

HIV Specialist



This issue produced
in conjunction with the
National Coalition of
STD Directors

Combating the STD Epidemic

**Confronting HIV
and Other STDs**

18

**Funding Solutions for
Moving Forward**

23

**The Intersection
of U=U and STIs**

28

STDs and Stigma

32



#1 PRESCRIBED FOR ADULTS WITH HIV-1 STARTING AND SWITCHING ARV REGIMENS

Source: Ipsos Healthcare US HIV Therapy Monitor & Scope Study Q3 2018.

INDICATION

BIKTARVY is indicated as a complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen for ≥ 3 months with no history of treatment failure and no known resistance to any component of BIKTARVY.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- ▶ **Severe acute exacerbations of hepatitis B have been reported in patients who are coinfectd with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are coinfectd with HIV-1 and HBV and discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted.**

Contraindications

- ▶ **Coadministration:** Do not use BIKTARVY with dofetilide or rifampin.

Warnings and precautions

- ▶ **Drug interactions:** See Contraindications and Drug Interactions sections. Consider the potential for drug interactions prior to and during BIKTARVY therapy and monitor for adverse reactions.
- ▶ **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.
- ▶ **New onset or worsening renal impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. In clinical trials of BIKTARVY, there have been no cases of Fanconi syndrome or proximal renal tubulopathy (PRT). Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
Renal monitoring: Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, also assess serum phosphorus.

Treatment-Naïve Study Designs¹⁻⁵:

The efficacy and safety of BIKTARVY for treatment-naïve adults were evaluated in Study 1489 and Study 1490.

In Study 1489, a phase 3, randomized, double-blind, active-controlled study, treatment-naïve adults with an eGFR ≥ 50 mL/min were randomized in a 1:1 ratio to receive either BIKTARVY (n=314) or ABC/DTG/3TC (n=315) once daily.

In Study 1490, a phase 3, randomized, double-blind, active-controlled study, treatment-naïve adults with an eGFR ≥ 30 mL/min were randomized in a 1:1 ratio to receive either BIKTARVY (n=320) or FTC/TAF+DTG (n=325) once daily.

The primary endpoint for both trials was the proportion of adults with HIV-1 RNA <50 copies/mL at Week 48.

Secondary endpoints included efficacy, safety, and tolerability at Week 96.

THE BEAUTY OF POSSIBILITIES

BIKTARVY® combines the FTC/TAF* backbone with bicitgravir, a novel and unboosted INSTI—for a powerful STR with a high barrier to resistance^{1,6}

No Treatment-Emergent Resistance Associated With BIKTARVY Through Week 96^{1,4,5,7}

0 CASES OF RESISTANCE WITH BIKTARVY

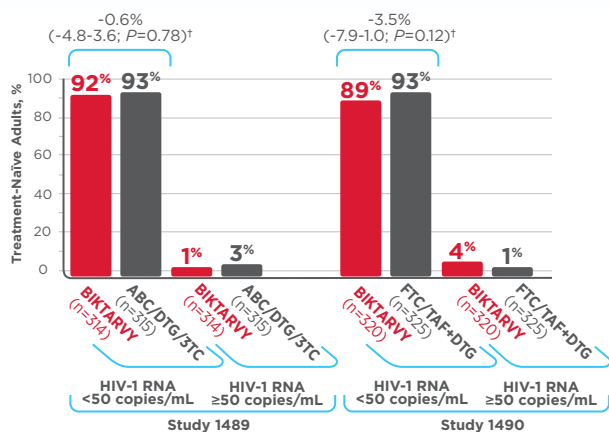
In two large phase 3 clinical trials in treatment-naïve adults^{1-5,7}

► Among 634 treatment-naïve adults in Studies 1489 and 1490, 7 treatment-failure subjects were tested and no amino acid substitutions emerged that were associated with BIKTARVY resistance

Powerful Efficacy in Treatment-Naïve Adults^{1-5,7}

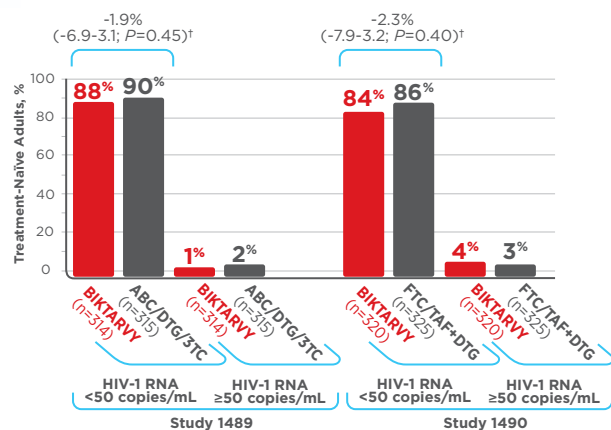
Results noninferior to comparators at Week 48¹⁻³

Virologic Response



Results noninferior to comparators at Week 96^{4,5,7}

Virologic Response



Most common adverse reactions (incidence ≥5%; all grades) in treatment-naïve clinical studies through week 96 were diarrhea (6%), nausea (6%), and headache (5%).^{4,5}

IMPORTANT SAFETY INFORMATION (continued)

Warnings and precautions (continued)

► **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue BIKTARVY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Please see additional Important Safety Information for BIKTARVY, including **BOXED WARNING**, and Brief Summary of full Prescribing Information for BIKTARVY on following pages.

*emtricitabine 200 mg/tenofovir alafenamide 25 mg.

[†]95% confidence interval.



BIKTARVY®
bicitgravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets
SIMPLY POWERFUL™



See the possibilities
at **DiscoverBiktarvy.com**

IMPORTANT SAFETY INFORMATION (continued)

Adverse reactions

- ▶ **Most common adverse reactions** (incidence $\geq 5\%$; all grades) in clinical studies through week 96 were diarrhea (6%), nausea (6%), and headache (5%).

Drug interactions

- ▶ **Prescribing information:** Consult the full prescribing information for BIKTARVY for more information on Contraindications, Warnings, and potentially significant drug interactions, including clinical comments.
- ▶ **Enzymes/transporters:** Drugs that induce P-gp or induce both CYP3A and UGT1A1 can substantially decrease the concentration of components of BIKTARVY. Drugs that inhibit P-gp, BCRP, or inhibit both CYP3A and UGT1A1 may significantly increase the concentrations of components of BIKTARVY. BIKTARVY can increase the concentration of drugs that are substrates of OCT2 or MATE1.
- ▶ **Drugs affecting renal function:** Coadministration of BIKTARVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions.

Dosage and administration

- ▶ **Dosage:** 1 tablet taken once daily with or without food.
- ▶ **Renal impairment:** Not recommended in patients with CrCl < 30 mL/min.
- ▶ **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.
- ▶ **Prior to or when initiating:** Test patients for HBV infection.
- ▶ **Prior to or when initiating, and during treatment:** As clinically appropriate, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, assess serum phosphorus.

Pregnancy and lactation

- ▶ **Pregnancy:** There is insufficient human data on the use of BIKTARVY during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for FTC shows no difference in the rates of birth defects compared with a US reference population.
- ▶ **Lactation:** Women infected with HIV-1 should be instructed not to breastfeed, due to the potential for HIV-1 transmission.

Please see Brief Summary of full Prescribing Information for BIKTARVY on following pages.

3TC, lamivudine; ABC, abacavir; ARV, antiretroviral; DTG, dolutegravir; eGFR, estimated glomerular filtration rate; FTC, emtricitabine; INSTI, integrase strand transfer inhibitor; STR, single-tablet regimen; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

References: 1. BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2018. 2. Gallant J, Lazzarin A, Mills A, et al. Bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir, abacavir, and lamivudine for initial treatment of HIV-1 infection (GS-US-380-1489): a double-blind, multicentre, phase 3, randomised controlled non-inferiority trial. *Lancet*. 2017;390(10107):2063-2072. 3. Sax PE, Pozniak A, Montes ML, et al. Coformulated bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir with emtricitabine and tenofovir alafenamide, for initial treatment of HIV-1 infection (GS-US-380-1490): a randomised, double-blind, multicentre, phase 3, non-inferiority trial. *Lancet*. 2017;390(10107):2073-2082. 4. Stellbrink HJ, Arribas J, Stephens JL, et al. Phase III randomized, controlled trial of bictegravir coformulated with FTC/TAF in a fixed-dose combination (B/F/TAF) versus dolutegravir (DTG) + F/TAF in treatment-naïve HIV-1 positive adults: week 96. HIV Glasgow; October 28-31, 2018; Glasgow, UK. 5. Wohl D, Yazdanpanah Y, Baumgarten A, et al. A phase 3, randomized, controlled clinical trial of bictegravir in a fixed-dose combination, B/F/TAF, vs DTG/ABC/3TC in treatment-naïve adults at Week 96. IDWeek; October 3-7, 2018; San Francisco, CA. Abstract 74246. 6. Tsiang M, Jones GS, Goldsmith J, et al. Antiviral activity of bictegravir (GS-9883), a novel potent HIV-1 integrase strand transfer inhibitor[...]. *Antimicrob Agents Chemother*. 2016;60(12):7086-7097. 7. Data on file. Gilead Sciences, Inc.



BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets
SIMPLY POWERFUL™

BIKTARVY® (bictegravir 50 mg, emtricitabine 200 mg, and tenofovir alafenamide 25 mg) tablets, for oral use

Brief Summary of full Prescribing Information. See full Prescribing Information. Rx only.

WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

Severe acute exacerbations of hepatitis B have been reported in patients who are coinfecting with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are coinfecting with HIV-1 and HBV and discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted [see Warnings and Precautions].

INDICATIONS AND USAGE

BIKTARVY is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 3 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of BIKTARVY.

DOSAGE AND ADMINISTRATION

Also see *Warnings and Precautions* and *Use in Specific Populations*.

Testing Prior to or When Initiating: Test patients for HBV infection.

Testing Prior to or When Initiating, and During Treatment: As clinically appropriate, assess serum creatinine, estimated creatinine clearance (CrCl), urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus.

Dosage: One tablet taken once daily with or without food.

Renal Impairment: BIKTARVY is not recommended in patients with CrCl <30 mL/min.

Hepatic Impairment: BIKTARVY is not recommended in patients with severe hepatic impairment.

CONTRAINDICATIONS

Also see *Drug Interactions*.

BIKTARVY is contraindicated to be co-administered with:

- dofetilide due to the potential for increased dofetilide plasma concentrations and associated serious and/or life-threatening events
- rifampin due to decreased BIC plasma concentrations, which may result in the loss of therapeutic effect and development of resistance to BIKTARVY

WARNINGS AND PRECAUTIONS

Also see *BOXED WARNING*, *Contraindications*, *Adverse Reactions*, and *Drug Interactions*.

Severe Acute Exacerbation of Hepatitis B in Patients Coinfected with HIV-1 and HBV: Patients with HIV-1 should be tested for the presence of chronic hepatitis B virus (HBV) before or when initiating ARV therapy. Severe acute exacerbations of hepatitis B (e.g., liver decompensation and liver failure) have been reported in patients who are coinfecting with HIV-1 and HBV and have discontinued products containing FTC and/or TDF, and may occur with discontinuation of BIKTARVY. Patients coinfecting with HIV-1 and HBV who discontinue BIKTARVY should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment. If appropriate, anti-hepatitis B therapy may be warranted, especially in patients with advanced liver disease or cirrhosis since post-treatment exacerbation of hepatitis may lead to hepatic decompensation and liver failure.

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions: Coadministration of BIKTARVY with certain other drugs may result in known or potentially significant drug interactions; this may lead to loss of efficacy and development of

resistance to BIKTARVY or clinically significant adverse reactions from greater exposures of concomitant drugs. Consider the potential for drug interactions and review concomitant medications prior to and during therapy. Monitor for adverse reactions associated with concomitant drugs.

Immune Reconstitution Syndrome (IRS): IRS has been reported in patients treated with combination ARV therapy. During the initial phase of treatment, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment. Autoimmune disorders have been reported to occur in the setting of immune reconstitution; the time to onset is variable, and can occur many months after initiation of treatment.

New Onset or Worsening Renal Impairment: Renal impairment, including acute renal failure and Fanconi syndrome, has been reported with the use of tenofovir prodrugs in animal studies and human trials. In clinical trials of BIKTARVY in subjects with no antiretroviral treatment history with eGFRs >30 mL/min, and in virologically suppressed subjects switched to BIKTARVY with eGFRs >50 mL/min, renal serious adverse events were encountered in less than 1% of subjects treated with BIKTARVY through Week 48. BIKTARVY is not recommended in patients with CrCl <30 mL/min. Patients taking tenofovir prodrugs who have renal impairment and/or are taking nephrotoxic agents including NSAIDs are at increased risk of developing renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. **Renal Monitoring:** Prior to or when initiating BIKTARVY, and during treatment with BIKTARVY, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, also assess serum phosphorus.

Lactic Acidosis/Severe Hepatomegaly with Steatosis: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including FTC and TDF. Treatment with BIKTARVY should be suspended in any individual who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

ADVERSE REACTIONS

Also see *BOXED WARNING* and *Warnings and Precautions*.

In Adults with No ARV Treatment History:

The safety assessment of BIKTARVY is based on Week 48 data from two randomized, double-blind, active-controlled trials: 1489 (n=314) and 1490 (n=320), in HIV-1 infected, ARV treatment-naïve adults. Through Week 48, 1% of subjects discontinued BIKTARVY due to adverse events, regardless of severity.

Adverse Reactions: Adverse reactions (all Grades) reported in ≥2% of subjects receiving BIKTARVY through Week 48 in Trials 1489 and 1490, respectively were: diarrhea (6%, 3%), nausea (5%, 3%), headache (5%, 4%), fatigue (3%, 2%), abnormal dreams (3%, <1%), dizziness (2%, 2%), and insomnia (2%, 2%). Additional adverse reactions (all Grades) occurring in less than 2% of subjects administered BIKTARVY in Trials 1489 and 1490 included vomiting, flatulence, dyspepsia, abdominal pain, rash, and depression. Suicidal ideation, suicide attempt, and depression suicidal occurred in <1% of subjects administered BIKTARVY; all events were serious and primarily occurred in subjects with a preexisting history of depression, prior suicide attempt, or psychiatric illness.

Laboratory Abnormalities: Laboratory abnormalities (Grades 3–4) occurring in ≥2% of subjects receiving BIKTARVY through Week 48 in Trials 1489 or 1490, respectively were: amylase >2.0 x ULN (2%, 2%), ALT >5.0 x ULN (1%, 2%), AST >5.0 x ULN (2%, 1%), Creatine Kinase ≥10.0 x ULN (4%, 4%), Neutrophils <750 mm³ (2%, 2%), and fasted LDL-cholesterol >190 mg/dL (2%, 3%).

Changes in Serum Creatinine: Increases in serum creatinine occurred by Week 4 of treatment and remained stable through Week 48. In Trials 1489 and 1490, median serum creatinine increased by 0.10 mg/dL from baseline to Week 48 in the BIKTARVY group and was similar to the comparator groups.

Continued on next page.

Continued from previous page.

Changes in Bilirubin: In Trials 1489 and 1490, total bilirubin increases were observed in 12% of subjects administered BIKTARVY through Week 48.

In Virologically Suppressed Adults: The safety of BIKTARVY in HIV-1 infected, virologically suppressed adults is based on Week 48 data from 282 subjects in a randomized, double-blind, active-controlled trial in which virologically suppressed subjects were switched from either DTG + ABC/3TC or ABC/DTG/3TC to BIKTARVY; and Week 48 data from 290 subjects in an open-label, active-controlled trial in which virologically suppressed subjects were switched from a regimen containing atazanavir (ATV) (given with cobicistat or ritonavir) or darunavir (DRV) (given with cobicistat or ritonavir) plus either FTC/TDF or ABC/3TC, to BIKTARVY.

Adverse Reactions: Overall, the safety profile in virologically suppressed adult subjects was similar to that in subjects with no antiretroviral treatment history.

DRUG INTERACTIONS

Also see **Indications and Usage, Contraindications, and Warnings and Precautions.**

Other Antiretroviral Medications: BIKTARVY is a complete regimen for the treatment of HIV-1 infection, BIKTARVY coadministration with other ARV medications for treatment of HIV-1 infection is not recommended. Complete information regarding potential drug interactions with other ARV medications is not provided.

Potential for BIKTARVY to Affect Other Drugs: BIC inhibits organic cation transporter 2 (OCT2) and multidrug and toxin extrusion transporter 1 (MATE1) *in vitro*. Coadministration of BIKTARVY with drugs that are substrates of OCT2 and MATE1 (e.g., dofetilide) may increase their plasma concentrations.

Potential Effect of Other Drugs to Affect BIKTARVY: BIC is a substrate of CYP3A and UGT1A1. A drug that is a strong inducer of CYP3A and also an inducer of UGT1A1 can substantially decrease the plasma concentrations of BIC which may lead to loss of efficacy and development of resistance. The use of BIKTARVY with a drug that is a strong inhibitor of CYP3A and also an inhibitor of UGT1A1 may significantly increase the plasma concentrations of BIC. TAF is a substrate of P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP). Co-administration of drugs that inhibit P-gp and BCRP may increase the absorption and plasma concentrations of TAF. Co-administration of drugs that induce P-gp activity are expected to decrease the absorption of TAF, resulting in decreased plasma concentration of TAF, which may lead to loss of efficacy and development of resistance.

Drugs Affecting Renal Function: Because FTC and tenofovir are primarily excreted by the kidneys by a combination of glomerular filtration and active tubular secretion, coadministration of BIKTARVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC, tenofovir, and other renally eliminated drugs, which may increase the risk of adverse reactions.

