

## INSIDE

### UPDATE FROM CROI 2014 6

Reports on the search for a cure and prevention.

### FIGHTING FOR LAMONT: THE BATTLE FOR TRANSPLANTS FOR PEOPLE WITH HIV 9



### Personal Perspective: LAMONT'S LEGACY 12

No one wanted to help. He was told to just go home and die.



### SPEAK UP! WATCHDOGGING THE ACA FOR PEOPLE WITH HIV 14

We want to hear about any issues with signing up for new health coverage or getting care and treatment.

### Personal Perspective: NAVIGATING THE ACA: ONE MAN'S JOURNEY 18

### HIV GENERICS IN THE U.S.: SOONER OR LATER? 20

Why do we spend billions for drugs that are available in cheaper generic forms overseas?



### HIV HEALTH LITERACY IN THE SOUTH: A WORK IN PROGRESS 22

### EDITORIAL 23

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## Promise and Peril



## The New Hep C Drugs

by Liz Highleyman

For the past few years experts have predicted a revolution in treatment for hepatitis C virus (HCV), making it simpler, shorter, and much more effective. With the approval of the first two next-generation direct-acting antivirals (DAAs) – and with several more expected over the next couple of years – that revolution has now arrived. But cost and other factors may limit access for many.

New HCV therapies were a major theme at the 21st Conference on Retroviruses and Opportunistic Infections (CROI) in March and the 49th EASL International Liver Congress in April. HCV treatment is undergoing a sea change comparable to the advent of effective HIV med combinations in the mid-1990s, but at a much faster pace. “It’s like HIV drug development at warp

speed,” according to Douglas Dieterich from Mt. Sinai.

### Where Are We Now?

The old standard of care, pegylated interferon plus ribavirin, required weekly injections and twice-daily pills taken for six to 18 months. It caused unpleasant and potentially dangerous side effects, including flulike symptoms, depression, and anemia – and it cured only about half of those who took it. (The benchmark for a cure is SVR12 – a “sustained virologic response”, which means an undetectable HCV viral load 12 weeks after finishing treatment.)

The first DAAs – the HCV protease inhibitors boceprevir (Victrelis) and telaprevir (Incivek) – were approved by the FDA in 2011. When added to interferon and ribavirin, they shortened treatment time by half and raised cure rates up to 75% in trials. But they require multiple daily pills and have side effects of their own (anemia with

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## EDITOR IN CHIEF

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## EDITOR

Mark Milano

## MEDICAL EDITOR

Jerome A. Ernst, MD

## PUBLICATIONS MANAGER

Mark Milano

## PUBLICATIONS ASSOCIATE

Laura Engle

For information on how to obtain bulk copies of *Achieve*, call 212-924-3934, ext. 134, email [achieve@acria.org](mailto:achieve@acria.org), or write to

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## Promise and Peril *cont. from previous page*

Victrelis; skin rash with Incivek). And SVR rates have been disappointing in clinical practice, especially for some of the hardest-to-treat people: those with liver cirrhosis, HIV/HCV coinfection, and those who did not respond to previous interferon.

The next-generation DAAs promise to overcome these barriers. The first out of the gate – Janssen's protease inhibitor simeprevir (Olysio) and Gilead's polymerase inhibitor sofosbuvir (Sovaldi) – were approved in late 2013. Other promising drugs in the final stages of testing include:

- ledipasvir – NS4A inhibitor (Gilead)
- daclatasvir – NS4A inhibitor (Bristol-Myers Squibb)
- asunaprevir – protease inhibitor (Bristol-Myers Squibb)
- faldaprevir – protease inhibitor (Boehringer Ingelheim)
- "3D" combo – three different DAAs (AbbVie)

Unlike interferon, which stimulates the body's natural immune response, DAAs interfere with enzymes the virus uses to reproduce. Like HIV meds, they work best when drugs that target different steps of the viral lifecycle are combined. They can shorten treatment to 12 or 24 weeks – and maybe even 6 or 8 weeks for some people – and they do not add many side effects.

For people with HCV genotype 1 (the most common type in the U.S. and until now the most difficult to treat), the FDA approved both Olysio and Sovaldi for use in a 12-week regimen with interferon and ribavirin. Sovaldi has the edge since it is active against more HCV genotypes and has fewer drug interactions than Olysio.

But what most people with HCV and their providers have been waiting for is interferon-free treatment.

## The Robert Mapplethorpe Clinical Research Program

### Prolastin-C

People with HIV aged 18 to 65 on stable ARVs with a viral load below 1,000 and a CD4 count between 200 and 600 will receive weekly infusions of the proteinase inhibitor Prolastin-C or a placebo for 8 weeks, to study its effect on CD4 counts. People who are HIV negative will have lab tests done.

### BMS-663068

People with HIV who are 18 and older will take BMS-663068 (an experimental HIV attachment inhibitor) or Reyataz for up to 96 weeks. Everyone will also take Isentress and Viread.

### BI 201335

People aged 18 to 70 who have hepatitis C virus will take BI 201335 (an experimental HCV protease inhibitor) with peg-interferon and ribavirin for 12-48 weeks.

### Ibalizumab

People with HIV will receive infusions of ibalizumab (a monoclonal antibody) to study its safety and effect on the immune system.

### Selzentry

People with HIV who are 18 and older and who have not taken HIV meds will take either Selzentry or Truvada for 22 months. Everyone will also take Prezista with Norvir.

For more information on these trials, contact us at 212-924-3934, ext. 100.

Compensation is available for some studies.

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## No Interferon or Ribavirin

For people with HCV genotype 2 or 3, Sovaldi plus ribavirin is the first FDA-approved regimen without interferon. Taken for 12 weeks for genotype 2 or 24 weeks for genotype 3, it cured more than 90% of previously untreated patients.

Recognizing the eagerness – and for many, the necessity – to go interferon-free, the FDA said people with genotype 1 who are ineligible to take interferon can use Sovaldi plus ribavirin alone for 24 weeks. Though the FDA did not define “ineligible”, many providers are interpreting it to include people who are unwilling to take interferon as well as those who cannot tolerate it.

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**The SYNERGY trial showed that close to 100% of people starting HCV treatment for the first time can be cured with two DAAs taken once daily for 12 weeks or three DAAs taken for just six weeks.**

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An expert panel (AASLD, IDSA, and IAS-USA) went further, saying people who can't or won't take interferon may take Sovaldi plus Olysio for 12 weeks. This regimen has not completed Phase 3 trials but led to cure rates above 90% in the Phase 2 COSMOS trial. In new guidelines released at the Liver Congress, European experts agreed, and also gave the nod to Sovaldi plus soon-to-be-approved daclatasvir.

“Recently approved medications and several others on the horizon promise to cure nearly all treated patients without

the many side effects that have plagued past treatment regimens”, said AASLD panel co-chair Donald Jensen.

In addition to causing anemia, ribavirin can also cause birth defects, and should not be used by pregnant women or their male partners. While research is still scarce, it is reasonable to believe safer treatments taken during pregnancy would further reduce the already low risk of mother-to-child HCV transmission.



## In The Pipeline

The SYNERGY trial showed that close to 100% of people starting HCV treatment for the first time can be cured with two DAAs taken once daily for 12 weeks or three DAAs taken for just six weeks. This trial enrolled 60 African-Americans with genotype 1, including about 25% with advanced liver fibrosis or cirrhosis. “We believe this population is really reflective of the hepatitis C population in the U.S., which historically has been a difficult-to-treat population”, said lead researcher Anita Kohli.

A Gilead trial of Sovaldi plus ledipasvir taken for 12 weeks produced an SVR12 rate of 100%. Adding either the polymerase inhibitor GS-9669 or the protease inhibitor GS-9451 yielded cure rates of 95% and 100% in only six weeks. And the ION trials showed cure rates above 90% for a combo

pill of Sovaldi and ledipasvir in people treated for 12 or even 8 weeks.

But Gilead is far from the only player in the interferon-free game. A 12-week regimen of AbbVie’s “3D” combo pill (the protease inhibitor ABT-450, NS5A inhibitor ombitasvir, and polymerase inhibitor dasabuvir) has also demonstrated high cure rates. In the PEARL-III trial, SVR rates reached 99% for previously untreated genotype 1 patients without liver cirrhosis. AbbVie expects approval by the end of 2014.

Similarly, a regimen of daclatasvir, asunaprevir, and the polymerase inhibitor BMS-791325 taken for 12 weeks cured 92% of previously untreated patients. Merck also has a promising combo in the works: the protease inhibitor MK-5172 and NS5A inhibitor MK-8742.

Daclatasvir resulted in SVR rates near 100% when taken with Sovaldi. Gilead declined to pursue this regimen, but now that Sovaldi is FDA approved, research by other companies is continuing. And once drugs are approved, providers can mix and match them as they choose. In fact, the recently released guidelines from the European Association for the Study of the Liver recommend combos that include daclatasvir, even though it is not yet approved.

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## More Benefit for More Patients

In the past, being African American, having a high HCV viral load, or having HIV coinfection all predicted a poor response to interferon. Fortunately, these factors don't lower cure rates as much for the new DAAs. Even liver cirrhosis does not reduce response to some of the new meds. On the other hand, genotype 3 is now known to be harder to treat than genotype 2, and genotype 1a is harder than 1b.

