

tagline

NEWS ON THE FIGHT FOR BETTER TREATMENT, A VACCINE, AND A CURE FOR AIDS

Julie Davids Reflects on CHAMP and the Future of HIV Prevention Justice

INTERVIEW WITH VETERAN HIV PREVENTION AND SOCIAL JUSTICE ACTIVIST JULIE DAVIDS

In December 2010, TAGline caught up with the super energetic and visionary HIV activist Julie Davids, veteran of ACT UP/Philadelphia, HealthGAP, and a slew of more recent U.S. HIV prevention and social justice organizations such as CHAMP, Project UNSHACKLE, and the HIV Prevention Justice Alliance. In January 2011, Julie took over as national advocacy and mobilization director for the AIDS Foundation of Chicago. TAGline asked Julie to address the following questions:

- *What changes have happened to HIV prevention research and programs domestically since CHAMP was formed?*
- *How have they changed over that period?*
- *What are the challenges facing HIV prevention research and programs today?*
- *What are the key activist strategies to deal with these challenges?*
- *What is needed, and who needs to do it?*

Julie Davids: The Community HIV/AIDS Mobilization Project (CHAMP) has ended operations as of this writing, though we are sustaining our two main networks (Project UNSHACKLE and the HIV Prevention Justice Alliance) through excellent allied organizations (NYCAHN/VOCAL and AIDS Foundation of Chicago, respectively).

Having had the privilege of founding the group in 2003, and working with it until its closure, my feelings about this transition are understandably complex—but I appreciate the opportunity to reflect a bit on the past and speculate on the future in these pages.

But first, I wish to invite anyone who has had experiences with CHAMP and/or thoughts on the past decade of mobilization, organizing, and policy work on HIV/AIDS in the United States to join our online reflections on our work, the climate in which it occurred, and ideas for future directions. The discussion will be hosted by www.preventionjustice.org on an ongoing basis, and submissions can be made as letters, statements, comments on other posts, or links to online media.

Continued on page 2

Moving An Exciting New TB Diagnostic from Policy to Practice

BY JAVID SYED

On December 8, 2010, the World Health Organization (WHO) endorsed the use of the new Xpert® MTB/RIF test as the initial test offered to people suspected of having HIV-associated tuberculosis (TB) or multidrug-resistant tuberculosis (MDR-TB). The test, developed by Cepheid, the Foundation for Innovative and New Diagnostics (FIND), and the

University of Medicine and Dentistry of New Jersey (UMDNJ), is highly accurate and can diagnose TB and MDR-TB in two hours. It represents a major advance over microscopy, which has been the primary method of diagnosing TB for the last 125 years. In 2010, by using microscopy, the world was only able to detect 63% of TB cases. The rate of MDR-TB case detection was far worse: an abysmally low 12%.¹ The WHO has also recommended that the Xpert MTB/

Continued on page 5

WHAT'S INSIDE

Vaccine Breakthrough Comes with Caveats 6

Clinical Trials Will Play a Vital Role in Charting the Path to an HIV Cure 7

Julie Davids, continued from page 1

In 2002, I began to engage in dialogue with other HIV/AIDS and social change activists as I sought to sketch out what became CHAMP. That fall I had the opportunity to craft some thoughts on domestic HIV/AIDS organizing in this newsletter (“The Way Forward: Philly ACT UPer and Health Gap Founder Tackles the Challenges of an Aging Activist Movement,” *TAGline*, October 2002).

At that time I assumed that a regional or national HIV mobilization initiative focused on building a new generation of leadership while maintaining our community’s history of strong advocacy would and should be focused on *treatment*. But as I moved forward in talking to others about these ideas, people started to confront me, asking, “What about HIV prevention?”

There was a sense of frustration that HIV prevention was, for the most part, outside the scope of much of the AIDS community’s diverse organizing and policy change efforts while remaining underfunded and underresearched. Yet it was visibly in the crosshairs of conservative politicians in the seemingly endless days of the [George W.] Bush administration. And I was part of the problem for sure: I remember my broad ignorance on the subject, thinking, “HIV prevention? That doesn’t *really* work, does it, outside of syringe exchange and PMTCT?”

But the more I learned, the more I felt compelled to jump in. I got schooled in the need for HIV prevention advocacy, which had to not only build the power to resist attacks but integrate a broad range of social justice and equity issues; broaden the concept of HIV prevention beyond abstinence, condoms, and clean needles; and delve into challenging research questions that had never been adequately explored.

