HIV SPECIALISI

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Novel Virus, Familiar Disparities

2020 has been an "at the time this was written" kind of year, and this edition of the HIV Specialist mirrors that leitmotif. The articles written herein are a snapshot in time of an evolving, all-consuming worldwide pandemic, and we hope they are still accurate and relevant as you read them. As a professional healthcare organization, obviously we felt compelled to devote much of the entire June issue to COVID-19 concerns (while still maintaining an HIV focus), even as many providers are starting to feel a kind of "coronavirus fatigue" with regard to medical narratives, clinical trainings, guidelines and strategies—and really just a full saturation of attention from all media.

It's hard to predict exactly what the SARS-CoV2 pandemic will look like when this magazine goes to print and arrives on your desks. Nevertheless, there are emerging universal themes in viral pandemics like HIV and COVID-19 that allow us to retain certain lessons. As Dr. Birx pointed out early on, there's still a lot to learn

from and remember about the early days of HIV/AIDS, as we confront another novel virus. I started working in the field well after HIV became considered - due to incredible treatment advances—a chronic condition, as opposed to the dire prognosis of the 80s and 90s. Many of the medical providers who worked on the clinical frontlines in the early days of "GRID", AIDS, HIV and so on are aging out of the workforce and have the stories to tell. They've seen something like this before and can apply those themes to clinics dealing with something similar today.

One of those themes, quite obviously, is disparities in health outcomes for blacks and other minorities in the US. Going back to the "at the time this was written" point, as I push these computer keys into my laptop, I can hear the now-ambient, ubiquitous sound of helicopters circling low over Washington, DC. Protests, most peaceful, some less so, have been raging in this and many other cities since the brutal killing of yet another unarmed black citizen by agents of the state. The protests were certainly triggered by police brutality, but have come to be infused, inevitably, with a much broader outcry against systemic racism. They could just as easily be about the staggering disproportionate effect of the coronavirus outbreak on black communities, where the mortality rate is about two and a half times higher than white Americans. As with HIV, this is not just about the microbiology of viruses.

Many of the changes to healthcare systems that we are witnessing now will likely be an engrained part of care delivery long term. New ways of caring for HIV patients, and those at risk, are being refined, as in-person clinic visits are restricted. There is cause for optimism here, even if there remain challenges. We need to learn more, too, about how the coronavirus interacts with HIV. Likely there are hundreds if not thousands of HIV patients who have acquired SARS-CoV2 in the US, and there is a strong desire to understand how that co-infection relates and responds to specific ARV regimens, CD4 counts, other OIs and any of the salient clinical markers of HIV disease. The Academy is co-sponsoring an HIV/COVID-19 registry started by the Institute of Human Virology at the University of Maryland in an effort to garner more clinical data on co-infections. You can read more about the registry here in this issue, and we hope you will participate.

As always, Academy members, HIV specialists and other frontline providers are the heroes of this story, not only in fighting a new virus, but also in advocating for and pursuing equality in healthcare access and outcomes for all patients regardless of demographics. We know "business as usual" is a difficult proposition at this juncture; but HIV care providers are trained and prepared for moments exactly like these. Thank you.





Ryan White Providers to Receive Funds Through the CARES Act

YAN WHITE HIV/AIDS PROGRAM (RWHAP) providers will receive grant awards from the Department of Health and Human Services (DHHS) enabling them to "prevent, prepare and respond" to COVID-19 as it affects RWHAP clients. In late March, Congress allocated \$90 million to be distributed to 581 RWCA grantees through the passage of the 2020 Coronavirus Aid, Relief and Economic Security Act or CARES (Public Law 116-136). CARES is designed to enable RWCAP providers to pay for their sudden and heavy COVID-related expenses. The grant allows reimbursement of related expenses to be dated back to January 20, as well as throughout the rest of the year.

CARES enables HIV health care services and providers to cope with the costs incurred by the combination of COVID-19 risk and HIV. It addresses a broad array of costs, including technical assistance and workforce training for RWCA personnel on COVID-19, overtime pay, expanded operating hours and adapting systems to provide safe home-based meals and

transportation assistance that meet social distancing requirements.

While DHHS clearly specifies that "all RWHAP COVID-19 awards must be used for services, activities and supplies needed to minimize the impact of COVID-19 on RWHAP clients," there are still questions as to what will or will not be covered by the Act. DHHS' "Frequently Asked Questions #CARES" document addresses many of these.

Some states are seeing this emergency funding as a much-needed windfall—not only due to the COVID-19 pandemic, but also as a response to the long-term, chronic underfunding they have endured. In 2018, for example, New Mexico's RWHAP services were provided to only 2100 out of the 3500 eligible state residents living with HIV. Further, 10.5 percent of the state's residents have no health insurance at all. U.S. Senator Tom Udal (D-NM), in a recent press conference said, "I will continue to fight for New Mexicans in subsequent coronavirus funding packages to increase support for critical programs like Ryan White funds that are vital to the health and well-being of our families and communities."

HRSA Funding Opportunity Supports HIV Care Planning in 7 Rural EHE States

The Health Resources and Services Administration's Federal Office of Rural Health Policy (FORHP) has issued a funding opportunity announcement under the Rural HIV/AIDS Planning Program to assist in the development of an integrated rural HIV health network for HIV care and treatment that will collaboratively plan to address key strategies identified in Ending the HIV Epidemic: A Plan for America (EHE). Rural public and rural nonprofit private health care provider organizations or providers of health care services in the seven states (Alabama, Arkansas, Kentucky, Mississippi, Missouri, Oklahoma and South Carolina) prioritized in the first phase of EHE because of a substantial number of HIV diagnoses in rural areas are eligible to apply.

Up to \$1 million is available to support up to ten \$100,000 one-year awards. Applications are due by July 10, 2020, with an anticipated project start of September 1, 2020.



HRSA defines a rural HIV health network (also called consortium) as an organizational arrangement among at least three separately owned regional or local health care providers that come together to develop strategies for improving health services delivery systems in a community. Health networks can be an effective strategy to help smaller rural health care providers and health care service organizations align resources, achieve economies of scale and efficiencies, collaboratively address challenges, and create impactful, innovative solutions.

The Rural HIV/AIDS Planning program offers rural health care providers the opportunity to collaborate on a plan to

address community HIV needs, gaps, and challenges, including issues related to the need for early diagnosis, comprehensive care that includes support services such as transportation, substance use treatment, innovative service delivery models with the goal of improving health outcomes among people with HIV, addressing stigma, and reducing the number of new HIV infections. The intent is for rural HIV health networks to expand access to HIV care, increase the use of health information technology such as Centers for Disease Control and Prevention data to care models, use telemedicine models for training and care, partner with Ryan White HIV/AIDS Program (RWHAP) recipients, explore innovative health care delivery models, and continue to promote quality health care across the continuum of care.

For more information on eligibility and other requirements as well as the application, visit HRSA's grants page.



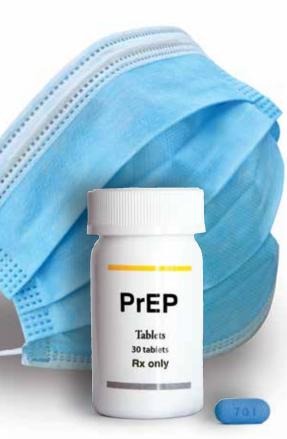
CDC Offers New Guidance on PrEP During COVID-19

HE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) developed guidance for providing PrEP when facility-based services and in-person patient-clinician contact is limited. For programs experiencing disruption in PrEP clinical services, CDC offers the following guidance for clinics to consider in the context of local resources and staff availability.

- 1. Reducing the number of new HIV infections remains a public health priority, and providing PrEP care is an essential health service. Clinicians should continue to ensure the availability of PrEP for patients newly initiating PrEP and patients continuing PrEP use.
- 2. Quarterly HIV testing should be continued for patient safety. Lab-only visits for assessment of HIV infection and other indicated tests for the provision of PrEP are preferred. When these are not available or feasible, CDC recommends considering two additional options.
 - The first option is a home specimen collection kit for HIV and sexually transmitted infection (STI) tests, which is covered by most insurance plans and can be ordered by clinicians. Some laboratories (such as Molecular Testing LabsTM) have validated protocols for testing home-collected samples for the panel of tests required for those initiating or continuing PrEP. Specimen kits are mailed to the patient's home and contain supplies to collect blood from a fingerstick or other appropriate method (e.g. self-collected swabs and urine). The kit is then mailed back to the lab with test results returned to the clinician who acts on results accordingly. This laboratory-conducted test is sensitive

- enough to detect recent HIV infection.
- The second option is self-testing via an oral swab-based test. Although this type of HIV self-test is usually not recommended for PrEP patients due to its lower sensitivity in detecting recent HIV infection during PrEP use, clinicians could consider use of these tests when other options are not available.
- 3. When HIV-negative status is confirmed, consider providing a prescription for a 90-day supply of PrEP medication (rather than a 30-day supply with two refills) to minimize trips to the pharmacy and to facilitate PrEP adherence. Several programs are available to help provide affordable PrEP medication including Ready, Set, PrEP, a nationwide program that makes PrEP medications available at no cost to individuals who qualify and lack prescription drug coverage; state drug assistance programs; and Gilead's Medication Assistance Program (MAP), which assists eligible HIV-negative adults in the United States who require assistance paying for PrEP.
- 4. If a PrEP clinic is considering closing or suspending services temporarily, health care providers should establish referral relationships with other clinics, telemedicine services, or pharmacies so that clients may remain engaged in PrEP care.

If PrEP clinical services have not been disrupted, providers should continue to follow recommendations outlined in the 2017 PrEP Clinical Guidelines and Clinical Providers' Supplement. To further ensure safe delivery of critical public health services, CDC has issued guidance for protecting public health workers engaged in public health activities that require face-to-face interaction.



NIH Study: Long-Acting Injectable Drug Prevents HIV Among Men Who Have Sex with Men and Transgender Women

N INVESTIGATIONAL longacting form of the HIV drug cabotegravir injected once every 8 weeks safely and effectively prevents HIV acquisition in men who have sex with men and transgender women who have sex with men. This finding, from a planned interim analysis of study data, marks the first time a large-scale clinical trial has shown a systemic, long-acting form of HIV prevention to be highly effective. The trial and an ongoing companion study evaluating long-acting injectable cabotegravir for HIV prevention in women are sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

Daily oral pills containing the drugs tenofovir and emtricitabine, such as Truvada or Descovy, are the only currently FDA-approved form of HIV pre-exposure prophylaxis, or PrEP. Taking a daily pill while feeling healthy can be challenging for some people, so investigators have been working to develop a long-acting alternative to oral PrEP that would be at least equally effective at preventing HIV. Such a long-acting prevention method may offer an easier, discreet option that may be more desirable for some people.

NIAID collaborated on the Phase 2b/3 clinical trial in men who have sex with men and transgender women with ViiV Healthcare, Gilead Sciences, Inc., and the NIH-funded HIV Prevention Trials Network (HPTN). NIAID and ViiV Healthcare co-funded the trial. called HPTN 083, and ViiV Healthcare and Gilead Sciences, Inc., provided the study medications.

Beginning in 2016, the HPTN 083 study team enrolled 4,570 HIV-negative men who have sex with men and transgender women who have sex with men at 43 sites in Argentina, Brazil, Peru, South Africa,



Thailand, the United States and Vietnam. The participants were considered at risk for HIV acquisition. Two-thirds of study participants were under 30 years of age, and 12 percent were transgender women. Half of the participants in the United States identified as black or African American. Participants were randomly assigned to receive either injections of cabotegravir and placebo oral tablets or placebo injections and daily oral Truvada tablets. Neither the participants nor the study team knew who was receiving which medication.

In a planned interim review of HPTN 083 on May 14, 2020, an independent data and safety monitoring board (DSMB) found that the study data clearly indicated that longacting injectable cabotegravir was highly effective at preventing HIV in the study population. Among the 50 people in the trial who acquired HIV, 12 were receiving longacting cabotegravir and 38 were receiving daily oral Truvada. This translated to an HIV incidence rate of 0.38 percent (95% confidence interval [CI] 0.20%-0.66%) in the cabotegravir group and 1.21 percent (95% CI 0.86%-1.66%) in the Truvada group.

Both cabotegravir and Truvada were generally safe and well-tolerated in the study population, and the DSMB found no safety concerns. Most participants in the cabotegravir group (80%) reported pain or tenderness at the injection site, compared to only 31 percent of those in the Truvada group, who received placebo injections.

Consequently, the DSMB recommended that NIAID stop the blinded phase of the trial, which was originally expected to continue until 2021, and share the results. NIAID has accepted the DSMB's recommendations and is releasing the results now to serve the interests of public health. The study investigators will report more detailed information about the HPTN 083 results

in the coming weeks.

The HPTN 083 study team and participants are being notified of the study results. All study participants, including those who initially received Truvada, will be offered long-acting cabotegravir as soon as it can be made available. Study investigators will continue following HPTN 083 participants to gather additional data about the long-term safety of injectable cabotegravir for HIV

The DSMB also reviewed data on May 14 from the Phase 3 companion study of long-acting cabotegravir for HIV prevention in women in southern and east Africa, called HPTN 084. That trial began a year later than HPTN 083, and the DSMB recommended that it continue as planned. To date, more than 3,000 sexually active women in seven African countries have enrolled in HPTN 084, which is co-funded by NIAID, ViiV Healthcare and the Bill & Melinda Gates Foundation.

More information about HPTN 083 and HPTN 084 is available on ClinicalTrials.gov using the identifiers NCT02720094 and NCT03164564, respectively.



Academy joins Lambda Legal to Urge Supreme Court to Uphold the Affordable Care Act

HE AMERICAN ACADEMY OF HIV MEDICINE is one of 16 non-profit HIV organizations that joined Lambda Legal and Ropes & Gray to file a friend-of-the-court brief with the U.S. Supreme Court arguing in support of 19 states and DC, led by California, and the U.S. House of Representatives who are collectively defending the Affordable Care Act (ACA). The brief also appeals a ruling from the Fifth Circuit Court of Appeals that invalidates a key provision of the ACA and threatens the law in its entirety.

In the brief, Lambda Legal urges the Court to uphold the constitutionality of the ACA and describes the role it has had in expanding health care coverage for people living with HIV, particularly those with lower incomes or who have faced barriers to care in the past such as LGBTQ people and people of color.