"All the old predictors of response are gone when you have a potent two or three drug combination", said Dieterich. He added that response rates for HIV-positive and HIV-negative people are "exactly the same".

The FDA unexpectedly included people coinfecting with HIV in its approval of Sovaldi – a group that usually has to wait. In the PHOTON-1 trial of coinfecting people, Sovaldi plus ribavirin for 24 weeks cured 75% of genotype 1 patients who had no prior treatment and more than 90% of treatment-experienced genotype 2 or 3 patients.

Some HCV drugs (especially protease inhibitors) can interact with some HIV meds. Fortunately, drug companies are now testing new DAAs in people with HIV earlier in the development process. Jurgen Rockstroh from the University of Bonn and others have suggested that coinfecting people be included in early HCV trials, since response rates are similar to those of HIV-negative patients.

## What About The Cost?

While these advances are cause for celebration, it's unclear how they will be used in the real world. Of the three million people with HCV in the U.S., only half have been diagnosed, a third are referred to care, 10% start treatment, and only 5% are cured.

Janssen and Gilead have both taken heat for their high prices: \$66,000 for Olysio and \$84,000 for Sovaldi for a 12-week course. Sovaldi's \$1,000-per-pill price tag has drawn attention well beyond the usual ranks of activists, with criticism

coming from medical providers, insurance companies, and legislators. The New York Times even asked whether there are ways to finance research into new drugs without making profit the main reason for their development.

Some cancer drugs are priced equally high, and Gilead argues that Sovaldi is a good value. Unlike HIV drugs that must be taken for life, or cancer drugs that prolong life by only a few months, Sovaldi offers a permanent cure. Because it is so effective, its cost per cure compares favorably to Incivek, which has a higher chance of failure. And curing hepatitis C can avoid more costly long-term consequences such as a liver transplant, which runs about \$500,000.

But the price of new DAAs is a major concern because so many people with HCV rely on public funding like Medicaid, Medicare, the VA, or prison

has increased emphasis on cost containment. "Cost is the biggest obstacle of all," said Ingo van Thiel of the European Liver Patients Association.

Advocates are concerned that not only will many patients die without treatment, but many others will be required to try interferon first, before being considered for more effective and well tolerated DAAs as second-line treatment.

Despite its high price, Sovaldi has been "flying off the shelves" according to Dieterich, at a rate of more 4,000 prescriptions per week in February. After years of "warehousing" HCV patients waiting for interferon-free treatment, doctors are now starting to work through their backlogs, starting with the sickest patients first.

Some experts estimate Sovaldi sales for 2014 could reach \$10 billion (compared with \$9 billion for all of Gilead's HIV meds combined). That would make

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budgets. A recent analysis by University of California Riverside researchers estimated that treating all U.S. prisoners with hepatitis C could cost more than \$30 billion.

"We'd like to think we could make decisions about what's best for the individual [patients]," former AASLD president Gregory Fitz said, "but thinking about this on a population scale is daunting."

While the FDA and expert guidelines do not take cost into account, price will play a major role in the real world. It will be an issue in low- and middle-income countries, of course, but also in Europe, where national health programs take cost-effectiveness into account, and in the U.S., where the Affordable Care Act

it one of the top-selling drugs ever and allow Gilead to quickly recoup the \$11 billion it spent to acquire Pharmasset (which discovered the drug).

## Who Needs It?

Only about 25% of people with chronic hepatitis C develop severe liver disease, and it's difficult to predict who they will be. While Sovaldi may be a cost-effective alternative to liver transplants, most people with HCV will never need a transplant.

But with the new meds, some experts think more people should be eligible for treatment. This is especially true for HIV-coinfecting people, who often have more rapid liver disease progression. As with HIV, treating HCV early may prevent

other problems like heart disease, and may reduce deaths even among people who do not develop severe liver damage. Plus, curing hepatitis C prevents transmission, leading some to favor a universal “test-and-treat” approach.

But cost could make such expansion impossible. Already, some private insurers and state Medicaid programs are requiring prior authorization or seeking supplemental funding for Sovaldi and Olysio. Express Scripts, for example, has asked doctors to delay prescribing Sovaldi to people who do not need immediate treatment. America’s Health Insurance Plans, an industry trade group, called Sovaldi’s price “unsustainable”.

A report prepared for the California Technology Assessment Forum found that treating all HCV patients with advanced liver disease would cost the state more than \$6 billion in a year, and treating everyone currently in care would cost at least \$18 billion. The panel stated that at current prices, people with little or no liver damage generally should not be treated.

The National Association of Medicaid Directors went further, questioning whether studies – most of which were funded by Gilead – provide strong enough evidence that Sovaldi is really better than older treatments. The “unprecedented nexus of cost and widespread demand threaten to disrupt the healthcare landscape in the near term,” said the group’s executive director Matt Salo.

## The World Responds

But people with hepatitis C are concerned about their own health – not the impact on the healthcare landscape.

In March, representatives Waxman, Pallone, and DeGette (all Democrats) took the unusual step of sending a letter to Gilead stating, “Even in cases where public or private insurers pay for the medication, it will impose substantial costs on taxpayers and could cause premium increases for those with employer or individual coverage.”

The following week, Gilead agreed to give federal health plans a 23% discount, with further price reductions for the V.A.



(which treats a large number of HCV patients). Gilead then agreed to license Sovaldi to drug makers in India at \$2,000 for a 24-week course. And Gilead could price its Sovaldi/ledipasvir combo pill at less than the two drugs used separately, as Abbott did with Kaletra for HIV.

Production costs for DAAs can be quite low. A recent study from Liverpool University estimated manufacturing costs topping out at \$136 for Sovaldi and \$270 for Olysio for a 12-week course.

Outside of legislative action and negotiated discounts, the best hope for lowering the cost of new HCV drugs is increased competition. AbbVie’s “3D” regimen will require more pills per day than Gilead’s combos, but this may be an acceptable trade-off for a lower price.

In May, the WHO’s World Health Assembly passed a hepatitis resolution supporting the use of global trade provisions to allow low- and middle-income countries to produce or import generic versions of DAAs if companies won’t offer them at affordable prices. The first Hepatitis C World Community Advisory Board meeting, held in Bangkok in

February, brought together advocates from around the world. They hope to get the price for a course of DAA treatment below \$500, similar to the annual cost of HIV treatment in developing nations.

“We are witnessing a revolution in the treatment of HCV with powerful molecules capable of curing the infection”, as Françoise Barré-Sinoussi stated in a recent report by Médecins du Monde. “There is no question that these treatments that can save millions of lives must be made universally available at an affordable price.” ■

AASLD/IDSA/IAS-USA Recommendations for Testing, Managing, and Treating Hepatitis C are available at: [hcvguidelines.org](http://hcvguidelines.org)

EASL guidelines are available at: [files.easl.eu/easl-recommendations-on-treatment-of-hepatitis-C](http://files.easl.eu/easl-recommendations-on-treatment-of-hepatitis-C)

*Liz Highleyman is editor-in-chief of HIVandHepatitis.com and has written about HIV and hepatitis for various publications for 20 years.*





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by Donna M. Kaminski, DO, MPH, and Mark Milano

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In addition to exciting hepatitis C cure research (see cover story), the 21st Conference on Retroviruses and Opportunistic Infections, held in Boston in March, brought some important news on HIV transmission and treatment research.

### Cure Update

In the opening plenary, John Mellors of the University of Pittsburgh provided an overview of HIV cure research. He defined three types of cures: the Eradication Cure, in which all HIV is eliminated from the body and no further treatment is needed; the Functional Cure, in which HIV remains, but can be controlled by the immune system without ongoing treatment; and the Hybrid Cure, which attempts to dramatically decrease the HIV reservoir and modify the immune system so it can control whatever HIV remains without ongoing treatment.

Looking at eradication, Mellors discussed Timothy Brown, the only adult who apparently has achieved this, and the two Boston patients who underwent similar stem cell transplants. The latter patients failed to achieve a cure, since the CD4 cells they received came from donors

whose CD4 cells did not have the CCR5 deletion that prevented Brown's HIV from re-establishing an active infection.

The surprising bit of info on the Boston patients was that even though only .001% of their original CD4 cells remained after their transplants, that was enough to lead to a complete return of HIV. According to Mellors, this shows how high the bar is for HIV eradication: even a single infected cell holds the possibility of re-establishing the infection.

will cure HIV. But if you stood up at the microphone in 1987 and said, 'I think we'll be able to control 90% of HIV infection with one pill once a day or cure 90% of HCV infection with one pill once a day', they'd cart you off to the psychiatric hospital. So, yes, I think it's possible."

Turning to the Functional Cure, Mellors discussed the French VISCONTI cohort, in which about 10% of people treated immediately after HIV infection have been able to control their infection

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In response to a question as to whether we will ever see an Eradication Cure that will be widely available, Mellors said, "If you say no, you're bound to be proven wrong. It's hard to imagine that we will have a scalable, simple product that with high efficacy

after stopping HIV meds. This approach would be far more possible if fourth-generation HIV tests (which can detect infection in as little as a month) are more widely used. Studies have shown that the sooner HIV treatment is started, the smaller the reservoir of HIV-infected CD4 cells.

With regard to the Hybrid Cure, Mellors focused on attempts to reduce the size of that reservoir. HDAC inhibitors like vorinostat and panobinostat are being studied to see if they can activate the resting CD4 cells that harbor HIV, so the immune system can eliminate them or HIV meds can enter them. But he noted the ongoing debate as to whether these drugs can activate enough resting cells to make a difference, and doubted whether they could if used alone. Fortunately, there have been reports that the drugs are more effective when used in combination with each other.

