Hypothesis in Action: Evidence that the ‘Live’ Polio Vaccine Fires Up Immune System Protecting from SARS-CoV-2 Infection

Two recent studies from the University of Maryland School of Medicine’s (UMSOM) Institute of Human Virology (IHV) in partnership with the Petroleum Industry Health Organization of Iran provided evidence that getting the oral polio vaccine made from live, weakened polio-virus may protect people from COVID-19 infection by stimulating the immune system. This hypothesis was proposed by Co-founder and Director of the IHV Robert Gallo, MD, and Konstantin Chumakov, PhD, a GVN Center of Excellence Director, early on in the pandemic to protect people before a vaccine specific to COVID-19 could be developed. Dr Gallo quickly notes it has been raised earlier in other viral diseases by some other investigators, mainly in Europe, and most notably by fellow GVN Center Directors, Peter Aaby, MSc, DMSc, and Christine Stabell-Benn, MD, PhD, DMSc, of Denmark and Mihai Netea, MD, PhD, of Holland.

One of these studies demonstrated a lower incidence of COVID infections in countries in which people received the ‘live’ polio vaccine compared to countries that only received the polio vaccine that does not contain a live virus—findings published in March in PLOS One.

A second report from the research team showed that when young children received the ‘live’ polio vaccine their mothers, who were indirectly exposed to the poliovirus vaccine, did not get infected with COVID. This study was published late last year in JAMA Network Open.

Within a few hours of exposure to any pathogens—including weakened viruses like those in the oral polio vaccine—the immune system activates its first line of defense. This defense produces an immune response to a broad variety of pathogen-related molecules and ramps up the immune system’s readiness for invaders—a process sometimes called ‘trained innate immunity.’ The outcome from one of these newest studies indicate that this trained innate immune response spurred by vaccination using the live polio-virus may provide protection for up to 6 months against COVID infection.

The researchers say that this implies that these live vaccines, technically known as live attenuated vaccines, may be used temporarily to protect people in low-income countries that do not yet have access to COVID vaccines.

“Although countries like the U.S. and those in Europe are dropping pandemic restrictions, many people in lower income countries remain unvaccinated due to lack

continued on page 3
of supply. Individuals in these countries are still at high risk for COVID infection and potential complications, particularly since these regions still lack the latest treatments and enough ventilators for those who need them,” said co-author Shyam Kottilil, MBBS, PhD, Professor of Medicine and Director of the Division of Clinical Care and Research, IHV, Chief of the Division of Infectious Diseases at UMSOM, and senior advisor to the GVN. “These live vaccines may provide a stop gap to reduce hospitalizations and deaths until we can get these people COVID vaccines.”

Senior author on the studies Dr. Gallo, The Homer & Martha Gudelsky Distinguished Professor in Medicine at IHV at the University of Maryland School of Medicine, a GVN Center of Excellence, and Co-Founder of the GVN and Chair of the GVN’s Scientific Leadership Board, said, “This idea directly stemmed from my GVN colleague and co-author Dr. Konstantin Chumakov, whose parents were vaccine researchers in the 1970s Soviet Union. His parents observed that flu rates seemed to drop in those people given the oral polio vaccine. Other GVN colleagues joined us in advocating for studies to determine if these live attenuated vaccines would be a feasible strategy during the coronavirus pandemic. Now we have some of the first evidence that they do offer protection. I hope funders take notice and increase support for these types of trials that study the innate immune response and provide significant hope in mitigating future pandemics.”

Co-author Dr. Konstantin Chumakov said, “These observations are yet another confirmation that live vaccines induce broad protection against infections caused by pathogens other than their direct target. They urgently call for the direct prospective clinical studies of this phenomenon that could lead to the development of a novel class of vaccines based on stimulation of trained innate immunity. Such vaccines could become the badly needed universal countermeasure against emerging infections.”

Christian Bréchot, MD, PhD, President of the GVN, Associate Vice President for International Partnerships and Innovation at University of South Florida (USF), and Professor, Division of Infectious Disease, Department of Internal Medicine at the USF Health Morsani College of Medicine, the GVN Southeast U.S. Regional Headquarters said, “The GVN serves as a catalyst to bring together the world’s foremost virologists. We are pleased to work with varying nations to initiate these important clinical trials.”

In the PLOS One study, the researchers compared infection rates per 100,000 people in 146 countries that received both the live and the injectable polio vaccine, which does not contain live virus, compared to 56 countries that only used the injectable, non-live version. They found infection rates in countries that did not use the live polio vaccine were about three times higher than those that did use the live polio vaccine.

For the JAMA Network Open study, the researchers followed 419 mothers in Iran whose young children were given the live polio vaccine compared to 3,771 mothers whose children did not receive the live polio vaccine. None of the mothers whose children received the live polio vaccine developed COVID, whereas 28 mothers whose children did not receive the live polio vaccine did contract COVID within 9 months. Researchers know that polio-virus and even the weakened virus from the vaccine can be shed in the stool. The researchers surmise that the mothers were exposed to the virus when caring for their children through bathing and diaper changing.

“IT IS HEARTENING TO FIND SIMILAR STUDY RESULTS OBTAINED FROM VERY DIFFERENT APPROACHES STRENGTHENING OUR HYPOTHESIS THAT USING THE ORAL VACCINE MAY PROVIDE PROTECTION AGAINST SARS-CoV-2, THE VIRUS THAT CAUSES COVID,” said the first author on the studies Farrokh Habibzadeh, MD, Special Consultant on Public Health for the GVN and the
Taking a Stand

The Global Virus Network (GVN) is an apolitical global organization comprised of the world’s leading scientists, including those from Russia and Ukraine, who specialize in education and research for the purpose of protecting mankind from viral proliferation and viruses that cause pandemics. The scientists of the Global Virus Network collaborate to alleviate the pain and suffering caused by viral pathogens and to mitigate the threat they pose to mankind.

The members of the Global Virus Network are motivated by the fundamental tenet of medicine “to do no harm” and are dedicated to honoring the sanctity of life irrespective of culture, ethnicity, nationality or race. We are scientists, not politicians, but we are compelled to raise our voices in unison to protest the invasion and wanton destruction of Ukrainian cities and the savage killing of innocent civilians and members of the military who are defending their Homeland in the name of freedom and autonomy. They seek only peace. Mr. Putin, grant them peace. Mr. Putin, cease the armed hostilities immediately and enter into negotiations conducted in accord with respect for human life and dignity. We are committed to universal moral principles that govern the humane treatment of human beings and dictate the norms of civilized relations between nations. The current invaders of Ukraine are not exempted from the unequivocal adherence to these principles, for all members of humanity, “are not islands separate and apart, but part of the main.” Mr. Putin, stop the aggression now!

In the spirit of interconnectedness, we urge the combatants to cease hostilities and engage in negotiations to peacefully resolve their armed conflict. May this war in which the bitterest enmities have been invoked, be terminated with “malice toward none and justice for all.” May the sacrifices and suffering already endured be an impetus for peace, and may our common humanity provide the moral imperative by which the sanctity of life and human dignity take precedence over the bristling antagonisms which provided an incitement to force.

Let peace not be cast as a victory or defeat for either side, but as a triumph of morality arrived at by ethical individuals acting on behalf of their respective nations. When morality emerges as victorious, we can rest assured that mankind endures and prevails as the ultimate beneficiary.
Managing Director of the Research & Development Unit of the Petroleum Industry Health Organization of Shiraz, Iran. He added that, “This hypothesis should be tested in additional quality clinical trials, preferably conducted in countries where the oral polio vaccine is currently in use as part of their national immunization for polio.”

Co-author Kristen Stafford, PhD, MPH, Associate Professor of Epidemiology & Public Health, Division of Epidemiology & Prevention, and Deputy Director of the Center for International Health, Education, & Biosecurity (Ciheb) at UMSOM’s IHV, and member of the GVN, said, “Some high-income countries declare pandemics over when in fact they just transition to only affecting low-income countries. We do not want this pandemic to become like the HIV-epidemic, where years and years of delays led to millions of excess deaths because the antiretroviral medications were too limited in supply or expensive to reach those disproportionately affected. We need to find simpler, inexpensive solutions to protect people until they can get their full doses and boosters of the COVID vaccines.”

One of the limitations of the live, weakened vaccines, is that they are not recommended for people with suppressed immune systems, as it could lead to infection.

“The important observations that the oral polio vaccine may protect against different infections such as COVID-19 is crucial for future pandemic preparedness. Understanding the mechanisms of protection induced by the oral polio vaccine and other live attenuated vaccines can open the door for the development of improved vaccination strategies to protect against broader infections, and thus provide partial protection against new pathogens during a pandemic until specific vaccines can be developed,” said Mihai Netea, MD, PhD of the Department of Internal Medicine and Radboud Center for Infectious Diseases, Radboud University Medical Center, a GVN Center of Excellence, and GVN Center Director.

