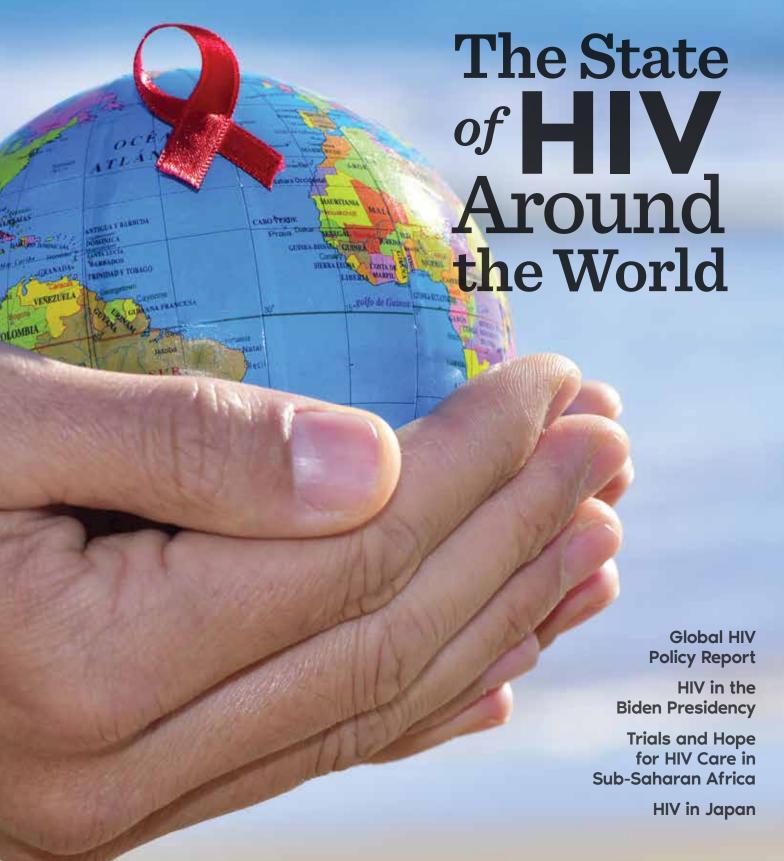


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A Global Perspective

THE WORLDWIDE CORONAVIRUS PANDEMIC beginning in 2020 was a stark reminder of the interconnectedness of the world and how much we rely on international cooperation and consensus in our research, recommendations and response to public health crises. While the American Academy of HIV Medicine, as its name suggests, focuses its attentions primarily on the specific needs of domestic HIV providers, there is no denying the truly global nature of the work that we do.

As we pass the 40th anniversary of the first reported cases of HIV/AIDS in the U.S., and in that spirit of requisite worldwide collaboration and cooperation, we are once again looking here in the HIV Specialist at the impact and prospects of the HIV epidemic on an international level. We know that fairly significant geographical disparities exist in access to care, treatment and prevention services even within the U.S. itself, so it must be that the unevenness of policies affecting HIV/AIDS and the quality of access is underscored even more dramatically on a global scale.

In this issue, we take a close look at the broad misalignments of individual U.N. member nation states' HIV policies with the core international recommendations. It would be tempting to think that the US should or would be leading the way in full alignment with these evidence- and science-based recommendations, but even domestically we still fight against various deleterious criminalizations, including sex work, HIV transmission laws, bans on certain harm reduction efforts, etc.

We also look at the impact of the ongoing HIV/AIDS epidemic in Latinx communities, in sub-Saharan Africa, Ethiopia, Japan, Puerto Rico and the Caribbean, and elsewhere. While significant resource and other challenges in these places clearly remain, the prospects are not all grim: PrEP is increasing in uptake and availability worldwide (though obvious geographical disparities of access and acceptability remain); newer ARV options are more broadly distributed; and governments and international programs are laser focusing on the populations most in-need. This issue also expertly delves into the new U.S. Administration's efforts to End the Epidemic, with a marked increase in appropriations aimed at eradication of new transmissions, a reinvigorated Office of National AIDS Policy and a host of new appointments of HIV thought leaders to key positions.

Only through a truly globally concerted effort and from an ecumenical point of view, involving all the major international organizations, programs, and nation states, will we truly be in a position to see the end of HIV/AIDS in our lifetime, and that starts with understanding the specific challenges and policies confronted in all parts of the world, whether resource-poor and incidence-high, or the reverse. We thank our global HIV experts who have contributed thoughtfully to these pages, and we hope it serves as an enlightenment to all HIV providers in whatever setting, domestic or abroad, about the nature of the challenges faced as well as the cooperative opportunities and examples of progress and success.





NEWS FROM THE ACADEMY

Harold Phillips Appointed Director of Newly Reopened ONAP

N JUNE 5TH, the 40th anniversary of the first reported cases of AIDS, President Biden reaffirmed his commitment to ending the HIV epidemic by reopening the White House Office of National AIDS Policy (ONAP) and appointing Mr. Harold Phillips as the office's new director. The American Academy of HIV Medicine enthusiastically supports the reopening of ONAP and believes Mr. Phillips is an excellent choice to lead the office. Through Mr.

Phillips' years of service dedicated to eradicating the HIV epidemic, we know that he is the right choice for making the goal of functionally eliminating new transmission of HIV by 2025 a reality.

Most recently, Mr. Phillips led the previous Administration's Ending the HIV Epidemic (EHE) initiative and has served as the Senior HIV Advisor and Chief Operating

Officer of the Office of Infectious Disease and HIV/AIDS policy (OIDP) and in the Office of HIV/AIDS Training and Capacity Development (OTCD) at the Health Resources and Services Administration's HIV/AIDS Bureau (HRSA/ HAB). Thanks to his time at HAB, Mr. Phillips has extensive experience working with the Ryan White Program's AIDS Education and Training Centers (AETC), the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the AIDS Drug Assistance Programs (ADAP), all critical programs for achieving the goal of ending the HIV epidemic here and abroad.

"Thanks to advances in treatment and prevention, the clinical components needed to end HIV exist and—through the appropriate training and education—hould be in providers' hands across the country," stated

Bruce J. Packett, executive director of the Academy. "The real barriers to eliminating HIV are societal and systemic. These can only be addressed by truly understanding the daily challenges facing people with and at risk for HIV and creating policies that eliminate these disparities. We hope having knowledgeable leaders like Mr. Phillips will create meaningful change."

After the launch of the EHE in 2019, the Academy highlighted critical barriers to ending the HIV epidemic as

> identified by HIV care providers in the hardest hit areas of the country. The survey participants and HIV credentialed providers targets within the EHE initiative. According to respondents, the

made up of Academy members resided in the 50 counties, urban jurisdictions and seven states identified as initial geographic most urgent challenges include

a critical workforce shortage, homelessness/unstable housing, HIV stigma, and transportation barriers.

"As a clinician, I endeavor to offer my patients the very best in clinical care, but I also know that on the frontlines, there are tremendous everyday challenges including stigma and health disparities," stated Margaret Hoffman-Terry, MD, AAHIVS, chair of the Academy's policy committee. "We have to address the totality of issues people with HIV grapple with every day, and the Administration's reopening of ONAP and its strategic appointment of Mr. Phillips demonstrate its earnest commitment to confronting these challenges and ending the epidemic."

The Academy looks forward to working with Mr. Phillips in this new role.



NEWS THE

AAHIVM and the Institute for **Technology in Health Care Names CAN Connect as its** 2021 Award Winner

HE AMERICAN ACADEMY OF HIV MEDICINE and the Institute for Technology in Health Care have awarded the 2021 Cesar Augusto Caceres Award for Technology in HIV Practice to Dr. Laura Armas-Kolostroubis of CAN Community Health in Sarasota, Florida. Dr. Armas-Kolostroubis is being recognized for CAN Connect, alongside Mark Baksh, Director of IT, for conceptualizing a program that leverages existing technology by configuring old laptops that are then delivered to community partner organizations representing marginalized populations often reluctant to come into a clinic setting.

CAN Connect automatically launches as the machine is turned on, allowing for a telehealth visit to occur with very little machine interaction or proficiency. It also provides an easy interface with the clinic's telehealth electronic medical records (EMR).

Patients are also able to conduct an audio-visual meeting to access prevention specialists, patient care coordinators or case managers and browse for other needed assistance (jobs/housing/ coverage). After the visit(s), the machine is rebooted and ready for its next use. The technology combats the marginalization due to stigma which prevents people with or at risk for HIV from coming into a specialty clinic. The mobility and ease of this technology aims to remove barriers to care.

"The benefits of this program are extensive, with minimal startup costs depending on the machine being used," says Dr. Armas-Kolostroubis. "CAN Connect improves persistence in care and adherence to ARV and PrEP, resulting in improved viral suppression and decreased new infections. All without burdening the clinical setting already strained by COVID-19 precautions."

For more information on CAN Connect, please visit cancommunityhealth.org.

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

American Academy of **HIV Medicine Names** Leslie McGorman as Director of Public Policy



The American Academy of HIV Medicine recently announced the appointment of Leslie McGorman, MPPA as their new Director of Public Policy. A seasoned professional in both federal and state government affairs, Leslie brings a wealth of political experience to the organization. Leslie has 20 years of health-policy

experience - spanning the non-profit, governmental, and private sector. During that time, she has provided deep policy expertise for complex problems.

"We are excited to have Leslie join the team during this important time when ending the HIV epidemic is within our reach," said Executive Director Bruce J. Packett. "Her expertise at both the state and federal levels, as well as in helping to turn advocacy efforts into lasting change, will undoubtedly serve Academy members well."

For nearly nine years, Leslie was a registered federal lobbyist. More than seven of those years, Leslie spent at NARAL Pro-Choice America—a leading political and advocacy organization focused on preserving and expanding reproductive rights. Most recently, she served as the Deputy Policy Director, as well as built out the organization's state-level advocacy and lobbying arm.

Leslie managed a team of healthcare lobbyists focused both on state and federal policy issues related to reproductive freedom, including advising NARAL's 20+ state chapters and affiliates on legislative strategy. Leslie also served as a spokesperson for the organization, as well as a nationally recognized subject matter expert on the status of women's reproductive rights in the United States.

Leslie will oversee the Academy's extensive advocacy efforts which seek to advance policies that support the ability of the HIV care provider to deliver optimal care to people with HIV and ensure access to treatment and prevention options.

HIV NEWS FROM AROUND THE WORLD

New HIV/AIDS political declaration seeks to end inequalities and get on track to end AIDS by 2030

UNITED NATIONS Member States at the High-Level Meeting on HIV and AIDS adopted a Political Declaration in order to get the world on track to end AIDS as a public health threat by 2030.

- HIV, ensuring that by 2025, at least 34 million people living with HIV access to medicines, treatment and diagnostics.
- ensure that 95 percent of people at risk of HIV infection, are protect-
- commend the progress achieved in several regions of the world as a result of implementing research which has led to massive and rapid scaling-up of pre-exposure prophylaxis (PrEP), and the use of post-exposure prophylaxis (PEP), in conjunction with treatment as prevention (TasP), resulting in the rapid reductions in the number of new HIV infections.

"With 1.5 million new infections in 2020, a clear focus on the communities and settings with the highest rates of transmission is urgently needed. WHO welcomes the new Political Declaration and looks forward to working with partners on a coordinated response based on global solidarity and shared responsibility, said Dr Meg Doherty, Director of WHO's Department of Global HIV. Hepatitis and STIs Programmes.

The 2021 UNGA High-Level Meeting on AIDS took place in New York from June 8-10, 2021, at a historic moment for the AIDS response, 40 years after the emergence of the first cases of HIV. WHO has organized and supported different official side-events at the High-Level meeting to address important aspects of the response to HIV/AIDS, through diverse lines of action, such us: science as the basis for the HIV/AIDS and other pandemic responses, accelerating progress and addressing inequalities through primary health care and how the step up the momentum to end TB deaths among people with HIV.



Re-committing to urgent action over the next five years, Member States agreed to:

- reduce annual new HIV infections to under 370 000 and annual AIDSrelated deaths to under 250 000 by 2025, ending pediatric AIDS and eliminating all forms of HIV-related stigma and discrimination.
- achieve the 95-95-95 testing, treatment and viral suppression targets within all demographics and groups and geographic settings, including children and adolescents living with
- ed against pandemics, including COVID-19 and have access to HIV prevention options by 2025.
- eliminate all forms of sexual and gender-based violence, including intimate partner violence, by adopting and enforcing laws that address multiple forms of discrimination and violence faced by women living with, at risk of and affected by HIV.
- ensure that 90% of people living with HIV receive preventive treatment for TB and reduce AIDSrelated TB deaths by 80% by 2025.



ACTG Launches Phase 1 Combination HIV Cure Study

THE AIDS CLINICAL TRIALS GROUP (ACTG), the largest global HIV research network, announced the launch of A5386, a phase 1 HIV cure study evaluating two promising therapies. A5386 will study whether N-803 can control HIV alone or together with combination broadly neutralizing antibodies (bNAbs) after participants stop their antiretroviral therapy (ART) and they are carefully monitored.

In pre-clinical and clinical research, N-803 (an IL-15 superagonist) has exhibited three activities that may help the immune system eliminate HIV reservoirs or control virus rebound. First, N-803 has been shown to reverse HIV latency (the process of no reproduction of HIV within long-lived cells in the immune system), allowing it to be detected by the immune system. Second, it activates NK cells and CD8+ T-cells, two elements of the immune system that specialize in killing virus-infected cells. Finally, it enables NK cells and CD8+ T-cells to move to lymphoid tissues where they will encounter and hopefully eliminate HIVinfected cells.

The actions of bNAbs (or antibodies that neutralize different variants of HIV) are well-matched to that of N-803. bNAbs neutralize HIV that is produced upon reactivation, preventing new infections; target (label) HIV-infected cells for destruction by NK cells; and may act to boost CD8+ T-cell responses. A5386 will utilize an array of virologic and immunologic tests to evaluate the degree to which each of these expected activities are induced in study participants. Ultimately, the study will test whether this approach results in immune control of HIV when ART is paused with careful monitoring.

"HIV cure clinical trials remain a fundamental element of the ACTG's research agenda," said ACTG Chair Judith Currier, M.D., M.Sc., University of California, Los Angeles. "A5386 is particularly exciting as it marries two of the approaches

in the HIV cure research space with the most potential. We believe this study will provide important insights as we continue to pursue our ultimate goal of identifying a cure for HIV and making it available to the millions of people living with HIV around the world."

A5386 is a phase 1, open-label, randomized study evaluating the safety, tolerability, and efficacy of N-803 both with and without combination bNAbs. It will enroll 46 people living with HIV (23 in each study arm) whose virus

has been suppressed by ART for approximately two years, including at least 30 percent cisgender

women or transgender men. Participants will undergo leukapheresis (a medical procedure in which white blood cells, or leukocytes, are separated from the blood) to measure their HIV reservoirs and a subset will undergo optional lymph node fine needle aspirations to assess the effect of N-803 on lymphoid tissue. They will then be randomized to one of two arms: N-803 alone or N-803 with combination bNAbs. After receiving treatment, participants will stop taking ART

and will be followed closely to monitor for signs that they need to restart ART. Most participants will be followed for approximately 100 weeks after receiving treatment.

"Pre-clinical studies have shown that this approach enables the immune system to control viral replication and suggest that N-803 and bNAbs will have a complementary effect on each other," said A5386 Protocol Vice-Chair Richard Brad Jones, Ph.D., Weill Cornell Medicine. "We hope A5386 will demonstrate whether this new approach can enable us to safely decrease the amount of participants' HIV."

A5386 is led by Timothy Wilkin, M.D., M.P.H. (Weill Cornell Medicine), Marina Caskey, M.D., (The Rockefeller University) and Dr. Jones. It is funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and N-803 is provided by ImmunityBio, Inc. NIAID and collaborating NIH Institutes fund the ACTG.



GLOBAL HIV PRE-EXPOSURE PROPHYLAXIS DISEASE ANALYSIS REPORT 2021

Uptake of PrEP is Expected to Continue Following Positive European Reimbursement Decisions

NEW REPORT, the "Disease Analysis: HIV Pre-Exposure Prophylaxis (HIV PrEP)" report looks at the potential uptick in global use of HIV pre-exposure prophylaxis (PrEP). Since its initial U.S. and E.U. approvals in 2012 and 2016, respectively, Truvada's PrEP-specific sales have steadily risen to blockbuster levels in the U.S. and five major European markets.

Truvada's strong performance has been driven by its status as the only approved therapy for PrEP until Descovy's U.S. approval in October 2019, the favorable recommendations for its use in U.S. Centers for Disease Control (CDC) and WHO guidelines, and reimbursement by the healthcare systems of four of the five major European markets in either national or pilot programs.

However, PrEP remains underutilized due to poor awareness and lack of/limited reimbursement in some European countries, though uptake is increasing due to recent favorable reimbursement decisions in Germany, Spain, England, Wales, and Northern Ireland, as well as Gilead's marketing efforts.

The U.S. has the highest rate of uptake (estimated at 22.6% of at-risk individuals in 2020) and generates the majority of global PrEP revenues, though the October 2020 launch of generic versions of Truvada has triggered a steep decline in the drug's sales. Within the E.U. and U.K., Truvada is the only approved agent for PrEP but generates minimal sales due to generic competition since July 2017. PrEP uptake is also estimated to be much lower in the five major European markets (5.3% in 2020), due partially to a historical lack of reimbursement in some countries and continued lack of

reimbursement in Italy.

In order to protect PrEP revenues from generic versions of Truvada, since October 2019 Gilead has been promoting swapping to Descovy, which has displayed non-inferior efficacy and marginal improvements in bone and renal safety.

Despite the COVID-19 pandemic reducing interaction between physicians and their patients, Gilead has successfully converted approximately half of patients to Descovy (46% market share versus 54% for Truvada as of the end of Q3 2020), due largely to Descovy being priced at parity to Truvada. However, in October 2020, Teva launched the first generic version of Truvada, which will severely limit further swapping to Descovy as widespread use of Descovy in patients with no pre-existing renal or bone risk factors is unlikely to be deemed as cost effective compared to lower-cost generic Truvada.

Descovy does have a potential growth opportunity in the planned HIV Women's Prevention Study, which is expected to begin in mid-2021 and will support its US approval in adolescents and adult women (the FDA refused to approve Descovy for women as the sole pivotal DISCOVER trial only included men who have sex with men [MSM] and transgender women).