He also highlighted anti-PD1 drugs, one of the cancer immunotherapy drugs that Science magazine hailed as the “2013 Breakthrough of the Year”. These drugs may be able to prevent the T-cell activation that is an important factor in HIV disease progression. One such drug was able to control infection in half the monkeys treated with it.

## Two Babies Cured?

Last year this same conference was all abuzz about the “Mississippi baby”. The story of the infant who was born with HIV and started on aggressive HIV meds 30 hours after birth filled us all with hope, since the child maintained an undetectable viral load after stopping treatment. It was hoped this meant a cure might be possible if infants start HIV medication soon after birth.

This year, several studies fueled that same excitement, beginning with the Mississippi baby. Now three years old and off treatment for two years, the child continues to have an undetectable viral load levels in both peripheral blood and HIV reservoirs. While we don’t know yet whether this is a cure, it does appear that the virus is in remission.

A second baby, born in Long Beach, California, was presented as a second case of early treatment. In this case, a

control of the virus, or even eradication? Newborns have no CD4 memory cells, which are the main reservoir for HIV. Could their lack of these immune cells be the answer?

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Now three years old and off treatment for two years, the child continues to have an undetectable viral load levels in both peripheral blood and HIV reservoirs.

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It’s too soon to tell. The California baby is still on HIV meds. We don’t know whether her viral load will remain undetectable after stopping the drugs, and no timetable for doing that was announced. A larger study will offer triple-drug HIV treatment to newborns within 48 hours of birth and should provide some real answers.

## The PARTNER Study

Another exciting study looked at how HIV treatment affects transmission. Researchers from the PARTNER study reported on 727 couples in which only one person had HIV. The analysis presented at CROI reported on couples that did not regularly use condoms, and in which the partner with HIV had a viral load below 200. None of the HIV-negative partners took PEP or PrEP to prevent HIV transmission. They were followed for an average of 1.2 years.

This study had two significant differences from HPTN 052, which showed that early HIV treatment can lower transmission by 96%. First, PARTNER included many gay couples (39% as opposed to only 2% in HPTN 052). Second, no couples in PARTNER reported regular condom use, while couples in HPTN 052 reported using condoms 94% of the time.

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Mellors closed with the attempts by Sangamo and Calimmune to remove people’s CD4 cells, genetically modify them to resist HIV infection, and then re-infuse them. He mentioned new research showing that cyclophosphamide can increase the number of cells that remain in the body after being modified by the Sangamo drug, SB-728-T.

His final thought: “Buckle up – it’s going to be a wild ride!”

newborn girl who had HIV in her blood and cerebrospinal fluid four hours after birth was started on AZT, Epivir, and Viramune. Two weeks later, the Viramune was changed to Kaletra. Her viral load dropped from 139,000 at birth to undetectable after a month, and this has been maintained for nine months. In addition, she has a normal CD4 count. Does this mean that starting HIV meds right after birth will lead to long-term



In total, PARTNER couples reported more than 30,000 condomless sex acts. But even with all of those encounters, no cases of HIV transmission linked to the positive partner occurred. Several STDs were transmitted, but no HIV. Had the people with HIV not been on treatment, we would have expected to see 15 cases of HIV transmission in the heterosexual couples and 86 in the homosexual couples.

The researchers were quick to point out that this result does not mean that people with HIV who have an undetectable viral load cannot transmit HIV. Due to the length of the study and the number of people in it, confidence levels were not high enough to show that. Researchers from this study estimated that the risk of transmission from vaginal intercourse with someone with an undetectable viral load was 0-2% a year, and the risk from anal sex was 0-4% a year.

In order to increase confidence in the result, PARTNER2 is being planned. It will add 450 more homosexual couples to the 458 already being followed in PARTNER and will report final results in 2017. If it also finds no transmissions, that result will be highly significant (although no study can definitively show a risk of zero). Until then, we can only say that having an undetectable viral load significantly lowers the risk of HIV transmission, but does not eliminate it.

## Prednisolone

Another interesting study looked at this corticosteroid in people with HIV. People have long proposed using anti-inflammatory drugs for HIV, but since they can suppress the immune system, researchers have been reluctant to do studies. At CROI, a team of German researchers (C. Kasang et al) presented a poster looking at prednisolone's effect on immune activation markers, CD4 counts, and disease progression.

A total of 326 people with HIV who were not yet eligible for antiretroviral therapy in Tanzania (because their CD4 count was above 300) took either 5 mg of prednisolone a day or a placebo for two



**In total, PARTNER couples reported more than 30,000 condomless sex acts. But even with all of those encounters, no cases of HIV transmission linked to the positive partner occurred.**

years. No one took antiretrovirals. Those on treatment saw lowered immune activation markers (sCD14 and suPAR) but also a two-fold increase in HIV viral load. CD4 counts increased (+39 for prednisolone and -30 for placebo) and people taking prednisolone had significantly fewer AIDS-defining conditions (4 patients versus 11). Unlike earlier studies that used a much higher dose, there were few side effects.

The authors conclude that drugs that target immune activation slow HIV disease progression despite high viral loads, demonstrating that chronic immune activation is a factor in progression. They

suggest that corticosteroids should be explored as an early treatment option in poor countries. And they might be used along with HIV meds in people who have high levels of immune activation and low CD4 counts despite having an undetectable viral load. Could this also be an option for the many people with HIV who refuse approved antiretrovirals out of fear or other concerns?

*Donna M. Kaminski, DO, MPH, has accepted a faculty position at Somerset Medical Center/ RWJ Hospital.*

*Mark Milano is the Editor of Achieve.*





# Fighting For Lamont

## The Battle for Transplants for People with HIV

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by Stephen Helmke

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One Monday night in December of 2013, ACT UP/NY's weekly meeting bustled with an energy reminiscent of earlier times. Issues about home-grown action campaigns, educational efforts, digital activism, and a timely prevention agenda were scrawled on the agenda board. New members were angry about rising HIV infection rates among young gay men and transwomen of color. Some had been inspired by recent documentaries on ACT UP and felt the need for direct action to end the AIDS crisis. And some were returning veterans like myself who'd picked up passions and practices set aside decades ago.

We all knew that the fight is far from over. Stigma, criminalization, lack of housing, poor access to care, and a host of other issues still plague people with HIV. True, some gains have been made – although they are often limited to the privileged, not accessible to all, and under the constant threat of political whim – but none of these problems can be set aside.

### Lamont

That December night, ACT UP veterans Adam Melaney and Kate Barnhart brought the story of Lamont Valentin to the meeting. Born with HIV nearly 30 years ago, he had fought AIDS in the crib and on the playground as we fought it on the street. But Lamont had just lost another fight – the fight to get a lung transplant – which he needed due to years of lung infections. He was denied a lung simply because he was infected with HIV. He had recently died.

As I heard Adam and Kate speak of Lamont's defeat, I recognized what a tremendous struggle this was. The road to an organ transplant sounded like an obstacle course.

In the maze of policy around organ waitlists, people are required to prove things like domestic stability. In much the way adoptive parents must show they can care for a child, organ recipients are deemed best able to care for themselves (and the organ they will receive) when they have food, shelter, and a family.

Unrelated health problems often prevent access to organs. Other diseases or conditions, such as a high HIV viral load, opportunistic infections, asthma, diabetes, hepatitis, or substance abuse could make it unlikely for people to recover from the transplant, or would severely limit life expectancy after a transplant.

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**Lamont had just lost the fight to get a lung transplant – which he needed due to years of lung infections. He was denied a lung simply because he was infected with HIV. He had recently died.**

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I knew of heart transplants to people with HIV. Larry Kramer, one of ACT UP's founders, had a liver transplant. He broke a barrier because of his influence, and I knew that kidney and liver transplants to people with HIV were occurring more frequently. I strongly hoped that the transplant centers' refusals for Lamont were based on current science and transplant ethics.

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Unfortunately, we soon learned that none of the transplant centers had been required to explain a thing. All they had to do was point to the guidelines published by the International Society of Heart and Lung Transplantation (ISHLT). Last updated in 2006, they describe HIV as an “absolute contraindication”, meaning that centers can refuse anyone with HIV for transplant – without rationale or justification.

The grief was palpable that night, and moved all of us to action. Preparations were quickly made for a Memorial March and Mourning at the Rockefeller Center Christmas tree. A group from City College carried a large banner saying “No Xmas for Lamont!” Clients of his from Streetworks, colleagues from Camp AmeriKids, friends and family, and dozens of ACT UP members descended upon Rockefeller Center. We marched just behind the Christmas tree, chanting and singing repurposed Christmas carols to tell Lamont’s story. By expressing our collective, tangible loss, we were bearing stark witness to outdated science and unjustifiable policies.

## Transplant Realities

Organ failure seems rare, but people with HIV suffer from it all too often. Many who have suppressed viral loads remain at risk of organ failure due to periods of untreated HIV infection, other diseases, drug side effects, and aging.

Unfortunately, the availability of organs for transplant is low, and deciding who gets them is an ethical challenge. The surgery itself is risky for both the recipient and any living donor. Medically unstable people often may not survive the surgery or live to use the organ. And in order to keep the immune system from rejecting the organ, large doses of immune-suppressive drugs must be taken for long periods of time.