Additional authors on the studies include Mohammad Sajadi, MD, Professor of Medicine at the Institute of Human Virology at the University of Maryland School of Medicine and member of the GVN; Mahboobeh Yadollahie, MD, Ashraf Simi, BScN, Saeid Saeidimehr, MD, (JAMA Network Open only), Mohammad Rafiei, MD, (JAMA Network Open only), and Iman Hafizi-Rastani, MSc (PLOS One only) of the Petroleum Industry Health Organization of Iran.

The authors received no specific funding for this work. Dr. Kottilil received grants from Gilead for other research and serves on the advisory boards of Merck and Regeneron.

About the Global Virus Network (GVN)

The Global Virus Network (GVN) is essential and critical in the preparedness, defense and first research response to emerging, existing and unidentified viruses that pose a clear and present threat to public health, working in close coordination with established national and international institutions. It is a coalition comprised of eminent human and animal virologists from 69 Centers of Excellence and 11 Affiliates in 37 countries worldwide, working collaboratively to train the next generation, advance knowledge about how to identify and diagnose pandemic viruses, mitigate and control how such viruses spread and make us sick, as well as develop drugs, vaccines and treatments to combat them. No single institution in the world has expertise in all viral areas other than the GVN, which brings together the finest medical virologists to leverage their individual expertise and coalesce global teams of specialists on the scientific challenges, issues and problems posed by pandemic viruses. The GVN is a non-profit 501(c)(3) organization. For more information, please visit www.gvn.org. Follow us on Twitter @GlobalVirusNews.
NIH Awards Grant to train Global Health Scientists in Low- and Middle-Income Countries

This past March, researchers at the University of Maryland School of Medicine’s (UMSOM) received a $5.5 million award from the National Institute of Health’s Fogarty International Center to help foster the next generation of global health scientists. The award entitled, “Integrated Network of Scholars in Global Health Research Training (INSIGHT)” will expand global health research across sub-Saharan Africa, South Asia, Latin America, and the Caribbean by providing one-year mentored research training to U.S. and lower-middle income country scholars.

The INSIGHT grant was awarded to principal investigator Man Charurat, PhD, MHS, Professor of Medicine, Director of the Division of Epidemiology & Prevention in the Institute of Human Virology (IHV) at UMSOM and Global Director of the Center for International Health, Education, and Biosecurity (Ciheb), and multiple other principal investigators from University of Alabama, Baylor College of Medicine, and University of Pittsburgh. INSIGHT will include multidisciplinary research training in the areas of HIV, emerging and reemerging infectious diseases, noncommunicable diseases, and mental health across the lifespan using evidence-based research and practices, clinical science, laboratory science, and behavioral and social sciences. This research will take place across 24 institutions in 20 lower-middle income countries.

“When the enthusiasm of young scientists from the U.S. and lower-middle income country institutions and strong mentorship from seasoned scientists across the globe, we hope to contribute to the next generation of impactful and innovative global health researchers,” said Dr. Charurat.

The five-year grant will train 105 scholars as predoctoral or postdoctoral fellows. The trainees will spend most of the year at a location in a lower-middle income country. The trainee will have an onsite mentor, as well as one based in one of the U.S. partner institutions.

“The INSIGHT program hosted by the University of Maryland School of Medicine will help train the next generation of leaders in global health research—both US and foreign,” said Roger I. Glass, MD, PhD, Director, Fogarty International Center, NIH. “This grant will provide mentored fellowships to build strong research collaborations and future leaders who will accelerate the advance of biomedical research that will lead to real improvements in human health in all areas while also enhancing our biosecurity against the next pandemic.”

The INSIGHT Steering Committee and other subcommittees is comprised of UMSOM faculty including Miriam Laufer, MD, Professor of Pediatrics at the Center for Vaccine Development and Global Health and Associate Dean of Student Research and Education; Nadia Sam-Agudu, MD, Associate Professor of Pediatrics and Senior Technical Advisor of Pediatric HIV, Division of Epidemiology & Prevention at IHV; Alash’le Abimiku, PhD, Professor of Medicine, Division of Epidemiology & Prevention at IHV and Director of the International Research Center of Excellence IHV-Nigeria; Nicaise Ndemi, MSc, Phd, Adjunct Associate Professor of Medicine, Division of Epidemiology & Prevention at IHV; Patrick Dakum, MBBS, MPH, Associate Professor of Epidemiology & Public Health, Division of Epidemiology & Prevention at the IHV and CEO of IHV-Nigeria; Kristen Stafford, PhD, MPH, Associate Professor Epidemiology & Public Health, Division of Epidemiology & Prevention at IHV and Deputy Director of Ciheb; and Yolanda Ogbolu, PhD, CRNP, Associate Professor of Nursing, as well as and faculty from partner institutions. Their guidance will support recruitment and selection of the scholars to launch these emerging leaders into global health research.

“I am both pleased and proud that the University of Maryland School of Medicine will play such a valuable role in training the next generation of global health researchers,” said E. Albert Reece, MD, PhD, MBA, Executive Vice President for Medical Affairs, University of Maryland Baltimore, and the John Z. and Akiko K. Bowers Distinguished Professor and Dean at the University of Maryland School of Medicine. “The leadership, mentorship, and impact our faculty and institution will impart will leave a legacy of influence felt worldwide.”

For more information on INSIGHT or to apply, please visit the INSIGHT Fogarty Scholars webpage.

www.ihv.org
In January 2022, researchers at the University of Maryland School of Medicine (UMSOM)'s Institute of Human Virology (IHV) received funding from the National Institutes of Health’s National Institute of Allergy and Infectious Diseases (NIAID) for $2.7 million to study genetic changes in two genes from the HIV-1 virus that may make it resistant to antiretroviral therapy. The study, named INSPIRE, will analyze genetic variation in types of HIV circulating in a handful of African countries that will help to better understand the implications of these mutations and will improve clinical management of patients.

The HIV virus weakens the immune system when untreated, so the body cannot fight infections. Once a person tests positive for the virus, a health care provider prescribes an antiretroviral drug regimen that keeps the virus in check. However, if the patient does not tolerate the side effects, does not consistently take their medication, or if the virus no longer responds to the treatment, then the patient is switched to a second-line regimen with a different combination of drugs.

“Our study’s goal is to identify factors that predict when certain drugs found in the second-line regimens no longer suppress HIV infection and help guide third-line antiretroviral therapy strategies for resource-limited settings. This will be particularly important, as those people that do not respond to second-line regimens are at an increased risk for developing resistance to another drug in the third-line treatment regimen,”

said one of the study principle investigators Man Charurat, PhD, MHS, Professor of Medicine, Director of the Division of Epidemiology & Prevention, and Director of the Center for International Health, Education, and Biosecurity (Ciheb) in the IHV at UMSOM. Third-line drug regimens tend to be more expensive, have not been tested as extensively in children and pregnant women, so these medications are less conducive for use in lower income countries.

Along with Dr. Charurat, Nicaise Ndembí, McS, PhD, Adjunct Associate Professor of Medicine, Division of Epidemiology & Prevention in IHV at UMSOM, will serve as the other principal investigator on the study. Dr. Ndembí also serves as the Chief Science Advisor at the Africa Centers for Disease Control and Prevention (Africa CDC).

Based on earlier findings by Dr. Ndembí, the researchers hypothesized that genetic sequences in the HIV genes env and gag could contain compensatory mutations that could evade antiretroviral treatment.

“Our studies demonstrated the first instance of new Env mutations conferring resistance to dolutegravir naturally in human cell lines in the laboratory. Our findings likely mean that these kinds of mutations may already be occurring outside of the laboratory in patient populations,” said Dr. Ndembí.

Dolutegravir is a class of drug known as an integrase inhibitor that prevents HIV from inserting itself into a person’s DNA, which it needs to do in order to make more copies of itself.
“We attribute the decreased effectiveness of the drug to the ability of the Env mutants to mediate highly efficient cell-to-cell transmission, increasing the multiplicity of infection,” said Dr. Ndembi.

The env gene encodes the Env protein that helps HIV bind to and infect human cells. The thought is that new mutations could potentially make the Env protein more effective at doing its job binding and infecting, making the virus more infectious.

A class of drugs in the second-line regimen that HIV develops resistance to is known as the protease inhibitors. These drugs stop HIV proteases from working, which have the job of cutting other HIV proteins as a final step in their production. The researchers theorize that mutations in the gag gene may be what leads to the drug resistance. The gag gene encodes the Gag protein, which is snipped by the protein cutter protease. Exactly how the gene mutations select for drug resistance though, is unknown.

The study participants will be composed of people from the AFRICOS study, which is part of the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), and the PASER study. The AFRICOS study enrolled 4,200 people, including 3,500 with HIV from sites in Kenya, Nigeria, Tanzania, and Uganda. The PASER study enrolled just over 3,000 participants with HIV/AIDS with the goal of tracking treatment resistance in patients from sites in Kenya, Nigeria, South Africa, Uganda, Zambia and Zimbabwe.

