

# INNOVATIONS

OCTOBER 2019

# The Gene Therapy Moment

New Technologies, New Hope for a Cure

## Also Inside:

amfAR Second Largest Funder of HIV Cure Research Worldwide

A Global Response to HIV Requires the Global Fund

NIH Awards Research Training Grant to TREAT Asia—Columbia University Collaboration



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#### OCTOBER 2019

The biannual newsletter of amfAR, The Foundation for AIDS Research

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Photo: Evan Rummel

# **Quantity and Quality**

It was deeply gratifying to read in a report released this summer that amfAR is the second largest funder of HIV cure research in the world—second only to the U.S. National Institutes of Health (NIH). And we are the leading funder of HIV cure research among philanthropic organizations (see page 11). But what's truly important is the quality and value of our investments.

At the Conference on Cell and Gene Therapy for HIV Cure in August, amfAR's support was acknowledged by 25 percent of the presenting researchers. And last year, research supported by amfAR resulted in a record 80 papers published in peer-reviewed scientific journals. These numbers validate a grant-making strategy that relies on rigorous screening of all research proposals, and are a testament to the quality of our researchers, our reviewers, and the science in which we invest.

In the pages of this newsletter, you will read about some of the research made possible by our investments—and your generous support. You will also read about our important work in the advocacy arena—much of which is the result of original research conducted by our Public Policy Office in Washington, D.C. Their invaluable efforts are helping to advance the evidence-based policies necessary for ending the HIV epidemic in the U.S. and around the world.

The strength and importance of our TREAT Asia program, launched nearly 20 years ago to counter the threat of HIV/ AIDS in the Asia-Pacific region, is evidenced by a new partnership with Columbia University supported by a five-year grant from the NIH (see page 13). Mental health is an often neglected aspect of HIV and with this new initiative, we are excited to be taking the lead on integrating HIV, mental health, and implementation science research in Asia.

Collectively, all of our work is about improving lives—the lives of people living with and affected by HIV and all who are vulnerable to infection. As always, we couldn't do what we do without the generous support of our donors in the U.S. and around the world, and you have our grateful appreciation.

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# The Future of the HIV Response

In a report released at the International Conference on HIV Science (see page 7) in July, amfAR, AVAC, and Friends of the Global Fight Against AIDS, Tuberculosis and Malaria demonstrated how dramatic reductions in HIV incidence and mortality have been accomplished in six very different settings: Thailand; Malawi; Rakai, Uganda; New South Wales, Australia; London, England; and San Francisco.

The report provides a graph for each location, illustrating declining HIV rates and deaths, as well as policy decisions that drove advances against the epidemic. The report also maps out the future, showing how the required policy and structural and research advances can propel dramatic progress.

"This report highlights the reality that progress toward ending HIV shouldn't be limited by geography or demographics," said Greg Millett, Vice President and Director of Public Policy at amfAR. "It also highlights how much easier we can achieve our goal by continuing to invest in scientific research, as well as policies that promote human rights."

Common contributors to lowering HIV incidence and mortality across the six locations include:



- Campaigns to encourage HIV testing, particularly among groups that are most vulnerable to infection
- Free and easy access to treatment at the time of diagnosis with HIV
- Scale-up of evidence-based HIV prevention, such as voluntary medical male circumcision,
- pre-exposure prophylaxis (PrEP), and harm reduction
- Concerted efforts to provide human rightsbased services and social supports alongside programs to fight stigma and discrimination

"There is nothing easy about achieving epidemic control, but in Malawi, a country with

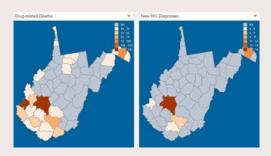
few resources, we have found that innovation and early adoption of new guidelines is key to rapid scale-up of treatment and prevention," said Maureen Luba, Africa Regional Advocacy Advisor for AVAC. "With 91% of people who are aware of their status on HIV treatment, Malawi is beginning to show progress on the way to ending the epidemic."

The six locations profiled in the report were selected based on their progress in response to the epidemic and the availability of data and information about local policy interventions. The report's authors also aimed to assess a mix of types of epidemics—some among key populations and others impacting broader populations.

To read the full report, visit endaids.org

## The Power of Data

A leader in data-driven advocacy, amfAR's Public Policy Office has developed three user-friendly free online databases for policy-makers, advocates, journalists, and researchers, in addition to its new *Ending the HIV Epidemic* database (see page 6).



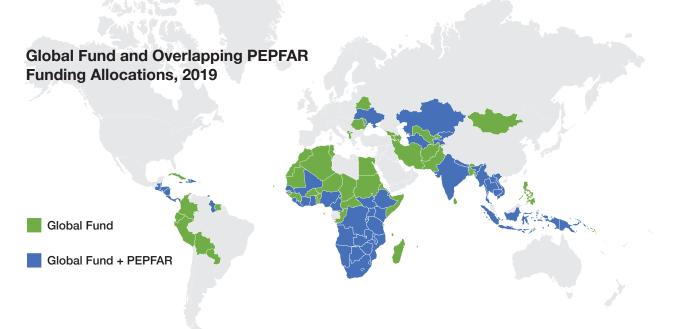
Explore the **PEPFAR Monitoring, Evaluation, and Reporting (MER) Database** to chart the crucial impact of PEPFAR and the current state of the HIV/AIDS epidemic. **mer.amfar.org**.

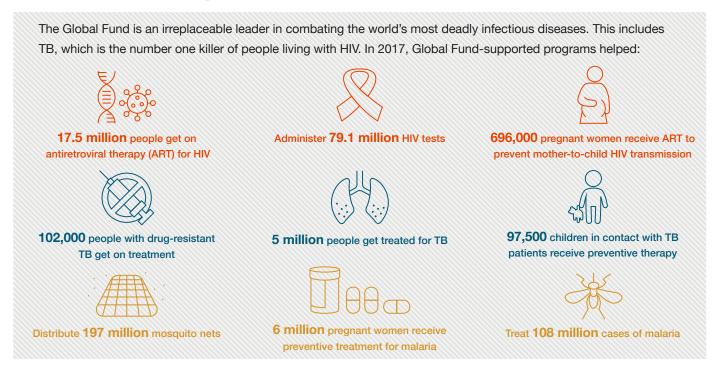
Track the opioid epidemic and its intersection with HIV and Hepatitis C using the **Opioid & Health Indicators Database**. Maps from the database have been used in congressional briefings and local news broadcasts and featured in the *New York Times*. **opioid.amfar.org**.

