POZ 30
POSITIVELY AWARE
HONORING THIRTY YEARS PUBLISHED BY TPAN
MAY+JUNE 2020

VIRTUAL REALITY: CROI 2020 UPDATE

#DAILYLOOKCHALLENGE: LIFTING US ALL UP ON SOCIAL MEDIA

THE EFFECT OF HIV/AIDS ON AGING

SEX AND PLEASURE IN THE TIME OF COVID-19

IT'S A BRAVE NEW WORLD

—and living with HIV helped prepare him for it, says **QUINTIN CAMMACK**

POSITIVELY AWARE

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EDITOR-IN-CHIEF
JEFF BERRY
@PAeditor

ASSOCIATE EDITOR
ENID VÁZQUEZ
@enidvazquezpa

HEPATITIS C EDITOR
ANDREW REYNOLDS
@AndrewKnowsHepC

CREATIVE DIRECTOR
RICK GUASCO
@rickguasco

PROOFREADER
JASON LANCASTER

PHOTOGRAPHERS
JOHN GRESS
CHRIS KNIGHT

ADVERTISING MANAGER
LORRAINE HAYES
L.Hayes@tpan.com

DISTRIBUTION MANAGER
DENISE CROUCH
distribution@tpan.com

SUBSCRIBE OR ORDER COPIES
positivelyaware.com/subscribe

LIVE LIFE POSITIVELY AWARE.

FOR 30 YEARS, PUBLISHED BY
TPAN
5537 N. BROADWAY
CHICAGO, IL 60640-1405
(773) 989-9400
FAX: (773) 989-9494
inbox@tpan.com
positivelyaware.com
@PosAware

TPAN was founded in 1987 in Chicago as Test Positive Aware Network, when 17 individuals living with HIV gathered in a living room to share information and support in response to the HIV/AIDS epidemic. POSITIVELY AWARE is the expression of TPAN's mission to share accurate, reliable, and timely treatment information with anyone affected by HIV.

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BRAVING A NEW WORLD

AN HIV DIAGNOSIS can change your world; the COVID-19 pandemic has changed the world for everyone. Quintin Cammack, who appears on the cover of this issue, says that living with HIV helped prepare him for a new, new normal.

How has living with HIV prepared you in coping with the COVID-19 pandemic?

Being a Black same-gender-loving man living in America prepared me most for COVID-19. I grew up in a small town in Alabama where the environment had been polluted. Monsanto Chemical operated a plant that leaked polychlorinated biphenyl, or PCB, into the air and water, and a nearby army base incinerated chemical weapons. When I was 12 years old, we were issued ventilators and gas masks, and my family was told to "shelter in place" because of a possible exposure to chemical weapons. From losing my mother to breast cancer in 2014 to getting diagnosed with HIV in 2017, you build this bulletproof-like resilience. Resilience has taught me the importance of cherishing the simplest things. Another day's not promised to any of us, which is why I have "Live to Die Another Day" tatted on my chest. It's helped me to live each day to the fullest.

Being diagnosed with HIV changed so many things for me. I found educating myself about my new-normal helped me to combat the stigma, fear, and isolation that came with my diagnosis. When COVID-19 struck the U.S., there was so much inaccurate and incomplete information floating around, especially in black and brown communities. Educating myself with reliable sources, webinars, and state and community news has helped the most. Also, asking my primary care provider (PCP) questions related to HIV and COVID-19. It's helped me to eliminate worry so I can focus on keeping moving as healthy as possible.

What are you doing as self-care during the pandemic?

Creating and keeping busy has probably been the best self-care for me. I've been cooking from fresh produce and juicing a lot, and I fit cardio and workouts into my remote work schedule. Sticking to a fitness plan at home has been the hardest adjustment since the stay-at-home order was issued in Illinois. I've set some goals, but haven't been as consistent as I would be in an actual gym setting.

Telehealth is still taking me some time to get used to. It has been awesome to check in with my therapist biweekly via phone. I'm grateful as well to have a great relationship with my PCP. The pandemic adds a different type of awareness to my overall health and how I communicate with my doctor. Utilizing community services and resources like Walgreens Community Pharmacy's delivery service gives me peace of mind in knowing my medication will arrive in the mail when needed.

I'm learning during the pandemic to slow it down a bit and not rush. Waking up early to catch the sunrise with a cup of tea helps to separate the days and plot my next moves. Our enclosed back porch has become my escape from reality.

Is there anything new or different you've been doing—a hobby or activity—since the pandemic?

I started an indoor garden where I spend most of my time meditating and creating. Growing up, we always had a garden, and I found the environment therapeutic. I've planted a few herbs and some succulents to start and plan to add some lettuce, garlic, and peppers soon. Organizing my music has been on my to-do list for a while. I've had the extra time to make some mood playlists—one of many things I've marked off my list since the pandemic.

How are you reaching out to other people—family members, friends, other people living with HIV?

Google Duo has been the winner for me in staying connected with everyone. I like that you can talk to both iPhone and Android users. Before social distancing, we'd link with friends at The Sit Down in Hyde Park, so we named our group "The Sit Down." I also love chatting on iMessage, too.

On Facebook, I manage the Black Men's Health page and group. We share content to inspire black men to develop and learn new habits around holistic health and wellness. I've been engaging more on my digital platforms as well to speak candidly and transparently about my personal experiences of being black and living with HIV.

There's a required level of vulnerability to open up and share your experiences, especially in a time of uncertainty and misinformation. I think it's essential that we are contributing to accurate information related to COVID-19 to combat stigma and educate those living with HIV/AIDS and other autoimmune diseases.

COMPILED BY **RICK GUASCO**

FOLLOW Quintin on Instagram (@fromwest15th) and check out his work using #fromwest15th.

MAY+JUNE 2020

VOLUME 30 NUMBER 3 positivelyaware.com @posaware

EVERY ISSUE

4
EDITOR'S NOTE
Let's stay connected: The loss of another's touch is depriving many of us of a basic, fundamental need we have as humans to connect.

6
BRIEFLY
Interim COVID-19 guidance for persons with HIV. U=U guidelines. Egrifta and NASH. Crixivan discontinued. New pediatrics recommendation. Philadelphia Safehouse update.

25
POSITIVELY AGING
THE LIFE-SAVING POWER OF CONNECTION
In the face of uncertain times, here's what we can do to stay connected to each other, suggests **David Fawcett PhD, LCSW**.

43
THE CATEGORY IS...
SELF-CARE REALNESS.
What are you doing for self-care during the COVID-19 pandemic?

THIS ISSUE

14
THE EFFECTS OF HIV/AIDS ON AGING: STILL UNCLEAR
Why do some thrive while others struggle? What researchers know.
BY **JOHN-MANUEL ANDRIOTE**

18
STRUGGLING WITH COPD
My sister's fight for air.
BY **ENID VÁZQUEZ**

20
COVID-19 UPDATE AND RESOURCES
Information on the coronavirus for people living with HIV.

26
THE UNDISCOVERED COUNTRY
How telehealth is taking HIV care into new territory.
BY **RICK GUASCO**

29
COVID-19 Q&A WITH DR. DAVID WOHL
An infectious disease specialist who witnessed the Ebola epidemic offers insight into the current pandemic.

38
PICKETT FENCES
LOVE THE ONE YOU'RE WITH
Sex and pleasure in the time of COVID-19.
BY **JIM PICKETT**

40
#DAILYLOOKCHALLENGE
Using social media, art, and creativity to lift us all up.
BY **JEFF BERRY**

PA30 THIRTY YEARS OF POSITIVELY AWARE

44
THREE DECADES OF POSITIVELY AWARE
Empowering people living with HIV with support and information.
COMPILED BY **ENID VÁZQUEZ**

CONFERENCE UPDATE
CROI 2020

30
VIRTUOSITY AT CROI 2020
Leading HIV conference goes virtual in a time of pandemic.
BY **ENID VÁZQUEZ**

31
TAKING MEDS MONTHLY—OR POSSIBLY ONCE A YEAR
An overview of long-acting medications for HIV treatment and prevention.
BY **ENID VÁZQUEZ**

32
NEW LONG-ACTING DRUGS IN DEVELOPMENT
Trend towards long-acting HIV medications continues.
BY **ENID VÁZQUEZ**

34
FATTY (T)ISSUES
Weight gain and HIV medications.
BY **ENID VÁZQUEZ**

36
ADVANCE WORK
2020 Pre-CROI Community HIV Cure Research Workshop.
BY **RICHARD JEFFERYS**

JEFF BERRY

Let's stay connected

When I first started seeing the news reports coming out of China and Italy, it felt like I was trapped in a nightmare and couldn't wake up. Reading the accounts from doctors who were fighting on the frontlines and risking their lives was surreal. When news arrived in early April that the first physician in the U.S. had died, Frank Gabrin of New York, 100 doctors, nurses, and providers around the globe had already lost their lives, mostly from Spain, Italy, and China. There are now over 500 health care workers on that list, which is likely incomplete. Gabrin, who was 60, died at home in the arms of his husband, Arnold Vargas, whom he called Angel, after being sick for nearly two weeks. He had been using the same N95 mask for four days in a row due to a lack of personal protective equipment (PPE).

The loss of another's touch is depriving many of us of a basic, fundamental need we have as humans to connect.

One of the cruelest things about COVID-19, the disease caused by the SARS-CoV-2 virus, is that people often die alone, with no one by their side to comfort them or hold their hand. To make matters worse, families aren't able to gather to honor the lives of their loved one.

As I write this, Illinois Governor J.B. Pritzker has extended the state's stay-at-home order for another five weeks, through the end of May. My husband and I will continue to shelter in place, wear our masks when we leave the house, and wash our hands frequently. But I know we are incredibly lucky to be able to continue to have a job (although his hours have been significantly reduced because he works in the travel industry), health insurance, a roof over our heads, and each other. This experience has in some ways actually brought us closer together, we're so grateful that we haven't lost the ability to give and receive touch and intimacy—many who live alone don't have that. The loss of another's touch is depriving many of us of a basic, fundamental need we have as humans to connect.

This virus disproportionately affects black and brown communities, and lays bare the deadly effects of centuries of inequality and racism. Lack of access to health care, unstable housing and homelessness, malnutrition and lack of food, and economic disparities all lead to poorer health outcomes with more pre-existing conditions such as diabetes and high blood pressure. As of this writing there have been over 51,061 deaths in the U.S. due to COVID-19, and nearly 200,000 worldwide. In those cases in the U.S. where race has been reported, over 33% of those deaths were in black or African American people while they represent only 13.4% of the U.S. population. The CDC reports that Latinos represent 27% of deaths in COVID-19 hotspots, but just 18% of our country's population.

What is currently happening in our jails and prisons is unconscionable. Chicago's Cook County Jail has already seen seven deaths, including at least one correctional officer. Nearly 400 inmates and scores of correctional officers have tested positive at the jail. In an Ohio federal prison, now one of the leading hotspots in the country, 73% of inmates tested positive for COVID-19, with 3,762 inmates and 319 staff testing positive in the state's prison system overall. *The New York Times* Editorial Board has called for the immediate release of non-violent inmates, speeding up of paroles, and for law enforcement to issue citations for non-violent offenders instead of sending them to jail, in an effort to curb new infections from occurring within the prison system.

While many of us know people with HIV who have died from COVID-19, people with controlled HIV (on treatment and undetectable) and with no pre-existing conditions do not seem to be at notably greater risk of getting sick. But with over 50% of people living with HIV now over the age of 50, our survival has become a double-edged sword. Older adults are at increased risk, especially if they have a severe underlying condition such as diabetes or hypertension, so it seems that many of us survived one epidemic only to be facing another. *The New York Times* reports that people age 70 and up account for two-thirds of all deaths in New York, though they make up less than 10% of the population. Luckily a lot of smart folks, including many HIV activists, researchers, and physicians, are working on finding a treatment and eventually a vaccine for COVID-19, but it's going to take some time.

So, what does all this mean? I have no idea, but I do know that when we come out of this, *and we will*, life will be forever changed. A few weeks ago, I was out walking our dog and saw a young girl with her mother. They had just pulled up and parked in front of an apartment building, with a sign taped to

JOHN GRESS

the van that said "Happy Birthday, Amanda!" They rang the doorbell, placed a gift bag and balloon on the stoop, and stepped back. Another young girl came out and took the gifts while they exchanged a few words. It was such an incredible act of kindness, but suddenly a great sense of sadness washed over me, and I began to get emotional. Young people everywhere are being robbed of the occasions in their lives that we all got to experience and took for granted: birthday parties, graduation ceremonies, weddings, and other family gatherings and events are now being postponed or cancelled. This is nothing compared to the sacrifices being made by people working on the frontlines of the pandemic, and it's a small sacrifice to be made in the grander scheme of things. But it still made me incredibly sad.

There is a video that recently went viral of a young doctor who arrives home from work and is still in his scrubs. His little boy runs toward him to greet him, and suddenly the man shouts, "No, no, no!!" and the toddler stops. His father then falls to his knees and begins to weep, leaving his young son likely unable to understand why he can't leap into his father's arms as he surely had done every other night.

I realize I've been grieving the loss of life as it was. I also sometimes find myself fearful of what the future may hold.

This is where self-care comes in. It's important for us to take care of ourselves if we are ever going to get through this. I try to limit my intake of news, and the weekends I pretty much unplug from it altogether. I try to stick to a regular schedule; keeping a routine is important. Each weekday morning I take a shower and put on a nice shirt before I sit down at my desk. Stephen and I both go to bed around the same times as we used to (besides, our dog and cat still wake up early!). I even pulled out my mixing board and have been deejaying at home on some weekends playing disco and dance music from the '70s, '80s, and '90s, and have live-streamed it a few times. One friend commented, "I've never seen you so happy!" I realized that it's important to find things that bring you, and others, joy.

We've all been finding new ways of connecting whether it be Zoom, FaceTime, Skype, or some other platform. It's important to stay connected and interact with others, even if you can't hug or see them in person.

A friend of mine was recently profiled in a story in the *Wall Street Journal* about using Zoom as a way to keep in touch with his family. Abel is able to be with his mom to do her daily rosary via Zoom, which he says had helped keep her calm during a recent birthday gathering. The article states that although Abel doesn't share all his mother's religious beliefs, he draws comfort from praying together. "I 100% realize the benefit of community that religion creates, and I know this is the time for this kind of community support to be kicked into motion."

Let's continue to find ways to stay connected and build community as we get through this pandemic, and beyond. Let's imagine the world as we want it to be, and work together to help make it happen. The situation we are in now is giving us an opportunity to pause, rethink and reimagine everything that we once took for granted. Life will be different, yes, but change isn't necessarily always a bad thing. We have an opportunity for a change in perspective, and to look at the world in a new and different way.

Take care of yourself, and each other.

© 2020 POSITIVELY AWARE (ISSN: 1523-2883) is published bi-monthly by **Test Positive Aware Network (TPAN),** 5537 N. Broadway, Chicago, IL 60640. TPAN is an Illinois not-for-profit corporation, providing information and support to anyone concerned with HIV and AIDS issues. POSITIVELY AWARE is a registered trademark of TPAN. All rights reserved. Readership: 100,000. For reprint permission, email inbox@tpan.com. Six issues mailed bulk rate for $30 donation; mailed free to those living with HIV or those unable to contribute

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inbox@tpan.com

@posaware

POSITIVELY AWARE
5537 N.
BROADWAY
CHICAGO, IL
60640-1405

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BRIEFLY

COVID-19 outbreak and HIV

At press time, information regarding the outbreak of COVID-19 continued to change rapidly. On March 20, the U.S. Department of Health and Human Services (HHS) released recommendations regarding the outbreak in its HIV treatment guidelines. See pages 8–9.

POSITIVELY AWARE on March 11 published a COVID-19 update for PLHIV online that included safer drug use information for people who use drugs. GO TO positivelyaware.com/coronavirus.

The outbreak of COVID-19 and large-scale isolation policies and shutdowns to prevent it have caused a wave of event postponements and uncertainty in the HIV services and advocacy sector. Numerous major conferences, fundraisers, and non-profits have been affected.

Organizers of the **23rd International AIDS Conference, also known as AIDS 2020**, announced that it is going virtual. AIDS 2020 is scheduled to be held July 6–10. Approximately 20,000 individuals from around the world have attended past conferences, an event that is both medical and community-oriented.

"We are acutely aware that there is not yet sufficient research on the impact of COVID-19 on people living with HIV. We are also conscious of the fact many delegates working in health and research are currently stretched and are providing essential support to their communities. We feel a special obligation to reducing any potential risk to both of these groups," the organizers stated.

Go to aids2020.org for more information.

HIV2020, the alternative community conference organized by MPact that was to be held in Mexico City at the same time as AIDS 2020, has been cancelled, and alternatives are being explored. "Canceling HIV2020 as an in-person conference was a difficult but necessary decision, given the COVID-19 crisis," says MPact Executive Director George Ayala. "The health, wellness, and safety of our communities must come first. MPact is working closely with the other HIV2020 organizers—NSWP, INPUD, ITPC, GNP+, ICSS, and Mexican advocates—to produce a series of community-led virtual sessions, drawing from the top scoring proposals we received. In addition, we will be conducting online consultations to solicit inputs from activists about steps the International AIDS Society could take to more meaningfully and consistently engage our communities in their decisions about the location, frequency, structure, and scale of future AIDS conferences. So stay tuned." GO TO HIV2020.org for future announcements.

On March 30, the Sero Project announced it was postponing its training academy on HIV decriminalization. "We have reluctantly, but unanimously, decided for the safety of our staff, advocates, and community members that we must postpone **HIV is Not a Crime IV National Training Academy** until 2021." The academy, organized in collaboration

VÁZQUEZ: JOHN GRESS • FACE MASK: ISTOCK

with the Positive Women's Network-USA, Positively Trans, THRIVE SS, and the U.S. PLHIV Caucus, is now scheduled for May 22–25, 2021, at Ohio State University. GO TO seroproject.com.

The SYNChronicity conference (SYNC 2020) on HIV, HCV, STI, and LGBTQ health education, training, advocacy, and research is going virtual, June 23–25. SYNC 2020 is organized by HealthHIV, HealthHCV, and the National Coalition for LGBT Health. GO TO sync2020.org.

The United States Conference on HIV/AIDS (USCHA) is scheduled to take place in San Juan, Puerto Rico October 10–13. NMAC said at press time that it will make a decision as to whether the conference will continue as scheduled, go virtual, or be postponed to Spring of 2021. Those who wish to attend should still continue to register and apply for scholarships, but there are no hard deadlines. NMAC will refund applications if needed. GO TO uscha.life.

In April, the **HIV Research for Prevention (HIVR4P)** conference was postponed to January 17–21, 2021. Other deadlines related to the conference, to be held in Capetown, were also moved back.

The impact of COVID-19 on fundraising for some of the nation's leading HIV service organizations has been far-reaching. The majority of HIV service organizations licensed to host **Dining Out For Life** in their respective cities (including TPAN in Chicago, the publisher of POSITIVELY AWARE) have postponed their events, some to fall dates, others until further notice. GO TO diningoutforlife.com.

The AIDS/Lifecycle, benefiting the Los Angeles LGBT Center and the San Francisco AIDS Foundation, was set to take place in late May and June and is one of the largest HIV-focused fundraisers in the country. Organizers announced on March 17 that the event would be cancelled in its traditional format and that they would pursue their goals through online fundraising.

"We are heartbroken that the AIDS/LifeCycle 2020 event won't happen in the way we've all come to know and love this year, but we remain as committed as ever to [its] mission," the organization stated on its website.

