



POSITIVELY AWARE

MAY+JUNE 2012

TWO EPIDEMICS **INCARCERATION AND HIV**

How the criminal justice system can
play an effective role in the treatment
and prevention of HIV

**THE BENEFITS
OF OPT-OUT
TESTING**

**RISK FACTORS
FOR WOMEN**

**CONFERENCE
UPDATE: CROI**



YOU'VE WORKED TO CONTROL YOUR HIV. NOW, TIME TO WORK ON YOUR HIV-RELATED EXCESS BELLY FAT.



In two separate clinical trials of HIV-infected people with lipodystrophy, each lasting 6 months, **EGRIFTA®** (tesamorelin for injection) reduced HIV-related excess belly fat by an average of 18% in the first trial, and 14% in the second trial.

This reduction in excess belly fat resulted in an approximate 1-inch reduction in waist size. Individual results may vary. On average, patients on **EGRIFTA®** did not lose weight.

Like HIV, HIV-related excess belly fat is a chronic condition. In clinical studies:

- People who used **EGRIFTA®** continuously for 1 year maintained their results over this time period
- People who stopped taking **EGRIFTA®** after 6 months had their HIV-related excess belly fat come back

EGRIFTA® is believed to work with your own body to produce natural growth hormone to reduce your excess belly fat.

Indication:

EGRIFTA® is a daily injectable prescription medicine to reduce the excess abdominal fat in HIV-infected patients with lipodystrophy.

Limitations of use:

- The impact and safety of **EGRIFTA®** on cardiovascular health has not been studied
- **EGRIFTA®** is not indicated for weight-loss management
- It's not known whether taking **EGRIFTA®** helps improve compliance with antiretroviral medications
- **EGRIFTA®** is not recommended to be used in children

Important Risk Information

Do not use **EGRIFTA®** if you:

- Have pituitary gland tumor, pituitary gland surgery, or other problems related to your pituitary gland
- Have active cancer (either newly diagnosed or recurrent) or are receiving treatment for cancer
- Are allergic to tesamorelin or any of the ingredients in **EGRIFTA®**, including mannitol or sterile water
- Are pregnant or become pregnant

Before using **EGRIFTA®**, tell your healthcare provider if you:

- Have or have had cancer
- Have diabetes
- Are breastfeeding or plan to breastfeed
- Have kidney or liver problems
- Have any other medical condition
- Take prescription or non-prescription medicines, vitamins, or herbal supplements

EGRIFTA® may cause serious side effects, including:

- Serious allergic reaction. Stop using **EGRIFTA®** and get emergency help right away if you have any of the following symptoms: rash over your body, hives, swelling of your face or throat, shortness of breath or trouble breathing, fast heartbeat, feeling of faintness or fainting
- Swelling (fluid retention). **EGRIFTA®** can cause swelling in some parts of your body. Call your healthcare provider if you have an increase in joint pain, or pain or numbness in your hands or wrist (carpal tunnel syndrome)
- Increase in glucose (blood sugar) intolerance and diabetes

- Injection-site reactions, such as redness, itching, pain, irritation, bleeding, rash, and swelling. Change (rotate) your injection site to help lower your risk for injection-site reactions

The most common side effects of **EGRIFTA®** include:

- | | |
|-------------------------|-------------------------|
| • joint pain | • numbness and pricking |
| • pain in legs and arms | • nausea |
| • swelling in your legs | • vomiting |
| • muscle soreness | • rash |
| • tingling | • itching |

EGRIFTA® will NOT cure HIV or lower your chance of passing HIV to others.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Consumer Brief Summary of **EGRIFTA® on following page.**

Ask your healthcare provider if **EGRIFTA®, the first and only FDA-approved medicine for HIV-related excess belly fat, may be right for you. For more information, visit www.egrifta.com or call the AXIS Center at 1-877-714-AXIS (2947).**



Consumer Brief Summary for **EGRIFTA®** (tesamorelin for injection)

EGRIFTA® (eh-GRIF-tuh)

(tesamorelin for injection) for subcutaneous use

Read the Patient Information that comes with **EGRIFTA®** before you start to take it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is **EGRIFTA®**?

- **EGRIFTA®** is an injectable prescription medicine to reduce the excess in abdominal fat in HIV-infected patients with lipodystrophy. **EGRIFTA®** contains a growth hormone-releasing factor (GRF)
- The impact and safety of **EGRIFTA®** on cardiovascular health has not been studied
- **EGRIFTA®** is not indicated for weight-loss management
- It is not known whether taking **EGRIFTA®** helps improve compliance with antiretroviral medications
- It is not known if **EGRIFTA®** is safe and effective in children. **EGRIFTA®** is not recommended to be used in children

Who should not use **EGRIFTA®**?

Do not use **EGRIFTA®** if you:

- have pituitary gland tumor, pituitary gland surgery, or other problems related to your pituitary gland
- have active cancer (either newly diagnosed or recurrent) or are receiving treatment for cancer
- are allergic to tesamorelin or any of the ingredients in **EGRIFTA®**. See the end of this leaflet for a complete list of ingredients in **EGRIFTA®**
- are pregnant or become pregnant. If you become pregnant, stop using **EGRIFTA®** and talk with your healthcare provider. See "What should I tell my healthcare provider before using **EGRIFTA®**?"

What should I tell my healthcare provider before using **EGRIFTA®**?

Before using **EGRIFTA®**, tell your healthcare provider if you:

- have or have had cancer
- have diabetes
- are breastfeeding or plan to breastfeed. It is not known if **EGRIFTA®** passes into your breast milk. The Centers for Disease Control and Prevention (CDC) recommends that HIV-infected mothers not breastfeed to avoid the risk of passing HIV infection to your baby. Talk with your healthcare provider about the best way to feed your baby if you are taking **EGRIFTA®**
- have kidney or liver problems
- have any other medical condition

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. **EGRIFTA®** may affect the way other medicines work, and other medicines may affect how **EGRIFTA®** works. Know the medicines you take. Keep a list with you to show your healthcare provider and pharmacist when you get a new medicine.

How should I use **EGRIFTA®**?

- **Read the detailed "Instructions for Use"** that comes with **EGRIFTA®** before you start using **EGRIFTA®**. Your healthcare provider will show you how to inject **EGRIFTA®**
- Use **EGRIFTA®** exactly as prescribed by your healthcare provider
- Inject **EGRIFTA®** under the skin (subcutaneously) of your stomach area (abdomen)
- Change (rotate) the injection site on your stomach area (abdomen) with each dose. Do not inject **EGRIFTA®** into scar tissue, bruises, or your navel
- Do not share needles or syringes with other people. Sharing of needles can result in the transmission of infectious diseases, such as HIV

What are the possible side effects of **EGRIFTA®**?

EGRIFTA® may cause serious side effects including:

- Serious allergic reaction. Some people taking **EGRIFTA®** may have an allergic reaction. Stop using **EGRIFTA®** and get emergency help right away if you have any of the following symptoms:
 - a rash over your body

- hives
- swelling of your face or throat
- shortness of breath or trouble breathing
- fast heartbeat
- feeling of faintness or fainting

- Swelling (fluid retention). **EGRIFTA®** can cause swelling in some parts of your body. Call your healthcare provider if you have an increase in joint pain, or pain or numbness in your hands or wrist (carpal tunnel syndrome)
- Increase in glucose (blood sugar) intolerance and diabetes. Your healthcare provider will measure your blood sugar periodically
- Injection-site reactions. Change (rotate) your injection site to help lower your risk for injection-site reactions. Call your healthcare provider for medical advice if you have the following symptoms around the area of the injection site:
 - redness
 - itching
 - pain
 - irritation
 - bleeding
 - rash
 - swelling

The most common side effects of **EGRIFTA®** include:

- joint pain
- pain in legs and arms
- swelling in your legs
- muscle soreness
- tingling, numbness, and pricking
- nausea
- vomiting
- rash
- itching

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of **EGRIFTA®**. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. To report side effects, contact EMD Serono toll-free at 1-800-283-8088, ext. 5563. You may report side effects to the FDA at 1-800-FDA-1088.

Keep **EGRIFTA®** and all medicines out of the reach of children.

General information about the safe and effective use of **EGRIFTA®**:

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use **EGRIFTA®** for a condition for which it was not prescribed.

Do not give **EGRIFTA®** to other people, even if they have the same symptoms you have. It may harm them.

Do not share your **EGRIFTA®** syringe with another person, even if the needle is changed.

Do not share your **EGRIFTA®** needles with another person.

This Patient Information leaflet summarizes the most important information about **EGRIFTA®**. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about **EGRIFTA®** that is written for healthcare professionals.

For more information about **EGRIFTA®**, go to www.EGRIFTA.com or contact the AXIS Center toll-free at 1-877-714-2947.

What are the ingredients in **EGRIFTA®**?

Active ingredient: tesamorelin

Inactive ingredients: mannitol and Sterile Water for Injection

EMD Serono

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CONFERENCE UPDATE: Mount Rainier looms over Seattle's skyline as the city hosted the 19th Conference on Retroviruses and Opportunistic Infections in March. [PAGE 44](#)

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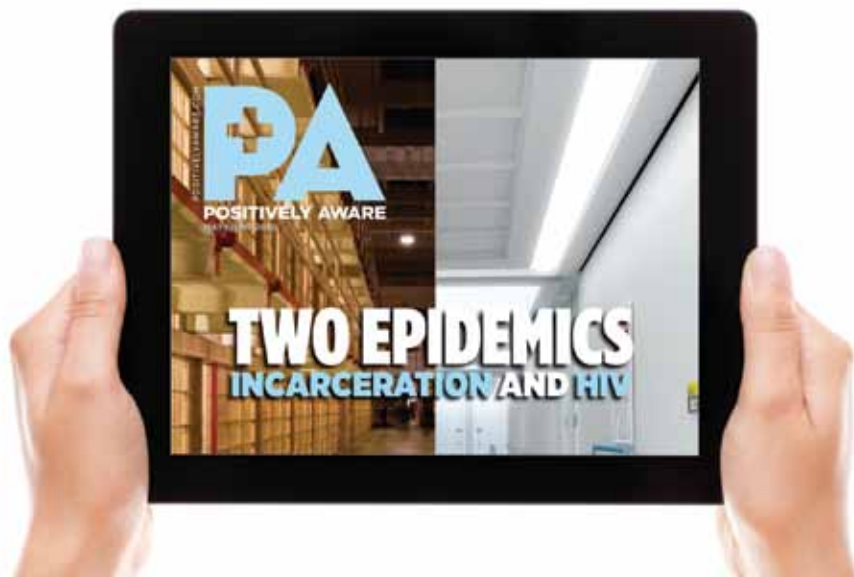
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5537 N. BROADWAY ST.
CHICAGO, IL 60640
PHONE: (773) 989-9400
FAX: (773) 989-9494
inbox@tpan.com
www.positivelyaware.com

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More news from CROI

Aging with HIV—not as bad as previously thought? Update on hormonal contraceptives and transmission. Advances in pediatric therapy.

www.positivelyaware.com/2012/12_03/croi.shtml

Activist Arick Buckles

The journey of an HIV advocate continues.

www.positivelyaware.com/2012/12_03/arick.shtml

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EDITORIAL

EDITOR-IN-CHIEF **Jeff Berry**
ASSOCIATE EDITOR **Enid Vázquez**
COPY EDITOR **Sue Saltmarsh**
PROOFREADER **Jason Lancaster**
WEB MASTER **Joshua Thorne**
CREATIVE DIRECTOR **Rick Guasco**

CONTRIBUTING WRITERS

**Keith R. Green, Liz Highleyman,
Sal Iacopelli, Laura Jones,
Jim Pickett, Matt Sharp**

PHOTOGRAPHERS

Chris Knight, Joshua Thorne

MEDICAL ADVISORS

**Daniel S. Berger, MD
Gary Bucher, MD
Michael Cristofano, PA
Joel Gallant, MD
Swarup Mehta, PharmD**

ADVERTISING INQUIRIES

Lorraine Hayes
l.hayes@tpan.com

DISTRIBUTION COORDINATOR

Bradley P Mazzie
distribution@tpan.com

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IS PUBLISHED BY

TPAN

POSITIVELYAWARE.COM



EDITOR'S NOTE

JEFF BERRY

@PAEDITOR ON TWITTER

A prison of our own making

THERE ARE TIMES IN OUR LIFE WHEN WE MAY FEEL trapped and caught up in circumstances or situations over which we have absolutely no control. Whether it's an unhappy or unhealthy relationship, an addiction, a boring job or a career that's going nowhere, we find ourselves looking for an escape, but somehow can't seem to find a way out, or a path forward.

An individual who is in jail or prison would seem to be the prime example of a person who is powerless and doesn't have the ability to make any choices or decisions to improve their current situation. It's no surprise that there is gang activity, rape, and drug abuse behind bars—undoubtedly, for some, these seem to be the only choices they have to exert any kind of power or control.

When a person tests positive for HIV, they may often feel a similar sense of loss of power or control, and for those who find out they're positive when they enter a correctional facility, that powerlessness is multiplied. This is a crucial point in their viral life cycle, if you will. The support systems they could have had in place, such as family, friends, other people living with HIV who they can trust, a good doctor who is knowledgeable about HIV and AIDS, and access to quality health care and treatment, can make all the difference in how well a person manages their diagnosis and their health going forward. But there are often times when even more basic needs, such as food, housing, substance abuse and/or mental health treatment, and employment, must first be addressed before someone can even consider treatment.

In March of 2007 I was invited to give a talk on AIDS activism at the Los Angeles County Jail, the largest county jail in the U.S., which has 20,000 inmates at any given time. Housed in the men's tower of the immense twin tower jail is the K-11 unit, where inmates who are gay, bisexual, or transgender can choose to live in a segregated facility (see "The K-11 Unit" in the May/June 2007 issue).

The experience for me was scary, exhilarating, and illuminating, all at once. It certainly quashed any gay prison sex fantasies I may have had, and it was nothing like the homoerotic scenes from the HBO series "Oz." After going through security and walking down what seemed like endless hallways and locked, barred

doors, I found myself standing in a glass control room which was stationed in the center of a large gymnasium-like room, with bunk beds all around, and no privacy whatsoever. The inmates who were in for murder or violent crimes were sectioned off from the rest of the unit, and it was all quite dehumanizing. It makes one wonder what

living with the rest of the general population of the jail must be like, to choose to live in K-11.

I did learn a very valuable lesson that day, in that the experience shattered any preconceived notions I had held up until then about individuals who are behind bars. As I spoke to a group of about 50–60 men, I realized that these guys were bright, articulate, and eager to learn about HIV, and they blew me away with their knowledge and their questions. It was obvious that they had made a choice to exert some power over their own set of circumstances, and take control of their future. It gave me hope, and it was an experience I will never forget.

Just like those men in the K-11 unit had taken control of their lives and the situations they found themselves in, so can we all. If you're in an unhealthy relationship, get out. If you are suffering from an addiction, seek help. And if you don't like your job, well, at least you have one. Deal with that situation at work that makes you miserable. Or maybe it's time to think about going back to school so that you can get a job that's more fulfilling. Stand up for yourself, believe in yourself, and make that change, because believe me, no one is going to do it for you. You may just be in a prison of your own making, or you may be behind bars, but remember that you have the power to tear down those internal bars and start building a better life, one in which you are empowered to make healthy and positive choices that are good for you, and good for those you care about. The limits and challenges of living in any kind of prison, be it in our minds, our bodies, or the real thing, are never more powerful than our will to survive.

Take care of yourself, and each other.

It was obvious that they had made a choice to exert some power over their own set of circumstances, and take control of their future. It gave me hope, and it was an experience I will never forget.

'Positively impressed'

I was very positively impressed with what you presented in the March+April issue on HIV drugs. We are primary and secondary providers of HIV care within a huge academic environment and are always looking for ways to ensure patients understand the importance of credibility and good sources of reliable information to help them engage in and manage their own care.

As pharmacy team case managers, we have contact with every patient who starts or changes an antiretroviral treatment regimen in order to assess their readiness and understanding of treatment, so all of what you presented in this issue is of tremendous relevance and importance. We pull information from several sources to assist our patients, but this is the first time I've seen something so concise in one publication that is not only useful to the patients but to those of us who have to refer back often to this information as well. I've also bookmarked your website for future reference.

Thanks for offering such great information in your publication!

—**Robert B. Blackwell, MSN, RN, ACRN**

VANDERBILT COMPREHENSIVE CARE CLINIC
NASHVILLE, TN

Beyond belief

As an openly HIV-positive person and a proud Atheist, I was glad to see that your recent "Living on a Prayer" [January+February] issue did not forgo any of the truly necessary items for somebody living with HIV—particularly the medical journal summaries and clinical trial information. My life is not sustained on any prayers, but on advanced medical science.

I found the most fascinating and successful aspects of your issue were those that focused on the topic of keeping HIV/AIDS patients healthy, tested, medicated, informed, and educated. These articles did an excellent job, even while approaching their religious topics (for example, the article about gay Muslims with HIV by Ms. Saltmarsh, or while addressing the church's restraint of scientific research over the past 1,000 years by Mr. Iacopelli).

But when your focus shifted to attempt to keep (or move) HIV/AIDS patients to a more God-based mind-set? I found this to be most definitely inappropriate and unsuccessful. Your articles made no new convert of me, and, in fact, much of the information you provided (such as Ms. Patterson's confusing article on faith-based-organizations which are admittedly not fully rooted in religious principles, or in the wholly unhelpful advice by Father Kovach) showed the effort would—and should—be futile.

I have expressed my full thoughts in a three-part series on my Atheist blog. These can be found at <http://bit.ly/FaithandHIV>, <http://bit.ly/FaithandHIV2>, and at <http://bit.ly/FaithandHIV3>, and at Facebook.com/thehonestatheist.

Again, thank you for the work that you do. I will continue reading your important journal!

—**Mark Panzarino**

VIA THE INTERNET

Article of faith

I just love PA. Your magazine has been my guide and teacher since 2004 and I always appreciate the insights and the info. We order multiple copies for our support groups, and I think PA has been a lifesaver for some of our clients. Can't wait for the next issue.

I run a faith-based HIV/AIDS service organization and we have worked tirelessly for 16 years against fundamentalist ideology and stigma, and, dare I say, hate in the Christian community. It is there for sure, but it's not all of us, by any means.



There are many, many Christian allies in the fight. We are gay, straight, black, white, Methodist, Catholic, Church of Christ, Presbyterian (you get the picture), and even Baptist. We are followers of Christ and we come in all stripes.

What I want Sal Iacopelli to know is that we fight for him, too. We use our Christian values, that he derides, to push for love, compassion, and social justice. We get in trouble. We "act up" and we stand up for him. It's what Jesus would do.

Please don't paint us all with the same brush.

—**Wayne Smith, Director**

SAMARITAN MINISTRY
CENTRAL BAPTIST CHURCH OF BEARDEN
KNOXVILLE, TN

Book of love

The "church" never has been and never will be perfect. One cringes at all the harm that the church has caused in the name of Christ. And, unfortunately, the present day church in many cases is no better. The problem, to me, has always been, and probably will always be, when we try to use the Bible as a "proof text" to support a preconceived set of beliefs or behavior.

The Bible is not a science text, or philosophy, or even an accurate history. Every time in history that the church has tried to make the Bible something it isn't, the church has run into problems. The Bible cannot be used as a proof text for science,

for philosophy, or for history. What the Bible does is tell us how we are to relate to God and to our fellow man.

When we treat the Bible as a love story—God’s love for His creation and our response to His love, we can come to a better understanding of what the Bible actually teaches. Just as God’s love is all-embracing so should our love be. My suggestion to anyone who doubts what the Bible really teaches is that they read, re-read, and study 1 John. John’s letter is filled with the teaching of love. 1 John 4:16 has become the one verse which, to me, seems to summarize the entire Bible—“And so we know and rely on the love God has for us. God is love. Whoever lives in love lives in God, and God in them.”

In spite of all the harm the church may have caused over the years, there is also no other organization which has brought about as much good. And who can really deny the results that could be realized if all mankind would live by the commandments to love God and neighbor.

—Richard Servis
VIA THE INTERNET

Personal belief

I just want to applaud Sal Iacopelli for telling the truth about not just the Catholic church, but the whole “Christian” mess.

It is way too popular, even among gay, HIV-positive people, to gush about “God’s love” when way too many experience anything but love from those who claim to be devoted to a religious faith. That was clear in the article about the Muslim community too.

This country was formed from a desire for religious freedom, but these days, that is becoming lost in the fundamentalist Christian determination to obliterate everyone else’s freedom and impose the absurd, illogical, and hypocritical “teachings” of the Bible on everyone.

I respect the right of anyone to choose to believe in that fairytale as long as they respect my right to believe in my own and don’t try to tell me what I can and can’t do with my body, or who I can and can’t love.

Sometimes I think it would be best for us all if those who believe in the Christian myth were to live in one area of the country (they can have Texas and their President Rick Santorum) and the rest of us could be free of them and their fundamentalist terrorism. For me, I’d want to live where Sal does.

—Lynn O’Biele
VIA THE INTERNET

There’s an app for that

I saw your article regarding active intervention on gay social apps and wanted to share some thoughts on the Know Your Status campaign we use at Hornet.

Since stats show that HIV infections are on the rise and public awareness campaigns are muted, less present, and fatigued, we built our positive intervention strategy around focus groups and ways to help remind our community about their personal choices.

In addition, the choices an individual user makes for having a community talk about HIV are equally important. Many social apps go to great lengths to hide this discussion and limit it. In fact, we sometimes prevent users from disclosing their status in profiles. However, for some users it’s hard for them to find the right time to disclose, and there needs to be more understanding around viral loads, early detection, and STIs.

