LATEST UPDATE ON INITIATING AND MONITORING HIV PREVENTION THERAPY ACROSS HEALTHCARE SETTINGS

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Disclosures

- Receiving honorarium from Abbott for today's presentation

Objectives

- Present an update on HIV pre-exposure prophylaxis (PrEP) and evidence-based recommendations for implementation
- Describe recommendations for eligibility and baseline evaluation of patients before starting PrEP
- Evaluate clinical protocols for individuals taking PrEP and resource enhancements to improve medication acquisition, adherence, and follow-up
- Examine the role of various settings in providing PrEP to eligible clients
- Discuss future therapies for HIV prevention including long-acting injectable drugs

My worksite:

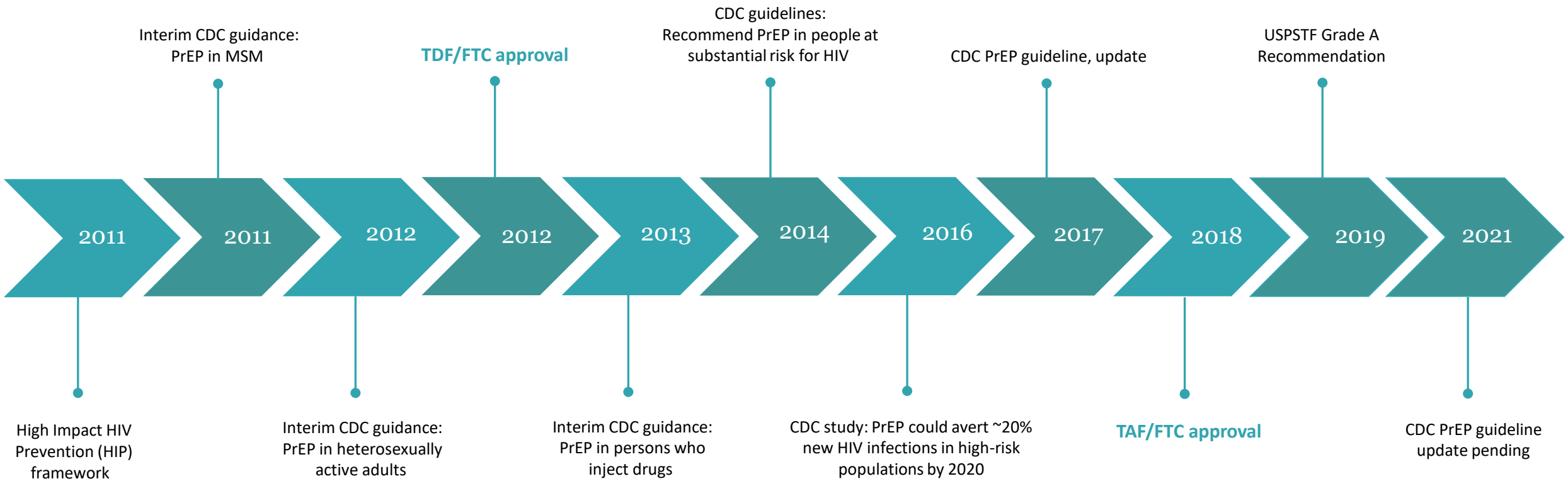
a) Currently prescribes PrEP
b) Is planning to prescribe PrEP
c) Does not prescribe PrEP
d) I'm not familiar with PrEP, but interested