However, if trial timelines are comparable to the DISCOVER trial, supplementary approval for use in women is unlikely to occur until late 2024, leaving Descovy little time to capitalize on the new indication before its anticipated patent expiry in June 2025. It also seems likely that Gilead will shift its PrEP development focus to its six-monthly subcutaneously administered lenacapavir, which would be more competitive against longer-acting

pipeline rivals and was added to the HIV Women's Prevention Study in December 2020.

There are currently six agents in clinical development for pharmacological PrEP, comprising five antiretrovirals and a single broadly neutralizing antibody. All of the pipeline agents aim to offer less frequent dosing schedules in order to address the issue of suboptimal adherence to oncedaily Truvada/Descovy, which can result in impaired effectiveness in real-world practice. Notable threats to Truvada/Descovy include ViiV Healthcare's Vocabria, which is dosed intramuscularly every two months (eight weeks) and has already demonstrated superior efficacy compared to Truvada in the HPTN 083 (cisgender men and transgender women) and HPTN 084 (cisgender women) trials.

Vocabria's bimonthly administration could be very attractive to patients who struggle to adhere to daily pills, though its injectable nature and requirement for physician administration will deter some patients, meaning Descovy will still be able to maintain some market share following Vocabria's anticipated U.S. launch in late 2021/early 2022. Merck & Co's oral oncemonthly islatravir is another major threat, as a once-monthly option should greatly improve adherence while avoiding the need for physician administration, though no in-human proof-of-concept efficacy data are currently available for islatravir in the PrEP setting.

The overall likelihood of approval of a Phase I antiviral asset is 13.1 percent, and the average probability a drug advances from Phase III is 68.3 percent. Antiviral assets, on average, take 8.5 years from Phase I to approval, which is slightly less than the average of 9.0 years for the overall infectious disease space.



England on Track to Achieve Elimination of HIV Transmission by 2030

Model shows sharp decrease in HIV incidence



THE ANNUAL NUMBER of new HIV infections among men who have sex with men (MSM) in England is likely to have fallen dramatically, from 2,770 in 2013 to 854 in 2018, showing elimination of HIV transmission by 2030 to be within reach—suggests work by researchers from the MRC Biostatistics Unit

at the University of Cambridge and Public Health England, published in The Lancet HIV.

To manage the HIV epidemic among men who have sex with men (MSM) in England, enhanced testing and earlier treatment strategies were scaled-up between 2011 and 2015 and supplemented from 2015 by pre-exposure prophylaxis (PrEP). The researchers examined the effect of these interventions on the number of new infections and investigated whether the United Nations (UN) targets for HIV control and elimination of HIV transmission by 2030 might be within reach among MSM in England.

A complexity in this assessment is that HIV infections are not observed. Routine surveillance collects data on new HIV diagnoses, but trends in new diagnoses alone can be misleading as they can represent infections that occurred many years previously and depend on the testing behaviour of infected individuals.

To estimate new HIV infections among adult MSM (age 15 years and above) over a 10-year period between 2009 and 2018, the researchers used a novel statistical model that used data on HIV and AIDS diagnoses routinely collected via the national HIV and AIDS Reporting System in England, and knowledge on the progression of HIV. Estimated trends in new infections were then extrapolated to understand the likelihood of achieving the UN elimination target defined as less than one newly acquired infection per 10,000 MSM per year, by 2030.

The peak in the number of new HIV infections in MSM in England is estimated to have occurred between 2012 and 2013, followed by a steep decrease from 2,770 new infections in 2013 to 1,740 in 2015, and a further steadier decrease from 2016, down to 854. The decline was consistent across all age groups but was particularly marked in MSM aged 25-34 years, and slowest in those aged 45 years or older. Importantly, this decrease began before the widespread roll-out of PrEP in 2016, indicating the success of testing and treatment as infection prevention measures among MSM in England.

Through extrapolation, the researchers calculated a 40% likelihood of England reaching the UN elimination target by 2030 and identified relevant age-specific targeting of further prevention efforts (i.e., to MSM aged ≥45 years) to increase this likelihood.

Senior author, Professor Daniela De Angelis, Deputy Director of the MRC Biostatistics Unit, University of Cambridge, said: "This is very good news and suggests that prevention measures adopted in England from 2011 have been effective. With the rollout of PrEP, England looks on course to meet the goal of zero transmissions by 2030. Our study also shows the value of regular estimation of HIV incidence to recognise and respond appropriately to changes in the current downward trend. The challenge now is to achieve these reductions in all groups at risk for HIV acquisition."

Valerie Delpech, Head of National HIV Surveillance at Public Health England, said: "We have made good progress towards ending HIV transmission by 2030 in England. Frequent HIV testing and the use of PrEP amongst people most at risk of HIV, together with prompt treatment among those diagnosed, are key to ending HIV transmission by 2030.

"You can benefit from life-saving HIV treatments if you are diagnosed with HIV and it also means you cannot pass

"HIV and STI tests are still available through sexual health clinics during the COVID pandemic. Many clinics offer online testing throughout the year—people can order tests on clinic websites, take them in the privacy of their own home, return by post and receive results via text, phone call or post."

This research is funded by the UK Medical Research Council, UK National Institute of Health Research Health Protection Unit in Behavioural Science and Evaluation, and Public Health England.

Program Led by St. Michael's Hospital Will Reach the Undiagnosed with the Goal of Ending Canada's HIV Epidemic

TORONTO—A new research program is distributing 50,000 free HIV self-testing kits across Canada to reach people who are undiagnosed and get them connected to care, with the goal of identifying factors that affect access to testing and care and ultimately, ending Canada's HIV epidemic.

The I'm Ready research program, which launched June 2 with an online event featuring Canada's Chief Public Health Officer Dr. Theresa Tam, is accessible through a website and mobile app, which users can access anonymously. Participants will receive an HIV self-testing kit—which is proven to be fast and highly effective—and have access to a telehealth-style peer navigation service to link them to more information about prevention and care.

Researchers will evaluate in real-time how well the program is able to reach and support people in accessing testing, care and treatment. They will use this information to adapt the program to ensure there are low-barrier options for access to testing. An estimated 8,000 Canadians live with HIV and are unaware of their status. HIV disproportionately impacts men who have sex with men, African, Caribbean and other Black people, Indigenous Peoples and people who use and inject drugs.

"We have come so far in the global fight against HIV/AIDS and we now have all the tools that we need to end HIV," said Dr. Sean B. Rourke, the study's principal investigator and a scientist at the MAP Centre for Urban Health Solutions. "Our program uses technology to reach and serve people who are marginalized because of systemic racism, residential schools and the legacy of ongoing colonization, and stigma and discrimination in various forms—including gender-based and against

The I'm Ready research program is funded by the Canadian Institutes of Health Research (CIHR), the St. Michael's Hospital Foundation and the Canadian Foundation for AIDS Research (CANFAR)'s Strategic Initiatives, and it launches in collaboration with the Canadian HIV/AIDS Black, African & Caribbean Network (CHABAC), Women's Health



LGBTQ2+ communities. We designed I'm Ready to create access and choice for testing and care in ways that can work for these populations in their communities."

Once a participant has their selftest kit, they will follow the steps in the app and use the test kit's instructions to take the self-test. Once complete, they will anonymously record their results in the app and receive access to more information about treating or preventing HIV. in Women's Hands (WHIWH) and the Community-Based Research Centre (CBRC), among other community partners across Canada.

Self-testing is seen as a critical tool in HIV prevention because it allows people to safely learn their status in the privacy of their own home and seek out care or prevention as needed. In Canada, an estimated 65,000 people live with HIV, the virus that causes AIDS, and 13 percent of those are unaware of their status.

FRONTLINES

Sounding the Alarm on the Rising Health Crisis within the Latinx community

BY GUILLERMO CHACÓN, PRESIDENT, LATINO COMMISSION ON AIDS AND FOUNDER OF THE HISPANIC HEALTH NETWORK

LTHOUGH MAJOR ADVANCEMENTS in research and treatment have been made in the past three decades, Latinx communities continue to be disproportionately impacted by HIV. HIV disease and the fear and stigma that go with it impacts more than 195,000 Hispanic/Latino men in the U.S. and its territories, including Puerto Rico.

To address this rising issue within the Latino community, we partnered with ViiV Healthcare to explore the impact of HIV among Latino gay and bisexual men. To learn from men's experiences overcoming these forces and to tell the stories behind the statistics, we looked at men's daily lives and the social networks that help fuel and sustain their resilience. Through interactive, community-guided listening, we heard stories of how men are confronting internal and external challenges by holding up a mirror to their own lives, building strength and resilience and striving to create communities that help them feel whole and sustain them when they falter or feel vulnerable.

The result was Tal Como Soy/Here as I Am, a community research report delving into socio-economic forces affecting access to HIV care for Latinx gay and bisexual men. Our findings found five key insights for this community:

- Family and community are central to the lives and identities of Latinx men, shaping their health and wellness for better or worse
- Interruptions in care happen for many reasons beyond Latinx men's
- Anti-immigrant sentiment and anti-immigrant laws have a powerful effect on Latinx men's health.
- Latinx men want diverse and responsive care that reflects their needs, identity and language.
- Networks and services by and for Latinx men, especially youth, can help link and keep men in care.

Beyond these critical insights, Tal Como Soy suggests addressing the barriers to HIV care for Latinx men who have sex with men (MSM) involves a holistic approach that considers their multiple identities – as sons and brothers, as gay, bisexual or trans men, as men living with HIV and as Latinx men - and focuses on expanding accessibility and availability of health services. Here is a deeper look at these insights.

Insight One: Family and community are central to the lives and identities of Latinx men, shaping their health and wellness for better or worse

Latinx communities in the U.S. face many of the same challenges as other communities of color, including poverty, poor access to education, inadequate housing, and unreliable or unsafe public transportation, all of which impact health outcomes. I've seen firsthand that the impact of HIV and HIV-related stigma on communities of color, including Latinos, manifests everywhere. Larger organizations may provide more resources and ultimately more support; however, people can face isolation due to stigma, whether in big cities or rural communities. As HIV advocates, our goal is to build more inclusive and healthy communities where these individuals facing stigma feel safe. With that, putting an end to HIV-related stigma is a crucial step in ending the HIV epidemic.

There are many layers of stigma that the Latino MSM community faces. These stigmas can exist in overlapping spheres of men's lives, including their families of origin, their culture, Latinx gay communities, broader LGBTQ communities, health service organizations, and society. To confront stigma in a meaningful way, we must address the challenges that Hispanic/Latino men living with HIV face every day.

The interconnectedness of race, gender, and socioeconomic status is something we all should be conscious of if we are to impact the health outcomes of communities most in need and affected by the consequences of the economic and social conditions and generations of distrust towards a segmented

healthcare system. An intersectional perspective is vital to understanding the experiences and consequences of living with multiple identities, such as being a Latino MSM in America living with HIV. We need to encourage health institutions to develop introspective processes to better serve communities whose well-being and health have been long neglected due to socioeconomic disparities.

Insight Two: Interruptions in care happen for many reasons beyond Latinx men's control.

Many of the challenges the Latinx population faces are beyond their control. These individuals feel misunderstood and are often faced with the implication of institutional racism, discrimination, stigma, and marginalization when seeking medical help.

We need to embrace other conditions, identities and develop a commitment to reducing health disparities in making lasting improvements in health and wellness in our diverse communities. Our communities need strategies to navigate a segmented healthcare system without missing perspective of the intersectionality and advocate to change the healthcare system. We need to create a more integrated approach and drive to improve health outcomes free of stigma and discrimination.

Insight Three: Immigrant sentiment and anti-immigration laws have a powerful effect on Latinx men's health.

One of the most prominent examples of discrimination that this group faces is the impact of the sweeping political and media attention to immigration seen in the past decade. Latino patients and providers described a heightened sense of fear as a primary outcome of such laws and sentiment, causing them to delay or avoid healthcare.

Fears of deportation are a big challenge amongst immigrant communities. Creating awareness about where to test for HIV and receive services without those fears is essential. The U.S. laws vary by state, which is critical when dealing with perceived and real fears for testing. There is also a need to deal with immigration policies (immigration is a federal law) as barriers to accessing health

services. Creating awareness and developing favorable policies promote access to health for all, regardless of immigration status.

Insight Four: Latinx men want diverse and responsive care that reflects their needs, identity and language.

As a country, we need to recognize that access to healthcare for immigrants is an important public health issue and needs to be addressed with a national policy on healthcare for noncitizen and undocumented immigrants. Until we do this, these Hispanic/Latino men living with HIV will continue to face disparities in care - including that for HIV disease.

Unfortunately, anti-immigrant rhetoric has impacted the health profession and providers' attitudes towards immigrants and disenfranchised communities. This stigma creates another critical barrier to access to care. To better understand the Latinx community, leaders and advocates need to address the need for more culturally responsive training for healthcare providers beyond just speaking Spanish. Developing trust and building closer relationships between Latino MSM and healthcare providers and establishing routines that promote and support patient trust are keys to improving treatment among immigrant communities.

With both ethical and professional obligations, the healthcare industry should be developing new and innovative strategies to support safety-net health care facilities, such as community health centers and hospitals that provide a disproportionate share of care for patients who are uninsured and from low socioeconomic status.

Insight Five: Networks and services by and for Latinx men, especially youth, can help link and keep men in care.

Vulnerable Hispanic/Latino men living with HIV feel too isolated by the healthcare system. The socioeconomic health disparities this group faces have become incredibly clear during the COVID-19 pandemic. Our responsibility is to remind the general public and policymakers that HIV is not over. COVID-19 is a major pandemic that has created an extra layer to the HIV epidemic. We need more than ever to come together to respond to the

impact of COVID-19 without abandoning the mission and vision to design a world without AIDS and to find a cure for HIV.

To address all the challenges that Latinx men face, we need to create open communication lines with this community through advocacy networks. Across all cities, many people agree that engaging and developing young, gay Latinx as leaders, ambassadors, navigators, and mentors is crucial if we want to move forward.

If we want to properly respond to the rising HIV epidemic within the Latinx appropriately, we need to immediately address these community challenges. Like all efforts to end the social stigma surrounding HIV, we need to learn to listen, understand, respect and embrace the communities at risk and act accordingly.

Tal Como Soy/Here as I Am is available online in Spanish and English. HIV



GUILLERMO CHACÓN is President, Latino Commission on AIDS and founder of the Hispanic Health Network. Since 2010, Guillermo has served as President of the Latino Commission on AIDS,

where he is a vocal advocate on the impact of HIV. viral hepatitis, Sexually Transmitted Infections in Hispanic/Latinx communities. Under his leadership, the Commission has invested in national community mobilization programs to promote HIV testing and linkage to care and capacity building programing nationwide and special investment in our regional work in the South of the United States.

Guillermo work focus on develop agendas on health policy issues affecting the health of Hispanics. Chacón was appointed by Mayor Bill de Blasio to serve in the NYC Commissioner of Human Right in November 2019, to the HIV/AIDS Services Administration (HASA) community advisory board and the Committee on New York City Healthcare Services. Governor Cuomo appointed Chacón to the New York State AIDS Advisory Council and re-nominated him for the New York State Minority Health Council, where the New York State Senate later confirmed him in July 2020. Guillermo Chacon also serves on various Boards and Committees, NYS COVID 19 Vaccination Equity Taskforce, NYC COVID19 Vaccine, Test & Tracing (T2) program as part of Community Advisory Committee (CAB T2), the National Hispanic/Latinx Health Leadership Network, New York Immigration Coalition, the New York City AIDS Memorial, advisor for Alianza Americas, AIDSVu.org, and co-chairs the Latino Jewish Coalition in New York.

2020 GLOBAL HIV



POLICY REPORT

POLICY BARRIERS TO HIV PROGRESS BY: THE HIV POLICY LAB

This article is an abbreviated excerpt of the 2020 Global HIV Policy Report created and distributed by the HIV Policy Lab, a unique collaboration between academic, United Nations, and civil society organizations to track, measure, and improve the HIV-related law and policy environment in countries around the world. The HIV Policy Lab is produced by Georgetown University and Talus Analytics, in partnership with UNAIDS, the Global Network of People Living with HIV (GNP+), and a growing set of partners around the world, and with support from PEPFAR and USAID.To learn more about the HIV Policy Lab or to read the 2020 Global HIV Policy Report in its entirety, visit www.HIVPolicyLab.org.

ORTY YEARS SINCE THE DISCOVERY and isolation of the human immunodeficiency virus (HIV), the science of HIV has never been better. Today, we have a better understanding of how the virus functions and how to test, treat, and prevent HIV infection. We have clear evidence on the biomedical, social, and structural drivers of new HIV infections and deaths, and new tools to halt them. Antiretroviral medicines (ARVs), for example, are available to save lives and to stop transmission—with new long-acting injectable forms shown just this month to be effective prevention for women. We have clear evidence that differentiating delivery of HIV service delivery to meet the needs of people works, that self-testing helps reach populations poorly served by other methods, that healthcare user fees push people out of HIV care, that criminalization of key populations undermines access and drives HIV, and much more. 2

Yet the translation of science into law and policy remains a drag on the AIDS response. Despite rapid scientific advances, the world will not achieve the 2020 global HIV goals. This reality stems from progress that is highly unequal. As shown in the UNAIDS 2020 Evidence Review, some countries and communities are seeing real success while others see little. Some countries have made remarkable use of HIV science—14 countries from throughout the world had attained the global target of at least 73 percent of all people living with HIV achieving viral suppression by 2019. AIDS deaths were cut in half in eastern and southern Africa.

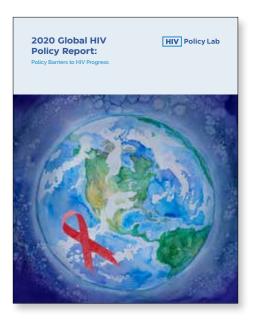
Others see growing epidemics and are far off track. New HIV infections have increased by 72 percent in Eastern Europe and Central Asia, 22 percent in the Middle East and North Africa and 21 percent in Latin America. Differences between countries are stark. While

most in Eastern and Southern Africa have seen remarkable progress, in Madagascar and South Sudan less than half of people living with HIV know their status. In Angola a majority of people who know they are living with HIV are not accessing treatment. Viral load suppression levels in the United States are much lower than in the rest of the Western and Central Europe and North America region. The AIDS-related mortality rate in Haiti, a low-income country, declined by 52 percent between 2010 and 2019 and is now lower than that of Jamaica, an upper middle-income country where AIDS-related mortality increased by seven percent over the same period. Stark differences exist, too, in populations within countries. Compared to the general population, the risk of acquiring HIV is on average about 26 times higher for gay men and other men who have sex with men, 29 times higher for people who inject drugs, 30 times higher for sex workers, and 13 times higher for transgender people than for adults in the general public. This can, at least in part, be explained by the significant gap that remains between science and law/policy in much of the world. Laws and policies drive who has access to the benefits of science, how people living with and affected by HIV are treated, how health systems are structured, and how officials engage with communities.