Thank you for the article on reaching out to young gay men through Grindr. This is an important conversation and I hope you continue to explore gay social apps.

—Sean Howell
VIA THE INTERNET

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POSITIVELY AWARE
5537 N. BROADWAY ST.
CHICAGO, IL 60640
inbox@tpan.com



WE READ YOU.
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ABOUT OUR ARTICLES AT
POSITIVELYAWARE.COM

READERS’ POLL

What matters to you most about HIV medications: convenience, effectiveness, side effects, long-term toxicity, or cost/access?

RESULTS FROM THE MARCH+APRIL READERS’ POLL

CONVENIENCE:  3%

SIDE EFFECTS:  8%

COST/ACCESS:  18%

LONG-TERM TOXICITY:  23%

EFFECTIVENESS:  48%

YOUR COMMENTS:

“It makes no difference if a medication is convenient, effective, or has side effects if you cannot afford or have access to it.”

“I’m most worried about long-term side effects and problems caused by the medication since the regimen is once daily, for life, and I’m just 25.”

“These factors have to all be taken into consideration. However, the ultimate importance is how effective an ARV or any medication is.”

THIS ISSUE’S POLL QUESTION:

What do you think is the best way to provide HIV testing in prisons?

- Test if inmate requests it
- Test unless inmate refuses it (opt-out)
- Test whether inmate wants it or not (mandatory)
- Don’t test at all
- Not sure

CAST YOUR VOTE AT
POSITIVELYAWARE.COM



BRIEFLY

ENID VÁZQUEZ

Victrelis ‘not recommended’ with some HIV meds

The new hepatitis C drug Victrelis (boceprevir) is “not recommended” to be taken with some HIV medications, according to a “Dear Doctor” letter issued in February by Merck & Co. Merck reported drug interaction data showing that **Victrelis and some HIV medications reduce each other’s effectiveness when taken together.** As a result, the company does not recommend that Victrelis be taken with any Norvir-boosted HIV protease inhibitor (Aptivus, Crixivan, Invirase, Kaletra, Lexiva, Prezista, or Reyataz).

The Food and Drug Administration (FDA) reported that patients already taking Victrelis along with a boosted HIV protease inhibitor should not stop any of their medications, but consult with their doctor. The FDA also suggested that providers closely monitor these patients for their antiviral response to both treatments.

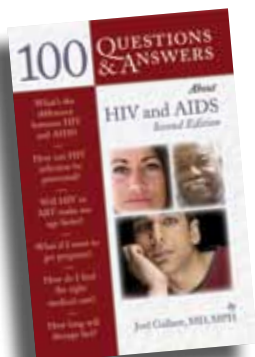
Along with Victrelis, Incivek (telaprevir), the other new hepatitis C protease inhibitor medication that was FDA approved in May of last year, also interacts with some HIV medications. Of the HIV protease inhibitors, it can only be taken with boosted Reyataz. It can also be taken with Sustiva and Isentress, with an increased dose of Incivek if taken with Sustiva. But the company behind Incivek, Vertex Pharmaceuticals (with development originally by Tibotec Pharmaceuticals), made these interactions known at the time of FDA approval.

In his outstanding blog *HIV and ID Observations*, Dr. Paul Sax wrote, “For now, the bottom line is that there really is no optimal HCV protease inhibitor for HIV/HCV co-infected patients, especially for those on a boosted PI. And why careful assessment of those with HIV/HCV is critical [since] many patients are stable enough to wait for the next wave of HCV drugs.”

New edition of HIV Q&A book available

The second edition of *100 Questions & Answers About HIV and AIDS* by Dr. Joel Gallant is now available. Dr. Gallant is a frequent contributor to PA and the doctor for the POSITIVELY AWARE HIV Drug Guide for the last two years.

This handy **book provides answers to the most common questions** asked by people living with HIV and AIDS, their partners, and their families. Order your copy today from Amazon.com and jblearning.com.



Intelence now for kids ages six and older

The HIV drug Intelence (etravirine) received approval from the Food and Drug Administration (FDA) **for use by children ages six to 18 weighing at least 35 pounds**, who have previous anti-HIV treatment experience. This includes children whose virus has developed drug resistance to the same class of medications as Intelence (non-nucleoside reverse transcriptase inhibitors, or NNRTIs). Sustiva and Viramune are the NNRTIs previously available for pediatric use. A new scored 25 mg tablet of Intelence is now available for pediatrics.

For more information about the drug, go to www.positivelyaware.com/intelence.

FDA to consider Truvada for PrEP

The HIV medication Truvada (Viread plus Emtriva in one pill) has been accepted by the FDA for a **six-month Priority Review for use in preventing HIV infection.** Such use by HIV-negative individuals is called PrEP, for pre-exposure prophylaxis (prevention). Gilead Sciences’ supplemental New Drug Application (sNDA) for Truvada PrEP is set to go before the FDA on June 15.

Dolutegravir aces SPRING-2 study, now available via EAP

Initial results of a large Phase 3 study of dolutegravir, an investigational second-generation integrase inhibitor, showed it to be non-inferior to Isentress. “Non-inferior” is a scientific designation applied to study results meaning that the drug studied is not less effective than the one it is compared to. If approved, **dolutegravir may be at an advantage because it is given once a day**, while Isentress is given twice daily.

The SPRING-2 study looked at about 800 individuals taking HIV therapy for the first time, half of them on a regimen with 50 mg dolutegravir once daily and half on a regimen with Isentress (400 mg twice daily). ViiV Healthcare and Shionogi & Co. reported that through 48 weeks, both groups achieved undetectable viral load (less than 50 copies per mL): 88% of the study participants given dolutegravir vs. 85% of those given Isentress.

Dolutegravir is now **available through an expanded access program (EAP)**, which allows for drugs not yet approved by the FDA to be provided free of charge to those in great need.

Go to www.positivelyaware.com/dolutegravir and www.dolutegravir-eap.com for details.

New guidelines recommend ART for all

Treatment guidelines from the U.S. Department of Health and Human Services now **recommend that all people with HIV be put on antiviral therapy**. According to the panel of experts (including advocates living with HIV) that updated the guidelines on March 27, this and other changes “are primarily based on increasing evidence showing the harmful impact of ongoing HIV replication on AIDS and non-AIDS disease progression. In addition, the updated recommendations reflect emerging data showing the benefit of effective ART [antiretroviral therapy] in preventing secondary transmission of HIV.”

The panel divides the strength of their recommendations into three categories.

For people with less than 350 CD4+ T-cells, the recommendation is “strong” based on data from randomized controlled studies (the gold standard of research). For people with CD4 counts between 350 and 500, the recommendation is also “strong,” but based on data from “well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes.” And for people with CD4 counts greater than 500, the recommendation is “moderate” and based on expert opinion.

As always, there are certain groups of individuals for whom the panel recommends treatment no matter what their CD4 counts are:

- Pregnant women

- People over age 50
- Anyone with a history of an AIDS-defining illness
- People with HIV-associated nephropathy (HIVAN)—kidney damage or disease, and
- People who also have hepatitis B

Other changes to the guidelines include new sections on older patients with HIV, the use of hormonal contraception (there is conflicting data on whether they increase the possibility of transmission), hepatitis C and tuberculosis information, new drug interactions, and updates on transmission. See the guidelines at www.aidsinfo.nih.gov.

Viread and kidney risk

Despite new data from the Veterans’ Administration (VA), the Viread (tenofovir) story remains the same: **patients taking Viread should be monitored for kidney toxicity, especially if they have risk factors** such as hepatitis C, high blood pressure, or diabetes. The study was published in February’s issue of *AIDS* and is available at www.natap.org.

Dr. Joel Gallant of Johns Hopkins University explains that, “The VA study essentially confirms what we already know: that tenofovir can cause kidney damage in some people who take it. It isn’t surprising that the risk increases with longer time on the drug; that’s true of most drug toxicities. Tenofovir has been included in the vast majority of clinical trials involving initial antiretroviral regimens. These trials have universally shown excellent long-term safety, including minimal development of kidney toxicity.”

The risk of kidney damage may be higher when Viread is combined with protease inhibitors, used by older people or those with pre-existing kidney disease, or in people who are taking other kidney-toxic drugs, such as non-steroidal anti-inflammatory drugs (e.g., ibuprofen).

However, Dr. Gallant added, “We know how to monitor for kidney toxicity, which generally happens gradually. We can always change drugs if it occurs.”

The observational study conducted by the San Francisco VA Medical Center and the University of California, San Francisco looked at the electronic health records of nearly 11,000 VA patients with HIV (the majority of them male). The study looked at three types of renal problems and after controlling for other risk factors, they found that each year of tenofovir use was associated with a 34% increased risk of proteinuria, 11% increased risk of rapid decline in kidney function, and 11% increased risk of chronic kidney disease (CKD). These risks were found after weighing other risk factors such as older age, non-white race, and smoking.

The researchers wrote that based on this data, “If you were to follow 1,000 HIV-infected patients for a year, you would expect to see 50 extra cases of significant protein in urine, 38 extra cases of rapid decline, and 11 extra cases of chronic kidney disease in users of tenofovir versus non-users.”

Said Dr. Gallant in an email message, “Remember that while an increased risk of ‘11% to 34%’ sounds scary, an 11% to 34% increase in a very low risk is still a very low risk. As an example, if your risk of developing kidney disease without tenofovir is 1% per year, and tenofovir increases your risk by 11% to 34%, then your risk of kidney disease on tenofovir becomes 1.11% to 1.34% per year.”

Doing what *Fred Says*

Dr. Rob Garofalo is a physician who has treated HIV-positive children and adolescents for more than two decades. He was diagnosed with cancer in 2006 and at a particularly low point in his life, he searched the Internet for “puppy Chicago” and an image of Fred popped up. Although

he had never previously had a pet, Garofalo credits the Yorkshire terrier with bringing both peace and joy to his life again.

Fred’s healing properties have now led to a **creative project aimed at helping teens who are HIV-positive and uninsured.**



By selling “Fred Says” greeting cards online, Garofalo is raising money to help this vulnerable population. According to their website, doc and dog have four goals:

- to raise as much money as possible for HIV-positive teens without health insurance,
- to be as popular as “Boo” on Facebook (he’s Fred’s idol),
- to have their efforts noticed by Ellen Degeneres, and to go on her show (Fred just loves her), and
- to sell enough cards that they can make a beneficial impact on teens with HIV.

Garofalo is an attending physician at Children’s Memorial Hospital in Chicago, and Director of both the hospital’s Adolescent/Young Adult HIV Program and the Gender, Sexuality, and HIV Prevention Center. Garofalo is a strong advocate for HIV-positive adolescents through primary patient care and innovative HIV prevention research projects. To help him and Fred reach their goals, go to www.fredsays.org. A \$1 e-card can help teens living with HIV.



Video readies inmates for return to society

The video “Outside the Walls: Life Beyond HIV,” from the AIDS Foundation of Chicago (AFC), will be shown inside Illinois Department of Corrections (IDOC) facilities starting this year. The **four-minute video features two former inmates who are living with HIV** along with AFC Director of Correctional Health and Community Affairs Rev. Doris J. Green.

Angela McLaurin describes that moment in 1995 when she tested positive for HIV while in prison as “the wake-up call.” Upon her release, Angela used an HIV services directory to link herself to resources, but she knows that a booklet of information is no substitute for individual assistance. That’s why she and Tawon Dale, both members of the AFC Community Advisory Board, agreed to appear in the educational video, to encourage inmates to know their HIV status and connect to HIV/AIDS services upon release.

“I’m a testament to the fact that there is life beyond HIV,” says Angela, a motivational speaker and educator. “Early detection is key because what I’m seeing is that people don’t get tested until it’s way too late. And it’s sad because the help is out here.”

Rev. Green talks about the services available, including housing, and says, “When you return to the community, know people care.” Rev. Green has worked for years to bring HIV education into prisons and jails and it was through her work as liaison between AFC and IDOC that production of the video was possible.

The video is available as a free download at <http://bit.ly/outsidethewalls> and is also being distributed in Chicago neighborhoods as a DVD through Men & Women in Prison Ministries, a non-profit organization that provides support to incarcerated populations, their families, and the community at large. It can also be viewed at www.aidschicago.org/corrections.

1.5%

PERCENTAGE OF THE 2.2 MILLION INMATES INCARCERATED IN U.S. PRISONS AND JAILS WHO HAVE HIV OR AIDS, ROUGHLY FOUR TIMES THE RATE OF THE GENERAL POPULATION.

SOURCE: U.S. BUREAU OF JUSTICE STATISTICS (2008)



Jim Parsons and Luke Macfarlane in the 2011 Broadway production of *The Normal Heart*.

'The Normal Heart' goes to Washington

Larry Kramer's Tony Award-winning play to coincide with the International AIDS Conference

BY JEFF BERRY

THE NATIONAL TOUR OF THE BROADWAY PRODUCTION

of Larry Kramer's Tony Award-winning play *The Normal Heart* launches in Washington, D.C. in June, with the end of the play's run coinciding with AIDS 2012, the biennial international AIDS conference, this year held in D.C. July 22-27.

The winner of three Tony Awards in 2011, including Best Revival of a Play, *The Normal Heart* follows the sexual politics of New York during the initial AIDS crisis as a tight-knit group of friends refuse to bury the truth of an unspoken epidemic. Larry Kramer, the co-founder of both ACT UP (AIDS Coalition to Unleash Power) and Gay Men's Health Crisis in New York City, wrote the play while he was in Washington, D.C. following the devastating experience of watching many of his friends succumb to AIDS.

Arena Stage will produce the first

regional production of *The Normal Heart* at the prestigious Kreeger Theater. In an interview with POSITIVELY AWARE, Edgar Obie, Arena Stage's Executive Producer, admits that there was a lot of serendipity involved with the timing of the play.

"When we got it all sorted out," says Obie, "Daryl Roth, who is the commercial producer, said 'it's as if it was always meant to be.'" Molly Smith, the theater's artistic director, saw the play on Broadway and was deeply affected by it, according to Obie. When a play which had been

initially slated to run suddenly dropped out, there was an opportunity to bring *The Normal Heart* to Arena Stage.

This production of the play has been sanctioned as an official event of AIDS 2012, which is the first international AIDS conference being held in the U.S. since President Obama lifted the 22-year travel ban against HIV-positive individuals entering the U.S. More than 20,000 delegates will descend upon the nation's capital for the conference, as well as national and international press, during the final week of the play's run. But even beyond that, says Obie, it was seen as an opportunity to engage with the community for the entire seven-week run on what is still a very important story.

When asked about the play's significance some 25 years after it was first written, Obie simply states, "It's timeless." There was definitely a tide that turned at some point during the course of the epidemic, continues Obie, "but it's only because of the work of advocates and activists like Larry Kramer, who were passionate and managed to sustain that passion in their work and in their activism over the last several decades."

The production is a replica of the original Broadway show, says Obie, including director George C. Wolfe and designers David Rockwell (sets), and Martin Pakledinaz (costumes). "Obviously it's moving from city to city, so it's something that had to be made 'troupe-able' as they say." At press time, the show was being cast from New York City, and the casting director had reached out to original cast members, some of whom had expressed interest, though maybe in different roles. However, Obie says that as a regional theater, they felt it important to try to include some regional actors in the play as well.

"It feels good to know that the Arena Stage has the capacity, and has the relationships with the artists, to deliver something as important as this to our community."

THE NORMAL HEART runs June 8–July 29, 2012, at the Kreeger Theater, 1101 Sixth St., SW, Washington, D.C. For tickets call (202) 488-3300 or go to www.arenastage.org. For information about AIDS 2012 or to register, go to www.AIDS2012.org.



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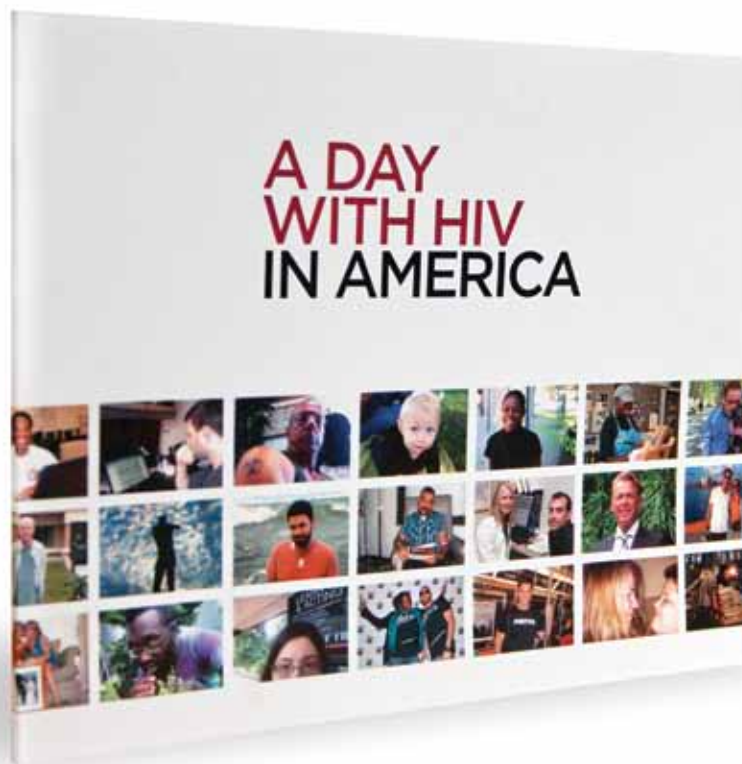
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TWO EPIDEMICS: INCARCERATION AND HIV

How the criminal justice system has played a role in the HIV epidemic

BY DAVID ALAIN WOHL, MD

HOW DID HIV AND OUR CRIMINAL JUSTICE SYSTEM BECOME

so well acquainted? The answer involves Darwinian evolution, 1980s era AIDS activists, the science of viral transmission, and Richard Nixon—a confluence of seemingly unrelated events, crossed with the laws of unintended consequences, that led the virus that infected Rock Hudson to now be concentrated among those who find themselves doing time.

Here in the U.S. during the infancy of the HIV epidemic, it was the bathhouses and bars that urban gay men favored where the virus was to be found. Within a few years, thousands of infected gay men died and an anguished community responded with a strong push for safer, less risky sex.

HIV then found an opportunity among

2,500,000

THE U.S. HAS 5% OF THE WORLD'S POPULATION BUT 25% OF ITS PRISONERS. WE INCARCERATE MORE PEOPLE PER CAPITA THAN ANY NATION—A TOTAL OF 2.5 MILLION.

injection drug users and heterosexuals living in poverty—people who were no strangers to the U.S. criminal justice system. Before long places like the Bronx and central Philadelphia had rates of HIV that rivaled those found in some African countries. Cut to our nation's prisons and jails.

AN EPIDEMIC OF INCARCERATION

The U.S. is a superpower when it comes to locking people up. We have 5% of the world's population but 25% of its prisoners.¹ We incarcerate more people per capita than any nation on the planet—about 2.5 million—and have another five million under parole or other form of supervision in their communities.² This massive incarceration has been brought to us by the “war on drugs.” Launched in the early 1970s by President Nixon, the campaign to stamp out drug use through arrest and imprisonment led to a stratospheric increase in the number of people, especially people of color, sent to prisons and jails. Further swelling our correctional facilities were the Sentencing Reform Act of 1984, curtailing alternative sentencing, the “three strikes” laws of the 1990s, and harsher sentencing guidelines for crack cocaine than for powdered coke.

The number of people incarcerated each year has started to level out, and the population that is incarcerated has declined—a consequence of an aging population, fairer sentencing laws, and a move away from conditional release, such as parole, that can make re-incarceration more likely. Still, one in 32 Americans is involved in the criminal justice system in one way or another.¹

WHEN EPIDEMICS COLLIDE

At the same time that the nation went on its incarceration spree, HIV was jumping from gay men to substance abusers. It did not take long for HIV (and hepatitis C or HCV) to find its way into our correctional facilities. The exact number of people with HIV in our prisons and jails can only be estimated. A few state prisons mandate HIV testing of all inmates, but

most, including the federal prison system, offer HIV testing on a voluntary or opt-out basis. Therefore, not everyone, including those at high risk, is tested.

According to government estimates there are about 22,000 people with HIV in prison, but the prevalence rates vary considerably (0.2% in Montana and 5.8% in New York).² The number of HIV-positive inmates in jails, where people are housed before conviction and transfer to prison, is a mystery, but if the prevalence is close to that seen in prison, we are talking about another 11,000 HIV-positive detainees.

THE EFFECTS OF INCARCERATION ON THE SPREAD OF HIV

With the entrenchment of HIV in our correctional populations, there has been considerable thought given to the ways in which incarceration facilitates the spread of HIV. It is a common perception that HIV is spread within correctional settings, as predatory and consensual sex is known to occur in prisons and jails, places where condoms are contraband.

While there are clearly documented cases of HIV transmission in correctional settings, most data point to the lion's share of the HIV-positive individuals in prisons and jails having acquired the virus while free. Testing of inmates entering prison and jails finds high rates of infection, as described above—likely reflecting the incarceration of those with or at high risk of HIV rather than the locking up of uninfected people who are then placed in a high-risk environment. One study that actually tested inmates in Rhode Island both on prison entry and then again on release found no cases of HIV acquisition during incarceration.⁴

On the other hand, an attention-grabbing report a few years ago did describe the detection of a number of inmates who tested HIV-negative when entering the state prison in Georgia and then were found to be HIV-positive during their incarceration.⁵ This demonstrates that transmission during incarceration does occur, but we remain unsure how often, and

whether this is mostly sexual or via tattooing and needle sharing. In almost all states, condoms are not permitted in prisons and jails. Similarly, clean needles, bleach, and safe tattooing equipment are typically unavailable. Data from Canada and Europe suggest that such interventions, proven effective in other settings, can be implemented safely in prisons. However, there has been little interest in uptake of these measures in the U.S. This reflects a long-standing philosophical tension between the mores of the correctional culture in the U.S. and public health's reliance on evidence-based prevention methods.