Although we struggled with issues of capacity and sustainability, CHAMP had a noted impact on HIV prevention advocacy. Entering a realm with little public, strategic conversation and a wide

gap between the small but growing body of prevention research and the underfunded, earnest prevention programs at the community level, we found ourselves bridging disciplines and sectors, becoming a trusted “content provider” feeding honest and strategic information to hardworking front-line prevention workers and policy leaders alike, and a leader in strategic campaigns and coalition efforts.

Over time we crafted a national network of 12,000 people—many deeply involved in the fight against HIV/AIDS—who were able to take quick action through online alerts, and who were invited to contribute to debate and dialogue at our events, conference calls, and trainings.

CHAMP began in 2003 by drawing community attention to the secretive process the Centers for Disease Control and Prevention (CDC) was using to revamp their prevention efforts under the “Advancing HIV Prevention” rubric, which was to have major implications, including the near fossilization of interventions into a set of mandated “boxed” interventions.

Now the broader federal government, with much leadership from the CDC, stands poised to reorient prevention approaches in a time of the National HIV/AIDS Strategy (NHAS). Last year was a very busy year that saw the release of the unprecedented NHAS as well as encouraging results of partial efficacy from microbicide and preexposure prophylaxis (PrEP) trials. But CHAMP, which grew out of those initial constructive confrontations from prevention advocates seeking a national movement, is shutting down.

TAGLine: *So what do we do now?*

JD: We continue the fight.

Looking at the successes and failures of CHAMP and other efforts, I’ve learned that this fight must not be limited to one-time or short-term trainings, small-scale technical assistance, capacity building, and/or online organizing. For those who have noted and respected our work, I’d ask you

to look at our capacity struggles as well as our successes as useful data about the need to have strategic alliances and resources to stabilize efforts over the course of years, allowing activists to work together with support and a sustainable home for ongoing campaigns and flexible networks.

In the near term, state-level and regional efforts—providing training and support for new and longtime leaders—need to be scaled up in partnership with national initiatives. We can leverage interest in the 2012 International AIDS Conference (AIDS 2012) in Washington, D.C., and the presidential election of that year into resources for leadership development, political education, and on-the-ground field organizing. But we also should reap the benefit of skilled facilitation and strategic support for healthy collaboration to ensure that passionate and opinionated individuals and organizations in our movement are best able to build our collective power in the coming years, and to allow new leaders to emerge for the fight that will continue long past the conference and election.

And fundamentally, we need to continue the fight for the very basics of HIV prevention, such as condom access and funding for syringe exchange, that remain out of reach for many.

We must amplify the fight against the social drivers of HIV in our country, like mass imprisonment, lack of safe and affordable housing, and LGBTQ marginalization.

And we should challenge ourselves across and beyond the HIV sector—whether people living with HIV, prevention providers, public health advocates, funders or cogs in the wheels of struggling public systems—to bridge the now-artificial distinction between treatment and prevention and aim higher for cross-cutting efforts that have a shot at reaching population-level success to reduce HIV incidence and health inequities.

Continued on page 3

Julie Davids, continued from page 2

We must also use the momentum of the NHAS and the upcoming spotlight on the U.S. epidemic at AIDS 2012 to ensure that more and better coordinated resources reach, and are accountable to, the populations most affected by HIV in our country: gay men, other MSM, and transgender people of all races and ethnicities; and people of color of all sexual orientations.

We need to continue the fight because HIV prevention *does* work.

The basic HIV prevention package—including counseling, access to condoms and sterile syringes, and STD treatment—has helped and continues to help many people avoid infection. Its success has actually made it *harder* to get results from efficacy studies of additional or alternative prevention interventions, since the systematic inclusion of the basics in the placebo arms has often meant the overall infection rate in trial participants declined substantially.

We have never had a basic, solid, comprehensive foundation of HIV prevention in our country upon which to build more innovative solutions or combination approaches. Notably, it was just this past year that the CDC released a powerful and clear set of data and recommendations on condoms as a structural intervention in HIV prevention. Not just an individual intervention, where one person chooses or is able to use a condom, but a *structural* intervention, meaning that overarching civic structures can and should make condom access a priority (as has been done in New York City).

