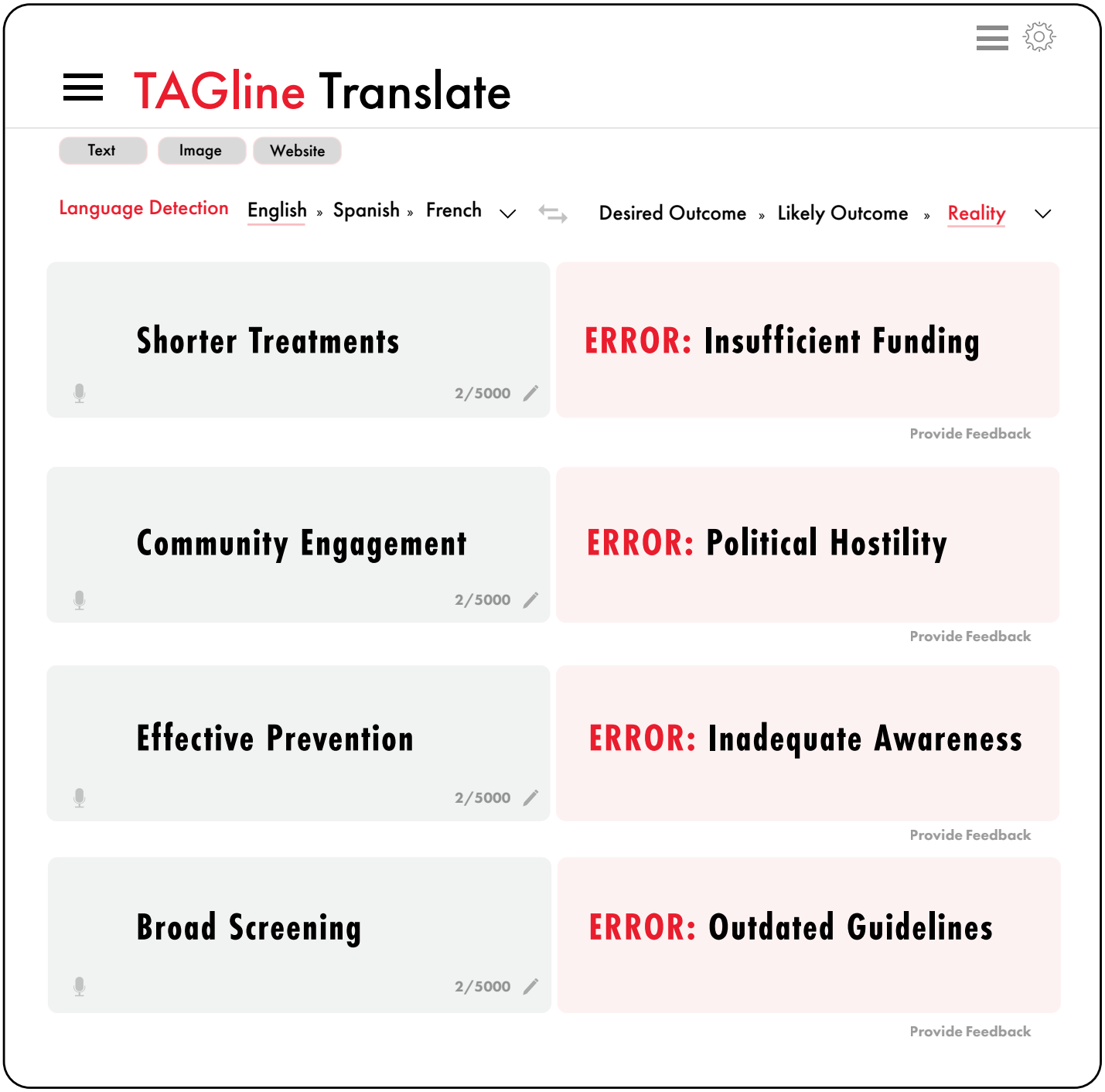
tagline Vol. 30, No. 1, October 2023

tagline

NEWS ON THE FIGHT TO END HIV/AIDS, HEPATITIS C, AND TUBERCULOSIS

LOST IN TRANSLATION



TRANSLATING SCIENTIFIC RESEARCH FROM LABS TO LIVES

By Natalie Shure

In the years since I developed drug-resistant tuberculosis (DR-TB) in 2010, the field has welcomed several scientific advances that would have fundamentally changed my experience of living with the disease. For one thing, my two-year treatment course, anchored by painful injectables and inconvenient infusions that warped my hearing, could likely be replaced with a six-month all-oral regimen today. The process to test drug susceptibility on TB cultures that took weeks in 2010 can now be completed in two hours on a GeneXpert machine, and the then six-month preventive treatment doled out to close contacts can now be accomplished in as little as one month. And scientific research of the not-so-distant past has had an even more dramatic impact on HIV and HCV, with the introduction of combination antiretroviral therapy (ART) and direct-acting antivirals greatly improving the prognosis of anyone who acquires these viruses.

As anyone who works in HIV, TB, and HCV knows, even the most groundbreaking scientific research can't implement itself.

All told, the state of the science surrounding HIV, TB, and HCV today is on much more solid ground than it has been in decades past. Years of community-led advocacy for research into better prevention, diagnostics, and treatment — much of it still ongoing — have finally paid off.

Yet scientifically validated new tools can only do so much on their own. As anyone who works in HIV, TB, and HCV knows, even the most groundbreaking scientific research can't implement itself. Information about emerging and longtime frontline treatment, not to mention drugs themselves, still aren't making their way to everyone who needs them. Nearly a quarter of people living with HIV around the world are not currently accessing ART, and fewer than a quarter of people who could benefit from preexposure prophylaxis (PrEP) are currently taking it. Over three-quarters of people with HCV have not been treated, and fewer than 60% of people living with TB disease are on treatment — even fewer for drug-resistant TB and for children. Throughout the TB prevention and care cascades, updated tools and insights — gold standard testing strategies, most effective regimens, research on effective psychosocial interventions — are delayed or denied over the course of their translation from research studies into practice in people's lives.

For the 2023 issue of *TAGline*, we take a closer look at just a few of the multitude of factors that contribute toward science getting lost in translation from the laboratory to real-world settings. Making this process faster and smoother could be the difference between an arduous, unacceptable intervention and a convenient one, a minimal failure rate or a moderate one, suppression or cure and ongoing transmission, or even life and death. The articles that follow go beyond merely analyzing barriers to implementing research that could result in progress toward ending HIV, TB, and HCV to discuss how various actors could rise to meet these challenges.