Of even greater importance than the spread of HIV within prisons and jails are the broader socially disruptive effects of incarceration. The impact of imprisonment extends well beyond the individual placed in a cell and reaches his relationships and his community. Stable, protective, intimate partnerships are disrupted, if not ended, especially with prolonged incarceration.^{6,7} This can lead the partner left in the community vulnerable to infection via new relationships formed in the absence of the incarcerated partner. In communities where HIV and other sexually transmitted infections are more endemic, this can greatly increase the risk of infection.

As the vast majority of prisoners are released, those returning to their communities may now face an even greater risk of HIV transmission. For the HIV-negative former inmate, reconnecting with a partner who had sex with other partners during the incarceration, or who finds new partners post-release can result in exposure to HIV. The risk behavior of HIV-negative released men is well described and demonstrates that the potential for acquisition of HIV after, rather than during, incarceration is real.⁸ Much less is known about the behavior of HIV-positive men and women after prison release. Work conducted in North Carolina suggests that re-engagement in sex after release is a slow process, but that, as is the case with HIV-positive people in general, some do practice behaviors that can risk transmission of the virus.⁹

TREND

HIV MORTALITY RATES IN PRISONS HAVE PLUMMETED, MIRRORING SURVIVAL TRENDS SEEN IN THE FREE WORLD, ATTRIBUTED TO PARTNERSHIPS WITH ACADEMIC CENTERS AND HEALTH DEPARTMENTS.

The collateral damage of incarceration extends even beyond the partner pair to the community at large, where the effects of the absence of a significant proportion of men alters the social landscape. Most directly, the gender ratio (number of men compared to the number of women) is shifted, influencing gender power (including negotiation regarding monogamy and condom use), and partner parity (social status, economic status, and HIV risk). Communities are further harmed by the loss of working age men and women, leaving a vacuum that saps vitality and stability. Therefore, incarceration has toxic societal effects that can promote the circumstances in which HIV thrives.

CARE FOR HIV IN PRISONS AND JAILS

The confluence of HIV and incarceration has forced jails and prisons to provide medical care and services to infected inmates. Prisons provide HIV therapy to inmates at no cost and monitor viral load and CD4 cell counts. All indicators suggest HIV care in prisons is good, with the majority of HIV-positive individuals behind bars achieving undetectable HIV viral loads.¹⁰ Further, rates of death due to HIV have plummeted in prisons over the past several years, mirroring the survival trends seen in the free world.² Much of this success can be attributed to partnerships between corrections, academic centers, and departments of health, as well as the hiring of correctional health care providers with HIV expertise.

Additionally, there is a sense among providers of HIV care in corrections that inmates may do better than free-world peers in terms of health outcomes due to structural factors that can lead to access to better nutrition, opportunities to exercise, limited or no access to substances of abuse, and close monitoring of adherence to medication and laboratory values.

The situation in jails may not always be so rosy. Unlike prison systems, which are run by the Federal or state governments, counties, municipalities, and towns fund

jails. Unless they are one of the mega-jails like those in Chicago and Los Angeles, budgets are typically small and there are usually few or no staff with HIV expertise. The chaos of jails, where stays can be as short as a few hours or as long as months to even years, further challenges HIV care. Those entering jail without their medications can expect a lapse in dosing. With an average stay of a couple of days, there is also limited time to provide screening, treatment, and linkage to community care.

TRANSITION TO THE COMMUNITY

In the cascade of HIV care that extends from finding those who are infected to establishing care, retaining patients in care, and suppressing viral load long term, each point in this spectrum is an opportunity for those in corrections. As described above, screening for HIV is common in correctional settings and quality care is provided, especially in prisons and larger jails. The weakest link of this chain has been maintenance of the benefits of that care following release. It is ironic that incarcerated people living with HIV fare better, in terms of metrics of physical health (weight, viral load, and CD4 cell count), than those living with the virus in the communities from which they came. With release, much of the available data paints a bleak picture of unfilled ART prescriptions, missed medical appointments, and a return to behaviors that often lead to a return to a jail or prison.¹¹ Much work has gone into identifying transitioning strategies that are effective at maintaining HIV care and service post-release. The model of HIV transition programming was pioneered in Rhode Island and involves pre- and post-release intensive case management.¹² Other states have adapted this approach with reported success. One trial conducted in North Carolina found that among 89 HIV-positive inmates, those randomized to a case management program, modeled on the Rhode Island program, that spanned the periods before and after release had no more success in making doctor appointments post-release

than those assigned to routine discharge planning by the prison. In all, about half of the former inmates in both study arms saw a medical provider within a month of release, at which time their prison-provided HIV medications would run out.¹³

Innovative approaches to linkage to care are being explored and the National Institutes of Health (NIH) and others have been funding efforts to test these in order to identify evidence-based models that can be implemented. Failure to link those under correctional supervision to ongoing HIV care would bode poorly for the broader effort to increase the proportion of all HIV-positive people with undetectable viral loads from its current 28%.

CONCLUSIONS

Incarceration is one of a number of forces that have shaped the domestic HIV epidemic. The massive imprisonment of the members of populations that bear a disproportionate burden of HIV has significantly perpetuated the spread of the virus and it is unlikely we will see an overhaul of the legal system any time soon. The sentencing laws that feed a gluttonous criminal justice system with inmates are likely to remain, as will policing policies that lead to the arrest of people of color and those living in poverty. Few people under correctional supervision will receive the substance abuse and mental health care they need. So, behind the walls of our correctional facilities, the virus will remain. **PA**

FOR REFERENCES,
GO TO POSITIVELYAWARE.COM

DAVID ALAIN WOHL, MD, is an Associate Professor of Infectious Diseases and Co-Director of the AIDS Clinical Trials Unit at the University of North Carolina. Metabolic complications associated with HIV infection and the nexus between HIV and incarceration are his major areas of research interest. His e-mail address is wohl@med.unc.edu.



Model

INDICATIONS

ISENTRESS is a medicine used to treat the human immunodeficiency virus (HIV). **ISENTRESS must be taken with other HIV medicines** to improve your chances of fighting the virus. You must remain under your doctor's care.

ISENTRESS has not been studied in children.

ISENTRESS **will not cure** HIV or reduce your chance of passing it to others.

IMPORTANT RISK INFORMATION

Severe, life-threatening, and fatal skin reactions and allergic reactions have been reported in some patients taking ISENTRESS. If you develop a rash with any of the following symptoms, stop using ISENTRESS and contact your doctor right away: fever, generally ill feeling, extreme tiredness, muscle or joint aches, blisters or sores in mouth, blisters or peeling of skin, redness or swelling of the eyes, swelling of the mouth or face, problems breathing.

Sometimes allergic reactions can affect body organs, like the liver. Contact your doctor right away if you have any of the following signs or symptoms of liver problems: yellowing of the skin or whites of the eyes, dark or tea colored urine, pale colored stools/bowel movements, nausea/vomiting, loss of appetite, pain, aching or tenderness on the right side below the ribs.

Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor right away if you start having new symptoms after starting your HIV medicines.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness while taking ISENTRESS. This is because on rare occasions muscle problems can be serious and can lead to kidney damage.

I am active. I am devoted to family. I am inspired. I am HIV positive.

You are special, unique, and different from anyone else.
And so is your path to managing HIV. When you're ready to start HIV therapy, talk to your doctor about a medication that may fit your needs and lifestyle.

In clinical studies lasting 96 weeks, patients being treated with HIV medication for the first time who took ISENTRESS plus *Truvada*:

- ◆ Had a low rate of side effects
 - The most common side effect of moderate to severe intensity (that interfered with or kept patients from performing daily activities) was trouble sleeping
 - This side effect occurred more often in patients taking ISENTRESS plus *Truvada* (4%) versus *Sustiva* plus *Truvada* (3%)
- ◆ Experienced less effect on LDL cholesterol ("bad" cholesterol)
 - Cholesterol increased an average of 7 mg/dL with ISENTRESS plus *Truvada* versus 21 mg/dL with *Sustiva* plus *Truvada*
 - When they began the study, the average LDL cholesterol of patients on ISENTRESS plus *Truvada* was 96 mg/dL versus 93 mg/dL for those on *Sustiva* plus *Truvada*

Ask your doctor about ISENTRESS.

Not sure where to start? Visit isentress.com/questions

When ISENTRESS has been given with other anti-HIV drugs, side effects included nausea, headache, tiredness, weakness, trouble sleeping, stomach pain, dizziness, depression, and suicidal thoughts and actions. People taking ISENTRESS may still develop infections, including opportunistic infections or other conditions that occur with HIV infection.

Tell your doctor about all of your medical conditions, including if you have any allergies, are pregnant or plan to become pregnant, or are breast-feeding or plan to breast-feed. ISENTRESS is not recommended for use during pregnancy. Women with HIV should not breast-feed because their babies could be infected with HIV through their breast milk.

Tell your doctor about all the medicines you take, including prescription medicines like rifampin (a medicine used to treat infections such as tuberculosis), non-prescription medicines, vitamins, and herbal supplements.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please read the Patient Information on the adjacent page for more detailed information.

Need help paying for ISENTRESS? Call 1-866-350-9232

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ISENTRESS®
raltegravir tablets

Patient Information

ISENRESS® (eye sen tris) (raltegravir) Film-Coated Tablets

ISENRESS® (eye sen tris) (raltegravir) Chewable Tablets



Read this Patient Information before you start taking ISENRESS and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is ISENRESS?

ISENRESS is a prescription HIV medicine used with other HIV medicines to treat adults and children 2 years of age and older with human immunodeficiency virus (HIV-1) infection. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

When used with other HIV medicines, ISENRESS may reduce the amount of HIV in your blood (called "viral load"). ISENRESS may also help to increase the number of CD4 (T) cells in your blood which help fight off other infections. Reducing the amount of HIV and increasing the CD4 (T) cell count may improve your immune system. This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).

It is not known if ISENRESS is safe and effective in children under 2 years of age.

ISENRESS does not cure HIV infection or AIDS. People taking ISENRESS may still develop infections or other conditions associated with HIV infection. Some of these conditions are pneumonia, herpes virus infections, and Mycobacterium avium complex (MAC) infections.

Patients must stay on continuous HIV therapy to control infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others:

- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.**
- **Do not have any kind of sex without protection.** Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

What should I tell my doctor before taking ISENRESS?

Before taking ISENRESS, tell your doctor if you:

- have liver problems.
- have phenylketonuria (PKU). ISENRESS Chewable Tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if ISENRESS can harm your unborn baby.

Pregnancy Registry: You and your doctor will need to decide if taking ISENRESS is right for you. If you take ISENRESS while you are pregnant, talk to your doctor about how you can be included in the Antiretroviral Pregnancy Registry. The purpose of the registry is to follow the health of you and your baby.

- are breastfeeding or plan to breastfeed.
 - Do not breastfeed if you are taking ISENRESS. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby.
 - Talk with your doctor about the best way to feed your baby.

Tell your doctor about all the medicines you take, including: prescription and non-prescription medicines, vitamins, and herbal supplements. Taking ISENRESS and certain other medicines may affect each other causing serious side effects. ISENRESS may affect the way other medicines work and other medicines may affect how ISENRESS works.

Especially tell your doctor if you take:

- rifampin (Rifadin, Rifamate, Rifater, Rimactane), a medicine commonly used to treat tuberculosis.

Ask your doctor or pharmacist if you are not sure whether any of your medicines are included in the list above.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine. Do not start any new medicines while you are taking ISENRESS without first talking with your doctor.

How should I take ISENRESS?

- **Take ISENRESS exactly as prescribed by your doctor.**
- You should stay under the care of your doctor while taking ISENRESS.
- Do not change your dose of ISENRESS, switch between the film-coated tablet and the chewable tablet or stop your treatment without talking with your doctor first.
- Take ISENRESS by mouth, with or without food.
- If your child is taking ISENRESS, your child's doctor will decide the right dose based on your child's age and weight.
- ISENRESS Chewable Tablets may be chewed or swallowed whole.
- ISENRESS Film-Coated Tablets must be swallowed whole.
- If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not double your next dose or take more than your prescribed dose.
- If you take too much ISENRESS, call your doctor or go to the nearest emergency room right away.
- Do not run out of ISENRESS. Get your ISENRESS refilled from your doctor or pharmacy before you run out.

What are the possible side effects of ISENRESS?

ISENRESS can cause serious side effects including:

- **Serious skin reactions and allergic reactions.** Severe and life-threatening skin reactions and allergic reactions have been reported in some patients taking ISENRESS. If you develop a rash with any of the following symptoms, stop using ISENRESS and contact your doctor right away:
 - fever
 - muscle or joint aches
 - redness or swelling of the eyes
 - generally ill feeling
 - blisters or sores in mouth
 - swelling of the mouth or face
 - extreme tiredness
 - blisters or peeling of the skin
 - problems breathing

Liver problems may be caused by an allergic reaction. Contact your doctor right away if you have any of the following signs or symptoms of liver problems:

- yellowing of the skin or whites of the eyes
- dark or tea colored urine
- pale colored stools/bowel movements
- nausea/vomiting
- loss of appetite
- pain, aching or tenderness on the right side below the ribs
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor right away if you start having new symptoms after starting your HIV medicine.
- **Phenylketonuria (PKU).** ISENRESS Chewable Tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU.

The most common side effects of ISENRESS include:

- headache
- trouble sleeping

Less common side effects include:

- nausea
- dizziness
- tiredness
- depression
- weakness
- suicidal thoughts and actions
- stomach pain

Tell your doctor right away if you get unexplained muscle pain, tenderness, or weakness while taking ISENRESS. This may be a sign of a rare but serious muscle problem that can lead to kidney problems.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ISENRESS. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ISENRESS?

Film-Coated Tablets:

- Store ISENRESS Film-Coated Tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Chewable Tablets:

- Store ISENRESS Chewable Tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Store ISENRESS Chewable Tablets in the original package with the bottle tightly closed.
- Keep the drying agent (desiccant) in the bottle to protect from moisture.

Keep ISENRESS and all medicines out of the reach of children.

General information about ISENRESS

Medicines are sometimes prescribed for conditions that are not mentioned in Patient Information Leaflets. Do not use ISENRESS for a condition for which it was not prescribed. Do not give ISENRESS to other people, even if they have the same symptoms you have. It may harm them.

This leaflet gives you the most important information about ISENRESS.

If you would like to know more, talk with your doctor. You can ask your doctor or pharmacist for information about ISENRESS that is written for health professionals.

For more information go to www.ISENRESS.com or call 1-800-622-4477.

What are the ingredients in ISENRESS?

ISENRESS Film-Coated Tablets:

Active ingredient: raltegravir

Inactive ingredients: microcrystalline cellulose, lactose monohydrate, calcium phosphate dibasic anhydrous, hypromellose 2208, poloxamer 407 (contains 0.01% butylated hydroxytoluene as antioxidant), sodium stearyl fumarate, magnesium stearate.

The film coating contains: polyvinyl alcohol, titanium dioxide, polyethylene glycol 3350, talc, red iron oxide and black iron oxide.

ISENRESS Chewable Tablets:

Active ingredient: raltegravir

Inactive ingredients: hydroxypropyl cellulose, sucralose, saccharin sodium, sodium citrate dihydrate, mannitol, red iron oxide (100 mg tablet only), yellow iron oxide, monoammonium glycyrrhizinate, sorbitol, fructose, natural and artificial flavors (orange, banana, and masking that contains aspartame), crospovidone, magnesium stearate, sodium stearyl fumarate, ethylcellulose 20 cP, ammonium hydroxide, medium chain triglycerides, oleic acid, hypromellose 2910/6cP, PEG 400.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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U.S. Patent Nos. US 7,169,780

MONEY WELL SPENT

Opt-out testing in prisons can catch STD cases—
and save taxpayers money in the long run



BY CHAD ZAWITZ, MD

HOW MUCH DO YOU THINK IT WOULD COST THE HEALTH department of a major American city to reduce the amount of gonorrhea, Chlamydia, syphilis and possibly even HIV by 20%? More importantly, if you had to devise the simplest and most cost-effective way to do this, how would you do it?

Millions have been spent on print ads in magazines and newspapers, TV spots, billboards, and Internet messages. Additional monies have been spent for

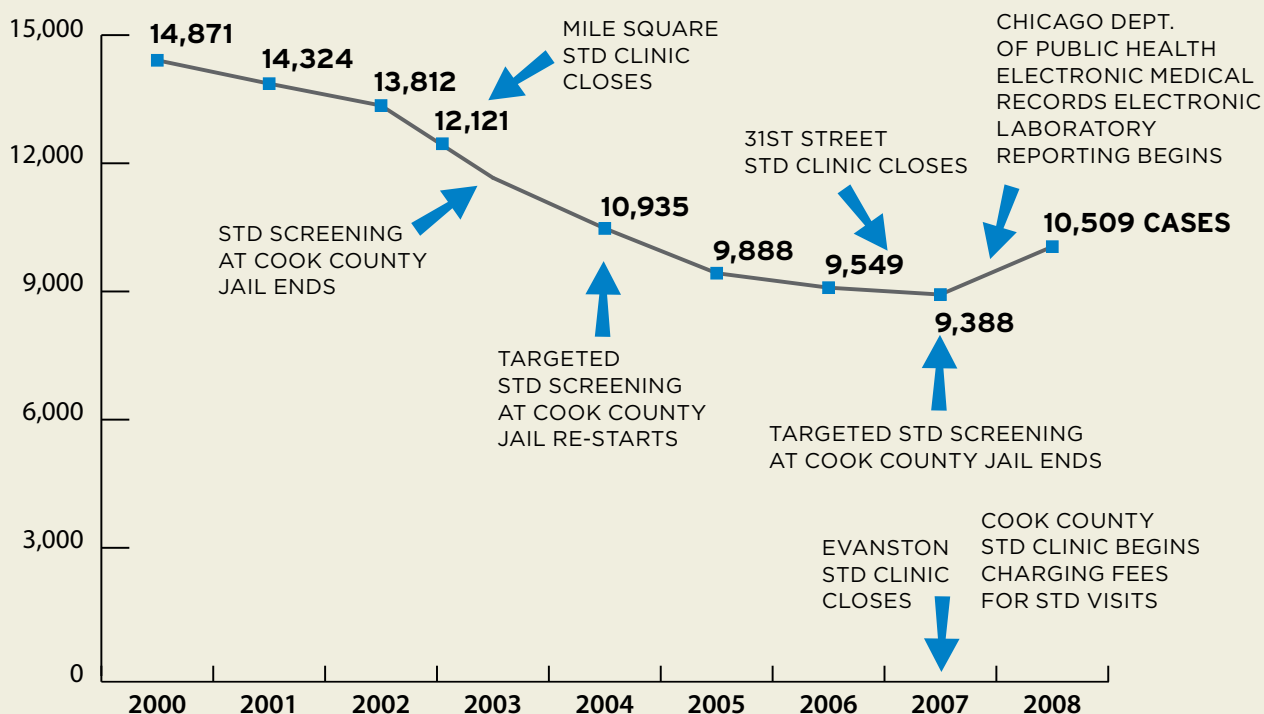
peer and provider education. Schools teach sexual health. Public health agencies spend millions more performing services such as partner tracking and notification.

Despite all these efforts, sexually transmitted infections continue to plague our communities.

Perhaps another approach might be to seek out a subpopulation that has a higher than average prevalence of infections. Better yet would be if that population could be gathered into one location to streamline testing, diagnosis, treatment, and linkage to care. In most major metropolitan areas, such places exist: jails and prisons.

OPEN AND SHUT CASES

EVENTS THAT AFFECTED GONORRHEA CASE REPORTING IN CHICAGO, 2000-2008



STI TESTING LESSONS

In Chicago, this very scenario played out in reverse. In April 2002–March 2003 the Cook County Jail performed “universal voluntary screening” for gonorrhea and Chlamydia. More than 85% of men and women entering the facility participated in testing, leading to large numbers of diagnoses and treatment.¹ An estimated one in five cases of gonorrhea in the entire county was diagnosed and in most cases treated during incarceration at the jail.

Testing was switched to symptoms-based screening only in March 2003. In the following year, the number of cases of gonorrhea and Chlamydia that were diagnosed in the jail declined by nearly 80%! While this is not exactly comparing apples to apples, it demonstrates the power and dramatic impact opt-out testing can have on the community. All those undiagnosed and untreated patients are potential vectors of disease transmission in the community at large.

In 2007, all intake screening was discontinued, and the number of cases of gonorrhea diagnosed in the County reached its lowest point in more than seven years. This

doesn't mean there was any less gonorrhea in Cook County. It just means that the largest single-site testing and treatment facility in the county had ceased to have an impact. All those previously diagnosed and treated cases were going untreated and ultimately returned to the community to be spread to new partners.

By 2008, the number of new cases diagnosed in Cook County had increased by nearly 10% in a single year. This was without having resumed large scale testing at the Cook County Jail. These were all cases diagnosed at the community-level clinics and other health care settings. It was clear that the jail served a massively important role in the cycle of transmission of sexually transmitted diseases. By focusing initiatives on correctional facilities, communities have that cost-effective magical constellation of high disease burden, captive audience, screening, treatment, and linkage to care.

Might jails and prisons be able to have a similar impact on HIV?