Our 2020 Global HIV Policy

Report shows that policy barriers exist throughout the world that undermine the quality of HIV treatment and prevention, undermine access to HIV treatment and prevention, and increase the vulnerability to HIV infection and AIDS death. Key findings from the report shows that:

- No country in the world has fully aligned its laws and policies with the best HIV science and core international recommendations. In fact, across all 194 UN member states, the median country has aligned just over half of policies tracked with international standards.
- On the whole, the regions and countries making the most progress have adopted many or most of the laws and policies recommended by evidence and international normative bodies. Every country, however, has laws and policies that would need to be updated to align with international recommendations.
- Many of those countries and regions that are furthest off track—those facing growing epidemics and rising death rates—have the fewest policies that align with current evidence.
- Many countries have not yet fully adopted upto-date policies on some of the most critical new interventions, including differentiated service delivery and PrEP.
- Every country in the world has at least one law criminalizing same-sex sexual relations, sex work, drug use, or HIV exposure/transmission, often all four, despite evidence that criminalization is counterproductive.
- Countries are inconsistent in adopting recommended policies—the majority of countries do well in some policy categories



but worse in others.

- The regions with the highest rates of policy adoption are Eastern and Southern Africa and Western and Central Europe and North America. The country with the highest rate of policy adoption is South Africa.
- In general, policy recommendations related to HIV clinical care and treatment are adopted at a much higher rate than policies related to testing and prevention, structural barriers, or health systems factors. Even so, quite a few countries still lag behind in adopting key clinical/treatment policies, including updating HIV treatment guidelines to include the latest first-line ART regimens.

Policy is the indispensable mechanism by which governments bring effective, evidence-based interventions to scale to benefit all. That laws and policies do in fact affect health outcomes in general, and HIV outcomes in particular, has been demonstrated by scholars analyzing the "legal determinants of health"—for example, showing that eliminating parental consent policies is linked to increased rates of HIV testing, countries with a constitutional right to health have better health outcomes, and that countries not criminalizing sex work have significantly lower HIV prevalence among sex workers.4

Today there are multiple mechanisms in place to disseminate science-based policy recommendations and support their adoption by national governments via technical guidance and fund implementation through UNAIDS, the World Health Organization (WHO), UNAIDS, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, the US President's Emergency Plan for AIDS Relief (PEPFAR), etc.⁵

It would be tempting to think that, several decades into a truly global AIDS response, most countries have aligned their laws and policies with current science and evidence, and that the quality of implementation is what explains differences between countries. Data from the HIV Policy Lab shows this is not the case—that policy- and law-reform remain an essential task of the global AIDS response. Data also shows that countries have much to learn from each other. Achieving an end to AIDS as a public health threat—the global goal set for 2030 by the UN General Assembly—will require more than good science and scaled up programs. It will require laws and policy aligned with that science. In 2020, the clear message from the HIV Policy Lab data is that there is much work to do to put us on that path. HIV

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Seeking to End the HIV Epidemic Amidst a New Pandemic

BY: BILL MCCOLL

N JUNE 5, 2021, the United States and the world commemorated the 40th anniversary of the first Centers for Disease Control and Prevention (CDC) report on a cluster of a rare pneumonia in five gay men that would later come to be identified as HIV, marking the beginning of the epidemic. That publication would kick off a struggle against a powerful disease that to date has killed between 24.8 to 42.2 million according to the Joint United Nations Programme on HIV/AIDS (UNAIDS). The U.S. refused to take the epidemic seriously to the point that President Ronald Reagan refused to publicly mention HIV until September of 1985, four years after its emergence and a full year after its identification as a disease.



HIV/AIDS has spawned protest and research, sorrow and death, and occasionally joy and beauty by illustrating both the best and worst in our society. It has been impacted by racism and bigotry around sexual orientation and gender identity and arguably furthered the struggle of LGBTQ rights. ...That struggle now continues with new President, Joe Biden, who with Vice President Kamala Harris, campaigned in part on a promise to end the HIV epidemic in the U.S. by 2025.

Since that time, the world and the U.S. has struggled for four decades to end the epidemic. HIV/AIDS has spawned protest and research, sorrow and death, and occasionally joy and beauty by illustrating both the best and worst in our society. It has been impacted by racism and bigotry around sexual orientation and gender identity and arguably furthered the struggle of LGBTQ rights. But in the U.S., it has also shown the power and impact of protest, furthering Congressional and eventually administrative support for direct funding of HIV prevention, treatment, housing and research eventually leading to the introduction of antiretrovirals (ARV) and, most recently, pre-exposure prophylaxis (PrEP). That struggle now continues with new President. Joe Biden, who with Vice President Kamala Harris, campaigned in part on a promise to end the HIV epidemic in the U.S. by 2025.

The Biden-Harris Administration passed 100 days in office in April, marking a traditional milestone in U.S. politics by which we can begin to understand their basic roadmap on tackling issues on their agenda, including ending the epidemic. While signs are hopeful that they will intend to make good on their campaign promise, it is a sobering thought that the Administration comes to the task of ending HIV amid a new global pandemic, COVID-19. Unfortunately, some of the earliest patterns of denial and misinformation that first showed up in the early 1980s, with

HIV/AIDS, reemerged during the 2020 election year, creating a deeper divide between those who trust in science and those who deny it. This has left the U.S. in a position of continually having to respond to false and misleading reports that have threatened the ability of Congress and the Administration to act. However, the Biden Administration has managed to build a team that appears capable addressing both HIV and COVID-19.

A WHO'S WHO IN HEALTHCARE

Notable new members of the President's senior health team include the new Secretary of Health and Human Services (HHS), Xavier Becerra, previously the Attorney General of California. For many, this choice was regarded as a surprise since Mr. Becerra does not have specialized experience on healthcare issues. However, as Attorney General in California, he has been among the leaders defending the Affordable Care Act (ACA) and has further experience on the Ways and Means Committee and speaking out on behalf women's health when he was in Congress. He is the first Latino to lead the department.

Dr. Rachel Levine has also been confirmed as the Assistant Secretary of HHS. Her responsibilities will include many HIV treatment and prevention activities. Dr. Levine is the first known transgender individual to have gone through a Senate confirmation hearing and the first transgender person to become an Assistant Secretary. She previously led Pennsylvania's HHS through the onset of the COVID-19 pandemic.

Other appointments include Dr. Rochelle Walensky, a well-known and respected HIV/AIDS researcher with expertise in vaccine delivery, as the Director of the CDC. Dr. Vivek Murthy was named as Surgeon General, a role that he also fulfilled during the Obama Administration. Dr. Anthony Fauci will maintain his current position as Director of the National Institute of Allergy and Infectious Diseases (NIAID) and has also been named Chief Medical Adviser on COVID-19 to the President. President Biden also nominated Miriam Delphin-Rittmon for the position of Assistant Secretary for Mental

Health and Substance Use, a position with substantial influence on the HIV epidemic, including response to transmission among people who use drugs. She may be the first advocate for harm reduction in the position but is still subject to Senate confirmation.

There is additional speculation that an upcoming Biden Administration would restore the position of the Director of Office of National AIDS Policy, a position that was not filled during the Trump Administration. The picks so far place a priority on expertise and the effective ability to manage and run large scale health programs.

ADVANCING POLICY PLANS

With these new hires, the first task of the Biden Administration has been to gain control of the COVID-19 pandemic in the U.S. While the future of the pandemic is unclear, as of this writing, there has been a strong focus on vaccination, including support of grassroots organizers to educate communities on the safety and efficacy of the vaccine. This focus has resulted in one legislative victory thus far, passage through both chambers of Congress of the American Rescue Plan. The Plan expands benefits for those impacted by COVID-19, supplements unemployment benefits, provides \$20 billion in emergency rental insurance and supported state, local and tribal health departments with \$350 billion. One small but notable development is that the American Rescue Plan includes a \$30 million line providing emergency funding for harm reduction programs and has stated that funds may be used to purchase syringes by syringe-services programs. This is the first time that funding has been designated for harm reduction, a notable step forward on a highly politicized issue in the U.S.

The Administration has additionally taken action to shore up healthcare in the U.S. and defend and expand the ACA. As a result, they reopened the open enrollment period ensuring that people who missed the previous deadline now have healthcare coverage during the pandemic. The Administration has also taken several executive actions including to ensure protections for LGBTQ people and people living with HIV under the ACA and allowing undocumented people access to healthcare without penalty.

THE ROLE OF CONGRESS

In the meantime, the new 117th Congress has also been busy with HIV issues that could come up in the next Congress and reviewing the legislative agenda. The newly elected members of Congress were sworn in on January 3rd and Nancy Pelosi (D-CA) was reelected Speaker of the House. Democrats have a narrow majority in the House with 222 votes to 211 for Republicans. The Senate is evenly divided 50/50 with the Vice President holding a tie-breaking vote, for those votes not subject to a filibuster. Achieving legislative success for the Biden Administration will likely be determined by the ability to hold various coalitions of Democrats together and to attract the few moderate Republicans who might consider voting across party lines.

Congress' healthcare agenda will remain a major priority due to the COVID-19 pandemic and ongoing attacks on the ACA through the courts. One overlooked issue is that overdose rates have steadily climbed since the beginning of the pandemic, potentially resulting in over 100,000 overdose deaths this year alone, representing a nearly 40 percent increase in deaths over the highest level ever.

With President Biden's focus on ending the HIV epidemic by 2025, many key members of Congress have offered their support. Therefore, it is likely that legislation will emerge to implement such a plan. PrEP is likely to play a major role in ending the HIV epidemic and there have already been several bills introduced in Congress to increase the availability of PrEP. Look for the PrEP Access and Coverage Act sponsored by Rep. Adam Schiff (D-CA) and the PrEP Assistance Program Act by Rep. Bonnie Watson Coleman (D-NJ) to be reintroduced.

The Real Education for Healthy Youth Act and the REPEAL HIV Discrimination Act are expected to be reintroduced this Congress as well. The Real Education for Healthy Youth Act awards grants for comprehensive sex education for adolescents. The REPEAL Act would require the federal government to conduct a national review of federal and state criminal and civil commitment laws and policies and to create best practices to eliminate discrimination. Both bills are both likely to be reintroduced relatively early in the new Congress.

On March 26th, representatives Lisa Blunt

Rochester (D-DE), Barbara Lee (D-CA) and Nikema Williams (D-GA) reintroduced the HIV Epidemic Loan-Repayment Program (HELP) Act to address HIV workforce shortages. The HELP Act, a piece of legislation that the Academy has been championing, will provide up to \$250,000 in loan repayment for up to five years of service to physicians, nurse practitioners, physician assistants, dentists and clinical pharmacists who treat or provide oral healthcare to people living with HIV in a health professionals shortage area or at a clinical site funded by the Ryan White HIV/AIDS program.

It is conceivable that the U.S. has the capability to end the epidemic in the U.S. While HIV is still politicized, ending the epidemic has attracted bipartisan support in Washington. Notable HIV initiatives such as PEPFAR and the EHE initiatives are associated with Republican presidents.

On her first full day in the White House, First Lady Dr. Jill Biden visited Whitman-Walker Health, a federally qualified health services clinic that has long provided HIV/AIDS services in Washington, D.C. Amidst all the turmoil of policy and politics, it showed that there is still compassion and understanding for people with HIV. And perhaps it highlights the Administration priorities of healthcare issues. HIV advocates in the U.S. have high expectations for this Administration and hopefully they are poised to deliver. **HIV**



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criminal justice and harm reduction policy issues. He is a long-time advocate on behalf of criminal justice reform, healthcare policy, and HIV/AIDS and alcohol and other drug treatment and reform issues. An expert in Congressional appropriations and advocacy, he is currently consulting with organizations regarding the response to COVID-19, criminal justice sentencing alternatives, HIV/AIDS issues and overdose prevention. He has long worked to enact and implement healthcare reform, effectively advocated for ending the ban on federal funding for syringe exchange, multiple successful reauthorizations including SAMHSA and the Ryan White CARE Act, treatment instead of incarceration, almost all facets of HIV national policy, ending HIV-specific criminal prosecutions throughout the U.S. and other state level advocacy.

President's Budget Proposes Key Investments in Ending the HIV Epidemic

BY: LESLIE MCGORMAN

THE WHITE HOUSE released its long anticipated President's budget request (the first step in the Congressional appropriations process), prioritizing \$6 trillion in spending aimed at economic recovery and expansion. Through the "American Jobs Plan" and the "American Families Plan," the budget proposal calls for massive and historic investments, including in the country's public health infrastructure and in the Department of Health and Human Services' (HHS) many responsibilities. The White House has also committed to ending the HIV/AIDS epidemic and has requested significant funding to execute that goal.

Ending the HIV Epidemic (EHE)

The budget proposes an acceleration and strengthening of efforts to end the epidemic in the U.S. with a \$670 million investment in programming to reduce new HIV cases, increase treatment, and expand the use of PrEP, while ensuring equitable access to services and supports. Of importance to Academy members, those dollars primarily will be focused on strategies that closely align with the communities where HIV transmission is the highest and will continue to include prevention, diagnosis, and treatment interventions.

Centers for Disease Control and Prevention (CDC)

With these dollars, the CDC is committed to providing additional expertise, technology, and resources to the 57 EHE focus jurisdictions. The \$275 million in funding for EHE (a \$100 million increase) is estimated to result in approximately 14,000 new diagnoses, 12,000 people re-linked to health care, 13,000 people enrolled in PrEP services and treatment, and investigation of and response to 75-100 HIV clusters or outbreaks. The CDC has also prioritized health equity as being central to addressing the HIV epidemic, including utilizing innovative strategies to increase access to HIV prevention services, enhance community engagement, and combat stigma.

The budget also includes funding to address the disproportionate impact of HIV and hepatitis C infections in Tribal communities. However, while the amount requested for Indian Health Services'



Ending the Epidemic plan is significantly higher than in previous years (\$27 million - a \$22 million increase!), the amount requested for viral hepatitis within the (CDC) budget remains unchanged-a frustrating decision by the administration and disappointing news for providers working across issues.

Health Resources and Services Administration (HRSA)

Also important to Academy members is the budget proposal's investment in HRSA. As a reminder, HRSA ensures equitable access to services and supports for low-income people with HIV through Health Centers as well as the Ryan White HIV/AIDS Program. This budget proposes \$152 million for Health Centers (a \$50 million increase), and \$190 million in the Ryan White HIV/AIDS Program (an \$85 million increase). Total Ryan White funds are proposed to increase by \$131 million, but only across Part A, B, and C.

National Institutes of Health (NIH)

The budget proposal also includes \$26 million for implementation research

within the NIH, a \$10 million increase. In particular, this funding will go to NIHsponsored Centers for AIDS Research to support the initiative to end HIV/ AIDS through evidence-based research on new strategies for the successful delivery of integrated prevention and treatment.

Housing and Urban Development (HUD)

One disappointing element of the President's budget is in the Housing Opportunities for Persons With AIDS (HOPWA) program. This critical program is the only federal program that's dedicating to the housing needs of people with HIV/AIDS, and expressly benefits those with low incomes and their families. We know this program is particularly important as the country moves toward economic recovery, with many folks still struggling with permanent, safe, and affordable housing. As such, the broader coalition of HIV-related provider groups and community organizations requested the administration boost HOPWA funding from \$450 million to \$600 million, a hefty increase that would actually make progress in the lives of so many. Unfortunately the President's budget only proposes a \$20 million increase, which is obviously a significant and disappointing difference from the community's ask. HIV



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CHXNGING THE STORY

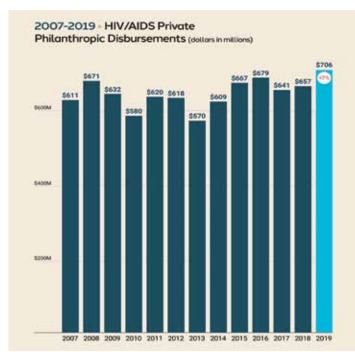
Flatlining Philanthropic Funding for HIV in the COVID-19 Era

BY JOHN BARNES, EXECUTIVE DIRECTOR, FUNDERS CONCERNED ABOUT AIDS

HERE IS MUCH THAT HAS CHANGED IN THE WORLD as a result of COVID-19, but one thing has not: the ways in which marginalized communities are disproportionately impacted. This is not new; it is a reflection of systemic issues that have affected these communities—particularly those affected by HIV—for decades. For LGBTQ and Black, Indigenous and people of color communities in the U.S.—and for key populations globally—the pandemic did not create these inequalities and vulnerabilities. But it has certainly deepened them.

Recent reports from Funders Concerned About AIDS (FCAA) tell two parts of an ongoing story. Though the story is not yet over, we are at a critical juncture. These two reports, particularly when viewed in aggregate, are intended to support the course correction needed to ensure that the next chapter is more hopeful.





Source: Funders Concerned About AIDS' 2019 Philanthropic Support to Address HIV/AIDS report

CHAPTER 1: Stagnating Philanthropic Funding for HIV and AIDS

In early May, FCAA published its 18th annual Philanthropic Support to Address HIV/AIDS report which showed an increase of \$49 million, or seven percent from 2018, for a total of nearly \$706 million. This is the highest level of giving since the organization began tracking HIV-related philanthropy almost 20 years ago. However, that rise was driven almost entirely by a single, \$100 million payment from one funder and belies what would have otherwise been an overall decrease in HIV-related philanthropy.

Over the past several years, this report has shown that philanthropic resources for HIV/AIDS have remained relatively flat. This comes at a time when we can ill-afford stagnation in the response to the epidemic. What's more, the number of funders is shrinking, with the majority of grants given by just a few grant-makers. This puts us in a very vulnerable position should the priorities of an ever-smaller number of funders shift.

