INSTITUTE OF HUMAN VIROLOGY

Discovery

Laboratory • Clinic • Community • World • Fall / Winter 2021

$6.5M Grant Awarded to Develop Treatment for Alcoholic Liver Disease-Associated Kidney Dysfunction

University of Maryland School of Medicine's Institute of Human Virology and MitoPower to Initiate Studies

The Institute of Human Virology (IHV) at the University of Maryland School of Medicine (UMSOM) and MitoPower LLC ("MitoPower") were awarded an SBIR (Small Business Innovation Research) grant of up to $6.5 million over five years from the National Institutes of Health's National Institute on Alcohol Abuse and Alcoholism. The funds will support the development of MitoPower's lead compound, MP-04, for the treatment of kidney dysfunction due to alcoholic liver disease, a condition known as alcoholic liver disease-associated hepatorenal syndrome (HRS). The IHV, a Center of Excellence of the Global Virus Network (GVN), will conduct first-in-human single and multiple ascending dose studies to test the safety of the compound, followed by a Phase 1b study in patients.

"There are no current therapeutic options that specifically address the cellular dysfunction and systemic inflammatory response that contribute to the severe impairment of liver and kidney function and progressive organ failure in patients with severe alcoholic hepatitis," said **Mani Subramanian, MD, PhD**, and CEO of MitoPower. "We are working to complete IND-enabling studies for MP-04 and are excited to collaborate with IHV to characterize this promising compound in human studies."

More than 250,000 hospitalizations each year in the U.S. are due to complications of alcoholic liver disease. HRS is an acute complication of cirrhosis (liver scarring) or a severe alcoholic hepatitis (liver inflammation) progressive condition leading to kidney failure. HRS is associated with mortality rates reaching 50%, with many patients requiring invasive treatments such as dialysis and/or liver transplant.

"There is an urgent, unmet need for an effective therapy to treat HRS caused by severe alcoholic hepatitis and cirrhosis. Globally, the incidence and prevalence of alcoholic liver disease continues to increase and remains a significant cause of liver failure and liver transplantation," said Prof. **Shyam Kottilil, MBBS, PhD**, Professor of Medicine and Director of the Division of Clinical Care and Research, Institute of Human Virology at the University of Maryland School of Medicine, and senior advisor to the Global Virus Network (GVN). "MP-04 is a novel therapeutic that has shown promise in preclinical studies to reverse organ dysfunction and systemic inflammatory response syndrome (SIRS) that holds promise in potentially reversing HRS."

Shyam Kottilil, MBBS, PhD

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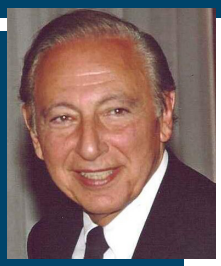

Robert C. Gallo, MD

For this issue's *Director's Message:*

I am sharing a reprint from the *American Journal of Physiology-Lung Cellular and Molecular Physiology*, November 30, 2021, editorial on "Some Reflections on HIV/AIDS Research After 40 Years."

"We will never forget." Words spoken by many commentators referring to the current coronavirus disease 2019 (COVID-19) pandemic. But we will. As I review the prior viral pandemics [influenza, polio, human immunodeficiency virus (HIV), and now, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)—all RNA viruses], much of the public health and preparation lessons from one to another were lost after about a generation and a half from the pandemic ending by both the public and the biomedical scientific community. Indeed, some current commentators have referred to the last pandemic as the great flu of 1918–1919, running past not only polio of the 1950s but also one of the greatest pandemics in history and still ongoing, HIV/acquired immunodeficiency syndrome (AIDS). When HIV/AIDS is mentioned, it has sometimes been to contrast how quicker and better we have been with COVID-19 in finding the cause and determining its genomic sequence (less than 6 mo). Of course, that comparison is absurd for at least three reasons. First

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UNIVERSITY of MARYLAND SCHOOL OF MEDICINE

$6.5M Grant Awarded to Develop Treatment for Alcoholic Liver Disease-Associated Kidney Dysfunction

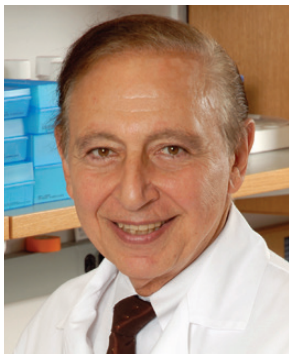
Stephen N. Davis, MBBS, FRCP, FACE, MACP

The Theodore E. Woodward Chair in Medicine **Stephen N. Davis, MBBS, FRCP, FACE, MACP**, said, "We are honored to partner academic research with industry to develop therapies that improve our patients' health and quality of life, especially for chronic diseases for which we have no known treatments."

UMSOM Dean **E. Albert Reece, MD, PhD, MBA**, Executive Vice President for Medical Affairs, UM Baltimore, and the John Z. and Akiko K. Bowers Distinguished Professor, said, "HRS affects many Native American and Alaskan Natives disproportionately, and Black and Mexican Americans are more likely to suffer worse outcomes. Developing an effective treatment will be the first step in finding a way to address these disparities."

E. Albert Reece, MD, PhD, MBA

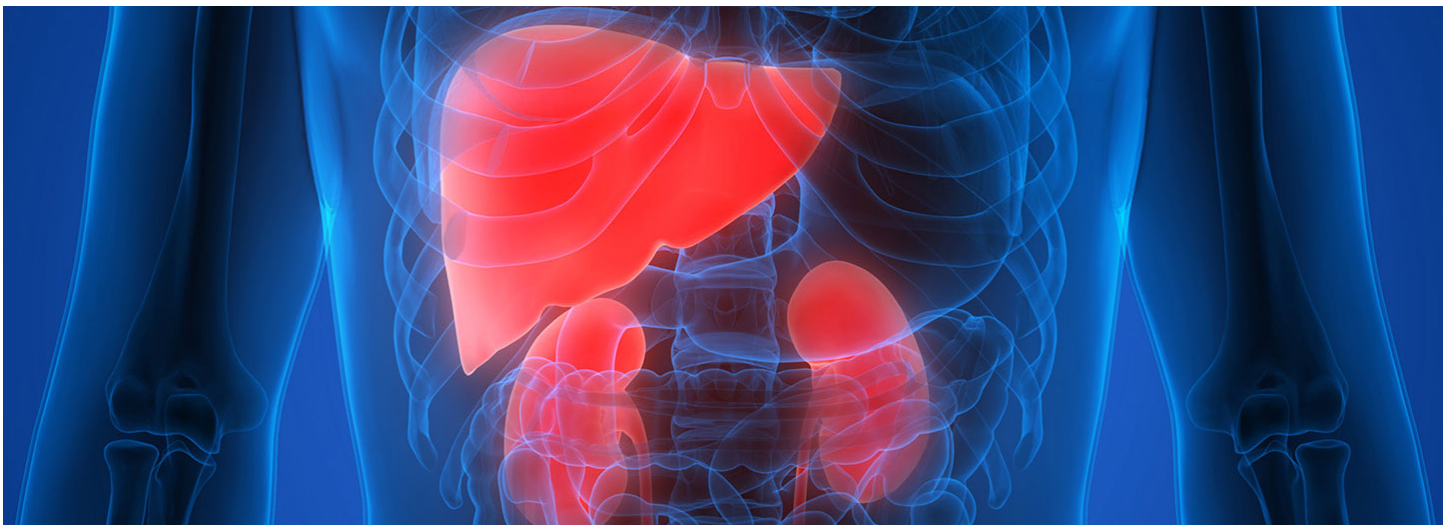
Robert Gallo, MD, the Homer & Martha Gudelsky Distinguished Professor in Medicine, Co-Founder & Director of the Institute of Human Virology at UMSOM, and Co-Founder and International Scientific Director of the Global Virus Network (GVN), said, "The Institute is pleased to see our Clinical Trials Unit's portfolio continue to grow under the terrific leadership of Professor Kottilil. While we continue to focus on therapeutics for viruses such as HIV and SARS-CoV-2, it is also important that we research innovations that can combat devastating chronic illnesses, such as liver disease and kidney dysfunction."



Robert C. Gallo, MD

This award was granted by the National Institutes of Health under Award Number U44 AA029833. The content of this press release is solely the responsibility of the author and does not necessarily represent the official views of the NIH.

More than 250,000 hospitalizations each year in the U.S. are due to complications of alcoholic liver disease.



Robert Gallo, MD at the NCI in 1985

and foremost, AIDS was a very new and mysterious kind of disease. There was no similar precedent, and when a person was able to be clinically recognized as having AIDS, the patient had many infections. Which if any of the recognizable infections was the cause? We learned none were. The causative agent was very far from obvious. In strong contrast, COVID-19 is caused by an acute infection from a highly replicating and obvious coronavirus, easily identified from respiratory secretions like most acute respiratory infections. HIV is a retrovirus. We had only recently discovered human retroviruses, the first, human T-cell leukemia virus-1 (HTLV-1), in 1980 and the second, HTLV-2, in 1982, and the belief that humans were or could be targeted by these viruses was only just beginning to be accepted. AIDS was just being recognized (1981). On the other hand, we were very fortunate to have made these discoveries at this time because they guided our ideas and technology for finding HIV. Second, HIV was far less detectable. Its target cells are much more restricted, and its main target, activated CD4 T-cells, are almost depleted from the peripheral blood, the chief source for study, and often the virus is dormant. In contrast, like acute virus infections in general, SARS-CoV-2 is highly replicating in easy-to-sample sources and has multiple target cells. Third, HIV was 40 years ago. Obviously, the technology has improved by now. The late Jonathan Mann of the Centers for Disease Control and Prevention (CDC) and then the World Health Organization (WHO) in 1986 called the pace of HIV/AIDS research the fastest in medical history, from the inception of this strange new disease in 1981 to the epidemiological risks (1982), finding the virus and showing it to be the cause (1983–1984), development of the very sensitive and specific blood test (1984), the full genomic sequence (1985), and the early development of a proven effective antiviral drug (AZT-1985), which proved to be the first time in medical history a drug was shown to be effective against a serious systemic viral disease.