"The COVID-19 pandemic highlights why broad and easy access to health care is so important. As a country, we must ensure access to health insurance and comprehensive, affordable care. The ACA, and in particular its expansion of Medicaid, has helped countless people obtain health insurance who were otherwise left to fend for themselves when they got sick. Its antidiscrimination protections on the basis of sex, race, disability, and those who have pre-existing conditions such as HIV have been critical to eliminating barriers to health care," said Omar Gonzalez-Pagan, Senior Attorney and Health Care Strategist at Lambda Legal.

"If the Court does not uphold the ACA, the impacts to our communities, especially on LGBTQ people and people living with HIV who are people of color and lower-income, will be catastrophic."

ACA reforms have helped an estimated 20 million people obtain health insurance and with it access to lifesaving medical care, including many living with HIV who were previously denied coverage because their HIV status constituted a pre-existing condition or because they simply could not afford it.

"By making HIV testing, PrEP and antiretroviral medications more easily accessible, the ACA has ushered in an era of new progress in the fight against HIV," said Scott Schoettes, HIV Project Director at Lambda Legal.

"We are starting to see the positive impact of this policy in reduced rates of HIV transmission in states like Louisiana and Illinois, which have reported significant drops in new cases. An end to the HIV epidemic is within reach and to dismantle a successful health policy that has made that level of optimism possible is unfathomable."

This is the third challenge to the ACA since its enactment in 2010 to come before the U.S. Supreme Court. The Justices will consider the constitutionality of the individual mandate, now that the penalty for failing to obtain health insurance was reduced to \$0, and whether it can be "severed" from the rest of the law, allowing the other provisions to stand, including such provisions as the expansion of Medicaid and antidiscrimination protections for LGBTQ people and those who have pre-existing conditions such as HIV.

In March 2020, the U.S. Supreme Court announced that it would review the decision from the Fifth Circuit Court of Appeals. which ruled that the individual mandate was unconstitutional and indicated in remanding the case that it likely cannot be severed from important aspects of the rest of the law.

Oral argument is expected to take place in the Fall of 2020 and a decision would likely happen by the end of the term in the summer

The cases are California v. Texas, brought by 19 states led by California and includes New York, Illinois, Virginia, Massachusetts,



Connecticut, Delaware, Hawaii, Minnesota, New Jersey, North Carolina, Oregon, Rhode Island, Vermont, Washington, Colorado, Iowa, Michigan, Nevada, the District of Columbia, and the governor of Kentucky, and Texas v. California, led by Texas on behalf of that state, Alabama, Arizona, Arkansas, Florida, Georgia, Indiana, Kansas, Louisiana, Mississippi, Missouri, Nebraska, North Dakota, South Carolina, South Dakota, Tennessee, Utah, and West Virginia.

The U.S. House of Representatives intervened in support of the states led by California and in defense of the ACA.

Lambda Legal Senior Attorney and Health Care Strategist Omar Gonzalez-Pagan. Counsel Gregory R. Nevins and Counsel and HIV Project Director Scott Schoettes joined Kirsten Mayer, Douglas Hallward-Driemeier, John T. Dey, Brendan McLaughlin, Ryan Sullivan and Megan A. McEntee of Ropes & Gray LLP as counsel on the brief.

Signatories include AIDS United, American Academy of HIV Medicine, Black AIDS Institute, Center for Health Law and Policy Innovation, GLBTQ Legal Advocates & Defenders, Housing Works, Human Rights Campaign, Latino Commission on AIDS, National Alliance of State & Territorial AIDS Directors, National Black Justice Coalition, National Center for Transgender Equality, National Minority AIDS Council, Positive Women's Network - USA. The AIDS Institute. and Whitman-Walker Health and the Whitman-Walker Institute.

AAHIVM and the Institute for Technology in Health Care Name PositiveLinks as their 2020 Award Winner

he American Academy of HIV Medicine and the Institute for Technology in Health Care have awarded the 2020 Caceres Award for Technology in HIV Practice to Drs. Rebecca Dillingham and Karen Ingersoll of the University of Virginia (UVa) Ryan White Clinic for their PositiveLinks (PL) digital application. PL is a clinic-deployed, smartphone-based platform that provides tools and support to people with HIV (PWH) to improve medication adherence and engagement with care. It includes a patient-facing app, a provider-facing app, a web portal for providers, and an on-line training system. (See website here: www.positivelinks4ric.com).

The technology was developed to address the stigma, poor access to transportation, isolation, substance use, and mental health challenges facing many PWH in rural Virginia. Dr. Dillingham, an infectious disease physician, and Dr. Ingersoll, a clinical health psychologist, collaborated to create PL by adapting evidence-based behavioral interventions to improve adherence to ART, as well as to reduce stigma, depression, and isolation.

The PL patient app features include medication reminders, mood and stress check-ins, educational resources, an anonymous community message board (CMB), secure document upload, and private provider messaging. PL shrinks physical and psychological distance between patients and care providers. It expands connections among PWH in a space that is experienced as safe. It provides important tools that support self-monitoring, care coordination, and social support—all in a secure mobile app.

The provider-facing PL app and web portal facilitate providers' ability to monitor patient-reported data about adherence and mood. They also permit "texting"-like messaging in a health system-approved environment that allows for the flexibility and efficiency of texting. Embedded telehealth

capability was recently added to PL, allowing PWH who participate in the program the option of securely accessing medical and mental health care through the PL app while maintaining social distancing.

Development of PL was supported originally by AIDS United beginning in late 2012. Since 2017, based on the successful pilot, the Virginia Department of Health (VDH) has supported expansion of PL as a usual care service at UVA and at other organizations that support the care of PWH.

Thanks to the visionary support of the Virginia Department of Health (VDH), the tool is available at no cost to clients, and, in fact, if used regularly, can qualify clients for assistance with cellular voice and data access, an increasingly recognized social determinant of health.

"The ability to remain in touch through a cell phone, whether with calls or through an app, may become increasingly important as the recommended number of visits to an HIV care provider decreases based on the less frequent need for CD4 and viral load monitoring," stated Dr. Dillingham. "In addition, care coordination and secure messaging is growing in importance for our aging PWH population who have a rising number of medical co-morbidities."

Dr. Dillingham, Dr. Ingersoll and their team

have documented the impact of PositiveLinks in a demonstration project with the first 77 enrollees. PL implementation resulted in a 30 percent absolute increase in engagement in care (51% to 81%) and a 22 percent absolute increase in viral suppression (47% to 79%) at 12 months in a population of PWH who were identified by providers as being poorly engaged in care. These positive results have now been extended to 24 months, as reported in a recent publication.

in the US including a rural-based academic hospital; an urban health system; a rural Federally Qualified Health Center; a community-based organization serving a large population of people who speak Spanish; an adolescent clinic; and an independent RW clinic associated with a community-based organization.

In its ninth year, the Caceres Award for Technology in HIV Practice seeks to acknowledge those who have created, adapted and/or used innovative technology in their HIV practice and to share that technological knowledge with others in the practice of HIV medicine to improve patient care. The name of the award was recently changed to honor the passing of Dr. Cesar Caceres, founder of the Institute for Technology in Health Care.

IN HONOR OF DR. CESAR CACERES, founder of The Institute for Technology in Health Care, the Academy will be changing the name of our joint award to the Caceres Award for Technology in HIV Practice. Dr. Caceres passed away earlier this year, leaving behind a profound legacy in HIV care innovation.

In 1970, Dr. Caceres opened his private practice integrating computer technology into the day-to-day real world of medical practice. Beginning in the 1980's Dr. Caceres developed for use in his practice The System Integrated Record, S.I.R. Dr. Caceres is also credited with coining the term "Clinical Engineering." Dr. Caceres joined the Board of Directors of the Association for the Advancement of Medical Instrumentation (AAMI) in 1969 and as President of AAMI from 1971-1972.



TLIGHT

BY AARON AUSTIN, MEMBERSHIP DIRECTOR

Ogechika Karl Alozie, M.D., MPH, FACP, AAHIVS

El Paso, Texas

EFORE LAUNCHING HIS CAREER IN HIV CARE, Dr. Alozie attended medical school at the University of Benin Medical School in Benin, Nigeria, His education in the developing world was public health-focused and centered on issues like water, malaria and tuberculosis. After medical school, Dr. Alozie moved to Minnesota to complete his Internal Medicine residency at Hennepin County Medical Center before doing an Infectious Diseases fellowship and earning his MPH at the University of Minnesota, where he also served as head of student health services and volunteered for a few organizations that handled HIV care in minorities.

It was about 10 years ago when he moved to El Paso, Texas. Since then, Dr. Alozie has worked in every hospital in the city and has created not one, but two HIV clinics from the ground up. First, working as a new assistant professor with an academic health center, Dr. Alozie led a team in creating the university's first dedicated HIV clinic. In 2014, Dr. Alozie left the university to pursue new ventures. He founded a non-profit organization focusing on Ryan White care and providing a shared clinic case management navigation space for HIV clients; ensuring these patients received the best care possible. Dr. Alozie recalls, "Truthfully, I really had no idea how Ryan White funding mechanisms worked, what 340B was, or how to grow a team and clinic. However, with lots of determination, we have built one of the best, we believe, HIV groups in the state of Texas and I'm immensely proud of that."

When asked what motivated him to pursue specializing in HIV care, Dr. Alozie recalls, "As I began my career, initially my desire was to become a cardiologist. As I was pursuing my MPH in cardiology, one summer my mom called me and told me her sister, my aunt, had been diagnosed with HIV in Nigeria. I'm not sure what it was, if it was the process of engaging with my mom and aunt learning about resources for HIV care in Nigeria and the host of many other things to help her with her journey, but something ignited a fire in me and HIV became my new focus; HIV, infectious diseases and a focus on public health as a whole."



moday, Dr. Alozie's non-profit organiza-is responsible for the care of about 1,300 persons living with HIV (PLWH) and other related viral diseases, like hepatitis C. SWVM uses technology and outreach to engage deeply with the community and drive some of the best HIV outcomes in the state of Texas. Dr. Alozie is joined on his team by a nurse practitioner, clinical PharmD, outreach navigators, as well as core clinical staff such as their Director of Operations, HIV Technology Specialist, and two certified medical assistants. At SWVM, the most common age demographic is between 25 and 44; this has changed over the last few years away from the 45+ demographic. Of their total patients, 88 percent are male, 12 percent are female, which has remained consistent over the years. Over 90 percent of their patient population is Hispanic/Latinx.

At SWVM, Dr. Alozie is driven by public health and epidemiology and is constantly analyzing data to improve systems of care. They leverage technology to engage patients and ensure they have access to care, particularly with newer populations of young 'digital natives.' Whether it's the patient portal, text outreach campaigns or telemedicine, providing multiple channels of access to care is what they consistently analyze. They gauge effectiveness, make revisions and remain flexible to try something different.

"My approach to patient care has always been the same," says Dr. Alozie, "to be compassionate but honest with my patients. They come to me and look to me to tell them the truth yet still give them hope. I know they say hope is not a strategy, but when it comes to patient care in the disease state of HIV, AIDS, and hepatitis C, that initial hope is what people latch onto to give them strength to go on and fight that battle. I've always been that kind of physician and my patients know I will support them. I'll be that to them, but also tell them when I think they're not being honest with me, but more importantly themselves, and they need to make changes. There's a saying I'm sort of famous for, I'm not even sure where I got it, I probably stole it from someone. But during one of the initial visits I tell my patients, 'This is like a date. If the date goes well, I hope you come back and we'll continue working through this relationship. If it doesn't, and I'm not the right one for you, let's find a provider with whom you'll have a thriving, successful, happy relationship.' I let my patients know we are in this together, but if they are doing something to jeopardize their ability to thrive, I'm going to correct them and that's really my approach to patient care."

Dr. Alozie cites talking to clients and their families, especially during initial visits, as the most rewarding part of his job as an HIV specialist. He takes pride in having the ability to bring a sense of calm to these patients by explaining HIV is not a death sentence. Medicine has evolved and HIV is something we can work together to manage, work through, and not only survive, but thrive. Says Dr. Alozie, "The thoughts that bring me the most joy are those patients I've seen in the hospital. They had been put on hospice care. other physicians told them they were going to die so their families had given up. However, working with them, finding the right regimen, combining medicine with our care management and navigator teams, it's amazing that six months later they've come back into clinic

"... I know they say hope is not a strategy, but when it comes to patient care in the disease state of HIV, AIDS, and hepatitis C, that initial hope is what people latch onto to give them strength to go on and fight that battle..."

unrecognizable, totally new people with a new lease on life." Dr. Alozie's biggest challenge or obstacle is having patience to deal with the bureaucracy around getting patients the care they need and deserve. "I've learned to understand that systems are in place sometimes for a reason and sometimes they are there just to exist. We must stay dedicated to continue to look for ways to improve the systems and educate, educate, educate!"

The subject of education is one about which Dr. Alozie is passionate. "When I look at HIV and understand that it's a disease of the U.S. South, it makes me sad that in most academic health centers across the South young Black and Hispanic students are not being educated on HIV in an engaging, enlightening and exciting manner." Dr. Alozie hopes to continue to work with organizations like AAHIVM, AIDS Education and Training Centers (AETC), academic health centers and pharmaceutical industry supporters to ensure we are equipping the future of healthcare with the tools and mindset necessary to work in healthcare today and in the future.

Looking to the future, Dr. Alozie envisions a greater focus on prevention and long-acting suppression. He considers today's advances around Undetectable = Untransmittable (U = U), rapid start and the new round of injectable medications to be just the tip of the iceberg. Upcoming therapeutics have the ability to reduce patients' viral loads consistently and durably, but also to reduce the risk of new persons contracting HIV. From a workforce or person-power standpoint, Dr. Alozie thinks the future of HIV is in the hands of clinical pharmacists, nurse practitioners and physician assistants. This is not because he

believes physicians shouldn't manage HIV, but Dr. Alozie says, "the financials of healthcare and a dwindling workforce of physicians in HIV and infectious diseases make it imperative that we focus on the young healthcare team members who are out there."

utside of work, sports, especially basketball and soccer, and his family have always been Dr. Alozie's drivers. "Showing my kids that hard work and the ability to adapt and overcome are important aspects of life." He prioritizes giving back to his community. For the last two years, he has volunteered and worked with friends to set up public health and eye exam fairs in areas within Nigeria. "Giving back to my community has always been important from when I was a student to now being a respected professional here in El Paso and other communities. I believe giving back via community service is critically important to growth and I've focused mine around my passion for education. I am dedicated to educating the next generation, being available for them to ask questions and learn from my speeches and presentations."