Lynette Mabote-Eyde and Mike Frick take stock of the state of TB preventive treatment (TPT) around the world, exploring nuances that help explain why newly validated TPT regimens still aren't universally used by household contacts of people living with active TB disease. While previous iterations of TPT

Making this process faster and smoother could be the difference between an arduous, unacceptable intervention and a convenient one, a minimal failure rate or a moderate one, suppression or cure and ongoing transmission, or even life and death.

lasted for six to nine months or more and caused considerable liver toxicity, the more recently introduced 1HP and 3HP — meaning one month of daily isoniazid (H) and rifapentine (P), or three months of once-weekly H and P — regimens using rifapentine can now prevent TB in as little as one or three months with relatively minimal side effects. They point to issues including inadequate contact tracing, rifapentine shortages, and low public awareness of advances as reasons TPT isn't catching on as quickly as it should be and highlight community partnerships through the Aurum Institute's IMPAACT4TB initiative as a model for increasing uptake of 1HP and 3HP in high-burden communities.

Ultimately, the questions explored in this edition of *TAGline* are at the heart of our work.

De'Ashia Lee, Kendall Martinez-Wright, and Lizzy Lovinger warn that rising anti-LGBTQ+ sentiment in the United States and around the world poses an existential threat to public health. They walk readers through research on how homophobia and the legal landscape affect things such as HIV testing and access to care, concluding that recent legislation and political events are creating hostile environments in many jurisdictions where LGBTQ+ people are being stigmatized, discriminated against, and driven away from services where they might access evidence-based interventions to preserve their health and lives.

Erin McConnell offers a somber assessment of how social media supercharges anti-vaccine movements, turning people away from these lifesaving prevention tools. She reminds us that ensuring research doesn't get lost in translation requires proactive early action, arguing that digital advocacy must be part of vaccine preparedness and rollout strategies for future vaccines, including those for HIV, TB, and HCV.

Finally, Joelle Dountio Ofimboudem and Sara Helena Gaspar look to reimagine HCV elimination strategies now that intellectual property is no longer restricting access to generic cures. They explore how the lack of political will, under-resourced national-level regulatory bodies, countries' failure to modernize guidelines for diagnosis and harm reduction to reflect best available evidence, and a lack of funding are preventing DAAs from wider dissemination.

Ultimately, the questions explored in this edition of *TAGline* are at the heart of our work. By fighting for affected-community engagement at every step of the research, development, implementation, and policymaking process, we aim both to advocate for the generation of useful scientific research and also to ensure it translates into meaningful benefits for people living with HIV, TB, and HCV.

ARE WE THERE YET? TB PREVENTIVE TREATMENT BEYOND TB/HIV INTEGRATION

By Lynette Mabote-Eyde and Mike Frick

Too often, major scientific advancements against tuberculosis (TB) get lost on the long and winding road of policy translation into practice. TB preventive treatment (TPT) has faced decades of dislocation between progressive global World Health Organization (WHO) guidance and lagging national-level guidelines and programmatic implementation. In some places, however, TPT programs are coming closer to matching recommended practice thanks to persistent advocacy by civil society and communities affected by TB. Speaking in a united voice, advocates have leveraged the components of the Availability, Accessibility, Acceptability and Quality (AAAQ) framework — a human rights standard for defining access under the rights to health and scientific progress — to strengthen national-level TPT responses by policymakers and HIV and TB programs within ministries of health.

This advocacy has brought about a tectonic shift in the visibility of newer, short-course TPT regimens called 3HP and 1HP that are based on the drug rifapentine. These regimens pair rifapentine with a second drug called isoniazid and can be completed in 12 weeks (3HP) or as little as 28 days (1HP). According to WHO data, 185,350 people in 52 countries were treated with rifapentine-containing TPT regimens in 2021, an increase from 25,657 people in 37 countries in 2020.[1] This sizable jump did not result from the concerted effort of a single year, but rather the accumulation of many actions taken over the last five years. Using the shortest, best regimens based on rifapentine to prevent TB is key to realizing Sustainable Development Goal 3, which aspires "to ensure healthy lives and promote well-being for all at all ages," including by ending the TB epidemic by 2030. This impressive recent progress demonstrates the importance of community-led TPT implementation and advocacy, and provides a roadmap for navigating the considerable distance left to travel before access to the best available standard of TB prevention becomes the norm rather than the exception.

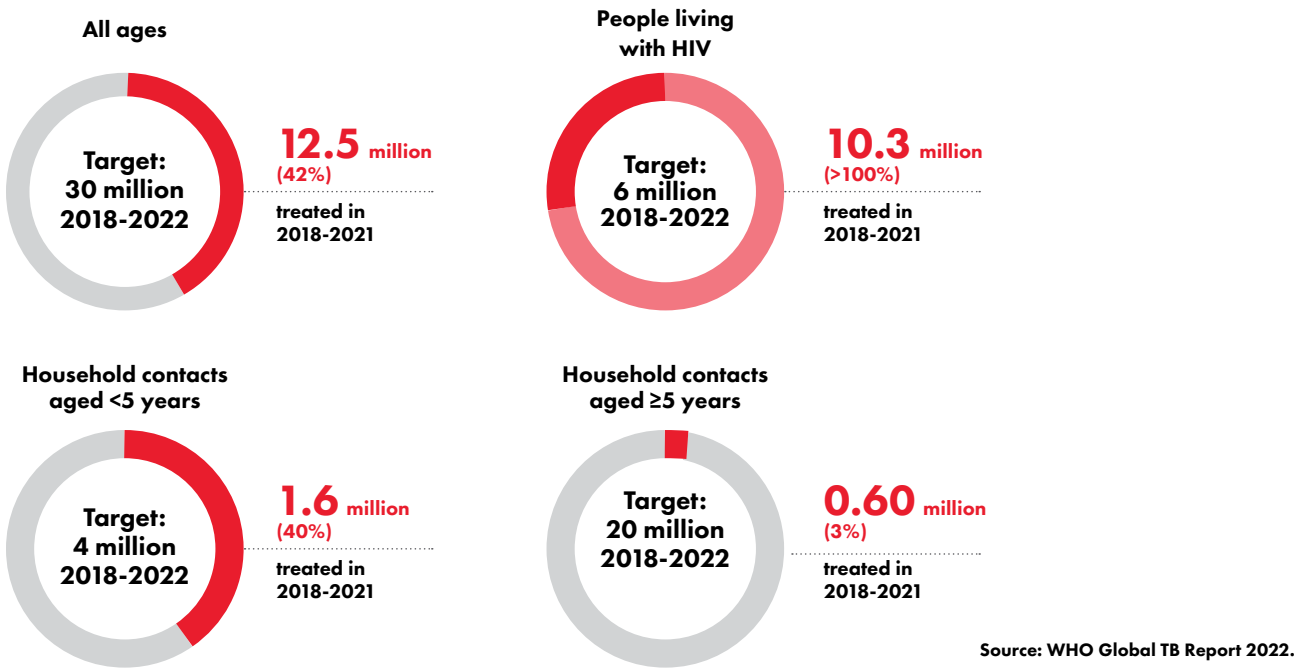
Embracing Newer TPT Regimens to Save Lives