The **PEPFAR Country/Regional Operational Plans (COPs/ROPs) Database** highlights planned PEPFAR funding by program area, country, and organization for each year that has been publicly released. This tool is particularly useful to researchers, civil society organizations, and officials in ministries of health and finance. **copsdata.amfar.org**.

# A Global Response to HIV Requires the Global Fund

The Global Fund to Fight AIDS, Tuberculosis and Malaria is among the world's largest and most effective investors in global infectious disease eradication. In 2017, the Global Fund mobilized nearly \$4 billion to support life-saving initiatives to fight HIV, tuberculosis (TB) and malaria in 104 countries. In addition to complimentary work with the President's Emergency Plan for AIDS Relief (PEPFAR) to deliver quality HIV programs, the Global Fund operates programs in 51 additional countries, with a total population of 1.2 billion people.





The majority of international investments in TB and malaria programs come from the Global Fund.

# Title X Rule May Hinder Plan to End HIV Epidemic

Planned Parenthood announced it would withdraw from the Title X federal family planning program in response to a Trump administration rule that prohibits Title X recipients from providing abortions or referring clients for

abortion services. The organization, which has been in the program since its inception in 1970 and serves 40 percent of all Title X patients, has said it refuses to deny its patients the highest standard of reproductive care and full medical information.

Shortly before the final rule was published, the administration also proposed a plan to end the domestic HIV epidemic. Under the plan, resources will be deployed to jurisdictions with the highest HIV burden in an effort to reduce new infections to less than 3,000 yearly by 2030. A major obstacle to achieving this goal is reaching people at highest risk of acquiring HIV who are underserved by a U.S. healthcare system marked by vast disparities.

Given these disparities—in healthcare access and quality—in addition to issues such as poverty and stigma, a service provider such as Planned Parenthood that provides critical services affordably is an essential part of the

"Budget cuts to Planned Parenthood health centers may force reductions in client load and service delivery, or site closures."

HIV response. The organization administers about 740,000 HIV tests annually and provides the effective preventive medication PrEP—a key component of the administration's plan to end the epidemic. Budget constraints due to the loss of federal funding jeopardize these services.

Planned Parenthood is widely seen as a safe and affirming care provider of reproductive health

services, and often is the primary or the only source of a woman's healthcare. Women often report free or low-cost services and respectful staff as reasons for visiting Planned Parenthood health centers. A 2012 analysis showed that 20

percent of all women who had received an HIV test, and were living below the poverty line, did so at a Title X-supported clinic.

"While it is too early to project the full impact of Planned Parenthood's withdrawal from Title X, we

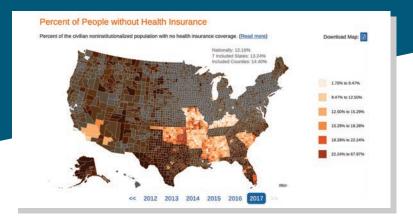
know that the landscape of sexual and reproductive health service delivery in the U.S will change," amfAR Policy Associate Jennifer Sherwood wrote in *The Advocate*. "Budget cuts to Planned Parenthood health centers may force reductions in client load and service delivery, or site closures."

Read amfAR's detailed analysis at www.amfar.org/IB-Title-X/

# Ending the HIV Epidemic Database

President Trump's plan to end new HIV transmissions in the U.S. by 2030 focuses on "geographic hotspots" where the epidemic is concentrated.

amfAR's *Ending the HIV Epidemic* (EHE) Database is an interactive visual tool that helps quantify service availability and infectious disease information for each locality under the plan.



- Spotlight sites across indicators
- Monitor trends
- Track policy and services



Explore the database at **ehe.amfar.org** 

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# **Cell and Gene Therapy Among Highlights at IAS Conference on HIV Science**

In July, amfAR-funded researchers presented the latest cure research studies and strategies at the International AIDS Society Conference on HIV Science in Mexico City. For example, Dr. Paula Cannon of the University of Southern California gave a plenary talk on stem cell and gene editing—techniques that could play an important role in the development of a cure (see cover story).



At a symposium co-chaired by Drs. Sharon Lewin of the University of Melbourne (pictured above), and Eileen Scully of Johns Hopkins University, Annemarie Wensing of the University Medical Center Utrecht spoke on HIV cure by stem cell transplantation. Dr. Wensing is co-principal investigator of amfAR's ICISTEM research consortium, which reported the case of the London patient, who shows no signs of HIV after a stem cell transplant.

Dr. Jonathan Karn of Case Western Reserve University presented research demonstrating that postmenopausal women's HIV reservoirs are more like men's in their ability to be reactivated out of latency. His earlier work had shown that premenopausal women's reservoirs were harder to reactivate than men's, and that this difference was due to estrogen.

Other findings reported at the conference include:

Sexually transmitted infections and reproductive health. Building on the recently completed ECHO study showing extremely high rates of HIV and other sexually transmitted infections (STIs) among young women in sub-Saharan Africa, new data revealed more detailed information about vulnerability to HIV and STIs in women and girls.

Dolutegravir and birth defects. Recent studies have shown lower risk of neural tube defects than was previously reported in babies born to women taking the integrase inhibitor dolutegravir. Findings from the study helped inform updated WHO guidance on antiretroviral treatment including dolutegravir.

Improving and simplifying treatment. In three trials (GEMINI 1 and 2 and TANGO), the two-drug regimen of dolutegravir and lamivudine (3TC) has been shown to be as effective as the three-drug combination of dolutegravir, tenofovir, and emtricitabine, both among treatment-naïve patients and among patients switching regimens after achieving viral suppression.