Established and Potentially Significant Drug Interactions: The listing of established or potentially clinically significant drug interactions with recommended prevention or management strategies described are based on studies conducted with either BIKTARVY, the components of BIKTARVY (BIC, FTC, and TAF) as individual agents, or are drug interactions that may occur with BIKTARVY. **An alteration in regimen may be recommended.**

- **Antiarrhythmics:** dofetilide. Coadministration is contraindicated due to potential for serious and/or life-threatening events.
- **Anticonvulsants:** carbamazepine, oxcarbazepine, phenobarbital, phenytoin. Coadministration with alternative anticonvulsants should be considered.
- **Antimycobacterials:** rifampin. Coadministration is contraindicated due to the effect on BIKTARVY. Rifabutin, rifapentine. Coadministration is not recommended.
- **Herbal Products:** St. John's wort. Coadministration is not recommended.
- **Medications/oral supplements containing polyvalent cations (e.g., Mg, Al, Ca, Fe):** **Antacids containing Al/Mg or Calcium:** BIKTARVY can be taken under fasting conditions 2 hours before antacids containing Al/Mg or calcium. Routine administration of BIKTARVY simultaneously with, or 2 hours after, antacids containing Al/Mg or calcium is not recommended. **Supplements containing Calcium or Iron:** BIKTARVY and supplements containing calcium or iron can be

taken together with food. Routine administration of BIKTARVY under fasting conditions simultaneously with, or 2 hours after, supplements containing calcium or iron is not recommended.

- **Metformin:** Refer to the prescribing information of metformin for assessing the benefit and risk of concomitant use of BIKTARVY and metformin.

Consult the full Prescribing Information prior to and during treatment with BIKTARVY for important drug interactions; this list is not all inclusive.

USE IN SPECIFIC POPULATIONS

Also see Dosage and Administration, Warnings and Precautions, and Adverse Reactions.

Pregnancy: Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to BIKTARVY during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263. **Risk Summary:** There are insufficient human data on the use of BIKTARVY during pregnancy to inform a drug-associated risk of birth defects and miscarriage. BIC and TAF use in women during pregnancy has not been evaluated; however, FTC use during pregnancy has been evaluated in a limited number of women as reported to the APR. Available data from the APR show no difference in the overall risk of major birth defects for FTC compared with the background rate for major birth defects of 2.7% in a U.S. reference population of the Metropolitan Atlanta Congenital Defects Program (MACDP). The rate of miscarriage is not reported in the APR.

Lactation: The Centers for Disease Control and Prevention recommend that HIV-infected mothers not breastfeed their infants to avoid risking postnatal transmission of HIV. Based on published data, FTC has been detected in human milk; it is not known whether BIKTARVY or all of the components of BIKTARVY are present in human breast milk, affects human milk production, or has effects on the breastfed infant. BIC was detected in the plasma of nursing rat pups likely due to the presence of BIC in milk, and tenofovir has been shown to be present in the milk of lactating rats and rhesus monkeys after administration of TDF. It is unknown if TAF is present in animal milk. Because of the potential for HIV transmission in HIV-negative infants, developing viral resistance in HIV-positive infants, and adverse reactions in nursing infants, mothers should be instructed not to breastfeed.

Pediatric Use: Safety and effectiveness of BIKTARVY in pediatric patients less than 18 years of age have not been established.

Geriatric Use: Clinical studies of BIKTARVY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Renal Impairment: BIKTARVY is not recommended in patients with severe renal impairment (CrCl <30ml/min). No dosage adjustment of BIKTARVY is recommended in patients with CrCl >30ml/min.

Hepatic Impairment: No dosage adjustment of BIKTARVY is recommended in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. BIKTARVY is not recommended for use in patients with severe hepatic impairment (Child-Pugh Class C) as BIKTARVY has not been studied in these patients.

OVERDOSAGE:

If overdose occurs, monitor the patient for evidence of toxicity. Treatment consists of general supportive measures including monitoring of vital signs as well as observation of the clinical status of the patient.

210251-GS-000 February 2018



BIKTARVY, the BIKTARVY Logo, GILEAD, the GILEAD Logo, and SIMPLY POWERFUL are trademarks of Gilead Sciences, Inc., or its related companies. All other marks referenced herein are the property of their respective owners.

© 2019 Gilead Sciences, Inc. All rights reserved. BVYP0247 01/19

CHAIR/BOARD OF DIRECTORS

Margaret L. Hoffman-Terry,
MD, FACP, AAHIVS

EXECUTIVE DIRECTOR

Bruce J. Packett II

DIRECTOR OF MARKETING & COMMUNICATIONS

Amber McCracken

COPY EDITOR

Christy J. Adams, PA-C, MHS

PUBLICATION DESIGN AND ART DIRECTION

BonoTom Studio, Inc.
703-276-0612, info@bonotom.com

ADVERTISING

Jane Dees Richardson
AAHIVM Advertising Sales
c/o Ad Marketing Group, Inc.
703-243-9046 ext. 102, Fax: 856-219-8957
jrichardson@admarketinggroup.com

PUBLISHER

The American Academy
of HIV Medicine
1705 DeSales St., NW, Suite 700
Washington, D.C. 20036
202-659-0699 • 202-659-0976
info@aahivm.org • www.aahivm.org

EDITORIAL ADVISORY GROUP

CHAIR

Jeffrey T. Kirchner,
DO, FAAFP, AAHIVS
Medical Director
Penn Medicine/
LGHP Comprehensive Care
Lancaster General Hospital, Lancaster, PA

Joseph S. Cervia,
MD, MBA, FACP, FAAP, FIDSA, AAHIVS
Clinical Professor of Medicine
and Pediatrics,
Hofstra North Shore-LIJ
School of Medicine;
Regional Medical Director,
HealthCare Partners, IPA & MSO,
Garden City, NY

D. Trew Deckard,
PA-C, MHS, AAHIVS
Steven M. Pounders, MD, PA
Dallas-Fort Worth, TX

Theresa Mack,
MD, MPH, FACP, AAHIVS
St. Lukes—Roosevelt Hospital
New York, NY

Richard C. Prokesch,
MD, FACP, FIDSA, AAHIVS
Infectious Diseases Associates,
Riverdale, GA

William R. Short,
MD, MPH, AAHIVS
UPenn Perelman School of Medicine
Philadelphia, PA

CONTENTS

SEPTEMBER 2019 | Volume 11, No. 3 | www.aahivm.org

FEATURES

14 Confronting HIV and Other STDs

Success Against One Requires Action Against All

BY DAVID C. HARVEY

18 Doing More to Prevent, Screen, and Treat STI's is Part of Ending the HIV Epidemic

By JEFFREY S. CROWLEY, MPH

23 An STD Epidemic with No End in Sight

Funding Solutions for Moving Forward

BY GABRIELLA VAVALA, BA, and
JEFFREY D. KLAUSNER, MD, MPH

28 The Intersection of U=U and STIs

Reframing our Messages and Practice

BY MURRAY PENNER



32 STDs and Stigma

We All Have Something to Learn

BY AMANDA DENNISON, MPH

DEPARTMENTS

6 LETTER FROM THE DIRECTOR

Taking a Close Look at Sexual Health

BY BRUCE J. PACKETT, EXECUTIVE DIRECTOR, AAHIVM

7 IN THE NEWS

Where Will Most Women get HIV and STD Testing now?; HIV, Infectious Diseases Provider Organizations Call for Inpatient Antiretroviral Stewardship; First Ever Phase 1 of Genital Chlamydia Vaccine Finds it is Safe and Provokes Immune Response; myLAB Box Announces Safe is Sexy Checklist for Back to School; DHHS "Proposed Rule" Proposes to Sidestep Non-discrimination Protections

11 BEST PRACTICES

Understanding the Challenges with PrEP Uptake and Testing

BY GINA M. SIMONCINI, MD, MPH, FACP, AAHIVS

32 AT THE FOREFRONT

All Of Us

35 AT THE FOREFRONT

Customs and Border Patrol Endangers People with HIV and Their Children

BY ANNA FORBES

36 CLINICAL RESEARCH UPDATE

BY JEFFREY T. KIRCHNER, DO, FAAFP, AAHIVS

By BRUCE J. PACKETT II

Executive Director, AAHIVM

Taking a Closer Look at Sexual Health

THIS IS A PARTICULARLY EXCITING ISSUE of *HIV Specialist* for us. In this issue, we are introducing a discussion on how we might actively incorporate sexual health counseling and care alongside routine HIV services. I want to extend my appreciation to our editorial partner, the National Coalition of STD Directors (NCSD), for their outstanding guidance on the topics and authors that best shape this discussion. NCSD Executive Director David Harvey and his staff provided invaluable insight to the in-depth content.

AAHIVM and its healthcare provider members have always been conscious of the broader issues of overall sexual health of persons living with and at risk for HIV. HIV specialists will be the first to point out that sexual health in the clinic isn't just about treatment guidelines and tackling infection and disease; it's also about reframing sex in an affirming and positive way for each patient to help them live their best and healthiest life and to avoid stigma (as it relates to sex and sexuality) and the risk factors that go along with it.

AAHIVM, moving into our third decade of existence, has undertaken an organizational strategic planning process in 2019. This issue of *HIV Specialist* on sexual health presents an opportunity to offer a glimpse into some of the results of this process: We will be broadening our efforts as an organization to tackle 'sexual health' in the clinic as a whole, how we might better marry **sexual health** specialization alongside our **HIV expertise**. In the coming months, we will conduct a robust assessment of the sexual health needs in clinical settings across the country—not just in HIV clinics, but for healthcare providers generally—in order to give providers the resources they require to deliver optimum sexual health services to patients.

We are exploring all aspects of HIV care and prevention, STIs, sex positivity, LGBTQ needs, how to take a proper sexual history, family planning and reproductive health, sexual violence and other topics across all ages, from adolescence to seniors. All the pieces fit together, not just in terms of ending the HIV epidemic, but also seeing a marked decrease in STIs, stigma and other barriers to living a healthy and sexually fulfilling life. From this **we hope to build a curriculum on overall sexual health**. Alongside this, we will explore leveraging our positioning as the HIV credentialing body to expand into clinical sexual



health certifications as well. As an organization representing providers, many of whom responded to the original AIDS crisis and are now on the clinical frontlines of the HIV epidemic in its fourth decade, we feel especially well-positioned to address this need in the US. As always, I invite our readers' participation and insights on how best to accomplish our goals in this space. Please talk to us. Share your thoughts here: bruce@aahivm.org.

Also in this issue, we confront the key question of how to best use the HIV care and prevention infrastructure and the goals and resources of the End the Epidemic initiative in order to take on the broader issue of a dangerous and growing STI epidemic in the US. As Jeffrey Crowley points out in his article in these pages: "HIV prevention and care programs already are overburdened, but we still need more from them—and HIV providers—to address STIs." It's a critical challenge that

we must solve together in order to properly address the HIV, HCV and STI syndemics.

PrEP and "U=U" messaging play a key role in this integration of HIV care and prevention and confronting the increasing numbers of chlamydia, gonorrhea and syphilis in the US. There are clear and obvious opportunities in both PrEP and U=U campaigns for targeting messaging, screening and treatment for STIs, but the obstacles of time, provider attention, substance use disorder, stigma, mental health, costs and resources have to be addressed in order for systemic success to take hold. **HIV**



In the NEWS

Where Will Most Women get HIV and STD Testing now?

WHEN THE DHHS-IMPOSED DEADLINE arrived on August 19th, Planned Parenthood officially withdrew from receiving Title X funding—the federal program established in the early 1970s to ensure access to sexual and reproductive care services for low income people. For the last fifty years, Planned Parenthood (established in 1917) has been the largest provider of services to Title X patients. In 1987, they added HIV testing to their range of services which already included testing and treatment for other STIs, cancer screening and a range of reproductive healthcare services. Most of its clients are people of color, young people, immigrants, LGBTQ people, and people in rural areas. With no more Title X support going to Planned Parenthood, these people will likely have to travel farther for these services, pay more for them and possibly do without.

The withdrawal was triggered by Planned Parenthood's refusal to comply with the DHHS' new rule barring recipients from performing or even providing information about abortion in a Title X funded facility. When DHHS proposed the new rule last year, they received over 500,000 public comments, most of them in strong opposition to the change. NPR reports that Planned Parenthood officials "had been holding out

hope that a federal court would intervene or that Congress would act to preserve their funding." In July, the House of Representatives passed a Title X Protection Act that would preserve the funding. The Senate, however, has not passed it.

This new status quo can only be revised now by either a court decision or by passage of the Title X Protection Act in both chambers. Right now, you can speak up on the issue by calling both of your Senators, telling them you are a healthcare professional, and asking them to support the Act. The number for the Senate switchboard is 202-224-3121.

Other major provider associations supporting the Act include the American Medical Association, American Nurses Association, National Association of Community Health Centers, American Academy of Pediatrics and American College of Obstetrics and Gynecologists among others. They are opposing the rule change on the grounds that it damages the patient-provider relationship and intrudes in a provider's practice.

At last count, nearly three million (2,840,000) people use Planned Parenthood services in the U.S. Almost half (41%) of the women who get their care from publicly funded family planning centers identify the local family planning provider as their *only* source of health care. Where will they get their HIV testing and care now?

HIV, Infectious Diseases Provider Organizations Call for Inpatient Antiretroviral Stewardship

IN A POLICY PAPER RELEASED in early September, the Infectious Diseases Society of America, its HIV Medicine Association and the American Academy of HIV Medicine called for the establishment of antiretroviral treatment stewardship programs in hospital settings to support appropriate use of the drugs, to avoid use of medicines that are incompatible with patients' regimens, and to avert development of treatment-resistant HIV.

The paper, "A Call to Action: The Role of Antiretroviral Stewardship in Inpatient Practice," was published in *Clinical Infectious*

Diseases. It cited errors in administration of antiretroviral treatment regimens for hospitalized patients with HIV that included incorrect dosing or scheduling of medicines and drug interactions occurring as frequently as 86 percent of the time in some settings studied. While inpatient errors are often corrected within 48 hours, the paper noted, in some settings they may not be corrected prior to patient's discharge.

The authors, who include AAHIVM Pharmacist Committee member David Koren and HIVMA Chair Dr. W. David Hardy, wrote that

antiretroviral stewardship programs, modeled on current programs overseeing the use of antibiotics and other antimicrobial medicines in clinical settings and adapted to local needs would help to ensure the continuity of antiretroviral therapy during hospital admission, enhance clinical outcomes and improve overall inpatient care.

The organizations called for advocacy, assessment of best practices, multidisciplinary, institutional-based approaches and resources to expand existing stewardship programs to include expert oversight of antiretroviral treatment.

In the NEWS

First Ever Phase 1 of Genital Chlamydia Vaccine Finds it is Safe and Provokes Immune Response

THE FIRST EVER chlamydia vaccine to reach phase 1 clinical trial has been found to be safe and able to provoke an immune response, according to a study published in *The Lancet Infectious Diseases* journal. The randomised controlled trial of 35 healthy women demonstrates promising early signs of what could be an effective vaccine, but further trials are required to determine whether the immune response it provokes effectively protects against chlamydia infection.

Chlamydia, caused by the bacterium *Chlamydia trachomatis*, presents a major global health burden, with 131 million new cases occurring annually. However, as three out of four infections are symptomless, the number of cases is likely to be underestimated. The highest number of new cases are found in teenagers and young adults.

Vaccination may be the best way to tackle the epidemic, as national treatment programs have largely failed to curb the epidemic, despite availability of diagnostic tests and effective antibiotic treatment. Previous studies have suggested that people infected with chlamydia develop either partial or temporary natural immunity to the pathogen, but no previous vaccines for genital chlamydia have reached clinical trials.

“Given the impact of the chlamydia epidemic on women’s health, reproductive health, infant health through vertical transmission, and increased susceptibility to other sexually transmitted diseases, a global unmet medical need exists for a vaccine against genital chlamydia,” says study author, Professor Peter Andersen, from Statens Serum Institut, Denmark.

For one in every six women infected with chlamydia, the infection travels up from the cervix and causes pelvic inflammatory disease. This can result in chronic pelvic pain and even

infertility or ectopic pregnancy, especially in the developing world, where access to treatment and screening is limited. In addition, chlamydia is strongly associated with susceptibility to other sexually transmitted infections, particularly gonorrhea and HIV, and chlamydia infection during pregnancy can increase the risk of adverse outcomes such as miscarriage, stillbirth, and preterm birth.

In the trial, the authors aimed to assess the safety and ability to provoke an immune response, in humans, of a new chlamydia vaccine CTH522 based on the major outer membrane protein of the *C trachomatis* bacterium. The researchers compared two different formulations—one with added CAF01 liposomes designed to aid cellular immunity and one with aluminium hydroxide known for its ability to help produce antibodies—to examine which formulation would perform better.

The 35 women not infected with chlamydia included in the trial were randomly assigned to three different groups: two with the new vaccine, CTH522, and one to placebo (five

participants received saline). Of those receiving the vaccine, 15 participants received the vaccine combined with CAF01 liposomes (CTH522:CAF01), and the other 15 received the vaccine with aluminium hydroxide (CTH522:AH).

The vaccination was given to participants in three intramuscular injections in the arm administered on day 0, 28, and 112 and two intranasal boosts administered on day 126 and 140. Thirty-two participants received all five vaccinations.

Both formulations of the vaccine provoked an immune response in 15 out of 15 (100 percent) participants, whereas no participants in the placebo group achieved an immune response.

While both formulations of the vaccines were found to provoke an immune response, CTH522:CAF01 consistently performed better (producing 5.6 times more antibodies), so the authors suggested this formulation should be pursued for further clinical development. CTH522:CAF01 showed additional signs of better performance compared with CTH522:AH including an enhanced mucosal antibody profile



myLAB Box Announces Safe is Sexy Checklist for Back to School

that serves as first line of defense against the infection, and a more consistent cell-mediated immune response profile that is associated with long-lived immunity.

Although the vaccine provokes an immune response, whether this translates into protective immunity remains unclear. First author Helene B Juel, Statens Serum Institut, Denmark says: "Studies of antibodies in mice have found that antibodies in the vagina are the first line of defence against chlamydia infection, which suggests they are key to how effective the new vaccine may be. In our trial, significantly increased concentrations of these antibodies were found in both CTH522:CAF01 and CTH522:AH-vaccinated individuals.