Looking back at that period and the preceding decades, I recall that in the mid-1960s when I first joined the National Cancer Institute (NCI), there was a healthy respect for the possibility of new epidemics and perhaps pandemics, but roughly a decade later, an overconfidence about such matters had slowly kindled to the point even that some medical schools minimized the teaching of microbiology. Arguments were made to seriously alter funding away from this area and to focus much more on "chronic degenerative diseases." Parenthetically, some such diseases may be caused by an unknown infection. This fostered some of us to form the Global Virus Network, now consisting of 65 centers of excellence in 36 countries. Its goals include training of new virologists, the capacity to advise on any virus type pathogenic to humans or animals, advocacy, and helping solve virus threats. I believe COVID-19 showed we could not fully rely on governments, beginning with the fact that governments have differed in their early policies (which one do we follow) and how do we pursue the essential need for a pandemic to include potentially all governments. The government will always be needed for oversight, guidance, and funding help but not necessarily driving the science and collaborations, which might be improved with a stronger role for private organizations in close association with WHO.

Returning to HIV/AIDS and to the present and immediate future, the main issues facing the field have been, are now, and will be the attempts to obtain virological freedom. This is likely to be unobtainable and certainly not provable, and perhaps with too many committed to doing the same thing. Some of the important advances are developing longer-lasting nontoxic therapies that foster a normal life. This has been happening but, in the United States, has been hindered by another epidemic, that of drug addiction, one that is infectious in another way.

The second issue is our complete failure to develop an effective preventive vaccine. What seems apparent is that we need less control, less huge groups, and more funding for creative new approaches, which will likely come more from independent new investigators.

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Laboratory of Tumor Cell Biology Annual Meeting 1985

Nurse Practitioner Toma Guberski Remembered for Mentoring, Patient Care

Dr. Guberski in the white shirt and lanyard sits with her IHV colleagues

Thomasine "Toma" Guberski, PhD, CRNP, had been associated with the Institute of Human Virology (IHV) since its inception, although she only officially joined about six years ago as a Nurse Practitioner in the Division of Clinical Care and Research. She spent decades of work first on the frontlines during the 80s AIDS crisis. This was followed by work establishing new care centers in regions hard hit by the HIV/AIDS epidemic around the world through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program in partnership with IHV. After a short retirement from her extensive career this summer from both IHV and UM School of Nursing, she passed away unexpectedly in early October.

Nurse Educator

Toma came to Maryland in the early 1970s and underwent a year of nursing education. She was among the first nurse practitioners in Maryland, who at the time were labeled as clinical pariahs "who would destroy health care as we know it." Whether it was due to egos or a control issue, or perhaps even a sexist power struggle, the fact was many nurse practitioners were women and most physicians were men at the time.

Toma joined the University of Maryland School of Nursing (SON) as a nurse educator in the nurse practitioner certificate program, one of the most popular graduate programs in the school. The nurse practitioner program originally produced most of the NPs in the state, as the Johns Hopkins program did not emerge until years later.

When the SON developed the nurse informatics program to help build the computer systems and ensure the clinical data was included in the systems they built. Toma fearlessly joined the technology revolution working with electronics, PDAs, and working with the tech support folks in IT over the years as the machinery evolved and grew more complex.

Dr. Guberski teaching on one of many trips to Kenya

Early Days in the AIDS Epidemic

When she was not teaching, Toma worked in a primary care practice for some years. When the primary care physician that she worked with was planning to move to another practice in the later 1980s, her colleague mentioned to her about a new concerning health condition they were working on. Toma went over to visit and see for herself, which ultimately led to her joining this other clinic. In the early days of HIV, the vast majority of patients were diagnosed when hospitalized with opportunistic infections. They would then be sent to her clinic for follow up care.

"It concerned me that people who were diagnosed with HIV were treated like pariahs and nobody wanted to take care of them," said Toma. "When you could provide care, you could immediately see an improvement in their quality of life. Just providing some compassion and showing you cared about their wellbeing made a tremendous impact on our patients."

When she started in the clinic, the average lifespan of her patients was only 9-11 months. It was unusual to see a patient live longer than a year. She says her and her colleagues went to many funerals and saw a lot of people whose families had abandoned them.

"The mental set of patients was similar to someone getting a diagnosis of metastatic cancer, it was 'this is a disease where I need to start getting my affairs in order because I'm going to die soon," said Toma. "Over time as the treatment has become lifesaving, there has been an evolution of the mindset. Most people now think, 'I have a chronic health problem that I have to manage.' We still get people who see it as a death sentence because they remember when it was."

She said up until recently she was still seeing patients from the late 90s—a couple were not sure if they would live—that held out until the next line of protease inhibitor drugs became available.

Treating the World

With the development of antiretroviral therapies and HIV testing, in first-world countries HIV became another comorbidity like diabetes or high blood pressure. But in developing countries without the resources, HIV remained deadly.

Anthony Amoroso, MD

It was in the late 1990s when **Anthony Amoroso, MD**, Associate Professor of Medicine, Associate Director of the Division of Clinical Care and Research and Head of Clinical Care Programs, Institute of Human Virology, then a fellow, met Toma. She was working in IHV's Evelyn Jordan Clinic then and would support the physicians when they needed help. Dr. Amoroso says she was the first person to drag him on trips internationally to the State Departments at embassies in South Africa and Tunisia to educate government officials on HIV.

"Toma was an interesting character who would speak her mind and l critique you on the spot if she thinks you are not doing something well," said Dr. Amoroso. "She gave very poignant criticism when you needed it in a way that was nurturing. I always looked over to see if she was giving me the headshake or thumbs up as to whether I was getting my message across and whether it was being received."

In the early 2000s, IHV Co-Founder Bob Redfield, MD, and Dr. Amoroso, submitted the proposals for the U.S. PEPFAR grants. These were rolled out by former President George W. Bush, to provide care and treatment globally to combat HIV/AIDS. IHV wrote their grants in collaboration with Catholic Relief Services as they already had the health care infrastructure in place in many African countries. IHV was assigned to Ghana, Haiti, Nigeria, Rwanda, Uganda, Zambia, South Africa, and Botswana.

"When we were choosing who would go, I knew I wanted Toma on my team," said Dr. Amoroso. "She was old school and knew how the clinic worked, how it should flow, and what nurses should and should not do."

There were not enough nurses and physicians to handle the population of people who needed treatment in these African countries, so the IHV group helped establish care clinics and train health care workers to care for their patients. The group would do tours of 4 to 8-week stints in each country and then circle back.

"We had to change the mindset of how to give care to people who were going to live with HIV rather than die of AIDS," said Toma. She would hire nurses in the community, train them, even sending them to Baltimore for education.

"It was one of the most exciting things I've done in my career and we had fun," said Toma. "We were able to do it, because IHV's Clinical Division believes in a team approach to care for people with HIV."

"Toma was in high demand," said Dr. Amoroso. "If Toma was going to be there that day the African nurses would be anxious and excited because she would evaluate their skills. She touched a lot of people, nurses, clinics, and countries."

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Nurse Practitioner Toma Guberski Remembered *(cont.)*

Michael Obiefune, MD, MBBS, Assistant Professor of Family and Community Medicine, Division of Clinical Care & Research, Institute of Human Virology met Toma when he worked at Healthcare for the Homeless. He later worked with Toma as one of the directors of the UM programs in Africa.

MIchael Oblefune, MD, MBBS

"Toma expected nurses to have a professional role rather than be at the beck and call of doctors," said Dr. Obiefune. "She encouraged doctors to be open with nurses and have a team approach to care even in countries that did not see nurses in that light. She uplifted nurses and pushed them to do more education." He says many nurses went on to get their masters or doctorate degrees because of her.

Dr. Obiefune says they traveled to remote villages, some on a boat, some on bad roads, sometimes sleeping in not so comfortable hotels. He said, "She was not worried about this. She just wanted to touch people and help them."

In Upper Uganda, they stayed in a compound, where the children would come into at night to protect themselves from being kidnapped by the Lord's Revolutionary Army. She said she knew they would be fine because the people were protective of them. One day one of the Chief's wives came to get treatment.

Some memorable times, Dr. Obiefune says were encounters with tough to deal with food. "Toma and Dr. Amoroso were always game to taste and eat anything," he said. "It was fun to watch them sweat and try to survive eating spicy food. They were always game."

Over the years as these African clinics became more established, less was required. The pandemic shut down travel to the clinics, but she was still able to do training over video conferencing.

Up through the summer, she was still treating her Baltimore patients.

"Toma's patients loved her," said Dr. Obiefune. "When she was on vacation, they would send their love. She was very direct with no nonsense. She had honest conversations and would make them understand that their treatment journey was a mutual understanding between her and them." He added, "The patients who have stayed with her all these years are going to miss her."

IHV members at Dr. Guberski's memorial

Inroads on Ciheb's Efforts in Malawi

After only 2 years, the Center for International Health, Education, and Biosecurity (Ciheb), founded by the Institute of Human Virology within the University of Maryland, Baltimore's School of Medicine, has made major progress on upgrading the diagnostic laboratory infrastructure in the East African country of Malawi through funds from the United States President's Emergency Plan for AIDS Relief (PEPFAR). The Centers for Disease Control and Prevention (CDC) and Malawi Ministry of Health brought in Ciheb as partners in 2019 to strengthen the quality and capabilities of laboratories in Malawi and to support them in attaining international accreditation standards. The goal of these endeavors includes strengthening the quality of testing for diseases, such as HIV or tuberculosis, in order to improve diagnosis for appropriate care management and treatment.

Only several months into their work, the team encountered a wrench in their plans with the emergence of the COVID-19 pandemic. The team pivoted and trained their laboratory personnel to run tests for SARS-CoV-2, the virus that causes COVID-19. Even in the midst of the pandemic, for the first time in history, the teams already successfully earned international accreditation for four of their laboratories in Malawi.

Alashl'e Abimiku, PhD

"It is the intention of the Institute and the University of Maryland, Baltimore to be in Malawi for an extended period of time," said **Alashl'e Abimiku, PhD**, Professor of Medicine, Director of Laboratory Services at Ciheb, Institute of Human Virology, University of Maryland School of Medicine. "This is just the start of a wonderful partnership. In most of the African countries that we support, the Institute has operated for close to 20 and 30 years because we really believe in a long and meaningful partnership and collaboration."

Dr. Abimiku is the principal investigator for the **AMPLIFY** grant, which stands for Accelerating Malawi's PEPFAR Laboratory Logistics and Infrastructure for Quality, that provides technical assistance to Malawi to increase access to quality laboratory services.

COVID-19 Testing

When COVID-19 arrived in Africa, the CDC supported the team with additional funding to develop COVID-19 testing in Malawi and Mozambique in support of the governments of both countries.

Laboratory technicians in one of the Ciheb-supported laboratories in Malawi

In Malawi, the team converted 11 diagnostic laboratories into COVID-19 testing centers. As part of activating each laboratory, they sent biomedical engineers to inspect and service biosafety cabinets, developed training materials for lab technicians to run the COVID-19 tests accurately, and supplied each lab with needed protective gear.