The postponement of in-person events like galas, sporting events, and volunteer gatherings has left many non-profits re-organizing how they will meet their fundraising needs. "We're determined as ever to rally our community and ensure that people affected by HIV have the resources and services they need during this crisis," said Bryant Dunbar, Director of Development at TPAN." TPAN's **Ride for Life Chicago** (formerly, the Ride for AIDS) currently holds to its schedule of September 12-13. "We are rolling out more virtual opportunities to make a difference, and we're planning contingencies so that our riders and volunteers stay safe, as we work together to safeguard the health of thousands of people." GO TO rideforlifechicago.org.

Treatment as prevention (U=U) guidelines

U.S. treatment guidelines have made official what we already knew: the use of HIV therapy to successfully suppress viral load to undetectable prevents transmission to sex partners.

The magic of undetectable viral load in preventing HIV was initially debated with the release in 2008 of the Swiss statement (and naturally, there was evidence before then that led up to the statement). In 2011 interim results from the landmark HPTN 052 study showed a 96% reduction of HIV transmission within serodiscordant couples assigned to early antiretroviral therapy (ART). (Final study results found that there were no transmissions of the virus within the couple when the partner with HIV remained undetectable.)

The reality was confirmed with the international PARTNER study findings published in 2016, and Opposites Attract in 2017, again showing zero transmissions occurred between partners when the person with HIV was on ART and had suppressed viral load.

On December 18, 2019 the U.S. guidelines provided updated guidance on prevention with HIV therapy, stating "Clinical trials have shown that using effective antiretroviral therapy (ART) to consistently suppress plasma HIV RNA levels to [less than] 200 copies/mL prevents transmission of HIV to sexual partners. **When ART is used to prevent HIV transmission, this strategy is called treatment as prevention (TasP), commonly known as Undetectable = Untransmittable or U=U.**

"The Panel on Antiretroviral Guidelines for Adults and Adolescents (the Panel) has added a new section to help providers integrate TasP into their clinical practice. The key recommendations include:

- Providers should inform persons with HIV that maintaining HIV RNA levels [less than] 200 copies/mL with ART prevents HIV transmission to sexual partners (AII).*
- Persons starting ART should use another form of prevention with sexual partners for at least the first 6 months of treatment and until an HIV RNA level of [less than] 200 copies/mL has been documented (AII). Many experts recommend confirming sustained suppression before assuming that there is no risk of sexual HIV transmission (AIII).
- Persons with HIV who rely on ART for prevention need to maintain high levels of ART adherence (AIII). They should be informed that transmission is possible during periods of poor adherence or treatment interruption (AIII).
- Providers should inform patients that maintaining an HIV RNA level of [less than] 200 copies/mL does not prevent acquisition or transmission of other sexually transmitted infections (AII)."

* Indicates strength of recommendation based on evidence. AI is the highest rating.
The guidelines can be accessed at aidsinfo.nih.gov.

Interim Guidance for COVID-19 and Persons with HIV

FIRST ISSUED March 20, and updated as necessary by the U.S. Department of Health and Human Services in its Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Follow updates at aids.info.nih.gov. Also go to coronavirus.gov from the Centers for Disease Control and Prevention (CDC) and nih.gov/coronavirus from the National Institutes of Health.

This interim guidance reviews special considerations for persons with HIV and their health care providers in the United States regarding COVID-19. Information and data on COVID-19 are rapidly evolving. This guidance includes general information to consider. Clinicians should refer to updated sources for more specific recommendations regarding COVID-19.

GUIDANCE FOR
All persons with HIV

In current reports, individuals aged [greater than] 60 years and those with diabetes, hypertension, cardiovascular disease, pulmonary disease, or obesity are at highest risk of life-threatening COVID-19, the illness caused by the virus known as SARS-CoV-2.

The limited data currently available do not indicate that the disease course of COVID-19 in persons with HIV differs from that in persons without HIV. Before the advent of effective combination antiretroviral therapy (ART), advanced HIV infection (i.e., CD4 cell count [less than] 200/mm^3) was a risk factor for complications of other respiratory infections. Whether this is also true for COVID-19 is yet unknown.

Some people with HIV have other comorbidities (e.g., cardiovascular disease or lung disease) that increase the risk for a more severe course of COVID-19 illness. Chronic smokers are also at risk of more severe disease.

Thus, until more is known, additional caution for all persons with HIV, especially those with advanced HIV or poorly controlled HIV, is warranted.

Every effort should be made to help persons with HIV maintain an adequate supply of ART and all other concomitant medications.

Influenza and pneumococcal vaccinations should be kept up to date.

Persons with HIV should follow all applicable recommendations of the U.S. Centers for Disease Control and Prevention (CDC) to prevent COVID-19 (cdc.gov/coronavirus/2019-ncov/prepare/prevention.html), such as social distancing and proper hand hygiene. These recommendations are regularly updated.

Information on COVID-19 prevention in children with HIV for pediatric health care providers (cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html) and the general public (cdc.gov/coronavirus/2019-ncov/prepare/children-faq.html) is available from CDC.

CDC also provides information about COVID-19 prevention during pregnancy (bit.ly/covid19andpregnancy).

ANTIRETROVIRAL THERAPY

Persons with HIV should:

- Maintain on-hand at least a 30-day supply—and ideally a 90-day supply—of antiretroviral (ARV) drugs and other medications.
- Talk to their pharmacists and/or healthcare providers about changing to mail order delivery of medications when possible.
- Persons for whom a regimen switch is planned should consider delaying the switch until close follow-up and monitoring are possible.

To date, no drug has been proven to be safe and effective for treating COVID-19. Many drugs, including some ARV agents (e.g., lopinavir/ritonavir, boosted darunavir, tenofovir disoproxil fumarate/emtricitabine), are being evaluated in clinical trials or are prescribed for off label use for the treatment or prevention of COVID-19. Persons with HIV should not switch their ARV regimens or add ARV drugs to their regimens for the purpose of preventing or treating SARS-CoV-2 infection.

Clinic or laboratory monitoring visits related to HIV care:

- Together with their health care providers, persons with HIV and their providers should weigh the risks and benefits of attending, versus not attending in-person, HIV-related clinic appointments at this time. 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.
- 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.

Persons with HIV and in opioid treatment programs:

Clinicians caring for persons with HIV who are enrolled in opioid treatment programs (OTPs) should refer to the Substance Abuse and Mental Health Services Administration (SAMHSA) website (samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines/covid-19-guidance-otp) for updated guidance on avoiding treatment interruptions. State methadone agencies are also responsible for regulating OTPs in their jurisdictions and may provide additional guidance.

GUIDANCE FOR
Persons with HIV who have fever or respiratory symptoms and seeking evaluation and care

Health care workers should:

Follow CDC recommendations (bit.ly/COVID19inhealthcaresetting), as well as state and local health department guidance on infection control, triage, diagnosis, and management.

Persons with HIV should:

- Follow CDC recommendations regarding symptoms.
- If they develop a fever and symptoms (e.g., cough, difficulty breathing), they should call their health care provider for medical advice.
- Call the clinic in advance before presenting to the care providers.
- Use respiratory and hand hygiene and cough etiquette when presenting to the healthcare facility and request a face mask as soon as they arrive.
- If they present to a clinic or an emergency facility without calling in advance, they should alert registration staff immediately upon arrival of their symptoms so that measures

can be taken to prevent COVID-19 transmission in the health care setting. Specific actions include placing a mask on the patient and rapidly putting the patient in a room or other space separated from other people.

GUIDANCE FOR
Persons with HIV in self-isolation or quarantine due to SARS-CoV-2 exposure

Health care workers should:

- Verify that patients have adequate supplies of all medications and expedite additional drug refills as needed.
- Devise a plan to evaluate patients if they develop COVID-19-related symptoms, including for possible transfer to a health care facility for COVID-19-related care.

Persons with HIV should:

- Contact their health care provider to report that they are self-isolating or in quarantine.
- Specifically, inform their health care provider how much ARV medications and other essential medications they have on hand.

GUIDANCE FOR
Managing persons with HIV who develop COVID-19

When hospitalization is not necessary, the person with HIV should:

- Manage symptoms at home with supportive care for symptomatic relief.
- Maintain close communication with their health care provider and report if symptoms progress (e.g., sustained fever for [more than] 2 days, new shortness of breath).
- Continue their ARV therapy and other medications, as prescribed.

When the person with HIV is hospitalized:

- ART should be continued. If the ARV drugs are not on the hospital's formulary, administer medications from the patients' home supplies.
- ARV drug substitutions **should be avoided**. If necessary, clinicians may refer to recommendations on ARV drugs that can be switched (bit.ly/ARVswitch) in the U.S. Department of Health and Human Services (HHS) guidelines for caring for persons with HIV in disaster areas.
- For patients who receive ibalizumab (IBA) intravenous (IV) infusion every 2 weeks as part of their ARV regimen, clinicians should arrange with the patient's hospital provider to continue to administer of this medication without interruption.
- For patients who are taking an investigational ARV medication as part of their regimen, arrangements should be made with the investigational study team to continue the medication if possible.
- For critically ill patients who require tube feeding, some ARV medications are available in liquid formulations and some, but not all, pills may be crushed. Clinicians should consult an HIV specialist and/or pharmacist to assess the best way for a patient with a feeding tube to continue an effective ARV regimen. Information may be available in the drug product label or from this document from the Toronto General Hospital Immunodeficiency Clinic (bit.ly/TGHIC-pdf).

ADDITIONAL GUIDANCE FOR
HIV clinicians

Some Medicaid and Medicare programs, commercial health insurers, and AIDS Drug Assistance Programs (ADAPs) have restrictions that prevent patients from obtaining a 90-day supply of ARV drugs and other medications. During the COVID-19 outbreak, clinicians should ask providers to waive drug-supply quantity restrictions. ADAPs should also provide patients with a 90-day supply of medications.

Persons with HIV may need additional assistance with food, housing, transportation, and childcare during times of crisis and economic fragility. To enhance care engagement and continuity of ARV therapy, clinicians should make every attempt to assess their patients' need for additional social assistance and connect them with resources, including navigator services when possible.

During this crisis, social distancing and isolation may exacerbate mental health and substance use issues for some persons with HIV. Clinicians should assess and address these patient concerns and arrange for additional consultations, preferably virtual, as needed.

Telehealth options, including phone calls, should be considered for routine visits and to triage visits for patients who are ill.

The CDC website provides information about COVID-19 for people with HIV (cdc.gov/coronavirus/2019-ncov/specific-groups/hiv.html).

THE ORIGINAL GUIDELINES also include information for pregnant women with HIV; persons with HIV in self-isolation or quarantine due to SARS-CoV-2 exposure (including information for health care workers); and investigational or off-label treatment for COVID-19 ("person with HIV should not be excluded from these trials"). The original document includes references.

New pediatrics recommendation

The U.S. HIV treatment guidelines for children now **recommends "rapid initiation of antiretroviral therapy (ART) for *all* children, not just those aged [less than] 1 year**. Rapid initiation is defined as initiating therapy immediately or within days of HIV diagnosis." In addition, the guidelines state, "The Panel [of experts producing the guidelines] acknowledges that, on a case-by-case basis, initiation of ART may be deferred based on a patient's clinical or psychosocial factors." The update was published April 14. **READ** the update in its entirety at aidsinfo.nih.gov/guidelines/html/2/pediatric-arv/0.

Symtuza pediatric label change

The HIV single-tablet regimen **Symtuza can now be used by children weighing at least 88 pounds** (40 kg). All patients, whether adult or pediatric, must be taking HIV therapy for the first time (antiretroviral-naïve) or be switching from a stable regimen taken for at least for six months and have less than 50 viral load (undetectable) and no drug

CORRECTION
In the March+April 2020 issue, the 2020 HIV Drug Guide, the price of Trogarzo was listed incorrectly as $2,724 per vial, instead it's $2,724 *per box*, with two vials per box. POSITIVELY AWARE apologizes for the error. Therapatient support can assist with your private or government insurance coverage, including an AIDS Drug Assistance Program (ADAP), and will also assist in applying any eligible co-pay assistance. Call 1-833-23THERA (1-833-238-4372).

resistance to the darunavir and the tenofovir contained in Symtuza. Symtuza also contains emtricitabine and the booster medication cobicistat.

The U.S. Food and Drug Administration (FDA) updated the Symtuza drug label on March 4 to add the pediatric use.

"No clinical trials with Symtuza were performed in pediatric patients," the FDA reported in its announcement of the label change. "However, the safety of the components of Symtuza was evaluated in pediatric subjects of 12 to less than 18 years of age through clinical trials GS-US-216-0128 (virologically-suppressed, N=7 with weight ≥40 kg) for darunavir co-administered with cobicistat and other antiretroviral agents, and GS-US-292-0106 (treatment-naïve, N=50 with weight ≥35 kg) for a fixed-dose combination regimen containing cobicistat, emtricitabine, and tenofovir alafenamide together with elvitegravir. Safety analyses of the trials in these pediatric subjects did not identify new safety concerns compared to the known safety profile of Symtuza in adult subjects."

READ MORE from the FDA announcement at bit.ly/2WFvbWo. **GO TO** symtuza.com and positivelyaware.com/symtuza.

Egrifta and NASH

Theratechnologies, maker of Egifta SV, announced that it has entered into a long-term agreement with Massachusetts General Hospital and Dr. Stephen Grinspoon, chief of the hospital's Metabolism Unit, to examine the use of the medication in non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) in people living with HIV.

Dr. Grinspoon is a prominent researcher in metabolic complications in HIV. Egrifta SV (tesamorelin) is an injectable treatment for HIV-related excess belly fat.

"We feel privileged to collaborate with the Massachusetts General Hospital, the largest Harvard Medical School teaching hospital. The MGH will give us access to the talent, knowledge, and expertise of Dr. Grinspoon. We also look forward to working with Dr. Grinspoon since he is one of the world's foremost experts on metabolic conditions related to HIV," Theratechnologies stated in a February 4 press release announcing the agreement.

In that press release, Dr. Grinspoon said, "**Tesamorelin appears to be an important therapeutic candidate for the treatment of NAFLD/NASH in people living with HIV** based on data from a recently completed NIH-funded Phase II trial. I look forward to advancing this important work and finding ways to improve and extend treatment options for HIV patients with NAFLD/NASH."

Dr. Grinspoon and his research team published results of tesamorelin in HIV-related NAFLD/NASH late last year in *The Lancet HIV* journal.

READ the release at theratech.com/en/theratechnologies-signs-agreements-with-massachusetts-general-hospital-and-dr-steven-grinspoon. **GO TO** positivelyaware.com/egrifta-sv.

Crixivan discontinued

Who? Crixivan (indinavir sulfate) is an HIV medication from the protease inhibitor drug class. **It was one of the first three protease inhibitors** on the market, back in 1995–1996. It was these protease inhibitors, and others soon to follow, that most turned the epidemic around by bringing people back to strong health. Unfortunately, the early PIs were associated with large, complicated doses and side effects that were hard to tolerate long-term.

"I am writing to inform you that after careful consideration, Merck has decided to voluntarily discontinue the manufacture of Crixivan (indinavir sulfate) capsules for distribution in the United States," announced Eliav Barr, Senior Vice President, Medical Affairs for Merck & Co., on March 12. "This decision, which was not made lightly, was based on the significant scientific advancements since Crixivan became available, changes to treatment guidelines, and declining demand. The discontinuation is not related to a product quality or safety issue."

Today, the only HIV protease inhibitors in common use are darunavir (Prezista, Prezcobix, and Symtuza) and atazanavir (Reyataz and Evotaz).

Grants for Ending the HIV Epidemic

The U.S. Department of Health and Human Services (HHS) on February 26 announced **$117 million in awards to expand access** to HIV care, treatment, medication, and prevention services. The awards were determined through the department's Health Resources and Services Administration (HRSA) as part of the Administration's campaign, Ending the HIV Epidemic: A Plan for America, known as EHE. EHE aims to reduce the number of new HIV infections in the country by 90% by 2030. **READ** the announcement at hrsa.gov/ending-hiv-epidemic.

Philadelphia Safehouse update

In the continuing struggle to open the nation's first safer consumption site, activists behind the proposed Safehouse, in Philadelphia, put their plans on hold at the end of February. A day later, however, **the group lost the lease for the proposed location** following resistance from area residents.

Safe injection sites prevent overdose deaths by allowing drug users to inject in a monitored facility. They also prevent the transmission of disease, including HIV. Sites exist in Canada, Australia, and Europe. As with syringe exchanges, the sites also provide people who use drugs with referrals to drug treatment programs, housing, and other services. See "Safer Drug Consumption Sites: An idea whose time has come," by PA hepatitis editor Andrew Reynolds, at positivelyaware.com/articles/safer-drug-consumption-spaces.

The activists behind Safehouse, a non-profit organization, promised to continue moving forward in establishing a site. The group will also work more closely with community members and leaders in creating a safe haven. Safehouse leaders include former Pennsylvania Governor Edward G. Rendell; Jose Benitez, Executive Director of Prevention Point Philadelphia; and Ronda Goldfein, Executive Director of the AIDS Law Project of Pennsylvania. "A federal court has ruled that supervised injection sites are legal in Philadelphia," said Goldfein. "Safehouse is a life-saving public health approach and we are committed to opening in Philadelphia."

Prominent on the organization's homepage is a quote from the American Medical Association: "Studies from other countries have shown that [overdose prevention services] reduce the number of overdose deaths, reduce transmission rates of infectious disease, and increase the number of individuals initiating treatment for substance use disorders without increasing drug trafficking or crime in the areas where the facilities are located."

GO TO safehousephilly.org.

Mary Bowman Arts in Activism Award

In honor of poet and performance artist Mary Bowman, ViiV Healthcare announced in March the **establishment of the Mary Bowman Arts in Activism Award**. The award comes through the company's Positive Action programs, promoting community involvement in efforts against HIV/AIDS. It is awarded in collaboration with the National AIDS Memorial.

ViiV, a subsidiary of GlaxoSmithKline that is devoted solely to HIV treatment development, brings together community members, including editorial staff of POSITIVELY AWARE, annually for information exchange and relationship building. Bowman, who had devoted her life to art and working on behalf of people living with HIV, participated in ViiV's youth leadership development. She may be best known for her tour de force poem "Dandelion," illuminating a childhood and life lived with HIV.

In announcing the award, ViiV Healthcare stated, "In May of 2019, the HIV/AIDS world lost its most promising poet, advocate, author, singer, and young person living with AIDS, Mary Bowman. Mary was 30 years old. Born with HIV, she lived out her experiences of growing up and living with HIV (and losing a mother to AIDS) through her art. As a young, out woman of color, she was a dynamic, vital voice for the next generation of individuals living with HIV—proud, willing to speak of her own challenges with not just her own health needs (mental health, social support)—but also a fierce advocate for other young people with HIV for whom a voice was lacking. For Mary, the arts gave her the platform and voice to channel her creative energy, her passion, her truth."

The HIV-specialty pharmaceutical company also writes that it "proudly supports arts and culture programs that engage and inspire individuals and communities in the fight against HIV/AIDS, and recognizes the power of culture to break down stigma and isolation. Mary Bowman was an icon of hope and resilience, and recently performed at the 2018 ViiV Healthcare Youth and Community Summit where she inspired leaders across the movement.

"To honor Mary's legacy and support other accomplished young artivists like her, ViiV Healthcare and the National AIDS Memorial have partnered to create the Mary Bowman Arts in Activism Award. This $5,000 award is intended to support one young artivist (27 years of age or younger) each year who exemplifies Mary's passion for the arts as the vehicle for their own HIV/AIDS community activism and expression. In general, artivism harnesses the critical imagination to design events and strategies that provoke new questions and new meaning in pursuit of more respectful ways of being. As an example, with respect to HIV/AIDS, such artistic statements are frequently borne from a variety of perspectives in terms of gender, sexuality, age, class, ethnicity, and nationality, and wield artistic expression as a tool for combating stigma. Stigma, and all it entails—shame, isolation, embarrassment, exclusion, shunning—remains among the most formidable barriers to fighting the epidemic," ViiV explained.