Asked why he joined AAHIVM as an Academy member, Dr. Alozie says, "As I was finishing my HIV fellowship at University of Minnesota, I came across AAHIVM. It was organization that conducted continuing education and outreach, which is what piqued my interest, and I became drawn to it. Not only to have a community of HIV care providers, but to increase my skillset, make connections and really develop in my HIV career. Since I've been in Texas and aligned with the Academy, I've had opportunities to attend sessions and been able to teach sessions. I truly believe that the Academy continues to push HIV-focused agendas for the future of HIV in America." HIV

AARON AUSTIN is the AAHIVM Membership Director. Aaron began working with the Academy in 2008 and is currently completing coursework for his MPH at the George Washington University Milken Institute School of Public Health.

FRONTLINES

Trichomonas Vaginalis in Women with HIV

The Forgotten Pathogen

BY WILLIAM R. SHORT, MD, MPH, AAHIVS

RICHOMONIASIS, caused by the protozoan Trichomonas vaginalis, is the most common non-viral sexually transmitted infection (STI). The prevalence of Trichomonas vaginalis in the United States (US) is estimated to be approximately 8 million cases annually.

Determining the exact prevalence is difficult for several reasons: Trichomonas is not a reportable infection, there is a low sensitivity of wet mounts, and many infections are asymptomatic. In a nationally representative sample of 4463 females using urine samples who participated in the National Health and Nutrition Examination Survey (NHANES) in 2013-2016, the prevalence was 2.1 percent among women aged 14–59. Prevalence was 9.6 percent for African American women, 1.4 percent for Hispanic women, and 0.8 percent for non-Hispanic white women. Factors that were associated with Trichomonas vaginalis were younger age at sexual debut, greater number of sex partners, and a history of Chlamydia infection in the past year.1

Microbiology

Flagellated protozoa are widespread in nature and move by means of a flagellum. Although several flagellate genera parasitize humans, only four, Trichomonas, Giardia, leishmania, and Trypanosoma, commonly induce disease. Three members of the genus trichomonas parasitize humans but only one, Trichomonas vaginalis, is an established pathogen.

Trichomonas vaginalis is oval and measures 7um by 15um and has

five flagella that arise anteriorly (Figure 1). It exists only in the trophozoite stage and lacks a cyst form so it can only survive outside of the body on moist surfaces for 1-2 hours. Trichomonas can be isolated in the vagina, cervix, urethra, bladder, Bartholin glands, and Skene glands where they replicate by binary fission. (see life cycle Figure 1)

Clinical Presentation

Transmission of Trichomonas occurs predominantly through sexual intercourse. The organism is commonly isolated from vaginal secretions in women and symptoms can range from none to pelvic inflammatory disvaginal discharge which may be purulent,

frothy, or bloody. Other clinical manifestations include vulvovaginal itching, burning, dyspareunia, dysuria, post coital bleeding, lower abdominal discomfort.2

Trichomonas and HIV Interaction

There is strong evidence that *Trichomonas* vaginalis both increases both the transmission and acquisition of HIV among women but with successful treatment genital shedding of HIV is reduced. A recent systematic review and meta-analysis demonstrated that Trichomonas vaginalis is an important factor in HIV acquisition and suggests that it augments the likelihood by 50 percent (HR 1.5; 95% CI 1.3 to 1.7).3 This highlights the rationale for routine screening and prompt treatment.

Diagnostic Considerations

The most common method for diagnosing Trichomonas vaginalis is by a wet mount because it can be done in the office by obtaining a swab of vaginal secretions, looking under the microscope, and making a quick diagnosis; however, the sensitivity from vaginal secretion is very low 51-65 percent. In addition, the sensitivity declines over time and is decreased by 20 percent within 1 hour after collection. If you are relying on this test, you are most likely missing the diagnosis of Trichomoniasis.2

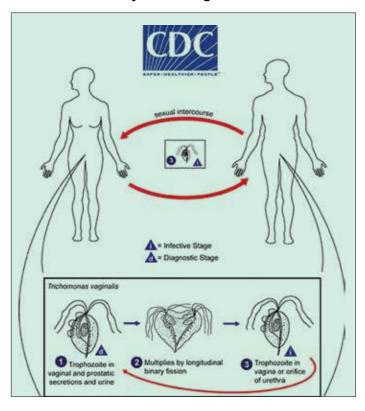
In the past, culture was the gold standard and it was much more sensitive. It has a sensitivity of 75 percent to 99 percent and a specificity of up to 100 percent. However, it requires that you have the culture medium, Modified Diamonds Medium or other media formulated to support the growth of *Trichomonas* vaginalis, readily available in your office and it needs to be inoculated immediately. Modified Diamonds Medium has been found to be an effective medium for the culture of this organism. It is enriched with yeast extract and

FIGURE 1. Two trophozoites of T. vaginalis obtained from in vitro culture, stained with Giemsa



ease. Women often present with an abnormal

FIGURE 2. The Life cycle of T. vaginalis



supplemented with inactivated horse serum, Amphotericin B, penicillin G, and gentamicin which allows trichomonads to grow while suppressing bacterial growth.

Currently, the use of highly specific tests, Nucleic acid amplification tests, (NAATs), are recommended for detecting Trichomonas. This assay detects RNA by transcription-mediated amplification. The APTIMA T. vaginalis assay is FDA-cleared for detection of Trichomonas vaginalis in vaginal, endocervical, or urine specimens and it has a sensitivity of 95.3 percent to 100 percent and specificity of 95.2 percent to 100 percent.

TABLE 1. Treatment Recommendations

	Women with HIV	Women without HIV	
Recommended treatment	Metronidazole 500 mg twice daily for 7 days	Metronidazole 2g orally in a single dose OR Tinidazole 2g orally in a single dose	
Alternate treatment		Metronidazole 500 mg twice daily for 7 days	

Screening Recommendations

Routine screening is recommended for all women with HIV. Screening should occur at entry into care and at least annually. In addition, women who present with vaginal complaints should be tested for Trichomonas vaginalis.2

Treatment

Women with HIV should receive the same treatment as those who are HIV negative with the exception of the dosing frequency.2 Table 1 summarizes the recommendations. A randomized clinical trial involving women with HIV demonstrated that a single 2g dose was less effective when compared to 500 mg twice daily for 7 days. Patients were randomly assigned to treatment with metronidazole 500 mg twice daily for 7 days or with metronidazole 2g in a single dose and the seven day treatment group had a lower rate of positive cultures 6 to 12 days after treatment completion (8.5% versus 16.8%; relative risk 0.5, CI 0.2555-1.00) and at 3 months (11% versus 24.1%; relative risk 0.46, CI 0.21-0.98).4 Based on this randomized trial, the recommended treatment dose and duration is metronidazole 500mg twice daily for 7 days.2

On additional concern with the use of the single dose of metronidazole is that there is a high rate of asymptomatic bacterial vaginosis in women with HIV and other factors such as the vaginal ecology and impaired immunity that may interfere with the efficacy of standard dosing.5 The Centers for Disease Control and Prevention (CDC) recommends rescreening at 3 months after the treatment for women living with HIV due to the likelihood of recurrent or persistent infection.²

Conclusion

Trichomonas vaginalis is the most common non-virally transmitted STI and is found in a high proportion of women living with HIV. Providers need to be familiar with Trichomonas and its clinical presentation, diagnostic dilemmas, treatment considerations, and complications. In addition, treatment of Trichomonas vaginalis may have an impact on HIV acquisition and transmission. HIV



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How lessons from one pandemic may save lives in another

BY JOSEPH S. CERVIA, MD, AAHIVS

ELEASED IN 1985, the same year as HIV antibody testing, the sci-fi classic, Back to the Future, is the story of small-town California teen Marty McFly (Michael J. Fox) who is thrown back 30 years into the past when an experiment by his eccentric scientist friend Doc Brown (Christopher Lloyd) goes awry. Marty recognizes that he must ultimately return to his own time, using what has been learned and achieved in order to save a life.

As I observe the current global SARS-CoV-2/COVID-19 pandemic, I feel as though I have been thrown back three decades, my heart racing like Marty's, eager to capture some lessons learned from our early struggles with the ongoing HIV/AIDS pandemic, which may better inform our response and save lives today.

Reflecting upon the unspeakable suffering experienced by HIV-infected patients, their loved ones and caregivers in the early years, it is difficult to miss a striking parallel to the anguish borne by those battling the current pandemic of COVID-19. For certain, the two pandemics have a number of important similarities as well as differences. Both are due to novel viruses with zoonotic origins. However, their modes of transmission are very different. Both HIV-1 and SARS-CoV-2 can be deadly and attack indiscriminately, while disproportionately impacting communities struggling with poverty; however, the latter has advanced through the population with much greater facility and alacrity, resulting in more sudden and widespread disruption of life across the globe.

Finally, both viruses emerged, at first, rather poorly understood, with limited diagnostic testing and no known treatment; whereas, today's more advanced molecular tools have vastly facilitated the development of targeted diagnostics, and offer the promise of swifter development of vaccines and therapeutics. Modern electronic media offer means for more efficient communication and data sharing.

Acknowledging these important similarities and differences, the following 10 lessons learned three decades ago in the early response to the HIV/AIDS pandemic can enlighten the current journey for patients, caregivers and clinicians battling SARS-CoV-2/COVID-19.

Silence = Death: Denial can be Deadly

Denial, a very human initial defense mechanism when coping with a new and frightening reality, can become extremely dangerous when it hampers a prompt and effective response to that reality. Although early reports of what ultimately became known as AIDS were published in June 1981, it was not until 1985 that President Ronald Reagan first mentioned it publicly. Subsequently, global HIV/AIDS denialism, which ignored clear scientific evidence of HIV as the etiology of AIDS, discouraged HIV-positive individuals from using proven treatments. It also justified the policies of some nations which would not sustain the cost and effort to make treatment available, resulting in countless additional infections and lives lost. Recognizing the critical importance of truth and transparency, AIDS activists embraced the slogan, "Silence = Death."

Dr. Li Wenliang, a Chinese ophthalmologist who worked as a physician at Wuhan Central Hospital, warned his colleagues in December 2019 about a possible outbreak of an illness that resembled severe acute respiratory syndrome (SARS), later acknowledged as COVID-19. Dr. Li, who subsequently contracted and died of the infection, was initially discredited by his government. Meanwhile, closer to home, as COVID-19 began to spread across the United States, President Donald Trump repeatedly insisted that it was nothing to worry about. Two months later, the United States became the first country in the world with more than 100,000 cases, the

economy had ground to a near standstill, and the virus had killed more than 104,000 in the US alone

Refuse to Play the Blame Game: Fight the Stigma

As observed in society's early response to HIV/AIDS, inadequate scientifically-driven understanding of pandemic illnesses contributes to stigma, and promotes the tendency to lay blame upon victims, which in turn, delays definitive efforts directed toward enhancing diagnostic testing, research and appropriate care. Community support and activism by groups such as Gay Men's Health Crisis (GMHC) and AIDS Coalition to Unleash Power (ACT UP), and by professional societies such as the American Academy of HIV Medicine (AAHIVM) have demonstrated the critical role of advocacy. Today, individuals affected by the current pandemic and those who care for them must lend their voices to rally continuing support for better understanding and scientifically sound, effective preventive strategies and treatments for COVID-19 illness. This may take the form of public advocacy, by means of financial and/or volunteer support for healthcare organizations, political activism (e.g. lobbying efforts), research involvement (e.g. volunteering as collaborators or subjects), and active participation in community-wide educational efforts in the press, and electronic media

It's a Small World After All

Pandemics have a way of reminding society that it's one human family, inhabiting a predominantly microbial world. With its origins in Africa, blood and body fluid-borne HIV silently crept across continents in the 1970s, before becoming evident in the succeeding decades. Abetted by its very efficient respiratory transmission, SARS-CoV-2 raced much more rapidly across the globe following its early identification in Wuhan, China in December 2019. Respecting no geopolitical boundaries, deadly viruses illustrate that the world is a small after all. We must remain vigilant and concerned about emerging infections and the underlying socioeconomic and cultural challenges faced by neighbors across the globe.

Individuals and families grappling with serious COVID-19 illnesses and their loved ones often face cruel separations wrought by the nature of the affliction, which are only exacerbated by the nature of care delivery in the setting of an acute public health crisis. Courageous and compassionate cooperation with and among embattled care providers is inspiringly reminiscent of the early days of HIV/AIDS.

Team Up: Collaboration is Critical

An optimal model of multidisciplinary primary care with integrated HIV subspecialty services has been offered for decades by teams optimally consisting of physicians, physician assistants, nurse practitioners, nurses, pharmacists, social-work case managers, mental health professionals, nutritionists, chaplains and other dedicated caregivers. These team members have often developed long-standing and intimate bonds with patients and family members. The very strength of these bonds, forged by shared struggles against demons such as poverty and its associated calamities, social stigmatization, substance use, and all too often, the concurrent illnesses and deaths of multiple family members, has made it possible to compassionately and systematically address the needs of individuals and families battling HIV. Similarly, individuals and families grappling with serious COVID-19 illnesses and their loved ones often face cruel separations wrought by the nature of the affliction, which are only exacerbated by the nature of care delivery in the setting of an acute public health crisis. Courageous and compassionate cooperation with and among embattled care providers is inspiringly reminiscent of the early days of HIV/AIDS.

The value of team effort also extends to clinical research infrastructure. The pace of developments in the fight against HIV/AIDS could never have been attained without strong industry, academic, community and government collaboration. Multi-centered clinical trials networks, such as the AIDS Clinical Trials Group (ACTG) and International

Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network have learned and demonstrated the synergies accruing to organizing themselves into research agenda committees and working groups, comprised of physicians, basic scientists, pharmacologists, biostatisticians, nurses, mental health professionals, and community advisory board members infected with and/or affected by HIV. The research community has certainly appreciated the critical role of collaboration, and has rapidly rallied to accelerate the development of COVID-19 treatments, with for example, the World Health Organizations' (WHO) March 20th launch of the "Solidarity" trial, an unprecedented collaborative study intended to simplify enrollment and follow-up of thousands of patients in dozens of countries amidst the onslaught of the pandemic. The WHO's website will randomize patients to local standards of care or with one of four drug regimens, utilizing the ones available in the patients' hospitals.