A recent modeling study published in *Lancet Global Health* found that by scaling-up short-course TPT to people living with HIV and TB contacts, governments can prevent 850,000 deaths through 2035; 700,000 of these averted deaths would be among children aged 15 years and younger.[2] In particular, the study demonstrated that delivering short-course TPT regimens like 3HP via contact tracing — a process in which people exposed to TB through close contact with someone with the disease are screened for TB — could lead to a 13 percent reduction in the number of contacts who develop TB and a 35 percent reduction in deaths over the next 12 years. This evidence shows that short-course TB prevention is not a luxury but a matter of urgency for persons affected by TB, their household members, and other close contacts.

Yet too few people receive TPT: only 12.5 million out of a global target of 30 million people from 2018 to 2021. Most of these people were people living with HIV (PLHIV), meaning other groups at risk — including children and family members and other close contacts of people with TB — are still in need of protection (see Figure 1). Among those who did receive TPT in recent years, most were given versions of an older regimen called isoniazid preventive therapy (IPT), which must be taken daily for 6 to 36 months, instead of newer, shorter, and safer options like 3HP and 1HP.

Evidence that IPT can protect against TB has been available for more than six decades, yet the first global guidelines recommending TPT did not appear until after the turn of the twenty-first century.[3] Initially, these guidelines focused on preventing TB among PLHIV. This was mostly due to the fact that TB is the leading cause of death for PLHIV, who are 20–30 times more likely to acquire TB than HIV-negative people.[4] Even among PLHIV, uptake of TPT was dismal until 2016–2018 when there was a strong push to initiate people with HIV on IPT.

Figure 1: TPT Coverage Gaps Measured Against Global Goals



Source: WHO Global TB Report 2022.

For PLHIV this was no easy ride. Many people complained about the high pill burden, little to no treatment literacy around IPT, and the lack of follow-up and psychosocial support. Many were reported to have either hidden or thrown away their IPT medicines. Others reported that due to reoccurring stock outs of vitamin B6 in their health care facilities, side-effects of IPT like peripheral neuropathy were unbearable. The reality was that IPT was "prescribed, but not taken as prescribed." More had to be done — not only for people living with HIV, but also for those people who were not HIV positive but affected by TB, such as household or other close contacts, who remained on the margins of this evolving narrative.

Changing the TPT Narrative

The story started to change when scientific advances brought forward newer regimens to IPT that were shorter and more tolerable. Results from the PREVENT-TB study demonstrating the safety and efficacy of 3HP were published in 2011 and results from the BRIEF-TB trial of 1HP in 2019. The introduction of these two rifapentine-based regimens led to an overhaul of TPT. The combination of isoniazid with rifapentine was a game changer: people no longer have to take 6 to 12 to 36 months of daily treatment to prevent TB. As a result, affected communities (including those living with HIV) began to demand access to TPT as a tool to achieve their #RightToPreventTB and to protect their families from this deadly yet preventable disease.

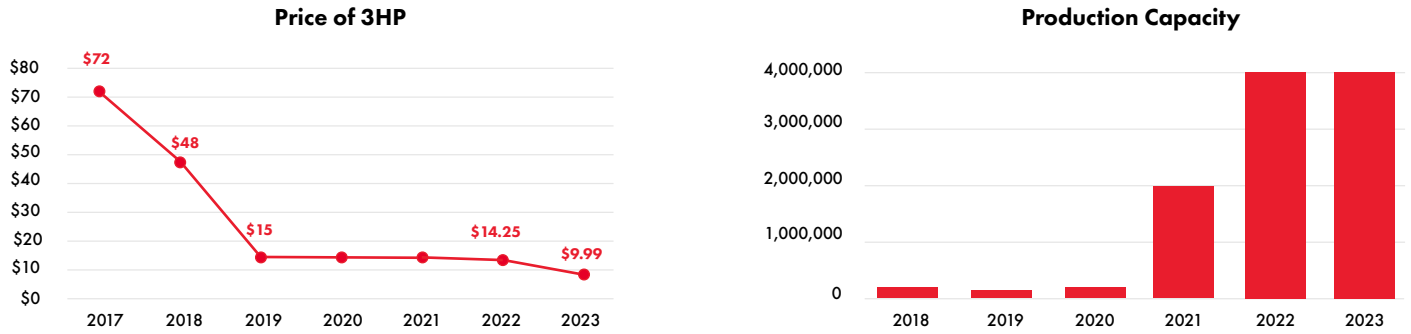
But the narrative only really changes when countries adopt WHO guidance and translate that science into implementation. Country-level efforts continue to move at a snail's pace. "The government may think that policies alone are enough. But, like a chain message, many surprising things are often encountered at the grassroots level. People must be aware and responsive of their right to health to demand their rights be fulfilled," says Lusiana Aprilawati from the TB survivor organization PETA in Indonesia, explaining that community empowerment must accompany policy change.

It was through persistent advocacy by a growing movement of TB advocates, survivors, activist researchers, and responsive policymakers that the TPT story entered its next chapter. Attaching a human face to TB and promoting responsive, client-centered TB services was difficult. This advocacy required taking TB prevention out of the laboratories and into communities while pushing for decentralized care. These efforts found an initial footing within the more coordinated HIV movement, which had a long-standing commitment to patient-centered care as expressed through innovative models such as differentiated service delivery (DSD).