Although many more years of research are needed before this vaccine is marketed, we are planning the next stage of research—a phase 2a study of CTH522:CAF01."

CTH522 with either CAF01 or aluminium hydroxide appeared to be safe and well tolerated. There were no related serious adverse events reported. The most frequent adverse events were mild local injection-site reactions (all 15 participants in the two vaccine treatment groups had a mild reaction, which seemed to occur more frequently than in the placebo group [three out of five participants affected]). The most common local reactions were injection-site pain, tenderness, and movement impairment, with 88-93% of events being reported as mild in each of the groups, lasting a median of two to four days in all groups.

The authors note that the main limitation of the study was its sample size. As with other phase 1 trials, the small sample size limited its ability to pick up rarer adverse reactions to the vaccine or provide robust evidence on its ability to provoke an immune reaction.

Writing in the linked comment, Professor Toni Darville from University of North Carolina, noted: "A vaccine for prevention of C trachomatis infection would have enormous public health and economic impact. Although clinical vaccine testing for chlamydia is in its infancy, this trial suggests optimism for the future."

WITH MANY STUDENTS either starting college for the first time or returning to school, the number of STDs remain high for this particular demographic. According to **CDC**, "there are about 20 million new cases of STDs each year in the United States. About half of these infections are in people between the ages of 15 and 24. Young people are at greater risk of getting an STD." To that end, **myLAB Box**, the first nationwide at-home STD testing service, announced a series of sexual health tips to college students designed to decrease the likelihood of catching a disease during the most formidable years.

Among the sexual health tips from myLAB Box for college students:

- **Schedule a Doctor's Visit & Get Tested:** Before packing up for the big move back to college, make an appointment to see your doctor so you can receive all the needed vaccines and medications. Consider getting vaccines for hepatitis A, hepatitis B, and HPV. Making sure you are up to date on vaccinations like the HPV vaccine is extremely important as this vaccine helps to safeguard against cervical cancer. Regular testing is the best way to consistently know your status. If you're too nervous to go to a clinic, you can order an at-home STD testing kit and do the test right in your dorm room. It's so easy that it leaves you with no valid excuse for not getting tested. Parents can help too by sending their children a test kit in their care packages this upcoming fall.
- **Educate Yourself About All Things Sex Related:** STDs are not only passed through intercourse. They can be contracted through oral sex and, in some cases, even from kissing. For example, herpes, chlamydia, and gonorrhea are three infections that can directly affect your mouth or throat. It pays to educate yourself on the common signs and symptoms of the most common STDs and remember that as many as 80 percent of infections may show little to no symptoms at all. Think twice before you kiss someone at those house parties of the year and test regularly.
- **Stock Up On Condoms:** Condoms are one of your best methods of defense against infection and unwanted pregnancies. When used correctly, it can offer a 98 percent chance of preventing pregnancy. While not perfect, latex condoms are also among the best ways to protect against many STDs, however, some infections can be passed by skin to skin contact so stay vigilant even if you practice safe sex. Don't forget to stock up this fall!
- **Remember Contraceptives:** There are other contraceptives to protect yourself as you go back to school and back in bed. These include the birth control pill, the patch and the ring, all of which are prescribed by your doctor. All of these methods are designed to administer hormones to your body—via pill, a patch that is worn on your skin, or a ring that you insert vaginally—for three weeks at a time, with your period occurring in the fourth week.

To help college students everywhere take greater control of their sexual health, myLAB Box is offering a 20 percent discount from now until the end of September with the following discount code—backtoschool2019. And for students with either a medical Flexible Savings Account (FSA) or a Health Savings Accounts (HSA) accounts, myLAB Box proudly accepts both **FSA and HSA** as payment options, making its service even more affordable and accessible for men and women in every state.

In the NEWS

DHHS “Proposed Rule” Proposes to Sidestep Non-discrimination Protections

ON AUGUST 13th, AAHIVM joined with 40 other organizations in signing a Public Comment letter (<https://www.chlpi.org/wp-content/uploads/2013/12/HHCAWG-1557-Comments-8-13-2019.pdf>) to Alex M. Azar, II, Secretary of the Department of Health and Human Services (DHHS), regarding a “Proposed Rule” that, if allowed, would seriously distort, reduce and block compliance with existing legal protections designed to counter discrimination.

The new Proposed Rule (ironically called Nondiscrimination in Health and Health Education Programs or Activities) would effectively “produce a weak, confusing mix of legal standards and remedies that would be difficult for federal and state agencies to enforce... mak[ing] it more difficult for consumers with complaints of intersectional discrimination to file complaints.”

Our existing legislation—called Section 1557 of the ACA or the “Final Rule”—is built upon the Civil Rights Act of 1964 and other laws passed to ensure access to civil rights remedies for all. Since DHHS can’t change this current law, they have introduced the Proposed Rule to sharply narrow the protections that are currently and deliberately broadly defined. The current Section 1557 provisions, for example,

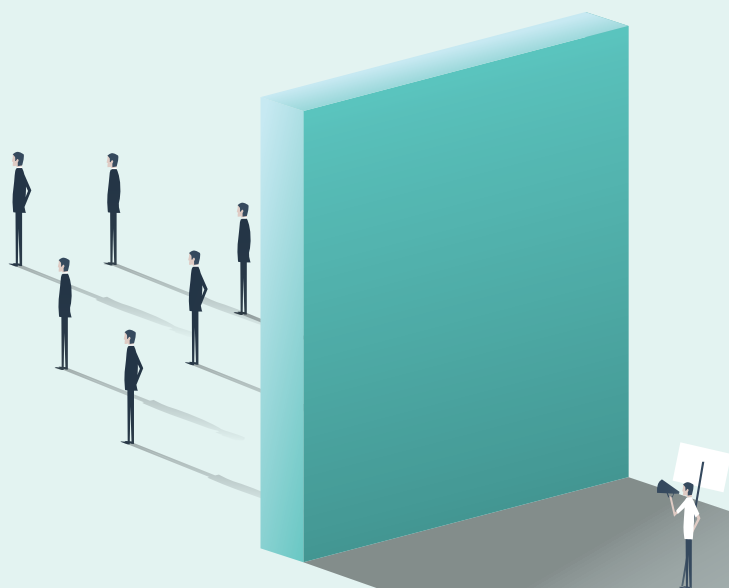
recognize sex discrimination as including discrimination on the basis of gender identity and sex stereotyping—a position accepted within the last decade. The new Proposed Rule, however, does not include this definition and, in fact eliminates most legal definitions altogether, thus effectively impeding future plaintiffs’ ability to sue DHHS for discriminatory actions in these areas.

Our Public Comment letter describes this change as, “contrary to the plain language of the law and, if finalized, would create a vague, unworkable rule with significant impacts on people living with HIV and other chronic illnesses and disabilities, lesbian, gay, bisexual, transgender, and queer (“LGBTQ”) people, people who need reproductive healthcare (including abortion), women of color, and people whose primary language is not English—all people who already experience significant barriers when accessing healthcare.”

The Proposed Rule also distinguishes sharply between what DHHS requires of entities not principally engaged in direct healthcare provision and what is required of providers who are engaged in direct care paid for with federal assistance. The latter would have to comply with Section 1557 regulations (no discrimination). Because most insurers don’t provide direct healthcare services, they would generally be exempt from the existing regulations. Plans or programs that do provide direct services while housed within insurance companies would be an exception. These plans and programs would still have to comply with Section 1557, if federally subsidized. But overall, the Proposed Rule would allow increased discrimination in healthcare settings.

The comment letter spells out additional ways in which the Proposed Rule flatly overrides the plain reading of Section 1557, which currently states that a person shall not “be excluded from participation in, or be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance.”

This Proposed Rule, if approved, would make it much more difficult for people to understand or access anti-discrimination protections. Therefore, the Public Comment letter urges the Department to rescind the Proposed Rule entirely.



Understanding the Challenges with PrEP Uptake and Testing

DESPITE THE MANY advances in prevention and treatment, HIV disease remains highly prevalent in the United States. More than 1.1 million Americans are living with HIV.¹ There are still approximately 40,000 new infections each year and approximately 15,000 people die from HIV/AIDS annually.^{1,2} An additional estimated 15 percent of Americans do not know that they have been infected with the virus.³

Studies have shown a significant difference between HIV providers and primary care providers in awareness, knowledge, comfort and experience with prescribing PrEP.

Over the last seven years, one of the most important advances in HIV prevention has been the introduction of pre-exposure prophylaxis (PrEP), a daily pill that includes two antiviral agents—tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC)—for people who are HIV negative to protect against acquisition of the virus. Clinical trials have shown that when taken on a daily basis, PrEP is highly effective, reducing the likelihood of HIV infection by greater than 90 percent.^{4,5,6}

Although about 1.2 million people are eligible for PrEP in the United States, only 77,000 people were prescribed PrEP in 2016.⁷ Despite its efficacy, PrEP has been implemented with limited scale in the United States, largely among the men-who-have-sex-with-men (MSM) population.⁸ Women make up only 7 percent of all PrEP users, despite accounting for 19 percent of all new HIV diagnoses.⁷

In addition to gender differences, PrEP usage follows some interesting geographical patterns. Nearly 50 percent of PrEP users in 2016 were located in just five states: New York, California, Florida, Texas, and Illinois.⁷ The Southern United States accounted for 52 percent of all new HIV diagnoses, yet represented only 30 percent of all PrEP users.⁷ Of note, the states with the highest PrEP uptake had a reduction in HIV infections of nearly 5 percent. Conversely, the states without high PrEP uptake experienced a 1 percent increase in new HIV infections.⁹

The U.S. Centers for Disease Control and Prevention (CDC) recommend that PrEP be considered for people who are HIV negative and at risk for HIV infection.¹⁰ In June 2019, the U.S. Preventive Services Task Force (USPTF) published their recommendations on the use of PrEP for HIV prevention, giving it a “Grade A” rating.¹¹ In light of these strong evidence-based recommendations for the use of PrEP to prevent HIV infection, it is important to understand why PrEP usage in the U.S. is so low. This article is a brief introduction to some of the major challenges in PrEP uptake.

Examining the Barriers

There are many barriers to the widespread adoption of PrEP, both at the provider and patient levels. A key barrier remains

access to PrEP providers. There are also complexities with baseline counseling, testing and subsequent monitoring of PrEP patients which are challenging for busy clinical practices to manage. More education and training are needed to help HIV specialists and primary care providers (PCP) expand the knowledge and skills needed to effectively prescribe PrEP. In addition, access and stigma must be overcome to increase PrEP use by patients.

Challenges for Healthcare Professionals

Knowledge Disparity between HIV Providers and Primary Care Providers

In order to prescribe PrEP, healthcare providers need to be aware of and knowledgeable about a range of PrEP-related topics. Providers must overcome intrinsic biases and engage patients in open discussions about sexual behaviors and risk reduction. Studies have shown a significant difference between HIV providers and primary care providers in awareness, knowledge, comfort and experience with prescribing PrEP. According to a survey of 525 PCPs and HIV providers, fewer PCPs than HIV providers had heard of PrEP (76 percent vs. 98 percent), felt familiar with prescribing PrEP (28 percent vs. 76 percent), or had ever prescribed it (17 percent vs. 64 percent). Primary care providers were also less comfortable than HIV providers with PrEP-related activities such as discussing sexual practices (75 percent vs. 94 percent), testing for acute HIV infection (83 percent vs. 98 percent), or delivering a new HIV diagnosis (80 percent vs. 95 percent). PCPs reported limited knowledge about PrEP as a major prescribing barrier.¹²

These findings suggest that PrEP uptake could be increased immediately by connecting potential PrEP users with current PrEP providers—both HIV providers and PCPs—through PrEP navigation. The data also suggest the need for PrEP provider capacity building. In fact, in the studies cited above nearly all PCPs were willing to participate in at least some aspects of PrEP provision (e.g., discussing PrEP with patients and referring eligible patients to PrEP providers) and more than

Results from Survey: PrEP Awareness, Familiarity, Comfort, and Prescribing Experience among US Primary Care Providers and HIV Specialists

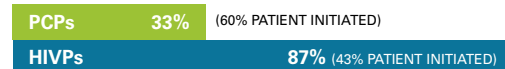
PERCEIVED BARRIERS TO PRESCRIBING PrEP



SOMEWHAT OR VERY FAMILIAR WITH PRESCRIBING PrEP



EVER DISCUSSED PrEP



EVER PRESCRIBED PrEP



2015 survey: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5500978/>

While there has been significant progress with PrEP implementation for certain groups, such as MSM, sex workers and injection drug users, there remain healthcare disparities.

75 percent were willing to prescribe PrEP if properly trained. More education is needed to help providers stay abreast of changes in PrEP guidelines and new clinical information. Educational programs that include skill-building around sexual history-taking and knowledge-based PrEP content would also be beneficial.

Involved Counseling Process

Initiating a new PrEP treatment plan may require a significant time investment for healthcare professionals. The provider needs time for initial and subsequent counseling sessions to address a variety of topics, including lab testing, PrEP side-effects and adherence, risk-reduction counseling, and ongoing clinical and lab monitoring. Studies have found that investing time to adequately counsel patients can yield significantly better outcomes, especially with PrEP adherence. In one study, enhanced counseling with problem-solving and motivational interviewing techniques was linked to better PrEP treatment compliance among an MSM population.¹³

Complex Monitoring and Testing Processes

As part of HIV prevention with PrEP, the CDC had issued specific guidelines in 2014 (updated in 2017) that included baseline testing and laboratory monitoring of patients on PrEP.¹⁰ Full implementation of these guidelines can lead to operational complexity and burden for healthcare providers and their practices. Baseline testing and follow-up screening tests at three and six months can easily add up to nine different tests for each patient to undergo and have the provider track for their PrEP patients.

Before PrEP initiation, healthcare providers must conduct an HIV test to ensure that the patient is not already infected with the virus. While a patient is taking PrEP, they should ideally be tested for HIV at three-month intervals to ensure that they have not seroconverted. This could

lead to drug-resistance as TDF/FTC is not a complete HIV treatment regimen.

Baseline renal function (serum creatinine) must be measured, as PrEP is only recommended in patients with creatinine clearance greater than 60 mL/min. As part of ongoing monitoring, renal function should be checked at six-month intervals to assure the medications are not causing renal toxicity—a rare but potential complication of TDF.^{14,15}

Because TDF is active against hepatitis B virus (HBV) infection, the CDC recommends baseline HBV testing, including antibody and antigen. If patients have chronic HBV, it is safe to use PrEP, but treatment can become more complicated. For women who are prescribed PrEP, healthcare providers should conduct a pregnancy test at baseline and every three months. In addition, the guidelines recommend that sexually transmitted infection (STI) screenings be performed every three to six months, depending on the patient's STI risk factors. It is important for healthcare providers to screen for gonorrhea and chlamydia at all sites: pharyngeal, genital and rectal. This may be challenging for providers who do not have the skills to perform extra-genital STI testing and also be resisted initially by some patients. The guidelines do note that self-collected samples have similar clinical performance as those obtained by providers so this may be a consideration for some practices.

Challenges for High-Risk Individuals

Limited Access

The availability of PrEP is currently very limited, with only about 5 percent of persons at substantial risk of HIV infection having access to PrEP.¹⁶ While there has been significant progress with PrEP implementation for certain groups, such as MSM, sex workers and injection drug users, there remain healthcare disparities. With 64 percent of all PrEP

users between the ages of 25 and 44, those under the age of 25 may be overlooked.⁷ Additionally, gaps remain with delivery to Latinos and Blacks who made up only 3 percent and 1 percent respectively of all PrEP users in 2015-16.¹⁷ Last but certainly not least, 93 percent of all PrEP users in 2016 were male, which is 14 times higher the number of female PrEP users.

Stigma

Stigma plays a key role in impacting uptake and adherence to PrEP. For example, in some settings, PrEP may be negatively associated with high-risk sexual activity. Patients may believe that, if they take PrEP, others may view them as irresponsible, promiscuous or even living with HIV. Some patients may be suspicious of the pharmaceutical industry or have distrust of the healthcare system, based on prior experiences, so they never try to access or start PrEP.¹⁸ Other patients do not perceive they are at risk for HIV, so they may believe they do not need PrEP. Ongoing public awareness and education about the benefits of PrEP in lowering the risk of acquiring HIV and the overall incidence of HIV infection is needed to help remove this stigma.

Adherence and Commitment

Patients ideally should commit to taking PrEP every day for it to be most effective. PrEP users also must visit their healthcare provider every three months to assess the continued need for PrEP and recommended laboratory monitoring. These follow-up appointments may necessitate travel and time away from work, which is a burden to many patients. Patients may ultimately decide that the commitment to PrEP is not sustainable. Providers and clinical sites should make all efforts to meet patients where they are and make PrEP access convenient and affordable. Although not consistent with current CDC/USPHS guidelines, some PrEP programs have moved to six-month interval visits for patients as a way to limit the burden of frequent appointments and testing.

Efforts to Address Key Challenges

Currently, there are a range of initiatives underway to address and raise awareness surrounding the challenges with PrEP uptake and testing. Organizations such as the American Academy of HIV Medicine (AAHIVM) are implementing educational programs to help healthcare providers better understand PrEP, testing, and associated coding. The CDC has excellent online resources on PrEP for clinical practice.¹⁰ To address the burden of monitoring, testing and reporting, simplification of these processes with order sets or proprietary PrEP laboratory panels, such as Quest Diagnostics PrEP Panels, can improve testing efficiency for healthcare providers and patients. Specific order sets that include all of the CDC-recommended tests can greatly improve provider and office staff efficiency and allow providers to spend less time looking up tests and more time with their patients.

To address many of the patient-level barriers, there is ongoing work to expand convenient and affordable PrEP services in unconventional settings, such as emergency departments, pharmacies and telemedicine visits. Still, more work is needed to address the stigma and perceived low risk that many people have surrounding HIV and the need for PrEP. Hopefully, continued efforts to simplify HIV pre-exposure prophylaxis will increase its availability and access, so everyone has the best HIV prevention tools available to them.