Screen Widely

Shortly after the viral etiology of AIDS was identified, reliable screening tests became available. Nevertheless, their widespread implementation lagged despairingly. There was little enthusiasm for identifying individuals afflicted by a stigmatizing illness for which effective treatment appeared to be lacking. With attention to fighting stigma and establishing operational care and research networks, screening has continued to become much more widely accepted. In addition, success in generating more efficacious and better-tolerated therapeutic options has

further bolstered support for widespread screening.

Reliable screening for SARS-CoV-2 and associated antibodies has proven critical in early identification of those at risk and affected. Efforts to more rapidly roll out widespread, community-based screening will facilitate the effort to fully comprehend the extent and nature of this pandemic, and to better direct evidence-based public health efforts. However, more effective screening cannot await optimal therapeutic options, since as was learned in battling HIV, research advances toward safer, more efficacious treatments await the participation of those at risk and infected. If better solutions are to be uncovered in the lifetimes of those infected, they and those who care for them must be a part of that effort.

Let Science Take the Lead

The early years of the HIV/AIDS pandemic were marked by a very real sense of fear and foreboding. This fear sometimes found expression in irrational and cruel responses, such as the avoidance of infected individuals. The ultimate antidote to fear proved to be science and education. Advances in the understanding of the virus promoted more rationale, effective, and humane responses.

Fear of COVID-19 today is palpable, and has found expression in isolation, hoarding and shortages of much needed items such as personal protective equipment. Unfortunately, in the early weeks of this pandemic, limited community-based testing has resulted in incomplete information and inconsistent messaging, which has only exacerbated public anxiety. The ultimate solution lies in allowing science to once again lead. With the benefit of myriad advances in molecular virology, immunology, pharmacology, and information technology over the past three decades, the tools to better comprehend and address the challenges presented by SARS-CoV-2 and the means to communicate about them are well within grasp.

Sometimes Old Drugs can Learn New Tricks

The first weapon against HIV, zidovudine or azidothymidine (AZT), was originally developed in the 1960s as an anti-neoplastic agent; however, it was set aside after having

been found ineffective for that purpose in animal models. Two decades later, Burroughs Wellcome, already known for its antiviral drugs, included AZT in its screen for possible anti-retroviral agents and uncovered its efficacy. At this early stage in COVID-19 research, repurposed older drugs such as the anti-malarial immunomodulatory agent hydroxychloroquine with or without the acid-reducing histamine 2 receptor blocker famotidine, the nucleotide analogue anti-Ebola viral drug remdesivir, and immunomodulators tocilizumab and sarilumab, both approved for rheumatoid arthritis are among the early objects of clinical trials.

Share the Wealth

Translating promising basic and clinical research findings into standards of care requires attention to regular communication among experts, and between those experts and front-line providers, patients and caregivers. For many years, comprehensive HIV care guidelines have been widely available and regularly updated with each version prominently marked with a freshness, 'last updated' date. This practice becomes all the more relevant as the pace of research progress accelerates.

Novel basic science and clinical research advances in the diagnosis, prevention, and treatment of COVID-19 must be regularly vetted by experts, and best practices disseminated in the form of comprehensive and current clinical practice guidelines. Armed with modern electronic media, the integral collaboration of government, industry, and the community as part of the larger research team will facilitate this ongoing process of communication.

It's a Marathon, not a Sprint

The HIV/AIDS pandemic is now in its fourth decade, and despite all of the advances in prevention, diagnosis, and therapy, some 38 million individuals remain infected, with as many as 1.7 million new infections each year globally. Clearly, patient and persistent efforts must continue in order to finally put an end to it. With it being only months into the SARS-CoV-2/COVID-19 pandemic, it is already deeply impacting lives throughout the world. Many are expressing great impatience with the public health efforts directed at controlling it, but it is key to remain steadfast and diligent in the efforts.

Keep the Faith

In what might arguably have been the darkest days of the HIV pandemic, I shared a vision with my pediatric HIV team of a time in the not too distant future that we would be able to hang a "Gone Fishin" sign on the clinic door. It seemed laughable at the time, but we kept smiling, and worked to ultimately bring reality to that vision.

All who would venture to undertake the goal of better outcomes for those battling COVID-19 must share a steadfast belief that it can and will be achieved. In the words of Francis of Assisi, "Start by doing what's necessary, then do what's possible, and suddenly you are doing the impossible." Fortified by lessons learned three decades back, with ardent advocacy, relentless research, compassionate care, and limitless love, this is another battle worth fighting to win. HIV



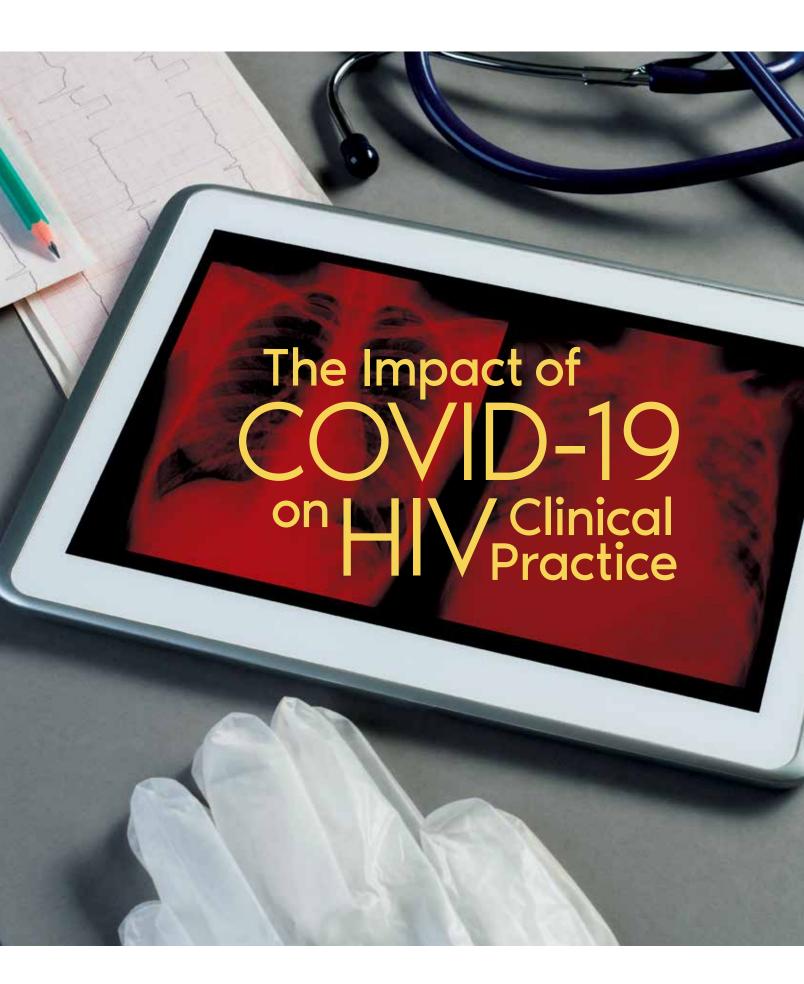
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SHUTTERSTOCK/ KHAKIMULLIN ALEKSANDR

BY CLEOPHAS d'AUVERGNE, MD, MPA, (DIP TB WHO/USAID), AAHIVS

ARS-COV-2 is an RNA virus from the coronavirus family, the causative agent of COVID-19. With nearly 6,000,000 cases worldwide, 365,000 deaths and detection in at least well over 200 countries, it continues to evolve with devastating medical and socio-economic sequelae. The challenge with this virus is that the global population has no underlying immunity since it is novel and much about SARS-CoV-2 unknown. Likely zoonotic transmission occurred from infected bats to an intermediate host mammal which is believed to be a Pangolin.² Symptoms of COVID-19 are non-specific and the disease presentation can range from no symptoms (asymptomatic/presymptomatic) to severe pneumonia and death.

According to data from the Chinese Center for Disease Control and Prevention, almost 80 percent of persons who contract the virus will experience no or mild symptoms, while 15 percent may experience severe symptoms requiring hospitalization and about five percent, critical care.3

One of the most troubling aspects of the disease is the silent spread among pre-symptomatic persons. Studies from China indicate pre-symptomatic transmission of 12.6 percent while investigation of all 243 cases of COVID-19 cases in Singapore during January 23rd through March 16, 2020 revealed a 6.4 percent rate of pre-symptomatic transmission. 4 The shedding is more impactful in children because of their mild symptoms, low disease severity and depth of interaction with other age groups.

The median incubation time for SARS-CoV-2 is four to five days and of those that are symptomatic, 97.5 percent will experience symptoms within 11.5 days of exposure. Moreover, the serial interval is between five to six days and the Ro- is two to three which means that one person can pass the virus on to two to three other persons through simple direct contact and droplet spread.

Populations at Risk

COVID-19 disproportionally affects medically vulnerable persons. These include the elderly, persons with chronic diseases, persons diagnosed with cancer, those with an underlying immunodeficiency and those on immunosuppressive therapy. Early studies from U.S. hospitals indicate age (generally > 65 years) as risk factor for increased mortality (Table 1). This is important for the HIV population since in a few years over 50 percent of the people living with HIV (PLWH) will be over 50 years of age according to the Centers for Disease Control and Prevention (CDC).5

Studies from hospitalized patients in Wuhan, China show that persons with co-morbid conditions such as diabetes (7%) and cardiovascular disease (10%) have higher case fatality rates compared to persons with no underlying condition (0.6%). The effect is even more pronounced in persons with pre-existing conditions that become worse during hospitalization in which case the case-fatality rate rises to as much as 49 percent for this vulnerable cohort.7

Pathogenesis of SARS-CoV-2

The pathogenesis of advanced COVID-19 disease is related to the destruction of type 1 and type 2 pneumocytes in the lungs. The destruction of type 2 pneumocytes is responsible for alveolar membrane integrity and type 1 pneumocytes responsible for gaseous exchange. When both cell types are compromised this leads to alveoli collapse, increased work of breathing and severe gaseous exchange problems resulting in profound lung and systemic hypoxemia. The detection of the SARS-CoV-2 virus by macrophages initiates an intense inflammatory process resulting in neutrophils recruitment, IL-6 initiation and reactive oxygen species. These milieu of reactive oxygen species and other mediators including cytokines induces a "cytokine storm" that causes indirect and perhaps direct destruction to lung and other organ tissue that possess

TABLE 1. Hospitalization, intensive care unit (ICU) admission and casefatality percentages for reported COVID-19 cases, by age group—United States, February 12-March 16, 2020

Age group (yrs) No. of cases	%		
	Hospitalizations	ICU Admissions	Case-Fatality
0-19 (123)	1.6-2.5	0	0
20-44 (705)	14.3-20.8	2.0-4.2	0.1-0.2
45-54 (429)	21.2-28.3	5.4-10.4	0.5-0.8
55-64 (429)	20.5-30.1	4.7-11.2	1.4-2.6
65-74 (409)	28.6-43.5	8.1–18.8	2.7-4.9
75-84 (210)	30.5-58.7	10.5-31.0	4.3-10.5
≥85 (144)	31.3-70.3	6.3-29.0	10.4-27.3
Total (2,449)	20.7-31.4	4.9-11.5	1.8-3.4

Source: Severe Outcomes Among Patients with Coronavirus Disease 2019 (COVID-19—United States, February 12-March 16, 2020) Morbidity and Mortality ReportWeekly / March 26, 2020 / 69(12);343-346 (6)

the ACE2 receptors such as the kidney, heart and gastrointestinal tract. The cascade of inflammatory process increases coagulation, decreases fibrinolysis and increases the risk of thrombosis in the small blood vessels. Not only is lung tissue damaged but so are other organs resulting in acute respiratory distress syndrome, acute renal failure, septic shock, multi-organ failure and death.8 Although not much is known about the effects of the SARS-CoV-2 virus on T-cell mediated immunity, preliminary research from China indicates a severe decrease in CD4 and CD8 T cells in the acute phase of infection. This may have implications for immune restoration in the short and long term as for HIV infection.9

Clinical Manifestations of SARS-CoV-2 in Adults and Children

COVID-19 has a wide range of symptoms that may appear anywhere from two to 14 days after exposure to the virus. The most common symptoms are a persistent dry cough, and progressive shortness of breath with at least two of the following symptoms: fever, fatigue chills, repeated shaking with chills, muscle pain, headache sore throat and loss of taste or smell. Other symptoms include, nausea, vomiting, and diarrhea. Conjunctivitis has also been reported in some patient cohorts raising the possibility that this coronavirus may be present in the conjunctival secretions of patients with COVID-19. Children have similar symptoms to adults but those are generally milder. Typical symptoms are cold-like and include cough, fever and rhinorrhea. 10,11 However, concerning symptoms in children include persistent fever, lethargy, convulsions poor oral intake and persistent vomiting and diarrhea. Due to the risk of cytokine storm, children are also at increased risk of progressing to respiratory failure, shock, coagulation dysfunction and renal injury.12

Several countries in Europe and states such as New York have begun reporting cases of Kawasaki-like disease in children, recently named Multisystem Inflammatory Syndrome (MIS). It is characterized by some or all of the following symptoms: fever, truncal rash, swelling of the hands and feet, conjunctivitis, lymphadenopathy, strawberry tongue and elevated blood markers for inflammation such as elevated sedimentation rate (ESR).13

Aagnitude of Response Viraemia **Pneumonitis** IgM IgG **IgM** Viraemia **Pneumonitis Incubation** IgG Period Days Post Infection (approximate) 10 12 11 Infection Onset of Symptoms Antibody test is appropriate for asymptomatic or convalescant patients PCR and Viral Antigen tests **IgM Test** are appropriate for acute phase of illness **PCR Viral Antigen Tests** Source: Caribbean Med Labs Foundation: 2020

FIG 1. Illustrative Graphic of Disease Progression and Laboratory Test for COVID-19

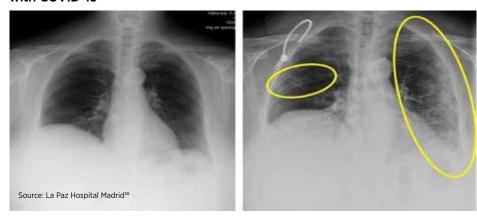
Diagnosis SARS-CoV-2/ COVID-10

The diagnosis of COVID-19 is most commonly performed through nucleic acid detection technology, (RT-qPCR), by sampling and detecting the virus in respiratory secretions via a nasal or pharyngeal swab. The CDC continue to recommend these methods of testing antigen and not antibody testing. Antibody testing can be used to ascertain patients who have recovered from COVID-19 through levels of IgM and IgG antibodies, (Fig. 1) but data on the utility of antibody testing including sensitivity and specificity of currently available tests as well as correlates of immunity continues to evolve. Studies using antibody testing are on-going looking at population-based seroprevalence of infection but the clinical implications of such data remain to be determined.14

Radiological diagnosis for COVID-19 can start with a simple chest X-ray. This may show ground glass opacities, consolidation and pleural edema. (Fig. 2)

Such high case fatality rates are important for PLWH in that many are over the age of 50 years. They suffer from multi-morbidity syndrome which is characterized by a panorama of chronic diseases that are inherently managed with polypharmacy requiring careful attention.

