

# INNOVATIONS

MAY 2019

# The London Patient

## A milestone in HIV cure research

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### Also Inside:

Bioengineering Collaborations Enter  
Critical Phase

Study Suggests Most Drug Treatment  
Facilities Don't Test for HIV

Enhancing Access to Newer HIV and  
Hep C Meds in Asia

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MAY 2019

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*Photo: Getty Images*

## Company for the Berlin Patient?

By now, you have probably heard the exciting news about the London and Düsseldorf patients, who seem to be the second and third persons in whom we can no longer find any trace of HIV after a stem cell transplant. Regardless, I urge you to read our cover story and the companion piece on stem cell transplantation by amfAR's Dr. Rowena Johnston (see pages 8 and 9). Both articles provide important details and context that can help you make sense of these potentially game-changing developments.

There are three key aspects of these new cases to bear in mind. First, we don't know exactly if and when we'll be able to say with certainty that either of these patients is cured. We're supporting researchers who are trying to resolve this critical issue. And the more people we can cure, the more likely we'll be able to identify a marker or sign showing that a person has been cured—without having to wait for years to see whether the virus rebounds.

The second point is that stem cell transplantation clearly will never be a practical way to cure large numbers of people of HIV. But, as Dr. Johnston says (see page 12), there are some things about curing HIV that you can only learn from people

who have been cured. And every new case of a cure brings new knowledge that boosts our efforts to develop a broadly applicable cure.

Third, any cure we ultimately develop must be effective for everyone. That's why we're supporting research on sex differences in the HIV reservoir to make sure a cure would be effective in both men and women. It's why we recently awarded grants to researchers in sub-Saharan Africa and Southeast Asia who are looking at reservoir differences in HIV subtypes that predominate where HIV is most prevalent (see page 11). And it's why a gene therapy cure study we're supporting is aimed at developing an intervention that can be delivered in a practical fashion.

We are energized by these new developments and grateful as always for your help in making them possible.

# Expanding Access to PrEP for Adolescents and Young Adults

In May 2018, the U.S. Food and Drug Administration (FDA) approved the once-daily oral medication Truvada as pre-exposure prophylaxis (PrEP) for adolescents, in combination with safer sex practices, for reducing the risk of acquiring HIV.

Previously, Truvada was approved as PrEP only for adults aged 18 and older. Adolescents and young adults bear a disproportionate HIV burden. In 2016, youth aged 13 to 24 made up 21% of all new HIV diagnoses in the United States. Of these diagnoses in youth, most (81%) occurred among young gay and bisexual men, with Black and Latinx gay and bisexual men disproportionately affected.

Ensuring that adolescents and young adults at risk for HIV can access PrEP is a key step toward reducing new HIV diagnoses. Now that one barrier to PrEP has been eliminated, it is important to systematically assess and address other barriers to PrEP for adolescents and young adults.

**“Ensuring that adolescents and young adults at risk for HIV can access PrEP is a key step toward reducing new HIV diagnoses.”**

Examining how three jurisdictions address policy issues related to consent, confidentiality, and payment barriers, a new amfAR report highlights successful HIV efforts to reform public health laws or adopt programs specific to the adolescent and young adult populations.

The report, titled *Expanding Access to Pre-Exposure Prophylaxis (PrEP) for Adolescents and Young Adults: Models for Addressing Consent, Confidentiality, and Payment Barriers*, recommends the following for jurisdictions grappling with how to build consensus for legal and policy reform in order to get PrEP to these at-risk populations:



- **Update consent laws:** Jurisdictions must find the most salient approach to updating laws to permit minors to consent to PrEP access without parental permission.
  - **Maintain confidentiality:** Consider ways to establish patient rights to direct where and in what format an explanation of benefits is sent, so that it goes to the recipient of the service rather than the policyholder.
  - **Payment Access:** Reduce payment-related barriers with initiatives similar to the AIDS Drug Assistance Program (ADAP)—a critical part of the HIV care system for uninsured and underinsured individuals seeking treatment—and harness local resources offered by patient assistance programs, pharmaceutical companies, and charitable organizations.
- To read the full report, visit [www.amfar.org/prep-in-youth/](http://www.amfar.org/prep-in-youth/)

## amfAR Launches New PEPFAR Advocacy Resource

amfAR’s PEPFAR Monitoring, Evaluation, and Reporting (MER) Database is a free resource for policymakers, advocates, journalists, academics, and anyone else interested in exploring the impact of PEPFAR and the current state of the HIV/AIDS epidemic.

Learn more at

**[mer.amfar.org](http://mer.amfar.org)**

# PEPFAR Programming Disrupted by Expanded Mexico City Policy

The recently expanded Mexico City Policy prohibits foreign NGOs from receiving U.S. global health funding if they perform abortions, counsel on or refer for abortion, or advocate for its liberalization – outside of limited exceptions. For the first time, the Policy applies to HIV/AIDS funding through the President's Emergency Plan for AIDS Relief (PEPFAR), implicating hundreds of additional organizations.

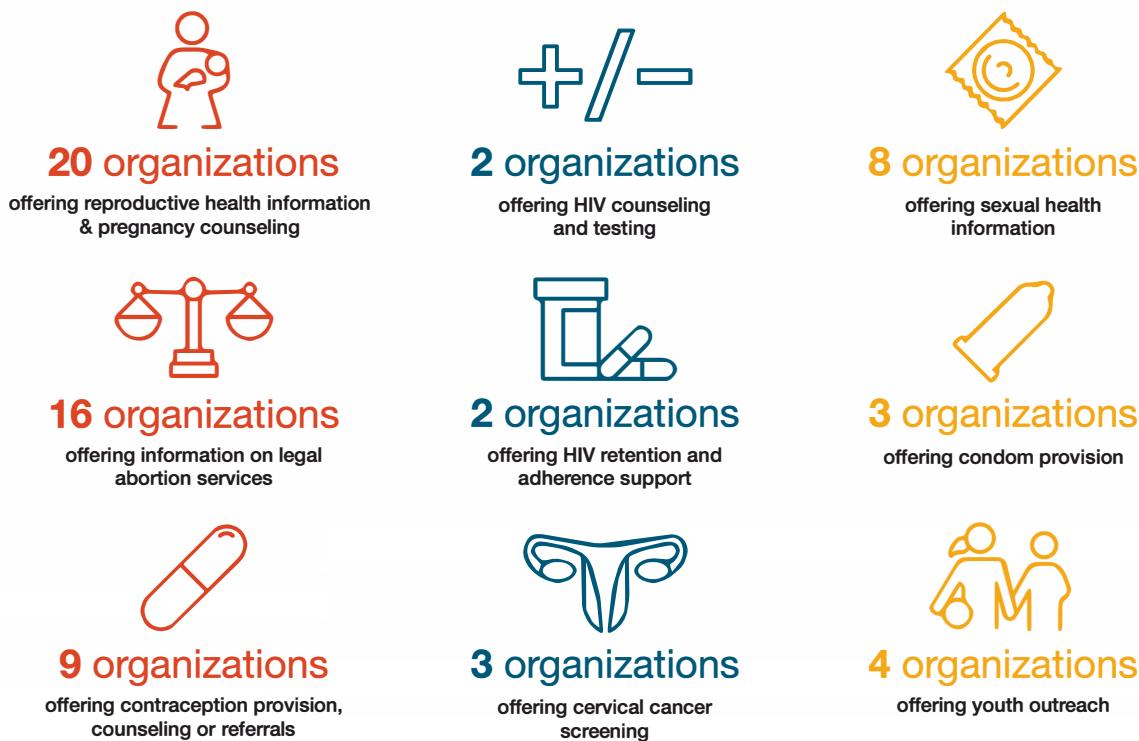
amfAR completed a confidential online survey targeting all PEPFAR prime partners in the 2016-2017 PEPFAR country operational plans to understand the initial impacts of this policy expansion. **Responses were received from 286 partners operating in 45 countries.**

The survey revealed that PEPFAR partners in 31 countries report disruptions in service provision due to the Mexico City Policy.



