



# VIRTUAL CONFERENCE

MAY 20-22, 2021

Join us at **ACTHIV 2021** in real time from your home or office! ACTHIV has continued to assess the impact of the COVID-19 pandemic on our ability to offer a safe ACTHIV 2021 Annual Conference experience. Indicators are that large meetings will continue to be restricted into 2021 due to potential health concerns.



ACTHIV remains committed to providing education for the frontline HIV care team, and with this in mind we are pleased to announce that - like 2020 - we will be offering the 2021 conference from May 20-22, 2021 as a safe, virtual experience!

# WHAT CAN I EXPECT?

- Sessions will, as always, continue to feature nationally- and internationallyrecognized faculty educators
- During live Q&A sessions the speakers and panelists will be available to address your questions in real time
- Real-time case discussions will be led by experienced, interprofessional HIV provider panels
- Earn CME/CE credits

- New providers track will be conducted virtually to allow for follow-up discussions about daily sessions and expanded case presentations
- Live virtual exhibits will offer opportunities to engage virtually with our exhibitors, which include:
  - Pharmaceutical companies
  - HIV specialty pharmacies
  - HIV community-support organizations

As an added offering, live sessions will be available for on-demand replay to registered attendees for two weeks after the live-streamed conference in case you miss a session you wanted to attend.

# **CONFERENCE FEES**

Recognizing that during this challenging time funds may be limited to participate in educational activities - ACTHIV is pleased to again reduce the conference registration fee by \$100 from previous years' conferences.

Registration:
Regularly \$400 | NOW \$300

New Student/Resident/Fellow Registration:
Regularly \$275 | NOW \$175

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# Enhancing the Delivery of Care

**PROVIDERS OF HIV CARE** are used to adapting and navigating rapid changes in clinical modalities, payer systems, patient needs and treatment advances - but on the one year anniversary of the COVID-19 pandemic which brought about significant changes to social and public health protocols, we have a clear look at how entire health delivery systems had to almost immediately pivot and how routine care and prevention had to be deftly re-imagined. Some of these changes will have been transitional and temporal, but there is certainly, with the right regulations, legislation and coordination, a positive future for telehealth in terms of delivering care to and retaining those who may be harder to reach and potentially reducing health disparities. The challenges of refining and de- and re-regulating telehealth are outlined expertly in this issue of the HIV Specialist to help us maintain and enhance those benefits seen by delivering "digital" care and dodging some of the trickier challenges presented by this evolving platform for healthcare delivery, even as the public health crisis begins to abate.

While we've been remote for the past year, the Academy, too, has strived to rethink and virtualize many of its core offerings to members, including its ongoing advocacy and policy work, medical education, credentialing and networking. We recently launched the "Be Part of Something Bigger" membership campaign that really underscores the point that the Academy is the HIV provider voice in DC, as we look to coordinate with federal agencies engaged in Ending the Epidemic, and help pass important federal legislation, such as the HELP Act. An all-new (2021) volume of the Fundamentals of HIV Medicine comprehensive clinical textbook is forthcoming, with pre-orders starting in mid-March and a May 1 targeted publication date. Also recently updated is the Core Curriculum in HIV CME activity hosted on the Academy's Provider Education Center, along with a number of other digital CME activities, including two recent webinars, one on transgender HIV care and another on medical mistrust.

While there's no discounting the sheer scale of loss and deleterious effects of what has amounted to a year-long (and counting) crisis and worldwide shutdown, there has still been plenty of innovation, advancements and friction-reducing refinements to the healthcare system in the US as a result of the challenges. It turns out that there may be better and more efficient ways to deliver HIV care and prevention services than how we've traditionally viewed this realm, and the payers of care are coming on board. Some of these refinements of digital systems for care delivery may be perfectly-timed as the federal government gets serious about ending HIV transmission by reaching those disenfranchised communities and vulnerable populations. The entire concept of "the clinic" is undergoing a significant reimagination as a result of our peril, and, as usual, our members, experts and other providers in HIV are leading the charge.





# ViiV Healthcare Submits Supplemental New Drug Application to US FDA for Expanded Use of Cabenuva (cabotegravir, rilpivirine) as an HIV Treatment for Use Every 2-Months

VIIV HEALTHCARE announced the submission of a supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) for the expanded use of Cabenuva (cabotegravir, rilpivirine). The sNDA seeks to expand Cabenuva's label to include every 2-months dosing for the treatment of HIV-1 infection in virologically suppressed adults (HIV-1 RNA less than 50 copies per milliliter [mL]) on a stable regimen, with no history of treatment failure, and with no known or suspected resistance to either cabotegravir or rilpivirine. Cabenuva is a complete long-acting regimen with two separate injectable medicines, ViiV Healthcare's cabotegravir and rilpivirine, a product of Janssen Sciences Ireland UC. The medication was approved by the FDA in January 2021 as a once monthly treatment for HIV-1 infection in virologically suppressed adults. Prior to initiating treatment of Cabenuva, oral dosing of cabotegravir and rilpivirine should be administered for approximately one month to assess the tolerability of each therapy.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said: "Today's submission of Cabenuva dosed every 2-months marks another meaningful step forward in our ongoing commitment to bring innovative HIV treatments to the community. This first-of-its-kind regimen reflects the evolving needs of people living with HIV, and, if this expanded use is approved, could allow adults living with HIV to maintain virologic suppression with six dosing days per year. At ViiV Healthcare, we

will continue to advance new approaches to care as part of our mission of leaving no person living with HIV behind."

The sNDA is based on results from the global phase IIIb ATLAS-2M study, which showed the antiviral activity and safety of Cabenuva administered every 2-months was non-inferior when compared to once monthly administration. Non-inferiority was determined by comparing the proportion of participants with plasma HIV-1 RNA ≥ 50 copies per milliliter (c/mL) using the FDA Snapshot algorithm at Week 48 (Intent-to-Treat Exposed [ITTE] population), which showed that the every 2-months arm (9/522 [1.7%]) and once monthly arm (5/523 [1.0%]) were similarly

effective (adjusted difference: 0.8%, 95% confidence interval [CI]: -0.6, 2.2). The study also found that rates of virologic suppression (HIV-1 RNA <50 c/mL), a key secondary endpoint, were similar, whether Cabenuva was administered every 2-months (492/522 [94.3%]) or once monthly (489/523 [93.5%]) (adjusted difference: 0.8%, 95% CI: -2.1, 3.7). Treatment with Cabenuva was generally welltolerated across both study arms. In the every 2-months arm, rates of serious adverse events (SAEs: 27/522[5.2%]) and withdrawals due to adverse events (AEs: 12/522 [2.3%]) were low and similar to those experienced in the once monthly arm (SAEs: 19/523 [3.6%], withdrawals due to AEs 13/523 [2.5%]).

## About ATLAS-2M (NCT03299049)

THE ATLAS-2M STUDY is an ongoing phase IIIb, randomized, open-label, active-controlled, multicenter, parallel-group, non-inferiority study designed to assess the non-inferior antiviral activity and safety of long-acting cabotegravir and rilpivirine administered every eight weeks (2-months, 3mL dose of each medicine) compared to every four weeks (once monthly, 2mL dose of each medicine) over a 48-week treatment period in 1,045 adults living with HIV-1.2 Subjects were required to be virologically suppressed for six months or greater, on first or second antiretroviral regimen, with no prior virologic failure. The primary outcome measure for the study was the proportion of participants with HIV-1 RNA ≥ 50 c/mL at Week 48 using the FDA Snapshot algorithm (Intent-to-Treat Exposed [ITT-E] population).

ATLAS-2M is part of ViiV Healthcare's extensive and innovative clinical trial program and is being conducted at research centers in Australia, Argentina, Canada, France, Germany, Italy, Mexico, Russia, South Africa, South Korea, Spain, Sweden and the United States.

For further information please see https://clinicaltrials.gov/ct2/show/NCT03299049.



# Biden Administration Moves to Roll Back Medicaid State Work Requirements

CCORDING TO POLITICO, the Department of Health and Human Services has created a draft rollout plan calling for a rescission of Medicaid Work Requirements, essentially a cancellation of the Trump Administration's program calling for work requirements to access Medicaid. This mostly affects any Republican-led states (Arizona, Arkansas, Georgia, Indiana, Nebraska, New Hampshire, Ohio, South Carolina, Utah, Wisconsin) that had applied and been approved for waivers to implement work rules.

The Academy has long been concerned about the impact of work requirements since early impositions of such requirements resulted in loss of insurance for tens of thousands of people. For example, in

Arkansas, the only state to fully implement work requirements, over 18,000 people lost coverage in seven months of implementation of the policy representing 1 in 4 people subject to the requirement. Further, studies showed that the work requirement increased the number of uninsured people without increasing employment rates. Although a court case stopped implementation in Michigan, 80,000 people were at risk for loss of coverage. A study from the Kaiser Family Foundation showed that job losses due to the economic downturn related to the COVID-19 pandemic had the potential to create further loss of coverage due to work requirements.

The move additionally has the possibility of impacting court cases regarding Medicaid work requirements that had worked their

way to the Supreme Court. The court had scheduled oral arguments on the issue for March 29th in a case which ruled that Arkansas' work requirements were unlawful and that the ruling applied to similar work requirements in New Hampshire. Due to the court cases, both Arkansas and New Hampshire's work rules are technically still pending, and the Administration could move to reject them outright. Additionally, if the Biden Administration does rescind the guidance in advance of the Supreme Court arguments the court case could be considered moot.

The Academy strongly believes that people's access to insurance should not be subject to removal based on arbitrary criteria such as work and applauds the Administration's efforts to resolve this issue.

# Dr. Jeffrey Kwong Named Co-Medical Director of National HIV & Aging Initiative

HE AMERICAN ACADEMY OF HIV MEDICINE is pleased to announce the appointment of Dr. Jeffrey Kwong as Co-Medical Director of the National HIV and Aging Initiative. A collaboration of the Academy, the American Geriatrics Society (AGS) and ACRIA, the Initiative is made up of nationallyrecognized HIV specialists and gerontologists. The goal of the Initiative is to provide the latest science and clinical guidance for optimal care of older people with HIV.

Launched in 2011 with the website HIV-Age.org, the Initiative's first act was publishing "Recommended Treatment Strategies for Clinicians Managing Older Persons with HIV." With formal clinical guidance from the U.S. Department of Health and Human Services several years away, these strategies remain the only clinical guidance for treating older adults with HIV.

"As with many aspects of HIV care, care and treatment approaches are constantly changing, and new research emerges on treating the older adult with HIV," said Bruce J. Packett, Executive Director of the Academy, "The National HIV and Aging Initiative continues to be a valuable resource for medical providers by regularly issuing updated clinical content, and we welcome Dr. Kwong as Co-Medical Director and recognize the unique perspective he brings to guiding the



expansion of our work in this space."

Dr. Kwong, a widely respected academic in HIV treatment and prevention is also a leading expert in the provision of care to the lesbian, gay, bisexual, and transgender (LGBT) community and focuses on older LGBT adults. His work includes the feasibility and benefit of nurse-led models of care for older LGBT adults and he currently serves as a Professor at the Rutgers School of Nursing where he was also

the program director of the Adult-Gerontology Primary Care Program.

Dr. Kwong earned his doctoral degree from the University of Colorado and his master's degree in nursing from the University of San Francisco. He also holds a master's degree in public health and a bachelor's degree in social welfare from the University of California. Dr. Kwong is a Fellow of the American Association of Nurse Practitioners (AANP), is certified by the American Nurse Credentialing Center, the HIV/AIDS Nursing Certification Board, and is credentialed as an HIV Specialist<sup>™</sup> by the American Academy of HIV Medicine.

Dr. Kwong joins Dr. Meredith Green, Assistant Professor of Medicine at the UC San Francisco School of Medicine as Co-Medical Director, along with a diverse team of experts in HIV and Gerontology to lead the National HIV and Aging Initiative.

# **USPSTF Members Release Statement on Addressing Systemic Racism**



IN A REMARKABLE
EDITORIAL, Addressing
Systemic Racism Through
Clinical Preventive Service
Recommendations From
the US Preventive Services
Task Force, published in
JAMA, the members of the

U.S. Prevention Services Task Force (USPSTF) observed that health services offering lifesaving benefits are "not equitably available to Black, Indigenous, and Hispanic/Latino people." The USPSTF is a volunteer body of prevention and medical experts responsible for making evidence-based recommendations regarding clinical preventive services such as screenings, counseling services and preventive medications. The committee assigns a letter grade (A-D) to these services. Under the Affordable Care Act services with a recommendation of A or B must be covered without cost sharing. For example. the USPSTF gave an A recommendation that people with high risk of HIV acquisition be offered Pre-Exposure Prophylaxis (PrEP).

In the editorial, the USPSTF committed to

"identify when systemic racism contributes to health inequities and to include evidencebased strategies that will reverse the negative effects of systemic racism on preventable disease." They further committed to taking the specific actions:

- Consider race primarily as a social and not a biological construct and use consistent terminology throughout recommendation statements to reflect this view.
- Promote racial and ethnic diversity in addition to gender, geographic and disciplinary diversity in membership and leadership of the USPSTF and foster a culture of diversity and inclusivity as an enduring value of the USPSTF. This will be assessed annually prior to soliciting nominations for new members and internally assigning leadership roles.
- Commission a review of the evidence, including an environmental scan and interviews with clinicians, researchers, community leaders, policy experts, other guideline developers and patients from groups that are disproportionately affected to summarize the evidence on how systemic racism undermines the

- benefits of evidence-based clinical preventive services and causes preventable deaths. This will be completed by June 2021.
- Iteratively, update USPSTF methods to integrate the best evidence and consistently address evidence gaps for Black, Indigenous, and Hispanic/Latino populations. This includes measures to identify and track strategies to demonstrate progress in addressing health inequities regarding clinical preventive services.
- Use a consistent and transparent approach to communicate gaps in the evidence related to systemic racism in preventive care in Recommendation Statements and the USPSTF's annual report to Congress. This includes an ongoing assessment of how the effects of systemic racism on the quality of the evidence and receipt of clinical preventive services perpetuate health inequities.
- Collaborate with other guideline-making bodies, professional societies, policy makers, and patient advocacy organizations on efforts to reduce the influence of systemic racism on health.

# HIV research yields potential drug target

UMANS POSSESS a formidable multi-layered defense system that protects us against viral infections. Better understanding of these defenses and the tricks that viruses use to evade them could open novel avenues for treating viral infections and possibly other diseases.

For example, a human protein called SAMHD1 impedes replication of HIV and other viruses by depleting deoxynucleotides — building blocks needed for the replication of the viral genome. It has long remained a mystery whether and how this protein is activated in response to infection.

Now researchers from UT Health San Antonio have discovered that SAMHD1 recognizes a unique molecular pattern in nucleic acids. This pattern, called "phosphorothioation," may act as a signal for action. It's like a sentinel atop a palace wall who sees an invading horde in the distance and calls the troops to battle stations.

Understanding the mechanism of SAMHD1 activation could be a step forward in the fight against HIV/AIDS.

"If we are able to increase SAMHD1 activity using a specific drug, that could potentially have anti-HIV activity," said Corey H. Yu, PhD,

postdoctoral fellow in the laboratory of Dmitri Ivanov, PhD, at UT Health San Antonio.

Today's antivirals target the viral proteins. If, in addition, therapies could unleash the power of our existing immune defenses on the virus to help eliminate it from the body, that could be a game-changer.

"It's a different way to look at antiviral drugs," Dr. Yu said. "We want to know if we can try to target a protein to hopefully boost its activity against HIV."

Dr. Yu is first author of the study findings published Feb. 2 by the journal *Nature Communications*. The National Institutes of Health funded the research.

Nucleic acid binding by SAMHD1 contributes to the antiretroviral activity and is enhanced by the GpsN modification.

Corey H. Yu, Akash Bhattacharya, Mirjana Persaud, Alexander B. Taylor, Zhonghua Wang, Angel Bulnes-Ramos, Joella Xu, Anastasia Selyutina, Alicia Martinez-Lopez, Kristin Cano, Borries Demeler, Baek Kim, Stephen C. Hardies, Felipe Diaz-Griffero and Dmitri N. Ivanov.

First published: Feb. 2, 2021, *Nature Communications*. https://doi.org/10.1038/s41467-021-21023-8



# Study Examines Attitudes Toward Long-Acting Injectable HIV Therapy Among Women with a History of Injection

STUDY led by Columbia University Mailman School of Public Health researchers examines attitudes toward long-acting injectable (LAI) HIV therapies, among women with a history of injection—including medical purposes and substance use. The findings appear in the journal AIDS Patient Care and STDs.

Currently, most HIV therapies for treatment and prevention (pre-exposure prophylaxis, PrEP) necessitate daily pills, which pose barriers to adherence. Recently, however, LAI for HIV has emerged as an alternative with the potential to boost adherence, although little research has been done on how people with a history of injection feel about these new forms of injectable

HIV therapy. There are 258,000 women in the United States living with HIV.

The study involved interviews with 89 women across six different sites in the United States. Overall, participants highlighted how LAIs may improve adherence by freeing women of treatment fatigue and reminders associated with daily pill-taking, thus eliminating potential stigma, and facilitating confidentiality. Most women with a history of periodic injectable medication (such as birth control) would prefer LAI, but those with other frequent injections (such as for diabetes) who expressed a desire to limit the number and frequency of injections and clinic visits might not. Women with a history of injection drug use

expressed mixed sentiments: some feared LAI might trigger a recurrence while others felt that familiarity with needles would predispose people who use injection drugs towards LAI.

The authors write that LAI HIV therapies would ideally coincide with existing LAI treatments (e.g., birth control) to minimize inconvenience and the need for multiple clinic visits, an approach currently used in some clinics that co-locate care for HIV and substance use.

"Future research needs to address injection-related concerns, and develop patient-centered approaches to help providers work with their patients to best identify which women could most benefit from LAI use," says first author Morgan Philbin, PhD, assistant professor of sociomedical sciences at Columbia Mailman School. "As LAI ART for HIV treatment and prevention is scaledup, systems must be created for women and providers to collaborate in order to best identify which women might need additional support for LAI use and which might be better candidates for daily pills."

The researchers conducted indepth interviews at six sites (New York, NY; Chicago, IL; San Francisco, CA; Atlanta, GA; Chapel Hill, NC; Washington, D.C.) as part of the Women's Interagency HIV Study, including women living with HIV and women at risk for HIV.

A complete list of authors, their affiliations, and funding sources is available online, as part of the published article.



# The Immune System Mounts a Lasting Defense after Recovery from COVID-19

S THE NUMBER OF PEOPLE who have fought off SARS-CoV-2 climbs ever higher, a critical guestion has grown in importance: How long will their immunity to the novel coronavirus last? A new Rockefeller study offers an encouraging answer, suggesting that those who recover from COVID-19 are protected against the virus for at least six months, and likely much longer.