HIV TESTING BEHIND BARS

HIV testing is generally considered to

be cost-effective, but the biggest “bang for your buck” occurs when screening is applied to populations where the presence of disease is predicted to be higher than average. Correctional settings represent an ideal example of a population that may receive the biggest direct benefit from opt-out HIV testing. The U.S. prevalence of HIV is estimated to be between 0.3 to 0.5%, but in jails and prisons the rate is three to five times higher (as many as 2.5 people out of 100). The reason for the higher rate is because many people who are incarcerated have a higher prevalence of HIV risk factors (e.g., injection drug users, sex workers, the mentally ill, and “risk-takers”). Further, jails and prisons tend to represent a similar economic strata as those who do not routinely have access to health care in their communities (the un- or underinsured) and therefore are less likely to have been offered testing prior to incarceration.

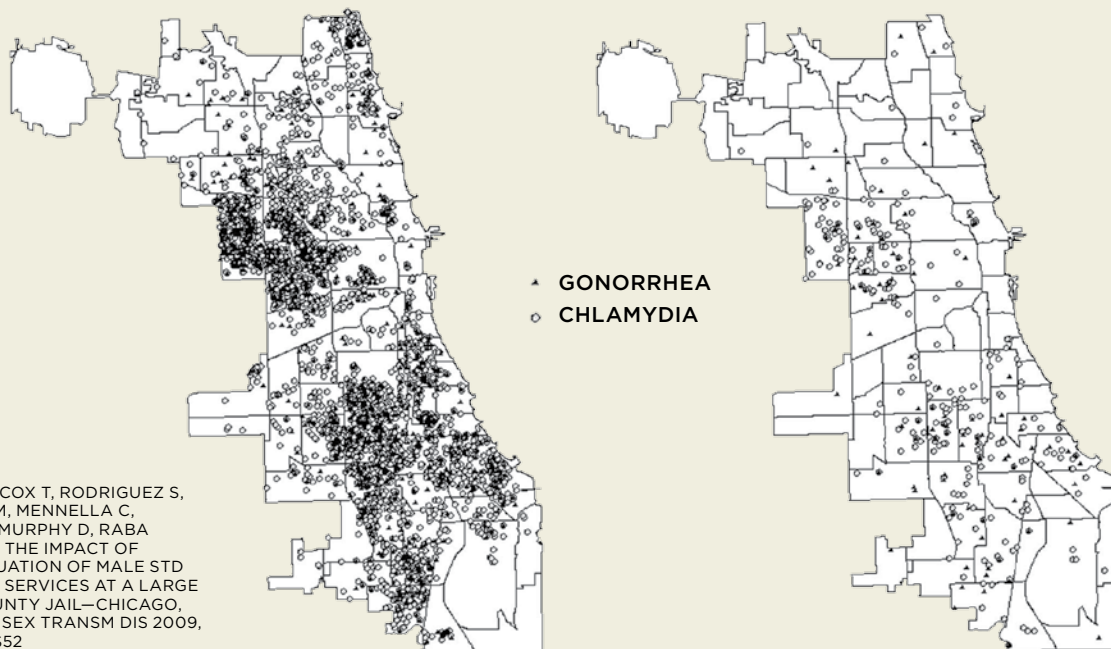
It is estimated that as many as 25% of all Americans who are infected with HIV are currently unaware of their diagnosis. This means there may be more than 250,000 citizens who are not in care and

SCREENINGS MAKE A DIFFERENCE

REPORTED CHLAMYDIA AND GONORRHEA FROM COOK COUNTY JAIL
BEFORE AND AFTER DISCONTINUATION OF UNIVERSAL STD SCREENING

BEFORE: APRIL 2002–MARCH 2003

AFTER: APRIL 2003–MARCH 2004



BROAD JM, COX T, RODRIGUEZ S, MANSOUR M, MENNELLA C, SWALLOW-MURPHY D, RABA J, WONG W. THE IMPACT OF DISCONTINUATION OF MALE STD SCREENING SERVICES AT A LARGE URBAN COUNTY JAIL—CHICAGO, 2002–2004. SEX TRANSM DIS 2009, 36(2): S49–S52

therefore not on medications. An estimated 20% of all HIV-positive people will pass through a correctional facility at some point. Their health may be in jeopardy, but in a broader view, public health is also directly affected. HIV-positive patients not diagnosed and not on treatment are more infectious and may not be taking additional precautions to safeguard their partners (condoms, strategic positioning, serosorting, altering sexual practices, abstinence, etc.). The financial impact of delayed access to HIV treatment is also substantially greater. Presenting with advanced HIV leads to longer and more frequent hospitalizations, more medication expenses, more utilization of HIV primary care resources, and so on.

In 2006 the CDC issued a recommendation that HIV testing should be considered a routine part of an effort to diagnose and ultimately treat the “missing 25%.” This included testing anyone ages 13–64 in all health care settings, increased frequency of screening for those at higher risk for HIV, eliminating separate written consent, eliminating the requirement for prevention counseling, including HIV

testing in all prenatal panels, and utilizing opt-out testing wherever possible.

OPTING OUT

Opt-out testing is a method where everyone who engages a particular care setting will be tested unless they decline. Due to laws that vary from state to state, consent still must be acquired in most instances. Fortunately, verbal consent (which must still be documented in the medical record) is acceptable in most cases. This is important because high-volume settings such as jails and emergency rooms must have streamlined and efficient procedures to screen as many patients as possible. Any additional steps, such as finding and filling out a lengthy written consent form, adds substantial time to each patient encounter.

Once the patient has consented and agrees to participate in opt-out screening, they are sent for an HIV test. There are basically two major types of HIV tests that can be used in an opt-out setting: ELISA antibody tests (blood) or a rapid test (finger stick or oral swab). The advantages of rapid testing include being less invasive than a blood draw (no needles in veins),

results in minutes, and most importantly, the ability to give the preliminary result to the patient before they are gone. The advantages of plasma ELISA testing include lower cost, delayed results (a benefit if patients are not stable enough to hear results immediately), and less utilization of space and staffing in a busy intake setting.

Delivering test results may seem like it should not be an issue in a jail setting where you have a captive audience to give results from a slower test such as an ELISA. The reality is that many detainees leave jails in hours to days depending on their charges, are released on home-monitoring, or are bailed out. Waiting even two or three days may mean up to 30% of those tested might not receive their result. Furthermore, is a jail intake facility an ideal place to tell someone for the first time they probably have HIV? Intake facilities are generally hot, crowded, high-pressure environments where there is little real privacy, if any. Incoming detainees are often intoxicated or coming down from a high, possibly angry about being arrested, mentally unstable (especially the people with severe mental health concerns), and



Cermak Health Services provides health care to approximately 9,000 detainees at the Cook County Department of Corrections.

physically and emotionally exhausted. Imagine a health care provider telling you your result, then sending you back out into a bullpen with 60 other detainees who are yelling, jostling for space, and maybe even reading the new look of shock on your face.

In a prison setting, most inmates have a clearly defined sentence. The health care staff knows the exact date of release from the facility, and therefore, there's a higher probability that those who are tested will receive their result. Additionally, by the time inmates reach prison, they are usually sober, better rested (as compared to the day they went to jail), and more emotionally and mentally stable. In resource-limited settings, including correctional facilities, screening with a less-expensive test (ELISA) may make expanded screening via opt-out more palatable to the budget-makers. Lastly, with known discharge dates, linkages to HIV care in the community become at least a little easier than they are in a jail setting (where one never really knows if or when the patient will be leaving).

COMMUNITY BENEFITS

As a real-world example, in 2006-2007, Washington, D.C. began expanded routine HIV screening in health care settings, including jails. The number of HIV tests

performed increased by more than 68% in just one year simply by implementing the 2006 CDC recommendation for opt-out HIV screening.² Not only were more tests conducted, but more results were available and delivered. This ultimately led to more patients becoming linked to care in their communities, and this led to more diagnoses made in an earlier stage of the disease (the average baseline CD4 went from 262 to 332 in the first year alone). In addition, more people aware of their status means more people on treatment. More people on treatment means less chance of infecting new partners. That was clearly shown with HPTN 052, a study of more than 1,700 couples in which successful treatment of the HIV-positive partner led to a 96% decrease in transmission. Awareness of one's HIV status also often means behavioral changes to protect partners. Fewer newly infected people means additional benefits to the community at large.

With renewed support from the county government, the Cook County Jail in Chicago began opt-out HIV and STI (sexually transmitted infection) screening in April 2011 for females entering the facility. More than 7,000 female intakes occurred from April through the end of 2011. More than 50% agreed to participate in HIV opt-out screening, and more than 60% in gonorrhea and Chlamydia screening.

This process nearly tripled the number of HIV, syphilis, and GC/Chlamydia tests performed in the full calendar year of 2010. Many of these women remained in the facility long enough to not only receive their results, but to complete treatment (in the case of GC/Chlamydia) or linkage to care (in the case of those diagnosed with HIV). With "second-chance" testing offered at later times during their incarceration, an additional 20-30% of women ultimately agreed to be tested. The Chicago Department of Public Health was notified of any women leaving the jail before their results were available in order to attempt to locate them in their communities to provide treatment, as well as to notify sexual partners.

You might still be asking, "So why does this matter to me?" Remember, the majority of men and women entering a jail do not go to prison or otherwise just disappear. They return to their communities, bringing any untreated communicable diseases they have with them. With government budgets stretched thin, focusing limited resources to sites with the ability to have the greatest impact is wise. Some people may harbor resentment that tax dollars are being used to improve the health of people who may have broken the law, but this is shortsighted. In the long run, spending your tax dollars in jails and prisons for HIV and STI testing and treatment has a major downstream benefit to the broader community. **PA**

FOR REFERENCES,
GO TO POSITIVELYAWARE.COM

CHAD ZAWITZ, MD, is Attending Physician and Clinical Coordinator of HIV/Infectious Disease Services for Cermak Health Services at the Cook County Jail, providing care to HIV-positive detainees and inmates there and also at his continuing care clinic at the CORE Center. In 2005, he received the HIV Leadership Award as Up and Coming Physician from The Body.com. Dr. Zawitz has written for POSITIVELY AWARE on a variety of topics, including the physician's comments in the 2006 10th Annual HIV Drug Guide.

should know that the condition of health care in our country's correctional institutions is lacking, to say the least.

Here at PA we frequently hear from inmates who are not able to be adherent with their HIV regimen because facility personnel don't understand the importance of uninterrupted treatment with a consistent combination of medicines, or they miss their doses due to being on lockdown, or they develop resistance to one drug, but are not able to change their regimen.

On the other side, prison administrators deal with funding cuts from the state or federal government and are frequently faced with not having the money to pay for enough nurses and doctors, let alone the expensive drugs used to treat not

- **To provide** comprehensive medical treatment to inmates who are HIV-positive
- **To promote** HIV/AIDS awareness and prevention among inmates
- **To encourage** inmates to take personal responsibility for their health
- **To reduce** the risk of inmates spreading HIV throughout the community upon their release

In Illinois, in August of 2011, an amendment was added to the Unified Code of Corrections that provides HIV testing be offered to inmates on an opt-out basis with no co-pay. It also directs that pre-test information be provided to the inmate and informed consent obtained as required in

processing facility for male inmates in state custody—that the disparity between the intent of the law and what was actually going on first surfaced. When JHA asked for the lab reports that should have accompanied the testing, they discovered that the testing was not being done.

Maki is concerned that the same thing is happening with hepatitis C testing, in some ways an even greater risk than HIV for inmates.

Maki explained that within the Department of Corrections (DOC), there is often miscommunication and evidently, people on staff at the facility, as well as those at other facilities, thought the tests were taking place when indeed they were not. This would often lead to inmates not

5X PREVALENCE OF HIV IN PRISONS IS UP TO FIVE TIMES HIGHER THAN OUTSIDE THE CELLS, THOUGH IT IS ALSO TRUE THAT MOST NEW INFECTIONS HAPPEN OUTSIDE PRISON WALLS.

only HIV, but also any other illnesses the inmates live with.

Add to that the high risk behavior that goes on in prison (sex, consensual or not; tattooing; needle sharing; etc.) and it's no wonder that the prevalence of HIV in prisons is up to five times higher than outside the cells, though it is also true that most new infections happen outside prison walls. Unfortunately, other factors associated with high risk for HIV—poverty, race, drug abuse, and stigma for instance—are at play in communities that also have the highest crime rates.

LEGISLATIVE EFFORTS

However, there are attempts to reduce the transmission of HIV in correctional facilities. On the federal level, Congresswoman Maxine Waters (D-CA) introduced the "Stop AIDS in Prison Act" in December 2011. Besides also providing for opt-out testing in all federal prisons, it goes further, listing the following purposes:

- **To stop** the spread of HIV among inmates
- **To protect** prison guards and other personnel from HIV infection

the AIDS Confidentiality Act. The amendment also speaks to the release of inmates from prison, providing that all inmates due to be released receive "appropriate information in writing, by video, or other electronic means, concerning HIV and AIDS."

JOHN HOWARD ASSOCIATION

The John Howard Association (JHA) is a non-profit organization that works in Illinois to achieve "a fair, humane, and cost-effective criminal justice system by promoting adult and juvenile prison reform, leading to successful re-integration and enhanced community safety." Teams of four to six trained volunteers led by JHA staff conduct tours of Illinois' state correctional facilities. The observations of the volunteers are recorded in written reports prepared by JHA, focusing on such issues as medical and mental health care, disciplinary procedures, and the physical condition of facilities.

John Maki, Executive Director of JHA, spoke with PA about the state of HIV testing in these facilities. Maki said it was during the monitoring of the Northern Reception and Classification Center—the nation's largest intake, classification, and

being offered the test because the staff thought they'd already had it or it had been done at another facility. JHA was suspicious when the number of new diagnoses was much lower than expected.

One of Maki's frustrations was with the law itself. The way the statute is written, testing is not mandatory—it says the facility "may conduct" opt-out testing—so the prison itself can "opt out" of providing it just as the inmates can opt out of taking a test.

There is also lack of clarity in the language of the law about the timing of the testing. According to an internal JHA memo, "Although the amended statutes undoubtedly were born of the best intentions, they are ambiguous as to whether HIV testing must be provided to inmates upon initial entry into DOC, at the point of reception and classification. To provide opt-out HIV testing when an inmate is about to be released from prison (as some facilities do), rather than at the point of initial entry into the system is counterproductive, particularly if the goal is to promote early detection, entry into care, and prophylactic treatment to reduce secondary infection and mortality, and prevent further disease transmission."

The good news is that JHA's investigation of the situation led to pinning down a timetable with the DOC for implementation this spring and Maki says JHA will hold them to that.

THE FUNDING BARRIER

When an inmate is identified as HIV-positive the DOC is legally obligated to provide "medical care while incarcerated, counseling, and referrals to support services."

However, the JHA memo states that "implementation [of the statute] relating to treatment is 'subject to appropriation,'" i.e., the legislature actually providing DOC with the funds necessary to fulfill the mandate. So unless the legislature comes up with that funding, there is no duty to

computer, via Skype or a similar service, with HIV-positive inmates, monitor their lab tests, and discuss any questions or concerns they may have about their drug regimen.

"It's getting rave reviews!" Maki exclaimed. "Not knowing anything about telemedicine, when I first heard about it I thought it seemed like a way of cheating on care," he admitted. "But when I really looked at it, I realized that it was really improving the quality of care."

He also pointed out that, though it was not the goal, telemedicine is providing oversight by getting "another pair of eyes" on the medical conditions in DOC. He went on to say that since the implementation of telemedicine, reports have shown

telemedicine and medical conditions at DOC. Though there are obvious problems, he gave the DOC credit for doing some innovative things, such as their partnering with the AIDS Foundation of Chicago to produce and screen "Outside the Walls," a video educating inmates on HIV treatment and prevention and encouraging them to take charge of their health upon their release (see Briefly, page 10).

HOPE FOR THE FUTURE

What would Maki ultimately like to see in terms of HIV and the DOC?

"I think the opt-out testing is a good start," he said. "But I'd like to see the DOC really seeing diagnosis and treatment education as part of its mission and that it's

CHANGE

SMALL VICTORIES MEAN A LOT
AND EVEN SMALL CHANGES
CAN BE REALLY POWERFUL.

implement the statute. There is also a financial disincentive for the DOC to test inmates upon entry rather than waiting to test them when they are nearing release, thereby avoiding the cost of treating them while they are in custody.

And so a vicious cycle of unknown HIV status, risky behavior that results in more infections, leading to more HIV-positive inmates being released without knowing of their infection, ending with ongoing new infections in the community is perpetuated.

With so many states in financial trouble, it seems likely that the same situation exists throughout the country and perhaps in federal prisons as well. And funding for Medicaid, community health centers, and HIV prevention is cut with no thought to the long-term consequences.

TELEMEDICINE

But there is some good news, at least here in Illinois. A partnership of DOC with the University of Illinois Medical School is providing telemedicine monitoring of HIV-positive inmates, a program that Maki is enthusiastic about. Telemedicine allows for an HIV specialist to communicate by

improvement in the delivery of meds to inmates and their adherence to their HIV regimens. He would love to see it expanded to serve inmates with other conditions besides HIV, especially since telemedicine enables the prisons to gain the benefit of experts in specific diseases at a fraction of the cost.

"It's really the best of both worlds," said Maki. "You're saving money while you're providing better care."

There is also exciting potential for telemedicine to provide some "infrastructure" that could be used by parole officers to better understand and monitor the medical needs of their parolees. Maki wishes that parole officers and soon-to-be parolees could meet well ahead of the release date in order to establish awareness of the inmate's medical and mental health needs, as well as providing a better foundation for this most important relationship between the inmate and law enforcement. "An inmate is going to live or die by their parole officer," says Maki, so the more the officer knows, the better the outcome for them both.

Maki says that JHA intends to use an upcoming grant to delve into the issue of

really instrumental to public health." He'd also like to see more emphasis on prevention, including condoms being provided.

To Maki, continuity of care is also crucial and that means from the point of entry, through the sentence, to the transition back to the community. He mentioned Sheridan Correctional Center and Southwestern Illinois Correctional Center, the so-called "drug treatment prisons," as places that focus on providing continuity of care. The fact that they focus on treating drug addiction and the other issues that often come with it gives them a somewhat different mindset than other prisons and it encourages a focus on continuity of care. Plus, the drug treatment facilities often have better resources than other facilities.

A man who likes a challenge, Maki admits to being "intrigued" by the "messiness" of the whole situation. He takes the DOC at their word when they say the testing program will be implemented in the spring. While it is just a first step in the right direction, in a system where things are so dysfunctional, he says, "Small victories mean a lot and even small changes can be really powerful." **PA**



COMPLERA (emtricitabine/rilpivirine/tenofovir disoproxil fumarate) is a prescription medicine used as a complete single-tablet regimen to treat HIV-1 in adults who have never taken HIV medicines before. COMPLERA does not cure HIV or AIDS or help prevent passing HIV to others.

The  one for me

Patient model. Pill shown is not actual size.

INDICATION

COMPLERA® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg) is a prescription HIV medicine that contains 3 medicines, EMTRIVA® (emtricitabine), EDURANT™ (rilpivirine), and VIREAD® (tenofovir disoproxil fumarate) combined in one pill. COMPLERA is used as a complete single-tablet regimen to treat HIV-1 infection in adults (age 18 and older) who have never taken HIV medicines before.

COMPLERA does not cure HIV and has not been shown to prevent passing HIV to others. It is important to always practice safer sex, use latex or polyurethane condoms to lower the chance of sexual contact with any body fluids, and to never re-use or share needles. **Do not stop taking COMPLERA unless directed by your healthcare provider. See your healthcare provider regularly.**

IMPORTANT SAFETY INFORMATION

Contact your healthcare provider right away if you get the following side effects or conditions while taking COMPLERA:

- Nausea, vomiting, unusual muscle pain, and/or weakness. These may be signs of a buildup of acid in the blood (lactic acidosis), which is a serious medical condition
- Light-colored stools, dark-colored urine, and/or if your skin or the whites of your eyes turn yellow. These may be signs of serious liver problems (hepatotoxicity), with liver enlargement (hepatomegaly), and fat in the liver (steatosis)
- If you have HIV-1 and hepatitis B virus (HBV), your liver disease may suddenly get worse if you stop taking COMPLERA. Do not stop taking COMPLERA without first talking to your healthcare provider. Your healthcare provider will monitor your condition

COMPLERA may affect the way other medicines work, and other medicines may affect how COMPLERA works, and may cause serious side effects.

Do not take COMPLERA if you are taking the following medicines:

- other HIV medicines (COMPLERA provides a complete treatment for HIV infection.)
- the anti-seizure medicines carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol-XR®, Teril®, Eptol®), oxcarbazepine (Trileptal®), phenobarbital (Luminal®), phenytoin (Dilantin®, Dilantin-125®, Phenytek®)
- the anti-tuberculosis medicines rifabutin (Mycobutin), rifampin (Rifater®, Rifamate®, Rimactane®, Rifadin®) and rifapentine (Priftin®)
- a proton pump inhibitor medicine for certain stomach or intestinal problems, including esomeprazole (Nexium®, Vimovo®), lansoprazole (Prevacid®), omeprazole (Prilosec®), pantoprazole sodium (Protonix®), rabeprazole (Aciphex®)
- more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate
- St. John's wort (*Hypericum perforatum*)
- other medicines that contain tenofovir (VIREAD®, TRUVADA®, ATRIPLA®)
- other medicines that contain emtricitabine or lamivudine (EMTRIVA®, Combivir®, Epivir® or Epivir-HBV®, Epzicom®, Trizivir®)
- rilpivirine (Eduvant™)
- adefovir (HEPSERA®)

In addition, also tell your healthcare provider if you take:

- an antacid medicine that contains aluminum, magnesium hydroxide, or calcium carbonate. Take antacids at least 2 hours before or at least 4 hours after you take COMPLERA
- a histamine-2 blocker medicine, including famotidine (Pepcid®), cimetidine (Tagamet®), nizatidine (Axid®), or ranitidine hydrochloride (Zantac®). Take these medicines at least 12 hours before or at least 4 hours after you take COMPLERA
- the antibiotic medicines clarithromycin (Biaxin®), erythromycin (E-Mycin®, Eryc®, Ery-Tab®, PCE®, Pediazole®, Ilosone®), and troleandomycin (TAO®)
- an antifungal medicine by mouth, including fluconazole (Diflucan®), itraconazole (Sporanox®), ketoconazole (Nizoral®), posaconazole (Noxafil®), voriconazole (Vfend®)
- methadone (Dolophine®)

This list of medicines is not complete. Discuss with your healthcare provider all prescription and nonprescription medicines, vitamins, or herbal supplements you are taking or plan to take.