### **Which services are PEPFAR partners reducing in response to the EMCP?**

The graphic below shows the number of organizations that have reduced or stopped, or anticipate curtailing, the following services:



# Can We Make Global HIV/AIDS Investments More Efficient?



U.S. funding for global HIV programs has remained static for several years, despite increasing numbers of people living with HIV on lifesaving treatment. This makes it crucial to find ways to increase efficiencies.

An analysis conducted by amfAR is the first of its kind to attempt to quantify indirect costs

charged by organizations implementing the U.S. President's Emergency Plan for AIDS Relief, or PEPFAR. Examining data from 2007 to 2016, the study found that between \$1.85 billion and \$4.34 billion was spent on indirect costs.

Much of PEPFAR's work in providing lifesaving HIV treatment and prevention programs in

low- and middle-income countries is implemented by partner organizations. A proportion of the funds awarded to these organizations is allocated to indirect costs—the general costs of administering and running programs, including buildings, maintenance, depreciation, and staff.

The authors point out that their analysis is not an indictment of indirect costs, but is intended to “enable more informed debate regarding potential areas for increased efficiencies.” They say that “the lack of transparency in indirect costs or rates has made both evaluations of the effectiveness of indirect costs, and organizational accountability for these rates, difficult.”

“As the funding environment for global HIV programming grows ever more constrained,” said Brian Honermann, amfAR’s deputy director of public policy, “country programs are having to make difficult decisions and we should be asking hard questions about where they prioritize funding.”

## Study Suggests Most Drug Treatment Facilities Don't Test for HIV

In 2015, rural Scott County, Indiana, became ground zero of the worst HIV outbreak in the state’s history. All told, more than 200 people would test positive for HIV.

Most had a common story. They injected opioids and shared needles with others. The transmission rate for these individuals was 80%, according to Dr. William Cooke, the sole physician in heavily impacted Austin, Indiana, and 90% of those who tested positive for HIV were co-infected with hepatitis C (HCV).

amfAR Policy Associate Austin Jones and colleagues analyzed how the substance abuse treatment system is addressing the overlap of the opioid epidemic and recent outbreaks of HIV and HCV by assessing the availability of HIV and HCV testing in substance abuse clinics nationwide.

The authors report sobering statistics: in 2017, only 28.1% of substance abuse facilities reported offering

HIV testing and 27.5% reported offering HCV screening. Numbers vary widely by state, from 8.1 percent in North Dakota to 62.5% in the District of Columbia.

Particularly concerning is that several states with large numbers of vulnerable counties had low rates of testing.

A recent outbreak in the Massachusetts cities of Lawrence and Lowell shows this can happen anywhere without robust preventive services. Jones and colleagues report that only two of seven substance abuse facilities in Lawrence and none of the three facilities in Lowell offer HIV testing.

“At this point in the opioid epidemic, infectious disease testing is a basic need for people who inject drugs,” said Jones. “All parts of the health system should be prepared to meet this need, including substance abuse facilities.”

## Tracking the Opioid Epidemic

amfAR’s online Opioid & Health Indicators Database is a free resource for policymakers, advocates, journalists, academics, and anyone else interested in learning more about the opioid epidemic and its intersection with HIV and Hepatitis C. It provides a window into the deadly opioid epidemic unfolding across every American’s backyard.

Learn more at

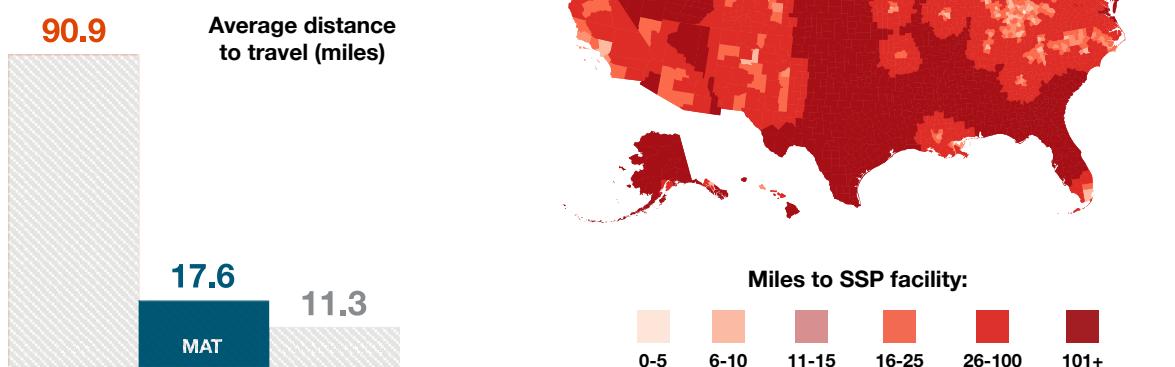
[opioid.amfar.org](http://opioid.amfar.org)

# Getting to Services: Far, Far Away

The number of drug-related poisoning deaths in the United States more than tripled between 1999 and 2017, accompanied by a rise in injection drug use. Since uptake of treatment for substance use disorder and harm reduction services at syringe services programs can reduce the risk of HIV and hepatitis C acquisition, access to services is critically important.

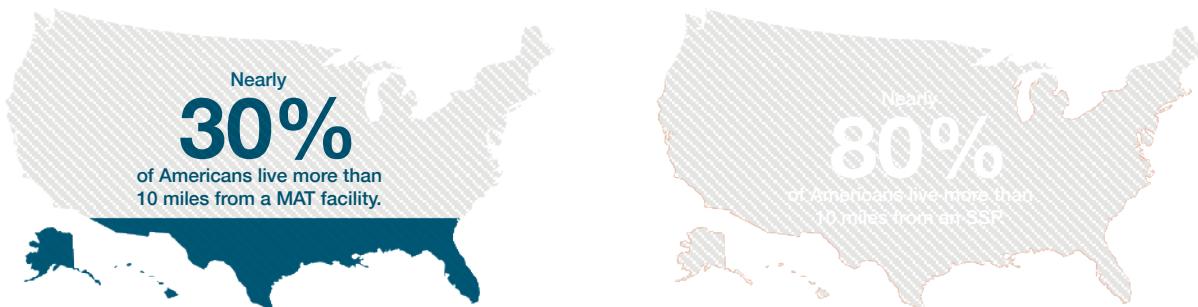
## Many miles to go

The average distance required to travel to a substance abuse treatment facility is 11.3 miles, 17.6 miles for a facility providing medication-assisted treatment (MAT), and 90.9 miles for a syringe services program (SSP).