FIG. 2. Pre and Post Chest X-ray in a 72-year-old Female Patient Diagnosed with COVID-19



Although remdesivir is for now considered standard of care for hospitalized patients with COVID-19, comprehensive treatments must include mechanisms to control viral replication, the inflammatory process (cytokine storm), and other aspects of supportive care including high-flow oxygen and mechanical ventilation.

> For high yield diagnosis, some clinical practice guidelines recommend chest CT scan especially for moderate to severe COVID-19 patients requiring admission to the hospital. Common findings include bilateral ground glass appearances in the upper lobes and areas of consolidation. Lung disease has been categorized in two forms of disease: "type L" which is a milder disease and "type H" type which is a more severe form, exhibiting extensive areas of consolidation on CT scannning.16

Clinical Management of COVID-19

The clinical management of COVID-19 is complex and continues to evolve. The CDC has recommended that patients with COVID-19 minimally require supportive care and stringent infection prevention and control. Several professional societies have issued clinical practice guidelines including the IDSA.17

There was some early enthusiasm for hydroxychloroquine with or without azithromycin for patients with COVID-19 with these drugs undergoing testing in numerous clinical trials—including persons with HIV disease. The most recent data reported found these agents do not appear to confirm any benefit on in-hospital outcomes when used alone or with a macrolide antibiotic. Moreover, these drug regimens were associated with decreased in-hospital survival and increased frequency of cardiac arrhythmias.18

The National Institute of Health (NIH) has supported clinical trials of several drugs for COVID-19 treatment. In late April 2020, the FDA approved the drug remdesivir for the emergency use in COVID-19 patients. This was based on a randomized control trial with placebo, conducted at 68 multiple sites in the U.S., Europe and Asia. The study, Adaptive COVID-19 Treatment Trial (ACTT) showed that in hospitalized patients with advanced disease time to recovery was 31 percent faster for patients who received remdesivir than those who received placebo (P<0.001). The median time to recovery was 11 days for patients treated with remdesivir compared with 15 days to those who received the placebo. Moreover, results also suggested a survival benefit with a mortality rate of 8 percent for the group receiving remdesivir and 11.5 percent for the patients that received the placebo (P=0.59). 19 Although remdesivir is for now considered standard of care for hospitalized patients with COVID-19, comprehensive treatments must include mechanisms to control viral replication, the inflammatory process (cytokine storm), and other aspects of supportive care including high-flow oxygen and mechanical ventilation.

Infection Control

Infection control remains a priority for healthcare workers in the fight against COVID-19. Clinicians must be prepared to avoid the risk of

acquisition of the SARS-CoV-2 through the implementation of administrative procedures and the use of personal protective equipment (PPE) based on risk assessment. The principle strategy should be triage, early recognition and source control. In the case of COVID-19, the risk for healthcare workers is both for direct contact and respiratory droplets which means that they need to have PPE for their eyes, nose, mouth and body necessitating the use of surgical masks/medical masks, N95 or higher FF2, goggles, respirator fit, aprons, gowns and gloves. The use of aerosolized procedures such as bronchiolar lavage requires the use of powered air purifying respirators and comprehensive personal protection equipment for the rest of their bodies. 20,21

Patients in turn should use surgical masks and practice proper respiratory hygiene as well as hand washing. As more persons continue to graduate from stay at home orders, it is germane that social distancing from at least six feet continue as an effective means of controlling SARS-CoV-2 community transmission until effective therapies and (ideally) a vaccine becomes available.

Clinical Considerations and Recommendations for **HIV Management and Risk** Stratification

Based on the possibility of severe CD4 and CD8 T cell depletion in the acute phase of COVID-19, it may be worth risk-stratifying PLWH during the COVID-19 pandemic.²² However, more data are needed to ascertain the implication of this recommendation. The overall treatment goals should continue to be maintaining HIV viral suppression through treatment adherence, ensuring a multi-month supply of antiretrovirals (ARV), prophylaxis for opportunistic infections, recommended vaccinations and infection prevention and control.

The Department of Health and Human Services (DHHS) in collaboration with the CDC. They have issued interim guidance for PLWH which include the following;

- · Persons age 60 years and older and those with co-morbidities are at greater risk for more severe disease
- Smokers appear to be at increased risk for complications

- · The limited data currently available does not indicate that the disease course of COVID-19 in PLWH differs from that in persons without HIV. Before the advent of effective combination antiretroviral therapy (ART), advanced HIV infection (i.e., CD4 cell count <200/mm3) was a risk factor for complications of other respiratory infections. Whether this is also true for COVID-19 is yet unknown. Until more data is available, caution is advised for those with advanced or poorly controlled HIV disease.
- ART and concomitant medication supply for PLWH should be prioritized and a minimum of 30 days and maximum of 90day-supply of ART is advised.
- Influenza and pneumococcal vaccinations should be kept up to date.
- · PLWH should follow all applicable CDC recommendations to prevent the spread of COVID-19, such as social distancing and proper hand hygiene.
- · Although pregnancy is in itself an immunosuppressive condition, studies have not shown thus far that infection with SARS-CoV-2 in pregnant women with HIV bears any increased risk in pregnancy compared to someone without HIV. However, many hospitals have instituted universal screening for SARS-CoV-2 in woman admitted for delivery.23 Clinical practice and management should continue as usual. Additional Information on pregnancy and COVID-19 is available from CDC,

the Society for Maternal-Fetal Medicine, and the American College of Obstetricians and Gynecologists.

With regards to HIV and opioid abuse, the CDC recommends medically assisted therapy (MAT) including buprenorphine and methadone be continued. Clinicians caring for PLWH who are enrolled in opioid treatment programs (OTPs) should refer to the Substance Abuse and Mental Health Service Administration (SAMHSA) website for updated guidance on avoiding treatment interruptions. State methadone agencies are also responsible for regulating OTPs in their jurisdictions and may provide additional guidance.

Clinic or Laboratory Monitoring Visits Related to HIV Care

• Together with their healthcare providers, PLWH should weigh the risks and benefits of attending, versus not attending in-person, HIVrelated clinic appointments.

Factors to consider include the extent of local COVID-19 transmission, the health needs that will be addressed during the appointment, the person's CD4 cell count and HIV viral load as well as their overall health.

Telephone or virtual visits for routine or non-urgent care and adherence counseling may replace face-to-face encounters.

For persons who have a suppressed HIV viral load and are in stable health, routine medical and laboratory visits should be postponed to the extent possible.

For further guidance on the quarantining of PLWH, it is prudent to refer to the DHHS guidelines and CDC guidelines. HIV



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through decentralization and integration of HIV in the public sector and the justice system....

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BEST PRACTICES

Ever-Changing During the COVID-19 Crisis

We are learning together

BY D. TREW DECKARD, PA-C, MHS, AAHIVS

N FRIDAY MARCH 6TH, I realized things were about to change in our clinic here in Dallas, Texas and around the country as CROI 2020 abruptly sent all of its attendees, including myself, an email stating that the 2020 Live Conference on Retroviruses and Opportunistic Infections (CROI) had been cancelled and that it had become a virtual conference.

Although I had prepared to wear a mask on my flights, socially distance while there, and take as many precautions as possible, I didn't expect to cancel all my plans for travel the day before the conference was to begin. Clearly the organizers at International Antiviral Society-USA (IAS-USA) had made the correct decision.

Over the next five days, the virtual CROI conference went surprisingly smooth. On the Tuesday during the conference, the organizers presented a special COVID-19 update led by Dr. Anthony Fauci. This special session shown a light on a quickly emerging pandemic that had taken everyone by storm. Everyone was interested in attempting to understand what was known about this new coronavirus, SARS-CoV-2 and how it may affect our patients, our practices and our communities.

When I returned to our practice, an Internal Medicine practice with a specialty in HIV/ AIDS, on Thursday March 12th, I swabbed what would be the first of many patients with COVID-19 symptoms. We were not accustomed to wearing PPE outside of patients with high risk respiratory symptoms and for certain procedures, therefore beginning to wear PPE regularly was a new reality. As an Internal Medicine practice, we regularly work with LabCorp and Quest for most of our laboratory needs. However we were unsure what to expect from the new COVID-19 PCR tests, how to interpret these new tests with only internally validated sensitivity and specificity data, how quickly we could expect these tests to return, and the correct verbiage to deliver to our patients while they were awaiting results. The Centers for Disease Control and Prevention (CDC) guidelines began being disseminated and updated regularly, as we would soon find out would become the norm. The virus was beginning to spread into more U.S. states and communities quickly, including our own.

That weekend on March 15th, I happened to be on-call and took the first call from our Dallas County Health Department informing me we had a positive COVID-19 result. What followed was a panic of calls, clarifications, and researching of information on current CDC COVID-19 guidelines regarding quarantining if a medical professional has a high-risk exposure with a known positive. The result of this inquiry was that one provider and another staff member were determined to be at risk and self-quarantined over the next 14 days.



It was clear that the next day would be a turning point as to how we would approach our patients, our practice and our own protection. On Monday March 16th, I was able to convince our building's owners that it was in the best interest of all persons entering our building that our practice should be allowed to offer drive-up testing in the parking structure adjacent to our building. That would reduce the risk of COVID-19 exposed individuals exposing others to the virus, while maintaining a safe and familiar environment to our patients, in a scheduled setting. The owners agreed—with the caveat that only our patients would be allowed to be tested and no advertising of this service would be allowed. In a building where at least 50 percent of the tenants are not medical, we understood this request of discretion was reasonable.

Over the coming weeks, all six of our providers would become familiar with the process of dressing in full PPE to test for COVID-19 on a regular basis. Simultaneously in-clinic protocols were quickly updated to increase protection for patients, providers, staff and anyone needing to enter our practice (e.g. deliveries, suppliers, etc.). Updating our Electronics Health Record (EHR) system, learning how to start up telehealth visits, and updating all our internal protocols concurrently was a challenge.

s we began testing for COVID-19, we began to experience a per- ${f A}$ centage of our patients cancelling their appointments due to risk of exposure to COVID-19. Therefore, we quickly transitioned most of our patients to telehealth. We stressed continuity of care for all our patients as we are their PCPs and their HIV specialists if necessary.

One large on-going challenge has been which laboratory tests are appropriate to use and how to interpret the results. As CDC guidelines and the evolving data have attempted to keep us all abreast of these changes, confusion has remained a mainstay. We began using COVID-19 PCR tests from the usual large corporate laboratories, such as LabCorp and Quest as these were two of the first to market. Learning quickly that many PCR tests could have false negative rates as high as 30 percent, we quickly learned that our clinical acumen would serve us well when interpreting these results.

By the first week in April, we had tested many of our patients resulting in several positive results, most of who were symptomatic since we were following CDC protocol and testing only patients who were showing symptoms consistent with probable infection.

Once our office entered the second half of April, we had gotten into a new norm for our clinic. This includes constant disinfecting of our equipment, exam rooms, laboratory, common areas, and our own office spaces; daily calls to every scheduled patient (regardless of visit type) to obtain newly developed symptoms creating a 'pre-triage' system; wearing of PPE for all providers, staff, and any patients having in-clinic visits; becoming more efficient in our telehealth interactions; streamlining outside COVID-19 testing and regular follow-ups for each of these patients; allthe-while stressing that our HIV positive patients, and all patients with chronic co-morbidities continue their regular healthcare engagements.

We then recognized that COVID-19 antibody tests were about to be released and it was our responsibility to research how to test, which laboratories or platforms were more likely to give our reasonably

accurate results, and if it was appropriate to even use these tests. This was going to add yet another layer of conversation and interpretation that, like so many other areas of focus recently, would test our ability to continue to give scientifically rigorous and accurate information to our patients.

As we move through this pandemic, we seem to be continually discovering new manifestations of this devastating disease. Whether gastroenterological, cardiovascular or neurological, this virus appears to deviously affect just about every human body system. Anecdotally in our own clinic, we have seen very few of our HIV patients test positive for COVID-19.

As in the writing of this article, new COVID-19 cases and deaths in Dallas, in our metropolitan area, and in Texas are all on the rise as our state is now "opening up." Weeks ago, the CDC recommended that the first phase of beginning to relax 'safer at home' orders would be to see at least 14 days of decline in cases and deaths. Our trajectory is moving in the opposite direction. Those recommendations are not being adhered to here nor in many other states in the country. As providers confronting the realities of COVID-19 daily, we ask ourselves many questions. Most are currently unanswerable. In the meantime, we will continue to show up and do our best because that is what our patients deserve. As we in our practice and many others have experienced, recovery and death, fear and joy, despair and hope, we will discover the answers through scientifically rigorous research and compassionate delivery of care. HIV



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engaged in community outreach. He transitioned into administration in the HIV/AIDS community providing these services from 1987-1991 in San Francisco. He began his career in medicine after his Bachelor's, which he received at the University of Texas at Arlington in 1995. He completed his Master's in Health Sciences and his P.A. degree from Duke University in 2000. Immediately he began his practice in Internal Medicine and HIV/AIDS specialty in Dallas. Since 2001 he has been practicing at the same outpatient Internal Medicine-HIV/AIDS practice.

Over the coming weeks, all six of our providers would become familiar with the process of dressing in full PPE to test for COVID-19 on a regular basis.