All of these factors affect the order of people on the waiting list, and whether they get on the list in the first place. The list is administered by the United Organ Sharing Network, or UNOS. Professional organizations like ISHLT publish guidelines suggesting the best medical practices for people before, during, and after transplant.

For many years transplants weren’t offered to people with HIV, since they did not have a normal life expectancy. The thinking was that someone without HIV would benefit for a significantly longer period of time. Not so today. Updated and improved guidelines for transplants for people with HIV are important, since HIV-positive recipients often can have a normal life expectancy.

Managing organ rejection with immune-suppressive drugs in someone with HIV was once near impossible. With earlier HIV drugs it was extraordinarily difficult, but with newer drugs like integrase inhibitors, drug interactions are much less of a problem. There are even drugs being studied that inhibit both HIV and organ rejection. For all of those reasons and more, it’s time for transplant equity.

## Fighting for Transplants

Tim Horn, who directs HIV research and policy for the Treatment Action Group, wrote to the lung transplant team at Columbia University for an explanation of its refusal of Lamont. There was no response. After the ACT UP demonstration, a letter was sent to the ISHLT demanding a change in the guidelines along with ACT UP’s participation in revising them.



As long as the guidelines refused people with HIV out of hand, no center would ever have to offer any reason for denial.

ACT UP was informed that changes to the guidelines were coming soon, and that they would meet our demands. We have since been told that we could review them before a final decision is made, but we have not have a hand in their drafting.

The news that heart and lung transplant guidelines will soon be revised is a great opportunity. We must work to ensure that the new guidelines are realistic and fair to people with HIV. And we must celebrate every victory and use it to cast a light on the thorny struggle to make sure the new guidelines are followed.

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## HIV Transplant Activism

Even though the new guidelines will state that transplants should be considered for people with HIV, transplant centers can still refuse applicants based on the other reasons stated above. The new guidelines will make it more difficult for centers to flat-out deny lungs and hearts to people with HIV, but they won't require them to transplant organs into people with HIV. They will not even require centers to offer reasons for denial. That will be the job of HIV transplant activists.

We must demand that people with HIV are included on advisory boards at UNOS and professional transplant societies. Since these organizations may not value an HIV-positive life as highly as an HIV-negative one, they need HIV advocates to ensure that the most current scientific information about HIV is considered. We need people who think first about our interests – who can report on any policy that disregards our needs.

The natural first instinct – to demand transplants for all people who need them – is not realistic. Not everyone who needs an organ transplant is able to survive and recover from the surgery. Also, the number of those who need organs and are good candidates is much larger than the number of organs available.

Policies have been proposed that would increase the number of potential donors. For example, if the option to list yourself as an organ donor on your driver's license was opt-out rather than opt-in, the supply of organs would greatly increase because people would have to choose if they did not want to be a donor. Compare this to the current policy for people with HIV: we are not allowed to donate organs.

## Expanding Access

The HOPE act, signed into law last year, aims to change the blanket exclusion of people with HIV as organ donors. The law allows research on organ transplants between people with HIV. This could make more organs available for transplant into people with HIV. What should not be the end result is a “separate but equal” organ pool. We must be vigilant in demanding access for people with HIV to all available UNOS organs.

There is one important shortcoming in the proposed guidelines. They will be written at the lowest category of authority, that of “expert opinion”. In simple terms, a transplant center could declare, “We're experts and we do not agree that people with HIV should be eligible.” Stronger guidelines require published studies of successful transplants, combined with data demonstrating specific need for transplants in people with HIV.

Organizing registries for HIV-positive people with organ failure would prove the need for transplants, build solid evidence of successful transplants, and help to get more people the care they need. Such a registry would make it far easier for advocates to identify and support people in need. With this information, we could move on transplant centers that refuse to list HIV patients, demand strengthened guidelines from societies, legislate requirements to justify denial, and promote organ donation at large.



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**We must demand that people with HIV are included on advisory boards at UNOS and professional transplant societies.**

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## Lamont's Legacy

The fact sheet we printed for Lamont's Memorial March ended: *!Lamont Valentin presente!* He is present, reminding us all that no matter how much we seem to have accomplished in the fight against AIDS, people are dying even today. As before, they die from the effects of the virus and from wrong-headed policies fraught with silence, shame, apathy, and fear. They are dying from the poor science that persists and enables those enemies of health. But as before, people with HIV and their advocates are taking on this fight – in Lamont's name. ■

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*Stephen Helmke works in cardiology research and is a long-time HIV activist.*



# Lamont's Legacy

by *Lan-Anh Nguyen-Valentin*

I met Lamont Valentin in 2010 at a bar on the Lower East Side. I overheard someone singing to all of the songs being played and I told him he was like a human jukebox. We chatted and danced and he kept telling me that I looked beautiful. All of a sudden a friend of mine was being harassed by another guy. Lamont intervened with the bar staff and had the guy removed from the club. I liked that he went out of his way to help a stranger, like a knight in shining armor. And so one of the most important relationships of my life began.

**All the providers and programs in New York just kept refusing him. No one wanted to help. No one felt his life was important enough to reevaluate the transplant policy. He was told to just go home and die.**

Lamont was a jokester – sarcastic, generous, and very social, always inviting people over before asking me. He was protective of everything important to him, especially with our son, Mason. He was inspirational and always encouraged others never to give up, but to follow their dreams.

During our first month of dating, Lamont opened up to me that he had been placed in the foster care system at the age of seven after his mother died from AIDS. In that moment I assumed he was living with HIV but I didn't ask – it was his way of telling me without really telling me. Two months

later, Lamont asked if we could talk about something privately. He told me, "This is really tough to say..." and I thought that it was the beginning of a breakup conversation. Then he said, "I was born with HIV. I'll understand if you don't want to be with me anymore." I answered, "Look, I'm not the type of person to run away from a situation you have no control over. I'm not going away unless you push me away. I have feelings for you and this doesn't change anything."

Everyone seemed to be worried about Lamont being HIV positive, but he took his medications, saw his doctor regularly, and was undetectable so I wasn't worried about his health or my own. I saw him as a person, but other uneducated people saw him as a disease.

The same day Lamont told me his HIV status, he had seen his doctor and been given a portable oxygen concentrator. I knew that he had a lung condition but I didn't think it was that serious because it didn't stop him from doing anything he wanted to do. I first realized his lung problems could be life-threatening in October of 2011. Before then, he only used an oxygen concentrator at home, but now he actually had to carry oxygen tanks with him to breathe when he left the apartment. At the time, he was working with homeless youth at Safe Horizon's Streetwork Project, providing workshops and one-on-one counseling. He loved the kids there and loved his job. But he quit because he didn't want the clients to see him with all of the tanks and tubes.

Before we met, Lamont knew that he might need a lung transplant one day. He was doing other pulmonary treatments and was confident that would be enough to save him. He was so strong and such a fighter – he didn't think it would actually come down to a transplant. He didn't want to give me all the details. It was frustrating because he would only let me help so much and no more. He would say, "Don't worry about it. I'm okay." I felt like he was trying to protect me. He had faced so many medical issues throughout his life and had always come out on top.

Lamont began to consider a transplant seriously in 2011. He discussed it with his ID specialist at St. Luke's-Roosevelt and then with his pulmonologist at Beth Israel. But he was told that because he was living with HIV he could not be added to the waiting list. That was it – you're HIV positive so you can't receive a lung transplant.

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He believed that if he could get his story on “Ellen DeGeneres” or the local news, the craziness of his situation would finally force some doctor to take care of him.

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In the summer of 2012 he met with a GMHC staff person who wanted to have a lawyer from GMHC try to convince the doctors to list him, but nothing really came of that. All the providers and programs in New York just kept refusing him. No one wanted to help. No one felt his life was important enough to reevaluate the transplant policy. He was told to just go home and die.

In the fall of 2013 we knew that he was getting sicker. He was becoming more bloated, had less and less energy, and was on more oxygen. Even though he had always been very private about his medical situation, he made the difficult decision to go public about it. He believed that if he could get his story on something like “Ellen DeGeneres” or the local news, the craziness of his situation would finally force some doctor to take care of him.

He spent days sending out emails to all of the major news programs. Two articles appeared on ABC online. The reporter, Gillian Mahoney, did her best but it didn't change anything. At the same time that we were trying to get Lamont's story to the public, we found doctors in San Francisco, Kentucky, and Boston who agreed to evaluate Lamont. No one in New York would even do that. But we didn't have the means to move, and Lamont was becoming more frail.

On December 1, 2013, Lamont's therapist, Adam Melaney, encouraged him to pursue some activism ... since nothing else was working. They watched “How to Survive a Plague” and learned more about how ACT UP had saved so many lives. But on December 3, Lamont died while riding a bus with his home health aide.

Adam attended the next ACT UP/NY meeting to ask them to help bring justice to Lamont and to mobilize to change the transplant policies so no one would ever have to go through this tragedy again. ACT UP was amazing.



They really showed empathy and backed it up with a rally to honor Lamont and to raise awareness that dated transplant policies had murdered him. ACT UP also sent a letter to the International Society for Heart and Lung Transplantation insisting on a policy review around lung transplants for people living with HIV.