HIV



ABOUT THE AUTHOR

Dr. Gina M. Simoncini is an Associate Professor of Clinical Medicine, Section of General Internal Medicine, at the Lewis Katz School of Medicine at Temple University. Dr. Simoncini received her medical degree from Temple University School of Medicine and her Master's in public health at the College of Public Health at Temple University. Dr. Simoncini practices in the HIV Comprehensive Program at Temple, with a clinical and research focus on the screening, treatment and prevention of HIV & Hepatitis C.

REFERENCES

- Centers for Disease Control and Prevention. HIV in the United States: At a glance. <http://www.cdc.gov/hiv/statistics/overview/ata glance.html>.
- Centers for Disease Control and Prevention. Today's HIV/AIDS epidemic. <http://www.cdc.gov/nchhstp/newsroom/docs/factsheets/todaysepidemic-508.pdf>.
- HIV.gov. U.S. statistics. <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics>
- McCormack, S. et al (2014) 'Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomized trial' *The Lancet* 387(10013):53-60
- Baeten, J.M. et al (2012) 'Antiretroviral Prophylaxis for HIV-1 Prevention among Heterosexual Men and Women' *New England Journal of Medicine* 367(5):399-410
- Grant, R.M. et al (2010) 'Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men' *New England Journal of Medicine* 363:2587-2599
- AIDS Vu. Mapping PrEP: First Ever Data on PrEP Users across the U.S. <https://aidsvu.org/prep/>
- Mayer KH, Chan PA, Patel R, Flash CA, Douglas S Krakower. Evolving models and ongoing challenges for HIV pre-exposure prophylaxis implementation in the United States. *J Acquir Immune Defic Syndr.* (2017) 77:119-27.
- Sullivan P et al. The impact of pre-exposure prophylaxis with TDF/FTC on HIV diagnoses, 2012-2016, United States. 22nd International AIDS Conference (AIDS 2018), Amsterdam, abstract LBPEC036, 2018.
- Centers for Disease Control and Prevention: US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. Published March 2018. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017>
- Preexposure Prophylaxis for the Prevention of HIV Infection. : US Preventive Services Task Force Recommendation Statement Article Information *JAMA.* 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390
- Petroll, A.E. et al (2017) PrEP awareness, familiarity, comfort, and prescribing experience among US primary care providers and HIV specialists. *AIDS Behav.* 2017 May; 21(5): 1256-1267.
- Mayer KH, Safren S, Haberer J, et al. HIV Research for Prevention. Cape Town, South Africa: 2014. Project PrEPARE: high levels of medication adherence with continued condomless sex in U.S. men who have sex with men in an oral PrEP adherence trial. Abstract OA07.06 LB.
- Venter WD. What does preexposure prophylaxis mean for treatment; what does treatment mean for preexposure prophylaxis? *Curr Opin HIV AIDS* (2016) 11:35-40.
- World Health Organization. WHO Implementation Tool for Pre-Exposure Prophylaxis (PrEP) of HIV Infection World Health Organization. <http://www.who.int/hiv/pub/prep/prep-implementation-tool-policy/en/>
- UNAIDS. 2016. Prevention Gap Report. http://www.unaids.org/sites/default/files/media_asset/2016-prevention-gap-report_en.pdf
- Buchbinder SP, Liu AY. CROI 2018: Epidemic trends and advances in HIV prevention. *Topics Antiviral Med* 2018; 26: 1-16.
- Mera Giler R, Mangnuso D, Trevor H, Bush S, et al. Changes in Truvada (TVD) for HIV pre-exposure prophylaxis (PrEP) utilization in the United States: (2012-2016). Paper presented at the 9th International AIDS Society Conference on HIV Science; Paris, France; July 23-26, 2017.

Confronting **HIV** and other **STD**s

Success
against one
requires action
against all





By **DAVID C. HARVEY,**

Executive Director, National Coalition of STD Directors

BY ALL ACCOUNTS, the United States is on the cusp of a remarkable new phase in its response to the HIV epidemic. After a decade of scientific and programmatic innovations, President Trump's stated commitment to end the epidemic within 10 years is not only welcome, it is within the realm of possibility.

Often neglected, however, is the fact that HIV cannot be eliminated unless we also reinforce the prevention of other sexually transmitted diseases (STDs). On that front, we are moving in the wrong direction. Even as HIV diagnoses gradually decline, the incidence of other STDs has rapidly risen to all-time highs in the face of insufficient federal funding.¹ Undiagnosed and untreated STDs drive a substantial portion of ongoing HIV transmissions, and STDs represent a major strain on our nation's health and finances in their own right.

HIV clinicians have an enormous stake in reversing these trends. As important guardians of their patients' sexual health, they can directly improve STD diagnosis, treatment, and prevention in communities most affected. Just as importantly, as a community, HIV care providers have the credibility to demand the investments and policy changes on which our collective success depends.

The HIV and STD epidemics are inextricably linked

STDs are an underlying driver of new HIV infections, increasing the risk of HIV transmission as much as five-fold.² A recent Emory University study found that 10 percent of new HIV infections are attributable to gonorrhea and chlamydia—and many others are linked to syphilis infections.³ Even with all the progress that has been made in HIV prevention and with an infusion of new resources from the proposed federal Ending the HIV Epidemic plan, transmission of HIV will continue if STD rates remain unchecked.

The current outlook is not good. In 2017, the most recent year with reported data, approximately 2.3 million cases of chlamydia, gonorrhea, and syphilis were diagnosed in the United States—a more than 30 percent increase over the last five years and the highest reported case count in history. Several state surveillance reports show these figures increasing in 2018.¹

HIV and other STDs are also linked by the populations they affect. As HIV clinicians know, people at risk for HIV are typically also at risk for other STDs. Broadly speaking, this includes racial and ethnic minorities, people with limited access to healthcare, transgender women, and black and Latino women. It also includes gay and bisexual men, who are by far the most affected by HIV and have experienced alarming increases in other STDs in recent years. Providing quality care means addressing these populations' sexual

health needs beyond HIV prevention and treatment.¹ This is also a key component to effectively combat the HIV and STD epidemics in this country.

Why are STDs on the rise?

It is not uncommon for people to attribute recent STD increases to progress in HIV treatment and prevention. As the use of pre-exposure prophylaxis (PrEP) for HIV prevention increases and as more and more people living with HIV achieve viral suppression (rendering their infections “undetectable” and therefore “untransmittable”), it is logical to assume that condom use would decline as people's chosen safer sex option.⁴ In fact, we have seen a decrease in condom use, but this trend existed before the rise of PrEP. Evolving safer sex choices, like opting for methods other than condoms, can increase STD transmission risk for some individuals. However, some modeling suggests that the healthcare and STD testing requirements that accompany HIV treatment and PrEP can also have a positive influence, increasing diagnosis and reducing STD rates in these populations in the future.⁵

Ultimately, the sum total impact of advances in HIV prevention on the risk of other STDs remain debatable. But that is not the debate we should be having—it is not where we will find answers to our STD crisis. There are two fundamental areas where our nation's approach to STDs is falling short: funding and integration with HIV-related services.

Inadequate funding has hampered STD prevention efforts for too long. The federal government's commitment to STD prevention has dwindled for more than a decade, even as HIV prevention receives a well-deserved injection of resources and attention. Since 2003, federal funding for STD prevention has seen a 40 percent decrease in purchasing power.⁶ In parallel, local funding has lagged. On average, states and cities contribute roughly 43 cents to STD prevention budgets for every federal dollar, but that figure varies substantially state-to-state. The good news is that that Congress may be poised to inject some much needed funding into federal STD prevention at CDC with the House approving a \$10 million budget increase for FY 2020. Unfortunately, this new money would amount to a down payment on what's truly needed to address this growing crisis.

STD clinics have been particularly strained by declines

in STD prevention funding. The cuts have significantly curtailed the services they're able to provide—forcing some to reduce hours of operation and others to close altogether. This has devastating consequences for STD and HIV prevention and public health. Many Americans—including those who are at increased risk for HIV and other STDs—rely on publicly-funded clinics for testing, treatment, and partner

of including STD prevention specialists and advocates in the planning process and my hope is that this will ensure STDs are given the attention they deserve as part of implementation.

At the clinical practice level, the uncomfortable truth is that healthcare providers—including HIV care providers—are not consistent enough in addressing their patients' other sexual health needs, including STD testing, treatment, and prevention. For example, research suggests that screening for chlamydia and gonorrhea, even among HIV-positive gay and bisexual men known to be at higher risk, is far below what is recommended by CDC guidelines.

The solution

To put our nation on the path to ending HIV, we need to embrace STD prevention as a priority at every level—from the clinic to the halls of Congress.

In the clinic, we must adopt an integrated approach to sexual health, encompassing patients' HIV care and prevention needs together with STDs and other aspects of sexual well-being. This should include:

- Following STD screening guidelines for all patients and taking thorough sexual health histories
- Taking a consistently non-judgmental approach to care that is supportive of diverse lifestyles, sexual identities, and sexual health choices
- Addressing sexuality as a core element of a person's overall health, whether they are living with HIV or not
- Promoting healthy and respectful sexual behaviors as critical to overall mental and physical health
- Embracing effective biomedical HIV prevention and HIV therapy as benefits to sexual health, and opportunities to engage people in care
- Coordinating more closely with our mental and behavioral health allies to provide more holistic care to address HIV and STDs

HIV care providers must be on the vanguard in this effort—and I am thankful that many already are. Changes in how sexual health services are delivered can play an important role in reversing STD trends and ensuring the drive to end HIV has the best chance of success. We will not get far, though, without real action from Congress.

Substantial new investments are needed to reverse declines in STD prevention funding. Research shows that STD prevention is a high-value investment. For every dollar spent on STD prevention, \$43 is spent on STD-related treatment.⁹ Furthermore, in the past 15 years, CDC-funded STD programs prevented an estimated 5.7 million cases of gonorrhea, syphilis, and chlamydia, and 3,300 STD-attributable HIV infections, saving an estimated \$2.4 billion in lifetime medical costs.¹⁰

My organization, the National Coalition of STD Directors, has called on Congress to allocate an additional \$70 million to next year's federal budget to support federal STD prevention at CDC so we can stave off what could be a public



The current outlook is not good. In 2017, the most recent year with reported data, approximately 2.3 million cases of chlamydia, gonorrhea, and syphilis were diagnosed in the United States—a more than 30 percent increase over the last five years and the highest reported case count in history.

notification services. For at-risk populations, these clinics also serve as a critical entry point to the healthcare system and other health services. This includes HIV diagnosis and treatment and, critically in this era, opioid and other substance misuse prevention and treatment.

To the detriment of both, HIV and STD prevention have too often been addressed as separate issues. At the state level, HIV and STD programs often have divergent if not entirely separate funding streams and budgets. In most cases there is good reason for this, but it demands that coordination be effective and consistent, which it often is not. Surveillance and medical record systems are often siloed, offices are housed in different buildings or even cities, and, in some cases, these programs are integrated on paper, but operate separately. For true coordination to work, these programs need to be at the same tables and working from the same data. In many parts of the U.S. we have a long way to go to truly make this happen.

At the level of federal policy, one doesn't have to look any further than the Ending the HIV Epidemic plan to understand that there are gaps in how well other STDs are addressed. STDs are mentioned just a handful of times in the proposal for how CDC funding for the plan will be spent.⁷ Thankfully, state and local planning teams are recognizing the importance

health catastrophe. These dollars would help re-open the doors to clinics nationwide, boost surveillance activities that allow us to respond more quickly to STD outbreaks in specific populations or locations, support greatly needed prevention and awareness campaigns, and engage people in high quality sexual healthcare, positively affecting both the HIV and STD epidemics.

In addition to ensuring adequate funding, we must foster a more integrated, comprehensive response to HIV and other STDs at the national level. The STI Federal Action Plan—due out next year—will be an important first step. For it to be successful, it will need to address STDs comprehensively—including (though not only) by:

- Reflecting an integrated approach to HIV, STDs, and overall sexual health
- Addressing health disparities and stigma in a meaningful way
- Attending to the overlapping nature of the drug, opioid, and STD epidemics
- Proposing concrete steps to increase training of healthcare providers in how to take sexual health histories and test for STDs
- Improving surveillance systems to allow for better information sharing between HIV and STD programs, as well as increasing data sharing between jurisdictions
- Increasing coordination on STD prevention, including testing and treatment, across all federal agencies
- Aligning with the Ending the HIV Epidemic plan, to ensure coordination and synergy

We know from experience that success is possible when political will, financial resources, and clinical approaches are aligned in addressing HIV and STDs together.

Perhaps the best example comes from New York City, where in 2015, as part of New York State's strategy for "getting to zero" new HIV infections and eliminating disparities, the

city launched its own "Ending the Epidemic" plan. The plan was comprehensive—addressing issues from the integration of harm reduction and biological HIV interventions, to the importance of training doctors to provide holistic, culturally-informed sexual healthcare.¹¹ Key elements of the strategy included transforming STD clinics into destination clinics for sexual health services, establishing clinics as a gateway for HIV treatment and prevention by launching same-day starts for PrEP and antiretroviral therapy, and committing to making New York City a "status neutral" (stigma-free) jurisdiction. According to Demetre Daskalakis, deputy commissioner for the Division of Disease Control of the New York City Department of Health and Mental Hygiene, these efforts not only improved the effectiveness of New York City's HIV and STD prevention efforts, but they converted local HIV activists into some of the city's strongest advocates for sexual health.

While HIV care providers and their allies are just one part of the solution, they have a tremendous potential to shape our nation's future on HIV and STDs. In the clinic, they can serve as a model for all healthcare providers in providing the integrated sexual healthcare that patients need. As a community, they have the credibility to serve as advocates for a fully funded, well-coordinated approach. It is our hope that this issue of *HIV Specialist* will inform and inspire the community to embrace that potential. **HIV**

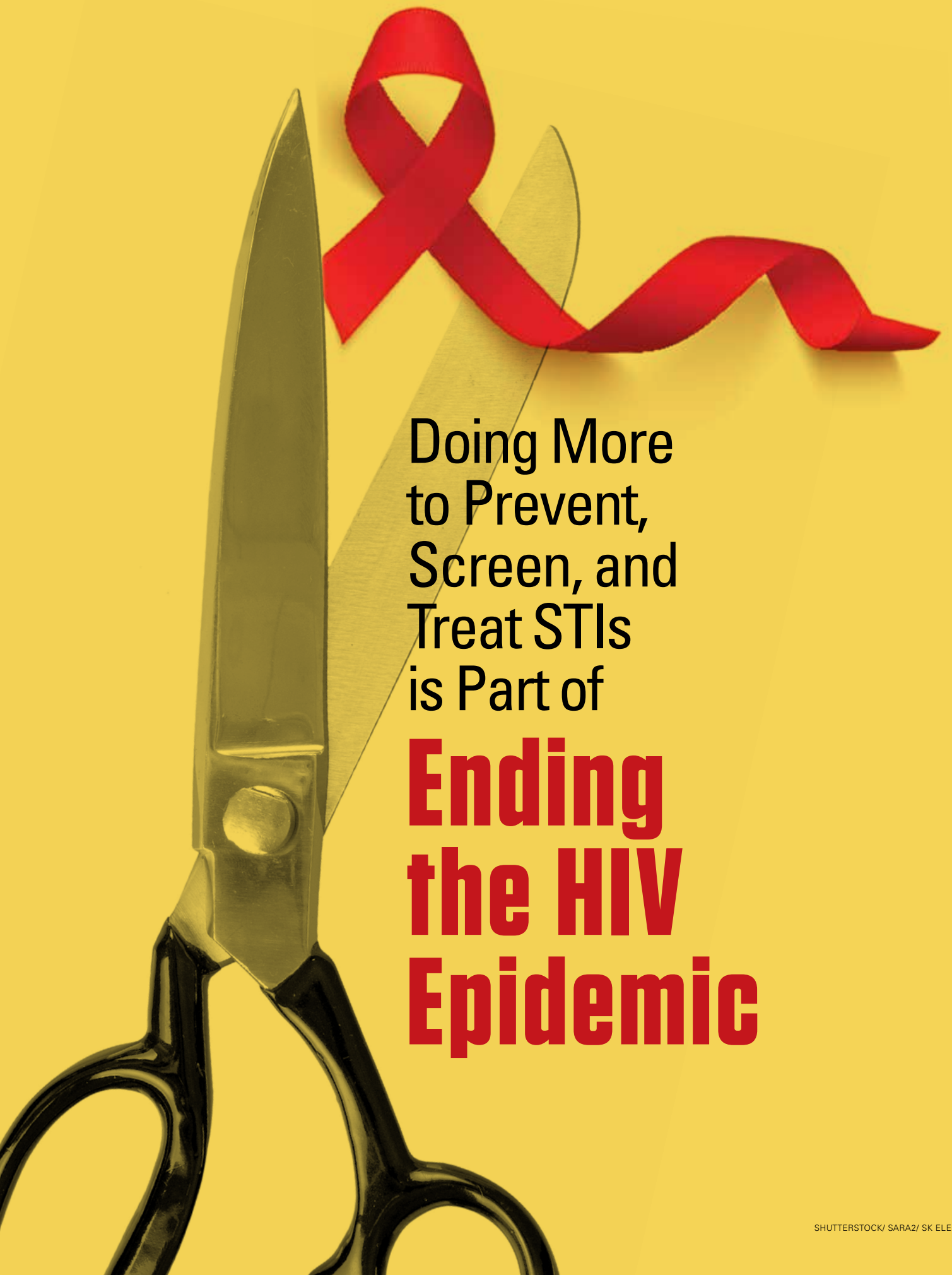


ABOUT THE AUTHOR

David C. Harvey, MSW, is executive director for the National Coalition of STD Directors, a national public health membership organization representing health department STD directors, their support staff, and community-based partners across 50 states, seven large cities, and eight US territories. David was founding executive director of AIDS Alliance for Children, Youth & Families and has served as CEO of Proliteracy and executive director at LIFT-DC.

