Vol. 23, No. 2, October 2016

tagline

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

HEALTH, HUMAN RIGHTS, and SOCIAL JUSTICE

By Tim Horn

Maximizing HIV, tuberculosis (TB), and viral hepatitis outcomes depends on the availability of state-of-the-art diagnostic and prognostic tools, engagement in expert and supportive care, and access to safe and effective drugs. Numerous technical barriers to these core components of health and survival exist, such as failures to maintain or improve healthcare infrastructure and capacity building, inadequate funding commitments, bureaucracy and corruption, and corporate rapacity, all of which are priorities for Treatment Action Group and its advocacy partners.

But it's not simply about advancing good global health policies. It's also about pushing for good global policies for health, notably those that take aim at the larger social, political, and economic conditions that exacerbate disparities and inequities among those living with, and at risk for, HIV, TB, and viral hepatitis. In this issue of ***TAGline***, several TAG staff members call out some of the most critical social and structural challenges that we continue to face in ending these pandemics.

We begin with an edited transcript of Mike Frick's thought-provoking presentation at the International AIDS Society TB2016 conference held in Durban in July. In "Science and Solidarity," Frick demonstrates how human rights can be harnessed to advance TB research and the benefits of this research to all people with TB. While Frick argues that governments bear a great deal of responsibility for ensuring that scientific progress is upheld as a human right, Erica Lessem and the University of Chicago Law School's Brian Citro add in "Who's Responsible? Pharma's Obligations Under the Right to Science" that the private sector—notably the drug industry—is also obligated to respect, protect, and fulfill public health needs.

In "Countering the Contagion of Racism Through Resistance," Suraj Madoori sheds light on an often unacknowledged part of the HIV and TB movements: the history of Black activism and mobilization to construct the reality of these epidemics through data, organizing, and engaging with political structures to shift resources. The Tuskegee Syphilis experiment and the resulting health disparities and mistrust of biomedicine among African Americans is the focus of Kenyon Farrow's "Beyond Tuskegee," but with an emphasis on the need to reframe the consequences of history as opportunities to create educational, advocacy, and funding opportunities to address ongoing healthcare engagement challenges.

TAG's new HCV Project Co-Directors Annette Gaudino and Bryn Gay explore two critical components of global efforts to end the viral hepatitis pandemics. In "Decriminalization is a Public Health Strategy," Gaudino argues that the war on drugs and the resulting high rates of incarceration are the antithesis of effective strategies for combatting hepatitis C. Against the backdrop of the recent approval of the first single-tablet direct-acting antiviral regimen active against all HCV genotypes, Gay emphasizes the need for conscientious solidarity among countries of the global South, as well as across countries in the North and South, to make universal access to low-cost generic formulations a reality.

We conclude with Jeremiah Johnson's "Toward Health Equity," an appraisal of under-representation in the US's response to the HIV epidemic, notably the absence of transgender women in surveillance and intervention data-collection efforts and the dearth of both transgender women and gay and bisexual men of color in positions of stakeholder leadership and high-level engagement.

The sum of these parts is clear: recognizing and addressing the root causes, longstanding inequalities, and power imbalances that contribute to health injustices is essential If we are to respond effectively to the disparities of these life-threatening diseases. •

SCIENCE and SOLIDARITY

Using human rights to strengthen TB research and access

By Mike Frick

Editor's note: The following is based on the transcript of a plenary address delivered by the author at TB2016, a two-day TB conference held before the July International AIDS Conference in Durban, South Africa.

The close connection between tuberculosis (TB) research and human rights is something that civil society and TB-affected communities have already recognized and articulated. It's an idea that TB activists, led by our comrades in South Africa's Treatment Action Campaign (TAC), have taken to the streets. At the 46th Union World Conference on Lung Health in Cape Town, South Africa, TAC organized a march of over 500 people under the rallying cry "invest in TB R&D". The marchers called on political leaders of the BRIICS countries—Brazil, Russia, India, Indonesia, China, and South Africa—to triple their funding for TB research, delivering an urgent reminder to these politicians that their people are still dying of TB.

The close connection between human rights and TB research has also been recognized in Geneva, where one of the foundational planks of the World Health Organization (WHO)'s *End TB Strategy*—protecting and promoting human rights, ethics, and equity—upholds the strategy's three pillars of interventions, including intensified research and innovation. So TB activists have voiced demands for increased investment in TB science on the basis of human rights consequences, such as loss of life, and the WHO has suggested that there is a connection between protecting and promoting human rights and TB research. But understanding the demands of TB activists and the aspirations of the WHO's *End TB Strategy* requires understanding what we talk about when we invoke rights. Human rights are more than vague aspirations or ideals. They refer to specific entitlements that are timeless, fundamental to the human person, and defined by international law. As such, human rights primarily concern the relationship between individuals and their governments, which are charged with upholding rights through a set of actions we refer to as respecting, protecting, and fulfilling rights.

Discussions about human rights and TB research are often limited to the observation that the conduct of research must respect medical ethics and rights. But beyond ethical research conduct, TB research affects human rights in a number of ways. TB research, and access to its benefits, can either reinforce or resolve ethical dilemmas in TB prevention, diagnosis, treatment, and care. Consider how the slow progress in TB drug development has left people with TB reliant on poorly performing, poorly tolerated regimens that complicate adherence in ways that raise a host of ethical issues that TB programs must navigate. TB research can also change the way that TB is culturally perceived. Imagine having the power to work against fear and stigma if the message that TB is curable were widely known. Imagine the reverse: the gains against stigma and fear that could be rolled back if, due to a lack of research, what was once curable becomes more chronic and deadly, as is happening with the rise of drug-resistant TB.

Research can also galvanize advocacy and clarify legal petitions for redress of TB-related harms. We've seen that happen in two landmark court cases this year. In Kenya, the High Court ruled that sending people with TB to jail to ensure adherence is not consistent with human rights standards, a decision that confirmed what should be self-evident: TB is not a crime. In South Africa, miners won the right to act as a class in their litigation against gold mining

companies for failing to protect them against silicosis and TB. Both cases drew heavily on the science of TB transmission. Finally, research can either reinforce or resolve inequities that drive the TB epidemic. Think about who has access to clinical trials, how research is regulated, and the difficulties of ensuring that the products of research—new tools for fighting TB—reach all of the people in need.

Human rights also hold the potential to strengthen advocacy for intensified research and innovation by setting higher standards that research activists can appeal to and by establishing the legal duties of governments in regard to science. Within international human rights law, two rights have particular relevance for advancing research. The first is the right to the highest attainable standard of health (e.g., Article 12 of the International Covenant on Economic, Social, and Cultural Rights [ICESCR]). The right to health, in part, charges governments with ensuring that the conditions conducive to a healthy life are in place, including the availability of health goods and services. Where inadequate or outdated tools hinder a vigorous public health response to an epidemic, fulfilling the right to health may require governments to ensure the availability of health technologies by promoting the research required to create them.

The second human right with the potential to advance TB research is the right of everyone to enjoy the benefits of scientific progress and its applications (e.g., ICESCR Article 15). Under this right, scientific progress does not just refer to the general knowledge that accrues from scientific discovery, but instead extends to the actual applications of knowledge. In medicine, applications of scientific progress often take the form of tangible benefits—e.g., new disease-fighting tools. In keeping with the human rights principle of non-discrimination, all people are entitled to enjoy the right, and particular attention must be paid to vulnerable and marginalized groups. ICESCR Article 15 tasks states with two obligations: to develop science and to diffuse it. In other words, development and diffusion are distinct, yet related, steps to be taken on the same plane of concern for governments.

