THE AMERICAN ACADEMY OF HIV MEDICINE www.aahivm.org JULY 2018
Patient Care, Practice Management & Professional Development Information for HIV Care Providers

HIV Specialist

Transplanting HOPE

HIV infection, organ donation and solid organ transplant

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PROGRAM GOALS

- Discuss how the existing HIV-treatment infrastructures can facilitate treatment of HCV among co-infected patients
- Identify barriers to HCV elimination relative to local/regional circumstances
- Share success stories and best-practices from established care models in other geographic and therapeutic areas
- Build linkage-to-care networks within local/regional systems
- Begin the establishment of a roadmap specific to regional needs and resources for HCV elimination in HIV/HCV co-infected patients

Joint Accreditation Statement

In support of improving patient care, this activity has been planned and implemented by the Postgraduate Institute for Medicine and Integritas Communications. Postgraduate Institute for Medicine is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the health care team.

Physician Continuing Medical Education

The Postgraduate Institute for Medicine designates this live activity for a maximum of 6.25 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Continuing Pharmacy Education

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In collaboration with: AAHIVM, American Liver Foundation, NHCN, Postgraduate Institute for Medicine, Integritas Communications

Jointly provided by Postgraduate Institute for Medicine and Integritas Communications

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CONTENTS

JULY 2018 | Volume 10, No. 2 | **www.aahivm.org**

FEATURES

DEPARTMENTS

This issue's Letter from the Director is being written by Amber McCracken, Communications Director for AAHIVM.

The Gift of Life

FIRST, I would like to thank AAHIVM Executive Director Jim Friedman for acquiescing his column to me for this issue. Jim and I have worked together for many years and he understands that I am a huge champion and advocate for organ donation. My passion is born from the fact that the miracle of transplantation saved my father.

I am my father's daughter in every way. A vivacious and wise extrovert, my father was as close to Andy Griffith as one can get. As an only child, I became my father's constant fishing companion, golfing partner and hunting buddy from as far back as I can remember. Even into adulthood, we remained very close.

In the early 2000's, my father's liver began to fail. It was a slow, but steady breakdown, and it was exceedingly painful for me to watch his health deteriorate. As clinicians, you know the debilitating symptoms…the yellow skin and eyes, belly pain, bloating, nausea, fatigue and mental confusion. It was becoming more and more apparent that his only chance was a liver transplant.

Being the only child, it fell to me to begin navigating the transplantation world. I immediately found that transplantation is a precarious thing. You have to be sick enough to be on the top of the list, but well enough to survive the surgery. It's a delicate balance. At the time, my father was in his 60's with a number of other pre-existing conditions making him a very unpopular candidate.

Despite taking him to a number of transplantation hospitals for evaluation, both close to him in North Carolina and close to me in Washington, DC, he was only accepted at Georgetown University Hospital. While we were hopeful, I could see there was a distinct supply and demand problem there. Many at the top of the list were not able to get their organs in time. I tried to be a living donor for my father. Unfortunately, after a litany of tests, I was not approved.

In desperation, I turned to the only resource I had…the Internet. I googled "shortest waiting times for livers." Up popped the Mayo Clinic in Jacksonville, Florida. Unlike the national average of 2 years (which my dad didn't have), the recipients on the Mayo Clinic transplant list were waiting an average of 2 months. I quickly flew him down there for an evaluation and, thankfully, he was accepted. He and my mother took up residency in Jacksonville and he received his new liver in just six weeks.

Since then, my father has not been without other health problems. He's suffered two strokes over the last few years. But we all recognize the joy in every day he is here. He has been able to watch his granddaughter grow up and met his grandson who was born shortly after his transplant in 2006. I am so extraordinarily thankful to the amazing medical staff at the Mayo Clinic. But I am most grateful to the donor family. What an amazing gift.

Every day, organ donors turn tragedy into hope. That's why when Dr. Cameron Wolfe approached me at an AAHIVM workshop about doing an issue of this magazine on the new hope of transplantation for people living with HIV, I jumped at the chance.

As clinicians, I hope this issue leaves you with two important takeaways. One, we have tried to include a clinical glimpse at the latest in transplantation for your patients that might be in need of a liver or kidney. But just as importantly, I hope you recognize the extraordinary responsibility you have to educate your healthy HIV patients that they are now eligible to register as a donor.

I would like to personally thank Dr. Wolfe for acting as an extraordinary co-editor for this issue. Dr. Wolfe identified the preeminent players in the field of transplantation to contribute, including those that have worked diligently on the passing of the HOPE Act.

I believe this issue will leave you feeling inspired, educated and, most importantly, hopeful for the future of transplantation for the HIV community. **HIV**

In the NEWS

FDA Approves Expanded Indication for Truvada to Lower HIV Risk in Adolescents

GILEAD SCIENCES, INC. announced that the US Food and Drug Administration (FDA) approved once-daily oral emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (Truvada) in combination with safe sex practices, to reduce the risk of sexually acquired HIV-1 in at-risk adolescents.

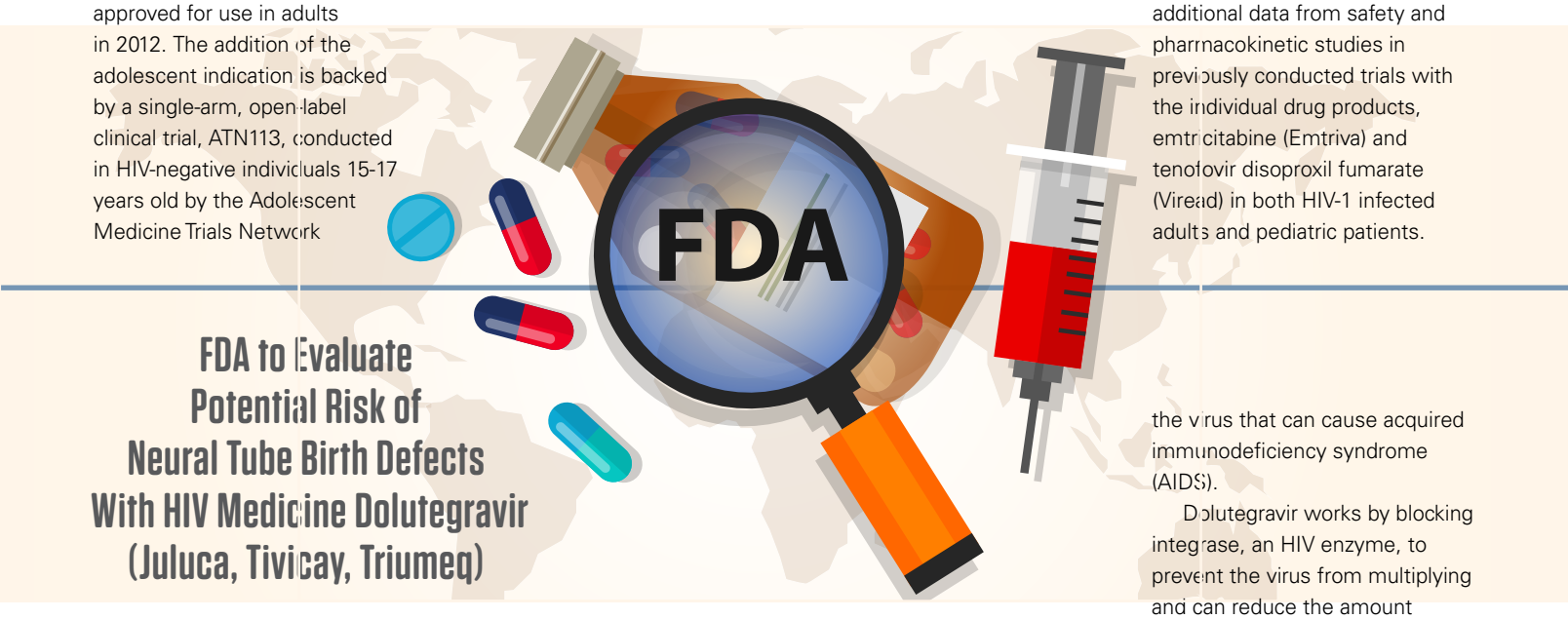
Truvada for pre-exposure prophylaxis (PrEP) was first approved for use in adults in 2012. The addition of the adolescent indication is backed by a single-arm, open-label clinical trial, ATN113, conducted in HIV-negative individuals 15-17 years old by the Adolescent Medicine Trials Network for HIV/AIDS.

In the study, 61 HIV-1 negative young men who have sex with men, 15–17 years old, received Truvada once daily for PrEP. The safety profile in the study is similar to the profile observed in adults. Common adverse reactions that greater than 2% and more frequently observed than in placebo include headache, abdominal pain and weight loss.

Bone mineral density was also monitored and 4 study participants were observed to have a decrease through 48 weeks (3 adolescents had a modest decrease and 1 had a >4% decline in total bone mineral density at week 24).

Truvada for PrEP is now indicated in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 in at-risk adults and adolescents weighing at least 35 kg. Individuals must test HIV negative immediately prior to initiating Truvada for PrEP.

The safety and efficacy profile of Truvada for PrEP in at-risk adolescents weighing at least 35 kg is supported by both the ATN113 study data and adequate and well-controlled studies of Truvada for PrEP in adults, with additional data from safety and pharmacokinetic studies in previously conducted trials with the individual drug products, emtricitabine (Emtriva) and tenofovir disoproxil fumarate (Viread) in both HIV-1 infected adults and pediatric patients.



FDA to Evaluate Potential Risk of Neural Tube Birth Defects With HIV Medicine Dolutegravir (Juluca, Tivicay, Triumeq)

THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) is alerting the public that serious cases of neural tube birth defects involving the brain, spine, and spinal cord have been reported in babies born to women treated with dolutegravir used to treat human immunodeficiency virus (HIV). Preliminary results from an ongoing observational study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects.

Neural tube defects are birth defects that can occur early in pregnancy when the spinal cord, brain, and related structures do not form properly. Dolutegravir is an FDA-approved antiretroviral medicine used in combination with other antiretroviral medicines to treat HIV, the virus that can cause acquired immunodeficiency syndrome (AIDS).

Dolutegravir works by blocking integrase, an HIV enzyme, to prevent the virus from multiplying and can reduce the amount of HIV in the body. Stopping dolutegravir without first talking to a prescriber can cause the HIV infection to become worse. Approved in 2013, dolutegravir has been on the market for 5 years, and is available as a single ingredient product under the brand name Tivicay and as a fixed dose combination tablet with other HIV medicines under the brand names Juluca and Triumeq.

Ongoing monitoring will continue as part of the observational study in Botswana. Additional birth outcomes are projected from pregnant women who were exposed to dolutegravir at the time of becoming pregnant. The FDA will conduct a comprehensive review of the results and any other data that becomes available.

SHUTTERSTOCK/ BAKHTIAR ZEIN

In the NEWS

HIV Vaccine Elicits Antibodies in Animals That Neutralize Dozens of HIV Strains

AN EXPERIMENTAL vaccine regimen based on the structure of a vulnerable site on HIV elicited antibodies in mice, guinea pigs and monkeys that neutralize dozens of HIV strains from around the world. The findings were reported in the journal *Nature Medicine* by researchers at the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and their colleagues. A preliminary human trial of the new vaccine regimen is anticipated to begin in the second half of 2019.

The experimental vaccine described in the report is based on an epitope called the HIV fusion peptide, identified by NIAID scientists in 2016. The fusion peptide, a short string of amino acids, is part of the spike on the surface of HIV that the virus uses to enter human cells. According to the scientists, the fusion peptide epitope is particularly promising for use as a vaccine because its structure is the same across most strains of HIV, and because the immune system clearly "sees" it and makes a strong immune response to it. The fusion peptide lacks sugars that obscure the immune system's view of other HIV epitopes.

To make the vaccine, the researchers engineered many different immunogens — proteins designed to activate an immune response. These were designed using the known structure of the fusion peptide. The scientists first assessed the immunogens using a collection of antibodies that target the fusion peptide epitope, and then tested in mice which immunogens most effectively elicited HIV-neutralizing antibodies to the fusion peptide. The best immunogen consisted of eight amino acids of the fusion peptide bonded to a carrier that evoked a strong immune response. To improve their results, the scientists paired this immunogen with a replica of the HIV spike.

The researchers then tested different combinations of injections of the protein plus HIV spike in mice and analyzed the antibodies that the vaccine regimens generated. The antibodies attached to the HIV fusion peptide and neutralized up to 31% of viruses from a globally representative panel of 208 HIV strains.

Based on their analyses, the scientists adjusted the vaccine regimen and tested it in guinea pigs and monkeys. These tests also yielded antibodies that neutralized a substantial fraction of HIV strains, providing initial evidence that the vaccine regimen may work in multiple species.

The scientists are now working to improve the vaccine regimen, including making it more potent and able to achieve more consistent outcomes with fewer injections. The researchers also are isolating additional broadly neutralizing antibodies generated by the vaccine in monkeys, and they will assess these antibodies for their ability to protect the animals from a monkey version of HIV. The NIAID scientists will use their findings to optimize the vaccine and then manufacture a version of it suitable for safety testing in human volunteers in a carefully designed and monitored clinical trial.

Syphilis on the Rise Among People Living With HIV

BETWEEN 1999 AND 2015, syphilis rates among people living with HIV (PLWH) in the U.S. increased more than five-fold, a study published in *Clinical Infectious Diseases* showed.

The research examined data from the massive, ongoing HIV Outpatient Study. Overall syphilis incidence among 6,888 participants living with HIV was 1.8 per 100 person-years over the course of the entire 16 years. However, while in 1999 the rate was 0.4 per 100 person-years, it had increased to 2.2 by 2015. Syphilis risk was greater for men who have sex with men compared to heterosexual men, those aged 18-30 years compared to 31-40 years, and African Americans compared to whites.

Testing for this sexually transmitted infection (STI) also increased during the study period. While this may have contributed to more syphilis cases being detected, it also reflects the fact that this STI is on the rise among PLWH, study authors noted. The results show the ongoing sexual risk in this population, especially among younger non-Latino MSM, they concluded, and called for sexual risk reduction interventions, as well as ongoing syphilis screening and treatment.