REFERENCES

1. CDC National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. New CDC analysis shows steep and sustained increases in STDs in recent years. <https://www.cdc.gov/nchhstp/newsroom/2018/press-release-2018-std-prevention-conference.html>. Accessed August 2, 2019.
2. HIV.gov. What do you need to know about STDs? <https://www.hiv.gov/hiv-basics/staying-in-hiv-care/other-related-health-issues/sexually-transmitted-diseases>. Accessed August 2, 2019.
3. Jones J, Weiss K, Mermin, Dietz P, et al. Proportion of incident HIV cases among men who have sex with men attributable to gonorrhea and chlamydia: A modeling analysis. *Sex Transm Dis*. 2019; 46(6):357-363.
4. NIH. The science is clear: with HIV, undetectable equals untransmittable. <https://www.nih.gov/news-events/news-releases/science-clear-hiv-undetectable-equals-untransmittable>. Accessed August 2, 2019.
5. Jenness SM, Weiss KM, Goodreau SM, et al. Incidence of gonorrhea and chlamydia following human immunodeficiency virus preexposure prophylaxis among men who have sex with men: A modeling study. *Clin Infect Dis*. 2017;65(5):712-8.
6. National Coalition of STD Directors. Annual CDC—STD prevention budget FY 2003—FY 2018. http://www.ncsddc.org/wp-content/uploads/2018/08/Syphilis-over-time-vs-Federal-funding_NCSD.pdf. Accessed August 2, 2019.
7. Centers for Disease Control and Prevention. Notice of funding opportunity PS19-1906: Strategic partnerships and planning to support ending the HIV epidemic in the United States. <https://www.cdc.gov/hiv/funding/announcements/ps19-1906/index.html>. Accessed August 2, 2019.
8. Hoover K, Butler M, Workowski K, et al. STD screening of HIV-infected MSM in HIV clinics. *Sex Transm Dis*. 2019;37(12):771-776.
9. National Coalition of STD Directors. STD prevention 101. <http://www.ncsddc.org/resource/stds-the-basics/>. Accessed August 2, 2019.
10. Centers for Disease Control and Prevention. CDC's STD work improves health and saves money. <https://www.cdc.gov/nchhstp/budget/infographics/std.html>. Accessed August 2, 2019.
11. The New York City Department of Health and Mental Hygiene. Ending the epidemic overview. <https://www1.nyc.gov/assets/doh/downloads/pdf/ah/ete-strategy.pdf>. Accessed August 2, 2019.



Doing More
to Prevent,
Screen, and
Treat STIs
is Part of

**Ending
the HIV
Epidemic**

By JEFFREY S. CROWLEY, MPH

THE POLITICS OF THE MOMENT are divisive and it seems that even long-settled policy issues are being revisited. It can be hard to know what to do or how to cope. Every day, we see more threats to the communities most impacted by HIV, more open racism and discrimination, and indeed, more cause for despair. In this environment, it was more than a little surprising to hear President Trump announce a bold goal in his State of the Union address earlier this year that his administration is committed to working toward ending the HIV epidemic in the United States over the next decade. His team has defined this to mean that they are seeking new funds and new approaches to reduce HIV transmission by 75 percent within five years and by 90 percent within ten. Additionally, the Trump administration is working on an update to the National HIV/AIDS Strategy, as the current plan set goals for 2015-2020, as well as an update to the National Viral Hepatitis Action Plan, and a first-ever Sexually Transmitted Infection (STI) Federal Action Plan.

The Administration is to be applauded for recognizing the connections between HIV, viral hepatitis, and STIs. In fact, HIV community stakeholders need to remind ourselves how integral prevention, screening, and treatment of other infectious diseases is to meeting our own goals for not only reducing new HIV transmissions, but also improving the health and quality of life of people with HIV. In this context, it is important to recognize that when it comes to STIs, the Nation's house is on fire.

At the beginning of this century, there was confidence that we were close to eliminating syphilis and we were making great progress at controlling chlamydia and gonorrhea. Today, we have raging epidemics of chlamydia and gonorrhea and we are seeing troubling increases in syphilis, including among newborns. Some of this is intertwined with the opioid crisis. HIV prevention and care programs already are overburdened, but we still need more from them—and HIV providers—to address STIs.

What is needed?

More screening for chlamydia, gonorrhea, and syphilis

HIV testing has been and remains a central tool for preventing HIV and the success of this commitment means that, as of 2016, 86 percent of all people with HIV in the U.S. had been diagnosed.¹ HIV physicians also have led the charge in working to remove barriers to HIV screening by pushing for policy changes to permit opt-out testing with oral consent. Additionally, the US Preventive Services Task Force reviewed the evidence and gave population-based screening an “A”



CDC data, from *Quick Take: The US STI Crisis*, O'Neill Institute, 2019.

rating. A similar focus on expanding access and routinizing STI screening could yield important improvements.

CDC has invested heavily in HIV testing and screening and there is presently a wonderful mix of community and clinical HIV testing options. But, when the risk behaviors are the same for HIV and other STIs, is there a rationale for not doing broader STI screening when we are screening for HIV? Clearly, current capacity and financing limitations may inhibit complete HIV-STI screening integration, but providers and program

administrators should re-visit this issue and consider whether more can be done to lower costs and make it feasible to screen more broadly for STIs when conducting HIV testing.

For persons using pre-exposure prophylaxis (PrEP), CDC guidelines call for STI screening before enrollment, with follow-up screening every six months. For some populations, such as highly sexually active men who have sex with men (MSM), many clinicians recommend STI screening every three months. Questions have arisen, however, over whether providers are showing a high fidelity to these guidelines.

A study of 15 safety net clinics in San Francisco found that provider adherence to PrEP monitoring guidelines was “sub-optimal.”² When starting patients on PrEP, providers did not order chlamydia, gonorrhea, or syphilis testing in one of every five cases. For the recommended follow-up STI screening every six months, STI testing was not ordered roughly one-third of the time. This is one study and more research is needed to understand if this is representative of STI screening as part of PrEP in other settings, but it does raise questions and concerns.

As we have taken steps to reduce the frequency of clinic visits for well-controlled patients and streamlined the visit, is it possible that STI screening and treatment has inadvertently fallen by the wayside? Again, I am not seeking to prescribe the solution as much as to enlist HIV providers in a dialogue about how they can contribute more to addressing a large and growing problem of STIs in our communities.

HIV providers have an important role in helping to increase provider adherence to these screenings as PrEP delivery is expanded into primary care with practitioners with less experience increasingly prescribing PrEP. There is also an urgent need to give consumers more options for regular STI screenings in a manner that reduces the burden and stress on PrEP users and providers alike. HIV providers have insights to share and the field needs their knowledge and creativity.

For people living with HIV, there also is evidence that STI screening is not being prioritized in clinical care. Data from CDC's Medical Monitoring Project (MMP), which provides nationally representative estimates of the experiences of

people with HIV in care, found that fewer than 40 percent received at least one test for each of chlamydia, gonorrhea, and syphilis in the preceding year, and the high point estimate rose to 45 percent among only those who were sexually active.³

As a non-clinician, I imagine that many providers face significant time pressures and resource constraints so that maybe STI screening is a lower priority than other facets of HIV clinical care. Surely, if a person with HIV is challenged in adhering to his or her HIV treatment regimen, addressing adherence must be a top priority. But, as we have taken steps to reduce the frequency of clinic visits for well-controlled patients and streamlined the visit, is it possible that STI screening and treatment has inadvertently fallen by the wayside? Again, I am not seeking to prescribe the solution as much as to enlist HIV providers in a dialogue about how they can contribute more to addressing a large and growing problem of STIs in our communities.

HIV Programs and Practitioners to Work with STI Programs and Practitioners to Promote Sexual Health Practice Transformation

As a non-clinician, I am often struck at how uncomfortable many physicians are at taking a sexual history or discussing

STIs Contribute to HIV Transmission

IN 2019, researchers at Emory University and the CDC published a modeling study that estimates that **1 0.2 percent of HIV infections among men who have sex with men (MSM) are believed to be attributable to infection with chlamydia or gonorrhea.** Since STIs contribute significantly to both transmission and acquisition, public health responses must better screen and treat both individuals living with HIV and HIV negative persons.

PrEP and STIs

Pre-exposure prophylaxis (PrEP) is recognized as a safe and highly effective intervention for preventing HIV infection. The introduction of PrEP, however, has been raised as a potential contributor to increased risk behaviors that could lead to more STIs, yet the PrEP regimen requires STI screening at PrEP initiation and every six months, with many clinicians screening every three months.

What is the likely net impact of PrEP on STI incidence and prevalence?

Jenness and colleagues conducted a US modeling study that estimates that STI screening as part of PrEP care would prevent 42 percent of gonorrhea cases and 40 percent of chlamydia cases among MSM over 10 years if implemented according to CDC guidelines. Their model estimates that under CDC's current guidelines of six-month STI screening, the PrEP regimen treated 17 percent more asymptomatic infections and 16 percent more rectal infections compared to their baseline assumptions. Their model also estimates that with STI screening and treatment every three months, STI incidence could be reduced by a further 50 percent.

Source: Jones, J et al, "Proportion of Incident Human Immunodeficiency Virus Cases Among Men Who Have Sex with Men Attributable to Gonorrhea and Chlamydia: A Modeling Analysis," *STD*, 2019.



Ending the HIV Epidemic (EHE) Initiative

Key pillars of the Ending the HIV EHE Initiative are:

- **Diagnose all people with HIV as early as possible:** As of 2016, 86 percent of people with HIV in the U.S. have been diagnosed, but this initiative aims to raise that higher.
- **Treat HIV infection rapidly and effectively to achieve sustained viral suppression:** Rapid start of antiretroviral therapy (ART) can be transformative, but also difficult to adopt across the U.S. healthcare financing system. A difficulty that must be overcome. Of course, more support is needed to achieve sustained adherence to ART to maintain durable viral suppression and other important health outcomes.
- **Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs:** The U.S. has achieved some declines in the number of new HIV infections after a period of many years of diagnoses totaling around 50,000 per year. As of 2017, about 40,000 people were newly diagnosed each year. EHE seeks to respond to troubling signs that national progress at lowering new infections has stalled.
- **Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them:** EHE seeks to advance the use of new tools to respond to transmission clusters in a more timely and focused manner. While supporting larger efforts to modernize HIV criminal statutes to follow the science of HIV transmission, there is a window of opportunity to enact laws and policies to ensure that HIV molecular data used in cluster detection analysis (and derived from the resistance testing that providers routinely order for clinical care) is not shared with law enforcement.

We now have more than 30 antiretroviral therapy (ART) agents for HIV treatment with more in the pipeline, yet some drugs for the treatment of STIs have been used for decades and there is a limited drug development pipeline.

sex with their patients. More than once, I have asked, “what exactly do they teach you in medical school?” But, joking aside, HIV providers are often ahead of the curve compared to other physicians and have a lot to share with other providers and policy makers as we seek to adopt a new framework for sexual health and create a new vocabulary about sex. Here, STI and HIV programs have a common agenda. Exciting work has begun to happen with transforming clinics and physical sites from places that communicated that there was something shameful about seeking sexual health services to something that is normal and positive.

New York City has been recognized for its leadership on this front.⁴ Health departments across the country are beginning to adopt new language and seeking new approaches, but what many of these jurisdictions need are clinical champions for a new sexual health approach.

HIV Surveillance and Research Initiatives to Contribute More to Our Understanding of Sexual Networks

The HIV community has been fortunate to have a sophisticated National HIV Surveillance System, as well as numerous research resources that enable us to monitor and learn about the HIV epidemic. Another surveillance system, MMP, monitors people with HIV in care. HRSA's Ryan White HIV/AIDS Program now operates a client-level dataset that provides valuable information about HIV health outcomes.

Moreover, the National Institutes of Health funds a wide range of studies and operates the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD), as well as various clinical trials networks. Further, the NIH's extramural HIV research program is organized around the Centers for AIDS Research (CFAR) network. These resources already contribute to our understanding of STI trends in the U.S., but more can be asked from these HIV resources. As clinicians, many of whom are also researchers, what are your ideas for how we can do even more with our HIV surveillance and research assets to assist the STI response?

Champions for STI Innovation

Compared to HIV, it can seem that there is less urgency around other STI research and programs. STIs threaten public health and impose major costs on society, but it can

be perceived that society tolerates the status quo. We now have more than 30 antiretroviral therapy (ART) agents for HIV treatment with more in the pipeline, yet some drugs for the treatment of STIs have been used for decades and there is a limited drug development pipeline. HIV providers are not expected to quit their day jobs to become STI advocates, but they have essential knowledge and expertise. Their voices are needed to create momentum for investing in STI innovation and for articulating priorities where progress is achievable.

It is laudable that the Trump administration is explicitly connecting their HIV, viral hepatitis and STI efforts. We all must applaud their exciting vision for Ending the HIV epidemic. HIV providers are on the frontlines every day grappling with complex challenges of HIV and STI patient care. Even as they struggle with the overwhelming burdens imposed in trying to provide high-quality HIV patient care, HIV providers have much to offer as we better integrate HIV and STI programs and care to strengthen our communities.

HIV

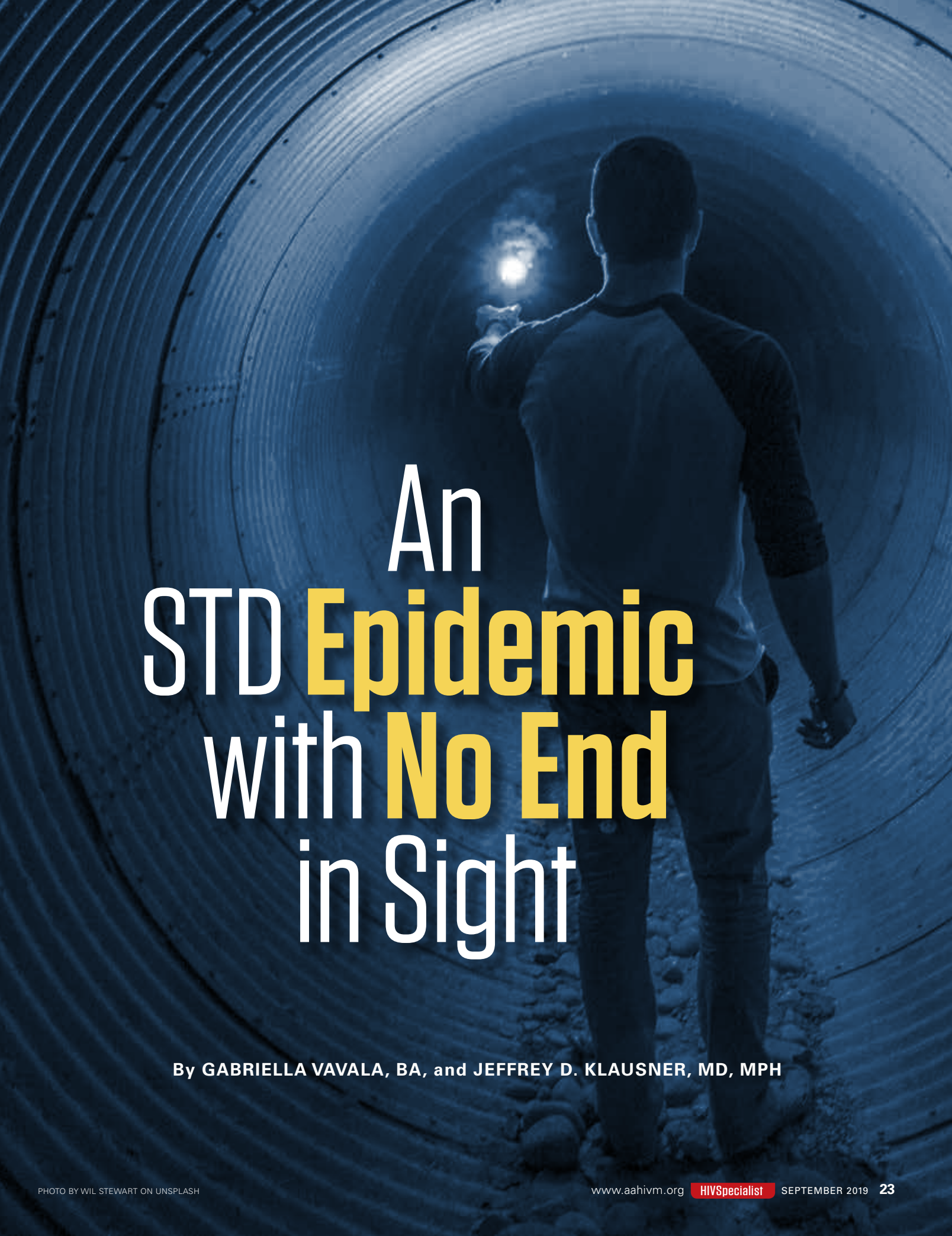


ABOUT THE AUTHOR

Jeffrey S. Crowley, MPH, is a Distinguished Scholar and Program Director of Infectious Disease Initiatives at the O'Neill Institute for National and Global Health Law at Georgetown Law. This article is adapted from a forthcoming brief, *Big Ideas: HIV Prevention and Care Systems Have Critical Roles in Addressing the Crisis of Sexually Transmitted Infections (STIs)* and was informed by a stakeholder consultation held in February 2019. This brief and other materials may be accessed at bit.ly/USHIVpolicyproject.