The findings, published in Nature, provide the strongest evidence vet that the immune system "remembers" the virus and, remarkably, continues to improve the quality of antibodies even after the infection has waned. Antibodies produced months after the infection showed increased ability to block SARS-CoV-2, as well as its mutated versions such as the South African variant.

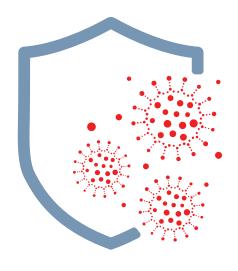
The researchers found that these improved antibodies are produced by immune cells that have kept evolving, apparently due to a continued exposure to the remnants of the virus hidden in the gut tissue.

Based on these findings, researchers suspect that when the recovered patient next encounters the virus, the response would be both faster and more effective, preventing re-infection.

"This is really exciting news. The type of immune response we see here could potentially provide protection for quite some time, by enabling the body to mount a rapid and effective response to the virus upon re-exposure," says Michel C. Nussenzweig, the Zanvil A. Cohn and Ralph M. Steinman Professor and head of the Laboratory of Molecular Immunology, whose team has been tracking and characterizing antibody response in Covid-19 patients since the early days of the pandemic in New York.

#### Long-lasting memory

Antibodies, which the body creates in response to infection, linger in the blood plasma for several weeks or months, but



their levels significantly drop with time. The immune system has a more efficient way of dealing with pathogens: instead of producing antibodies all the time, it creates memory B cells that recognize the pathogen, and can quickly unleash a new round of antibodies when they encounter it a second time.

But how well this memory works depends on the pathogen. To understand the case with SARS-CoV-2, Nussenzweig and his colleagues studied the antibody responses of 87 individuals at two timepoints: one month after infection, and then again six months later. As expected, they found that although antibodies were still detectable by the six-month point, their numbers had markedly decreased. Lab experiments showed that the ability of the participants' plasma samples to neutralize the virus was reduced by five-fold.

In contrast, the patients' memory B cells, specifically those that produce antibodies against SARS-CoV-2, did not decline in number, and even slightly increased in some cases. "The overall numbers of memory B cells that produced antibodies attacking the Achilles' heel of the virus, known as the receptor-binding domain, stayed the same," says Christian Gaebler, a physician and

immunologist in Nussenzweig's lab. "That's good news because those are the ones that you need if you encounter the virus again."

#### Viral stowaways

A closer look at the memory B cells revealed something surprising: these cells had gone through numerous rounds of mutation even after the infection resolved, and as a result the antibodies they produced were much more effective than the originals. Subsequent lab experiments showed this new set of antibodies were better able to latch on tightly to the virus and could recognize even mutated versions of it.

"We were surprised to see the memory B cells had kept evolving during this time," Nussenzweig says. "That often happens in chronic infections, like HIV or herpes, where the virus lingers in the body. But we weren't expecting to see it with SARS-CoV-2, which is thought to leave the body after infection has resolved."

SARS-CoV-2 replicates in certain cells in the lungs, upper throat, and small intestine, and residual viral particles hiding within these tissues could be driving the evolution of memory cells. To look into this hypothesis, the researchers have teamed up with Saurabh Mehandru, a former Rockefeller scientist and currently a physician at Mount Sinai Hospital. who has been examining biopsies of intestinal tissue from people who had recovered from COVID-19 on average three months earlier.

In seven of the 14 individuals studied, tests showed the presence of SARS-CoV-2's genetic material and its proteins in the cells that line the intestines. The researchers don't know whether these viral left-overs are still infectious or are simply the remains of dead viruses.

The team plans to study more people to better understand what role the viral stowaways may play in both the progression of the disease and in immunity.

# **FOREFRONT**

# Q&A with Dr. Michael Stefanowicz

Assistant Professor at the University of Texas Austin and a Member of the HIV Clinical Leadership Fellowship Program class of 2018-2020

## Why did you choose to pursue a career in HIV Primary Care?

I chose a career in HIV primary care for a few reasons. One, I was already very passionate about the primary care movement in general, even before I had an interest in HIV medicine. I chose family medicine because it has long held a historically special place in advocating for whole person care. Many people may not know this but family medicine as a distinct specialty was in many ways born out of the counterculture movements of the 1960s. Family Medicine was a direct response to the trend towards partitioned specialty care. It focused not only on the individual but their family unit, their broader ecosystem, and the psychosocial influences unique to each person. If this all sounds rather mainstream these days it's probably because it is.

In part, we have Family Medicine to thank for bringing the concepts of whole person primary care to the forefront. HIV primary care is now coming into its own as well and builds on these principles. With people with HIV (PWH) living longer the trend has been away from strictly HIV-centric care and more towards a focus on the traditional elements of primary care: chronic disease management, primary and secondary prevention, wellness, and aging in a healthy way. The HIV practitioner is both primary care doctor and specialist. I think HIV care has also informed primary care in so many ways. Primary care is now focusing more on teambased care, which is something that practitioners of HIV medicine have appreciated for decades.

## What brought you to the HIV Clinical Leadership Fellowship Program in particular?

I had a fair amount of experience caring for PWH in my training at UT Austin Dell Medical School's Family Medicine Residency. However, I knew that I wanted to be more than a medical practitioner alone. I wanted to accrue foundational skills that would empower me to be a change agent for the healthcare system at large. The HIV Clinical Leadership Program, in partnership with the Pacific AIDS Education and Training Center at the University of Southern California, exposes fellows to a myriad of care models around Los Angeles County, while at the same time housed within a training ground with academic bonafides. It offered a unique clinical training experience but also access to many excellent mentors who helped me discern the right career path for myself.

## What did you particularly enjoy about the HIV Clinical Leadership Fellowship Program?

The breadth of clinical experiences is one of the biggest strengths of the program. In HIV medicine we talk a lot about the "HIV Care Continuum" in terms of testing, linkage, rapid initiation of ART, retention, and viral suppression. The fellowship ensures that all fellows participate in every single-entry point on that care continuum. Fellowship training requires all fellows take call at the LAC+USC County hospital emergency department to facilitate face to face linkage for new HIV diagnoses and to interface with patients who have not been retained in care. We talk to patients about their diagnosis and then arrange a prompt follow up appointment at our continuity clinic, the Rand Schrader clinic. We also see patients experiencing homelessness at our EIS clinic in Skid Row and at the LA County Jail. A few other training sites include the Maternal and Child Clinic (MCA), Homeless Healthcare LA needle exchange and harm reduction program, and the inpatient infectious disease consult service at LAC+USC. It's an incredible strength of the program that fellows can insert themselves anywhere on the care continuum and so it really offers patients flexibility in seeing their same provider if life's circumstances change, guaranteeing a level of care continuity that few other clinical systems can offer.

## What was your favorite clinical experience and why?

I valued every clinical experience I was afforded but my time with our street medicine team was my favorite. For those who may not know, street medicine is an emerging model of care focused on delivering medical care to some of the most marginalized groups of men and women in the U.S. living on the streets. Keck Medicine of USC has a robust street medicine program charged with delivering care to persons living on the streets and scaling up the pipeline of competent street



medicine providers. I value this experience for several reasons. As many HIV medicine practitioners know, concerns around adherence to ART weigh heavily on our minds because we know adherence is tied to therapeutic efficacy and better outcomes. Some providers routinely consider unstable housing to be a barrier to ART adherence. I've seen housing status, substance use or serious and persistent mental illness used as rationales for delayed initiation of ART therapy. Unfortunately, those who may face innumerable barriers to traditional medical care at a brick-and-mortar clinic site are often not the ones in the clinic waiting room. As such, many of these patients tend to be seriously ill and also deeply skeptical of traditional medical models because, to be quite honest, what have we done to meet the needs of some of these patients? The program afforded me the opportunity to partner with our street team to build more HIV primary care on the

We cannot wait for people to "enter a more stable living situation" because that just is not the reality of things. We have to adjust our care systems and create alternative care models to meet the unique needs of people experiencing homelessness. If that means routine labs don't happen within the same time frames or we deliver ART to someone in their tent in Skid Row, then so be it. That is the essence of real patient centered care. The HIV Clinical Leadership Program really permitted me the space to build something with our street team that is truly unique.

## What was the best part of your training in the HIV Clinical Leadership Fellowship Program?

The faculty are undoubtedly the foundation for our program. Our clinic has a myriad of physicians who have been caring for PWH for decades, both in terms of clinical care but also in terms of taking part in some groundbreaking HIV research since the dawn of the epidemic. Drs. Jenica Ryu and Christian Takayama are our two primary clinical preceptors at the Rand Schrader (5P21) clinic. Their clinical skills are second to none and they both have over a decade of experience in HIV primary care. More importantly, I still learned plenty from them both about how to be a good physician. Many think of themselves as "fully formed" physicians when they graduate from residency, believing their ideas and medical practices are complete. But the program proved me wrong with respect to that notion. Dr. Ryu is the most thoughtful, caring, selfless physician I have ever met. She not only has an impressive wealth of medical knowledge, but she is able to apply that knowledge in a way that recognizes each patient's unique lived experience. HIV medicine can inherently be very academic because it is evolving so fast. But it takes a very special clinician to take that knowledge and still meet the patient where they are, whether it's on the streets in Skid Row or in the LA County Jail. There honestly isn't a week that goes by in my medical practice that I don't ask myself "what would Dr. Ryu do here?" She inspires me to be a better doctor and a more empathic person for my patients.

## How did the HIV Clinical Leadership Fellowship Program prepare you for a career as an HIV Specialist?

So far, I've spoken a lot about systems of care, but I think the program really prepares fellows for HIV clinical practice better than any fellowship out there. Working in different practice settings also affords physicians the



opportunity to get a range of experience with different antiretrovirals, clinical conditions and age groups. I've had experience managing HIV in children, adolescents, pregnancy, and among older populations aging with HIV. We also have a lot of experience managing opportunistic infections given the population we serve face multiple barriers to timely diagnosis and many are acutely hospitalized for HIV related illnesses. One other unique component of the program is a focus of HIV resistance and salvage therapies. With the advent of newer single tablet regimens with high genetic barriers to resistance multidrug resistance is thankfully less common. Nonetheless, there is still a need for clinicians who can navigate the nuances of drug resistance and build a functional ART regimen for these patients. While many new HIV clinicians can gain basic competencies in HIV medicine independent of a fellowship program, I do not believe they would have the requisite skill set to manage the small fraction of patients who have accumulated multiple drug resistant mutations over the years. This is a great selling point for the fellowship. Lastly, I will say the fellowship really exposes fellows to many wonderful leaders in the field, both in clinical medicine, academics, and health policy. The opportunities for mentorship are endless.

## Now that you have completed the HIV Clinical Leadership Fellowship Program, where have you taken your career?

I have since returned to Austin, Texas with my husband. Austin has been home to us for quite some time and I always had the desire to return here to build up our status neutral care model. As the clinical lead for sexual health programming, I oversee the clinical implementation of our status neutral care model for CommUnityCare, which is one of the two largest FQHCs in Texas. We are building a care model that integrates HIV primary care into existing primary care medical homes because stigma associated with our traditional Ryan White clinics is a very real barrier to some patients. Not to mention the geographic barriers to accessing certain clinical sites given the limited availability of HIV primary care services. Our leadership at CommUnityCare also recognizes that prevention services are of equal importance, which is why we are concurrently scaling up the availability of our PrEP and HIV prevention services. I also work in our homeless healthcare settings doing more to build out alternative care models for PWH experiencing homelessness. With the highest uninsured rate in the nation and a reticence to expand Medicaid practicing medicine in Texas poses many unique challenges. However, there is an immense need here. Many of our HIV medicine physicians, both in Texas and nationally, have been practicing since the dawn of the AIDS epidemic. So, there is a need to cultivate a pipeline of upcoming clinicians who can carry the baton and build on the gains that have been made in HIV primary care. **HIV** 

#### FIND OUT MORE AND APPLY TODAY www.hivmedfellowship.com

#### **Application and Selection Process**

Applications are available online at www.hivmedfellowship.com. Applications are being accepted for the 2022-2024 cycle starting on July 1st, 2021 and run through October 1st of each application year. Once we receive your completed application, we may contact you for an interview. Final cohort selection is completed by November 30th.

Ideal candidates are board-eligible graduates of a residency program in Family Medicine, Internal Medicine, or Medicine-Pediatrics with a strong interest in HIV medicine or an interest in building community programs to improve access to quality HIV care.

#### More questions? Visit the program website or contact:

#### Gina Rossetti, M.D.

Director, HIV Clinical Leadership Program grossetti@dhs.lacounty.gov

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PI and Director, AIDS Education and Training Center at the Keck School of Medicine of USC jdgates@usc.edu



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BY: Joseph S. Cervia, MD, MBA, FACP, FAAP, FIDSA, AAHIVS

I DR. JOE, it is great to be with you...if only virtually!" I suspect that many of us have been hearing greetings of this sort frequently this past year. Although we may have previously utilized telephone, electronic information and digital communication technologies in the care of our patients, the COVID-19 pandemic has driven dramatic growth in telehealth visits over the past year. Telehealth is broadly defined as the use of electronic information and telecommunication technologies to support and promote long-distance clinical healthcare, patient education, public health and health administration. During the first quarter of 2020, the number of telehealth visits in the U.S. increased by 50 percent, compared with the same period in 2019, with a 154 percent increase in visits noted in surveillance week 13 in 2020, compared with the same period in 2019.<sup>2</sup>

Throughout recorded history, pandemics have taught humanity a great deal: driving progress in biomedical science, public health and health care delivery. And such calamities will continue to teach us if we remain attentive, adaptive and humble enough to learn. The past year has certainly motivated progress in each of these areas. Nevertheless, many challenges and opportunities remain. In battling the dual pandemics of HIV/AIDS and SARS-CoV-2/COVID-19, telehealth has offered numerous important opportunities to address critical challenges in delivering care for individuals living with HIV.

#### **Eliminating Geographic Barriers**

For decades, it has been recognized that limited geographic access to HIV specialty services in rural areas has been problematic. Rural residents are less likely to get tested for HIV, more likely to internalize HIV-related stigma, more likely to be tested in non-rural places, more likely to be diagnosed with AIDS at the time of initial HIV diagnosis and less likely to be retained in care as well as be virally suppressed.<sup>3</sup> In rural states, there is a general shortage of clinical providers, pervasive barriers to providing care, and community stigma around HIV and its risk factors. 4 Although there have been repeated efforts

to recruit skilled healthcare professionals to these areas, they have frequently fallen short of what is needed to assure enhanced outcomes for individuals at risk for or infected with HIV.

Telehealth services offer the potential to eliminate geographic barriers to HIV care. As we have learned in this past year, physical distances and geopolitical boundaries need not prove to be insurmountable. During the COVID-19 pandemic, many states have altered or eliminated licensing requirements for telehealth services, allowing broader access to quality primary and specialty care. 5 If some of these changes are continued, expanded, and made permanent, telehealth may grow to assume a pivotal role in rendering geographic barriers to high quality HIV care obsolete.

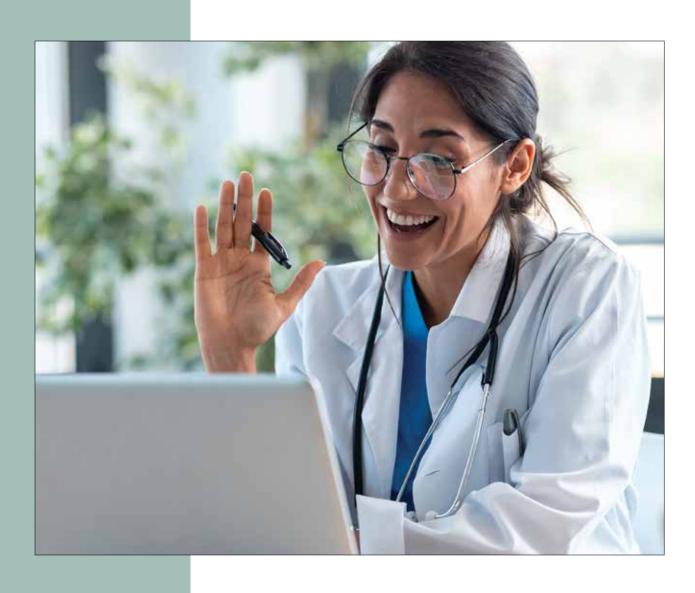
## Minimizing **Transportation Issues**

In both urban and suburban environments, transportation to and from regular healthcare visits can be costly and difficult, and can thus challenge engagement and adherence for individuals living with HIV. Inclement weather, traffic and public transportation infrastructure issues can often complicate the efforts of even the most conscientious patients and providers. Moreover, homebound individuals and others with mobility issues may face even greater difficulties with multiple recurring appointments for in-person visits to various healthcare services.

Telehealth can eliminate the need for patients and providers to travel, increasing efficiency and reducing cost. It also reduces the number of missed visits attributable to

# unile A PART

The Opportunities and Challenges of Telehealth in HIV Care



#### TOGETHER WHILE APART

inclement weather, traffic or other transportation issues. Enhanced efficiency may also permit increased availability of and flexibility with scheduled appointments, and less time spent travelling, waiting and away from work for patients. With these advantages, it is no wonder that many urban and suburban patients and providers have embraced telehealth services for their regular follow-up care.

## **Reducing Care Disparities**

Underserved populations, including those afflicted with poverty, who have been disproportionately affected by the dual pandemics of HIV and COVID-19, by definition have also suffered disproportionally the effects of limited access to HIV specialty services. Although 80 percent of all U.S. households have access to the internet, data from the Health Information National Trends Survey suggest that significant disparities in internet access exist by age, sex, race, ethnicity, income, and education. Likewise, as noted in AHRQ's 2018 National Healthcare Quality and Disparities Report, while some of the observed disparities have declined over the past two decades, many persist, especially for poor and uninsured populations in all priority areas.<sup>6</sup>

With the possibility of broadening access to HIV specialty services to traditionally underserved populations, telehealth can help to reduce healthcare disparities. Nevertheless, it has become very clear through early efforts to establish remote learning and virtual workplace environments in addressing the COVID-19 pandemic that much good work remains to be done to enhance the equitable availability of broadband internet access. As telehealth and other essential digital services continue to grow and progress in the 21st century, accomplishing that work will become even more critical. If telehealth is to take its rightful place among the tools for reducing disparities in access to quality healthcare, disparities in access to the internet and digital technologies must first be eliminated.