SHUTTERSTOCK/ JARUN ONTAKRAI

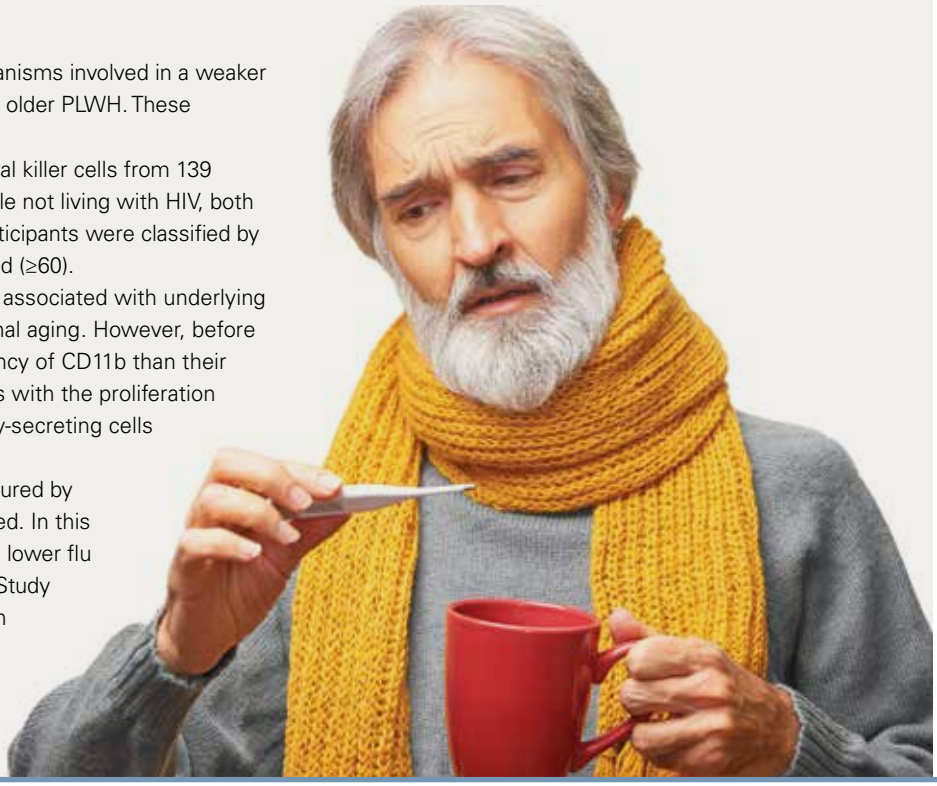
Study Pinpoints Impaired Influenza Vaccine Response Among Older PLWH

RESEARCHERS found some of the mechanisms involved in a weaker response to influenza vaccination among older PLWH. These findings were published in *AIDS*.

The study team analyzed monocytes and natural killer cells from 139 PLWH who were virally suppressed and 137 people not living with HIV, both before and after they received the flu vaccine. Participants were classified by age into young (19-39), middle-aged (40-59) and old (≥60).

Increased CD11b expression on monocytes is associated with underlying inflammation in diabetes and HIV, as well as normal aging. However, before vaccination, "old" PLWH showed a higher frequency of CD11b than their general-population counterparts. CD11b interferes with the proliferation of specific CD4 T-cells that help generate antibody-secreting cells after vaccination.

A person's response to the flu vaccine is measured by the quantity of antibodies that person has produced. In this study, higher CD11b+ levels were associated with lower flu antibody levels after PLWH had been vaccinated. Study authors called for more research on the interaction between inflammatory monocytes and T cells to better understand how flu vaccine responses are inhibited.



SHUTTERSTOCK/ KUDIA

GSK's Two-Drug HIV Treatment Meets Main Goal in Late Stage Studies

GLAXOSMITHKLINE's two-drug treatment for HIV met its main goal in late stage studies. The combination of dolutegravir and lamivudine was shown to be as effective as a dolutegravir-based combination of three drugs, GSK's majority-owned ViiV Healthcare revealed. It said its push for two-drug regimens addressed long-term toxicity concerns of people living with HIV by reducing the number of medicines.

Gilead Sciences in February won U.S. Food and Drug Administration approval for Biktarvy, a triple-combination HIV treatment, paving the way for the biotech company to capture more of the HIV drug market.

Single-Tablet TAF-Based Regimen Non-Inferior in Treatment-Naive Participants

A **SINGLE-TABLET COMBINATION** of darunavir/cobicistat/emtricitabine/tenofovir alafenamide was found non-inferior to a two-tablet comparator regimen among treatment-naive participants in a clinical trial, the results of which were published in *AIDS*.

Seven hundred twenty-five people were randomized 1:1 to the study drug, also known as D/C/F/TAF, or darunavir/cobicistat (Prezcobix) plus emtricitabine/tenofovir disoproxyl fumarate (Truvada). A similar percentage of participants (91.4% in the D/C/F/TAF arm versus 88.4% in the control group) achieved undetectable viral loads (< 50 copies/ml) by week 48. In the D/C/F/TAF arm, bone mineral density and renal measurements were better, but lipid profiles were worse, than in the control arm. Study authors attributed this result to the lipid-lowering effects of Truvada, rather than lipid-related side effects of the study drug.

The EMERALD trial previously found D/C/F/TAF to be non-inferior to a regimen of a boosted protease inhibitor plus Truvada, but it was conducted as a switch study in treatment-experienced people. D/C/F/TAF has already been approved in Europe under the name Symtuza, but is still under investigation by the U.S. Food and Drug Administration.

BY SHANNA LIVERMORE, MPH, MCHES®

Increasing the Number of HIV Care Providers One Fellow at a Time

HIV Clinical Leadership Program Adds Talent to a Shrinking Workforce

THE EVIDENCE that suggests the supply of HIV clinicians might not be keeping pace with the growth in the demand for HIV health care services cannot be ignored. In September of 2010, amid growing concern about the potential shortage of HIV clinicians, the Health Resources and Services Administration within the U.S. Department of Health and Human Services (HHS) sponsored the first national study to quantify the number of clinicians providing HIV medical care in the United States and to forecast the magnitude of the HIV clinician shortage or surplus.[1]

Overall, the study showed a small but rapidly expanding shortage of HIV providers. The forecasting model predicted that by 2015 the supply of HIV clinicians will be sufficient to meet only three quarters of total demand for HIV-related medical services under current market-based assumptions.

These statistics illustrated why the availability of HIV fellowship programs is so essential to the growth of the clinical community. One such program is the HIV Clinical Leadership

Interview with April Soto, Recent HIV Clinical Leadership Fellow

Why did you choose to pursue a career in HIV Primary Care?
I choose to practice HIV medicine for 3 main reasons.
1) It brings me fulfillment to provide care for those who society tends to cast away
2) it is mentally challenging and its good for me to be challenged.
3) the stories I get from patients are incredible and I could not get these anywhere else!

What brought you to the HIV Fellowship in particular?
During my Family Medicine residency, I was sent to rotate through USC HIV clinic. It was then that I fell in love with this medicine and I applied for fellowship shortly thereafter. I am grateful that I was accepted!

What did you particularly enjoy about this fellowship program?
I enjoyed working and rotating in a variety of clinics and institutions. The variety was awesome and helped me form a strong foundation. I also enjoyed the conferences I attended.

What was your favorite clinical experience and why?
There are a few favorites.
- Skid Row was super tough but also very educational and fun.
- Children's Hospital LA Dr. Church immunology was really interesting.
- Inpatient palliative care was awesome with Susan Stone
- Gay and lesbian center with Dr. Bolan

What was the best part of your training in the fellowship?
Having a variety while also structure with some half days open to further my learning. Attending conferences also helped me solidify my learning. Learning how to teach from Dr. Kathy Jacobson was awesome.

Program. This is a unique HIV fellowship for physicians committed to improving primary care for people living with HIV in under-served communities. This program brings together the unique strengths of Los Angeles County Department of Health Services (DHS), the AIDS Education Training Center at Keck School of Medicine of USC, ViiV Healthcare, and the UCLA David Geffen School of Medicine Clinical Leaders Program.

The purpose of this fellowship is to train physicians in the knowledge and skills necessary to provide expert HIV care. Each fellow will develop and initiate patient-centered primary care and community-specific HIV interventions. The fellowship provides a unique opportunity to explore passions surrounding HIV care and gain additional skills through the various partnerships the program has to offer.

Candidates are competitively selected through a national search. Fellows will be eligible for specialist certification through the American Academy of HIV Medicine. Fellows who complete the two-year program are eligible for loan repayment up to $150,000 over three years, and fellows who complete the one-year program are eligible for loan repayment up to $50,000 over three years.

Sample Clinical Rotations

- Communicable Disease/ Infectious Disease Clinic
- Inpatient ID Service
- Colorectal Clinic
- Community HIV Clinics
- Correctional HIV Clinics
- Dermatology
- Emergency Department
- Hematology/Oncology
- HIV Resistance Test Interpretation
- HIV Test Counseling
- Neuropsychology
- Neurology
- Palliative Care
- Pediatric & Adolescent
- Pulmonary Medicine
- OB/GYN
- STD Clinics
- Women's Health

Basic Overview of the Fellowship

There are two fellowship tracks: a two-year clinician scholar track and a one-year clinician track. The purpose of these fellowships is to train physicians in the knowledge and skills necessary to provide expert HIV care, to be health systems leaders, and to be successful community partners in patient-centered and community-specific HIV interventions.

Two-Year Clinician Scholar: This is a two-year program that focuses on training physicians to enter leadership positions in HIV healthcare.

Year 1 is focused on academic course work in partnership with the UCLA National Clinician Scholars program. Fellows will gain knowledge in health policy, research methods, community-based participatory research, pressing issues in healthcare, and pathways to leadership. Fellows will rotate through various HIV clinics, consult in the emergency department on HIV cases that require specialty care, and begin to build their continuity clinic. Fellows will participate in regular case-based learning other didactic sessions on major HIV medicine topics, including multidrug resistance and opportunistic infections.

Year 2: Fellows will be expected to manage patients with more independent decision-making in specialty or elective rotations, as well as maintaining their continuity care clinic panels and precepting first-year fellows, residents, and students. Second-year fellows will spend a significant amount of time implementing their chosen scholarly project which will be presented at a regional/national conference and/or will be submitted to publication in a peer-review journal.

One-Year Clinician: A one-year intensive clinical experience that includes rotations in safety net clinics, the jail system, and community-based clinics to gain exposure to all aspects of general and subspecialty HIV care for patients of all ages. Didactic training is weaved into the track and includes treatment of multidrug resistant and opportunistic infections. Fellows are required to complete a focused research and/or quality improvement project related to a topic of interest in HIV care. At the end of the Clinician track, fellows will be fully prepared to provide comprehensive HIV Clinical care to a variety of populations.

Applications are currently being accepted for the 2019 cohort! Deadline November 15th annually. Application details can be accessed at: https://www.hivmedfellowship.com/. If you have any general questions about the fellowship, or would like to request additional information, please contact Shanna Livermore by emailing Shanna.Livermore@med.usc.edu. For specific inquiries, please contact Raymond Perry, M.D., Director of the DHS HIV Public Health Fellowship at rperry@dhs.lacounty.gov. HIV

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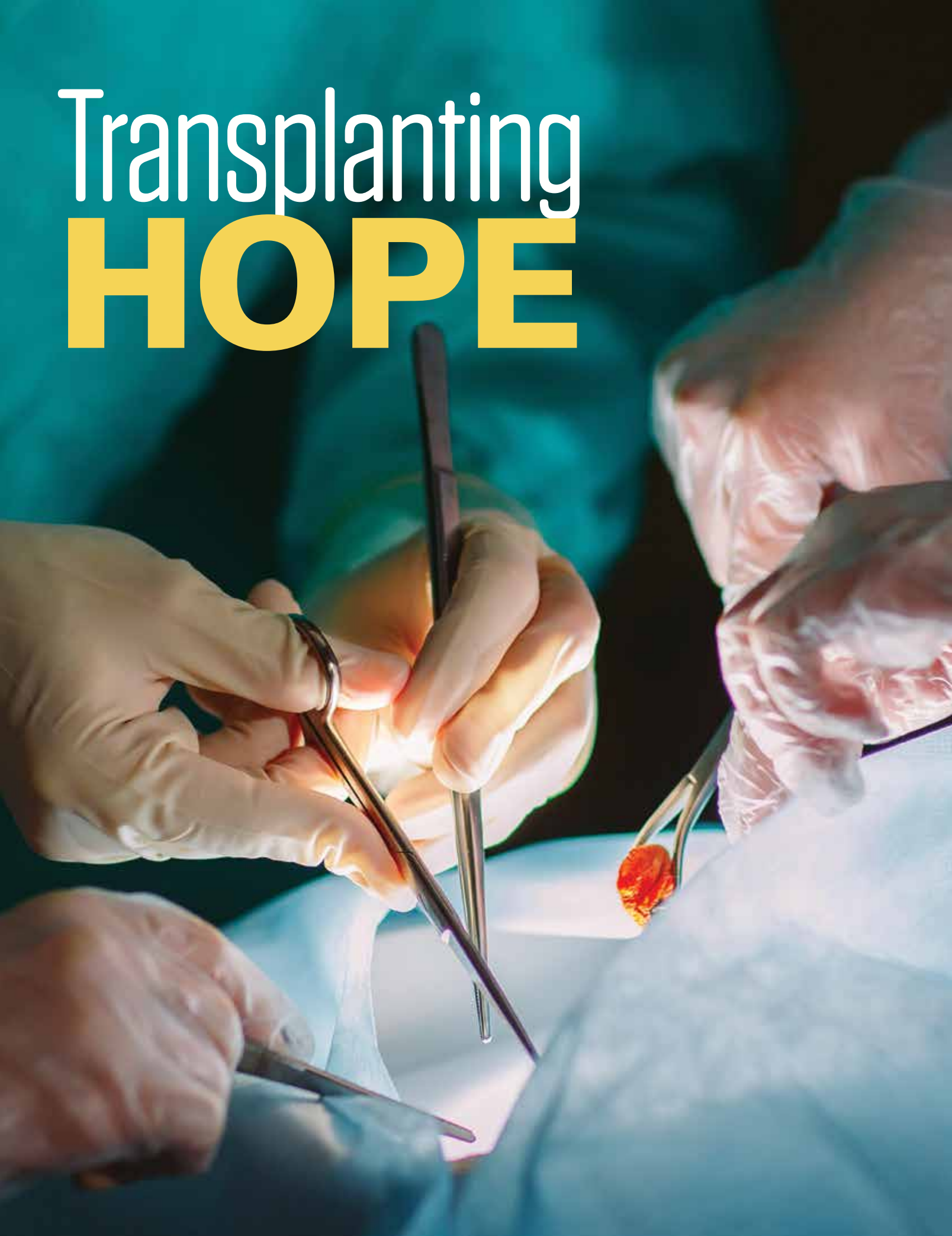
Shanna Livermore, MPH, MCHES®, is the Program Manager for the HIV Clinical Leadership Program.