Save up to
\$200
per month

You may be able to save on the co-pay for your COMPLERA prescription with a Gilead HIV Co-pay Assistance Card.

Call 1-877-505-6986 for more information or visit www.COMPLERA.com.*



COMPLERA. A complete HIV treatment in only 1 pill a day.

Ask your healthcare provider if it's the **one** for you.

Before taking COMPLERA, tell your healthcare provider if you:

- have **liver problems**, including hepatitis B or C virus infection
- have **kidney problems**
- have ever had a **mental health problem**
- have **bone problems**
- are **pregnant or plan to become pregnant**. It is not known if COMPLERA can harm your unborn child
- are breastfeeding; **women with HIV should not breast-feed** because they can pass HIV through their milk to the baby

Contact your healthcare provider right away if you experience any of the following serious or common side effects:

Serious side effects associated with COMPLERA:

- **New or worse kidney problems** can happen in some people who take COMPLERA. If you have had kidney problems in the past or take other medicines that can cause kidney problems, your healthcare provider may need to do blood tests to check your kidneys during your treatment with COMPLERA
- **Depression or mood changes** can happen in some people who take COMPLERA. Tell your healthcare provider right away if you have any of the following symptoms: feeling sad or hopeless, feeling anxious or restless, or if you have thoughts of hurting yourself (suicide) or have tried to hurt yourself
- **Bone problems** can happen in some people who take COMPLERA. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do additional tests to check your bones
- **Changes in body fat** can happen in people taking HIV medicine. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long-term health effect of these conditions are not known
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider if you start having new symptoms after starting your HIV medicine

Common side effects associated with COMPLERA:

- trouble sleeping (insomnia), abnormal dreams, headache, dizziness, diarrhea, nausea, rash, tiredness, and depression

Other side effects associated with COMPLERA:

- vomiting, stomach pain or discomfort, skin discoloration (small spots or freckles), and pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of COMPLERA. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Take COMPLERA exactly as your healthcare provider tells you to take it

- **Always take COMPLERA with a meal.** Taking COMPLERA with a meal is important to help get the right amount of medicine in your body. A protein drink does not replace a meal
- **Stay under the care of your healthcare provider during treatment with COMPLERA and see your healthcare provider regularly**

Please see Patient Information for COMPLERA on the following pages.

*The co-pay program covers up to \$200 per month for 1 year from card activation or until the card expires, up to \$2400 in a calendar year. The program is subject to change or cancellation at any time.



COMPLERA[®]
emtricitabine 200mg/rilpivirine 25mg/
tenofovir disoproxil fumarate 300mg tablets

Learn more at www.COMPLERA.com

FDA-Approved Patient Labeling

Patient Information

COMPLERA® (kom-PLEH-rah)

(emtricitabine, rilpivirine and tenofovir disoproxil fumarate) Tablets

Important: Ask your doctor or pharmacist about medicines that should not be taken with COMPLERA. For more information, see the section “What should I tell my healthcare provider before taking COMPLERA?”

Read this Patient Information before you start taking COMPLERA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about COMPLERA?

COMPLERA can cause serious side effects, including:

1. Build-up of an acid in your blood (lactic acidosis). Lactic acidosis can happen in some people who take COMPLERA or similar (nucleoside analogs) medicines. **Lactic acidosis** is a serious medical emergency that can lead to death.

Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. **Call your healthcare provider right away if you get any of the following symptoms which could be signs of lactic acidosis:**

- feeling very weak or tired
- have unusual (not normal) muscle pain
- have trouble breathing
- have stomach pain with
 - nausea (feel sick to your stomach)
 - vomiting
- feel cold, especially in your arms and legs
- feel dizzy or lightheaded
- have a fast or irregular heartbeat

2. Severe liver problems. Severe liver problems can happen in people who take COMPLERA or similar medicines. In some cases these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis) when you take COMPLERA.

Call your healthcare provider right away if you have any of the following symptoms of liver problems:

- your skin or the white part of your eyes turns yellow (jaundice).
- dark “tea-colored” urine
- light-colored bowel movements (stools)
- loss of appetite for several days or longer
- nausea
- stomach pain

You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking COMPLERA or a similar medicine containing nucleoside analogs for a long time.

3. Worsening of Hepatitis B infection. If you also have hepatitis B virus (HBV) infection and you stop taking COMPLERA, your HBV infection may become worse (flare-up). A “flare-up” is when your HBV infection suddenly returns in a worse way than before. COMPLERA is not approved for the treatment of HBV, so you must discuss your HBV therapy with your healthcare provider.

- Do not let your COMPLERA run out. Refill your prescription or talk to your healthcare provider before your COMPLERA is all gone.
- Do not stop taking COMPLERA without first talking to your healthcare provider.
- If you stop taking COMPLERA, your healthcare provider will need to check your health often and do regular blood tests to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking COMPLERA.

What is COMPLERA?

COMPLERA is a prescription HIV (Human Immunodeficiency Virus) medicine that:

- is used to treat HIV-1 in adults who have **never** taken HIV medicines before. HIV is the virus that causes AIDS (Acquired Immunodeficiency Syndrome).
- contains 3 medicines, (rilpivirine, emtricitabine, tenofovir disoproxil fumarate) combined in one tablet. EMTRIVA and VIREAD are HIV-1 (human immunodeficiency virus) nucleoside analog reverse transcriptase inhibitors (NRTIs) and EDURANT is an HIV-1 non-nucleoside analog reverse transcriptase inhibitor (NNRTI).

It is not known if COMPLERA is safe and effective in children under the age of 18 years.

COMPLERA may help:

- Reduce the amount of HIV in your blood. This is called your “viral load”.
- Increase the number of white blood cells called CD4+ (T) cells that help fight off other infections.

Reducing the amount of HIV and increasing the CD4+ (T) cell count may improve your immune system. This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).

COMPLERA does not cure HIV infections or AIDS.

- Always practice safer sex.
- Use latex or polyurethane condoms to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.
- Never re-use or share needles.

Ask your healthcare provider if you have any questions about how to prevent passing HIV to other people.

Who should not take COMPLERA?

- Do not take COMPLERA if your HIV infection has been previously treated with HIV medicines.
- **Do not take COMPLERA if you are taking certain other medicines.** For more information about medicines that must not be taken with COMPLERA, see “What should I tell my healthcare provider before taking COMPLERA?”

What should I tell my healthcare provider before taking COMPLERA?

Before you take COMPLERA, tell your healthcare provider if you:

- have liver problems, including hepatitis B or C virus infection
- have kidney problems
- have ever had a mental health problem
- have bone problems
- are pregnant or plan to become pregnant. It is not known if COMPLERA can harm your unborn child
- **Pregnancy Registry.** There is a pregnancy registry for women who take antiviral medicines during pregnancy. Its purpose is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breast-feeding or plan to breast-feed. The Centers for Disease Control and Prevention recommends that mothers with HIV not breastfeed because they can pass the HIV through their milk to the baby. It is not known if COMPLERA can pass through your breast milk and harm your baby. Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

COMPLERA may affect the way other medicines work, and other medicines may affect how COMPLERA works, and may cause serious side effects. If you take certain medicines with COMPLERA, the amount of COMPLERA in your body may be too low and it may not work to help control your HIV infection. The HIV virus in your body may become resistant to COMPLERA or other HIV medicines that are like it.

Do not take COMPLERA if you also take these medicines:

- COMPLERA provides a complete treatment for HIV infection. Do not take other HIV medicines with COMPLERA.
- the anti-seizure medicines carbamazepine (CARBATROL®, EQUETRO®, TEGRETOL®, TEGRETOL-XR®, TERIL®, EPITOL®), oxcarbazepine (TRILEPTAL®), phenobarbital (LUMINAL®), phenytoin (DILANTIN®, DILANTIN-125®, PHENYTEK®)
- the anti-tuberculosis medicines rifabutin (MYCOBUTIN®), rifampin (RIFATER®, RIFAMATE®, RIMACTANE®, RIFADIN®) and rifapentine (PRIFTIN®)
- a proton pump inhibitor medicine for certain stomach or intestinal problems, including esomeprazole (NEXIUM®, VIMOVO®), lansoprazole (PREVACID®), omeprazole (PRILOSEC®), pantoprazole sodium (PROTONIX®), rabeprazole (ACIPHEX®)
- more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate
- St. John's wort (*Hypericum perforatum*)

If you are taking COMPLERA, you should not take:

- other medicines that contain tenofovir (VIREAD®, TRUVADA®, ATRIPLA®)
- other medicines that contain emtricitabine or lamivudine (EMTRIVA®, COMBIVIR®, EPIVIR® or EPIVIR-HBV®, EPZICOM®, TRIZIVIR®)
- rilpivirine (EDURANT™)
- adefovir (HEPSERA®)

Also tell your healthcare provider if you take:

- an antacid medicine that contains aluminum, magnesium hydroxide, or calcium carbonate. Take antacids at least 2 hours before or at least 4 hours after you take COMPLERA.
- a histamine-2 blocker medicine, including famotidine (PEPCID®), cimetidine (TAGAMET®), nizatidine (AXID®), or ranitidine hydrochloride (ZANTAC®). Take these medicines at least 12 hours before or at least 4 hours after you take COMPLERA.
- the antibiotic medicines clarithromycin (BIAXIN®), erythromycin (E-MYCIN®, ERYC®, ERY-TAB®, PCE®, PEDIAZOLE®, ILOSONE®), and troleandomycin (TAO®)
- an antifungal medicine by mouth, including fluconazole (DIFLUCAN®), itraconazole (SPORANOX®), ketoconazole (NIZORAL®), posaconazole (NOXAFIL®), voriconazole (VFEND®)
- methadone (DOLOPHINE®)

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. Your healthcare provider and your pharmacist can tell you if you can take these medicines with COMPLERA. Do not start any new medicines while you are taking COMPLERA without first talking with your healthcare provider or pharmacist. You can ask your healthcare provider or pharmacist for a list of medicines that can interact with COMPLERA.

How should I take COMPLERA?

- **Stay under the care of your healthcare provider during treatment with COMPLERA.**
- **Take COMPLERA exactly as your healthcare provider tells you to take it.**
- **Always take COMPLERA with a meal.** Taking COMPLERA with a meal is important to help get the right amount of medicine in your body. A protein drink does not replace a meal.
- Do not change your dose or stop taking COMPLERA without first talking with your healthcare provider. See your healthcare provider regularly while taking COMPLERA.
- If you miss a dose of COMPLERA within 12 hours of the time you usually take it, take your dose of COMPLERA with a meal as soon as possible. Then, take your next dose of COMPLERA at the regularly scheduled time. If you miss a dose of COMPLERA by more than 12 hours of the time you usually take it, wait and then take the next dose of COMPLERA at the regularly scheduled time.
- Do not take more than your prescribed dose to make up for a missed dose.
- When your COMPLERA supply starts to run low, get more from your healthcare provider or pharmacy. It is very important not to run out of COMPLERA. The amount of virus in your blood may increase if the medicine is stopped for even a short time.
- If you take too much COMPLERA, contact your local poison control center or go to the nearest hospital emergency room right away.

What are the possible side effects of COMPLERA?

COMPLERA may cause the following serious side effects, including:

- **See “What is the most important information I should know about COMPLERA?”**
- **New or worse kidney problems** can happen in some people who take COMPLERA. If you have had kidney problems in the past or take other medicines that can cause kidney problems, your healthcare provider may need to do blood tests to check your kidneys during your treatment with COMPLERA.
- **Depression or mood changes. Tell your healthcare provider right away if you have any of the following symptoms:**
 - feeling sad or hopeless
 - feeling anxious or restless
 - have thoughts of hurting yourself (suicide) or have tried to hurt yourself
- **Bone problems** can happen in some people who take COMPLERA. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do additional tests to check your bones.
- **Changes in body fat** can happen in people taking HIV medicine. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long term health effect of these conditions are not known.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider if you start having new symptoms after starting your HIV medicine.

The most common side effects of COMPLERA include:

- trouble sleeping (insomnia)
- abnormal dreams
- headache
- dizziness
- diarrhea
- nausea
- rash
- tiredness
- depression

Additional common side effects include:

- vomiting
- stomach pain or discomfort
- skin discoloration (small spots or freckles)
- pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of COMPLERA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 (1-800-332-1088).

How do I store COMPLERA?

- Store COMPLERA at room temperature 77 °F (25 °C).
- Keep COMPLERA in its original container and keep the container tightly closed.
- Do not use COMPLERA if the seal over the bottle opening is broken or missing.

Keep COMPLERA and all other medicines out of reach of children.

General information about COMPLERA:

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use COMPLERA for a condition for which it was not prescribed. Do not give COMPLERA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about COMPLERA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about COMPLERA that is written for health professionals. For more information, call (1-800-445-3235) or go to www.COMPLERA.com.

What are the ingredients of COMPLERA?

Active ingredients: emtricitabine, rilpivirine hydrochloride, and tenofovir disoproxil fumarate

Inactive ingredients: pregelatinized starch, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, povidone, polysorbate 20. The tablet film coating contains polyethylene glycol, hypromellose, lactose monohydrate, triacetin, titanium dioxide, iron oxide red, FD&C Blue #2 aluminum lake, FD&C Yellow #6 aluminum lake.

This Patient Information has been approved by the U.S. Food and Drug Administration Manufactured and distributed by:

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Foster City, CA 94404

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FEMALE TROUBLE

Studies look at the factors that lead women to HIV and incarceration

BY CLAIRE FAREL, MD, MPH



“WELL, I’M 36 YEARS OLD, I’M AN AFRICAN AMERICAN WOMAN in prison, I’m HIV-positive, and my favorite color is purple.”

For the past year I have been conducting a study of women like this one, interviewing them about their lives and their risk for HIV. My research has me focused on risk—which is substantial. According to the latest report from the CDC, in 2009 one in every 139 women in the U.S. will be diagnosed with HIV in her lifetime, with numbers jumping to one in 32 African American women.¹ But I was losing sight of the fact that these were real people with families and dreams and, yes, favorite colors.

Just because I was thinking about HIV did not mean that they were. Women in prison have high rates of poverty, mental illness, histories of physical and sexual abuse, substance abuse, and lack of social support. It can be a disheartening setting for those with an eye toward public health but also a galvanizing one. Where I work in North Carolina, the prevalence of HIV

among incarcerated African American women has been twice that of free African American women for years. What makes being in prison so risky?

Most women in prison are not there for a life sentence—they do their time, often for a financial or drug-related crime, and return to life outside bars, typically within a year. This is where real life comes in: money, food, sex, families, violence, mental illness, and the temptation to return to whatever activities led to the prison sentence. As one woman told me, “It’s there. It’s always there.” Too often this endangers a released woman’s health, either through neglect of her own HIV care or, in the case of an HIV-negative woman, substance abuse and sex that put her at risk of contracting HIV.

When health care providers think about preventing HIV in high-risk women, we think about sex being exchanged for money,

drugs, food, housing, or survival, or “transactional” sex. It is a logical target, as women who have been in prison have a higher rate of transactional sex and may be more likely to rely on it again. Transactional sex is an important risk factor for HIV in itself and in the vulnerability it conveys—a woman having sex for survival may not be able to negotiate condom use or other safer-sex measures. She may have an increased number of partners. Many of the women in our study who reported a history of transactional sex knew they were putting themselves at risk. Many of them had been tested for HIV in the past. But what about women who don’t see themselves as at risk? What about women who trust their partners, or assume their partners are HIV-negative, or who think this is a disease that affects other people? This is the more insidious problem. If something about being in prison, a combination of factors in a woman’s life that led her to that point, increases HIV risk, this represents a key opportunity for testing, prevention, and change.

Several studies have looked at the practice of “opt-out” HIV testing, or testing that is performed unless a person specifically declines, among men and women entering jail or prison. The findings on jailed populations found that, in 2007, the majority of persons “opting in” to HIV testing who tested HIV-positive on jail entry were not previously known to be HIV-positive. Of these, the percentage of women who were diagnosed HIV-positive for the first time

Another large study from the HIV Prevention Trials Network (HPTN), called HPTN 064 or the ISIS study, looked at women living in areas with a high prevalence of poverty and HIV in the Northeast and Southeast U.S. Most women were African American or Hispanic. The rate of new HIV infection was found to be five times higher than the national average for African American women, comparable to rates in some countries in Sub-Saharan

by a number of other factors, including mental illness and poor access to health care. The prison system in our state tries to offer a range of resources to women about to face this turbulent time: safer sex education, mental health counseling, and, if the period of incarceration is long enough, sometimes substance abuse treatment, GED preparation, or job training. But with relatively short prison sentences, the threat of budget cuts, and a population with an

5X THE RATE OF NEW HIV INFECTION WAS FOUND TO BE FIVE TIMES HIGHER THAN THE NATIONAL AVERAGE FOR AFRICAN AMERICAN WOMEN, COMPARABLE TO RATES IN SOME COUNTRIES IN SUB-SAHARAN AFRICA.

when entering jail was almost twice that of men. Included in the highest-risk groups for a new HIV diagnosis were individuals from the southern U.S., African Americans, women, and people between the ages of 40 and 49. This study also noted that 30% of newly-diagnosed men and women identified themselves as at “no risk” or reported only “low-risk” sexual partnerships. Importantly, these numbers do not include jailed men and women who “opt out,” many of whom were already known to be HIV-positive and didn’t want to go through another test.² Jail stays are usually shorter than prison stays and may represent an abbreviated opportunity for public health intervention if people are released quickly without going to prison. Another recent study compared the practice of “opt-in” to “opt-out” HIV testing among people entering prison and found that there was a low rate of previously undetected HIV. The people who were HIV-positive tended to know they were positive entering prison, unlike the earlier study of jailed men and women.³

Entering prison is a memorable and defining period, one of forced sobriety and guaranteed food and shelter but accompanied by a host of other burdens, stressors, and painful reminders. Amidst this chaos, these men and women may not be experiencing the wake-up call that an HIV test represents for many outside the prison walls. We may not be catching new cases at the time they enter prison, but that does not change lifetime HIV risk for many and for women in particular.

Africa. The same study also looked at these women and their male partners and found that in many of these partnerships, one or both partners had never been tested for HIV. The results of the study’s HIV testing found more than five times as many serodiscordant (when one partner is HIV-positive and the other is HIV-negative) partnerships than were reported by study participants.^{4,5} Transactional sex is risky, but sometimes a partnership is too.

What does this tell us about African American women in prison and their lifetime risk of HIV? Quite a bit. Many of these women are returning to the communities studied in the ISIS study. Most of these women get HIV from male partners—intravenous drug use is less common in the Southeast U.S.—in communities with high rates of both HIV and incarceration like the ones in the ISIS study. The majority of men and women in prison in North Carolina are African American, as are the majority of those in prison who are HIV-positive. Incarceration and HIV are dual epidemics that, in our state, feed off crack cocaine, poverty, and destabilized relationships. Repeat incarcerations are the norm. This is the “real life” stuff that the women in my study face when they leave prison.^{6,7}

Other recent studies have underscored the high-risk period following release and shown a greatly increased risk of death in the few weeks following prison release. This risk remained increased for years following release.^{8,9} Living a healthy life as an HIV-positive person may not be in the cards for our patients. Their risk of death is increased

overwhelming range of needs, we can always do more to help keep women who are being released from prison healthy.

I am asked all the time why people don’t just use condoms and why women don’t insist on them. If their lifetime risk of HIV or another sexually transmitted infection is so high, why don’t they? These are real women in situations that are all too common. None of them is clueless about the fact that a condom may protect her, but the condom question is much more knotty. A history of sexual and/or physical abuse is very common and, for some women, speaking up may not be an option. Many of these women view their relationships as committed ones, ones in which they choose to forgo a condom as an indication of trust or deference to a partner’s preference. Maybe they hope to become pregnant. Maybe they don’t feel comfortable negotiating condom use, or think that HIV is something that happens to other people. They are complicated people, with complicated lives and favorite colors, and it is clear that we can do better in helping them lead the healthy lives they deserve. **PA**

FOR REFERENCES,
GO TO **POSITIVELYAWARE.COM**

CLAIRE FAREL, MD, MPH, is an Infectious Diseases physician and HIV clinical researcher at the University of North Carolina. Her research interests lie in the intersection of incarceration and HIV risk, especially among women.

DISCONNECTED.

Incarceration cuts you off from your social network—and HIV thrives on that

BY MARIA KHAN, PhD AND MATTHEW EPPERSON, PhD

MOST PEOPLE ARE NOT SURPRISED TO LEARN THAT HIV infections cluster in jail and prison inmates. At any given time, there are over 2.2 million adults in U.S. jails and prisons, and one of every seven HIV-infected Americans are released from these facilities each year.¹ Correctional facilities are holding places for those among the most economically and socially disadvantaged in the U.S.

These populations are disproportionately affected by adverse life circumstances and behaviors, such as drug use, that drive HIV risk. However, the process of incarceration itself may also contribute to infection

transmission.

