who are HIV negative in a series of four doses over two months. The first two doses contain fragments of DNA from the virus, which will trigger the immune system. The second two doses contain an altered

pox virus designed to boost the immune system, Blattner said.

Blattner said he anticipates delivery of the first vaccine doses in the next week to 10 days. "Once it's here, we'll be ready to start vaccinating," he said.

If approved for market, the vaccine will target sexually active adults 18 to 45 years old. "One of the important things to remember is that there are 10 people getting infected around the world every minute every day. There's a huge need for this vaccine," Blattner said.

The vaccine was developed at Emory's Yerkes National Primate Research Center, where work began in 1997. In tests on monkeys, it protected 22 of 23 rhesus macaques for more than three years, said Holly Korschun, an Emory spokeswoman.

The product is one of more than 30 preventive AIDS vaccines in the early stages of human clinical trials in two dozen countries, according to the International AIDS Vaccine Initiative, a prevention group.

A prototype vaccine was tested in 2003 and 2004 at other research centers. The testing at Maryland and the other three centers is an step in the FDA approval process, Korschun said.

"It's one of the most promising HIV vaccines being put out there for testing," Blattner said.

Four volunteers are being sought, he said. If initial tests show the vaccine is safe, additional tests involving more volunteers will be conducted.

By next year, Blattner said, the institute will need up to 100 volunteers for HIV vaccine testing.

Those interested in volunteering should call 866-448-4448.

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DISCOVERY would like to thank its corporate sponsor, **sanofi pasteur**, for continued support of the IHV and its mission.



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