#amfAR's Dr. Rowena Johnston talks about the latest #HIV cure research with Phill Wilson (@blackaids) and Paula Cannon (@PaulaUSC) on Ep. 2 of #IAS2019's In The Studio: https://bit.ly/2Z6f9De



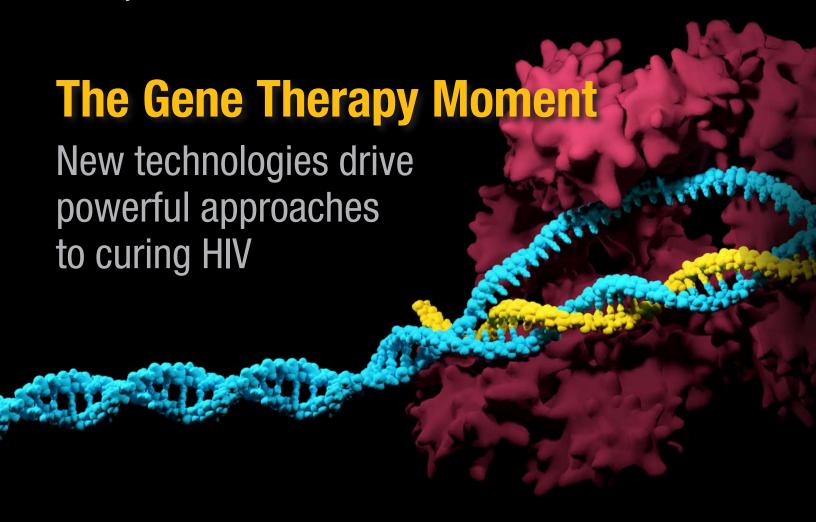


Vaccine research. Ongoing vaccine trials, including a new phase III vaccine efficacy trial, Mosaico, are renewing hope for the development of an effective HIV vaccine. amfAR grantee Dr. Dan Barouch of Harvard Medical School was among the scientists at the conference presenting research on "mosaic" vaccines, which incorporate genetic material from different strains of HIV found around the world.

**Making prevention easier**. Encouraging prevention studies are under way, including the first human trial of an implant designed to provide HIV pre-exposure prophylaxis (PrEP) for one year.



Dr. Jonathan Karn



The appeal of gene therapy lies in the ability of researchers to conceive—and engineer—any kind of cell type and function they want. For example, rather than repeatedly dosing drugs or immunotherapy, they might engineer cells in the body to keep producing the therapy, lifelong if necessary. Or rather than trying to coax an immune system already damaged by HIV into making strong and effective responses against the virus, they could perhaps engineer cells directly to have the desired antiviral function.

It is this ability to go beyond the constraints of biology that appealed to amfAR when we funded ARCHE-GT, a consortium of gene therapy researchers, beginning in 2017. The researchers are using a combination intervention aimed at curing HIV by 1) inducing CAR stem cells to kill HIV reservoir cells; 2) expressing antibodies to neutralize virions (virus that exists outside cells) in the blood and tissues, and; 3) using the geneediting tool Brec1 to remove the provirus (virus integrated into a cell's DNA) from infected cells.

"All three cases-Berlin, London, and Düsseldorf-share a characteristic that could hold the key to a cure."

#### A landmark year

It has been a landmark year for cell and gene therapy approaches to HIV cure research. In March, researchers affiliated with amfAR's ICISTEM consortium presented two new cases of remission—and possible cure—in patients with HIV and cancer who had received a stem cell transplant: "The London patient" had been undetectable for 18 months after stopping antiretroviral therapy and "the Düsseldorf patient" for five months. Both patients continue to show no sign of HIV.

amfAR established and funded the ICISTEM research consortium in 2012 in an effort to replicate Timothy Ray Brown's ("the Berlin

patient") cure, announced in 2009, and to understand its underlying mechanisms. ICISTEM has since developed the largest cohort of patients with cancer and HIV—like Mr. Brown—who have received or will receive stem cell transplants.

All three cases—Berlin, London, and Düsseldorf—share a characteristic that could hold the key to a cure. Each received donor cells with a genetic mutation causing a deletion of CCR5, the co-receptor, or doorway, that enables most types of HIV to enter and infect cells.

Gene therapy took center stage at the IAS Conference on HIV Science in Mexico City in July when amfAR-funded researcher Dr.

Paula Cannon of the University of Southern California delivered a plenary talk on "Stem Cell and Genome Editing for HIV Cure." Dr. Cannon outlined studies and clinical trials using gene-editing technologies to target the CCR5 co-receptor.

Also at the IAS conference, Drs. Cannon and Rowena Johnston, Vice President and Director of Research at amfAR, were interviewed on the topic of promising cell and gene therapy approaches to HIV cure for the conference's morning broadcast, "In the Studio." The discussion was led by amfAR Trustee and founder of the Black AIDS Institute Phill Wilson.

#### Powerful new technologies

In a study published in July, Dr. Howard Gendelman, of the University of Nebraska Medical Center, and Dr. Kamel Khalili, of the School of Medicine at Temple University, achieved partial success in curing mice. The researchers delivered a potent one-two punch using LASER ART—a slow-release, long-acting nanomedicine able to penetrate deep into tissues—to expose and extinguish hidden viral reservoirs, and CRISPR-Cas9, a powerful gene-editing tool, to excise HIV DNA from infected cells.

Dr. Cannon and another team of researchers, whose study was published in August, took a different approach. The researchers—from the

"In the study, the duoCAR T cells eliminated the virus from five of six mice." University of Pittsburgh, the biotech company Lentigen, and Albert Einstein College of Medicine—built on a highly effective cancer treatment using CAR T cells. The cells are engineered with surface proteins called chimeric antigen receptors that can target HIV-infected cells. The research team developed potent new "duoCAR T cells" that wield two pincer-like proteins simultaneously targeting separate parts of the HIV gp120 surface protein. In the study, the duoCAR T cells eliminated the virus from five of six mice.

amfAR designed ARCHE-GT to address this issue by requiring that the gene therapy intervention be deliverable in vivo, in other words directly by injection. In vivo delivery bypasses the expensive and complex laboratory procedures typical of gene therapy that contribute greatly to its cost. Recently, amfAR awarded a new grant to Dr. Keith Jerome, of the University of Washington, to compare 11 vectors and identify the most efficient one for delivering gene-editing tools to specific tissues (see page 10).