Transplanting HOPE



HIV infection, organ donation and solid organ transplant

By CAMERON WOLFE, MD, MPH, FIDSA

I **CAN STILL REMEMBER** the first patient I met in medical school who was living with HIV. In the late 90's in my home country of Australia, HIV was more of a medical curiosity than it was the scourge it was in other parts of the world. Seeing this patient during my time as a medical student sparked a curiosity due to the complexity of the condition, the seemingly endless array of infections, the malignant complications that needed to be considered, and the entanglement between the psychosocial milieu and the immunologic factors at play.

That curiosity, along with the zest and compassion shown by leaders in the field, led me to ultimately complete an Infectious Disease Fellowship, concentrating on HIV medicine. In Australia, we were fortunately rich in resources, and few in patients, thanks mainly to an aggressive early public health campaign. Consequently, patients coping with the virus had many options to turn to.

Yet still, with all the resources at my fingertips, my overwhelming feeling throughout medical school, residency and fellowship, was that of a stigma and a societal ostracizing that I could never really wrap my head around. Perhaps it was that struggle to balance emotions that ran through the HIV-negative community, trying to empathetically negotiate a fear of the disease, a lack of understanding of sexual and gender identity, the medical complexity and the socioeconomic overlay. Perhaps HIV just simply did not fit well within the macho Australian identity that existed at the time. Whatever the reason, the social isolation and the lack of normalcy faced by so many I cared for was indelible.

When I moved to North Carolina to practice at Duke University, a sense of that same stigma quickly flushed through the clinics. Even though our HIV clinic has a wonderful history of staunch support for the HIV positive community, there were challenges that still existed including difficulties in getting colleagues to see patients; anchor bias suffered by fellow clinicians struggling to move beyond 'HIV' on the Past History list, even for well-controlled patients; access to preventative public and sexual health education.

Organ transplant access was impossible, as one senior clinician once told me, because scarce organs shouldn't be given to people who "don't deserve them or will die anyway." I still shudder remembering that conversation.

This edition of *HIV Specialist* follows the progression of the HIV Organ Policy Equity (HOPE) Act. Enclosed herein, are a number of articles written to explore the complexity of organ donation, and the slow yet methodical approach to changing the transplant community since the HOPE Act was signed. We look at the process of transplant approval, what it can do, and when it should and should not be considered. As our clinic population grows older, and end-organ disease, especially renal failure and cirrhosis, become more prevalent, this is a timely discussion.

When I think back to the first HIV patient I saw over 20 years ago, it is encouraging to see how far we've come. He was suffering end-stage liver disease thanks to the grueling combination of untreated HCV and inadequately treated HIV. At the time, he and I both knew he was soon going to die. Organ transplantation was not an option. The possibility that he might gift a legacy of organ donation, so that someone else might not suffer the same fate, was not yet imagined.

Today, I end clinic visits with my HIV patients on a high-note, asking "Have you considered becoming an organ donor?" Patients look confused, fleetingly uncomfortable considering the option. Many had always assumed this was impossible, that it was illegal, that no one would want "them"-literally. Then, as we sprout the conversation further, and they realize as a well-controlled patient they could be a donor of a kidney or a liver if they pass away, I see a glint of HOPE.

To think that their organs could save the life of someone else living with HIV is an enlightening thought, an encouraging thought, an empowering thought. I wish I had the chance to go back to my first patient and have the conversation about bringing him to long lasting HIV suppression, and finally, walking with him to transplant, perhaps with a liver donated by another patient living with HIV. It is an empowering conversation for patients to have. **HIV**

ABOUT THE AUTHOR:
Dr. Cameron Wolfe is an Associate Professor in the Transplant Infectious Disease section at Duke University Medical Center. He practices HIV medicine, as well as Transplant Infectious Disease, and is the Duke site PI for the HOPE Act. Cameron is the current Chair of the Disease Transmission Advisory Committee, overseeing transplant safety.

SHUTTERSTOCK/ DAVID TADEVOSIAN


HUMAN
ORGAN

The Transformation of TRANSPLANTATION

A NEW HOPE

By CHRISTINE DURAND, MD

THE NUMBER OF PEOPLE living with HIV infection in the United States has risen steadily over the last 30 years. Current estimates suggest that over 1.2 million people are HIV-positive, and although improvements in public health and educational infrastructure have resulted in a decline in the number of new incident cases over time, some 35,000 people are newly infected every year.[1] Concurrently, the advent of multiple highly effective and safe antiretroviral drugs have enabled patients to greatly extend their life expectancy. In 2018, for a newly diagnosed patient presenting to care in the US, one might anticipate an average life span of over 70 years.[2]

However, as life expectancy increases, so does the incidence rates of chronic severe organ disease. This is particularly true for end-stage renal failure (ESRF), where HIV infected patients with ESRF now make up approximately 1.5% of the patients on long term dialysis.[3] There are similar increases in the numbers of patients with late-stage cirrhotic liver disease, and to a lesser extent cardiopulmonary disease. Consequently, better strategies are required not only for preventing organ damage, but for supporting patients with ESRF, cirrhosis or heart failure. Transplantation is one such option, and thus far has been found to be a safe and cost-effective strategy for many persons living long-term with HIV disease.

SHUTTERSTOCK/ DICRAFTSMAN

Solid organ transplant for people living with HIV has been available for over 20 years in a number of centers in the United States. Although outcomes from organ transplantation were initially inferior to those seen with HIV-negative recipients, there has been a marked improvement in the quality of life of transplanted patients in recent years, especially for patients undergoing kidney transplantation.

Outcomes from a series of multi-center NIH-sponsored kidney and liver transplant studies showed that life expectancy and graft survival was largely comparable with HIV-negative controls.[5] Patient and transplant survival, as well as quality of life, has improved further as modern antiviral regimens have become safer and more effective—particularly those that include Integrase Strand Transfer Inhibitors (INSTi).

The advantages with these drugs are many. Not only are they generally well tolerated and highly efficacious but they have fewer drug interactions compared with pharmacologically boosted regimens containing ritonavir or cobicistat. These older ART regimens remain challenging when trying to dose calcineurin inhibitor immunosuppression regimens, often resulting in wildly different tacrolimus and cyclosporine dosing regimens that may have historically resulted in higher rates of rejection. With newer antiretroviral drugs to maintain viral control, and a better understanding of immunosuppression requirements to avert tissue rejection, transplantation should be standard of care for the majority of persons living with HIV and suffering from a transplantable condition.

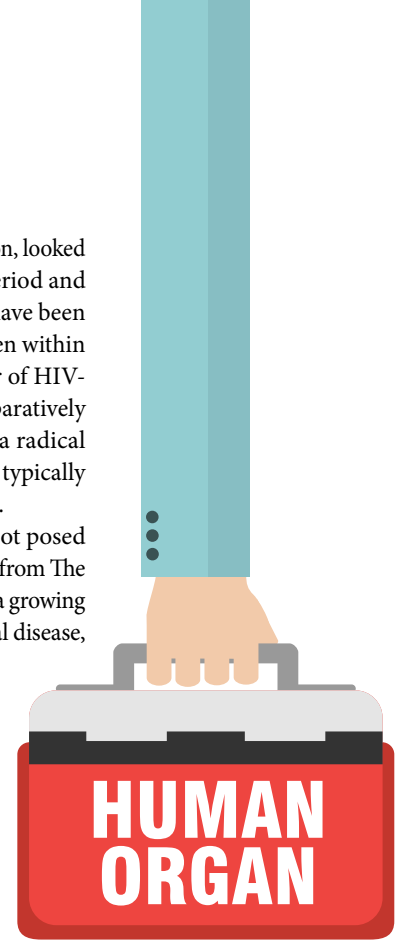
As the knowledge that transplantation is an optimal solution for patients living with HIV and chronic organ failure has grown, so has the disparity between the organ transplant waitlist and the number of organs available. Currently, in the United States, there are approximately 95,000 patients on the waiting list for kidney transplant—yet in 2017 fewer than 20,000 kidney transplants occurred (14,308 deceased donor transplants and 5811 living kidney donor transplants).[6] Patients living with HIV are disproportionately affected, with high mortality on the renal and liver wait list.

Historically in the United States, patients living with HIV were unable to be donors, deceased or living. Federal Law passed in 1988—during a time of unprecedented anxiety around the HIV epidemic—prohibited the intentional donation of HIV+ units of blood or tissue. Many states enacted similar laws that were designed to minimize the risk of inadvertent spread of the virus.

These regulations caused hospitals and Organ Procurement Organizations (OPO) to decline donation from HIV positive individuals, living or deceased, no matter how good their organs might have been, and no matter how urgently someone on the transplant waiting list needed them. Modelling projections suggested that if these laws were relaxed, and HIV positive donor organs were allowed for HIV-infected recipients, up to 500 additional organ donors might be available, per year, across the United States.[7]

Another study from the greater Philadelphia region, looked retrospectively at deaths reported over a 6 year period and estimated that up to 20 additional donors might have been available for transplant during the time period, even within the boundaries of the city.[8] Although the number of HIV-positive patients wait listed for transplant is comparatively small, the addition of these donors could make a radical difference to the HIV-specific wait time, which is typically longer than for matched HIV uninfected patients.

Outside the United States, similar laws have not posed such a restriction. In South Africa, Dr Elmi Mueller, from The University of Cape Town, faced with the dilemma of a growing number of young patients with HIV-associated renal disease, limited dialysis options and a high proportion of suitable donors who were also HIV-positive, began cautiously transplanting HIV positive donor organs into positive recipients.[4] Results have been extremely encouraging. The first 49 patients matched historical controls seen for HIV positive recipients in the United States, with no accelerated surgical, infective or immunologic complications.[9] The 5-yr survival is currently 82%.



The HOPE Act

Following initial success in South Africa, legislative efforts were made in the United States that culminated in 2013, when President Obama signed the HIV Organ Policy Equity (HOPE) Act into law. The Act represented bipartisan legislation, allowing HIV-positive individuals to donate certain organs (currently only kidneys and livers), but only as part of a research study conducted with oversight by an academic institution.

Unfortunately, even though Federal Law was relaxed, many states enacted restrictions that went beyond the HOPE Act and locally limited the donation and acceptance of HIV-infected organs. Consequently, further efforts were needed to create change on a state by state basis.

In one example, North Carolina was found to have a long standing clause written into the HIV Control Measures prohibiting organ donation under any circumstances. The control measure was also written in 1988, and was a subsection of legislation administered by the Commission for Public Health.

Following initial success in South Africa, legislative efforts were made in the United States that culminated in 2013, when President Obama signed the HIV Organ Policy Equity (HOPE) Act into law. The Act represented bipartisan legislation, allowing HIV-positive individuals to donate certain organs (currently only kidneys and livers), but only as part of a research study conducted with oversight by an academic institution.

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The signing of HOPE Act was able to stimulate a local conversation that eventually culminated in a relaxation of the law.

Additionally, the revision also afforded the state an opportunity to modernize the language around sexual disclosure and safe sexual behavior that reflected thirty years of updated science, a revelation for the local HIV community.

At the same time as state laws were changing, work was carried out on the research framework for studying HIV+ donor transplants. The HOPE Act directed the Secretary of Health and Human Services (HHS) to develop and publish guidelines for the conduct of research relating to transplantation of organs from HIV-infected donors. This task was assigned to The National Institutes of Health (NIH).

The bill also requires the Organ Procurement and Transplantation Network (OPTN) to revise its standards of quality regarding HIV-infected organs and the Secretary to revise related regulations. Regulations require that for a hospital to participate they must have experience in transplanting at least 5 HIV-positive recipients. At this stage, some 25 centers have applied to receive an OPTN waiver allowing them to accept HIV positive donors, specifically for liver and kidney transplantation. It is hoped that in the future centers will be able to gain enough experience to also expand into heart and lung transplant.

Deceased donors currently make up the entirety of the HIV positive organ donors pool in the United States. That said, the HOPE Act does allow for living organ donation, and generally speaking living kidney transplants do tend to outperform those from deceased donors, so are greatly valued. To date, there have been no HIV positive living donors in the US. For such a transplant to work, participating centers would not only have to ensure recipient safety and predict post-transplant HIV viral control in both recipient and donor, but would also predict the likelihood of accelerated renal decline in the donor. Given the inherently higher rates of progression to ESRF seen with patients living with HIV, especially in African Americans, living HIV-positive organ donation is expected to remain uncommon.

Results to Date

With much celebration, the first HIV to HIV transplants performed under the HOPE Act took place at the Johns Hopkins Hospital in Baltimore in March 2016. To date, led by a multisite research consortium directed through Johns Hopkins called "Hope In Action", almost 30 patients have received transplants from positive donors through the research, providing those patients with an accelerated pathway to transplant and the benefits that accrue afterwards.