Dr. Charurat and Dr. Ndembi will work alongside researchers from the Amsterdam Institute for Global Health and Development—Amsterdam (AIGHD), U.S. NIH’s National Cancer Institute, Stanford University, U.S. Military HIV Research Program (MHRP) via the Henry M. Jackson Foundation, and University of Cambridge—United Kingdom.

“Decades of research have provided life-saving treatment to a virus once thought of as a death sentence,” said E. Albert Reece, MD, PhD, MBA, Executive Vice President for Medical Affairs, University of Maryland Baltimore, and the John Z. and Akiko K. Bowers Distinguished Professor and Dean at UMSOM.

“It is essential that we ensure that this virus remains treatable by staying on top of HIV’s mutation rate and responding with new combinations of medications if necessary.”

Almost 38 million people around the world live with HIV with about 75% of these people managing the disease with antiretroviral therapy, according to the U.S. Department of Health and Human Services.
In January of this year, in a collaboration under AFREhealth (the African Forum for Research and Education in Health), a consortium of cross-disciplinary health personnel across Africa, a study was published that assessed clinical outcomes of children and adolescents hospitalized with COVID-19 in six African countries. Their findings, published in *JAMA Pediatrics*, showed that African children and adolescents hospitalized with COVID-19 experienced much higher mortality rates than Europeans or North Americans of the same age.

Researchers from the Institute of Human Virology (IHV) at the University of Maryland School of Medicine (UMSOM) and the Institute of Human Virology Nigeria (IHVN), both members of the Global Virus Network (GVN), co-led the study.

“This study provides important information about COVID-19 among African children, which was not previously available at this scale. We now have evidence from multiple countries to show that African children also experience severe COVID-19; they experience multisystem inflammatory syndrome; some require intensive care; some also die, and at much higher rates than outside Africa,” said Nadia Sam-Agudu, MD, Associate Professor of Pediatrics, Division of Epidemiology & Prevention, at UMSOM’s IHV, and Senior Technical Advisor for Pediatric and Adolescent HIV, IHVN. Dr. Sam-Agudu is a co-first author along with Principal Investigator Dr. Jean Nachega of the University of Pittsburgh and Stellenbosch University in Cape Town, South Africa.

The AFREhealth study collected data from 25 health facilities across Nigeria, Ghana, Democratic Republic of the Congo, Kenya, South Africa, and Uganda. The study included 469 African children and adolescents aged three months to 19 years hospitalized with COVID-19 between March and December 2020. The team reported a high overall mortality rate of 8.3%, compared with 1% or less totaled from Europe and North America. Furthermore, African children less than a year old and with pre-existing, non-communicable diseases were more likely to have poorer outcomes, such as requiring intensive care, and death.

Eighteen participants had suspected or confirmed multisystem inflammatory syndrome (also known as MIS-C), and four of these children died.

Dr. Sam-Agudu, who led the West Africa team for the study, urged health authorities and policymakers in Nigeria and other African countries to act upon the study findings “to protect children by expanding vaccine approvals and procurements for children specifically, as the variants emerging since our study’s completion have either caused more severe disease and/or more cases overall. We cannot leave children behind in the pandemic response.”

Dr. Sam-Agudu was recently awarded a 2022 Dr. Thomas Hall-Dr. Nelson Sewankambo Mid-Career Leadership Award from The Consortium of Universities for Global Health. The award acknowledges outstanding individuals for accomplishments and commitment to contributing to the advancement of global health worldwide.
According to Associate Professor of Epidemiology and Public Health, Division of Epidemiology & Prevention at UMSOM's IHV and IHVN Chief Executive Officer, Patrick Dakum, MBBS, MPH, “This data from Dr. Sam-Agudu and AFREhealth collaborators puts science from Nigeria and the rest of Africa squarely on the map for pandemic-responsive research, particularly for young populations. We will continually work towards contributing to research discoveries in Nigeria, West Africa and beyond,” he said.

Alash’le Abimiku, PhD, Professor of Medicine, Division of Epidemiology & Prevention at the UMSOM’s IHV, and Executive Director of the IHVN’s International Research Center of Excellence, also noted that, “The high impact pediatric COVID-19 findings of this collaborative research underscores the value of sustained investments in strong research institutions, collaborations, and leadership in Nigeria and across Africa. We can generate rigorous local data to guide local, regional, and international health policy and practice.”

The Director-General of the Nigeria Centre for Disease Control, Dr. Ifedayo Adetifa, remarked: “The AFREhealth study findings show that COVID-19 affects children and can cause severe consequences. Thus, we seriously need to factor children into age-disaggregated COVID-19 disease surveillance and reporting, and consider COVID-19 illness when they present to the hospital. Furthermore, the high in-hospital mortality rate reported indicates a need for investments in critical care for children in African settings. We need more of such rigorous multicenter studies to inform evidence-based policy-making in Nigeria and other African countries.”

Robert Gallo, MD, The Homer & Martha Gudelsky Distinguished Professor in Medicine, Co-Founder and Director of the UMSOM’s IHV, a GVN Center of Excellence, and Co-Founder and Chair of the Scientific Leadership Board of the GVN, said, “I am pleased to see our team of researchers continue to build upon the Institute’s eighteen years of work in African nations, particularly Nigeria, and successfully advance a study across varying nations to garner much needed data as this pandemic continues to evolve. Africa is the epicenter of many epidemics, and an important partner in researching viral threats. ‘Pan’ means all, and we must all work together to combat viral threats against mankind.”

Dean E. Albert Reece, MD, PhD, MBA, Executive Vice President for Medical Affairs, University of Maryland Baltimore, and the John Z. and Akiko K. Bowers Distinguished Professor at UMSOM, added: “Studies like this are essential to ensure that no one country or region is suffering any unneeded hardship. As a result, policy makers and world leaders can better allocate resources to those people and places who need them most.”

The research builds upon the presence of the UMSOM’s IHV International Program and the network of international experts who work with local stakeholders to combat infectious diseases across the globe.
An experimental drug initially designed by former Institute of Human Virology (IHV) faculty members and partially developed at IHV for potential use as a cancer immunotherapy agent or to prevent organ transplant rejection, turned out to be effective in treating severe COVID-19. The drug, CD24Fc, was shown to decrease time until clinical improvement in patients with COVID-19 receiving supplemental oxygen by a few days. So, how did this drug progress from the realm of cancer and organ transplant to treating SARS-CoV-2 infection?

When working at Children’s National Medical Center, former IHV faculty members Yang Liu, PhD, and Pan Zheng, MD, PhD, studied the cell surface protein CD24, which wears many hats in regulating the immune system with one of its functions being a suppressor of inflammation. Dr. Liu and Dr. Zheng hoped to exploit the function of CD24 to develop improved cancer immunotherapies—effective enough to kill cancer, but less likely to trigger a dangerous autoimmune response in the patient. The couple then created the experimental drug using the CD24 protein and combining it with the tail piece of antibodies, known as the Fc region. The Fc portion of the drug essentially helps stabilize CD24, so it stays in the body for weeks giving the drug more time to do its job. They established the company Oncoimmune, Inc., as a way to eventually bring the drug to market.

Early studies in animals and healthy volunteers showed that the drug reduced inflammation and “bad” cholesterol by stimulating a family of immune system regulatory molecules. Although it seemed to tamp down the inflammation, the drug did not seem to interfere with the body’s ability to fight viruses, which particularly piqued the interest of IHV’s expert virologists.

“HIV infection ramps up the immune system and even when controlled with antiretroviral medications, we see problems in our patients eventually in the form of end-organ disease, which can affect the kidneys, heart, and brain due to this residual immune activation caused by HIV,” said Shyam Kottilil, MBBS, PhD, Professor of Medicine, Director of the Division of Clinical Care and Research in the IHV at the University of Maryland School of Medicine, and senior advisor to the Global Virus Network (GVN). “We wanted to develop this drug to see if it would tone down the immune system and ultimately help stave off this end-organ disease in our long-term patients with HIV.”
Diagram showing how CD24Fc mimics/augments natural CD24 activity

Since that time, the researchers completed the phase III trial of CD24Fc and published the date in March of this year in *Lancet Infectious Diseases*. The findings included results from nine medical centers in the U.S. in 116 patients given the drug compared to 118 controls. The controls were allowed other COVID-19 treatments, including remdesivir and steroids. The trial results showed that CD24Fc shortened the time to clinical improvement as measured from an average of 6 days compared to ten-and-a-half days in those people only given the other standard drugs.

Clinical development of CD24Fc is currently under the leadership of Merck Inc, since they acquired the drug. Further research and development of Cd24Fc offers hope to manage a variety of infectious diseases, inflammatory conditions, and cancer therapeutics.

“The Institute recruited Drs. Yang Liu and Pan Zheng in 2018 to begin a new era of research on immunotherapy of cancers and inflammation. Their research focused on innate immune check points against tissue injuries, that is now being shown highly effective against COVID-19,”

said Robert C. Gallo, MD, The Homer & Martha Gudelsky Distinguished Professor, Co-founder & Director at the Institute of Human Virology, University of Maryland School of Medicine and Co-Founder of the Global Virus Network (GVN) and Chairman of GVN's International Scientific Leadership Board.