## Too many Americans left behind

Syringe services programs and medication-assisted therapy often require daily or weekly visits to facilities. According to one study,<sup>1</sup> people typically do not access SSPs if they are more than ten miles from where they live. Yet nearly 30% of Americans (95.7 million people) live more than ten miles from a facility providing medication-assisted treatment, and nearly 80% (260.9 million people) live more than ten miles from an SSP.



See how your state compares at [opioid.amfar.org](http://opioid.amfar.org)

Source: Sharp A, Jones A, Honermann B, Millett G. 220 Vulnerable counties: One year later. [Poster presentation] Conference on Retroviruses and Opportunistic Infections (CROI). 2018 March.  
Available online at [http://www.croiconference.org/sites/default/files/posters-2018/1430\\_Sharp\\_1158.pdf](http://www.croiconference.org/sites/default/files/posters-2018/1430_Sharp_1158.pdf)

<sup>1</sup> Canary L, Hariri S, Campbell C, Young R, Whitcomb J, et al. Clin Infect Dis. 2017 Aug; 65(3):514-7.

# The London Patient

amfAR's ICISTEM researchers report no signs of HIV in patient off antiretroviral therapy for 18 months, a milestone in HIV cure research

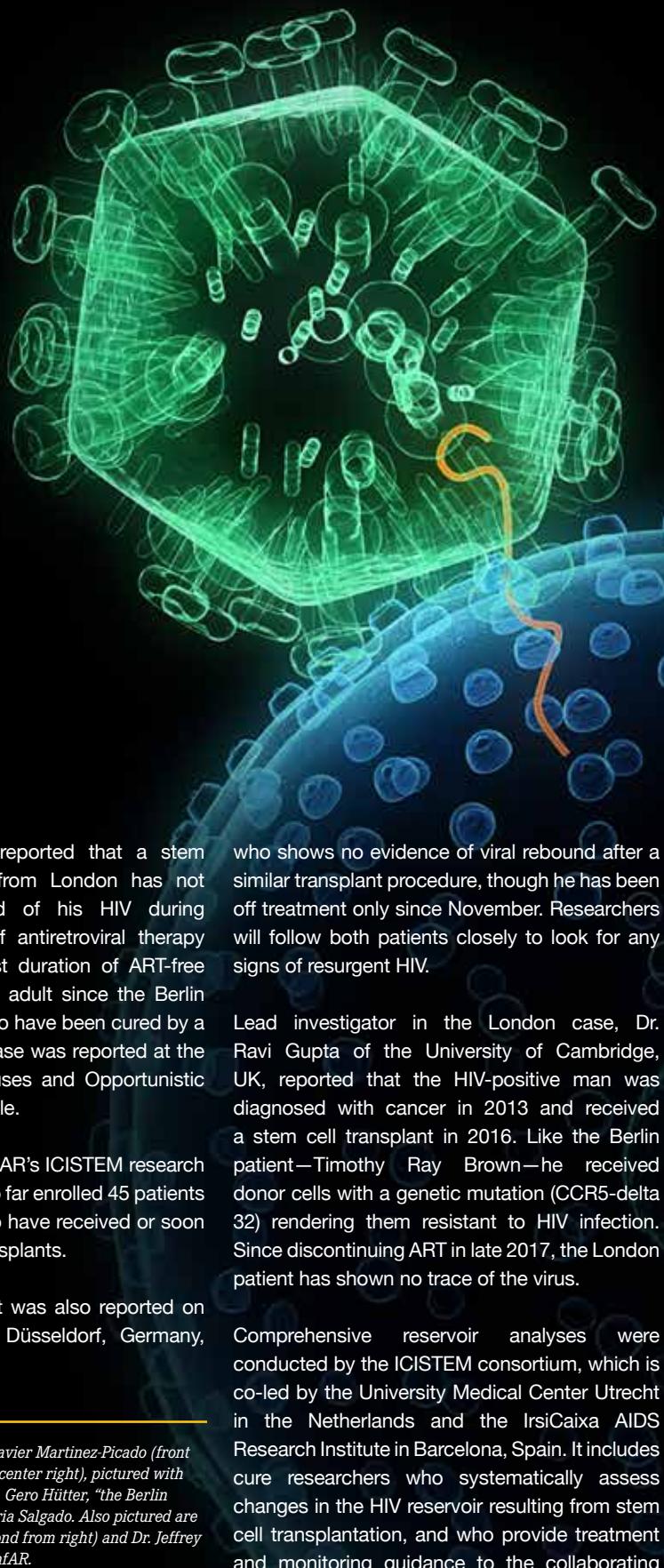


In March, researchers reported that a stem cell transplant patient from London has not experienced a rebound of his HIV during the past 18 months off antiretroviral therapy (ART). His is the longest duration of ART-free undetectable virus in an adult since the Berlin patient, who is believed to have been cured by a similar procedure. The case was reported at the Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle.

The patient is part of amfAR's ICISTEM research consortium, which has so far enrolled 45 patients with cancer and HIV who have received or soon will receive stem cell transplants.

Another ICISTEM patient was also reported on at CROI—a man from Düsseldorf, Germany,

*Co-Principal Investigators Drs. Javier Martinez-Picado (front right) and Annemarie Wensing (center right), pictured with ICISTEM members including Dr. Gero Hütter, "the Berlin patient's" physician, and Dr. María Salgado. Also pictured are Dr. Rowena Johnston (front, second from right) and Dr. Jeffrey Laurence (back row, right) of amfAR.*



who shows no evidence of viral rebound after a similar transplant procedure, though he has been off treatment only since November. Researchers will follow both patients closely to look for any signs of resurgent HIV.

Lead investigator in the London case, Dr. Ravi Gupta of the University of Cambridge, UK, reported that the HIV-positive man was diagnosed with cancer in 2013 and received a stem cell transplant in 2016. Like the Berlin patient—Timothy Ray Brown—he received donor cells with a genetic mutation (CCR5-delta 32) rendering them resistant to HIV infection. Since discontinuing ART in late 2017, the London patient has shown no trace of the virus.

Comprehensive reservoir analyses were conducted by the ICISTEM consortium, which is co-led by the University Medical Center Utrecht in the Netherlands and the IrsiCaixa AIDS Research Institute in Barcelona, Spain. It includes cure researchers who systematically assess changes in the HIV reservoir resulting from stem cell transplantation, and who provide treatment and monitoring guidance to the collaborating

# What Stem Cell Transplants Can Teach Us About Curing HIV

By Rowena Johnston, Ph.D.

transplant doctors. The researchers are now able to compare changes in the HIV reservoir across the patient cohort.

The ICISTEM group has screened over two million stem cell donors to identify those with the CCR5-delta 32 mutation, increasing the chance that new candidate transplant recipients may receive donor cells with this rare genetic mutation. With additional patients in the cohort about to stop ART in what is known as an analytic treatment interruption, researchers are cautiously optimistic that there may soon be additional cases of sustained undetectable virus in the absence of therapy.

"While we fully understand that stem cell transplantation is not a practical way of curing large numbers of people, we can learn a tremendous amount from these cases," said amfAR Chief Executive Officer Kevin Robert Frost. "And we can apply that new knowledge to the development of strategies aimed at a more widely applicable cure."