Fortunately, the real-time polymerase chain reaction (PCR) platform to test for HIV is the same for COVID-19. The team successfully trained 66 lab technicians to conduct COVID-19 PCR testing. The automated machines in each lab completed a range of 400-800 tests per day.

"We got our PCR process for HIV up and running in the nick of time. When COVID hit, the government engaged those laboratories including ours already doing viral PCR to handle the COVID testing," said Dr. Abimiku. "For a while COVID testing became a significant focus of the work we did. At some stage, we were behind on HIV samples because there was so much demand. There is still a bit of a backlog, but we are doing much better now."

Last year, a limiting factor in expanding COVID-19 testing was the supply of test kits, which were difficult to obtain everywhere, but much more so on the African continent. Now, the African CDC has ensured that African countries have access to test kits and vaccines, and have been successful in getting private companies and laboratories to pitch in.

As labs are located in different regions of the country, the biological samples must be delivered to them by courier. The team partnered with Riders for Health International—a nonprofit organization that provides healthcare-related transportation services for rural African populations—to supply 80 motorbikes to deliver the samples. The Riders ensure that sample collection and transportation is done

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Inroads on Ciheb's Efforts in Malawi *(cont.)*

A member of the Riders for Health International, a group that provides healthcare-related transportation services for rural Africa

safely and efficiently. This national sample transportation system runs in all 28 districts covering 662 health facilities.

To further improve the turnaround time from collection to testing, computer software engineers at Ciheb developed an open system app for the system that works on a tablet or smartphone, known as Sample Tracking and Results Transmission (STaRT). The app effectively tracks, monitors, and reports events such as pickup and delivery of biological samples. Now, the team is piloting barcode scanners and GPS tracking to further improve the monitoring capabilities.

"The progress that we have made in Malawi in improving diagnostics will help as we roll out the same support in Mozambique and other African countries we operate in," said Dr. Abimiku. "For example, we are translating the training materials and other guidance we have developed for Malawi from English into Portuguese, which is Mozambique's national language."

Ciheb has a similar grant for efforts in Mozambique, named the Laboratory Systems Enhancement for AIDS Pandemic Control (LAPSEC), also funded by the CDC to help the Mozambique government improve its medical diagnostic testing for HIV and tuberculosis.

Getting Accreditation

Dr. Abimiku estimates that it takes about 2-4 years to get a diagnostic laboratory accredited, when not in the middle of a global pandemic. Most diagnostics labs, like LabCorp in the U.S., are required to have accreditation to operate.

"It's a process. You have to address everything from wall signs, safety procedures, customer service, documentation, standard operating procedures, test reliability, and prompt return of quality test results," said Dr. Abimiku.

In spring of 2021, her team was able to get medical laboratory accreditation, known as ISO 15189:2012, for four of the laboratories supported by Ciheb in Malawi. Accreditation was given by the Southern African Development Community Accreditation Service (SADCAS), marking the first time these international standards have been achieved in Malawi. This was followed by an awards ceremony with Ciheb, where the Malawi's health minister, Honourable Khumbize Kandodo Chiponda, MP, and the US ambassador to Malawi, Ambassador Robert Scott, led the celebration of the accreditation of a total of six laboratories in Malawi held in Lilongwe, along with other partners.

"Although this last year and a half has been challenging, there was another beneficial event: In the past, each lab is usually dedicated to testing one pathogen, but we broke down the silos with COVID-19 showing that a lab can test a whole range of pathogens from TB, HIV, Lassa fever to COVID-19 using a single platform based on edge cutting molecular technology," said Dr. Abimiku. She says this will be essential infrastructure that can help to manage any future outbreaks in the region.

At the awards ceremony to celebrate the ISO 15189:2012 medical laboratory accreditation of six facilities in Malawi, four of them supported by Ciheb

Fine-Tuning Natural Antibodies against HIV to Develop New Therapies

One of the reasons that developing an HIV vaccine has been so difficult is that the body typically does not make potent enough antibodies able to prevent infection over an extended time period. Some of these HIV antibodies are called neutralizing antibodies with the ability to disable the virus leaving it no longer infectious to the body. Researchers found that over decades of having the virus in their system some people not on antiretroviral medications develop very potent neutralizing antibodies against HIV.

Mohammad Sajadi, MD, Professor of Medicine, Division of Clinical Care and Research, Institute of Human Virology, University of Maryland School of Medicine, has been studying these HIV neutralizing antibodies for more than a decade. His team and colleagues have isolated HIV antibodies from patient's blood samples from Baltimore that seem promising for developing therapies. He says these antibodies could either guide vaccine design or be used by themselves as a preventative or therapy to inactivate circulating HIV virus.

Mohammad Sajadi, MD

As there are dozens of pills and pharmaceutical treatments that work for treatment and prevention, why pursue more treatments or preventatives?

"The problem lies in that once people who have HIV stop taking their meds then the HIV replicates again, so medications can't cure the disease," said Dr. Sajadi. "There's a lot of data showing that people can have long-term complications from the virus and the meds, even if the virus is suppressed. Ultimately, we want to find a way to cure our patients. It's possible that these antibodies could be used in conjunction with many other approaches being tested to one day reach a real cure once and for all."

As for prevention, two medications are already FDA-approved as a one or two pill a day regiment in the form of PrEP (pre-exposure prophylaxis).

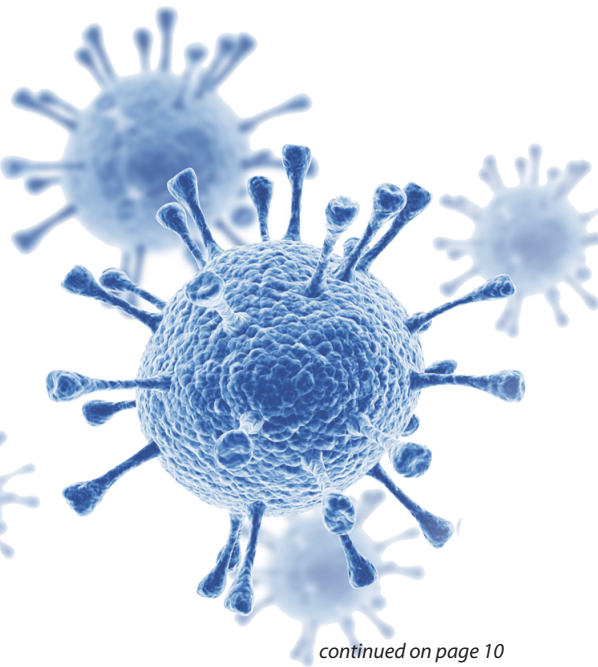
"In the clinical trials, PrEP worked great. But in the real world, it is hard to stick to that regimen if you don't have HIV," said Dr. Sajadi. "People take it intermittently or stop taking it altogether. So, ideally a vaccine would be the most effective preventative."

There are newer prevention medicines consisting of injections once a month or two. Although, this helps combat forgetfulness for taking a pill every day, getting people to commit to 6 to 12 more shots a year may still be a barrier. Some people don't like needles and others may not be able to visit their physician a dozen times a year.

"As for using antibodies in a simple vaccine, we don't know yet whether it's possible to teach the body to make these antibodies or whether it requires decades to make like it did in our Baltimore patient from where it came," he said.

Dr. Sajadi works with collaborators at Scripps Research, University of Maryland College Park, and Dr. Paolo Lusso from the National Institutes of Health's National Institute of Allergy and Infectious Diseases. Among their group, they have narrowed it down to two particularly potent families of antibodies with the most promising potential as a therapy—both of which came from a patient in Baltimore.

"The volunteer (N49) from whom these antibodies were isolated was very special," said Dr. Sajadi. "She really dedicated herself to the research and we developed a close relationship over the years. Unfortunately, she passed away early during the pandemic, but I know she would have been happy with the progress we have made. Her body had figured out a way to make antibodies that could potently neutralize nearly all strains of HIV from around the world, and it was because of her selflessness that we were able to start and continue the work."



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From left to right: Xin Ouyang, Narjes Shokatpour, Rahim Abbasi, PhD, Dr. Sajadi, Zahra Rikhtegaran Tehrani, PhD, and Maryam Karimi, MSc

"The antibodies we isolated from N49 are some of the best ones against HIV that have ever been isolated," said Dr. Sajadi. "They may be tied for the record in the number of strains of HIV they are effective against and are potent in that you need very little to show an effect."

Unlike COVID-19 in which only a handful of strains exist (like the delta variant), HIV has been circulating for many decades and there are now hundreds of strains out there. HIV is very "promiscuous" and if a person contracts different strains, they will commonly recombine together to form a new HIV strain.

The researchers are engineering their candidate antibodies to be more effective against even more HIV strains. They take the original antibody and tweak the sequence just a bit by altering one or two letters in the protein sequence of the antibody at a time. Then they grow the antibodies in human cell lines and test the modified antibodies against HIV strains that the original antibody could not disable.

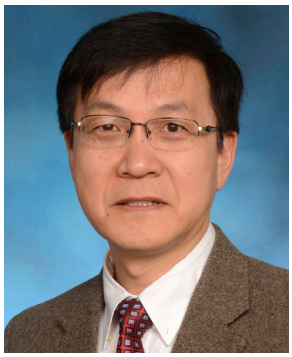
Ideally for a therapy, the antibody also needs to be easy to manufacture for ultimate use in large scale production. This means the antibody can hold up to changes in temperature, pH, and be easily dissolved in a solution. The team has a Bill and Melinda Gates grant to improve the manufacturability of their candidates.

The next steps will be testing in animals for safety and effectiveness. Then they will do human safety trials in healthy volunteers before they get to the point of testing in people who have HIV, which could be several years or more down the road.

"People are investigating many different ways to find a true preventative or cure for HIV, but the solution that will deliver the ultimate answer remains to be seen," said Dr. Sajadi. "I will continue working on the antibody component as my piece of the puzzle."

Developing New Cancer Therapies

In the three short years that he has been at the Institute of Human Virology, cancer researcher and cell biologist **Yin Wang, PhD**, Assistant Professor of Surgery, Division of Immunotherapy, has seven solid publications from his laboratory with an eighth in revision. His lab's main interest is in investigating new cancer treatments.



Yin Wang, PhD

Dr. Wang was not always a cell biologist. He initially completed his PhD in chemical engineering developing cancer drugs. It was from a desire to test his synthesized chemicals in action against cancer cells that led to him pursuing the next stage of his career. He completed a Postdoctoral Fellowship at Ohio State University and then took a position as a Research Scientist at University of Michigan, where he delved more into the biology of cancer. Then, he joined Children's National Hospital in Washington, DC before landing at IHV.