ViiV has collaborated with many artists to produce profound performances and publications, including stories of people living with HIV.

An "Intent to Apply" form must be submitted no later than Sunday, May 31, 2020, 5:00 p.m. (PST), and a complete application form with required attachments must be submitted no later than Monday, June 29, 2020, 5:00 p.m. (PST).

TO APPLY, go to aidsmemorial.org/mary-bowman-arts-in-activism-award.

NOTE: Young artist Farah Jeune dedicates her work to destigmatizing HIV and illustrating leaders in HIV/AIDS.

MARY BOWMAN: ART BY FARAH JEUNE, COMMISSIONED BY VIIV HEALTHCARE

The effects of HIV/AIDS on aging: STILL UNCLEAR

Why do some thrive while others struggle? Here's what researchers know

BY **JOHN-MANUEL ANDRIOTE**

CRAIG WASHINGTON,
60, OF ATLANTA, HAS LIVED WITH HIV SINCE 1985

EDITOR'S NOTE: This story originally appeared on Next Avenue, public media's first and only national journalism service for America's booming older population. To follow Next Avenue's in-depth look at aging with HIV/AIDS, GO TO nextavenue.org/hiv.

Craig Washington has never spent a night in the hospital because of HIV. Not even the time in the early '90s when he got cryptosporidiosis, one of the opportunistic infections that can wreak havoc on someone with a weakened immune system.

The Atlanta-based social worker and therapist's good health is especially impressive for a 60-year-old man diagnosed with HIV back in 1985—the year the HIV antibody test first became available.

"For the most part," said Washington, "I have been very blessed, very fortunate, that my health is pretty good and a lot of the day-to-day energy level I've been able to sustain." He attributes his good fortune to his doctors, regular exercise and a support network of friends.

Washington says his ability to continue working, and thereby remain continually insured, provides a level of continuity in his health care that many people living with HIV/AIDS don't have.

Diagnosed in 1992, 53-year-old **Michael Luciano**'s reality is very different.

The New York City native now living in Charleston, S.C. returned to the workforce three years ago after spending 24

years on disability. Today, he holds a two-thirds-time job as a treatment educator for Palmetto Community Care, an HIV services organization in Charleston.

"I stayed on disability and felt trapped there because the thought of going off disability and finding a job locally that would pay enough for co-pays and insurance paralyzed me," Luciano said. Although his job provides "not the greatest" insurance coverage, Luciano hopes this position lasts—or another one arises that would help him stay off disability. "I sort of lucked into a position that worked out for me," he said.

But it's not only a matter of job security. Luciano wonders how long he will be able to continue working. Although he manages HIV with medication, other chronic conditions he's developed over the years give him trouble.

"One of my major, ongoing challenges—and that makes me anxious about continuing working to retirement age—is osteoarthritis in my hands and both knees," he said.

Even after finally beginning to manage with medication the rheumatoid arthritis in his hands, Luciano's severe osteoarthritis makes exercise virtually impossible. "Osteoarthritis presented much earlier than expected," he said. "It's a classic symptom of advanced HIV infection and has had secondary impacts on my health."

He also experiences kidney dysfunction due to the HIV drugs. There's bone density loss. And on top of it all, Luciano said, there is the "ongoing level of anxiety it generates for my future as I approach the age when all of these conditions manifest."

If that's not enough to make someone worry about aging with HIV/AIDS, there are also financial concerns (medications and frequent medical visits aren't cheap), not to mention managing mental health. "[Mental health] is intimately tied to physical health," Luciano said. He occasionally finds himself "overwhelmed by anxiety or depression."

Luciano's experience is much like that of many long-term HIV/AIDS survivors—those diagnosed before effective treatment became available in 1996, as defined by long-term survivor Jésus Heberto Guillen Solis, founder of the nearly 5,000-member HIV Long-Term Survivors group on Facebook.

Aging ahead of their time?

IT'S NOT YET CLEAR to researchers how HIV/AIDS and the natural aging process interact—mainly because the first people ever to age with HIV are in the process of doing so. For this reason, debate rages as to whether people living with HIV/AIDS are prone to so-called "accelerated aging," and, if not, who is most vulnerable, what causes it and what might be done to slow it down.

Even "normal" aging involves losing muscle mass, bone loss, weight loss, memory loss, decreased kidney, brain and heart function and a deteriorating immune system. Many factors, both genetic and environmental, affect its pace from one person to another.

Medical research on aging with HIV/AIDS can seem contradictory. One study says accelerated aging is real and that getting older with HIV/AIDS seems to inevitably bring on conditions and diseases usually seen only in much older people. Another says it's not really accelerated but only accentuated — that medically-controlled HIV/AIDS is only one of the conditions inflicting harm. Myocardial infarction or end-stage renal disease, for example, in anyone with the same overall profile, is different only in their HIV status.

Monty Montano, assistant professor of medicine at Harvard Medical School, scientific director of the Boston Pepper Center at Brigham and Women's Hospital and researcher on chronic HIV, prefers the term "asynchronous" to "accelerated" to describe HIV/AIDS' effects on aging.

"Think of a concert, a symphony, with a large orchestra," Montano said. "Each instrument plays its role. But if one section of the symphony is playing at the wrong time—too early or too long—it creates an asynchronous progression."

In other words, some of the common effects we associate with older age may be present in an HIV-positive individual in their 40s or 50s, but not all of them. So, while some things may be off-kilter (high blood pressure or osteoarthritis, say), the overall picture isn't that of an "old" person.

To an extent, it's semantics, as researchers are trying to explain why so many people aging with HIV/AIDS experience what we think of as aging-associated conditions at an earlier age. It's also a matter of teasing out precisely what is meant by whichever words (accelerated, asynchronous, accentuated, age advancement, etc.) are used and avoiding generalizing findings of limited research studies to the millions of people living with HIV/AIDS.

Current research says...

A 2019 STUDY REPORTED in the journal *AIDS* found there wasn't a significant difference between treated HIV-positive and HIV-negative individuals when considering 10 biomarkers that are used as measures of biological age. The researchers compared HIV-positive and HIV-negative individuals with similar age, sex, years of education,

MICHAEL LUCIANO,
53, LIVES IN CHARLESTON, SOUTH CAROLINA, AND WAS DIAGNOSED WITH HIV IN 1992

WASHINGTON: BRIDGET CASWELL LUCIANO: COURTESY OF MICHAEL LUCIANO

cigarette smoking and recreational drug use to gauge what they called "age advancement" by subtracting their chronological age from their biological age.

They found that ethnicity, sexual orientation or lifestyle factors such as smoking cigarettes or using recreational drugs apparently didn't matter. What *did* matter for both the HIV-positives and negatives was having cytomegalovirus (CMV), chronic hepatitis B virus (HBV), CD4 and CD8 white blood cell counts and their ratio to each other; time since HIV diagnosis; the lowest CD4 cell count below 200/mm^3 [normal range is 500–1,400] and how long someone was on anti-HIV medications.

The study also implicated some of the older HIV/AIDS drugs, particularly saquinavir, the first protease inhibitor drug approved in 1995 to be used in the "combination therapy" that marked a dramatic turning point in the HIV/AIDS epidemic when it became possible to live with the virus rather than almost inevitably progress to AIDS and die. Many long-term survivors took saquinavir when it was first approved, combined with other drugs in the so-called "cocktail." Research suggests saquinavir had significant negative long-term effects in those who took it. That's one reason it is no longer used as a first-line HIV treatment.

People treated with earlier, partially-effective HIV medications are likely to have a different experience.

These researchers concluded that people with managed, undetectable HIV viral loads "may experience accentuated aging compared with HIV-negative individuals with similar lifestyles" based on the set of biomarkers they used to measure aging. "This age advancement appears to be related to viral coinfections such as CMV and chronic HBV, but also to historic severe immunosuppression and possibly exposure to particular antiretroviral drugs," they wrote.

A 2014 study of 98,687 male American military veterans—31% HIV-positive, 69% HIV-negative—supports the idea of "accentuated" aging for HIV-positive people, but not "accelerated" aging. The study, reported in the journal *Clinical Infectious Diseases*, found that HIV-positive and negative men, who had traditional risk factors such as diabetes or high cholesterol, were at heightened risk and developed such aging-associated conditions as myocardial infarction, end-stage renal disease and cancers not related to HIV at about the same age. They did not occur earlier in the HIV-positive participants.

"Our data show that HIV is a risk factor for these outcomes," wrote the researchers in their report, "however, many traditional risk factors have a similar or greater magnitude of relationship with these outcomes." They suggested that targeting those risk factors "may help decrease the excess burden of aging-related diseases among HIV-infected adults." They added, "These findings should reassure HIV-infected patients that they are unlikely to experience these conditions decades earlier than those aging without HIV."

But what of those people aging with HIV/AIDS who are experiencing conditions—like Luciano's severe osteoarthritis—that seem to have arisen so much earlier than typically seen in HIV-negative people?

"No two individuals who have HIV or not are likely to age exactly the same way," said Dr. Amy Justice, Long Professor of Medicine at Yale University, clinical epidemiologist and one of the researchers on the 2014 veterans study. "We bring our individual exposures and genetics and lifestyles to the table—the prior slings and arrows that we have experienced. And one of those slings and arrows can be HIV infection."

Justice added that people treated with earlier, partially-effective HIV medications are likely to have a different experience than those who receive treatment at an earlier stage of the infection. But even with today's highly-effective HIV treatments, Justice said, "It's not as though we can wipe away all the effects of HIV." She explained that even with well-managed HIV, "there is still likely to be some effect because we're not curing folks."

Of course, there are still those other "slings and arrows" that affect our health no matter our HIV status. That's why Justice gives the same advice to anyone over age 65, with or without HIV/AIDS: exercise, eat well, either don't smoke or stop smoking tobacco, use alcohol modestly, think carefully about all the medications and supplements you take and have a good doctor.

Boring isn't bad

IT ALSO HELPS to be what **Harold R. "Scottie" Scott** of Lebanon, Tenn. calls himself: the most boring patient.

HAROLD R. "SCOTTIE" SCOTT, FROM LEBANON, TENNESSEE, CALLS HIMSELF "THE MOST BORING" HIV/AIDS PATIENT

©VANDERBILT UNIVERSITY

"I've never done drugs, have an occasional drink and smoked pot once," Scott, who was diagnosed in 1991, said.

At 58, Scott is dealing with high blood pressure and chronic kidney disease. He continues on disability because, he said, "I'm healthy enough to do some things, but not enough to go full force."

Unfortunately, most HIV-positive people in the over-50 population don't fit that definition of boring. They frequently experience polypharmacy, being on five or more non-HIV drugs. And with each additional medication comes an increased potential for adverse drug interactions. Studies find they are far likelier than the general population to be co-infected with either hepatitis B or C; have chronic human papillomavirus (HPV); are up to three times likelier to smoke cigarettes and have far higher rates of mental illness and substance abuse than people who don't have HIV/AIDS.

Another important factor affecting aging and risk: inflammation. Even HIV-positive people with an undetectable viral load experience chronic, low-grade systemic inflammation. The immune system remains hyper-vigilant knowing there's a hostile foreign presence in the body.

The result is what is referred to as "inflamm-aging," a significant risk factor for illness and death in elders. Fundamentally, "inflammation is aging," said Dorcas Baker, a research nurse at Johns Hopkins University in Baltimore and co-founder of a support group for HIV-positive women called Older Women Embracing Life (OWEL).

Since the immune system is centered in what we call the gut, it makes sense that keeping the gut as healthy as possible is essential to fighting inflammation. Although further research is needed, scientists have found intriguing connections between taking probiotics for a healthy gut and improved immune health.

'What we are now realizing is that HIV as a disease is really a disease of inflammation.'

"What we are now realizing is that HIV as a disease is really a disease of inflammation. We are looking at simple interventions to affect the immune system, so probiotics and prebiotics would be the way of modulating the gut microbiome, the inflammation, and then see the aging effects or the noncommunicable diseases being reduced," said Alan Landay, chair of the immunology and microbiology department at Chicago's Rush University Medical Center in an interview with SciDev.Net.

In the meantime, the good news for those aging with HIV/AIDS is that there already are well-known ways to make growing older with the virus as healthy an experience as it can be.

HIV-suppressing antiretroviral drugs are the first line of defense, dramatically reducing inflammation. "There is profound resolution of inflammation with treatment," said Montano, adding, "but it's still not back to normal."

In Short: Don't generalize

JUST AS SCREENS and blood tests present ranges of what is considered normal or not, it's important to remember that aging with HIV/AIDS also presents a range of possible experiences that are affected and shaped by individual factors.

"This idea of aging needs to be reframed to what you define as a good quality of life for your life," said Montano.

Mark Brennan-Ing, a senior research scientist focused on HIV and aging at Hunter College's Brookdale Center for Healthy Aging in New York City, praised work like Justice's with veterans that shows the spectrum of individual experiences with HIV, notably that "the HIV-positive and negative folks also share similar types of characteristics." Broad-brushing everyone aging with HIV as all facing the same level of risk or complications "further stigmatizes HIV," Brennan-Ing said.

Brennan-Ing, whose psychosocial research focuses on how vulnerable older adults cope and adapt to chronic conditions, said it's important to "swat down" discussions veering toward suggesting that "accelerated" aging is inevitable simply because someone has HIV, that all people with HIV/AIDS will age the same way or that it will invariably mean aging poorly. "Growing older with HIV is hard enough," said Brennan-Ing, "let alone exaggerating it with this."

There may be something even more important to learn from people aging with the virus beyond its physiological effects. It's impossible, after all, to consider "health" without factoring in mental health, financial health and a host of other factors that affect our overall health and well-being. "When we talk about long-term survivors," says Brennan-Ing, "there is a degree of resilience and hardiness that has let people become long-term survivors. That is something to capitalize on." PA

JOHN-MANUEL ANDRIOTE has reported on HIV/AIDS as a journalist since 1986. He has been open about his own 2005 HIV diagnosis since coming out publicly about it in a first-person story for *The Washington Post*. Andriote's most recent book is *Stonewall Strong: Gay Men's Heroic Fight for Resilience, Good Health, and a Strong Community*, a "bookend" for his award-winning history *Victory Deferred: How AIDS Changed Gay Life in America*. Andriote mines his and other gay men's experiences for insights on resilience in conference and university talks and in his Stonewall Strong blog for *Psychology Today*.

Struggling with COPD

My sister's fight for air

BY **ENID VÁZQUEZ**

My sister Sylvia climbed up the three flights of stairs to my condo and had to stop to catch her breath.

It was an awful sight to see. *She just couldn't breathe.* She sat there for more than five minutes, heaving in her struggle to get air. I was horrified.

I remembered the time years ago when I woke up in the middle of the night unable to breathe for almost a minute, shortly after getting a kitten for my German Shepherd (RIP, Tiger B. and Nico). I learned then that being unable to breathe was the worst feeling in the world.

Sylvia would also struggle to breathe after five minutes of walking her dog or shopping in a store.

Then, at last year's CROI, I heard Kristina Carothers, MD, of the University of Washington in Seattle, talk about COPD (chronic obstructive pulmonary disease), and myocardial infarctions (MIs, or heart attacks) in HIV.

It seems that many individuals living with HIV and COPD have their respiratory illness undertreated. For example, they may be given short-term treatments when they probably should use long-acting medications. They may need two medicines for their COPD, but receive only one.

I sat in a press conference listening to Dr. Carothers discuss the findings of her research team, and it scared the hell out of me. My sister has been living with HIV since the early '80s and was diagnosed with AIDS in 1993. I suddenly realized that Sylvia's pulmonologist (her lung doctor) probably doesn't know what she goes through. *He doesn't see her struggling to get air.* Never mind a heart attack. *My sister can't breathe.* She was probably not receiving adequate care for her respiratory problems.

This is a woman who always says she has "bad lungs." She had three episodes of pneumocystis *jiroveceii* pneumonia (PCP) back in the 1980s. Her lungs must be scarred.

After hearing Dr. Carothers, I asked Sylvia if she had ever been diagnosed with COPD. She had. She took medicine for it.

Months later, after seeing a new pulmonologist in the town in Wisconsin where she was now living, she was put on a new medication. She started using long-acting Anoro Ellipta (umeclidinium and vilanterol inhalation powder). "It releases 24 hours of medication relief to my bronchioles, every 24 hours. It's an inhaler."

And just like that, my sister could breathe.

All it took was running out of her old prescription refills, a trip to the emergency room, and her insistence while in the ER that something was wrong despite normal test results.

The crisis

MORE THAN a year ago, Sylvia had moved from one Wisconsin town to another. She still had refills for her COPD medication from her pulmonologist in the previous town, so she continued using them. She had paid $80 a pop for her rescue inhaler, because, she said, Medicaid wouldn't pay for something that was not considered necessary but simply a "rescue."

In January, however, before she could renew her COPD medication prescription or see her pulmonologist, she experienced a medical crisis while at home. Her heart was pounding. She felt dizzy. She lost her balance.

SYLVIA VÁZQUEZ
AT HOME WITH HERCULES.

"I thought I was going to have a heart attack," Sylvia said. It was enough for her to go to the emergency room.

There in the ER test results came back normal.

She knew, however, that something was wrong. The hospital needed to keep looking, she thought.

"It's not my imagination," she said. "I have a hard time walking. I have a hard time breathing. So I said, 'Something's not right.'"

Sylvia said that's when a nurse took heed and measured her oxygen level, putting one of Sylvia's fingers in a small plastic device, called a "fingertip pulse oximeter." It measures blood oxygen levels.

The nurse found that Sylvia's oxygen levels dropped by half when she walked. Something *was* wrong.

Sylvia was referred to a new pulmonologist, who was local. He put her on Anoro Ellipta. She continued using her previous rescue inhaler once a day.

She said that she still couldn't walk and talk, but she could walk. "When I can't breathe, it makes it hard for my heart to pump blood," she said.

At first, she thought she wanted a higher dose of Anoro. But then her Anoro ran out and her symptoms of diarrhea went away. She needed a new drug.

She was scheduled for an ECHOgram, "to see if my heart is doing its job. They'll

compare it to the ECHO I had a year ago." She was also getting a CT scan of her lungs. Her new doctor will be coordinating efforts with her HIV specialist, Dr. Ron Gonzales at Northstar Medical Center in Chicago.

Dr. Gonzales told Sylvia that he didn't want her to go back on Anoro, because he didn't want her on a steroid. As of press time, she had not seen her pulmonologist. Her breathing was less of a problem because she was staying home due to the COVID-19 outbreak.

Sylvia says she was off her HIV therapy for nearly a year when she went to the ER. "Dr. Gonzales has really tried to talk me back onto HIV meds. But [if I had] three months of being healthy and able to do what I want vs. pain and agony—I'd rather have three months. It's so uncomfortable, all this fat around my torso and my back. I can't function. It was hard to clean myself. That in itself was enough for me to say enough."

Now her T-cells hover around 200 and her viral load is around 2,000. She's being very careful about COVID-19. PA

COPD AND HIV

FROM KEN KUNISAKI, MD, MS, pulmonary staff physician at the Minneapolis VA and Associate Professor at the University of Minnesota:

HIV INCREASES a person's risk for developing COPD.

We don't know exactly how HIV does this, but if you are living with HIV, the best way to reduce your risk for COPD is to avoid smoking.

In people with HIV, previously having a very low CD4 count and past pneumonias might also increase COPD risk.

Cigarettes are clearly the strongest risk factor for COPD, and although we don't know as much about vaping and marijuana effects on COPD, any inhaled substance entering the lungs can cause lung problems.

If you have a chronic cough, or regularly cough up sputum, or have shortness of breath, you should talk to your provider about getting a lung function test, which is the way we determine if someone has COPD.

Many people think having COPD means you need to use oxygen tanks, which is not true. Supplemental oxygen can be life-saving for people with very advanced COPD, but most COPD patients do not need oxygen tanks, especially if we make an early diagnosis and take interventions to preserve as much lung function as possible.