Because the London and Düsseldorf patients received an intervention similar in many respects to the case of the Berlin patient, researchers can begin to compare and contrast the procedures. Mr. Brown, for example, underwent two stem cell transplants, whereas the London and Düsseldorf patients received just one. While Brown had intensive chemotherapy and irradiation to prep for the transplant, the London patient had low intensity conditioning and no irradiation, and the Düsseldorf patient received myeloablative conditioning but no irradiation.

A key question that has vexed researchers is whether or not the CCR5-delta 32 mutation was necessary to achieve Mr. Brown's cure. Since it was present in the cells transplanted into both Mr. Brown and the London and Düsseldorf patients, it will be important to follow them over time.

"Although it's too early to say for sure, we're certainly hopeful that the London patient is cured," said Dr. Rowena Johnston, amfAR vice president and director of research. "amfAR's investments in innovative and forward-thinking projects like ICISTEM give us the opportunity to learn which factors will form the scientific basis of a cure for HIV."

Stem cell transplants are used to treat cancers of the immune system, and are typically used in people for whom other cancer treatments have failed. The stem cells are taken from adult donors or from cord blood, and when transplanted into the recipient, those stem cells mature into a new and healthy immune system.

Sometimes people living with HIV (PLWHIV) develop one of these immune cancers, and they become candidates for stem cell transplants. Under these circumstances, we have an opportunity to learn a lot about how HIV persists even when it's well controlled by antiretroviral therapy (ART), and how replacing the immune system affects the ability of HIV to persist.

amfAR set up and provided funding to the ICISTEM consortium so that we could learn some important lessons about curing HIV that could be applied to designing a cure that would work in anyone, whether or not they receive a stem cell transplant. The researchers in ICISTEM analyze the blood and tissues of

cancers. Two of these patients—the London patient and the Düsseldorf patient—received cells from donors who had the CCR5-delta 32 genetic mutation. Both have stopped taking ART without any signs of HIV returning, but it's important to note that while the London patient has been off ART for 18 months, the Düsseldorf patient stopped taking ART only four months ago. PLWHIV who stop taking ART typically experience HIV rebound in 2-4 weeks, but the Mississippi child took 28 months to rebound, so although we're hopeful that the London and Düsseldorf patients are cured, it will take more time to know for sure.

## What kinds of things can we learn from these transplant patients?

When Timothy Ray Brown, the Berlin patient, was cured of both his cancer and his HIV following a transplant of CCR5-delta 32 cells, the scientific community was unable to determine how crucial the mutation was to his cure outcome. Timothy also received a myeloablative conditioning regimen, as well as total body irradiation, designed to destroy the

**"Although we're hopeful that the London and Düsseldorf patients are cured, it will take more time to know for sure."**

HIV-positive transplant recipients. They can then compare the outcomes between people who received transplants that have functional CCR5—the main doorway that allows HIV to enter cells—and those whose transplanted cells contained the CCR5-delta 32 genetic mutation. This is of particular interest because cells with the genetic mutation are highly resistant to HIV.

great majority of his own immune cells, before ultimately receiving two stem cell transplants. ICISTEM researchers will be able to determine the relative importance of the myeloablation, irradiation, the CCR5-delta 32 genetic mutation, and number of transplants by comparing many HIV-positive stem cell transplant recipients in their cohort, because each patient receives a different combination of these factors.

## What/Who are ICISTEM, the London patient, and the Düsseldorf patient?

ICISTEM is a large consortium of HIV researchers and transplant specialists who are currently studying HIV in a cohort of 45 patients who have already received, or will soon receive, stem cell transplants to treat their

If we learn that the CCR5-delta 32 mutation is a critical factor, this finding points a promising way forward for gene therapy. In fact, other researchers have been working on CCR5 gene therapy in HIV for many years, and interesting

CONTINUED ON PAGE 12

# amfAR Awards New Funding for Gene Therapy Study

Grant supports next phase of three-pronged approach to gene therapy-based cure

In November, amfAR awarded \$800,000 in new funding to researchers developing an ambitious gene therapy-based approach to curing HIV. The award launches a critical new phase in a study initiated in 2017 with \$2.3 million in grants awarded to seven teams of researchers. Six of the teams will move forward with the next phase of the project.

amfAR has forged a unique collaboration among world leaders in gene therapy. An amfAR-led 2016 think tank led to a plan to create the first combination intervention that will simultaneously address the main barriers to a cure. In a three-pronged attack on the HIV reservoir, the researchers will employ broadly neutralizing antibodies, CAR stem cells—cells genetically reprogrammed to recognize and attack disease cells—and molecular scissors targeting the virus.

"This is an ambitious and complex project with very exciting potential," said amfAR Chief

Executive Officer Kevin Robert Frost. "It's a carefully constructed strategy that involves some of the most talented and innovative scientists in the field. We think it holds great promise for developing the scientific basis of a cure by the end of 2020, which is the aim of our Countdown to a Cure for AIDS initiative."

**"It's a carefully constructed strategy that involves some of the most talented and innovative scientists in the field."**

The researchers will test an approach that combines CAR stem cells that secrete broadly neutralizing antibodies, together with an enzyme (Brec1) that targets HIV DNA in the cell it has infected (leaving other DNA intact), and long-term secretion of a broadly neutralizing antibody from the liver. The goal is to 1) induce CAR

stem cells to kill reservoir cells; 2) to express two different antibodies to neutralize virions (virus that exists outside of cells) in the blood and tissues, and; 3) to use Brec1 to remove the provirus (virus that has been integrated into a cell's DNA) from infected cells.

The investigators are: Hildegard Büning, Ph.D., (co-principal investigator) of Hannover Medical School, Germany; Keith Jerome, M.D., Ph.D., (co-principal investigator), of the University of Washington, Seattle; Hans-Peter Kiem, M.D., Ph.D., of Fred Hutchinson Cancer Research Center, Seattle; Scott Kitchen, Ph.D., of UCLA, Los Angeles; Drew Weissman, M.D., Ph.D., of University of Pennsylvania, Philadelphia; and Richard Wyatt, Ph.D., of The Scripps Research Institute, La Jolla, CA.

The grant was supported in part by the Bill and Melinda Gates Foundation.

# Bioengineering Collaborations Enter Critical Phase

New amfAR grants advance high-tech nanotechnology and protein "fingerprinting" projects



*Dr. Kim Woodrow*

amfAR has awarded new funding to researchers using cutting-edge technology to address the main barrier to a cure for HIV: persistent viral reservoirs not cleared by antiretroviral therapy. Totaling \$1.6 million, this new round of Investment grants launches the critical third phase of two research projects launched in 2017.

Investment awards are milestone-based grants for research studies undertaken over four years in three phases. In this third phase, bioengineers are working in partnership with leading HIV cure scientists to tackle some of the most difficult challenges in HIV cure research.

One of these challenges is to find a biomarker unique to HIV reservoir cells—thus allowing researchers to pinpoint and kill these reservoir cells. Dr. Hui Zhang of Johns Hopkins University, a leading expert in the field of mass spectrometry, is applying this protein "fingerprinting" technique to the challenge.