Out of the 264 funders analyzed in the report, the top 20 account for 92 percent of the year's total, the highest level of resources concentrated among these top funders to date. Compare this to just five years ago, when the top 20 funders accounted for only 80 percent of total giving. Furthermore, the top two funders—The Bill & Melinda Gates Foundation and Gilead Sciences, Inc.—represent over 50 percent of grantmaking each year.

There are other alarming trends highlighted in this year's data. The vast majority of people living with HIV/AIDS reside in low- and middle-income countries (LMIC), yet HIV-related philanthropy to LMIC decreased by 32 percent from 2018 to 2019. Similarly, while

key populations and their sexual partners account for the majority of new global HIV infections, the data found a 12 percent decrease in HIV-related philanthropy for key populations overall in 2019, as well as substantial declines for nearly every population tracked within this category.

While the 2019 calendar year data examined in this latest report was not impacted by the COVID-19 pandemic, it highlights gaps in the response that existed pre-COVID-19 that will now be compounded. Understanding where funding around these issues was in pre-COVID-19 times will help to measure and guide the response moving forward.

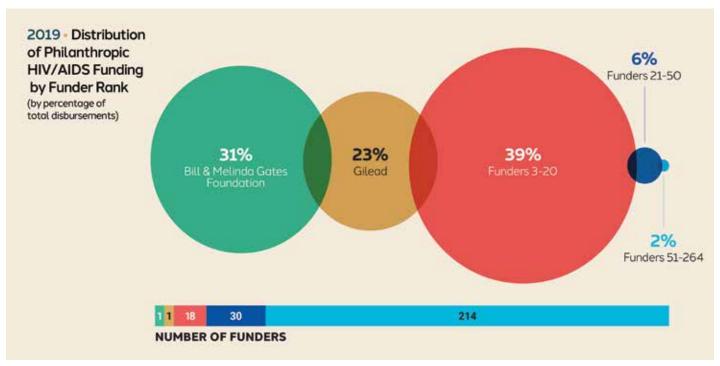
This leads us to a second report which explores the converging epidemics of COVID-19, HIV, and inequality.

CHAPTER 2: COVID-19 Deepens Existing Gaps in the Response

In January 2020, COVID-19 was first reported in the U.S., quickly revealing a pattern of deeper impact on communities of color. Globally, the same groups, known within the HIV/AIDS policy response as key-affected populations, experienced further marginalization at the onset of the pandemic and faced additional barriers in access to HIV care (and other health services), efforts to protect themselves from COVID-19 transmission, and accessing appropriate care after SARS-CoV-2 infection.2

In order to better understand how best to respond to the evolving needs of vulnerable communities at the intersection of HIV/ AIDS, COVID, and (in the U.S. context) racial justice, FCAA convened a Learning Group and, with the Elton John AIDS Foundation as a partner, commissioned a report. It quickly became clear that the crisis needed to be evaluated in a more intersectional way.

The pandemic raised barriers to health and wellness even higher for marginalized populations living with or at risk of acquiring HIV-specifically, men who have sex with men, people who use drugs, sex workers, and young people, globally, and Black women, transgender women and the LGBTQ community in the U.S. The early months of the crisis left people struggling to meet basic needs such as food, shelter, and cash, and fearing for their safety and security:



Source: Funders Concerned About AIDS' 2019 Philanthropic Support to Address HIV/AIDS report

- The struggle to survive infection, illness, death, and the day-to-day impact of COVID-19 compounded mental health challenges for vulnerable and key populations, however mental health services were not available in many settings.
- The *medical supply chain* has also been affected, with reports of severe disruption to HIV testing, monitoring, sexual and reproductive healthcare, and harm reduction services.
- Affordable, timely *access to available technology* was not always possible. As more and more services transitioned to digital platforms, the infrastructure and training costs were not sufficiently supported.
- Gender based violence and human rights infringement increased in countries around the world as COVID-19 exacerbated the stigma, discrimination, harassment and violence experienced by marginalized, criminalized populations.

Bringing the conversation back to funding, as resources shift to address COVID-19, there is concern that already plateauing resources for HIV/AIDS may be further—and permanently—diminished. The implications of this shift are particularly severe on long-standing activism to overcome health inequities that impact HIV care, treatment, and advocacy. Already, HIV services have come to a halt in some communities and prevention is not being funded. The risk of high HIV infections in the future is significantly increasing.

CHAPTER 3: Changing Course

We do not yet know the full extent of the COVID-19 pandemic's impact on the levels and types of HIV-related philanthropic funding. As we await the data, we have the opportunity to adjust course in order to combat the converging epidemics of COVID-19, HIV, and systemic

inequality. To do this, we must increase funding for the strategies and populations that demand additional attention, support, and flexibility to help combat the compounding effects of COVID-19. In addition to funding, we must also accelerate intersectional, multi-level work, with particular attention to viewing both the HIV and COVID-19 response through a racial justice and human rights lens.

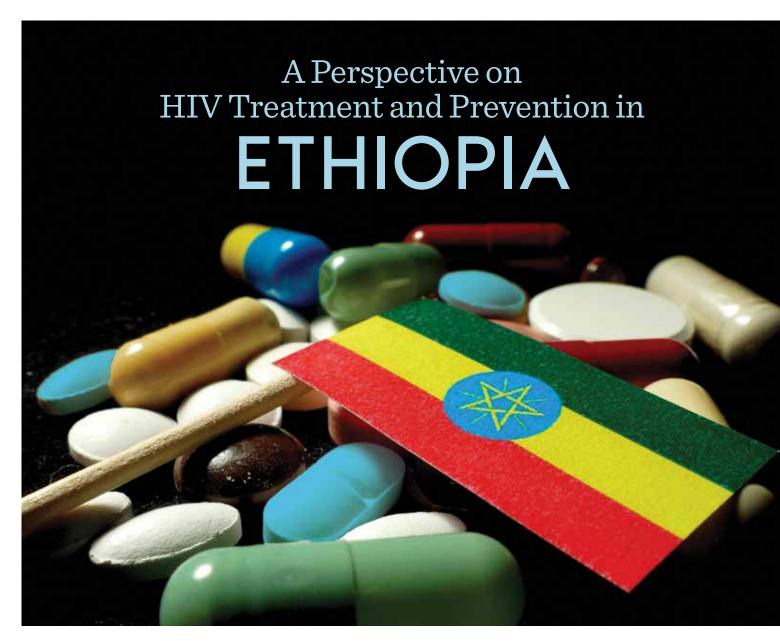
COVID-19 has highlighted long-standing inequities and gaps in the response to HIV and AIDS. But the next chapter is not yet written. By taking the necessary steps, we will ensure a far better outcome for this story. HIV



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ENDNOTES

- The term "key populations" refers to the following population groups: gay men/men who have sex with men, people who inject drugs, transgender people, sex workers, general LGBTQ, and key affected populations not broken
- 2. Excerpted and adapted from FCAA COVID-19 Learning Initiative Terms of Reference



BY: ANTENEH ZEWDE, MD, ZACH KALTENBORN, MD, ASIYA JEYLAN HUSSEN, BSC, MSC

N THE UNITED STATES, HIV clinicians are already selecting patients for long-acting injectable anti-retroviral therapy (ARV) and preparing for long-acting pre-exposure prophylaxis (PrEP). 1-6 While these innovations are exciting and welcome, there is a staggering divide in the daily provision of HIV care across the world, especially in sub-Saharan Africa. Clinicians struggle with inadequate testing supplies, medication shortages, shifts in funding priorities, and severe opportunistic infections. While a significant proportion of patients diagnosed with HIV in the United States may have advanced disease, there are major differences in how clinicians are recommended to approach the management and evaluation of these patients.

Integrase inhibitor-based therapy is relatively new across much of the developed world and ARV options are limited. Efforts to improve access to and the acceptance of pre-exposure PrEP are underway but differ substantially between countries and regions. While most countries across the world have

aspirational goals for ending the HIV epidemic, the export of policies with roots in systems of inequity could ultimately undermine efforts to curb the spread of HIV by replicating these same patterns in other countries.8

In Ethiopia, substantial progress has been made over the last several decades to reduce

the burden of HIV. The ARV clinic within the Adama Hospital Medical College is one of the largest government affiliated clinics in the Oromia region and serves a large number of people living with HIV. We will consider several aspects of HIV care within this context to highlight important differences

and a few of the many challenges facing HIV providers and their patients in Ethiopia.

Advanced HIV Disease

The burden of advanced HIV disease is substantial across the developing world. In Ethiopia, two out of every three people diagnosed with HIV may have World Health Organization (WHO) stage III disease or a CD4 count less than 200.9 Tuberculosis (TB) also weighs heavily on patients with co-infection being present in one out of every four patients. 10 While the WHO has a recommended care bundle for patients with advanced HIV disease, there are often barriers to local implementation.11 For example, CD4 counts are considered a basic element of care but large percentages of patients enrolled in HIV programs may not receive this testing despite well-validated point-of-care tests. 12 There are numerous mechanisms that make routine CD4 testing unpredictable including changes in funding priorities, lack of reagents, lack of trained personnel, or erratic utilities (e.g. power outages).

On review of our own data from Adama during the early years of the WHO endorsed test-and-treat policy, less than two percent of patients had a CD4 count over a four-year period. 13 An unintended consequence of this policy at Adama led to shifts in funding allocation with frequent supply shortages as well as de-prioritization with the focus shifting to immediate ARV initiation. However, patients with advanced disease are at substantial risk for adverse outcomes in areas where cryptococcal disease and tuberculosis are endemic without appropriate prophylaxis and carefully timed ARV. 14-16

Through a recently developed partnership between the Adama Hospital HIV clinic and the Department of General Internal Medicine at the University of Minnesota, we focused on following the outcomes of and improving adherence to WHO recommendations for the management of advanced HIV. This package consists of several interventions including screening, treatment and/or prophylaxis for major opportunistic infections and a focus on the rapid initiation of ARV with careful consideration of CD4 count at the time of care engagement (Table 1). While these guidelines are modeled on large studies with demonstrable survival benefit, the real-world impact of these guidelines is largely unknown. 17, 18

Since the initiation of our program,

there has been a high acceptance rate of the bundled care approach given that much of the work-up can be done in a single day. This has helped providers be more confident in differentiating between which patients should be recommended to start antiretroviral therapy immediately versus those that should have a deferred approach. Data collection is ongoing and we expect to have results later this year. While our approach strives to meet the guidelines set forth by the WHO, there continue to be limitations. For example, in patients

with symptomatic cryptococcal disease, amphotericin cannot be locally sourced and patients receive second line high dose fluconazole despite the established superiority of amphotericin.

First-Line Antiretroviral Therapy

While integrase inhibitor-based therapy for HIV is nearly taken for granted in the United States, dolutegravir was not fully endorsed by WHO guidelines until 2018 and many patients initiating ARV around the world

Table 1 Components of the package of care for people with advanced HIV disease

	Intervention	CD4 cell count	Adults	Adolescents	Children
Diagnosis	Sputum Xpert® MTB/ RIF as the first test for TB diagnosis among symptomatic people	Any	Yes	Yes	Yes
	LF-LAM for TB diagnosis among people with symptoms and signs of TB	s100 cells/mm ³ Or at any CD4 count if seriously ill	Yes	Yes	Yes*
	Cryptococcal antigen screening	≤100 cells/mm³	Yes	Yes	No
Prophylaxis and pre-emptive treatment	Co-trimoxazole prophylaxish	s350 cells/mm³ or clinical stage 3 or 4 Any CD4 count in settings with high prevalence of malaria or severe bacterial infections	Yes	Yes	Yes For criteria, see Annex 1
	TB preventive treatment*	Any	Yes	Yes	Yes
	Fluconazole pre- emptive therapy for cryptococcal antigen- positive people without evidence of meningitis	<100 cells/mm ³	Yes	Yes	Not applicable (screening not advised)
ART initiation	Rapid ART initiation (as recommended in Chapter 3)	Any	Yes	Yes	Yes
	Defer initiation if clinical symptoms suggest TB or cryptococcal meningitis (see Chapter 3)	Any	Yes	Yes	Yes
Adapted adherence support	Tailored counselling to ensure optimal adherence to the advanced disease package, including home visits if feasible	<200 cells/mm ¹	Yes	Yes	Yes

^{*}Limited data available for children. * Co-trimoxazole, isoniazid and pyridoxine are available as a fixed-dose combination tablet. For children younger than 12 months, only those with a history of TB contact should receive TB preventive treatment if the evaluation shows no TB disease.

remain on non-nucleoside reverse transcriptase inhibitor (NNRTI) based regimens. 19 While the superiority of dolutegravir was well established for years prior to this, there was hesitation for widespread implementation due to concerns regarding the risk for neural tube defects. Thankfully, further observations regarding the safety of dolutegravir during pregnancy have been re-assuring.20 While dolutegravir has a higher genetic barrier to resistance than efavirenz, underlying resistance mutations could lead to functional monotherapy with dolutegravir in some patients.21 However, evidence continues to support integrase-based regimens despite these concerns. Countries supported by The President's Emergency Plan for AIDS Relief (PEPFAR) have been undergoing a transition towards a dolutegravir-based regimen containing tenofovir disoproxil fumarate (TDF), lamivudine (3TC), and dolutegravir (DTG).²²-²⁵ Many programs already have a reliable supply of these drugs in a once daily single tablet formulation and newly diagnosed ARV naïve patients (and many experienced patients on first-line NNRTI regimens) are being successfully initiated on this medication.

In Adama, the HIV clinic has approximately 7500 total patients on ARV. Nearly eighty percent of these patients are currently on a dolutegtavir-based regimen with the single tablet formulation of TDF, 3TC, and DTG being the most common. Though resistance mutations to integrase inhibitors appear relatively uncommon in Ethiopia, programs in which the majority of patients are on integrase inhibitor therapy still have patients without adequate virological suppression.²⁶ In these patients, there are likely multiple factors at play such as patient adherence, access to care, viral genotype, exposure to economic or political instability, and other social factors. Outside the context of a study, genotypic testing is not a routine element of HIV care throughout sub-Saharan Africa placing clinicians in a challenging position when patients are failing first-line therapy. When a viral load is available, it is often unclear whether the ongoing viremia is due to drug-resistance or other factors. More commonly, clinicians are faced with clinical evidence of treatment failure without the luxurv of a viral load to inform treatment decisions.

Pre-Exposure Prophylaxis

PrEP poses a challenge in much of the developing world. Though many countries have incorporated PrEP into their national strategies for combatting the HIV epidemic, there are often cultural, inter-personal, systemic, economic, or political barriers that hinder efforts in the clinic. Daily oral medications such as emtricitabine-tenofovir face similar barriers as those seen in the United States such as daily adherence, pressure from romantic partners, and side effects.

Formal policies regarding PrEP are relatively new in Ethiopia. Pilot programs have been initiated at various locations including Adama with priority populations identified including serodiscordant couples and female sex-workers.²⁷ However, there are rarely mechanisms that support the cost of PrEP and there may be limitations in drug availability. The recent WHO endorsement of the dapivirine vaginal ring creates choice and options among women at risk for HIV acquisition.²⁸ However, mechanisms for prioritizing these at risk populations and ensuring access among these groups remain important hurdles for more widespread implementation.

Policy Supports

On paper and in rhetoric, regional governments are almost universally supportive of prioritizing HIV care and improving population health. Ethiopia generally aligns its national guidelines with recommendations from the WHO. However, for clinicians treating HIV, there are frequent and unpredictable shortages of needed supplies which can make routine evaluation difficult. Thankfully, the bulk of costs associated with HIV care continue to be carried by local health ministries and international aid programs such as PEPFAR. However, throughout the healthcare landscape in the developing world there are increasing examples of out-of-pocket expenditures being shared by people with HIV (PWH).

In Ethiopia, ARV, TB therapy, and co-trimoxazole are provided free of charge but other medications indicated in the treatment or prophylaxis of other opportunistic infections are not. While this can often help support the costs associated with care delivery, the shift away from public sector financing towards private sector financing is based on neoliberal

economic theories which are often encouraged in subtle (or not so subtle) ways by foreign governments.²⁹ To achieve equity in care delivery, out-of-pocket costs should be minimized as they have a disproportionate impact on the poor. Within the context of the United States, Ryan White funded HIV programs represent a highly successful example of how increased public sector funding can work towards health equity.30 However, when considering the HIV epidemic within the U.S. as well as the healthcare system more broadly, there are staggering health disparities which have been exacerbated in the context of the COVID-19 pandemic.31-34 While the overall positive impact of the monetary support provided by international governments on the health of PWH in the developing world cannot be understated, exporting models of care delivery and financing that have generated profound health disparities could prolong and perhaps exacerbate the HIV epidemic in the coming decades.

Conclusion

Caring for PWH in Ethiopia shares many features with the care provided in the United States. There is a focus on drug adherence, counseling on side effects, and an emphasis on the importance of viral suppression. PWH in Ethiopia also tend to carry a higher burden of social determinants within the local context. Overall, there continues to be a substantial burden of advanced HIV disease and careful adherence to evidence-based guidelines regarding the management of opportunistic infections is paramount to high-quality care.

When considering available ARV, PWH in the developing world are increasingly being started on safer and more effective integrase based therapy. However, while clinic visits in the U.S. often focus on 'upgrades' in therapy, changes to ARV in Ethiopia focus on transitions because of suspected virological failure or interruptions in drug supply chain. PWH in Ethiopia continue to be subject to a higher long-term risk of osteoporosis and chronic kidney disease due to continued exposure to TDF containing regimens. When second line therapy is required, the side-effect profile endured can be substantial. Though the increasing availability of dolutegravir is exciting and welcomed, the lack of global equity in HIV

care delivery is profound. While novel drug delivery methods hold promise for further improving the care of PWH, disruptive financing models with a focus on equitable care delivery could be more effective in improving the long-term survival and reducing the morbidity among those patients living with HIV in Ethiopia and throughout sub-Saharan Africa. HIV



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From Tropical Tanzania to the Deserts of Botswana

BY KIRK SCIRTO, MD, MPH, FAAFP, AAHIVS



T TOOK A TWO-DAY JOURNEY THROUGH

torrential rains and flooded roads to reach our clinic in Mwanza, Tanzania-an area of East Africa with 7.2 percent HIV prevalence. There were other HIV clinics closer to their village, but then rumors could spread and the stigma weighed heavily on them. They feared that his perpetual cough would lead him to be even more ostracized than his HIV diagnosis, as was often the case. His parents died from AIDS and his grandmother tried to remember to give him nevirapine/lamivudine/zidovudine despite her advanced dementia. He was just skin and bones, and we would later find that he had a viral load (VL) of 175,000. His chart indicated that he was four years old, but he could easily be mistaken for only two. He suffered from severe acute malnutrition that was caused by poverty, food insecurity, HIV viral failure, and kifua kikuu—"big chest/cough" in Swahili, or tuberculosis (TB). I admitted him to a 1,000-bed government hospital with minimal lab and treatment capacity.