#### **Managing Biopsychosocial Dimensions**

Telehealth has certainly become an important tool in our clinical toolkit. Nonetheless, it is not always appropriate for every task. On occasion, patients and providers may feel less comfortable with some of the logistical aspects of telehealth, particularly in addressing complex psychosocial and medical issues. Carving out personal space for private telehealth visits may be more challenging for some individuals due to housing issues. Practitioners in HIV medicine care for a disproportionately large number of individuals whose health outcomes are affected by social determinants of health, including race, ethnicity, gender, income, housing stability, mental health, substance use, education, language, incarceration history, and others. These same social determinants as well as English language skills predict digital health readiness.7

Although telehealth services alone may not prove optimal or even sufficient in every instance, experience in recent years and particularly over the past year has clearly demonstrated the value that these services may provide in the broader context of HIV care. This is especially the case for individuals who have previously established care with a knowledgeable and trusted provider with whom ongoing follow-up via telehealth can be maintained. Indeed, outcomes for individuals



In battling the dual pandemics of HIV/AIDS and SARS-CoV-2/COVID-19. telehealth has offered numerous important opportunities to address critical challenges in delivering care for individuals living with HIV.

on antiretroviral therapy (ART) in terms of adherence and clinical response to therapy, psychological and emotional states and quality of life have been demonstrated to be similar for individuals utilizing telehealth and in-person visits.8

## **Bridging the Digital Divide**

Technology literacy and access may be limiting factors in the successful implementation of telehealth services, particularly for those who struggle with poverty. Individuals living with HIV infection are disproportionately impacted by poverty, and would be expected to be at risk for substantial challenges to the availability of and facility with the necessary technological components of telehealth services. The digital divide has been painfully evident in the many challenges presented by the COVID-19 pandemic, which has rapidly driven the necessity to conduct so much of daily life online. With so much at stake, we are challenged now more than ever as a society to ensure that the fruits of technological advances are more equitably distributed.



That stated, there is growing evidence that technology skills and access have never been better. Among all U.S. households in 2016, 89 percent had a computer and/or smartphone, and 81 percent had a broadband internet subscription.9 Although we have not completely bridged the digital divide, we are certainly moving in a direction that is favorable for the successful implementation of telehealth services for individuals and communities struggling with HIV.

### Funding High-Value Care

Although the value of telehealth services for individuals with chronic conditions, such as HIV, is considered to be high, insurance reimbursement for such services has varied.

The HRSA Ryan White HIV/AIDS Program has been promoting the expansion of HIV care through telehealth since before the pandemic. 10 However, the COVID-19 pandemic has driven more rapid changes in reimbursement for telehealth services. The Centers for Medicare & Medicaid Services (CMS) has broadened access to Medicare telehealth services so that beneficiaries can receive a wider range of services from their doctors without having to travel to a healthcare facility. 11

Under an expanded new 1135 waiver, beginning March 6, 2020 and for the duration of the COVID-19 public health emergency, Medicare will reimburse for office, hospital, and other visits furnished via telehealth across the country. A range of providers, including doctors, nurse practitioners, clinical psychologists, and licensed clinical social workers, are able to offer telehealth to their patients. Additionally, the HHS Office of Inspector General (OIG) is providing flexibility for healthcare providers to reduce or waive cost-sharing for telehealth visits paid by federal healthcare programs. Prior to this waiver Medicare could only pay for telehealth on a limited basis when the person receiving the service was in a designated rural area and when they would leave their homes and go to a clinic, hospital, or certain other types of medical facilities for the service.

Even before the availability of this waiver authority, CMS made several related changes to improve access to virtual care. In 2019, Medicare started making payments for brief communications or Virtual Check-Ins, which are short patient-initiated communications with a healthcare practitioner. Medicare Part B separately pays clinicians for E-visits, which are non-face-to-face patient-initiated communications through an online patient portal.

Medicare beneficiaries are able to receive a specific set of services through telehealth including evaluation and management visits (common office visits), mental health counseling and preventive health screenings. This will help ensure Medicare beneficiaries, who are at a higher risk for COVID-19, are able to visit with their providers from their homes, without having to go to an office, clinic or hospital, which may put them and others at increased risk.

## Staying Together While Apart

"Stay safe Dr. Joe!" At the conclusion of each telehealth visit, my patients and I exchange kind words and virtual hugs. Although we look forward to the end of the COVID-19 pandemic and with it greater opportunities to exchange these in person, we acknowledge with gratitude the critical contributions that telehealth has made in filling otherwise unmet healthcare needs. It remains to be seen what elements of telehealth will remain as the public health crisis posed by COVID-19 is perceived to subside. What appears certain is that as we continue to address the ongoing pandemic of HIV, telehealth will continue to afford us valuable opportunities for staying together while apart. **HIV** 

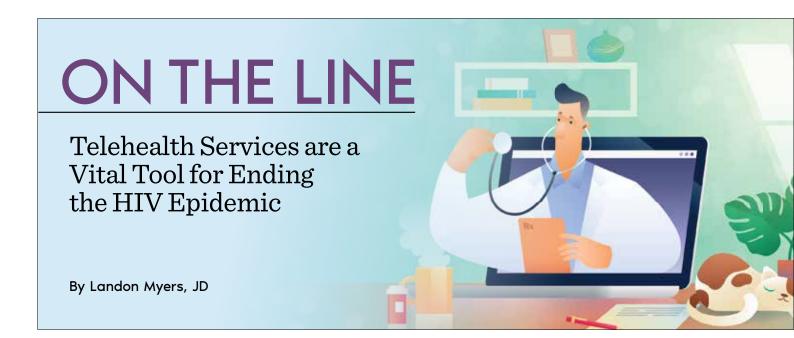


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USTAINED ENGAGEMENT IN HIV PREVENTION and care is crucial for maintaining the health of people with HIV (PWH) and reducing new HIV transmissions. It is no secret, however, that many people struggle to stay in care and many providers are frustrated by no-shows, gaps in care, and all of the barriers that arise in helping to keep PWH engaged in care. The COVID-19 pandemic did not make this feat any easier. While telehealth has been around for a while, and HIV providers have used it to varying degrees, the COVID-19 crisis was an unforeseen catalyst that spurred telehealth adoption. What began as an emergency response has opened up a world of possibility for improving patient outcomes, reducing provider stress, and has the potential to become an integral aspect of HIV care delivery well after the current COVID-19 pandemic is behind us.

Before the COVID-19 pandemic, some healthcare providers were utilizing methods of telehealth to provide services to patients.<sup>1</sup> Oftentimes though, the extent of these services were simply telephone calls and patient portal chat boxes. Beginning in March of 2020, healthcare delivery of HIV prevention and related services shifted dramatically due to the partial closure of many clinical settings and community-based organizations. Even where operations resumed, capacity was significantly reduced and new barriers arose, such as fewer options for drop-in visits. The state of affairs forced healthcare providers to adjust their systems of triage, evaluation, and patient care to utilize more technology-oriented methods rather than in-person ones.<sup>2</sup> Although initially seen as a temporary stopgap to reduce staff exposure to patients with COVID-19, preserve personal protective equipment (PPE), and minimize the impact of patient surges on facilities, telehealth technologies have the potential to become an integrated component of sustainable, high-quality care delivery for HIV services.

# What is Telehealth? What is Telemedicine? Why do They Matter?

Telehealth services use electronic information and telecommunication technologies to support long-distance healthcare along with other health education, public health, and health administration.3

Asynchronous telehealth services involve utilizing technology where the patient and the provider are not accessing information at the same time and can be used to collect messages, images, and/or data at one point in time and be interpreted or responded to later, oftentimes through a patient portal. These services can be useful for activities like scheduling appointments or delivering laboratory results.

Telemedicine is a form of synchronous services. It consists of two-way, real-time interactive communications facilitating clinical care through telephones, text messages, or live audio-video interactions via a smartphone, tablet, or computer for both the healthcare worker and patient.<sup>5</sup>

Telehealth services are not one thing or one service but involve an evolving combination of services. Many practices start with asynchronous services, and as staff capacity and financial resources evolve, they expand into a broader mix of services, including, in many instances since the onset of the COVID-19 pandemic-full telemedicine services.

## Key Challenges Accompany the Implementation of Telehealth

Although providers and patients found a way to make telehealth work in an unprecedented public health crisis, it does not mean that either party wants to use these same responses over the long term. We can wear masks, practice social distancing, and avoid indoor dining, but few of us would choose to keep up all of these practices once there is a critical mass of vaccination in our communities and COVID-19 cases have declined substantially. This raises questions about what are the most pressing issues that must be addressed to move telehealth from a necessary emergency response to a long-term component of HIV care delivery models that improve engagement in care and satisfaction with care for both patients and providers. Following are three pressing issues to consider:

### Navigating overlapping and competing regulation of telehealth:

Telehealth is regulated both at the federal and state levels, and different programs such as Medicare, Medicaid, self-insured health plans (sometimes called ERISA plans) and fully insured health plans are subject to different requirements. In response to COVID-19, there was relaxed enforcement of several restrictions in order to facilitate an increased use of telehealth. For example, the Department of Health and Human Services (HHS) waived enforcement of the Health Insurance Portability and Accountability Act (HIPAA) to allow commonly used communications platforms like Zoom and Skype to be used for telemedicine visits even if they are not fully HIPAA compliant, and states relaxed restrictions on provider licensing, online prescribing and written consent. Many of these modifications, however, will expire when the public health emergency ends. Resolving issues such as how to prevent inappropriate disclosure of protected health information likely requires different responses for the long term than simply not enforcing HIPAA. Further, untangling overlapping regulations at the state and federal levels is complex and time-consuming and will require broad stakeholder engagement and significant policy dialogue.

## POTENTIAL BENEFITS OF TELEHEALTH SERVICES

Telehealth has the potential to overcome several persistent barriers to engagement in care. While not an exhaustive list, potential benefits include:

- Could overcome transportation barriers: In both rural and urban areas, lack of access to transportation can limit access to health care. Telehealth can reduce the necessity for inperson visits.
- Could give flexibility over when to access services: Telehealth can give people more options for when they engage in care. Communicating via a patient portal or scheduling services can be done at any time, even outside of clinic hours. It also can prevent people from needing to arrange childcare or take time off from work for a short provider visit.
- · Could reduce stigma: Telehealth can offer opportunities to improve access to LGBTQ+ health services or avoid microaggressions or other stigmatizing encounters that may happen at a clinic visit.
- Could increase privacy: For some people, accessing services from their own home is a way to avoid inadvertent disclosures, such as seeing friends in a waiting room or having conversations overheard.
- · Could strengthen engagement: Provider phone calls and text messages can increase engagement for some by demonstrating that providers are invested in their ongoing engagement in care.

# POTENTIAL DRAWBACKS OF TELEHEALTH SERVICES

Telehealth services can create new and different challenges for providers and clients alike if not appropriately addressed. Some of these challenges include:

- · Could increase inequities: The US has a large Digital Divide in which low-income people (often racial and ethnic minorities) and persons in non-urban areas have less access to technology. Further, differences in comfort with and preferences for technology can exacerbate inequities among groups.
- Could challenge staff and clinic capacity: Adopting telehealth services can be expensive and disruptive to a clinic's workflow and can increase staff burden.
- Could reduce access to supportive services: The medical visit may underpin access to a variety of other services. People who do not come into a clinic may have less access to food and nutrition services that require being in person to access.
- Could raise privacy concerns: Some people with shared living arrangements may have limited options for private communications with a provider. Using telehealth services could increase the risk of inadvertent disclosure.
- Could weaken the patient-provider relationship: The loss of regular in-person visits could weaken the bond and lead to reduced communication and less satisfactory interactions.

# MAO OF ALABAMA OFFERS A MODEL FOR RURAL ACCESS TO HIV SERVICES

Medical Advocacy and Outreach (MAO) of Alabama has been an early adopter of HIV telemedicine services. MAO launched its Alabama eHealth program in 2011 to better serve a low-income rural population spread across several counties.

#### MAO'S EHEALTH MODEL

eHealth is a telemedicine program that uses a secure video chat between a client and a provider at different locations. The client visits a nearby clinic, staffed by a nurse, who uses telemedicine equipment to conduct an exam. Images and sounds (i.e. heartbeats, breath sounds, images of ear canals, etc.) are transmitted to an MAO provider in realtime. eHealth currently operates out of 3 provider locations and 11 clinics, serving 28 counties.

#### EHEALTH OUTCOMES

In 2019, about 13% of MAO's clients with HIV received clinical care via telemedicine. The telemedicine retention rate roughly matched inperson clinic patients (80.5% vs. 80.3%), and viral suppression was slightly higher for telemedicine patients (90.2% vs. 88.4%).

## MAO'S 10 STEPS TO STARTING A TELEMEDICINE PROGRAM

- 1. Do your homework
- 2. Obtain funding
- 3. Convert to electronic medical records
- 4. Build and cultivate community partnerships
- 5. Obtain an adequate broadband connection
- 6. Hire and train staff
- 7. Obtain telemedicine equipment
- 8. Train staff at partner sites
- 9. Offer HIV medical care via telemedicine
- 10. Offer additional services via telemedicine

SOURCES: (1) Making Connections: A Guide to Starting a Rural HIV Care Telemedicine Program. AIDS United and Medical Advocacy and Outreach (MAO), October 2017. (2) Personal communication, Michael Murphree, CEO, MAO, July 2020.

Ensuring adequate and appropriate reimbursement for the varying range of telehealth services: Providers, rightfully, need to be assured adequate reimbursement to sustain their practices, but also to make needed investments in technology and practice transformation. This issue is complex, and providers and insurers have competing interests. Some states require parity of reimbursement with in-person services provided in a clinic. Payers and policymakers often assert, however, that actual costs for telemedicine services are lower than in-person services and wish to reimburse these services at lower costs.8 Further, do current reimbursement practices differentiate between high-intensity telehealth services and low-intensity services? Or do they account for provider time spent e-mailing patients that may now require much more time than in the past? Going forward, ensuring adequate reimbursement may be contentious and may require new or more innovative billing models than those that currently exist. HIV providers must be engaged in this dialogue both with healthcare programs and health plans.

Using the deployment of telehealth to increase equity for patients and clinical practices: The field of HIV care has been ahead of the country in recognizing inequities in access to care and achieving good outcomes. But the inequities within our communities remain large and include disparities for low-income people, people in rural areas and people of color. Further, the providers and practices serving these communities

can also be disproportionately under-resourced. This phenomenon, known as the Digital Divide, impacts providers as much as patients. For patients, some lack access to phones or have inadequate minutes or data on cell phone plans while others do not have reliable access to broadband internet. Services providers may also lack technical, financial and other resources to implement telehealth. To overcome these barriers, there will need to be increases in funding, training and innovative solutions. Using telehealth adoption to reduce inequities needs to be at the top of the agenda for HIV providers and the broader HIV community.

# **Policy Actions are Needed** to Support Telehealth Sustainability

Telehealth can shift from an emergency response to a more permanent component of HIV care delivery. While many policy actions are needed, it is important to keep in mind four critical goals:

- 1. Give patients more control. Patients should be able to decide where, when and how to access services. Providers also should be given more flexibility in responding to patients and more tools to overcome barriers to care, such as transportation barriers or the constraints of normal office hours. Doing so will increase privacy, reduce stigma and provide better support to providers when delivering telehealth services.
- 2. Promote equity. Policy attention is needed to ensure equitable access to smartphones, broadband access and other technology for all individuals and community-based organizations, but especially those of racial and ethnic minorities, LGBTQ+ individuals, persons in rural areas and immigrants.
- 3. Expand shared learning. Clinics and providers need new opportunities for shared learning to circulate best practices while also working to avoid common pitfalls. With greater experience with telehealth, model practices are emerging that can serve as a useful guide to providers across the country.
- 4. **Invest in research.** Continued research is needed to learn more about which services are most useful and desired by which patient populations; establish best practices around in-person visit frequency; develop differentiated care models that allocate more time and resources to subsets of people with greater barriers to care; and determine cost-effective approaches to telehealth services.

Introducing telehealth services into HIV prevention and care programs is an important opportunity to improve outcomes and increase client and provider satisfaction. For telehealth to be a viable and sustainable option and become an integral part of HIV service delivery, it will require upfront investments in technology, an understanding of the regulatory environment and adaptations to the service and billing models. Although the COVID-19 pandemic has allowed Congress to remove some of the pre-existing regulatory barriers to using telehealth services, inequities, such as the persisting Digital Divide, must be addressed now, as well as after the COVID-19 emergency is over. Doing so can help to improve engagement in care and achieve positive health outcomes. HIV

# **Self-collected Lab Testing** Is an Important Innovation

IF TELEHEALTH AND THE MOVE OUT OF THE CLINIC for the delivery of critical services is an important innovation that can improve outcomes, then the ability to enable individuals to self-collect samples for HIV testing, sexually transmitted infections (STI) screenings and other routine screenings can be a critical advancement. The ability to conduct home self-collection and have these services covered by insurance has the potential to improve access to care and contribute to the sustained use of telehealth services in clinical practices.

Do individuals want the option of at-home self-collection? Yes. As one example, early studies have affirmed support for pre-exposure prophylaxis (PrEP) treatment as well as PrEP@Home testing, if this service was available.(a)

#### What are the potential advantages with home self-collection?

- 1. There is no need to travel to a clinic or schedule an appointment.
- 2. Collecting specimens at home offers privacy and helps to reduce stigma-related avoidance of clinical settings.
- 3. It provides an option for specimen collection for those individuals who would otherwise not have access to a proximate, welcoming clinic or provider that offers PrEP services.(b)

What, if any, potential challenges regarding home self-collection have arisen so far? Although home-based sample collection has proven to be safe and has been held to the same accuracy standards as traditional testing, labs analyzing samples collected at home are also being held to stringent standards by the Food and Drug Administration (FDA), thus limiting the willingness of some insurers to cover these tests.(c)

Self-collection lab testing is likely to grow in importance. With consumer demand increasing, more labs ready to accept and analyze these tests and more insurers willing to reimburse for these costs as an alternative to clinic-based testing, this new flexible option for patients can increase PrEP adherence and expand the reach of HIV testing.

SOURCES: (a) Aaron J Siegler, et al., Developing and Assessing the Feasibility of a Home-based Preexposure Prophylaxis Monitoring and Support Program, 68 Clin Infect Dis. 501-04 (Jan. 18, 2019), doi: 10.1093/cid/ciy529. (b) At-home Self-Collection Lab Testing for Sexually Transmitted Infections, National Coalition of STD Directors, www. ncsddc.org/wp-content/uploads/2020/06/NCSD-TA-Brief-Home-STI-Testing-Care-FAQ-v5.20.2020.pdf (last the content of the contenupdated May 20, 2020). (c) Id.



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Integrating Telehealth Into HIV Services Systems Can Help To Sustain Improved Outcomes, which is available at https://oneill.law.georgetown.edu/projects/ national-hiv-aids-initiative/hiv-publications/.