Dr. Zhang is teaming up with HIV scientist Dr. Weiming Yang, also of Johns Hopkins University, to determine whether killing cells displaying any of 17 proteins identified in previous phases of the study will eliminate the latent reservoir.

At the University of Washington in Seattle, Dr. Keith Jerome and bioengineer Dr. Kim Woodrow are working to identify a potent latency reversing agent (LRA) that can shock the reservoir out of latency, the first stage in a "shock and kill" strategy to cure HIV.

Drs. Woodrow and Jerome are using tiny nanoparticles as vehicles to precisely deliver multiple drugs to a single cell. To date, the researchers have formulated nanoparticles loaded with LRAs including an ingenol—one of the most effective classes of LRA developed to date, but with toxic side effects—and have reduced its toxicity in a mouse model. In the next phase, they will test their nanoparticles for elimination of the reservoir in a preclinical study.

# New amfAR Grants Address Crucial HIV Cure Research Questions

More than \$800,000 awarded to researchers studying post-treatment control and differences in the HIV reservoir

In January, amfAR awarded a new round of grants to advance two crucial areas of HIV cure research. Five awards will support a range of efforts to understand the mechanisms and predictors of post-treatment control, whereby a small number of individuals are able to control their HIV after stopping treatment. Three additional grantees will study HIV-positive populations in low- and middle-income countries to look for differences in how the persistent viral reservoir forms and changes over time.

"Post-treatment controllers may hold the key to understanding how the immune system naturally controls the virus, so it's essential that we understand what mediates post-treatment control," said amfAR Chief Executive Officer Kevin Robert Frost. "It's also vital that we improve our knowledge of the crucial differences in the viral reservoir that may exist in those hit hardest by the epidemic."

**"Post-treatment controllers may hold the key to understanding how the immune system naturally controls the virus."**

Dr. Jonathan Li of Brigham and Women's Hospital in Boston has assembled a cohort of post-treatment controllers from one of the largest HIV clinical trial networks in the world. Using next-generation genomic sequencing, he is investigating whether characteristics of the virus or immunologic responses can predict post-treatment control. Understanding the combination of factors that contribute to post-treatment control may help scientists design interventions to enable viral control after stopping ART.

Another grantee, Dr. Godwin Nchinda, a researcher in Yaounde, Cameroon, has identified a cohort of women who received ART during pregnancy and continue to control their virus despite stopping treatment after giving birth.

Much of what is known about HIV comes from research done in high-income countries, where HIV subtype B predominates. But subtype B accounts for just 12% of global HIV infections. In previous studies, Dr. Edward Kankaka of the Rakai Health Sciences Program in Kampala, Uganda, has shown that non-B HIV-positive Ugandans had a smaller reservoir of persistent virus compared to people infected with subtype B.



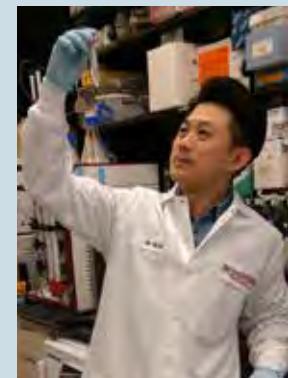
*Dr. Edward Kankaka*

Dr. Kankaka will expand these studies to determine whether formation and maintenance of the reservoir differ in these populations. His findings will add to our understanding of the potential effectiveness of curative interventions in people infected with HIV subtypes other than B.

# Researcher Awarded Krim Fellowship

In December, amfAR announced the 2018 recipient of the Mathilde Krim Fellowship in Basic Biomedical Research. Named in honor of amfAR's Founding Chairman, who passed away in 2018, these awards support promising young scientists pursuing innovative solutions to HIV/AIDS.

The Fellowship was awarded to Yen-Ting Lai, Ph.D., of the Vaccine Research Center/National Institutes of Health, Bethesda, MD, who will receive \$150,000 over two years. Working under the mentorship of Dr. Peter Kwong, Dr. Lai is applying his expertise in structural biology to understand how resistance develops to a drug in the entry inhibitor class called temsavir, which is now in phase III clinical trials.



*Dr. Yen-Ting Lai*

Currently, there are only two FDA-approved drugs in this class, which targets the earliest stage of the HIV life cycle, when the virus enters the cell. Understanding the cause of resistance to temsavir, which has been observed in some studies to date, could help in the development of a new and improved generation of the drug.

In Durban, South Africa, Dr. Alex Sigal will examine the influence of tuberculosis—a common co-infection in low- and middle-income countries—on the HIV reservoir. He will explore whether the immune response to TB alters HIV reactivation—a key component of the "shock and kill" approach to curing HIV.

"This group of grantees brings diversity to our efforts in their approaches, goals, and geographic focus," said Dr. Rowena Johnston, amfAR vice president and director of research. "Our efforts must support every promising approach that gets us closer to our goal of a cure for every person living with HIV."

## Research

CONTINUED FROM PAGE 9

results are emerging concerning how many of the transplanted cells need to have the genetic mutation in order to make a difference in the clinical outcome.

We also have the opportunity to learn from the processes by which a stem cell transplant may clear out any remaining vestiges of HIV. If the conditioning regimen before a transplant does not completely clear the HIV-infected cells, we can learn which cells of the newly transplanted immune system finish the job, and how. If specific subsets of immune cells are especially effective at clearing small numbers of remaining HIV cells, we can turn that knowledge into a more broadly applicable intervention.

By following transplant patients over time, and ultimately confirming they're cured, we may be

able to go back to samples collected earlier during the transplant and recovery process. Researchers could look at cells, proteins, and other substances in their blood to determine whether there are signs

understand which regimens kill which subsets of cells. We may learn, for example, that some subsets of HIV-infected cells are the most important to target, and that others, even if they

### **"If we learn that the CCR5-delta 32 mutation is a critical factor, this finding points a promising way forward for gene therapy."**

that could have predicted a cure, without having to wait years to know for sure. These biomarkers would then be valuable in assessing whether other more broadly applicable interventions have been effective in achieving a cure.

We can also compare the chemotherapy regimens the patients receive for their different cancers, and

contain HIV, might be less important sources of rebounding virus and can be left alone.

And even transplant patients whose HIV we can still detect play an important role in our search for a cure. Because their remaining HIV reservoirs are so small, they may be ideal candidates to test early-generation immunotherapies for their ability to remove any remaining pockets of HIV.

## Clinical Trials, Community Voices

Dispatch from the 2018 Cure Summit

"For a lot of folks, having a cure for HIV would bring a kind of freedom," said HIV advocate Rob Newells in his opening remarks at amfAR's HIV Cure Summit in November. "Freedom from pill popping, freedom from HIV stigma, freedom from discrimination and criminalization." Held at the University of California, San Francisco, home to the amfAR Institute for HIV Cure Research, the summit featured a range of perspectives from members of the community advisory board for the amfAR Institute and other community leaders.

Much of the discussion centered on analytic treatment interruption (ATI). The only means currently available to prove a person has been cured "is to remove antiretroviral therapy," said Rowena Johnston, amfAR vice president and director of research. "And when we do that, it's under closely controlled and monitored conditions." For a study participant whose HIV might rebound and who may be infectious, ATI can be a prolonged period of enormous anxiety.