FOR CLINICAL/ HIV CARE SITES

POLL QUESTION

#1

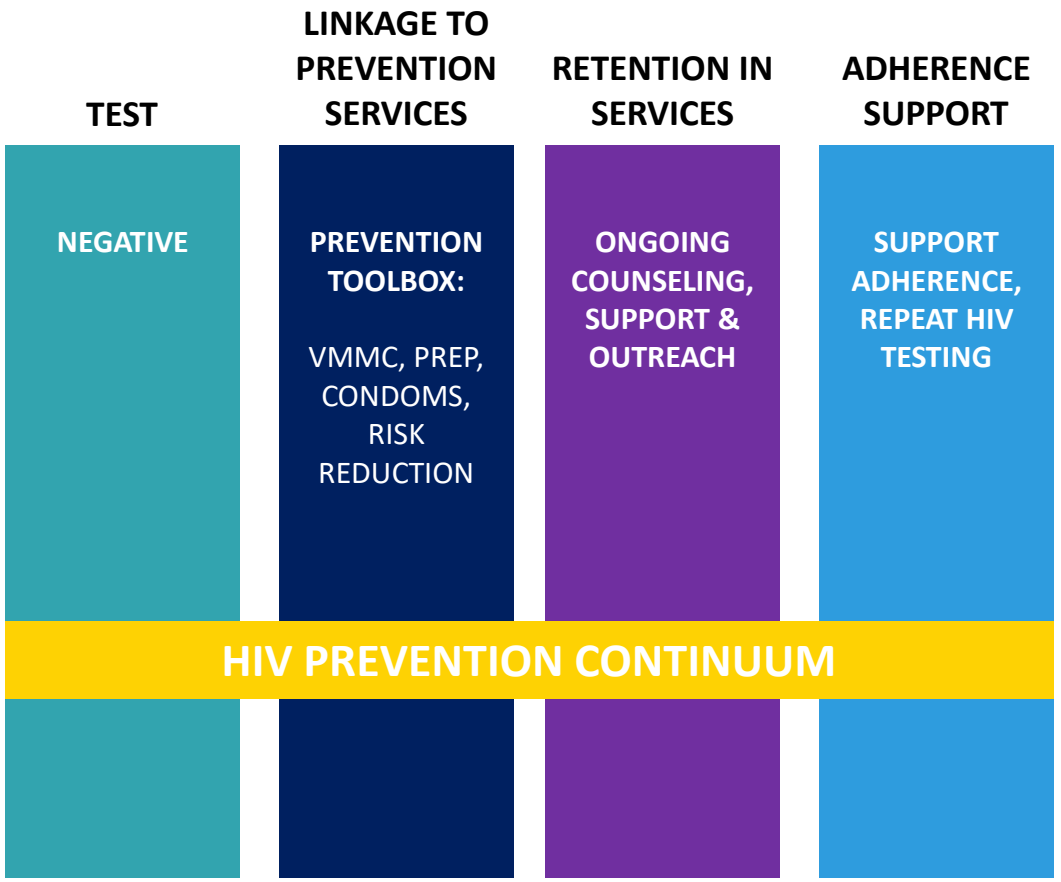
Historical Time-Line for PrEP



PrEP, pre-exposure prophylaxis; MSM, men who have sex with men; FTC/TDF, emtricitabine/tenofovir disoproxil fumarate; FTC/TAF, emtricitabine/tenofovir alafenamide

Some Key Aspects of PrEP

- Used by an HIV-negative individual to reduce the risk of acquiring HIV infection
- Component of HIV prevention toolbox as part of the HIV prevention continuum[1]
- Used in addition to behavioral risk reduction
- Does not protect against other STIs



VMMC, voluntary medical male circumcision

1. McNairy ML, El-sadr WM. A Paradigm Shift: Focus On The HIV Prevention Continuum. Clin Infect Dis. 2014;59 Suppl 1(suppl 1):S12-S15. Doi:10.1093/Cid/Ciu251

PrEP Efficacy Evaluated in Numerous Clinical Trials

MSM

- iPrEx[1]
- US MSM Safety Trial[2]
- Adolescent Trials Network (ATN) 082[3]
- Ipergay[4]
- Open-label trials
  - iPrEx open-label extension study[5]
  - PROUD[6]
  - Kaiser Permanente[7]
  - Demo Project open-label study[8]
  - Ipergay open-label extension study[9]
  - Discover Trial[10]