My wife and I spent nearly two years from 2018-2020 working in Tanzania and Botswana with the Baylor International pediatric AIDS Initiative (BIPAI). The peds HIV Center of Excellence in Mwanza, Tanzania was started with local partnership in 2011. It has been run by a Tanzanian nonprofit and staff, serving as part of the public HIV and TB care system. As the only foreigners working at the clinic, we were lost without Swahili interpreters and cultural guides such as our social worker and counselors. Together with Tanzanian clinicians, we provided HIV and primary care to over 1,700 people with HIV (PWH). In addition to our malnourished patient, we provided treatment for active TB to 140 people at that time. We lightened the load of patient care, yet our most sustainable role involved training local healthcare students, residents, attending doctors, and nurses in HIV and TB care.

Hospital with Empty Shelves

Our four-year-old patient with viral failure could not hold up his head, and I did a lumbar puncture as he became increasingly obtunded despite dextrose. Rapid labs only gave some reassurance, as his blood glucose was 80 mg/dL, CD4 325 cells/mm3, and his hemoglobin was 10 g/dl. Testing was negative for malaria as was his serum cryptococcal antigen test. We gave IV ceftriaxone and prepared a one-week supply of this antibiotic for them to bring to the hospital. He had ripped clothing and no shoes, and so we knew they couldn't afford this and other meds and labs for his hospitalization. We drew the rest of the labs available to us and also sent him with trimethoprim/sulfamethoxazole (TMP/ SMX), vitamin A, folic acid, zinc, and albendazole from our clinic.

The Malnutrition Wards lacked various medications and ran out of therapeutic formula, so we also sent over some of our readyto-use food. The hospital's chest x-ray fee was beyond the reach of his grandmother, so we paid. The results showed bilateral asymmetric hilar adenopathy common in pediatric pulmonary TB. The Tanzanian government claimed that there was free inpatient medical care for children under five years old, yet this was an empty promise. Quite simply, only sick patients who could afford healthcare



truly had a chance of survival from serious illnesses.

One of our community health workers brought TB treatment to the hospital for our young patient. He had not been receiving antiretroviral therapy (ART), and two weeks later, I brought lopinavir/ritonavir and lamivudine/abacavir with me on hospital rounds. He gained weight and stopped coughing on this standard Tanzanian ART, so we discharged him. His uncle took over his care and administered ART and TB treatment, yet he was repeatedly admitted back to the hospital for severe acute malnutrition. We could treat his medical problems, but not the glaring social and economic ones. Crippling poverty created a revolving door to this crowded hospital.

His admission was a typical new patient visit for a Tanzanian child with HIV disease and virologic failure. We lost such patients most often to severe pneumocystis jirovecii pneumonia (PJP), cryptococcal meningitis, and especially severe acute malnutrition with TB. Other new patients presented with Kaposi sarcoma, lymphocytic interstitial (and other) pneumonia, diarrhea, mumps, sepsis, schistosomiasis, and malaria. Healthcare needs were often overwhelming relative to the resources available. During our patient's first admission, we ended up newly diagnosing and treating two other children with HIV and three with various forms of TB in the same malnutrition wards.

Sunrise and Sunset on HIV Care

In contrast to this eventful first visit, many HIV care visits gave great hope for the future of PWH in Tanzania. Most patients did an excellent job keeping their appointments and being adherent to ART. As a result, 85 percent of our patients achieved VL suppression. Only 61 percent of PWH in Tanzania are aware of their status; yet of these, 94 percent are on ART and 87 percent of those on ART have suppressed VLs.2

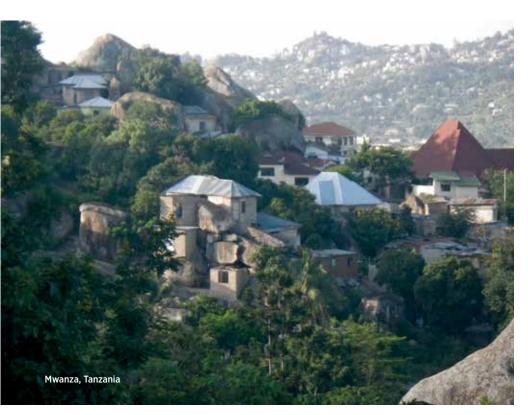
A national HIV treatment program was started in 2004 and it fueled progressive declines in incidence.3 In 2013, all pregnant PWH became eligible for ART. As of 2016, all PWH were offered ART regardless of CD4 and clinical stage. Expanded ART access had a major effect, as vertical transmission rates were halved from 2012 to 2015.4 We followed some 500 HIV-exposed babies once a week, and thankfully 94 percent of them turned out to be HIV negative.

Some 200 HIV Teen Club members met each month at our clinic, as they danced, performed skits, and otherwise supported each other and their improved adherence. Meanwhile, our nutritionist cooked healthy food with families while teaching gardening methods. With these and other programs, we were able to prevent and treat most cases of malnutrition without the need for a hospital stay.

Missing Labs and Medication

Despite these successes, our clinic dealt with many of its own challenges. We often ran out of CD4 cartridges, bacterial cultures, lumbar puncture needles, and HIV rapid tests. Meanwhile, VL results could take a few months to come back from the Ministry of Health (MOH). We lacked resistance testing but made ART switches based on a lack of VL response that occurred despite intense adherence counseling and presumed improved adherence to HIV therapy.

As a public clinic, we were also dependent on the MOH for our ART supply. There were frequent ART shortages throughout the nation, which explained why the village clinic was giving nevirapine to our malnourished patient. It was the only HIV anchor medication available



at theirs and many other centers. Therefore, it was given despite the fact that up to 60 percent of children with HIV in sub-Saharan Africa have pretreatment resistance to non-nucleoside reverse transcriptase inhibitors (NNRTI).5 HIV treatment guidelines in Tanzania are routed in evidence-based World Health Organization (WHO) guidelines for resource-limited nations.⁶ At that time, these guidelines called for patients like him to be on lopinavir/ritonavir and lamivudine/abacavir for first line ART.7

However, lopinavir/ritonavir syrup needed to be refrigerated and most of our patients lacked electricity. Further, this syrup is foul-tasting and therefore rejected by many children. Although we could offer our patient this ART combination at our center, we later ran out of lopinavir/ritonavir syrup as well as oral tablets. For this reason, suppressed patients had to be switched to older therapeutic options such as efavirenz or nevirapine because we had no other anchor medications available based on patients' weight.

Frequent switches were confusing to patients and staff, and they were sometimes responsible for viral failure or severe drug reactions such as Stevens-Johnson Syndrome. At one point, we had such a short supply of ART that we could only dispense two weeks of meds at a time. This was very trying for our patients who travelled far to reach us. This also meant that a few clinicians saw over 130 patients daily, stirring Tanzanian Clinicians to leave for other practices.

The 2019 rollout of dolutegravir in Tanzania was a breath of fresh air. We switched over hundreds of patients from less effective regimens with higher pill burdens and poor tolerability due to drug side-effects. Yet we did not have a reliable supply from the MOH, so it joined our constantly changing list of ART which was out of stock. Although Tanzania approved the use of pre-exposure prophylaxis (PrEP) in 2019, we did not have enough Emtricitabine/Tenofovir DF to offer it (nor were we approved by the MOH to do so). We ran out of various antibiotics at times, but thankfully, our stock of TMP/SMX was maintained. However, they often lacked it in the rural areas where we trained HIV providers and there were many lives unnecessarily lost to PJP as a result.



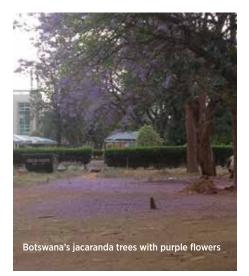
Desert of Hope

East Africa clearly has a multitude of challenges due to HIV, however Southern Africa has been hit even harder by the pandemic. From the thick tropical vegetation and incessant rains of Tanzania. I will now shift over to the deserts of the sparsely populated nation of Botswana. Our center was created in partnership with the MOH in 2003, standing as the first pediatric HIV clinic in Botswana. It was initially bustling with young children with HIV and AIDS, yet this is no longer the case. The average patient age has increased from four years to 18 given impressive national achievements on preventing and treating HIV. For the most part, the children served by this clinic grew up healthy. We saw over 2,400 PWH on a regular basis, however we rarely saw a young child or any newly infected patients.

Botswana had a whopping 40 percent HIV prevalence rate in the early 2000s, yet it has been halved. Further, its vertical transmission rate has dropped to only two percent.8 The national prevalence rate plunged following high mortality and decisive government action.9 The national government

wisely used funding from diamond mining to cover significant HIV care services, while it courted necessary donor support as well.¹⁰ Impressive results followed, as 92 percent of PWH in Botswana are currently aware of their HIV status; of these, 82 percent are on ART and 79 percent of those on ART have suppressed VLs.11

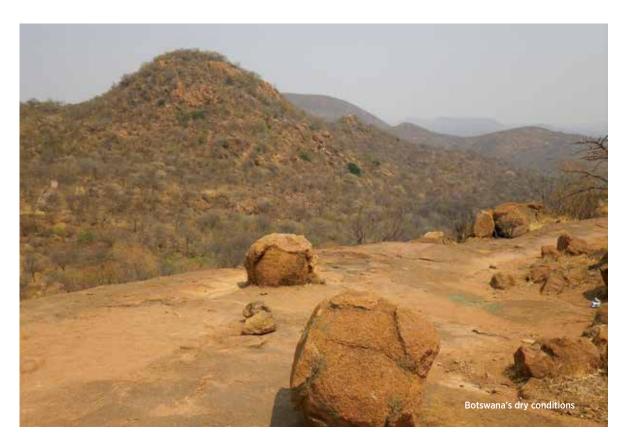
Well-endowed with resources, we did not run out of ART or lab supplies in Botswana;



resistance testing was even accessible. Dolutegravir was piloted here before other sub-Saharan African nations, and most of our patients were taking it. We even had access to emtricitabine/tenofovir DF for PrEP.

Clinic and hospital staff were more plentiful and they even had the time to sing every morning with beautiful harmonies in the Setswana language. Acute malnutrition was much less common, even as many of our patients were severely stunted, hinting at prior years without adequate ART and food access. Ninety-two percent of our clinic patients had undetectable viral loads and opportunistic infections were far less common here. Yet TB served as the major exception, as it was our patients' most common cause of cough after pneumonia. The HIV Teen Clubs that thrived in Tanzania were modeled after clubs that originally began in Botswana, and then years of success were translated to other cultures throughout the continent.

Despite the higher HIV prevalence here, there unfortunately seemed to be even more stigma in Botswana than in Tanzania. We encountered many cases of families disowning members with positive HIV status. Mothers



would sometimes hide their own status from their children, even though vertical transmission had occurred.

The public hospital behind our clinic was overrun by monkeys leaping from one garbage can to the next, yet it was quite impressive compared with public hospitals in Tanzania. I admitted a patient with TB pericarditis, and he was able to access life-saving pericardiocentesis at this facility. Yet there were less resources in rural areas, where our team would consult on patients with viral failure while training HIV providers. These sites had less options for ART as well as no available resistance tests and issues with CD4 results taking over one year to return.

The heavy burden of HIV in Africa can be seen with a glimpse into care in these two countries. Tanzania—and similar nations—have faced the highest hurdles to quality HIV care given their deep poverty and paucity of treatment resources. Yet nations in sub-Saharan Africa have overcome many challenges, as is evident in Botswana. These countries are generally moving the needle in the right direction regarding HIV care. Therefore, there is reason to have much hope for HIV care among the kind and hard-working people of this beautiful continent. HIV



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Lessons Learned From a Low **Prevalence Country**

BY: NAOKATSU ANDO, MD, AAHIVS

HERE ARE 38 MILLION PEOPLE living with HIV globally.¹ However, Japan has been known as a country with a low HIV prevalence rate. According to the annual report of the National AIDS Surveillance committee for the year 2019 in Japan, the number of new HIV/AID cases was 1,236 and the incidence rate was 0.98 per 100,000 people respectively.2 (Fig.1) These estimated numbers are considered to be very small compared to that reported from high prevalence countries such as the United States with 36,400 new HIV infections in 2018 and an incidence rate of 13.3 per 100,000 people. 3 However, there is still room for improvement. The proportion of AIDS patients in Japan in the total number of newly diagnosed infections has remained constant at about 30 percent for more than 10 years.2 (Fig. 1) This means that we have not been able to detect people with HIV (PWH) at an early stage. This is an important issue to consider in order to further reduce HIV infection.

In Japan, over 90 percent of PWH are men who have sex with men (MSM). The proportion of woman is less than five percent and pediatric cases are extremely rare. As a cause of HIV transmission, intravenous drug use (IDU) is also very rare, at two to three cases per year. These values suggested that in Japan the spread of HIV is limited mainly to MSM, while heterosexual and IDU transmission is less frequent. However, since IDU is considered to be spreading among MSM in Japan, IDU transmission of HIV may be underestimated.

Drug-Resistant HIV Strains

Among over 500 newly diagnosed PWH in 2019, 6.4 percent were infected with HIV harboring major drug resistance mutations. By antiretroviral therapy (ART) class, 3.7 percent of nucleoside reverse-transcriptase inhibitors (NRTI), 3.7 percent of non-NRTIs, 1.8 percent of protease inhibitors (PI) and 0.2 percent of integrase strand transfer inhibitors (INSTI) were reported.4 This is low compared to the resistance rate reported from other countries, including the United States which reports 31 percent resistance to at least one drug and INSTI resistance at 8 percent. In the era of INSTI-based regimens as a first choice in treatment naïve patients, this class of medications can safely be selected for patients in Japan without concern for HIV resistance.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) has set the goal of "90-90-90"-- 90 percent of all people living with HIV will know their HIV status, 90 percent of all people with diagnosed HIV infection will receive sustained treatment, and 90 percent of all people receiving treatment will have viral load suppression. In Japan, the numbers are close to hitting this target. According to the recent study, 85.6 percent of PWH knew their HIV status, 82.8 percent of those were on antiretroviral therapy (ART) and 99.1 percent of PWH on ART achieved viral suppression at the end of 2015 (85.6-82.8-99.1)⁶ (Fig.2).

The results suggest that one of the characteristics of HIV care in Japan is that once PWH initiate ART, a high rate of are retained in care, leading to excellent outcomes. The success rate is unbelievably high. This including high rates of viral suppression. These data are consistent with my own clinical experience.

Figure 1. Annually reported new HIV and AID patient from 1985-2019 in Japan.

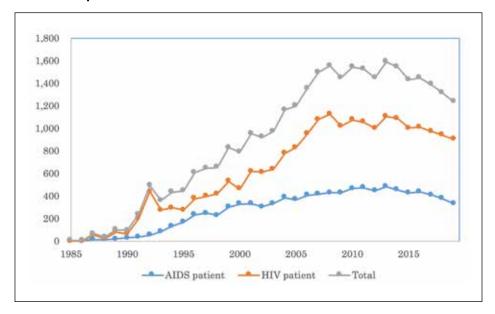
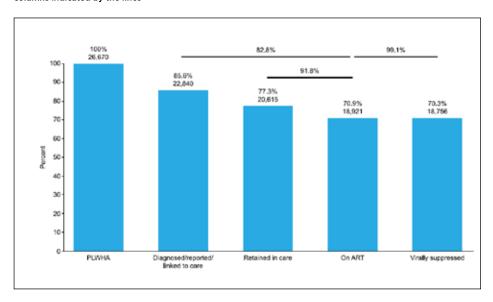


Figure 2. HIV care cascade in Japan. From reference 8. Columns in blue and the numbers and percentages above them show the care using the number of PLWHA (26,670) as the denominator. The lines and percentages above them show the cascade calculated between the columns indicated by the lines



Since 2008, the number of newly diagnosed HIV/AIDS cases has been decreasing and the number of HIV-positive samples detected through blood donation in Japan has been decreasing (Fig.1). This downward trend has continued for more than 10 years. This trend may reflect a potential effect of treatment as prevention within the localized MSM population given the high success rate.

Life expectancy of PWH has significantly increased due to the development of ART,

especially in high income countries such as Japan and the U.S. However, regarding the mortality in PWH, AIDS-related death and non-AIDS-defining malignancy contributed to 39 percent and 47 percent of death from 2005-2016 in Japan respectively. Moreover, in this same study by Nishijima, mortality of PWH on ART, even with early diagnosis or without history of AIDS, was four times higher than the general population.

Similar to other countries around the

world, we emphasize the importance of HIV prevention. Pre-exposure prophylaxis (PrEP) with antiretroviral drugs is an effective strategy for preventing HIV infection and many countries have approved oral medications for PrEP However, in Japan PrEP is not readily available because there are no drugs approved for this indication and thus remains an important issue for our country to address.

Social Security System for Medical Expenses

In Japan, there is both government and private health insurance options. In most cases, 70 percent of medical costs are covered by these insurance systems which means the patients is responsible to pay 30 percent of their medical costs. In the case of PWH, insurance is more complicated. Before starting HIV treatment, the insured person needs to apply for another supportive system to receive subsidies for the self-paid portion of the expenses for HIV care. By using this system, the self-paid portion drops to 10 percent. However, there is a ceiling for the self-paid amount according to the income earned by the patient in the previous year.

The application process is complicated. Therefore, in most hospitals in Japan where HIV specialists provide comprehensive HIV care, several coordinators generally help PWH apply for these subsidies. The greatest benefit of this system is that a primary are the patient's primary doctor can select any approved ART without limitations. The treating physician and prescribe single-tablet therapies such as Biktarvy® (bictegravir/tenofovir alafenamide/emtricitabine), Dovato® (dolutegravir/lamivudine) or other acceptable ART regimens at the same cost.

Japan adopted the universal health insurance system which covers all citizens. Therefore, in most cases, people can start



Japan's light blue health insurance card, red medical examination card, and personal medical card.