Having a history of incarceration or having an intimate partner who has been incarcerated are correlates of HIV risk behaviors and sexually transmitted infection, independent of important factors such as poverty and substance use.²⁻⁷ There is emerging evidence to suggest that incarceration may lead to HIV risk because incarceration disrupts social and sexual networks, and HIV thrives on network disruption.

SEPARATION

Because incarceration removes an individual from society, it is expected that ties between offenders and members of their networks will be weakened. This can be a positive event for the offender if ties in the community were negative influences. For example, some inmates are wary of

returning home after incarceration for fear of again encountering family members, friends, and acquaintances who were part of a lifestyle that led to the incarceration, such as one characterized by drug use or trade.⁸

However, one unintended effect of incarceration is to weaken and, in some cases, permanently fracture ties to committed partners, family members, and friends who are positive influences and who provide important sources of social support. Losing a committed partner, in particular, has potential consequences for an inmate's HIV risk. Those who are in committed partnerships are less likely to engage in multiple sexual partnerships.^{9,10} Consequently, the destabilization and dissolution of committed relationships that occurs during incarceration could promote HIV risk-taking upon release.

RELATIONSHIP DAMAGE

Many inmates are in committed relationships when they leave for jail or prison, and many of these relationships end during the incarceration.¹¹⁻¹⁵ We interviewed a sample of HIV-positive men incarcerated in

North Carolina prison facilities to learn more about the committed relationships of prison inmates.¹⁴

Among the inmates, 52% reported having a primary partner at the time of incarceration. The inmates' lives had been highly interconnected with those of their partners. The majority of inmates reported that prior to the incarceration they had lived together with their partners (85%), had seen their partners daily or nearly daily (88%), and had been in long-term relationships with them, for six months or longer (64%) or on and off for a number of years (30%). Over half reported that their partners in the community had relied on them financially. Inmates who were in committed relationships prior to the incarceration reported much lower levels of pre-incarceration multiple partnerships and sex trade than those who did not have committed partners, highlighting the protective effect of these partnerships. Over half of inmates' relationships had ended during the incarceration. These findings suggested to us that those who have lost a primary partner during incarceration may experience heightened levels of sexual risk-taking as they re-enter the community.

We also interviewed a number of individuals at social venues in a North Carolina city to assess how commonly people in the community reported having been in a relationship that was interrupted by incarceration.¹⁵ The results told the same story—incarceration-related relationship disruption and dissolution was common.

Among men who had ever been incarcerated for one month or longer, 43% had a marital or non-marital primary partner at the time of the longest prior

52%

AMONG INMATES, 52% REPORTED HAVING A PRIMARY PARTNER. OVER HALF OF THOSE RELATIONSHIPS ENDED DURING INCARCERATION.

sentence. Among women, 22% had ever had a primary partner who had been incarcerated for one month or longer. Of those who were in a relationship that was disrupted by incarceration, more than 40% of men and 30% of women reported the relationship ended during the incarceration. Further, those who had lost a partner during incarceration were twice as likely to report recent multiple partnerships as those who remained with their committed partner during the incarceration.

It's not surprising that relationships end during incarceration, given the barriers to maintaining ties during detention.

Incarceration physically divides prisoners from their intimate partners, making maintenance of the relationship difficult.

Partners may speak infrequently by telephone, as calling is restricted by prison regulations, is monitored for security purposes, and is expensive.¹⁶ Likewise, logistical and financial obstacles can prevent visitation, especially because many inmates are held far from their home communities.¹⁶ Even when visitation occurs, physical contact is often prohibited and lack of privacy prevents partners from maintaining intimacy during the incarceration.¹⁷ For example, in many states, conjugal visits are not permitted. Even written communication is affected, as prisons screen incoming letters for security reasons. Physical separation during incarceration can lead to loneliness and emotional division which puts considerable stress on relationships during incarceration.¹⁸⁻²⁰

CONSEQUENCES OF INSTABILITY

Loss of a partner during incarceration may

contribute to HIV risk during re-entry in a number of ways. First, if an inmate loses a stable partner during incarceration, upon release, he may seek new partners and potentially engage in multiple partnerships and/or buy sex for money or drugs to meet needs for sexual and emotional companionship. In addition, losing a partner during incarceration may lead to distress and mental health problems. Specifically, incarceration weakens social cohesion and support networks when an individual most needs them—during the stressful periods of incarceration and re-entry.²¹⁻⁴⁵ An inmate may experience stress during the incarceration due to loss of freedom, isolation, and stigma.¹⁸ The period of re-entry is also highly stressful, because released inmates must negotiate a place to live, employment, re-establishing family ties, and returning to high-risk situations.^{16,19} Social support may buffer the stress associated with incarceration and re-entry by enabling the inmate to cope, thereby reducing negative emotional and behavioral responses.⁴⁶ However, losing a partner may lead to distress and diminish mental health.^{47,48} In turn, the former inmate may self-medicate with drugs or sex.

While incarceration disrupts existing networks, it also helps form new ones and may lead to involvement in high-risk social and sexual networks. There is evidence that incarceration introduces inmates into high-risk networks characterized by high levels of drug trade and use (i.e., gangs).^{49,50} The networks may have high levels of sexual risk-taking and infection, thereby leading to increased risk of sex with an infected partner.⁵¹⁻⁵³ Hence, by destabilizing existing networks, incarceration may influence HIV risk not only by increasing the numbers of partners a former inmate has but also by changing the types of partners a former inmate may have sex with.

Finally, when offenders leave for jail or prison, they leave behind loved ones.

During an incarceration, the prisoner's partner may seek other partners to fill an emotional or financial void.¹⁸ We have found that incarceration is associated with elevated levels of HIV risk behaviors not only of the offender but also of their sexual partners.²⁻⁷

Given the high rates of incarceration in many U.S. communities, the influence of incarceration on inmates and their families is high. The fracturing of networks that occurs during incarceration appears to influence HIV risk-taking. For these reasons, it is critical to promote efforts which will diminish the disruptive effects of incarceration on healthy relationships, and to understand the public health implications of incarceration-related relationship disruption. **PA**

FOR REFERENCES,
GO TO POSITIVELYAWARE.COM

MARIA R. KHAN is an Assistant Professor in the Department of Epidemiology and Biostatistics at the University of Maryland College Park School of Public Health. Her recent work has focused on investigating STI/HIV among those with a history of incarceration. She was recently funded by the National Institute on Drug Abuse to study how incarceration-related dissolution of relationships influences the HIV risk of African American men released from prison.

MATTHEW W. EPPERSON is an Assistant Professor in the School of Social Service Administration at The University of Chicago. His primary focus is intervention research on co-occurring problems of HIV, substance abuse, mental illness, and criminal justice involvement. Before earning his PhD in social work from Columbia University, Dr. Epperson spent 15 years as a social worker in behavioral health and criminal justice settings.



PROSECUTING HIV: TAKE THE TEST—AND RISK ARREST?

BY SEAN STRUB

IMAGINE MEETING SOMEONE ONLINE, HAVING A NICE CHAT, and then deciding to hook up. You have HIV, but you're adherent to your meds and have had an undetectable viral load for years. You and your sexual partner use a condom. Sometime later, the partner learns you have HIV and presses charges against you for failing to disclose your HIV status prior to sex.

Your life is suddenly turned upside down, with your name and picture splashed across the media. You are called an "AIDS Monster." You and your family and friends feel humiliated and embarrassed. Your employment, housing, and relationships may be put in jeopardy and you need to find tens of thousands of

dollars for legal fees for the impending prosecution.

If convicted, you face decades in prison, lifetime registration as a sex offender, and other restrictions; if acquitted, your life is still never the same, because you will always be known as the "AIDS Monster."

Think about that for a moment:

Consenting adults. No intent to harm. Undetectable viral load. A condom was used. No HIV transmission. Twenty-five years in prison. This isn't hypothetical; it is exactly what happened in a recent case in Iowa. In fact, as of July 2009 Iowa had convicted nearly 1% of all Iowans with HIV under their HIV-specific criminal statute.

There have been hundreds of prosecutions for HIV crimes in the U.S., all over the country. As of today, 36 states and territories have HIV-specific statutes, but a targeted law isn't required to prosecute an HIV crime. These prosecutions usually have little bearing on the actual level of risk of HIV transmission, ignoring factors like whether a condom was used or the viral load of the person with HIV.

It's important that people with HIV



and their advocates understand the issues at stake, the risk they present for people with HIV, and how they may undermine public health strategies to reduce HIV transmission. The issue is complicated, especially since the public is generally supportive of criminal prosecution of people with HIV who do not disclose their HIV status to a partner before sex. One study, from the University of Minnesota, showed that about two-thirds of gay men supported such prosecutions; among very young gay men, it approached 80%.

Even among gay men with HIV, it was nearly

40%. Outside of gay men, it is likely that support for these statutes is even higher.

Criminalization supporters often believe these statutes are effective in reducing HIV transmission, but there are no data to support this; in fact, there is a growing body of research demonstrating that they do not reduce HIV transmission and may even contribute to its further spread.

A VIRAL UNDERCLASS

Since the earliest days of the AIDS epidemic, stigma has been a major obstacle to effective HIV prevention and care. Even as fear of contagion from casual contact has lessened over the years, profound stigma persists. People with HIV face judgment, marginalization, discrimination, and misunderstanding about the actual risks of transmission.

Many people with HIV internalize and accept this judgment, perpetuating the perception of those with HIV as toxic, highly infectious, or dangerous to be around. This has serious adverse effects on them personally, as well as for the broader effort to combat the epidemic while protecting sexual freedoms.

Stigma discourages people at risk from accessing care—including testing for HIV—and it discourages people who know they are HIV-positive from disclosing to potential sexual partners and others. Much of this stigma is based in racism and homophobia.

Nothing drives stigma more than when government sanctions it by enshrining discriminatory practices in the law. That is what has happened with HIV, resulting in the creation of a “viral underclass” of people with rights inferior to other citizens. Stigma driven by HIV criminalization promotes illegal discrimination against people with HIV, including prohibitions on certain occupations and licensing.

After three decades of the epidemic, people with HIV continue to experience punishment, exclusion from services, and a presumption of guilt in a host of settings and for practices that are, for those who have not tested positive for HIV, unremarkable.

This is reflected perhaps most dramatically in the criminal prosecution of people who know they have HIV but are unable to prove they disclosed their status prior to sexual contact. The ostensible purpose of these statutes is to deter HIV-positive people from putting others at risk. The inherent problem with these laws is that they focus primarily on the existence of proof of disclosure, not on the nature of the exposure, the actual level of risk present, or whether HIV was transmitted. Consequently, as studies have demonstrated, they do nothing to advance their intended purpose.

THE ORIGINS OF HIV CRIMINALIZATION

The legal obligation to disclose stems, in part, from the 1990 Ryan White CARE Act. That legislation required that states demonstrate an ability to prosecute intentional HIV exposure, a recommendation from the head of President Reagan’s AIDS commission. At the time, it was widely believed that simple exposure to the virus—or having intimate contact with someone who was infected—was a “death sentence.” This requirement was dropped in the 2000 renewal of Ryan White, but the criminalization statutes it spawned remain in force.

Some states considered their existing assault and public health statutes

adequate to meet the Ryan White requirement, but many added HIV-specific laws (see map). These vary widely, both in what they punish and sentencing provisions.

In states without HIV-specific statutes, criminal law (and in one recent case, an anti-terrorism statute) has been used to prosecute people with HIV for behaviors that posed little or no risk of transmission. In these cases, HIV, or the blood, semen, or saliva of a person with HIV, is often characterized as a “deadly weapon.” Heterosexual men of color are the most likely to be prosecuted.

Typically, sentencing is vastly disproportionate to the harm caused or the level of risk present in the sexual encounter. In one Texas case, a man was sentenced to 35 years in prison for spitting at a police officer. In fact, about 25% of recent prosecutions are for behaviors like spitting or biting, which pose no measurable risk of HIV transmission. Many of the prosecutions for failing to disclose prior to sex have been of someone with an undetectable viral load and/or who used a condom, but who is still sentenced to decades in prison.

The ethical obligation of people with HIV to disclose health factors that could put sexual partners at risk was codified in the Denver Principles, the historic 1983 manifesto that launched the AIDS empowerment movement. Defining what constitutes a risk sufficiently serious to require such disclosure is where it gets tricky.

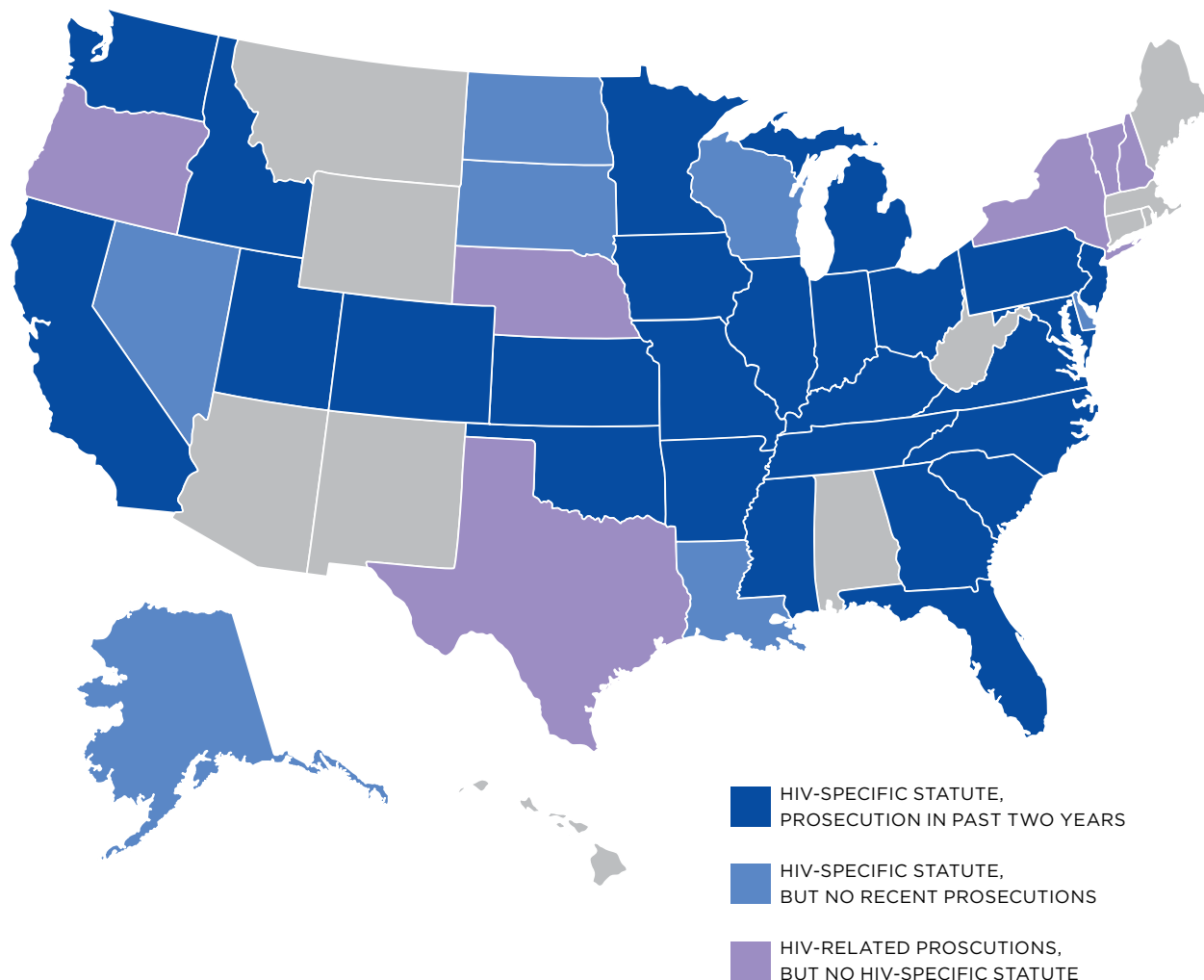
The Denver Principles also recognize sexual freedom as a fundamental human right, noting that people with HIV have a right “to as full and satisfying sexual and emotional lives as anyone else.” Fully integrating people with HIV into society, in part by allowing them to have fulfilling sexual lives without the risk of incarceration, is critical to combating the stubborn stigma that remains an enormous obstacle to preventing new HIV infections.

The fact that HIV is so linked with homosexuality and communities of color has made it easier to “punish” people with HIV—an example of how race or sexuality can be used to form policies that isolate individuals and limit their freedoms.

Ethical obligations aside, criminalizing the sexual conduct of those living with HIV is justified only when there is proof of the intent to harm another person, like

PROSECUTORIAL STATES OF AMERICA

WHERE HIV DISCLOSURE LAWS STAND IN EACH STATE



a situation where someone intentionally injected someone with HIV with a syringe or had sex with the explicit purpose of transmitting the virus. Existing state and federal criminal laws are adequate to deal with these extremely rare cases. Prosecutions in these instances should focus on the proof of intent to harm, the degree of risk present, and the resulting injury.

Other cases—including some that have received widespread media attention—involve people with mental health issues who are recklessly and repeatedly putting others at risk. Those situations should be handled through existing public health policies for people with mental health issues.

Those who support criminal prosecution of people with HIV who fail to notify partners in advance of intimate contact

must consider whether they also support similar prosecutions of those with hepatitis viruses, herpes, viruses like CMV, EBV, HPV, and other pathogens that can be transmitted sexually.

PROSECUTIONS

Highly publicized HIV criminalization cases are frequently driven by inaccurate and inflammatory media coverage and sometimes by politically ambitious prosecutors. They feed into the public's ignorance and anxiety about HIV, reinforce negative stereotypes about people with HIV, and send conflicting messages about the real risks of HIV transmission.

They depict people with HIV as dangerous infectors who must be controlled and regulated, making it more difficult to create

an environment that encourages people to get tested and disclose their status.

The Iowa case mentioned earlier provides a sobering illustration. The person with HIV who was charged with failing to disclose his status to a sexual partner was a 34-year-old gay man. He met a male partner online and went to his house. He was on HIV medication, had an undetectable viral load, and used a condom when anally penetrating his partner, so the risk of transmission was negligible to nonexistent.

When the partner heard the man had HIV, he went to the county prosecutor and pressed charges. The person with HIV was convicted and sentenced to 25 years in prison. Fortunately, advocates were successful in getting the sentencing reviewed, and after serving eleven months he was released

on five years probation. But he must register as a sex offender for the rest of his life, may not be around his nieces or nephews without adult supervision, is subject to wearing an ankle-monitoring bracelet, and cannot leave his home county without permission from the court. Iowa's statute is particularly broad—in theory, it could cause a person with HIV who kissed someone without disclosing to spend 25 years in prison—but other states' statutes are equally as absurd. Here are some examples:

- **Texas doesn't have** an HIV-specific statute, but Willy Campbell, who was sentenced to 35 years for spitting on a police officer, was convicted of "assault with a deadly weapon" even though spit from a person with HIV doesn't infect someone, let alone kill them.
- **Gregory Smith was** within a year of his release from a New Jersey prison when he was charged with attempted murder, assault, and terrorist threats following an incident in which he allegedly bit and spat on a guard (Smith denied the charges). An additional 25 years was added to his sentence; he died of AIDS in prison.
- **In late 2009**, using laws designed to combat terrorism, Michigan charged Daniel Allen, who has HIV, with "possession of a harmful biological agent" after he was involved in an altercation with a neighbor. Prosecutors equated his HIV infection with "possession or use of a harmful device."
- **A man with HIV** in Ohio could not prove he had disclosed to his girlfriend that he was positive and was sentenced to 40 years in prison. He claims she knew he was positive and only went to a prosecutor after he stopped dating her and moved in with another woman.

These cases highlight one of the significant problems with HIV criminalization statutes: Not only do they require people

to disclose their HIV status to potential partners, but also to be able to prove it in a court of law. Imagine this line at a bar: "Let's go home and get it on. Since I have HIV, could you sign this affidavit stating that I told you that? We can stop by a notary public on the way home and get it notarized."

Yet that scenario is not so far-fetched, as more people with HIV are seeking ways to document their disclosure, either by saving text or email messages, disclosing in the presence of a third-party witness, or in some cases taking a partner with them to a doctor's appointment and asking the doctor to note the disclosure in the medical record.

Spitting poses no risk of HIV transmission. Yet in the past several years, there have been at least six convictions of people with HIV for spitting. And as a practical matter, it is the person biting, rather than the person bitten, who is at the greater risk of acquiring the virus.

Criminalization is also reflected in "pile-on" charges and more aggressive prosecution or sentencing of people with HIV charged with other crimes. In 2009, a woman with HIV in Maine who was eligible for release was sentenced to continued confinement when the judge learned that she was pregnant.

He sought to "protect" the fetus from infection by having the jail supervise the woman's treatment, also typifying how courts sometimes elevate the perceived interest of a fetus over the rights of a pregnant woman. Although legal advocates secured her release shortly thereafter, the desire of a federal judge to confine a woman with HIV to prison, despite testimony that she was engaged in appropriate prenatal care, reveals ignorance and an inclination to criminalize illness by even the most educated and privileged members of our society.

What all of the cases above have in common is that none of them resulted in transmission of HIV to another person.

A NEW STRATEGIC APPROACH

Historically, the discussion among

advocates and policy leaders concerning HIV criminalization has focused on civil liberties concerns. Yet a growing realization that HIV criminalization is also a serious public health challenge has helped propel the issue to the forefront. An important step was the recognition of the need for changing HIV criminalization statutes in President Obama's National HIV/AIDS Strategy, released this past July:

"Since it is now clear that spitting and biting do not pose significant risks for HIV transmission, many believe that it is unfair to single out people with HIV for engaging in these behaviors and [they] should be dealt with in a consistent manner without consideration of HIV status. Some laws criminalize consensual sexual activity between adults on the basis that one of the individuals is a person with HIV who failed to disclose their status to their partner. CDC data and other studies, however, tell us that intentional HIV transmission is atypical and uncommon.... [These laws] may not have the desired effect and they may make people less willing to disclose their status by making people feel at even greater risk of discrimination.... In many instances, the continued existence and enforcement of these types of laws run counter to scientific evidence about routes of HIV transmission and may undermine the public health goals of promoting HIV screening and treatment."