Drs. Rowena Johnston
(left) and Paula Cannon
discussed the latest in
cell and gene therapy
approaches to curing HIV
at the IAS Conference on
HIV Science

#### The challenge of gene therapy

There is some skepticism among HIV scientists and others that gene therapy could ever be deployed against HIV in low- and middle-income countries. After all, the gene therapy most recently approved by the FDA, to treat spinal muscular atrophy, costs more than \$2 million. Stem cell therapy is costly, risky, and only applicable to individuals with both cancer and HIV—a very small percentage of people living with HIV. While the three cases to date demonstrate the potential role of gene therapy in curing HIV and the central importance of CCR5, more practical approaches are clearly needed.

The idea of in vivo gene therapy delivery was the theme of a full-day of program at the Cell and Gene Therapy conference in Seattle in August. The program explored a range of technologies that could achieve the goal of delivering gene therapy tools to the right cells in the right areas of the body to achieve the desired outcome.

"We've always known that curing HIV will be incredibly difficult, and we need to study, refine, and perfect every tool we can bring to bear," said Dr. Johnston. "The challenges of delivering gene therapy are real and complex, but they are being addressed and I'm confident we'll overcome them."

# New amfAR Grants Advance HIV Cure and Post-Treatment Control Studies

Awards totaling \$1.16 million support 'Trojan horse' approach to curing HIV and effort to unlock the secrets of post-treatment control

Through the amfAR Research Consortium on HIV Eradication (ARCHE), a grant program that fosters collaboration among teams of scientists, in August amfAR awarded new grants totaling \$1.16 million to advance a pair of innovative research studies attacking HIV from very different angles.

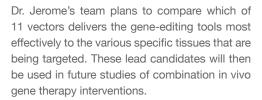
"Discovering what leads to post-treatment control in some people could help to achieve durable ART-free control in all people living with HIV."

Keith Jerome, Ph.D., of the University of Washington, Seattle, was awarded \$344,000 for a project that aims to advance a gene therapy strategy for curing HIV. Gene therapy is emerging as one of the most promising interventions across all of biomedical science, including HIV, but it carries a number of risks and challenges. Scientists need to find ways to improve the

Dr. Keith Jerome

efficiency of appropriately altering DNA, effectively target the correct cells, and enable the therapy to safely persist long enough to have an effect.

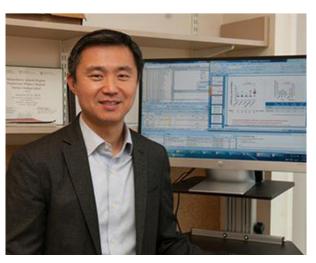
Moreover, a substantial limitation of current approaches is their cost in the clinic, which can be as much as \$2 million or more. amfAR's ARCHE-GT consortium plans to reduce costs by developing in vivo gene therapy in which the genengineering tools are injected directly into the patient. These tools are delivered inside vectors, which function as 'Trojan horses.'



Another area of HIV research in which amfAR is particularly interested is post-treatment control. Post-treatment controllers (PTCs) are HIV-positive individuals who, unlike the majority of people living with HIV, are able to control

their virus after stopping antiretroviral therapy (ART). But discovering the mechanisms of this control has proven difficult since the rarity of PTCs has so far precluded analysis of a sufficient number of samples.

amfAR's ARCHE-PTC collaboration consists of the world's leading experts in PTC research and brings together clinical cohorts of PTCs from all over the world, including an all-female cohort from Cameroon, under one streamlined analysis plan. Dr.



Dr. Jonathan Li

Jonathan Li of Brigham and Women's Hospital in Boston has assembled an impressive cohort of post-treatment controllers from one of the largest HIV clinical trial networks in the world.

Supported by an amfAR grant of \$815,000, Dr. Li and his team will gather and analyze samples from this multinational PTC cohort and will be able to employ cutting-edge tools to investigate whether characteristics of the virus or immunologic responses can predict post-treatment control. Discovering what leads to post-treatment control in some people could help to achieve durable ART-free control in all people living with HIV.

"We're excited to be supporting these immensely talented research teams and their very different but very promising avenues of investigation," said Dr. Rowena Johnston, amfAR Vice President and Director of Research. "These research areas have enormous potential for giving us the tools to control the virus without the need for lifelong treatment or, in the case of gene therapy, to eliminate it altogether. Either outcome could dramatically alter the lives of the millions of people living with HIV worldwide."

# amfAR Second Largest Funder of HIV Cure Research Worldwide

Modest global HIV cure funding increases sustained in 2018

amfAR has been named the second largest HIV cure research funder in the world—second only to the U.S. National Institutes of Health. Released at the 10th IAS Conference on HIV Science in Mexico City, Global Investment in HIV Cure Research and Development in 2018 shows total global investments continuing to steadily increase.

The report—compiled by the Cure Resource Tracking Group, a collaboration between AVAC and the International AIDS Society—estimates global investments in HIV cure research of \$323.9 million in 2018, a 12 percent increase over the \$288.8 million invested in 2017. Compared to the \$88.1 million invested since tracking began in 2012, this is a 268 percent increase.

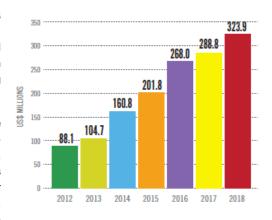
The public sector accounted for the majority of funding, with the remaining \$19.7 million invested by philanthropies. amfAR accounted

for more than half of all philanthropic investment, with \$10.9 million in funding last year.

"amfAR is proud to be recognized for its commitment to HIV cure research," said Dr. Rowena Johnston, amfAR Vice President and Director of Research. "We remain steadfast in our pursuit of the most innovative and promising paths toward a cure."

"The inclusion of 'cure' in the global response should not direct funding away from treatment, prevention and care programmes, or from biomedical research on HIV and its consequences, including vaccine and other prevention research," noted the report's authors. "However, it is imperative that donors, governments and the AIDS community make a viable and sustained economic investment in HIV cure research."