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N NEW YEAR'S DAY, Massachusetts Governor Charlie Baker signed into law a healthcare reform bill that is a metaphor for the state of telehealth. The American Telemedicine Association (ATA) has plenty to be pleased with in the final legislation. The law requires that payers doing business in the state, including Medicaid, reimburse for behavioral telehealth visits the same way they cover in-person care and mandates rate parity for two years for primary and chronic illness management.

Ten days later, New York Governor Andrew M. Cuomo announced legislation to expand and improve access to telehealth. According to a statement issued by Governor Cuomo's office, this legislation includes "comprehensive telehealth reform to help New Yorkers take advantage of telehealth tools and address key issues such as adjusting reimbursement incentives to encourage telehealth, eliminating outdated regulatory prohibitions on the delivery of telehealth, removing outdated location requirements, addressing technical unease among both patients and providers through training programs, and establishing other programs to incentivize innovative uses of telehealth."

Texas Governor Greg Abbott recently outlined his healthcare priorities for 2021, recognizing telehealth as an important tool to extend quality care, and also made the expansion of broadband access an emergency item this session.

Nearly 40 states currently have pending telehealth legislation, which will determine whether or not patients will continue to have access to essential telehealth services after the public health as possible this year to ensure telehealth remains available to all, wherever and whenever it is needed.

Likewise, on the federal level, President Biden has already indicated support for telehealth and is focused on expanding access to virtual care services for underserved populations to address health inequities. For example, Biden's administration will likely support the idea that broadband infrastructure alone will not be enough for parity in digital health. But we also anticipate that there will be some things that remain in question, like payment parity.

The ATA recently expressed strong support of the Protecting Access to Post-COVID-19 Telehealth Act of 2021, which was reintroduced by telehealth champions on the Congressional Telehealth Caucus. This bipartisan bill would permanently ensure access to telehealth after the COVID-19 public health emergency by eliminating restrictions on telehealth in Medicare beneficiaries and requiring a study on its use during the pandemic. This bipartisan bill, first introduced in July 2020, is an important step towards breaking down discriminatory geographic restrictions and includes four major and vital provisions to ensure all Medicare beneficiaries continue to have access to important telehealth services:

- Eliminating most geographic and originating site restrictions on the use of telehealth and establishing the patient's home as an eligible distant site so patients can receive telehealth care at home and doctors can still be reimbursed.
- Preventing a sudden loss of telehealth services by authorizing the Centers for Medicare and Medicaid Service (CMS) to continue reimbursement for telehealth for 90 days beyond the end of the public health emergency.
- Making permanent the disaster waiver authority, enabling Health and Human Services (HHS) to expand telehealth during all future emergencies and disasters.
- Requiring a study on the use of telehealth during COVID, including its costs, uptake rates, measurable health outcomes, and racial and geographic disparities.

Healthcare providers and patients alike are becoming comfortable with telehealth and voicing their desire to continue using virtual care delivery. For example, a study published in the American Journal of Managed Care looked at how people living with HIV (PWH) felt about using telehealth for HIV care instead of face-to-face clinic visits. Of the 371 participants, 57 percent (n=211) reported a greater likelihood of using telehealth versus one-onone in-person care if the former were offered. Nearly 40 percent (n=137) reported they would use telehealth more frequently, possibly always, instead of an in-person visit. The authors noted a "positive attitude toward the use of telehealth for HIV care among PWH."

With seemingly positive movement on both the state and federal level, and patient and provider satisfaction with telehealth, this all seems like good news, right? It is, mostly, but sets up some potential administrative challenges. Providers make care decisions independent of insurance status. Ideally, that leads to more egalitarian care. But we also have concerns about direct billing patients for services that insurance doesn't uniformly cover. Take my practice as an example. I think the new Massachusetts law will guarantee I can bill insurance for caring for an acne patient but not a patient with a new changing mole. We are not set up to parse patients in this way.

This is just one example of the betwixt and

between state we find ourselves in concerning telehealth in this 'new normal.' There is no doubt we are leaps and bounds ahead of where we were at the beginning of last year, but there is much critical work to be done in this next phase. Much of this revolves around the change in our healthcare delivery apparatus from a one channel (everything in the office) system to a two-channel or hybrid environment where telehealth co-exists with in-person care.

Here are some priorities to consider:

We need to create new roles. In one-channel healthcare delivery, when a patient requests an appointment with a provider, the provider's office simply needs to find a time in his or her schedule for the patient to come to the office. The options offered by a hybrid system require different decision making. Is the patient appropriate for telehealth? Should the choice be one of convenience for the patient or guided by clinical criteria? I would argue strongly for the latter (see the use case discussion below). If so, the person scheduling the appointment needs either some clinical training and sound judgment skills or a very well thought out flow diagram to aid in decision making.

A second example is in my field of dermatology, where we ask patients to electronically submit images of their skin for review before our telehealth visits (The resolution of even HD video is not good enough for dermatologic diagnosis.). We currently employ nurses to ensure that the images are of diagnostic quality. I would argue that a trained, non-clinical person could do this.

We need to define clinical use cases for telehealth. I see three broad categories-examples where telehealth is ideal (e.g., behavioral health); examples where in-person care is required (e.g., procedural work) and examples that could fit in either category depending on other variables (e.g., if the patient lives very far away, telehealth becomes more attractive). Which scenarios fit into these categories will vary by clinical specialty, possibly by practice, and maybe even at the individual practitioner level. I had hoped that each of the specialty societies would intuitively begin to work on this, but I have seen only spotty evidence of any effort.

We need to rethink how we use our brick-and-mortar facilities. I do my telehealth sessions every Tuesday afternoon from the comfort of my home office. In doing so, I consume much less institutional overhead than I do when I go to the office to see patients on Wednesdays. Most provider organizations are now doing 15 percent to 25 percent of their ambulatory activity via telehealth. The legislation noted above is an example of a trend that will likely sustain this mix. We need to rethink how we use our physical clinical space and how we plan for

#### We need to tackle the disparities issue.

new facilities.

Beyond advocating for universal broadband and continued reimbursement for audio-only telehealth (The latter appears to be in peril.), we need an industry-wide approach to this glaring problem.

While the initial lockdown in early March of last year was the stimulus that catapulted telehealth into both providers' and patients' everyday lexicon, it gave people a sense that we could render all care that way. That simplistic view has become a disadvantage as we get into the groove of two-channel delivery. Our best estimate is that telehealth usage will calibrate to around 15 percent to 20 percent of care delivery, striking an appropriate balance of in-person and virtual care. Now it is time to make telehealth a legitimate care delivery channel for the long haul by tackling policy, reimbursement, and implementation challenges in the new year. HIV



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# TELEHEALTH



# TALES

BY: Nupur Gupta, DO, MPH, and Deborah McMahon, MD

# from a University-Based Ryan White Clinic

LTHOUGH SOME FORM OF TELEHEALTH HAS BEEN AROUND SINCE THE EARLY 20TH CENTURY, it hasn't been quite brought to the forefront of medicine until the COVID-19 pandemic. Previously, telephones and radios were used to share medical information from rural areas and the National Aeronautics and Space Administration (NASA) used remote monitoring to support their deployed astronauts. However, telehealth had been initially a slow-growing model likely due to regulations, costs, and lack of demand. But, it has now grown exponentially given how our world has been transformed with the internet and has been employed in all aspects of medical care. Here, we describe the various models and settings where telehealth has so far been utilized in human immunodeficiency virus (HIV) and co-morbidities care delivery as well as describe our own experience at a Ryan White Clinic in Pittsburgh, Pa. in Allegheny County.

Often, the term "telemedicine" is confused with "telehealth," but they are not interchangeable. According to the Health Resources Services Administration (HRSA), telehealth refers broadly to electronic and telecommunications technologies and services used to provide both non-clinical care and clinical services at a distance.<sup>2</sup> This includes patient and provider health education, health administration, and telemedicine. Technologies used within telehealth include videoconferencing, streaming media, and wireless communications. Conversely, telemedicine refers to the use of technology to deliver clinical care at a distance. Thus, a healthcare provider at one location uses a telecommunications infrastructure to deliver care to a patient at a distant site.<sup>2</sup> Telemedicine includes video visits, telephone visits, and electronic consults. Furthermore, telemedicine can be divided into two groups: synchronous and asynchronous. Synchronous telemedicine refers to real-time patient and provider interaction using encrypted videoconferencing which is the most similar to traditional clinic or hospital encounters. Whereas, asynchronous telemedicine consists of consultations based on a review of the patient's clinical history and data to formulate an opinion and plan without a live interaction. Lastly, telehealth also includes mobile health, or mHealth, which incorporates wearable technology with integrated software to perform medication monitoring, chronic disease management, and monitoring disease parameters. Suffice it to say, all of the above examples of telehealth have been

used and studied in HIV care delivery.

Telehealth can be beneficial in resource-limited situations and allow delivery of enhanced care. Young et al. demonstrated that by using telemedicine, both audio and video interface, to provide HIV subspecialty care in a large prison system, the inmates in this group had greater virologic suppression, lower community viral load, better adherence, and higher mean CD4 count compared to the on-site management group. 4 This study showed that not only subspecialty care, but also telemedicine contributed to improved patient outcomes. Leon et al demonstrated in an open-label, prospective, randomized trial that telemedicine could be used to monitor stable, chronically infected HIV patients. 5 Although, patient outcomes did not significantly vary between the two groups of telemedicine vs in-person visits, the virtual model was found to be cost-effective, feasible, and a safe alternative. Disease monitoring and text message reminders have been employed in low-income countries and have found greater adherence and fewer greater than 48-hour medication lapses. 6 Telemedicine has also been utilized in HIV co-morbidities. Talal et al. used telemedicine to treat hepatitis C infection in those with opioid use disorder and HIV co-infection thus integrating subspecialist care and treatment.7 Overall, there have been multiple models that have been utilized to deliver HIV care via telehealth. The data on clinical and patient outcomes varies, but most studies show increased access to subspecialty care and a cost-effective alternative. So, how has our clinic harnessed

Figure 1: Telehealth Considerations **Etiquette** Digital Divide **Triage**  Staying professional and on task Aging population with HIV . Who is right for this visit? Incorporating learners Trust and Privacy Concerns Limited physical exam Missing the human touch • Non-English speaking clients . Delay in labs and preventive care **Hidden Costs** Time Management • EMR, software and • On time patients hardware "Rooming" the patient Telemed centers Technical difficulties Trained telepresenters **Physician licensing**  Call coverage **Care Delivery** Reimbursement Provider Training Different payer rules Contracts

the power of telehealth to deliver care to our patients?

 Delayed payments due to changing processes

Loss of hospital clinic fee

Our Ryan White clinic is located at the University of Pittsburgh Medical Center (UPMC) and has been serving the southwestern region of Pennsylvania including some clients from West Virginia and Ohio since 1994. We have approximately 1900 clients with a median age of 52. Three quarter of the clients are male and 45 percent identify as African-American. Our care delivery model is comprehensive and in addition to HIV and primary care includes: behavioral health, nutrition, anal dysplasia, pain clinic, women's health, pre-exposure prophylaxis (PrEP), sexually transmitted infection (STI) testing and treatment, pharmacy and case manager support, and clinical and basic research. Historically, Medicare only covered very specific telehealth services that were delivered to patients living in a defined geography, e.g., rural health provider shortage area (HPSA).

In 2019, Medicare began to cover services such as brief check-in visits, electronic consults, and remote monitoring for patients living outside of HPSA. But, this was challenging to operationalize due to complicated rules. Thus, our clinic had stuck to a traditional brick and mortar style of delivering care. However, in early 2019, our UPMC health plan began to encourage all providers to conduct telemedicine visits which were being reimbursed at in-person rates. These visits demonstrated good outcomes and were deployed to include other health plans. With the system's support behind us, our clinic was able to implement two different models of telemedicine several months before the first case of COVID-19.

The first model uses a smartphone device to conduct a Health Insurance Portability and Accountability Act (HIPAA) compliant audio/video visit between the

provider (located in Pittsburgh) and the patient (located at home). All the documentation and orders are completed electronically. This model is similar to what most health systems and clinics have deployed since the start of the pandemic in order to be able to complete visits safely. However, given that all our providers were trained on and already using video visits, it was remarkably easy to switch to primarily telemedicine when the first confirmed case of COVID-19 was diagnosed in Allegheny County in March 2020. By then, Medicare had also made several changes to permit great access to virtual health for patients regardless of geography and modality.

Intersection of private entity

and non-profit

• Whose patients? Lab access

The second model takes the HIV care delivery model directly to the patient's rural community. Patients living in rural HPSA face multiple challenges including lack of access to subspecialty care, transportation issues, and stigma. The patient is seen at a clinical location which is a dedicated telemedicine medical practice. The physician (located in Pittsburgh) uses audio/video interface to conduct the visit, but the patient also has a trained tele-presenter (registered nurse) in the exam room. This model allows us to conduct a history and a head-to-toe physical exam with the tele-presenter's assistance and Bluetooth enabled equipment (i.e. stethoscope, otoscope, ophthalmoscope) via HIPAA compliant software. All the documentation and orders are completed electronically. Although the patient is never seen in-person in Pittsburgh, they have full access to the standing clinic and its services.

We currently have two telemedicine clinics in rural Pennsylvania, and although they temporarily closed at the onset of the pandemic for the safety of patients and staff, both reopened quickly. Amongst the nine patients that have been seen via this model in the past year, six

are now virally suppressed (all were previously detectable), and six have had at least two visits or more. Three of the patients were updated to newer HIV medications due to previously unidentified side effects and drug-drug interactions. All patients stated either transportation or lack of HIV care in their community as the reason for choosing this model. Although the cohort is small, it is already demonstrating promising results.

There are several benefits afforded to both the patient and the provider with either model. Both improve access for those restricted via geography or disabilities. Patients have reduced or no transportation costs (driving, parking, public transportation, etc.) which removes a huge barrier to retention in care. Patients served by the second model get linked to HIV subspecialists which leads to increased virologic suppression, reduction in HIV-related comorbidity and mortality and transmission to others. By bringing the care to their local area, patients in rural HPSA are less stigmatized. These models are especially helpful for certain types of visits: check-ins, medication monitoring, and counseling. The second model is even more beneficial when there are exam findings involved. Both the patient and provider have a choice in selecting telemedicine vs in-person visit with the first model thus providing some autonomy. This leads to increased patient and provider satisfaction. Providers also experience less burnout due to flexible schedules and ability to work from home.

Despite the wide variety of benefits, telehealth does have several limitations and many considerations (Figure 1). There exists a digital divide especially amongst the aging HIV population and although instructions



and software walk-throughs can be conducted, a large part of the visit can be spent overcoming the technological issues. The technology isn't perfect and privacy concerns still persist along with challenges in incorporating telehealth for non-English speaking clients. There are many hidden costs including licensure, software, hardware, staffing, training, and call coverage which can add up without the backing of a large health system. Triaging patients i.e. "Who is right for this visit?" is an acquired skill. Clients with unstable housing may not have a safe way to conduct a video visit and rely on telephone visits. New patients should ideally be seen in-person or at a telemedicine clinic for the first visit to allow a proper introduction. Home video visits lead to limited physical exam and delay in labs and preventative care. Lastly, despite all the advances, telemedicine cannot overcome the human touch as established in a face to face visit.

Although telehealth has been practiced for years, it really rose to prominence due to the ongoing pandemic. Our models already show favorable outcomes in terms of promoting retention in care, improved value by reducing costs and increasing quality of care, and expanding the clinic's reach. Current

and future plans include implementation of video visits with behavioral health and nutrition, expansion of the telemedicine clinical locations to other rural areas, and continuing to assess the effectiveness of telehealth care delivery by monitoring viral load suppression and retention in care. These plans are also dependent upon the ever-changing landscape of billing and reimbursement rules which may evolve further as the pandemic rages. Regardless, telehealth is here to stav for the foreseeable future thus we all have to adapt. HIV



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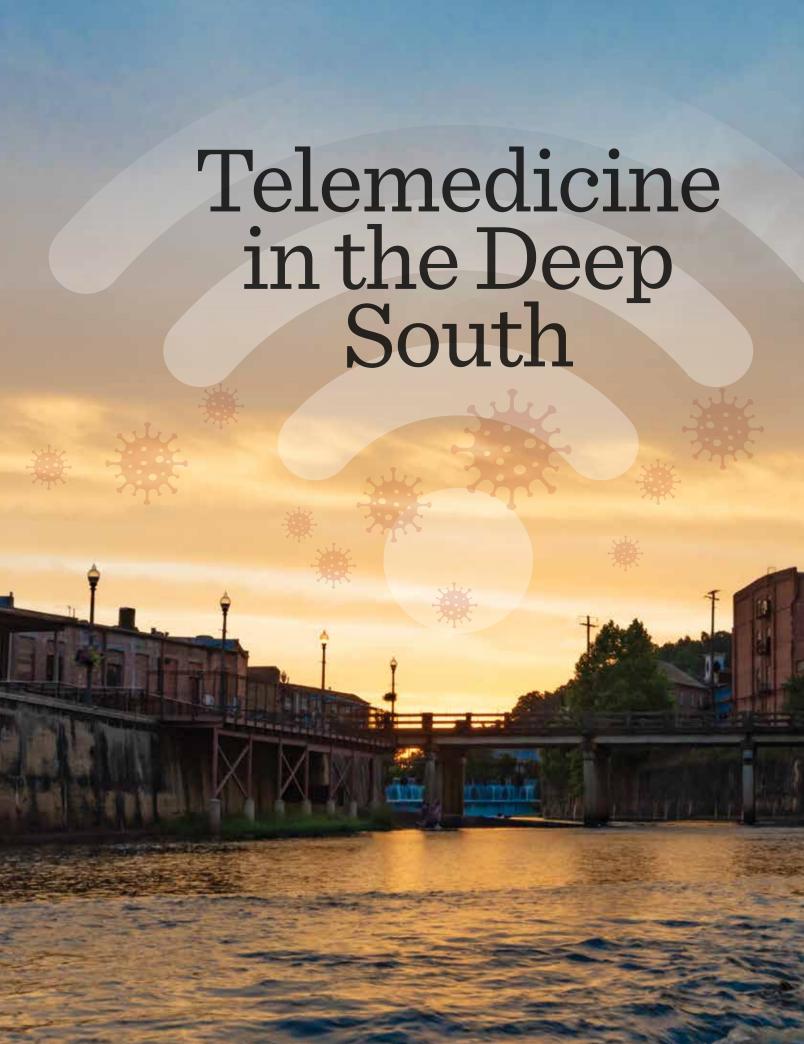