If you have COPD, it is treatable with things like inhalers and pulmonary rehabilitation programs that help improve daily function.

Respiratory infections can be troublesome for people with COPD, so vaccinations are recommended against things like the flu and pneumonia. Good hand hygiene and avoiding contact with people who are sick also helps COPD patients stay as healthy as possible.

Dr. Kunisaki's research interests are COPD, obstructive sleep apnea (OSA), and HIV-associated lung and sleep disorders.

COVID-19 update and resources

Information on the coronavirus for people living with HIV

POSITIVELY AWARE and TPAN are committed to keeping our community and staff safe. Our main concern is that everyone, particularly people living with HIV, takes the necessary precautions to protect themselves and their loved ones. Following is some general information and a list of resources that we've compiled from multiple sources that we hope you'll find useful. Check back at positivelyaware.com/coronavirus frequently as we continue to update this information. The CDC website (CDC.gov/coronavirus) and HIV.gov/coronavirus also have information that is continually being updated. The U.S. Dept. of Health and Human Services updated its Antiretroviral Guidelines and issued Interim Guidance for COVID-19 and Persons with HIV on March 20 (see Briefly).

What is a coronavirus?

Coronaviruses are a large family of viruses that usually cause mild respiratory illnesses such as the common cold. The virus (SARS-CoV-2) that causes the disease (COVID-19) is currently spreading around the world, and was officially declared a pandemic by the World Health Organization (WHO) in March. At least six other types of coronavirus are known to infect humans, with some causing the common cold and two causing epidemics: SARS in 2002 and MERS in 2012. SARS-CoV-2 is a new coronavirus that was not identified in humans before December 2019, and is thought to have originated in bats.

Who is at risk?

Some people are at higher risk of getting very sick from this illness. This includes:

- Older adults
- People who have serious chronic medical conditions such as:
  - Heart disease
  - Diabetes
  - Lung disease

What are the symptoms?

Most cases are mild, but reported illnesses have ranged from mild symptoms to severe illness and death for confirmed COVID-19 cases.

These symptoms may appear 2–14 days after exposure to the virus:

- Fever
- Cough
- Shortness of breath or difficulty breathing
- Chills
- Repeated shaking with chills
- Muscle pain
- Headache
- Sore throat
- New loss of taste or smell

How is it spread?

The virus is thought to spread mainly from person-to-person.

- Between people who are in close contact with one another (within about 6 feet).
- Through respiratory droplets produced when an infected person coughs, sneezes or talks.
- These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.
- Some recent studies have suggested that COVID-19 may be spread by people who are not showing symptoms.
- Have recently traveled from an area with widespread or ongoing community spread of COVID-19 (bit.ly/howCOVIDspreads).

Maintaining good social distance (about 6 feet) is very important in preventing the spread of COVID-19.

It may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly their eyes. This is not thought to be the main way the virus spreads, but we are still learning more about this virus.

Wash your hands often with soap and water. If soap and water are not available, use an alcohol-based hand rub. Also, routinely clean frequently touched surfaces.

When to seek medical attention

If you develop any of these emergency warning signs* for COVID-19 get medical attention immediately:

- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion or inability to arouse
- Bluish lips or face

*This list is not all inclusive. Please consult your medical provider for any other symptoms that are severe or concerning to you.

Call 911 if you have a medical emergency:

Notify the operator that you have, or think you might have, COVID-19. If possible, put on a cloth face covering before medical help arrives.

Recommendations for people with HIV:

- Ensure you have an ample medication supply; if possible, keep a 30-day supply at all times
- Keep vaccinations (such as for influenza, pneumococcal) up to date
- Establish a plan for clinical care if you become isolated/quarantined
  - Telemedicine options
  - Physician online portals
- Maintain a social network, but remotely; social contact helps us stay mentally healthy and fights boredom

At this time, the Chicago Department of Public Health recommends that people living with HIV follow the same guidance as the general population and do not need to take additional precautions (**READ** the PDF, Preparedness Checklist for Individuals and Households, bit.ly/COVIDchecklist), unless individuals are considered higher risk (Read the PDF, Guidance for People at Higher Risk at bit.ly/2Xq2DQZ).

Those at higher risk include:

- Persons over 60 years of age.
- People, regardless of age, with underlying health conditions including cardiovascular disease, diabetes, cancer, heart disease, or chronic lung diseases like COPD.
- People, regardless of age, with severely weakened immune systems.

According to the CDC, "At the present time, we have no specific information about the risk of COVID-19 in people with HIV.

"Older adults and people of any age who have a serious underlying medical condition might be at higher risk for severe illness, including people who are immunocompromised. The risk for people with HIV getting very sick is greatest in:

- People with a low CD4 cell count, and
- People not on HIV treatment (antiretroviral therapy or ART).

"People with HIV can also be at increased risk of getting very sick with COVID-19 based on their age and other medical conditions."

In a special session on COVID-19 at CROI 2020 in March (see page 30), John T. Brooks, U.S. Centers for Disease Control and Prevention, in his presentation "Global Epidemiology and Prevention of COVID-19," spoke about high-risk groups:

"Unfortunately, **there aren't data at the present time about persons who are immunocompromised**, whether by medical therapy or acquired infection," he continued. "But for persons with HIV, we think the risk for severe illness would be greater for persons at lower CD4 cell counts and who aren't virally suppressed [have undetectable viral load], since we've seen the same pattern in other intercurrent illnesses in people living with HIV. Nonetheless, all persons with HIV should take precautions against this new virus about which we're still learning a lot. And I want to note that CDC estimates that equal to or more than 50% of people with HIV are over 50 years old."

People with compromised immune systems are especially vulnerable to respiratory infections (bit.ly/NYTcoronaconditions). That group includes those who have autoimmune disorders such as lupus and arthritis, those who have had organ transplants, patients undergoing chemotherapy and other cancer treatments, and anyone who is taking steroids as treatment.

"People with H.I.V. are not on the list as yet, however. With powerful antiretroviral drugs, many now have immune systems strong enough to stave off infections," said Dr. Monica Gandhi, an infectious disease expert at the University of California, San Francisco.

"There is some very preliminary evidence that certain H.I.V. drugs in wide use may help slow the coronavirus."

The CDC says that "until more is known about the effects of these medicines on COVID-19, people with HIV should not switch their HIV medicine in an attempt to prevent or treat COVID-19."

DAVIS: AFC

COVID-19, Black America, and the deadly cycle of racism

BY **AISHA N. DAVIS**, DIRECTOR OF POLICY
AIDS FOUNDATION OF CHICAGO

In the past month, the COVID-19 pandemic has led us into a new reality that we have never experienced, both here in Chicago and across the United States. However, one emerging trend is not novel—Black people and communities across the nation are being disproportionately impacted by pandemic hot spots and COVID-19 related deaths.

Systemic racism has led to poor health outcomes in Black communities in the United States since the inception of this nation. From the display and dismemberment of Saartje Baartman, to the Tuskegee syphilis experiments from the exponentially disproportionate maternal mortality rates for Black women, to the discriminatory health care available in Black communities fighting to end the HIV epidemic, Black communities and Black bodies have borne the scars, diagnoses and pain of racism. And, with the reports of discrimination faced by Black celebrities, there is no option to buy your way out of this cycle of health disparities.

In Illinois, on April 7, there had been a total of 380 COVID-19 related deaths. Of those deaths, 163 were Black people. That means that Black people account for nearly 43 percent of COVID-19 related deaths in a state where we only make up about 15 percent of the total population. These numbers are not a coincidence, but the damning proof of the divestment in, discrimination towards, and disenfranchisement of Black communities.

This pandemic has forced those outside of our communities to come face-to-face with what we have known—when America catches a cold, Black people get pneumonia.

Responses and reactions from local, city, county and state agencies and actors that have begun and will continue in the coming days are welcome as we seek to slow the devastation ripping through our families, neighborhoods and communities. To be sure, we must all work together to address this pandemic. However, we cannot use this moment for temporary galvanization. For those that we have already lost, it is too late, but for the future generations of Black people in America, we will be charged with having continued the trend of ignoring the intentional suffering heaped upon Black communities if we fail to look beyond what is happening right now and address what has led to these statistics.

Yes, open hospitals to treat those currently suffering from COVID-19—but do not shutter them when this pandemic ebbs. Track the numbers of diagnoses of the novel coronavirus—but also track the number of Black people experiencing homelessness who cannot shelter in place. Distribute information and resources about best practices—but remember those practices when we are not in the midst of a health care epidemic.

Black communities have always shown resiliency in the face of hatred, but we deserve a future where we are proven wrong about how much worse our health outcomes will be in relation to other communities. As we consider the best ways to address the effects of COVID-19 on Black Illinoisans, let us also plan for a future where these disparities do not exist.

READ Aisha Davis' open letter at COVID-19inBlackAmerica. **SEE** AFC's COVID-19 page at aidschicago.org/covid19.

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THE LIFE-SAVING POWER OF CONNECTION

In the face of uncertain times, here's what we can do to stay connected to each other, suggests **David Fawcett, PhD, LCSW**

As a long-term survivor whose body and mind carries battle scars from another virus, the rise of the coronavirus has reinvigorated a swirl of old emotions. There are many ways in which the present pandemic differs from the HIV epidemic, but as both an aging person living with HIV and a mental health practitioner, I am acutely aware of how present circumstances create an emotional bridge to old and disturbing memories and emotions.

These are the remnants of trauma which I will no doubt always carry within me despite years of therapy and self-work. They are old wounds patiently waiting to be reawakened by the ripples of a new experience. These reminders of past events, some from long before HIV crashed into my life, reinvigorate very powerful emotions deep in the oldest part of my brain which direct me to react. Old emotions, thoughts, and false beliefs begin to whisper to me: *I am unsafe, I am alone, I am powerless.*

Fortunately, I now have tools to counteract these old triggers. I use my breath to ground myself and quiet my thoughts. I listen to my heart and to my body. I connect with my intuition. But one aspect of the current coronavirus epidemic continues to disturb me: the total isolation of those who become gravely ill. Just when they need each other most, loved ones are separated. Images abound of elderly husbands or wives singing or talking to their isolated loved ones through windows, unable to be in the same room. Although essential medical practice, it is reminiscent of the early days when AIDS patients were dying in their beds with no one to hug them or hold their hands or simply be there (in that case due to fear and stigma). Dying alone is particularly cruel, and underscores the importance of an essential element for survival and resilience: connection.

Less extreme interventions such as social distancing and isolation also have the potential to do emotional harm even as they keep us physically safe. Yet connecting with others doesn't just feel good. It is essential to thrive and remain physically and emotionally healthy.

Images of people in Italy and Spain creating music with their neighbors from their windows have been uplifting. Most of us don't live on quaint streets surrounded by folks with nearby windows and terraces, but there are other things we can do to maintain healthy connections in these turbulent and unpredictable times. Here are a few:

1. Connect with yourself and your feelings. I lose resilience when I lose touch with my inner thoughts and emotions. Fear, which is in abundance today, can cause people to cope in maladaptive ways with addictions, anger, and even confusion. Several daily practices can especially help, including routinely checking in with yourself and your feelings, activating and frequently using your social network, engaging your spiritual resources and, although it sounds counterintuitive, making a daily gratitude list. Each of these contributes to staying grounded and balanced.

2. Reach out to others. Connect with at least one other person each day. We are fortunate to have a variety of technological means to do this. I find that seeing someone on a screen, while not the same as visiting in person, adds a dimension to the experience that is far superior to a phone call alone. And this outreach isn't just an act of self-preservation. It can be a lifesaver for the person to whom you reach out. A kind word, a gesture to help, or simply saying hello is highly therapeutic and healing for everyone involved.

3. Get creative with technology. Many of my therapist colleagues are rushing to incorporate telehealth into their practices as legal and privacy constrictions on such practices are loosened. Therapy, support groups and twelve step meetings have gone increasingly virtual in just a matter of days. The internet, which of late has been such a tool of divisiveness, has become an essential component of life-saving connectivity, providing a platform for all sorts of meetings and gatherings that would have been unthinkable just a few years ago.

4. Be of service. Stepping out of ourselves and into service—even virtual—not only has personal therapeutic benefits but fosters good will and healing at a societal level. There are countless ways to do this. If you see a need, volunteer to organize a virtual support group. Participate in a webinar for information or support. Join a virtual prayer group or reiki circle for healing. We are limited only by our creativity.

As we face the next weeks and months there will be ongoing challenges to our resolve and resilience. Maintaining robust connections both to our feelings and with those around us will be essential. PA

DAVID FAWCETT, PHD, LCSW is a social worker and clinical sexologist who has worked in addictions and mental health for over three decades. He is the author of *Lust, Men, and Meth: A Gay Man's Guide to Sex and Recovery* (Healing Path Press 2015) which explores the intersection of gay men, drug use, and high-risk sexual behavior. The book was named "2016 Best Nonfiction Literature" by POZ magazine. He is also Vice President for Clinical Programming at Seeking Integrity LLC where he, in collaboration with Dr. Rob Weiss, develops and operates treatment programs for sex and porn addiction and chemsex. He is the producer of the podcast "Sex, Love, and Addiction: Healing Conversations for Gay, Bisexual and Transgender Men" and, in 2018, David co-produced the award-winning documentary *Crystal City,* which follows the journeys of several men in recovery from chemsex in New York. He is a regular contributor to TheBody.com and TheBodyPRO.com and he has been published in *Huffington Post*, POSITIVELY AWARE, and other journals.

THE UNDISCOVERED COUNTRY

How telehealth is taking HIV care into new territory

BY **RICK GUASCO**

For years, telehealth was an emerging technology that couldn't quite deliver. It promised to bring patients and health care providers closer together through smartphones, high-speed internet access, and video conferencing. But it was always held back for one reason or another.

And then, the COVID-19 pandemic—with its social distancing and sheltering at home—hit. Telehealth became just what the doctor ordered.

Sometimes called "telemedicine," telehealth is a broad term that covers how individuals and their care providers use communications technology to share information. It can be as simple as a phone call or text, or as sophisticated as a video conference over your computer, smartphone, or other device. It can refer to medical and mental health care, as well as services such as case management or linkage to care. While the two seem interchangeable, most people nowadays are using "telehealth" to describe the entire field.

In March, as states and municipalities issued stay-at-home orders to prevent exposure to and mitigate the spread of COVID-19, health care organizations, doctors' offices, and hospitals have increasingly made telehealth the everyday delivery method of providing care, especially to those most vulnerable, such as people living with HIV.

Only several months before the pandemic, Rutgers University Hospital had started looking into telehealth.

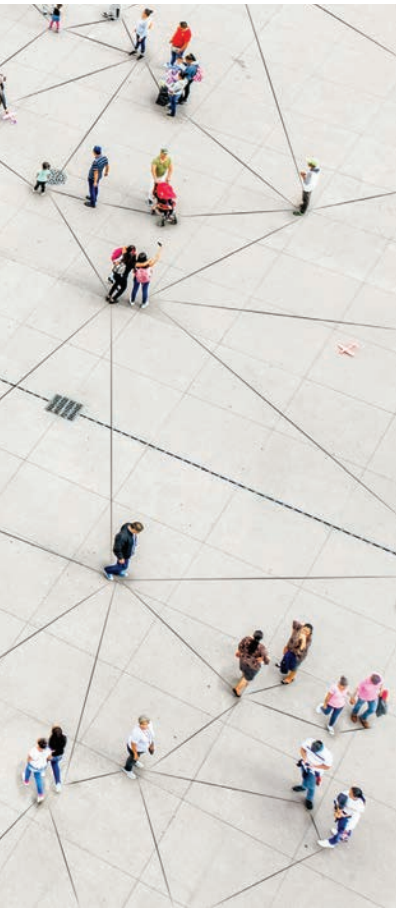
"Over the last six months, as an HIV clinic, we were looking into telemedicine because we hoped that it could be a very good tool to keep patients in care—people who might otherwise be vulnerable to disengaging in care," said Michelle DallaPiazza, MD, assistant professor of medicine at the hospital's infectious diseases division. "Harder to reach patients may be younger and tech savvy, but they may have busy lives or schedules that could make it difficult to come in for an appointment during regular clinic hours."

The telehealth program was still just getting off the ground when the pandemic hit.

"Like many places, we hadn't really had a lot of investment from the hospital in telemedicine until the COVID-19 pandemic," said DallaPiazza. "But now both the medical school and the hospital with which we are associated diligently and rapidly got a telemedicine system up and running to be able to avoid major interruptions in care during the pandemic. We've been contacting patients to change their in-person appointments to telehealth visits. For patients who have a smartphone, it's as simple as tapping on a link sent via text, and they can video chat with their provider. For patients who don't have a smartphone, we are reaching out to them with a simple phone call."

This changes everything

IF THE PANDEMIC forced a change in how medical care is delivered, it has also changed the rules—at least for now—easing some of the



ISTOCK

restrictions that had held telehealth back.

One of the most significant changes came March 17 when the U.S. Department of Health and Human Services (HHS) Office for Civil Rights announced it was relaxing enforcement of the HIPAA patient privacy rules, essentially allowing clinical visits in most non-public facing audio and video platforms. Most organizations are opting for commercial platforms such as Zoom, which offer at least some measure of security, as opposed to consumer applications such as FaceTime and Skype.

Another major shift was the decision by the U.S. Centers for Medicare & Medicaid Services (CMS) to pay for telehealth services, stating, "with the emergence of the virus causing the disease COVID-19, there is an urgency to expand the use of technology to help people who need routine care, and keep vulnerable beneficiaries with mild symptoms in their homes while maintaining access to the care they need."

The announcement by CMS removed what had been one of the biggest barriers to telehealth's expansion.

"There's been tremendous movement in the past few weeks to change the standards and relax HIPAA privacy requirements and other barriers—some of them temporarily, some of them permanently—so that more telehealth services can be provided," said Brian Hujdich, executive director of HealthHIV, a national organization that provides education and capacity building for other agencies in the areas of HIV, hepatitis C, and LGBTQ health.

Shaping those standards will be an alphabet of stakeholders—federal agencies such as the CDC, CMS, and HRSA; professional medical associations such as AMA and AACME (Accreditation Council for Continuing Medical Education), weighing in on medical standards; and the FCC, which will help set technical requirements.

"That's where the nonprofits can engage," said Hujdich. "As a community, we can make sure that we are letting the decision makers, the policymakers, the funders of the situation. We have to develop telehealth programs that are meaningful and reflective of everyone in the community. We will help inform how these efforts are developed, funded, and implemented."

In March, HealthHIV announced the launch of a new program aimed at helping community-based organizations and public health departments to develop and expand their own HIV prevention and care telehealth services by providing education and technical assistance.

"There are so many unknowns at this point that the more we keep assessing what's happening and what's needed, the more relevant telehealth will be," said Hujdich. "Depending on how well it is adapted, this could set about some significant and permanent change in how HIV care is delivered."

Satellite system

MEDICAL ADVOCACY & Outreach (MAO, formerly Montgomery AIDS Outreach) is the primary care provider for people living with HIV in south Alabama. MAO's service area encompasses central and southern Alabama—18,675 square miles—some of the poorest counties in the U.S., and a region hard hit by HIV.

"There's no way we can have enough staff to go out there and do what we need to do," said MAO chief executive officer Michael Murphree, LICSW. "So, telemedicine was the answer for us."

In 2012, MAO partnered with two other agencies—Thrive Alabama, based in Huntsville and Whatley Health Services in Tuscaloosa—to launch Alabama eHealth, a program providing telehealth services to 50 of Alabama's 67 counties. HIV-specific care is provided through a network of primary care medical clinics.