“This novel breakthrough is a prime example of the importance of designing mechanism-based translational research to develop therapies to battle the current COVID-19 pandemic. I also recognize the IHV immunotherapy and clinical teams for this accomplishment.”
Myron Cohen, MD
University of North Carolina at Chapel Hill

Dr. Cohen received his BS degree, Magna Cum Laude, from the University of Illinois, Champaign-Urbana in 1971. He received an MD degree from Rush Medical College, Chicago, Illinois. He completed training in internal medicine at the University of Michigan, and training in infectious diseases at Yale University. After working in 1979 in the People’s Republic of China on hemorrhagic fever with nephrosis nephritis, Dr. Cohen joined the faculty of the University of North Carolina in 1980. He rose to the rank of Professor over ten years and served as the Director of the Division of Infectious Diseases from 1991 until 2019. He founded the UNC Institute for Global Health and Infectious Diseases in 2007. Dr. Cohen has served as Co-PI of the NIH HIV Prevention Trials Network, since 2012 and as one of the founders and leaders of the NIH COVID Prevention Network in 2020. Dr. Cohen is the Yeargan-Bate Eminent Professor of Medicine, Microbiology and Immunology, and Epidemiology at the University of North Carolina at Chapel Hill.

For three decades, Dr. Cohen’s research has focused on the transmission and prevention of transmission of viral pathogens. Since the onset of the COVID-19 pandemic, Dr. Cohen has worked on vaccines and monoclonal antibodies for prevention of COVID-19 as a leader of the NIH COVID-19 Prevention Network. He is the author of more than 600 publications and one book.

Dr. Cohen is a Fellow of the American Society for Microbiology, the American College of Physicians, and the Infectious Disease Society of America. He is a member of the National Academy of Medicine, the American Society for Clinical Investigation, and the American Association of Physicians.

Henry Masur, MD
Clinical Center, NIH

Dr. Masur has been the Chief of Critical Care Medicine at the National Institutes of Health since 1989, focusing on building a multidisciplinary department with a strong emphasis in infection prevention and management. He is a leader in infectious diseases, serving as President of Infectious Disease Society and as Associate Editor of Critical Care Medicine.

In 2007, he started the District of Columbia Partnership for AIDS Progress (DC PFAP) with Dr. Carl Dieffenbach and Dr. Anthony Fauci, as a program that is transforming Washington’s ability to reduce the impact of HIV on this city. The program is now focusing on another important HIV morbidity, opioid use disorder. The program has received over $20 million in funding commitments from NIH Office of AIDS Research and the NIH HEAL initiative (Helping End Addiction Long Term).

He is also the Co-Chair of the NIH COVID-19 Guideline Panel with Dr. Clifford Lane and Dr. Roy Gulick. Dr. Masur received the 2018 IHV Lifetime Achievement Award for Excellence in Medical Education, Clinical Care, and Clinical Research.
Kenneth Sherman, MD, PhD
University of Cincinnati College of Medicine

Dr. Sherman received his BS and PhD in Microbiology from Rutgers University and his MD from George Washington University. He is a University of Cincinnati Distinguished Research Professor and holds an endowed chair as the Robert & Helen Gould Professor of Medicine. Dr. Sherman has served as the Director/Chief of the Division of Digestive Diseases at the University of Cincinnati College of Medicine since 2003.

Dr. Sherman’s research interests center around viral hepatitis, and the immunopathogenesis, evaluation, and treatment of liver disease in those living with HIV infection. Dr. Sherman is the author of over 300 peer-reviewed articles, abstracts, and book chapters.

He has held numerous leadership positions including service as the Chair of the American Gastroenterological Association’s Liver and Biliary Section and is a former member and acting Chair of the FDA Antiviral Advisory Committee. He has previously led the NIAID/ACTG Hepatitis Transformative Research Group. He has formally mentored over 50 students, trainees, and junior faculty.
RIISING to the Occasion in Caring for Our Most Marginalized Community Members

Through the years the University of Maryland School of Medicine’s Institute of Human Virology (IHV) has strived to improve the health of the local community. One of those initiatives entails reaching out to the most marginalized members of the community that typically slip through the healthcare cracks, such as people who inject drugs, sex workers, transgender individuals, people who are homeless, and others. Many of these people are at risk of getting or need treatment for infectious diseases, such as HIV, hepatitis C, sexually transmitted infections, or blood or heart valve infections.

Through the Research Initiative on Infectious Diseases and Substance Use (RIIS) program (pronounced “rise”), investigators provide clinical care and conduct clinical research in partnership with community-based organizations and clinical sites accessing these at-risk populations. Through their clinical collaborations in Washington, D.C. and Baltimore and a mobile van on the Eastern Shore, the RIIS team members provide on-site treatment for infectious diseases such as hepatitis C (HCV), HIV treatment and prevention, as well as medications for opioid use disorder (OUD), and gender affirming hormone therapy, while conducting clinical research aimed at understanding and improving how care is delivered for these populations. These clinical and research interventions occur in sites where patients can also receive harm reduction services such as a needle and syringe exchange, and can engage with providers who lend a non-judgmental, sympathetic ear.

“First, we have to embed ourselves in the community, establish a strong relationship as a culturally competent partner with other community-based organizations, and assess the unmet needs of the people in that community,” said Sarah Kattakuzhy, MD, Associate Professor of Medicine, Baltimore RIIS Director, Division of Clinical Care & Research at IHV in the University of Maryland School of Medicine (UMSOM).

“These needs are ones that we would not understand without seeing first-hand their requirements, and without earning our patients’ trust.”

Elana Rosenthal, MD, Assistant Professor of Medicine, Washington D.C. RIIS Director, Division of Clinical Care & Research at IHV in UMSOM, added,

“We want to provide clinical care and eventually do research, but there is a whole process to get both the care and the research off the ground. It’s only once we have this foundation that we can grow our clinical services and eventually we can open the door to research. People do not have an obligation to participate in our research to receive care or treatment, and there is never any coercion.”

Through implementation research, they determine gaps in care, then come up with effective care delivery methods, enact them, and evaluate these methods compared to baseline standards of care.

RIIS’ Roots

The RIIS program is the offshoot of a program that originated in 2008 from an intramural National Institutes of Health (NIH) program in coalition with the George Washington School of Public Health, and the District of Columbia Department of Health known as DC PFAP (DC Partnership for HIV/AIDS Progress). The initiative was spurred by data from the DC Department of Health which demonstrated a 3% HIV prevalence in D.C. Led by Henry Masur, MD, of the NIH, the community program initially focused on HIV treatment and prevention, but over time evolved to encompass other needs of the community such as hepatitis C treatment, substance use treatment, and more. Dr. Masur also received IHV’s 2018 Lifetime Achievement Award for Excellence in Medical Education, Clinical Care, and Clinical Research.

continued on page 15
In 2014 the leader of the program’s research arm, Shyam Kottilil, MBBS, PhD, Professor of Medicine, Director of the Division of Clinical Care & Research at IHV in UMSOM, left the NIH to join the IHV. Dr. Kottilil wanted to bring a similar program to Baltimore given the history of economic struggles, opioid use disorder, and high prevalence of sexually transmitted infections within the community. He also wanted to better integrate IHV’s research footprint with the needs of the community we serve, complementing other IHV’s other programs, such as the Jacques Initiative and THRIVE.

He recruited Dr. Kattakuzhy and Rachel Silk, RN, MPH, now Director of Clinical Research Operations, Division of Clinical Care & Research, from the National Institutes of Health (NIH) and Dr. Rosenthal from Beth Israel Deaconess Medical Center in Boston shortly thereafter. Now they have 12 members on the team serving the community by focusing on treatment and prevention of infectious diseases and co-occurring conditions such as substance use disorder.

Making a Difference

RIIS has adapted to changing needs of the community. For example, in 2020 during the pandemic, many of the community members lost access to care as doctor’s offices closed. People were having difficulty getting their HIV medication and transgender individuals lost access to gender affirming hormone therapy. RIIS responded by providing low barrier care for the people who had lost access to their routine care.

Alongside the expansion of clinical care for transgender patients, the RIIS team also implemented a study aimed at understanding barriers to care and risk behaviors for transgender individuals. In addition, in collaboration with researchers at the IHV, the team is conducting assessments aimed at understanding the impact of gender affirming hormone therapy on inflammation, cardiovascular health, and immune system activation. This data collection allows RIIS investigators to understand unmet needs of their community members.

continued on page 16
Another unmet need among transgender individuals is early screening for anal cancer. People who engage in anal receptive intercourse can be at higher risk for human papilloma virus (HPV) and anal cancer. Just like the gynecologist performs a PAP smear test on the cervix to look for abnormal cells potentially indicating early cervical cancer risk, anal PAPs can identify abnormal cells. If abnormal cells are detected, then early interventions can help to decrease progression to anal cancer. The RIIS team is partnering with collaborators at the NIH to better understand HPV persistence and progression, and abnormal anal PAPs in transgender individuals.

