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tagline

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

BEND THE CURVES

ACTIVISM AND THE
ELIMINATION OF HIV,
HCV, AND TB



BEND THE CURVES: ACTIVISM AND THE ELIMINATION OF HIV, HCV, AND TB

By Tim Horn

Do your little bit of good where you are; it's those little bits of good put together that overwhelm the world.

— Desmond Mpilo Tutu

Incremental change—activism that successfully defends or advances critical research or policy—can sometimes feel inconsequential, particularly when it is hard won, resource intensive, and intangible. But in the context of public health strategies with ambitious targets and formidable stakeholder engagement, it is an undeniable facet of progress. In this issue of *TAGline*, we highlight some important recent successes and challenges in meeting TAG's overarching goals: moving beyond achingly slow trends and sharply bending the curves on new HIV, hepatitis C, and tuberculosis infections, suffering, and deaths.

We begin with Jeremiah Johnson's "The Usual Suspects" (page 3), which focuses on the experiences and observations of TAG's partners working to develop and implement plans to end HIV and AIDS as epidemics in some of the most affected states, counties, and cities.

In "The Role of Vaccines and Cures in HIV Elimination" (page 7), Richard Jefferys illustrates that, although the benefits of antiretroviral treatment and biomedical prevention are undeniable, they do not preclude the need for sustained long-term investments in the development of HIV vaccines and cures.

Shifting to the accomplishments and tasks ahead for HCV advocacy, Annette Gaudino reflects on the paradox of New York State. In "It's Up to You, New York" (page 9), Gaudino recalls the milestones of a campaign to eliminate HCV in the state, which closely mirrors the HIV stakeholder End the Epidemic initiative, but with much more political inertia.

The World Health Organization (WHO) has established targets to eliminate HCV globally by 2030. As is

evidenced in Bryn Gay's and Gaudino's "Global HCV Elimination Targets and Challenges: an Interview with Andrew Hill" (page 11), some countries are on track, others are lagging behind, and all are in jeopardy if they do not scale up screening, testing, and linkage to care for the more than 56 million people living with undiagnosed HCV.

In advance of the United Nations High-Level Meeting (HLM) on TB, Safiq Khimani and Mark Harrington illustrate in "From Moscow to New York and Beyond" (page 14) that the success of the HLM will require that the resulting UN General Assembly Political Declaration include clear commitments to expand the quality and breadth of TB programs and increase investment in the research and development necessary to eliminate TB as a global threat.

And in the U.N.'s host city, New York, the incidence of TB is on the rise, whereas funding to fight the disease has decreased considerably. As Erica Lessem deftly explains in "The United Nations' Back Yard: TB Elimination in New York and the U.S." (page 16), looking to countries to commit to global TB programs and research at the HLM is crucial, but so too is a robust local response to a growing national problem.

Finally, "In a State of Disunion" (page 18), Suraj Madoori provides a sweeping look at the precarious HIV, TB, and HCV elimination policies and priorities under the Trump administration. And although the 2018 landscape looks bleak, observations from the successful ACA, Medicaid, and NIH defenses of 2017 speak to the value of incremental change: activism can win in any policy environment seemingly stacked against it.

THE USUAL SUSPECTS: COMMON CHALLENGES FOR ETE PLANNING AND IMPLEMENTATION IN EMERGING JURISDICTIONS

By Jeremiah Johnson

Since 2014, several states, cities, and counties have announced plans to End the Epidemic (EtE), with many more preparing to announce their own initiatives in 2018. In New York, early successes have emerged in the most recent surveillance data (see: "New York State EtE Campaign Update: Successes & Challenges," page 6), and several other jurisdictions are seeing the benefits of EtE plan implementation. However, a number of common challenges have become apparent across different jurisdictions. Here, leaders and experts in EtE planning processes share their perspectives on some of the most common roadblocks.

Galvanizing Community-Based Organizations and Avoiding Turf Wars

Community mobilization is at the heart of the EtE process. But galvanizing community leadership is challenging. Advocates may feel skeptical after previous grandiose initiatives produced limited results, or there may be a perception that the community lacks the resources or the ability to exact ambitious change.

"Every group that I've worked with knows their community has unique challenges and is significantly different from any other community that has embarked on the EtE journey," shares Jaron Benjamin, Housing Works' Vice President of Community Mobilization and National Advocacy, who has consulted with several EtE jurisdictions. "But the challenge is that some groups assume that their uniqueness means that they'll never be able to demand action from their government in a meaningful way."

Decades of competing for scarce resources may also dampen collaboration between community entities that are trying to protect their turf. "That has been a major challenge for the [Ending HIV in Houston] plan," says



Jaron Benjamin, Vice President of Community Mobilization and National Advocacy, Housing Works
Photo credit: Nick Childers (nickchilders.com)

Venita Ray, Public Policy Manager at Legacy Community Health and one of the leaders of the Houston EtE process. "I believe there is still reluctance to embrace the concept that ending the epidemic is possible, and most entities are still focused on testing and treating and not engaged in strategic discussions addressing the real core issues like racism, poverty, etc. We have had to spend additional time re-starting community engagement via our END work groups and strategic assignments of co-chairs from various community-based organizations (CBOs) to encourage involvement and shared leadership."

John Saperro, Office Chief of the HIV Prevention Program in the Arizona Department of Health Services and a key figure in the Arizona EtE process, highlights the challenges outside of urban areas. "Rural agencies were reluctant to invest the energy without a return. During our planning process, our stakeholders were adamant that

we establish regional plans and funding allocations. It was a ton of extra work, but we created three regional plans. The goals and objectives are really no different for each region, but the implementation strategies really capitalize on the strengths of the local CBOs and AIDS service organizations (ASOs). 'By us, for us' strengthened regional collaborations and buy-in."

Ensuring All Affected Communities and Key Stakeholders are Engaged

Engagement of ASOs and CBOs does not always mean that the most affected communities in a jurisdiction are participating in leading the initiative, which can significantly limit the benefits of community mobilization in the implementation phase. From the start, a jurisdiction should have a plan in place to foster leadership from people living with HIV, communities of color, and transgender populations. Although building inclusive movements will be uniquely challenging in each jurisdiction, experiences in Arizona and Houston provide some insight.



John Sapero, Office Chief, HIV Prevention,
Program Arizona Department of Health Services
Photo credit: John Sapero

According to Mr. Sapero, "We engaged these communities by bringing in nationally recognized CDC technical assistance providers to facilitate multiple planning activities dedicated to each population. This really energized our stakeholders, especially women, to get commitment from community and faith leadership."

"In Houston, we have engaged in a number of initiatives with PLWHA [person living with HIV/AIDS] and other marginalized communities with mixed results thus far,"

explains Ms. Ray. "We have ensured involvement of the HIV community by linking our efforts with other HIV leadership efforts. We also require one of the co-chairs to be a PLWHA. We were able to get funding to provide stipends to PLWHA to provide trainings to task forces on using people-first language."