Dr. Steven Deeks, a professor of medicine at UCSF and a lead investigator at the amfAR

Institute, explained the complex clinical study he is leading. "We're going to make the first serious attempt to achieve remission or cure in HIV-infected people," he said. In the five-stage trial, Dr. Deeks and his team will administer a series of therapeutic vaccines, broadly neutralizing antibodies, and an agent to shock the virus out of its hiding places.



### **Why do we need transplant patients to learn these things?**

There are some things about curing HIV that you can only learn from people who have been cured. In the absence of other interventions so far that cure HIV, we need to learn those lessons from transplant patients.

For example, people living with HIV experience consequences of the persistence of the virus, such as damage to the architecture of their lymph nodes, that can hamper effective immune responses. If we remove the HIV, does their lymph node anatomy and function return to normal? If so, then we have learned that removing HIV may be sufficient for restoring lymph node health, without needing to devise additional interventions.

Similarly, PLWHIV have higher rates of atherosclerosis, a sign of possible heart disease and stroke. If those signs and symptoms return to normal after a stem cell transplant that removed HIV, then perhaps we've learned that no further interventions will be needed to deal with heart health after an HIV cure.

*Dr. Johnston is an amfAR vice president and director of research.*

# Expanding Access to Newer HIV and Hepatitis C Medications in Asia

With the availability of newer drugs for HIV and hepatitis C still limited in much of the Asia-Pacific region, amfAR's TREAT Asia program organized a roundtable discussion with the goal of improving access to these life-saving medications. Held in Bangkok, Thailand, September 25–26, 2018, the meeting was planned in collaboration with the World Health Organization (WHO) South East Asia Regional Office (SEARO) and Western Pacific Regional Office (WPRO).

"Although these drugs are often manufactured in Asia, the regulatory approvals to ensure their availability and uptake in national programs have scope for improvement," said Giten Khwairakpam, TREAT Asia's program manager for community and policy. Participants from nine Asian countries attended the roundtable, along with representatives from the Clinton Health Access Initiative, Medicines Patent Pool, Drugs for Neglected Diseases initiative, UNAIDS, and the WHO.

The discussion focused on enhancing access to direct-acting antivirals to treat hepatitis C, as well as the newer HIV medications, including dolutegravir, the fixed-dose combination of tenofovir/lamivudine/dolutegravir (TLD), and the 4-in-1 pediatric formulation of ritonavir-boosted lopinavir with abacavir or zidovudine and lamivudine. Participants explored recent scientific data on the clinical benefits and development pipelines of the medicines, the status of regulatory approvals, intellectual property issues, and avenues to achieve fast-track approval by national regulators.

"The meeting was an opportunity for representatives from intellectual property offices, national regulatory bodies, and program managers to come together to explore means to enhance availability, use, and access to these new medicines in national programs," said Dr. Manisha Shridhar of WHO SEARO.

In the Asia-Pacific region, some countries have been "early adopters" of medications such as TLD. The Philippines, for example, has used a WHO collaborative process for drug registration to fast-track the registration of medicines for HIV and other conditions. Lao PDR has also started using TLD in its national program. Reports of the ongoing experience of these two countries were presented at the meeting.

"The discussions led to improved understanding of the situation on access to HIV and hepatitis medicines, and how countries overcame barriers in access, paving the way for regulatory approvals and the use of these medicines in national programs," said Dr. Takeshi Nishijima from WHO WPRO.

"We plan to continue this collaboration and regularly share information to sharpen strategies for enhancing access to these medications," said Mr. Khwairakpam. "Knowing what has worked and what hasn't will make us better able to influence policy and improve national drug programs."



*(Left to right) Liudmyla Maistat, Drugs for Neglected Diseases Initiative (DNDi); Leena Menghaney, MSF Access Campaign; and Janice Lee, DNDi*



*(Left to right) Chase Perfect, Coalition Internationale SIDA; Jessica Burry, MSF Access Campaign; and Dr. Manisha Shridhar, World Health Organization, SEARO*



*Participants at the roundtable discussion: "Enhancing Access to Newer HIV and Hepatitis C Medications," September 25–26, 2018, Bangkok, Thailand*

# Improving the Quality of Care for Young Adults With HIV



(Left to right) Dr. Yasmin Gani, Sungai Buloh Hospital, Malaysia; Smita Nimkar and Dr. Shashikala Sangre, BJ Medical College, India

There has been a slow decline in mother-to-child transmission (MTCT) of HIV in the Asia-Pacific region. Although there are still high rates in other countries, the World Health Organization has certified that Thailand and Malaysia have eliminated MTCT. With this overall declining trend, the number of children and adolescents in care at clinical sites within the TREAT Asia network who were infected with HIV at birth is shrinking. While this is good news, there are increasingly large numbers of young adults in the region with more recently acquired infections.

In 2017, 30% of new HIV infections in the Asia-Pacific region occurred in young people aged 15–24. And many youth still receive inadequate treatment and suffer poorer outcomes than older adults.

"With much of TREAT Asia's research now focusing on the transition of adolescents living with HIV from pediatric to adult clinics, we recognize the need to study the broader health outcomes of older adolescents and young adults," said Dr. Annette Sohn, amfAR vice president and director of TREAT Asia.

To that end, a think tank exploring the rationale for and potential scope of a new regional young adult cohort study was organized in Bangkok in January 2019. The meeting was attended by TREAT Asia network clinical care providers and researchers from Cambodia, India, Malaysia, the Philippines, Thailand, and Vietnam—as well as other regional experts.

"It was extremely helpful to come together with other investigators to plan how best to study this vulnerable and changing population. While each

country in the region has different HIV policies and varied needs, this think tank has set the groundwork for cohesive research that could substantially improve care and outcomes," said Dr. Yasmin Binti Mohamed Gani of Hospital Sungai Buloh in Malaysia.

Participants considered data gaps and priorities, and the financial and technical resources required to expand research in this area. Mental health, sexually transmitted infections, stigma, and substance use emerged as priority issues for data collection and future research.

"I feel that research now should be tailored to help clinical practice move and change government policies, raise awareness, and support services for this at-risk cohort," continued Dr. Gani. "We need to look at novel strategies that study the reasons behind poor adherence and poor retention in this population. Many adolescents need help with a smooth transition to adult care, especially those living in shelter homes and without family members to guide them. More often than not these homes provide basic housing but minimal support, mostly due to financial constraints."

The think tank will inform pilot research aimed at impacting health and legal policies around the management of young adults living with HIV in the Asia-Pacific region.

## Modeling the Adolescent HIV Epidemic in Thailand

How many adolescents in Thailand are living with HIV, how many are newly infected, and how many are in care? A team of researchers from TREAT Asia, Massachusetts General Hospital, and Harvard Medical School is working with the Thai Ministry of Public Health (MoPH) and the Thai MoPH-U.S. Centers for Disease Control and Prevention HIV/AIDS Collaboration to develop a model of Thailand's youth HIV epidemic to better answer these questions.

The study has identified the most reliable local data to use in the model, including

coverage of prevention of mother-to-child transmission services, the number of youth receiving antiretroviral therapy (ART) through the Thai national AIDS program, the number of new HIV infections among youth, and survival among youth receiving and not receiving ART.

If successful, the model could provide the basis for a Thailand-specific pediatric and adolescent HIV epidemic model that could be used by national-level stakeholders to better inform strategic planning, policy, and programming.