Dr. Kattakuzhy and Dr. Rosenthal realized that many new training physicians do not get enough medical education on the diagnosis and treatment of opioid use disorder.

“It just is not prioritized in medical education,” said Dr. Kattakuzhy. “Most of what I learned about methadone and buprenorphine, the medications used to treat the disorder, I learned on the job and from patients. The University of Maryland School of Medicine’s Department of Psychiatry has an excellent Division of Addiction and Treatment, but we needed educational interventions for trainees in internal medicine and primary care.”

Both RIIS leaders now contribute to medical education in seminars, lectures, workshops to educate trainees about medications for opioid use disorder, the pathophysiology of addiction, and many of the other co-occurring conditions.

“The trainees have the impression that it is somehow harder to treat someone with addiction, but we teach them if you can treat diabetes, you can treat people with addiction,” said Dr. Rosenthal.

Alongside Shiva Narayanan, MBBS, MD, Assistant Professor of Medicine, Division of Clinical Care & Research at IHV, they recently created a track for second year fellows to train in addictions and infectious disease that gives trainees the opportunity to come to the clinic and work with medications. They have two fellows this year, one working on opioid use disorder and the other on LGBTQ health.

Another unmet need that the team is addressing is the continuum of care for patients hospitalized from infections due to injection of opioids. Many of these patients receive inadequate addictions interventions and are not connected to outpatient addiction treatment, and ultimately end up in and out of the hospital with complications. The team is devising interventions and standards of care to help manage and treat these patients and prevent more infections.

“Conducting community-based care and research in a setting that does not represent a traditional healthcare setting can be challenging, but rewarding,” said Dr. Rosenthal. “We do not have the setting or the resources of a traditional clinic, but if we do not give our patients their care on-site then the care may not happen. We have to figure out how to make things work on the fly.”

Dr. Kattakuzhy added, “We are committed to expanding the work, and growing our footprint in the community.”
IHV’s Experts Performed Pathogen Surveillance for Unprecedented Pig-to-Human Heart Transplant

On January 7, the University of Maryland Medical Center (UMMC) performed a successful transplant of a genetically-modified pig heart into a patient with terminal heart disease. The University of Maryland School of Medicine (UMSOM)’s Institute of Human Virology (IHV), a Global Virus Network (GVN) Center of Excellence, physician researchers played a collaborative role in the transplant by creating pathogen surveillance strategies and developing an infection prevention strategy for this unprecedented significant medical advancement.

“Infectious disease complications are always a concern in the field of organ transplantation, whether it is infections related to the recipient or the donor, which in this case remarkably happens to be a pig,” said Kapil Saharia, MD, MPH, Assistant Professor of Medicine, Division of Clinical Care & Research, in the IHV at the UMSOM and Chief of Solid Organ Transplant Infectious Diseases Service at UMMC.

“We are excited to work synergistically on this first-of-its-kind transplant through innovating the laboratory assays and protocols which allow for the surveillance of potential pig donor-derived infections.”

To decrease the risk of infection, the donor pig was raised in a facility using methods designed to prevent potential pathogens from infecting donor animals. The healthy donor pig used for the xenotransplant was screened for pathogens multiple times. It was tested just before shipment to Maryland, and just before the transplant a few days later. The testing followed protocols that were accepted by the U.S. Food and Drug Administration (FDA). Although all pigs are known to have the porcine endogenous retrovirus, researchers had not detected any transmission to humans or to non-human primates in earlier studies.

Procedures that transfer tissue or organs from one kind of animal to another are known as xenotransplants. The Cardiac Xenotransplantation Program at UMSOM, led by Bartley Griffith, MD, the Thomas E. and Alice Marie Hales Distinguished Professor in Transplant Surgery at UMSOM, and Muhammad M. Mohiuddin, MD, Professor of Surgery at UMSOM, tapped into the world-renowned Institute to preemptively minimize any possible risk of potential infection.

“The quality of IHV support for our experimental surgery has enabled us greatly,” said Dr. Griffith. “Our pre-op preparation and post-op monitoring for pathogens has been a pathway of discovery and meaningful treatment.”

The patient died two months after receiving the transplant. The cause of death is still being studied. Among these potential causes was the patient’s advanced state of heart failure before the transplant. Dr. Griffith also noted that they found evidence of a virus called porcine cytomegalovirus (pCMV) through highly sensitive special testing.

“There is no evidence so far that the virus caused an infection in the patient or caused disease in the porcine donor heart,” said Dr. Mohuiddin. “That said, as plans move forward for future clinical trials, more sophisticated testing techniques are being developed and validated to ensure this virus does not go undetected.”

Robert C. Gallo, MD, The Homer & Martha Gudelsky Distinguished Professor in Medicine and Co-Founder and Director at the Institute of Human Virology at UMSOM, and GVN Co-Founder and Chair of the Scientific Leadership Board said, “Almost four years ago, the xenotransplant group came to us at the Institute of Human Virology for our expertise, particularly related to human
retroviruses not unlike the one in pigs.” Dr. Gallo is world renowned for his discovery of the first human retroviruses.

Researchers at IHV developed an in-house PCR test that was used to screen for porcine endogenous retrovirus in the organ recipient. The test is also being used for surveillance of healthcare workers involved in the care of the xenotransplant recipient for possible exposure to this retrovirus. Researchers at IHV are now developing an in-house PCR test to perform surveillance for porcine cytomegalovirus in healthcare workers given this virus was unexpectedly identified in the organ recipient.

As a prerequisite of FDA emergency authorization, the team put together a hospital infection prevention plan for the University of Maryland Medical Center. The physicians designing the program included Dr. Saharia, Anthony Harris, MD, MPH, Professor of Epidemiology & Public Health and Division Head of Health Care Outcomes Research at the UMSOM; Surbhi Leekha, MBBS, MPH, Associate Professor Epidemiology & Public Health at UMSOM and Medical Director of Infection Prevention and Hospital Epidemiology at UMMC; and Michelle Harris Williams, Director of Infection Prevention at UMMC.

“We are pleased to be part of a team led by Drs. Mohiuddin and Griffith for the past several years. This is certainly an important milestone in the history of organ transplantation,” said Shyam Kottilil, MBBS, PhD, Professor of Medicine, Director of the Division of Infectious Diseases in the Department of Medicine, and Director of the Division of Clinical Care and Research at IHV at UMSOM and a Senior Scientific Advisor at the GVN. “We will continue to work hand-in-hand with the team to ensure safety and enhance clinical outcomes in the future.”

Anthony Amoroso, MD, Professor of Medicine, Associate Chief of Infectious Diseases, Chief of Clinical Care Programs, and Associate Director of the Division of Clinical Care & Research for IHV at UMSOM, said,

“This is very exciting that we are able to work collaboratively to support a pioneering accomplishment of Drs. Griffith and Muhammad that is moving xenotransplantation into the clinical arena.”

Dr. Gallo added, “I want to congratulate my colleagues at the Department of Surgery, its leader, Dr. Christine Lau, and others who contributed to this successful transplantation. Further, in particular, I commend our Institute’s team of Drs. Saharia, Kottilil, and Amoroso and their colleagues, on their steadfast commitment to support this important program and their ongoing contribution in this unprecedented infectious disease control and detection program particularly in the face of an immune-suppressed challenging clinical environment.”

The infection prevention plan used disposable equipment when possible and stringent protocols for disinfection. Additionally, healthcare workers were instructed to use enhanced contact precautions when caring for the patient, which included wearing gloves, gowns, and appropriate hand hygiene, as well as face masks and eye protection due to the ongoing COVID-19 pandemic. To further reduce risk, patient samples were hand delivered to the lab and handled in a manner similar to other highly infectious agents.
Knowing the Origins of COVID-19 Won’t Change Much

Editorial written by Robert C. Gallo and Dean T. Jamison originally published by TIME on Feb 23, 2022. Dr. Gallo is Homer & Martha Gudelsky Distinguished Professor in Medicine and Professor in Microbiology and Immunology, Co-Founder & Director, Institute of Human Virology at the University of Maryland School of Medicine, Baltimore, and Co-founder and International Scientific Director, Global Virus Network, Baltimore. Dr. Jamison is Edward A. Clarkson Professor, Emeritus, Department of Epidemiology and Biostatistics and Institute for Global Health Sciences, University of California, San Francisco.

Over two years since the first cases started appearing in Wuhan, China, there is much we don’t know about the origins of SARS-CoV-2, the virus causing COVID-19. But a quick resolution to that question is possible: scientists could find bats in a cave somewhere in China or in southeast Asia and trace a chain leading from those bats to the COVID-19 outbreak in Wuhan. Realistically, however, recent history offers little promise for this to happen quickly. For example, about 14 years elapsed between the identification of HIV as the virus that causes AIDS and a demonstration of its modern transition to humans from a specific group of chimpanzees, although this had been suspected some years earlier. About a decade passed from the time of the 2003-4 epidemic of SARS and definitive delineation of the origin of its causal coronavirus, and seven years passed before the 2009-10 influenza pandemic was shown to have originated in Mexican swine. The alternative possibility to a natural origin—a laboratory leak—will be difficult to definitively prove or disprove.