ART therapy inexpensively. However as noted above the process is time consuming, and it generally takes one to two months to complete the process. Clinicians in Japan cannot initiate ART soon after the diagnosis of HIV except for patients with AIDS-defining illness. This is a serious problem in Japan because the evidence for rapid initiation of ART is growing worldwide. The system needs to be changed little by little based on scientific evidence.

Special Population

In the 1980's, about 30 percent (n=1,432) of hemophiliacs in Japan were infected with HIV through contaminated blood products. This also happened in other countries including the United States and the United Kingdom before it was determined that HIV could be transmitted by the transfusion of blood or blood products. 8 This is sometimes referred to as the "blood scandal". Among those in Japan who were infected with HIV, 50.4 percent of were still alive as of the end of 2017. One of our missions is to provide continuous care for these individuals. They have some unique clinical characteristics

such as co-infection with hepatitis C virus. Remarkably, the prevalence and the incidence of non-AIDS defining malignancies were 5.8 percent and 2.99 per 100 person between 2016-2019 in this population. 9 This surprisingly high rate could mean that Japanese hemophiliacs might be at increased risk for non-AIDS defining malignancies. Consequently, some experts believe hemophiliacs with HIV should be screened more frequently for non-AIDS defining malignancies than the general population.

In summary, Japan is a country with low HIV prevalence and those PWH in Japan achieve very good treatment outcomes with ART. However, there are still many issues to be addressed to improve HIV prevention, early diagnosis and treatment - key issues which will contribute to the global goal of ending the HIV epidemic. HIV

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LEARNING FROM

How can governments improve access to HIV testing and treatment in Latin America and the Caribbean?

BY: EZEQUIEL CARMAN

N 2014 UNAIDS set the 95-95-95 targets set to end the AIDS epidemic by 2030. This ambitious target aims to ensure that 95 percent of all people with HIV (PWH) will know their status, 95 percent of all people diagnosed will receive sustained antiretroviral therapy (ART), and 95 percent of all people receiving ART will have viral suppression.

These targets are in reach. Yet to achieve them, policymakers must ensure that their countries' laws and policies align with the latest scientific advances and evidence-based recommendations around HIV prevention and treatment and healthcare access. In doing so, they can learn from one another's other's experiences with policy change. To help them in this task, the HIV Policy Lab, a research and accountability platform, provides cross-national data that allows NGOs and policymakers to identify and visualize the effectiveness of different policies that have been implemented among 194 countries. When governments, NGOs, and local activists understand the policies that promise to be most effective for public health, it significantly increases the speed and support for adoption.

The last data from the HIV Policy Lab shows that the region's progress in implementing treatment and prevention policies recommended by UNAIDS and WHO is below the global average.1

YOUR NEIGHBORS

At the end of 2019, 81 percent of people with HIV knew their status, and 67 percent were on antiretroviral therapy.2 Although some countries in the world have made significant progress against HIV, Latin America and the Caribbean (LAC) have not seen a substantial decline in new infections.3

Due in part to the limited allocation of government funds into health systems, progress against HIV has stalled, and thus, new infections have risen over the last years.⁴ Data from UNAIDS shows HIV infections in Latin America have increased by 21 percent since 2010.5

To prevent new infections and deaths, we must ensure that PWH (1) are aware of their HIV status (and so able to take precautions to prevent transmission); (2) are receiving treatment; and (3) have achieved viral suppression (which also prevents transmission). This requires policies that expand HIV testing, decrease barriers to accessing HIV services, and facilitate adherence to treatment.

A thoughtful policy implementation plan requires efforts from several ministries such as health, education, and justice. Drafting and implementing a policy without tailoring to the particular need of the target population or considering the interaction of various policies can result in a poor outcome. For example, offering HIV treatment to all people with HIV, regardless of CD4 count, will not be as effective as it could be if PWH experience high levels of stigma and discrimination or are targeted by laws that criminalize same-sex relationships, sex work, drug use/possession, and non-intentional HIV exposure/transmission-all of which are known to deter people from seeking and accessing services. 6 In 2019, 44 percent of new adult HIV infections in 2019 in the LAC region were among gay men and other men who have sex with men (MSM). Yet data from the HIV Policy Lab shows that 14 of the 33 LAC countries at least partially criminalize same-sex relationships. There is evidence of rising cases among young people within key population, yet 73 percent of LAC countries do not allow adolescents to access HIV testing and/ or treatment without parental consent.8



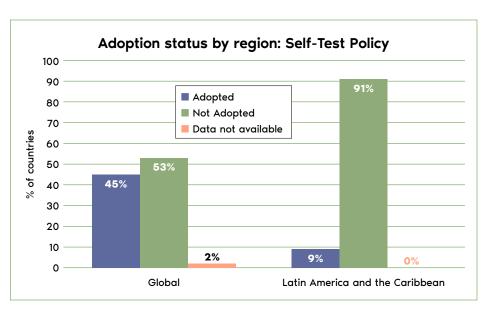
If LAC countries hope to achieve the 95-95-95 goals, national policymakers must collaborate and to enact laws and policies that put new scientific advances into practice and remove existing barriers to accessing HIV services. In particular, they should focus on self-testing and PrEP. In doing so, they can learn lessons from other countries in the region that have already adopted these policies.

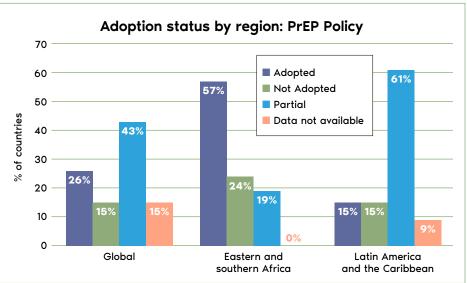
Self-testing

In LAC, only 77 percent of PWH know their status (compared to the global average of 81 percent).9 Implementing a policy offering self-testing kits can help overcome stigma and discrimination barriers that discourage people from getting tested and the World Health Organization recommends this strategy to increase HIV testing. Data from the HIV Policy Lab shows that globally, 45 percent of countries allow HIV self-testing, but LAC countries lag far behind; only Brazil, Mexico and Haiti have adopted HIV self-testing policies.10

In 2015, Brazil began offering self-testing kits to the general population. People can get these kits from pharmacies, medication distribution centers, as well as through the mail.11 Additionally, the country facilitated its access by implementing an online platform where people can order home delivery of free self-test kits. Research shows that this innovation has helped to overcome barriers and increase the testing ratio among MSM.12 During the COVID-19 pandemic, Brazil's home delivery policy had the added benefit of allowing people to continue to access HIV testing without leaving home, reducing their COVID-19 exposure as well as the burden on overcrowded hospitals. 13 The self-test kits provide a safe method, free of the stigma and discrimination, that can be manifested within a medical center. Additionally, in countries with vast rural areas, where people have limited access to medical facilities, self-testing kits can be home delivered and help reach underserved populations.14

Additionally, Latin American countries are facing another barrier that must be resolved: age of consent. Due to age-of-consent policies, many adolescents face barriers to access for HIV testing and contraception methods. 15 Only 24 percent of the region-8





countries—has enacted national policies that do not require adolescents (≥12 years) to obtain parental or guardian consent to access HIV testing and/or treatment.16

Criminalization barriers and PrEP

Another excellent strategy to decrease new cases is to offer PrEP to at-risk populations. This is another policy area where LAC countries lag behind other regions—for example, in comparison to Eastern and Southern Africa.

Before implementing a PrEP policy, the first step is to analyze which populations are most at-risk of HIV infection, in accordance with WHO guidelines. Since 2015 PrEP must be a priority for populations with an HIV incidence of about 3 per 100 person-years or higher.¹⁷ High-risk populations may include sex workers, serodiscordance couples, MSM, people who inject drugs, transgender people, and people in prisons and other closed settings. In LAC countries, gay men and other men who have sex with men constitute the vast majority of new cases (44%). Therefore, PrEP policy implementation should be focused in particular on reaching this key population.¹⁸

A second consideration in implementing a successful PrEP policy is to understand the sociopolitical landscape and the laws and regulations that hinder access to HIV services. These policy barriers can include laws that criminalize sex work, same-sex relations, and drug use. 19 Thus, we need to analyze the barriers that could discourage the targeted population from seeking and accessing the benefits of the treatment.

Of the 33 countries in the Latin American and Caribbean region, 19 have legal systems that avoid criminalizing consensual same-sex sex acts and there are no reports of people being prosecuted for such action. The other 13 had a partially adopted policy meaning that their law criminalizes samesex sex or that their judicial system prosecutes those cases. Finally, the only country that did not adopt any policy avoiding same-sex sex is Jamaica.

If governments want to adopt a policy, they must address criminalization, stigma, and discrimination against MSM and create a welcoming environment that does not deter this population from accessing services.²⁰ However, these policies require time to see results. In countries where MSM still face stigma and discrimination, it could be a good policy plan to implement PrEP in collaboration with local NGOs and community-based approaches, since members of key populations may be more comfortable accessing services through these modalities rather than in government health centers.

Finally, countries seeking to implement PrEP policies should learn from the experience of peer countries. In Latin America and the Caribbean, only the Bahamas, Barbados, Brazil, Chile, and Suriname have fully implemented PrEP policies. Brazil, the regional leader, provides PrEP through the public health system, private clinics, the Internet, and nongovernmental organizations.²¹ These experiences suggest that given the discrimination and stigma barriers that PLHIV in Latin America face, a good strategy might be to offer PrEP by home delivery, peer network, or even through an online platform. By implementing

differentiated community-based models, governments can "democratize PrEP access" and accelerate the results.22

There is an expression that says, "information is power." Having policy data from all over the world in one place can speed up the research phase. Policymakers and NGOs need to continue building from where others have left off. The information lets us know what is working and what is not, and in the latter case, learn from mistakes and decide how to avoid repeating them. Policy surveillance can impact health, and when activists understand the set of policies that are shown to have the greatest impact on public health, they can significantly increase the speed and support for adoption. HIV



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The Management and Care of

BY VILMARY SIERRA ROSA, MD, AAHIVS

CCORDING TO THE CENTERS FOR DISEASE CONTROL (CDC), Puerto Rico has one of the highest HIV infection rates in the U.S. and has been identified as one of the target areas in the Ending the HIV Epidemic: A Plan for American (EHE)¹. In 2018, 440 persons were diagnosed with HIV in Puerto Rico with HIV diagnosis rates among adults and adolescents ≥13 years 15.7 per 100,000 population.² There have been a total of 49,639 reported cases of HIV/AIDS on the island between 1980-2018.² According to new data from the University of Puerto Rico's Medical Sciences Campus' Integrated Clinical Trials Unit, the coronavirus pandemic has raised the figure to over 50,000 cases.

The COVID-19 pandemic also came on the heels of another disaster, Hurricane Maria, which hit the island in September of 2017. In a study conducted by the University of Puerto Rico's Medical Sciences Campus and Columbia University, Puerto Ricans living with HIV/AIDS were one of the groups that Maria impacted most. The study notes viral suppression decreased from 71 percent to 65 percent in the entire sample as a result of Maria's impact. Access to medical assistance and health services for these patients fell by more than two percent.

However, today, with the number of COVID-19 cases slowing declining, and thanks to advocates, patients, doctors and other community advocates in Puerto Rico, conditions are improving for most people with HIV (PWH). Access to HIV testing, treatment and prevention are

increasing and becoming more readily available.

There are many clinics on the island, both government funded clinics and private practice offices. Puerto Rico's federally qualitied community health centers are also known as 330 Centers because they were established by Section 330 of the Public Health Service Act. Many of these centers and some private health clinics also receive Ryan White funding. The Puerto Rico Ryan White Part B/ADAP Providers Network consists of 55 centers:

- Puerto Rico Department of Health (PRDOH) Communicable Diseases
 Prevention and Treatment Centers (CPTET, acronym in Spanish) which includes 8 regional HIV/STI/Hep/TB
- ADAP External Providers Network consisting of 39 HIV clinical centers

 Community-based Coordinating Agencies (CBOs) including 8 agencies, each designated to a specific DOH Health Region

A big part of the population living with HIV have government-based health insurance, which covers most medications, labs and medical care. If these services are not covered, Ryan White is the insurer of last resort

Unfortunately, most insurance, including Ryan White, does not cover the use of pre-exposure prophylaxis (PrEP). PrEP is typically accessed through private clinics who have made arrangements with pharmaceutical companies to distribute the medication.

This is starting to change with the EHE initiative, bringing more access to PrEP through government support. I am hopeful we will have access to PrEP services



People with HIV in Puerto Rico

throughout the island soon.

Access to PrEP will be critical for those most at risk for HIV, including men who have sex with men (54%).² There is also increased risk for people participating in intravenous drug use.

In my clinic, I see a range of ages from 16 to 65. One of the biggest problems I see is with the young population. They have what I call "superhero syndrome." They do not believe they are at risk, think HIV can never happen to them and do not fear the virus if they do become infected. They say to me "We have medications available, only one pill daily keeps us healthy and alive, so we don't have any fear or problems if we have HIV."

I understand that, in part, this is a positive point of view because if managed properly, HIV is no longer a death sentence. This outlook can help with stigma. However, the young people I see do not consider that this is a lifelong condition that will always need care. They do not think ahead to the future to consider the co-morbidities that might complicate their health as they age.

We are currently working with universities, pharmacies, the HIV Treaters
Association and the government of Puerto
Rico on a public health campaign targeted
to young people and the general population

to encourage testing and to know your HIV status. We also raise awareness of prevention options like PrEP.

The campaign connects PWH to support groups throughout the island, helping members of the group find access to care, work opportunities, housing options and general emotional encouragement. These support groups are also a safe place to address stigma, an issue that continues to plague Puerto Rico, the rest of the U.S. and many other countries worldwide.

Many of the support groups, such as COAI and APPIA, are localized with the communities. Other centers have support for transgender people, such as Translucent and PRCONCRA. Ryan White clinics also offer support groups for all their patients, offering resources and special events, while at the same time building trust and maintaining better retention in care.

Like in the continental U.S., the political policies in Puerto Rico need to better protect against health inequities and health disparities. While we are a U.S. territory, we don't necessarily have the same policies or are as equally represented as a U.S. state. Because we need better representation within the U.S. government, often we have to make our own policies to ensure our citizens are

safe. On December 1st, 2018, our governor signed a letter stating the rights of PWH. The letter protects the rights that PWH have for housing, access to medications and treatments. It denounces discrimination of all kinds. This is a step in the right direction.

We need to have better tools for improving patient care in order to attract a new generation of doctors who will fall in love with HIV care like I did. It is hard to medical schools to showcase the passion and satisfaction many of us feel for our jobs. It is important for them to understand that PWH are not just patients. They are our friends, sons, daughters, siblings and parents. We care about our patients; we love what we do. **HIV**



DR. VILMARY SIERRA ROSA is

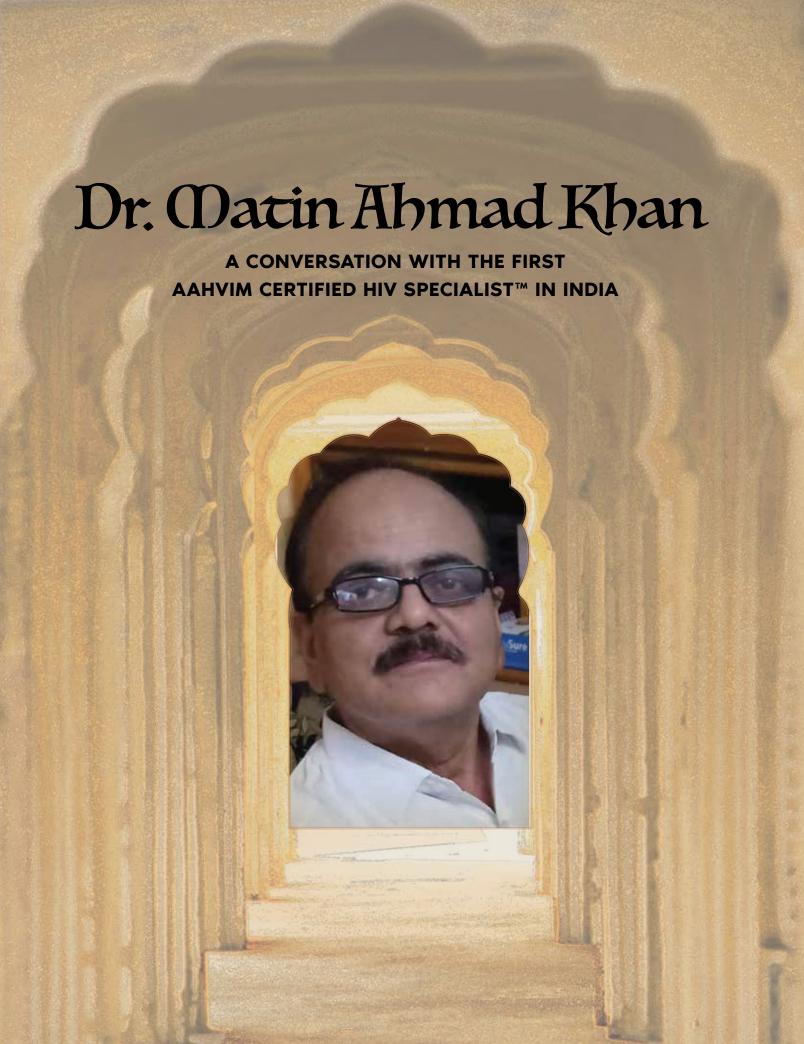
president of the HIV Treaters Association of Puerto Rico, Chair of the American Academy of HIV Medicine's Puerto Rico Chapter,

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Why did you decide to become a doctor?

ENTERED INTO MEDICINE FOR TWO REASONS. The first is because of my father. He wanted to me to study medicine, but passed away before he could see me become a doctor. I did this as a homage to him. Second, I wanted to become a doctor to help serve the poor. I had come from modest beginnings and had seen the poor suffer due to a lack of medical facilities. In fact, my father died in front of me from a massive myocardial infarction. The only doctor on duty was not in the hospital that day. Because it was a Sunday, he was tending to the sports teams playing that day in our town. We just didn't have the medical staff available to save him.

Tell me about your medical training.

I completed my Bachelor's Degree in Medicine (MBBS) and residency from Patliputra Medical College in Dhanbad, Jharkhand in India under Ranchi University Ranchi Jharkhand.