One of the most important interventions came in 2018 from the Unitaid-funded IMPAACT4TB project led by the Aurum Institute (TAG is a funded member of the consortium). The project worked in 12 countries to pilot studies, support early program experience, and expand access to rifapentine-based TPT. Project partners helped governments reform

Figure 2: Improvements to Affordability and Availability of Rifapentine

Source: Adapted from IMPAACT4TB Project



their TPT guidelines to incorporate 3HP and are now doing the same for 1HP. The IMPAACT4TB project worked on all four dimensions of the AAAQ framework — effectively promoting human rights-based, client-centered TPT responses to galvanize a paradigm shift from long-course IPT to short-course 3HP and now 1HP.

Advocating for AAAQ

The IMPAACT4TB project increased the **availability** and ensured the **quality** of 3HP and 1HP by creating the conditions for two generic manufacturers to bring new formulations of rifapentine to the market and have them quality assured by the WHO and Global Fund. As a result, the global supply of 3HP increased dramatically: from 180,000 patient courses in 2018 to over 4 million in 2023. At the same time, the accessibility and affordability of 3HP improved with successive negotiations between suppliers and purchasers that reduced the price of 3HP from $72/patient course in 2017 to $14.25 by the end of 2022 (see Figure 2). On the sidelines of the United Nations High-Level Meeting on TB in September 2023, the U.S. Government unveiled an even lower price of $9.99 per 3HP patient course from the manufacturer Lupin (a 30% price decrease).

While working on availability, accessibility, and quality, the IMPAACT4TB project did not forget about the fourth AAAQ plank: **acceptability**. A hallmark of the project was its work with civil society and affected communities to undertake county-level policy advocacy and community demand creation. Acceptability concerns about the short-course TPT regimens are often lost in translating policy to practice. Countries are slow in developing TPT data collection systems, job aids, and training courses for health care workers to ensure that people prescribed TPT understand the importance of TB prevention for their households and other close contacts.

Civil society and affected communities have worked hard since 2019 to promote TPT treatment literacy as well as community-led monitoring. Leveraging a "training of trainers" treatment literacy strategy, an IMPAACT4TB community partner, the Coalition of Women Living with HIV (COWLHA) in Malawi, has reached 5,678 people by working with women expert clients in the last four years. At the policy level, their advocacy led to Malawi being the first country to recommend rifapentine-based regimens as the preferred option for populations for which the treatment was indicated. Short-course TPT regimens are included in the HIV Clinical Management Guidelines and name PLHIV, TB contacts, children under the age of five years old, and prisoners as priority populations. Financial support for national TPT scale-up was secured from development partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria as well as PEPFAR. COWLHA's literacy sessions, focus-group discussions, and community campaigns have increased the number of people accessing TB screening services and asking for short-course TPT in health facilities. As of March 2023, these expert clients — who receive "refresher trainings" to keep their TPT knowledge up-to-date — have referred 466 household contacts for TB screening, and a total of 2,685 people from their support groups have accessed 3HP. COWLHA also worked with partners such as the Malawi TB CSO Network, the National TB and Leprosy Control program, and UNAIDS to develop a data collection tool to promote community-led monitoring (CLM). Data generated through CLM were used to lead national-level advocacy to improve the scalability of 3HP beyond their focal districts.

While creating the conditions for communities to accept TPT, advocates in Malawi and other countries at the same time fought for the **affordability** of rifapentine-based TPT regimens, playing a pivotal role in reducing the commodity price from $75 to around $10 per treatment course. The

price should come down even further as countries increase the target populations eligible for TPT and guidelines adopt simpler screening algorithms, which will ensure that contacts of people with active TB are also protected from TB. "The price of the short-course TPT regimens has affected scaling up 3HP to all eligible recipients, as well as affected the policy and treatment guidelines whereby Malawi guidelines indicate that only those [PLHIV] newly initiated on ART be the ones prioritized for 3HP. It is unfortunate that household contacts and children under 5 years of age are still given IPT," lamented Edna Tembo, director of COWLHA.

"The government may think that policies alone are enough. But many surprising things are encountered at the grassroots level. People must be aware of their right to health to demand their rights be fulfilled"

– Lusiana Aprilawati, PETA Indonesia

Is the End in Sight?

We have much to celebrate. But the fact remains that while high-burden countries have come some ways forward with TB prevention, we still have a long way to go to eliminate TB by 2030. Following the second United Nations General Assembly High-Level Meeting on TB in September 2023, we need more ambitious, time-bound targets for revising TB prevention guidelines to meet evolving global standards set by WHO and more ambitious and far-reaching implementation. And we need to firmly center TB prevention within agendas for pandemic prevention preparedness and response (PPR) and universal health coverage (UHC).

Next, we need to ensure that TPT is not lost at the national level during program implementation, especially for household contacts and other close contacts of people with TB. With a renewed focus on TB prevention under the UHC agenda, advocates can work to make these short-course treatments more acceptable and accessible to patients and to sustainably integrate and monitor community TPT programs. The importance of eliminating TB aligns with the recognized "prevention is the cure" approach prioritized by both the UHC and PPPR agendas.

Access to novel TPT treatments will remain key moving forward, even with new TB vaccines on the horizon. Countries should commit to bold, time-bound, concrete, and comprehensive targets. Here are some of the commitments we would like to see:

1. Update national TPT guidelines within six month of WHO making changes to global guidance.
2. Track the number of people who both start *and* complete TPT to obtain a measure of the quality of TPT programs.
3. Transition from IPT to newer regimens like 3HP and 1HP, for example by ensuring that three-quarters of people receiving TPT over the next five years receive a shorter regimen based on rifapentine.
4. Entrench community-led monitoring in all programs to track performance, stockouts, and quality of care while supporting communities who may face challenges during their TPT treatment from initiation *through* completion.

This remains the vision: neither to reduce nor control the TB epidemic but to eliminate TB by 2030, the deadline set by the Sustainable Development Goals.

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HOW RISING ANTI-LGBTQ SENTIMENT HARMS PUBLIC HEALTH

By Kendall Martinez-Wright, Elizabeth Lovinger, and De'Ashia Lee

Many people recognize advances the LGBTQ+ community has made in the United States and other countries, including the freedom to marry their partners, sexual orientation and gender identity protections, and the fact that various states and territories have granted sanctuary status for queer people fleeing oppression elsewhere. Queer visibility in pop culture and media has risen significantly over the past three decades.

We must collectively fight back by supporting laws that reflect up-to-date, evidence-informed, and LGBTQ-affirming public health policy, including non-stigmatizing and non-punitive approaches to HIV prevention and care.