# Total Global HIV Cure Research Investment, 2012-2018 (US\$ millions)



Read the full report at www.avac.org/resource/global-investment-hiv-cure-research-and-development-2018.

# A Biomarker for the "Active" HIV Reservoir?

By Marcella Flores, M.P.H., Ph.D.

HIV persists in a small number of infected cells—the viral reservoir—that are not cleared from the body by antiretroviral therapy. A major goal of HIV cure research is to identify a molecule, or biomarker, that distinguishes reservoir cells from healthy cells. Having such a biomarker would allow researchers to target these reservoir cells and clear them with precision.

#### **The Research Question**

In 2017, a team of researchers in France reported that they had found a potential biomarker of the reservoir in the blood—a protein called CD32. In their attempts to replicate the discovery, several

other research teams found that CD32 may be a marker of HIV activity in blood cells rather than a specific marker of the latent reservoir. Scientists in this study asked: Could CD32 be a biomarker of HIV activity in the tissues, too?

#### **Findings**

Scientists examined gut biopsies from four study participants whose medication had reduced the HIV in their blood to undetectable levels. First, researchers noted that despite having undetectable virus in the blood, about four in every 100,000 cells in the tissue had jump-started activity of the provirus, meaning they had begun

the first steps towards producing new viruses. These "actively" infected cells may be the first to re-seed viral infection in the blood if antiretroviral therapy is stopped.

Next, the researchers explored whether CD32—the possible biomarker—was present in the actively infected cells, and to what degree. Using two separate techniques, the researchers found that those with undetectable virus in the blood had 100 times fewer actively infected cells in the tissue than those with detectable virus in the blood (viremia). But by one assay, between 60 and 100 percent of actively infected cells had CD32, compared to only 20 percent in those with viremia.

#### Impact

This study confirms the conclusion of other researchers that CD32 may not be a biomarker of the latent

reservoir. However, CD32 may be a biomarker of what might be called the active reservoir—the persistent virus that is probably first to reseed infection when antiretroviral therapy is stopped. Thinking on the nature of the reservoir is evolving to include not only latent, but also active reservoir, and both are major barriers to a cure. Finding a way to differentiate cells harboring active reservoir from healthy, uninfected cells would be an important advance.

#### amfAR's Role

The co-lead scientists of this study, Drs. Timothy Henrich and Peter Hunt, are funded by amfAR and are members of the amfAR Institute for HIV Cure Research.

Dr. Flores is amfAR's associate director of research.

# **UNAIDS Calls for Urgent Action to Achieve 2020 HIV Targets**

Donor government funding for global HIV programs shows no increase in 10 years

For the second year in a row, UNAIDS warns that progress in reducing new HIV infections, increasing treatment access, and ending AIDS-related deaths is not keeping pace with targets and urgent action is needed. Three recent reports show a mixed global response, with some countries making significant progress and others seeing increases in new HIV infections and AIDS-related deaths.



#### Global Gains Are Slowing, Results Are Mixed

"We urgently need increased political leadership to end AIDS," said Gunilla Carlsson, UNAIDS Executive Director, in a new UNAIDS Global AIDS Update. "This starts with investing adequately and smartly and by looking at what's making some countries so successful."

Among the report's findings:

 Key populations are still being marginalized and left behind. In 2018, more than half (54%) of new HIV infections around the world occurred in key populations, including people who inject drugs, gay men and other men who have sex with men, transgender people, sex workers, and prisoners.

- Prevention efforts need to be stepped up, even in regions that have shown remarkable gains. Proven prevention strategies, such as pre-exposure prophylaxis (PrEP) and harm reduction for people who inject drugs, are not being used to maximum effect.
- There have been troubling increases in new HIV infections in Eastern Europe and Central Asia (29%), the Middle East and North Africa (10%), and Latin America (7%).
- There has been progress toward the 90-90-90 targets. In 2018, about 79% of people living with HIV knew their status, 78% who knew their HIV status were accessing treatment,

"We urgently need increased political leadership to end AIDS."

-Gunilla Carlsson, UNAIDS Executive Director

- and 86% of people living with HIV who were accessing treatment were virally suppressed. But there are huge regional variations.
- AIDS-related deaths are falling. Since 2010, AIDS-related deaths have declined by 33%.
- The rate of new infections among young women has gone down 25% since 2010, but young women are still 60% more likely than young men to acquire HIV.
- Stigma and discrimination still impede the HIV response.

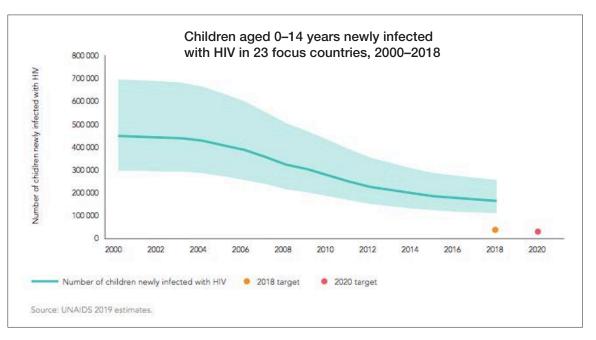
## The World Must Accelerate Its Commitment to Children and Adolescents

Start Free, Stay Free, AIDS Free, a UNAIDS report released at the 10th IAS Conference on HIV Science in Mexico City, shows that progress in lowering the rate of new HIV infections among children and expanding access to treatment for children, adolescents, and pregnant women living with HIV has slowed significantly. About 90% more pregnant women living with HIV are accessing antiretroviral therapy compared with 2010, with a corresponding 41% decrease in new HIV infections in children. Yet in 2018 there were about 160,000 new HIV infections

among children, far from the target of fewer than 40,000. Children and adolescents are also not being diagnosed and treated at the same rate as adults, and are less likely to be virally suppressed.

#### **Donor Funding Has Flattened**

A new analysis from the Kaiser Family Foundation and UNAIDS reports that donor governments spent \$8 billion on the global HIV epidemic in 2018, similar to levels from ten years ago. When all funding sources are taken into account, data show a \$1 billion decline in global funding for HIV programs. After adjusting for inflation, this leaves a \$7 billion gap between resources and need in 2020.