More importantly, focusing on origins begs a question were there really major health policy or research directional changes for previous pandemics when the origins were determined? Take HIV for instance: we learned the chimp to man transmission occurred in rain forests, but we did not interrupt visits or human life in rain forests. We learned HIV likely came to cities because of population movements and increased prostitution, and then became global by changes such as frequent travel by large numbers, increased sexual contacts, blood and plasma medical use, and IV drug addiction. Needless to say, public policy changed little. SARS origin was learned but we now have SARS-CoV-2. The great influenza pandemic may have originated in WW I army barracks, but we moved on to WW II and did not stop soldiers being in barracks. In short, knowing origins made little difference in how we treated and dealt with the disease—in most if not all cases.

Yet the World Health Organization (and much of the scientific community) initially agreed with the Trump Administration’s claim that understanding the origin of SARS-CoV-2 was of vital immediate importance. The administration’s concern was, plausibly, less a matter of dispassionate interest in science but more an effort to open a new front in the U.S. response to a rising China, or an effort to divert attention from a delayed and chaotic U.S. response to the pandemic. Those who advocate for an intensive effort to discover the origins of SARS-CoV-2 assert there would be value in terms of establishing public or public health policy based on that understanding. Just what should be done differently to counter Delta or, now, Omicron by understanding the origin of SARS-CoV-2 better? Knowing origins could bring closure to the ongoing politically charged debate and contribute importantly to scientific understanding. We doubt, however, that knowledge of origins would change anything about how we should respond to the challenges of SARS-CoV-2, or how we would prepare for a future pandemic. We can act now on the assumption that either hypothesis (nature or laboratory leak) could be correct.

Here is where the origins discussion now stands: One idea is that there was a natural origin; bat to man directly or through an intermediary animal. The other is that the cause was research error. Scientists studying bats in the field could have become infected themselves or have brought infected bats back to the laboratory. Then by accidental release the virus spread. It is also possible that “gain-of-function” research could have created SARS-CoV-2, followed by its accidental release. Early expression of support for the gain-of-function hypothesis concerned CGG, one of the codons specifying the amino acid arginine for its insertion into the virus’s newly forming spike protein thereby enabling a human protease (furin) to more efficiently cut the coronavirus spike protein which can facilitate infection. Nobel Laureate David Baltimore has expressed the view that CGG coding for arginine was so exceptional it would be suggestive of man-made origins, but this proves unconvincing. Other coronaviruses, such as ones causing the common cold, do have the CGG codon for arginine, albeit only a limited number in the so-called beta subgroup to which SARS-CoV-2 belongs.

continued on page 20
President Biden gave agencies of the U.S. intelligence community (IC) 90 days to assess the likelihood of natural causes versus research error, and they reported their findings in late August. While one agency concluded that research error was more likely, four other agencies concluded that likelihood lay with natural causes, and the summary conclusion of the National Intelligence Council (NIC) likewise favored the natural origins hypothesis although both the individual agencies and the NIC placed only low to moderate confidence in their conclusions. The declassified version of the IC report also pointed to the Chinese government’s “...frustration [that] the international community is using the issue to exert political pressure on China...” as a reason why further Chinese cooperation in establishing origins remains unlikely. While research error remains a possibility, we doubt that a definitive answer will be soon coming. That said, evidence increasingly accumulates in favor of the natural origins hypothesis, and earlier assessments that pointed toward a laboratory leak, like the furin hypothesis discussed above, have weakened with scrutiny.

We return to the question of how much it really matters. We know how to respond to each scenario for origin. There is a very limited number of directions to take, and prudence dictates that each should be taken.

Disease surveillance. Increased investment in disease surveillance at the human-wildlife interface, and in interrupting potential pathways of spillover of viral infection from animal to human are clearly priorities. Even if SARS-Cov-2 originated from research error this remains true.

Research safety. Safety expectations for laboratory research on dangerous pathogens should be enhanced. We have ample evidence in past decades of accidental releases from laboratories in all parts of the world. Safety protocols for field research and specimen management should also be reviewed and strengthened. Better standards of training should be defined in order to work with a given kind of pathogenic virus, accompanied by some form of accreditation. Research funding should more carefully weigh the (often important) knowledge to be gained against the residual risk of studying dangerous microbes.

Gain-of-function research. To most virologists this phrase as currently used indicates research that seeks to determine whether certain genetic changes deliberately made in the laboratory with a virus can lead to enhanced capacity of the virus to infect cells. In the case of human coronaviruses, it means greater capacity to infect human cells. The goal is to try to learn how to be better prepared in developing protection against such viruses that may develop these changes in nature and possibly cause a serious human epidemic or pandemic. No doubt this goal is a worthy one as it would give the medical community advance knowledge for diagnostics, vaccines and therapy if such a virus did emerge. Again, we must weigh risk versus benefit. Virologists are well aware that escape of viruses from research laboratories can happen. In each such experiment the risk to reward estimate must be made. Gain of function research is now reviewed by established virologists with these points in mind, yet we must admit that the involved scientists are generally tempted to go forward confident of their ability and confident that they have adequate control of the laboratory situation. Most scientists will want to push forward. If reviews are positive such research is more than likely to be funded by NIH, and their reviews are not very transparent. We might take a page from the molecular biologists and their meetings held in Asilomar, Ca. where detailed discussions occurred on the ethics and potential hazards of some kinds of gene cloning experiments. These discussions led to guidelines of the acceptable and unacceptable. One idea we feel has merit is to include non-specialists, including even nonscientists, as part of the review process to provide added independent oversight on the funding of the research.

There is much scientific interest in understanding the origins of SARS-CoV-2. And, let’s be honest, it would be nice to know. At the same time knowing origins may add little to what we already know in terms of addressing Delta, Omicron and whatever might come next. The best way forward may be to minimize the distraction of a politicized attempt to assess origins while, instead, investing in long-term international collaborative endeavors on SARS-CoV-2 and in preparation for future epidemics and pandemics.
Faculty News

Awards

John Baddley, MD, MSPH, Professor of Medicine, Division of Clinical Care & Research, was named as Interim Co-Editor-in-Chief of the journal Open Forum of Infectious Diseases as of July 1, 2022. He previously served as an OFID associate editor.

Robert Gallo, MD, The Homer & Martha Gudelsky Distinguished Professor in Medicine, Co-founder & Director of IHV, Co-founder & Chair of the Scientific Leadership Board of the Global Virus Network, was awarded the IRVA Basic Science Award 2022 by the International Retrovirology Association on May 10, 2022. Dr. Gallo was also awarded the Distinguished Alumni Award by the University of Chicago Medical & Biological Sciences Alumni Association (UChicago MBSAA) for his lifetime achievements. Honorees participated in a panel discussion on May 10 and were presented the award on May 21 at the Hyde Parke campus.

Mohammad Sajadi, MD, Professor of Medicine, Division of Clinical Care & Research, was elected to the American Society for Clinical Investigation (ASCI), one of the U.S.'s oldest and respected nonprofit medical honor societies that focuses on supporting research efforts, medical education, and clinical practice in their members to improve the health of all people. Dr. Sajadi is one of 95 new members that were inducted into the Society at the ASCI Dinner and New Member Induction Ceremony during their annual meeting on April 8.

Nadia Sam-Agudu, MD, Associate Professor of Pediatrics, Division of Epidemiology & Prevention, was awarded a 2022 Dr. Thomas Hall-Dr. Nelson Sewankambo Mid-Career Leadership Award from The Consortium of Universities for Global Health in January 2022. The award acknowledges outstanding individuals for accomplishments and commitment to contributing to the advancement of global health worldwide.
Faculty News (continued)

Grants

Niel Constantine, PhD, Professor of Pathology, Division of Epidemiology & Prevention, has been awarded $203,760 for 9 months from Family Health International 360 for the USAID Global Health Supply Chain Quality Assurance Program. This award, an extension from a previous 3-year award, supports the continuation of Dr. Constantine’s work to evaluate HIV, hepatitis, syphilis, cryptococcus, and other rapid test kits sent from international locations and manufacturers to determine if their performance characteristics meet manufacturers’ claims. Technical Assistance activities are provided also.

Mingyue Liu, PhD, Research Associate of Pharmacology, Division of Immunotherapy, was awarded a two-year, $200,000 contract with OncoC4—a privately held, clinical-stage biopharmaceutical company. OncoC4 is actively engaged in the discovery and development of novel biologicals for cancer treatment. Dr. Liu will be performing acute toxicity analysis and immunotherapeutic effects of ONC-841 and two other clinical products provided by OncoC4.

Peter Memiah, DrPH, MSc, Associate Professor of Medicine, Division of Epidemiology & Prevention and the Center for International Health Education and Biosecurity, through LVCT Health Kenya were awarded $100,000 for a one-year project funded by Grand Challenges Canada. The funding is to addressing gender-based violence among adolescents and other vulnerable populations in project AGILE for Accelerating access to Gender-based violence Information and services Leveraging on technology Enhanced chat bot in Kenya.