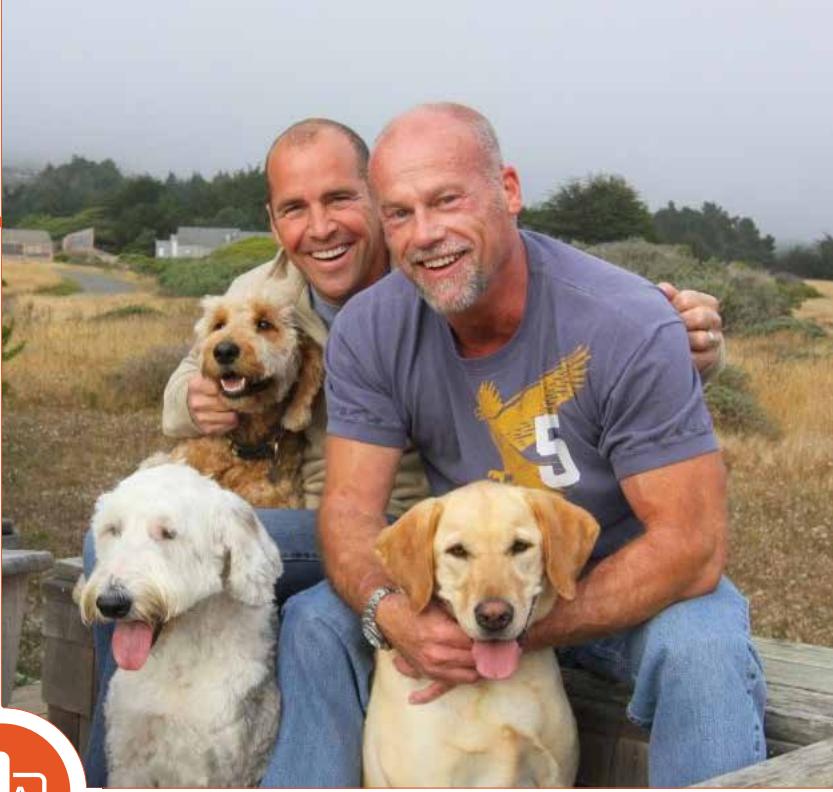


Dr. Annette Sohn, TREAT Asia; Tulathip Suwanlerk, TREAT Asia; Dr. Sophie Desmonde, Massachusetts General Hospital; Dr. Jeremy Ross, TREAT Asia

## Donor Profile

# Why We Give

Paul Arata and Scott Foster are longtime generous supporters of amfAR. We asked them about their reasons for giving and why they remain optimistic that researchers will find a cure for HIV.



### How did you learn about amfAR?

We grew into our adult selves during the height of the AIDS crisis. Both of us were coming out and building our friendships and new families. Unfortunately, we were also losing a lot of friends and family at the same time to the disease. We often think of the friends and loved ones we lost and how our lives would be enriched even more if they were still with us.

**"You are not this disease. Live your life fully and completely."**

At that time, there were many groups working on politics, care, and support for those affected, but only amfAR was primarily focused on finding the cause and a cure. The messages from Mathilde Krim were focused on what needed to be prioritized. The incredible Elizabeth Taylor, Kenneth Cole, and other celebrities' support of amfAR was also very visible when others were trying to distance themselves from or ignore the crisis.

### Why did you choose to support amfAR in particular?

In the early days we participated in and supported many walks, fundraisers, auctions,

and other local and regional events. We found that too much of what was being given was going to the promoters and planners and not the organizations that needed the funds and those in need, and we became disenchanted. We decided to focus our support to amfAR directly so that more of what we gave actually went to the research and people working to find a cure.

### As longtime supporters of amfAR, what drives you to continue giving?

In the fall of 2015, we attended the kickoff for the amfAR Institute for HIV Cure Research at UCSF. The annual updates review exciting new information about the virus, which gives the researchers new avenues to explore. It is exciting to hear from the scientists and their teams about this advanced work and progress that is coming out of amfAR's research grants. This work is a great motivator for us to continue our support.

Although we have many drugs that help people with HIV/AIDS lead seemingly normal lives, there are still so many challenges with finding the right treatment protocols, debilitating side effects, and the strain to maintain compliance on required medication regimens. Then there are the pharmaceutical costs and insurance coverage challenges. Meanwhile, HIV/AIDS continues to dramatically alter lives and impact

families around the world, especially among disenfranchised and underserved communities.

### What would having a cure for HIV mean to you?

It would mean peace of mind for us and many of our friends as well as the possibility to control or eliminate this disease in underserved countries and people. HIV does not just affect the person infected with the virus; it affects everyone important in their lives. It can become deeply rooted in their persona. Not having that burden to carry in today's world would be very freeing.

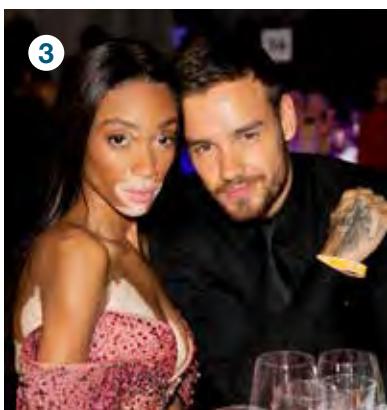
### Are you optimistic that we could achieve a cure in the foreseeable future?

We are. Having lived through the last 30-plus years and seeing the progress made towards controlling the virus, we know that with the talented individuals and teams focused on understanding and eliminating the virus, we will one day find a cure.

### Is there a message of hope you'd like to convey to families contending with HIV?

You are not this disease. Live your life fully and completely. Take care of yourself. There are amazingly brilliant people working with a laser focus on understanding this virus and how we can change how it affects you and all mankind.

## Events



## amfAR Gala Milano

Edward Enninful, editor-in-chief of *British Vogue*, was honored with the Award of Courage at the tenth annual amfAR Gala Milano, September 21, during Milan Fashion Week. Supermodel Adwoa Aboah presented the award in recognition of Enninful's philanthropic efforts and commitment to the fight against AIDS. Singer-songwriter and model Karen Elson opened the evening, which featured a live auction and outstanding performances by Swedish pop sensation Zara Larsson and British star Julian Perretta. Luminaries in attendance included Halima Aden, Nina Agdal, Bianca Balti, Mariacarla Boscono, Winnie Harlow, Liam Payne, Ashlee Simpson Ross, Evan Ross, and Amber Valletta. The gala raised \$1.2 million.

**Special thanks:** Pernod Ricard, Champagne Perrier-Jouët, Absolut Elyx, Delta Air Lines, Boroli

**1.** Honoree Edward Enninful and award presenter Adwoa Aboah **2.** Zara Larsson **3.** Winnie Harlow and Liam Payne **4.** amfAR Chairman Bill Roedy (Photos: Getty Images, Kevin Tachman)

## amfAR Mexico City

Zoe Saldana, Soumaya Slim, Sami Hayek, Zelika Garcia, José Bastón, Moises, and Rafael and Jaime Micha were among those in attendance at amfAR's inaugural amfAR Mexico City Dinner on February 5 at the contemporary art-filled home of collector and museum patron Eugenio López. The event featured a live auction of contemporary artwork curated by Estrella Provas and directed by Eli Rodríguez of Sotheby's, and included works by Otto Zitko, José Dávila, Catherine Opie, Gonzalo Lebrija, Joe Goode, Sterling Ruby, Nacho Carbonell, and Pablo Vargas Lugo. The evening concluded with a spectacular performance by legendary singer Grace Jones.