In addition, **most students and young people never get fully comprehensive sexuality education.** There is still no data at all about whether or how sex ed is protective or helpful for LGBTQ youth, and abstinence-only programs still spread misinformation on the public's dime. These days, the basic prevention package should also include seamless access to postexposure prophylaxis (PEP) for serodiscordant couples and those who have

a risky encounter and/or self-identify as at high risk for HIV acquisition, even as we puzzle out how to best move forward on interpreting and implementing initial PrEP results. While there are longstanding public health service guidelines on PEP, actual local programs to get it quickly into the hands of those who need it are rare. That's why it's encouraging to see that a 12-city expanded HIV planning initiative that's one of the first cross-agency offerings out of the NHAS box—Enhanced Comprehensive HIV Prevention Planning and Implementation for Metropolitan Statistical Areas Most Affected by HIV/AIDS (ECHPP; <http://blog.aids.gov/2010/10/national-hiv-aids-strategy-working-across-agency-lines.html>)—mandates “PEP access for populations at greatest risk” as one of the required interventions.

Of course, we could hope that syringe access could become more reliably a part of the basic package, now that the federal funding ban has finally been lifted. But two major barriers remain.

Sadly, the NHAS perpetuates Bush-era bias against harm reduction, in a time in which those on the front lines believe we could virtually eliminate HIV in injection drug users through concerted, systemic efforts.

For example, the ECHPP doesn't even list sterile syringe provision as a “recommended” intervention, much less require it (though it notably highlights a brief alcohol screening/intervention for HIV positive and high-risk people that's seen some success in New York). Even if many of these municipalities are already committed to sustaining syringe exchange (which we cannot count on in this economic climate), the absence of these words in the intervention list of this much-publicized new initiative is chilling.

And there's just not likely to be new money for HIV prevention federally (and much less money given recent and pending cuts at the state and local levels.) This probably

means that federal funds must be taken from something else in HIV prevention in order to be redirected to syringe access, setting up competition between different camps or constituents in HIV prevention. While this could and should provoke healthy conversations about the most vital interventions in the current era, it's not an easy process, especially while our organizations and constituents are battered by economic challenges.

Clearly, it's not just syringe access that's threatened by budget woes. The now-worldwide recession is not likely to disappear any time soon—and if/when it does, there's nothing guaranteeing that funds will flow into the path of justice and public health rather than into the pockets of the banks and corporations that are steering much of the decision making around the U.S. economy.

This is a challenge to us on multiple levels. It's not only harder to find the city, state, federal, and private funds to implement the best strategies of the NHAS and push for much needed investments in HIV prevention, treatment and care. Those hardest hit by economic turmoil are those who are or will be put in harm's way and made more vulnerable to HIV. The CDC has now acknowledged that *poverty* is a major driver of HIV in heterosexuals, and as the number of impoverished people goes up, we could guess that HIV incidence will as well—and not just in straight people; poverty jeopardizes the health of all.

Even in this economic downturn we are finding potential innovations in prevention, like PrEP. But we must use these breakthroughs to inspire us to find ways to confront and overcome, rather than reenforce, longtime and persistent health disparities based in economic, racial, and social injustice in order to ensure that interventions reach *all* people who could use them.

So we need to also continue the fight because in order to prevent HIV; we need *prevention justice*.

Continued on page 4

Julie Davids, continued from page 3

During CHAMP's lifetime, we launched and promoted an HIV prevention justice movement—one that will be sustained and expanded, in part, through the HIV Prevention Justice Alliance (HIV PJA; <http://www.preventionjustice.org/>) as it moves forward with its two other cofounders, the AIDS Foundation of Chicago and SisterLove. Prevention justice asserts that advocates for HIV prevention must join in common-cause struggles for social, racial, and economic justice, and that human rights are essential in furthering our fight against HIV.

The HIV PJA has identified three key social drivers as major contributors to stubbornly high HIV incidence rates in the United States: shortage of stable, safe housing access (which is a marker of economic injustice), mass imprisonment (particularly of people of color), and the marginalization of LGBTQ people.

As we move forward in coming generations, we must twin our efforts to combat the *proximate*, or immediate, causes of HIV, such as sex without condoms or syringe sharing, with an ongoing commitment to the *distal* causes that determine relative vulnerability or resiliency against HIV, such as poverty and discriminatory policies, that are the focus of HIV prevention justice.

For example, by joining efforts to fight for fair housing for all people at the local level, we bring the strength and passion of the HIV/AIDS community to a human rights struggle that is concretely tied to HIV prevention, treatment, and care. And when we do so as people openly living with HIV and their allies, we create visible space for others to come out, and that's also a good, grassroots way to combat HIV stigma.