As a child, Lamont was told he would not live past the age of ten. He never thought he would fall in love, marry, and become a father. His son, Mason, and I are his legacy. Our family was his dream come true, but the medical establishment of New York killed his dream. I will continue to speak up about this horror and unacceptable tragedy. I demand justice for Lamont and every person who is living with HIV. While Lamont was reaching out to doctors in other states, he realized that he wasn't fighting just for his own life and his own family. He knew that others had died before him and others would continue to die senselessly if he did not help to change the unjust and discriminatory transplant policies.

Lamont hoped that by obtaining a transplant, his life would serve as an example so that “Lamont's Law” would be passed making it possible for all people living with HIV to be listed for a lung transplant. It's too late for him, but I don't want a broken-hearted wife and a confused, fatherless son to be his legacy. “Lamont's Law” is the only legacy worthy of Lamont's incredible and passionate life. ■



## Watchdogging the ACA for People with HIV

by Robert Greenwald

**T**he first open enrollment period of the Affordable Care Act (ACA, also known as Obamacare) ended on March 31, 2014. The good news is that we've made significant progress for many uninsured people, including those with HIV. More than eight million people signed up for private health insurance through the insurance marketplaces, and more than three million people signed up for Medicaid. In states that have expanded Medicaid under the ACA, almost all low-income people now have access to comprehensive health care.

Since 1996, the Treatment Access Expansion Project (TAEP) has been working to expand access to health care for low-income people with HIV, hepatitis, mental illness, and other chronic health conditions. Currently, TAEP is working to ensure that the promises offered by the ACA become a reality.

### Medicaid Expansion

The ACA fits together like a puzzle. Everyone up to 133% of the Federal Poverty Level (FPL) – about \$15,000 a year for an individual – could now be eligible for Medicaid. Under the old Medicaid program, in most states, you not only had to be poor, but you also had to be disabled to be eligible. People with HIV had to become sick and disabled by AIDS to qualify for Medicaid, instead of getting the treatment that could have prevented them from getting sick in the first place. The ACA Medicaid expansion eliminates the disability requirement – now, if you have a low income, you're in.

But, since the Supreme Court made Medicaid expansion optional for states, the sad reality is that where you live now makes a big difference, especially if you have a chronic health condition like HIV. That's distressing, given that in the past decade we've really made progress, particularly with the Ryan White program, to make sure there is a balanced distribution of resources. Now, our lowest-income people living in states that have not expanded Medicaid are just left out—an awful and unacceptable situation. Many of the non-expansion states are in the South, which has high numbers of people newly diagnosed with HIV. Without Medicaid expansion, the growing number of people with HIV who have poor health outcomes will only increase.

The ACA's subsidies for private health insurance cover people from 100% FPL to 400%. There's a little overlap: people who make between 100–133% of FPL can choose between subsidies to buy private health insurance or can enroll in Medicaid, if they live in a Medicaid expansion state. However, there are no subsidies for people who earn below 100% FPL. When the ACA was written, it was expected that everyone below 100% FPL would be covered through Medicaid expansion. So a person below 100% FPL in a state that has not expanded Medicaid can apply for a private marketplace plan, but will not get any subsidy to help them pay for it.

**Many states not expanding Medicaid are in the South, which has high numbers of people newly diagnosed with HIV. Without Medicaid expansion, the number of people with HIV who have poor health outcomes will only increase.**

We're hopeful that this situation will change. When Medicaid was first enacted in 1965, there were many states that resisted its implementation and held out for long periods of time. It took years for states like Texas and Arizona to sign on. But ultimately they came on board, and now all 50 states provide traditional Medicaid to all eligible residents. We are optimistic that, eventually, that will happen with the new Medicaid expansion.

People who live in states that have not yet expanded Medicaid are soon going to realize that not only are they being denied health insurance, but that their federal tax dollars are paying for coverage in other states. People are going to make their politicians feel the heat. Those elected officials are denying the citizens of their states access to care that is overwhelmingly federally



supported, just for their own political posturing and gain. That is unacceptable and they should ultimately face the choice of signing on to health reforms or losing their jobs.

Right after the last presidential election, many Republican governors changed their positions to support Medicaid expansion. Over time, this trend will continue as people in non-expansion states demand access to the benefits of health reform that are taking place in expansion states. So again, I'm optimistic that we're going to get many, many states onboard within the next five to ten years. We just need to stay the course and we will win.

## Marketplace Plans

It's also exciting that so many people with HIV now have access to private health insurance through the marketplaces. In addition to the subsidies for people from 100% to 400% FPL, the ACA includes many reforms to the health insurance system. Insurers can no longer exclude people or charge them more based on pre-existing health conditions. They can no longer impose annual or lifetime caps on benefits for a specific health condition. And now young adults can remain on their parents' health plans until they are 26.

In exchange for these new provisions, the ACA created the "individual mandate" – everyone who is not otherwise insured now has to buy insurance or pay a penalty. So the insurance companies, in exchange for no longer "cherry-picking" (trying to keep sick people out of their plans), are getting millions more customers.

In theory, the ACA's reforms to private insurance should mean that longstanding barriers to insurance coverage for people with HIV and other chronic conditions are now eliminated. But the reality is that the insurance industry is resistant to change. Insurers have spent billions of dollars for decades to keep sick people off their plans and to maximize their profits. That isn't going to change overnight – it would be naïve to think that they won't keep trying to do that in some way. In fact, that's what we're seeing: discriminatory practices that are intentionally designed to reduce enrollment by people with HIV and other expensive health conditions.

Here is a brief summary of some of the trends we are seeing used by insurers to restrict access to health insurance for people with HIV:

## Transparency

The ACA mandates that marketplace plans must clearly state what services they cover, what drugs they cover, what costs come with their plans, and which providers are part of their plans. Yet we are seeing a pattern of intentionally leaving HIV meds and HIV providers off these lists. The companies say, "Oh, the websites are a work in progress" or "We just forgot to include them."

The fact is, these practices effectively discourage people with HIV from enrolling in these plans, and that's discriminatory. By law, plans are not allowed to leave the HIV meds they cover – or any other meds they cover – off the public list of drugs covered by their plan. Every time TAEP sees this, we are holding them accountable, and we are working to ensure that government insurance regulators also hold them accountable.

We've made tremendous progress in getting insurers to be more transparent, as more and more plans now show the complete list of covered meds and network providers. However, there is still a lot of work to do to ensure that people get the information they need in an easy-to-read, standard format. That would make it possible for consumers to compare plans and make informed decisions as to which plan truly meets their health care needs.

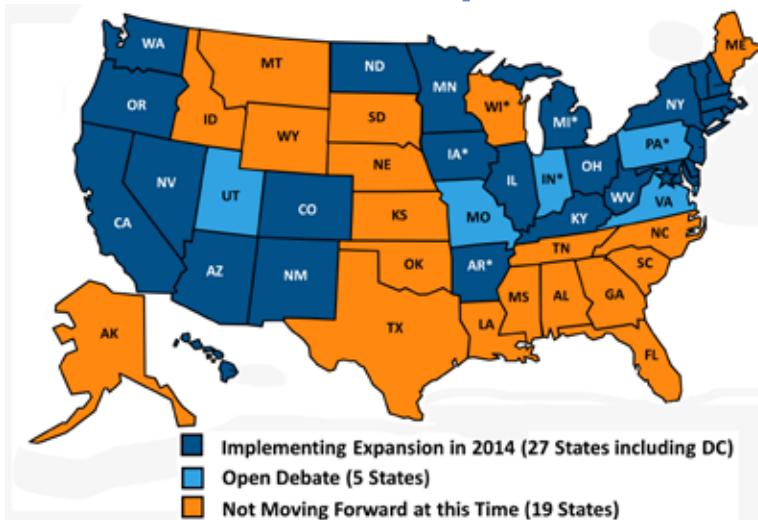
## Covered Medications and Services

Access to HIV drugs, specialists, lab tests, and other HIV-related services is important, but so are all of the other services people with HIV need – whether to treat diabetes, heart disease, or the other health conditions that arise as we get older. That's why access to private health insurance is an important step forward for many people with HIV, as they now have coverage for comprehensive health care beyond just treating their HIV.

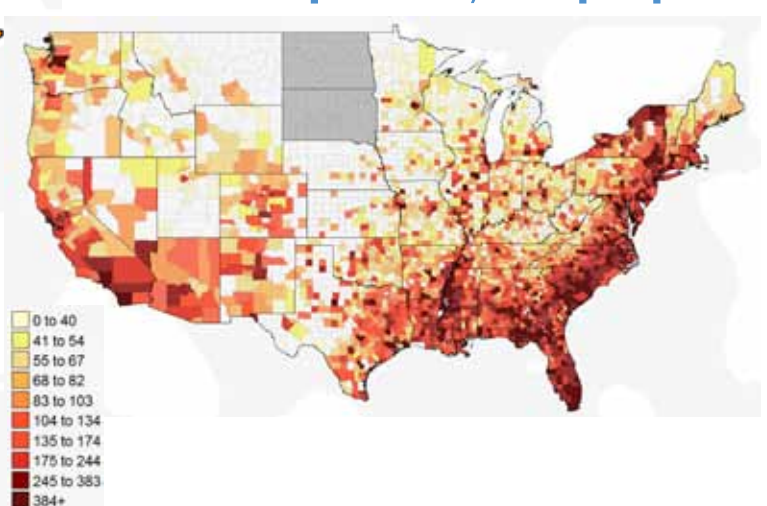
The ACA also requires that all plans sold on the marketplace provide essential health benefits (EHBs) including hospitalization, maternity care, mental health and substance use services, prescription drugs, rehabilitative services, lab tests, preventive care, chronic disease management, and other services.