COVID-19 and HIV

Resources for Health Care Providers

People with HIV may have concerns and questions related to their risk for coronavirus 2019 disease (COVID-19). We know that people at higher risk include older adults and those with serious underlying medical conditions like heart disease, diabetes, and lung disease.

In the United States, nearly half of people with HIV are aged 50 and older. Additionally, people with HIV may have higher rates of chronic heart and lung disease. The risk of getting very sick from COVID-19 is likely greatest in those with a low CD4 cell count and people not on HIV treatment.

To support health care providers managing these patients, the Centers for Disease Control and Prevention's (CDC's) Let's Stop HIV Together campaign for health care providers offers a collection of key federal resources on COVID-19 and HIV. These resources:

- Address concerns related to COVID-19 and HIV.
- Provide guidance to health care providers managing people with HIV.
- Highlight how people with HIV can protect their health.

To access COVID-19 and HIV resources for your practice and patients, visit:

www.cdc.gov/HIVNexus

Practice Tips for Health Care Providers

- Encourage people with HIV to continue taking HIV medications as prescribed. Achieving and maintaining an undetectable viral load is one of the best things your patients with HIV can do to stay healthy.
- If possible, prescribe a 90-day supply of antiretroviral therapy (ART) to maintain their ART regimen during physical distancing. Consider changing to mail-order delivery of medications when possible.
- Underscore the importance of following all CDC precautions to prevent COVID-19, such as physical distancing, hand-washing, wearing cloth face coverings in public settings, disinfecting surfaces, avoiding travel, and ensuring essential vaccinations are up to date.
- Together with each patient, weigh the risks and benefits
 of attending in-person, HIV-related clinic appointments.
 Factors to consider include the extent of local COVID-19
 transmission, the health needs that will be addressed
 during the appointment, and the person's HIV status (e.g.,
 CD4 cell count, HIV viral load) and overall health.
- Consider telemedicine visits for routine and non-urgent visits and adherence counseling.



HEALTH DEP [MANAGING EPIDEMICS

BY LORI TREMMEL FREEMAN, MBA

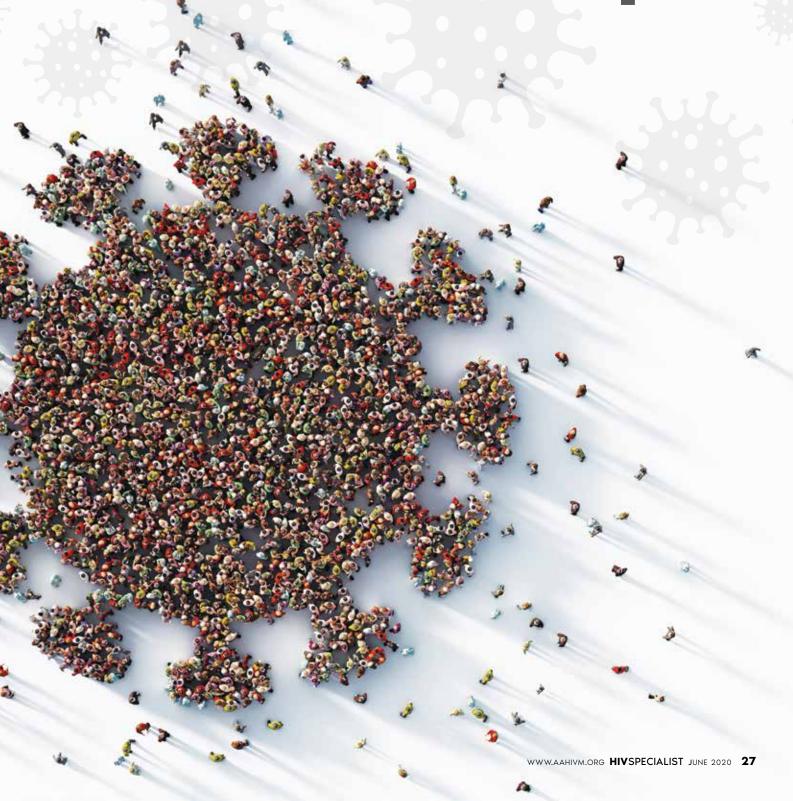
HE COVID-19 RESPONSE has taken time, attention, and personnel away from many other heath priorities, as underfunded and understaffed local health departments (LHDs) respond to this extraordinary crisis. However, in doing so, existing services—including those for HIV, STIs, and viral hepatitis—are strained or paused, with health impacts that will ripple through communities.

Local health departments play a critical role in the prevention, detection, and treatment of various infectious diseases in the U.S. by monitoring disease trends, promoting and implementing best practices, and addressing gaps in the healthcare system. Health departments are often the first to identify and respond to local outbreaks and work closely with local providers to promote new biomedical interventions (e.g., pre-exposure prophylaxis (PrEP), direct-acting antivirals for hepatitis C (HCV)) and best practices (e.g., rapid initiation of antiretrovirals, extragenital STI testing). They also meet the needs of populations disproportionately affected by HIV, STIs, and viral hepatitis, including people of color, LGBTQ+ people, young people, low-income or un/under-insured people, people who use drugs (PWUD), and those in the criminal justice system. This involves conducting outreach and education to marginalized populations, operating clinics that provide critical care for people who may not be able to access it elsewhere, and implementing prevention strategies, such as immunization clinics or syringe services.

Local health departments also must consider the broader context in which people access health services by addressing syndemics (linked health problems that contribute to excess burden of disease in a population), and social and structural barriers. This involves establishing connections among services and providing case management to ensure access to shelter, food, and transportation, so that clients can initiate and adhere to necessary medical treatments.

The COVID-19 pandemic exposes and exacerbates inequities and gaps in our healthcare system. People of color are more likely

ARTMENTS DURING A PANDEMIC]



to be diagnosed with and to die from COVID-19; people experiencing homelessness may not have a safe place to quarantine. 1 Persons who use drugs or who are in recovery may have limited access to substance use and harm-reduction services, putting them at risk for overdose, relapse along with the acquisition of HIV and HCV. While health departments work to protect marginalized populations, many are already stretched thin after more than a decade of budget cuts. Consequently, health departments and affiliated medical providers must work together to address inequities and ensure no one is left behind in the response to COVID-19.

The Impact of COVID-19 on HIV, STI, and Hepatitis Services

In March 2020, the National Association of County and City Health Officials (NACCHO) queried a convenience sample of LHD HIV, STI, and viral hepatitis programs regarding the impact of the pandemic on their programs and communities. More than 50 responded.² As LHD staff are pulled away from their regular work to respond to COVID-19, and as they implement social distancing guidelines to protect clients and staff, many have had to close their STI clinics, reduce their hours, or eliminate walk-in appointments. Local health departments also reported suspending outreach and education efforts, reducing HIV/STI partner services and testing, or only treating symptomatic HIV/STI cases and partners of confirmed cases. Many expressed concern for increased transmission of infections including HIV and hepatitis during the pandemic and are exploring innovative ways to adapt programs and services.

Maintaining HIV, STI, and Hepatitis Services

Health departments are using a variety of strategies to maintain clinical services during the pandemic. Many are using telehealth to offer screening, counseling, case management, and partner services. To prevent and diagnose HIV, some health departments are mailing HIV testing kits to clients or using dating apps to encourage PrEP initiation. They are also using express testing-triage-based STI testing without a full clinical examination—to offer STI testing with fewer staff and limited face-to-face contact. Express strategies include using technology to automate the intake process or deliver test results, having patients collect their own samples, or testing asymptomatic patients without a provider visit. Health departments are also relying on syndromic management and presumptive treatment of STIs, which involves diagnosis and treating clients based on their symptoms. Others have expanded the use of expedited partner therapy (EPT), which involves treating the sexual partners of STI cases without a visit. To maintain harm reduction services, some programs are distributing more syringes per visit and letting clients place orders by phone.

Local health departments and healthcare providers should consider how they can continue to offer HIV, STI, and hepatitis services through telehealth, self-testing, and other strategies during the pandemic. While COVID-19 underscores the need to expand telehealth services, it will remain an important strategy to increase access to clinical services, especially for young people, those in rural communities, and others who face heightened barriers to care. Self-testing for HIV and other

STIs can address gaps in care during and beyond the pandemic, reducing the burden of undiagnosed cases - including the more than 160,000 people living with undiagnosed HIV in the U.S.3 However, providers should still deliver education and counseling, even when self-testing is used, and ensure access to timely treatment as needed.

The Toll of the Pandemic on Mental Health

Nearly half of Americans report that the pandemic has had a negative impact on their mental health.4 This is likely due to social distancing, which limits our ability to connect with loved ones; unemployment, which causes financial anxiety and distress; and the grief resulting from the loss of so many lives. This may contribute to substance use, which is closely associated with mental health disorders, and often serves as a coping strategy in response to stress, grief, or pain.5 Mental health and substance use disorders can prevent patients from seeking health services or adhering to treatment for chronic health conditions. To mitigate these trends, it will be important to establish linkages between clinical care, mental and behavioral health, and social services and to treat the whole patient—not merely one disease or condition.

Certain populations of people living with HIV (PLWH) are more likely to be lost to care, such as those with mental health or substance use disorders, as well as minorities or people experiencing housing instability or poverty. 6,7,8 Case managers, patient navigators, linkage to care specialists, and community health workers-many of whom come from and are positioned within the community they are trying to reach—can form meaningful relationships with clients. These relationships enable them to link patients to care and address unmet needs that are keeping patients from being retained in care. However, many of the strategies, including outreach and peer support groups, that link vulnerable populations to prevention and care services have been suspended during this pandemic. Therefore, it is critical to re-evaluate current strategies and what is defined as "essential services" to ensure no one is left behind.

Local health departments and healthcare providers should consider how they can continue to offer HIV, STI, and hepatitis services through telehealth, self-testing, and other strategies during the

pandemic.

Addressing Stigma, Discrimination, and Bias

HIV is a highly stigmatized condition, and it's important to address potential forms of stigma that may occur when PLWH seek treatment for COVID-19. As reflected in the U.S. Department of Health and Human Services guidance, PLWH who are diagnosed with COVID-19 should not be treated or clinically managed differently than the general public, including during triage determinations.9 Other priority populations such as LGBTQ+ people or PWUD also experience stigma and discrimination when seeking health services, and implicit bias against people of color is common among healthcare providers. 10,11,12 The legacy of racism and unethical research practices has engendered medical mistrust among communities of color, and may deter people from seeking timely testing and treatment for COVID-19, and continued bias and discrimination has already resulted in people of color being misdiagnosed or turned away when presenting with COVID-19 symptoms. It is important to recognize and work to overcome medical mistrust and implicit bias, as they can be barriers in educating, testing, and caring for populations disproportionately affected by COVID-19. Health departments should monitor inequities in COVID-19 case and deaths and consider how they can access marginalized communities with testing initiatives to ensure early diagnosis and rapid treatment and containment.

Looking Forward: Strengthening the Public Health Workforce

Since the "Great Recession" of 2007 to 2009, local health departments have lost nearly one-fourth of their workforce, leaving many overburdened and under-resourced. In 2013, 62 percent of their STI programs reported budget cuts, and of those, 42 percent reported reductions in partner services—a critical strategy to prevent further HIV/STI transmission and ensure access to timely treatment. Not only has this hindered their ability to combat HIV and other STIs, but it undermines their ability to respond to outbreaks, as the skills required for partner services translate well to contact tracing and other response activities. Reopening the United

States through the COVID-19 pandemic will require at least 100,000 contact tracers. While the expertise of the health department-based clinical programs can be leveraged to support this work, far more resources are needed to expand and strengthen the workforce. Our health departments are key leaders in the prevention and care of HIV, STIs, viral hepatitis, and other infectious disease and work closely with the healthcare sector to assure access to health services. Ending the HIV epidemic, eliminating viral hepatitis, and combatting the STI crisis are in reach, but we must ensure that local public health has the resources and support to maintain clinical services while concurrently playing a critical role in COVID-19 response efforts. HIV



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mission is to improve the health of

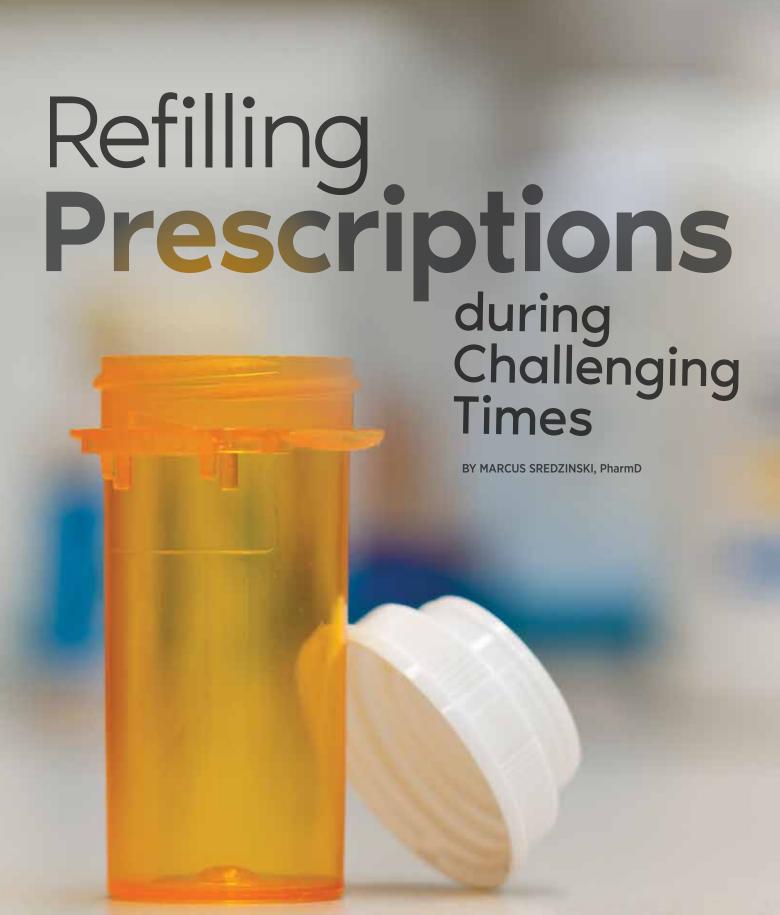
communities by strengthening and advocating for the nation's nearly 3,000 local health departments.