# NIH Awards Research Training Grant to TREAT Asia—Columbia University Collaboration

Five-year award will support research training on HIV, mental health, and implementation science



Dr. Annette Sohn, amfAR Vice President and Director of TREAT Asia, with CHIMERA fellows

The U.S. National Institutes of Health (NIH) awarded a 5-year, \$1.4 million grant to amfAR's TREAT Asia program and Columbia University to establish an innovative platform for integrating HIV, mental health, and implementation science research in the Asia-Pacific region.

The CHIMERA program (Capacity development for HIV and mental health research in Asia) will address the interlinked burdens of HIV and mental health. Co-led by Principal Investigators Dr. Annette Sohn, amfAR Vice President and Director of TREAT Asia, and Dr. Milton Wainberg, Professor of Clinical Psychiatry at Columbia University and the New York State Psychiatric Institute, the program aims to build a team within the region with the capacity to lead HIV—mental health—implementation science research that will inform public health policy and improve clinical care for people living with HIV.

The program is nested within the IeDEA (International epidemiology Databases to Evaluate AIDS) research network that TREAT Asia directs. CHIMERA will create the opportunity to bring together stellar training faculty from academic centers and public health and development agencies within the region and across the world, and

will build on existing NIH-funded mental health research being conducted through IeDEA Asia-Pacific.

"We are very fortunate to have this opportunity to work together and plan how to improve the mental health of those we care for by first having bi-directional capacity training in order to design optimal approaches to implement sustainable efforts," said Dr. Wainberg, who has led multiple global mental health and implementation science training programs in the U.S. and Africa.



"The Fogarty International Center has successfully contributed to the global HIV research workforce for almost 30 years," said Fogarty Program Scientist Dr. Geetha Bansal. "Investing in the CHIMERA program is especially exciting for us as this training program will provide a bridge to an existing HIV research network (IeDEA Asia-Pacific) to enable training in data science management and analysis to guide health policy and improve the quality of clinical care."

# Dolutegravir: A Key HIV Drug That Too Many People Cannot Get

The integrase inhibitor dolutegravir (DTG) has shown great promise as a medicine to treat HIV since it was first approved by the U.S. Food and Drug Administration in 2013 and by the European Commission in 2014. Used in combination with other antiretrovirals, it has limited side effects, is effective at suppressing HIV, and has a high barrier against the emergence of drug resistance.

In 2018, the WHO recommended dolutegravir-based regimens as the preferred first-line HIV treatment for adults and adolescents. While DTG has been implicated in neural tube defects in infants born to women who were taking the drug at the time of conception, women of childbearing potential can take DTG as long as they are on consistent and reliable contraception.

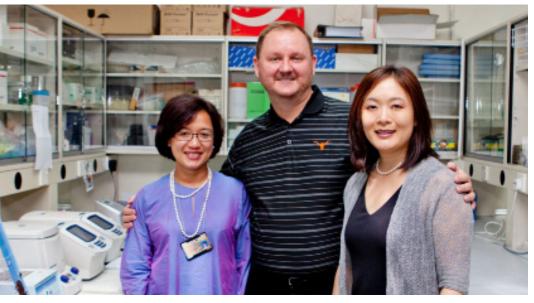
A generic form of dolutegravir has been available in India since February 2017. In September 2017, governments, development agencies, and drug access groups negotiated a pricing agreement that established a ceiling price of US\$75 per person per year for the dolutegravir-based regimen commonly known as "TLD" (tenofovir disoproxil fumarate, lamivudine, and dolutegravir). Several countries in Africa have implemented TLD as a preferred first-line treatment in their national HIV programs. But in the Asia-Pacific region, access to DTG-based regimens remains severely limited.

"Numerous regulatory approval delays have interfered with access to DTG in the Asia-Pacific," said Giten Khwairakpam, TREAT Asia's program manager for community and policy. "Very few national HIV programs include the drug, and some countries are unnecessarily prohibiting its use in all women."

To accelerate DTG scale-up in the region, TREAT Asia and the Clinton Health Access Initiative organized a workshop in Bangkok in March 2019 to help networks of people living with HIV and other treatment access advocates better understand issues around DTG access and use, and coordinate future advocacy efforts. Attended by 25 participants from nine Asian countries, the workshop built upon earlier collaborative efforts with the WHO to enhance access to newer HIV and hepatitis C medications.

# Malaysian Stalwart Takes the Helm at IAS

An Interview with Dr. Adeeba Kamarulzaman



Dr. Adeeba Kamarulzaman (left) with Kevin Robert Frost, CEO of amfAR, and Dr. Annette Sohn, amfAR VP and Director of TREAT Asia, at the University of Malaya Medical Center, Kuala Lumpur, in 2012.

International AIDS Society (IAS) President-Elect Dr. Adeeba Kamarulzaman, the first person from Asia to hold this position, is Dean of the Faculty of Medicine at the University of Malaya. Dr. Adeeba established the Infectious Diseases Unit and the Centre of Excellence for Research in AIDS (CERiA) at the University of Malaya Medical Centre. She is chair of the Malaysian AIDS Foundation and was previously chair of the steering committee of amfAR's TREAT Asia program and a founding site principal investigator for the TREAT Asia HIV Observational Database.

# amfAR: Malaysia is the first country in the Western Pacific region to eliminate mother-to-child transmission of HIV. How was this accomplished?

**Dr. Adeeba:** Initially we had a predominantly male epidemic of injecting drug users. So we had a lot of lead time before it spilled over to women—who were mostly sexual partners of male injecting drug users. So relatively speaking we had fewer affected women at first. On top of that, the Malaysian Ministry of Health proactively introduced antenatal screening in the late 1990s, and it also instituted the prevention of mother-to-child transmission protocol.