*continued on next page*

## Medicaid Expansion



## HIV Cases per 100,000 people



Source: Kaiser Family Foundation, March 26, 2014

Source: AIDSvu.org, 2010

Yet, despite the EHB requirement, we are seeing plans that keep some HIV medications, like single-tablet regimens, off their lists of covered meds, or that don't cover HIV genotype tests – another way for insurers to discourage people with HIV from enrolling. While we're making progress in these areas, as many insurers have agreed to add the missing HIV meds to their covered drug lists, there's a lot more work to be done. Many drugs and necessary services are still not covered by some insurance plans. Also, we must be continually on guard against new, similar attempts by insurers to get around the law and save money by denying needed services to people with HIV.

### Costs

While transparency and covered services have improved, one increasing cause for alarm is the trend in the new insurance plans to put HIV and other expensive medications into very high cost-sharing tiers. "Cost-sharing" refers to the amount that consumers have to pay for medications or services. Some companies have put every HIV med on the highest tier, charging 50% co-insurance. This means that consumers have to pay half of the price of the medication! So, even though people have insurance, they still have to pay thousands of dollars until they reach the out-of-pocket maximum allowed under the ACA, which is \$6,350 per year for people with incomes above 250% FPL. While the ACA does reduce the maximum out-of-pocket limit for people below 250% of the FPL, it can still be as high as \$5,200 for an individual, and that's also unacceptable. Charging 50% co-insurance for a med that has no generic alternative is simply a way to keep people with HIV from enrolling in their plan. It's discriminatory and will be challenged in the months ahead.

### The Speak Up Project

While tens of thousands of people with HIV now have increased access to health care, barriers continue to exist. Perhaps the most blatant effort by insurers to restrict access happened when insurers in both Louisiana and North Dakota tried to stop accepting third-party payments, including payments from the Ryan White Program that have for many years helped people with HIV meet their health care costs. When this happened, thousands of people with HIV could not enroll in new insurance plans, since the insurers refused to accept payments from the Ryan White Program.

Fortunately, our advocacy efforts first led a federal district court to stop the insurers from refusing to accept the payments, and then to the federal government issuing new rules requiring insurers to accept the payments. This shows the power of advocacy. The key is continued vigilance. We hope we won't have to go to court for each new barrier, but if that's what it takes, we will. And to make sure we know what the issues are for people with HIV across the country, we have created the "Speak Up" project, along with AIDS Foundation of Chicago and several other partners.

Speak Up is a website where people with HIV and their service providers can report problems with the new health plans. We want to hear about any issues with signing up for new health coverage (either Medicaid or private insurance). Once people have insurance, we want to hear about any problems getting care and treatment.

We are monitoring and analyzing all these problems. We use the information to educate officials about the needs of people with HIV, to show the need for improvements to the ACA, and to advocate for change. Whenever possible, we refer people facing barriers to local attorneys and advocates who can help them file grievances and appeals. We will also be reporting back to the community on what we learn.

To find out more about Speak Up or to report a problem with health insurance, go to [www.hivhealthreform.org/speakup](http://www.hivhealthreform.org/speakup).

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### Next Steps

While Speak Up is only a month old, we have already identified some key problem areas. Addressing these issues will require regulations that:

- Amend the Essential Health Benefits (EHB) rule to require coverage of all HIV medications, including fixed-dose combinations and single-tablet regimens, in accordance with HIV treatment guidelines.
- Require health insurance plans to provide complete and accurate health provider and coverage information (including which meds are covered) in a standard format, including the actual out-of-pocket costs that consumers must pay.
- Amend the EHB rule to prohibit coinsurance from exceeding 25% for HIV drugs that are widely accepted in treatment guidelines if there is no generic version.

We can win these reforms, but it will take advocacy. Otherwise, we'll see too many people with HIV falling through the cracks even though they have health insurance. There are also a few other advocacy issues that must be among our top priorities.

### Premium Assistance

We must help people with HIV in states that have not expanded Medicaid. In states with governors or legislators opposed to "Obamacare" the best hope may be to allow states to expand Medicaid through what is called "premium assistance." This means that the state uses Medicaid dollars to purchase private insurance for people who would be newly eligible for Medicaid. Several states, starting with Arkansas, have implemented this route to expansion.



## Support for Ryan White

The success of the ACA for people with HIV also depends upon adequate levels of funding for the Ryan White Program. Despite their strengths, both Medicaid expansion and the marketplace private health insurance plans still have significant gaps in coverage. For example, they generally don't include vision and dental care. They often don't cover essential support services, like transportation, food, child care, and other services. These services, which are provided by Ryan White, are critical to ensuring that people with HIV achieve the viral suppression that improves both individual and public health. Without these services, we will not be able to address the challenges of HIV care.

Since its creation, the Ryan White Program was meant to be a safety net, filling gaps in health care. Because the holes were so big before the ACA, Ryan White essentially became the health system for uninsured people with HIV.

In addition, Ryan White can help with costs for people who are newly insured. Coinsurance is often extremely high and even with subsidies, the costs are out of reach for many low-income

people with HIV. Ryan White can help them meet their premium and copayment costs.

Perhaps most important, Ryan White remains the primary source of care for low-income people with HIV left out of new insurance options because they live in states that have not expanded Medicaid or because they are immigrants. For these people, Ryan White remains the sole source of health care, which is essential to address the HIV epidemic effectively. Ryan White reduces health care costs and improves individual and public health outcomes, since treatment is also prevention.

## The Beginning

The start of the ACA is not the end of the story, it's the beginning. The foundation is in place, but the floor that has been set is not sufficient to meet the needs of all people with HIV. We must raise the floor to make sure that all of the health care needs of people with HIV in the U.S. are met. While there is no cure or vaccine for HIV, we do have the tools to keep people with HIV retained in care, virally suppressed, and healthy. We have what it takes to dramatically reduce the transmission of HIV and create an AIDS-free next generation – now it's time to go out and do it. ■

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*Robert Greenwald is Director of the Treatment Access Expansion Project and Director of Harvard Law School's Center for Health Law and Policy Innovation.*

TAEP supports this option as long as the state provides all the benefits and services of Medicaid at no additional cost to consumers. The political reality is that without it many low-income people, including many people with HIV, will lack health care. Too many politicians have pinned their political careers on opposing Obamacare. Premium assistance allows them to say, "I'm not doing Obamacare. Instead, I'm going to take their money and I'm going to privatize Medicaid and get people private health insurance." If they want to spend millions of extra dollars to privatize Medicaid, and they are willing to guarantee that low-income people get the same benefits at the same cost as everyone else, we aren't going to try to stop them. In fact, we spend a lot of time in Southern states working with legislators to help them see this as a path forward. And it appears to be working well in Arkansas and other states.

Stacey Bowser, the director of the Ninth Street Ministries Clinic in Arkansas recently said, "Because people are qualifying for insurance through the ACA, our free medical clinic will not be needed anymore. There was such a need for many years that we would have people coming through the medical clinic from the time the doors opened early in the morning all the way until 4:00 in the afternoon." But over the past several months, the number of patients has dwindled to next to nothing. Only about 80 people came through the clinic in February. By March, that was down to just three people. "Our services won't be needed anymore, and this will conclude our mission," Bowser explained.



# Navigating the ACA: One Man's Journey

by Matt Sharp

I've been living with HIV for over 26 years, so health insurance is obviously something I've never taken for granted. Everyone with HIV understands the challenges of maintaining comprehensive insurance coverage. My situation is complicated but offers an instructive story of how complex health insurance system is for people with HIV, even under the Affordable Care Act (ACA).

Most of the years I've lived with HIV I've been healthy enough to work and so had health insurance options through my employers. But that coverage was spotty and constantly changing, never a good thing for a person with HIV who needs consistent health care.

In 2013, I became self-employed and had no health insurance. My COBRA had run out from my last job, and I was just over the lower income limit for any entitlement programs. I live in the Bay Area in California – which has one of the highest tax bases in the country, with expensive real estate, food, and just about everything else. In my situation, I felt as though I was being punished for working and living with HIV. I made just enough money to support myself in an expensive city, but still did not make enough for health insurance.

I was eligible for an early ACA insurance program in California known as the Pre-Existing Condition Insurance Program (PCIP.) The program was designed specifically for people with pre-existing health conditions. While offering me health insurance, the program did everything wrong, including a prohibitive deductible and high premiums. It became essentially a band-aid until I could apply for the ACA.

I had to cancel PCIP before the ACA health insurance marketplaces finally rolled out, because I simply couldn't afford it. I knew the ACA would take over in a few months and I was pretty sure all would be seamless. I had a lot to learn.

**When I first looked at the plans offered by the ACA, they were confusing and far out of my budget. The “Covered California” website, which people here use to enroll in ACA plans, was a complicated mess.**

When I first looked at the plans offered by the ACA, they were confusing and far out of my budget. The “Covered California” website, which people here use to enroll in ACA plans, was a complicated mess. It was certainly not intuitive, nor user-friendly. The telephone support line only referred people to the online “chat” support, which disconnected me after hours of waiting. I faced an endless cycle of confusion and frustration.