Much of Dr. Wang's work revolves around the protein hypoxia-inducible factor 1 alpha (HIF1α). Originally thought to be important for solid tumor growth, HIF1α detects when oxygen is low and turns on genes that form new blood vessels. This brings blood and thus a fresh oxygen supply to a tumor thereby feeding it and allowing it to grow. However, Dr. Wang found that HIF1α was not only important for solid tumors. In stem cells from a type of leukemia, Dr. Wang showed that HIF1α is always on and active even under normal oxygen conditions.

He went on to do some more background research into HIF1α's role in this leukemia. Dr. Wang's team showed that HIF1α seems to be required for cancer stem cell maintenance and function. They also showed HIF1α activity to be regulated by tumor a suppressor protein that is commonly mutated the bone marrow cancer, known as acute myeloid leukemia.

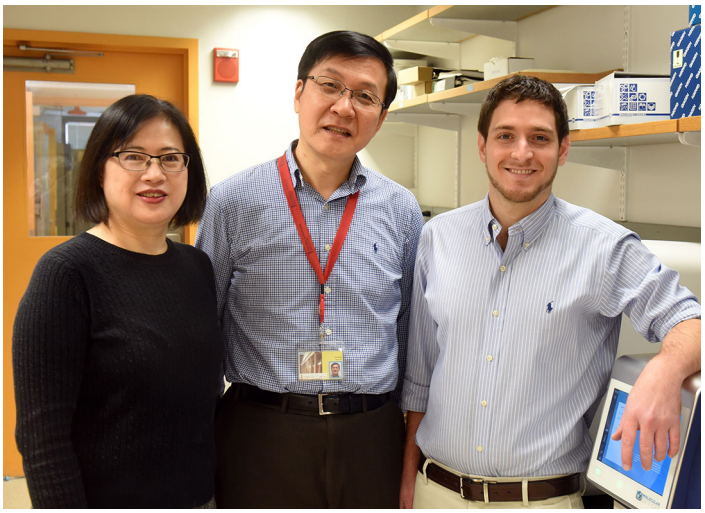
Reviving an old drug

Based on these findings, Dr. Wang decided to investigate whether targeting HIF1α would be a way to treat leukemias. After screening 20 HIF1α inhibitor drugs in three leukemia mouse models, they found that the drug echinomycin was the most potent. Echinomycin is an antibiotic from a strain of Streptomyces bacteria identified in the South African country Angola.

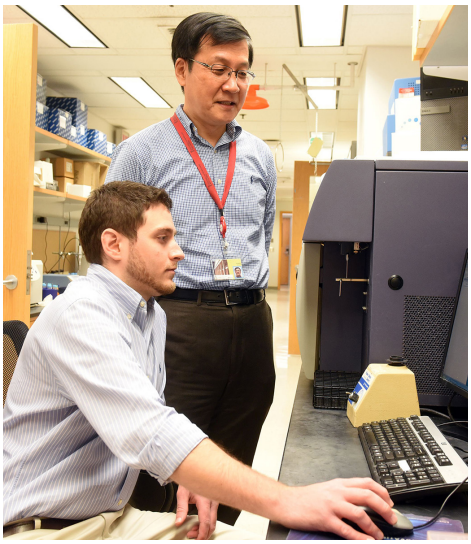
"Echinomycin is an old drug that the NIH [National Institutes of Health] tested in the 1990s against breast cancer, but it failed against solid tumors," said Dr. Wang. "A small group of patients did respond to the drug though. We think that this may have to do with some cancers having lots of HIF1α and others not so much. Back then, they did not know how the drug worked and that it targeted HIF1α, so the researchers did not measure HIF1α levels in the tumors from the clinical trial participants."

Now, researchers know that echinomycin binds to DNA in the same places that HIF1α normally does on the hypoxia-response elements, so HIF1α cannot get to the DNA to turn on genes when echinomycin is there. As researchers know more about how the drug works, they are better able to choose which candidate tumors the drug will be more likely to respond to—those with high levels of HIF1α.

Although the echinomycin proved very effective at treating cancers in cell cultures that have high levels of HIF1α, Dr. Wang's team noticed they did not seem to be as effective in mice with the same tumors. The researchers thought this may have to do with how the drug is formulated and delivered. Echinomycin is not water soluble and has to be dissolved in an oily-like substance. In the NIH's original phase I/II clinical trials, the researchers noted that this original formulation dissolved in modified castor oil caused some hypersensitivity in certain people.



Dr. Yan Liu (left), Dr. Yin Wang (center), and Dr. Chris Bailey



Dr. Chris Bailey (seated) and Dr. Yin Wang

"We decided that perhaps the vehicle was not as good for getting the drug into the tumor cells as it could be," said Dr. Wang. "We tried something similar that was done for the breast cancer drug Taxol. We formed it into liposomes." Liposomes are vesicles of fats—essentially mini bits of cell membrane. Then, Dr. Wang's team treated cancer cells with these drug-containing fats blobs that fuse with the cancer cells' outer membranes to deliver the drug directly inside. They showed that the newer formulation lasts longer, and since the delivery is improved is more effective.

Using their new formation, they demonstrated that echinomycin was effective in mice that had several human samples of acute myeloid leukemia, even more so than a combination of chemotherapy drugs. In addition to the leukemia cancer models, the team effectively treated mouse models of breast, kidney, and brain cancer with their newly formulated version of echinomycin.

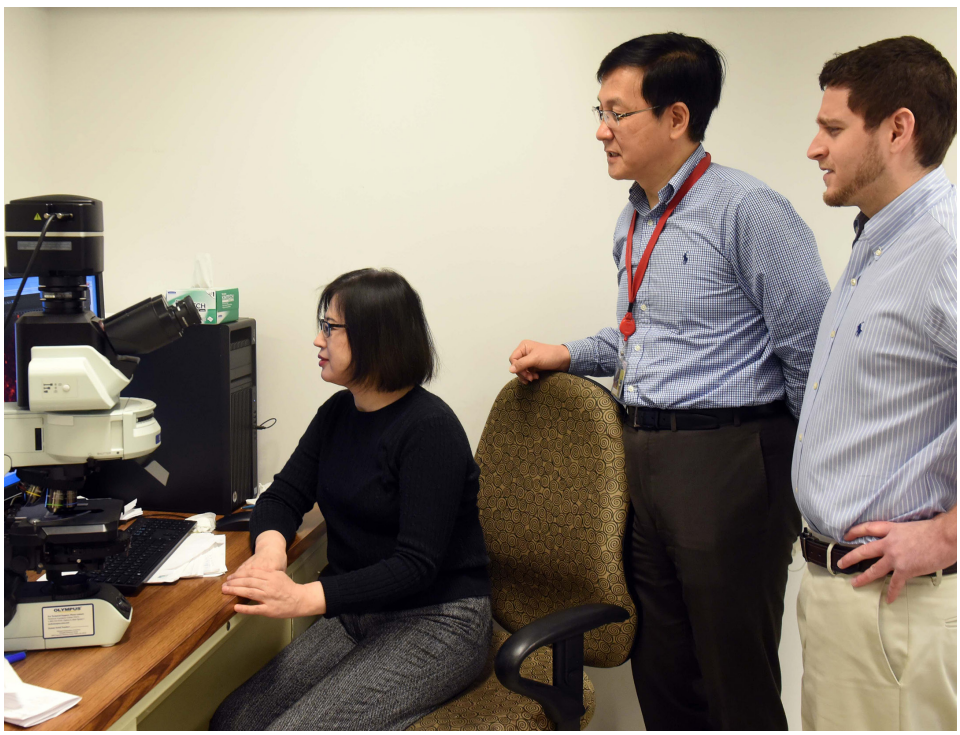
Now, Dr. Wang's focus is on ramping up production of their echinomycin formulation in a collaboration with Stephen Hoag, Ph.D., Director of the Applied Pharmaceutics Lab at the University of Maryland School of Pharmacy. They plan to collaborate with clinicians, such as Maria Baer, MD, Professor of Medicine at the University of Maryland Marlene and Stewart Greenebaum Cancer, to eventually test the drug in human clinical trials.

Immunotherapy

In another cancer treatment research angle, Dr. Wang's team hopes to use drugs against HIF1α in immunotherapy. Current immunotherapies use two molecules that help ensure the cell is ready to progress to the next stage during the cell division cycle, known as checkpoint inhibitors, as a way to train the immune system to attack cancer.

Although highly effective—particularly for cancers that do not respond to other treatments—sometimes these therapies can cause immune-related adverse events. These adverse events are essentially autoimmune responses to the immunotherapy, which can cause someone to discontinue therapy or occasionally even kill the patient. Using only one of these checkpoint inhibitors rather than two, does reduce the chance of these autoimmune responses, but also makes the cancer treatment less effective.

Dr. Wang and his team are exploring whether using a HIF1α drug in combination with one checkpoint inhibitor is a way to have a more effective cancer treatment, without the risk of the immune-related adverse events. He hopes to publish his findings in the next several months.



Dr. Yan Liu (left), Dr. Yin Wang (center), and Dr. Chris Bailey

the THRIVE program

Together Healing, Reaching, Inspiring, to achieve Victory over illness, and Embrace life

IHV's THRIVE Moves to Sleek, Modern Space

In 2016, IHV moved its outpatient practices including the JACQUES Initiative, the Evelyn Jordan Center, The General Infectious Disease Clinic, and the IHV Clinic within the Family Health Center at Midtown to form the University of Maryland Center for Infectious Diseases, located on the University of Maryland Medical Center's Midtown Campus. The HIV arm of the Center has since been named the THRIVE Program of the Institute of Human Virology's Division of Clinical Care and Research. In late September, the THRIVE program (which stands for Together, Healing, Reaching, Inspiring to achieve Victory over illness and Embrace life), received a space upgrade into the newly opened Midtown Outpatient Tower. The THRIVE program provides medical care and addresses mental health and social needs for people living with HIV.

Sarah Schmalzle, MD

"The Department of Medicine, in partnership with the IHV, wanted to emphasize the clinical expertise of the medical subspecialties and have these experts in one site to help coordinate and improve care—THRIVE being a component of this mission," said THRIVE's Medical Director, **Sarah Schmalzle, MD**, Assistant Professor of Medicine at the Institute of Human Virology at the University of Maryland School of Medicine.