Establishing Equitable Transparent Partnerships with Health Departments

Although community leadership is critical, close partnership with local and state health departments is also essential for EtE success. But pre-existing power dynamics and differing motivations can interfere with collaboration.

"The health department has different interests than the community groups, and even if those interests aren't nefarious, it means that there will typically be some information withheld or that the community wants to go further than the health department feels able," Mr. Benjamin explains. "And that's fine; in most community and government partnerships, some tension is healthy and necessary because of the power differential between the two."

Mr. Sapero highlights the importance of health department transparency and accountability in establishing partnership. "Our planning activities were designed to bring governmental, private, and community-based organizations, PLWHA, and other stakeholders to the table as equals. We've committed to reporting our performance metrics on time, provide high-level programmatic reporting, and continually share the work of our partners with each other. More importantly, I believe our commitment to EtE energized many of our stakeholders."

Perceived Competition with Other HIV/AIDS Plans and Initiatives

EtE planning is unique in its combination of ambitious targets, community leadership, focus on structural drivers, and emphasis on implementation. However, no planning occurs in a vacuum, and integrating the EtE process into existing initiatives, including HRSA/CDC-required state Integrated Prevention and Care Plans, is challenging. Mr. Benjamin agrees, noting, "almost every jurisdiction that we've worked with had some sort of plan for responding to the HIV epidemic, and, to some extent, the more creative and innovative ideas had been passed over. The trick is to understand that a successful EtE effort isn't reinventing the wheel, but building a bigger and more inclusive one."



Venita Ray, Public Policy Manager, Legacy Community Health
Photo credit: KHOU-TV

"I have to be honest and say our previous prevention and care planning efforts were nowhere near as performance and goal driven as our EtE plan," says Mr. Sapero, introducing some of the synergistic approach that worked in Arizona. "No one had an issue moving toward something more visionary. We did a lot of front-end work to bring our three planning bodies into the same mindset before we started. Then, we started from scratch, aligning our plan development with the National HIV/AIDS Strategy, and using other EtE plans to guide us. We didn't integrate the planning bodies, as we felt it was going to be a lot of work on top of developing our plan. We're starting to explore integration now."

Funding and Political Commitment

For emerging EtE jurisdictions in politically indifferent or hostile environments, understanding the role of political support and funding to achieve the recommendations in the plan should be an early focus in the planning process.

According to Mr. Benjamin, "I think it's important to have an idea of who has funds to pay for your plan before you start writing the plan, and the best barometer of political buy in is whether you can get elected officials to fund the EtE plan. Sometimes elected officials have responded after public demonstrations, and sometimes after intimate closed-door meetings. I think you've got to consider every appropriate option to ensure that the responsible officials come through for the community."

Ms. Ray explains the challenges and victories in Houston. "Our local governments are fiscally strapped for money and conservative government makes the issues difficult to build political support. Still, during the 2017 legislative session, we were able to prevent HIV criminalization legislation from being introduced, supported two syringe

exchange bills and supported opt-out testing legislation. These are all policy recommendations in the END plan. With funding, our initial hope is to improve coordination of existing resources and beginning to solicit political support for funding initiatives."

"We're fortunate that ADAP 340b rebate funds are helping initiate some great work," explains Mr. Sapero. "The mayor of Phoenix signed onto the Fast-Track Cities charter in 2016, the state health department has showcased our work to the media, and there's currently a bill in the state legislature to formally recognize and adopt the plan. Several local representatives and county supervisors are supporting us as well."

Lessons for Emerging EtE Jurisdictions

As reflected in the wisdom of Ms. Ray, Mr. Benjamin, and Mr. Sapero, much of the work to end epidemics begins with building effective relationships and avoiding the usual pitfalls between affected communities, CBOs/ASOs, and health departments. Emerging jurisdictions that invest time and resources into fortifying robust, transparent, diverse, and equitable partnerships between these key stakeholders are more likely to find success. An early focus on funding and political strategies, particularly with an intention to work synergistically with existing initiatives, will greatly facilitate implementation.

For the past year, as part of its Southern States EtE initiative, TAG has worked closely with three jurisdictions that have shown a strong commitment to redefining relationships between key stakeholders. Alabama, Louisiana, and Nashville, Tennessee, have held initial jurisdictional EtE meetings with a specific focus on inclusion and transparency; steering committees in each jurisdiction are now in the process of identifying ways to fill in any gaps in inclusivity and foster more open conversation between existing partners. In the case of Nashville, political support from the Mayor and early conversations about funding EtE planning and implementation are adding even more depth to the work of key stakeholders. TAG remains committed to documenting and advising emerging districts on these best practices in the south; including reaching out to support new cities, counties, and states that are prepared to embark on their own process.

For more information on EtE initiatives, please visit TAG's website: treatmentactiongroup.org/ete

NEW YORK STATE ETE CAMPAIGN UPDATE: SUCCESSES & CHALLENGES

By Jeremiah Johnson

The December 2017 release of the New York State (NYS) 2016 HIV/AIDS surveillance data shows that the efforts to End the Epidemic (EtE) in New York are having an impact.

In 2014, Governor Andrew Cuomo backed a community-developed plan to aggressively scale up testing, linkage to care and treatment, and pre-exposure prophylaxis access to dramatically reduce new infections below epidemic levels by the year 2020. Numerically speaking, the number of new infections would decrease from approximately 3,000 annually to fewer than 750 a year, effectively “bending the curve” on prevalence for the first time while simultaneously improving the quality and longevity of life for people living with HIV. A mobilized coalition of advocates, in partnership with NYS and New York City (NYC) health department leadership, has since been deeply engaged in implementing the recommendations of the state EtE Blueprint, a 2015 guiding document drafted with input from multiple key stakeholders.

Leaders in the NYS EtE initiative have been eager to see 2016 surveillance data for the state, which are considered by many to be a key indication of the real value of the EtE process.

The 2016 surveillance report definitively showed dramatic progress on many of the key EtE indicators monitored by the state. New diagnoses dropped from 3,443 in 2014 to 2,881 in 2016. Notably, new diagnoses among gay and bisexual men overall dropped by 12 percent from 2015. Much of the decrease in diagnoses in men who have sex with men (MSM) was driven by a dramatic 18 percent reduction in new diagnoses among Latino gay and bisexual men, giving hope that the state is simultaneously addressing racial and ethnic disparities. This trend was also reflected in aggregate statistics in which Black and Latino communities both saw 11 percent decreases compared with a 7 percent increase in whites.

Estimated incidence, overall, declined from 2,436 new infections in 2015 to 2,115 in 2016. Although impressive, this drop did not quite reach the intended 2016 target

of 2,050 estimated new infections. Efforts will need to be accelerated to meet next year’s targets, but the gap of 65 infections is a modest failure in the context of ambitious targets.