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ANY PEOPLE in the U.S., including those with HIV, may be having difficulty getting their prescriptions filled during the COVID-19 pandemic. A lag in refills causes anxiety for all, but for HIV patients, a delay in medication can cause additional anxiety and compromise their health. Making it even more stressful for these patients, the retail cost of HIV medications can range from \$3000 to \$5000 per month which is unaffordable for most without prescription coverage.

A person living with HIV is typically able to obtain a 30-day supply or their antiretroviral therapy(ART). However, it is not typical to simply walk into a pharmacy and request a 60 or 90 day supply. To better accommodate, some health insurers and State ADAP programs are adapting to the current COVID-19 pandemic by lifting restrictions for refills. According to America's Health Insurance Plans (AHIP) these emergency plans "may include easing network requirements, prescription drug coverage, referral requirements, and/or cost sharing." Many insurance companies are waiving limits on 30-day supplies of prescriptions and encouraging people to get 90-day supplies instead in order to maintain shelter-in-place recommendations. This not only provides patients with three months of their medication, but also reduces wait time and burden on pharmacy staff. However, providers and patients interested in a 90-day-supply should make sure that their insurance has changed their policies before placing the order.

Rules and Regulations Vary by State

Every state has the ability to set their own pharmaceutical regulations with laws guiding pharmacy standards and requirements. During the pandemic, states continue to amend their general regulations to combat COVID-19. In terms of pharmaceutical regulations, pharmacies are starting to change how they deliver prescriptions to people who are in quarantine. For example, at Northern Pharmacy in northeast Baltimore, the front door is locked, and employees wearing masks and gloves greet customers at the back entrance. Other states are taking even more drastic measures to help those in need of their medication.

Finding the Best Price

The Kaiser Family Foundation reported earlier this year the annual cost of family health coverage for Americans will hit a new record in 2020, exceeding \$20,000. That's a 5 percent increase from last year, pushing a large number of American workers into plans that cover less or cost more—or force them to live without health insurance altogether. These costs may be even higher as they sometimes do not include co-payments, deductibles and other forms of cost-sharing once patients need care. Kaiser's research shows that while employers pay most of the costs of health coverage, workers' average contribution is now \$6,000 for a family plan. For many HIV patients, there are discount prescription programs and coupons that can help them with the cost of ART. ScriptSave WellRx has a prescription discount program that has helped more than half a million consumers save more than \$10 billion dollars on prescription costs. Patients need to be reminded by their care providers and pharmacist of these different discount programs.

Prescription Delivery

Many pharmacy chains such as CVS, Rite Aid, HEB and Walgreens, are now offering free home delivery of prescriptions in 1-2 business days.

Although delivery for prescriptions is available, there are some restrictions that may leave patients ineligible for this service. Specific medications for HIV patients are available for free delivery in select areas from pharmacies such as Walgreens and CVS.

Pharmacy Benefit Managers Principles

America's pharmacy benefit managers (PBMs) manage prescription drug benefits on behalf of health insurers. They have a significant behindthe-scenes impact in determining total drug costs for insurers, shaping patients' access to medications, and determining how much pharmacies are paid. In this case, PBM's are instilling new principles that change how prescription drugs are managed during the coronavirus pandemic.

These principles are:

- PBMs, other drug supply chain stakeholders and federal, state, and local government partners should work together to sustain access to care for patients and prevent drug shortages.
- PBMs recommend multiple approaches be made available that ensure patients have access to their prescription drugs now and in the days ahead, by balancing convenient, reliable access—such as home delivery and additional supply on handwith the potential for drug shortages.
- PBMs recommend guidance from federal, state, and local government agencies that balances patients' need to stay at home, the clinical appropriateness of supply for any given drug, and the need to prevent future drug shortages. **HIV**



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Missed Opportunity

BY KAYLA L. CARR, FNP-C AND ROBERTO PARULAN SANTOS, MD, MSCS, FAAP, AAHIVS, FIDSA

HE COVID-19 PANDEMIC creates a significant challenge in delivering services to a vulnerable group of patients—youth with HIV. Before the pandemic, there were missed opportunities in the care of this vulnerable population. Patients ages 13 to 24 years old are the least likely to be aware of their HIV status.¹ Adolescents are also among the most challenging group to engage in healthcare.2

In the era of COVID-19, the younger population is less likely to be correctly social distancing. The footage of young spring breakers flocking to the beaches, declaring their invincibility to the virus is just one example. This is a common mentality that HIV providers have to confront. And yet medical providers continue to be creative and strive to be better providers for the youth.

While COVID-19 presents obstacles to HIV testing and care, it also challenges providers to be creative, innovative and to confront the pandemic head on so as to ease the burden in caring for patients with HIV disease. As providers strive to optimize the care of adolescents and young adults, consider these missed opportunities that occurred before the pandemic.

Transgender Clinic

An 18 year old was recently diagnosed with HIV at a local transgender clinic. He reports being sexually active and quite "versatile" in his behaviors. He lives in a rural community and like other teenagers of his age, enjoys the company of friends.





If the 18 year old had been offered HIV testing at the hospital clinic and found to be negative, he could have been counseled on risk-reduction strategies including safer sex practices, pre-exposure prophylaxis (PrEP) and guidance towards a healthy sexual life. If he had been found to be positive, he could have been linked earlier to care, immediately started ARV medication and learned about how undetectable = untransmittable.

More than a decade after the CDC recommended routinely testing for HIV, the rate of HIV testing among adolescents remains low. In the recent Youth Risk Behavior Surveillance, only nine percent of high school students had been tested for HIV.3 In the southeastern U.S., where HIV infections are the most prevalent, HIV testing rates were reported in Texas (13.5%), Louisiana (22.5%), South Carolina (12.1%) and North Carolina (10.8%) while Alabama, Georgia and Mississippi did not have available weighted data.3

There have been reports of missed opportunities for HIV screening among adolescents in the emergency department (ED) settings and among those with acute STDs. In a pediatric ED in Dallas, Texas, a retrospective chart reviewed among more than 200 adolescents noted a missed opportunity encounter score (MOE, defined as inpatient, outpatient and ED encounters without HIV screening performed) of 6.7 for every new HIV infection compared to a nearby adult ED with a MOE score of 0.9. (p<0.01). 5 The research team stated that universal HIV screening is key in identifying gaps in the diagnosis of HIV infection particularly in areas with high HIV prevalence.5

Another retrospective study involving at least 1300 adolescents between the ages of 13 and 24 years old from July 2014 to December 2017 were evaluated for acute STDs (chlamydia, gonorrhea, syphilis and trichomoniasis) in two urban clinics. Only half (55%) of those with an acute STD were tested for HIV, when in reality all should have been. This is another reminder of how HIV testing rates remain suboptimal among adolescents even among those evaluated for STDs.6

New epidemiologic data from the CDC suggests declining HIV diagnoses (reduced by 10%) among youth overall from 2010-2017.1 The trend for HIV infections varied for different groups of youth. It is important to note that HIV diagnoses decreased among those disproportionately affected previously including young Black, gay and bisexual men.¹ A poster presentation from the Conference on Retroviruses and Opportunistic Infections (CROI) in 2018, entitled "The changing face of the HIV epidemic among people who injects drugs" authored by Lyss SB, et al noted that HIV diagnoses increased among 13 to 34 year olds (by age group), among Whites (by race/ethnicity), and in those living outside larger central metropolitan areas (by urbanicity). This data provides a changing landscape for HIV infections among youth and how providers can adopt strategies to prevent missed opportunities for diagnosing HIV.

Adolescent Clinic

In this scenario, the same 18 year old learned about sexual health issues and prevention of STDs, including HIV prevention and testing, from a local school nurse. He discovered his HIV diagnosis through an HIV test performed at the school clinic. When his pediatrician learned that he had tested positive, he referred him to an adolescent clinic.

Schoolbased health services may include HIV education, school-wide programming, creation of safe and affirming spaces for sexual minority youth and Condom **Availability Programs** (CAP)

Opportunity Not to Be Missed

Approximately 15 million adolescents per day attend public schools, on average six hours a day, during these formative developmental years.8 The American Academy of Pediatrics recognizes school health services as a critical piece in the health safety net.9 Certified school nurses and their aides are equipped to provide safe, confidential and cost-effective care in context. School-based health services may include HIV education, school-wide programming, creation of safe and affirming spaces for sexual minority youth and Condom Availability Programs (CAP).

Nurses effectively implement HIV counseling, screening and referral protocols in collaboration with physicians. In some states they independently perform Medicaid Early and Periodic Screening, Diagnostic and Treatment (EPSDT) visits. EPSDT visits can serve as critical points for HIV counseling and screening. School-based health centers (SBHC) offer an expanded scope of services where physicians, nurse practitioners and nurses offer collaborative care, often in partnership with local hospitals or healthcare systems. For students, a visit to the school health room or clinic can be an opportunity for nurses to provide education, HIV screening, and if needed linkage to an HIV provider.

Despite the CDC's recommendations to increase the number of adolescents with access to school health services, disparity remains with approximately 25 percent of schools in the U.S. having no school nurse or SBHC.¹⁰ Advocating for school nurses is critical in the prevention of HIV infection and helps bridge the gap in HIV diagnoses among adolescents.

Informed by the Whole School, Whole Community, Whole Child (WSCC) Model, the CDC provides several resources related to HIV care in schools.11 Get Yourself Tested is an evidence-based HIV prevention toolkit, complete with a Get-Tested locator tool to help find testing sites, should screening not be available within the school. 12-14 CDC funding for state and local education agencies is available for school health services, 15 although funding restrictions such as having to provide care for 10.000 students over a five-year funding period may be a challenge for many

schools. Alternate sources of funding for HIV programming in schools include Medicaid billing, partnerships with local state health departments and Title X funding.16

Amidst COVID-19 Pandemic

On March 20, 2020, the Department of Health and Human Services (DHHS) published its "Interim Guidance for COVID-19 and Persons with HIV" despite limited data available and the rapidly evolving information between HIV and SARS-CoV-2 infections.17 The guidance provides some framework for HIV medical providers to continue caring for patients with HIV. It addresses the use of virtual clinic visits using the telehealth platform, Drive Thru Blood Draw, and other creative strategies, which can facilitate medical care during a time when access to clinic sites is extremely limited or not an option.

The COVID-19 pandemic could be an ideal time to adopt quality improvement (QI) projects intended to mitigate the effects of SARS-CoV-2 infections. There are various harm reduction strategies including calling patients to check on their medication needs as well as reminding patients of the importance of adherence to their

medications. Another is a video clip highlighting the four principles of hand washing awareness in cartoon format (https://www.henrythehand.com/) endorsed by the American Medical Association and the American Academy of Family Physicians regarding how to appropriately wash hands to prevent respiratory viral infections, includes SARS-CoV-2. These are few of the positive attitudes that healthcare providers can foster and make a difference in the behaviors and lives of patients.18

The tales of the two adolescents give perspective to providers to be resilient, creative and innovative in the delivery of care to this vulnerable population who remain at risk for or are already at risk for HIV. It takes a village to end the HIV epidemic and everyone's collaborative effort should be sought. Patients rely on providers to guide them with simple, straight forward and honest advice, especially during the COVID-19 pandemic. **HIV**



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CURE

HIV-COVID Registry Laun



EVALUATING THE IMPACT OF COVID-19 CASES IN HIV PATIENTS

BY ANITA KOHLI, MD

ched by HIV Providers





TO AID IN THE UNDERSTANDING of the impacts of COVID-19 on HIV patients, physicians from the University of Maryland, Baltimore and Arizona Liver Health in Chandler, Ariz., have launched the CURE (Coronavirus Under Research Exclusion)

registry. CURE is an HIV-COVID registry for providers from any location in the United States to report confirmed cases of COVID-19 occurring in HIV patients.

The goal of the registry is to help elucidate the natural history of COVID-19 in patients with HIV, determine the effects of treatments given, and analyze the impacts of factors like age, CD4 counts, and comorbidities on COVID-19 outcomes. Through updates published twice every week, these findings are being shared with providers around the world to accelerate the understanding of COVID-19 and its impact on persons with HIV disease.

There is little data on how COVID-19 affects patients with HIV. For persons living with HIV (PLWH), the effect and outcomes of co-infection with SARS-CoV-2 is unclear. The HIV virus causes abnormal or impaired response to infections, so there is a potential for increased adverse outcomes in patients with HIV who become infected with SARS-CoV-2. Through the data collected from the registry, providers can learn how best to manage and treat patients with HIV and COVID-19 and improve the care of patients co-infected with both viruses, as well as overall survival rates.

Summaries of data reported to the registry will be shared and updated on the website at least twice a week for medical providers to review. Given our unique patient population, we hope providers will take the time to share this critical information so we can rapidly find answers on how best to care for HIV patients with COVID-19.

Data entry into HIV-COVID registry should only take approximately five minutes. Providers are encouraged to report all cases regardless of severity, including asymptomatic cases detected through public health screening.

Similar efforts to gather data on COVID in subpopulations are in place by other groups including The Global Rheumatology Alliance and Surveillance Epidemiology Coronavirus Under Research Exclusion (SECURE-IBD). We were inspired to establish this registry after seeing how other groups have gathered important and timely information to aid their colleagues in managing patients.

To find out more information or to report a case as a provider in the U.S., visit the CURE HIV-COVID Registry at www.hivcovid.org. HIV



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PRACTICES





IF YOU HAVE A PATIENT that has been diagnosed with HIV/AIDS and is unable to work because of the condition, he or she may qualify for disability benefits from the Social Security Administration (SSA). An individual with an HIV/AIDS diagnosis is likely to

be approved for disability benefits if he or she has a symptomatic infection. Those who have symptomatic HIV/AIDS will need to meet specific medical criteria to have their claim approved.

The SSA uses a very detailed process, and the patient must meet the medical criteria established for a qualifying condition to confirm that he or she is disabled and unable to work. The disability claims process is complex, requiring a detailed form to be completed and supporting documentation provided, including hard medical evidence, to have a claim approved. As a healthcare provider, you can help apply for disability benefits on behalf of a patient.

Meeting the Medical Criteria

The SSA uses a medical guide, which is called the Blue Book, to determine if a claimant medically qualifies as disabled per the guidelines used by the SSA. To show a claimant meets the criteria of the listing for HIV/AIDS, you will need to provide medical documentation, including accepted medical tests that confirm an HIV diagnosis. Accepted tests include HIV antibody tests, HIV RNA or DNA detection tests, HIV p24 antigen test, isolation of HIV viral culture or other highly specific lab tests effectively used to diagnose HIV.