# amfAR: Are these lessons that could be applied to other countries in the region?

**Dr. Adeeba**: In Malaysia we are proud that more than 90% of our funding for treatment and prevention is domestic. We are a middle-or upper-middle-income country, and have a smaller epidemic than many countries around us. But we've still had that commitment to address it. We also have a pretty good health

infrastructure. I think the necessary factors came together: the political will, the financing, and the infrastructure. But we, like many other countries in the region, are seeing a rise in the epidemic among men who have sex with men, driven partly by the amphetamine epidemic. And stigma and discrimination still drive people underground and form a barrier to testing and treatment.

# amfAR: Is the stigma directed primarily at the LGBT community, or drug users, or both?

**Dr. Adeeba:** To some extent, harm reduction lessened the stigma towards people who use drugs, but it's definitely still there. Stigma towards LGBT people and sex workers is very deep and ingrained, and is pervasive among healthcare workers. At the University of Malaya we're including stigma in the medical curriculum. One intervention that works is exposing students to affected people. We have sessions with people from the LGBT community, people who use drugs, and people living with HIV. Some of the students have led very sheltered and isolated lives, and before this haven't met anyone who's not like them.

# amfAR: Is religious conservatism still a major problem?

**Dr. Adeeba:** I think it is still a problem, not just in Malaysia, but around the world. Unfortunately the respect for human life, dignity, and compassion that's part of Islam and other religions gets drowned out by negativity towards LGBT people. Health professionals in particular need to separate those attitudes from our obligations.



# **A Charming Man's Lasting Legacy**

Endowed with a radiant smile, Paul Merrill was a fashion model who found his calling as a realtor selling the homes of Hollywood stars. He was also a dedicated philanthropist whose generous bequest to amfAR spoke of his commitment to helping people living with HIV.

Born in 1935 in Toledo, Ohio, Mr. Merrill was the youngest child in a family with three older sisters. He went on to make his longtime home in Los Angeles, California, where careers in modeling and later in real estate both flourished. He is remembered by friends as a handsome man about town who used his disarming memory for names and funny stories to charm everyone he met.

Mr. Merrill lived for simple pleasures but also appreciated evenings out on the town. He was on a first-name basis with maître d's at the finest restaurants across LA and could get a table for a meeting with high-end real estate clients at a moment's notice.

"Think you can get into Spago?" his close friend David Verdery recalls asking him. "They usually have a two-month waiting list." Mr. Merrill smiled and picked up the phone. That very evening

the two friends dined out at the famed Beverly Hills hotspot.

They once scored a pair of tickets to see Barbra Streisand in what was to be the legendary singer's highly anticipated return to performing. She did not disappoint. "Seeing Barbra Streisand singing with an orchestra conducted by her friend Marvin Hamlisch was spectacular," recalls Mr. Verdery. "It was bone-chilling."

But challenging times lay ahead for Mr. Merrill. In 1995 he tested positive for HIV. Through friends connected with amfAR, he was referred to an excellent physician in Palm Springs, where he had moved to slow down. Thanks to good medical care and antiretroviral treatment, he was able to lead a mostly healthy life for another 24 years.

Over the years, Mr. Merrill had the opportunity to attend amfAR galas, where he heard Elizabeth Taylor speak. "She was very inspiring," recalls Mr. Verdery. "I would give her most of the credit for getting the government motivated to do something about AIDS. And if you had a chance to hear her talk, you would have chosen her as a recipient of financial donations."



"I've pledged my life to trying to help others live long enough to get a cure."

"I've been very successful in maintaining my health," Mr. Merrill once told Mr. Verdery. "And I've pledged my life to trying to help others live long enough to get a cure."

Mr. Merrill's generosity will help amfAR continue to fund the most promising research that will move us toward an HIV cure and fulfill his wish.

For information on donating to amfAR through a bequest or other estate plans, email sebastian.gheith@amfar.org or visit www.amfar.org/donate.

amfAR: There has been concern that the Asia-Pacific is falling behind in its AIDS response. Are there strategies that need to be implemented or improved upon to make progress towards the 90-90-90 targets that UNAIDS has set for 2020? (The "90-90-90" targets call for 90% of all people living with HIV to know their status, 90% of diagnosed individuals to be on treatment, and 90% of those on treatment to be virally suppressed.)

**Dr. Adeeba:** I think that two major factors have collided. One is that the epidemic is concentrated among key populations in most countries. Because of the stigma that makes people fear coming forward, you're not even getting to the first 90. And because many of our countries fall into the middle- or upper-middle-

income income bracket, we're not eligible for PEPFAR funding for treatment and prevention scale-up. In Malaysia, we're grateful for the little bit of funding that the Global Fund has provided. But it's not as much as we need.

amfAR: When you were interviewed by amfAR in 2006, you described some of TREAT Asia's work. How would you characterize the evolution of TREAT Asia and its impact since then?

**Dr. Adeeba:** It's still going very strong, and we have more sites. One of the aims of the late Professor David Cooper in creating TREAT Asia with amfAR's Kevin Frost was to develop a cadre of scientists and researchers in Asia and the Pacific. Most sites are seeing newer,

younger people coming on board. I wish we could do more original clinical trials. But of course, randomized controlled trials in multiple sites swallows millions of dollars.

# amfAR: What are your hopes and aspirations for the next five years?

**Dr. Adeeba:** I hope that with me coming on board as the first Asian President-Elect of IAS, we could shift the spotlight onto Asia a little bit and to the issues we just talked about. And hopefully I could lend my voice at a global level to treatment and support for people who use drugs—people who are very, very behind—not just in Asia, but all around the world.

#### **Events**



















## amfAR Gala Cannes

It was a night to remember at the 26th annual amfAR Gala Cannes in Antibes, France, on May 23, during the Cannes Film Festival. The starstudded black-tie event was hosted by Chris Tucker and featured unforgettable performances by Mariah Carey, Dua Lipa, Tom Jones, Charli XCX, The Struts, and Andreas Schager. All eyes were on longtime amfAR supporter Carine Roitfeld's stunning We Can Be Heroes Collection fashion show featuring a who's who of elite designers. The collection-modeled by many of the world's top models, including Kendall Jenner, Stella Maxwell, Sara Sampaio, and Josephine Skriver-fetched \$1.15 million in the event's live auction. Among many highlights of the auction was Takashi Murakami's platinum Yume Lion sculpture, which sold for \$2 million.