Despite these gains, anti-LGBTQ+ bigotry has persisted — and in some places now is on the rise. In the last few years, signs of open anti-LGBTQ+ hatred have intensified. One study showed that in the United States, anti-LGBTQ+ hate crimes rose by 52 percent in 2022.[1] In 2023 alone, state legislators have filed over 520 pieces of anti-LGBTQ legislation; 220 of these bills were aimed specifically at the transgender community, ranging from banning gender-affirming health care for minors to laws requiring educators to misgender students.[2] These developments threaten the health of queer individuals and communities.

Most obviously, surging homo- and transphobia damages mental health. According to data from The Trevor Project, an estimated 86 percent of transgender youth have been negatively affected by proposals to limit gender-affirming care.[3] In a survey of over one hundred clinicians providing gender-affirming care for trans youth, nearly all reported that restrictions on care negatively impacted the mental health of their patients.[4] These effects are likely even more dramatic for young queer people of color: one recent study found that Black and Hispanic LGBTQ+ youth had higher rates of depression in states that don't have laws against conversion therapy or sexual and gender identity-based bullying.[5] Psychological distress emanating from anti-queer sentiment is hardly relegated to vulnerable young people; laws and policies reflecting institutional homophobia and transphobia can lead to increased suicidality among LGBTQ+ adults, particularly Black men, who are oppressed in multiple ways by institutional white supremacy.[6]

It's become increasingly clear that wielding anti-LGBTQ+ hatred as a political cudgel also has dire negative effects on health education and access to health care. One casualty of anti-queer political backlash has been sexual education, particularly information about HIV. This year in Iowa, Governor Kim Reynolds signed a bill striking down requirements that public schools teach students about HIV.[7] This legislation directly bans a critical public health intervention, as HIV education is associated with reduced risky behavior and higher HIV testing rates.[8] Gutting sexual health curricula is unacceptable in light of ongoing epidemics of HIV and other sexually transmitted infections (STIs) in the US, particularly as it singles out and stigmatizes health issues that disproportionately affect LGBTQ+ people.

More causes for alarm have emerged from state and local governments, conservative organizations, and other groups. Most recently, the Supreme Court decision in *303 Creative LLC. v Elenis* granted small private businesses, including health care providers, the right to deny services to members of the LGBTQ+ community.[9] In another troubling trend, private organizations and governments are attempting to limit access to preventive health services, including preexposure prophylaxis (PrEP). For example, a Texas district judge in *Braidwood Management vs Becerra* struck down the Affordable Care Act requirement

to cover PrEP medication for HIV prevention and claimed that this provision violates providers' religious rights because it "encourages homosexual behavior, prostitution, sexual promiscuity, and intravenous drug use."[10] TAG recently signed an amicus brief in support of the defendants prepared by HIV+Hepatitis Policy Institute, arguing that the decision stands to limit access to PrEP for the people who may benefit most.

Earlier in 2023 the Tennessee Department of Health (TDH) under Governor Bill Lee refused to accept federal Centers for Disease Control and Prevention (CDC) funds for HIV prevention and monitoring, a move that severely restricts resources for organizations serving Black and sexual minority communities. Governor Lee later explained the decision, stating, "We think we can do that better than the strings attached with the federal dollars that came our way and that's why we made the decision."[11] Governor Lee also instructed the TDH to concentrate HIV prevention services on first responders, mothers and children, and victims of human trafficking, groups that together account for only 1 percent of new HIV cases annually.[12] Governor Lee's comments and actions target LGBTQ+ communities by diverting vital CDC HIV prevention funding away from those disproportionately affected, implying that unrelated priority groups are more "deserving" of support, despite being minimally affected by HIV. This refusal creates a harmful precedent of states rejecting federal funding and oversight of public health programs. With nearly 50 percent of current HIV cases located in Southern states with conservative governors and legislatures, the implications for LGBTQ+ public health and human rights are extensive, particularly for Black men and trans people.[13]

Unfortunately, such anti-LGBTQ rhetoric and policies are not limited to the US. One of the worst examples of global anti-LGBTQ+ policies is the Anti-Homosexuality Act recently passed in the Ugandan legislature and signed into law by President Museveni, assigning stiff criminal penalties — up to death — for homosexual activity. This law has severe ramifications for the fight against HIV in the already struggling country, with citizens afraid to utilize vital services such as HIV diagnosis and treatment. As Uganda is one of the countries The United States President's Emergency Plan for AIDS Relief (PEPFAR) operates in, the law poses a serious threat to global efforts to end HIV.

Anti-LGBTQ+ legislation casts a shadow over public health, particularly as it relates to HIV prevention and treatment. We must collectively fight back by supporting laws that reflect up-to-date, evidence-informed, and LGBTQ-affirming public health policy, including non-stigmatizing and non-punitive approaches to HIV prevention and care. Public and private funders can dedicate increased funding toward improving the health and well-being of LGBTQ+ people and communities, and local and national LGBTQ+ community organizations can support their people and work in solidarity with public health organizations and providers. In these ways, activists can help ensure that critical health interventions equitably serve all individuals regardless of their sexual orientation or gender identity, in spite of political threats that make that task difficult.

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MISINFORMATION AND VACCINE PREPAREDNESS: THE CASE FOR DIGITAL ADVOCACY

By Erin McConnell

A special thanks to Abraham Johnson, for contributing to an earlier draft of this piece

Hesitancy around immunization has such deep historical roots that it predates the first vaccine. Before the term "anti-vaccine" was coined in the early 1800s to describe those opposing Edward Jenner's new smallpox vaccine, some individuals had refused to be inoculated using the centuries old method of variolation.[1] A half century later, a more organized anti-vaccine movement arose in response to mandates passed by the British government in 1853. Other anti-vaccine movements followed, flaring up throughout history as new vaccines were introduced: backlash followed the measles vaccine in the 1960s, the measles, mumps, and rubella (MMR) vaccine in the late 1990s, MMR again in the 2010s, and most recently COVID-19 in the 2020s.[1,2]

Modern anti-vax movements are generated and circulate largely on the global internet, with people interacting with sensationalized stories, posts, and retweets while casually scrolling.