If a patient doesn't have the results from one of those tests, other medical evidence will need to be provided, such as a proof of the diagnosis of an opportunistic disease that is common for those who have HIV/AIDS. For example, the opportunistic disease must show there is a defect in cell-mediated immunity and it must have supporting laboratory evidence. For cancer, you must provide biopsy results. For toxoplasmosis of the brain, you must show a brain imaging scan, positive serology tests or proof of the symptoms of the condition.

Using an RFC and Medical Vocational Allowance

If a patient doesn't meet the specific criteria of the HIV/AIDS disability listing, they may still qualify using a medical vocational allowance and through the support of a residual functional capacity (RFC) form. The SSA will review the medications taken for the condition and how they limit functioning. While some medications improve symptoms from the condition, they may have disabling side effects. The SSA will likely need to look at any adverse reactions that occur, as well as the difficulty and time involved in a treatment plan, how long treatment plan lasts, and any effects of that treatment on mental functioning.

There are many common side effects of medications for treating HIV/ AIDS. Those side effects may include fatigue, diarrhea, nausea, joint pain, abdominal pains, diarrhea, hypersensitivity, fatigue, sleep disturbances, depression, dizziness, general weakness and anxiety. Sometimes there

are even more severe side effects from treatment, such as liver damage or fat, sugar or acid buildup in the blood stream. Confusion, inability to concentrate, memory problems, insomnia and fatigue caused by the medications can be disabling.

A treating physician may complete an RFC for the patient, which will be very detailed and explain what he or she can and cannot do. It will say how long a patient can stand, how frequently he or she must reposition, how far he or she can walk and detail any mental impairments. By considering medical problems, restrictions and limitations, age, educational background, and work history then reviewing the RFC, the SSA can determine if a claimant can work, and if so, what kind of work he or she can do.

Applying for Disability Benefits with HIV/AIDS

If a patient has HIV/AIDS and it is disabling, he or she will want to start the disability claims process. You can start his or her application process online at the SSA website, or by calling 1-800-772-1213 and speaking with a representative. The patient can also make an appointment to apply at a nearby SSA field office. Remember, detailed medical evidence is essential to a claim's success, so no matter how you apply, have a patient's medical evidence ready when applying on his or her behalf. HIV



RACHEL GAFFNEY is an Outreach Specialist at Disability Benefits Center, an independent organization dedicated to helping people of all ages receive the Social Security disability benefits they deserve. She

currently lives in Boston, Mass. but helps those seeking assistance nationwide. If you have any questions on this article or would like a little more information on how to qualify for disability benefits, she can be reached at rsg@ssd-help.org.

RESOURCES

https://www.ssa.gov/benefits/disability/

https://www.ssa.gov/disability/professionals/bluebook/ AdultListings.htm

https://www.disabilitybenefitscenter.org/glossary/ acceptable-medical-source

https://www.ssa.gov/disability/professionals/bluebook/14.00-Immune-Adult.htm - 14_11

https://secure.ssa.gov/apps10/poms/images/SSA4/G-SSA-4734-U8-1.pdf

https://www.disabilitybenefitscenter.org/ state-social-security-disability



UPDATE

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

FEATURED LITERATURE FROM CROI 2020

Chinula L et al. Safety and Efficacy of Dolutegravir versus Efavirenz and Tenofovir Disoproxil Fumarate versus Tenofovir Alafenamide in Pregnancy: IMPAACT 2010 Trial. CROI 2020, Boston, MA. Abstract # 130

This study compared the safety and virologic efficacy in pregnancy of three antiviral regimens: Dolutegravir (DTG) + emtricitabine (FTC)/tenofovir alafenamide fumarate (TAF); DTG + FTC/tenofovir disoproxil fumarate (TDF) and efavirenz (EFV)/FTC/TDF. The trial included 643 HIV-infected women from 22 sites in nine countries. The subjects were randomized (1:1:1) to open-label DTG+FTC/TAF, DTG+FTC/TDF, or EFV/FTC/TDF at 14 to 28 weeks gestational age. The women were allowed to have taken no more than 14 days of antiretroviral therapy (ART) before randomization. The baseline median gestational age at study entry was 22 weeks. Median viral load at baseline was 903 copies/mL and the median CD4 count was 466 cells/uL.

The primary goal of the IMPAACT trial was comparing the two combined DTG-containing arms to the EFV arm for non-inferiority (-10% margin), and also superiority, with regards to having a viral load of < 200 copies/mL at time of delivery. Safety outcomes between the three arms included: A) Adverse pregnancy outcomes (preterm delivery <37 weeks, small for GA <10 percentile, spontaneous abortion or stillbirth; B) Maternal grade > three adverse events through 14 days postpartum; C) infant grade > three adverse events including neonatal death at < 28 days. At time of delivery, 97.5 percent of women in the combined DTG arms compared to 91 percent in the EFV arm had viral loads of <200 cp/ mL. This difference was statistically significant (p=0.005). Pregnancy outcomes were available for 99.5 percent of the subjects. Only 24 percent of women in the DTG+FTC/TAF arm had an adverse pregnancy outcome compared to 33 percent in the DTG+FTC/TDF and 33 percent in the EFV/ FTC/TDF arms. Two infants were diagnosed with HIV at <14 days, one each in DTG+FTC/TAF and DTG+FTC/TDF arms. For one, the maternal VL at delivery was 58,590 cp/mL however, the second mother was undetectable (< 40 cp/mL), suggesting in-utero transmission occurred.

AUTHOR'S COMMENTARY:

The findings of the IMPAACT trial should influence clinical practice including an update of the Department of Health and Human Services (DHHS) perinatal guidelines for HIV treatment in pregnancy. Not only were virologic outcomes superior with DTG but there were also fewer adverse events with DTG + FTC/TAF. Data published in 2019 re-established the overall safety and efficacy of DTG use in pregnancy regarding neural tube defects and this update was included in guidance by the World Health Organization (WHO). Prior to the IMPAACT trial there was little data on the use of TAF in pregnancy. This study suggests that it may be preferable to TDF.

Webcast Link: http://www.croiwebcasts.org/p/2020croi/croi/130

FEATURED LITERATURE FROM CROI 2020

Orkin C et al. Long-acting CABOTEGRAVIR + RILPIVIRINE for HIV Treatment: Flair Week 96 Results. CROI 2020 | Boston, MA. # 482

The 48-week data on the FLAIR study investigating the use of two long-acting (LA) injectable agents, the integrase strand transfer inhibitor (INSTI) cabotegravir (CAB) and the non-nucleoside reverse transcriptase inhibitor (NNRTI) rilpivirine (RPV) were recently published in The New England Journal of Medicine (NEJM) and discussed here (March 24, 2020). At CROI, the 96-week data from the study was presented. The trial included 566 antiretroviral therapy (ART)-naïve patients who were virologically suppressed (HIV-1 RNA < 50 c/mL) while taking a three-drug oral regimen of dolutegravir/abacavir/lamivudine. After 16 weeks, participants were randomized (1:1) to either continued oral therapy or switch to CAB + RPV given as two IM injections every four weeks. Those randomized to the CAB/RPV arm first received oral formulations of these agent for four weeks. The two endpoints assessed at 96 weeks were subjects with viral loads ≥50c/mL and <50c/mL. Confirmed virologic failures included those with two consecutive viral loads ≥200c/mL. At week 96, only nine (3.2%) participants in each arm had viral loads > 50c/ mL, confirming non-inferiority seen at week 48. The rate of virologic failure in the CAB + RPV was unchanged at about one percent from week 48 to week 96. Of these four participants, three had NNRTI mutations and one had an INSTI mutation. The rate of failure was the same (n=4) in the oral therapy arms.

Across both arms, adverse events (AE) were uncommon and led to treatment withdrawal in only one percent in the oral therapy arm and four percent in the IM arm. Injection site reactions were the most common drug-related AE but their frequency decreased over time. Moreover, at week 96 those receiving the IM therapy reported greater overall treatment satisfaction compared to those in the oral therapy arm. These results attest to the durability of CAB+RPV LA. An extension phase of the FLAIR study is ongoing.

AUTHOR'S COMMENTARY:

These data complement the 96-week data from ATLAS 2M and provide additional evidence for the efficacy and tolerability of long-acting injectable ART. On March 20th, IM CAB plus RPV (Cabenuva®) was approved for use in Canada. As noted in my commentary on ATLAS2M, I would anticipate having these agents available sometime during 2020 with hopefully an eight-week treatment option for patients. The initial FDA approval of CAB-RPV was expected in December 2019 but reportedly delayed due to manufacturing problems and not specifically efficacy or safety concerns.

Webcast Video Link: http://www.croiwebcasts.org/p/2020croi/ croi/482-PS

FEATURED LITERATURE FROM CROI 2020

Overton ET al. CABOTEGRAVIR + RILPIVIRINE every two Months is Non-Inferior to Monthly: ATLAS-2M Study. CROI 2020, Boston, MA. Abstract #34

The two-drug regimen of long-acting (LA) cabotegravir (CAB) and rilpivirine (RPV) given IM every four weeks was found to be highly effective and non-inferior to daily oral antiretroviral therapy (ART) in two Phase 3 studies. These results and the known pharmacokinetics of CAB+RPV enabled the evaluation of a longer and more convenient eight-week dosing interval.

The ATLAS-2M is a multicenter, open-label, Phase 3b noninferiority (NI) study of CAB+RPV maintenance therapy given Q 8-weeks or Q4-weeks to treatment-experienced, HIV-infected adults. The study randomized 1,045 persons who were virologically suppressed on IM CAB+RPV every four weeks (rolled over from the ATLAS study) or on oral therapy, to receive CAB+RPV every eight or every four weeks. Sixty-three percent were naive to CAB+RPV LA while 37 percent transitioned from the Q4-week arm of the ATLAS trial. The primary endpoint (at week 48) was the proportion of subjects with plasma HIV-1 RNA ≥ 50 c/mL with a NI margin of four percent and the secondary endpoint was the proportion with HIV-1 RNA < 50 c/mL based on a NI margin of 10 percent. For the primary endpoint CAB +RPV given Q8 weeks was noninferior to Q4-week dosing (1.7% vs 1.0%) and for the secondary analysis 94.3 percent vs 93.5 percent had viral loads < 50 c/mL. There were eight confirmed virologic failures (two sequential VLs of > 200 c/mL) in the eight-week arm and two confirmed virologic failures in the Q4-week arm. Five and 0 (NOT SURE WHAT THIS MEANS) of the virologic failures respectively, had archived resistance-associated mutations to RPV either alone (n=4) or with a CAB mutation (n=1) at baseline. On-treatment resistance mutations to RPV, CAB, or both drugs not present at baseline were found in five out of eight of the eight-week virologic failures and both of the four-week virologic failures. The safety profiles were similar for four-week and eight-week dosing. Injection site reactions were reported in 98 percent of participants but were mild or moderate and lasted a median of three days. Discontinuation for an adverse event occurred in only two percent of patients including 12 in the eightweek and 13 in the four-week groups. Of those treated every eight weeks (rolled over from ATLAS Q 4-weeks), 93 percent expressed a preference for Q8-week dosing. This study concludes that Q8-week dosing of LA CAB+RPV is non-inferior to Q4-Week dosing and generally well tolerated, thus supporting the therapeutic effectiveness of these two antiviral agents given at two-month intervals.

AUTHOR'S COMMENTARY

This is the follow-up data from the 48-week data recently published in The New England Journal of Medicine (NEJM) and presented as the Clinical Research Update on March 24th (ATLAS and FLAIR trials). It appears likely by the end of this year, if not sooner, long-acting IM CAB+RPV will be a therapeutic option for some of our patients.

However, there will be logistical issues with clinical sites and reimbursement factors to work out. Overall, an eight-week option for this treatment would certainly be preferable to every four weeks.

Webcast Link: http://www.croiwebcasts.org/p/2020croi/croi/34

FEATURED LITERATURE FROM CROI 2020

Marcus JL. Increased Overall Life Expectancy but not Comorbidityfree Years for People with HIV. CROI 2020, Boston, MA. Abstract # 151.

The life expectancy for persons living with HIV (PLWH) is often noted in the post-antiretroviral (ART) era to be "normal" or "similar" to those without HIV. However, this opinion is perhaps more observational than quantitatively factual. This study included a large cohort (N=39,000) of adult PLWH who lived in California, Maryland, Virginia and the District of Columbia. They were matched 1:10 for ethnicity/race, sex, calendar year and site of medical care to uninfected adults. These patients were in care from 2000 to 2016. The authors used abridged life tables to estimate the average number of total and comorbidity-free years of life remaining, beginning at age 21 by calendar year. The co-morbidities specifically looked at included: cancer, cardiovascular disease (CVD), diabetes, liver disease, renal disease or respiratory disease. Among the 39,000 PLWH, there were 2,661 deaths compared to 9,147 deaths in the control group which translated to mortality rates of 1,303 verses 390 per 100,000 person years. From 2000-2003, life expectancy at age 21 was about 58 for PLWH compared to 79 for those without HIV-a gap of about 20 years.

Over time, life expectancy for both groups improved and in 2016 a PLWH were expected to live until age 77 compared to age 86 for someone not infected—a significant gap of nine years. However, for those who initiated ART with a CD4 count > 500 cells/mm3 the study found no difference in life expectancy. In regards to comorbidities, PLWH were likely to have a first onset of one of these conditions at age 37 compared to age 52 in persons without HIV. This number has not improved over time. For persons who initiated ART with a CD4 count > 500 cells/mm3 there was a decrease in incidence of CVD and cancer but not diabetes, kidney, liver or lung disease or renal disease.

AUTHOR'S COMMENTARY

This is an important study rich with data that has significant clinical implications for our patients. While it is true patients with HIV are living longer, life expectancy across the board is NOT the same as those without HIV, except for those who had a normal CD4 count at the time of diagnosis and had early initiation of ART. This supports our goals of early diagnosis and treatment known to be imperative for a variety of reasons, including preventing new infections. Conversely, HIV infection appears to still confer increase risk for co-morbid illness with a much earlier onset than in persons without HIV, resulting in "fewer healthy years." I would encourage you to watch the FULL presentation of this study by Dr. Julia Marcus at the link below. http://www.croiwebcasts.org/console/player/44840?mediaType=slideVideo& HIV

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