What do development and diffusion entail? According to a 2012 report by the UN Special Rapporteur in the field of cultural rights, development points to public investment in science. Diffusion refers to the dissemination of scientific knowledge and its applications, not just within the community of scientists, but within society as a whole. Human rights scholar Audrey Chapman has outlined a number of steps that governments can take to promote the development and diffusion of science and to introduce accountability mechanisms so that the public can hold state and non-state actors accountable for taking these steps.

1. Set priorities for public funding and channel sufficient investment in a "purposive development of science and technology" to meet the needs of disadvantaged groups.
2. Establish regulatory schemes to oversee the conduct of research and to evaluate products developed elsewhere, allowing for their importation to the benefit of constituents.
3. Create opportunities for public participation in science. This starts with acknowledging that individuals have the right to participate in research as more than just clinical trial participants and that the public has a role to play in scientific agenda setting and the translation of science into policy and practice.
4. Devise programs to ensure that the benefits of science are equitably distributed.

For more on the obligations of non-state actors, see "Who's Responsible? Pharma's Obligations Under the Right to Science " by Erica Lessem and Brian Citro, page 6.

So how are governments doing when it comes to the development and diffusion of TB science? Not very well. Global funding for TB R&D is woefully inadequate. It has never exceeded US$700 million per year globally and has remained flat since 2009, falling behind the pace of inflation. Moreover, funding is highly concentrated among a few institutions. In 2014, 50 percent of the US$674 million spent on TB R&D came from just two organizations: the U.S. National Institutes of Health and the Bill & Melinda Gates Foundation. Whether governments recognize their obligation to develop TB science is critical, as TB research depends on public budgets. Sixty percent of all money spent on TB research in 2014 came from public agencies, a reliance that has only intensified since 2011, the year when pharmaceutical companies began to pull out of TB research (combined, industry spent US$100 million on TB R&D in 2014 compared with US$145 million in 2011).

What are the consequences of limited funding for human rights? It limits the equity proposition of TB research from the outset. It also means that compromise is woven into the fabric of TB research itself. There is a real sense at TB research meetings that investigators are conditioned to think not just in terms of efficiencies, but actual scarcities. This has created an assumption of austerity that has affected how the field prioritizes different research objectives. For example, there is little money for research to meet the needs of the groups most vulnerable to TB: pregnant women, children, people who use drugs, and people with HIV. Limited funding has also affected the quantity and quality of TB science. Compare the number of studies behind the new TB drug delamanid with those behind dolutegravir, one of the newest antiretrovirals. By the time dolutegravir received approval, it had completed or initiated 61 studies, compared with six for delamanid. This disparity partly reflects differences in funding. In 2011, the world spent more than US$2 billion on HIV drug development, compared with under US$300 million on TB drug development in 2014. In terms of innovation, TB is not keeping pace with its sister epidemic, a fact borne out by U.S. Food and Drug Administration (FDA) approvals. Since 1987, the FDA has approved over 37 drugs, formulations, or drug combinations for HIV, compared with just two drugs for TB.

So that's the development story. How are governments doing in terms of their other obligation: diffusion? Here, too, things are not looking good. A survey of 24 countries conducted by Médecins Sans Frontières revealed that national TB policies are seriously out of step with global guidelines. Of 24 countries surveyed, only 30 percent had policies to ensure that rapid molecular tests are used as the initial diagnostic for everyone evaluated for TB, only 12 percent had all of the drugs used to treat drug-resistant TB on their national essential medicines list, and only 65 percent had a process in place to access the newest TB drugs for patients out of other options. So whether it's old technologies or new technologies, governments have failed to diffuse the benefits of TB research in policy and practice.

In an article published in the *American Journal of Public Health* in 1999, Paul Farmer singled out the imperative to place the right to scientific progress alongside the right to health to advance human rights and medicine. With the example of drug-resistant TB in the Russian prison system in mind, he wrote: "[what we need is] an agenda for research and action grounded in the struggle for social and economic rights, an agenda suited to public health and medicine whose central contributions for future progress in human rights will be linked to the equitable distribution of the fruits of scientific advancement."

More than 15 years later, we have yet to firmly link science to human rights. We are still in need of an agenda for "research and action" to meet the challenges of TB and other diseases. •

ROLE OF GOVERNMENT:

protect rights (accountability for non-state actors) **&**
fulfill rights (through funding and supportive regulatory environments)

PURPOSIVE INVESTMENT

GOVERNMENTS SHOULD use their convening power and funds to:

- **support investigator-initiated research**
- **identify and fill research gaps** by developing area-specific calls to address high-priority health needs (particularly those affecting vulnerable groups)
- support and **engage in responsible public-private partnerships**
- create frameworks that **facilitate combination product studies** (including involving multiple developers)
- **plan early for diffusion**, including making public funding for research dependent on meeting availability, accessibility, acceptability, and quality (3AQ) and enforcing this

ACCOUNTABILITY FOR AFFORDABILITY

GOVERNMENTS SHOULD:

- ensure people have access to legal tools to **challenge unaffordable drug prices**, including through pre- and post-grant patent challenges

REGULATORY ENVIRONMENT

GOVERNMENTS SHOULD:

- **facilitate research** through empowered, efficient regulators, protecting participants and public without undue delays in approvals
- **create regulatory incentives** for research in neglected fields or vulnerable populations (and make incentives contingent on novelty and widespread diffusion)
- **facilitate access** though mechanisms for safe and efficient pre-approval access for those without approved alternatives
- **collaborate and harmonize internationally** where appropriate to reduce the registration burden on developers
- **build transparency** with opportunities for public comment and clear timelines for decisions
- **monitor and enforce** conditions of approval and quality standards; recall products if necessary

DEVELOPMENT • • DIFFUSION

BASIC & TRANSLATIONAL SCIENCE

ACADEMIA SHOULD:

- **create responsible intellectual property (IP) policies and licensing agreements** driven by the human rights principle of diffusion and the needs of end users rather than pharma profits

DEVELOPERS SHOULD:

- **link with independent investigators** to scout basic science developments for product potential, and make compound libraries available to investigators for screening
- **incorporate planning for diffusion** early on in licensing and IP agreements

PRECLINICAL DEVELOPMENT

DEVELOPERS SHOULD:

- **advance candidates rapidly** through development (and contribute human and financial resources to do so),
- **evaluate lead candidates' potential** to meet the needs of vulnerable populations and acceptability criteria
- **engage early with regulators**

CLINICAL DEVELOPMENT

DEVELOPERS SHOULD:

- **make products and study data available for collaborative research**
- **include vulnerable populations** in trials appropriately
- **plan early for post-trial access** (both compassionate use and approvals and marketing)
- **conduct trials ethically**
- **allow for public participation** (community engagement) in decision-making on trial design, implementation, and planning for diffusion
- **promote transparency** in research, decision-making, and public dissemination of data

MARKETING APPROVAL

DEVELOPERS SHOULD:

- **file widely for marketing approval**, especially in high-burden settings
- **pursue indications** relevant to vulnerable groups
- **meet terms of approval** and publicly report on progress

POST-MARKETING

DEVELOPERS SHOULD:

- **uphold 3AQ commitments** (availability, accessibility, acceptability, and quality), including through flexible IP policies such as non-restrictive voluntary licenses
- **continue to optimize products**
- **monitor for harm**
- **make post-marketing data available**

ROLE OF NON-STATE ACTORS:

respect rights (through avoiding any violation of rights), and invest in products and develop portfolios that meet the needs of end-users—including those of the most vulnerable—rather than catering to shareholders exclusively

WHO'S RESPONSIBLE?