Not all of the findings are necessarily rosy, however. When we look at the data for parts of the state outside of NYC, much of the progress seen in the aggregate statistics diminishes considerably. Although the decrease in diagnoses between 2015 and 2016 was 12 percent in NYC, the rest of the state saw only a 1 percent decrease, with an increasing number of infections in Albany. Incidence estimates back this up, showing only a modest decline outside of NYC between 2014 and 2016. In addition, although there has been an overall drop in new diagnoses for people who inject drugs, for the first time ever the number of diagnosed infections related to injection drug use was higher for areas outside of NYC.

Indicators looking at linkage to care for people living with HIV have stalled or even gone slightly in the wrong direction throughout the state, highlighting a weak spot in statewide EtE efforts.

Much of the success in NYC is undoubtedly a result of a number of progressive policy victories, including increased funding for the city sexual health and wellness clinics, policy changes that facilitate screenings for HIV testing, coverage of transgender health services under Medicaid, and significant increases in housing assistance for people living with and vulnerable to HIV infection, just to name some of the highlights. Even more successful, evidence-based policy changes will be needed to accelerate progress in the city and ensure that the rest of the state is not left behind.

The blueprint created by New York State’s Ending the Epidemic Task Force can be accessed at:
health.ny.gov/diseases/aids/ending_the_epidemic/.
Progress toward the 2020 goals of the NYS EtE initiative can be tracked via the NYS EtE Dashboard:
etedashboardny.org/

THE ROLE OF VACCINES AND CURES IN HIV ELIMINATION

By Richard Jefferys

The development of highly effective approaches to HIV treatment and prevention—in the form of combination antiretroviral therapy (ART) and pre-exposure prophylaxis (PrEP)—stands among the most impressive scientific achievements in human history. As detailed elsewhere in this issue of *TAGline*, the widespread implementation of these interventions has the potential, at least theoretically, to effectively end the HIV pandemic. However, the practical challenges associated with implementation leave room for even a moderately efficacious HIV vaccine to make a significant additional contribution to halting the virus. And for HIV-positive people, a true end to HIV lies not in an epidemiological calculus, but in a cure.

The first glimmer of hope that an efficacious HIV vaccine can be developed emerged from the RV144 trial in Thailand. A prime-boost regimen comprising an ALVAC canarypox vector followed by AIDVAX B/E (dual HIV Env proteins in adjuvant) reduced the risk of HIV acquisition by 31.2%—a slight, but statistically significant, degree of efficacy.¹ Post-trial analyses provided suggestive evidence that the protective effect may have been higher—around 60%—during the first 12 months, before vaccine-induced immune responses waned.

The encouraging findings from RV144 prompted the design of an efficacy trial with a similar regimen that is now underway in South Africa, which is recruiting a population at higher risk of HIV infection (HVTN 702).² Additional booster immunizations are being administered after 12 months in hopes of achieving and sustaining efficacy of 50% or greater.

More recently, a combination of an adenovirus serotype 26 (Ad26) vector prime and HIV Env protein boost entered efficacy testing among women in five southern African countries (HVTN 705/HPX2008). In preclinical macaque studies, the vaccine led to a 94% diminution in per-exposure risk of simian immunodeficiency virus (SIV) acquisition, with complete protection being observed in 66% of animals after a series of six weekly SIV exposures.³

These two large ongoing trials offer at least some cause for optimism that a partially effective HIV vaccine could become available in the relatively near term.

In a paper published last year in the *Proceedings of the National Academy of Sciences*, Jan Medlock and colleagues modeled the possible effect of an HIV vaccine that reduced the risk of HIV infection by 50% when implemented in tandem with efforts to achieve UNAIDS diagnosis, treatment, and viral load suppression targets across 127 different countries.⁴

At the most basic level, HIV will not have entirely ended if daily treatment is still required for the majority of HIV-positive people.

In a variety of scenarios, vaccination had a synergistic beneficial impact. Even if current levels of diagnosis, treatment, and viral suppression remained unchanged, rolling out a vaccine with 50% efficacy starting in 2020, with scale up proceeding at 25% coverage annually up to a maximum of 70% coverage, was estimated to reduce the number of people living with HIV by 36% and HIV-related mortality by 11%. Analyses in which vaccine availability was delayed to 2025 and/or scale up slowed to 10% per year still predicted significant benefit. A vaccine with a higher efficacy of 70% was estimated to have the potential to avert 24 million HIV infections between now and 2035.

In an opinion piece published in *JAMA* last October, Anthony Fauci (Director of the National Institute of Allergy and Infectious Diseases) drew on the work of Medlock and others to articulate the view that “development of a moderately effective vaccine, together with optimal implementation of existing treatment and prevention modalities, could end the current HIV pandemic.”⁵

At the 2015 edition of the International AIDS Society's annual Towards an HIV Cure Symposium, longtime HIV-positive community activist Matt Sharp gave a plenary address highlighting that talk of "Ending AIDS" can seem empty without the promise of curative interventions on the horizon. Sharp advocated powerfully that cure research is a vital component of the effort to vanquish HIV.⁶

Although efficacy trials of candidate cures still appear to be a long way off, researchers have brought models to bear on the question of how hypothetical approaches might affect HIV at the population level. Andrew Phillips and colleagues, in a paper published in the *Journal of Infectious Diseases* in 2016, concluded that an intervention that allowed ART-free viral suppression in a majority of recipients could reduce both the costs and the burden of disease; however, they noted that "given the effectiveness and cost of ART, such interventions would have to be inexpensive and highly effective."⁷

The research group of Rochelle Walensky has similarly found that model outcomes are extremely variable, depending on the estimated effectiveness and cost of a cure intervention.⁸ But Walensky and colleagues also articulate the profound benefits that may elude modeling studies, albeit using the dry and understated language of academia. "This analysis does not account for the psychosocial benefits of being cured. Studies show that stigma, even among HIV-infected people on ART, decreases health-related quality of life. By failing to account for the intangible (but nonetheless real) benefits of complete disease eradication, we may have undervalued cure."

At the most basic level, HIV will not have entirely ended if daily treatment is still required for the majority of HIV-positive people.

The take home message is that, although it's essential that the benefits of the tools available to tackle HIV are maximized as quickly as possible, this will not

obviate the need for sustained long-term investment in the development of effective vaccines and cures. Thus, advocates need to push back against efforts to slash HIV research funding at the National Institutes of Health (or elsewhere) based on a false narrative that the interventions needed to stop the pandemic have already been created.

Continued community engagement with the vaccine and cure research fields remains essential to ensure that there is dialogue and input regarding the challenges that arise—such as the appropriate provision of PrEP to participants in HIV vaccine efficacy trials or the use of ART interruptions to test the effect of cure-related therapeutic approaches.

Ultimately, if success can be achieved in these fields, it has the potential to deliver the coup de grace necessary to finally consign HIV to history.

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IT'S UP TO YOU, **NEW YORK:** MOVING TOWARDS **HCV ELIMINATION** IN THE EMPIRE STATE

By **Annette Gaudino**

Governor Andrew Cuomo's March 16 announcement committing New York State (NYS) to ending the hepatitis C virus (HCV) epidemic was the culmination of years of advocacy on a path that paralleled—and is built upon—the state's nation leading efforts to end the HIV epidemic.