REFERENCES:

1. Centers for Disease Control and Prevention. *HIV Prevention Progress Report, 2019*. March 2019. <https://www.cdc.gov/hiv/pdf/policies/progressreports/cdc-hiv-preventionprogressreport.pdf>.
2. Spinelli, MA et al, “Provider Adherence to Pre-exposure Prophylaxis Monitoring Guidelines in a Large Primary Care Network,” *OFID*, 2018.
3. See Table 5, Centers for Disease Control and Prevention. *Behavioral and Clinical Characteristics of Persons with Diagnosed HIV Infection—Medical Monitoring Project, United States, 2016 Cycle (June 2016–May 2017)*. HIV Surveillance Special Report 21. June 2019. <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-special-report-number-21.pdf>.
4. Chelsea Sexual Health Clinic Reopens After an Extensive Expansion and Modernization of Its Historic Building. New York City Department of Health and Mental Hygiene website. March 15, 2018. <https://www1.nyc.gov/site/doh/about/press/pr2018/pr019-18.page>.



An STD Epidemic with No End in Sight

By GABRIELLA VAVALA, BA, and JEFFREY D. KLAUSNER, MD, MPH

Funding solutions for moving forward

CENTERS FOR DISEASE CONTROL and Prevention (CDC) reports that the sexually transmitted diseases (STDs) chlamydia, gonorrhea, and syphilis are steadily rising in the United States. Between 2016 and 2017 (the year of most recently available data), the frequency of reported gonorrhea cases increased 18.6 percent, representing a 75 percent increase since 2009. Additionally, there were 918 cases of congenital syphilis in 2017, the highest reported number in more than 25 years.

The U.S. government response to the epidemic has been languid. Policy makers debate over paltry increases in CDC STD funding (See Figure 1) and states and local jurisdictions fail to rebuild programs decimated by the Great Recession of 2008. Surveillance data cited above are more than 18 months out of date. Small hope emerges with a protracted effort like the creation of the STI Federal Action Plan and the U.S. Department of Health and Human Services (DHHS) initiative entitled “Ending the HIV Epidemic.”^{1,2}

How did we get here and where do we need to go?

Historically, publicly funded STD clinics and county disease prevention programs were the backbone of STD control in the U.S. A recent survey by Meyerson found over 4,000 clinics that provide STD services. Those clinics were classified into 10 types: local health department (62.0 percent), family planning clinic (17.1 percent), community health center (7.8 percent), school-based clinic (3.6 percent), state health department-sponsored clinic (3.4 percent), hospital-sponsored clinic (2.2 percent), AIDS service organization (2.1 percent), university-sponsored clinic (1.2 percent), jail clinic (0.6 percent), and other (0.1 percent).³ STD clinics primarily serve minority males, uninsured or underinsured individuals, and men who have sex with men.⁴ STD clinics identify and treat STDs that would not be addressed otherwise.

Despite the critical role of STD clinics in maintaining public health, the number and scope of STD clinics suffer from a lack of funding. A recent study by the National Association of County and City Health Officials found that nearly half of local health departments reported budget cuts between 2009 and 2012.⁵ Those budget cuts resulted in direct layoffs of STD clinic staff and cessation of services leading to reduced clinic hours and long lines for services.⁶

According to a study by Leider and others, the public health workforce has shrunk by over 50,000 staff since the 2008 recession.⁷ Budget cuts forced local health departments to reduce partner services, treatment verification, condom distribution, health promotion, and sex education. Those activities along with surveillance and case or outbreak investigations are proven

The public health workforce has shrunk by over 50,000 staff since the 2008 recession.

Budget cuts forced local health departments to reduce partner services, treatment verification, condom distribution, health promotion, and sex education. Those activities along with surveillance and case or outbreak investigations are proven means to control STDs.

means to control STDs.⁸ With staffing reductions, clinics must streamline their services; and the first line of service eliminated tends to be partner services, an evidence-based STD effective STD control strategy.⁹ Cuffe et al. reported that local health departments with budget reductions were 21.3 percent less likely to offer partner services and 10.1 percent less likely to assure treatment and follow-up with an STD case.⁹ State health departments with reported staffing reductions were 40.0 percent less likely to offer partner services and 15.0 percent less likely to assure treatment and follow-up with an STD case.⁹

Partner services are crucial for STD control by notifying the partner of exposure, increasing the likelihood that partners are treated and reducing the likelihood of reinfection in the index case. Furthermore, partners benefit because early detection prompts treatment before STD-related complications develop. Early detection also limits the duration a partner is infectious reducing the frequency of STD transmission. In the absence of health department partner services, partner notification by the patient and the provider is increasingly important. In most states, public health laws require physicians

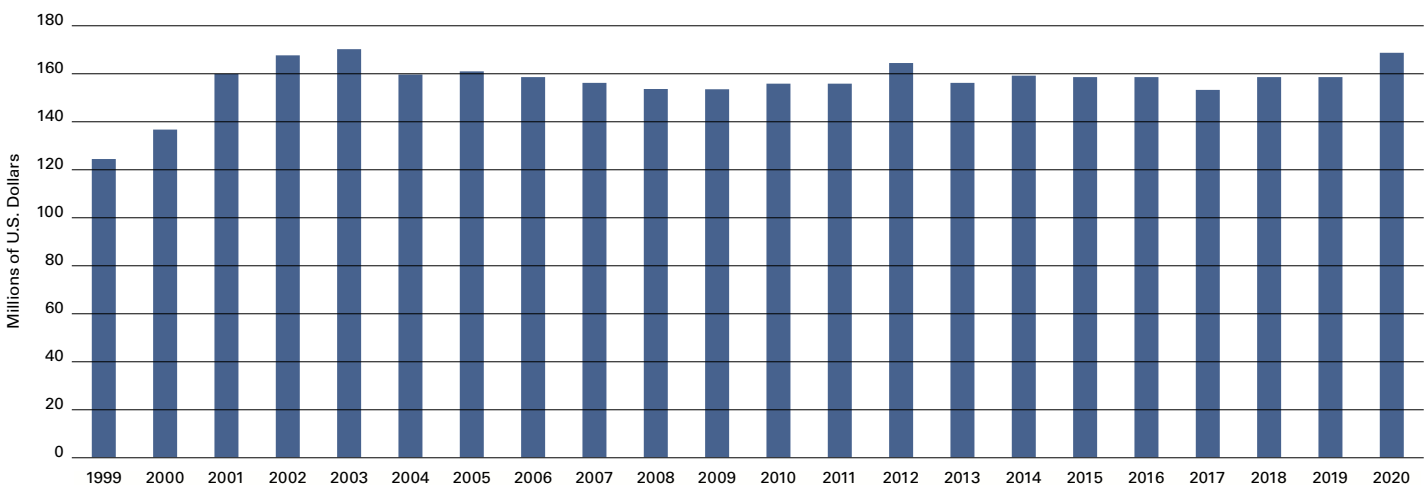
who diagnose STDs to make a reasonable effort to notify recent sex partners of exposure. While we are not aware of any recent liability for a physician's failure to perform that duty, the responsibility remains. Documentation in the medical record of a discussion with the patient regarding partner notification is good medical practice.

Other key STD control activities include condom distribution, health promotion, and sex education. Local health departments may provide and support condom education and distribution in schools, community venues like bars and clubs and health centers. Health promotion through social media and advertising on the radio, television, billboards or on public transportation has a long tradition in public health efforts to control STDs; however, there are few or no current local campaigns.

Finally, assuring the availability and completeness of comprehensive sex education has been a role of state and local health departments. With budget cuts, however, we are not aware of any programs systematically assessing or assuring adequate sexual and reproductive health education at the community-level or in schools.

Modelers have documented the relationship between adequate state and local program funding and these programs' ability to effectively prevent and treat STDs. Chesson and others looked at funding and gonorrhea prevalence in New York State. They found that decreasing STD prevention funding by \$200,000 resulted in an increased prevalence of gonorrhea from 1.6 percent to 3.6 percent.¹ In a second model, they found that over a 10-year period decreased STD prevention funding resulted in an estimated increase in medical costs of \$3.7 million to \$8.4 million. In both the

Figure 1: Centers for Disease Control and Prevention Sexually Transmitted Disease Funding Per Fiscal Year



*2020 is provisional data based on the allocation of sexually transmitted disease prevention funding in the Labor, Health and Human Services, Education, and Related Agencies (LHHS) funding bill for fiscal year 2020.

Assuring the availability and completeness of comprehensive sex education has been a role of state and local health departments. With budget cuts, however, we are not aware of any programs systematically assessing or assuring adequate sexual and reproductive health education at the community-level or in schools.

high and the low scenarios of that model, the authors found it more cost effectiveness to invest funds in STD prevention than in the treatment of curable STDs.

With the loss of local and state STD infrastructure and services, innovative and more cost-effective strategies like internet-based STD care to increase access to screening and treatment are urgently needed. A recent National Institutes of Health (NIH) study piloted such a program by mailing requested vaginal specimen collection kits to women within the age range of 18 to 30 years.¹⁵ Those who tested positive but were asymptomatic had prescriptions faxed to their local pharmacy while those who tested positive and were either symptomatic or pregnant were required to seek clinical care for treatment.

Similarly, NIH-funded programs in Maryland, Washington, D.C., and Alaska have shown both high acceptability and feasibility. These have been in place for several years but funders have never scaled the program to assess population scale (www.iwantthekit.org). Successful commercial programs like MyLabBox.com with thousands of self-pay users could potentially have a wider public health impact through funding from local and state health departments and insurers.

STDs increase the susceptibility and infectiousness of HIV. Specifically, the risk of acquiring HIV infection increases four-fold in the presence of another STD while the risk of transmitting HIV increases two- to three-fold.^{3,10} The underlying biological mechanisms for increased HIV acquisition and transmission include disruption in mucosal epithelium, HIV target cell recruitment and activation, increased HIV viral replication, reduced CD4 T-cell count and altered cytokine production.^{11,12} One NIH-funded study in Mwanza, Tanzania, demonstrated that community-level STD treatment reduced HIV incidence by about 40 percent.¹³ As STDs and HIV demonstrate synergistic effects, STD control is key to HIV prevention.

Effectively responding to the current STD epidemic will not only require restoration of public health activities but a restructuring of public funding for HIV and STD control. That restructuring must be a component of the End the HIV Epidemic strategy. In jurisdictions with the greatest success in HIV control—San Francisco, Seattle, New York City—integration and close-collaboration between HIV and STD programs has been the norm. The continuation of silo-based funding in some settings, where federal or state funders specifically designate resources for HIV or STD prevention activities must end. HIV is an STD, impacting

Figure 2



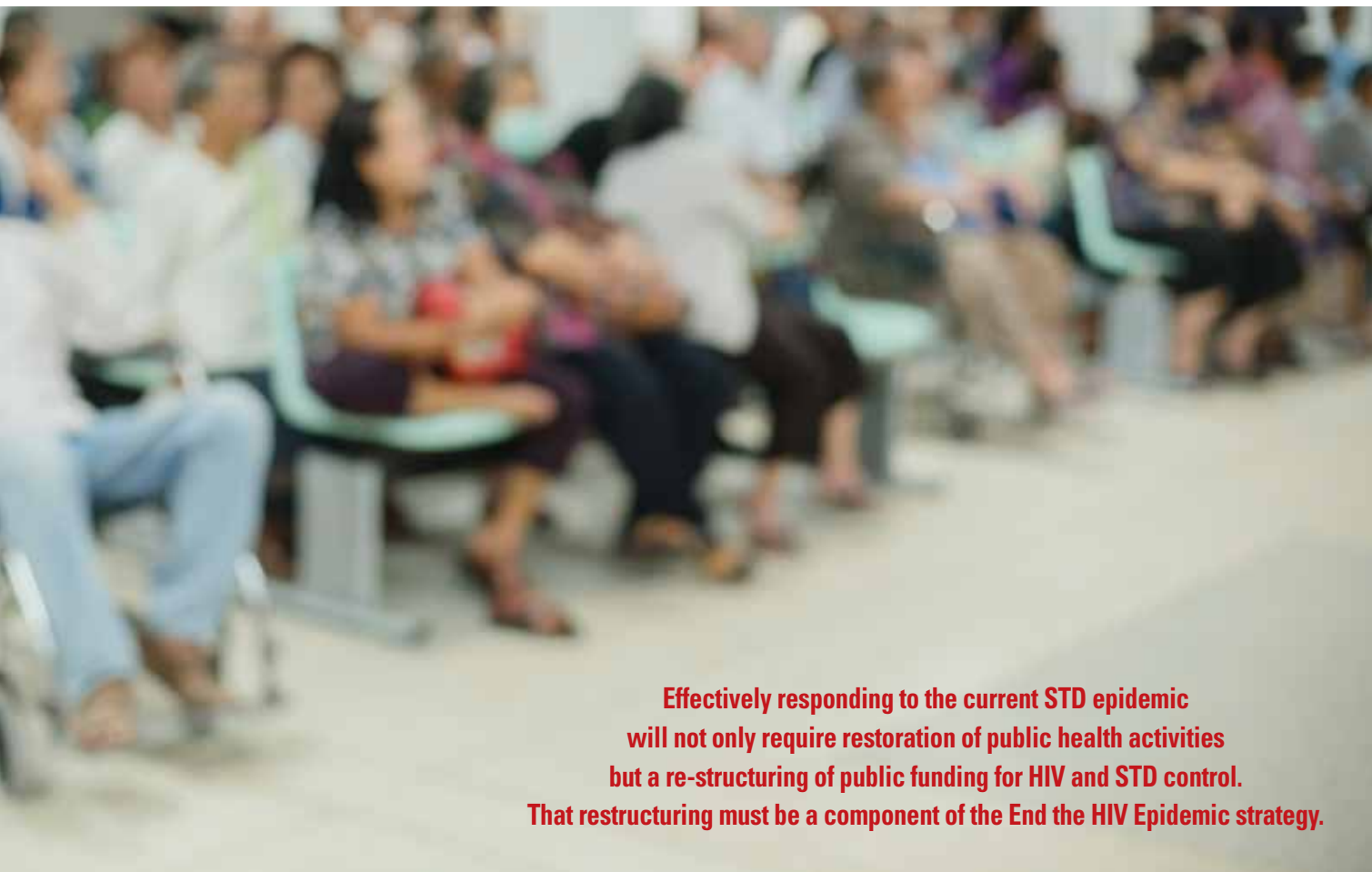
similar populations and requiring similar control activities such as surveillance, health promotion, condom distribution, sex education, and case-identification through testing, treatment and partner notification (See Figure 2). STDs like syphilis and gonorrhea have long been medical indications for the consideration of Pre-Exposure Prophylaxis (PrEP) for HIV infection.¹⁴ Without strong systems to identify those STDs, the use of PrEP as an effective strategy to control HIV may not be realized.

HIV care providers can play a critical role in the response to the current STD epidemic through advocacy, community and patient education about STDs. They have the capability to regularly screen their HIV-infected patients for STDs and those on PrEP. They can also make sure that recent sex partners of cases are treated through partner notification and/or expedited partner therapy the provision of extra-medication or a prescription to partners. Ending the HIV epidemic, as called upon by STI Federal Action Plan and the United States Department of Health and Human Services (DHHS), will require recognition of the synergetic effects between HIV and STD, a large amount of new funds and changes in silo-based funding (funding for HIV prevention that excludes funding for STD prevention). The fight to eliminate HIV goes hand-in-hand with the fight to end STDs. **HIV**



ABOUT THE AUTHOR

Gabriella Vavala, BA, earned her B.A. from the University of California, Berkeley in 2018 and currently works in STD research at the University of California, Los Angeles.



**Effectively responding to the current STD epidemic
will not only require restoration of public health activities
but a re-structuring of public funding for HIV and STD control.
That restructuring must be a component of the End the HIV Epidemic strategy.**



Jeffrey D. Klausner, MD, MPH, is a Professor of Medicine in the Division of Infectious Diseases in the David Geffen School of Medicine and Adjunct Professor of Epidemiology in the Fielding School of Public Health. From 1998-2009 Dr. Klausner was a Deputy Health Officer, Director of STD Prevention and

Control Services at the San Francisco Department of Public Health, member of the UCSF School of Medicine faculty in the Divisions of AIDS and Infectious Diseases and Attending Physician at San Francisco General Hospital. Before that he was an Epidemic Intelligence Service Officer at the Centers for Disease Prevention and Control.

REFERENCES

- Office of Infectious Disease and HIV/AIDS Policy. STI Federal Action Plan Overview. *US Department of Health and Human Services* (2019). Available at: <https://www.hhs.gov/programs/topic-sites/sexually-transmitted-infections/action-plan-overview/index.html>. (Accessed: 13th August 2019)
- What is 'Ending the HIV Epidemic: A Plan for America'? *HIV.gov* (2019). Available at: <https://www.hiv.gov/ending-hiv-epidemic>. (Accessed: 13th August 2019)
- Peterman, T. A., Newman, D. R., Maddox, L., Schmitt, K. & Shiver, S. Risk for HIV following a diagnosis of syphilis, gonorrhea or chlamydia: 328,456 women in Florida, 2000–2011. *Int J STD AIDS* **26**, 113–119 (2015).
- Golden, M. R. & Kerndt, P. R. What is the role of sexually transmitted disease clinics? *Sex Transm Dis* **42**, 294–296 (2015).
- National Association of County and City Health Officials. *Impact of Budget Cuts on Local Health Department HIV, STI, and Viral Hepatitis Programs*. (National Association of County and City Health Officials).
- Branham, D. Dallas County saw nation's highest increase for chlamydia and gonorrhea rates last year, study shows. *Dallas Morning News* (2019). Available at: <https://www.dallasnews.com/news/public-health/2019/03/19/dallas-county-saw-highest-increase-us-chlamydia-gonorrhea-rates-last-year-study-shows>. (Accessed: 13th August 2019)
- Leider, J. P., Coronado, F., Beck, A. J. & Harper, E. Reconciling Supply and Demand for State and Local Public Health Staff in an Era of Retiring Baby Boomers. *American Journal of Preventive Medicine* **54**, 334–340 (2018).
- Klausner, J. D., Kent, C. K., Wong, W., McCright, J. & Katz, M. H. The public health response to epidemic syphilis, San Francisco, 1999–2004. *Sex Transm Dis* **32**, S11–18 (2005).
- Cuffe, K. M., Leichter, J. S. & Gift, T. L. Assessing STD Partner Services in State and Local Health Departments. *Sex Transm Dis* (2018). doi:10.1097/OLQ.0000000000000803
- Johnson, L. F. & Lewis, D. A. The effect of genital tract infections on HIV-1 shedding in the genital tract: a systematic review and meta-analysis. *Sex Transm Dis* **35**, 946–959 (2008).
- Cohen, M. S. & Pilcher, C. D. Amplified HIV Transmission and New Approaches to HIV Prevention. *J Infect Dis* **191**, 1391–1393 (2005).
- Kaul, R. *et al.* Prevalent Herpes Simplex Virus Type 2 Infection is Associated with Altered Vaginal Flora and an increased Susceptibility to Multiple Sexually Transmitted Infections. *J Infect Dis* **196**, 1692–1697 (2007).
- Grosskurth, H. *et al.* Impact of improved treatment of sexually transmitted diseases on HIV infection in rural Tanzania: randomised controlled trial. *The Lancet* **346**, 530–536 (1995).
- US Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update Clinical Practice Guideline. (2018).
- Spielberg F, Levy V, Lensing S, *et al.* Fully integrated e-services for prevention, diagnosis, and treatment of sexually transmitted infections: results of a 4-county study in California. *Am J Public Health*. 2014;104(12):2313–2320. doi:10.2105/AJPH.2014.302302

The Intersection of **U=U** and **STIs**

Reframing our messages and practice

By MURRAY PENNER

WITH GROUNDBREAKING HIV PREVENTION TOOLS AVAILABLE that could allow us to end new HIV infections, and at the same time an exploding STI epidemic in America, we are at a crossroads in how we respond to these epidemics. But we are also at a crossroads for how we talk about HIV and STIs and the tools we have at our disposal to address the epidemics. Business as usual is not achieving the impact we so urgently require. Undetectable equals untransmittable, or U=U, is an entrée to change.