Alison G. Brown, MPH, President of the University of Maryland Medical Center Midtown Campus said, "As the THRIVE program name implies, living with a long-term infectious illness like HIV or hepatitis C need not interfere with living a full life—which the latest advances in treatment extend in both quality and length. But people need simplified access to this treatment, and important supportive services. Our mission is to be the healthcare partner that simplifies their journey by providing comprehensive, connected care and services under one roof."

Now on the 7th floor of the Tower, THRIVE is located in the same building as other specialty centers for eye, cardiology, kidney, diabetes, sleep disorders, pulmonary, and gastrointestinal care.

Anthony Amoroso, MD

"One vision of the new ambulatory Tower is to provide space for the provision of excellent comprehensive medical care and care coordination to patients with complex, chronic medical conditions with a special focus on diseases which disproportionally affect the surrounding community," said **Anthony Amoroso, MD**, Professor of Medicine and Chief of Clinical Care Programs for the Institute of Human Virology at the University of Maryland School of Medicine. "This is a shared mission for how the Institute of Human Virology approaches HIV care and treatment. We have been waiting for about 5 years, and are very grateful to continue to be part of the core practices moving into the Tower. It will allow us to not only spread out more but also integrate the IHV's care coordination staff better. Importantly, the move co-locates other medical practices allowing us to easily access the expertise of the department of medicine faculty for our patients."

Rendering of the new Midtown Outpatient Center

The new location has a large, open check-in desk and waiting room immediately at the suite's front entrance, which provides a more welcoming atmosphere than the Armory location with individual glass check in cubes and a waiting room down a hall.

THRIVE's Director of Social Work, **Robyn Palmeiro, LCSW-C**, spent more than 20 years in the Armory Building space at the University of Maryland Medical Center Midtown Campus as a founding member at the then named IHV Clinic in the Family Health Center. She says the Armory location functioned well enough, but it was an older space in need of a facelift.

Robyn Palmeiro, LCSW-C

"It's a beautifully constructed and designed building, and a more uplifting experience to be in a new space versus something that hasn't been updated in several decades," said Palmeiro. "Everyone is talking about all the light coming in the windows."

continued on page 14

IHV's THRIVE Moves to Sleek, Modern Space *(cont.)*

Construction of the Midtown Outpatient Tower

At the older location, her team of social workers, along with housing, employment, and insurance counselors, were located in a single hallway.

"This was great for us to bounce ideas off of each other, but we were isolated from the care team and sometimes missed seeing patients after their medical visit," said Palmeiro.

The new space has a customized layout of office assignments, so all members of the team are around a more central area. There are two pods with a pod containing two teams each. The pods provide a centralized location for everyone on the team so they can work together better. A nurse sits in the pod workspace and the social workers are in a circle around the pod. The physicians move in and out of the pods as needed.

The new space now has negative pressure rooms with higher air circulation required for evaluating, treating, and testing for airborne disease, such as tuberculosis or COVID-19. Although they could do these things at the old location, Dr. Schmalzle says there were extensive protocols to make the area safe again, so the patient rooms used for these purposes would become unusable for some time.

Some other considerations for the space that were specifically needed for THRIVE included a room for infusions (for antibiotics, antivirals, or injectable HIV medications), room for penicillin-allergy testing, and designated rotating space for other services. The rotating space will be used for research, peer navigators, sexual health conversations, or for members of the home and community case management program to meet with patients.

But, the most important thing is what do the patients think? "The patients seem to love it," said Dr. Schmalzle. "It's much brighter, newer, welcoming, and uplifting."

"For some of our patients, they hold their head high, and own their diagnosis. But for others, walking into an HIV clinic is a huge challenge as we are a reminder of something or someone they want to avoid thinking about," said Palmeiro. "We are often our patients' support system—their family essentially—the people that have been loyal to them and held their secret for years. In the new tower, our patients can walk into a space that has dignity to it and it feels like a place our patients deserve."

Rendering of THRIVE's waiting room and front Desk area in the new location

IHV Helps Out One of Their Own

When a program manager for the Institute of Human Virology's Center for International Health, Education, and Biosecurity (Ciheb) needed urgent brain surgery and was scheduled to travel from Kenya to India for the procedure at the height of a COVID surge, **Constancia Awiti's** colleagues knew they had to find a way to get her to Baltimore instead. After much logistical coordination and donations from many of her colleagues, Constancia had her 14-hour surgery on August 25, 2021, at the University of Maryland Medical Center and has made a full recovery. Without the time and effort of her colleagues who went over and above the call of duty, none of this would have been possible.

Constancia worked on Kenya's TAPHIK (Technical Assistance for Public Health Impact in Kenya) project as the Program Manager ensuring that the program was on-schedule and on-budget. The project was a collaboration with the University of Maryland Baltimore and the Kenya Medical Research Institute (KEMRI) with Constancia as the go-between for the two institutions. The five-year project funded by the US Center for Disease Control and Prevention under the United States President's Emergency Plan for AIDS Relief response helped provide technical support for KEMRI to strengthen its programs in public health to control infectious diseases, such as HIV or tuberculosis.

But in October of 2020, she started getting headaches and developed weakness in one of her arms. For the next couple of months, she traveled 5-6 hours by car from her home in Kisumu in Western Kenya to Nairobi for doctor's visits and tests, where they diagnosed her with a parafalcine meningioma—a tumor in the membrane lining the brain. While not an urgent life or death situation as the tumor was not necessarily cancerous, if not dealt with it would continue to slowly grow and her symptoms would worsen until she eventually succumbed to them.

By Spring 2021, Constancia's symptoms worsened with crushing headaches, vision loss from the pressure of the tumor, and she could no longer work. In Kenya, people with these kinds of tumors tend to have a poor prognosis. So, Constancia was scheduled to have surgery in the nearest location with a good track record of removing these tumors successfully—in India. Unfortunately, at that time the COVID delta variant was at a peak there and it was not safe to travel to India.

It takes a village—or an entire Institution

When her IHV colleagues found out the plan for travel to India for surgery, they were determined to figure out how to get her to Baltimore instead. Still, there were some hurdles to get through though, such as travel logistics and the portion of the medical bills not covered by insurance.

"Initially organizing this seemed insurmountable in the middle of the pandemic and it looked like it could not be done, but we would try," said her colleague **Caroline Ng'eno, MBChB, MPH**, Interim Country Director for Ciheb's global program in Kenya, who had worked with Constancia for more than four years. "Constancia would remind me this was not my scope of expertise to logistically figure this out,

Caroline Ng'eno, MBChB, MPH

Constancia Awiti

but I thought, if this isn't my scope then what is? Everyone rallied together as a team embodying everything we believe in and we just took it a day at a time."

Dr. Ng'eno reached out to our colleagues in Kenya within our program, in KEMRI, and at the African CDC to ask for donations to help fund the Constancia's expedition using a Kenyan mobile money platform (M-PESA). Constancia's colleagues in Africa raised more than $18,000.

In the states, **Dave Wilkins**, Chief Operating Officer, and **Man Charurat, PhD**, Professor of Medicine, Director of Ciheb, and IHV's Division of Epidemiology and Prevention, got to work and solicited help from colleagues at the university and IHV. They set up a GoFundMe and asked colleagues for donations.

Dave Wilkins

Man Charurat, PhD

Bob Gallo, MD, the Homer and Martha Gudelsky Distinguished Professor in Medicine and Co-Founder and Director of IHV, reached out to his connections to identify the right surgeon for her particular kind of tumor.

Graeme Woodworth, MD, Professor and Chair of the Department of Neurosurgery at the University of

Maryland School of Medicine, was highly recommended. Dr. Woodworth looked over the scans and said he was happy to do the surgery and connected the IHV group with his administrator to hammer out the logistics.

The team lined up the surgery date and transferred medical records, scheduled medical testing, pre-surgery tests, booked flights, the rounds COVID tests needed for travel, COVID vaccination, and more.

"By this point Constancia's sister Mary was acting her behalf, because she was no longer able to function on her own," said Mr. Wilkins. "We had to ensure that that we had funds for her travel, as well." All said and done, he says that 110 US IHV colleagues donated more than $16,000.

"Mary was a pillar, who dropped everything to help her sister," said Dr. Ng'eno. "She did not have the paperwork ready to leave the country, but she was ready to leave immediately. We were on the phone with CDC Africa, who helped connect us with the US Embassy, so we could get the proper visa for her to accompany Constancia on the trip."

And soon after they were off, arriving in states a few days before Constancia's surgery. Mr. Wilkins picked up Constancia and her sister Mary from Dulles airport and brought them to Baltimore, and ensured she made it to her appointments and tests leading up to the surgery.

Following surgery, Constancia and Mary stayed at the home of former IHV Database Constructer **Dave Onime** and his wife. The couple had left IHV to move to Nigeria, but kept their Baltimore house and kept in touch with Constancia. Another former IHV colleague, and current Epidemiology PhD student, Sunday Ikpe and his wife Grace Ikpe Odo live near the Onime's home and took care of the visitors. The couple entertained, ran errands, and shuttled Constancia and her sister to the hospital and the airport. They also introduced her to some Nigerian home cooked dishes. **Kristen Stafford, PhD, MPH**, Associate Professor of Epidemiology and Public Health and Deputy Director of Ciheb also prepared meals, including a Nigerian delicacy.

A few days following surgery, Constancia had a seizure that landed her back in the ICU for a few days. According to Dr. Woodworth, scar tissue from the surgery can lead to this less common complication. The UMMC care providers got her stabilized and on the appropriate medication, and she returned to the Onime's home. Her trip home was delayed by an extra 10 days to allow her more time to recover, build up strength, and be ready for the long journey home.

"The last hour before Constancia left for the airport was very emotional," said Mr. Wilkins. "This whole experience has shown IHV's humanity in all its strength. So many people pulled together to make this happen."

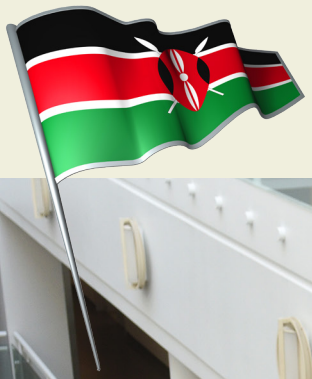
"What we all have experienced together really demonstrates how we function as a global family," said Dr. Charurat. "And, I thank everyone in coming together to make this a reality for Constancia and our Kenya program."

Less than a month following her surgery from her home in Western Kenya, Constancia wrote her colleagues in Kenya and the US.

"I find myself short of words to suitably convey my gratitude," said Constancia. "I am humbled and incredibly fortunate having been associated with an organization whose leadership is furiously dedicated, uncompromisingly humane, and most importantly willingness to help even in the most daunting situation. You have left an indelible mark to define my destiny and I have picked those virtues from you."