Keynotes

Robert Gallo, MD, The Homer & Martha Gudelsky Distinguished Professor in Medicine; Co-founder & Director, Institute of Human Virology at the University of Maryland School of Medicine; Co-founder & Chair of the Scientific Leadership Board, Global Virus Network, presented “Lessons and Ideas from the Two Recent Pandemics-HIV/AIDS and SARS-CoV-2/COVID-19- and How We Can and Must Do Better” on Tuesday, December 14. The talk was sponsored by the Centre for Global Development and University College Cork (Ireland) Research Staff Association.

Dr. Gallo will present “HIV: Past and Present” on Thursday, June 23 at 1:30pm–3:30pm EST to the Royal College of Physicians of Edinburgh (RCPE) USA: Updates in Public Health and Clinical Medicine. Dr. Anthony Fauci and Dr. Katherine Baicker will also be speaking on the panel.
Robert Gallo, MD, The Homer & Martha Gudelsky Distinguished Professor in Medicine, Co-Founder and Director of the Institute Human Virology at the University of Maryland School of Medicine and Co-Founder and Chair of the Scientific Leadership Board of the Global Virus Network, was awarded the Distinguished Alumni Award by the University of Chicago Medical & Biological Sciences Alumni Association (UChicago MBSAA) for his lifetime achievements. Honorees participated in a panel discussion on May 10 and were presented the award on May 21 at the Hyde Park campus.

“Being at the University of Chicago was a great inspiration for me by being so surrounded by excellence and by mentors who delighted in helping the beginning physician-scientist,” said Robert C. Gallo, MD, ’65. “I will never forget those days which deeply impacted my entire career. Obviously, I am honored and grateful to receive this recognition.”

“The University of Chicago uniquely nurtured scientific discovery in Dr. Gallo’s training in the practice of medicine,” said I. David Goldman, MD, ’62, Susan Fischer Chair, Albert Einstein College of Medicine and Director Emeritus, Albert Einstein Cancer Center. “This was followed by the National Cancer Institute’s recognition of the extraordinary talent and passion of a young physician-scientist providing Dr. Gallo with the freedom and resources to go on to make seminal discoveries on the biology of retroviruses and human T-cells that culminated in unraveling the causation of human T-cell leukemia and AIDS.” Dr. Goldman is a former resident of the University of Chicago.

“The UChicago MBSAA takes great pride in recognizing our alumni who, through their work, have made significant contributions to the biological sciences and medicine,” said Mark R. Aschliman, MD, ’80, Chair, Alumni Awards Committee.

Dean E. Albert Reece, MD, PhD, MBA, Executive Vice President for Medical Affairs, University of Maryland Baltimore, and the John Z. and Akiko K. Bowers Distinguished Professor at the University of Maryland School of Medicine, said, “My sincerest congratulations to Dr. Robert Gallo for receiving this prestigious award from
one of our most preeminent academic medical institutions. Dr. Gallo is a world-renowned scientist whose breakthrough discoveries and scholarly contributions have made major contributions to global health for more than four decades. He is a visionary investigator who has unlocked many important mysteries of human viruses and diseases. He embodies all of the attributes of what it means to be a great scientist. We have been fortunate to have him as one of our most distinguished members of the University of Maryland School of Medicine faculty for many years. He has led our Institute of Human Virology, which has been transformative in its work to eradicate chronic and deadly viral and immune disorders. He is most deserving of this honor from the University of Chicago Medical Alumni Association.”

Dr. Gallo graduated from Thomas Jefferson University School of Medicine before completing his medical training at the University of Chicago. After 30 years at the National Cancer Institute at the National Institutes of Health in Bethesda, Maryland, he became the co-founder of the Institute of Human Virology and the founding director and The Homer & Martha Gudelsky Distinguished Professor of Medicine and Microbiology and Immunology at the University of Maryland School of Medicine. In 2011, Dr. Gallo became the Co-Founder and Chair of the Scientific Leadership Board to the Global Virus Network.

Dr. Gallo’s career interests have focused on studying the basic biology of human blood cells, their normal and abnormal growth, and the involvement of viruses in these abnormalities.

Dr. Gallo and his co-workers pioneered human retrovirology, discovering the first human retrovirus (HTLV-1) and, along with others, showing it was a cause of a particular form of human leukemia. A year later, he and his group discovered the second known human retrovirus (HTLV-2). Dr. Gallo and his colleagues independently discovered HIV and provided the first results to show it was the cause of AIDS. They also developed a lifesaving HIV blood test. In 1986, he and his co-workers discovered the first new human herpes in more than 25 years, Human Herpes Virus-6 (HHV-6). Previously in 1978, Gallo discovered a variant of gibbon ape leukemia virus—Hall’s Island strain—which causes T-cell leukemia.

Dr. Gallo and his co-workers discovered Interleukin-2 in 1976, thus setting the stage for all groups to culture human T-cells. Gallo and his co-workers spent years developing detailed biochemical and immunological characteristics of human cellular DNA polymerases alpha, beta, and gamma and reverse transcriptase (RT) from several retroviruses to use RT as a sensitive and specific surrogate marker for retroviruses.

In 1995 he and his colleagues discovered the first natural (endogenous) inhibitors of HIV, which led to the discovery of the HIV co-receptor, CCR5, and opened new approaches to treatment. Currently, Dr. Gallo and his team have been working on a HIV preventive vaccine candidate.

Dr. Gallo has received 35 honorary doctorates from universities around the world. He was the most cited scientist from 1980 to 1990 and was ranked third in the world for scientific impact from 1983 to 2002, publishing nearly 1,300 papers.

Dr. Gallo is a member of the National Academy of Sciences and the National Academy of Medicine and has received several international prizes, including the U.S. Albert Lasker Award twice.
Alash’le Abimiku, PhD, Professor of Medicine, Kristen Stafford, MPH, PhD, Deputy Director of Center for International Health, Education, & Biosecurity (Ciheb), Associate Professor of Epidemiology and Public Health, both of the Division of Epidemiology & Public Health, and other authors published “Validation of xMAP SARS-CoV-2 Multi-Antigen IgG assay in Nigeria” in PLoS One in Apr 2022, DOI: 10.1371/journal.pone.0266184

Carla Alexander, MD, Director of Palliative Care for IHV Clinical Programs, Clinical Assistant Professor of Medicine, Division of Clinical Care & Research, and other authors published “Young Same-Gender-Loving Men (SGLM) Living with HIV Continue to Experience Symptoms that May Impair Their Retention in Care” in Journal of Health Care for the Poor and Underserved in Feb 2022, DOI: 10.1353/hpu.2022.0029

Natarajan Ayithan, PhD, Research Associate of Medicine, Alip Ghosh, PhD, MSc, Research Associate of Medicine, Shyam Kottilil, MBBS, PhD, Director of the Division of Clinical Care & Research, Professor of Medicine, all of the Division of Clinical Care & Research, and other authors published “Oral Selective TLR8 Agonist Selgantolimod Induces Multiple Immune Cell Responses in Humans” in Viruses in Nov 2022, DOI: 10.3390/v13122400

John Baddley, MD, MSPH, Professor of Medicine, Division of Clinical Care & Research, and other authors published “Coronavirus Disease 2019-Associated Invasive Fungal Infection” in Open Forum of Infectious Diseases in Nov 2021, DOI: 10.1093/ofid/ofab510

John Baddley, MD, MSPH, Professor of Medicine, Division of Clinical Care & Research, and other authors published “Deep dissection of the antiviral immune profile of patients with COVID-19” in Communications Biology in Dec 2021, DOI: 10.1001/jama.2021.24939

John Baddley, MD, MSPH, Professor of Medicine, Joel Chua, MD, Assistant Professor of Medicine, Shyam Kottilil, MBBS, PhD, Director of the Division of Clinical Care & Research, Professor of Medicine, Jennifer Husson, MD, MPH, Director of the Clinical Research Unit, Assistant Professor of Medicine, Shivakumar Narayanan, MBBS, MD, Director of Hepatitis Research, Assistant Professor of Medicine, all of the Division of Clinical Care & Research, as part of the Trial Investigators published “REGEN-COV Antibody Combination and Outcomes in Outpatients with COVID-19” in New England Journal of Medicine in Dec 2021, DOI: 10.1056/NEJMoa2108163

John Baddley, MD, MSPH, Professor of Medicine, Division of Clinical Care & Research, published “Coronavirus Disease 2019-associated Pulmonary Aspergillosis: Do We Have the CAPAcity to Improve Outcomes?” in Clinical Infectious Diseases in Jan 2022, DOI: 10.1093/cid/ciab259

John Baddley, MD, MSPH, Professor of Medicine, Division of Clinical Care & Research, and other authors published “Impaired immune response to COVID-19 vaccination in patients with B-cell malignancies after CD19 CAR T-cell therapy” in Blood Advances in Jan 2022, DOI: 10.1182/bloodadvances.2021006112