The HCV burden in NYS, and in the U.S., is high and is growing, with the concurrent opioid epidemic driving a 290% increase in the number of new cases between 2010 and 2015.¹ In NYS this translates into 14,745 new HCV infections in 2016,² as compared with 2,881 new HIV cases in the same year.³

Prior to these recent spikes, the majority of people living with chronic HCV infection were "baby boomers," a fact recognized in the January 1, 2014 implementation of a state law requiring providers to offer an HCV antibody screening test to all patients born between 1945 and 1965. Given the eye-popping price of breakthrough direct-acting antiviral (DAA) cures, it should be no surprise that New York State's remains the only HCV screening law in the nation.

That same year, NYS Medicaid Director Jason Helgeson secured significant supplemental rebates for the most commonly used HIV antiretrovirals, creating the conditions for Governor Cuomo's launch of the End the Epidemic initiative. This bold action is a testament to the political power of the HIV movement and came a mere two years after Charles King and Mark Harrington brainstormed a call to end the epidemic after their arrest at the White House during the 2012 International AIDS Conference.

In contrast, 2014 saw the American Association for the Study of Liver Diseases (AASLD) release clinical treatment guidelines recommending that only patients with advanced cirrhosis receive DAAs. Cost-based rationing of treatment for a stigmatized infectious disease? Activists had seen this movie before, and sprang into action:

October 2014: ACT UP/NY and VOCAL NY greeted participants at an AASLD/EASL special conference demanding changes to their restrictive treatment guidelines, which were also being used by Medicaid programs and commercial insurers to deny DAAs to people with past or current substance use. They confront Gilead Executive VP Gregg Alton, calling out his admission on drug pricing: "We didn't base [the price] on our R&D costs, and we didn't base it on our acquisition costs. We spoke to all the payers many times...so how can they be surprised?"

Late 2014: The NY State Hepatitis C Coalition founded by TAG, ACT UP/NY, VOCAL-NY, and National AIDS Treatment Advocacy Project, and quickly grew to include Housing Works, Harm Reduction Coalition, Hepatitis C Mentor and Support Group, Coalition on Positive Empowerment, BOOM! Health, and other community-based organizations. The Coalition successfully rolled back NY State Medicaid Drug Utilization Review Board restrictions over the course of a year-long campaign.

August 2015: Coalition members met with Lisa Landau, the Health Care Bureau chief for NY State Attorney General Eric Schneiderman, catalyzing the office's lawsuit against seven private insurance companies, ultimately resulting in the removal of restrictions on DAA access.

March 2016: Coalition members met with State and New York City Department of Health officials to discuss a state-wide summit on eliminating HCV as a public health threat. Inspired by and loosely following the template created by the End the Epidemic Task Force, Working Groups were formed and met throughout the summer to draft initial recommendations across five overlapping areas: prevention; testing and linkage; care and treatment access; data, surveillance, and metrics; and social determinants of health.

CONSENSUS STATEMENT ON HEPATITIS C ELIMINATION IN NYS

The Consensus Statement consists of five pillars to guide the statewide elimination plan:

1. Enhance HCV prevention, testing, and linkage to care services for people who inject drugs, people who are incarcerated, MSM, and other populations disproportionately impacted by HCV infection.
2. Expand HCV screening and testing to identify people living with HCV who are unaware of their status and link them to care.
3. Provide access to clinically appropriate medical care and affordable HCV treatment without restrictions, and ensure the availability of necessary supportive services for all New Yorkers living with HCV infection.
4. Enhance NYS HCV surveillance, set and track HCV elimination targets, and make this information available to the public.
5. Commit NYS government and elected officials, public health professionals, HCV experts, and industry partners to leadership and ownership of the NYS Plan to Eliminate HCV alongside community members living with and affected by HCV.

Read the full consensus statement: <https://www.scribd.com/document/370608817/NYS-Consensus-Statement-on-Hepatitis-C-Elimination-With-Endorsements>

November 28, 2016: The NY State Hepatitis C Elimination Summit Work Groups Meeting brought together 94 stakeholders to discuss draft recommendations in context and began developing consensus on recommendations to be presented at the statewide Summit.

February 7, 2017: The NY State Hepatitis C Elimination Summit took place in Albany, the first jurisdiction to host such a meeting. Over 250 stakeholders attended the presentation of initial recommendations and a community consensus statement, and called on NY Governor Cuomo to appoint a state-wide Task Force to implement a blueprint to end the HCV epidemic.

December 2017: Members of the Summit Steering Committee, including TAG, Housing Works, Harm Reduction Coalition, VOCAL NY, Hepatitis C Mentor and Support Group, and Coalition on Positive Empowerment, launched the NY State HCV Elimination Campaign, calling on Gilead, AbbVie, and Merck to offer volume-based discounts for DAAs to Medicaid and the Department of Corrections.

January 2018: The HCV Elimination Campaign called on Governor Cuomo to publicly commit to volume-based discounts and other measures to dramatically increase the number of people treated for HCV. Representatives from Merck revealed that the company made an initial offer of volume-based discounts to Medicaid and the Department of Corrections in fall of 2017.

February 5, 2018: Three hundred people participated in HCV Advocacy Day in Albany, highlighting the State's failure to commit to HCV elimination. Citing reported declines in the number of Medicaid recipients treated for HCV between 2015 and 2017, they demanded

\$10.8M to fully fund HCV prevention, linkage to care, surveillance, and programs in jails and prisons.

February 12, 2018: Activists testified at the Joint Budget Hearing on Health and Medicaid in support of their budget ask and legislative platform. In response to ranking Health Committee Member Senator Gustavo Rivera, Director Helgerson announced a potential path to scaling up treatment, stating "We already have statutory authority to look at volume-based discounts [for hepatitis C treatment]. [W]e're going to...look at possibly utilizing that statutory language to see if we can't get ourselves an even lower price, which makes it even easier for us to actively promote the treatment."

March 16, 2018: New York State becomes the first U.S. jurisdiction to commit to eliminating hepatitis C as a public health threat. Advocates welcome the breakthrough, and fight on to fully fund a comprehensive, evidence-based plan to end the HCV epidemic.

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GLOBAL HCV ELIMINATION TARGETS AND CHALLENGES: AN INTERVIEW WITH ANDREW HILL

By Bryn Gay & Annette Gaudino

Are we on track with WHO targets^{1,2} to eliminate the hepatitis C virus (HCV) by 2030? Andrew Hill, Senior Research Fellow, Liverpool University unveils powerful research that compares 91 countries' data on HCV prevalence, diagnosis, treatment, and income level. One central concern is that annually treating an estimated 1.42 million (2%)³ people with diagnosed HCV infection—especially those with healthcare coverage—is insufficient given the enormity of the epidemic. We have yet to scale up screening, testing, and linkage to care for the estimated 56.8 million (80%)⁴ with undiagnosed HCV infection. In addition, we must remove the worldwide stigma in treating and re-treating prisoners and people who use drugs, and lift treatment restrictions. Health departments also need to understand the actual costs of “test and cure,” which are decreasing in the face of direct-acting antiviral (DAA) competition. There's no excuse not to commit to elimination.