CHAMP and others have worked assiduously to draw attention to the reality that gay men of all races and ethnicities are the largest group of those infected in the United States, with the highest rates in black gay men, and the only group in which incidence rates continue to increase.

Thus it can come as a shock to some that efforts to end LGBTQ marginalization are often at a distance from the HIV/AIDS community.

Data keep coming out about how events early in the lives of queer people—like whether or not we are accepted by our parents, or to what degree we are targeted for bullying in schools—are formative issues that set in place a cascade of vulnerability or resiliency for a lifetime of health issues, including substance abuse and intimate partner violence as well as HIV/AIDS. And groups like Queers for Economic Justice (<http://www.q4ej.org>) have challenged the AIDS community to recognize the distinct and compelling challenges faced by low-income and poor LGBTQ people that draw our attention right back to core social drivers like poverty, housing, imprisonment, and immigrant issues.

Fortunately, the NHAS explicitly states that we will never overcome HIV in the United States if we do not deal with the epidemic in gay men. But it remains to be seen if resources truly shift in a smart and sustained way to address the prevention needs of gay men (both HIV-positive and HIV-negative) across the lifespan—and if the HIV/AIDS community will bolster important justice efforts for the liberation of LGBTQ youth and adults that need to go way past issues of marriage.

We know that success in struggles for true justice and human rights do not happen overnight. These sorts of realities—despite encouraging news on the biomedical prevention front—make it clear that HIV will probably be a health and political challenge well beyond our lifetimes.

Moving forward, I think we should be honest that it's very likely that we are talking about a fight that will last multiple generations. While we may be able to drastically decrease HIV rates, we are likely to see sustained transmission in marginalized communities as well as the need for care and treatment in the absence of a cure for some time to come. (As an aside, the reemergence of campaigns

to fight for a true cure for HIV are encouraging and vital as a counter to any belief that it's acceptable to assign people with HIV to a lifetime of expensive and non-benign treatment.)

It seems increasingly disingenuous to state that the epidemic is fueled by longstanding, complex problems like racial injustice, homophobia, gender bias, and poverty, but then also assert that we could "end AIDS" in five or ten years if we just had enough funding.

We might want to look at the vision of groups like Generation Five (<http://www.generationfive.org/>), an Oakland-based initiative whose mission is to end childhood sexual abuse in five generations, and consider the following challenge: How would we fight HIV/AIDS in the current time if we both want to move forward to improve things today, and put things in place so our descendants can further the fight in their lifetimes?

The provisions of the Affordable Care Act do hold some promise for near-term resources for HIV prevention. The act's Prevention and Public Health Fund contributed some \$30 million to HIV research and prevention in fiscal year 2011, and is (hopefully) the source to pay for the implementation of the 12-city plans in fiscal year 2012, if it survives conservative attack. And the fund is slated to grow each year, without the need for annual appropriation battles.

In addition, the planned massive expansion of health care and medication access as many of the major provisions of the Affordable Care Act roll out in 2014 will increase access to care for many people living with HIV. This should spur innovative and collaborative planning to scale up prevention resources for people living with HIV, and the integration of PEP, PrEP, and testing into a more holistic vision of HIV prevention efforts that bridge behavioral support with treatment and biomedical approaches.

Continued on page 5

Julie Davids, continued from page 4

But it's not 2014 yet, and problems abound as AIDS drug assistance program waiting lists grow, immigrant populations are increasingly distanced from care with little hope of abatement from anything in health care reform, and the Affordable Care Act remains a big target for old-school conservatives and Tea Party leaders alike.

As we seek to survive to 2014 and beyond, we can acknowledge that this is a long-term struggle and bolster our strategies for furthering HIV-specific advocacy, marshalling the passion of the HIV/AIDS community as a powerful part of broader coalitions and collaborations to confront the social drivers of the epidemic while we confront HIV stigma through our very participation in these broader campaigns.

Despite cuts that are slimming the HIV sector and public health infrastructure, there are people ready to join and sustain the fight for HIV prevention justice.

We can and must usher in a next-generation approach to prevention that breaks down silos of treatment, care, behavioral interventions, mobilization, and research in order to innovate, evaluate, and expand combination interventions deeply rooted in community that marshals the strengths of large health care and public systems.