Anti-vaccine sentiments of the past and present center on strikingly similar themes: nineteenth century anti-vaxxers opposed governments dictating their bodily choices, feared modern medicine, and suspected the government was experimenting on the working class, rationales that still circulate in modern anti-vax spaces today. Such mistrust of government and medicine has been obvious in modern anti-vaccine rhetoric in assertions that the elite have some vested interest in promoting COVID-19 or that the medical community has suppressed discussion of potential harms. Among Black and Indigenous communities, these concerns are often compounded by shameful histories of mistreatment and exploitation by the state and medical system.[3,4,5,6]

Nonetheless, despite these similarities, modern anti-vax movements are generated and circulate largely on the global internet, with people interacting with sensationalized stories, posts, and retweets while casually scrolling.[7] Social media has made it easier than ever for anti-vaccine movements to spread propaganda, misinformation, and reach new recruits. To minimize this damage and ensure that people who need future vaccines are primed to accept them, an effective, global, digital advocacy strategy must be central to vaccine preparedness work moving forward.

If anti-vax narratives have been historically persistent, any wave of vaccine refusal was largely constrained geographically — but globalized social media allows these ideas to cross borders and race through social media networks. These platforms' functionality makes the problem worse: on Facebook, the closer content is to violating platform policy, such as posts containing hyperbole or misinformation, the more engagement it will generate.[8] When it comes to reposts on different platforms, posts containing misinformation generate the most overall engagement and sharing.[8] On Twitter and TikTok, posts with higher engagement get pushed to new users through discovery algorithms, and both platforms far outpace YouTube, Facebook, and Instagram in amplifying misinformation.[8] Around 90 percent of engagement on posts

containing misinformation happens within the first day, making it challenging to refute once people have seen it. One recent study showed that even when platforms attempt to minimize misinformation, around 30 percent of viewers are still unable to distinguish fact from fiction.[9]

Unfortunately, misinformation about vaccines has been particularly popular on social media. When hashtags like #StoptheVaccines can garner over 700 million views, not only will there be 700 million impressions with anti-vax content on one social media platform, but nearly 235 million individuals are at risk of accepting any falsities as truth regardless of fact checking.[10] Shockingly, misinformation about potential COVID-19 vaccine safety, development, and rollout was already spreading on social media before any vaccine had been developed or approved — giving the anti-vaccine movement a head start before public health officials even had data. Exposure to this type of misinformation on social media during COVID-19, especially when it is "scientific-sounding," was associated with around a six percent decline in intent to vaccinate.[11] Previously, online vaccine misinformation campaigns between 2016 and 2017 are associated with reduced measles vaccination rates and a number of outbreaks in Europe.[12] With over 33 percent of TikTok users, 53 percent of Twitter users, and 44 percent of Facebook users regularly getting news on these platforms, bad actors have clearly co-opted the role of social media in keeping people informed about public health — threatening vaccination rates and the future of public health as a whole.[13,14]

The centrality of social media to public communication, coupled with its susceptibility to virality, underscores the need to develop proactive strategies to build trust far in advance of rollout of specific vaccines. COVID-19 anti-vaxxers did not wait for a vaccine to exist before promoting fear and skepticism; public health professionals shouldn't wait until a vaccine exists to start actively preparing and promoting their benefits. Public health campaigns around vaccines must use social media platforms to push their own, factual, counternarratives and directly address and refute misinformation on these platforms before vaccine rollouts — ideally as they enter Phase III clinical trials.[13]

As HIV, TB, and HCV vaccine advocates, we can no longer afford to ignore social media or the existential threat of misinformation on these platforms. We must meet communities where they are — including online. Previous attempts to combat anti-vaccine misinformation from health departments, advocacy groups, and professional associations have struggled to reach audiences, analyze social media conversations for audience sentiment, or adapt to the pace of social media.[15] This limits the ability of organizations to develop critical rapport with audiences and tailor messages in response to community feedback and conversations.[15]As a result, social media messaging about vaccines from these groups can feel hollow and untethered from the communities they are trying to reach. This ultimately decreases engagement with posts as audiences are put off or uninterested in content that doesn't speak to them, and thus the amplification of truthful, pro-public health messages is dampened.[15]

COVID-19 anti-vaxxers did not wait for a vaccine to exist before promoting fear and skepticism; public health professionals shouldn't wait until a vaccine exists to start actively preparing and promoting their benefits.

Social media campaigns promoting vaccines should go beyond correcting misinformation to actively engaging individuals with credible ties to communities to amplify public health information tailored to their community. By understanding unique community perspectives around vaccine hesitancy through engagement in comment sections, monitoring popular trends, and calling on community members to influence messaging, public health officials can design and tailor social media campaigns that address hesitancy drivers specific and unique to each community's concerns.[16] Social media approaches to combat vaccine hesitancy should use the same tools that misinformation campaigns do – continuous messaging from community members speaking directly to community perspectives and supported by fact checking from experts.[17]

TAG's HIV program developed the HIV Vaccine Social Media Ambassador program with these themes in mind. The program was designed to leverage social media influencers who could foster responsive engagement with their followers to understand the conversation happening within their communities around vaccine hesitancy and to tailor social media campaigns to those concerns. TAG's goal is to combat misinformation around HIV treatments and future vaccines within the communities most vulnerable to online

...we can no longer afford to ignore social media or the existential threat of misinformation on these platforms. We must meet communities where they are — including online.

vaccine misinformation and who stand to benefit most from the scientific advancement of an HIV vaccine.[4,6,18] The first vaccine social media ambassador was Johneri'O Scott, an HIV advocate and health influencer who developed original content discussing HIV vaccine research for his audience. Scott's use of humor to discuss critical health topics has been well received by his followers — garnering over a million views. A single post to TikTok about signs your partner may have an STI received 375.5 thousand likes and over three thousand comments such as, "I am listening but I am also [laughing]." As the HIV Vaccine Social Media Ambassador program continues, we hope to foster scientific literacy and create forums for community dialogue with trusted sources like Scott — and do all we can to limit the ability of anti-vaccine sentiment to threaten our collective health and the success of lifesaving vaccines yet to come.

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BEYOND INTELLECTUAL PROPERTY: WHY IS GENERIC TREATMENT FOR HCV STILL SO HARD TO GET?

By Joelle Dountio Ofimboudem and Sara Helena Gaspar

Background

Intellectual property is a major barrier to access to medicines worldwide because it creates corporate monopolies that restrict supply, keep prices high, and prevent people from accessing innovative health products. However, in the context of hepatitis C virus (HCV), intellectual property is no longer the major barrier to treatment access in low- and middle-income countries (LMICs) included in voluntary licenses. In these licenses, originator drug manufacturers of the most-commonly used pangenotypic direct acting antivirals (DAAs) that cure HCV — sofosbuvir (SOF) and daclatasvir (DAC) combination — have authorized generic manufacturers to manufacture and commercialize generic versions of the DAAs in some LMICs at lower prices. Yet these DAAs still aren't reaching most of the people who need them in many of these countries. Globally, only about 21 percent of the estimated 58 million people living with HCV know their status, and four hundred thousand people continue to die of HCV-related causes each year.