And then, after finally enrolling in time for my coverage to start in January 2014, I discovered my HIV doctor was not using the insurance company I selected! This was not evident when I enrolled online, nor was there a place to research that. I knew I had to cancel my policy and seek another insurance plan that my doctor was using.

I was back to square one, very frustrated and disappointed. I had to go back to that daunting “Covered California” website. Finally I found the number for a local

“navigator” who helped me to cancel my current coverage and re-enroll me in a plan my doctor accepted.

I was advised to select the “platinum” plan that was needed for someone managing HIV and several other illnesses. It was expensive – a little under \$1,000 a month – with high co-payments. I may still face issues about which drugs are covered, out-of-pocket costs for specialty care, and high co-payments.

Luckily, I just barely qualify for California’s generous state AIDS program called OA-HIPP (Office of AIDS Health Insurance Premium Payment). With the subsidy I get from the ACA, plus the premium assistance I get from OA-HIPP, I’ll end up paying nothing for my health insurance. That’s great for me, but people in my situation in other states may not be so lucky.

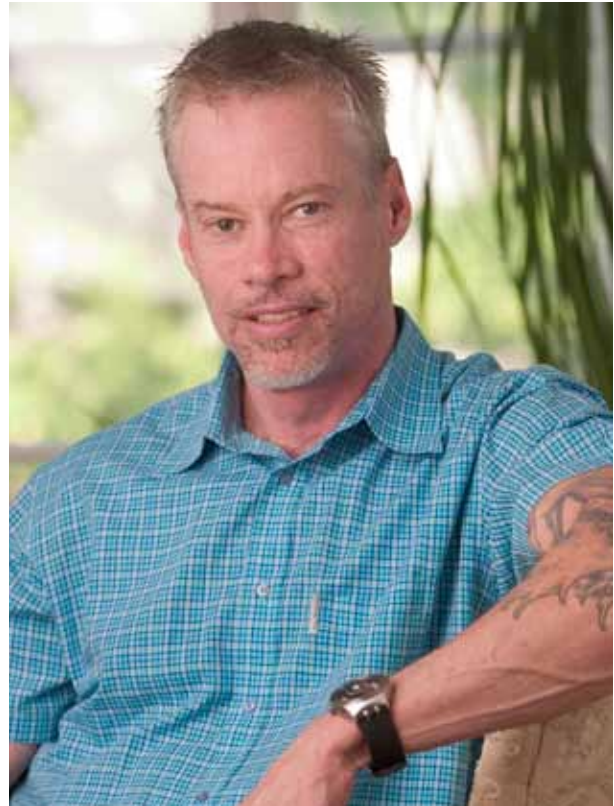
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Ultimately, there is much that may change for the better with the ACA, including the promise that costs should go down as more people enroll. I can only hope that will happen. While I’m grateful to have my own health insurance despite having a pre-existing health condition, I’m dismayed over the complicated enrollment process and shocked at how expensive it’s all going to be.

Make no mistake, having AIDS may make getting health insurance through the ACA more complicated. People need to be prepared for what they may experience. If you have not enrolled yet, get a case manager or “navigator” who can help make the process go more smoothly. Make sure you make copies of every document.



As advocates, we need to ensure that there is comprehensive care for people with HIV. Unfortunately, due to the Supreme Court ruling that allowed states to refuse Medicaid expansion, thousands of people with HIV will be left out of care. It is also unclear what is going to happen with the Ryan White CARE Program, which includes the all-important AIDS Drug Assistance Program. Wrap-around programs like Ryan White are essential to the complete HIV care we all deserve, and they must continue.

The ACA is not a panacea, but it is a good-sized band-aid. My dream is that one day we’ll have single-payer health insurance in this country. Why should our health care be dependent upon rates decided by private insurance companies, the health care industry, and pharmaceutical companies? Unfortunately, unless we get a Congress that truly cares about our health, we may never see a single-payer system. ■



# HIV Generics in the U.S. Sooner or Later?

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by Jerome Ernst, MD, MS

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In a 2013 article in the *Annals of Internal Medicine*, Rochelle Walensky estimated that savings of close to one billion dollars a year could be achieved if all people with HIV in the U.S. took generic antiretrovirals (ARVs). Replacing Atripla with a generic three-pill alternative was projected to lead to an average lifetime savings of \$42,500 for each patient. (It should be noted, however that the money saved is somewhat offset by possible lower adherence to a three-drug regimen.)

Why do we continue to spend billions of dollars for brand-name drugs that are available in cheaper generic forms in the developing world -- billions that end up as profits for pharmaceutical industry? A generic drug has the same active ingredients as the original, brand-name drug and is comparable to the branded drug in dosage, form, strength, and quality. The FDA requires that generic drugs be identical or fall within an acceptable range of their brand-name counterparts.

Generic drugs usually become available when the patent protections given to the original drug makers expire. In most countries, patents give branded drugs 20 years of protection. When generic products become available, market competition often leads to substantially lower prices for both the original branded drug and its generic versions.

## A Conference on HIV Generics

To discuss the issue of generic ARVs and their place in HIV care, the Forum for HIV Collaborative Research and its part-

ners, HIVMA and ACRIA, recently held a one-day conference in Washington D.C., "Use of Generic Antiretrovirals for Treatment of HIV in the United States". In attendance were policy makers, government regulators, physicians, and scientists.

Trip Gulick, MD, Chief of Infectious Diseases at Cornell, reported that, unlike in other countries, HIV treatment guidelines in the U.S. do not consider cost. Until recently,

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**Why do we continue to spend billions of dollars for brand-name drugs that are available in cheaper generic forms in the developing world -- billions that end up as profits for pharmaceutical industry?**

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physicians prescribed and health insurers paid, without regard to cost. For-profit health insurance and drug companies lobbied for policies such as non-negotiable drug prices for Medicare and no universal payer in the Affordable Care Act. At the conference, considerable discussion followed on the need for all of us to take drug prices into account, especially in light of the exaggerated costs of the new hepatitis C drugs and the increasing costs borne by patients. Participants expressed fear that if costs were not considered in HIV treatment guidelines, payers could impose requirements for the use of generics that would not be favorable to all patients.



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## Other Countries

France is an example of a country that does consider cost in its HIV treatment guidelines. The generic raltegravir is listed as an alternative for Isentress in the French guidelines. These guidelines recommend that Atripla be replaced by generic efavirenz and lamivudine, along with brand-name Viread. And they also suggest replacing branded protease inhibitors with generic efavirenz or nevirapine in virally suppressed patients.

In the developing world the use of generic ARVs is key to reaching the goal of an AIDS-free generation. PEPFAR, the President's Emergency Plan For AIDS Relief, has helped save the lives of millions of people with HIV the world over. Under this program, the FDA approves generic ARVs for distribution in other countries, even if they are still under patent in the U.S. These drugs cannot, however, be re-imported or marketed in the U.S. The FDA's Office of Generic Drugs maintains the same standards for generic ARVs as it does for branded drugs in the U.S. PEPFAR generic drugs meet all of the FDA's manufacturing, quality, safety, and efficacy requirements.

After approval, the FDA monitors the drugs by reviewing adverse event reports to ensure continued drug safety after products enter the market. The FDA also reviews any changes made to the approved drugs so that they continue to be safe, effective, and of acceptable quality. To date, 104 generic ARVs are approved for distribution in PEPFAR countries.

## Savings

The widespread use of generic ARVs would benefit patients, insurance companies, and government programs like Medicaid. Doctors and patients would be more strongly motivated to use generics if the savings were reinvested in programs that benefit patients. In addition, the HIV community would need to be assured that the quality of the generics was equal to brand-name drugs.

While the FDA is supposed to inspect generic manufacturers, budgetary constraints in the recent past have limited its ability to do so. The FDA has, however, made greater investments in such efforts recently, most notably in India where many generics and brand name drugs used in the U.S. are manufactured. The way drugs are priced in this country also needs to be more transparent. Current practices do not ensure that the savings from the use of generics get passed along to the consumer.

## Generics and Adherence

Forum participants discussed whether increasing the number of pills people with HIV must take might lead to lower adherence. Dr. Gulick reviewed a meta-analysis of 19 studies that showed that multiple-pill regimens taken twice daily led to lower adherence than single-pill regimens. This was not, however, shown to be the case for once-daily regimens. Interestingly, a higher number of pills lowered the chance of maintaining viral suppression for both once- and twice-daily regimens, something that seems to contradict the first finding. Also confusing was the finding that adherence was better for once-daily regimens (regardless of the number of pills taken), but there was no difference in virologic failure between once-daily and twice-daily regimens. Obviously, more research needs to be done.

Also discussed at the conference was the added expense of supporting adherence in some patient populations. Even in populations with high numbers of virally suppressed patients, over 25% of people with HIV are still not controlling their virus. For them, it takes more than just a pill to control HIV. The slogan "It's not just a pill" refers to the various adherence strategies that are needed to achieve maximum rates of viral suppression. Using the money saved by switching to generics may be one way to fund these efforts.

## Hepatitis C

The recent unveiling of the \$1,000-a-day hepatitis C drug Sovaldi weighed heavily on the discussions at the conference. Drug pricing is largely determined by whatever the maker believes the market will bear, and appears not to be tied to actual drug development costs. This realization seems to have tempered physician enthusiasm for prescribing expensive drugs with no demonstrated clin-



ical advantage. Recent refusals of oncologists to prescribe "me-too" chemotherapy drugs (new versions of older drugs) have led to some price reductions. Hepatitis C drug prescribing appears to be slower than predicted, although this may be changing.