Pharma's Obligations Under the Right to Science

by Erica Lessem and Brian Citro

Benefitting from scientific progress is a human right, but who's responsible for ensuring that this right is upheld? As Mike Frick clearly lays out in "Science and Solidarity" (page 2), governments must respect, protect, and fulfill the right to science through development and diffusion of science and its applications. Indeed, human rights are primarily concerned with the relationship between individuals and their governments. However, as many countries rely on the private sector for the vast majority of research and development (R&D), and increasingly privatize the provision of social services, activists must also ask what obligations private companies have to uphold human rights and take steps to hold them accountable when they do not.

At a minimum, all non-state actors—including pharmaceutical corporations—must respect human rights. The obligation to respect means that they must not take steps that violate rights. *The Universal Declaration on Human Rights* clearly states that no group or person may "engage in any activity or … perform any act aimed at the destruction of any of the rights and freedoms set forth herein." *The United Nations Guiding Principles on Business and Human Rights* also establish the corporate responsibility to respect human rights, meaning that corporations "should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved."

Corporations also have legal personhood under domestic and international law, as determined by international agreements that subject them to direct liability and by rights granted, for example, under the US constitution. Companies are increasingly assuming roles once reserved for states by providing public goods and services through, among other things, the privatization of prisons or the formation of public-private partnerships in the fields of military, education, and health care. In addition, corporations increasingly resemble states in scale; Pfizer's 2015 revenues, for example, were greater than the GDP of about three-fifths of the world's countries. If corporations are recognized as persons under the law and resemble states in both roles and scale, then, like states, they must be held directly accountable under human rights law.

With this in mind, let's consider how pharma fails to respect the right to science. It starts at development—driven by profit, companies invest in products with a highly remunerative market, ignoring conditions of the poor, and violating the principle requiring a focus on vulnerable groups. Hence the sparse pipeline for new tuberculosis drugs, which contains just six candidates with very few trials. Even when lifesaving products are developed, pharma often fails at diffusion, declining to register products where they're most needed, and setting prices prohibitively high in violation of the principle of nondiscrimination. Consider the painfully slow progress of HIV pre-exposure prophylaxis availability around the world and the exorbitant price of Gilead's sofosbuvir, at $90,000 in the US.

As the private sector continues to dominate the field of medical innovation, it's vital that we hold pharma directly responsible for respecting the right to science, through both the development and diffusion of products that respond to public health needs and that are available and affordable to those who need them.

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COUNTERING the CONTAGION of RACISM THROUGH RESISTANCE

Upholding narratives of Black science and treatment activism, and community mobilization in HIV/AIDS and TB

By Suraj Madoori

In February 2016, startling data released by the Centers for Disease Control and Prevention (CDC) at the Conference of Retroviruses and Opportunistic Infections (CROI) predicted that one in two black American gay men will acquire HIV in their lifetime. Illustrative data, however, carries a danger of historicizing HIV, which has led to narratives that portray the Black community, especially Black gay men, as the 'new face of epidemic' after a first-wave response led by mostly white gay men, when, as evidenced by Black activists, there has been a disproportionate effect on communities of color from the very beginning that no one has been paying attention to. It wasn't until HIV appeared in white bodies that HIV became a threat, which sparked Black activism and mobilization to construct the reality of the HIV epidemic through data, organizing, and engaging with political structures to shift resources.

Even after 35 years of HIV/AIDS, the stories of critical Black activism are notably absent in the dominant media and movement narratives. Although a vibrant movement history has been depicted in biopics ranging from *How To Survive A Plague* and *United In Anger,* the narratives of activists of color have somehow remained sidelined against a white-dominant backdrop. Yet the contributions of early Black activism in resisting medical racism and catalyzing a much-needed racial analysis to advocacy offers lessons in how we can embolden the national response to address structural issues, human rights, and social justice as a means of strengthening efforts in HIV prevention, treatment, and care.

Keith Cylar and Robert Vazquez-Pacheco are two of the most well-known Black activists in ACT UP, with Cylar being important in the creation of the Treatment and Data Committee of ACT UP, progenitor to the present-day Treatment Action Group (TAG). However, Vazquez-Pacheco in a 2012 interview with TheBody.com, recalls the tensions in race and class that were present in the movement, citing Cylar and Moisés Agosto-Rosario, currently the Director of Treatment at NMAC, as activists of color that called for a deeper analysis:

> *One of the things that I saw was that the gay white men organized in ACT UP ... let me preface this by saying that I will be forever grateful for them, because if they hadn't done anything, we'd all be dead, but they organized because they knew that the system that they grew up with wasn't working for them. It suddenly had betrayed them and didn't actually care about their lives. They didn't say that the system was flawed; they believed it could be repaired, tweaked for it to work better. Whereas for women and people of color, women and people of color said, "This system has never worked for us."*

Activists like Vazquez-Pacheco and Cylar challenged the dominant white narrative in a critical manner, suggesting that the epidemic among the African-American community was intertwined with deep systematic and sociopolitical injustices that complicated access to care and treatment. But this recognition and subsequent activism by African-American activists predates the HIV/AIDS epidemic. In fact, it may find its roots in an even more invisible racial narrative of an epidemic in the United States: tuberculosis.

Tuberculosis (TB) became one of the most infectious threats wreaking havoc among Black communities across the US in the beginning of the twentieth century. Much like the present-day HIV epidemic, infection rates in these communities would place the epicenter in concentrated urban centers with stark health disparities between Blacks and whites. For example, Professor and researcher of African-American History at Pennsylvania State University, David McBride, in his book *From TB to AIDS*, describes death rates as being 10 to 20 times higher among Black youths in Chicago in the 1920s than among their age-matched white counterparts. Similar patterns in TB death rates in the same decade repeated in urban Black communities in Baltimore, Cleveland, Detroit, New York City, Philadelphia, and Washington, DC.

But causative factors—such as growing poverty, socioracial divisions, migration, and unsanitary housing conditions—explaining the frequency of disease in poor Black communities were routinely ignored in a racially tumultuous era of American history. Instead, a theory of 'racialized susceptibility' to TB would be pushed by predominantly white public health institutions and supplant the epidemiology, leading to a simplified—and racist—notion that Black bodies were somehow 'predisposed' to TB infection. This skewed the public response to ignore obvious issues of racial justice that compounded the death rates among Black communities.

McBride further recounts the narrative of early Black community and science activism as being central to discounting theories of racial susceptibility and contagion in the US TB epidemic, in which a "community-based, Black public health sector provided a crucial bridge." In the 1920s and 1930s, McBride argues, the community mobilization efforts by a small cadre of Black medical activists were critical for catalyzing both the clinical and theoretical movement against medical racism.

Among these activists was H.L. Harris, a Black public health researcher who criticized deceptive data, notably by a public reply to a widely held commentary on declining TB rates in the Black community through improved social conditions. McBride wrote that, although the white statistician-author acknowledged that better social conditions could improve TB rates in the Black community, the author continued to uphold the idea that Blacks had a racial predisposition to TB and "further blamed immoral social behavior of Blacks for [their] higher rates of illegitimate births and venereal disease." In response, Harris argued that the slowness in the ability of the Black community to obtain benefits and access to adequate housing, better pay, and safer working conditions that were equal to those of white individuals would continue to result in excess deaths of Black people to TB, even as rates declined.

In his book *Infectious Fear,* Samuel K. Roberts, professor of history at Columbia University, details the story of another Black activist physician, M.V. Ball, who responded to published scientific literature on racial disposition to pulmonary TB. Roberts describes how Ball did so by discrediting methodology in sampling, such as the exclusion of critical controlling factors such as social class and past medical history in study samples, especially among the incarcerated.

As history would demonstrate again many decades later, an infectious scourge, social stigma faced by oppressed groups, lack of community representation in scientific institutions, and rising death rates would be conditions that catalyzed community mobilization and activism to fill the vacuum in the response. But most importantly, armed with science, Black activists were able to counter prevailing 'scientifically supported' research to build awareness on deeper socioeconomic challenges and racist conditions that heightened the TB epidemic among impoverished Black communities.