MEN AND WOMEN

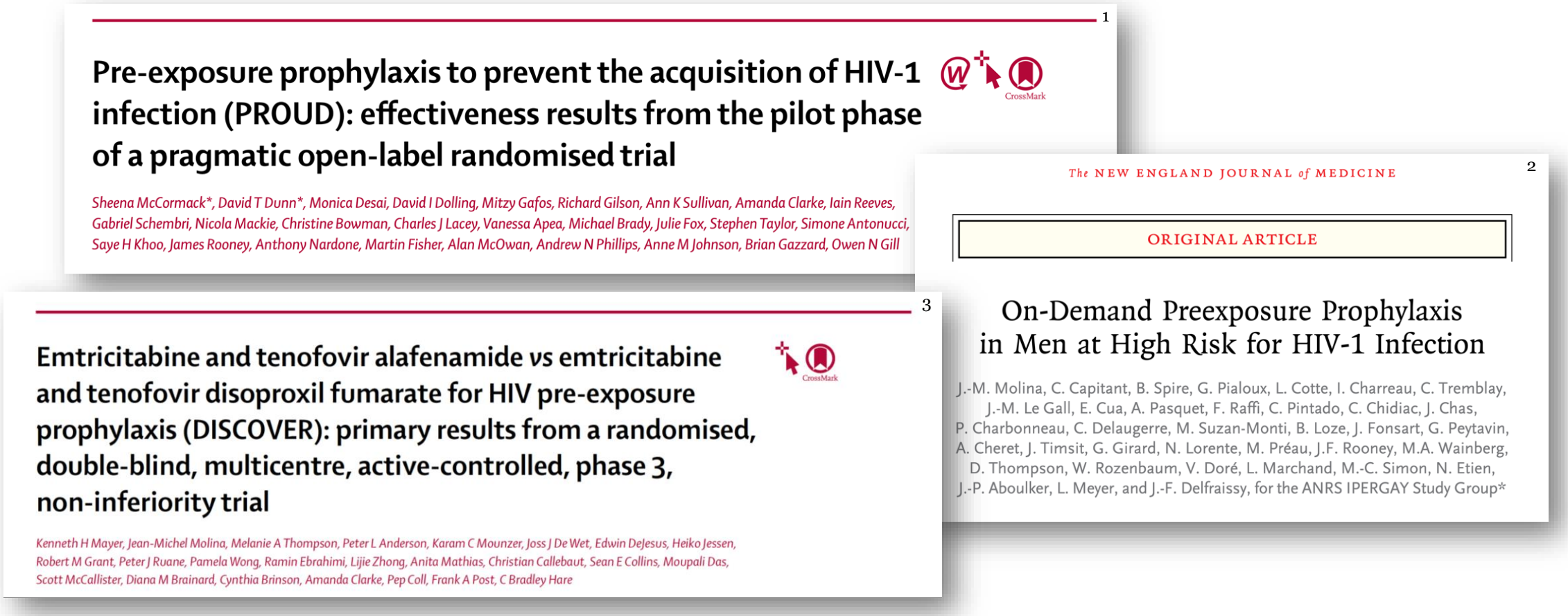
- Partners PrEP[11]
- TDF2[12]
- FEM-PrEP[13]
- Phase II TDF PrEP among women in Ghana, Cameroon, and Nigeria[14]
- VOICE[15]

PERSONS WHO INJECT DRUGS

- Bangkok Tenofovir Study (BTS)[16]
- Open label
  - Bangkok Tenofovir Study (BTS) OLE[17]

1. Grant. NEJM. 2010;363:2587. 2. Grohskopf. JAIDS. 2013;64:79. 3. Hosek. JAIDS. 2013;62:447. 4. Molina. NEJM. 2015;373:2237. 5. Grant. Lancet Infect Dis. 2014;14:820. 6. McCormack. Lancet. 2016;387:53. 7. Volk. Clin Infect Dis. 2015;61:1601. 8. Liu. JAMA Intern Med. 2016;176:75. 9. Molina. Lancet HIV. 2017;4:e402. 10. Mayer. Lancet. 2020 Jul 25;396(10246):239-254. 11. Baeten. NEJM. 2012;367:399. 12. Thigpen. NEJM. 2012;367:423. 13. Van Damme. NEJM. 2012;367:411. 14. Peterson. PLoS Clin Trials. 2007;2:e27. 15. Marrazzo. NEJM. 2015;372:509. 16. Choopanya. Lancet. 2013;381:2083. 17. Martin. Lancet HIV. 2017;4:e59.

Efficacy and Support for PrEP is Well-Established



1

Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial

Sheena McCormack*, David T Dunn*, Monica Desai, David I Dolling, Mitzy Gafos, Richard Gilson, Ann K Sullivan, Amanda Clarke, Iain Reeves, Gabriel Schembri, Nicola Mackie, Christine Bowman, Charles J Lacey, Vanessa Apea, Michael Brady, Julie Fox, Stephen Taylor, Simone Antonucci, Saye H Khoo, James Rooney, Anthony Nardone, Martin Fisher, Alan McOwan, Andrew N Phillips, Anne M Johnson, Brian Gazzard, Owen N Gill