The U=U movement is based on a medically significant but still widely unknown fact: a person with HIV who is on treatment with antiretroviral therapy (ART) and has a sustained undetectable viral load cannot sexually transmit HIV. This has been validated by numerous long-term clinical trials including the PARTNER1 and PARTNER2 studies, both of which observed no sexual HIV transmissions between either heterosexual or same-sex serodifferent couples.^{1,2} The world's most respected peer-reviewed journals and global health authorities have also confirmed the U=U reality. And U=U has blossomed into a movement with over 900 organizations in 98 countries pledging to spread this powerful message. (<https://www.preventionaccess.org/>)

Despite such broad scientific consensus, this information is not reaching the masses and it is time for bold leadership to share the unvarnished truth of this powerful new tool. With the U.S. embarking on a new strategy, Ending the

HIV Epidemic: A Plan for America, which would reduce new HIV transmissions by 90 percent in 10 years, there is a critical need for new and different approaches to reduce new transmissions.³ At the same time, it is important that we also address the intersecting epidemic of sexually transmitted infections (STIs) that is plaguing our country. U=U offers a unique and powerful opportunity to do both.

Centers for Disease Control and Prevention (CDC) recently updated their risk effectiveness estimates for HIV prevention interventions. U=U is now 100 percent effective, pre-exposure prophylaxis, or PrEP, is more than 90 percent effective, and condoms are rated highly effective (all include language that these estimates apply if the interventions are appropriately utilized).⁴ Dr. Anthony Fauci, head of the National Institute of Allergy and Infectious Disease at the NIH, unequivocally stated at the International AIDS Conference in Mexico City in July 2019 that U=U is “the foundation of being able to end the HIV epidemic.”

**The U=U movement
is based on a medically
significant but still
widely unknown fact:**

**a person with HIV who is on treatment
with antiretroviral therapy (ART) and
has a sustained undetectable viral load
cannot sexually transmit HIV.**

We now have the several tools to stop new HIV transmissions if we could scale-up these critical interventions. ART, the backbone of U=U, has triple benefits: 1) keeping people living with HIV healthy, similar to those who are HIV negative; 2) preventing transmission to their sexual partners; and 3), diminishing the stigma that so often isolates people with HIV so they can enjoy sex freely without the worry of transmitting HIV to their partners.

Despite the interventions we now have to prevent HIV, we still have a relatively stable rate of new transmission over the past several years (actually rising rates of transmission in some populations).⁵ However, we have an exploding STI epidemic in the U.S., and there is no question that there is an intersection between the two epidemics. People with an STI are up to five times more likely to acquire HIV. Whether or not U=U and PrEP are contributing to blame for rising STI rates remains debatable, yet they are clearly linked and the debate becomes irrelevant if we want to capitalize on the crossroads at which we find ourselves.

Whether or not U=U and PrEP are contributing to blame for rising STI rates remains debatable, yet they are clearly linked and the debate becomes irrelevant if we want to capitalize on the crossroads at which we find ourselves.

U=U provides an opportunity for a paradigm shift in the way we address the stigma associated with these dual and intersecting epidemics. For people with HIV disease and those at risk for HIV and STIs, we should move from strictly a disease prevention approach to one focused more on sexual wellness for both HIV and STIs. This does not mean we stop our efforts to prevent new transmissions. But it does focus on regular engagement in care for people with HIV and STIs and frequent STI testing along with monitoring viral loads for people with HIV. It also includes providers having open and frank conversations about sex and educating patients about the tools available to stay healthy and live a life free of stigma and shame. We have seen successes with this approach as many STD clinics have shifted their focus to sexual wellness, including STI screening and treatment, HIV testing, availability of PrEP, and immediate initiation of ART for those who test positive for HIV.

Until there is a cure for HIV, people with HIV will continue to need to take ART and monitor their health through regular medical visits. This is the backbone of U=U in order to ensure that people remain undetectable. People taking PrEP generally have three-month intervals whereby they are tested for HIV transmission and other STIs.⁶ So, we have obvious opportunities and responsibilities to screen for STIs for both HIV positive and negative individuals, particularly when they

are using U=U and PrEP as their HIV prevention tools. This presents an opportunity for us to screen and treat for STIs while ensuring people with or at risk for HIV remain HIV-negative.

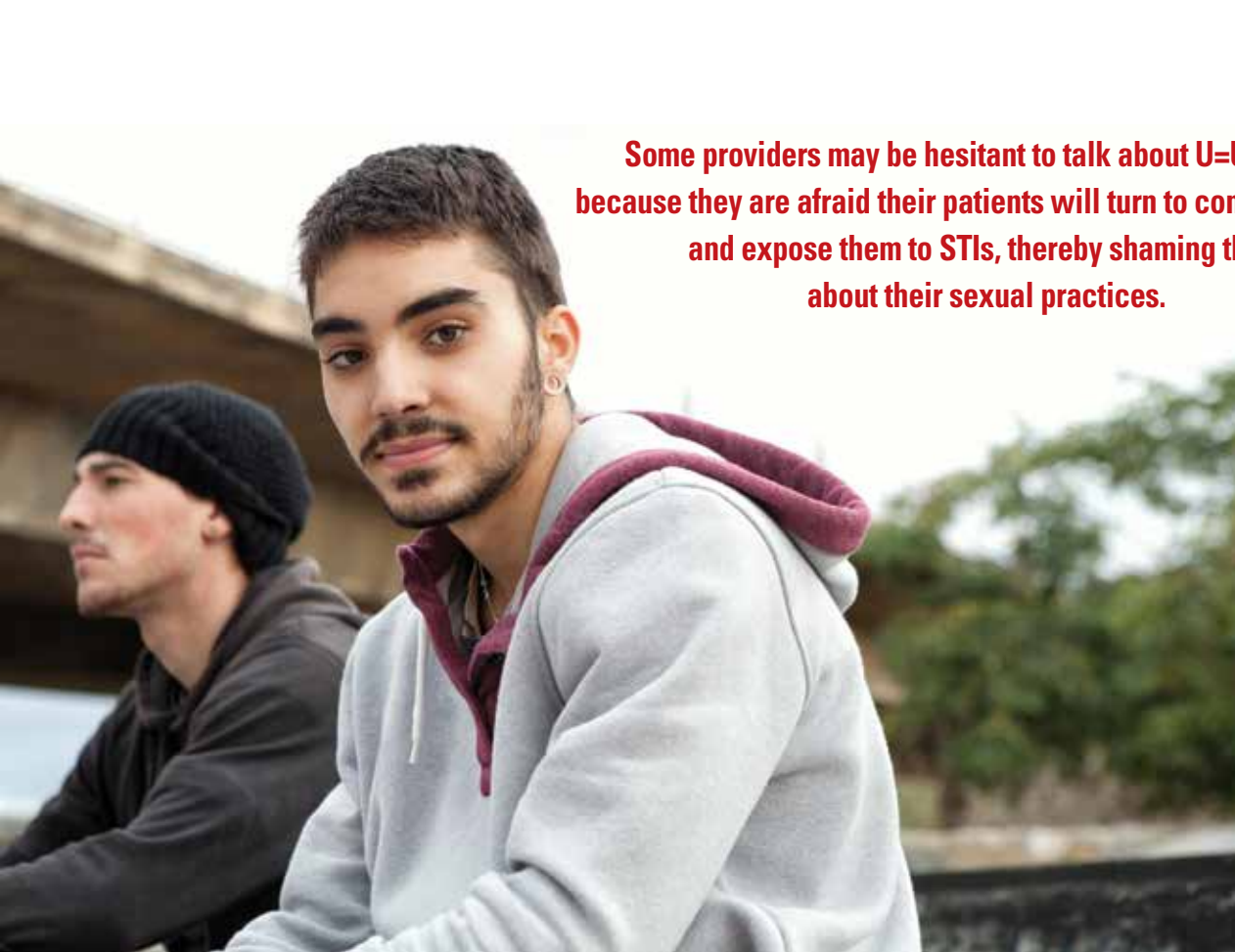
Culturally appropriate care is critical to reducing the stigma of HIV and STIs and intersects with this sexual wellness framework. Often when talking about U=U and PrEP, we hear the argument that it will increase condomless sex. That argument is akin to not providing comprehensive sex education to young people because we are afraid they may have sex. Nonetheless, we have an ethical responsibility to provide the truth that there are tools available to prevent HIV and STIs. We must work to educate patients and the general public how the tools are best employed and help them make choices for what will work with their situations.

HIV stigma is ever-present. It may be less drastic than in the early days of the epidemic, but it remains rampant and destructive. It manifests itself in far too many ways. HIV stigma isolates people, leads to depression and even suicide, and prevents healthy, fulfilling relationships. It deters people from testing for HIV and taking life-saving medications or staying in care if they are HIV positive. In healthcare settings, unintended actions by medical professionals reinforce stigma and drive people with HIV or those at risk away from care. And in a number of states, a person with HIV can be prosecuted for not revealing one's status prior to sexual intercourse, even if he or she are unable to transmit the virus.⁷ Where stigma exists, fear thrives. And this prevents people from engaging in care—from getting tested for HIV and STIs, from being on treatment, and from remaining in medical care or being adherent to their treatment regimens.

The time is now to address this stigma by having open and honest discussions with people about their sex lives. Some providers may be hesitant to talk about U=U or PrEP because they are afraid their patients will turn to condomless sex and expose them to STIs, thereby shaming them about their sexual practices. Rather than focus on what could happen, shifting to a discussion that if these are the chosen HIV prevention methods, regular screening for STIs should accompany their HIV prevention and care tools.⁸ On the flip side, condoms effectively prevent STIs, pregnancy, and HIV.

As we work to educate, we must be careful not to shame people who do choose to use condoms, as this also sometimes occurs. We also must not shame people who have difficulty achieving an undetectable viral load for whatever reason. While we have a responsibility to encourage everyone living with HIV to take ART as soon as possible, if they do not achieve an undetectable viral load we must also be careful not to shame them. They should instead be encouraged to use other prevention tools (PrEP for their partners and/or condoms). Our overall responsibility is to educate people and help them make informed choices to stay healthy.

How we message U=U and other HIV prevention options matters. Providers are key to ensuring that regular



Some providers may be hesitant to talk about U=U or PrEP because they are afraid their patients will turn to condomless sex and expose them to STIs, thereby shaming them about their sexual practices.

monitoring is occurring. And so, talking about a patient's sexual health becomes critical. We must thoughtfully acknowledge that people's sex lives are not all the same and a cookie-cutter approach to education may not work. What works for one person to have a sexually fulfilling life may not work for another. Providing a range of prevention options is important and giving accurate information about each is an ethical responsibility.

U=U has the power to address stigma, keep people healthy, and prevent new HIV transmission. U=U works when a person is on ART, is regularly monitoring their viral load and remains connected to care. PrEP requires the same connection and commitment to care. And throughout these connections we have tremendous opportunities to screen for

and treat STIs. The time is now to capitalize on all of the tools we have to ensure that people remain healthy, can live free of stigma and shame, and that we work collaboratively in bold new ways toward an end of the HIV and STI epidemics.**HIV**



ABOUT THE AUTHOR

Murray Penner is the executive director of North America for Prevention Access Campaign (PAC), which originated the Undetectable Equals Untransmittable (U=U) campaign. Penner previously served as Executive Director of NASTAD. He has been living with HIV since 1986 and is an advocate for universal treatment access, drug pricing, and helping people with HIV achieve their full potential to live healthy and stigma-free lives.

REFERENCES

1. Rodger AJ, Cambiano V, Bruun T, Vernazza P, Collins S, van Lunzen J, et al. Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV positive partner is using suppressive antiretroviral therapy. *JAMA*. 2016;316(2):171-81.
2. Rodger A et al. Risk of HIV transmission through condomless sex in MSM couples with suppressive ART: The PARTNER2 Study extended results in gay men. *AIDS* 2018, 23-27 July 2018, Amsterdam. Late breaker oral abstract WEAX0104LB. Retrieved from <http://programme.aids2018.org/Abstract/Abstract/13470>.
3. HIV.gov. What is 'ending the HIV epidemic: a plan for America'? 8 July 2019. Retrieved from <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>.
4. Centers for Disease Control and Prevention (CDC). Effectiveness of prevention strategies to reduce the risk of acquiring or transmitting HIV. 18 July 2019. Retrieved from <https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html>
5. Centers for Disease Control and Prevention (CDC). HIV in the United States and Dependent Areas. 9 May, 2019. Retrieved from <https://www.cdc.gov/hiv/statistics/overview/ata glance.html>.
6. U.S Public Health Service and Centers for Disease Control and Prevention (CDC). Preexposure prophylaxis for the prevention of HIV infection in the United States – 2017 Updated Clinical Practice Guidelines. 2017:47. Retrieved from <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>.
7. Centers for Disease Control and Prevention (CDC). HIV and STD Criminal Laws. 1 July 2019. Retrieved from <https://www.cdc.gov/hiv/policies/law/states/exposure.html>.
8. Calabrese, S, Mayer K. Providers should discuss U=U with all patients living with HIV. *The Lancet*. April 1, 2019;6:4:e211-e212. Published online February 13, 2019. Retrieved from [http://dx.doi.org/10.1016/s2352-3018\(19\)30030-X](http://dx.doi.org/10.1016/s2352-3018(19)30030-X)



STDs

We all have something to learn

and Stigma

By **AMANDA DENNISON, MPH,**

Director, Programs and Partnerships, National Coalition of STD Directors

I HAVE BEEN WORKING IN STD PREVENTION FOR OVER SEVEN YEARS. I have attended, participated in, and led countless presentations and workshops focused on addressing STD prevention education and STD-related stigma. As the Director of Programs and Partnerships for the National Coalition of STD Directors, I live and breathe STD prevention. But I still have a lot to learn about how stigma affects sexual health and healthcare. We all do.

Stigma manifests in numerous ways related to sexual health, including HIV and STD prevention and treatment. This topic has been explored in depth by many, including Tonia Poteat and Linda Wesp in the most recent issue of this magazine.¹ As they deftly explain, intersectional and structural stigmas must be fought proactively to ensure quality and culturally safe care for all.

What I want to focus on is the stigma that is attached to STDs and STD risk itself—a stigma that has helped drive STD rates in this country to record highs year after year, a stigma that must be faced head-on, just as HIV-related stigma has been fought for decades.² The struggle against HIV-related stigma is by no means over, but it has come a long way since the early days of the epidemic and has played a critical role in bringing down new HIV infections. We can and must extend this struggle to all STDs. Clinicians who serve patients living with and at risk for HIV have a critical role to play.

We all know that STD-related stigma can lead people to avoid important conversations with sexual partners. It also keeps people from seeking healthcare when they think they may be at risk. I have spoken with many of these people over the years, including people with HIV who sought care at the public clinics where I was working instead of from their HIV care providers for fear of the stigma and judgment they might face.

STD-related stigma can be overt, in ways we all recognize easily, and it can be subtle, in ways that even those of us who make a living promoting sexual health are prone to. This became all too real to me when I was diagnosed with herpes.

My Story

In June of 2015, I started feeling a little weird, then bad, then really, really sick. By the time I made an appointment with an OB-GYN, I was in the

throes of what I would later learn was my first genital herpes outbreak. The abdominal pain was unpleasant and troubling, but the nerve pain shooting down my legs was unbearable. I had to see a doctor.

My appointment was in the middle of an otherwise typical workday, and my doctor was a woman in green scrubs and clogs. I was a new patient, so I was meeting her for the first time. It can be nerve wracking to be examined by an unfamiliar OB-GYN physician, even for someone who works in the health sector, but under these circumstances it was downright painful. She was nice enough, but offered no reassurance and no apparent compassion for my situation. She asked me the bare minimum of questions, she didn't take a sexual history, and besides swabbing a sore to confirm the herpes diagnosis, she left it to me to request the other STD tests I knew I should be getting. When a young, female patient comes in with the symptoms I was having, it's no time to be shy about STDs.

I came back to get my results the following week, and my experience wasn't any better. I was still in pain, and despite everything I know about STDs and sexual health, I was scared. The doctor told me what I expected to hear. I had done everything I teach other people to do to prevent STDs but, like one-in-six Americans ages 14 to 49, I contracted genital herpes.³

Before I was diagnosed, I had counseled friends following their own herpes diagnoses, given pep talks to many patients following an STD diagnosis, and even comforted distraught parents asking if their newly diagnosed teenage daughter's clothes could be washed with everyone else's. I got no such reassurance. In fact, before the doctor hurried away, it was made clear to me that someone in my line of work ought to know better.