Early in 2011, the National Alliance of State and Territorial AIDS Directors (NASTAD) became the first major organization of public health professionals to join the effort to repeal HIV-specific criminal statutes. Their statement notes:

"HIV criminalization undercuts our most basic HIV prevention and sexual health messages, and breeds ignorance, fear, and discrimination against people living with HIV."

Advocates who focus on the serious public health ramifications of HIV criminalization can help repeal or end reliance on criminalization statutes and other criminal laws that persecute and stigmatize people with HIV. They can also help educate law enforcement, prosecutors, and the media,

STIGMA

REDUCING HIV TRANSMISSION CAN ONLY
BE ACHIEVED BY COMBATING CRIMINALIZATION,
IGNORANCE, AND THE ASSOCIATED STIGMA.

ultimately lessening HIV-related stigma and discrimination.

BAD PUBLIC HEALTH POLICY

HIV criminalization discourages people at risk from getting tested. Studies show that people with HIV who are aware of their status are more responsible in their sexual behavior than those who are unaware they have HIV. Testing is a basic tool of HIV prevention as well as an essential gateway to care.

Criminalization statutes also make it more difficult for people with HIV to disclose their status. Disclosing can be emotionally difficult, risking rejection from family and friends—often with great insult or abuse—and can jeopardize one's employment, housing, relationships, or personal safety.

Criminalization of HIV legitimizes the ignorance, homophobia, racism, and sex-phobia that fuel the inflated fears of those with HIV. It undermines efforts to prevent new HIV infections and provide access to care in many ways:

- **It undercuts** the most basic HIV and STD prevention message: that every person must take responsibility for his or her own sexual health.
- **Prosecuting the failure** to disclose values the “right” to an illusion of safety over the privacy rights of those with HIV.
- **Most new infections** are caused by sexual contact with people who are unaware they have HIV, yet only those who have taken responsibility and gotten tested are subject to prosecution.
- **Ignorance of one's** HIV status is the best defense against a “failure to disclose” prosecution, a powerful disincentive to getting tested and learning one's HIV status.
- **Young African American men** who have sex with men are among those at highest risk of acquiring HIV, yet also

among the most difficult to persuade to get tested. The prospect of prosecution for failing to disclose—especially since these prosecutions often boil down to a “he-said/he-said” or “he-said/she-said” situation—is a powerful disincentive to disclosure. “Take the test and risk arrest” is the message increasingly being heard on the streets.

RACISM AND HOMOPHOBIA

Prosecuting HIV nondisclosure but not prosecuting the failure to disclose other STDs also reflects an unconscious racism and homophobia. Human papilloma virus (HPV) provides a useful contrast. HPV causes a variety of cancers, including almost all cervical, genital, and anal cancers. Cervical cancer alone killed 4,000 women in the U.S. in 2009; every year hundreds of thousands of women in the U.S. get diagnosed with cervical dysplasia, which is caused by HPV and is a precursor to cervical cancer.

By the age of 50 more than 80% of American women will have contracted at least one strain of HPV. Yet unlike HIV, HPV is not associated with “outlaw sexuality” or with specific minority groups. HIV is associated with anal intercourse, gay men, African-Americans, and injection drug users, so racism and homophobia are inextricably linked with HIV stigma, discrimination, and criminalization.

CONCLUSION

Since the earliest days of the epidemic, stigma and ignorance have hindered an effective response to the HIV epidemic. Stigma and ignorance sanctioned in the law are its most extreme manifestation and are inherently unjust. HIV-specific criminal statutes do not slow the transmission of HIV but may facilitate its further spread. Reducing HIV transmission can be achieved only when combatting HIV criminalization and ignorance, and the associated stigma, are part of the approach.

To this end, nearly 40 HIV, human rights, public health, and other organizations founded the Positive Justice Project

(PJP) in the fall of 2010 to end government reliance on a positive HIV test result as proof of intent to harm. PJP is housed at The Center for HIV Law & Policy, a resource for leaders, attorneys, and advocates interested in HIV-related discrimination and criminalization. PJP's Resource Bank (hivlawandpolicy.org) is a comprehensive database of research, reports, court decisions, briefs, policy analyses, and other materials of importance to people with HIV.

Update: In recent weeks, there have been a number of new developments concerning criminalization. Iowa State Senator Matthew McCoy introduced legislation to amend that state's HIV statute to make it apply only in cases where there is a malicious intent to harm the other party, differentiate the penalty depending on whether or not the virus was transmitted, and remove the requirement that those convicted under the statute must be placed on the state's sex offender registry. Meanwhile, several Maryland legislators have introduced legislation to dramatically increase the penalties under their statute, from three to a maximum of 25 years. Advocates in a number of states have begun to organize to build statewide coalitions to work for reform of their statutes. **PA**

GO TO YOUTUBE.COM to watch *HIV is Not a Crime*, the short film about three people who were prosecuted for non-disclosure, including Nick Rhoades, the Iowa man sentenced to 25 years and lifetime sex offender registration.

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SEAN STRUB is executive director of The Sero Project (www.theseroproject.org), Senior Advisor to and a co-founder of the Positive Justice Project, founder of POZ.com, and co-chairs the board of directors of the Global Network of People with HIV/AIDS/North America. He has been living with HIV for more than 30 years.



ASK THE HIV SPECIALIST

JOSEPH BICK, MD, FIDSA, AAHIVS, CCHP



You have the right to treatment

Q: My brother is currently in jail, and may end up doing time in prison. I know that he was doing drugs on the street. The last time that I saw him, he had lost a lot of weight and he didn't look healthy. I am worried that he may have HIV. My brother is afraid to get tested, and I do not know what to do. Please help!

—LINDSAY

A: Thanks for advocating on behalf of your brother. He is lucky to have you!

Your brother could have HIV, though his weight loss might also be due to his drug use or he may have another medical condition that needs treatment. The only way that he will find out is by seeing a health care provider for a thorough evaluation.

Inmates of jails and prisons have a constitutional right to health care, including treatment for HIV disease. Only by knowing his HIV status can your brother get the care he needs to get healthy and stay that way. The time he spends in jail and prison is also a perfect opportunity to start getting a handle on his substance abuse. If he is not ready to stop using drugs, he can learn how to decrease his risk of picking up dangerous

infections. By doing so, your brother will have a much better chance of staying off drugs when he is released, and avoiding a return to prison.

If your brother is HIV-positive, treatment can provide him an opportunity to live a long, productive life. Unfortunately, approximately one in five Americans who are HIV-positive do not even know it. Of those who are infected, one-third are diagnosed so late that they develop a serious infection or cancer within one year. The earlier that HIV is diagnosed, the greater the chance of preventing these infections and cancers from developing. In addition, HIV treatment causes HIV-positive people to be much less infectious to their sex and needle-sharing partners.

Please encourage your brother to get a thorough evaluation that includes testing for tuberculosis, HIV, and hepatitis B and C. While in jail or prison, he will have to fill out a form requesting to see health care staff for these tests. You can also help him by checking out community resources that he can transition to when he gets released. Best of luck to you and your brother!

—JOSEPH BICK, MD

SEARCH FOR AN HIV SPECIALIST™

Finding an HIV Specialist™ is easy with AAHIVM's Referral Link: www.aahivm.org. Enter your ZIP code on the home page, and click on the "Go" button for a list of HIV Specialists™ near you.

Share your thoughts and help improve HIV education.



The American Academy of HIV Medicine is currently seeking participants in a survey to learn more about attitudes towards HIV care and treatment among both providers and people living with HIV. The study is enrolling about 250 providers and 750 patients. If you are at least 18 years old and currently being treated for HIV, participate in this web-based survey and let them know what you think.

To participate in the survey, go to <http://tinyurl.com/ceoutcomes>

It takes approximately 15 minutes to complete the survey.

The survey will ask questions that some people may find uncomfortable to answer, such as your income, education, race, and sexual practices, but you don't have to answer any questions you don't want to answer and your responses will be totally confidential. Each respondent will be identified by a unique code. You won't be identified by name in any database or publications that may result from this study. Each question is asked to help researchers learn how to improve HIV education for different groups of people. Your participation will be greatly appreciated!



CONFERENCE UPDATE

CROI 2012 SEATTLE

BY JEFF BERRY, MATT SHARP, & ENID VÁZQUEZ

Baby steps toward a cure

BY MATT SHARP

Science can seem to move along at an achingly slow pace, especially when curing HIV is the goal. Even though there has been extraordinary progress in understanding the virus and identifying targets for therapy, there is still much to learn about how HIV can be cured. One of HIV's survival mechanisms is to hide from our own immune system's response and to antiviral drugs that slow its progression. But **new research is beginning to frame HIV cure science** while we watch the developments unfold.

There were several oral sessions and posters dedicated to viral latency, eradication, and cure strategies in pre-clinical and animal studies, and some very encouraging early phase clinical trials. The *HIV Latency and Eradication: Clinical Perspectives* symposium was so popular that there were two overflow rooms for attendees that could not fit into the main session room.

Trying to understand HIV latency and attempts to activate or wake up so-called sleeper cells harboring the virus are in very early research stages. This is a critical HIV reservoir in which scientists are trying to figure ways to wake up the

CD4 memory cell so that the dormant virus can complete its replication process. Then, theoretically, antiviral therapy can move in to do its job. But there are many barriers to completely understanding this process, and uncovering safe and effective ways that may lead to a functional cure (stopping HIV without the use of long-term drugs).

Scientists must agree on the best way to measure virus inside the CD4 memory cell before and after attempts at activation. It is also difficult to find these cells with dormant HIV inside. Also, finding the best monkey model to test the latency and activation hypothesis is in progress, but access to study animals continues to be problematic.

In an elegant proof of concept clinical study from the University of North Carolina, David Margolis, MD, a leading cure researcher, showed for the first time that HIV can be purged from resting cells using one dose of an anti-cancer drug called vorinostat (known as SAHA for suberoylanilide hydroxamic acid). The drug is from a large class of drugs known as HDAC (histone deacetylase inhibitors). Histone deacetylase is an important enzyme that contributes to maintaining

latency of HIV genetic material integrated into human cells.

The UNC study looked at six HIV-positive men who had been on stable antiretroviral regimens with viral load less than 50 copies/mL (undetectable) and CD4 cell counts above 500 cells/mm³. First, CD4 cells were removed and tested to establish baseline virus levels inside the cell. Then the cells were exposed to vorinostat, and HIV RNA was measured to show whether HDAC was inhibited. The cells were compared before and after the single dose of vorinostat. There was a two-fold increase in histone deacetylation after eight hours of the dose. All six participants had a response from 1.5- to 10-fold HIV RNA increase inside the cell, showing that one dose of the study drug could activate the sleeping virus. Even though only one dose was used there were no drug-related adverse events or toxicities. "This proves for the first time that there are ways to specifically treat viral latency, the first step towards curing HIV infection," Margolis stated.

Other drugs such as pegylated interferon-alpha-2a, used as one of the backbone treatments for hepatitis C, and disulfiram (Antabuse—used for treating alcoholism) were presented at CROI with varying results. Still, the field is moving ahead as indicated by the number of positive results in pre-clinical, animal, and clinical studies presented. In time, the activation

PABLO TEBAS, MD



pathway combined with other approaches such as vaccines and immune modulators may all contribute to a functional cure. One remaining question is whether these or other approaches can target other HIV reservoirs such as the central nervous system.

Pablo Tebas, MD, showed additional data from the first zinc finger nuclease (SB-728) cohorts at UPenn and Quest/San Francisco presented at CROI and ICAAC last year. The two cohorts were immunologic responders with CD4 cells greater than 450 and immunologic non-responders with CD4 cells less than 500 who all were given one infusion of SB-728. There have been no serious adverse events except one transfusion reaction that went away after a few days. After about one year, dramatic CD4 increases were seen in both groups that investigators think was related to increases in IL-2, IL-7, and IL-15, cytokines associated with CD4 expansion. CD4:CD8



T-cell ratios normalized in the majority of participants. After infusion, SB-728 was detected in peripheral blood from 90 to 700 days thus far. The modified cells also traffic to the rectal mucosa, showing that the modified cells are reaching other important HIV reservoirs.

One remaining question was whether HIV RNA would be affected by SB-728. To show this, participants went on a treatment interruption during the trial. After increase in viral load levels, all had significant drops in virus levels before resuming ARVs again. One man who dropped to undetectable levels was found to be heterozygous for the delta 32 mutation, making him an “elite controller,” one whose HIV is controlled without ART. Because of this finding, a study has been enrolled to look at this very population to see if the antiviral effect is real. Another study is using a single infusion of a chemotherapy drug in order to make room for more expansion of the CCR5-modified CD4 cells.

AIDS treatment activists have been at the table in the latest developments in cure research since Martin Delaney stumbled upon the Timothy Brown “Berlin patient” poster several years ago. At CROI, that tradition continued in a one-day workshop organized by activists. Leading cure researchers, the FDA, the IAS (International AIDS Society), and pharmaceutical companies developing eradication molecules joined activists in a robust discussion. Issues

addressed were how to better inform the community about cure research and clinical trials, including revision of the cumbersome informed consent process. Also, the challenge researchers have in gaining access to experimental drugs from other companies for use in their experiments and the continuing problem of development of the best assays and animal models were all discussed. Sangamo, the biotech company developing zinc finger technology, is now scheduling a meeting with a few cure research activists. Investigators from UCSF, UNC, and the Fred Hutchinson Cancer Center presented programs being developed for the Martin Delaney Collaboratory. Activists are also working to create community advisory positions with this groundbreaking research.

The game changer at CROI was that cure research has reached the main stage. While no one knows how long it is going to take to find a cure for HIV, everyone agrees that a lot of work remains.

Diagnosed with HIV in 1988, **MATT SHARP**’s long history as an AIDS advocate includes belonging to ACT UP Golden Gate; directing the education programs at Test Positive Aware Network in Chicago and Project Inform in San Francisco; and helping to found the AIDS Treatment Activists Coalition. Currently, he acts as an international consultant.

Prevention study results yield more good news

BY ENID VÁZQUEZ

After two years of landmark studies, HIV prevention continued to dominate research news at CROI.

The Partners PrEP study enrolled nearly 5,000 heterosexual couples where one partner had HIV and the other didn’t. “PrEP” stands for pre-exposure prophylaxis (prevention), and is taken by HIV-negative people to prevent sexual transmission of HIV.

Final primary results from Partners PrEP showed a **67% reduction in risk of HIV infection** with Viread and a 75% reduction with Truvada (considered not to be a statistically significant difference). The two HIV medications were compared against placebo (fake pill) in couples in Kenya and Uganda.

“They worked approximately the same,” said presenter Jared Baeten, MD, MPH, of the University of Washington in Seattle, in a press conference. “This was definitive protection for people at high risk of HIV because of a known HIV-positive partner.” He added that the results were consistent no matter the viral load in the positive partner. For the HIV-negative partners who took the prevention medications, side effects included mild fatigue and nausea.

Asked about treatment as prevention (TasP), in which successful anti-HIV treatment of a positive partner has been shown to greatly reduce transmission of HIV to a negative partner, Baeten said a need for PrEP remains. Some HIV-positive individuals prefer to delay therapy, he said, but at the same time, heterosexual couples are concerned about conceiving children. Still, “we’ve been very aggressive about making sure infected partners are treated when eligible.” In some resource-poor countries, HIV-positive people are not eligible for government-sponsored antiviral treatment until their medical condition meets certain requirements, such as a CD4+ T-cell count under 200. “We can use PrEP as a bridge until a partner starts treatment,” he said.

Of the 27 individuals who seroconverted in Partners PrEP, none developed drug resistance to Viread or Truvada, the drugs studied for PrEP. The **development of drug resistance is a concern for individuals taking PrEP who become infected** because HIV treatment is heavily dependent on the use of Viread or Truvada (in wealthier countries, at least). But more and more, prevention studies with HIV



CONFERENCE UPDATE

CROI 2012 SEATTLE

BY JEFF BERRY, MATT SHARP, & ENID VÁZQUEZ

medications are showing that where they fail, it's because the drugs are not being taken as prescribed. A person's virus can develop drug resistance when medications are being taken inconsistently (missing doses).

Deborah Donnell, PhD, of the University of Washington and the Fred Hutchinson Cancer Research Center in Seattle, illustrated this issue with a Partners PrEP sub-study showing that only nine of the 27 infected individuals had any tenofovir in their blood at all at the time of seroconversion. (Tenofovir is the generic name of Viread, and it is also found in Truvada.) "Tenofovir detected in blood was highly correlated with protection from HIV infection," she said. "I think our results are clearly proof of concept that daily use of tenofovir can substantially reduce the risk of HIV infection."

Lut Van Damme, MD, of Family Health International, illustrated the same concept with the FEM-PrEP study, which disappointed HIV advocates when a daily Truvada pill failed to prevent HIV in women. However, Van Damme reported that the medication was found in blood levels of less than half of the 33 infected women who had been given it, as well as in less than half of the uninfected women in a matched control group. According to the FEM-PrEP abstract, studies will need to focus on what determines

adherence to preventative medicine in people at high risk of infection. Also of importance in this study was that the infected women perceived themselves to be at "little or no risk of HIV infection." They were actually at high risk of infection and didn't know it.

There was more welcome data on the potential problem of resistance. The CAPRISA 004 research team reported no resistance in either the blood or the genital tracts of women who became infected during the study. "This is a good news result," said Will Fischer of the Los Alamos National Laboratory. "There was only one case of high-level resistance and this was from a woman on placebo, so it was presumably a transmitted resistance [she picked up a drug-resistant virus from a sex partner]." CAPRISA 004 used a tenofovir gel applied vaginally.

"I guess this decade will be remembered as the tenofovir decade," said Linda-Gail Bekker of the University of Capetown, while co-facilitating a session on the use of HIV drugs for the prevention of sexually transmitted HIV. She noted that her research team has used tenofovir in all of its prevention studies.

Other encouraging tenofovir data: a small study from the Microbicide Trials Network with a **re-formulated tenofovir gel was found to be safe and acceptable as a rectal microbicide** used daily for seven days. A

previous formulation was safe but bothersome. The new reduced-glycerin formulation of 1% tenofovir gel is moving into a Phase 2, eight-week study.

Tenofovir and Truvada are ahead of the game now, but other HIV antivirals are also being tested for prevention. A small, early study with the new non-nucleoside rilpivirine (Edurant) was shown to penetrate vaginal and rectal tissue and fluids in an amount needed to inhibit HIV infection. Rilpivirine was used in a long-acting, injectable form in this research (used intramuscularly). The use of the HIV entry inhibitor drug Selzentry (maraviroc) is also being explored with a vaginal ring that releases maraviroc into the genital tract. The hope is that such medications will help counter the adherence problems found with prevention research to date.

Said Susan Buchbinder, of the San Francisco Department of Public Health and the University of California, San Francisco, "Lots of data was presented this morning—[showing that] HIV infections occur during periods of low blood exposure." See her talk on the possibilities for intermittent PrEP (not taken daily) in the Wednesday symposium "Next Steps in Using ARV for Prevention" at www.retroconference.org, along with a talk from Baeten, "What Can the Twisted Tale of PrEP Results Teach Us?" and two other presentations.

ART plus new drugs coming soon

BY JEFF BERRY

We often hear that there's not much new coming down the HIV drug development pipeline, but there were several presentations and plenty of posters on new HIV drugs in development at this year's CROI, including two new integrase inhibitors set to be approved in 2012, elvitegravir and dolutegravir, plus a reinvention of the popular HIV drug tenofovir (Viread), also found in Truvada (emtricitabine/tenofovir). There was also information regarding already approved drugs that will help inform us on how to make better use of the drugs that are currently in use. Go to www.retroconference.org.

THE QUAD

In a Phase 3 study, the once-daily single tablet regimen (STR) of elvitegravir, cobicistat, emtricitabine, and tenofovir, known as **the "Quad,"** was found to be non-inferior to the gold standard Atripla (efavirenz/emtricitabine/tenofovir) at 48 weeks. This is the first large head-to-head study of two single-tablet regimens. 700 treatment-naïve individuals were randomized to receive either the "Quad" or Atripla, with 88% of those on the "Quad" achieving undetectable viral load (less than 50 copies)



compared to 84% of those on Atripla. Side effects differed between the two groups, with higher rates of nausea in those on the “Quad” compared to Atripla (21% vs. 14%), while increased rates of CNS side effects and rash were seen in those taking Atripla versus the “Quad”—abnormal dreams (27% vs. 15%), insomnia (14% vs. 9%), dizziness (24% vs. 7%), and rash (12% vs. 6%). Both groups showed similar low rates of discontinuation due to side effects (4–5%), and similar low rates of virologic failure (7%).

In a related poster (#627) the “Quad” showed non-inferiority to boosted Reyataz (atazanavir/ritonavir) in combination with Truvada at 48 weeks, with 90% of those on the “Quad” achieving undetectable viral load compared to 87% of those using boosted Reyataz plus Truvada. This Phase 3 study is being conducted in parallel with the Quad vs. Atripla study discussed above.

An FDA advisory committee meeting on the “Quad” is scheduled for May 11.