BG: Based on 2016 data, your research shows that 10 countries⁵ have cured >5 patients for every new infection. Do trends suggest that these countries will eliminate HCV?

AH: We're going to have to start treating far more people—at least 5 million people worldwide every year [vis-à-vis] the 1.5 million new infections occurring annually. In some countries 2016 was the best year, and after that, treatment rates seem to be falling. To eliminate HCV [countries must cure 5:1] consistently for another 12 years. Countries like Australia that have unlimited access to treatment for a fixed price, they might be able to sustain it. Countries like the U.S., where [it seems] mostly insured patients are treated⁶, they might not be able to manage it. If you've got people who have been recently infected by using intravenous drugs [they're] a lot less likely to be insured. Even if they are covered, there might be [sobriety] restrictions at the state level. And even if they've been re-infected they might not be eligible for treatment for a second time. At the moment it's just not

looking like elimination is going to be possible because we are just not treating enough people.

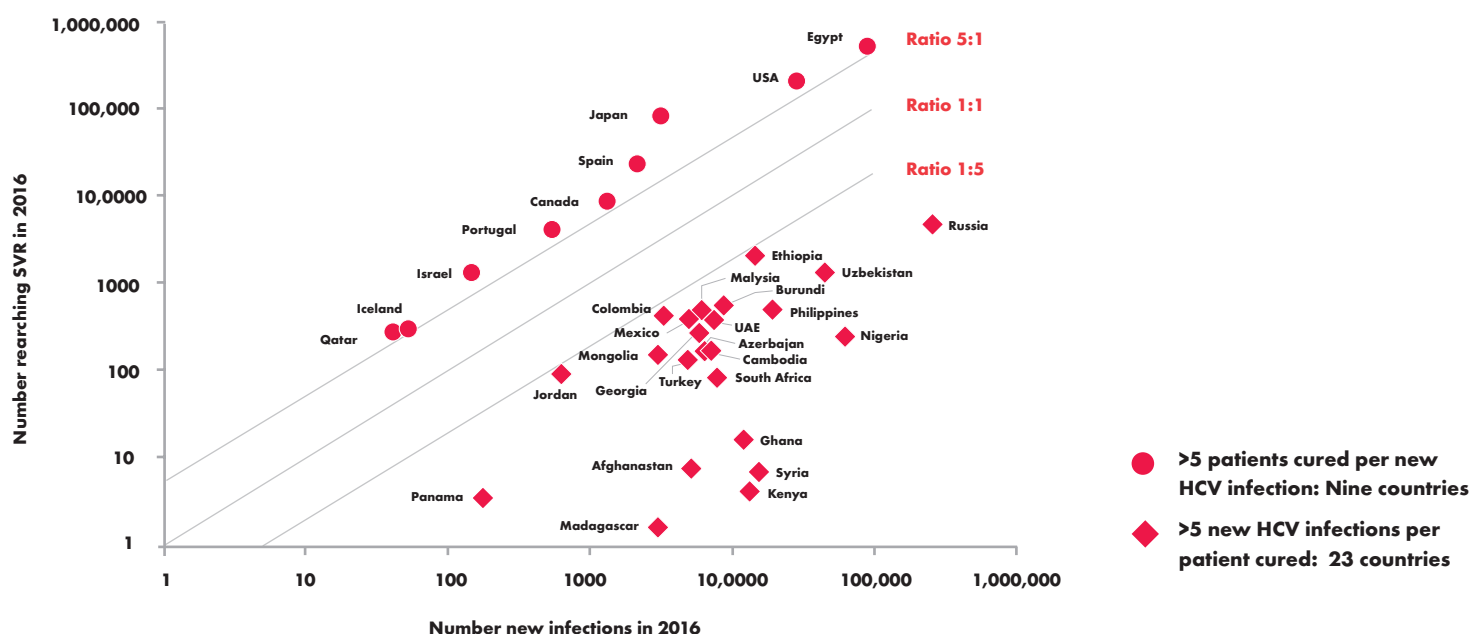
BG: You've coined the term “diagnostic burnout” to describe the point when all diagnosed people with HCV have been treated and you have to find and diagnose new cases. What can countries do to avoid diagnostic burnout?

AH: There's not enough people being diagnosed every year to keep up with the treatment rates, called “diagnostic burnout.” You'll run out of people who are known to have

They need to take the blame out of medicine. We can't keep blaming people for having particular diseases; we just need to get on with it and cure them.

HCV and who can get treated. Even among diagnosed people there are going to be some people who fall through the cracks, who live in states where they don't have health insurance. Countries [or states] need to be given an estimate of what it would really cost to test and treat. In Egypt, a 12-week cure costs US\$100, and all of the diagnostic tests cost US\$25, so they have an all-in package of the cure for US\$125. In the U.S., you could not even get one tablet of HCV treatment for US\$125. Meanwhile in Egypt, 3 million people have already been cured, and there are plans to test 42 million people in the next three years. Other countries need to learn from Egypt and set up similar low-cost test and treat programs.

The Road to Elimination



Countries that could meet elimination by 2030 are those that could sustain 5:1 ratio of treatment per new infection. Countries that could miss the targets are those that have treated no one or fewer than 1 person per 5 new infections.

Source: Hill A. The road to elimination of Hepatitis C: Analysis of SVR versus new HCV infections in 91 countries. Poster presented at: AASLD, 2017 October 20–24; DC.

BG: How does patients' treatment access compare across high-income countries, like the U.S., UK, or in Europe?

AH: [In the U.S.,] we're already starting to reach a situation where there are just not enough diagnosed, insured people who are linked to care, who can get cured. In Australia, they've paid a fixed amount of money and they get unlimited treatment. It's like "all you can treat"—like going into a restaurant and having unlimited access to the buffet. Last year they had a price for DAAs of US\$8,000, which is way below any price that's available in the U.S. or Europe. [It's] a very interesting model for other countries, [to] pay a fixed price to a company and [get] unlimited access, called a "risk-sharing" deal.

BG: Many countries have struggled to collect accurate surveillance data on HCV. How confident should we be with the data tracking our progress?

AH: Worldwide we still [have] an epidemic of 70 million people. We don't have the [same] accuracy [with HCV] estimates that we have in other diseases. Not enough samples have been done. If we look at the data we still don't have this assurance that we're on the right track. We have some countries where you're getting 100 people newly infected for every person cured. I think we

can be fairly sure that there's a huge range of responses to HCV between countries. Egypt, Spain, Australia, and Portugal are doing really well; other countries in Eastern Europe and Africa haven't really started to go on a path to eliminate HCV.

BG: What are immediate actions that countries lagging behind can take to accelerate progress toward elimination by 2030?