The need for a racial analysis and justice in the present-day epidemic remains an important and powerful framework for current Black HIV/AIDS activists. Kenyon Farrow, TAG's U.S. and Global Health Policy Director and self-described "dance and theater kid," recalls that his early days of working on incarceration issues with

Critical Resistance led him to embrace science-based HIV/AIDS activism. What shifted for Farrow was the power of utilizing data to tell a story and create contexts for community mobilization to explain what was happening systemically among communities of color. Or similarly in the case of early TB activism, how data could be used to counter prevailing racist narratives about Black communities.

In the early 2000s, the 'down-low' narrative began to break, which included stories suggesting an epidemic of gay sex in prisons that resulted in Black men transmitting HIV to their female partners after being released. Farrow began questioning HIV transmission rates in jails, delving into the statistics, and came across a Bureau of Prisons report on HIV in prisons. Farrow found disparities in HIV rates, with more women living with HIV being incarcerated than men—placing an important spotlight on HIV and incarcerated Black women. Farrow described this revelation as being influential: "[It] changed my perspective on what I thought I could do and created a shift in me in how it [data and science] pertains to Black activism and organizing."

The challenges are far from over. According to Farrow, one of the systemic failures that compels him to work on HIV prevention and treatment issues today is the decision by the U.S. Supreme Court to allow states to choose whether or not to expand Medicaid. The decision, would "break my heart," says Farrow, pointing to excessive data analyses on the HIV and poverty syndemic that affects predominantly vulnerable Black communities in Southern states that are not expanding Medicaid, denying millions of people access to HIV treatment and prevention. Using these data now, explains Farrow, is vital for structuring a sociopolitical argument that links treatment and prevention access issues among Southern Black communities, and mobilizing activists to urge Medicaid expansion to fill this vacuum created by policymakers.

Black community mobilization and science-based activism in HIV continues to be vibrant and essential for shifting the landscape of HIV care and prevention. Current community-led HIV activism includes the Counter Narrative Project (CNP), an Atlanta-based organization that mobilizes Black gay men through a lens of Black gay culture. In particular, CNP, in their 2016 *National HIV Testing Day Statement*, has looked to the recent data analysis from CDC at CROI as a call to action for Black gay men to counter the narrative on what has been termed as a "fearfully formulaic and increasingly predictable" public health response. In doing so, CNP argues that the power of important advances in biomedical prevention and treatment will continue to lag in communities of Black gay men unless critical social and structural factors, such as stigma, homophobia, unemployment, criminalization, and even Medicaid expansion, are also addressed. According to CNP Executive Director Charles Stephens, this also includes making critical investments in Black gay men's community institutions and movement leadership.

History has shown that Black activists, from TB to HIV, have repeatedly resisted the narrative brought forth by public institutions by providing the essential depth through a racial justice lens that clarifies specific targets to meet the needs of vulnerable communities with the potential to maximize treatment and prevention outcomes. In addition to Cylar and Vazquez-Pacheco, activists regard David Malbranche, Greg Millett, Dazon Dixon Diallo, Mario Cooper, Cathy Cohen, Bob Fullilove, Mindy Thompson Fullilove, Ibrahim Farajaje´, Craig Harris, and artists Essex Hemphill and Joseph Beam—even the dismantled Black Panther party—as critical individuals and institutions that have articulated intersectional health and social needs for Black communities in the current HIV/AIDS movement.

It will be the work of Black activists to shift the movement narrative into the next federal administration. Most recently, the national End the Epidemic (EtE) coalition was represented by the organizer and advocate Daniel Driffin, an HIV-positive, Black, gay man, before the 2016 Democratic National Convention, calling for more investment in research, prevention, and care with a critical eye towards improving data. Daniel's words and representation certainly do not just highlight the current state of the epidemic, but resonate the depth of history and resistance pushed forth by many Black activists and are a call to action to mobilize communities on the inevitable policy challenges ahead.•

Beyond TUSKEGEE

A case for a racial justice agenda in treatment and research

By Kenyon Farrow

The Tuskegee Syphilis study remains a primary citation in both the scientific literature and popular conversations to explain the reluctance of African Americans to engage with the US healthcare system—from partaking in regular medical visits and preventive care, to adherence to medications (including antiretrovirals) to participation in clinical research trials for the development of new diagnostics, treatments, vaccines, or curative therapies.

Unfortunately, this places the onus of health disparities onto African Americans, and not on the systems responsible for both the legacy of mistrust of health care and biomedical research and the continued inequalities in access to care. The way forward is to begin reframing these disparities not simply as the consequences of conspiracy, but to actually create the contexts in which African Americans have access to influence and shape policy and programs through leadership development, community-education programs that demystify health care and biomedical research, and access to funding for community-organizing projects that challenge these systems to be more responsive to the needs of people of African descent in the US and abroad.

Untreated Syphilis in the Male Negro

Twenty-Two Years of Serologic Observation in a Selected Syphilis Study Group

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Since 1932 there has been carried on a study of the outcome of untreated syphilis in the male Negro.* Although the primary objective of this study is the determination of the clinical outcome, this group of patients also furnishes valuable data on the serologic pattern of untreated syphilis.

No serologic data are available for the period from the initial examination in 1932-1933 to the first follow-up examination in 1938-1939. Since 1930, however, annual serologic examinations have been attempted. The last examination, completed in December, 1954, extended the observation period to 22 years. The initial serologic examination in 1932-1933 was based on the Kolmer complement fixation and Kahn standard flocculation tests for syphilis, performed at the National Institute of Health. For the 1938-1939 and subsequent surveys serologic testing has been done by the Venereal Disease Research Laboratory (formerly at Staten Island, N. Y., and now located at Chamblee, Ga.). Although a battery of tests has been employed, the Kahn standard is the only test remaining more or less constant throughout the 22 years of observation. The following analysis, except for a comparison of tests employed in the most recent surveys, will be limited, therefore, to results obtained by the Kahn technique.

In addition to the 408 men selected as syphilitic in 1932-1933, this analysis includes 10 of the 201 nonsyphilitic controls selected in 1933-1934 who later acquired syphilis and 13 of the 14 syphilitic patients added to the study in 1936-1939. The 14th patient in this latter group has been omitted because of questionable history of infection and large amount of antisyphilitic treatment received. Thus, the syphilitic group under consideration totals 431 men.

The status of these patients as of December, 1954, is shown in Table 1 by duration of infection on admission to the study. Of the 431 men, 176 (40.8%) were known to be dead. The death rate increased from 18% among patients with syphilis of less than 10 years' duration to 96% among patients with syphilis of 40 or more years' duration at time of admission to the study. These seemingly high death rates are attributable to the fact that 56% of the patients were over 40 years of age at the time of selection; 30%, over 50 years of age.

Submitted for publication Nov. 9, 1955.

This article is one of a series on untreated syphilis in the male Negro which the Venereal Disease Program, Division of Special Health Services, plans to assemble into a monograph. Single copies of the monograph will be made available upon request to the Venereal Disease Program, Division of Special Health Services, Public Health Service, U. S. Department of Health, Education, and Welfare, Washington 25, D. C.

From the Venereal Disease Program, Division of Special Health Services, Public Health Service, U. S. Department of Health, Education, and Welfare, Washington 25, D. C.

Formerly, Director, Venereal Disease Research Laboratory, now at Duke University, Department of Medicine (Dr. Olansky); Director, Venereal Disease Research Laboratory (Mr. Harris); Medical Director, Assistant to the Associate Chief for Program, Bureau of State Services (Dr. Cutler); Statistician, Venereal Disease Program, Division of Special Health Services (Miss Price).