"We are used to thinking of big picture global health in how many people we are reaching overall," said Dr. Ng'eno. "Sometimes it's about reaching individual people and affecting their lives for the good and we were able to do that for Constancia. It brought out the humanity in all of us. Everyone chipped in from the most unlikely of places."

Constancia has recovered her vision and her crippling headaches are gone. The TAPHIK grant that she managed has now run its 5-year course. Soon she will join another public health project.



Hosting a delegation...

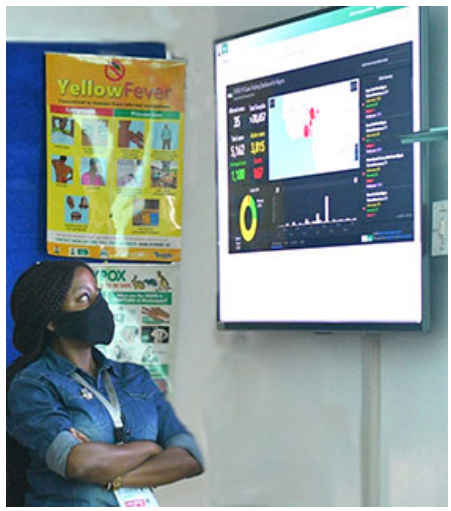
The IHV and senior representations from the Institute for Genome Sciences and the Center for Vaccine Development and Global Health at the University of Maryland School of Medicine hosted the delegation from the Kenya Medical Research Institute headed by its Director General, Professor Sam Kariuki (middle back), Board member Dr. Wenwa Akinyi, Director for Corporate Services Mr. Anthony Wachira, and Corporation Secretary Dr. Martin Ng'ati.

University of Maryland School of Medicine Institute of Human Virology Researchers Receive $6.5M to Create African Big Data Hub Designed to Address Public Health and Pandemic Preparedness

Alash'le Abimiku, PhD

Researchers at the University of Maryland School of Medicine (UMSOM)'s Institute of Human Virology (IHV), a Global Virus Network (GVN) Center of Excellence, have received $6.5 million from the U.S. National Institutes of Health (NIH) to streamline big data collection in Nigeria and South Africa in addressing public health needs of the COVID-19 and HIV pandemics.

The U54 grant, named *INFORM Africa*, was awarded in September 2021. As one of seven research hubs in Africa, *INFORM Africa* will serve as an NIH Data Science and Innovation Research Hub (DS-I Africa) to support data science and innovation training programs in Africa, promote research on the ethical, legal, and social implications central to health research and innovation in Africa, and establish an open data science platform and coordinating center. The funds also establish a Data Management and Analysis Core to collect and evaluate both existing and new data assembled for the Research Hub. Researchers of the *INFORM Africa* grant will work with public and private sectors led by Institute of Human Virology, Nigeria (IHVN), in collecting information to better understand the many variables impacting the COVID-19 pandemic.



"By utilizing large datasets on HIV and SARS-CoV-2 from two of Africa's largest and most affected countries, INFORM Africa will be able to provide new and unique insights on the relationships about both viruses' mobility, as well as their impact on each other, so that governments across Africa can better respond to these current epidemics and future threats," said grant co-awardee **Alash'le Abimiku, PhD**, Professor of Medicine, Institute of Human Virology, University of Maryland School of

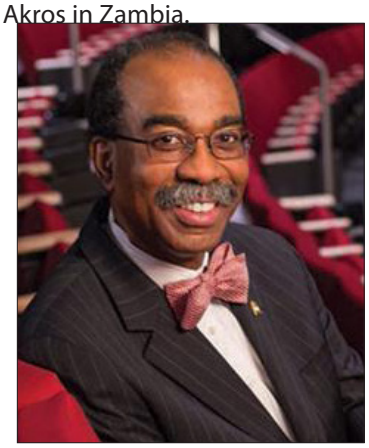
Medicine, and Executive Director of the International Research Center of Excellence, IHVN. "We look forward to addressing the longstanding challenge in Africa in lacking the capacity to secure, curate, and analyze high-quality, large datasets."


Man Charurat, PhD

INFORM Africa will focus on three research projects. One project will study the impact of how SARS-CoV-2 spreads by studying human movements. The second project will focus on where the virus is distributed and how it may mutate to form new strains that may change its behavior. The last project will look at the interplay between factors such as location, spread, and population demographics, as to how it effects the twin pandemics (SARS-CoV-2 and HIV).

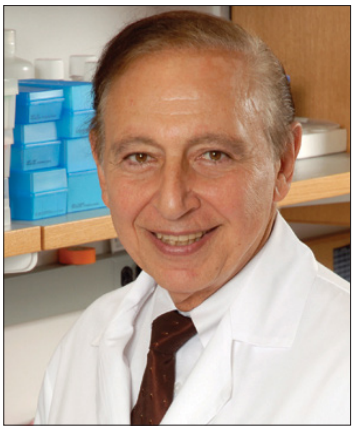
"Faced with a new highly infectious agent, and poor health infrastructure, IHV and UMSOM have engaged colleagues from the Maryland Transportation Institute and University of Maryland's Center for Advanced Transportation Technology Laboratory at College Park, led by Dr. Xiong, to facilitate the proposed data-driven research," said the grant's other co-awardee **Man Charurat, PhD, MHS**, Professor of Medicine, and Director of the Division of Epidemiology and Prevention, Research and Global Director of Ciheb, at University of Maryland School of Medicine's Institute of Human Virology. "This partnership will ensure optimal management of data streams and development of appropriate tools and workflows for innovative data analytics that will transform biomedical and behavioral research and improved health across Africa."

Dr. Abimiku and Dr. Charurat will work alongside **Kristen Stafford, PhD, MPH**, Associate Professor of Epidemiology and Public Health and Deputy Director of Ciheb, Institute of Human Virology, University of Maryland School of Medicine; **Mohammad Sajadi, MD**, Professor of Medicine, Institute of Human Virology, University of Maryland School of Medicine; **Patrick Dakum, MBBS, MPH**, Associate Professor of Epidemiology and Public Health, Institute of Human Virology, University of Maryland School of Medicine; **Meagan Fitzpatrick, PhD**, Assistant Professor of Medicine at University of Maryland School of Medicine and member of at University of Maryland School of Medicine's Center for Vaccine Development and Global Health; investigators from the Maryland Transportation Institute; CAPRISA and Stellenbosch University in South Africa; and Akros in Zambia.


E. Albert Reece, MD, PhD, MBA

"As a result of this team's extensive experience setting up the HIV-care infrastructure in several Sub-Saharan African countries, they are poised to take the next step forward in developing a more integrated infectious diseases monitoring network," said **E. Albert Reece, MD, PhD, MBA**, Executive Vice President for Medical Affairs at University of Maryland Baltimore, and the John Z. and Akiko K. Bowers Distinguished Professor and Dean, University of Maryland School of Medicine. "Rather than responding reactively, the team will be able to see patterns as they emerge, which will enable public health officials to intervene earlier and keep citizens safer."

Robert C. Gallo, MD, the Homer & Martha Gudelsky Distinguished Professor in Medicine, Co-Founder and Director, Institute of Human Virology (IHV), University of Maryland School of Medicine, and GVN Co-Founder and International Scientific Director, said: "Drs. Abimiku and Charurat have been integral in the Institute's seventeen years of work in countries funded through the President's Emergency Plan for AIDS Relief (PEPFAR), and more specifically and significantly, in Nigeria. I am pleased to see this team build upon their vast experience and grow their international portfolio with NIH to implement INFORM Africa and identify current public health needs and prepare for future outbreaks."


Robert C. Gallo, MD

The NIH Common Fund encourages collaboration for high impact innovative research, such as the African-led Human Hereditary and Health in Africa (H3Africa). NIH Director Francis Collins, MD, PhD, established the DS-I Africa initiative through the Common Fund to support the vision of harnessing data science in Africa for rapid advances to improve health.

Grants*

Shenghan Lai, MD

Shenghan Lai, MD, Professor of Epidemiology & Public Health, Division of Epidemiology & Prevention, was awarded $30,900.65 in collaboration with University of California Los Angeles for the project titled "Collaborating Consortium of Cohorts Producing NIDA Opportunities." The goal as the coordinating center for the National Institute on Drug Abuse (NIDA) is to stimulate the use of the NIDA longitudinal cohorts and address high priority research on HIV/AIDS in the context of substance misuse.

Caroline Ng'eno, MBChB, MPH, Interim Ciheb Kenya Country Director, Center for International Health, Education, and Biosecurity, was awarded $1,110,835 for "Supporting the Implementation and Expansion of High Quality, Sustainable and Comprehensive HIV Prevention, Care and Treatment Programs in Nairobi County in the Republic of Kenya under the President's Emergency Plan for AIDS Relief (PEPFAR)." The title of the project is county ownership and networks to maintain Nairobi epidemic control (CONNECT). The goal of this project is to strengthen program and surveillance data collection and reporting, and health information systems (HIS) by leading health informatics initiatives, particularly around data visualization, interoperability of systems, and longitudinal follow-up and CQI initiatives.

Caroline Ng'eno, MBChB, MPH

Caroline Ng'eno, MBChB, MPH, Interim Ciheb Kenya Country Director, Center for International Health, Education, and Biosecurity, was awarded $1,381,297 for project titled "Enhancing Technical Responses to the HIV Epidemic Control through Nimble County Health Systems (ENTRENCH)." The goal of the project is to provide comprehensive HIV prevention and treatment services to KP, PP, and GP while building CSOs capacity to do the same.

Caroline Ng'eno, MBChB, MPH, Interim Ciheb Kenya Country Director, Center for International Health, Education, and Biosecurity, was awarded $363,486 for project titled "Partnership for Advanced Care and Treatment [(PACT) Imara]." The goal of the project is to provide comprehensive HIV prevention and treatment services to KP, PP and GP by supporting referral to MAT clinics UMB helped establish in Nairobi, Kenya.

Rebecca Nowak, PhD

Rebecca Nowak, PhD, Assistant Professor of Epidemiology & Public Health, Division of Epidemiology & Prevention, was awarded $444,573.36 from the National Institute of Health for the R21 titled "Evaluating immunity to oral human papillomavirus to understand the lower oropharyngeal cancer risk among MSM." This study evaluates whether the oral cavity is better able to control HPV immunologically than other exposure sites, which could offer insight on strategies to strengthen oral cavity immunity to prevent OPC.