We can and should move forward on initiating no-cost, low-cost, or independently funded DIY and grassroots sex ed and HIV prevention that can be as down and dirty and explicit as it needs to be—without worrying about the political climate that can make funders balk.

Oh, there's so much we can and should do. But no matter what, we need strategic approaches that bring our best ideas together to give us a shot at succeeding. I feel lucky to have been able to be a part of CHAMP, which helped so many people turn frustration into power, and hope that the ideas, actions, and national activist networks that we helped to inspire will resonate for some time to come. ●

New TB Diagnostics, continued from page 1

RIF test might be used as a follow-up test to microscopy where TB/HIV and MDR-TB are less prevalent. Through these bold recommendations, the WHO has initiated a change in TB diagnostics that—if fully implemented—can address some of the major challenges in the care of TB, which is the leading cause of death among people with HIV globally.

The Xpert MTB/RIF test is a fully automated nucleic acid amplification test that can accurately identify 92% of patients with TB while the commonly used sputum smear microscopy test routinely misses nearly 50% of TB cases. The Xpert MTB/RIF test is also able to identify 72.5% of those TB cases that the smear test is unable to diagnose because there are too few bacteria in the sputum sample, a condition called smear-negative TB, which is more common in people with HIV. To detect smear-negative TB, the bacteria have to be grown or cultured over four weeks in a laboratory equipped with special safety equipment and skilled staff, making culture relatively inaccessible and time consuming.

Besides the advantage of accuracy and speed over currently available smear and culture tests, the Xpert MTB/RIF test also detects 98% of rifampicin-resistant TB cases within two hours.²

In addition, because it is fully automated and does not need a special laboratory equipped with protective gear or highly trained staff, this test can potentially be used at district-level health centers, bringing it closer to where patients access services.

Despite the significant improvements the test offers over current TB diagnostics, the path to the scale-up of the Xpert MTB/RIF test still faces challenges. The biggest barriers to the rollout of the test are cost, its need for uninterrupted power supply, and annual calibration to ensure its accuracy. FIND has negotiated a price that is 70% lower than the

commercial price for the public sector in low- and middle-income countries, but the machine and each test cartridge are still expensive at \$17,000 and nearly \$17, respectively. Although modeling studies suggest that the test is cost-effective at these prices, there is need to continue advocacy to further drive down the cost and ensure that funds are available to support its rollout. FIND and Cepheid are developing methods of training laboratory staff to enable them to perform the annual calibration, thereby keeping these auxiliary expenses low. The need for uninterrupted power cannot be circumvented, and this will place some limits on where the test can be used.

These limitations notwithstanding, if rolled out as widely as possible the test could significantly increase TB case detection rates (especially those of smear-negative and MDR-TB) and thereby pave the way to greatly reducing death and disease. For this reason the test has generated a lot of excitement in the public health community. The momentum it has generated can be judged by the reaction of the WHO, which moved the Xpert MTB/RIF test with uncharacteristic efficiency through its approval process—from examining data at its expert committee to recommending the use of the test within three months. In response to the WHO announcement, for the first time in history the three leading U.S. government agencies that contribute to global TB control—the U.S. President's Emergency Plan for AIDS Relief, the U.S. Agency for International Development, and the U.S. Department of Health and Human Services—put out a joint statement in support of the urgent need to make the test available. TAG also contributed by pushing for bold recommendations at the WHO expert committee meetings and global consultations, putting out its own press release, and holding a conference call with the test developers along with other advocates—all aimed at reducing the test cost and facilitating access to the Xpert MTB/RIF test for those most at risk of disease or death due to TB.

Continued on page 7

Vaccine Breakthrough Comes with Caveats

BY RICHARD JEFFERYS

One of the main sources of pessimism about prospects for an effective HIV vaccine has been the generally poor results obtained in animal models. In particular, a stringent system involving rhesus macaque monkeys challenged with highly pathogenic simian cousins of HIV (SIVmac239 or SIVmac251) has proven too stern a test for many vaccines—even those once considered promising like Merck's now-discontinued candidate. To date, only a live attenuated SIV (simian immunodeficiency virus) vaccine has demonstrated significant efficacy against these challenge viruses, and this approach is too dangerous to be adapted for use in humans.