AH: Every country needs to start testing the people who are at the highest risk of hep C infection. For some countries that's on par with having to go into prisons and testing all the prisoners, or reaching out to people who use intravenous drugs. They need to take the blame out of medicine. We can't keep blaming people for having particular diseases; we just need to get on with it and cure them. Once those people are cured, you've really started to tackle the epidemic.

BG: What are the implications if we miss the WHO targets?

AH: What a missed opportunity that would be—you've got an infectious disease that kills hundreds of thousands of people a year, and can be cured for about US\$50, and we're not tackling it. How crazy is that?! It would

just be such a classic case of great commercial success—companies making billions of dollars—but medically a failure. It would show that we just don't have our priorities right—where the rich people in high-income countries get cured for vast amounts of money, and still there's not enough left to treat the poor people who are in the most need?

AG: Trump has said Pharma is “getting away with murder” and claimed “the world is taking advantage of us.” Is he right? What are the reasons that other high-income countries pay significantly less than in the U.S. for the same medicines?

AH: The U.S. spends approximately US\$300 billion per year on medicines across all therapeutic areas. The U.S. pays, on average, 2.5–3 times more for patented medicines than countries like Spain, UK, or France. The overspend for the U.S. versus the UK is [about] US\$100 billion, which is a substantial proportion of the [US] Gross Domestic Product.

As part of US law, the main payers (Medicaid, Medicare) are not allowed to negotiate drug prices. If you look at the UK, we negotiate drug prices to justify the value of a medicine against its cost. [There are] similar systems across Europe, Australia, and Canada. The U.S. pays such a high amount of money because it doesn't negotiate. The exception to that is Veterans Affairs, where they actually do negotiate and they have significantly lower prices. [With this overspent amount], you could wipe out HCV, you could treat everybody for HIV. But it's not being done because of this ridiculous policy of not negotiating prices, which Donald Trump has actually done nothing about!

BG: Your other research highlights the significance of generic competition in dramatically reducing the cost of DAAs to a fraction of high-income country prices, even when a 10% profit margin is included. Has this increased people's access to the cure and increased treatment starts?

AH: If a country gets behind a health campaign, great things are achievable. You have to have commitment at the highest level. That helps to get rid of some of the stigma. [There needs to be] more health campaigns to make sure [scale up] actually happens. Fundamentally, countries need to start making this more of a priority. [HCV] is very cheap to diagnose, very cheap to cure. Just add it into your current services with minimal extra costs.

BG: How can activists use this research and participate in policy-making decisions that see more people getting tested and treated?

AH: We need to start going to health departments and saying, “This is the size of the epidemic, and this is how much it could cost to treat and cure everybody.” [When policy makers] realize how cheap it is, they would become interested in it. People hear it's US\$84,000 for one treatment course, but it's not that anymore. Even in the U.S. [the net price is] US\$20,000 to US\$25,000. Even if it's US\$100, and you've got 100,000 people, and you say, “It's US\$10 million,” for that you'll have an epidemic that's been eliminated. People are not going to

[HCV] is very cheap to diagnose, very cheap to cure. Just add it into your current services with minimal extra costs.

get liver cancer, they're not going to get liver cirrhosis, and most importantly, they're not going to spread it to other people. There are huge benefits to countries for eliminating epidemics. The cost of treating people with liver cancer—you've got people in the highest productive time in their lives, dying from liver cirrhosis—it's just unnecessary and it shouldn't be happening.

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FROM MOSCOW TO NEW YORK AND BEYOND: THE FUTURE OF TUBERCULOSIS RESEARCH AND DEVELOPMENT

By Safiqa Khimani and Mark Harrington

Global political will to combat tuberculosis (TB)—once again the world’s leading killer infectious disease—may be increasing as shown by intensified activities leading to the upcoming United Nations (UN) High-Level Meeting (HLM) on Tuberculosis in September 2018.

The build-up to the HLM included the Global Ministerial Conference on Ending Tuberculosis in the Sustainable Development Era—held in Moscow, Russian Federation, in November 2017—which endorsed the World Health Organization’s (WHO) End TB Strategy targets, an 80 percent decrease in the number of new TB cases and a 90 percent decrease in TB deaths by 2030.¹

To ensure the success of the TB HLM, TAG and its allies are working to ensure that the resulting UN General Assembly Political Declaration includes clear commitments to expand the quality and breadth of TB programs and to increase investment in research and development (R&D) necessary to make it possible to eliminate TB as a global health threat.

The UN General Assembly has held four previous health-focused HLMs, including the Special Sessions on AIDS (UNGASS) in 2001 and 2006. The 2001 UNGASS paved the way for the launch of the Global Fund to Fight AIDS, Tuberculosis, and Malaria, which has made considerable investments in all three disease areas and has saved more than 22 million lives as of 2016.²

The first-ever HLM on TB could be a pivotal moment to raise the bar for countries and donors on TB. UN member states now must come together to commit to investments required to meet the goals of the Stop TB Partnership’s *Global Plan to End TB: Paradigm Shift 2016-2020*.³

Current diagnostics and drug therapies will not be sufficient to achieve the required reductions in mortality and incidence. If the current rates continue, there will be 135.2 million new TB cases and 20.8 million deaths from TB by 2030.⁴ New drugs and diagnostic tests that have been developed over the past 15 years are only a start towards meeting these goals. Research and development must therefore be a critical focus of the HLM. The declaration that emerges from the UN HLM must endorse innovative mechanisms for revitalizing efforts to increase funding to expand the pipeline and commit to implementing a comprehensive, integrated, ambitious, high-quality TB research agenda that goes beyond the 2015 *Global Plan to End TB*.

2016 global investments in TB R&D exceeded \$700 million for the second time since 2005; however, this still falls short to the annual \$2 billion investment needed to achieve the *Global Plan*’s R&D targets.⁵ Thus, countries must exceed the *Global Plan*’s five-year funding target of \$8.836 billion to increase support for basic science and operational research to catalyze progress. TAG recommends a global commitment of \$10 billion to make headway on research priorities. Governments and relevant stakeholders must tap into new funding streams to meet this target.

Country-specific funding targets would allow national governments to contribute towards the \$8.836 billion global goal to invest in TB R&D. This would enable them to prioritize their own country’s needs through tangible national plans while investing in the global response. A public, quantifiable commitment will make it easier for civil society to hold their governments accountable and demand that necessary actions be taken in the fight against TB.