2

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection

J.-M. Molina, C. Capitant, B. Spire, G. Pialoux, L. Cotte, I. Charreau, C. Tremblay, J.-M. Le Gall, E. Cua, A. Pasquet, F. Raffi, C. Pintado, C. Chidiac, J. Chas, P. Charbonneau, C. Delaugerre, M. Suzan-Monti, B. Loze, J. Fonsart, G. Peytavin, A. Cheret, J. Timsit, G. Girard, N. Lorente, M. Préau, J.F. Rooney, M.A. Wainberg, D. Thompson, W. Rozenbaum, V. Doré, L. Marchand, M.-C. Simon, N. Etien, J.-P. Aboulker, L. Meyer, and J.-F. Delfraissy, for the ANRS IPERGAY Study Group*

3

Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial

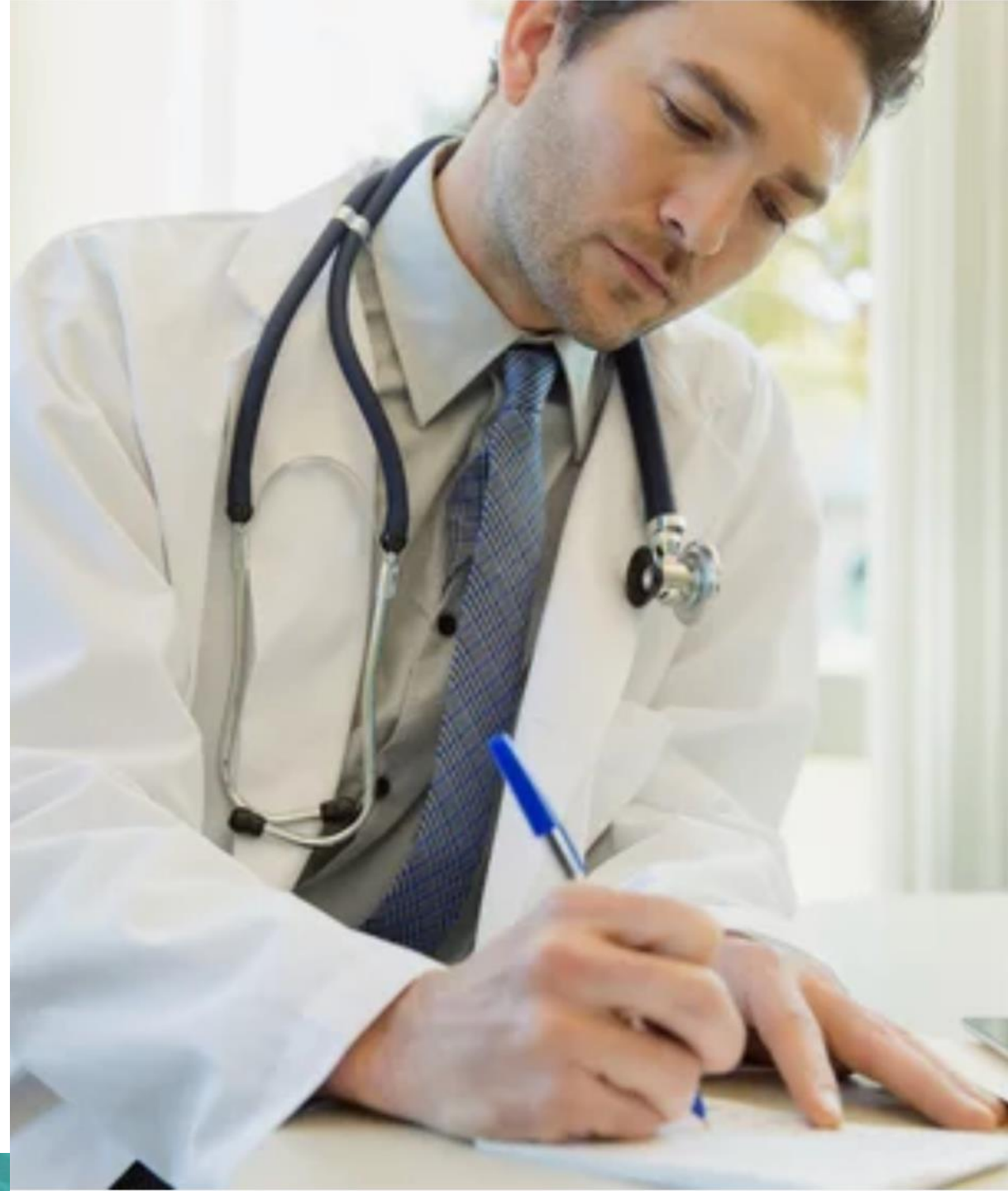
Kenneth H Mayer, Jean-Michel Molina, Melanie A Thompson, Peter L Anderson, Karam C Mounzer, Joss J De Wet, Edwin DeJesus, Heiko Jessen, Robert M Grant, Peter J Ruane, Pamela Wong, Ramin Ebrahimi, Lijie Zhong, Anita Mathias, Christian Callebaut, Sean E Collins, Moupali Das, Scott McCallister, Diana M Brainard, Cynthia Brinson, Amanda Clarke, Pep Coll, Frank A Post, C Bradley Hare