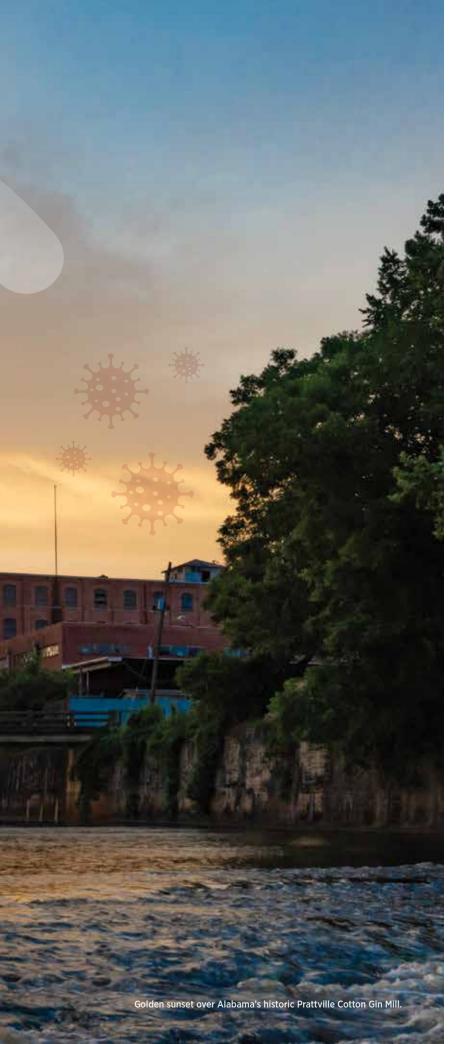
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# **Overcoming** the Challenges of COVID-19

BY: Laurie Dill, MD, AAHIVS, Cordelia Stearns, MD, AAHIVS and Elana Parker Merriweather, Ed.S., NCC, BC-TMH

**EDICAL ADVOCACY AND OUTREACH** (MAO) has evolved to be the largest organization of its kind in the state of Alabama with a rich history of marrying southern hospitality with compassionate, comprehensive HIV services. What started as a grassroots effort by volunteers in our founder's home more than 30 years ago, handing out food boxes and running an information hotline out of a garage, is now, an organization pushing the envelope of rural healthcare while continuing to further expand services for south Alabama residents. MAO's direct medical and behavioral care services and social supports programs, including housing, transportation, food, and payment assistance, are tailored to individuals infected and/or affected by potentially life-threatening illnesses, with its specialty being HIV treatment and prevention. Community education and outreach activities, focusing on risk-reduction and prevention of HIV, hepatitis C, sexually transmitted infections (STI) and more, are routinely delivered outside MAO's walls in a variety of formats and settings. Today, the MAO umbrella includes four fullservice locations in Alabama (Atmore, Dothan, Montgomery, and Selma) and eleven satellite clinics that comprise MAO's Alabama e-Health Network. More than 2,000 clients spanning more than 28 counties and 18,675 square miles rely on MAO today for stigma-free, comprehensive care.

Equity in telemedicine in the South, particularly in rural areas, is not there yet. While in some ways telemedicine takes away barriers like transportation, time away from work, needing to go to a clinic where one might see a nosy neighbor and get outed, plenty of our patients do not have minutes or data plans on their phones or devices capable of doing video calls, and broadband access remains a critical issue.

Adapting to the challenges of COVID-19 has required flexibility, innovation, dedication, and grit from our organization and clinic team members. From the beginning, it was clear that two absolute priorities had to be met: we had to do everything we could to keep patients and team members safe, while simultaneously continuing to provide the highest quality care to our patients living with and at risk for HIV. MAO was fortunate to have a robust telemedicine system in place, and a dedicated team of individuals with vast experience realizing innovative solutions to the challenges and obstacles time threw in their direction on MAO's journey to its current holistic care model. This meant, from the very beginning of the pandemic, we were able to see routine and follow-up patients safely via telemedicine, with both patient and provider at home, while seeing new patients and those with more acute needs in the clinic. This kept the volume of patients in the clinic area at the same time much lower. Initially, we had the majority of our team working in rotation from home on a day-to-day basis. However, once we identified solutions to the problem of consistently having the PPE we needed, had a clearer sense of how COVID-19 was spreading, and how to keep the people in our environment safe, most team members were able to return to their in person day-today roles while continuing to provide routine follow-up visits to patients via telemedicine. Of course, we were still adhering strictly to public safety guidelines, checking temperatures, etc.; we did not initially have access to COVID-19 rapid tests.

Today, we rapid test all staff for COVID-19 weekly. All patients and visitors with access to the building for more than fifteen minutes are also tested. With mandatory masking, physical distancing, escorting patients directly to exam rooms versus allowing them to cluster in waiting rooms, robust symptom screens. and contact tracing, we think we are safer in

the clinic buildings at MAO than at a supermarket or a coffee shop.

We did see an initial increase in patients returning to care, as did many HIV clinics. There were certainly patients motivated to resume taking medications due to fears about COVID. Thankfully, we have been able to retain those patients in care and help them become virally suppressed this past year. Overall, our patients have really appreciated the ability to see us via telemedicine when they need to while still having us available in the office for emergencies. Many patients who previously felt hesitant about telemedicine have embraced the technology, the convenience it offers, and, for many, the cost-savings associated with travel.

Our staff and patient population have been hit hard with COVID-19. While we are proud to say, thus far, we have had no transmission of COVID-19 in our clinic facilities as we can tell due to our safety precautions and contact tracing, we have had members of our community get sick. Most tragically, one of our nurse practitioners, Dr. Angela Lowery, died from COVID-19-related factors in the fall of 2020, only months after her sister had also died from COVID-19. Our staff and her patients continue to grieve, and, of course, it's challenging to fully process this loss as we continue the go, go, go of pandemic-shrouded clinic life. Helping our patients and colleagues through their grief over screens, avoiding hugs or hand-holding, wiping tears with masks on—it has all been a struggle. As a doctor, the Medical Director, and as a parent, I think everyone who works for MAO does so because of a deep investment in caring for our patients and people in general. Showing that care with masks on and physically social distancing is just different.

Equity in telemedicine in the South, particularly in rural areas, is not there yet. While in some ways telemedicine takes away barriers like transportation, time away from work, needing to go to a clinic where one might see a nosy neighbor and get outed, plenty of our patients do not have minutes or data plans on their phones or devices capable of doing video calls, and broadband access remains a critical issue. We have been able to fill in gaps with phone visits for many patients for whom video visits are not possible or add barriers. While this has taken some getting used to, I think we're all getting more comfortable with this care from a distance approach for stable follow up visits. With that said, we are all in agreement that even the most stable patient needs an in-person visit annually. Our patients with the most barriers to care including through telemedicine are the ones whose communities have also been devastated by COVID-19. Telemedicine can help expand access, but fighting against the systemic racism, poverty, and injustice that devastate our patients' health requires multiple tools and resources. Right now, we persevere with whatever tools we can get our gloved and Purelled ® hands on.

#### Tele-Behavioral Health Services

The use of tele-behavioral health options during the COVID-19 pandemic has been met with significant opportunities and challenges. Within MAO's behavioral health department, tele-behavioral health is defined as remote delivery of behavioral health services through the utilization of a laptop, tablet or mobile telephone device. Some of our most noteworthy highlights of 2020 included the provision of both individual counseling and support group services with patients and MAO team members. Our behavioral health therapists provided psychotherapy, consultations, screenings, and assessments for Ryan White patients.

The following support groups were also launched for agency constituents during the last six months: (1) Anxiety/Stress Management Support Group; (2) Coping with Grief and Loss; (3) Civic Health—Pre and Post-Election Anxiety; and, (4) Sisters Supporting Sisters (a women's only group). Through the use of tele-behavioral health options, we were able to host our Annual Recovery Month Celebration virtually. Alongside many opportunities, there were significant challenges which included: (1) patients' unfamiliarity with downloading features on their preferred device; (2) lack of familiarity with the agency's software platform; (3) varied levels of comfort and discomfort with the connectivity process; and, (4) limited capacity on behalf of the provider and patient to collaboratively troubleshoot technology problems. One of our most significant advancements during the last year was the availability of support staff to assist with developing tele-behavioral health procedures, troubleshooting connectivity challenges with both the provider and patient, and pre-assessing patients for appropriateness and "fit" for tele-behavioral health services. A noteworthy observation was that patients who received tele-behavioral health services expressed very minimal concerns about privacy and confidentiality issues. Most patients' expressed frustration and anxiety regarding their limited ability to connect to their providers when needed.

# Moving Forward during "Twindemics"

The COVID-19 pandemic has laid bare what we in the HIV world in the rural South already knew: the systemic issues of inequality and racism make our patients more vulnerable to health threats including HIV and COVID-19. We continue to gain inspiration from our courageous and resilient patients. The COVID-19 pandemic has brought tremendous challenges. It has also brought flexibility for innovative care delivery. The pivot to expanded telemedicine services will continue. We say in the Deep South that we have "expertise in barriers to care," matched by a willingness to try innovative ways around those barriers. One next step, as part of MAO's AL ePrEP project funded by HRSA,\* will be piloting home pre-exposure prophylaxis (PrEP) test kits, so that home-based labs combined with virtual PrEP appointments and MAO's mail-order pharmacy services are an option to our at-risk community members who already struggle with geographic and pandemic isolation issues. We are moving forward with plans to "End the HIV Epidemic" in the midst of the COVID-19 pandemic, while trying to keep patients and staff safe and provide excellent care.

To learn more about Medical Advocacy and Outreach (MAO), please visit www.maoi.org or call (800) 510-4704. You can also follow MAO on Facebook and Twitter (@MAOofAlabama) HIV

The AL ePrEP project is supported by the Federal Office of Rural Health Policy (FORHP), Health resources and Services Administration (HRSA), U.S. Department of Health and Human Services (HHS) under cooperative agreement award no. U66RH31459. The information, conclusions, and opinions expressed are those of the authors and no endorsement by FORHP, HRSA, or HHS is intended or should be inferred.



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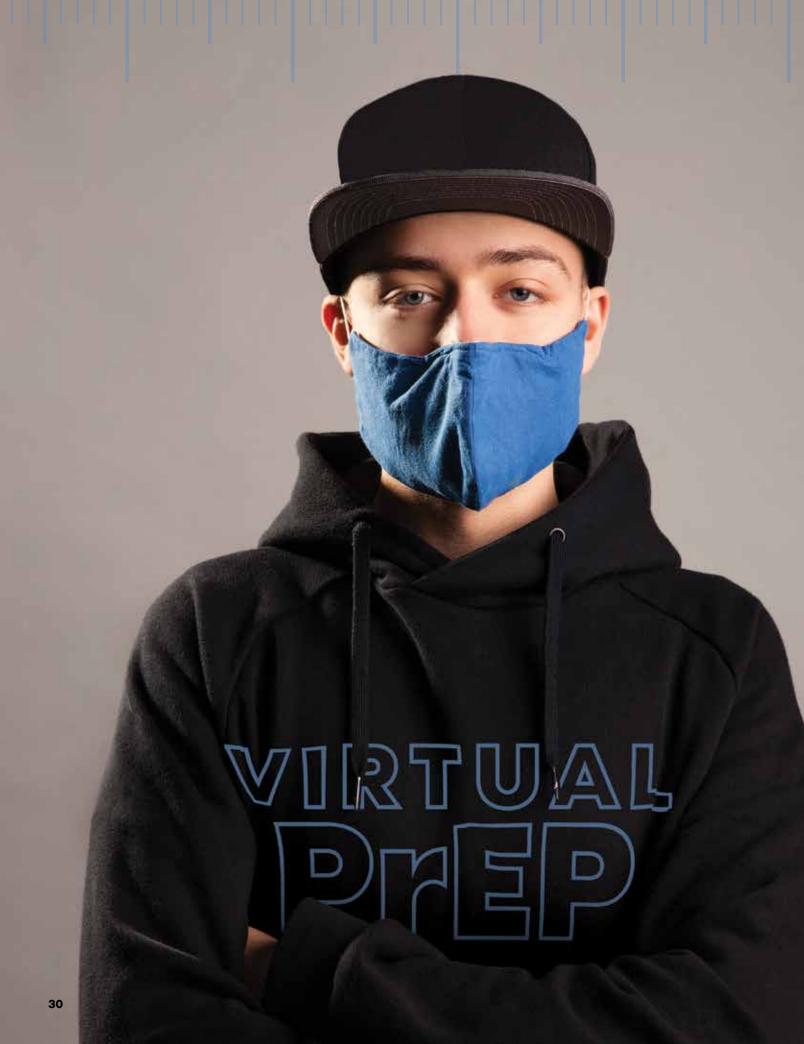
DR. CORDELIA STEARNS is a graduate of Bryn Mawr College and the Perelman School of Medicine at the University of Pennsylvania. She completed internship and residency at the University of California, San Francisco, with specialization in Health Equity and

Advocacy at San Francisco General Hospital. She is board certified in Internal Medicine and certified as an HIV Specialist by the American Academy of HIV Medicine. She joined Medical Advocacy and Outreach in 2018, and became Medical Director in January 2020, just in time for a worldwide pandemic. She is passionate about caring for underserved patients and reducing health disparities, and believes that equitable health care is crucial for social justice.



**ELANA PARKER MERRIWEATHER** currently serves in the capacity of Director of Behavioral Health for Medical Advocacy and Outreach/Copeland Care Clinic. She is responsible for the integration of behavioral health services including substance abuse and mental health

services into Ryan White Care settings. Elana works to develop the administrative, programmatic and clinical infrastructure for the integration of comprehensive behavioral health services to patients with co-occurring disorders. She has maintained an ongoing commitment of service to minority and underserved communities that have been impacted by social and health disparities. Elana is a graduate of Alabama State University with an advanced Education Specialist Degree in Clinical Mental Health Counseling. Elana has a fifteen year background in state government through her work with the Alabama Department of Public Health in the Center for Emergency Preparedness, Office of Women's Health, Office of Minority Health, Cancer Division, and HIV/AIDS Division. Elana was also appointed as the State Reentry Coordinator for a 2 year stint with the Alabama Department of Corrections. Elana is also a National Certified Counselor and Board Certified - TeleMental Health Provider through the National Board of Certified Counselors - Center for Credentialing and Education.



# **How to Scale PrEP for** Adolescents and **Young Adults**

By: Carrie Chan, CPNP, Geoffrey Hart-Cooper, MD and Megen Vo, MD

HE STATISTICS REGARDING HIV INFECTION RATES among adolescents and young adults are daunting:

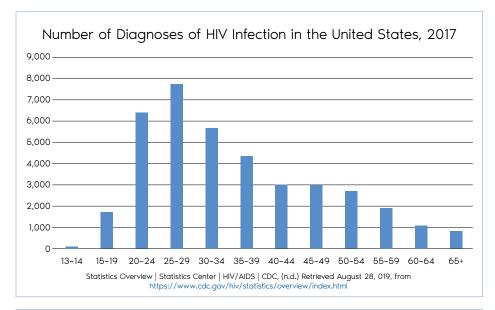
- About one in five new HIV diagnoses are among adolescents and young adults ages 13-24.1
- Not surprisingly, in many states including California, youth ages 13–24 have the greatest unmet pre-exposure prophylaxis (PrEP) needs compared with any other age group.<sup>2</sup>

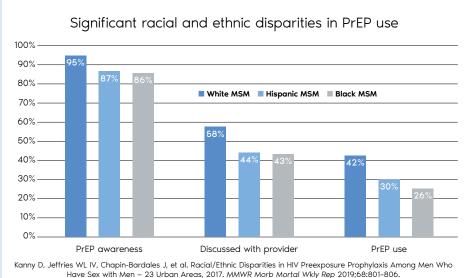
While pre-exposure prophylaxis (PrEP) was first approved for HIV prevention in 2012 by the U.S. Food and Drug Administration (FDA), its use for adolescents was approved in 2018. PrEP has been shown to reduce the risk of acquiring HIV from sex by about 99 percent if taken daily; however, uptake and adherence can be particularly challenging for adolescents and young adults.3,4

In addition, racial and ethnic healthcare disparities are discouragingly apparent in PrEP awareness and use. We see significant and concerning disparities in HIV diagnoses, PrEP awareness, discussing PrEP with a provider and PrEP use.<sup>5</sup>

# Create a program that appeals to adolescents and young adults

At Stanford Children's Health, we developed the Stanford Medicine Virtual PrEP Program for Adolescents and Young Adults to provide youth-focused PrEP care. Our pediatric and adolescent providers meet with patients from the comfort of their homes (or wherever they choose) through free, confidential and secure virtual visits. We are supported by a team of medical and physician assistant students who provide PrEP support as our PrEP Navigator team. These "PrEP Navs" are essential in frequently checking in with patients and navigating payment assistance programs.





Our experience caring for teens and young adults has taught us the importance of three concepts that must be in place to have successful interactions on any subject, but especially with sexual health:

- 1. **Trust.** The basic tenet of working with adolescents is establishing trust first; action and implementation will follow. But this takes time and patience. Repeat follow-up visits with the same provider can foster this.
- 2. Confidentiality. Adolescents and young adults won't trust providers unless they know for certain that the information they share about themselves will not be shared with anyone else.
- 3. Access. Texting/messaging is generally preferred. Our patients prefer to send us a quick secure message through our online portal that we can respond to quickly.

## Telehealth addresses need for trust and confidentiality

We turned to telehealth and virtual visits as a solution to meeting the needs of our adolescent patient population. Our efforts started before the SARS-CoV-2 pandemic, and though virtual visits were increasing in popularity, they hadn't become nearly as robust as they are now. We envisioned utilizing a digital health platform to provide the confidentiality that the program required.

Using a secure telehealth system, youth from anywhere in California can now enroll in the Stanford Medicine Virtual PrEP Program. Once they fill out an online form, they are connected with a pediatric or adolescent care provider specifically trained to provide sexual health counseling, recommended lab testing, and adherence support.

Virtual visits allow our patients to connect with us from anywhere—which has included the beach, the middle of a shift at a fast food restaurant, a school bathroom and a parked car. Of course home is also an option. but many of our patients prefer to keep their sexual health private. Virtual visits enable us to reach young people anywhere in the state, from big cities with many healthcare providers to rural areas where healthcare is less available or more difficult to access.

Most samples for STI screening including HIV are collected at the patient's local lab. Extragenital sexually transmitted infection (STI) collection materials are not often stocked by labs, so we mail these to an address of the patient's choosing, such as a college dormitory or a friend's house. Between visits, we use secure messaging through our online portal.

#### Establish an infrastructure

One of the first steps we took to establish our program was to create an infrastructure that would facilitate confidential enrollment both within and outside of our health system. All visits and labs are flagged internally as confidential. We also created a digital referral system so that other outside providers could easily send patients to our team.