Not only is the area poverty-stricken, like many rural areas in the U.S., much of MAO's service area also lacks high-speed broadband internet access. To overcome this, MAO devised a hub-and-spoke strategy for its delivery system, a network of 11 satellite clinics linked to three hubs tucked in corners of the agency's service area—in Atmore, Dothan, and Montgomery.

Connecting the network is a telecommunications bridge, an infrastructure that uses a military level of encryption called AES-256 to ensure privacy and security. In areas where broadband internet is available, MAO's doctors, mental health therapists, and case managers can send an email link to a patient or client who has access to a computer, smartphone, or other device that will allow for a face-to-face video appointment.

More typical, however, is a patient visiting one of the satellite clinics, where a nurse conducts a physical examination using medical equipment such as a wireless Bluetooth-enabled stethoscope. Blood pressure, temperature, and other readings are captured and entered wirelessly into the patient's medical record in real time. With high definition monitors and high resolution 1080p cameras at either end, Murphree says the patient often forgets they are talking with their doctor via a telehealth link.

But Murphree sees the next step in telehealth as what he calls, "suitcase units," portable equipment that allows a nurse to conduct the same clinic exam, connecting to a hub-based doctor, but from a patient's home. Not only would it increase the number of people living with HIV who are receiving care, Murphree says, but it would increase retention rates and improve viral suppression.

Navigating success

BASED OUT OF the University of Florida's hospital, UF Health, in downtown Jacksonville, UF Cares is the largest provider of HIV services in the Jacksonville area. The telehealth program was launched in 2017 by the neurology and family medicine department; it connected

a few iPads to the back of rescue units, implementing a program for stroke patients. Survival rates dramatically improved, and soon the program was expanded to include family medicine, training all primary care providers so that they could see patients via telehealth.

UF Cares' success earned it a grant from the CDC, funding a three-year project starting in September 2018 to adapt the telehealth program for people living with HIV, focusing on care in urban areas.

"There were first-year challenges," acknowledged Reetu Grewal, MD, UF Health's medical director of Family Medicine and Pediatrics at the Baymeadows clinic, listing some of the program's stumbling blocks. "The lack of insurance parity for telemedicine visits was a hindrance. A lack of staff members specifically tasked with certain roles, such as patient enlistment. Many patients were initially concerned about privacy of medical records. Some UF Health medical providers were also reluctant at first. Patients were having to get accustomed to the technology."

Without a staff member specifically tasked to the project, different telehealth assignments were relegated to various clinic staff, who were already busy with their own workloads. However, that changed in 2019.

"We hired a telemedicine navigator who attends the case management meetings every week," said Grewal. "We see someone would be a good match for telehealth, and it's her job to call the patient to see if they would want to enroll. Before, a patient might not get asked or receive a follow-up call. She also goes around the clinic, talking to patients to get them interested in telehealth, answering their questions. She takes people step by step through the process."

Grewal credits the patient navigator for substantially improving the project's recruitment and patients' satisfaction with telehealth. The program is integrated with the clinic's EPIC electronic medical records system. Patients connect to their telehealth appointment using the streaming video conferencing platform Zoom. However, if a person doesn't have a smartphone or the technical savvy to get online, they can visit any family medicine clinic throughout the UF Cares network or a number of local community-based organizations, and conduct their telehealth appointment there.

The convenience of telehealth and the personal attention patients receive has been critical to the success of UF Cares' telehealth program.

"The more that they use it, the more they like it," said Grewal. "I only see it growing in the future."

FROM MAO'S CLINIC IN MONTGOMERY, ALABAMA, LAURIE DILL, MD, AAHIVS (ON SCREEN) MEETS WITH A PATIENT IN ATMORE, 120 MILES AWAY.

Making the most of an uncertain future

THE COVID-19 pandemic has given telehealth the opportunity—if not the necessity—for explosive growth. But it has also forced health care and service organizations down an unfamiliar road.

"We'll learn from it," said John Scott, medical director of the telehealth program at the University of Washington, in Seattle. "Given the rapid expansion, it's not going to be perfect, but we are committed to getting it right and learning from it, and making it available to everyone."

Established in 2008, the UW program didn't really begin to grow until 2015, and even then was hampered by the absence of rules allowing for Medicaid reimbursement. But things suddenly changed with the rise of the coronavirus pandemic.

"One of the big challenges has been that we're not just doubling the number of patients we're seeing via telemedicine; we've gone up 50- to 100-fold because of the pandemic," said Scott. "The scaling is unprecedented. You have to be strategic about your process and how you manage the growth."

For organizations new to telehealth, his advice is simplicity.

"You've got to make it as simple as possible, both for patients and clinicians," he said. "Leverage what you have, and use telemedicine to scale it up. To the extent that you can, it's important to standardize processes, stick with one type of technology, and leverage the relationships you already have with other organizations.

"I think we're in this for the long haul," he added. "Any technology that allows us to stay connected while allowing us to maintain social distancing is going to be very empowering. For the most part, telemedicine works. Both patients and providers appreciate what it is doing for care."

HealthHIV's Brian Hujdich also sees opportunity in the uncertainty: "There are so many unknowns at this point that the closer we stay to each other, the more we keep assessing what's happening and what's needed, the more relevant telehealth will be. Depending on how well it is adapted, this could set about some significant and permanent change in how HIV care is delivered."

"Out of this pandemic, I believe that this has opened everyone's eyes to the fact that we must do something a little different in order to serve," said MAO's Michael Murphree. "All of us can be true advocates and say, let's not forget what happened—let's make sure this doesn't happen again, by preparing to use new ways to deliver confidential and compassionate services." PA

GET INFORMATION AND RESOURCES ABOUT TELEHEALTH

HealthHIV
healthhiv.org/capacities/capacity-building-assistance/telehealthhiv

MAO
maoi.org/telehealth

COURTESY OF MAO

COVID-19 Q&A with Dr. David Wohl

An infectious disease specialist who witnessed the Ebola epidemic offers insight into the current pandemic

What do people living with HIV need to know most about COVID-19?

One of our greatest challenges in this pandemic is uncertainty. There is a lot we still do not understand about COVID-19 and when we don't have information many of us tend to fear the worst. Right now, what holds for people living without HIV holds for people living with HIV. This includes keeping far enough away from others so they cannot infect you. In the HIV community we know a lot about prevention and some of those same principles apply to keeping from getting COVID-19.

There is no evidence that people living with HIV are at heightened risk of infection with this coronavirus or are more likely to have complications if infected. People with weaker immune systems may be at higher risk for both but many living with HIV have strong immune systems and high CD4 cell counts. It also seems like the severe respiratory failure that can occur during COVID-19 may be driven, at least in part, by an aggressive immune response. So, it is hard to say if people living with HIV are different from anyone else when it comes to these risks.

The clear danger to people living with HIV during this outbreak is the serious disruptions in health care that can impact getting HIV meds and accessing routine services like clinic visits and labs. People living with HIV will have to be strong advocates for themselves and make sure they have enough medications on hand and not wait until the last pill to start calling for a refill. Despite being more isolated, they will have to continue to take care of themselves—take their meds, exercise as best as they can, and avoid slipping into despair. Sew masks, call elderly neighbors, make art, blog about Cary Grant movies. Do something constructive.

What do providers need to know when it comes to treating PLWHIV with COVID-19?

Clinicians are understandably distracted, many clinics are closed, and patients are hunkered down at home. But, we still need to be able to provide HIV care whether by phone or video and make sure people have what they need until this all passes. Clinicians need to establish some clear pathway for their patients to contact them such as for a medication refill, or non-COVID-19 illness.

Just because we are in the middle of a pandemic does not mean people won't get kidney stones or shingles. I am finding that direct messaging from my patients is the most effective way for me to know what they need and then respond. This communicating can be done by text, email, or the electronic medical record. We clinicians also have to not wear COVID-19 blinders—thinking that every cough or shortness of breath is COVID-19 when it could be something much more routine. We have to fight hard not to let the outbreak become an impenetrable barrier to care.

What is the research being done that you find most promising or interesting?

It should be stated clearly: there is no proven treatment for COVID-19 right now (April 2020). Small studies suggest that hydroxychloroquine and lopinavir/ritonavir may work for some people with COVID-19, but these studies all have serious limitations and the researchers leading these investigations all say that much more definitive research is needed given the question of benefit and the known risks. Such studies are underway.

The research community has responded rapidly to COVID-19. It took many, many months before meaningful therapeutics and vaccine research was able to be launched during the huge West Africa Ebola outbreak—a sad missed opportunity. Many of us learned then that streamlined procedures are essential to get research from design to implementation during an outbreak.

With COVID-19 we are seeing a swift research response and important studies have already started or will very shortly to examine rigorously potential treatments as well as vaccines. One important aspect of this is understanding that what works early in the infection, when the virus is replicating in the upper airway, may not be effective in treating more advanced COVID-19, where inflammation in the lungs can shut down the passage of oxygen into the blood. We need to figure out what is most effective at the right point in the disease.

Has your work in Ebola helped to inform your work in COVID-19? What are the parallels, and what's different?

COURTESY OF DAVID WOHL, MD

Working in Liberia during and after the Ebola outbreak there, I was struck by the social distancing that people there were able to do—not for weeks, but for over a year. Seeing this again, but now at home really blurs for me the "here" versus "there" mindset that I had as a researcher working domestically and abroad. My experience learning about infection control in West Africa has certainly served me, assisting my incredible colleagues as we created drive-through COVID-19 testing centers and prepared our hospital for admitting patients with suspected and confirmed COVID-19.

After Ebola, members of our team created "Liberians are Survivors" bumper stickers to celebrate the strength that people showed in doing the hard things that made the end of the outbreak possible. I still see them there. We will do the same and survive through strength.

What is the most important thing people can do to help in the effort?

Don't freak out. It is hard to be separated and to not worry, to not miss the things we enjoyed but can't do now, and not feel sad for ourselves, our communities, and our world. No one knows when this outbreak will pass, but it will. And, when we can get back to a more normal existence we will appreciate it so much more. We will rejoice in what was once the mundane and, I hope, feel closer to one another. Until then, stay home.

David Alain Wohl, MD, is a professor of medicine at the University of North Carolina at Chapel Hill. There he leads the HIV Prevention and Treatment Clinical Research Site and sees patients in the university's Infectious Diseases Clinic.

Virtuosity at CROI 2020

Leading HIV conference goes virtual in a time of coronavirus outbreak

BY **ENID VAZQUEZ**

LIVE FROM BOSTON: JOSEPH ERON, MD; WAFAA M. EL-SADR, MD; AND ROBERT T. SCHOOLEY LEAD THE WEBCAST, INTRODUCING DR. ZUNYOU WU'S PRESENTATION ABOUT CHINA'S EFFORTS TO CONTROL THE SPREAD OF COVID-19.

In the seven days before the start of CROI 2020, the national situation changed day by day in the midst of a worldwide coronavirus outbreak. After meeting over the course of several days, CROI organizers at first pledged to move forward with the international conference. Then, just two days before many attendees were to arrive for the March 8 opening, the conference went online only—"virtual"—instead.

Please don't come to Boston, the organizers said. At that point, there was already an outbreak in Seattle and more importantly, three cases of COVID-19 linked to another medical conference in Boston a few days before. To their credit, conference organizers did go ahead with the event, just not how it had always taken place: face-to-face.

A virtual conference ended the ability of researchers, providers, and community representatives to meet in person with one another, at a loss of the resulting information exchange, inspiration, and collaboration that are an important piece of conferences like CROI. Clearly, in a time of an emerging new disease and unfolding pandemic, such an exchange was not possible.

"CROI leadership has continued to monitor the growing COVID-19 outbreak in the U.S. and globally each day," the organizers announced on March 6. "Many countries, agencies, and institutions have now banned travel, and many infectious disease physicians are urgently needed to care for patients with COVID-19 in their own institutions. Because of increasing concerns that travel to a large group gathering like CROI is not advisable from a personal and public health perspective, the CROI leadership has come to the difficult decision that the 2020 CROI meeting will be virtual.

"CROI leadership will be present in Boston to facilitate the success of the virtual program. We ask for your patience and understanding as we work through very difficult logistical issues in creating a virtual program in a few short days. There are many uncertainties and unknowns as we balance the need to act responsibly in the face of the growing COVID-19 pandemic while doing our best to protect the integrity of the science that serves those living with or at risk of HIV."

Stalwart organizers with their boots on the ground to help lead conference sessions included Drs. Wafaa El-Sadr of ICAP at Columbia University; Judith Currier of the University of California at Los Angeles (UCLA); Elaine J. Abrams, also of ICAP; Michael Saag of the University of Alabama; and Joseph J. Eron of the University of North Carolina at Chapel Hill. Presenters from around the world submitted a recording of their presentation.

Bravo.

COVID-19 session

CROI 2020 turned its attention to the coronavirus pandemic, holding a special session on COVID-19.

Dr. Zunyou Wu, director of China's Center for Disease Control and Prevention, in Beijing, talked about the spread of COVID-19 in China and the country's efforts to control the disease. **WATCH** the webcast presentation at croi-webcasts.org/p/2020croi/croi/CR-SS1-3.

John T. Brooks, MD, of the U.S. Centers for Disease Control and Prevention (CDC), discussed COVID-19 disease and what was known and unknown at the time. He also discussed populations most at risk (see page 20). The webcast of Dr. Brooks' talk is at croiwebcasts.org/p/2020croi/croi/CR-SS1-1.

"Persons with medical comorbidity and advanced age are at increased risk for severe illness and death," said Dr. Brooks. "In the Chinese data I showed previously, persons with cardiovascular disease, diabetes, or chronic respiratory disease had a case fatality rate greater than 5%."

In addition, Ralph S. Baric, PhD, of the University of North Carolina at Chapel Hill, addressed the virology of coronaviruses. Dr. Anthony S. Fauci, director of the U.S. National Institute of Allergy and Infectious Diseases (NIAID), spoke to "The Research Response to COVID-19: A View from NIAID."

WEBCASTS of these presentations are at croiwebcasts.org/s/2020croi/SS-1.

Taking meds monthly—or possibly once a year

A look at drugs in development for HIV treatment and prevention

BY **ENID VÁZQUEZ**

Several HIV drugs in development have clinical data showing efficacy when taken only once a month.

One of them has the potential to be taken only once every six months. Another, when used as an implant, has the promise of being taken only once a year for use as HIV prevention (PrEP).

The move towards long-acting medications "underscores the point that with the drugs in development, the approach that less than once-daily dosing, which was once radical, has become the norm among HIV drugs that are currently in development," said Ethel D. Weld, MD, PhD, Assistant Professor of Medicine at Johns Hopkins University School of Medicine.

Dr. Weld provided an overview of long-acting drugs for HIV treatment and prevention as part of a session on the topic.

"The injectable long-acting combination of cabotegravir long-acting and rilpivirine long-acting has blazed a trail and has established firm proof of concept that **long-acting injectable monthly regimens can sustain virologic suppression among people living with HIV with a high degree of acceptability**. The results from the ATLAS-2M trial presented at this conference show that a dosing frequency of every two months was non-inferior in efficacy to once monthly," said Dr. Weld.

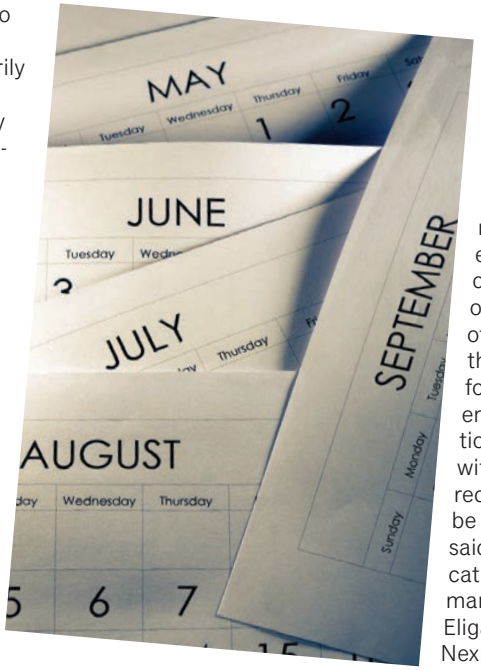
"I know from hiking that when you're blazing a trail and you're first in line on that trail, you tend to get all the spiderwebs in your face," she said.

She pointed to an FDA response on December 21, 2019 to ViiV Healthcare and Janssen Pharmaceuticals regarding their long-acting cabotegravir and rilpivirine combination, holding up approval of the dual injectable.

Dr. Weld said the response "is a slight stumbling block that hopefully can be parlayed into a collective step up and boost for the overall long-acting field in terms of anticipating regulatory and manufacturing consistency challenges, which may not be unique in these two compounds.

"GS-6207, the highly potent capsid inhibitor presented here by Eric Daar, has an EC_{50} in the 50 picomolar range [indicating high potency]. This year clinical data including the first in human studies of a single-dose subcutaneous injection showed efficacy and that concentrations were measurable at out to six months after this injection.

"Islatravir, also a very potent NRTI with translocation inhibition as well as part of its mechanism, has a proposed dosing frequency of once monthly as an oral formulation," said Dr. Weld. "It is also being explored as an implant primarily for a PrEP option that is once yearly and also as a dual-use implant that combines [with] contraception."



JL GUTIERREZ -ISTOCK

She listed other compounds as well, in earlier stages of development.

Dr. Weld talked about some of what she called "BIG" ideas in the move towards long-acting HIV therapy.

"I have to say that the first big idea is that non-adherence to daily medication is placed centrally and is accommodated without blame," she said.

"I hope it's safe to characterize the big ideas in HIV pharmacology as representing a shift rather than drift. Overall, the development of antiretrovirals, which has been such a win from the discovery of AZT to the evolution of highly potent safer and tolerable oral ART, has been a story of variations on a theme. And the theme has been daily lifelong oral medications. It depends on daily adherence and a provider-focused system of care delivery that people must access, and when people cannot, either temporarily or consistently, a whole different movement rather than variations on the same theme is needed.

"So, I see long-acting approaches, which historically directly improved adherence and therefore efficacy, as forgiving approaches to accommodate unfavorable psychosocial conditions for periods in our lives, logistical and access barriers, and stigma, as well as cover many of the gaps in our care continuum and our cascade with HIV.

"Another big idea is that formulation and delivery innovation can optimize PK [pharmacokinetics], often without requiring a device that needs a separate regulatory pathway of its own. [A specific type of hydrogels] are not particularly inflammatory when injected under the skin and slowly degrade within the body. It can improve the PK of not only small molecules but BNabs [which are large molecules]. Microneedle technology, or microneedle patches, are cones of nanoformulated drug that are solid, poured into a mold, adhere to an occlusive backing, and are self-applied by patients, and results in sustained concentrations of drug even when the patch is removed. [She later explains that this delivery system, as well as others, can be removed in case of adverse reaction or pregnancy.] It requires an every-week re-application and can demonstrate routine levels of antiretrovirals above the therapeutic targets for at least a week on end. Finally, formulation device approaches with regulatory track record can and should be leveraged," Dr. Weld said. Among such medications currently on the market, she said, are Eligard, ATRIGEL, and Nexplanon (etonogestrel implant).

As the field develops, several questions remain, said Dr. Weld.

"The question of long-acting drugs we have in development—what are their partners? What can we pair them with? Can we pair two highly potent drugs such as islatravir and GS-6207 with each other? How well do the PK profiles need to match? How can we study DDIs [drug-drug interactions] when we're developing these drugs? Do we need an oral formulation for every single long-acting

formulation we develop? For cabotegravir and rilpivirine long-acting, the trailblazing combination, can we reformulate to reduce volume and reduce injection frequency? Does a long PK tail actually necessarily confer antiretroviral resistance?

"For TAF implants there's been a local tissue necrosis issue observed in some animal models. So, establishment of first-principles thinking in modeling to predict which molecules and formulations cause local toxicity is needed.

"Implementation is a huge gap," Dr. Weld noted. Then there's predicting in whom long-acting ART will be best used and the combination of other preventative and treatment technologies such as contraceptives and antipsychotics and opiate substitution therapy.