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When discussing HIV disparities, the Ebola outbreak of 2014 in West Africa, or other infectious diseases, it is not uncommon to hear African Americans refer to the Tuskegee Syphilis Study as proof of government conspiracies to either create or intentionally allow disease to spread within the community. Unfortunately, the facts of Tuskegee are deplorable and remain a reason for mistrust of biomedical research, medical care, and public health—distinctions that most people, not just African Americans, do not fully understand.

In 1932, the Public Health Service (PHS) and the Tuskegee Institute initiated the *Tuskegee Study of Untreated Syphilis in the Negro Male*, in which 600 African American men in Macon County (399 men had syphilis, 201 did not) were enrolled to observe the natural progression of the disease. The men did not consent to being studied, and were told they were being treated for 'bad blood', a colloquial term poor rural African American communities used to describe illnesses that, without access to physicians or regular medical care, did not have a proper diagnosis. As studies were published, many people—particularly Black healthcare providers and researchers—criticized what was happening.

Not only was the lack of consent a great ethical violation, so was what happened next. In 1947, penicillin was standardized as the curative treatment for syphilis, yet the PHS researchers actively blocked the men from

accessing care—including care provided by a rapid treatment center set up in Macon County. The study persisted until it was shut down following national controversy in 1972, and a series of national reforms to clinical research trials soon followed, as well as paid restitution to the surviving men and their families.

Nine years after the study was shut down, the Center for Disease Control and Prevention's (CDC) Morbidity and Mortality Weekly Report case reported five gay men suffering from a rare pneumonia, which ushered in the AIDS pandemic. Given the recency of the syphilis study in its chronological proximity to the discovery of HIV, is it any wonder there were—and remain—entrenched conspiracy theories in Black communities, or that African Americans remained skeptical of biomedical research, modern medical practice, and public health?

Recent studies of Black communities' attitudes regarding HIV show that these rumors and conspiracies have continued to persist, and yet few, if any, public health approaches have been funded to directly engage communities in these myths and to provide educational resources to challenge the misperceptions, much less organize to address some of the persisting racial disparities that exist in biomedical research and access to treatment and care.

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men.

Continued on Page 8, Column 1

Heller J. "Syphilis victims in U.S. study went untreated for 40 years." The New York Times. 1972 July 26.

Government public health approaches have instead focused on knowledge and education about HIV risk factors for African Americans and the data illustrating the infection's disproportionate impact. However, providing this information may actually be fueling mistrust, as opposed to undermining it. In February 2016, the CDC released data indicating that, if current trends continue, one in two Black men who have sex with men will contract HIV in their lifetime. Many Black gay activists were angry with the CDC for publishing these data without any thought or consideration to the persistent high levels of stigma and defeat. In my own conversations with Black gay activists since these statistics were released, I've learned many simply don't believe the data anymore.

If the people in the community who have been invested in providing services or mobilizing Black gay men around the crisis have begun to tune out the CDC, what does that say for people in the community with far less access to information—who are already more likely to distrust public health, medical treatments, and research? A RAND Corporation telephone survey with a random sample of 500 African Americans published in the *Journal of Acquired Immune Deficiency Syndromes* in 2005 found that adult male participants who believed in conspiracy theories were less likely to use condoms. I recently had a discussion with a Black HIV-positive transgender woman and an advocate regarding her belief that there is a cure that is being intentionally withheld. Mistrust of government, health care and the pharmaceutical industry also made her skeptical of pre-exposure prophylaxis (PrEP); she doesn't encourage those who are HIV negative to explore taking it.

Although the hurdles seem high when it comes to shifting these dynamics, they are not insurmountable. A 2015 Kaiser Family Foundation survey assessing public attitudes and knowledge about HIV among Georgia residents found that, compared with white respondents, Black survey participants were far more likely to think HIV was a serious problem in the state, that people with HIV were regularly discriminated against, and were more likely to want more information to be available about HIV prevention, treatment, and how to support loved ones

living with HIV. This suggests that, despite histories of real violations by public health and biomedical research, African Americans still crave access to basic information, and it's clear that diffusing knowledge of treatment as prevention, the importance of viral suppression, and PrEP within Black communities has not been a public health priority. The work that many HIV activists are embarking on to effectively end the epidemic in the US—which includes ending racial disparities in transmission rates, morbidity, and mortality—must include a strategy to address the generations of medical and public healthcare mistrust among African Americans with the following actions:

- **Demystify Research, Health Care, and Public Health.** One of the reasons misinformation continues to persist is the scarcity of education efforts working to demystify biomedical research—even the basics of HIV and the science of transmission, treatment, prevention, and the current state of vaccine and cure development. Curricula and workshops, social media strategies, and traditional media outreach to engage African Americans on these issues are greatly underfunded, underdeveloped, and desperately needed. And that work has to be led by indigenous Black leadership.
- **Reframe Treatment and Research.** As activists, we have to do more to interrupt misinformation, not by strictly dismissing conspiracy theories, but by actually pointing to where there is institutional racism that has shaped disparities in HIV acquisition and access to prevention and care. Similar to Tuskegee, the existence of treatments that extend life and prevent infection being out of reach for most African Americans exemplifies institutional racism, and that's what we should be fighting, as opposed to denying the benefits of these advances. Similarly, we must to make the pricing of various treatments—particularly PrEP, antiretroviral treatment, and Hepatitis C virus drugs—an issue of racial justice.
- **Funding for Black Health/Medical Community Organizing and Advocacy Movement.** With the exception of HIV community-based organizations (including harm reduction) and Black women's groups largely focused on reproductive justice, there is very little infrastructure in place for Black activism on health and medical issues of any kind. This is contrary to the fact that African Americans have a long history of activism and advocacy for social justice in research, health care access, and treatment for a range of conditions including tuberculosis and sickle cell anemia, and African American civil rights groups (e.g., the National Medical Association, Congress of Racial Equality, Student Nonviolent Coordinating Committee, and the National Association for the Advancement of Colored People) were the leading advocates for the establishment of Medicare. We are going to need to provide leadership development and training—and perhaps even new national, state, and local organizations—to develop an infrastructure for Black leadership to use grassroots organizing, education, leadership development, policy advocacy, media, and direct action tactics to address health and medical issues from a racial justice perspective.

There are already dozens of community advisory boards that exist as part of organizations, federally qualified health centers (FQHCs), and centers for AIDS research (CFARs) that could be restructured to address broader social justice issues in health and medical care locally, make visible treatment and research activists as they currently exist in Black communities, and foster movement-building across other social justice organizations in the Black community, and in other communities as well.

I don't know a Black HIV or healthcare activist that doesn't face these questions about government or research conspiracies on a regular basis. Whether with an Uber driver, a barber, or a family member, as soon as people find out what you do, these kinds of questions and concerns emerge. But these issues could better be addressed if a social movement of Black healthcare and research activists could be better supported to both better engage community concerns that might improve healthcare engagement and to directly challenge the institutions, laws, and policies that actually do continue to perpetuate, as Black medical writer and historian Harriet Washington has described, medical apartheid. •