A number of important research questions are still being studied through the HOPE Act. Firstly, from the perspective of HIV, it remains important to know whether the use of HIV-infected donors will increase the risk of HIV viral breakthrough, and if so, whether it would be with the recipient or the donor virus, or perhaps even some recombinant version of the two. So far, results are excellent with essentially no viral breakthrough, and no resistance emergence.

To date, led by a multisite research consortium directed through Johns Hopkins called "Hope In Action,"almost 30 patients have received transplants from positive donors through the research, providing those patients with an accelerated pathway to transplant and the benefits that accrue afterwards.

Secondly, from the transplant perspective, understanding the quality of the kidney and/or liver outcomes and the rates of immunologic tolerance are important to understanding whether the risks associated with surgery are worthwhile. There has been a slight increase in the rates of transplant rejection seen whenever HIV patients are transplanted. Preliminary data from the HOPE Act, and from more than 50 HIV to HIV transplants completed overseas suggests that the rates of organ rejection are no higher. Although transplantation comes with a risk of infection, rates appear consistent with those typically seen in liver and kidney transplantation, with no increase in opportunistic infections.

A number of important procedural considerations still remain. Whilst the HOPE Act has provided transplants to a good number of liver and kidney patients so far, the initially high numbers of potential donors have not been realized. There are likely many factors at play, ranging from transplant hospital's initial caution, to donor hospitals' lack of familiarity with the donation process.

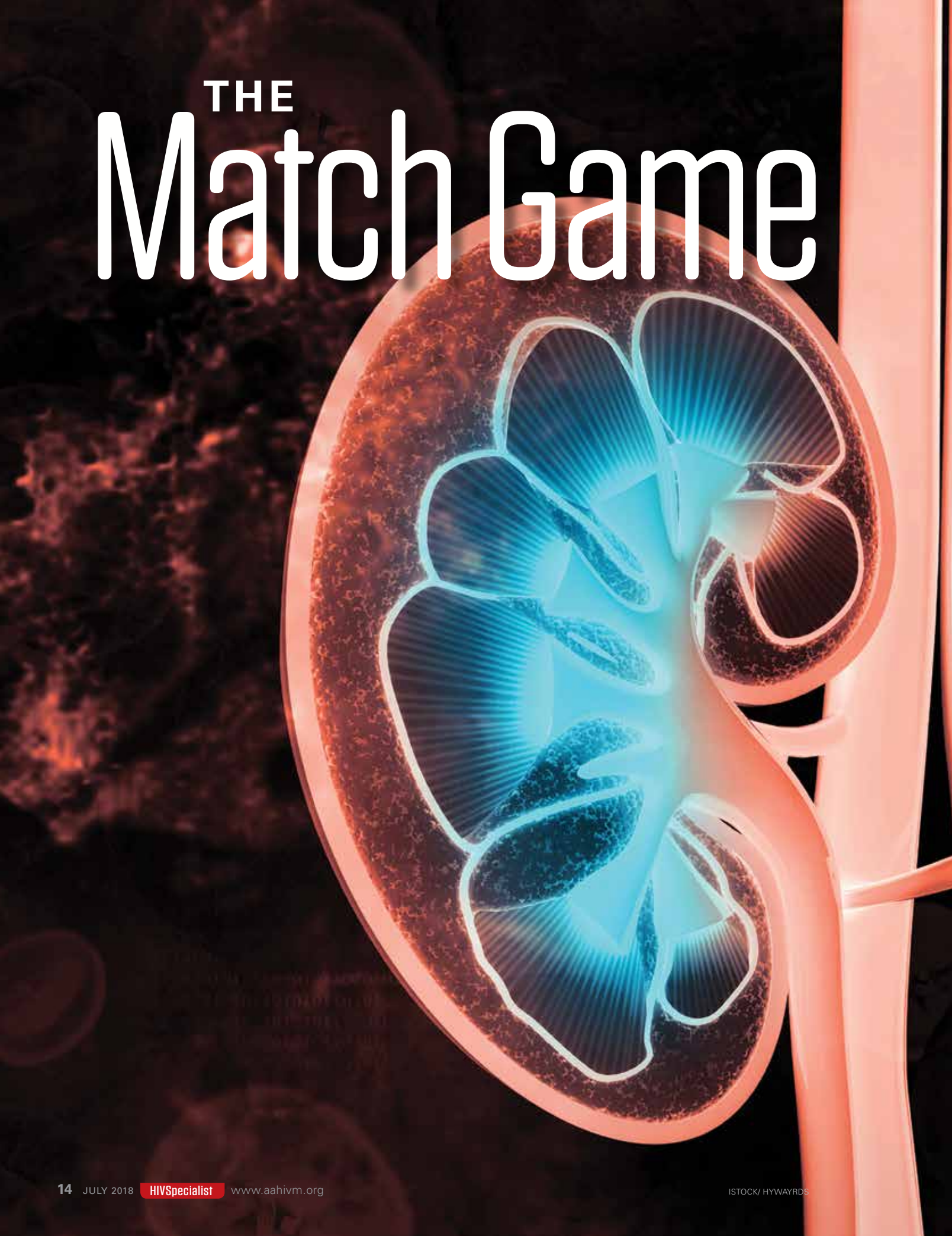
Additionally, it can be an emotional, expensive and time consuming activity for organ procurement organizations to evaluate potential deceased donors under any circumstance, let alone with the added social stigma, and medical complexity that comes with HIV.

Finally and perhaps most importantly, if patients living with HIV have not considered organ donation, or were not aware that it is an option for them, then the rates of donation will remain low. The HOPE Act has consequently become a call to action for HIV providers to educate their patients about donation opportunities, and to encourage them to talk with loved ones about their wishes. **HIV**

ABOUT THE AUTHOR

Dr. Christine Durand, MD, assistant professor of medicine and oncology and member of the Johns Hopkins Kimmel Cancer Center, is involved in clinical and translational research focused on individuals infected with HIV and hepatitis C virus who require cancer and transplant therapies. Her current research efforts include looking at outcomes of hepatitis C treatment after solid organ transplant, the potential use of organs from HIV-infected donors for HIV-infected solid organ transplant candidates, and HIV cure strategies including bone marrow transplantation.

THE Match Game



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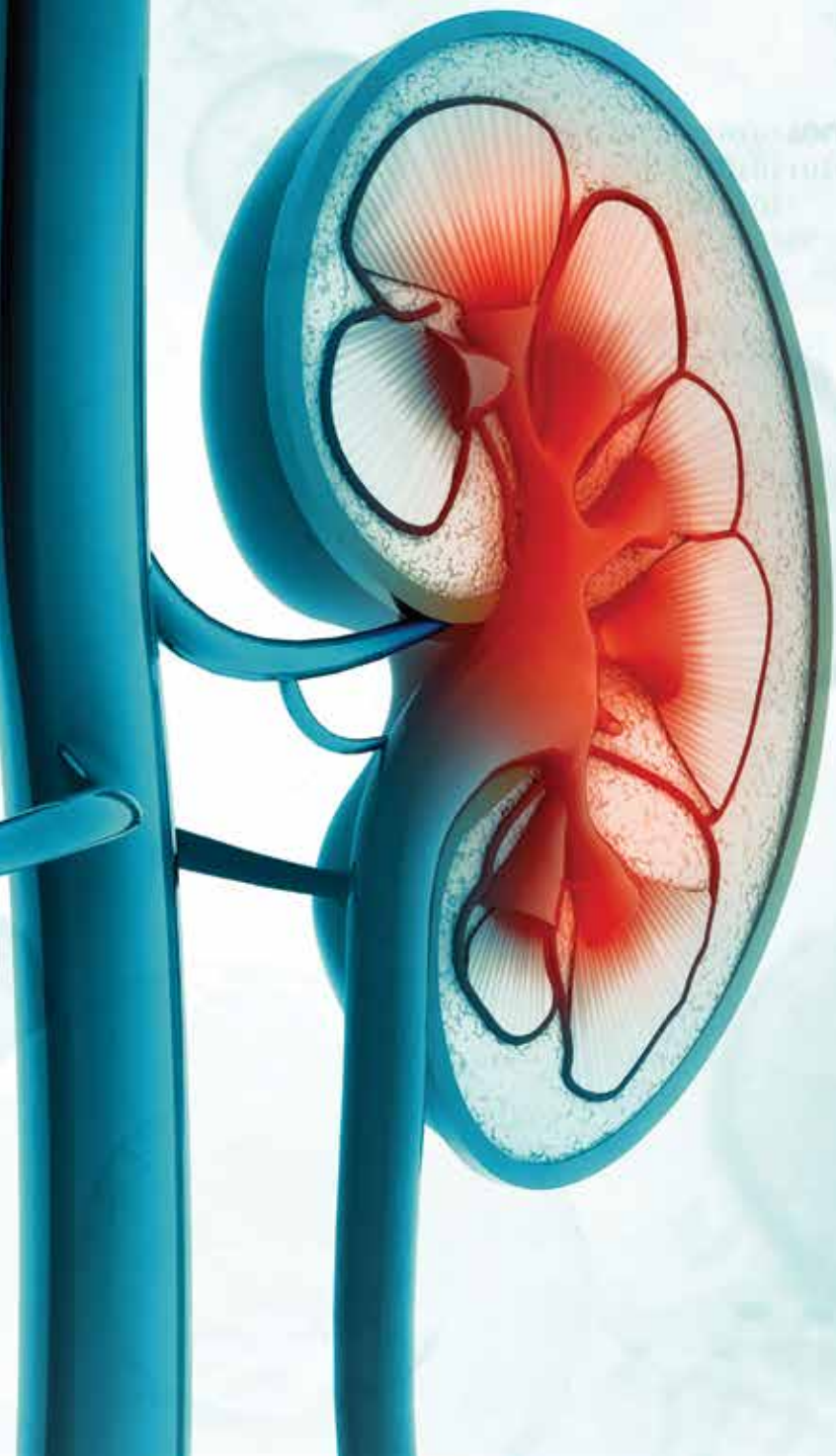
Organ Procurement Organizations are Spreading the Word of Hope

By R. PATRICK WOOD, MD, FACS, CTBS, and
SCHAWNTE' WILLIAMS-TAYLOR, RN, BSN, CCRN, CPTC



ORGAN PROCUREMENT ORGANIZATIONS (OPO) are the federally designated, not-for-profit organizations responsible for the recovery of organs from organ donors, the allocation process, and transportation of organs to appropriate patients on the recipient waiting list. With the signing of the Hope Act, the 58 OPO's covering the United States has the task of educating the medical community, as well as the public, that the procurement and transplant of organs from an HIV-positive done is no longer a violation of federal law.

Our organization, **LifeGift**, is an OPO in Texas which serves the Houston, Fort Worth and Lubbock/Amarillo areas. We were anxious to participate in the Hope Act and quickly undertook a program to educate our staff about recovery and transplantation of organs from HIV positive donors to HIV positive recipients. We recognized that allowing patients living with HIV to donate, and facilitating that gift, was going to require changing many years of entrenched behaviors and beliefs.

The staff in our communication center receive all initial referral calls for potential organ donors in our region. We began the educational process by insuring that these individuals understood that the presence of HIV in a potential organ donor was no longer a contraindication to donation. We also made sure that they understood that LifeGift had decided fully to participate in the Hope Act. We educated our family care specialists and donation clinical specialists about the details of the Hope Act. They could in turn approach families of HIV positive potential organ donors about authorizing donation of their loved ones organs.

Creating awareness of the opportunities for organ donation by individuals living with HIV is vital to saving lives, as well as gaining more information through medical research.

We also educated our donor hospital partners by reinforcing that HIV was no longer a contraindication to the recovery and transplantation of donor organs. Finally, we presented the details of the Hope Act at monthly donor council meetings, at our quarterly medical advisory board meeting and at our Board of Directors meeting.

The most important information to convey is that the families of potential organ donors who have HIV disease have two options under the Hope Act. If an HIV positive individual is not a suitable candidate for organ donation, the family can give authorization for blood to be drawn and sent for research purposes. Affording loved ones the chance to participate in research designed to help others can be an enriching move for families, at a time that is filled with grieving.

If the HIV positive individual is a suitable candidate to donate organs, the family can authorize the recovery of organs for transplantation. Livers and kidneys are currently the only organs approved for transplantation from HIV positive donors into HIV positive recipients as part of the Hope Act.

The Hope Act allows families of HIV positive patients to be offered 'hope', literally, through the process of organ donation or the advancement of medicine through research. The family care specialist from LifeGift meets with the family and presents the unique opportunity their loved one has to save lives. These families suffering loss often view donation and research as an opportunity to provide hope to others as well as gain information for the treatment and/or cure for HIV. Many families have also expressed that donation helps as they navigate the grieving process.

Honoring loved ones through the Hope Act creates a powerful, and meaningful outcome for families in what is usually a terminal life situation. As stated by the mother of one of patients enrolled in the HOPE ACT, "I welcome this opportunity and would feel happy that my daughter could help the doctors find a cure for this disease."

The family of the first HIV-positive kidney and liver donor, (performed at Johns Hopkins University Hospital in 2016), said she *wanted* to help. The New England woman was a "daughter, mother, auntie, best friend and sister," according to a statement from her family provided by the participating OPO, New England Organ Bank.

"From early childhood she always stuck up for the underdog," said the statement. "HIV was not a choice she made, but she fought it for herself and our family every day. As we all know, HIV carries great stigma and people with the disease are unfortunately at times treated differently. …She was able to leave this world helping those underdogs she fought so hard for."

Since the start of our participation in the Hope Act in August, 2016, we have enrolled 15 patients, 12 males and 3 females, with an average age of 48 years (range 27 to 63 years of age). Nine patients were authorized only to have blood drawn for research as they were ruled out for organ donation due to their age or medical condition. Four patients were authorized for organ donation but were not recovered due to the fact that there were no suitable recipients for the liver or kidneys. Two patients were organ donors. One patient donated both kidneys but unfortunately they could not be transplanted for medical reasons. The second patient donated both liver and kidneys and the liver was successfully transplanted. Thus far, only one family has refused to participate in the Hope Act.