In all of the science, lies the excitement of hope.

In her conclusion, Dr. Weld said that, "I see long-acting technologies as technologies for empowerment, and to fully realize that empowerment and the freedom that these technologies can enable, we need to optimize them and maximize their impact by seeking out whom best to use them for."

GO TO croiconference.org to view the presentations. Look for the webcast "Themed Discussion, The Long and Short of It: What's Next for Long-acting Drugs," on Wednesday, March 11, 2020.

LONG-ACTING COMPOUND IN DEVELOPMENT:

- cabotegravir long-acting (CAB-LA) with rilpivirine long-acting (RPV-LA), closest to actually being on the market
- GS-6207 capsid inhibitor
- dapivirine (DPV) vaginal ring
- islatravir (NRTTI, first in class), is a nucleoside analogue reverse transcriptase translocation inhibitor NRTTI (first-in-class). Used as an implant for prevention, islatravir has the potential of being taken once a year. Taken orally for prevention or treatment (in combination), there's the possibility of once-a-week dosing or once-a-month dosing.

PRE-CLINICAL DATA (NOT YET TESTED IN HUMAN BODIES) FOR:

- Broadly neutralizing antibodies (bNAbs)
- dolutegravir ultra-long-acting (DTG ISFI, ULA)
- tenofovir alafenamide (TAF) implant

New long-acting drugs in development

Trend towards long-acting HIV medications continues

BY **ENID VÁZQUEZ**

GO TO croiconference.org for more information about these medications and hundreds of additional reports on HIV therapy, treatment, and complications.

Just two shots every other month

The ATLAS-2M study found that **taking long-acting HIV therapy every other month was as good as taking it once a month**. The trial used long-acting cabotegravir (CAB-LA) plus long-acting rilpivirine (RPV-LA). The two-drug regimen is set to be approved this year by the U.S. Food and Drug Administration (FDA). The injectable therapy is given as two intramuscular shots.

There were 522 individuals switched from monthly shots to shots given every eight weeks instead. Another group of 523 individuals continued being given their two shots every four weeks.

At 48 weeks, the 8-week therapy was found to be non-inferior to the 4-week therapy. Undetectable viral load (less than 50) was achieved by 94.3% of the 8-week group and 93.5% of the 4-week group. The safety and tolerability were reported to be similar.

Of the 8-week group, 90% said they preferred their new dosing of every other month.

ATLAS-2M results were presented by Edgar T. Overton, MD, of the University of Alabama at Birmingham. **SEE** Abstract 34 at croiconference.org/abstract/cabotegravir-rilpivirine-every-2-months-is-noninferior-to-monthly-atlas-2m-study and webcast at croiwebcasts.org/p/2020croi/croi/34.

Stopping those injections

So, taking HIV medication once a month or every other month sounds good. But **what happens if therapy stops?**

Individuals who stopped the long-acting injectable regimen of CAB-LA plus RPV-LA were put on long-term follow-up (LTFU) oral therapy. No drug interaction problems were found in switching to oral therapy.

Good thing, since "CAB and RPV remain measurable in plasma for a year or longer." But the half-life—the time it takes for half the drug to leave the body—is 5.6 to 11.5 weeks for CAB-LA and 28 weeks for RPV-LA. Or, as the report puts it, "CAB and RPV have low drug interaction potential as perpetrators and pose no PK-related limitations to alternative ART [antiretroviral therapy] selection after discontinuation of injections." No safety or efficacy concerns were observed.

The findings were reported by Susan Ford, PharmD, of GlaxoSmithKline. The research tracked 38 individuals who had withdrawn from the LATTE-2 and ATLAS studies.

HIV therapy every six months

That's the potential of long-acting GS-6207. The HIV capsid inhibitor drug is a first-in-class medication, meaning that it has **a new take on treatment that hasn't been used before**.

GS-6207 was reported as generally safe and well tolerated in the 39 individuals who received dosing in an early Phase 1b study. The most common adverse event was mild to moderate injection site reaction.

With the favorable findings, GS-6207 will be observed in two new studies. NCT04143594 will enroll people taking HIV medication for the first time (treatment-naïve). NCT04150068 will study the drug in people who are heavily treatment-experienced.

Hang on to your hats, because the results are still early. GS-6207 has a lot more research to undergo.

Findings of the drug's dose-response relationship were presented by Eric Daar, MD, of the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center. **VIEW** the poster presentation at bit.ly/CROI-GS6207 and the poster video at croiwebcasts.org/p/2020croi/croi/469-PS. **WATCH** the webcast at croiconference.org/abstract/islatravir-metabolic-outcomes-in-phase-iib-trial-of-treatment-naive-adults-with-hiv-1.

Islatravir

Another new HIV drug in development is islatravir (ISL, also called MK-8591). Islatravir is in a new class of HIV medications, called nucleoside reverse transcriptase translocation inhibitors (NRTTIs). It is being studied for both HIV treatment and HIV prevention.

Islatravir is potent. A single half-milligram was found to suppress HIV for longer than seven days. **Islatravir has the potential for once-a-week dosing in addition to daily dosing.** It also has a high barrier to drug resistance.

At Virtual CROI 2020, there was a report that in early research using a primate model, a weekly oral dose provided efficacy for HIV prevention as post-exposure prophylaxis (PEP). This raises the hope for pre-exposure prophylaxis (PrEP). There is a PrEP study with islatravir using a once-monthly 60 mg dose compared to 120 mg in people at low risk of HIV.

Last year, Merck & Co. reported that an MK-8591 implant was tolerable in early research with primates. Drug levels showed adequate concentrations for protection against HIV. The implant showed potential for protection lasting a year.

A low dose of 0.75 mg of islatravir is also being studied as a two-drug regimen with doravirine (Pilfeltro) in three scenarios: first-time treatment; highly treatment experienced people (with at least three drug class resistance); and switch studies (for people changing over from Biktarvy).

Another study, DRIVE2Simplify, is looking at treatment simplification. Participants are started out with the triple drug regimen ISL/DOR/3TC and then the 3TC is dropped at 24 weeks (six months).

Islatravir metabolics

A report found that the metabolic profile of a drug regimen containing islatravir was similar to a comparative regimen.

The two-drug combination of islatravir with doravirine (DOR) was compared to Delstrigo (DOR/3TC/TDF).

The research team noted that, "As HIV has become a chronic, manageable disease through effective antiretroviral therapy (ART), **increased emphasis is being placed on long-term safety and toxicity, including weight gain, fractures, and metabolic disorders**. Certain components of approved ART have been associated with long-term adverse events (AEs), including weight gain, loss of bone mineral density (BMD), and metabolic abnormalities. The combined attributes of islatravir (ISL; MK-8591) and doravirine (DOR) create the potential for a potent, simple, 2-drug regimen with efficacy comparable with approved regimens that may address some of the long-term safety and toxicity concerns of traditional regimens."

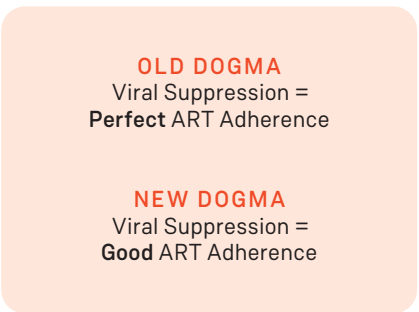
There were 121 participants out to one year on either ISL plus DOR or Delstrigo. The research team concluded, "The ISL regimens, regardless of dose, demonstrated minimal impact on BMD and similar changes in fat distribution, weight, and BMI compared to the DOR/3TC/TDF group, through 48 weeks of treatment."

The highly detailed report was presented by Grace A. McComsey, MD, of the University Hospitals Cleveland Medical Center. **READ** the abstract report at croiconference.org/sessions/islatravir-metabolic-outcomes-phase-iib-trial-treatment-naive-adults-hiv-1.

Adios to perfect adherence?

Finally, one doctor dared to say out loud what other doctors have feared to say: The need for perfect adherence with HIV therapy may be a thing of the past.

José R. Castillo-Mancilla, MD, of the University of Colorado Denver, laid it out with a simple graphic.



It's not that HIV medical providers and researchers haven't discussed this topic for years. Promoting perfect adherence with medication is a difficult job, especially when treatment is lifelong. Nor are providers happy with the burdens this can place on their patients. Changing the need for perfect adherence is one of the forces behind the development of new HIV medications.

Dr. Castillo-Mancilla detailed findings of clinical research and discussed technologies that can be used for improving adherence. **WATCH** the webcast, "Getting It Right: Practical Approaches to Adherence with Modern ARVs," at croiconference.org/abstract/getting-it-right-practical-approaches-to-adherence-with-modern-arvs.

In his presentation abstract report, Dr. Castillo-Mancilla writes that, "Along with the remarkable advancements in antiretroviral therapy (ART), **new paradigms have emerged on the importance of adherence**. Early studies with older antiretrovirals (ARVs) proposed that [more than] 95% adherence was required to achieve and maintain virologic suppression, which led to the concept that an undetectable HIV viral load (VL) was equivalent to full adherence. However, the potency and favorable pharmacology of the new ARVs have allowed for more forgiveness to missed doses, with recent studies demonstrating that the minimal level of ART adherence required to sustain viral suppression may range between 80-85% (and as low as 75%). While advantageous, achieving viral suppression despite variable ART adherence has de-emphasized the focus on adherence in clinical practice, limiting our understanding of its consequences at the individual (i.e., biological, virological) and population (i.e., transmission) levels. This is essential to maximizing the benefit of ART and controlling the HIV epidemic, since maintaining an undetectable HIV VL (mainly driven by adherence) is indispensable for the U=U (Undetectable = Untransmittable) strategy to be effective, and because adherence remains a lifelong challenge. However, despite its critical importance, we currently lack a gold-standard measure to quantify ART adherence. In response to this gap, several innovative methods and strategies to objectively measure ART adherence have emerged in recent years. These include: a) pharmacologic methods that inform about cumulative adherence and recent dosing by quantifying drug concentrations in plasma, urine, hair and dried blood spots; b) advances in electronic medication dispensers that monitor pill-taking behavior, and; c) digital pills that confirm medication ingestion. These novel methods have proven more accurate than self-report, can predict adverse clinical outcomes (i.e., viremia), and provide real-time adherence information that can lead to actionable interventions during a routine clinical visit. Moreover, pharmacologic methods can assess inter-individual pharmacokinetic differences not captured by HIV VL monitoring or other adherence measures."

With all the advances and all the potential, at the conclusion of his presentation slides, Dr. Castillo-Mancilla wrote, "Work in adherence is not done!"

Open discussions should help lead the way.

Fatty (t)issues

Weight gain and HIV medications

BY **ENID VÁZQUEZ**

"There's been a tremendous amount of interest in the past few years on emerging findings on excess fat gain in people living with HIV," said Judith Currier of the University of California, Los Angeles, as moderator of the "Fat in Focus" oral presentation at CROI 2020.

Providing an overview of the presentations making up the session was Jacqueline Capeau, MD, PhD, of the Sorbonne University in Paris.

Dr. Capeau began her discussion by noting important questions which were raised and for which answers are still being sought, arising from a similar presentation moderated by Janet A. O'Halloran, of Washington University in St. Louis, at last year's CROI.

1. **Do integrase inhibitors cause weight gain?**
2. **Is there a direct effect or consequence of viral suppression?**
3. **Is there a class-specific or drug-specific effect?**
4. **Is the risk restricted to certain sub-groups?**
5. **What are the consequences of weight gain during ART**?

The answer to the first question, she said, is yes. "Among integrase inhibitor medications, dolutegravir and bictegravir have been associated with weight gain, more so than raltegravir and elvitegravir/c. Among NRTIs, TAF [is associated with weight gain] and TDF could be protective. Among NNRTIs, efavirenz seems to be protective. [Efavirenz is no longer a first-line therapy for HIV in the United States.] This is clearly not a class-specific effect. Some integrase inhibitors and some NNRTIs, but not all, have been associated with increased weight."

For the second question, she said, "The risk is really markedly [similar] among subjects. But some at-risk groups have been identified, women are at risk and also black people. The major risk factors are linked to the severity of HIV infection, in the 'return to health' process, with the low CD4, high viral load, or BMI [body mass index] being the major risk factors. This is a global fat gain and in general there is also an increased lean mass.

"When looking at the switch situation in ART-controlled patients, they are generally over 50 years old. There is no reason for 'return to health' [because they are already healthy]. This is a global fat gain and generally lean mass is enhanced. The risk factors are different. There is high BMI and age. The molecules [drugs used] are the same. Again, women have a higher risk for weight gain. But regarding risk, black and white people [are similar] and regarding the metabolic consequences, clearly, lipid levels are improved, but probably there is a worsening insulin resistance."

'There are a number of mechanisms which could explain this weight gain in the presence of integrase inhibitors...'

"It is very important to identify what could be the consequences on the cardiometabolic risk, as this has not been done until now," she continued.

"Regarding the mechanism, there could be the direct impact of some integrase inhibitors on adipose tissue. First, adipose tissue is an HIV reservoir [hiding place for the virus]. And some HIV proteins could directly impact on some adipose tissue in particular, producing fibrosis and dysfunction. In addition, some integrase inhibitors have been shown to be able to induce adipose tissue hypertrophy and this could result in weight gain and possibly into cardiometabolic outcomes. Regarding the effect of TAF or TDF on adipose tissue, up to now there is no indication on the mechanism which could be involved, with the possibility of increased oxidative stress.

"There are a number of mechanisms which could explain this weight gain in the presence of integrase inhibitors. First, gender—the hormonal status—but also genetics and race. At the brain level, modifications in feeding [diet] but also appetite, mood, and sleep. At the gut microbiota, modification in immune activation at the fat level, with fibrosis, insulin resistance, and possible modification in energy expenditure. In addition, the traditional risk factors are generally playing an important role: diet, being sedentary, use of psychotropic drugs, corticoids, and stopping tobacco. The consequences at the cardio level remain unknown. The lipids are generally improved and possibly there could be an increase in insulin resistance, risk of diabetes, and also liver steatosis [fatty liver]."

Conclusions from Dr. Capeau

"FIRST, WE HAVE SEEN that increased weight and fat gain in HIV-infected individuals is really a very large multifactorial process. You have to think first of the traditional risk factors and factors related to [the] environment: age, gender, genetics, hormones, race, being sedentary, and [diet]. You also have to think that HIV is also present within adipose tissue and could result in [a] 'return to health' process. And finally, adipose tissue could be impacted by the different HAART molecules. ...

"Risk factors—it is very important to be able to identify patients who will gain excessive fat. The consequences, in particular the cardiometabolic consequences, need to be further assessed. Up to now there is no indication of increased cardiovascular risk. But clearly possibly there is an increased risk in insulin resistance and diabetes and it's important to identify the at-risk patients. Some very important points: reversibility if we stop these drugs, the severity of weight gain, and also the clinical outcomes."

GO TO croiconference.org to view the presentations, including a discussion of metabolic rate and caloric intake from Dr. Allison Ross Eckard and a look at the effects of HIV therapy from Dr. John Koethe. Look for the webcast "Themed Discussion, Fat in Focus," on Tuesday, March 10, 2020.

The 22nd International Workshop on Co-morbidities and Adverse Drug Reactions in HIV, is in New York September 12-13, 2020.

The scientific conference for medical providers this year will include many presentations on the relationship between HIV therapy and weight.

Actual patient living with HIV.

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- The long-term safety of *EGRIFTA SV™* on the heart and blood vessels (cardiovascular) is not known.
- It is not known whether taking *EGRIFTA SV™* helps improve how well you take your antiretroviral medications.
- It is not known if *EGRIFTA SV™* is safe and effective in children, do not use in children.

You should not take *EGRIFTA SV™* if you:

- Have a pituitary gland tumor, surgery, or other problems related to your pituitary gland, or have had radiation treatment to your head or head injury.
- Have active cancer.
- Are allergic to tesamorelin or any of the ingredients in *EGRIFTA SV™*.
- Are pregnant or become pregnant. If you become pregnant, stop using *EGRIFTA SV™* and talk with your healthcare provider.
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Before using *EGRIFTA SV™*, tell your healthcare provider if you:

- Have or have had cancer.
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- Have scheduled heart or stomach surgery.
- Have breathing problems.
- Are breastfeeding or plan to breastfeed.
- Are taking any other prescription and non-prescription medicines, vitamins, and herbal supplements.

***EGRIFTA SV™* may cause serious side effects including:**

- **Increased risk of new cancer in HIV positive patients or your cancer coming back (reactivation).** Stop using *EGRIFTA SV™* if any cancer symptoms come back.
- **Increased levels of your insulin-like growth factor-1 (IGF-1).** Your healthcare provider will do blood tests to check your IGF-1 levels while you are taking *EGRIFTA SV™*.
- **Serious allergic reaction** such as rash or hives anywhere over the body or on the skin, swelling of the face or throat, shortness of breath or trouble breathing, fast heartbeat feeling of faintness or fainting, itching and reddening or flushing of the skin. **If you have any of these symptoms, stop using *EGRIFTA SV™* and get emergency medical help right away.**
- **Swelling or fluid retention**. Call your healthcare provider if you have swelling, an increase in joint pain, or pain or numbness in your hands or wrist,
- **Increase in blood sugar (glucose) or diabetes**
- **Injection site reactions**. Injection site reactions are a common side effect of *EGRIFTA SV™*, but may sometimes be serious.
- Increased risk of death in people who have critical illness because of heart or stomach surgery, trauma of serious breathing (respiratory) problems has happened when taking certain growth hormones

The most common side effects of *EGRIFTA SV™* include:

- Pain in legs and arms
- Muscle pain

These are not all of the possible side effects of *EGRIFTA SV™*. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or to **THERA patient support®** toll-free at 1-833-23THERA (1-833-238-4372).

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THERA technologies

701-01-12/19

Advance work

2020 Pre-CROI Community HIV Cure Research Workshop

BY **RICHARD JEFFERYS**

The 2020 Conference on Retroviruses and Opportunistic Infections (CROI) was scheduled to take place in Boston starting on March 8, before concerns about COVID-19 forced a last-minute switch to a virtual online meeting. The annual Pre-CROI Community HIV Cure Research Workshop similarly shifted to a Zoom webinar format, retaining the original planned agenda thanks to the flexibility of all the presenters and panelists. Brief summaries of the workshop sessions are below, and complete recordings are available online at: treatmentactiongroup.org/webinar/pre-croi-community-hiv-cure-research-workshop-2020.

Dan Barouch is principal investigator of the Immunotherapy for HIV Cure (I4C) Collaboratory, one of six U.S.-based collaboratories funded by the National Institute of Allergy and Infectious Diseases (NIAID) to pursue HIV cure research. Barouch noted that I4C is pursuing a **dual strategy that aims to eliminate the majority of HIV-infected cells while also augmenting the ability of the immune system to control any virus that is left behind**. Current candidates being tested include:

- **Vestilamod,** an immune modulator known as a toll-like receptor 7 (TLR7) agonist which may both awaken the latent HIV reservoir and enhance the virus-specific immune response.
- **Broadly neutralizing antibodies (bNAbs)** that can both directly inhibit HIV and promote destruction of infected cells (see "Scenes from the bNAb revolution," Jan+Feb 2020).
- **Therapeutic vaccines** designed to boost HIV-specific immunity.

In virus-infected macaques treated very early with antiretroviral therapy (ART), the combination of vestilamod and the bNAb PGT121 significantly delayed viral load rebound after ART interruption. Barouch debuted results from a new study showing that addition of therapeutic vaccination may further improve outcomes — six out of 10 macaques that received the triple combination (vestilamod, PGT121, Ad26/MVA vaccines) controlled viral load to undetectable levels 84 days after an ART interruption. Human trials of these candidates are underway, aiming to discern the optimal combinations for further evaluation.