David Riedel, MD

David Riedel, MD, MPH, Associate Professor of Medicine, Division of Clinical Care & Research, Medical Director, Center for International Health, Education, and Biosecurity, was awarded $30,000 for two years to support the effort of the University of Maryland, Baltimore-Center for Global Engagement within Rwanda titled "Strengthening the National Cancer Registry in Rwanda." The goal of this project is to establish secure funding support for the Registry and staff through collaborative grants. As such, UMB faculty will work closely with the RBC staff on grant-writing during year 2 of the funding award in order to secure additional funding by 2022.

This list does not include the significant grants already featured in the newsletter

Grants

Mohammad Sajadi, MD

Mohammad Sajadi, MD, Professor of Medicine, Division of Clinical Care and Research and Anthony DeVico, PhD, Professor of Medicine, Division of Vaccine Research, will serve as co-principal investigators on an awarded $2,706,687 for four years for an NIH Grant to support the efforts of the National Institute of Allergy and Infectious Disease for the "Novel bNAB-based treatment and prevention of HIV-1." The ultimate goal of this project is to test in animals (mice and monkeys) antibodies that we have previously identified that have broad and potent activity against most HIV viruses for their ability to prevent and treat HIV infection. We hope that these antibodies can eventually be used to prevent or treat HIV infection in humans.

Rohit Talwani, MD

Rohit Talwani, MD, Associate Professor of Medicine, Division of Clinical Care & Research, was awarded $14,300 for one years to support the efforts for "Vir Biotechnology, Inc." A phase 3 randomized, multi-center, double-blind, placebo-controlled study to compare the efficacy, safety, and tolerability of monoclonal antibody VIR-7831 given intramuscularly for the early treatment of coronavirus disease 2019 (COVID-19) in non-hospitalized patients.

The IHV's Division of Vaccine Research was awarded a five-year, $3 million subcontract from Duke University as part of a large, multi-center consortium to identify windows of vulnerability to Fc-mediated activities during HIV infection and to demonstrate that non-neutralizing, FcR-dependent functions protect against HIV and SHIV infection in humanized mice.

Publications

John Baddley, MD, MSPH, Professor of Medicine, Division of Clinical Care and Research, **Kapil Saharia, MD, MPH,** Assistant Professor of Medicine, Division of Clinical Care and Research and another author published "Cryptococcosis" in *Infectious Disease Clinics of North America* in Jun 2021, DOI: 10.1016/j.idc.2021.03.012

John Baddley, MD, MSPH, Professor of Medicine, Division of Clinical Care and Research, among other authors published "MSG07: An International Cohort Study Comparing Epidemiology and Outcomes of Patients with *Cryptococcus neoformans* or *Cryptococcus gattii* Infections" in *Clinical Infectious Diseases* in Oct 2021, https://doi.org/10.1093/cid/ciab268

Francesca Benedetti, PhD, Research Associate of Biochemistry and Molecular, Division of Virology, Pathogenesis, and Cancer, **Giovannino Silvestri, PhD, MS,** Research Associate of Medicine, Division of Virology, Pathogenesis, and Cancer, **Olga Latinovic, PhD, MSc,** Assistant Professor, Microbiology and Immunology, Division of Virology, Pathogenesis, and Cancer, and **Davide Zella, PhD,** Assistant Professor of Biochemistry and Molecular Biology, Virology, Pathogenesis, and Cancer, among other authors published "Comparison of SARS-CoV-2 Receptors Expression in Primary Endothelial Cells and Retinoic Acid-Differentiated Human Neuronal Cells" in *Viruses* in Oct 2021, https://doi.org/10.3390/v13112193

Francesca Benedetti, PhD, Research Associate of Biochemistry and Molecular, Division of Virology, Pathogenesis, and Cancer, **Alonso Heredia, PhD,** Associate Professor of Medicine, Division of Clinical Care & Research, **Mohammad Sajadi, MD,** Professor of Medicine, Division of Clinical Care & Research, **Davide Zella, PhD,** Assistant Professor of Biochemistry and Molecular Biology, Virology, Pathogenesis, and Cancer, and **Olga Latinovic, PhD, MSc,** Assistant Professor, Microbiology and Immunology, Division of Virology, Pathogenesis, and Cancer, among other authors published "Combined cART including Tenofovir Disoproxil, Emtricitabine, and Dolutegravir has potent therapeutic effects in HIV-1 infected humanized mice" in the *Journal of Translational Medicine* in Oct, 2021, https://doi.org/10.1186/s12967-021-03120-w

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Manhattan Charurat, PhD, MHS, Professor of Medicine, Director of the Division of Epidemiology & Prevention, Director of the Center for international Health Education and Biosecurity, and **Patrick Dakum, MBBS, MPH,** Associate Professor of Epidemiology & Public Health, Division of Epidemiology & Prevention, Chief Executive Officer of Institute of Human Virology, Nigeria, among other authors published "Optimizing community linkage to care and antiretroviral therapy Initiation: Lessons from the Nigeria HIV/AIDS Indicator and Impact Survey (NAIIS) and their adaptation in Nigeria ART Surge" in *PLoS One* in Sept 2021, https://doi.org/10.1371/journal.pone.0257476

Manhattan Charurat, PhD, MHS, Professor of Medicine, Director of the Division of Epidemiology & Prevention, Director of the Center for international Health Education and Biosecurity, **Cassidy Claassen, MD, MPH,** Assistant Professor of Medicine, Division of Clinical Care & Research, **David Riedel, MD, MPH,** Associate Professor of Medicine, Medical Director of the Center for International Health, Education, and Biosecurity, Division of Clinical Care and Research, and **Lottie Hachaambwa, MB ChB,** Assistant Professor of Medicine, Division of Clinical Care & Research among other authors published "Economic evaluations of differentiated service delivery should include savings and ancillary benefits, not only health system costs" in *AIDS* in Nov 2021, DOI: 10.1097/QAD.0000000000003033

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Joel Chua, MD, Assistant Professor of Medicine, Division of Clinical Care and Research, **Jennifer Husson, MD, MPH,** Assistant Professor of Medicine, Director of the Clinical Research Unit, Division of Clinical Care & Research, **Anthony DeVico, PhD,** Professor of Medicine, Division of Vaccine Research, George Lewis, PhD, The Robert C. Gallo, MD Endowed Professorship in Translational Medicine, Director of the Division of Vaccine Research, **Robert C. Gallo, MD,** The Homer & Martha Gudelsky Distinguished Professor in Medicine, Co-Founder and Director, Institute of Human Virology, Division of Virology, Pathogenesis, and Cancer, and **Mohammad Sajadi, MD,** Professor of Medicine, Division of Clinical Care & Research, among other authors published "Safety and immunogenicity of an HIV-1 gp120-CD4 chimeric subunit vaccine in a phase 1a randomized controlled trial" in *Vaccine* in Jun 2021, DOI: 10.1016/j.vaccine.2021.05.090

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Cassidy Claassen, MD, MPH, Assistant Professor of Medicine, Division of Clinical Care & Research, **Brenna Roth, MD, MPH**, Assistant Professor of Medicine, Division of Clinical Care & Research, **Kristen A. Stafford, PhD, MPH,** Associate Professor of Epidemiology & Public Health, Associate Director of the Center for International Health, Education, and Biosecurity, Division of Epidemiology & Prevention, and **Lottie Hachaambwa, MB ChB,** Assistant Professor of Medicine, Division of Clinical Care & Research, among other authors published "Antibiogram Development in the Setting of a High Frequency of Multi-Drug Resistant Organisms at University Teaching Hospital, Lusaka, Zambia" in *Antibiotics* in Jun 2021, DOI: 10.3390/antibiotics10070782

Cassidy Claassen, MD, MPH, Assistant Professor of Medicine, Division of Clinical Care & Research, and **Kristen A. Stafford, PhD, MPH,** Associate Professor of Epidemiology & Public Health, Associate Director of the Center for International Health, Education, and Biosecurity, Division of Epidemiology & Prevention, among other authors published "Retrospective Review of Virologic and Immunologic Response in Treatment-Experienced Patients on Third-Line HIV Therapy in Lusaka, Zambia" in *Journal of the International Association of Providers of AIDS Care* in Jun 2021, DOI: 10.1177/23259582211022463

James Doub, MD, Assistant Professor of Medicine, Division of Clinical Care & Research, **Eleanor Wilson, MD, MHS,** Associate Professor of Medicine, Division of Clinical Care & Research, published "Observed transaminitis with a unique bacteriophage therapy protocol to treat recalcitrant Staphylococcal biofilm infections" in *Infection* in Jul 2021, DOI: 10.1007/s15010-021-01675-w

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Robert C. Gallo, MD, The Homer & Martha Gudelsky Distinguished Professor in Medicine, Co-Founder and Director, Institute of Human Virology, Division of Virology, Pathogenesis, and Cancer, **Mohammad Sajadi, MD,** Professor of Medicine, Division of Clinical Care & Research, **Shyamasundaran Kottilil, MBBS, PhD,** Professor of Medicine, Director of the Division of Clinical Care & Research, Co-Director of IHV's Clinical Research Unit, and **Kristen A. Stafford, PhD, MPH,** Associate Professor of Epidemiology & Public Health, Associate Director of the Center for International Health, Education, and Biosecurity, Division of Epidemiology & Prevention, among other authors published "COVID-19 Infection Among Women in Iran Exposed vs Unexposed to Children Who Received Attenuated Poliovirus Used in Oral Polio Vaccine" in *JAMA Network Open* in Nov 2021, DOI: 10.1001/jamanetworkopen.2021.35044

Alfredo Garzino-Demo, PhD, Associate Professor of Microbiology and Immunology, Division of Virology, Pathogenesis, and Cancer, **Cristiana Cairo, PhD,** Assistant Professor of Medicine, Division of Epidemiology & Prevention, and another author published "HIV-Associated Interactions Between Oral Microbiota and Mucosal Immune Cells: Knowledge Gaps and Future Directions" in *Frontiers in Immunology* in Sept 2021, DOI: 10.3389/fimmu.2021.676669

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Sarah Kattakuzhy, MD, Assistant Professor of Medicine, Director of the Research Initiative on Infectious Disease and Substance Use Disorder, Division of Clinical Care & Research, **Elana Rosenthal, MD,** Assistant Professor of Medicine, Co-Director of the DC Partnership for HIV/AIDS Progress Hepatitis Clinical Research Program, Division of Clinical Care & Research, among other authors published " Expanding the Evidence on Integrated Opioid Use Disorder and Infectious Disease Care" in the *Journal of Addiction Medicine* in Nov 2021, DOI: 10.1097/ADM.0000000000000802