Training pediatricians in how to provide PrEP is a priority. Due to how recently PrEP was approved for adolescents, many pediatric providers have not been trained to prescribe it. One additional barrier for pediatric

providers is that they are not as familiar with HIV treatment and prevention protocols as providers who care for adults. With a paucity of HIV-infected children in the U.S., there is no HIV-focused primary care in pediatrics.

We wanted to make this training relevant and timely through offering our providers just-in-time training. Unlike with adult patients, HIV testing is usually performed in a risk-based fashion for adolescents and young adults. Although it is worth noting that the CDC recommend routine HIV screening starting at age 13 and the American Academy of Pediatrics at age 16. If a pediatric provider orders an HIV test, it's generally because the patient has demonstrated an increased risk of HIV infection. This is largely because most adolescents and young adults do not get routine labs, in contrast with adult patients. Therefore, we modified our HIV test order in our electronic health record (EHR) to nudge providers to consider PrEP in these patients. Every HIV test contains a hard stop: "Would this patient benefit from PrEP (a safe, daily pill to reduce risk of HIV by ~99 percent)?" If a provider indicates that the patient would or he or she isn't sure, the provider is given an option to select a standardized order set to efficiently order the necessary labs and access patient educational materials, a link to provider educational materials (accessed at the provider's convenience), and/or a referral to our Virtual PrEP Program.

#### Outreach

Provider and youth outreach has been the driver to reaching patients, whether within or outside of the Stanford Children's Health system. Our goal is to reach providers and patients throughout the state of California.

To do this, we established several levels of outreach and communications:

■ Webinars to teach pediatric providers and

- pharmacists about PrEP
- Presenting at local provider meetings and grand rounds
- A PrEP website where teens and their providers can learn about and sign up for the program (prep.stanfordchildrens.org)
- A social media campaign targeting young people ages 13-25 in California, using Facebook and Instagram
- Search and display ads on Google
- A media relations campaign targeting pediatric providers

## Recommendations for scaling PrEP for adolescents and young adults

If providers are interested in starting a virtual PrEP program, we have a few suggestions that are keys to success:

- 1. Target your messaging to the patient's age: Your counseling will be very different for a 15-year-old than for a 35-year-old.
- 2. Ensure that your infrastructure supports easy access and confidentiality. There should be as few barriers as possible for youth to reach your services in ways that feel safe to them. If you use volunteers to reach out to PrEP enrollees, train them in how to support these necessary aspects of your program.
- 3. At every visit, make time to ask your patients if they have questions about subjects other than PrEP: "small talk before big talk." Also remember that adolescents and young adults are starting their sexual lives and will have many questions about their sexual health and logistics.
- 4. Create more touch points with the patients by expanding your care team to

- include medical assistants, nurses, other support staff and, potentially, medical/ physician assistant students as PrEP navigators. Remember to let patients know who will be on this team with you so they are assured that you are honoring their confidentiality.
- 5. To build adherence to PrEP, have a virtual visit at least once a month until the patient is managing well (then you can space them out to every two or three months). You're building a relationship and developing trust, which can take time. Our program will sometimes schedule a follow-up visit between the patient's initial labs and starting PrEP to answer any additional medication questions. For many patients, —this is likely the first time they will be taking a medication on a daily basis

Readers may contact us with any questions about the Stanford Medicine Virtual PrEP Program for Adolescents and Young Adults: PrEPadmin@stanfordchildrens.org. HIV



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# BEHAVIORAL

Using Virtual Platforms to Promote Mental Health and Well-Being Among

BY: Karen McKinnon, MA, Francine Cournos, MD, Daria Boccher-Lattimore, DRPH, Cody Lentz, BS, and Mari Millery, PHD

HEN COVID-19 FORCED THE SHUTDOWN of many face-to-face health services, the Northeast/Caribbean AIDS Education and Training Center (NECA AETC) took immediate action to create virtual mental health programming for HIV care teams. Our goals were to help all levels of staff to: 1) understand reactions to stress and anxiety that we experience as members of the healthcare community; 2) review approaches to burnout and compassion fatigue and address them in our daily work; and 3) identify opportunities to build and maintain the well-being of ourselves and our patients. Some of the content for this programming had been developed following the terrorist attacks on September 11, 2001 and again when Puerto Rico, part of our region (HHS Region II, which also includes New Jersey, New York and the U.S. Virgin Islands), was devastated by hurricanes. In each of these instances, we mobilized the workforce of our HIV Behavioral Health Regional Partner at Columbia University to bring their expertise to the HIV healthcare teams that were struggling to continue their work with patients in the face of disaster conditions that affected everyone in our community simultaneously.

The HIV workforce has been called into action during the COVID-19 pandemic in a number of ways. Many healthcare workers with the skills and expertise to treat HIV infection are responding to the medical needs of patients with COVID-19. HIV researchers, both biomedical and behavioral, have turned their attention to COVID-19 by studying who is most adversely affected by SARS-CoV-2, how to mitigate those effects and what the healthcare systems' response has been to the pandemic. While some of this activity has been delivered in person, much of it



# TELEHEALTH

# HIV Healthcare Workers and their Patients During the COVID-19 Pandemic



has needed to move to virtual platforms to ensure access to the large number of care team members and patients who might benefit. The now ubiquitous Zoom platform has become home to scientific conferences, informational webinars, workshops and small group-break-out sessions, individual and group therapy and telemedicine encounters. Moving these efforts to virtual platforms has met with both successes and failures, and an enormous investment in training healthcare teams to use these platforms has taken place during the COVID-19 pandemic. Arguably, among the most challenging of services to deliver virtually are mental health and substance use assessment and treatment.

# Advantages and Disadvantages of Providing Behavioral Health Services Using Virtual Platforms

As part of a NIMH-funded study of behavioral health (BH) integration into HIV care that was ongoing when COVID-19 emerged, we asked HIV care team members to tell us how they had shifted their work from in-person to virtual as a result of the pandemic. Among the 22 respondents to those key informant interviews were clinic or CBO directors, medical providers, BH providers, and community health workers.

# The following were listed as advantages to using virtual platforms:

- Working virtually makes integration efforts easier, as BH specialists and HIV care providers now coordinate via virtual meetings, as opposed to needing to occupy the same physical space.
- There are fewer missed appointments since providing all BH services virtually (as well as some medical services). This can help alleviate travel/time burdens on patients who are already engaged in care.
- Following the beginning of the pandemic, our care went entirely virtual, and we began instituting bi-monthly case conferences where the care teams could discuss especially difficult cases. Medical providers and licensed psychiatrists attended these conferences, allowing for more integrated planning about how to best meet the needs of each shared case.
- Most HIV care services continued in-person (We limited the number of patients who accessed the building at one time.), while mental health services were provided via telehealth, and this seemed to work well.

# The following were listed as disadvantages to using virtual platforms:

- A lot of patients fall through the cracks with telehealth because they can't access technology, are uneasy or uncomfortable speaking to their counselors over the phone/computer, can't secure private spaces and/or prefer in-person interactions because they offer more BH support.
- The shift to telehealth was not smooth. Patients can only connect with providers at the clinic if they have a certain type of smartphone, and the system doesn't permit face-to-face virtual visits only phone calls. This was a huge barrier to engaging and retaining patients in needed services, particularly mental health services.
- We can no longer provide group supportive therapy, which many patients miss. We tried to hold groups virtually, but many patients didn't join because they preferred that in-person contact and support.
- Some clients' insurance will not fully cover telehealth visits (though they will cover in-person visits), which makes this a less than ideal option for low-income clientele.
- Telehealth just doesn't work for some clients. Some are less candid about issues because they can't secure a private space, others really need the face-to-face contact and disregard virtual visits and attendance to virtual group sessions hosted by the agency has been very poor.
- Telehealth doesn't mesh well with the culture in Puerto Rico, where we don't speak of "social distancing" but of "physical distancing." Clients are averse to online/phone appointments with their care teams. They need to see people in person.

Our AETC is involved in training the healthcare workforce about multiple aspects of COVID-19, including the use of virtual platforms for service delivery. Nationally, AETCs received funding from the CARES Act to address the training needs around COVID-19 prevention, treatment, care, and now, vaccines. From March 2020 to December 2020, the NECA AETC conducted 120 virtual trainings reaching over 5,000 trainees. Of these, 36 (30%) addressed BH/wellness, ranging from BH interventions, self-care, post-traumatic stress disorder (PTSD), and dealing with grief and loss. Some training sessions were primarily targeted to the well-being of providers themselves who were responding to the COVID-19 crisis, while other sessions focused on meeting the mental health needs of their patients living with HIV who were now being simultaneously affected by the COVID-19 pandemic.

In a recent national webinar session with approximately 150 HIV care team members, anonymous polling indicated that 73 percent of participants reported experiencing "moderate stress to a great deal of distress" as a result of the COVID-19 pandemic. Prominent sources of distress included feeling traumatized by the upheaval COVID-19 has caused (56%); struggling with loss, grief, and/or loneliness (19%); loss of personal sense of safety, including worries about housing or other basic needs (14%); and worsening of pre-existing and/or new onset of substance use and other mental health disorders (8%).

In terms of how they were delivering HIV services to their patients, 46 percent of participants had been working exclusively remotely during the COVID-19 pandemic; 27 percent had begun working

The now ubiquitous Zoom platform has become home to scientific conferences. informational webinars. workshops and small groupbreak-out sessions, individual and group therapy and telemedicine encounters.

remotely but had returned to work; and 27 percent had been working in person all along. When we asked this HIV healthcare workforce about their readiness to get vaccinated, 62 percent reported that they were ready immediately; 32 percent were more comfortable waiting and seeing how it goes for others; and 6 percent indicated that they were not planning to get vaccinated. Although this was not a representative sample, we learned that healthcare providers from across the country who opted to participate in a learning opportunity related to COVID-19 and mental health, wellness, and resiliency were experiencing distress at relatively high levels for a range of reasons reflecting the extreme life changes the pandemic has wrought. Nearly half were working in person and two-thirds were ready to be vaccinated.

The COVID-19 pandemic has affected HIV care team members in ways that are both predictable and insidious. They may have no time to deal with their own circumstances but are expected to set aside their own distress to help patients, sometimes taking on work that's not part of their usual duties. Many healthcare workers express guilt over life and death decisions they have had to make as well as helping their family members before helping their patients or coworkers deal with the ill effects of the virus and changes to their daily lives that the virus required. When healthcare workers are overwhelmed, they may not be able to help their co-workers and the usual systems of support they've developed may break down. The healthcare system can be very hierarchical and no one wants to admit they're struggling. On the upside, healthcare workers often are at their best in a crisis and it may feel good and be its own reward to be able to help and be useful.

One unique factor taking place during the COVID-19 pandemic is that healthcare providers and their patients living with HIV are both affected by increased rates of mental health disorders. An online survey of 1,132 health workers at 25 medical centers throughout the United States in May, 2020 examined their experiences and wellness during the COVID-19 pandemic and found probable mental health disorders in high proportions: major depression, 14.0 percent; generalized anxiety disorder, 15.8 percent; PTSD, 23.1 percent; and alcohol use disorder, 42.6 percent. A June 2020 survey from the Centers for Disease Control and Prevention (CDC) of 5,412 U.S. adults found that 40.9 percent of respondents reported "at least one adverse mental or behavioral health condition," including depression, anxiety, posttraumatic stress, and substance use, with rates that were three to four times the rates just a year earlier.<sup>2</sup> Alarmingly, 10.7 percent of these adults reported seriously considering suicide in the last 30 days.

These spikes in mental health symptoms and conditions for both healthcare workers and patients are not surprising given the estimate that every COVID-19 death results in nine bereaved family members.<sup>3</sup> Such loss and grief, combined with the stress and social and economic disruption caused by the pandemic has created what has been described as a mental health "tsunami" of depression and anxiety globally, with preexisting psychiatric disorders and substance use disorders expected to worsen. It is important to note that just as COVID-19 has disproportionately affected communities of color, the mental health wave is expected to take a disproportionate toll on Black and Hispanic individuals, as well as on older adults, people living in poverty, and healthcare workers.4

HIV care team members need to take care of themselves and their patients simultaneously. Disaster psychiatry offers much to draw from in carrying out this dual role, including approaches to acute stress, distress, and post-traumatic stress; criteria for mental health disorders and how to differentiate them from distress; best practices for psychotherapy and medication treatments; and important DOs and DON'Ts for non-BH specialists working to support their co-workers and patients.5

# **RESOURCES**

Many local and national resources have been created to respond to COVID-19 and the behavioral health conditions that result or worsen from the pandemic.

- National Anxiety Foundation: www.lexington-on-line.com/naf.html
- National Center for Posttraumatic Stress Disorder (PTSD): www.ptsd.va.gov
- The HIV National Curriculum: Screening Linked to Use of Clinical Calculators & Tools: www.aidsetc.org/nhc
- Mindful Self-Compassion http://www.mindfulselfcompassion.org/
- The Maslach Burnout Inventory (MBI) http://www.mindgarden.com/products/mbi.htm
- https://store.samhsa.gov/product/SAMHSA-Disaster-Kit/ SMA11-DISASTER
- https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/ managing-stress-anxiety.html

In addition, local and national helplines have been launched to provide free screening, counseling, and referral.

- National Suicide Prevention Lifeline: 1-800-273-TALK (8255) for English, 1-888-628-9454 for Spanish
- National Domestic Violence Hotline: 1-800-799-7233 or text LOVEIS to 22522
- National Child Abuse Hotline: 1-800-4AChild (1-800-422-4453) or text 1-800-422-4453
- National Sexual Assault Hotline: 1-800-656-HOPE (4673) or Online Chat: https://hotline.rainn.org/online
- Veteran's Crisis Line: 1-800-273-TALK (8255) or text: 8388255 or Crisis Chat: https://www.veteranscrisisline.net/get-help/chat
- Disaster Distress Helpline: CALL or TEXT 1-800-985-5990 (press 2 for Spanish)
- The Eldercare Locator: 1-800-677-1116

There are also many AETC resources available online at https://aidsetc.org/searches/covid



# Mental health conditions that affect both HIV healthcare workers and their patients

Anxiety is a normal reaction to fear and stress which helps us to react to situations that produce those feelings, but it can become debilitating, producing physical reactions such as a rapid heartbeat, wobbly legs, feeling faint, choking, or an overwhelming sense of dread. Assessing these reactions may be easier in an in-person, face-to-face clinical encounter where they can be observed and asked about; however, once members of a care team are comfortable observing patients on virtual platforms (such as DoxyMe, FaceTime, Zoom) and asking questions about these physical manifestations of anxiety, being virtual is not a disadvantage in and of itself. Other aspects of regular check-ins with patients similarly are being successfully navigated on virtual platforms and assessing for tipping points between distress and disorder is an important task for care team members to continue during the pandemic.

# **Distress**

- Can occur in response to anv adversity.
- Commonly seen in response to the COVID-19 crisis.
- More severe among workers on the front lines of responding.
- Often does not meet criteria for a psychiatric diagnosis or require specialized mental health interventions.
- Often responds well to supportive strategies.

# **Disorders**

- Usually accompanied by persistent severe subjective distress and/or functional impairment.
- Meet recognized diagnostic criteria (ICD, DSM).
- Call for evidence-informed mental health interventions such as medication and psychotherapy.
- Rules have been relaxed for providing mental health services by virtual means.

Anxiety is a normal reaction to fear and stress which helps us to react to situations that produce those feelings, but it can become debilitating, producing physical reactions such as a rapid heartbeat, wobbly legs, feeling faint, choking, or an overwhelming sense of dread.

If distress impacts activities of daily life for several days or weeks, or if symptoms are severe, formal mental healthcare will be needed as part of the response. Healthcare workers may be very attuned to observing these aspects of their patients' health and well-being, but often are inclined to ignore or minimize their own need for care; awareness can combat some of the obstacles, including stigma, which keep people from seeking help.

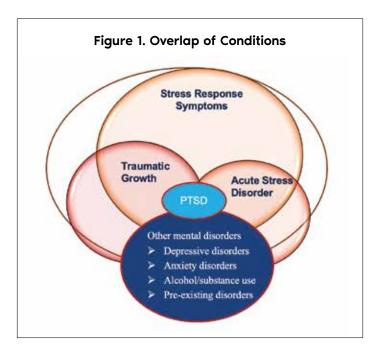
When attempting to gauge a person's level of distress during a crisis, the first mental health condition that typically comes to mind is PTSD. However, acute stress is associated with a multitude of mental health problems, most prominently depressive disorders, anxiety disorders, and substance use disorders. In the U.S., the rate of PTSD among people up to the age of 75 is 8.7 percent and in any given 12-month period the prevalence is 3.5 percent. And, of course pre-existing BH conditions may be exacerbated during the pandemic, and these disorders were prevalent among people living with HIV prior to COVID-19.7

As the World Health Organization (WHO) Pyramid of the Optimal Mix of Mental Health Services shows, much of what is helpful to people can be done at the informal and community levels.8 With greater intensity and severity of symptoms, the intensity of treatment increases and the need for more specialized services also increases. Effective approaches to treating symptoms associated with these disorders include either one-to-one or group Cognitive Behavioral Therapy (CBT); Cognitive Restructuring; Medication (antidepressants can help with symptoms of sadness, anxiety, and irritation); and relaxation, mindfulness, and improving sleep, diet, and exercise.<sup>7</sup>

In the domain of self-care, talking with someone about feelings, especially anger, sadness, and other strong emotions, no matter how difficult it seems, is one way of relieving stress. Being able to voice these feelings in a safe and supportive way is essential. Adopting methods to promote physical and emotional well-being through healthy food, rest, exercise, relaxation, and meditation can bring a sense of mastery and control over at least some of what is occurring during the pandemic. And, finally, within what's possible, maintaining a routine in the familiar and daily without taking additional responsibilities is an important limit to set for healthcare workers.

One concept that is worth noting is the idea of "post-traumatic growth." It feels good to have responded to a crisis, to have helped, to have been useful. For healthcare workers in particular, they have gotten better at caring for people with COVID-19, which is reflected in a lower rate of death, even when cases spike. They've increased their comfort and expertise in using the internet and a variety of virtual platforms for patient care, work meetings, and getting training to build their capacity for further growth. It is likely that many of the shifts to virtual care made during COVID-19 will be retained as they have solved many care integration and coordination as well as transportation issues for both healthcare workers and patients.

Healthcare workers and our patients share many of the deprivations and losses arising from the COVID-19 pandemic. Common human issues include loss, death, grief, social isolation and loneliness. We tackle these along with our patients, and all of us are maintaining our own well-being and that of our communities using virtual platforms for now and into the foreseeable future. HIV







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# We Can Do Better

**Managing Addiction in a Pandemic** 



# BY: William E. Cooke, MD, FAAFP, FASAM, AAHIVS

**OMETIMES** it takes an extraordinary event to allow us to see ordinary people and truths. As horrendous as the opioid, HIV, and COVID-19 crises have been for America, some good may come from these calamities if they help bring the unseen people out of the shadows and into the light.