DECRIMINALIZATION

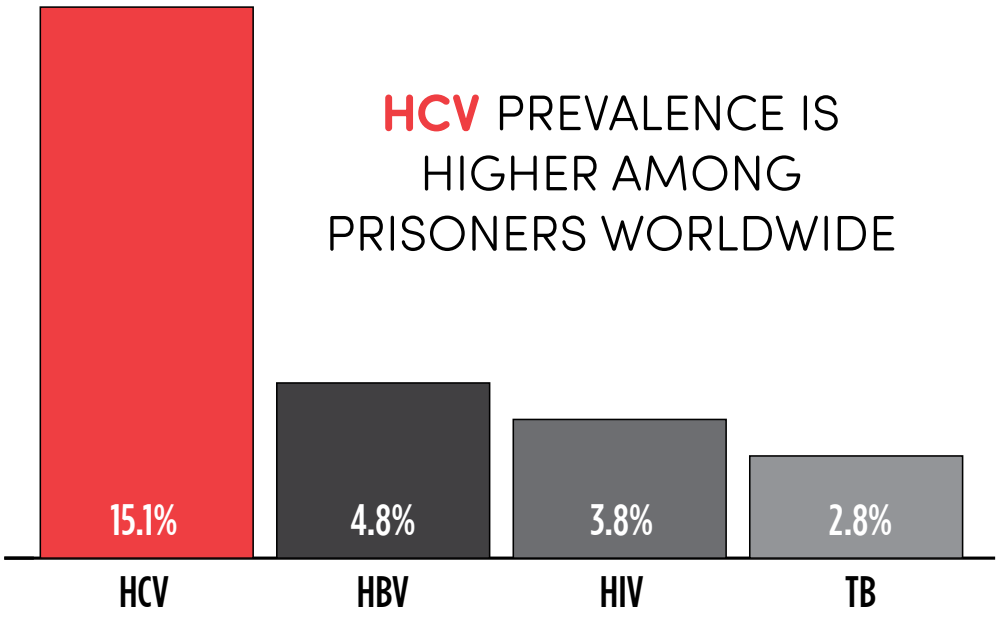
is a PUBLIC HEALTH STRATEGY

We can't end the viral hepatitis epidemics unless we end the war on drug users

By Annette Gaudino

"Unidentified Filipino male. Unidentified Filipino male. Unidentified Filipino female. Unidentified Filipino male…" It takes a long time to read 1,900 names, long enough to feel every inch of the concrete wall against my back. We had gathered outside the midtown Philippine Consulate to "die in"— dozens of activist bodies laid out under a large picture window through which a video of sandy white beaches and tropical flowers played on a loop. The protest of newly elected Philippine President Duterte's extrajudicial killing spree, directed at suspected drug users and dealers, received international press attention and unleashed a torrent of invectives on the social media accounts of organizers. This was further evidence, if any was needed, that the so-called war on drugs has always been a war on drug users: individuals systematically robbed of their freedom and dignity—even their names.

According to a new meta-analysis conducted by Kate Dolan, PhD (University of New South Wales), and colleagues on the burden of HIV, tuberculosis (TB), and Hepatitis C virus (HCV) among prisoners, there are 10.2 million incarcerated people worldwide, including 2.2 million in the US. An estimated 15.1% of prisoners worldwide have HCV and 4.8% have chronic Hepatitis B virus (HBV), which are higher prevalence rates than those for HIV (3.8%) and active TB (2.8%). In addition, 30 million prisoners transition between the community and prison each year. Research indicates that infection risk increases following release from prison, both for the formerly incarcerated and their sex and drug-using partners. Thus, to achieve the World Health Organization's (WHO) goal of eliminating viral hepatitis as a public health concern by 2030, civil society has a duty to intervene where criminalization and incarceration conflict with sound public health policy.



Meeting the challenges of access, equity, and rights were the animating themes of the 2016 International AIDS Conference in Durban. Participants in the Viral Hepatitis Pre-conference learned about the limits of using existing HIV infrastructure to implement the HCV response, and the need to think beyond the individual drug users. Presentations stressed that programs targeting individuals in isolation are unlikely to meet the challenge of eradicating viral hepatitis; rather, we must address individuals as members of social networks and larger communities. Although Durban 2016 highlighted the push to put key populations at the center of the HIV/HCV response, no one lives solely within a key population—and no population, no matter how marginalized, functions in isolation from other sectors of society. A person who uses drugs lives in a network of fellow users, but he or she is also a child, sibling, parent, student, employee, and neighbor; a member of an ethnic or racial community in a larger nation; and a peer to those who don't use drugs, but who share a common sub-culture or interests. Social drivers such as poverty and attitudes toward drug use serve as the backdrop for struggles to prevent disease and manage health.

For drug users, the primary intersection of these identities and social drivers is the criminal justice system, which sets drug use and its comorbidities apart from other public health issues and systems. There is a misperception that incarcerated individuals in the US have an absolute right to medical care. In fact, the Supreme Court has placed the burden on prisoners to prove their serious medical needs were known to prison officials and deliberately untreated (*Estelle v. Gamble*, 429 US 97, 1976). Furthermore, the federal Bureau of Prisons guidelines triage care based on liver disease progression and recommends only voluntary screening. This screening policy acknowledges that lack of confidentiality and safety inside the prison walls make knowing your status a risk for violence, not unlike the early years of the HIV epidemic. In practice, however, this means only the sickest will be identified and treated, allowing progressive liver damage and continued transmission of the virus.

Regardless of a country's overall GDP, prisons should be seen as resource-limited settings, with multiple financial and infrastructure barriers to care. Even with pan-genotypic drugs to simplify diagnosis and treatment, high prices render them a low priority for incarcerated individuals. Finally, you can't run an HCV program without access to HCV RNA testing to verify treatment success, a significant barrier in many low- and middle-income countries with regards to the general population, much less the incarcerated population.

Robust harm reduction services are also needed to prevent de novo infection and reinfection, but there are legal and funding barriers that prevent the rollout of evidence-based interventions, including syringe exchange, opioid substitution therapy, safe injection facilities, and drug consumption rooms. In the US, the use of naloxone to prevent overdose is receiving growing acceptance among law enforcement, but interventions to keep drug users safe and healthy before they overdose are still considered to be too radical for use in the community, much less in prisons.

Still, those working with the hardest-to-reach populations continue to innovate, with programs in India giving users testing coupons to identify and treat whole networks, and national and local health ministries—in Punjab, for example—stepping up to provide low- or no-cost HCV cure. Peer support is critical for linking individuals to care and ensuring treatment adherence, with the Community Network for Empowerment (CoNE) drug users' union in Manipur, India, and VOCAL in New York serving as two effective examples. Following the model pioneered by Partners in Health for TB treatment in Haiti, observed treatment programs may also help address the complex support required to achieve treatment success among those with substance use disorders. In fact, if elimination is the goal, those at highest risk for reinfection need treatment the most.

As numerous public health champions have said repeatedly, we must take morality out of public health. Treating and curing active drug and alcohol users, and removing prison as the primary intervention for those with substance use disorders, must be at the center of the global response to viral hepatitis. Simply put, we must value people with HBV and HCV—including prisoners and illicit drug users—enough to keep them alive.•

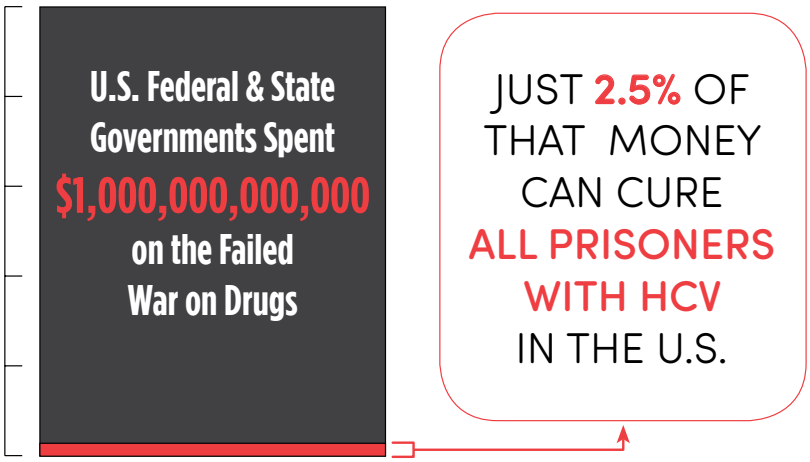
RALLYING the MULTITUDE to FREE the (generic) HCV CURE

Effective responses to the burgeoning hepatitis C pandemic requires solidarity between the global North and South

By Bryn Gay

We can now cure the hepatitis C virus (HCV) with a coformulation of drugs that yields sustained virologic responses for all genotypes. Epclusa (sofosbuvir/velpatasvir), however, joins the ranks of other high-cost direct-acting antivirals that are inaccessible to the majority of the 150 million people living with chronic HCV around the world. Treatment activists need to escalate their advocacy and political pressure, draw on lessons from the AIDS movement, and emphasize conscientious solidarity among countries of the global South, as well as across countries in the North and South, to make universal generic access a reality.