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Shyamasundaran Kottilil, MBBS, PhD, Professor of Medicine, Director of the Division of Clinical Care & Research, Co-Director of IHV's Clinical Research Unit, and another author published "Acute-on-Chronic Liver Failure: Pathophysiological Mechanisms and Management" in *Frontiers in Medicine* in Nov 2021, DOI: 10.3389/fmed.2021.752875

Shyamasundaran Kottilil, MBBS, PhD, Professor of Medicine, Director of the Division of Clinical Care & Research, Co-Director of IHV's Clinical Research Unit, and **Lydia Tang, MB Ch,** Assistant Professor of Medicine, Division of Clinical Care & Research, among other authors published "CCR5+ T-Cells Homed to the Liver Exhibit Inflammatory and Profibrogenic Signatures in Chronic HIV/HCV-Coinfected Patients" in *Viruses* in Oct 2021, DOI: 10.3390/v13102074

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Shyamasundaran Kottilil, MBBS, PhD, Professor of Medicine, Director of the Division of Clinical Care & Research, Co-Director of IHV's Clinical Research Unit, **Jennifer Husson, MD, MPH,** Assistant Professor of Medicine, Director of the Clinical Research Unit, Division of Clinical Care & Research, and **Eleanor Wilson, MD, MHS,** Associate Professor of Medicine, Division of Clinical Care & Research, among other authors published "Outcomes in Hepatitis C Positive Liver Transplantation: Timing of Direct-Acting Antiviral Treatment and Impact on Graft Fibrosis," in *Viruses* in Sept 2021, DOI: 10.3390/v13091831

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Shyamasundaran Kottilil, MBBS, PhD, Professor of Medicine, Director of the Division of Clinical Care & Research, Co-Director of IHV's Clinical Research Unit, **Paul Saleeb, MD,** Assistant Professor of Medicine, Division of Clinical Care & Research, and **Poonam Mathur, DO,** Assistant Professor of Medicine, Division of Clinical Care & Research, among other authors published "Oral Polio Vaccine to Protect Against COVID-19: Out of the Box Strategies?" in *Open Forum Infectious Diseases* in Jul 2021, DOI: 10.1093/ofid/ofab367

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Marie-Claude Lavoie, PhD, MSc, Assistant Professor of Epidemiology & Public Health, Strategic Information Director for the Center for International Health, Education & Biosecurity, **Kristen A. Stafford, PhD, MPH,** Associate Professor of Epidemiology & Public Health, Associate Director of the Center for International Health, Education, and Biosecurity, Division of Epidemiology & Prevention, **David Riedel, MD, MPH,** Associate Professor of Medicine, Medical Director of the Center for International Health, Education, and Biosecurity, Division of Clinical Care and Research, among other authors published "Factors Associated with Loss to Follow-Up Among Patients Receiving HIV Treatment in Nairobi, Kenya" in *AIDS Research and Human Retroviruses* in Sept 2021, DOI: 10.1089/AID.2020.0292

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Shivakumar Narayanan, MBBS, MD, Assistant Professor of Medicine, Director of Hepatitis Research, Division of Clinical Care and Research, and another author published "Pneumobilia" in American Journal of Medicine in Aug 2021, DOI: 10.1016/j.amjmed.2021.06.049

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Rebecca Nowak, PhD, Assistant Professor of Epidemiology and Public Health, Division of Epidemiology & Prevention, among other authors published "Brief Report: Herpes Simplex Virus Type-2 Shedding and Genital Ulcers During Early HIV in Zimbabwean Women" in the *Journal of Acquired Immune Deficiency Syndromes* in Jun 2021, DOI: 10.1097/QAI.0000000000002641

David Riedel, MD, MPH, Associate Professor of Medicine, Medical Director of the Center for International Health, Education, and Biosecurity, Division of Clinical Care and Research, among other authors published "HHV-6 Encephalitis After Chimeric Antigen Receptor T-cell Therapy (CAR-T): 2 Case Reports and a Brief Review of the Literature" in *Open Forum of Infectious Diseases* in Sept 2021, DOI: 10.1093/ofid/ofab470

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Brenna Roth, MD, MPH, Assistant Professor of Medicine, Division of Clinical Care & Research, among other authors published "A Protocol for a Comprehensive Monitoring and Evaluation Framework with a Compendium of Tools to Assess Quality of Project ECHO (Extension for Community Healthcare Outcomes) Implementation Using Mixed Methods, Developmental Evaluation Design" in *Frontiers in Public Health* in Sept 2021, DOI: 10.3389/fpubh.2021.714081

Patrick Ryscavage, MD, Associate Professor of Pediatrics, Division of Clinical Care & Research, **Kristen A. Stafford, PhD, MPH,** Associate Professor of Epidemiology & Public Health, Associate Director of the Center for International Health, Education, and Biosecurity, Division of Epidemiology & Prevention, and another author published "Assessing risk factors for hypertension in young adults with perinatally acquired HIV infection: A case-control study" in *HIV Medicine* in Nov 2021, DOI: 10.1111/hiv.13199

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Mohammad Sajadi, MD, Professor of Medicine, Division of Clinical Care & Research, among other authors published "SARS-CoV-2 vaccines for all but a single dose for COVID-19 survivors" in *EBioMedicine* in Jun 2021, DOI: 10.1016/j.ebiom.2021.103401

Nadia A. Sam-Agudu, MD, Associate Professor of Pediatrics, Division of Epidemiology and Prevention, and Senior Technical Advisor at IHV-Nigeria, and another author published "Using scientific authorship criteria as a tool for equitable inclusion in global health research" in *BMJ Global Health* in Oct 2021, DOI: 10.1136/bmjgh-2021-007632

Nadia A. Sam-Agudu, MD, Associate Professor of Pediatrics, Division of Epidemiology and Prevention, and Senior Technical Advisor at IHV-Nigeria, among other authors published "Opportunities and Challenges in North-South and South-South Global Health Collaborations During the COVID-19 Pandemic: The AFREhealth-CUGH Experience (as Reported at the CUGH 2021 Satellite Meeting)" in *Annals of Global Health* in Sept 2021, DOI: 10.5334/aogh.3440

Nadia A. Sam-Agudu, MD, Associate Professor of Pediatrics, Division of Epidemiology and Prevention, and Senior Technical Advisor at IHV-Nigeria, among other authors published "Acceptability of mentor mother peer support for women living with HIV in North-Central Nigeria: a qualitative study" in *BMC Pregnancy Childbirth* in Aug 2021, DOI: 10.1186/s12884-021-04002-1

Nadia A. Sam-Agudu, MD, Associate Professor of Pediatrics, Division of Epidemiology and Prevention, and Senior Technical Advisor at IHV-Nigeria, among other authors published "Psychosocial interventions for improving engagement in care and health and behavioural outcomes for adolescents and young people living with HIV: a systematic review and meta-analysis" in *Journal of International AIDS Society* in Aug 2021, DOI: 10.1002/jia2.25741

Nadia A. Sam-Agudu, MD, Associate Professor of Pediatrics, Division of Epidemiology and Prevention, and Senior Technical Advisor at IHV-Nigeria, published "Applying an Implementation Science Framework to Surgical Research and Practice in Tanzania" in the *Journal of the American College of Surgeons* in Aug 2021, DOI: 10.1016/j.jamcollsurg.2021.04.024

Sarah Schmalzle, MD, Assistant Professor of Medicine, Medical Director of THRIVE, Division of Clinical Care & Research, among other authors published "Current Considerations for Clinical Management and Care of People with HIV: Findings from the 11th Annual International HIV and Aging Workshop" in *AIDS Research and Human Retroviruses* in Nov 2021, DOI: 10.1089/AID.2021.0059

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Lishan Su, PhD, Director of the Division of Virology, Pathogenesis, and Cancer, Interim Director of the Division of Immunotherapy, among other authors published "Extracellular Microvesicles Released From Brain Endothelial Cells are Detected in Animal Models Of HIV-1 Signifying Unresolved Inflammation" in *Journal of Neuroimmune Pharmacology* in Aug 2021, DOI: 10.1007/s11481-021-10008-5

Lishan Su, PhD, Director of the Division of Virology, Pathogenesis, and Cancer, Interim Director of the Division of Immunotherapy, among other authors published "Review of Lambda Interferons in Hepatitis B Virus Infection:
Outcomes and Therapeutic Strategies" in *Viruses* in Jun 2021, DOI: 10.3390/v13061090

INSTITUTE OF HUMAN VIROLOGY

UNIVERSITY of MARYLAND SCHOOL OF MEDICINE

Together, Healing, Reaching, Inspiring to achieve Victory over illness and Embrace life

Dear Friend,

We formally recognize World AIDS Day only once a year on December 1, but the energy and solidarity of this day are felt year-round at THRIVE, a program of the Institute of Human Virology at the University of Maryland School of Medicine.

We remember those who are honored by this day, and we commit ourselves to **doing all we can to serve those who trust us with their care.** It is our privilege to be a provider for 2,500 patients who visit the THRIVE Program each year, and we hope you will join us in this effort.

This World AIDS Day, **please donate as generously as you can to help someone.** THRIVE's annual holiday week begins on December 13, with **gifts and personal care supplies for patients.**

Will you join this celebration with your THRIVE gift?

THRIVE patients have experienced greater challenges due to the lasting effects of COVID-19. For this reason, we are even more committed to making this time of year a special one for them. ***Are you dedicated to helping others THRIVE through your philanthropy?***

- **$5** may provide a set of small toiletries or a selection of snacks and packaged food items for a patient who needs them
- **$10** may provide warm weather gear including gloves, hats, scarves, and socks for one patient experiencing housing insecurity
- **$25** may provide a grocery store gift card for a patient experiencing food insecurity
- **$50** may provide a case of nutritional supplement for a patient with poor nutrition

We were humbled by the overwhelming support from friends of THRIVE who donate generously to this essential program. **Thank you to all who donated.** We hope you will renew your gift again this year as there continues to be a need.

Whether you have already donated to this effort, or if you choose to make your first donation today, we are so grateful for your philanthropy. **Please join us this World AIDS Day** in making a difference in the lives of Baltimore's most vulnerable citizens.

Thank you for making THRIVE a philanthropic priority for you, today and every day.

With thanks,

Sarah Schmalzle, MD
Medical Director of IHV's THRIVE Program

P.S. Your gift of any size this World AIDS Day -- or any time you choose to give before December 13—improves the lives of THRIVE patients, especially during this tumultuous year. You can donate securely online **by clicking here.** Thank you!

P.P.S. If you prefer to mail in your gift, please make your check out to **UMBF, Inc./IHV THRIVE**, and send it to:

University of Maryland School of Medicine
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