1. McCormack S, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. Lancet. 2016 Jan 2;387(10013):53-60. doi: 10.1016/S0140-6736(15)00056-2. Epub 2015 Sep 9.
2. Molina J-M, et al. On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. N Engl J Med 2015; 373:2237-2246.
3. Mayer KH, et al. Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial. Lancet. 2020 Jul 25;396(10246):239-254.

CDC Guidelines
(2014, 2017, …2021)

Physicians should offer PrEP

- Ideally to all persons at risk of acquiring HIV infection
  - Detailed sexual history
  - Screening for illicit drug



CDC. US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.%20March%202018. March 2018.

Comprehensive Guidelines for Prescribing PrEP

PrEP

For people **without HIV** but with risk of infection from sex or injection drug use

PEOPLE TO ASSESS FOR PrEP

1. Sexually active men who have sex with men (MSM) [1,2]
2. Sexually active heterosexual men and women [1,2]
3. Persons who inject drugs (PWID) [1,2]

Other populations to consider:

- Transgender persons
- Prescribed non-occupational post-exposure prophylaxis (PEP) with continued risk behavior, or have used multiple courses of PEP

FDA APPROVED 2012

CDC GUIDANCE 2014/2017[1]

U.S. PREVENTIVE SERVICES TASK FORCE GRADE A RECOMMENDATION[2]

1. CDC. US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.%20March%202018. March 2018.
2. USPSTF. Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213.

When to Initiate PrEP by Risk Group

1. Adult males who have sex with males (MSM):

- Any male sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative man

AND (at least one of the following)

- History of anal sex without condoms in the past six months
- STI diagnosed in the past six months

CDC. US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.%20March%202018. March 2018.

When to Initiate PrEP by Risk Group

2. Heterosexually active adult men or women

- Had sex with an opposite sex partners in past 6 months
- Not in a monogamous partnership with recently tested HIV-negative man

AND (at least one of the following)

- A man who has sex with both women and men (behaviorally bisexual)
- Infrequently uses condoms with 1+ partners of unknown HIV status at substantial risk of HIV infection
  - People who inject drugs (PWID)
  - Bisexual male partners
- In ongoing relationship with **person with HIV (PWH)***
- STI diagnosed in the past six months

*U = U

CDC. US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.%20March%202018. March 2018.