Creating awareness of the opportunities for organ donation by individuals living with HIV is vital to saving lives, as well as gaining more information through medical research. Individuals with HIV are encouraged to register to be organ donors on the national donor registry, www.donatelife.net or on their state organ donor registry. It is also important to note that once an individual signs up on the donor registry, this serves as first person authorization and their decision to be an organ donor cannot be revoked by their next of kin. **HIV**

ABOUT THE AUTHORS:

Dr. Patrick Wood is Vice President & Chief Medical Officer of LifeGift. Dr. Wood joined LifeGift as a regional medical director in 1991 and has served on the LifeGift Board of Directors for the past decade. In addition to being a former president of the Texas Transplant Society, he served on a number of UNOS committees.

Schawnte' Williams-Taylor is has been a member of the LifeGift team since October 1999 and currently serves as the director of family care. Schawnte is responsible for administering and coordinating exceptional customer care for professional partners and families to maximize donation opportunities. Schawnte also serves as administrator on call for to provide oversite for daily organ operations.

In the NEWS

Study Will Assess Safety of HIV-to-HIV Kidney Transplantation

The first large-scale study probing kidney transplantations between people with HIV has launched at clinical centers around the country, announced the National Institutes of Health. The HOPE in Action Multicenter Kidney Study will examine the safety of these transplantations by evaluating kidney recipients for potential transplant-related and HIV-related complications following surgery.

The study is the first study of its type in the United States to receive Institutional Review Board approval. Researchers will follow the outcomes of 160 kidney transplants. All study participants will be living with HIV; 80 will receive kidneys from donors who had HIV, and 80 will receive kidneys from HIV-negative donors and serve as controls.

While transplants like these have been successfully accomplished in South Africa since 2008, they were illegal in the US until the implementation of the HIV Organ Policy Equity (HOPE) Act in 2013. The act allows US transplant teams with approved research protocols to transplant organs from donors with HIV into qualified recipients with HIV and end-stage organ failure. Researchers expect this will shorten the wait time for those with HIV waiting to receive a transplant.

Throughout the study, researchers will closely monitor participants for signs of organ rejection, organ failure, failure of previously effective HIV treatments, and HIV-related complications. They will also track participants' psychological and social responses, changes in their reservoirs of latent HIV, and the potential development of HIV superinfection.

Those participating in the study are also eligible to co-enroll in a separate NAID-supported study, Impact of CCR5 Blockade in HIV+ Kidney Transplant recipients. The phase 2 study will evaluate the safety and immune response to the anti-HIV drug maraviroc in kidney recipients with HIV and determine if the drug reduces rates of kidney rejection in the patient population.

The Right Fit

HIV-Positive Solid Organ Transplant Recipient and Donor Suitability

By MARION HEMMERSBACH-MILLER, MD, PhD

SHUTTERSTOCK/ BLUEBAY

DUE TO IMPROVEMENTS in the survival of HIV-infected individuals, life expectancy of HIV positive patients approaches that of the general population. However, the number of patients with well controlled HIV, yet chronic renal failure or end-stage liver disease, is expected to increase worldwide. Organ transplantation has become progressively available for HIV-positive patients with end-stage liver or kidney disease. Unfortunately, this has added to an already existing shortage of available organs.

As such, HIV-positive organs have been made available to HIV-positive recipients under the HIV Organ Policy Equity (HOPE) Act. In 2015, the Organ Procurement and Transplantation Network (OPTN) made changes to implement the HOPE Act, which allows for research into transplanting organs from HIV-positive donors to HIV-positive recipients. Participating centers can be found here.[1]

From the perspective of the HIV physician, it is important to understand what criteria make a person living with HIV a suitable transplant candidate. Furthermore, the HIV provider should be able to discuss pre-transplant recipient and donor evaluation in the setting of HIV-positivity, and consequently accurately counsel appropriate patients. The clinical understanding of when to refer patients for transplant evaluation is crucial.

There are currently no formal guidelines for potential transplant recipient evaluation.[2] We will discuss common approaches taken by major centers in the United States, although similar criteria are used elsewhere. In the US, HIV-positive-to-positive kidney and liver transplantation is currently only allowed under a research protocol that follows

Table 1. Pre-transplant recipient evaluation.

General screening for all transplants
Medical history, particularly focusing on comorbid conditions impacting HIV control
Social and travel history
Physical exam, including height and weight (therefore impacting organ size selection)
Complete medication list (especially ones metabolized by P450 cytochrome, given anticipated anti-rejection medications, many of which have tight therapeutic windows)
Baseline labs: blood type, counts, complete metabolic profile, coagulation panel, urine (if kidney)
Pregnancy test (if indicated; to be repeated at time of organ offer)
Allo-sensitization history (e.g.: transfusion, pregnancy, prior transplant history), HLA screen
Chest x-ray, CT abdomen/pelvis (with particular focus on surgical bed and vascular suitability)
Updated age appropriate cancer screening
Immunization record:
Measles, Mumps, Rubella
PPV13, PPSV23
HBV, HAV
TdaP
HPV*
Menigococcal
Varicella / Shingles*
Seasonal influenza
Infectious disease evaluation:
Syphilis screen
CMV IgG
HBsAg, HBsAb, HBcAb, HCV Ab (with HCV PCRs if positive)**
PPD skin test / interferon-gamma-release assay
Toxoplasma IgG
In areas of endemicity, or if positive travel history: Coccidioides, Histoplasma, Chagas, Zika, etc
HIV-specific studies:
CD4 count
HIV viral load
Genotype and HIV CCR5 trofile co-receptor tropism assay, if available
HIV genotype archive resistance testing (if no other instructive resistance data available)
History of prior ART regimens: Compliance, treatment failures, intolerances and/or allergies
HLA B5701 (included in pre-transplant HLA screen for kidney transplantation, but not for livers)
History of prior OIs with treatment(s) and current status

* Follow current age-appropriate immunization guidelines. ** If HCV PCR is positive, further workup is indicated. HLA: human leukocyte antigens; PPV13: pneumococcal conjugate vaccine; PPSV23: pneumococcal polysaccharide vaccine; HBV: hepatitis B virus, HAV: hepatitis A virus; TdAP: tetanus, diphtheria, pertussis; HPV: human papillomavirus; CMV: cytomegalovirus; HBsAg: hepatitis B surface antigen; HBsAb: hepatitis B surface antibody; HBcAb: hepatitis B core antibody; HCV Ab: hepatitis C antibody; PPD: purified protein derivative; ART: antiretroviral therapies; OI: opportunistic infection.

strict NIH-stipulated guidelines, as well as Safeguard and Research Criteria.[3] Center-specific criteria might vary also, in accordance with their local transplant programs.

Adequate donor and recipient suitability is one of the keystone for a successful transplant and requires a multidisciplinary approach. This article will focus on the infectious-diseases related workup.

HIV-positive organ recipient evaluation

The pre-transplant evaluation process is rigorous. Many factors are taken into account and many will be unrelated to the recipients' HIV status. At most US centers, part of the evaluation includes consultation with transplant Infectious Diseases team member with expertise in HIV care and pre and post-transplant HIV management.

Some of our recipient requirements are shown in **Table 1**. This assessment will include a detailed medical history, physical exam, laboratory screening with baseline labs, but also infectious serologies to determine pre-transplant status as well as the need to update immunizations. Vaccinations should be updated in the pre-transplant setting, in accordance with the CDC guidelines. Preference is given to pre-transplant vaccinations when the healthy recipient's immune system responds more efficiently than after transplant, in the face of anti-rejection medication.

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Additionally, live vaccines are contraindicated post-transplant for the same reason, whereas they can usually be given safely in the transplant evaluation phase. In patients with end-stage renal disease, their typically longer waiting times on the transplant list allows for careful evaluation whereas some patients with end-stage liver disease need accelerated review. An accelerated immunization schedule exists for hepatitis B. Live-vaccines (e.g.: MMR) are contraindicated if time to transplant is less than 4 weeks. Age-appropriate cancer screening should be up-to-date. See table 1. Further workup might be required for cardiovascular risk assessment, as well as per transplant surgery for intraabdominal evaluation.

Social support networks are particularly important in HIV transplantation. Caregivers are frequently relied upon in the immediate peri- and post-operative period. Our personal experience is that there should be at least one member of the patients' care team that is aware of the HIV status and familiar with their medications, especially if an HIV-positive donor is ultimately used. The patient must be willing to take post-transplant antimicrobial prophylaxis as per center-specific guidelines; this usually involves *Pneumocystis jirovecii* prophylaxis and herpesviridae prophylaxis that will depend on the recipients and donors' cytomegalovirus (CMV) serostatus. Seronegative recipients who are receiving organs from donors who are CMV seropositive often require longer treatments or preemptive monitoring for CMV disease.

Regarding HIV control, patients should have a CD4 count that is above 200/mcl. Exceptions can be made in the presence of hypersplenism for candidates waiting for a liver, where a CD4 count of >100/mcl is satisfactory. The HIV viral load should be persistently undetectable, for at least 3-6 months. Individual patients with low-level detectable viral loads might still be considered eligible on a case-by-case basis. Patients with active opportunistic infections (OIs) do not meet recipient eligibility criteria. However past OIs are rarely a contraindication. A history of central nervous system lymphoma or progressive multifocal leukoencephalopathy likely exclude transplant, whereas a history of prior

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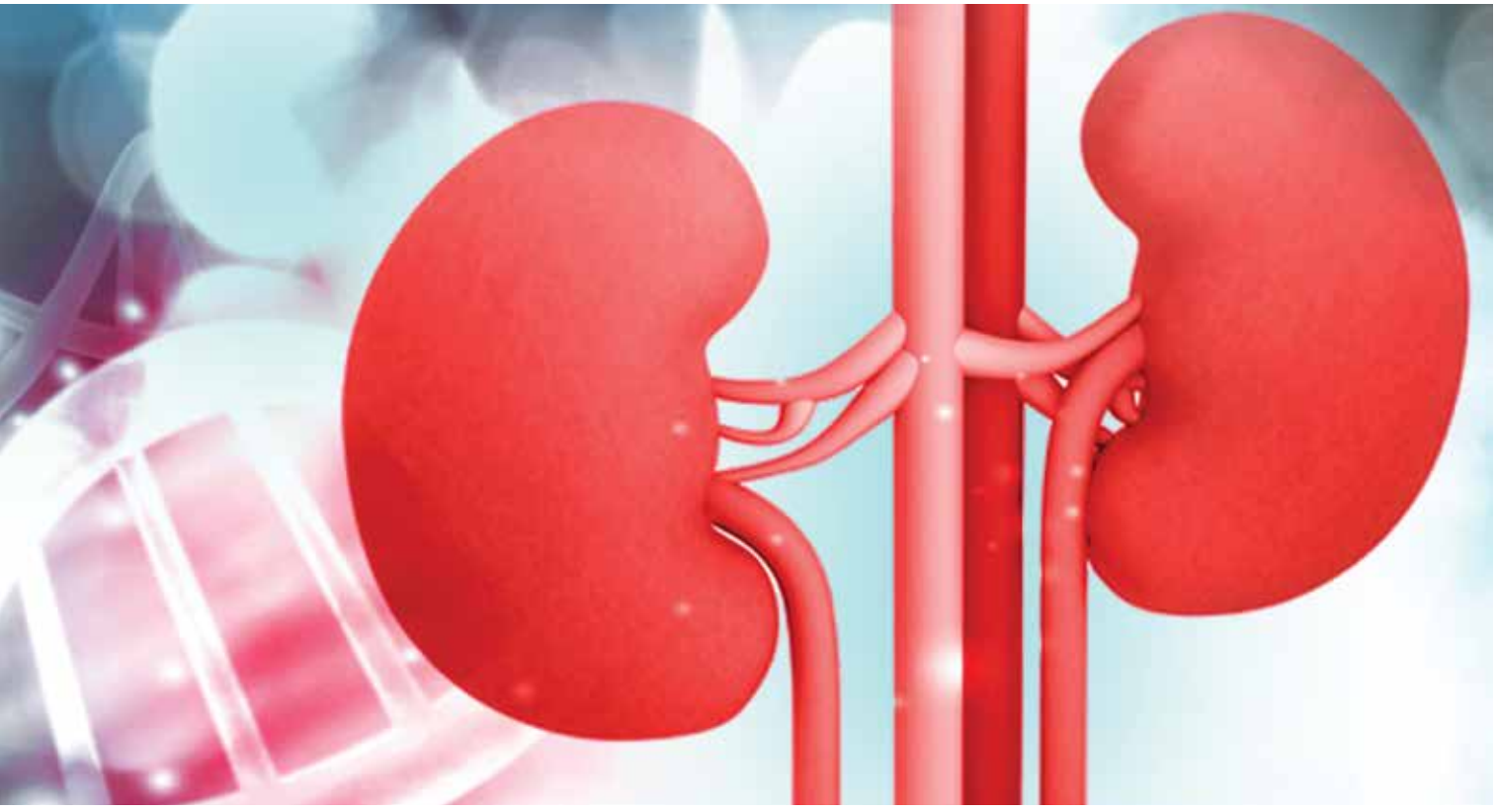


malignancy would certainly require further evaluation to assess for recurrence risk.

A patient should ideally be on a stable antiretroviral regimen (ART) prior to transplant, with good tolerability and adherence. Due to drug-drug interactions with the immunosuppressive medications needed in the post-transplant setting, regimens that contain ritonavir or cobicistat are not recommended. Long-term outcomes with boosting agents have been inferior, both in terms of graft survival and also rejection episodes. [4,5] Additionally, for kidney transplants our center avoids tenofovir disoproxil fumarate (TDF) to avoid challenges post-transplant when fluctuating renal function may make dosing difficult. Many other interactions between immunosuppressive medications and NNRTI and protease inhibitors exist.[2,6]

A patient should ideally be on a stable antiretroviral regimen (ART) prior to transplant, with good tolerability and adherence. Due to drug-drug interactions with the immunosuppressive medications needed in the post-transplant setting, regimens that contain ritonavir or cobicistat are not recommended.

Once approved for registration on the transplant list, HIV labs should be monitored every 3 months while on the waiting list. Our center allows for shared management with local HIV providers as well our transplant HIV providers to foster an atmosphere of trust and maintain good communications channels.