**1.** Eugenio López, guest, Toño Mauri, Carla Alemán, and Estrella Provas **2.** Zoe Saldana and Estrella Provas **3.** Grace Jones **4.** Gallerist Henry Ehrhardt and Ester Vina (Photos: Getty Images)



## TWO x TWO for AIDS and Art

Cindy and Howard Rachofsky hosted the 20th annual TWO X TWO for AIDS and Art benefit dinner and contemporary art auction on October 27, raising over \$9.3 million for amfAR and the Dallas Museum of Art. Alan Cumming was master of ceremonies for the spectacular event, held at the Rachofsky House in Dallas and chaired by longtime TWO X TWO supporter Tim Headington. The legendary Diana Ross wowed the audience with a 30-minute performance of hits including "I'm Coming Out," "You Can't Hurry Love," and "Stop in the Name of Love." A painting titled "Beat Out the Sun" by Dana Schutz, recipient of the 2018 amfAR Award of Excellence for Artistic Contributions to the Fight Against AIDS, sold for \$700,000 in the live auction.

**Special thanks:** Cadillac, Sotheby's, Dom Pérignon, Moët & Chandon, Casa Dragones, TODD Events



1. Cindy and Howard Rachofsky 2. Tim Headington 3. Hamish Bowles 4. John Runyon (2nd from left), Lisa Runyon (center), and guests 5. Auctioneer Oliver Barker of Sotheby's 6. Armie Hammer, Howard Rachofsky, Grant Schaffer, and Alan Cumming 7. Honored artist Dana Schutz and amfAR Chairman Bill Roedy (Photos: Kevin Tachman)

## Events

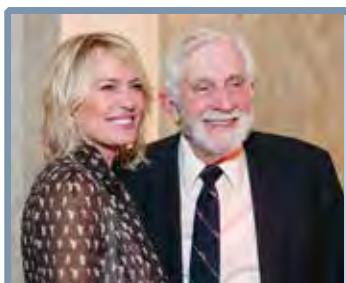


## amfAR Gala New York

At the 21st annual New York Gala on February 6, amfAR paid tribute to actress and amfAR Ambassador Milla Jovovich, legendary fashion photographers Mert Alas and Marcus Piggott, and tireless amfAR supporter and auctioneer Simon de Pury for their commitment to the fight against AIDS. Michelle Rodriguez, Kim Kardashian West, and Karolina Kurkova each presented awards. The evening featured performances by singer-songwriter and model Caroline Vreeland, and platinum singer-songwriter Parson James. To close the night, EDM-pop duo The Chainsmokers and special guest Kelsea Ballerini sang hit singles such as "Closer," "This Feeling," and "Hope," which had guests out of their seats dancing. The event raised over \$1.7 million for amfAR's life-saving research programs.

**Special thanks:** Absolut Elyx, Champagne Perrier-Jouët, The Points Guy, Mandarin Oriental, Boroli

1. Honoree Milla Jovovich 2. Alan Cumming 3. amfAR CEO Kevin Robert Frost and his sister Maureen Padillo 4. Honoree Simon de Pury and award presenter Karolina Kurkova 5. Honorees Mert Alas and Marcus Piggott with Kim Kardashian West 6. The Chainsmokers with Kelsea Ballerini 7. amfAR Trustee T. Ryan Greenwald, Michele Andelson, and amfAR Trustee Arlen Andelson 8. Brigitte Lacombe and amfAR Trustee Aileen Getty (Photos: Getty Images, Jared Siskin, Clint Spaulding)



Event Host Robin Wright and former amfAR Trustee Dr. Mervyn F. Silverman (Photo: Drew Altizer Photography)

## Inaugural amfAR Charity Poker Tournament

On November 17, Robin Wright, Karolina Kurkova, Jay Ellis, and Mia Maestro were among those gathered for amfAR's inaugural Charity Poker Tournament at the private San Francisco residence of Ann and Gordon Getty. Event host Wright welcomed guests and spoke of the impact their support would make in potentially ending the AIDS epidemic. CeeLo Green delivered a soulful performance and amfAR Trustee Aileen Getty detailed her personal experience fighting health complications resulting from HIV and spoke of the importance of funding research.

**Special thanks:** Bai, Dagne Dover, sharingbox



## amfAR Gala Los Angeles

Katy Perry and TOMS founder Blake Mycoskie were honored at the ninth annual amfAR Gala Los Angeles on October 18, for their profound commitment to the fight against AIDS. Los Angeles Mayor Eric Garcetti presented the Award of Courage to Perry while Liz Heller bestowed the honor on Mycoskie. Orlando Bloom, Heidi Klum, Leslie Mann and Judd Apatow, and Robert Pattinson were among those in attendance at the gala, which raised more than \$1.7 million for amfAR. Host Chris Tucker and Emmy Award winner Darren Criss performed, and Dame Shirley Bassey closed the evening with a show-stopping orchestral medley, including classics "Diamonds Are Forever" and "Goldfinger."

**Special thanks:** Pernod Ricard, Champagne Perrier-Jouët, Absolut Elyx, Bain Capital, Delta Air Lines

**1.** Dame Shirley Bassey **2.** Darren Criss performed a medley of Katy Perry hits **3.** Heidi Klum and auctioneer Simon de Pury **4.** Honoree Katy Perry **5.** Honoree Blake Mycoskie **6.** Event Chair Kevin Huvane (Photos: Getty Images, Kevin Tachman)



Lion Babe and Moe Moks performing (Photo: Getty Images)

## Dance2Cure Kickoff

amfAR kicked off its inaugural Dance2Cure dance challenge in West Hollywood on December 1—World AIDS Day. Hosted by Montana Tucker and including performances by AlunaGeorge and Lion Babe, the night featured a buzzing freestyle dance battle led by celebrity choreographers Tricia Miranda and Jason Samuels Smith. Dance2Cure is led by generationCURE.

**Special thanks:** Bai, Dagne Dover, sharingbox



“Pernod Ricard is thrilled to support amfAR, an organization leading the fight against HIV/AIDS with vision, scientific innovation, and an unbreakable spirit.”

— Jason Kim  
Director, Luxury Development

Pernod Ricard has supported amfAR’s fundraising events and programs around the world since 2017. As amfAR’s Official Spirits Partner, Pernod Ricard has generously donated nearly \$1 million to amfAR’s life-saving research.

Because of partners like Pernod Ricard, amfAR is able to continue leading the way toward the scientific breakthroughs necessary to end the AIDS epidemic.



## Upcoming Events

- |              |   |
|--------------|---|
| May 23       | amfAR Gala Cannes<br>Cap d’Antibes, France        |
| July         | generationCURE Solstice<br>New York City          |
| September 21 | amfAR Gala Milano<br>Milan, Italy                 |
| October      | amfAR Gala Los Angeles<br>Los Angeles, California |
| October 26   | TWO x TWO for AIDS and Art<br>Dallas, Texas       |