Total Funding Required For the Research And Development of New Tools, 2016–2020 in the *Global Plan to End TB: Paradigm Shift 2016–2020*

	Objective	(US\$ millions)
New Drugs	Expand the pipeline to include an effective, simplified treatment regimen (including for TB infection and MDR-TB) that is shorter and has less side effects, and is available for children and adults in order to improve treatment adherence and lower the cost of treatment	4,155
New Diagnostics	Improve TB case detection with a range of biomarker-based tests that can be deployed at all levels of the health system; develop a rapid, sensitive diagnostic test for all forms of TB disease that can be implemented closer to the point of care and takes into account difficult-to-diagnose patients (children, people living with HIV, and people with extra-pulmonary TB)	3,431
New Vaccines	Develop a vaccine that protects against all forms of TB, including infection, and is accessible to all members of the community	1,250
Total		8,836

The BRICS countries—Brazil, Russia, India, China, and South Africa—announced the establishment of a TB Research Network just before the Global Ministerial Conference; this was one of the few concrete pledges made in November. The BRICS TB Research Network aims to support and sustain collaboration, mobilize resources, and implement evidence-based TB care in these countries. This unified commitment allows BRICS countries to leverage new funding sources and go beyond the investments from the top two funders of TB R&D: the U.S. government and the Bill and Melinda Gates Foundation.⁶ The network has the potential to create a model that other countries could emulate.⁷

Although greatly increased funding is vital to ensuring that TB R&D needs can be met, a comprehensive, integrated, and ambitious research agenda will be essential to provide a clear and cohesive strategy amongst the TB community.⁸ The research agenda must span the full continuum of the pipeline, including basic science and biomarker discovery, new diagnostic tests, drugs and treatment regimens, vaccines and preventive therapies, and implementation science to define how best to use new tools in programmatic settings.

Continued on page 20

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THE UNITED NATIONS' BACK YARD: TB ELIMINATION IN NEW YORK STATE AND THE U.S.

by Erica Lessem

The road from Moscow has led us back to New York (see 14), home of the United Nations (UN) and TAG headquarters. New York is also home to one of the largest tuberculosis (TB) burdens in the U.S.¹ Incidence in New York City rose in 2017, and multidrug-resistant TB (MDR-TB), which is costly and difficult to diagnose and treat, is also on the rise.² Despite growing needs, funding for the TB response in New York City has dropped steadily over the past ten years, and fell

any countries in the world, the U.S. has been a global leader in funding TB R&D, and the U.S. TB response in the U.S. is well-resourced relative to that of many other countries. But stagnant domestic TB funding makes rhetoric about U.S. commitment to ending TB within its own borders ring hollow. Indeed, the U.S.'s national TB program at the Centers for Disease Control and Prevention (CDC) has been called the Department of TB Elimination (DTBE) for decades. A National Action Plan for Combatting MDR-TB was launched in 2015.³ Yet DTBE funding has been stuck at just \$142 million annually for the past several years (out of an estimated need of \$260 million per year), with inflation limiting the reach of those dollars each year. In turn, incidence is not budging and drug-resistant TB is increasing.

Such funding limitations mean programs must do more with less, which is especially problematic at a time when recent innovations mean we could actually be ending TB in the U.S. with the right resources. For example, addressing TB infection is an essential component of eliminating TB. DTBE research under the Tuberculosis Trials Consortium led to the development of a shorter regimen for treating TB infection, and complementary work with the DTBE's TB Epidemiological Studies Consortium has identified diagnostic and programmatic approaches that make addressing TB infection on a large scale much more feasible. But a proposed comprehensive TB prevention concept that employs all available tools and targets those at highest risk cannot launch due to the lack of funding.

These troubling national trends are magnified at the local level, where state and city funding is also stagnant or on the decline. New York City had 56% less funding per case in 2017 than it did in 2007, after adjusting for inflation, thanks to a 65% decline in CDC funding, a 38% reduction in City funding, and a 27% drop in

As we look to other countries to commit to improving the global TB response and financing for TB research and development at the UN High Level Meeting in September, it's also time to direct our gaze locally.

precipitously in 2017 when New York State issued a surprise cut to its main TB budget line. As we look to other countries to commit to improving the global TB response and financing for TB research and development (R&D) at the UN High Level Meeting (HLM) in September, it's also time to direct our gaze locally.

Global is National is Local

Chronic underfunding for TB research and programs has allowed the disease to persist with little decline in incidence globally, and even to surpass HIV as the leading infectious cause of death worldwide. Incidence in the U.S. is one of the lowest of

New York State funding. The resulting \$18.9 million funding gap after adjusting for inflation has led to the closure of six of the city's chest clinics, a reduction in clinic hours that makes it much harder for patients to seek care at convenient times, and the elimination of almost half of its TB workforce (plus additional part-time and temporary staff reductions). People who may have this life-threatening, communicable disease are having to wait weeks to even get an appointment.

History Repeats Itself

That TB rates haven't risen further despite this consistent assault on the City's TB response budget is a testament to the dedication and efficiency of the Department of Health and Mental Hygiene (DOHMH) Bureau of TB Control. But it is only a matter of time before the effect of this trifecta of financial battering from city, state, and federal levels hits hard. What's worse, we will know we had it coming: similarly short-sighted cuts in the late 1980s that dismantled the public health response to TB contributed to a massive outbreak of drug-resistant TB in New York City that cost over \$1 billion to control.⁴

Today's precarious funding for the TB response in New York City is also remarkably similar to that of three decades ago in its perpetuation of discrimination and injustice. Foreign-born New Yorkers comprise 85% of TB patients in New York City. The majority have lived in the U.S. for over five years before falling ill, meaning that with the right resources, there would be ample time to intervene and prevent TB. But we are leaving them behind, echoing ethnic and class injustice from when the epidemic largely affected African Americans. As Karen Brudney, MD, who worked for the DOHMH at the time of the earlier MDR-TB outbreak describes, "In New York City in the late 1980s there was no tuberculosis program. It had been completely decimated. It had been de-funded. Why? Talk about double standards. Who got TB in NY back in the 1980s? Poor people, African Americans. Absolutely nobody white or middle class."⁵

Regrettably, we've come full circle. New York prides itself on being a safe haven for immigrants. Yet if it does not have adequate resources to provide timely, culturally competent TB care and treatment, how safe can it really be?

Making Good on a Promise

The promise of ending TB in the U.S. will remain elusive until we dedicate adequate resources to do so. The HLM can galvanize the political will and resources required to eliminate TB as a public health threat not just abroad but in our own country, state, and home town. The federal government, New York State, and New York

New York prides itself on being a safe haven for immigrants. Yet if it does not have adequate resources to provide timely, culturally competent TB care and treatment, how safe can it really be?

City must commit to adequate funding to restore critical services to reverse the increase in TB cases, particularly MDR-TB, and accelerate the decline of TB. New York can be a pioneer in the fight to end TB and set an example to its guests in September.