According to the CDC, more than 81,000 people lost their lives to drug overdoses during the one-year stretch of May 2019 through May 2020. That represents an 18 percent increase over the previous year and the most annual overdose deaths ever recorded. The American Medical Association (AMA) announced in September 2020 that more than forty states had reported increases in the number of overdose deaths during the pandemic.2

The national opioid epidemic has also resulted in a dramatic rise in soft tissue infections, endocarditis, and blood-borne diseases including hepatitis C and HIV. These trends threatens years of advances in the prevention and treatment of infectious diseases. With regards to HIV, while transmission in the U.S. has declined by more than two-thirds from its historic peak, CDC data indicate further progress has stalled. New cases have remained around 38,000 a year since 2014.3 Transmission of HIV among people who inject drugs (PWID) threatens the tremendous progress we have made. Since 2014—as I witnessed firsthand when southern Indiana became the epicenter of the convergence of the opioid and HIV epidemics-new transmissions have increased by 51 percent nationally among white PWID.4

Meanwhile, only about 25 percent of PWID access treatment compared with 54 percent of the general population of people living with HIV globally.<sup>5</sup>

Increasing access to addiction services by leveraging technology is one way we can make a difference. Integrating the treatment of addiction into HIV prevention and treatment makes sense.

# Integrating HIV and Addiction Medicine

Physicians take a pledge to "do no harm." That feels passive when we know that most of what harms our patients happens outside of our clinic walls. I'd challenge my colleagues to pledge to a modern Hippocratic Oath to "protect from harm." This requires us to proactively respond to the needs of our patients by connecting with them as people, not diseases. One way to accomplish this is to integrate medication for opioid use disorder (MOUD) with HIV prevention and treatment.

Providers may harbor preconceptions that people who use drugs will be difficult or nonadherent, and that ongoing drug use will undermine any provided treatment.

Conversely, patients may be reluctant to fully engage in care for fear of being policed or judged for ongoing substance use.6

Despite the strong links between opioid use disorder (OUD) and HIV/AIDS, services for these two conditions have been fragmented in the U.S. However, studies have shown that successful linkage and engagement in care is possible in this population when substance use treatment services are combined with conventional HIV care.7

Holistic, integrated care moves us away from just treating a disease and toward a more life-affirming model of care.

# **Buprenorphine**

# X-waiver

A few months ago, the U.S. Department of Health and Human Services (HHS) removed the X-waiver requirement for physicians to be able to prescribe buprenorphine to people living with OUD.8 The new guidelines allow any physician to treat up to thirty patients living with OUD at any one time. 9 Of significant note, this thirty-patient cap does not apply to hospital-based physicians (such as those working in the emergency department). This simple policy change has the potential of reducing the cost of healthcare while significantly increasing the years of life saved and thus life expectancy.

#### Safety

Providers should be reassured that buprenorphine's safety profile ensures that adverse events like fatal overdoses are rare This risk

is far outweighed by the significant benefit of keeping patients engaged in care and safe from the life-threatening adverse events associated with relapsing.10

Data from a 2015 review consisting of 3,350 patients showed MOUD much more effective at saving lives and preventing relapses than abstinence-based treatment programs. 11

A 2018 study of 17,568 people who had experienced a nonfatal overdose showed MOUD reduced overdose and all-cause mortality compared to abstinence.12

#### Telemedicine

In 2018, the Drug Enforcement Administration (DEA) partnered with the Substance Abuse and Mental Health Services Administration (SAMHSA) to expand access to buprenorphine via telemedicine or telephone without first conducting an in-person evaluation. 13 The American Society of Addiction Medicine (ASAM) endorses leveraging telemedicine to treat people with substance use disorder (SUD). This not only reduces the risk of exposing patients and staff to COVID-19 but also removes many of the barriers people living with SUD have to life-affirming services. As with any telemedicine communication with our patients, ASAM recommends using "an audio-visual, real-time, two-way interactive communication system."14 But the organization acknowledges that when patients do not have access to video technology, a telephone-based visit may be utilized.

For providers concerned that patients may participate in diversion, ASAM points out that buprenorphine is diverted less often than other opioids<sup>15</sup> and usually occurs to help others self-treat opioid withdrawal rather than achieve euphoria.16

When buprenorphine treatment is initiated, visits can start off every few days to once a week. As trust is built, the frequency of these visits can be reduced and integrated into the routine care of the patient's other medical needs. Converting to telemedicine can reduce some of the barriers patients might otherwise have to these frequent office visits, such as finding transportation, arranging for childcare, and even taking time off work.

When planning visit frequency, amount of buprenorphine prescribed, and number of refills, ASAM recommends considering the following psychosocial and community factors:

1. During healthcare disasters such as COVID-19, does the patient fall into a high-risk group as outlined by the CDC or local health department? Having the patient frequently visit clinics or pharmacies may increase their risk of transmission, or the risk to providers and the public.

Converting to telemedicine can reduce some of the barriers patients might otherwise have to these frequent office visits, such as finding transportation, arranging for childcare, and even taking time off work.

2. Is the patient under quarantine or caring for a loved one in isolation? Patients will need access to an appropriate amount of medication to support recommended public health policy.

3. How able is the patient to safely store different amounts of buprenorphine/naloxone formulations? Without the ability to secure it, less medication may be preferable. For many of my patients, for example, the risk of weekly visits to the pharmacy outweighs the risk of a month's supply being stolen or lost.

4. Who might be able to access medications in the home, such as children, pets, or neighbors? While buprenorphine generally poses less of a risk for respiratory depression compared with other opioids and methadone, those without previous exposure to opioids, especially children or people on certain other medications can be harmed.

5. How stable is the patient's SUD? Prescribing a lower quantity of medication with more frequent refills and monitoring by telehealth or telephone may be safer or more effective in keeping patients in recovery.<sup>17</sup>

Clinicians should always co-prescribe or ensure there is naloxone in the patient's home. If naloxone access is limited, prioritize patients at high risk for relapse because of co-occurring benzo or alcohol use, or whose households include children, adolescents, or individuals with chronic cardiopulmonary disease.

# **Drug Testing**

ASAM states that the primary purpose of drug testing is to improve patient outcomes by: "(a) detecting substance use that could complicate treatment response and patient management; (b) monitoring adherence with the prescribed medication; and (c) monitoring possible diversion."18

However, drug testing should be complemented by a comprehensive approach to support these objectives. This is even more critical during times that in-office visits and testing are limited. Every state now has a prescription monitoring program (PDMP), which should be accessed prior to prescribing any controlled medication. Other strategies include increased frequency of telehealth or office visits, limiting the amount of medication dispensed, random pill counts, and partnering with psychosocial support services.

The standard frequency for drug testing is at least monthly. Less frequent testing may be considered for patients who are stable in their recovery or during times that in-office testing is not safe or practical. The guiding principle here remains to reduce potential harm and maintain access to life-affirming treatment for our patients.

For more information on drug testing, please refer to ASAM's consensus statement.19

# **Psychosocial Support**

Although psychosocial support is important to a patient's long-term recovery, ASAM's National Practice Guideline for the Treatment of Opioid Use Disorder states, "a patient's decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay pharmacotherapy, with appropriate medication management."20 This guidance is even more applicable during the COVID-19 pandemic and for people with other significant barriers to these services.

Peer support specialists can help patients be more successful by accompanying them along their path to recovery.<sup>21</sup> They can help ensure patients remain engaged in care by assisting patients with transportation, linking them to the recovery community, and even assisting with audio/video communication for telemedicine visits. One example of this is the way my practice partnered with our local Recovery Community Organization, THRIVE, Mental Health America of Indiana, and the Indiana Rural Health Association to equip peer support specialists with tablets to literally bring MOUD access to people otherwise unable or too frightened to access help.

# Final Thoughts

Telehealth can also be used to improve patient outcomes by increasing their access to ancillary services such as support groups, behavioral health, vocational support, and one-on-one peer support. Project ECHO uses telehealth to move expert knowledge by empowering local providers with the resources needed to care for their own patients.22

All of this assumes an infrastructure that supports telehealth. Many of our patients affected by adverse social determinants of health do not have access to broadband, Wi-Fi, or data plans. In our community, we are equipping community partners and even patients with data plan-equipped tablets to reduce this barrier.

In America, our Constitution proclaims that all people have the right to life, liberty, and the pursuit of happiness. Yet we tolerate a system that denies equal access to safety, health, and opportunity. Under this system, how much life someone has access to is far too often based on his or her ZIP Code, race, socioeconomic status, or what those in power think of them. This predictable outcome played out on a much larger scale during the COVID-19 pandemic when the disease, disability, and death disproportionately struck along the fault lines of race and socioeconomic class.

The harms that arise from adverse health and socioeconomic factors, childhood trauma, and isolation represent a real national

crisis. But as National Youth Poet Laureate Amanda Gorman recently said so eloquently, our nation is "not broken but simply unfinished." We can all work together to reduce harm to our neighbors by removing barriers and increasing access to opportunity, healthcare, and social support. HIV



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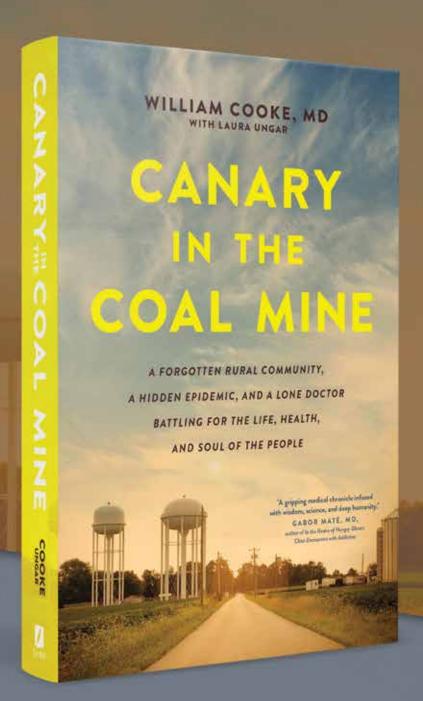
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# **PRACTICES**

# Impact of Delayed HIV Diagnosis on Non-AIDS Defining Cancers

# **A Case Report**

BY: MEGAN GAINES, PA-C, JEAN WIGGINS AND WILLIAM N. HANNAH, JR., MD

# INTRODUCTION

**EARLY IDENTIFICATION AND ADHERENCE** to antiretroviral therapy (ART) has generally increased the life expectancy for persons living with HIV to the same as that of non-HIV infected persons. Yet, these individuals often have substantial comorbidities that further decrease their chances to live full and productive lives. Untreated, HIV can lead to a weakened immune system response and Acquired Immunodeficiency Syndrome (AIDS) in as little as eight to 10 years.<sup>2</sup> As HIV manifests into AIDS, the risk increases for opportunistic infections and malignancies, and these diseases are often identified at an advanced stage in the disease process. While ART regimens have led to a decline in AIDS-defining cancers (ADC), non-AIDS defining cancers (NADC) now represent a substantial share of morbidity and mortality in HIV-infected individuals, especially those with late-stage AIDS.<sup>3</sup>

# CASE

A 48-year old white, female presented to the emergency department (ED) with a chief complaint of several months of recurrent perianal abscesses draining feculent material. Her past medical history included hypertension and endometrial cancer diagnosed in 2014 for which she underwent a hysterectomy, pelvic radiation, and vaginal brachytherapy. During this encounter the patient declined an HIV test.



On physical examination, a digital rectal exam revealed swelling in the left anal margin with sero-purulent drainage. Anoscopy with biopsy showed a deep and fungating ulceration of the left anal canal extending approximately 3 cm proximally. The biopsy revealed a tubulovillous adenoma with highgrade dysplasia; however, the pathologist also noted a small focus suspicious for invasion. An MRI of the pelvis also showed an annular mass extending from the anal verge to the mid rectum, which was 8.7 cm in length and below the peritoneal reflection. The patient was diagnosed with clinical stage IV anorectal adenocarcinoma. She subsequently underwent abdominoperineal resection with posterior vaginectomy. She was discharged home on post-operative day seven.

Three days later, the patient returned to the ED with acute onset of pain and numbness in her left leg secondary to a complete occlusion of her left common iliac artery, for which she underwent emergent right internal iliac artery stent dilation. During this visit, the patient received an opt-out HIV test. Her HIV Antigen/Antibody (AG/AB) test came back positive for HIV-1. Several days later her viral load resulted at 306,000 copies/mL, and her CD4 count was 134 cells/mm<sub>3</sub>. The patient was previously unaware of her HIV status, and no prior HIV test results were available in the electronic medical record despite 40 combined office and ED visits dating back as far as seven years.

# DISCUSSION

In 2006, the Centers for Disease Control and Prevention (CDC) recommended universal opt-out HIV screening for all individuals 13 to 64 years of age. 4 The CDC also included

in their recommendations that HIV testing be performed in persons who present clinically with infectious conditions such as tuberculosis or sexually transmitted diseases. Furthermore, those at high-risk for HIV should be screened at least annually.

For the past four years, Georgia has had the highest rate of HIV diagnoses in the United States (23.8 per 100,000).5 Outside of metropolitan Atlanta (1.02%), Chatham county has the highest prevalence rate of HIV out of Georgia's most populous counties (0.63%). Despite this, Georgia laws with respect to HIV testing have not changed since 2015.7 While other states, such as New York, have seen declines in HIV prevalence partially as a result of improved legislation, Georgia has not adopted similar legislation to combat its prevalence of HIV.8 As a result, many Georgia healthcare facilities do not routinely screen for HIV per CDC recommendations.

Many healthcare encounters only focus on immediate clinical needs and therefore neglect to assess and screen for HIV. Studies also show that approximately 47 percent of patients newly diagnosed with HIV present at least two or more times to healthcare visits with HIV-related symptoms; and, of those, only 21 percent actually receive a HIV test.9 As previously stated, our patient presented at 40 healthcare visits with multiple, potentially HIV-related symptoms in both the primary and specialty care settings, yet was never tested for HIV. Today, about 14 percent of the general population still do not know their HIV status.9 Since 2014, HIV has been declining in whites and all age groups, with the exception of those ages 18 to 24.9 During this same time period, CDC data shows HIV infections are rising in African American males who have sex with males (MSM). Nationwide, white heterosexual females represent the lowest number of HIV-positive persons. 10 In our case, the patient did not fit the demographic profile of the typical HIV patient.

The American Cancer Society now recommends colorectal screening at age 45 and even earlier if a person has a history of cancer and pelvic radiation treatment. 11 As noted, our patient previously received pelvic radiation for endometrial cancer. Persons living with HIV/AIDS (PLWHA) already have an increased risk for cancers and some data indicates that rectal cancer, a NADC, is on the rise among HIV-infected persons. 12

At this time, there are no recommendations indicating PLWHA should be screened for precancerous polyps and colorectal cancer (CRC) with colonoscopy earlier than people at average risk. One study suggested that PLWHA who have low CD4 counts (less than 500 cells/mm<sub>3</sub>) are nine times more likely to have precancerous polyps than PLWHA who have a CD4 count over 500 cells/mm<sub>3</sub>. <sup>13</sup> As previously stated, at the time of her HIV diagnosis, our patient had a CD4 count of 134 cells/mm3 and likely had been living with HIV infection for many years. Another study found that CRC may develop at an earlier age and be more aggressive in PLWHA than in people who do not have HIV.15 The study also revealed findings indicating there is an association between a longer duration of HIV and development of neoplastic lesions in the distal colon. 15 Additionally, it was concluded that immune suppression (i.e., CD4 count < 200 cells/mm<sub>3</sub>) is associated with formation of neoplastic lesions in the distal colon. A third study also found a correlation between HIV infection and an increased risk of colorectal adenoma in HIV patients. 16 It was determined that



patients with a low CD4 count have the highest risk for developing CRC.<sup>15</sup> The results of these three studies strongly suggest that earlier screening for colorectal cancer in PLWHA could be of benefit.

Approximately 50 percent of patients diagnosed with a malignancy will receive radiation therapy (RT) as part of their treatment plan. 16 While RT can lead to a reduction in recurrence and is even curative for some localized, early stage cancers, it may put patients at an increased risk for developing a second primary cancer. In regards to pelvic RT, patients are at an increased risk for late toxicity and the development of rectal cancer due to the proximity of the rectum to the radiation field. One study found that the risk for development of rectal cancer is increased if RT is received for a primary endometrial cancer.<sup>17</sup> It was also determined that, on average,



patients developed rectal cancer as a second primary cancer approximately six years after completion of RT for the first primary pelvic cancer. Rectal cancer is also often diagnosed with a higher Tumor Node Mets (TNM) stage. Our patient completed whole pelvic RT and vaginal brachytherapy in 2014 following a hysterectomy for a primary endometrial stromal sarcoma. Subsequently, she was diagnosed with stage IV rectal cancer in 2020.

#### CONCLUSION

Patients are infrequently screened for HIV as recommended by the CDC despite opportunities during healthcare encounters. This failure to diagnose HIV leads to delays and/or a lack of treatment. Even with ART, PLWHA have a higher incidence of developing certain cancers. These patients often present with more advanced cancers at a younger age and have worse outcomes. 18 Healthcare providers who care for persons with HIV should consider cancer screenings earlier than in those individuals who uninfected, although we also need more data from PWH to help guide these recommendations. HIV

This research was supported (in whole or in part) by HCA Healthcare and/or an HCA Healthcare affiliated entity. The views expressed in this publication represent those of the author(s) and do not necessarily represent the official views of HCA Healthcare or any of its affiliated entities.



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BY AARON AUSTIN, MEMBERSHIP DIRECTOR

# Lydia Aoun Barakat, MD, AAHIVS, New Haven, Connecticut

S MEDICAL DIRECTOR of the Yale HIV Ambulatory Center, Dr. Lydia Aoun Barakat oversees the care of over 1,000 people living with HIV or at risk for HIV. The clinic is located at the Yale New Haven Health Academic Medical Center in New Haven, Connecticut and is home to a staff of 30 providers including advanced practice providers and trainees. The care team features a deep bench of talented professionals including pharmacists, social workers, nurses, medical assistants, administrative assistants, medical case managers, and HIV counselors. They provide mental health and substance use disorder services on site. Dr. Barakat's clinic was the first in Connecticut to provide PrEP and remains the largest clinic in the state for HIV care. Additionally, hers is the site for several clinical trials, as well as translational and clinical research.