Special thanks: Presenting Sponsors Chopard, JOLLYONE, Young Merry Real International Group; and Signature Sponsors Absolut Elyx, Bosideng Down Wear Limited, Kodiak Pictures, Nickel City Pictures, and Perrier-Jouët

1. Event Host Chris Tucker 2. Event Chair Andi MacDowell and Adrien Brody 3. Karolina Kurkova 4. amfAR CEO Kevin Robert Frost (left) and Chairman of the Board Bill Roedy 5. Mariah Carey 6. Kendall Jenner 7. We Can Be Heroes fashion show curated by Carine Roitfeld 8. Tom Jones 9. Milla Jovovich (Photos: Getty Images, Rvan Emberley)

Thank you @carineroitfeld for having us @amfar and raising so much for such a great cause We had a blast.. wearing atelier @versace #AmfARCannes



@stellamaxwell





# Neiman Marcus amfAR MAKING AIDS HISTORY



1. Victoria Justice 2. Neiman Marcus and amfAR's double-decker bus 3. Pride marchers 4. amfAR beachball (Photos: amfAR)

# WorldPride | NYC Stonewall 50

amfAR partnered with Neiman Marcus to celebrate WorldPride 2019 and to commemorate the 50th anniversary of the Stonewall uprising in New York City on Sunday, June 30. Victoria Justice joined amfAR staff and supporters marching down Fifth Avenue alongside amfAR and Neiman Marcus's customized double-decker bus as part of the largest LGBTQ event in history.

Special thanks: Neiman Marcus





CeeLo Green gave a soulful performance. (Photo: Getty Images)

#### amfAR Paris

amfAR supporters enjoyed an intimate benefit dinner and auction on June 30 at The Peninsula Paris. Five-time Grammy Award-winning artist CeeLo Green performed for guests including Heidi Klum, Rachel Zoe, Caroline Scheufele, Tom Kaulitz, and Carine Roitfeld. Simon de Pury presided over the auction, which included an Andy Warhol silkscreen, Robert Rauschenberg lithograph, and an 18-karat rose gold Chopard pendant necklace set with 2.48 carats of glittering diamonds. During the event guests enjoyed Perrier-Jouët Cuvée Grand Brut Champagne and Absolut Elyx signature cocktails.

**Special thanks:** Signature Sponsors Perrier-Jouët and The Peninsula Paris

#### **Events**













# amfAR Gala Hong Kong

Heidi Klum, Kyle MacLachlan, Alexander Skarsgård, Pharrell Williams, and amfAR Ambassador Michelle Yeoh were among those who gathered at the sixth annual amfAR Gala Hong Kong on March 25. Businesswoman Pansy Ho, a leading supporter of the gala since its inception in 2015, served as Honorary Chair of the event. Williams, along with prominent gallerist Rachel Lehmann, presented the amfAR Award of Courage to renowned entrepreneur Adrian Cheng, who urged others to support amfAR's efforts. The evening featured sensational performances by Grammy Awardnominated singer Nicole Scherzinger and Lay Zhang, the highest charting Mandopop star in Billboard history. The gala raised over \$2.75 million for amfAR.

**Special thanks:** Presenting Sponsors APM Monaco and Rosewood Hotels & Resorts; and Signature Sponsors American Express and Perrier-Jouët

1. Rachel Lehmann, honoree Adrian Cheng, and Pharrell Williams 2. Nicole Scherzinger performs 3. Honorary Chair Pansy Ho 4. Alexander Skarsgård 5. Pierre Png and amfAR Ambassador Michelle Yeoh 6. Lay Zhang performs 7. Tom Kaulitz and Heidi Klum (Photos: Getty Images, Ryan Emberley)

Incredible night with amazing people supporting @amfAR #cureAIDS #amfARHongKong #PerrierJouet @Hong Kong https://www.instagram. com/kevinwoo\_officia ... -@Kevinwoo91

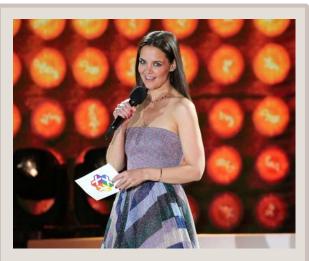




# Kiehl's 10th Annual LifeRide for amfAR

Marking the 10th annual Kiehl's LifeRide for amfAR, Kiehl's brought past motorcyclist participants, celebrity supporters, and the public together to celebrate a decade of support and over \$2 million raised for HIV/AIDS research. The event took place at Westfield Century City, Los Angeles, and featured a musical performance by amfAR ambassador and singer Serayah, as well as an appearance by LifeRider and actor Scott Patterson. Kiehl's took over The Terrace, a public space at Westfield Century City, to encourage the LA public to take part in its Instagram hand-heart campaign and to learn more about amfAR x Kiehl's longstanding partnership. Kiehl's LifeRide for amfAR has raised more than \$2 million via motorcycle rides and event donations since 2010.





Katie Holmes (Photo: Getty Images)

#### 26th Annual Life Ball

The Life Ball in Vienna, Austria, has long been Europe's largest and most spectacular HIV/AIDS fundraiser. To mark its 26th anniversary, on Saturday, June 8, amfAR Ambassador Katie Holmes gave remarks on the need for sustained funding for HIV cure research and political will to enact effective preventive and treatment programs.

The Life Ball has been a longtime supporter of amfAR's TREAT Asia pediatric and adolescent HIV program, which focuses on improving the health and lives of children and adolescents living with HIV across the Asia-Pacific region. Over more than a decade, LIFE+ has provided nearly \$7 million through Life Ball to the pediatric initiative.



1. amfAR CEO Kevin Robert Frost receives a check from Kiehl's 2. Serayah performs (Photos: Kiehl's Since 1851)



Sign up at amfAR.org/amfARNews



### **Upcoming Events**

October 26 TWO x TWO for AIDS and Art

Dallas, Texas

November 15 amfAR Charity Poker Tournament

San Francisco, California

January 10-12 amfAR Thailand

Phuket, Thailand

February 5 amfAR Gala New York

New York City

February amfAR Mexico City

Mexico City