Following pressure from health advocates and activists denouncing the high cost of life-changing DAAs that cure HCV, Gilead (the manufacturer of SOF sold under the commercial name Sovaldi®) granted voluntary licenses to seven Indian-based generic manufacturers in 2014, making it possible for the latter to manufacture and commercialize generic SOF and velpatasvir for 91 developing countries. Similarly, Bristol-Myers Squibb (the manufacturer of Daclatasvir sold under the commercial name Daklinza®) granted a voluntary license for Daklinza® to the Medicines Patent Pool (MPP) in 2015, allowing MPP to grant sublicenses to generic manufacturers. Five years later in 2020, Bristol withdrew marketing authorizations for DAC, allowing its patents to lapse. As of 2023, about six generic pharmaceutical companies have received World Health Organization (WHO) prequalification status[1] to manufacture and commercialize generic SOF and DAC.

Now that Viatris and Hetero, two of the leading WHO-prequalified generic DAA manufacturers, have pledged to reduce the cost of the full HCV treatment course to $60 to meet the 2030 HCV elimination goals, there is an urgent need for health advocates to identify and raise awareness about the current barriers to HCV care and mobilize to engage with policymakers and other stakeholders to address them and ensure everyone with HCV has access to the cure.

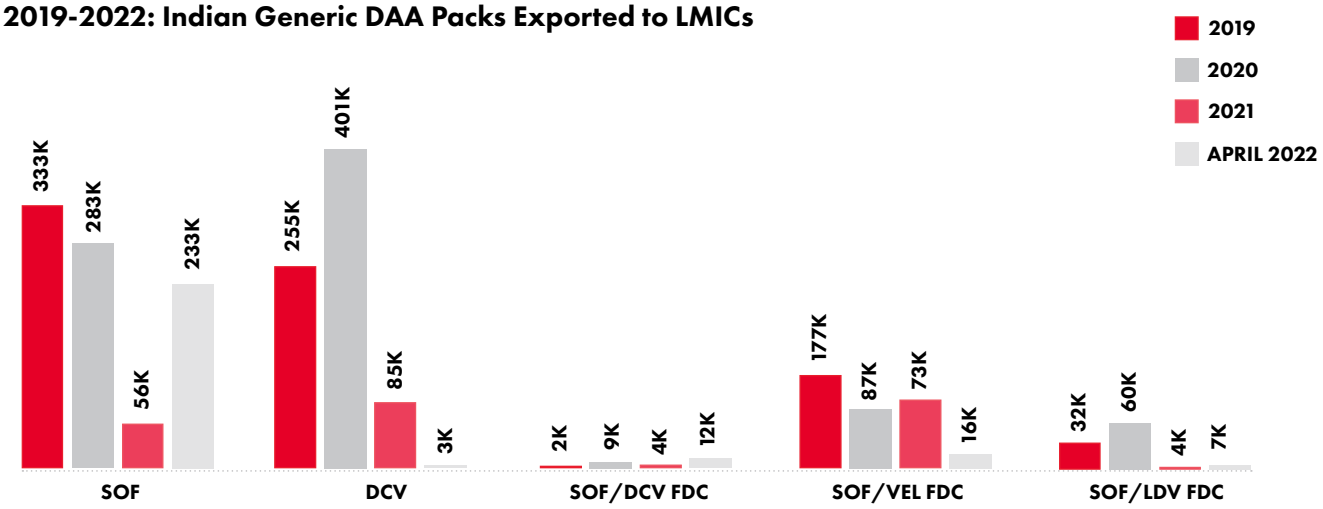
Non-Intellectual Property Barriers to HCV Care

1. Non-Registration of Originator Drugs and Failure of National Medicines Regulatory Authorities to Utilize Available Options for Drug Approval

Before a pharmaceutical product can be introduced into any country's market, its manufacturer must obtain market authorization from the national medicines regulatory authority (NMRA). Generic manufacturers are required by NMRAs to demonstrate the equivalence of generic drugs to the originator drug in order to obtain market approval. To demonstrate equivalence, generic manufacturers conduct bioequivalence studies according to specified guidelines comparing the generic (test) and the originator product.

When a generic manufacturer of a medicine that is WHO-prequalified seeks market approval in a country where the originator did not submit the dossier for market approval, the NMRA can use the WHO Accelerated Registration process to collaborate with the WHO in examining the dossier. In the case of DAC, for example, Bristol did not register Daklinza® in South Africa before leaving the HCV market, and the country's NMRA — the South African Health Products Regulatory Authority (SAHPRA) — requires that originator drugs must be registered before generic versions can be approved. An alternative approach for SAHPRA would be to use the WHO Accelerated Registration process to collaborate with the WHO to register generic DAC. Because SAHPRA has not used this approach, generic DAC cannot be introduced into the country. Hence, only originator pangenotypic DAA combinations developed by Gilead are available on the national market at between $1,000 and $1,500 for a full treatment course, which is unaffordable for most people with HCV and for the public health program.

2019-2022: Indian Generic DAA Packs Exported to LMICs



Source: CHAI Hepatitis C Market Memo, 2022 page 1 https://chai19.wpenginepowered.com/wp-content/uploads/2022/07/HCV-2022-Market-Memo_vf.pdf

To address this, NMRAs in countries where the lack of registration of Daklinza® hinders the registration of generic DAC should use the WHO collaborative registration process to promote competition and price reduction in the DAA market. In addition, given that Gilead's voluntary license covers another pangenotypic DAA, sofosbuvir/velpatasvir, policymakers in LMICs included in the voluntary licenses need to leverage these opportunities to ensure that more than one pangenotypic DAA combination is available on the domestic market to promote generic competition and price reduction.

2. Low Demand for DAAs

Demand for DAAs across LMICs is very low due to a lack of political will and leadership to prioritize and invest in HCV elimination, and low awareness and uptake of HCV testing. There is minimal effort to raise awareness about HCV, to scale-up HCV services, or to streamline the complex HCV diagnostics pathway, often involving high costs, multiple clinic visits, and delays in treatment initiation following a positive diagnosis. As a result of these gaps, and the fact that people with chronic HCV may remain asymptomatic for up to two decades after infection, only one in five people with HCV actually know their status. This has been further compounded by the 2019 COVID-19 pandemic as health programs across the world shifted focus away from other health priorities to focus on health needs arising from the pandemic.