I left the exam room with the knowledge that I had herpes, but having learned little else about how to navigate this new reality. I was reassured on one point: I could still get pregnant. (I was never asked if I

was interested in having children. I am not.) I was given a prescription for acyclovir, but no information on its effectiveness for prevention.⁴ In fact, I was reminded to use condoms, but I was given no information on other forms of prevention. The doctor provided information on what test was available for partners if they were interested in getting one, but I received no guidance on how to approach this subject or answers to questions some would undoubtedly ask (How likely is transmission? Where do I get the test? Do I have to pay for it? How accurate is it?). Given that I was single at the time, I could have used guidance on dating with an STD—or even a tip for finding information online, but I got none.

Despite my knowledge and experience helping others deal with an STD diagnosis, I was not prepared for the way mine was communicated to me. I was also unprepared for how difficult it would be for me to communicate about my herpes. If it was like this for me, imagine what it's like for someone with no background in STD prevention, let alone all the young people coming of age having had little to no sex education?

How we can do better

It has taken me years to get to the point where I feel empowered by my herpes. I don't think there's anything my OB-GYN could have done to make this an easy process, but there are many things she could have done to make it better.

We all know that healthcare providers are pressed for time. Sometimes even providers who serve patients at risk for HIV are unprepared to discuss other aspects of sexual health. But there are many things clinicians can do to reduce the shame and stigma involved in getting an STD diagnosis and to set patients on a path to empowerment and better health:

1. *Leave judgments and assumptions outside the exam room.* An STD diagnosis isn't fun and can be life-changing—it should be delivered with compassion and understandable information, even for patients you think may have heard it all before.
2. *Take the time to take a sexual history and be mindful of how you do it.* This can help patients understand how they acquired the infection and what they need to do to protect themselves and their sexual partners. The language you use and the way you ask the questions can make a big difference. The National Coalition for Sexual Health has very useful guidance *Sexual Health and Your Patients: A Provider's Guide* that is worth a read even for the most experienced among us.⁵
3. *Help your patients determine an action plan for informing partners.* Provide them with information, links to partner notification services, and other strategies to navigate this difficult topic.

4. Provide clear information about treatment and prevention options.

Providing patients with clear information about whether an STD is curable or treatable and how they can prevent transmission to sexual partners can help control the internal stigma that comes with an STD diagnosis and help support effective partner notification.

5. Consider linking your patients to mental health and other support services.

An STD diagnosis can be devastating, and many patients will need support.

Why we must do better

Addressing STD-related stigma is not just about making people feel better, it is about saving lives. We know stigma gets in the way of honest, open communication between partners, which is a critical part of STD prevention. It can also affect the quality of care clinicians provide, as I saw first-hand when I was diagnosed, which can lead to shame, misinformation and, ultimately, avoidable STD transmission.

Stigma also affects whether people get care in a timely manner—or at all. Many people avoid care (and STD testing specifically) because of stigma—both internalized and anticipated on the part of providers. Even patients living with HIV are deterred from seeking care because of the stigma attached to other STDs. I saw this first-hand while working in a clinic and then with local health departments. I spoke to many patients who were living with HIV and regularly seeing an HIV care provider, but went elsewhere for STD testing and treatment, fearing the judgment and lecturing they might get from their regular doctor.

Unfortunately, these fears are not unfounded—I have worked with numerous physicians specializing in sexual health who are unable to speak directly and non-judgmentally about their patients' sexual practices.

With STDs at all-time highs, babies dying from preventable syphilis infection, and the threat of drug-resistant gonorrhea on the horizon, we must face the problem head on.^{6,7,8} If we don't, we will fail in our fight against STDs and, very likely, in our efforts to eliminate HIV. **HIV**



ABOUT THE AUTHOR

Amanda Dennison, MPH, is director of programs and partnerships for the National Coalition of STD Directors, a national public health membership organization representing health department STD directors, their support staff, and community-based partners across 50 states, seven large cities, and eight U.S. territories. Amanda previously worked at the Ohio Department of Health where she managed STD, Hepatitis, and HIV prevention and surveillance programs.

REFERENCES

1. Poteat T, Wesp L. The HIV Provider's Role in Reducing Stigma. *HIV Specialist*. June 2019.
2. CDC National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. New CDC analysis shows steep and sustained increases in STDs in recent years. <https://www.cdc.gov/nchhstp/newsroom/2018/press-release-2018-std-prevention-conference.html>. Accessed August 2, 2019.
3. CDC Division of STD Prevention. Genital Herpes - CDC Fact Sheet. <https://www.cdc.gov/std/herpes/stdfact-herpes.htm>. Accessed August 2, 2019.
4. Corey L, Wald A, Patel R, et al. Once-daily valacyclovir to reduce the risk of transmission of genital herpes. *New England Journal of Medicine*. 2004 Jan 1;350(1):11-20.
5. National Coalition for Sexual Health. Sexual Health and Your Patients: A Provider's Guide. <https://nationalcoalitionforsexualhealth.org/tools-for-healthcare-providers/sexual-health-and-your-patients-a-providers-guide>. Accessed August 1, 2019.
6. CDC Division of STD Prevention. Sexually Transmitted Disease Surveillance 2017. https://www.cdc.gov/std/stats17/2017-STD-Surveillance-Report_CDC-clearance-9.10.18.pdf. Accessed August 2, 2019.
7. CDC National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Newborn syphilis cases more than double in four years, reaching 20-year high. <https://www.cdc.gov/nchhstp/newsroom/2018/std-surveillance-report-2017-press-release.html>. Accessed August 2, 2019.
8. CDC Division of STD Prevention. Addressing the Threat of Drug-Resistant Gonorrhea. <https://www.cdc.gov/std/herpes/stdfact-herpes.htm>. Accessed August 2, 2019.

BY ANNA FORBES,
AAHIVM PUBLIC POLICY DIRECTOR

Customs and Border Patrol Endangers People with HIV and Their Children

AT A HOUSE JUDICIARY COMMITTEE HEARING IN LATE JULY, Representative Jamie Raskin (D-MD) asked Brian Hastings, Chief of Law Enforcement for the Customs and Border Patrol (CBP), if his staff were instructed to separate immigrant parents from their children at the Mexican/American border if the parent was living with HIV. Hastings said they are required to do this because, “it’s a communicable disease under the guidance.” Noting that the flu is also a communicable disease, Rankin asked if border staff would similarly separate children from a parent with the flu. Hastings replied they would not.

By the next day, the CBP was attempting to walk Chief Hastings erroneous statements back. They issued a public statement directed to Rep. Raskin’s office saying that the CBP “would not separate families due to the communicable nature of HIV,” but added that HIV “does present additional considerations that may affect how migrants might move forward in processing.” By way of an example, they noted that, if a parent needs hospitalization, a decision has to be made regarding whether it would be better for the child to “wait for their parent in CBP or Health and Human Services custody.”

In 2010, CDC removed HIV from the list of communicable diseases of public health significance that necessarily bar immigrants from entering the U.S. Attention to this classification, however, seems to be increasingly disregarded. Rep. Raskin’s concern about possible regression on this issue was first triggered by a case last November in which three girls (ages 11, 12 and 14) were separated at the border from their father who has HIV. According to KIND (Kids in Need of Defense) an organization tracking the case, a permanent separation was ordered in this case and the girls have not seen their father since.

Another recent, HIV-related tragedy occurred last June when a transgender woman living with HIV died in CBP custody. Johana Medina Leon, age 25, was a certified nurse in El Salvador but was not allowed to practice there because she was living openly as a transgender woman. She was held in the Otero County Processing Center, a private detention facility for ICE detainees, for seven weeks. While there, she complained of chest pains, said repeatedly that she was dehydrated and needed to give herself an infusion. She asked the guards for water, sugar and salt so she could make an infusion using her own equipment and was refused.

Finally, she was brought before an immigration judge and cleared to take the first crucial step in the immigration process. Shortly afterwards, she was transferred to a hospital due to her chest pains. She died on June 1st. Ultimately, her cause of death was listed as pneumonia. Less than a year



before, another transwoman named Roxana Hernandez died in ICE detention from dehydration and HIV complications.

“This is yet another unfortunate example of an individual who illegally enters the United States with an untreated, unscreened medical condition,” said Corey A. Price, field office director for ICE Enforcement and Removal Operations in El Paso.

On July 29th, Rep. Raskin and three other members of Congress sent a letter to Kevin K. McAleenan, Acting Secretary of the U.S. Department of Homeland Security, on this issue. It expressed profound concern about DHS policy and implementation, noting that the separation of children from parents on the basis of parents’ HIV status “flies in the face of expert judgement of the Centers of Disease Control and Prevention.” The letter asks DHS to “promptly provide us with a full explanation of the Policy and Practice of the Department of Homeland Security with respect to parents and other individuals encountered at or near the border who are HIV-positive, particularly with respect to family separation.”

HIV



ABOUT THE AUTHOR

Anna Forbes is the Director of Public Policy at the American Academy of HIV Medicine.

UPDATE



JEFFREY T. KIRCHNER, DO, AAHIVS
AAHIVM Chief Medical Officer

FEATURED LITERATURE

Gupta SK et al. Renal safety of tenofovir alafenamide vs. tenofovir disoproxil fumarate: a pooled analysis of 26 clinical trials. *AIDS* 2019;33:1455-65. doi: 10.1097/QAD.0000000000002223.

Tenofovir disoproxil fumarate (TDF), a nucleotide reverse transcriptase inhibitor, has been used for many years as a key component of many ART regimens. Although highly effective and well-tolerated, it has been associated with proximal renal tubulopathy and Fanconi syndrome. The use of TDF has progressively been replaced by tenofovir alafenamide (TAF) which has a mean 91 percent lower plasma level. Despite much lower drug exposure and favorable changes in renal biomarkers (proteinuria, creatinine clearance), it has been uncertain if the use of TAF results in better renal outcomes. This study was an integrated analysis of 26 phase 2 and phase 3 clinical trials conducted between 2011 and 2017. The studies include 9,322 adults and children with HIV. There was a cumulative exposure of 12,519 person-years to TAF and 5,947 person-years to TDF. Primary renal safety outcomes included incidence of proximal renal tubulopathy and study-drug renal discontinuation events. There were zero cases of tubulopathy and three cases of drug discontinuation in persons receiving TAF compared to 10 cases of tubulopathy in the TDF group and 14 discontinuations. Although overall the number of clinical events were small, both were statistically significant and support the renal safety of TAF compared to TDF.

COMMENTARY: This pooled analysis from 26 trials included adults, children, naive patients and those patients who were part of switch studies. Hence the populations were quite diverse. It is worth noting that nine out of 10 patients who developed proximal renal tubulopathy were on a boosted regimen with ritonavir or cobicistat and not an integrase inhibitor. Whether these types of data will be enough to justify the higher cost of TAF instead of generic TDF for both treatment of HIV and use for PrEP remains to be determined.

FEATURED LITERATURE

Capetti AF et al. Durability of dolutegravir plus boosted darunavir as salvage or simplification of salvage regimens in HIV-1 infected, highly treatment-experienced individuals. *HIV Clinical Trials* 2018; 19(6):242-248.

There are many long-term HIV-infected patients with multi-drug resistance. These individuals usually require “salvage” therapy to maintain viral suppression. In recent years, fewer patients are failing first-line INSTI-based regimens, and thus there are few clinical trials of salvage therapy. This study from Italy included 130 subjects of who were switched from 42 different ART regimens to dolutegravir (DTG) plus boosted darunavir (bDRV). Reasons for switching included simplification (45 percent), virologic failure (30 percent), or toxicity (16 percent). At baseline, 118 of the patients had resistance from one to five different drug classes. There was not resistance testing available for the other 12. Eighty-one had been on bDRV at baseline and one on DTG. All participants who were taking DRV with ritonavir were switched to co-formulated DRV/cobicistat between weeks 48 and 60. At 96 weeks on treatment with DTG/bDRV, only two patients had a viral load > 50 copies. Twenty-three patients had detectable viremia of 1-49 copies/mL, and 101 had no detectable virus. Median increase in CD4 count was 54 (3.2 percent) from baseline although this was not a statistically significant change. Other safety and metabolic parameters including lipids and renal function either remained stable or improved during the 96-week time period.

COMMENTARY: This data is reassuring for patients who may have broad NRTI resistance, transmitted resistance or intolerance to this class of HIV medications. There are several other studies supporting this combination of a boosted PI and INSTI. I have used this for a few patients in my clinical practice. A PubMed search revealed at least three other published studies showing the effectiveness of this two-drug combination in treatment-experienced patients.

Vizcarra P. *Antivir Ther*. 2019 Jun 7.
doi: 10.3851/IMP3319;

Navarro J. *Pharmacotherapy*. 2019 Apr;39(4):501-507.
doi: 10.1002/phar.2227.

Lee SA. *Infect Chemother*. 2018 Sep;50(3):252-262.
doi: 10.3947/ic.2018.50.3.252.

FEATURED LITERATURE

Gilbert L et al. Herpes Zoster rates continue to decline in people living with HIV but remain higher than rates reported in the general US Population. *Clinical Infectious Diseases*® 2019; 69(1):155–158.

Data from several HIV cohorts have found a 40 percent decline in the incidence of Herpes Zoster (HZ) in the modern ART era. However, the rate of HZ is still three to five times higher in persons with HIV compared to the general population. This paper looked at data from the U.S. Military HIV Natural History Study (NHS)—a cohort of more than 6100 HIV-infected Department of Defense beneficiaries who are followed at six military facilities. At each office visit, clinical diagnoses (including HZ) are obtained by patient interviews and review of the medical record. From the time it began collecting data in 1986, the NHS recorded 858 cases of HZ. Not surprisingly, the highest rates of HZ were pre-1996 (3.2) and declined to 0.9 from 2011–2016. The incidence varied by age and was highest in those aged 20–30 years. Nine percent of the patients had at least one recurrence of HZ and 3 percent of all cases required hospitalization. At the time of first HZ diagnosis, the median age was 39 years, CD4 count was 459 and VL was 1950 copies. Seventy-seven percent were receiving ART at the time of diagnosis with HZ. The authors concluded that HZ remains a significant problem among people with HIV even in the ART era, and rates are at least three times higher than in the general population.

COMMENTARY: Although seen much less frequently than in the pre-ART era, HZ remains quite common and in several cohorts such as NHS, occurs at younger ages. With the approval of a recombinant subunit vaccine (RZV/Shingrix®), in 2017 more adults >50 years of age are being vaccinated, although the CDC/ACIP has not made any specific recommendations for the use of the vaccine in PLWH. We had been giving RZV to our patients over 50 although currently there is a national shortage of this vaccine. The fact that HZ in PLWH has a higher incidence in younger people suggests a waning of the immune responses to varicella zoster virus. This also suggests the need for efficacy and safety studies of RZV in persons less than 50 years old.

FEATURED LITERATURE

Lam, JO et al. Colorectal Cancer Screening in People With and Without HIV in an Integrated Health Care Setting. *JAIDS Journal of Acquired Immune Deficiency Syndromes*: July 1, 2019; 81(3):284–291

Numerous observational studies have found a higher prevalence of malignancies in persons with HIV (PWH). This has raised questions regarding appropriate screening intervals for various cancers such as breast, prostate, or lung in PWH and whether screenings should be different than with the general population. This study is from the Kaiser Permanente system in Northern California, a large integrated healthcare network. The study included PWH aged 50 to 75 years and compared them with HIV-negative persons from 2005 to 2016 who had not previously undergone screening for colorectal cancer (CRC). The authors evaluated for time to initial screening by colonoscopy, sigmoidoscopy, or fecal blood test. They also assessed for the detection of CRC or adenomas by HIV status, accounting for CRC-related risk factors including sex, age, race/ethnicity, smoking, BMI, type-2 diabetes, and inflammatory bowel disease. Among PWH, they also evaluated for any association between CD4 count (<200/200–499/≥500 cells/μL) and adenoma and CRC. Among 3177 PWH and 29,219 persons without HIV, PWH were more likely to be screened (85.6 percent vs. 79.1 percent) within five years of study inclusion. Among those who had a colonoscopy or sigmoidoscopy, adenomas were found in approximately 20 percent of PWH and 23 percent of persons without HIV. Colon cancer was diagnosed in 0.5 percent of PWH and 1.0 percent of persons without HIV. In an adjusted analysis, there was no difference in prevalence of either adenoma or CRC by HIV status. In addition, having CD4 counts < 200 cells/mL did not increase the likelihood of adenomas or CRC. The authors noted in their integrated healthcare system there were no disparities in CRC screening application or outcomes among persons with and without HIV.

COMMENTARY: This study is reassuring in several ways. First, there was not a higher incidence of CRC in PWH—unlike other malignancies including lymphomas and lung cancer. Second, the screening rates were actually higher for PWH compared to those without HIV disease. The current USPSTF guidelines recommend CRC screening starting at age 50 and continuing until age 75. Acceptable tests include colonoscopy every 10 years, flexible sigmoidoscopy every five years, fecal DNA testing every one to three years or fecal occult blood testing yearly. Periodic CRC should be part of the clinical work plan for programs providing adult HIV care. **HIV**



From HIV screening to management,
Quest covers all the steps along your patient's journey.

If considering PrEP for HIV prevention,
PrEP Panel is your first step.

Quest Diagnostics is the first national lab to offer an HIV PrEP Panel.

Our easy-to-use panel includes all the CDC-recommended tests in one place so you can spend more time with patients and less time looking up test codes.

With the Quest HIV **PrEP Panel**, prevention is just one test code away. Find out more about the accuracy and efficiency of our **PrEP Panels** at [HIVPrEPPanel.com](https://www.questdiagnostics.com/HIVPrEPPanel.com).