Jim Riley from the University of Pennsylvania delivered an **update on gene therapy in HIV cure research**. A major spur for this work has been the case of Timothy Brown, who was cured of HIV after receiving a stem cell transplant from a donor lacking the CCR5 receptor that most virus strains use to infect cells (two more individuals may have recently joined Brown, see addendum below). Brown's case has prompted efforts to eliminate CCR5 expression with gene therapies, and Riley is now testing whether this strategy can be combined with a different approach that genetically modifies T cells to better target HIV-infected cells. This latter type of gene therapy, called Chimeric Antigen Receptor (CAR) T cells, has been successful in the treatment of cancer and Riley showed results from macaque studies suggesting that virus-directed CAR T cells can contribute to viral load suppression. A clinical trial marrying CCR5 abrogation with HIV-specific CAR T cells is now ongoing at the University of Pennsylvania (clinicaltrials.gov/ct2/show/NCT03617198).

Women in HIV cure research session

Liz Barr presented an overview of **sex differences relevant to HIV cure research and the current status of women's participation in studies**. Barr described some of the relevant biological factors, including anatomic and genetic. The female genital tract is complex and there is evidence that it's an important site of HIV persistence, but much remains unknown and more studies are needed. The X chromosome harbors many immune-related genes and contributes to sex differences in immune responses between men and women. Hormones can also influence both immunity and the HIV reservoir; for example, estrogen has been shown to inhibit reactivation of latent HIV. In terms of the status of women's participation in cure-related research, results of a survey conducted in the fall of 2019 found that only 17% of participants were female—however only a subset of respondents were able to provide breakdowns by sex. The majority of studies did not have any pre-specified enrollment targets for women. Increased efforts are needed to overcome barriers to engaging women in the research.

Krista Dong described **a unique cohort study underway in the Umlazi Township outside Durban in South Africa: Females Rising through Education, Support, and Health (FRESH)**. The rate of HIV infection among young women in the region is disproportionally high, with studies showing prevalence up to 66% by the age of 23. FRESH provides education and social services focused on empowerment, life skills, career exploration, job readiness, and poverty alleviation along with HIV prevention interventions. Because there is frequent monitoring and HIV infections still occur in the cohort, researchers are also able to investigate the very earliest biological events after virus acquisition. This work is providing important information on immune responses and determinants of viral load control that can contribute to both prevention and cure research. Dong emphasized that FRESH is very much a partnership with the participants, whose feedback is playing a critical role in shaping the study. A clinical trial is currently being planned in collaboration with Gilead, with the aim of studying a combination of two bNAbs—CAP256 and VRC-7—in combination with vestilamod in cohort members with HIV who've been on ART for at least 12 months.

Karine Dubé discussed results from social science studies **exploring the views of women on participating in cure-related research**. Questionnaires were administered during an AIDS Clinical Trials Group (ACTG) trial that enrolled only women in order to test whether modulation of estrogen receptors with tamoxifen influenced activity of a candidate HIV latency-reversing drug (vorinostat). Responses revealed that altruism was a common motivator, with freedom from daily medication and the stigma of HIV infection seen as key aspects of a cure. Most participants were cognizant of the potential for risks. Compensation was frequently cited as a benefit of participation along with contributing to the search for a cure, and all respondents stated they would recommend the study to others. A larger survey conducted in 2018 found that both cisgender and transgender women were more likely than men to be motivated to

participate in research due to altruism, but were also more concerned about risks such as HIV transmission to others and pain or discomfort from study procedures.

David Hardy and Cynthia Gay provided an update on the fate of an ACTG trial evaluating the anti-PD-1 antibody cemiplimab in people with HIV on ART. Cemiplimab is an immune checkpoint inhibitor licensed for the treatment of cancer, and **there is some evidence that these therapies might have potential to both reverse HIV latency and enhance virus-specific immunity** by reinvigorating T cells that have become exhausted and dysfunctional. However, serious side effects can also occur, due to the potential for enhancing T cell responses against the body's own tissues, causing autoimmunity. Hardy noted that the study very carefully monitored for adverse events. When data from two participants showed evidence of toxicity, cemiplimab infusions and further study accrual were stopped (a total of five participants had been enrolled; four in the cemiplimab arm and one in the placebo arm). In one case there was evidence of inflammation in the thyroid gland (thyroiditis) leading to hyperthyroidism, in the other grade 3 elevations in liver enzymes occurred (these elevations subsequently resolved). All four participants who received cemiplimab will continue to be followed. The results raise concerns about the safety of studying anti-PD-1 antibodies in people with HIV who do not have cancers.

An afternoon session at the workshop was devoted to the topic of **analytical treatment interruptions (ATIs)—the temporary cessation of ART in trials** in order to measure the effects of interventions or learn about the mechanisms and kinetics of viral load rebound. A meeting on ATIs involving multiple stakeholders—including community representatives—was held in July 2018, and generated consensus recommendations that are accessible free of charge via *Lancet HIV* (see links below). The main theme is to minimize risk by recruiting individuals with relatively high CD4 T cells without significant comorbidities or prior histories of AIDS-related illnesses. However, a number of areas of uncertainty remain, including how high a viral load rebound can be allowed during an ATI without causing undue risk to participants or their sexual partners.

Lynda Dee outlined a series of suggested **best practices for mitigating risk of sexual transmission during ATIs** that have been generated by a collaboration between community members and researchers. While created with a specific trial in mind (a combination therapy protocol that will take place at the University of California San Francisco), the hope is that they can be useful guidance in other settings. Dee explained that two cases of sexual transmission from ATI trial participants to HIV-negative partners have been reported over the past few years. Recommended steps to address the issue include creation of an information packet on risk reduction and ongoing engagement between the study team, participants, and partners. For participants with partners, support for disclosing HIV status should be provided when appropriate. Information on pre-exposure prophylaxis (PrEP) and direct, user-friendly referrals to PrEP services should be made available to partners. The full set of recommendations are accessible online in an open access paper published in the *Journal of Virus Eradication* (see links).

Bill Freshwater, Chris Roebuck, and Beth Peterson from the BEAT-HIV Collaboratory outlined their work toward **a detailed educational position paper on ATIs**. The effort is led by the BEAT-HIV community advisory board, in collaboration with the principal investigators and the community engagement group of partner organization Philadelphia FIGHT. The paper will be written at an eighth grade level, and five modules are being developed on topics including ATIs, considerations for participating in cure-related studies, the informed consent process, the social implications of research participation, and women in HIV cure research. The paper will be accompanied by a bill of rights for research participants and staff. The plan is for the finalized publications to be available in the summer of 2020, although this might be affected by the current COVID-19 crisis situation.

The workshop also featured two wide-ranging panel discussions on issues related to women and HIV cure research and participation in cure-related community advisory boards; both of these sessions from the webinar are also available on the workshop webpage.

CROI ADDENDUM

At the main CROI meeting, **updates were provided on two individuals who may have been cured of HIV infection** in similar circumstances to that of Timothy Brown. Both had life-threatening cancers and received stem cell transplants from donors homozygous for the CCR5Δ32 mutation, leading to the generation of new, donor-derived immune systems lacking the CCR5 receptor that most HIV strains use to infect cells. The London Patient—first described at CROI last year—has now been off ART for over 2.5 years without viral load rebound and no intact HIV genetic material can be found in blood or tissue samples. The researchers believe this is strong evidence that a cure has been achieved. During CROI, the London patient also went public for the first time in an article published by the *New York Times*, courageously identifying himself as Adam Castillejo and stating his aim to be an "ambassador of hope." The second individual, known as the Düsseldorf patient, has now been off ART for just a little over a year, so greater caution is being exercised as to whether he may represent the third known case of an HIV cure.

Richard Jefferys began working in the field of HIV/AIDS in 1993 as a volunteer at the nonprofit AIDS Treatment Data Network in New York City. He joined Treatment Action Group (TAG) in 2001, and directs TAG's Basic Science, Vaccines, and Cure Project.

LINKS TO ADDITIONAL INFORMATION

Combined Active and Passive Immunization in SHIV-Infected Rhesus Monkeys - Dan Barouch *et al*, CROI 2020
croiwebcasts.org/p/2020croi/croi/78

Chimeric Antigen Receptor T Cells Control SHIV Replication in Post-ATI Macaques - Blake Rust *et al*, CROI 2020
croiwebcasts.org/p/2020croi/croi/76

Sex Differences in HIV - Eileen P. Scully, CROI 2020
croiwebcasts.org/p/2020croi/croi/63

Recommendations for Analytical Antiretroviral Treatment Interruptions in HIV Research Trials – Report of a Consensus Meeting - Boris Julg *et al*, *Lancet HIV*, March 15, 2019
ncbi.nlm.nih.gov/pmc/articles/PMC6688772

A collaborative, multi-disciplinary approach to HIV transmission risk mitigation during analytic treatment interruption - Michael J. Peluso *et al*, *Journal of Virus Eradication*, February 20, 2020
ncbi.nlm.nih.gov/pmc/articles/PMC7043899

The 'London Patient,' Cured of H.I.V., Reveals His Identity - Apoorva Mandavilli, *New York Times*, March 9, 2020
nytimes.com/2020/03/09/health/hiv-aids-london-patient-castillejo.html

Love the one you're with

Sex and pleasure in the time of COVID-19

BY **JIM PICKETT**

Back when I was a wee baby queen in the glorious, terrifying, and schizophrenic '80s, I remember going to Stop AIDS safer-sex parties in Chicago. They were kind of like sexy Tupperware or Avon parties where we practiced ways to eroticize condom use and have the hottest sex possible without exchanging body fluids, without inviting HIV.

We were fighting for pleasure.

We took the lead in teaching ourselves about safer sex because we had to, because the majority of the majority could not be bothered; because the majority of the majority didn't care if a bunch of immoral, dirty, unnatural fags (and whores and junkies) died. We had it coming.

We fought for pleasure, and we figured out safer sex way before public health did.

We practiced pleasure during a holocaust, when the weekly gay papers had large obituary sections filled with the death notices of people in their 20s, and 30s. Every week, every week. We fought for and practiced pleasure in the grisly faces of death and government inaction, fragmented and culturally incompetent healthcare, ignorance, legal discrimination, unequal rights, stigma, and hatred.

Here we are more than 30 years later. HIV is hardly a historical footnote; we have mountains to move if we are truly going to "end the epidemic" or "get to zero." But, hey, we now have extremely effective oral tablets that prevent HIV, exciting new ways to prevent HIV on the horizon, and we know that people living with HIV on successful antiretroviral treatment can't transmit HIV to their sexual partners. Governments and stakeholders around the world have plans (some of them good) to drain the HIV swamp.

It's 2020, and the entire planet is facing a brand-new virus—a fearsome pandemic spawned by a novel coronavirus that leapt from animals to humans—that you can catch from breathing... *literally*. We know COVID-19 can be transmitted by people who don't know they're sick, and by people who don't have any symptoms. There are many symptoms, and all of them look like other common things we all experience.

If you are exposed, you may not get sick for up to two weeks, and you may not get sick at all. Every person with COVID-19 has the potential to pass the disease on to one or more other people. Some have mild illness, some have severe illness that leads to death. So far, it's impossible to know what trajectory you may take should you become exposed. Will you remain symptom free? Will you have a mild version that isn't much to complain about? Will you be laid out at home for weeks of fever, pain, and hallucinatory agony, but recover?

GEORGE PETERS/ISTOCK

PLEASURE INCLUDES SEX,
but pleasure is much much much bigger and juicier than just sex.

Will you wind up in the ICU with battered lungs and a tube down your throat breathing for you, until that stops working and you die, alone?

There are some clear echoes of HIV there, can you hear them? And like HIV, COVID-19 is disproportionately hurting communities who are already marginalized and vulnerable due to white supremacy and structural, systemic racism, homophobia, and misogyny. To date, the majority of COVID-19 deaths in Chicago are among black people. Statistics from Michigan, the Carolinas, and Milwaukee show disproportionately high rates of COVID-19 infections among black people.

We don't have a vaccine for this coronavirus yet, and we don't have treatment. Testing is still inaccessible to many of us. We have a number of mitigation efforts we are using, including hand washing, staying inside, and physical distancing.

So HOW IN THE HELL do we talk about sex and pleasure now? More importantly, how do we do more than talk about it? Exactly HOW does sex occur when you have to be six feet away from everyone (except from the people you live with) and should probably be wearing a mask and keeping your hands away from your face, and their face?

Lots of sexy smart thoughtful people have weighed in. I've read clear, straightforward, non-judgmental guidance from the New York City Health Department, and perused articles in Huffington Post and *Glamour* and elsewhere. One of my favorite activists and cranky queers JD Davids wrote a fabulous piece reminding us that sex that is good for us is good for us while providing lots of creative ideas to make physical distancing hot. I watched The Counter Narrative Project's panel discussion on "Intimacy in the Age of COVID-19" focusing on black gay men. I came across this fantastic harm reduction info and resource guide for sex workers produced by COYOTE RI and written by @malanasqueendom. I was so happy to find that one that I squealed. And bonus—the guide is continually updated.

After all that researching and squealing, I got on the phone with the squeal-worthy Dr. David Malebranche, a brilliant physician/activist to talk it through. Of all the advice we had studied up on, the one tidbit that resonated the most with both of us was "love the one you're with." Masturbation. You are, after all, your best sexual partner. Who knows best what your buttons are, where to find them, and how best to press (or lick, bite, stroke) them? YOU. You are your sunshine, you light up your life, you are so beautiful to you. While every May is officially International Masturbation Month, every day of the year is an opportunity to enjoy a little afternoon delight morning, noon, and night. (Special bonus if you are of a well-seasoned age and got all those '70s music references.)

And the options to help take you there! There is so much porn to curate, what you are waiting for? Maybe it's time to do a little exploring and sampling to expand your taste boundaries. Untick your filters. You'll never really be alone on Porn Hub. And while we all can get most of the porn we want for free, consider paying for some of that material and support the humans who help you get off—a lot of them have suffered huge financial hits due to COVID-19.

Toys, toys, toys. Dildos, butt plugs, pocket pussies, thingamajigs, jing tinglers, and blum bloopers. There is an argument to be made that sex toys are essential items these days, though some folks at Amazon disagree.

Keep sending nudes, don't stop sliding into those DMs. Make naughty stories on FB and IG, let it fly on Freak Twitter. Play with FaceTime and Houseparty. Sext. Bring back phone sex. Oooooh, what are you wearing?

If you live with a person, or people, you have sex with – good on you as long as everyone in the household is following all the quarantining and physical distancing guidance. If you are on PrEP, keep taking it. If you are HIV-positive and on treatment, keep taking it.

Side note: if you have been on PrEP and you are NOT having sex with anyone other than your number one fan (that's you), you may want to consider a drug holiday. If you are not in situations where you could be exposed to HIV, you don't need the protection PrEP provides. That said, if you want to potentially explore a vacation from PrEP, discuss this with your PrEP navigator or your doctor/nurse to make sure you go off, and go back on when you are ready, as safely as possible. If you are someone who found it challenging to develop the PrEP habit—taking your pills consistently and correctly—you might want to consider just staying the course. You worked hard for that habit.

"Just say no" to hooking up during this COVID-19 era is the prevailing wisdom, and while my instinct is to rebel against that ultimatum, it makes sense. It makes all the sense in the world to do your best not to put yourself in harm's way—remember, it can be transmitted by breathing. And as Dr. Malebranche says, "There is just so much that is unpredictable and so much that is not known about this virus."

But let's be real, some of us are not going to follow "just say no." In that case, limit the number of your partners. Think about having a "quarantine bae" who is the only person you are having sex with, and vice versa, and you both are doing your best to follow all the other recs. Don't do anything if you are feeling sick in any way. Take careful consideration of where you will be hooking up. Avoid kissing. Put that face in a pillow, and choose other positions that are not face-to-face. You could position yourself six feet from each other and masturbate as well. All of this is harm reduction, not harm elimination.

Finally, a few notes on pleasure. Pleasure includes sex, but pleasure is much much much bigger and juicier than just sex. Multi-hyphenate Chicago leader Elijah McKinnon talks about the "three M's" in a recent Instagram post, "Meditation, Masturbation, and Moisturization." We've covered the second M, but the other Ms remind us that pleasure is about sensual and supple; it's about smooth elbows; it's about quiet, peace, and serenity; it's about connecting with your inner being. Pleasure also includes other Ms we could add to the list: Music, Movies, Magic, Macramé, Macaroons...

Eat delicious things. Drink tasty drinks. Take walks. And my favorite thing to do of all, nap. According to The Nap Ministry, rest is a form of resistance and sleep deprivation is a race and social justice issue. Ah, the pleasure of a cozy afternoon nap, while undermining capitalism and deconstructing white supremacy. What the fuck is hotter than that? PA

#DailyLookChallenge

Using social media, art, and creativity to lift us all up

BY **JEFF BERRY**

During times like these we look for ways to take our minds off the crisis at hand, and use humor to lift each other up. Keith Stryker, a long-time supporter of TPAN (the publisher of POSITIVELY AWARE) and its largest fundraiser the Ride for AIDS/Ride for Life Chicago, got together with a group of friends to create the DailyLookChallenge. We asked Keith and company to tell us what it's all about.

JEFF BERRY: **What is DailyLookChallenge?**

KEITH STRYKER: DailyLookChallenge is a daily opportunity to escape the tragedy that's befallen the world, and feel a bit of whimsy and creativity. A daily look challenge is chosen by the previous day's winner and participants upload their look to Instagram tagged @DailyLookChallenge.

How did it come about? Who is involved? Where did you get the idea?

My chosen family has a group text chat. One of the guys, Tom Slazinski, suggested the second day of the stay-at-home order [in Illinois] that we have a daily look challenge among ourselves and we'd vote on the winner. Our first one was private, just the crew, "Crazy Houseplant Goddess."I posted the photos on Facebook, and Harry Cross suggested we take this public since so many people expressed a desire to participate. We saw a need for distraction, connection, and creativity, so Leo created the Instagram page. The rest of us have been involved in submitting photos, uploading pics, and voting on the winner.

How does it work? How do you come up with the themes?

The winner of the day chooses the theme for the next day. All the photos are posted and the theme for that day

OPPOSITE PAGE: JOHNNY AND JAMES, *PROM*.
THIS PAGE, **TOP ROW:** BARBARA HAGUE, *DRESSED TO THE NINES*; ALFREDO, *SEQUIN FANTASY*; SHAYLA BROWN, *TEA TIME*.
BOTTOM ROW: KEITH STRYKER, *HUNGER GAMES*; SONNY G., *TIGER KING*.

is uploaded. Submissions are tagged on Instagram @DailyLookChallenge. At 10 p.m. [Central Time] that night we vote via WhatsApp and declare a winner.

Who is it for? What does it do, or what is the purpose?

This is for everyone. We originally started this as something we could do to occupy our stay-at-home time. We love to turn "lqqks" and it seemed like a perfect opportunity to do virtual runways individually from our homes. Since we opened it up for everyone, I get messages every day from people thanking us for doing this as it's one of the highlights of their day in such a dark time. It's all about bringing joy, laughter, happiness. If I have to be the brunt of the joke to get a laugh, I'm happy to do it. On a personal and maybe selfish level, this gives me 2–3 hours of occupied time, fun time, every day that I'm unemployed and quarantined. I've explored my creative side like I haven't in years, and it feels really good.

Can anyone play? Are there other groups like this that you know of?

Yes, this is open for anyone to participate. Post your looks to Instagram @DailyLookChallenge for the daily theme.