In terms of HIV-specific considerations at the time of listing, understanding the breadth of both recipient and potential donor resistance is key. Consequently, an adequate ART regimen should ideally be predictably active against both strains of HIV before accepting the organ. Depending on the donor history, genotype information is not always available, especially if HIV status is only discovered during the terminal illness. Potential recipients are counselled that ART regimens may change at the time of transplant if different donor resistance patterns are known. In the immediate post-operative phase, patients are frequently unable to tolerate oral medications, especially in liver transplantation. Fortunately, this is usually a temporary situation, but a reminder that most of the ARTs are only available orally and many cannot be crushed and administered via a nasogastric tube.

Once potential recipients have been evaluated for solid organ transplantation, and deemed to be good candidates, they will be listed in the United Network for Organ Sharing (UNOS). Allocation differs by organ. It will also vary depending on factors such as blood type, sensitization history, medical urgency and time on the waiting list. For kidney recipients, priority is given based on duration on dialysis. For liver recipients, priority is given according to MELD (Model for End-Stage Liver Disease) score. As there are many more people waiting for organs than there are donors, organ donations are carefully reviewed in order to go to their best match. HIV-positive patients that have consented to accept a HOPE Act organ will be listed on the regular waiting list, as well as the HIV-positive donation list. They will be offered the first organ that becomes available, regardless of the HIV status.

In the post-transplant phase, close follow up is important and frequency is center-specific. Patients should be made aware of drug interactions and to notify their transplant coordinators of any medications changes, including over the counter, in order to avoid any toxicities, HIV viremia or graft loss.[7]

HIV-positive donor evaluation

Organs from HIV+ donors can only be transplanted to HIV+ recipients under the HOPE Act. Living and or deceased donors must fulfill all criteria that are in place for HIV-negative donors. Regardless of the HIV status, the organ quality needs to be assessed; this often happens in parallel with other evaluations.

Regarding a potential deceased HIV-positive organ donor, there are three potential scenarios (Figure 1).

Other specific considerations for the HIV-positive organ donor are listed in **Table 2**.

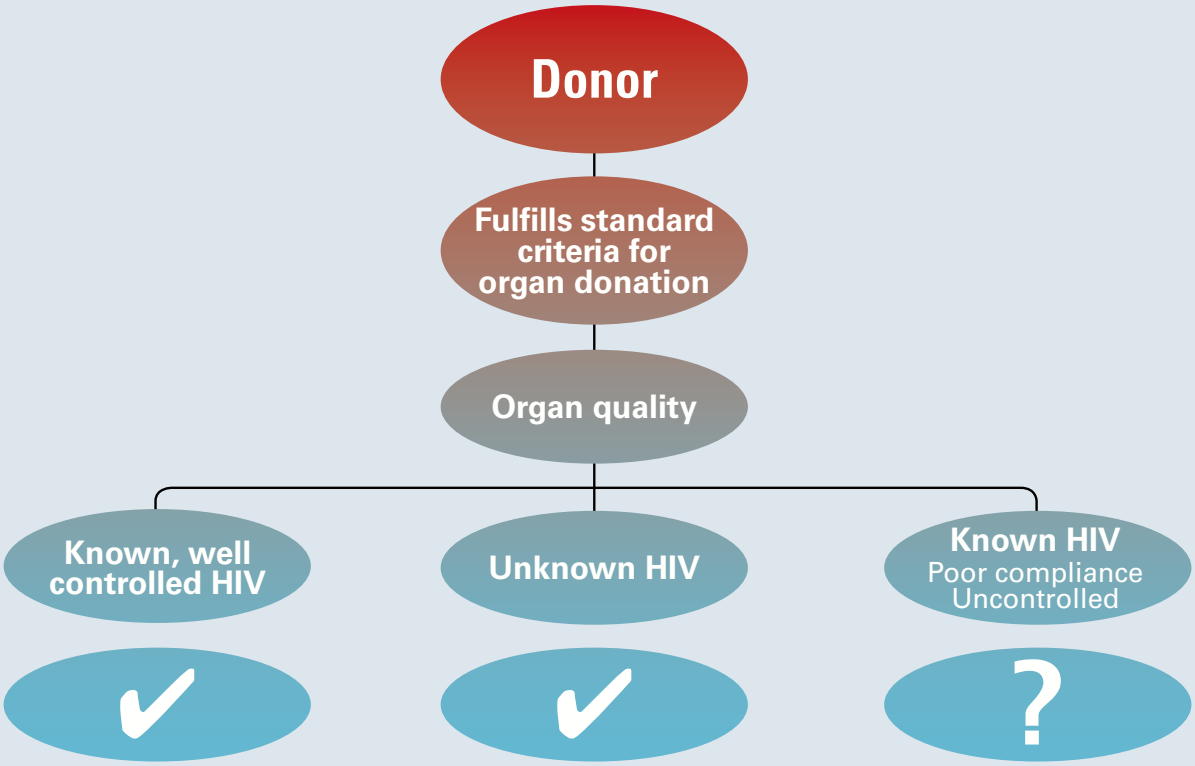
The Transplant Infectious Diseases team must be able to describe the anticipated post-transplant ART regimen (safe, tolerable and effective to cover the donors' and recipients' HIV strain).

HIV Living donation:

Although the HOPE Act itself was silent as to the use of the HIV positive living donors, minimum inclusion criteria have been incorporated into NIH protocols in the United States. To date, no HIV-positive living donor transplant has been undertaken. Living donation is almost always an elective surgery. Consequently, extra time can be taken to ensure adequate evaluation and risk mitigation. For example, if recipients need ART adjusted to match donor viral resistance patterns, this should be done as early as possible, to ensure safety, tolerability and effectiveness. We recommend at least 4-6 weeks prior to transplantation.

Living donors have to meet all requirements of the transplant center for becoming an organ donor. Their HIV should be well controlled (CD4 >500/mcl and HIV viral load <20 copies/ml in the preceding 6-months). A complete ART history has to be available, along with a genotype. There should be no evidence of active OI. Certain past OIs will also preclude donation. All potential living donors are required to meet with an "independent advocate."

Figure 1. HIV-positive deceased donor scenarios



1. **The well controlled HIV patient.** Organ quality notwithstanding, this will be a good organ donor. Transplant teams will endeavor to establish the current ART regimen, genotype and prior medical records, if available. The infectious diseases provider is a phone call away and we hopefully will be able to get more information about the organ donor. Careful review of medical records and pharmacy records can often reveal treating HIV providers and hint at compliance, even if the donors' loved ones are unaware of the diagnosis.

2. **The unknown HIV patient.** Because every potential donor in the US undergoes HIV testing, and as a result of our estimated 1 in 7 positive people in the US not knowing their HIV status, occasionally the first time that an individual tests positive is when they present with their terminal illness.[8] Such a patient can still be a suitable donor, and the presence of HIV viremia is not an exclusion criterion by any means. Judgement of local community resistant patterns should apply. For example, M184V and K103N are mutations occasionally seen in ART naïve individuals, although 'wild-type' virus predominates. INSTi mutations, on the other hand, are still seen less than 1–2% at most.[9–11] In this scenario, the organ procurement organization (OPO) can be contacted and a quantitative viral load and genotype can be obtained. This will not be available immediately but might of importance if HIV viremia occurs in the post-transplant setting. General donor screening rules apply, particularly focused on ensuring no AIDS-defining illness contributed to the terminal illness.

3. **The known HIV patient that is non-compliant or has uncontrolled disease.** This potential donor will need further workup and/or discussion among the Transplant Infectious Diseases team with HIV expertise and knowledge of potential recipients and their viral control. Non-compliance might have resulted in ART-resistant donor virus that can be a challenge for the organ recipient. In cases where resistances align with the potential recipient, this organ might still be acceptable, provided no OI is present and organ quality is good.

Organs from HIV+ donors can only be transplanted to HIV+ recipients under the HOPE Act. Living and or deceased donors must fulfill all criteria that are in place for HIV-negative donors. Regardless of the HIV status, the organ quality needs to be assessed; this often happens in parallel with other evaluations.

Table 2. Other specific considerations for the HIV-positive organ donor

General screening
Donor has known or suspected HIV infection
Comorbidities, medical and social history (might be incomplete in case of deceased donors)
Travel and exposure history, if known
No active opportunistic infections (old treated OI's are ok provided treated appropriately)
No active malignancy, (non-melanoma skin cancers may be considered acceptable)
For *living donors*, additionally: CD4 count > 500/mcl, and HIV viral load <20 copies/ml, for a minimum of 6-month prior to donation. Meeting with an "independent advocate".
Required Infectious Disease Screening
Must include HIV, HCV and HCV NAT, hepatitis B serologies, as well as CMV IgG, EBV, syphilis screen).
Will vary depending on OPO, seasonality and geographic location (e.g. West Nile Virus, Zika, Coccidioides, Chagas, etc)
For *living donors*: testing must be repeated as close to transplant as possible, but at most, 28 days prior
Additional HIV-specific testing
HIV NAT* (done by OPO)
HLA B5701 (HLA typing for class I is usually available for kidneys, but not always complete for livers thus might need to be requested separately)
Per request or contact with the donors' clinician the following might become available:
HIV viral load
CD4 count**
HIV Genotype
History of prior ART regimens, treatment failures
History of prior opportunistic infections with treatment(s) and current status

* This is a qualitative NAT. ** CD4 counts are commonly reduced after brain death in HIV-positive individuals and should therefore not influence the decision on donor suitability.[12]

UNOS: United Network for Organ Sharing; OPO: organ procurement organization; HCV: hepatitis C virus; NAT: nucleic acid testing; CMV: cytomegalovirus; EBV: Epstein Barr virus; ART: antiretroviral therapy.

ISTOCK/ AYDINMUTLU

HOPE Act living donors are also required to meet with HIV-specific advocates, individuals knowledgeable on HIV and transplantation, who are independent of the study teams, and can ensure donors feel no undue pressure or coercion. An organ biopsy should show no evidence of disease that would put the donor at increased risk for post-transplant complications or progression to end-stage organ disease. Additionally, living donors must be made aware of the possibility of organ function loss, and that this might prevent them from receiving certain types of ART in the future.[13] Long-term outcomes of HIV-positive living donors are still uncertain, and this should be clearly communicated during the donor evaluation and consent phase.

Donor-recipient suitability

Donor-recipient suitability depends on many factors, with the HIV-compatibility just being perhaps one of the least. Blood type (with some exceptions), HLA typing, history of allo-sensitization, graft size and organ travel time are all important. As always in transplantation, a multidisciplinary approach and close communication between the different teams is necessary.

Although molecular based testing is improving, the test windows, including for nucleic acid testing (NAT), are still imperfect. Results will depend on when testing takes place. This applies to HIV but also to hepatitis B and C. Co-infected donors and recipients may be considered for transplant as well, although the evaluation is beyond the scope of this article.

Finally, the dilemma of accepting an HIV-positive organ can affect the recipient in many ways, and a good clinician-patient relationship is vital. The potential recipient should be well informed throughout every step of this process, and this includes meeting with an "independent advocate." Accepting an HIV-positive organ can mean less time on the waitlist, which therefore might prevent decompensation while waiting for an organ offer and/or increased mortality. On the other hand, HIV-positive organ recipients have a higher rate of rejection and this should be made clear early in the pre-transplant process.[14,15]

Several risk factors for poor outcomes after kidney transplantation have been identified: non-thymoglobulin induction, HCV co-infection, more than three HLA mismatches.[16,17] Notably, many of the larger transplant database studies include patients from the pre-integrase strand inhibitor era and, as such, current outcomes might be different. In the era of the opioid and HCV epidemic, one might expect younger organ donors and as such better quality organs, which might shift outcomes in a favorable direction.

In conclusion, with careful pre-transplant evaluation of potential recipients living with HIV, and thoughtful donor evaluation, the successful use of HIV-positive donors offers a chance to safely expand a limited donor pool and improve transplant access for patients living with HIV. **HIV**

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PrEP in the

IN RURAL IOWA, with its picturesque farms and fields of corn and grain, there is a 42-year-old man who worries he may be at risk for HIV infection. He is sexually active with men and women and inconsistently uses a condom. He lives in a community of 2,000 people where everybody knows everybody—and their business.

So, he regularly travels more than 75 miles to access rapid HIV screening services in a public health clinic, bypassing clinics much closer to home. It's inconvenient and pretty much takes a day, but concerned about his privacy and the perceived stigma that could result, he takes the trip.

At the clinic, PrEP is recommended, but he is reluctant to discuss that with his doctor—once again, because of privacy concerns and stigma.

This vignette is really an amalgamation of cases in rural Iowa, according to Dr. Michael Ohl. With his team in Iowa City, IA, Dr. Ohl is the 2018 winner of the annual AAHIVM/Institute for Technology in Health Care HIV Practice Award, including a $27,000 stipend, for developing TelePrEP, a unique model for increasing the use of pre-exposure prophylaxis (PrEP) in rural areas.

SHUTTERSTOCK/ STOCKR

Heartland

Iowa team develops award winning TelePrEP system to bring more rural residents into care

By BOB GATTY

Developed through a collaboration with the Iowa Department of Public Health (IDPH) and the University of Iowa (UI), TelePrEP employs readily available technologies, such as video telehealth visits on smartphones and mobile devices, integrated electronic health records and SMS text messaging to create a statewide virtual PrEP delivery system.

"Through this local grassroots effort, and the process of trial and error, we developed a model that can improve access to PrEP in a rural setting," said Dr. Ohl in an interview with *HIV Specialist*. "It can overcome barriers related to distance and stigma and can be replicated in other areas by using resources commonly available."

For the client using PrEP, the program is convenient, improves accessibility and helps eliminate stigma. "We can do the video visits with clients in private at home or in their car, wherever they like," he said.