NEW INTEGRASE INHIBITOR DOLUTEGRAVIR

SPRING-1 is a Phase 2b dose-ranging study of dolutegravir, a once-daily unboosted integrase inhibitor, in approximately 200 treatment-naïve individuals. The study looked at 10, 25, and 50 mg doses of dolutegravir compared to Sustiva (efavirenz), both in combination with two

NRTIs. **Fewer participants on dolutegravir (3%) discontinued therapy due to adverse events compared to Sustiva (10%).** The study was not designed to demonstrate non-inferiority; however, the proportion of those with undetectable viral load was 88% for the dolutegravir group (using the 50 mg dose) compared to 72% for the Sustiva group, with no integrase inhibitor resistant mutations detected at 96 weeks. Two Phase 3 studies are currently enrolling for both treatment-naïve and -experienced individuals using the selected 50 mg dose, and an expanded access program (EAP) is now open for those failing or resistant to Isentress (raltegravir) or elvitegravir and who need access to dolutegravir now (see Briefly, page 8).

GS-7340—SON OF TENOFOVIR

GS-7340 is a pro-drug (a substance that becomes activated after entering the body) of tenofovir (Viread). Peter Ruane, MD, and colleagues conducted a 10-day monotherapy study which was to compare three different doses of GS-7340 (8, 25, and 40 mg once daily), 300 mg tenofovir, and GS-7340 placebo. The drop in viral load was greater in the GS-7340 groups compared to Viread, while blood levels of tenofovir were lower in all GS-7340 groups compared to those on Viread. This newer version of the popular drug Viread (also contained in Truvada, Atripla, and Complera) achieves

greater concentration of the active form of the drug within the cells, and lower levels in the bloodstream, while allowing for smaller doses—in other words, **greater antiviral activity, potentially less toxic, and a smaller pill** (making it easier to co-formulate with other drugs). Gilead is also planning to explore use of GS-7340 as a treatment for hepatitis B.

OTHER STUDIES

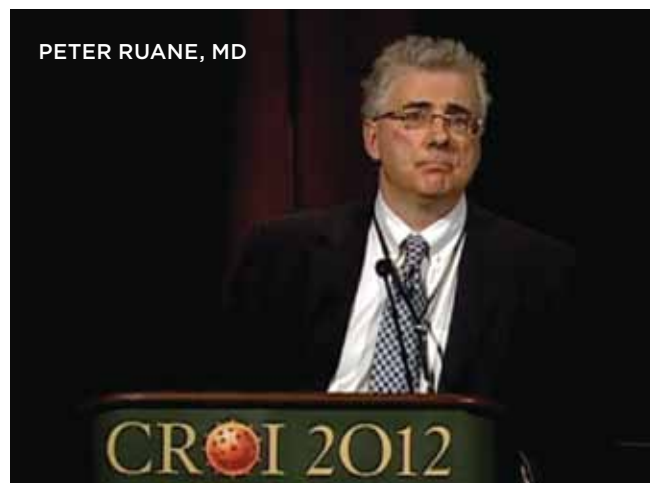
BMS-626529 (poster #725) is the **first in its drug class, an oral attachment inhibitor**, which blocks the first step in viral entry, using a different target than entry inhibitors. In a brief study, monotherapy with BMS-663068, a pro-drug of “529,” did not appear to select for BMS-626529 resistance for as long as eight days.

Rilpivirine (Edurant) is the newest non-nuke that was approved in 2011, and is also co-formulated with Truvada in a single-tablet regimen known as Complera.

The ECHO and THRIVE

studies compared rilpivirine versus efavirenz (Sustiva) in combination with Truvada, Epzicom, or Combivir. In a pooled analysis from both Phase 3 studies of 1,368 individuals, in those with a baseline CD4 count of 50 and above, responses were high and similar between the rilpivirine and efavirenz groups. There were lower responses for those on rilpivirine with a baseline CD4 count less than 50. Responses seen with rilpivirine were significantly higher than with efavirenz with both baseline viral load of less than 100,000 and CD4 cell count of 200 and greater. Overall responses were lower with rilpivirine compared to efavirenz with baseline viral load greater than 100,000, although non-inferiority between the groups was still met. Another poster (#617) demonstrated that rilpivirine 25 mg once daily and raltegravir (Isentress) 400 mg twice daily can be co-administered without dose modifications.

PETER RUANE, MD



Seen in Seattle

Glimpses of the Emerald City while in town for CROI

Between presentations and networking meetings, there really wasn't time for sightseeing while attending the 19th Conference on Retroviruses and Opportunistic Infections. Still, Seattle's beauty and charm are inescapable. Brief excursions through downtown led to the famous open-air Pike Place Market and the graffiti of nearby Post Alley. A number of eye-catching storefronts caught conference-goers' attention, including the original Starbucks, which opened in 1971. With its own distinctly classic style, Tiffany & Co. stands out. And in a city known for its unique culture and aesthetic, the Seattle Public Library makes a modern statement on the place of design in society.

PHOTOS BY JEFF BERRY AND ENID VÁZQUEZ





THE BUZZ

DANIEL S. BERGER, MD

CROI's hep C treatment news

THE REVOLUTION OF TREATMENT DEVELOPMENT WITH

direct acting agents against hepatitis C virus (HCV) is moving faster than a speeding bullet. As it once was for treatment development of HIV, it is dramatic.

Thus, one of many reasons to attend the 19th Conference on Retroviruses and Opportunistic Infections (CROI), held this year in Seattle in March, was the intensity and new data regarding HCV treatment. This was unusual for a conference historically focused on the basic science of HIV.

There is a growing incidence of hepatitis C infection among HIV-positive individuals (co-infection) and it is becoming clear that HCV treatment is complicated. Treatments differ in regards to HCV genotype, therapy for treatment-naïve vs. history of treatment failure, and drug-drug interactions for patients with co-infection. HIV specialists are accustomed to these kinds of complex issues while gastroenterologists, busy with endoscopic procedures, and hospital-based infectious disease specialists, with limited office hours, may not be able to tackle the rocketing numbers of patients with HCV infection growing to monumental proportions. With many future agents becoming developed, much heavy lifting treating HCV-infected patients will be left to physicians who manage HIV disease. However, there is a progressive decrease of physicians wanting to specialize in HIV disease treatment.

A poster presented by the Swiss Cohort team showed staggering statistics in regards to the growing hepatitis C epidemic among those infected by HIV. Their investigation of the MSM (men who have sex with men) population excluded intravenous drug users and heterosexuals. Of 3,333 MSM patients followed, the incidence of new HCV infections in 2011 (compared to 1998) increased 18-fold. Identified risk factors were unsafe anal sex, history of syphilis, and chronic hepatitis B infection. Indeed, the take home message for clinicians is the need for increased testing for HCV and for gay men engaged in unsafe sexual practices, the message is beware and exercise prevention; one needn't be engaged in intravenous drug use to become infected.

The "Breakthroughs in HCV Treatment" session began with presentations of studies with telaprevir (Incivek) and boceprevir (Victrelis), both inhibitors of NS3/4A HCV protease. Both won FDA approval

in 2011 for use with pegylated interferon and ribavirin in adults with genotype 1 chronic HCV and compensated liver disease. However, neither boceprevir nor telaprevir is licensed for use in HIV/HCV co-infection. At CROI, two co-infection studies were highlighted; both trial designs included combinations with pegylated interferon and ribavirin (P/R), and both included the conventional "futility rules" that have become standard for patients undergoing treatment. Protocols put futility rules in place so that patients who experience viral rebound or those who do not reach rapid declines in hep C RNA (viral load) or undetectability within a specified time frame are discontinued from treatment, avoiding resistance mutations or further side effects with failing treatment. Also discussed were HIV drug interactions, crucial for understanding their use with HIV treatment.

TELAPREVIR

Dr. Douglas Dieterich presented a trial of treatment with telaprevir (TVR) in genotype 1 HCV co-infected patients; genotype 1 is the most common and, unfortunately, the most difficult to treat HCV strain.

Patients were administered telaprevir (750 mg every 8 hrs)+P/R for 12 weeks followed by 36 weeks of P/R alone; in the P/R control group, patients were treated for 48 weeks with P/R alone. Further, the trial was divided into parts A and B. In part A, 13 patients were treated without ART (antiretrovirals); 7 randomized to P/R+TVR and 6 on P/R alone. In part B, 24 patients were on Atripla, 16 treated with P/R+TVR and 8 on P/R alone. Also, 23 patients were on ritonavir-boosted atazanavir (Reyataz/Norvir) with either Truvada (emtricitabine/tenofovir) or Viread/Epivir and of these, 15 were treated with P/R+TVR and 8 with P/R alone.

At 12 weeks post-treatment the overall SVR (sustained virologic response—indicates treatment success),

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The standard of care for HCV treatment includes pegylated interferon despite its difficult side effects, so treatment without interferon is of keen interest.

was 74% in the P/R/TVR-treated patients vs. 45% in controls. There were no HIV treatment failures; three HCV treatment failures occurred—at week 4 with one patient in each of the Atripla and Reyataz groups and one at week 12 in the Atripla group. Patient discontinuations due to futility rules were more common in the P/R controls (32 vs. 5%) and discontinuations due to adverse events were 8% in the TVR group vs. 0% in the P/R group. The most common side effect was fatigue in both groups (41-42%) with pruritis (itchy skin), nausea, headache, and rash being more common in the TVR treatment groups. No dosage adjustments were necessary except for a higher dose of telaprevir (1,125 mg every 8 hours) required to offset reduced exposure of it with efavirenz (Sustiva, in Atripla).

BOCEPREVIR

Dr. Mark Sulkowski presented treatment with boceprevir (BOC) in untreated patients with genotype 1 HCV. In this randomized study, all patients began with a lead-in of four weeks P/R therapy, followed by 64 and 34 patients continuing with P/R+BOC vs. P/R alone, respectively. At 12 weeks post-treatment 61% on P/R+BOC vs. 27% on P/R alone achieved an SVR.

HIV treatment failure occurred in three patients on boceprevir vs. four patients on P/R alone. In a separate abstract (Abstract 771LB), drug-drug interactions of boceprevir with boosted protease inhibitors showed that both ritonavir-boosted protease inhibitors and boceprevir inhibit the same CYP3A4 enzymatic systems and other complex enzyme transporter interactions. At the time of this study, these interactions were unknown; we now understand that boosted PIs should not be used with boceprevir. Boceprevir reduced steady-state exposure of Kaletra, Reyataz, and Prezista by 43, 49, and 59% respectively. There is also a significant reduction in boceprevir exposure with Kaletra and boosted Prezista. Healthcare professionals recently received a letter in which Merck stressed they do not recommend the co-administration of Victrelis (boceprevir) and ritonavir-boosted HIV protease inhibitors (see Briefly, page 8).

Side effects with boceprevir treatment included anemia, pyrexia, asthenia, decreased appetite, diarrhea, vomiting, flu-like illness, and neutropenia. However, serious adverse events were 17% in the BOC group vs. 21% in the group taking P/R alone.

MK-5172

In another presentation, Richard Barnard presented a Phase 1 study of Merck's next generation HCV protease inhibitor, MK-5172. Preliminary evidence shows activity against other protease inhibitor-resistant variants.

In this Phase 1 trial, there were six treatment arms with doses ranging from 50 to 800 mg once daily administered to genotype 1 treatment-naïve patients over seven days. Thirty out of forty, or 75%, achieved viral load reductions to below detection at seven days during which there were no viral breakthroughs (treatment failures) with viral load reductions persisting for several days beyond administration. During the conference, information released by Merck discussed the two higher doses being associated with an elevated liver enzyme signal. However, because the trial showed all arms, including 50 mg, to have superimposed viral load declines, we hope that further studies will move forward, expecting to use the lower doses.

GS-7977

In a much anticipated session, GS-7977 was presented. Gilead Sciences has recently acquired this agent from Pharmasset and it has been much in the news lately due to its ability to result in SVRs without need for interferon; it is also one of the agents that is ahead of others in development for treating HCV. Currently, the standard of care for hepatitis C treatment includes pegylated interferon despite its difficult side effects, so successful HCV treatment without the need for interferon is of keen interest to both clinicians and providers.

7977, a nucleotide analog with potent anti-HCV activity, is administered in one pill daily, with or without food. In the prior study, ELECTRON, patients with genotype 2 or 3, naïve to HCV treatment, were given 7977 at 400 mg daily plus ribavirin for 12 weeks, but importantly, without pegylated interferon. Continuing, in the ELECTRON study, all 40 patients studied achieved an SVR out to 24 weeks. Moreover, one arm of the study had 7977 administered as monotherapy and 60% achieved SVR out to 24 weeks.

In the latest segment of ELECTRON, the newest data studied HCV patients with genotype 1 in two groups: null responders (those who previously failed treatment) and patients naïve to HCV therapy. All patients received 7977 with ribavirin for 12 weeks. At the conference only the results of the null responders were available. Remarkably, of the 10 patients, no patient rebounded while on the 12 weeks of treatment, demonstrating 7977 to have a high barrier for resistance. However, nine out of 10 patients relapsed soon after cessation of treatment. The authors concluded that these particular patients with genotype 1, also previously treatment failures, would probably require another direct acting agent, such as an NS3 inhibitor. From this writer's standpoint, patients who fail treatment with P/R probably develop resistance; thus being offered one new agent (7977), although together with ribavirin, would

be tantamount to monotherapy. We anticipate the results from the naïve patients to be presented at EASL (European Association for the Study of the Liver) in Barcelona this April.

DRUG INTERACTIONS WITH NEWER AGENTS: DACLATASVIR, TMC 435, AND BOCEPREVIR

Daclatasvir (DCV) is a potent NS5A replication complex inhibitor of HCV, administered once daily, currently in Phase 3 trials in combination with P/R. PK data showed no effect on tenofovir (Viread), efavirenz (Sustiva), or boosted atazanavir (Reyataz/Norvir). However, DCV dosage adjustments will be needed: 30 mg when used with boosted atazanavir, 90 mg with efavirenz. Both have equivalent exposure of DCV as in the 60 mg dose used alone.

TMC 435, another potent NS3/4A protease inhibitor, currently in Phase 3 for genotypes 1 and 4 HCV-infected patients, is about to begin trials in co-infection. Data of drug-drug interactions showed it to be not recommended for use with efavirenz due to the reduced exposure to TMC 435 in the presence of efavirenz. However,

rilpivirine (Edurant), raltegravir (Isentress), and tenofovir (Viread) can be used with TMC 435 without dosage adjustment.

Lastly, for the first time, drug-drug interactions were presented regarding using raltegravir (Isentress) in combination with boceprevir (Victrelis) with the conclusions that boceprevir does not affect raltegravir exposure and can be used safely.

DR. DANIEL S. BERGER is a leading HIV physician in the U.S. and is Clinical Associate Professor of Medicine at the University of Illinois at Chicago. He is founder and medical director of Northstar Healthcare, has published extensively in such prestigious journals as *The Lancet* and *The New England Journal of Medicine* and currently serves as principle investigator at Northstar Healthcare. Dr. Berger has been honored by Test Positive Aware Network with the Charles E. Clifton Leadership Award. He can be reached at DSBergerMD@gmail.com and www.Nstarmedical.com.

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What our incarcerated readers should know

Over the years of receiving letters

from readers who are behind bars, there have been a handful of issues that have come up repeatedly. It seemed appropriate to address them in this issue.

NOT RECEIVING PA

We frequently hear from inmates who complain of not getting their “monthly issues,” of having requested a subscription but never received magazines, or of having moved and not having their subscription follow them.

First, POSITIVELY AWARE is published every other month, so no one will receive an issue monthly.

For those who've requested subscriptions but haven't received them, there may be several reasons. Prison mailrooms may have regulations we don't know about. One is that some require complete return addresses. Because of confidentiality policy, PA is shipped in a plain manila envelope with only our street address, not the name of the magazine. Also, PA is held together with staples, which are evidently sometimes viewed as dangerous. If you haven't received your magazines, it might be wise to check with the mailroom or other prison

authority to see if there is a regulatory reason you're not receiving them.

As a last resort, you could always request that PA be sent to someone on the outside who could then send it to you in compliance with regulations.

CHANGES OF ADDRESS

PA is shipped through a mailing house and we have no control over how quickly they process any changes made to the subscription list. While most inmates write to tell us of their change of address in time to have uninterrupted delivery of their magazines, there may be some lag time during which you might not receive your issue.

If you've gone for three months without receiving PA, write to us again so we can make sure your change of address was recorded.

WHAT WE DON'T DO

Mail that we receive from inmates is often disturbing, even heartbreaking. We hear of the anguish they suffer trying to keep their HIV a secret and of loneliness and the desire to connect with people on the outside.

While we feel compassion for our incarcerated readers, we do not publish

personal ads, run a dating service, or arrange for pen pals. Our purpose is more medical than social and unfortunately we have neither the staff nor resources to provide those things.

We are also not a clearinghouse for other publications. Inmates should write Prisoner Activist Resource Center (PARC), PO Box 70447, Oakland, CA 94612 for a directory of information resources on many topics, including HIV/AIDS and hepatitis C.

KNOWLEDGE IS POWER

We hope that POSITIVELY AWARE informs, encourages, and empowers you to take care of your health, even while dealing with the challenges of prison life. We hope that you'll share your knowledge with other inmates, both HIV-positive and not, so there will be better understanding of how HIV is spread and more will protect themselves and others.

The circumstances that bring people to prison are as varied as the ones that result in them being HIV-positive. In order to survive both, knowledge—of yourself, your body, your choices, and your potential—is key and with that knowledge comes hope.

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WHOLISTIC PICTURE

SUE SALTMARSH

Law vs. injustice

AS THE GULF BETWEEN THE HAVES AND THE HAVE-NOTS

in this country grows to Grand Canyon-esque proportions, it seems only reasonable that the crime rate, and the number of people in prison, will also grow.

We've all heard stories of people being arrested for shoplifting food to feed their children; runaways becoming pickpockets and prostitutes in order to survive (that "transactional sex" thing); young black men becoming drug dealers because they "have no choice."

As someone who has experienced the panicky, nerves-on-edge feeling of not knowing the source or components of my next meal, I can easily forgive that parent for shoplifting and I am forever grateful that I had no mouths to feed besides my own. I may never have resorted to stealing, prostitution, or drug dealing, but I can easily understand that, just as necessity may be the mother of invention, poverty may be the father of crime.

Having known good people through my years working in the HIV community who have survived horrific, dehumanizing circumstances, I am frequently blown away by their ability to overcome the trauma and scars of physical/sexual/emotional abuse, drug addiction, crime, and imprisonment in order to become bright spots of inspiration and success, shining examples for others to follow. They may be few, but they are powerful proof that there is always a choice if you have the courage to make the hard ones.

We see almost daily proof that our country, supposedly "ruled by law," becomes more and more unjust, the laws more and more harmful to the Whole. The lawmakers and those in "power" are hardly ever called to account for their violations of not only manmade laws, but also laws of Nature and laws of logic, and common sense dies a gruesome death in our political process. Mustn't we ask ourselves who the criminals really are?

Are the worst of our society the ones in prison for carrying around crack instead of powdered cocaine? Are they the people driving without car insurance? Are they the women who killed abusive men in self-defense (but who had no "stand your ground" law to fall back on)? Are they the rapists, or the doctors who perform the abortions that enable the raped women to heal and go

forward in their lives? Are they the bank robbers, or the CEOs of hedge funds who are still free to enjoy the luxuries their ill-gotten gains afford them? Are they the parents who force hospital doctors to care for

their sick child at gunpoint, or are they the health insurance companies that refuse to cover that child's care?

In case you think I'm just a bleeding heart liberal, naively willing to buy that everyone in prison is really innocent, let me correct you. There are plenty of people behind bars who deserve to be there and they know who they are. But if there was some mystical machine that could tell us who was truly evil and had committed violent or destructive crimes as opposed to those who had made a horrible mistake, been in the wrong place at the wrong time, or were desperate to survive in the only way they knew how, I have no doubt that the prison population would shrink.

Out here, as well as inside jails and prisons, there is one thing in our society that there is more than enough of—injustice. It is insidious, whether it's in a poor, black neighborhood where gang bangers kill innocent children because they're too stupid to know that they're killing off their own communities, or in "middle class" neighborhoods where mortgage bank fraud is creating ghost towns and families are homeless, or in Congress where white men who call themselves "Christian" conservatives try to pass laws forcing women to have the children resulting from rape and incest while at the same time refusing to fund programs that would enable those women to take care of those unwanted children. Sadly, it is also in the minds of Americans who hate with white hot intensity anyone who is different from them to the point where Matthew Shepherd, George Tiller, Shaima Alawadi, and Trayvon Martin can lose their lives as a result.

It's not an easy time to be alive in the world, but perhaps the tide is slowly turning as the 99% hit the streets, as more people start to say, "No MORE!" I have hope that the prison population will begin to shrink because there will be fewer people allowing injustice to drive them there, and that we'll all keep working at eradicating the injustice that is the true crime.

Breathe deep, live long.

I have hope that the prison population will begin to shrink because there will be fewer people allowing injustice to drive them there, and that we'll all keep working at eradicating the injustice that is the true crime.

A MESSAGE FROM YOUR IMMUNE SYSTEM

A photograph of a person's back, showing a tattoo that reads "HIV treatment can help me now. My T-cells are at 461." A hand is placed on the person's right shoulder, symbolizing support and care.

**HIV treatment
can help me now.
My T-cells are at 461.**

Talk with your doctor about ways to help protect your immune system.

HIV treatment is now recommended for everyone with a T-cell count of 500 or less and should be considered when T-cells are higher than 500, according to the DHHS* and the IAS-USA†, along with other factors. Starting treatment early may help protect your immune system and vital organs. Today's medicines may have fewer, more manageable side effects. They may help you live a longer, healthier life. Receive helpful information about living with HIV that you should know. Call toll free 1-888-447-1728, or visit **TREATHIVNOW.COM**.



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