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IN A STATE OF **DISUNION**: HIV, TB, AND HCV **ELIMINATION** POLICIES AND **PRIORITIES** UNDER THE **TRUMP** ADMINISTRATION

By Suraj Madoori

During Trump's first-ever State of the Union address on January 30, activists observed a dearth of clear priorities to eliminate HIV/AIDS, tuberculosis (TB), and hepatitis C virus (HCV) in the U.S. Science and longstanding bipartisan interest in global health have paved the way for potential monumental political wins by the Trump administration: federally funded research has brought us multiple effective HIV treatments and PrEP for

the tremendously important Ryan White program, continuing to flat-fund the U.S. Centers for Disease Control's (CDC) Division of TB Elimination, and seemingly shifting money from HIV prevention in the name of addressing the opioid epidemic are only a few ways the administration is turning its back on public health progress and needs. There's also the administration's anti-LGBTQ stances, violent rhetoric towards the drug-user community, rules for protecting discriminatory healthcare providers, attacks on 340B drug pricing program, support for states implementing Medicaid work requirements, constant disarray at the State department, and skimming on commitments to the Global Fund, all of which further muddle the policy routes towards domestic and global elimination of HIV, TB and HCV.

Weak proposals and bloated rhetoric have done very little to lower drug prices, leaving this key election campaign promise unfulfilled.

HIV prevention, PEPFAR catalyzed treatment access to millions of people living with HIV globally, HCV has seen an influx of promising cures, and global recognition of the importance of U.S. government leadership in addressing the growing threat of drug-resistant TB. Eliminating these three epidemics from the U.S. and globally are only a few strategic moves away, and yet...

The policy moves made by the administration, this year alone, have been illogical. The President's fiscal year (FY) 2019 budget defies what's left of any momentum toward reducing the deficit, which has already been intensified by the administration's disastrous 2017 tax reform package passed at the end of 2017. It is also the clearest signal yet of how Trump prioritizes these epidemics. Cutting

However, as evidenced by last year's successes in stopping full ACA repeal and Medicaid dismantling, progress with a budget deal with relief to the caps, which effectively raises the federal spending limit by nearly \$300 billion over two years, as well as saving the Fogarty International Center at NIH from elimination, activism can win in a policy environment that is seemingly stacked against it especially in a critical election year. In addition, the union of HIV, TB, and HCV activists is stronger than ever. But with a bleak, unclear roadmap given by our government, what do we prioritize and where do we as a community go from here?

Money, namely through federal budget appropriations, will be the key driver for public health programs geared towards elimination. As this issue of *TAGline* goes to press, advocates are preparing FY 2019 budget priorities and asks to Congress. HIV/AIDS, TB, HCV, and sexually transmitted infection advocates collectively hope, for the first time,

to push the federal government to increase a single number: \$1.12 billion for the CDC's National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), which constitutes a miniscule 2% of the total CDC budget.

Research and messaging on investments in prevention as a strategy that can yield significant savings could potentially appease conservative Congressional deficit hawks. For example, averting TB cases has saved an estimated \$6.7 to \$14.5 billion in societal and economic costs to the U.S. between 1992 and 2014.¹ With respect to HIV, CDC projections predict \$379,000 in savings across the government, healthcare system, and individuals for every new infection prevented.² There's also cost-effectiveness data from a New York City-based needle exchange program, with estimated savings of \$1,300 to \$3,000 per individual.³ Another analysis strongly recommends funding a national syringe program: "three-fourths of HIV treatment costs in the US are borne by the public sector, expanding syringe exchange could contribute to reducing the country's public budget deficit in the long run."⁴

However, it's vital to underscore that some of these significant cost-saving projections are factoring in the high price of treatment in the U.S., which must be another target for activists. The CDC, while making a case for prevention and syringe exchanges as critical access to treatment, acknowledges a stark unevenness in the math by noting, "HCV treatment can save \$14.3 billion in health costs while costing \$69.5 billion to implement, raising budgetary issues for Medicaid and other insurance plans."⁵ The high costs of HCV and other prescription drugs have been recognized by the Trump administration and federal and state lawmakers. But weak proposals and bloated rhetoric have done very little to lower drug prices, leaving this key election campaign promise unfulfilled. Alarming, a white paper released from the White House Council of Economic Advisors skirts the issue by scapegoating other countries for the high prices in the U.S., rather than U.S. government capitulation to the PhRMA lobby.

Instead, a questionable two-pronged strategy is recommended to "reduce prices for what Americans pay now for pharmaceutical products" and "raising innovation incentives," which is a cover for manipulation and deregulation tactics.⁶ The white paper surmises policies that underpricing of drugs in foreign countries has a profound effect on the cost of drugs to the American consumer.⁷

HIV, TB, and HCV advocates must target the U.S. Trade Representative, a position that will likely be used under the guise of reducing prices domestically to clamp down on other countries' ability to exercise Trade Related Aspects of Intellectual Property Rights (TRIPS) flexibilities. Furthermore, any attempts to deregulate the FDA further, whether through the implementation of the flawed 21st Century Cures Act, to advance dangerous Right-to-Try bills that favor PhRMA must be met with community opposition.

To that end, without real meaningful policy and reform aimed at lowering the price of prescription drugs head-on—with drug pricing proving to be important structural barriers to HIV, TB, and HCV treatment in the U.S.—and shoring up underfunded programs, the Trump administration will remain woefully short of achieving much what of it has promised, and we will be even farther as a community from achieving true elimination in the remaining time left in this presidency. But there are policy opportunities in the chaos. In 2018 and in advance of the November midterm elections, advocates and activists will need to continue to be the change we seek by convincing winning conservatives with the cost-effectiveness of prevention to rectify their own tax reform debacle, and come together as a community to push real policy strategies to mitigate high-price of drugs across HIV, TB, and HCV.

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The pace of product development in TB has been incremental rather than transformational, despite the advances in the TB pipeline, such as the urine LAM dipstick—a simple test to diagnose TB in hospitalized HIV-positive patients—and the first approval of two new drugs from novel classes to treat TB.^{9,10} Lack of investment has dramatically slowed the actions needed to bend the epidemic curve towards achieving the global goals. *The Global Plan* strategy on R&D outlines the specific funding required to implement the key objectives and proposes specific tools that need to be developed to narrow gaps in research (see table).¹¹

TB researchers have made noteworthy progress with the introduction of two new drugs into programs for drug-resistant TB. Other new approaches include the NIX-TB trial, which uses just three all-oral drugs to treat extensively drug-resistant TB (XDR-TB).^{12,13} If these results are confirmed in larger studies and in programmatic practice they will mean a major breakthrough in simplifying and shortening treatment of XDR-TB.

Accelerating a medical breakthrough such as this requires new financing mechanisms to fund research on TB. We could be nearing a transformative turning point in the struggle against TB. We must intensify our efforts to ensure that the upcoming UN HLM on TB creates meaningful momentum in research and programs to end the disease.

SUPPORT TAG

As TAG works to advance its campaigns to end the HIV, TB, and HCV epidemics while defending against new and unprecedented political challenges, your support is needed now more than ever before. Donate online: www.treatmentactiongroup.org/donate.

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When you shop on Amazon, enter the site at smile.amazon.com. Choose TAG Treatment Action Group as your designated charity, and 0.5 percent of the price of your eligible purchase will benefit TAG.

ABOUT TAG

Treatment Action Group (TAG) is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and hepatitis C virus.

TAG works to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information.

We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions.

TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end HIV, TB, and HCV.

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