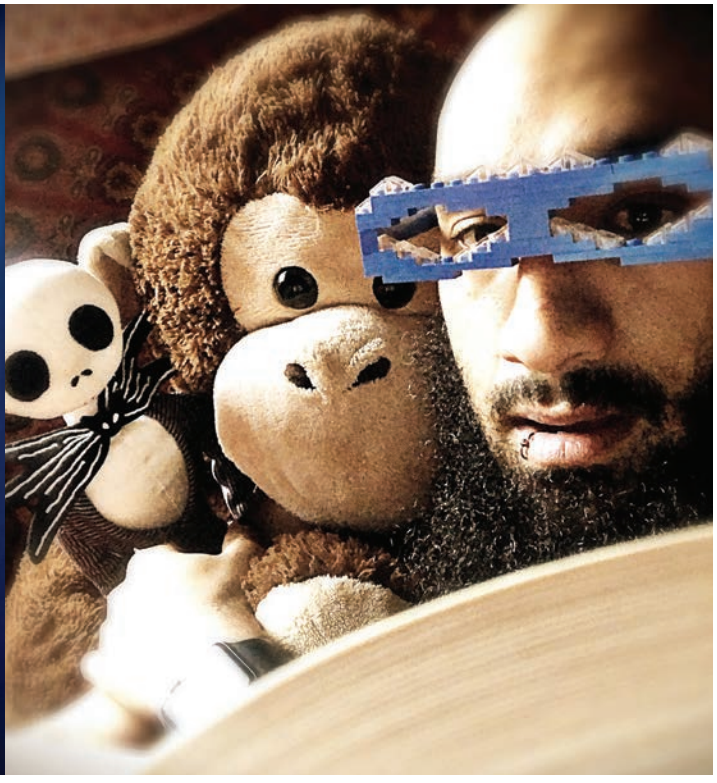
Anything else you'd like to add?

I'm overwhelmed with gratitude for the people participating. There are amazing entries every single day. I feel connected to my friends that I'm not able to see. And I know on some level we are bringing a ray of light into people's lives through our silliness.

SOME OF OUR FAVORITE PARTICIPANTS:

Shawn Watson: Shawn has participated

TYLER, *'80s*; SHAWN WATSON, *READing is FUNdamental*



in nearly every one of our daily challenges and he's won twice. He lives here in Chicago. This is what he has to say about it: "The DailyLookChallenge has been an awesome creative outlet that I look forward to each day. Being unemployed from the arts industry right now, this has given me an alternative way to connect with my students, friends, and family."

Shayla Brown: Shayla has also participated in nearly all the challenges. She lives in South Bend, Indiana. "As a stylist and makeup artist (who in the current crisis cannot safely and legally continue my work), the DailyLookChallenge has been a great way to stay active and creative in my field of work while also putting something out there that's fun and positive. I've had so many reach out and say they look forward to seeing the looks, as well as being in closer contact with other friends doing the challenge, so it's been a great way to stay connected while practicing social distancing."

Jason Brouseau: Jason, from Chicago, is a regular contributor and his enthusiasm is contagious. He's won one of the competitions but is a regular second-placer. "Some friends and family have checked in on me because they think I've lost it. But mostly I hear from people I haven't spoken to in a while that tell me how much they look forward to seeing our looks every night!"

Tyler Dean: "It's hard to even want to get out of bed during all this, and we have been giving people something to look forward to to cheer themselves and us up."

Participant Adam November explains how it works: We started an Instagram account (@dailylookchallenge) and anyone can enter by hashtagging their photo in the daily theme, and submitting it before 10 p.m. Central Time. (We have been liberal with the deadline and are not going to disqualify anyone.) We were going to have it be an Instagram poll to decide the winner or base it on likes but honestly didn't want it to become a popularity contest based on the number of followers. So, we determined that we would just judge the entries and come to a consensus on who best interpreted the theme. I think we're looking for story, art, and creativity, and I hope that is who the winners represent. It is very difficult, honestly, to judge because people are being really creative and though this is not a serious endeavor at all, there is often fierce competition to pick a winner.

The winner picks the theme for the following day. Tyler Dean, Shawn Watson, Shayla Abernathe, Keith Stryker, and Jason Brusseau have all brought brilliant ideas to the themes. There is a Hunger Games theme photo of two people not from Chicago where they used a MacDonald's Happy Meal box and a bag to make a look that was phenomenal. Keith Stryker as Tiger King and blossoming beauty is great. Shay in horror and at the beach one are fantastic. Jason in Step Dad too. Shawn has had so many good ones, Hunger Games and A Day at the Beach. He also did a story for Prom where he had cards that asked Keith Stryker to go with him that was adorable.

I think my favorite picture is from Johnny Perez, in the READing is FUNdamental category where he's holding a copy of "And the Band Played On" and he's looking at a wall where "I will wash my hands" is written repeating. I thought it was so timely and brilliant and artistic too.

Thanks for being interested in our little diversion. We were just trying to add some joy and light during this otherwise dark time. PA

PREVIOUS CHALLENGE THEMES:
A Day at the Beach
Blossoming Beauties
Boots on the Ground
Cocktails & Togas
Crazy House Plant Goddess
DMT Visions
Haunting
Heroes & Villains
Hippie Love
Home Workout
Hunger Games
Prom
READing is FUNdamental
Rhythm & Flow
Spice
Step Dad Vibes
Tiger King
'80s

GO TO INSTAGRAM to view all the entries: @dailylookchallenge

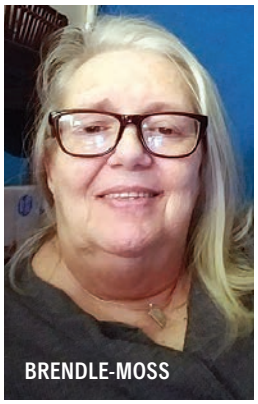
SELF-CARE REALNESS

What are you doing for self-care during the COVID-19 pandemic?

That's the question we asked our followers on Facebook, Instagram, and Twitter, and they served up some honest feelings and experiences.

"Physical Distancing yet remaining socially close. Living with my daughter, son-in-law, and granddaughter. They are keeping the outside world away from me—disinfecting packages, groceries, and themselves when they've had to brave grocery shopping. Me, I'm passing along hopefully helpful information. #DontGiveUp"

—Wanda Brendle-Moss



BRENDLE-MOSS

"I am increasing my knitting knowledge, making a baby blanket for a friend."

—Mark L Grantham

"One thing I'm doing to cope is baking. And also eating. Sometimes I bake cookies, like right here, and I can't help it, eating the cookie dough straight out of the bowl. And don't talk to me about raw egg danger. I've got bigger worries!

—Charles Sanchez

SANCHEZ

"My husband, Joshua, and I planted our garden and have been cleaning out flower beds."

—Brady Dale Etzkorn-Morris

"I'm trying to focus on myself. Also, working on my resume and job search even though it is not a good time for that. In addition, learn new skills every day!"

—Christian Gabriel Reynoso

"I am a registered nurse and shift coordinator for an inpatient psychiatric unit. My hospital is a 120-bed facility in the rural Midwest. We are as prepared as we can be for the possible 'surge' of COVID patients. One of the most difficult things for me has been not knowing what will happen, and when. There has been so much information and so many changes recently is it difficult to keep up, so much so that one day my head literally felt like I had a funnel of information on my head to filter and distribute. I don't have the luxury of self-isolation and at the same time worry about what my risk of exposure is. I have been making sure I get to bed on time, and to watch what I eat (which is a lot of not-so-good food lately). I try to be a cheerleader of sorts for my staff, recognizing that if we go down, the system goes down. We will see what the next several weeks hold for us in this area."

—Joe Franklin

"Lots of breathing practices, eating a bit less (since I am less active), but lots of meditation and simple movement practices (somatic), and NOT watching the news. Also, cleaning things that I have not cleaned in a long time."

—Per Erez

"Working mostly online, doing some indoor physical activities, reading some books, some online readings about HIV and STD, preparing a small project for community-based HIV services."

—@HivAidsAlbania

"Work has been busy. I work for a university where we've had to switch to exclusively online delivery of our courses and associated services very rapidly—but in my spare time I've also been keeping busy with online watch parties of *Doctor Who* and the Eurovision song contest. I chair our LGBT+ staff network and we're holding a virtual cheese and wine party tomorrow evening. Cheers!"

—Ant Babajee

"I distract from the craziness as best as I can. I've been taking lots of naps and reading! However my recommended isolation is over; I go back to work tomorrow. I'll be sure to have my sanitizer fully loaded and wash my hands often. My self-care after work will likely consist of a warm bath with candles then my book and my bed."

—Marissa Gonzalez

"I am exercising and making sure I take the time to meditate about how grateful I am for so many things."

— Andrea Johnson

"I coordinate a self-help/education group for HIV-positive veterans at the Hines VA as a volunteer. Since Hines has cancelled all volunteer activities for now, I started a private Facebook group called Hines PAV. Members can still be social during this time of distance. We used to have 15–25 guys show up for our bimonthly meetings. There are 21 members in the Facebook group. Most show up at least once day. Every day, I post a *Good Morning, Family*, along with any funny, informative, inspiring posts. Nothing political. I miss our bi-monthly meetings but for now this is the best I can do."

—Roy Ferguson

"Family walks. Resting in the sun a minute—mom, daughter, and our three doggies."

—Xio Mora-Lopez

MORA-LOPEZ (RIGHT)

Three decades of *Positively Aware*

Empowering people living with HIV with support and information

COMPILED BY **ENID VÁZQUEZ**

"The Eyes Have It" declares the first cover of POSITIVELY AWARE, November 1990. Back then, figuring out what to do about complications of AIDS—like cytomegalovirus (CMV) that can cause blindness—weighed heavily. There was only one HIV medication, AZT, and used by itself it was a weak fighter against the virus.

Today we don't even say "AIDS" anymore. True, too many people, even young people, still develop AIDS and even die.

Most people who acquire HIV today, however, are expected to remain AIDS-free if they can stay on the powerful and tolerable medications available today—just one pill a day. They can also enjoy a normal lifespan.

Today, as then, POSITIVELY AWARE is here to help for better health and for a better life. Below are excerpts from our journey over the decades.


POSITIVELY AWARE

THE MONTHLY JOURNAL OF TEST POSITIVE AWARE NETWORK

YOU ARE NOT ALONE

By Jim Lewis and Michael Slocum

Maybe you tested HIV positive very recently, or maybe you've known for some time but this is the first time you have reached out for information or support. You need to know that YOU ARE NOT ALONE. There are an estimated 1.5 million people who are HIV positive in the United States and over 40,000 here in Chicago.

Testing positive for HIV does not mean you have AIDS, but HIV is probably the greatest threat to your life you have ever faced. This virus may remain inactive in your body for a long time, but it may not. If you are healthy now, you may still go on to develop some sort of health problems related to HIV. You may develop AIDS.

There remain many uncertainties surrounding HIV, and though there is currently no cure for HIV infection, there are treatments. You need to learn what information is available, and work to make informed choices about your health.

A Brighter Outlook

Many HIV positive people now live fulfilling and happy lives. Many are healthy and show no symptoms of disease. Many have chosen to take certain treatments and drugs that show promise to preserve and lengthen their lives. So, as serious as this is, THERE IS HOPE! You do not have to look at testing HIV positive as though you've just been given a death sentence.

It's a good thing you finally found out! As upsetting as testing positive may have been for you, you're better off knowing, so you can learn about this virus and decide what you want to do about it.

The fact that you cared enough about yourself to get the HIV test and the fact that you are reading this magazine shows that you are concerned about your health. So give yourself some credit. You have taken important first steps to take care of yourself and you should be glad.

Continues on page 20

FEBRUARY, 1991

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WINTER 1993

HIV A to Z, Editor's note

BY BOB HULTZ, SENIOR EDITOR

Looking for books about HIV and AIDS can be a depressing experience. Many stores carry nothing on the subject. Most have just a few lightweight titles. And a few have so many dense and expensive texts that the shopper is overwhelmed.

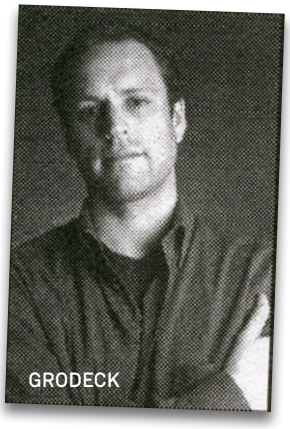
This issue of POSITIVELY AWARE is intended to provide relief for those who are thirsty for information and for those who are drowning in information.

SEPTEMBER/OCTOBER 1995

Ryan White Legacy Hangs On—For Now, Editor's note

BY STEVE MCGUIRE, EDITOR

More dramatically than ever—and more than just about any other illness—HIV/AIDS shows that questions of health cannot be disentangled from politics. And any politician, bureaucrat, or government official who argues that policy and funding decisions are made with little more than good health and good policy in mind is fooling no one but him- or herself.


GRODECK

JANUARY/FEBRUARY 1997

Interest Accrues Over Time, Editor's note

BY BRETT GRODECK, EDITOR

Since I tested positive for HIV 10 years ago, my battle cry has been a simple, satisfying phrase: "Charge it." Armed with credit cards, I became a shopping monster. I filled out credit applications like lightning. Bill me later? You bet. Deferred payment plan? I'll take the 10-year option. Interest accrued over time? No problem.

After all, I had HIV. And back in the 1980s, that meant I was going to die. Yeah, yeah, we're all going to die someday. The difference was that I was going to die about 50 years early. So I went shopping. I toured Europe. I hung out at nightclubs. I drank beer, smoked cigarettes, and ate greasy hamburgers. I figured I had little to lose.

...Thanks to recent medical breakthroughs, my T cells outnumber the dollars in my checking account. Those Visa bills have caught up with me. Oh, well. I'm thrilled to be around to pay.

MAY/JUNE 1999

HIV and Community: Discovering Treatment Strategies

BY STEVE WHITSON, EDITOR

At first it seems a rather odd notion that those who are HIV+ belong to a community. But the diversity that brings us together is a powerful and influential reminder that our many different voices speak to the same causes and concerns. Coming together politically and culturally empowers us in an activism coalition that is truly powerful.

MARCH/APRIL 2000

HIV, Drugs, and Feeling Like Crap

BY GEORGE CARTER

The meds are working. Your viral load is undetectable. Your T cell count is good. Yet

you feel like something the cat dragged in. Maybe you feel okay but you look like hell (at least as far as you're concerned). Or maybe you're not on drugs—because you're still relatively healthy and you want to wait, or you're scared of side effects. There is more to life than T cells and drugs. Just as you've taken care of your health and life confronting HIV disease, now you must also try to figure out how to get the best use from the drugs without them disfiguring or killing you.

MAY/JUNE 2003

ADAP in Crisis, Editor's note

BY CHARLES E. CLIFTON, EXECUTIVE DIRECTOR/EDITOR

This issue of POSITIVELY AWARE focuses primarily on the promising news related to HIV therapy and new treatment options coming out of the 2003 Conference on Retroviruses and Opportunistic Infections (CROI). Yet, the reality of the situation is that more and more men, women, and children in the U.S. are being left on the outside looking in when it comes to access to healthcare and medicines. In a guest editorial, my good friend Carl Winfield discusses the crisis in ADAPs across America and what it means as the number of uninsured and low-income people living longer with HIV climbs, as the annual cost of anti-HIV drugs continues to increase, and federal support for ADAP slows.

MAY/JUNE 2004

Organ Transplants

BY ENID VÁZQUEZ

Gone are the days when transplant centers refused patients with HIV. Today, it's common knowledge that with the powerful HIV medicines available, people living with the virus can expect a much longer and healthier life, making the arduous job of a transplant more feasible.

"Most transplant centers are not looking at HIV as a contraindication [two things that don't go together], but as a challenge," says Dr. Patrick Lynch, a hepatologist at Northwestern Memorial Hospital in Chicago. "Although not everyone with HIV will meet all the criteria for a transplant, it's good to know that it's available."

NOVEMBER/DECEMBER 2008

Sexual Encounters with Undetectable HIV-Positive Men

BY DANIEL S. BERGER, MD, IN HIS COLUMN, THE BUZZ

Many HIV experts have recently become embroiled in a new controversy: Does an undetectable viral load translate to significant reduction in HIV transmission during sex? If so, are condoms necessary? What message should be imparted by physicians to their patients who confront this situation in their lives?

In January 2008, an important and prestigious panel of experts from the Swiss Federal Commission for HIV/AIDS boldly produced the first-ever consensus statement saying that HIV-positive individuals on effective antiretroviral therapy and without sexually transmitted infections (STIs) are sexually non-infectious. This opinion was also published in the Bulletin of Swiss Medicine (*Bulletin des Médecins Suisses*). Hotly discussed at the International AIDS conference in Mexico City this summer, it was soon followed by a rejection statement by a joint Australasian group of experts.

...In layman's terms, this means that barebacking among HIV-positive persons who are on the cocktail who have undetectable viral load would not transmit HIV to their partners.

SEPTEMBER/OCTOBER 2009

HIV Stigma and Disclosure: Can Social Support Help?

BY ZOLTAN NABILEK

One might wonder how much our friends and family influence our lives. Being HIV-positive, we rely on our social network for advice, emotional support, and information. In order to receive this support, we have to disclose our HIV-positive status. Disclosing one's status almost always has some risk attached to it. We might be rejected by the friend or family member, or might suspect discomfort from them when they find out about our status. The advantages of disclosing one's positive status are well known, and one of them is that there is a "practice effect." After carefully considering when and to whom to disclose, we might receive a positive response from our social network. This positive experience could encourage us to disclose our status to others as well.

NOVEMBER+DECEMBER 2011

Reclaiming Emotional Wellness: The Challenges of HIV and Mental Health

BY DAVID FAWCETT, PHD

Deep in the shadows of the AIDS epidemic there are powerful forces that dramatically impact the quality of life for many living with HIV. Depression, anxiety, post-traumatic stress, and other mental health disorders can confuse, discourage, and stigmatize a significant portion of HIV-positive people.

Mental health impacts the full spectrum of HIV. It can determine who is at risk for acquiring the virus (people with a history of trauma or depressive disorders are more likely to become infected) and, after seroconversion, it affects quality of life, medication adherence, levels of social support, and even the progression of the illness.

NOVEMBER+DECEMBER 2016

A Day with HIV

(FROM THE COVER)

5:42 p.m.: Denver, Colorado; Davina Conner: At the park with my great niece. Showing everyone that joy doesn't stop. Live life to the fullest. Stop HIV stigma.

Trogarzo®
(ibalizumab-uiyk)
Injection
200 mg/1.33 mL (150 mg/mL)

LOWER YOUR VIRAL LOAD. AND MAKE UNDETECTABLE A POSSIBILITY AGAIN.*

* Undetectable viral load is defined as fewer than 50 copies of HIV per mL of blood.

Ask your doctor about TROGARZO® – A breakthrough HIV-1 treatment designed specifically for those with treatment failures

TROGARZO.com

WHAT IS TROGARZO®?
TROGARZO® (ibalizumab-uiyk) is a prescription medicine that is used in combination with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults who:

- have received several anti-HIV-1 regimens in the past, and
- have HIV-1 virus that is resistant to many antiretroviral medicines, and
- who are failing their current antiretroviral therapy.

It is not known if TROGARZO® is safe and effective in children.

IMPORTANT SAFETY INFORMATION
TROGARZO® can cause serious side effects, including changes in your immune system (Immune Reconstitution Inflammatory Syndrome), which can happen when you start taking HIV-1 medicines. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you start having new symptoms after receiving TROGARZO®.

The most common side effects of TROGARZO® include diarrhea, dizziness, nausea and rash. These are not all the possible side effects of TROGARZO®.

Before you receive TROGARZO®, tell your healthcare provider:

About all your medical conditions.

About all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

If you are pregnant or plan to become pregnant. It is not known if TROGARZO® may harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with TROGARZO®.

If you are breastfeeding or plan to breastfeed. Do not breastfeed if you are receiving TROGARZO® as it is not known if TROGARZO® passes into breast milk. You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

THERA technologies

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