## Conclusion

The ever-increasing costs of drugs may be brought under more control with the delivery of reliable, effective, and cheaper generics. Where the savings will go if this does occur needs to be addressed now. The support of the HIV community for generic drug use would certainly be strengthened if they were assured that the savings would be reinvested into programs seen as beneficial to the community. ■

Search [hivforum.org](http://hivforum.org) for "generics" to download the presentations given at the conference.

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*Jerome Ernst is the Medical Director of ACRIA and Amida Care.*

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# HIV Health Literacy in the South: A Work in Progress

**N**early half of all Americans with HIV live in the South, with prevalence rates in Georgia, Florida, and Louisiana now at 200 per 100,000 people – a rate surpassed in the U.S. only by the heavily populated Northeast. According to the Southern AIDS Coalition’s 2009–2010 HIV/AIDS Health Care Policy Brief and Recommendations, Southern states also continue to have “the highest newly reported HIV cases and the smallest decrease in deaths due to AIDS”, and “Providers have become increasingly concerned and frustrated at the prospect of having to provide increased care to meet increased need with fewer dollars.”

Unfortunately, as HIV rates in the region have continued to rise – especially among young, poor, black, and Latino men who have sex with men – government resources for people with HIV have decreased dramatically. As a result, people with HIV, their caregivers and service providers, and others face significant challenges in gaining access to accurate, up-to-date information about HIV treatment and prevention, as well as in receiving quality care.

Given the overwhelming needs in the South, ACRIA has given the region priority in its work providing desperately needed HIV treatment and prevention information, especially in rural areas where health care and other services are scarce. Over the past five years, our HIV educators have delivered training and capacity building

services in Tennessee, Alabama, Mississippi, Georgia, South Carolina, Arkansas, Florida, and Louisiana – states with some of the highest HIV rates in the country. This work has given us an up-close look at how barriers to care have devastated the region, but it has also shown us what is possible when communities come together to improve the health and lives of those most in need.

ACRIA has brought together diverse groups of service providers that include social workers, medical providers, correctional facility personnel, faith-based outreach workers, and others on the front lines of the epidemic. Our educators help them learn how to reach those with and at risk for HIV and to improve the health literacy of the people they serve so that they are better able to navigate our very complicated health care system. Although the national average reading level is 8th grade, many of the individuals who receive services in the South read at a much lower level. We provide tips, tools, and techniques that service providers can use to translate the jargon of health care into plain language.

Although ACRIA has helped improve services across the South, serious challenges remain. Our educators have encountered quite striking examples of homophobia and HIV stigma – devastating barriers to stopping the epidemic – during training sessions. In some cities, participants reacted to the subject of working with LGBT clients with more vehement negativity than we

have encountered in two decades of providing trainings in a variety of communities across the country.

Fortunately, we have found ways to engage participants to explain the importance of providing culturally competent care without judgment and effectively appealed to their urge to do well and right by those they aim to serve. Indeed, some of these very same participants have thanked our teams for opening the door to conversations around sexuality and gender identity and acknowledge that they are “a work in progress”. We’re pleased to have helped them take the first step toward greater understanding as we each work together to end the HIV/AIDS epidemic for all.

This year, thanks to the generosity of the Elton John AIDS Foundation, The Elizabeth Taylor AIDS Foundation, the H. van Ameringen Foundation, the MAC AIDS Fund, and Janssen Therapeutics, ACRIA has expanded its work to include three cities in Florida – Jacksonville, Orlando, and Miami – as well as Biloxi, Mississippi; Atlanta, Georgia; and Memphis, Tennessee. This support is making it possible for us to reach hundreds of service providers who in turn serve thousands of people with and at risk for HIV.

The HIV epidemic is far from over, and it continues to plague the most vulnerable and marginalized. With HIV rates among young, poor gay and bisexual men of color in the South increasing while they decline among the rest of the population, ACRIA is committed to its ongoing work with committed providers in the region by helping to ensure that people with and at risk for HIV receive the quality care and services they need and deserve. ■

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## A Note From the Editor-in-Chief

After serving more than eight years as ACRIA’s executive director, I was recently named the Chief Special Services Officer for New York City’s Human Resources Administration (Department of Social Services), overseeing the HIV/AIDS Services Administration, Adult Protective Services, the Office of Domestic Violence and Disaster Assistance, among other divisions. I believe that we must work to improve the lives of all our neighbors and couldn’t be happier for the opportunity to help improve these vital services for millions of New Yorkers.

It has been a genuine pleasure to work with the wonderful board and staff at ACRIA. During my tenure, we have expanded ACRIA’s research activities as well as its training,

capacity building, and program evaluation services. We have also very publicly committed ACRIA to furthering sensible, science-based public policy, and have actively advocated for the resources necessary to bring an end to the AIDS epidemic in the U.S. and around the world.

I’ve been especially pleased to see ACRIA grow its collaborations with researchers and providers around the world as we deliver much-needed HIV prevention, education, and related services to people over age 50, including training and capacity building to HIV and senior services providers across the U.S. and beyond.

Thank you for your support. I expect ACRIA’s board will soon name a new executive director and my successor as *Achieve*’s editor-in-chief.

Daniel Tietz

## The End of AIDS and an Aging Epidemic

**A**t the 20th International AIDS Conference in Melbourne, Australia in July, ACRIA will sponsor a seminar entitled “15 x 15 and the End of AIDS: Now What?” It will examine the intersection between increased access to HIV treatment, the resultant decrease of advanced AIDS, and what it means that millions of people with HIV will be able to live near-to-normal life spans.

UNAIDS recently announced plans to push world leaders to commit to a target of treating 15 million people with HIV by 2015, and to providing the significantly greater funding needed to diminish the course of the epidemic decisively over the next decade.

If UNAIDS is successful in this campaign, and if donor nations fully commit the necessary resources, the end of AIDS is within reach. We know from research that a person with HIV who is adherent to HIV medications and whose viral load is suppressed becomes significantly less infectious. HIV treatment markedly reduces new HIV infections even as it extends the life spans of those living with the virus. In addition, recent research has shown that daily use of Truvada as pre-exposure prophylaxis (PrEP) by people who do not have HIV but are at substantial risk of infection is highly effective in preventing HIV transmission.

Taken together, these findings are game changers. Broadening access to both HIV treatment and PrEP, along with other high-impact prevention strategies discussed in the most recent issue of *Achieve*, will end the epidemic sooner rather than later.

But we will still be confronted with the challenge of caring for 50 million people aging with HIV around the globe. A U.S. study found that some people with HIV, especially those treated before their CD4 count drops below 350, now have life expectancies equal to or even higher than the general population. We also know that many people develop multiple chronic illnesses and conditions as they age, and that everyone with HIV, even those successfully taking HIV meds, has a higher risk of developing such illnesses. Moreover, these diseases tend to develop earlier and can be more difficult to manage in people aging with HIV.

So our success will bring its own set of complications. The often fragile health and social service infrastructures in low- and middle-income countries may find it difficult to care for the growing number of older adults with HIV, particularly those affected by co-occurring illnesses. For example, the availability of long-term health care facilities

and systems is quite limited in poor countries. They may not have the infrastructure needed to maintain care engagement and treatment adherence, which will contribute to illness and further increase demands on their already strained health and services systems.

We need treatment guidelines for the ever-expanding population of older adults with HIV, some of which can be derived from geriatric care principles and practices. Further, we must provide training to providers in a wide variety of settings so that they can help people with HIV age successfully. Among our goals should be reducing pill burden and monitoring drug-drug interactions (polypharmacy). This includes not only prescription drugs, but over-the-counter medications as well as vitamins and

herbs. A recent study of older HIV patients found that as many of 20% of them were taking drugs that should not be taken together. Polypharmacy can lead to reduced function (dizziness, loss of appetite, blurred vision, etc.) as well as increased side effects, some of which can lead to organ damage and death.

Data from the NIH and the Patient-Centered Outcomes Research Institute show that for those with multiple illnesses, a defining shift in care and improved health occurs when patient care moves from “What’s the matter?” to “What matters to you?” The concerns of people aging with HIV must become the central consideration

in the health and services delivery process. They alone understand the world in which they are living and aging. Only they know if family, friends, community, and other social supports are available to help. They must decide if they can do what is needed to remain functional and independent, rather than face years of poor health, disability, and reliance on others in more institutional settings for care.

In short, the disease-centered care system, which is what largely drives the care of people with HIV today, should be abandoned. Instead, and again taking a hint from the best geriatric care systems, we should emphasize a person’s overall well-being by using holistic health and services delivery models. This will also help ensure that the patient is central to the decision-making process and that due consideration is given to psychosocial supports or lack thereof.

Integrating existing services across networks and systems, and avoiding wasteful duplication, must be our goal. Only with a coordinated response from U.N. agencies, national governments, NGOs, and communities will the millions around the globe aging with HIV receive the care and support they need to live long and healthy lives. ■





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All proceeds from the sale of works in the ACRIA Gallery benefit ACRIA, a leading HIV research and education organization, and the nation's recognized authority on the emerging issue of HIV and aging. By supporting ACRIA, you are helping people with HIV and AIDS in New York City, across the country, and around the world live longer, healthier lives.