Epclusa, approved by the U.S. Food and Drug Administration in June 2016, is a game-changing medication that is administered orally once a day for 12 weeks and reduces the need for genotype diagnostics, thereby saving money for cash-strapped budgets in lower- and middle-income countries. However, the $74,760 list price for Epclusa is expected to create enormous barriers to access. Public payers and private insurers in the US alone are limited in how many patients they can cover. By contrast, the $1 trillion failed drug war could have funded Epclusa treatment for 13.4 million people—four times the number of patients in the US. Adding to the public outcry, analyses by Andrew Hill of the University of Liverpool and his colleagues indicate that sofosbuvir can be produced with a 50% profit margin for as little as $62; thus, the current pricing of the cure is not justifiable.



We have human rights obligations and we must invoke legislation, especially those that frame national strategies for HCV elimination. Activists can point to UN-ratified conventions and agendas that affirm the right to health care to demand access to the cure (see Mike Frick's "Science and Solidarity," beginning on page 2). A comprehensive human rights approach is based on equality (treatment should not depend on income level), destigmatization and humanization of all people living with HCV (everyone should have access, including people who inject drugs, prisoners, Vietnam veterans, indigenous peoples, and those living in remote communities), and the value of medicines as a global public good (taxpayer-funded drugs should remain in the public domain for everyone to benefit).

The HCV movement requires the building of solidarity across borders because collective, cooperative actions are more powerful and resilient than individual ones. Universal rights to health can connect local struggles with international patient networks. Each struggle needs to be autonomous in how it employs strategies according to local conditions, but can gain strength by uniting with global movements.

HCV activism can be informed by lessons from the AIDS movement:

- The cure to hepatitis C exists; a curative vaccine for hepatitis B virus (HBV) may be next. As we have seen with antiretrovirals (ARVs), breaking the monopoly and enabling generic competition can dramatically lower prices.
- A multitude of activists, including people living with HCV, HBV, liver cancer, and HIV, as well as related health and human rights groups, can strengthen efforts to resist the enclosure of the medicinal commons.
- 'Inside/outside' strategies must be deployed. Provocative, non-violent civil disobedience and clever use of the media can put HCV on the national agenda. They must be paired with informed patients who can demand expedient drug and vaccine development, regulatory reform, and stable funding. Activists must become their own specialists and challenge the exclusive control of treatment research held by pharmaceutical corporations.
- Patients need to be included in health policy decision-making.
- Peer-support programs reach peers who use drugs and effectively link them to testing, treatment, and care.
- Activists must demand funding and preservation of civil society space to protect this human right.

Solidarity in the global South—countries predominantly in Africa, Asia, Latin America, and the Pacific, which are lower and middle income—and between the North and South is transnational political activism that seeks to transform imbalanced power relations for social change, primarily for the benefit of others. One framing principle is todo para todos, nada para nosotros (for everyone, everything; for us, nothing). Solidarity between the North and South recognizes distorted power dynamics in the North and histories of oppression in the South and among marginalized communities in the North, and connects common struggles to have a greater effect. Through mutual aid, solidarity, engagement, and support, this transnational solidarity can act across borders to bring attention to and confront human rights abuses at the nation-state level. Both solidarity movements tend to be based on non-hierarchical, democratic principles.

In a demonstration of both types of solidarity at the 21st International AIDS Conference in Durban, more than 150 South-African and Indian activists and comrades from the North marched to the Indian consulate to deliver a petition letter. South Africa has one of the highest HIV burdens in the world and relies on Indian generics for the majority of its ARVs. The Indian government has recently faced external pressure because its patent laws take advantage of flexibilities that enable generic manufacturing. The Lawyers Collective fights for this enabling environment and for the preservation of civil society space. This year, the Indian NGO has been suspended from receiving international funding, which potentially undermines its work. Without strong advocacy for generic access, developing countries' current ARV and future HCV direct-acting antivirals supplies are in jeopardy.

This action demonstrated good practices for North-South solidarity. Activists from the global North followed the collective leadership style, listened to organizers from the South, recognized their privilege, acknowledged critiques of their own governments, and worked to not impose their own agendas. They offered legal aid and funding, helped occupy the media center, and urged media coverage in the North.

Through practices of conscientious solidarity, activists can ground their advocacy in broader concerns of power imbalances and social inequalities to challenge the commodification of the cure, oppose drug monopolies, and demand legal flexibilities to liberate generics. Treatment activists can and must demand changes to the rules to make direct acting antivirals (DAAs) affordable for everyone who needs it.•

TOWARD HEALTH EQUITY

We will not end HIV as an epidemic without the expertise and leadership of Black and Latino gay and bisexual men and transgender people of color.

By Jeremiah Johnson

In February 2016, the CDC issued a new report with a frustratingly familiar conclusion: if the current rates of new infections persist, approximately half of Black gay and bisexual men and a quarter of their Latino counterparts could become infected with HIV in their lifetime.

Hearing about racial disparities among gay and bisexual men, ad nauseam and without change, is maddening—but at least the story is being told. For transgender women and men, the Centers for Disease Control and Prevention (CDC) has yet to produce any sort of substantial behavioral or surveillance data 35 years into the epidemic, rendering trans communities statistically invisible. The information that we do have from researchers outside of the CDC indicate that transwomen in the US, particularly transwomen of color, may be the most disproportionately affected group of all of the key populations in the US.

Given that we have known about these disparities for many years, if not decades, one might expect that those of us receiving a paycheck to work on HIV prevention in the US would be on top of our game when it comes to including Black and Latino gay and bisexual men and transgender men and women in new initiatives to help HIV-negative people remain HIV negative. In reality, however, the communities that are repeatedly overburdened when we discuss the problem remain consistently excluded and under-represented at almost all levels of our national HIV prevention response.

A recent analysis of data from 44 percent of US pharmacies conducted by Gilead, the pharmaceutical manufacturer with monopoly ownership of the only Food and Drug Administration (FDA)-approved HIV pre-exposure prophylaxis (PrEP), found that 90 percent of Truvada-as-PrEP prescriptions went to men. In terms of race, 74% of PrEP prescriptions went to white people, with only 10 percent going to Black individuals—a racial disparity that appears to be growing over time. Although PrEP isn't necessarily for everyone and uptake of PrEP is an imperfect indicator of prevention efforts, with around two-thirds of new diagnoses among men who have sex with men (MSM) occurring among men of color in 2014, we would hope that PrEP prescriptions would be proportionate. In terms of transgender women and men, they continue to be so invisible that even simple attempts to include them in the data on PrEP uptake have yet to be attempted by Gilead or the CDC, making it impossible to know how well we're doing.

These disparities in PrEP outcomes and data collection are disappointing, and in terms of representation in PrEP efficacy and implementation research, our nation's most affected communities no better off. Transmen typically do not exist in research, and transwomen, when included, are essentially misgendered and lumped in with studies focusing primarily on MSM. In iPrEx, the study that ultimately led to FDA approval of PrEP, a relatively small number of transwomen were included along with a large number of gay and bisexual men, with several transwomen dropping out or having challenges with adherence in the study. Follow-up analysis has indicated that the study design, which was clearly geared toward gay and bisexual men, may have created barriers to ongoing trans inclusion. Data from the study are no less sobering: no difference in new infections was observed between transwomen in the control arm and those receiving PrEP.