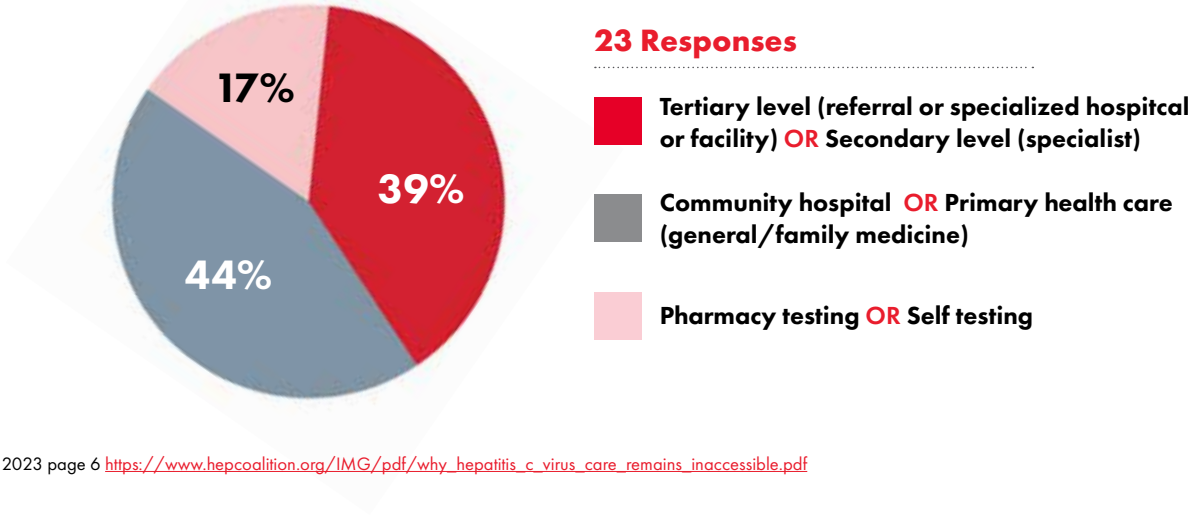
Some countries, however, such as Egypt and Malaysia, have shown political leadership resulting in robust measures to test and treat people with HCV to meet the 2030 viral hepatitis elimination goal. To increase demand for DAAs, health programs need to identify, fund, and implement measures to find and treat people with HCV. This includes public education about HCV; mass screening programs to find the missing millions of people living with HCV; and scaling up, simplifying, and decentralizing diagnostic services to enable early treatment initiation. Programs must implement test-and-treat programs to avoid loss to follow-up, and integrate HCV care into sexual and reproductive health programs, HIV programs, harm reduction and non-communicable diseases programs.

3. Treatment Restrictions

Various restrictions implemented by countries prevent people living with HCV from accessing treatment. Examples of restrictions include requiring people to be sober before they can access HCV treatment; limiting HCV care provision to specialists, as is the case in Cote d'Ivoire and Bangladesh; and a reluctance to launch mass HCV screening campaigns for fear of not being able to afford to treat all of those with confirmed viremic infection. While some of these measures may limit government spending on HCV in the short term, the long-term consequence on health programs is enormous. When treatment access is restricted, HCV transmission continues, and people who could have benefited from early cures develop complications like cirrhosis, end-stage liver disease, and liver cancer, requiring more expensive (and sometimes unavailable) interventions like liver transplants, which cost more to health programs.

Investment cases for HCV elimination in Uganda, Cameroon, and Vietnam have demonstrated that HCV elimination is cost-effective and would save health systems enormous resources in the long-term. To ensure that everyone with HCV has access to the cure, national health programs need to eliminate all restrictions to HCV care as recommended by the WHO and scale up screening to find and treat everyone with HCV.

Decentralization of HCV diagnostic services



Source: HCV policy brief, 2023 page 6 https://www.hepcoalition.org/IMG/pdf/why_hepatitis_c_virus_care_remains_inaccessible.pdf

4. Non-Implementation of Updated WHO Recommendations on HCV Care

In 2022, to expand access to HCV care, WHO published the Updated Recommendations on the Treatment of Adolescents and Children with Chronic HCV Infection and the Updated Recommendations on Simplified Service Delivery and Diagnostics for Hepatitis C Infection, outlining three key measures countries need to implement to ensure integration and task sharing:

- HCV testing and treatment services should be provided at the same site through decentralization of care to lower-level facilities.
- HCV care should be integrated into other services like primary care, harm reduction programs, prison health programs, and HIV services.
- Countries should promote task sharing through delivery of HCV testing, care, and treatment by appropriately-trained nonspecialist doctors and nurses.

Following a survey of 23 countries earlier in 2023, TAG found that these guidelines have not been put into practice: HCV diagnostic services are still highly centralized with 39 percent of the countries surveyed offering these services only in tertiary or secondary levels of care (specialist/reference hospitals and clinics).[2] Health programs must incorporate and implement WHO recommendations to ensure that HCV care is accessible to everyone.

5. General Neglect of HCV High-Burden Populations

HCV high-burden population groups include people who use and inject drugs (39.2%),[3] men who have sex with men (3.4%),[4] people in incarceration (15.1%),[5] and people living with HIV (2.4%).[6] Given that these population groups are marginalized instead of prioritized in national health strategies, these high-burden population groups may avoid health care facilities in fear of stigma, discrimination, and in some cases, police arrest. Health advocates need to work with their communities to raise community concerns and voices when engaging with policymakers and other stakeholders and to continue to push for evidence-based approaches to public health programming. Policymakers and health program implementers need to prioritize policies that address stigma and discrimination among high-burden key populations in HCV policy and health programs generally.

Endnotes

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Treatment Action Group (TAG) is an independent, activist, and community-based research and policy think tank committed to racial, gender, and LGBTQ+ equity; social justice; and liberation, fighting to end HIV, tuberculosis (TB), and hepatitis C virus (HCV).

TAG catalyzes open collective action by affected communities, scientists, and policymakers to ensure that all people living with or impacted by HIV, TB, or HCV — especially communities of color and other marginalized communities experiencing inequities — receive life-saving prevention, diagnosis, treatment, care, and information.

We are science-based activists working to expand and accelerate vital research and effective community engagement with research and policy institutions for an end to the HIV, TB, and HCV pandemics.

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