"TelePrEP really is based on collaboration between the healthcare system and public health departments—including teams of public health personnel, pharmacists and physicians. Public health personnel working in sexually transmitted infection clinics, HIV testing sites, and partner services programs identify clients with need for PrEP and refer them to pharmacist providers in our program. Through collaborative practice agreements with physicians, pharmacists video-chat with clients and arrange for laboratory studies in public-health affiliated labs. We also advertise on geosocial networking apps and the Iowa PrEP website so people can self-refer. The technology is simple. Wherever there are public health departments and healthcare systems wanting to improve access to PrEP in their area, this is a model that can be replicated," Dr. Ohl explained.

The Mission

An infectious disease physician and HIV clinician at the University of Iowa, Dr. Ohl has cared for people with HIV infection for 20 years, first beginning in San Francisco, CA before moving to Iowa, where he has family and roots.

"My colleagues and I share a sense of mission to make sure we are providing optimal care for people living with HIV and optimal access to preventive services for people who are at risk," he said. "As a result of a lot of experiences that I had early in my medical career in San Francisco, I committed to focusing on HIV care very early. I saw it as an opportunity to work with people over time in a primary care relationship, to hear their stories. Plus, I've been fortunate to work with colleagues committed to this shared mission. They are smart and creative and interesting to work with at the same time."

Dr. Ohl said discussions about TelePrEP began late in 2016. There were conversations with colleagues, people in community who wanted to improve access to PrEP, as well as those at Iowa Department of Health who wanted to expand access to PrEP.

Dr. Michael Ohl, MD, MSPH

TelePrEP really is based on collaboration between the healthcare system and public health departments—including teams of public health personnel, pharmacists and physicians. ... The technology is simple. Wherever there are public health departments and healthcare systems wanting to improve access to PrEP in their area, this is a model that can be replicated.

"We were hearing stories that people were having hard time accessing PrEP, that providers were not aware, of long travel distances—and the stigma that people are concerned about," Dr. Ohl recalled.

He pointed to conversations with patients who were taking Truvada as part of their treatment for HIV infection and were running out of their medication because they were sharing it with people who needed it for PrEP.

"It occurred to me, 'Gosh, it's just way too hard to get PrEP in Iowa, if this is how it's really working,'" he said.

Developing the Solution

So, Dr. Ohl and his colleagues discussed possible solutions with community representatives, public health officials, and the University of Iowa and subsequently began testing TelePrEP with Johnson County public health officials.

Over the course of 2017, Iowa TelePrEP was developed in concert with IDPH, UI Health Care and community representatives. Resources included IDPH programs, the UI HIV care team, telehealth platforms, and the existing public health STD clinic/lab network. There were stakeholder interviews with users, public health care representatives, and finally, rapid prototyping with Johnson County Public Health. Cody Shafer, the PrEP coordinator for the Iowa Department of Public Health, Angela Hoth, a pharmacist with experience in program development and public health, and Dena Dillon with the UI HIV care program were key collaborators.

From February 2017 through January 2018 a local TelePrEP pilot was conducted, with 103 referrals resulting in 73 initial visits with clients and 67 Truvada starts for PrEP. Routine screening identified 18 previously undiagnosed STDs among clients and one pregnancy in a client at high risk for HIV infection. The program made 54 vaccine recommendations in 39 clients (9 HPV, 28 hepatitis A and 17 hepatitis B). Retention in PrEP care at six months was 78 percent.

The creation of this new TelePrEP delivery model allows rural-dwelling individuals to obtain the same level of preventive care available to their urban-dwelling counterparts, contributing to greater health equity. TelePrEP partnerships allow public health disease intervention specialists to follow up with newly identified STDs among TelePrEP clients with greater efficiency.

Client Participation

For clients to participate in Iowa TelePrEP, they need to have access to smart phones, tablets or computers that they can use privately for video chat visits with TelePrEP team members. They also need to have access to one of a system of labs where they can go for blood draws and other tests.

In addition, Dr. Ohl stressed, people simply need to be aware of PrEP and be motivated to start. "They need to feel like it makes sense for them and move past their concerns about something new," he said. "They need to be prepared to talk to us about whether this makes sense for them—really, just a willingness to chat with us, and we'll start from there."

Patients do not need insurance to get started. "We will work to sign them up for insurance or the medication assistance program that Gilead runs," he said. "They just need to be willing to have a conversation."

Iowa TelePrEP uses social media to help spread the word, in addition to advertising and other forms of publicity.

"Social network referrals are important for people with the greatest concerns around privacy and the greatest perceived stigma," Dr. Ohl explained. "It's important for people considering TelePrEP to have referrals from people they can trust. So, we do our best to build good experiences for clients, make them feel secure, work with their situation, and build good stories that they will share."

New Developments

Now, Dr. Ohl said his team is working to develop an in-home HIV testing program so patients can do their own finger sticks, etc. and send them in for processing. "Our goal is to have everything done in clients' homes, which would go a long way towards eliminating stigma and privacy concerns and make trips to labs unnecessary," he explained.

In addition, efforts are underway to develop same-day access to PrEP through the new program. "We want to be able to provide comprehensive services the same day clients contact us," he explained.

Meanwhile, clients are encouraged to work with a primary care provider because of the importance of having holistic comprehensive care.

"We can't provide all of that through telemedicine," Dr. Ohl said. "But we want to Integrate their PrEP care with primary care. We know there are people who don't want to do that, so we see this as a safety net model. It's also a way for people to start PrEP telemedically and then transition to primary care from there."

The Iowa TelePrEP team is already receiving inquiries from elsewhere in the country regarding its award-winning program. In fact, the program just received funding from CDC—$500,000 per year for 4 years—to increase the rollout of the program in Iowa and expand the program to other states.

"We're happy to share our experiences and lessons learned" Dr. Ohl said. "We enjoy talking with people elsewhere in the country and we appreciate hearing the experiences they have had working to improve access to PrEP in their own communities. We have created this through trial and error, and perhaps we can help others avoid some of our mistakes, and also we learn from what others have done." **HIV**

SHUTTERSTOCK/ YAKOBCHUK VIACHESLAV

Igniting HIV Awareness IN THE MSM Community

Social Media as a Cost-Effective Outreach Tool for High Risk Populations

By MARIA ANTONIETA ANDREWS, FNP-C and AJ DOMINGUEZ

ACCORDING TO the most recent Arizona HIV/AIDS Epidemiology Annual Report, new HIV/AIDS diagnosis rates in 2016 were highest among men who have sex with men (MSM) in the age range of 25-29 year olds, and second highest among 20-24 year olds.[1] On January 2, 2018, in an effort to address the HIV epidemic, Phoenix, Arizona's Southwest Center for HIV/AIDS's community outreach program, IGNITE, launched an innovative weekly Facebook Live broadcast called IGNITE Live! with the intention of creating a fun, accessible approach to online education and outreach.

Specifically designed to reach some of the highest risk populations, the show was initiated and originally directed by Jeremy Bright, Southwest Center's former Director of IGNITE and MSM Outreach, with an equipment setup cost of just under $1000.

Outreach efforts to reach young MSM have traditionally revolved around work in LGBTQ+ bars, nightclubs, and other related establishments because those venues have typically served as safe gathering spaces for members of the LGBTQ+ population. However, millennials now find much greater acceptance across a diverse range of social networks and gathering spaces which makes targeted outreach efforts for this high-risk population much more difficult with the limited resources of community based organizations. By bringing conversations around HIV and safer sex to a digital arena that is easily accessible to those who are most at risk, IGNITE Live! is able to have a much broader reach into the LGBTQ+ community than an hour spent at a single outreach location or hosting a traditional educational workshop.[2,5] The broadcast typically receives about 500 live views and 100 post show.

By leveraging millennials' love for their local community, social video content, and their desire for questions to be answered "now,"

IGNITE Live! welcomes viewers to submit ANY question (in English or Spanish) live on Facebook during the hour long talk-show-style broadcast.[5] The topics covered vary widely from heavy discussions like "The Day I Was Diagnosed," to educational chats about condom use, PrEP, and "Trans Sex." Because talking about HIV and sexual health can be deeply personal, IGNITE Live! aims to create a "safe space" where viewers can ask questions without fear or shame.

The broadcast is hosted by IGNITE project leaders (who present part of the broadcast in Spanish), and has typically featured Southwest Center's bilingual Family Nurse Practitioner and high-profile members and allies from Phoenix's LGBTQ+ Community. Medical mistrust is more common in racial minorities and has been shown to decrease retention in care, medication adherence, and satisfaction with health care.[3,4] To that end, the NP's goal is to establish trust and familiarity with the audience, without dominating the discussions of the culturally diverse range of guests. Essentially, the NP serves as the medical "backup singer" to the highlighted guests, strategically disseminating medical information when possible.

Millennials now find much greater acceptance across a diverse range of social networks and gathering spaces which makes targeted outreach efforts for this high-risk population much more difficult with the limited resources of community based organizations.

In addition, the visible diversity on the show helps to ensure that the broadcast is appropriately addressing the needs of the Phoenix community in a culturally competent way. In Arizona, HIV/AIDS incidence rates are highest among "Non-Hispanic Blacks, Non-Hispanic American Indians and Alaska Natives, and Hispanics," and in 2016, "Non-Hispanic Blacks, Hispanics, and Mixed Race persons" had the lowest rates of linkage to care, retainment in care, on ART, adherence, and undetectable status.[1]

A variety of topics and guest appearances can be closely evaluated using Facebook's reporting tools to monitor information about the audience who views the weekly broadcasts. These tools allow Southwest Center and IGNITE staff to determine specific demographics such as gender, age, viewing drop-off points, and engagement high-points. For example, staff can see at what point reaction buttons were clicked during the broadcast to determine what content resonated the strongest with viewers.

Given the Southwest Center's goal of reaching young MSM, IGNITE staff have been able to identify increases in viewership among men ages 18-24, with the exception of one week's show. That show was missing a key component of the original mission—having a recognizable community member present. By evaluating the real-time data showing a drop in viewership, the program staff were able to quickly adapt the show's content and guests in order to bring viewership back up within a week.

Overall, by using the evaluation tools built into Facebook Live, IGNITE is able to develop best practices and learn valuable lessons about audience engagement and effective outreach strategies. After the IGNITE Live! launch, Southwest Center for HIV/AIDS has seen an increase in attendance in its clinical HIV 101 educational workshop, support group attendance for people living with HIV, and several of the NP's patients have admitted, during their visits, to watching the show.

Most importantly, anyone with moderate to advanced knowledge of sound and video equipment could implement a similar version of IGNITE Live! to meet the needs of their agency or jurisdiction. Specifically, this use of technology could be easily accessible to community-based HIV organizations who currently struggle with providing cost-effective education and outreach to young MSM or other vulnerable populations. A scaled-down version of IGNITE Live! would be possible by using a single web camera or even a smart phone or tablet. Adopting a social-media based web broadcast is within reach and has the potential to improve outreach to high-risk individuals, thereby tangibly addressing the HIV epidemic.[2,5] HIV

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SHUTTERSTOCK/ YAKOBCHUK VIACHESLAV

Developing an ICARE Data Tracking System

Using existing technology infrastructure to improve retention in care and HIV treatment outcomes

BY FIZZA S. GILLANI, AADIA A. RANA, and JOSEPH M. GARLAND

KEEPING PEOPLE LIVING WITH HIV/AIDS CONNECTED TO CARE is a major health care and public health priority as improving patient retention reduces mortality, co-morbidities, and HIV transmission. Retaining patients in HIV care is increasingly recognized as a crucial step in maximizing patient outcomes.[1] Supporting consistent engagement in HIV treatment requires the capability to address multiple barriers to care.

The Miriam Hospital Immunology Center (TMHIC) is the largest HIV clinic in the state of Rhode Island and cares for over 1700 HIV positive patients annually. It has more than 25 HIV physicians and approximately 50 staff members including nurses, medical assistants, physician assistants, case managers, outreach workers, secretaries, and other support staff members. TMHIC is supported by Ryan White funding which allows the formation of specialized case management programs to support retention efforts.

As part of the Health Resource and Services Administration mandate in 2006, the Center maintains regular Quality Management Programs and creates continuous quality improvement (CQI) projects to improve performance. The Immunology Center Adherence and Retention (ICARE) Program is one of the projects created under this mission to improve retention to care and achieve viral load suppression.

ICARE is a multidisciplinary team which includes physicians, adherence nurses, case managers, social workers, a clinical psychologist, and several other staff members. ICARE was initially created in 2013 and following a baseline assessment in conjunction with the InCare+ Campaign, the team began a practice-based approach with quarterly clinic database reviews to identify patients with gaps in care (>9months) or detectable HIV plasma viral load (PVL >200 copies/mL). Once identified, the team put protocols in place to perform targeted outreach to those patients with gaps in care or detectable viral loads.

In 2015, the ICARE team developed a customized tracking data management system to monitor the utilization and impact of ICARE team services and inform the need for modification or enhancement of the programs aiming to improve the patient care. Prior to the development of the tracking system, members maintained individual activity logs

which created a challenge in the sharing of care coordination activities among the ICARE team. The software developed by the ICARE team is now linked to a centralized database system which provides information related to patient tracking relatively easy to access.

The ICARE team meets biweekly and utilizes the ICARE tracking system to discuss patients followed by different team members. They also continuously review the barriers-in-care experienced by our clinic population. This review process serves to formulate and/or enhance existing programs to minimize barriers to care within the clinic and in collaboration with our community partners. It is our goal that with the help of the ICARE tracking system and continuous efforts by the retention team, TMHIC will be able to achieve the goals of 90-90-90 UNAIDS Campaign adopted by the state of Rhode Island. 90-90-90 is an international campaign aiming to reduce HIV transmission and increase engagement in effective treatment by addressing identification of undiagnosed patients and in "reducing the denominator" over time.[2] This can only be accomplished by diagnosing patients, connecting them to care, and retaining them in care therefore lowering their risk of transmitting HIV to others.