It is against this backdrop that a recent flurry of media stories celebrated the results of a new vaccine experiment published in the venerable science journal *Nature*. Conducted by Louis Picker and colleagues from the Vaccine and Gene Therapy Institute (VGTI), the study used cytomegalovirus (CMV) as a vaccine vector, altering its genetic makeup so that it produced SIV proteins in addition to its own protein payload. Rhesus macaques were immunized with the vaccine and challenged with SIVmac239 a little over a year afterward. The excitement about Picker's study stems from the unprecedented degree of long-term control of SIV replication observed in 12 out of 24 macaques that received the CMV vector; after transient postinfection peaks ranging from 60 to 10,000,000 copies, there were only occasional blips above the limit of detection that diminished over time. In four of these animals that were euthanized after 52 weeks of follow-up and had multiple tissues analyzed, replication-competent virus could not be found and viral RNA and DNA levels were extremely low, leading to the suggestion that SIV was being progressively cleared. Although this extraordinary degree of control was

only seen in 50% of the CMV vector recipients, it nevertheless represents a great leap forward compared to results obtained in the same model with other candidate vectors.

The researchers ascribe their success to a particular type of CD8 T-cell immune response induced by the vaccine. CD8 T-cells have the ability to identify and kill virus-infected cells (hence their alternate designation: cytotoxic T lymphocyte, or CTL), but the efficiency with which this function is performed can vary. A subset of CD8 T-cells called effector memory cells (or Tem cells, for short) appear to be the most trigger-happy of the killers because they are constantly on high alert; it turns out that the CMV vector is particularly adept at inducing and maintaining a large population of CD8 Tem cells targeting SIV, which correlated with the control of the challenge virus.

So far, so good. But what are the prospects for adapting CMV vectors for use in people? CMV is a member of the herpesvirus family and causes persistent infection; most people on the planet harbor the virus by the time they reach adulthood. Unlike some other vectors, preexisting infection and associated immune responses against the virus do not stop the vector from working, because CMV has evolved the ability to sneak under the immunological radar and reinfect. (All the monkeys described in the *Nature* article were already infected with rhesus macaque CMV.) Until quite recently, CMV was also thought to be relatively benign, only causing disease in limited settings such as in pregnant women and individuals with severe immune deficiencies (including AIDS, where CMV can reactivate and cause several horrendous opportunistic diseases, including retinitis and colitis).

Over the past decade or so, however,

evidence has emerged of another, more insidious long-term impact of CMV on human health. This was first described in a Swedish cohort of much older people (over 85 years of age) in whom CMV positivity was linked to an array of immune system perturbations (including an inverted CD4:CD8 ratio, diminished naive cell numbers, and poor proliferative responses) and an elevated risk of morbidity and mortality when compared to that of uninfected individuals. It appears that the presence of CMV causes persistent low-level inflammation, which in turn causes accumulated wear-and-tear on the immune system as people age, making CMV a major contributor to a phenomenon that is technically termed "immunosenescence": the progressive enfeebling of the immune system caused by a lifetime of work against pathogens and other stimuli.

More recent studies have found that CMV may have subtle pernicious effects on health at younger ages, also; infection was associated with a slight but significant increase in risk of all-cause mortality in a large nationally representative sample of individuals in the United States ages 25 and older. As with older individuals, inflammation associated with CMV infection is suggested as the likely explanation. Additional evidence comes from studies showing very direct links between the presence of CMV and inflammatory damage to blood vessels. The literature on the potential dangers of CMV thus represents a cloud of uncertainty hanging over plans to try and advance CMV vectors into human trials. It could be that the very properties of the virus that enable it to induce potent CD8 Tem cells and control a virulent SIV challenge are also those that underlie its apparent harmful long-term effects in humans. Alternatively, it might turn out to be possible to disentangle the effectiveness of CMV as a vector from its negative side; in the press reports on his *Nature* article, Picker makes it clear that efforts are underway to try and render CMV safe to use, but how this is being accomplished and whether it can be verified in human trials is unclear.

Continued on page 7

Clinical Trials Will Play a Vital Role in Charting the Path to an HIV Cure

The search for a cure for HIV has recently been given fresh impetus by the widely reported case of an HIV-positive individual named Timothy Brown who has remained free of detectable virus for four years (and counting) after a complex series of treatments for cancer. Although too impractical and risky for general application, the outcome of Brown's treatment is viewed as a compelling proof of concept that a cure for HIV infection is possible. Now, in order to build the knowledge necessary to develop a safe and broadly accessible curative therapy, clinical trials of approaches that may be able to deplete HIV from the body or contribute to drug-free control of the virus are being launched. In light of the importance of this research, the AIDS Policy Project, amfAR, Project Inform, and TAG recently sponsored a workshop on the conduct of clinical trials relevant to the goal of curing HIV infection. The event took place on 20–21 April 2011 at the Renaissance Harborplace Hotel in Baltimore.