Dr. Barakat has been providing care to people living with HIV for the last 25 years. "I have the pleasure to provide direct HIV primary care to a cohort of approximately 100 people with HIV and I supervise trainees for the care of approximately 150 people with HIV," shares Barakat. "Our patients are a mixture of young, middle aged and older. More than half of our patients with HIV are older than 50 years old. Around 40% are women. In addition, our patients with HIV come from different racial, socioeconomical, and educational backgrounds. Our new patients are young, majority men who have sex with men, and predominately Black. Almost 70% of our patients with HIV have Medicaid or Medicare and less than 5% are uninsured."

Dr. Barakat earned her Medical Degree from the Lebanese University in Beirut, Lebanon. She completed her residency at a Yaleaffiliated hospital residency program and her infectious disease fellowship at Yale University. She is board certified in Internal Medicine and Infectious Disease and is credentialed as an HIV Specialist.

"The main reason I was compelled with HIV care was the social injustice and health inequity associated with the disease," Barakat reflects, "In addition, HIV disease is a continuously evolving disease that is intriguing as an infectious disease. Lastly, I feel it is a privilege to be the primary care provider to my patients with HIV and establish a long-term relationship with them and their loved ones. I have patients who I have been caring for, for 25 years." Dr. Barakat engages and empowers her patients to take control of their health. Her advice?

I feel it is a privilege to be the primary care provider to my patients with HIV and establish a long-term relationship with them and their loved ones.

Treat them as a person first, then treat their disease. The relationship is built on listening, caring, and trusting.

Asked about the most rewarding part of her work, Dr. Barakat shares it is seeing pregnant women living with HIV giving birth to an HIV-uninfected baby due to advancement in treatment options. Dr. Barakat's favorite part of her job is training the next generation of physicians in HIV care and prevention. And as for challenges, "The greatest obstacle I face is the stigma associated with HIV and its impact on the social determinants of health."

Interested in successful or unique practices that other HIV care providers can learn from, adapt, or replicate, Dr. Barakat shares that her clinic started offering a wellness visit to people with HIV over 50 years old. "During this visit, we provide several assessments such as frailty, neurocognitive, nutritional, and more. In addition, the patient will meet with the pharmacist to address polypharmacy and any potential drug-drug interactions, and with the social worker to identify any personal or social needs including discussion about goals of care." When confronted with the COVID-19 pandemic Dr. Barakat's site implemented a telehealth program that was



well received and beneficial to their patients with HIV and their families.

Being a faculty at Yale University offers Dr. Barakat unique opportunities to collaborate in cutting edge research, establish training programs such as the Yale HIV Training Track and the AIDS Education Training Center, and to expand HIV care delivery across the globe to low resource countries. Looking to the future, Dr. Barakat would like to advance her administrative and leadership role and use this platform to advance health equity for every patient in our community locally and globally. "I hope in 10 years we will have a cure for HIV and we will get to Zero. HIV treatment modalities will look different,

long-acting drugs for treatment and prevention will dominate the field. However, we need to advocate for affordable drugs as well as universal and equitable access to safe and effective treatment."

Beyond HIV care, Dr. Barakat provides consultative services in infectious disease and attends on the medical inpatient unit. She is Program Director for the Yale HIV Primary Care Track enhancing training for future physicians in internal medicine and HIV care. In the last three years, she has been involved in establishing an educational program in Liberia to develop workforce after the Ebola pandemic. Together with her partners, Dr. Barakat has created the first HIV training program in one of the largest hospitals in Liberia.

Outside of work, Dr. Barakat enjoys meditation, hiking, reading, and painting. She shares, "I love my son and my puppy and I cherish spending time with them and cooking for them!" Asked why she joined AAHIVM as an Academy Member, Dr. Barakat says, "The Academy offers a fundamental platform for HIV providers from different disciplines for education, advocacy, resources, and networking. Academy members are so dedicated to the mission of HIV care and prevention. It is very empowering to be a member with such amazing and inspiring colleagues." HIV

**ABOUT THE AUTHOR:** AAHIVM Membership Director **AARON AUSTIN** organizes, engages and leads the Academy's global membership of frontline HIV care providers around initiatives of advocacy, education and professional development. He is currently completing coursework for his MPH at The George Washington University Milken Institute School of Public Health.

# **FRONTLINES**



# The Power of Advocacy

BY: GARY F. SPINNER, PA, MPH, AAHIVS

**EMONSTRATING IN WHITE LAB COATS** stained with bloody hands, they laid down in front of the Food and Drug Administration (FDA) building entrance with signs reading "Dead from FDA red tape." Described as rude and irreverent by many, this group of largely LGBTQ activists were enraged at what they considered genocidal and homophobic neglect of the HIV epidemic by the government and medical establishment. Their actions shook the establishment and helped effect long-lasting policy changes in HIV treatment. The FDA, feeling pressured, met with them and within months, the policy to expand access to investigational antiviral drugs was loosened.

Such was the earliest success of the AIDS Coalition to Unleash Power (ACT UP) in the late 1980 and early 1990s. Their activism moved policy makers and U.S. agencies to speed up the process of clinical trials, to implore researchers to study cures for opportunistic infections, and to move the National Institutes of Health (NIH) to better represent women and people of color in clinical trials of HIV/ AIDS medications. Their advocacy successfully pushed the Clinton administration to lift the ban on syringe exchange programs. They criticized pharmaceutical companies for charging exorbitant prices for antivirals, and pushed resource rich countries to open HIV treatment to resource poor ones.1

Many HIV specialists in practice today were not in practice in the early days of the HIV pandemic, and may not be aware of the long tradition of activism and advocacy in HIV/AIDS care, both within the U.S. and globally.

# The Power of Advocacy

The power of advocacy to move policy makers and impact meaningful change is vital, though oftentimes forgotten. Our organization, the American Academy of HIV Medicine (AAHIVM), works hard to advocate on behalf of our patients and our profession. But we as healthcare providers should not be content to have our professional organization be our sole voice for needed policy change. The voices of healthcare providers carry enormous weight when speaking on behalf of the needs of the patients under our care.

# Elimination of Hepatitis C

The 2016 World Health Organization (WHO) set a goal of elimination of hepatitis C (HCV) by the year 2030, given the highly effective curative therapies available.2 However, only 11 high-income countries are on track to meet that target. Not only is the U.S. not on track to meet that goal, it ranks last among all high-income countries to do so, projected to meet that target in 2050.3

In Connecticut, effective advocacy has been led to the projection that our state will become the first in the U.S. to meet the WHO goal of micro-elimination of HCV, meeting that goal by 2028.4 It is the work of advocates that has helped to make this possible.

Like every other state in the U.S., in 2015 the Connecticut Medicaid program enacted a restrictive prior authorization process which would only approve direct-acting agents to treat HCV by board certified Hepatologists, Gastroenterologists, and Infectious Disease physicians, and then only to patients with significant F3 or F4

> fibrosis. These restrictions, while in line with every other Medicaid program in the U.S., and nearly every commercial insurance plan at the time, undermined our ability to treat patients infected with HCV. With the mortality rate from hepatitis C already surpassing mortality from HIV, and cases

of HCV rising dramatically due to the opioid epidemic, Connecticut advocates began strategizing on how to loosen the

Our group included legal aid attorneys, public health researchers, faculty from Yale University School of Medicine and clinicians from community health centers. A joint letter signed by many of us, to the Social Services Commissioner, supported in tandem by a letter from the Academy, underscored the importance of treating our patients with the new curative therapies. A group of three clinicians met with the medical director of the Medicaid program to implore expansion of access for HIV specialists and others to be able to be able to treat all of our patients, and not only those with severe liver disease. We argued that treating patients with HCV earlier would improve patient health, was cost effective, and would ultimately reduce the future cost of treating complications of cirrhosis and hepatocellular carcinoma. The result of our advocacy was the elimination of all significant restrictions on who can treat patients with HCV (all licensed prescribers) and which patients can be treated (all except known terminally ill patients).

# The Need to Get Involved

restrictions on HCV treatment.5

In this time of heightened awareness of the pervasive racism in our society, taking an active advocacy stance is more important for healthcare providers. Bias in healthcare persists today, whether it is racial, gender, or sexual identity. Bias can be implicit, and even in those who see themselves as providing equitable care can unknowingly be treating certain patients differently. <sup>6</sup> Bias can lead to longer wait times, less thorough workups, offering different treatment options, or taking patient complaints less seriously. Racial bias can impact healthcare regardless of the level of education or socioeconomic status of the patient. Recent media attention was paid to the Black Internal Medicine physician hospitalized with Covid-19 who posted on her social media page her belief that had she been white, her treatment of COVID-19 would have been different. 8 Many HIV specialists work in academic medical settings, and are in a position to advocate for changes in medical education to help eliminate implicit bias in the next generation of healthcare providers.

Advocacy to local, state and federal policy makers for changes in systemic and institutional policies that keep black and brown people on an unequal footing with whites is even more important. Taking a stand against systemic racism, that impacts wealth inequality, racially-segregated housing, disparities in employment, or access to healthcare are all ways that the privileged status of healthcare providers can be a voice for change.

Becoming a voice that speaks for equal access to healthcare, or access to therapeutic medications that our patients need in their HIV treatment has never been more important.

The field of HIV medicine has a long and proud history of public advocacy that has moved policy makers to take action that would not have occurred without the voices of patients and clinicians speaking out for policy change. Today, the need for those voices has never been greater. HIV



# **GARY SPINNER, PA, MPH,**

**AAHIVS**, is Medical Director of the Ryan White HIV/AIDS Program at the Southwest Community Health Center in Bridgeport, CT, and a member of the

Academy National Board of Directors.

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JEFFREY T. KIRCHNER, DO, AAHIVS Outgoing AAHIVM Chief Medical Officer

Beginning 2021, Dr. Carolyn Chu assumed the role of Chief Medical Officer (CMO) for the Academy. We would like to thank retiring CMO Dr. Jeffrey Kirchner for his guidance and contribution over the years! This following Clinical Research Update consists of literature reviewed by both Dr. Kirchner and Dr. Chu.

Pilkington, V. et al. Tenofovir alafenamide vs. tenofovir disoproxil fumarate: an updated meta-analysis of 14,894 patients across 14 trials. AIDS 2020, 34:2259-2268

Tenofovir disoproxil fumarate (TDF) along with the newer formulation tenofovir alafenamide (TAF) are both highly effective treatments for HIV. There are concerns regarding the impact of TDF on bone mineral density and risk of nephrotoxicity. TAF produces higher intracellular concentrations but is thought safer due to lower plasma concentrations of tenofovir. In addition, when ritonavir or cobicistat are used as part of an ART regimen, they increase the concentration of TDF. This study is an update of a prior systematic review of 14 clinical trials looking at efficacy and safety of TDF vs TAF when used with and without boosted co-formulations. Differences in efficacy were based specifically on viral suppression. Safety endpoints included grades 3-4 adverse events and related drug discontinuation. Lastly, specific markers of bone and renal function were assessed. There was a statistically significant difference in efficacy seen in the boosted subgroup in favor of TAF but the difference was small (94% vs. 92% HIV RNA < 50 copies/mL) and there was no difference in the unboosted subgroup (89% vs 90% < 50 copies/mL). For renal outcome there was no difference in renal tubular events between patients taking TAF and TDF or the number of discontinuations due to renal adverse events. Overall, there were no significant differences between TAF and TDF for any of the key safety endpoints analyzed which included both bone markers and renal tubular events.

### DR. JEFFREY KIRCHNER'S COMMENTARY:

These studies included almost 15,000 patients with about 24,000 patient-years of follow up. Across all main safety endpoints, no significant differences between TAF and TDF were seen. Although there were some differences in patients on boosted regimens, these are now less commonly used with the majority of patients now taking INSTIs. Regarding the concern for renal tubular events, there were only 3 across these studies and the overall risk difference was zero percent. Another point of this TDF vs TAF discussion should include lipid abnormalities and weight gain seen with TAF. For the majority of patients who need tenofovir as part of their ART regimen or for PrEP these data support TDF as a safe, effective, and more affordable option. Generic "Truvada" (tenofovir disoproxil fumarate/emtricitabine) became available in the U.S. in October although the current retail price is about \$1500 which is not significantly lower than the branded formulation.

Lake JE et al. Risk Factors for Weight Gain Following Switch to Integrase Inhibitor-Based Antiretroviral Therapy. Clin Infect Dis. 2020 Dec 3;71(9): e471-e477. doi: 10.1093/cid/ciaa177. PMID: 32099991.

The majority of persons with HIV (PWH) are now being treated with integrase strand transfer inhibitors (INSTIs) as part of their ART regimens. Although highly effective, this class of drugs has been increasingly associated with excess weight gain. This study looked at weight gain in PWH who were virologically suppressed then switched to an INSTI – most from a PI or NNRTI. The authors included 691 patients (81% male, 50% non-white, median age 50 years) from two longitudinal ACTG cohorts who were in care from 1997-2017. The study adjusted for various factors including age, sex, race, baseline BMI, smoking, diabetes, nadir and current CD4+ count, and follow-up time with suppressed HIV-RNA. Weight and waist circumference change before and after ART switch were assessed at various time intervals. Looking at those with undetectable VLs at the time of changing to an INSTI, Black people, women, and persons ≥60 years of age had significantly greater weight gain in the two years after changing to an INSTI. In adjusted models, women who were of White or Black race, age > 60 years, and BMI of 30 kg/m2 or greater were associated with significantly greater annualized weight gain (0.9 - 2.0 kg/yr.). With men, age > 60 was the greatest risk factor for weight gain (0.8 kg/yr.) after switching to an INSTI. Dolutegravir appeared to be associated with the greatest increase in yearly weight gain and raltegravir the least. Concomitant increases seen in waist circumference suggest that this weight gain is associated with an increase in fat mass.

#### DR. JEFFREY KIRCHNER'S COMMENTARY:

This study adds to the data from other clinical trials and observational cohorts which have found INSTIs cause weight gain in many patients. The mechanism(s) remains uncertain and it is not clear if this is a class effect. This study also saw worsening in lipid and glucose levels among those with weight gain. When raltegravir was approved for use in 2007 and dolutegravir in 2013 the issue of weight gain was thought to be a "return to health" phenomenon. However, with the increased use of INSTIs, this trend has become more apparent, especially in women. It may be prudent for providers to risk-stratify certain patients who have been stable on a PI or NNRTI- based regimen before deciding to change to an INSTI. In addition, nutritional assessment and counseling regarding diet and exercise for PWH should be part of every clinical visit to help mitigate weight gain and adverse metabolic effects seen with INSTIs and other antivirals.



CAROLYN CHU, MD, MSC, AAHIVS
Incoming AAHIVM Chief Medical Officer

Pahwa S, Deeks S, Zou S et al. NIH Workshop on HIV-Associated Comorbidities, Coinfections, and Complications: Summary and Recommendation for Future Research. *J Acquir Immune Defic Syndr. 2021 Jan 1;86(1):11-18*. doi: 10.1097/QAI.000000000002528.

Due to the effectiveness of antiretroviral therapy (ART) most persons with HIV (PWH) are achieving normal lifespans but not normal or healthy aging. A higher-than-expected rate of coinfections, comorbidities and complications (CCC) which are worsened by stigma, poverty, and isolation have been found in PWH. To address the research needs for HIV-associated CCC, the NIH brought together 96 medical experts and community advocates. From this group of individuals, five working groups (WG) participated in a year-long process of assessing the "state of the art" regarding numerous aspects of HIV care. It was the responsibility of the WGs to select three to five priority topics for presentation and discussion. The NIH then held a two day CCC workshop (HIV ACTION) that included over 400 participants. The format included general and individual WG presentations and discussions. Priority lists of vital research issues were presented by the co-chairs of each WG. The NIH planning committee identified six key areas of research: epidemiology and population including aging with HIV; pathogenesis and basic science that includes immunopathogenesis; clinical research that includes comorbidity management; implementation science; syndemics research including HIV-infectious syndemics; and international research in lowand middle-income countries that consist of research needs and curricular training in HIV/AIDS comorbidities. Going forward, the participants in the HIV workshop emphasized the need for "collaborative efforts of many disciplines" to implement this ambitious research agenda needed to improve the health and wellbeing for persons with HIV.

#### DR. JEFFREY KIRCHNER COMMENTARY:

As this is my last Clinical Research Update for the Academy, I thought it was appropriate to highlight this article. Even though the workshop convened over one year ago this paper will be published in the January 2021 issue of AIDS. Despite the remarkable effectiveness of ART over the past 20 years, there is still a great deal regarding chronic HIV infection that we do not know. Until there is a cure or an effective vaccine, there remains significant work that must be done by the HIV research and clinical care communities and should include issues relevant to PWH in the developed and developing world. This article from JAIDS contains the streamlined list and a summary of WG discussions to inform investigators of current research priorities in the field of HIV medicine.

Hessol NA et al. Risk of smoking-related cancers among women and men living with and without HIV. AIDS. 2021 Jan 1; 35(1): 101-114. doi: 10.1097/QAD.000000000002717. PMID: 33048871.

Non-AIDS defining cancers remain a common cause of morbidity and mortality among persons with HIV, and high rates of established risk factors (e.g., tobacco use, oncogenic viral co-infection) have been described among PWH. This study examined data collected through September 2019 from two large, well-characterized U.S. cohorts (Women's Interagency HIV Study and Multicenter AIDS Cohort Study) to determine whether the effect of smoking on incidence of smoking-related cancers differed by HIV status, if sex modifies impact of risk factors for smoking-related cancers, and the sex-specific attributable risk of smoking. A unique feature of this analysis was availability of information for a highly-similar but HIV-seronegative comparison group. Incidence rates, relative risks, and adjusted population attributable fractions were calculated based on data from 4,423 WIHS and 6,789 MACS participants (representing over 139,500 person-years of follow-up). Investigators observed 214 smoking-related incident cancers among MACS participants and 192 among WIHS participants, with the majority involving the lung/bronchus and diagnosed in the modern ART era (defined as 2001-2018). Ageadjusted incidence rates were significantly higher among PWH than seronegative participants, and were also higher among women versus men. Further, adjusted interaction models demonstrated that effects of cumulative pack-years were significantly stronger in women. Authors estimated that 31 percent of all smoking-related cancers were attributed to smoking more than 5 pack-years in a lifetime among PWH.

### DR. CAROLYN CHU'S COMMENTARY:

This is one of the largest studies examining the contribution of smoking on cancer burden among PWH, and its findings reaffirm our understanding that HIV appears to be an independent risk factor for smoking-related cancer development. The observation of higher incidence rates among women with HIV compared to men with HIV warrants further investigation. Among PWH, current motivations to quit smoking may be very different from historical ones; pandemic-related stress has also led to increased smoking for some. Tobacco use screening and evidence-based treatment strategies for smoking cessation are among the most impactful health interventions HIV providers can offer. **HIV** 





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