Through the ICARE tracking system pertinent social determinants of health related to retention and barriers to care are collected. This information is not readily available anywhere else. In summary the ICARE tracking system is innovative in several aspects and will advance our understanding of barriers to HIV care. The key characteristics of the ICARE tracking system are as follows:

A) It is a cost-effective method for tracking and evaluating strategies to improve HIV treatment adherence and care outcomes. This unique software was created within an existing information technology system with no additional cost other than time and effort of the database designer/administrator and retention team members. Operating costs were also incurred in terms of time. Since it was built within an existing technical platform, it easily accessible to a diverse team of clinic staff.

B) It is easy to use with minimal training and documentation burden to the ICARE team members who have additional care delivery responsibilities within the clinic.

C) It can easily be replicated to other HIV care practices, especially those practices who already have established HIV care coordination databases. All that is required is a onetime initial mapping of the existing data items to the ICARE software.

D) The ICARE database system can also be created as a new stand-alone system. Any HIV care practice who does not have a data system in place and would like to start a retention program can design an MS Access, MySQL, or a SQL Server data base along with the ICARE tracking system user interface.

E) This data tracking system can be added or linked to other existing database management systems or software created specifically for quality management activities.

The usage of this technology has multiple outcomes for the Miriam Hospital Immunology Center, but most importantly are increased levels of viral suppression and engagement in care at the center due to the ICARE tracking system. The comprehensive list of barriers to care guides the clinic administration in introducing new services and program which help our HIV positive patients to continue their care.

In summary, cost-effective methods of tracking and evaluating strategies to improve HIV adherence are necessary to make an impact in the HIV continuum. It is possible to integrate these methods into existing clinical data systems and it is also important to include diverse staff in different roles to streamline HIV care coordination, capture relevant data, and be time-efficient. **HIV**

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BY LEAH ADAMS and BRUCE J. PACKETT

Challenges to Battling HIV and Hepatitis C Co-Infection

AAHIVM Members Respond to HIV/HCV Eradication National Strategy Survey

HEPATITIS C VIRUS (HCV) is the most common blood-born infection in the United States, and without proper treatment, chronic infection with HCV can lead to severe liver complications.[1,2] Diseases associated with HCV such as cirrhosis and hepatocellular carcinoma are estimated to reach an all-time high within the next ten years.[3] Direct-acting antiviral (DAAs) medications have drastically improved clinical outcomes for people living with HCV,[4,5] though barriers to screening and treatment continue to exist for many individuals affected.[6,7]

When people with HCV are co-infected with HIV, additional challenges may arise. Progression to cirrhosis and other effects of HCV can be accelerated in HIV-positive individuals. Chronic HCV infection is also independently associated with an increase in all-cause and liver-related mortality in this group.[8] While up to 30% of HIV-positive patients are co-infected with HCV,[9] that number varies greatly across patient risk groups. Nearly 85% of HIV-positive people who inject drugs (PWID) are co-infected with HCV, while approximately 16% of HIV-positive men who have sex with men (MSM) are co-infected.[10] Over the last decade, new HCV diagnoses among HIV-positive MSM who do not report a history of injection drug use has increased.[11] Given the high prevalence of HIV/HCV co-infection and the evolving epidemiology of HCV, HIV care providers represent a critical group in the fight against both conditions. Further, data suggest that HIV/HCV co-infected patients specifically *prefer* to receive their HCV treatment from their HIV care providers over gastroenterologists![12]

Even though it's clear that many HIV care providers treat patients with HCV, very limited research has been conducted to examine their specific beliefs, practices, or even their needs when it comes to working with this patient population.[13] In September 2017, AAHIVM and Gilead Sciences Inc. collaborated to examine this issue. Via a brief online survey, AAHIVM members shared their experiences treating HCV mono-infected and HIV/HCV co-infected patients. A full description of the survey's results is currently in press.[14] Here, we synthesize common themes that emerged from providers' quantitative and qualitative responses. Specifically, we highlight the providers' major barriers to caring for their HCV-infected patients and offer their recommendations for improving the overall system of care for HIV/HCV co-infected patients.

Who Responded?

A total of 168 providers active in treating HIV-positive patients completed the full survey. Early career through late career providers responded (29% <10 years in practice; 31% 10-20 years in practice; 40% >20 years in practice). These providers represented a variety of health professions (59% physicians; 22% nurse practitioners; 10% physician assistants; 9% pharmacists) and practiced throughout the United States (32% South; 29% West; 26% Northeast; 12% Midwest; 2% U.S. territories) in diverse settings (46% community or federally qualified health centers; 19% academic medical centers; 14% private practice; 8% hospital systems; 13% "other clinic settings").

Providers' caseloads of HCV-infected patients varied widely. Some providers reported treating no HCV-infected patients and others treating over 50 such patients each year. Although a quarter (25%) of providers did not treat any HCV mono-infected patients, nearly everyone (96%) reported that they treated HIV/HCV co-infected patients. Providers treated patients across the HCV care spectrum, including those who had been cured previously, never treated, currently receiving treatment, had failed treatment previously, and patients who had been re-infected following HCV treatment. A subset of providers (n=92) who treated HCV mono-infected patients estimated the percentages of their HCV mono-infected caseloads associated with each of these groups: 42% cured, 38% never treated, 12% currently receiving treatment, 7% failed treatment previously, <1% re-infected following HCV treatment.

A subset of providers (n=118) who treated HIV/HCV co-infected patients also estimated the percentages of each group in their caseloads of these patients: 57% cured, 28% never treated, 9% currently receiving treatment, 5% failed

treatment previously, <2% re-infected following HCV treatment. Notably, across both HCV mono-infected and HIV/HCV co-infected patients, those who had been cured previously and those never treated for HCV comprised the largest proportion of providers' caseloads.

Although the overwhelming majority of providers agreed (93%) that they were knowledgeable enough to treat HCV, four major barriers to treatment emerged through close-ended and open-ended questions asked in the survey.

Barrier #1: Insurance, Cost, & Access Issues

In multiple areas of the survey (both quantitative and qualitative) providers highlighted the ways in which insurance and financial issues created challenges when treating HCV-infected patients. Fully 60% of providers disagreed with the statement "I can prescribe treatment for HCV to my patients *without* insurance or cost barriers." This sentiment was emphasized in responses to an open-ended question asking providers to describe the most important ways to support care providers to improve the care and treatment of HCV-infected patients. One provider noted the need for "less expensive HCV medications," while another shared that "the number one reason our residents send HCV-infected patients to gastroenterology is so they don't have the insurance hassle."

When provided with options for supporting providers, over three-quarters (77%) endorsed a desire for policy and advocacy support specifically designed to address insurance and pricing barriers. Further, improving "access" was mentioned repeatedly as a key element in the creation of a national strategy to eliminate HCV, with some providers elaborating that access included access to mental health services, needle exchange programs, prevention services, improved medications, and more.

Barrier #2: Eligibility & Authorization Concerns

Throughout the survey, providers expressed their frustration with eligibility constraints when prescribing HCV treatment. Consistent with prior work,[15] 42% of providers reported that not being viewed as an eligible treater by insurance companies was a barrier to providing HCV care. In subsequent free response questions about needed support, providers expanded upon this issue. One provider wrote "stop requiring unnecessary prior authorizations for ID [infectious diseases] providers to treat patients" in response to the prompt, and another shared that "getting all insurance plans/types to NOT restrict by provider specialty type" should be a key element in a national strategy to end HIV/HCV co-infection.

Barrier #3: Unclear Guidelines

When asked whether they would prescribe treatment to patients with a variety of behaviors that could affect HCV treatment (e.g., treatment nonadherence, active substance misuse, active alcohol abuse), providers endorsed all possible options suggesting that some would absolutely prescribe, others may or may not, and some definitely would not prescribe. For example, while approximately two-thirds of providers reported that they would *not* prescribe treatment to people with poor medication adherence, the same proportion noted that they *would* offer HCV treatment to people with ongoing alcohol or substance use.

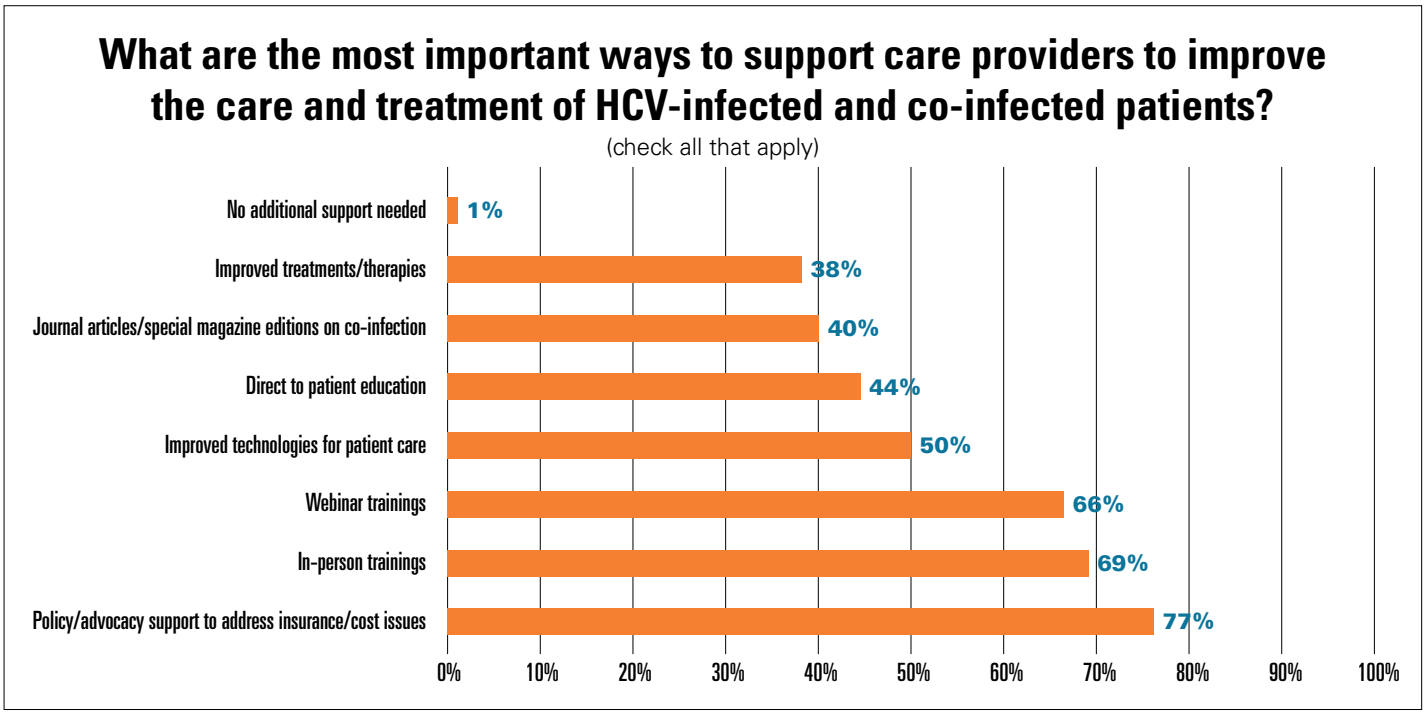
The desire for clearer guidelines in treating HCV, and HIV/HCV-coinfection specifically, was mentioned several times in providers' free responses, especially when providers responded to a question asking about key elements of a national strategy for treating HCV. One provider noted that "clear algorithms and recommended treatment guidelines like we have in HIV care" should be implemented, and another provider mentioned the need for national guidelines "similar to the HIV DHHS [Department of Health & Human Services] guidelines." With regard to improving providers' ability to treat patients with HCV, providers also reported that in-person trainings (69%), webinars (66%) and journal articles (40%) could be important sources of support [Figure 1].

Barrier #4: Limited Administrative Support

A minority of providers (14%) agreed with the statement "My schedule and responsibilities prevent me from caring for patients with HCV." Nonetheless, the need for administrative support emerged in providers' open-ended responses. One provider reported that "we could treat so many more patients than we currently treat, but we do not have the administrative support needed" and this was echoed with another provider's request for "support for the administrative burden that accompanies prescribing."

What Now?

AAHIVM providers who responded to this survey highlight the integral role that HIV care providers play in treating patients with HCV. The survey also highlights that over one-quarter of people with HIV/HCV coinfection remain untreated for their HCV. Further, these providers often have the additional task of managing two complex illnesses simultaneously (plus other comorbidities that might be present). Despite a commitment to this population and the reported knowledge to treat patients with HCV, HIV care providers highlight some real challenges in treating co-infected patients. Although we collapsed providers' responses to close-ended and open-ended questions across four primary barriers, this list is not exhaustive, and other barriers to treating patients with HCV certainly exist. While some of the barriers noted are not unique to treating HCV (e.g., administrative support issues), others represent issues specific to treating HIV/HCV co-infected patients (e.g., authorization issues, unclear guidelines). In order to better serve HIV care providers and patients, these concerns must be addressed.



To this end, AAHIVM—under the auspices of the AAHIVM HCV Institute—proposes the creation of an HIV/HCV Co-infection Eradication Task Force to create a well-honed action-item policy paper to address these and other issues and barriers preventing full elimination of co-infections in the United States and to determine whether HIV/HCV treatment guidelines should be issued. This Task Force should be comprised of HIV and HCV expert providers and will use the data and comments in the survey as a clear guide for the pressure points on which to focus these action items.

If you would like more information on the creation of this Task Force, to join, or to offer recommendations, please contact Bruce Packett at bruce@aahivm.org. **HIV**

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- Getting to Zero: Ending the HIV Epidemic
- Treatment as Prevention (TasP)
- Rapid ART Initiation
- Addressing Barriers to Rapid Start
- Concluding Comments: A Look Forward

EDUCATIONAL OBJECTIVES

After completing this activity, the participant should be better able to:

- Achieve viral suppression quickly after HIV diagnosis to optimize long-term patient outcomes and reduce the risk of HIV transmission
- Select appropriate regimens for same-day antiretroviral therapy (ART) or expedited ART based on current efficacy and safety data
- Implement strategies designed to overcome barriers to the provision of rapid ART to patients with newly diagnosed HIV infection

TARGET AUDIENCE

This activity is intended for infectious diseases clinicians and other HIV treaters, as well as primary care providers and other community stakeholders involved in the care of patients with HIV infection.

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