The 52 workshop participants—including scientists, community members, ethicists, research funders and regulators—discussed key issues, including:

- criteria for advancing potential therapeutic candidates into human trials
- the ethical and regulatory aspects of trials involving individuals at low risk of illness in which the main potential benefit is advancement of scientific knowledge
- laboratory tests to measure the impact of interventions
- the design of trials and appropriate endpoints (measurements of trial outcomes)

Among the priorities that emerged is the need to rigorously compare the variety of tests that are used to measure very small

amounts of HIV in individuals on long-term suppressive antiretroviral therapy (ART). In order to quantify the effect of an intervention on HIV reservoirs, tests need to be able to reliably show relatively tiny differences in amounts of virus. To imagine the scale of the challenge, imagine trying to use a bathroom scale to measure the difference in weight between one and two grains of sand.

Another important consideration is the use of analytic interruptions of ART to assess the impact of an intervention—the ultimate test, in the view of many. Because the rebound in viral load that occurs after stopping ART is associated with potentially dangerous bursts of inflammation, parameters to minimize risk to trial participants were recommended.

Moving forward, there was widespread agreement about the need to work on a range of issues to facilitate future HIV cure-related clinical trials. These included increasing awareness and knowledge regarding cure-related research among regulators and clinical trial review bodies (such as institutional review and community advisory boards), promoting increased funding for the field, and ensuring coordination and information sharing among scientists conducting relevant studies.

The sponsoring organizations will be following up on the advocacy issues identified at the workshop and a full meeting report is forthcoming. ●

For an updated list of relevant articles, clinical trials, and other resources (including the clinical research workshop report as soon as it is available), see TAG's HIV Cure-Related Research Resource Page at <http://treatmentactiongroup.org/base.aspx?id=4406>.

New TB Diagnostics, continued from page 5

In addition to these developments at the global level, there has been swift uptake at the national level. By March 2011, 17 countries had placed firm orders for the test, and India and South Africa, among others, have ambitious plans for making it widely available. There remains a need for the WHO's Global Laboratory Initiative, FIND, and Cepheid to work with national partners implementing the Xpert MTB/RIF test to ensure that funds are used efficiently and minimize overlap of efforts. Part of this coordination should include gathering evidence to show the impact the test has not just on diagnosis but on treatment outcomes. It will be important to find out how far the test can be decentralized in order to make it as accessible to TB patients as possible. All this evidence will strengthen advocacy to expedite global access—advocacy that in turn will lead to price reductions as the volume of the tests being used increases. Only through such coordinated efforts and continued advocacy can we ensure that the Xpert MTB/RIF assay will lead to the ultimate goal of increasing access to appropriate TB care, ultimately preventing illness and saving lives. ●

1. World Health Organization. Global Tuberculosis Control 2010. Geneva: World Health Organization, 2010

2. Catharina Boehme. Xpert MTB/RIF: Evidence and Operation Consideration. Presentation at WHO Global Consultation, Geneva, 30 November–2 December 2010.

Vaccine Breakthrough, continued from page 6

Although these caveats about CMV as a vector have not been well covered in the media, they do not negate the potential importance of the study results. Even if CMV cannot be developed for use in humans, the data provide a strong impetus to seek safe ways to induce similar CD8 Tem cells with vaccines, both in the preventive and therapeutic context. Most encouraging is that Picker's work has demonstrated the right type of vaccine-induced immune response can exert an extraordinary degree of control over a virus notorious for overwhelming everything the immune system throws at it. ●

TAG NEW WAYS TO CONTRIBUTE

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About TAG

Treatment Action Group is an independent AIDS research and policy think tank fighting for better treatment, a vaccine, and a cure for AIDS. TAG works to ensure that all people with HIV 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 AIDS.

Program areas include antiretroviral treatments, basic science, vaccines, prevention, hepatitis, and tuberculosis.

Join TAG's Board

TAG is always seeking new board members. If you are looking for a great place to invest your time and talents, please call Barbara Hughes, TAG board president, to learn more about board opportunities with TAG.

Call 212.253.7922 or email: barbara.hughes@treatmentactiongroup.org

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