When did you have your first introduction to HIV care?

I first learned of HIV in 1986 while still a medical student and it fascinated me! I followed the advances of HIV very religiously by reading whatever information was published. In those days, there was no internet available, so I would cut newspaper and magazine clippings to learn more. I still remember when the HIV was isolated from tears and the Science Today issue that was completely devoted to HIV/AIDS with a headline saying "Don't Die of Ignorance." I wanted to work in the area of HIV/AIDS, but there was no training available for medical students at the time.

Finally, in 2001, the IMA College of General Practitioners in New Delhi offered a course which I took. That led to a Fellowship in HIV medicine from the School of Tropical Medicine in Kolkata. Thanks to this program, I completed my Masters and Doctorate in HIV Medicine and passed the Academy's' HIV Specialist credentialing exam. I began treating patients in 2007.

I now have 32 years of comprehensive medical care involving 15+ years in government rural & public health and over 17 years in government medical colleges, rising to the level of Associate Professor and Joint Director Care Support & Treatment (JD CST) at Jharkhand AIDS Control under National AIDS Control Organization.

Where do you currently practice?

I currently practice in a private practice in Jamshedpur where I see HIV positive patients. There are some people with HIV that prefer to be seen at government ART centers because they can get free medications there. If my patients can't afford care, I also send them to the ART centers and instruct them to come back to me for follow-up. The more complex cases are usually hospitalize and treated.

How has HIV care and treatment changed since you entered the field?

Many things have changed. When we started treating patients, there were no viral loads available and treatment used to be started at CD4 cut off points. Earlier it used to be at CD4 < 200/mm3, then it was increased to 350 and then to 500. Finally 'Test and Treat' was launched in April 2017 irrespective of any stage or CD4 count.

Initially, we used to prescribe Zidovudine/Stavudine + Lamuvudine + Nevirapine, then Nevirapine was substituted with Efaviranz. Then Stavudine was phased out. Next, Didinosine was less and less used and Zidovudine was changed with Tenofovir (TDF). Many new antiretrovirals (ART) became available such as Atazanavir, Lopinavir, Darunavir, and Dolutegravir. Now, Dolutegravir has been a game changer. Present regimen followed in India is Tenofovir, Lamuvudine and Dolutegravir.

Similarly, we now have better modalities for HIV testing and monitoring treatments.

I have also seen a reduction in stigma among people with HIV (PWH) thanks to the passage of The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act 2017, which was passed September 10, 2018. It aims to prevent and control the spread of HIV/AIDS in India and provides penalties for discrimination against those affected by the virus. There have been laws passed decriminalizing homosexuality (section 377) and adultery (section 497).

What is the current data on HIV in India (how many new cases per year, deaths, etc)?

India, the second most populated country in the world with 1.35 billion people, is home to an estimated 2.349 million PWH, the third-highest population globally after South Africa and Nigeria. India has an HIV prevalence of 0.22 percent (0.17-0.29%). While overall prevalence at the national level continues to be low, the prevalence is much higher in specific locations and population

Around 69,200 (37,000 - 121,000 thousand) people were estimated to be newly infected with HIV in 2019. This is almost 37 percent lower than new infections in 2010 in comparison to the global average of 23 percent, but still, more than twice the envisaged 2020 milestone (75% reductions since 2010). While the number of new infections declined by 44 percent or more in high burden States of Karnataka, Andhra Pradesh, Telangana and Tamil Nadu, this number has been stable or is rising in the States of Mizoram, West Bengal, Chhattisgarh, Uttar Pradesh and Tripura.

Around 58.96 thousand (33.61 thousand-102.16 thousand) PWH population died due to AIDS-related illnesses nationally in 2019. A reduction of 66 percent was achieved since 2010 against the 2020 fast-track target of achieving 75 percent reductions by 2020. The decline has been more than the national average in many of the high-burden states including Andhra Pradesh, Maharashtra, Karnataka, Telangana, Tamil Nadu and West Bengal. Globally, the decline due to AIDSrelated illnesses has been 39 percent.

Nearly three in four (around 76%) PWH nationally knew their HIV status as of March 2020. Among the PWH who knew their HIV status, around 84 percent were on ART. Among PWH on ART, who were tested for viral load, 84 percent were found virally suppressed. Globally, in 2019, 81 percent of the estimated PLHIV were aware of their HIV status, 83 percent of PLHIV who knew their HIV status were on ART and 88% of PLHIV on ART had viral suppression.

Who is most at risk of acquiring HIV in India?

The HIV epidemic in India is highly heterogeneous. It is concentrated in specific regions of the country and in high-risk groups (HRGs) such as people who inject drugs (PWID), female sex workers (FSW), men who have sex with men (MSM) and transgender people. HIV prevalence among Injecting Drug Users (IDU) is almost 28 times higher than that of overall adult prevalence. Similarly, HIV prevalence among Hijra/Transgender (H/ TG) people, MSM and FSW is six to 13 times higher than the adult prevalence. Among inmates in central jails, where the population with high-risk behaviour is over-represented,



HIV prevalence is almost 9 times higher than the adult prevalence.

However, the main mode of transmission in India is heterosexual activity with the most at-risk population being males of reproductive age group who acquire HIV through sexual contact with commercial sex workers. They then, in turn, pass the virus to their wives.

Heterosexual activity accounts for almost 837 of every 1,000 new HIV detections in 2019-20 reported so far. In contrast, almost half (48%) of newly diagnosed cases in Punjab reported acquiring HIV infections through infected syringes and needles followed by 39 percent in Tripura and Mizoram and 25 percent in Manipur.

What are the greatest barriers to care in India?

There are many. And we have to address the all in order to have true progress.

Stigma and discrimination

As I stated earlier, I have seen a reduction in stigma in my personal observation, especially since the passage of the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act 2017, which provides for safeguarding human rights, legal rights and reinforcing constitutional rights of PWH. However, despite the Act's passage, PWH continue to experience moderate levels of discrimination. In 2016, a third of adults demonstrated a discriminatory attitude towards people living with HIV. This is a similar level recorded a decade earlier in 2006, suggesting current stigma-reduction activities are not working.

Stigma and discrimination are very common within the healthcare sector. A 2013 study of doctors, nurses and ward staff in government and non-government clinics in Mumbai and Bengaluru found discriminatory attitudes were common. This included a willingness to prohibit women living with HIV from having children (55 to 80%), endorsement of mandatory testing for female sex workers (94 to 97%) Dr. Khan at a guest lecture at Department of Community Medicine at Kasturba Medical College, Mangalore, Karnataka, India



Dr. Matin with his Principal, his colleagues, staff and wife at his Voluntary Retirement farewell ceremony at MGM Medical College, Jamshedpur, Jharkhand, India

and surgery patients (90 to 99%), and stating that people who acquired HIV through sex or drugs 'got what they deserved' (50 to 83%).

The treating HIV care providers also experience stigma, including myself. I have lost an estimated 25 percent of my general non-HIV patients because they don't want a doctor that treats people they consider "dirty."

Dr. Khan at work



Several studies in India have shown that experiences or fear of being stigmatised are significantly associated with a delay in seeking care, with people particularly worried about having their positive status disclosed to others without their consent. HIV stigma fears have also been reported to lead to suboptimal adherence, missed appointments, and delays in getting prescriptions refilled, thereby interfering with viral suppression.

Gender inequality

There is a need for greater access, analysis and applied use of data within the national HIV response. We need more trained staff to monitor the epidemic. There are also challenges associated with tracking people through the continuum of HIV diagnosis to care and treatment. It is particularly challenging to get "lost" patients back into the treatment system.

Women living with HIV are reluctant to access healthcare for fear of discrimination and marginalisation, leading to a disproportionate death rate in HIV among women.

Data issues

There is a need for greater access, analysis and applied use of data within the national HIV response. We need more trained staff to monitor the epidemic. There are also challenges associated with tracking people through the continuum of HIV diagnosis to care and treatment. It is particularly challenging to get "lost" patients back into the treatment system.

Structural and resource barriers

There has been supply chain bottlenecks more so during the COVID-19 pandemic. It is unfortunate that HIV care staff make very meager salaries.

Funding

The funding for HIV has been reduced globally. With declining funding from external donors, any change in policies may have major financial implications in India considering the fact that we have a large number of people living with HIV/AIDS..

Covid

Provision of ART during the pandemic restrictions and lock downs, particularly to HIV key populations, sex workers and LBGTIQ+ communities, has been very challenging. Naturally experts treating HIV/AIDS are worried that the COVID-19 pandemic has delayed the World Health Organisation's target to improve the life of people with HIV (PWH).

What is the government of India doing to help combat HIV/AIDS?

India is committed to achieving Sustainable Development Goal (SDG) 3.3 for ending the AIDS epidemic as a public health threat by 2030. We have a national initiative to combat HIV and reach this goal. The National AIDS Control Programme (NACP) was launched in 1992 and is implemented by the National AIDS Control Organization (NACO) under the Ministry of Health and Family Welfare. There are several programs and initiatives the NACP oversees.

One government initiative focuses on Opioid Substitution Therapy (OST). This program is being implemented as a critical component of harm reduction programme under NACP through 226 OST centers. Around 20 percent of the IDUs are on OST as of March 2020 in comparison to 15 percent coverage in 2017-18

The Government of India launched free ART on 1st April, 2004 at 8 centers under the second phase of the NACP. Since then, the program has evolved into a robust three-tier system. ART centers (n=553) across the country, mostly located at medical colleges and district hospitals, are fundamental to this service delivery mechanism. The decentralization of services has been achieved through the establishment of Link ART Centres (LAC) and LAC plus (1327). 310 Care & Support Centres (CSCs) facilitate access to essential services, thereby increasing treatment adherence and reducing stigma and discrimination. The ART centers are mapped to Centres of Excellence (CoE): Adult (11) and pediatric (7) and ART Plus centers (93) at select teaching institutions for timely initiation of the second and third line of ART.

The Government of India launched "Test and Treat" model on 28th April, 2017 to put PWH on ART as soon as they are detected HIV positive, irrespective of their CD4 count. The objective was to improve the survival rate and quality of life of HIV infected persons at the individual level. In 2019-20, for every 100 HIV infected people identified at HIV counselling and testing centers, 88 PWH were initiated on ART.



Dr. Matin delivering a Guest lecture on ART at Department of Pharmacology, Yenepoya Medical College, Mangalore Karnataka India.

India is a signatory to the Joint United Nations Programme on HIV and AIDS (UNAIDS) goal of Elimination of Mother to Child Transmission (EMTCT) of HIV by 2020. The Prevention of Parent to Child Transmission (PPTCT) programme is being implemented under NACP to achieve the EMTCT goal. Almost 2.45 crore HIV tests among pregnant women were conducted in 2019-20. This translates into 82 tests for every 100 estimated pregnant women against the target of 95 tests by 2020. Bihar, Nagaland, Odisha and Uttarakhand are critical States with around 67 HIV tests done for every 100 estimated pregnant women. Uttar Pradesh is another high burden State recording less than 75 tests for every 100 estimated pregnant women.

Among the total HIV-positive pregnant women covered under the programme, the proportion of ART has hovered around 90 to 91 percent since 2017-18. This is a significant challenge to the programme because of the committed ART coverage target of ≥95 percent under the program to achieve EMTCT. The challenge is specifically in the States of Arunachal Pradesh, Haryana, Himachal Pradesh, Jharkhand, Nagaland, Puducherry and Sikkim where less than 70 percent of HIV-positive pregnant women were initiated



on or were already on life-long ARTs.

During 2018/19, out of 13,760 babies exposed to HIV, 86 percent were initiated on antiretroviral (ARV) prophylaxis to prevent transmission. However, only 23 percent of babies born to mothers enrolled in PPTCT programmes were tested for HIV before eight weeks of age to confirm whether transmission had been prevented. In addition, only 20 percent of HIV positive mothers are thought to breastfeed exclusively in the first six months of their baby's life, despite this being likely to decrease the risk of HIV transmission by between three- and four-fold.

Has PrEP been well received in India?

Pre-exposure prophylaxis (PrEP) is not widely available in India because it is still not included in the NACP. There have been two community-led and community-owned initiatives to provide PrEP to female sex workers. Most notably, the Ashodaya PrEP demonstration project was supported by the Bill & Melinda Gates Foundation. Sex workers in India had been concerned by the fact that, although condom use was high, some sex workers still acquired HIV. The PrEP demonstration project, which began in April 2016 and ended in January 2018, reported good results. High levels of continuation on PrEP were reported, with 99 percent of the 647 participants completing the 16 months of follow-up.

During 2018, up to 800 people were accessing PrEP through one of these two demonstration projects. According to empirical data, by April 2021 the estimated number of current users of PreP is approximately 1000-1500 as per the demonstration projects and the PrepWatch dashboard.

Some physicians in more populated, metro areas may be prescribing PreP on demand, but no data are available.

What is your greatest accomplishment?

During my fellowship in HIV medicine in 2006, we participated in a project to diminish stigma and discrimination again PWH. At this time, stigma was very high. Our hospital was sending HIV positive mothers to different hospitals because no one wanted to deliver the babies due to fear and lack of proper scientific knowledge. I decided to work with the paramedics and nursing staff to educate them on the latest science and help them understand how to show affection and respect for PWH through role playing. At the end of the project, our staff successfully delivered a child for an HIV+ mother.

This still stands as my greatest accomplishment. Training the staff was also acknowledged by AAHIVM by awarding my Fellowship in HIV Medicine from School of Tropical Medicine with the Inaugural Peter Fox Award for excellence in 2012. This award and being the only credentialed HIV Specialist (AAHIVS) in India are close seconds as far as my accomplishments!

How long will you continue to practice medicine?

I have a plan to remain active in clinical practice until the age of 72, which is 12 years away. I have already practiced comprehensive health care for over 32 years, with almost 14 years in HIV care. I intend to complete at least 25 years in HIV care before retiring from my clinical practice.

Do you think we will have a cure for HIV one day?

Yes, we will have cure one day.

The cost of providing universal access has become unsustainable and accumulating evidence underscores the detrimental effects of persistent HIV infection even while plasma viral load is low and CD4 cell count is high. Achieving either a functional cure (long-term control of HIV in the absence of HAART) or a sterilizing cure (elimination of all HIVinfected cells) remains a major challenge.

Most recently, broadly neutralising monoclonal antibodies (bNab) have shown great promise. Results of a "proof of concept" study presented at the virtual 4th Annual HIV Research for Prevention Conference in Feb 2021 showed that one particular broadly neutralising monoclonal antibody (bNab)-called VRC01-prevented HIV infection in over 70 percent of people exposed to strains of HIV that is sensitive to this particular bNab. This is promising because it marks the first time that a natural substance, produced in a human body, can prevent HIV infection.

The familiar admonition to 'Cure occasionally, relieve often, console always "comes from the ancient French aphorism 'Guirer quelquefois, soulager souvent, consoler toujours.' This proverb superbly fits into the natural history of HIV/AIDS.

"Cure" comes from Latin word "cura" meaning "care, concern, attention." The current use of word seemingly sprang from the belief that proper and sufficient "care" was tantamount to "cure." If only this were so! HIV



Health Minister Jharkhand congratulating Dr. Khan as **COVID** warrior

PRACTICES

Critical Mentorship

Empowering Mentor-Mentee Relationships towards Transformative Learning

BY ROQUE ANTHONY F. VELASCO, MS, AGPCNP-BC, AAHIVS

The author, Roque Anthony Velasco, is a participant in the Academy Mentoring Program. To learn more about the program, please visit the Academy site at https://community. aahivm.org/mentoring.

ENTORSHIP IS ESSENTIAL to professional growth, especially among early career healthcare professionals. Several studies in various healthcare disciplines underscored the importance of mentorship in creating supportive and collaborative relationships, fostering professional development, and providing psychosocial support. 1-4 Mentorship programs, like the one offered by the American Academy of HIV Medicine, can also offer mentees additional training and education opportunities, promote research productivity such as increased publication and grant success, and enhance interdisciplinary professional networks.^{3,5} Similarly, mentoring relationships benefit mentors by creating opportunities to teach, influence their discipline, expand personal knowledge and skills, and reflect on personal practice. 6 Improved self-esteem by actively participating in the growth of their mentees is also a notable benefit of mentorship. Furthermore, mentors reported increased job satisfaction, career advancement, and productivity. 3,6-7

Building leadership capacity was also a notable benefit of mentorship.³ In a study of leadership development through mentoring programs, generativity—a term used to describe a commitment to caring and nurturing the next generation—was enhanced for both mentors and mentees. 8 In addition to mentors developing a stronger sense of generativity by preparing their mentees to be future leaders in their fields, a ripple effect of generativity was also observed among mentees when they started becoming informal mentors to others.8 These findings also substantiate current literature that described generativity as a strong predictor of socially responsible leadership, illustrating the vital role of mentorship in meeting the professional obligation to foster a new generation of healthcare professionals.

Towards Critical Mentorship

Mentorship can also empower mentors and mentees by creating a space for critical self-reflection that leads to growth and emancipatory learning. Programs that incorporate critical mentorship moves research and praxis from a dominant discourse to a transformative

examination of various socio-cultural identities such as race and ethnicity, gender, sexual orientation, and class. 10-12 This approach is particularly important in HIV care as people living with HIV are inherently subjected to oppressive structures and discourses that interfere with healthcare access and delivery.

For instance, when discussing vulnerability to HIV and pre-exposure prophylaxis (PrEP) for at-risk transgender people, my mentee and I had an in-depth conversation about inequities in care:

Some groups of people have increased vulnerability, which places them at risk for HIV. We need to assess these vulnerabilities so we can evaluate the need for interventions like PrEP.

Like with transgender people?

Yes. Transgender people are vulnerable to HIV.

But why are they at risk?

Well, we first need to talk about the difference between risk and vulnerability. When we talk about risk, it is about the likelihood of acquiring conditions like HIV. When we talk about vulnerability, it is about those factors that influence someone to engage in certain behaviors that might place them at risk for—in this instance—HIV.

Like transgender people and limited access to culturally informed care or how stigma is a barrier to care?

Yes! You are right! While HIV disproportionately affects transgender people, especially transgender women of color, gender identity is not what places them at risk for HIV. Transmisogyny, structural racism, and social and structural determinants of health all influence the risks of transgender people

to HIV. These social and structural factors make them vulnerable to HIV. We also have to understand how these factors contribute to the risk for HIV. Also, these vulnerabilities are significant contributors to the health disparities transgender people face.