John Baddley, MD, MSPH, Professor of Medicine, Division of Clinical Care & Research, as part of the HIV-COVID-19 Consortium published “Clinical outcomes after IL-6 blockade in patients with COVID-19 and HIV: a case series” in AIDS Research and Therapy in Feb 2022, DOI: 10.1186/s12981-022-00430-x

John Baddley, MD, MSPH, Professor of Medicine, Joel Chua, MD, Assistant Professor of Medicine, Shyam Kottilil, MBBS, PhD, Director of the Division of Clinical Care & Research, Professor of Medicine, Jennifer Husson, MD, MPH, Director of the Clinical Research Unit, Assistant Professor of Medicine, Shivakumar Narayanan, MBBS, MD, Director of Hepatitis Research, Assistant Professor of Medicine, and Uzoamaka Eke, MBBS, Assistant Professor of Medicine, all of the Division of Clinical Care & Research, as part of the COVID-19 Phase 3 Prevention Trial Team published “Effect of Subcutaneous Casirivimab and Imdevimab Antibody Combination vs Placebo on Development of Symptomatic COVID-19 in Early Asymptomatic SARS-CoV-2 Infection: A Randomized Clinical Trial” in JAMA in Feb 2022, DOI: 10.1001/jama.2021.24939

John Baddley, MD, MSPH, Professor of Medicine, Joel Chua, MD, Assistant Professor of Medicine, Shivakumar Narayanan, MBBS, MD, Director of Hepatitis Research, Assistant Professor of Medicine, all of the Division of Clinical Care & Research, and other authors published “Coronavirus Disease 2019-Associated Mucormycosis: Risk Factors and Mechanisms of Disease” in Clinical Infectious Diseases in Apr 2022, DOI: 10.1093/cid/ciab726

John Baddley, MD, MSPH, Professor of Medicine, Kapil Saharia, MD, MPH, Assistant Professor of Medicine, both of the Division of Clinical Care & Research, and other authors published “Clinical characteristics of COVID-19 in solid organ transplant recipients following COVID-19 vaccination: A multicenter case series” in Transplant Infectious Disease in April 2022, DOI: 10.1111/tid.13774

John Baddley, MD, MSPH, Professor of Medicine, Kapil Saharia, MD, MPH, Assistant Professor of Medicine, Jennifer Husson, MD, MPH, Director of the Clinical Research Unit, Assistant Professor of Medicine, all of the Division of Clinical Care & Research, and other authors published “Humoral immunity against SARS-CoV-2 variants including omicron in solid organ transplant recipients after three doses of a COVID-19 mRNA vaccine” in Clinical & Translational Immunology in Apr 2022, DOI: 10.1002/cti2.1391

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Shashwatee Bagchi, MD, Assistant Professor of Medicine, Jennifer Husson, MD, MPH, Director of the Clinical Research Unit, Assistant Professor of Medicine, Joel Chua, MD, Assistant Professor of Medicine, all of the Division of Clinical Care & Research, and other authors published “Assessment of coronary inflammation in antiretroviral treated people with HIV infection and active HIV/hepatitis C virus co-infection” in *AIDS* in Mar 2022, DOI: 10.1097/QAD.0000000000003125

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Man Charurat, PhD, MHS, Director of the Division of Epidemiology & Prevention, Director of Ciheb, Professor of Medicine, Patrick Dakum, MBBS, MPH, Associate Professor of Epidemiology and Public Health, Division of Epidemiology and Prevention, Nicaise Ndemb, PhD, Adjunct Associate Professor of Medicine, Division of Epidemiology and Prevention, and other authors published “Deep sequencing of HIV-1 reveals extensive subtype variation and drug resistance after failure of first-line antiretroviral regimens in Nigeria” in *Journal of Antimicrobial Chemotherapy* in Feb 2022, DOI: 10.1093/jac/dkab385

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Joel Chua, MD, Assistant Professor of Medicine, Division of Clinical Care & Research, Shyam Kottili, MBBS, PhD, Director of the Division of Clinical Care & Research, Professor of Medicine, and other authors published “Efficacy and safety of CD24Fc in hospitalised patients with COVID-19: a randomised, double-blind, placebo-controlled, phase 3 study” in *Lancet Infectious Diseases* in May 2022, DOI: 10.1016/S1473-3099(22)00058-5

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Peter Memiah, DrPH, MSc, Associate Professor, Medicine, Director of Continuous Quality Improvement in Ciheb, Division of Epidemiology & Prevention, and other authors published “Correlates of intimate partner violence among adolescents in East Africa: a multi-country analysis” in *Pan African Medical Journal* in Nov 2021, DOI: 10.11604/pamj.2021.40.142.23311

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Peter Memiah, DrPH, MSc, Associate Professor, Medicine, Director of Continuous Quality Improvement in Ciheb, Division of Epidemiology & Prevention, and other authors published “Voices from the Youth in Kenya Addressing Mental Health Gaps and Recommendations” in *International Journal of Environmental Research and Public Health* in Apr 2022, DOI: 10.3390/ijerph19095366

Devang Patel, MD, Associate Professor of Medicine, Paul Saleeb, MD, Assistant Professor of Medicine, both of the Division of Clinical Care & Research, and other authors published “Subacute Polymicrobial Bacterial Pericarditis Mimicking Tuberculous Pericarditis: A Case Report” in *American Journal of Case Reports* in Nov 2021, DOI: 10.12659/AJCR.933684

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Patrick Ryscavage, MD, Associate Professor of Medicine, Division of Clinical Care & Research, Kristen Stafford, MPH, PhD, Deputy Director of Ciheb, Associate Professor of Epidemiology and Public Health, Division of Epidemiology & Public Health, 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 May 2022, DOI: 10.1111/hiv.13199

Kapil Saharia, MD, MPH, Assistant Professor of Medicine, Division of Clinical Care & Research, as part of the ACTIV-3/Therapeutics for Inpatients with COVID-19 (TICO) Study Group and other authors published “Efficacy and safety of two neutralising monoclonal antibody therapies, sotrovimab and BRII-196 plus BRII-198, for adults hospitalised with COVID-19 (TICO): a randomised controlled trial” in Lancet Infectious Diseases in May 2022, DOI: 10.1016/S1473-3099(21)00751-9

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Nadia Sam-Agudu, MD, Senior Technical Advisor of Pediatric HIV, Associate Professor of Pediatrics, Division of Epidemiology and Prevention, and other authors published “Global Tuberculosis Report 2020 - Reflections on the Global TB burden, treatment and prevention efforts” in International Journal of Infectious Diseases in Dec 2021, DOI: 10.1016/j.ijid.2021.02.107

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Sarah Schmalzle, MD, Medical Director of the THRIVE program, Assistant Professor of Medicine, Division of Clinical Care & Research, Kristen Stafford, MPH, PhD, Deputy Director of Ciheb, Associate Professor of Epidemiology and Public Health, Division of Epidemiology & Public Health, and other authors published “People aging with HIV - protecting a population vulnerable to effects of COVID-19 and its control measures” in AIDS Care in Dec 2021, DOI: 10.1080/09540121.2021.2020208

Sarah Schmalzle, MD, Medical Director of the THRIVE program, Assistant Professor of Medicine, Division of Clinical Care & Research, and other authors published “Legionnaires’ disease presenting with exanthem; Case and review of previously published cases” in IDCases in Jan 2022, DOI: 10.1016/j.idcr.2022.e01376

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Kristen Stafford, MPH, PhD, Deputy Director of Ciheb, Associate Professor of Epidemiology and Public Health, Division of Epidemiology & Public Health, and other authors published “Enhanced mindfulness-based stress reduction in episodic migraine-effects on sleep quality, anxiety, stress, and depression: a secondary analysis of a randomized clinical trial” in Pain in Mar 2022, DOI: 10.1097/j.pain.0000000000002372

Lishan Su, PhD, The Charles Gordon Smith Professor for HIV Research, Director of the Division of Virology, Pathogenesis, and Cancer (VPC), Interim Director, Division of Immunotherapy, Professor of Pharmacology, and other authors published “Site-Specific Chemoenzymatic Conjugation of High-Affinity M6P Glycan Ligands to Antibodies for Targeted Protein Degradation” in ACS Chemical Biology in Mar 2022, DOI: 10.1021/acschembio.1c00751

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TOGETHER AGAIN: Baltimore’s LBGTQ+ Community is Thriving!

Monday, June 27 • 11:00 am – 2:00 pm
800 Linden Avenue, Baltimore MD, 21201

Join us as we celebrate Lesbian, Bisexual, Gay, Transgender and Queer Pride Month (LGBTQ+ Pride Month) to honor our LGBTQ+ workforce, patients and community members.

Talk by Dr. Harfouch on the Sexual Health of the LGBTQ+ Community

DJ Jack

Ice Cream, Health Information & Giveaways

FREE HIV testing and health screenings available at the Community Health Education Center (CHEC).

This event is in partnership with Gilead, ViiV Healthcare, and the Coalition of Baltimore HIV Providers.

Please note that while this event is primarily outside, masks will be required when entering the hospital.

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