A PrEP demonstration project specifically geared toward transwomen and transmen in California was launched in April—six years after iPrEx yielded its final results. This significant delay in vital trans-related research has had substantial policy repercussions: PrEP use among transwomen and transmen hasn't

received as strong a backing from the CDC and the World Health Organization as other key populations, due to a lack of data proving effectiveness.

Inclusion and retention of gay and bisexual men of color in research, particularly Black men, is similarly dismal. Only 9 percent of participants in iPrEx were African American. In a large three-site US demo project funded by National Institute of Allergy and Infectious Disease, only 9 to 13 percent of those screened for participation identified as being African American, depending on how researchers defined race and ethnicity. Although other large demo projects in the US are 'targeting' men of color, only HPTN 073 has been specifically focused on Black MSM. The results of that study have shown promise, but it was only funded to engage a modest 226 individuals through three sites.

We are aware of no study that is looking to specifically assess the needs of Latino gay and bisexual men, particularly those with differing levels of English comprehension and immigration status.

Given all we know in about HIV disparities, along with our own overblown talk about ending them, how is it that prevention research and services still so lopsidedly favor white cisgender men in America? Some of these poor outcomes are the product of many intersecting structural and social issues that are difficult to remedy, but under-representation issues in research, statistics, and funding are capable of being addressed directly by public health officials, academics, policy makers, and other powerful individuals in the national HIV prevention response.

The CDC could develop a comprehensive strategy for inclusion of transgender data and invest in it. The CDC, National Institutes of Health (NIH), and other federal agencies could commit to doing whatever it takes to find effective PrEP implementation in Black, Latino, and trans communities. Funding incentives could be built into all of the CDC and NIH prevention research grants for projects led by Black and Latino gay men and trans women and men. So why hasn't this happened?

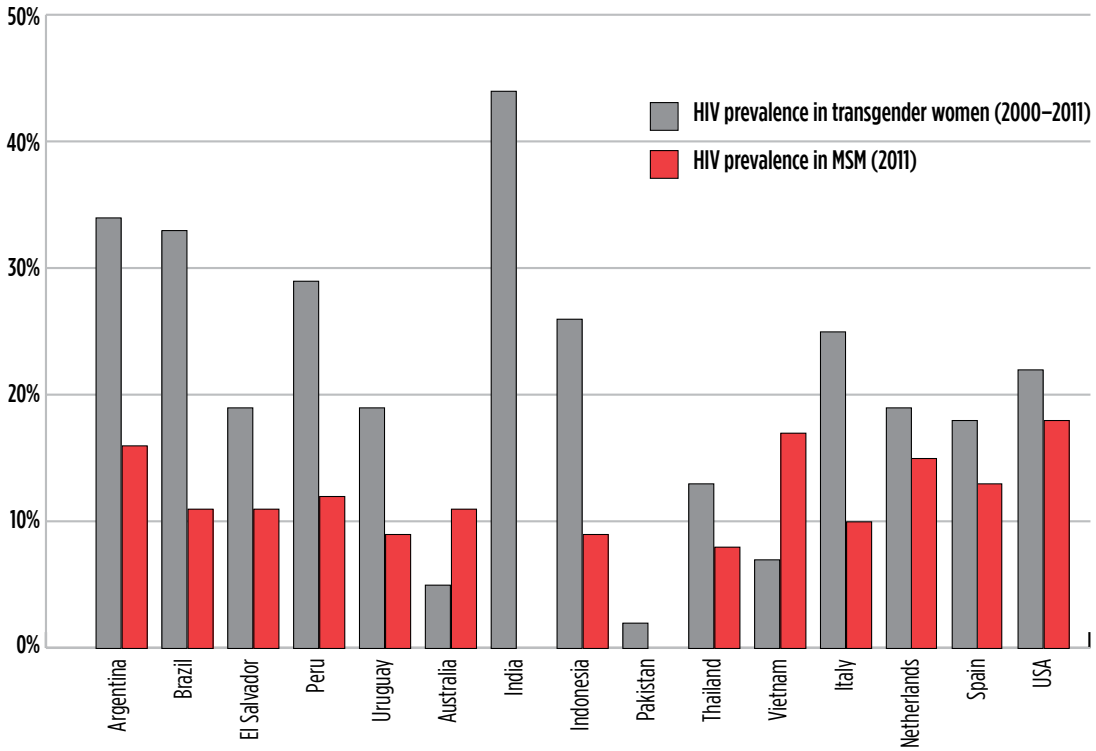
Conventional wisdom in HIV has for decades held that effective efforts cannot be built without direct involvement of affected communities. In 1983, a group of HIV-positive individuals attending a national conference on Gay and Lesbian health in Denver managed to pen one of the epidemic's most enduring and important human rights documents. The *Denver Principles* unambiguously and unapologetically articulated the importance of self-empowerment and the inclusion of people living with HIV in all aspects of the HIV response. It laid the groundwork for the notion that there should be "nothing for us without us;" that the most affected communities should be included in leadership related to HIV-related policies, research, and service delivery. To this day, the bravery of those authors influences the way we address the ongoing pandemic and highlight the essential role of community.

As is often the case in US, however, that spirit of community representation appears to have favored those who are white and those who adhere to traditional gender expressions. In the national HIV prevention response, Black and Latino gay and bisexual men, as well as transgender men and women, appear to be woefully under-represented in high-level research and policy meetings, key leadership positions, and critical discussions. Even in newer initiatives that could potentially be more inclusive, these inequalities are perpetuated. In New York, for example, the task force convened in 2014 to develop a blueprint for ending HIV as an epidemic in that state reportedly included only one young gay man of color, one transgender man, and one transgender woman out of nearly 60 members. Similar inclusion issues in leadership and membership have been noted in the Fulton County Task Force in Georgia. In addition, community advocates have expressed concern in recent years that organizations led by Black and Latino gay and bisexual men and transgender men and women have largely not received CDC prevention funding.

Data are needed to assess just how bad these observed issues with diversity are. Although the

essentiality of inclusion for white gay men has long been a foregone conclusion on the policy and research level, many may also argue that we can't prove that increased diversity among government and researchers will lead to better outcomes. A fair point; it certainly is a challenging argument to prove definitively with current data, and we can hardly design an ethical randomized control trial to test out the effect of systemic racism and transphobia. Still, one can't help but wonder if more diverse leadership might make a difference.

An opportunity to explore the great potential of diversified HIV leadership is upon us, however. U.S. presidential candidate Hillary Clinton recently committed to establishing a task force to develop a plan to end HIV as an epidemic in the US, similar to the one convened in 2014 by Governor Cuomo in New York. Should Ms. Clinton be elected, a commitment to finding highly qualified and diverse leadership in the task force could set an important procedural standard for how to best address HIV nationally. The task force could be the perfect high-profile opportunity to go beyond mere tokenism and ensure that gay, bisexual, and transgender people of color are appointed, recognized, and heard for their experiences, knowledge, and expertise—all of which are critical to stopping HIV as an epidemic. Bringing back the spirit of The Denver Principles just might make the difference in avoiding yet another plan that primarily helps white cisgender men, while ultimately contributing to growing disparities for the most overburdened communities. •



HIV prevalence estimates for transgender women in 15 countries from a systematic review of studies from 2000 to 2011, shown alongside 2011 prevalence estimates among gay and bisexual men and other MSM. In 11 of the 13 countries with both surveillance data sets available, the prevalence for transgender women is substantially higher.

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