This conversation illustrates that while didactic content is essential in building a solid foundation of HIV-related knowledge and skills through mentorship activities, a transformative learning process is critical to understand and contextualize the needs of people living with HIV.

Critical mentorship can also challenge power dynamics within traditional mentoring relationships by shifting modes of learning from a passive method to an active one. 11 Having this critical approach in mind, mentors must acknowledge how their privilege influences the mentoring relationship. Furthermore, mentors also need to recognize the fresh perspectives their mentees bring. Indeed, mentorship can empower both mentors and mentees by engaging with critical self-reflection leading towards growth and emancipatory learning.

Meeting the Demands through Mentorship

Mentoring can also facilitate recruitment and addressing HIV workforce shortages. In a survey of Academy members, 23 percent of respondents reported that they intend to retire from practice within the next 10 years. Furthermore, approximately 40 percent of Academy members reported difficulty hiring experienced HIV providers and

pharmacists. 13 These findings reflect the landmark study of HIV provider workforce that illustrated a small but growing shortage of HIV providers and pharmacists.¹⁴ The study also underscored the increasing importance of nurse practitioners and physician assistants in meeting these shortages.¹⁴ Since there are differences in scope of practice and HIVrelated education and training among nurse practitioners and physician assistants, it is even more imperative to have HIV-mentoring programs. These mentorship opportunities can also serve as a pathway of engaging non-HIV clinicians in HIV care, potentially providing some relief to the growing shortage.

The Academy's Mentoring Program

The Academy Mentoring Program provides an opportunity to connect experienced HIV care providers to other physicians, nurse practitioners, physician assistants, and pharmacists interested in HIV care. This mentorship program was designed to meet the learning and professional development needs of both the mentors and mentees. While the program was structured to be a one-on-one six-month mentoring relationship, mentors and mentees may decide to extend the relationship longer. The program was also thoughtfully planned to connect mentors and mentees with similar interests and backgrounds. This is particularly relevant in mentorship programs as formal mentor-mentee relationships can occur across various socio-cultural identities. Indeed, acknowledging that dyads match across different

races, ethnicities, sexual orientations, gender identities, and professional backgrounds and experiences is essential since these factors may play a significant role in the success of the mentoring relationships.

Conclusion

Mentoring is a collaborative and lifelong process that fosters professional and personal growth for both the mentors and mentees. With the increasing shortage of HIV providers, mentorship programs are a valuable solution in encouraging other providers to be involved in HIV care. Additionally, while mentoring relationships are often formalized and designed to facilitate career development and advance knowledge and skills, mentoring is also an effective medium in promoting socially responsible leadership while engaging both mentors and mentees in critical conversations about social justice and health equity. Indeed, mentorship programs can be used to create safe spaces for meaningful dialogues that foster learning that is participatory, transformative, and emancipatory while addressing the need for more HIV providers. **HIV**



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TLIGHT

BY AARON AUSTIN, MEMBERSHIP DIRECTOR

Leonard Sowah, MBChB, MPH, FACP, AAHIVS, Bethesda, Md.



THE YEAR WAS 2005 and Dr. Leonard Sowah was in the second year of his internal medicine residency at the John H. Stoger Hospital in Cook County, Ill. It was there that he began providing HIV care as part of a weekly clinic. "I grew up in Ghana and first heard about HIV in the early 1980s when almost all infected people died," Dr. Sowah recalls. "In my experience at that time HIV was the newest kid on the block, like we have Covid-19 today, so I must say I was attracted by the novelty and the many unknowns. I still was not sure at residency whilst I had a weekly HIV clinic, I also had an oncology clinic."

Prior to coming to the United States, Dr. Sowah studied medicine at the University of Ghana in Accra. While in Accra, he had internships in internal medicine and OBGYN. He then moved to Chicago to complete his internal medicine residency. During that time, Dr. Sowah's interest in HIV further developed, with a weekly HIV clinic. He accepted his first job after residency because it offered him the option of doing HIV care. Thereafter, Dr. Sowah then moved to Baltimore to work at Healthcare for the Homeless. Since that time, he has worked in academic and community hospital settings across the state of Maryland. Dr. Sowah practiced mostly in urban and suburban settings but also worked two days a week providing HIV care in rural communities on the Eastern Shore of Maryland. His patient populations tended to be older but over time most of his patients were younger gay Black men.

In 2013, as clinical faculty at the Institute of Human Virology at the University of Maryland in Baltimore, Dr. Sowah worked on a HIV workforce development project funded by the CDC in Georgetown, Guyana. He collaborated with University of Guyana physicians to develop a HIV-focused internal medicine residency at Georgetown Public Hospital. "This was a major undertaking in a country like Guyana with a medical school but no structured internal medicine residency in the country," Dr. Sowah shares, "Though we lost funding and had to leave in 2014, my sources in Guyana tell me our program still survives today."

As a HIV specialist physician in Baltimore, Dr. Sowah served on the Ryan White HIV Planning Council and was the chair at the time the Affordable Care Act (ACA) was passed. In this role, Dr. Sowah and his team strategized on how to reallocate funding since they knew Medicaid expansion could potentially make it difficult to adequately

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utilize Ryan White funds according to federal rules. "We realized that as primary medical care of most Ryan White clients ended up being taken care of by Medicaid, the funding which had always been allocated at a 75/25 split between medical care and support systems would have a challenge in spending money. Based on input we sought from multiple stakeholders including the late Dr. John Bartlett and former CDC Director Dr. Robert Redfield, we applied for a waiver from HRSA which allowed us more flexibility in the use of funds. HRSA ended up sending other EMAs (Eligible Metropolitan Areas) to our team when they were considering such initiatives."

Today, Dr. Sowah works at the Division of AIDS at the National Institute of Allergy and Infectious Diseases (NIAID/NIH). He serves as a clinical science consultant in the development of clinical trials in the area of HIV and viral hepatitis. His program, the Therapeutic Research Program, contains approximately 40 clinicians and scientists who serve in various roles in HIV research. His



specific focus areas are in HIV-associated co-infections, mostly viral hepatitis, as well as in non-infectious complications of HIV. Dr. Sowah shares, "In my current role I do not see patients in the traditional sense. I do, however, have clinical oversight of the participants enrolled in the trials within my portfolio. So, in that regard, my patients span multiple countries and continents."

Though he is no longer working at clinics, Dr. Sowah encourages all HIV care providers, especially those with gay men in their clinic, to include anal pap smears in their practice. Dr. Sowah also advises, "We should learn to appropriately screen for STIs like gonorrhea and chlamydia using rectal and oral swabs where appropriate. During my time at University of Maryland we started out by incorporating anal paps in our clinics and referring our abnormal screens to our colleagues in colorectal surgery. Over time, with the help of one of my colleagues, we started doing the high resolution anoscopies ourselves. This was a great addition to our practice at that time. One thing, though, that I do not believe we did well was figuring out how to make that procedure pay for itself. I still encourage providers to consider anal cancer screening as a quality improvement project for your clinics." Dr. Sowah also believes that success in getting patients to adhere to their medications lies in knowing their most important motivations. While there is no one-size-fits-all method for ensuring adherence, overall reduction in treatment complexity helps.

"What I like most about working in the HIV field is the clear change that I have seen in the lives of our patients over the decades. The progress that has been made in HIV treatment and research within the course of my lifetime is so transformative, I am in awe of all that has been done." Dr. Sowah continues, "Another aspect of my work which has brought joy was being able to cure hepatitis C. The wonder of research made possible for us to cure a person of hepatitis C after two to three months of treatment. The joy on the faces of patients when they hear they have been cured was enough to keep me working even in bad situations."

When asked to consider obstacles facing HIV care providers, Dr. Sowah says, "The greatest hurdles have always been the difficulties with coverage. I hate doing prior authorizations but will still do it to get a patient treated. The worst part that also sometimes was the most rewarding, was being on the calls with the insurance company medical directors. A well-crafted argument is usually all that is required to get a treatment approved."

As for the future of HIV, Dr. Sowah says, "Cabenuva, the combination for long acting carbotegravir and rilpivirine just got approved, so my future is already here. I hope in 10 years from now there will be more and easy to use long-acting agents for both HIV and associated infections like hepatitis B and C. Most patients will see their providers once to twice a year. There hopefully will be a vaccine or other non-user dependent HIV-prevention technologies available to patients." Beyond his professional life, Dr. Sowah is an avid cyclist and has been doing century rides for the past ten years. "Most of my Spring, Summer and Fall weekends are spent either biking or hanging out with my family. I also have a blog that I use to express my views on almost any topic that piques my fancy. My blog topics are, however, mostly health-related and in the past four years I wrote quite a few essays on current political situations." Asked why he became an Academy member, Sowah shares, "I first joined because my first job after residency required me to get credentialed. In those days, the Ryan White Grant Office in Baltimore encouraged its grant recipients to have their workers credentialed as HIV specialists." HIV

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

CLINICAL RESEARCH



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

FEATURED LITERATURE:

Schnittman SR, Zepf R, Cocohoba J, Sears D. Heplisav-B Seroprotection in People with HIV: A Single-Center Experience. J Acquir Immune Defic Syndr. 2021 April 1; 86(4): 445-449. doi: 10.1097/QAI.000000000002573. PMID: 33196553.

Hepatitis B virus (HBV) vaccination for people with HIV (PWH) is an important prevention intervention that decreases risk of developing chronic liver disease and related complications such as hepatocellular carcinoma. Among PWH, serologic response to primary vaccination with older HBV vaccines (e.g., Engerix-B, Recombivax HB) varies notably and has led to multiple vaccination studies and strategies. The purpose of this retrospective cohort study was to examine seroprotection rates (SPR) and predictors among adults without current HBV seroprotection (defined as anti-HBs < 10 mIU/mL) followed at a single quaternary care center HIV clinic who received at least one dose of Heplisav-B. Heplisav-B was approved in 2017 as a two-dose vaccine and contains an immunostimulatory adjuvant; of note, PWH were not included in the trials which led to initial FDA approval. Among 64 PWH engaged in care at the study location, 63 received a complete two-dose series, and 81 percent demonstrated post-vaccination seroprotection overall (defined as anti-HBs titers ≥ 10 mIU/ mL); 63 percent achieved anti-HBs titers ≥ 100 mIU/mL. Seroprotection rate was 86% in patients without significant non-HIV immunosuppression, e.g. decompensated cirrhosis, solid organ transplantation, metastatic cancer, active chemotherapy, or asplenia. Seroprotection rates among PWH who underwent primary vaccination with Heplisav-B versus among PWH without a history of seroprotection after receiving older HBV vaccines (and subsequently received Heplisav-B) were 79 percent and 84 percent, respectively. Higher current and nadir CD4 cell counts were associated with seroprotection (p < 0.001 for both). There were no differences in pre- and post-immunization HIV viral load measurements; 90 percent of patients were virologically suppressed on ART.

AUTHOR'S COMMENTARY

This is the first published report describing immunogenicity and factors associated with seroprotection among PWH who underwent Heplisav-B vaccination. Research findings presented at CROI and other large scientific and clinical meetings will likely command HIV providers' attention over the next few months. However this single-center analysis is informative and valuable. Despite a relatively small sample size, results suggest Heplisav-B associated seroprotection rates are high among PWH, especially persons with high CD4 counts and no significant immunosuppression. Favorable serologic response rates were also observed among persons who had not responded to older HBV vaccines. This may inform new revaccination strategies, which might be especially useful given ongoing differing approaches to revaccination. HIV providers will likely universally welcome future results from NIAID's B-Enhancement of HBV Vaccination in Persons Living with HIV (Bee-HIVe) study,* which aims to evaluate response to and safety of Heplisav-B in populations with HIV (NCT04193189, Clinical Trials.gov).

*Not yet recruiting

FEATURED LITERATURE:

Scherer M, Kamler A, Weiss L, et al. Toward safer opioid prescribing: effects of the TOWER intervention on HIV care providers. AIDS Care. 2021 March 9; 1-6. doi: 10.1080/09540121.2021.1887444. PMID: 33719775.

Recent shifts in opioid prescribing practices, although well-intentioned and necessary at times, have also led to decreased access and adverse outcomes for some stable, opioid-treated patients experiencing chronic pain. TOWard SafER Opioid Prescribing (TOWER) is a provider-facing intervention designed to support HIV primary care providers' adherence to CDC Opioid Prescribing Guidelines. TOWER includes three components: prescription opioid management training including patient-recommended communication strategies; access to patient-reported risk-benefit data via an app; and a medical encounter note template. This study describes qualitative findings of a randomized trial examining outcomes among TOWER-trained providers versus usual care. Review of visit content demonstrated greater guidelines alignment among intervention provider encounters: topic areas with greatest discrepancies included discussions of treatment goals and progress assessment, opioid medication adherence review, and evaluation (and discussion) of harms/risk factors.

AUTHOR'S COMMENTARY

Opioid use disorder, overdose deaths, and safer prescribing remain challenging issues for many providers and communities. These findings suggest that interventions such as TOWER are feasible and may help facilitate guidelines-concordant opioid prescribing and management. Further implementation and evaluation regarding intervention effectiveness and patient-oriented outcomes are important. Additionally, this information may motivate HIV providers to consider modifications to their patient interviewing and counseling styles/habits to include regular, collaborative discussions of benefits/ harms of long-term prescription opioid use and reassessment of individual treatment goals and progress toward those goals.

FEATURED LITERATURE:

Crawford ND, Myers S, Young H, Klepser D, Tung E. The Role of Pharmacies in the HIV Prevention and Care Continuums: A Systematic Review. AIDS Behavior. 2021 June; 25(6): 1819-1828. doi: 10.1007/s10461-020-03111-w. Epub 2021 Jan 2. PMID: 33386509.

Pharmacies are innovative access points to expand HIV care and services. However, the scientific evidence describing and evaluating pharmacy-based interventions is limited. This systematic review aimed to synthesize and assess the recent literature on pharmacist roles across the HIV prevention and care continuums and identify key research gaps/ priorities. Investigators searched studies published between January 2004 and August 2019 involving non-hospital-based U.S. pharmacy settings/ programs. Thirty-two studies underwent complete review and were organized around the following themes: (a) HIV testing; (b) syringe access and harm reduction; (c) post-exposure prophylaxis; (d) pre-exposure prophylaxis; and (e) antiretroviral therapy. Findings suggest pharmacy-based HIV testing is feasible and effective at reaching some populations believed to be at "highest risk" (e.g., people with no prior testing history and people who report high HIV stigma). A small number of studies have examined pharmacists' attitudes towards selling non-prescription syringes: the majority believe pharmacies to be important resources for people who use/inject drugs. In one study, 59 percent indicated willingness to provide health information and referrals.

The literature on pharmacy involvement with post-exposure and pre-exposure prophylaxis (PrEP) is modest. Recent studies have highlighted the benefit and feasibility of PrEP screening and same-day dispensing although important questions (including reimbursement-related concerns) remain. Few studies have utilized pharmacies to promote and/or support ART adherence among people with HIV. Data suggest people who obtain ART from HIV specialized pharmacies are more likely to obtain refills; also, when pharmacists provide more HIV counseling, adherence and viral load improvements are observed.

AUTHOR'S COMMENTARY

Pharmacy-based HIV testing appears to be highly feasible and acceptable to both staff and clients, especially in settings offering other routine prevention services (e.g. vaccinations, hypertension screenings). In comparison, pharmacy-based syringe access services, pre- and post-exposure prophylaxis, and ART/HIV treatment support are interventions that, while highly promising, are less well-studied. In many U.S. areas, and through legislative support, pharmacies have become uniquely positioned as vital community resources that can offer prevention services for people who inject drugs. Rigorous study design and inclusion of implementation science frameworks are critical elements for building a sufficient evidence base to help further raise the visibility of pharmacies in ending the HIV epidemic and promote broader adoption and scale-up.

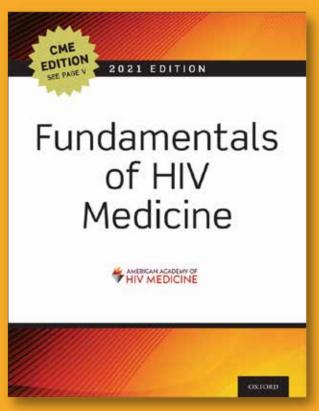
FEATURED LITERATURE:

Massad LS, Xie X, Minkoff HL, et al. Frequency of high grade squamous cervical lesions among women over age 65 years living with the human immunodeficiency virus. Am J Obstet Gynecol. 2021 May 3; S0002-9378(21)00535-4. doi: 10.1016/j. ajog.2021.04.253. PMID: 33957115.

Current guidelines for cervical cancer screening cessation differ by HIV status: specifically, screening in women with HIV is recommended throughout a woman's lifetime (i.e., not end at 65 years of age as recommended for the general population). This analysis, utilizing data from the WIHS cohort, attempted to determine the proportion of women reaching age 65 years who would be eligible to end screening and the incidence of subsequent high grade squamous intraepithelial lesions (HSIL) among such women. Pap testing data through September 2019 for 169 eligible participants (121 women with HIV, 48 seronegative women) were analyzed. 2.2 percent had high grade cytologic abnormalities; no cancers were diagnosed during follow-up. Twenty women had prior precancer and 74 had abnormal Pap results within the prior decade. Fourty-eight women (27 women with HIV, 21 without HIV) met current guidelines to stop screening; their risk of HSIL was 2.2/100 woman-years overall and did not vary by HIV status (2.3 versus 1.8/100 woman-years, p=0.81).

AUTHOR'S COMMENTARY

Optimal cancer screening for people aging with HIV remains an important topic of HIV medicine, and this analysis provides data that might help guide information-sharing and shared decision making for women with HIV who are 65+ years of age and their providers. Investigators found that most women with HIV who reach age 65 do not meet criteria for exiting screening. However, for those who do meet criteria, HSIL risk is similar to the risk observed among seronegative women. Thus, authors suggest "women living with HIV should be offered the option of screening cessation as part of an informed discussion of the risks and potential benefits of screening, recognizing that the 2 percent annual HSIL risk ... may persuade many in good health to continue screening." It is also worth noting that many patients have limited documentation of prior screening/testing results (which might be avoidable at times), often leading to challenges in confident decision making regarding ongoing screening. HIV



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