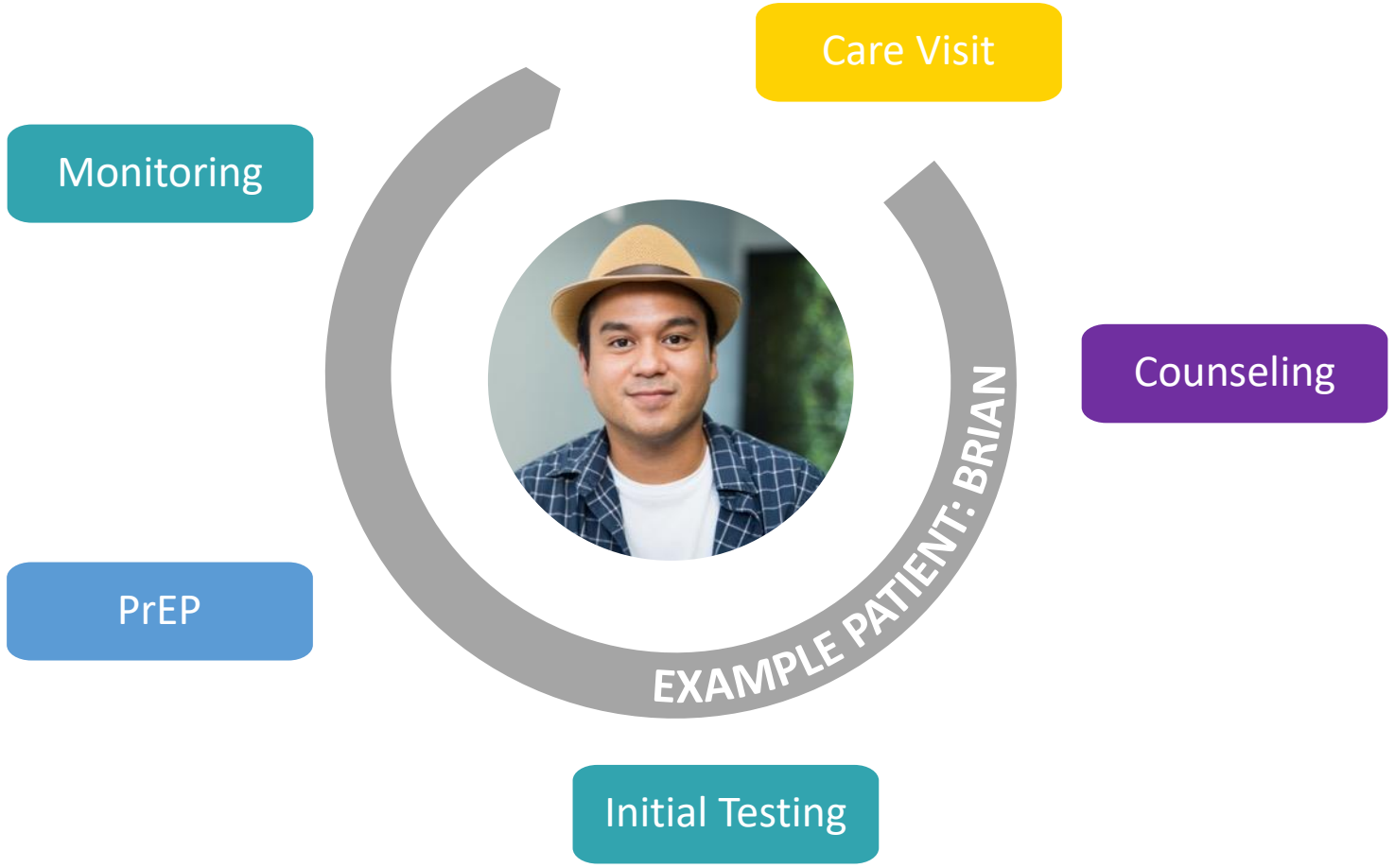
When to Initiate PrEP by Risk Group

3. **Persons who inject drugs**
   - Any illicit drug within past six months

   AND (at least one of the following)
   - Shared injection or drug preparation equipment in past six months
   - Risk of HIV acquisition based on sexual behavior

CDC. US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.%20March%202018. March 2018.

PrEP Patient Journey



Not an actual patient image. Image licensed by Abbott.

Example Patient: Brian

Not an actual patient image. Image licensed by Abbott.

History / Physical

- Good health with no medical concerns.
- Stable but open relationship with male partner (four years), occasionally engages in sex with other men
- Sometimes, but not consistently, uses condoms; usually only when with someone he does not know very well
- 6 mos ago, treated in urgent care for a sexually transmitted infection (STI) - "a shot and four pills". No follow-up testing post-treatment
- Last HIV test ~ one year ago; does not know when his regular partner was last tested

People at Risk for HIV in the U.S.

Brian's case is not unique…

~1.2 million
people engage in sexual or injection drug-use behaviors that place them at substantial risk of acquiring HIV infection[1]

Like Brian,
~70%
of new cases are men who have sex with men*[1]

Oral PrEP reduces
>90%
of risk of acquiring HIV infection when used consistently[2]

* Includes illicit drug users

1. HIV.gov. U.S. Statistics. https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics, accessed Nov 17, 2021.
2. PAHO WHO. Pre-Exposure Prophylaxis (PrEP). https://www.paho.org/en/topics/combination-hiv-prevention/pre-exposure-prophylaxis-prep, accessed Nov 19, 2021.

Example Patient: Brian

Address

Health maintenance, Diet, Exercise, Immunizations; Screening tests

Orders

- 4th generation HIV antibody/antigen
- STI screening tests (chlamydia, gonorrhea, syphilis)
- Basic metabolic panel (BMP)
- Hepatitis B antigen and antibody
- Hepatitis C antibody

Not an actual patient image. Image licensed by Abbott.

Our current method for HIV testing is:

a) In-house rapid antibody test
b) In-house rapid antigen/antibody test (4th gen)
c) Send out antigen/antibody test
d) a & c
e) b & c
f) Other

FOR CLINICAL/
HIV CARE SITES

POLL QUESTION

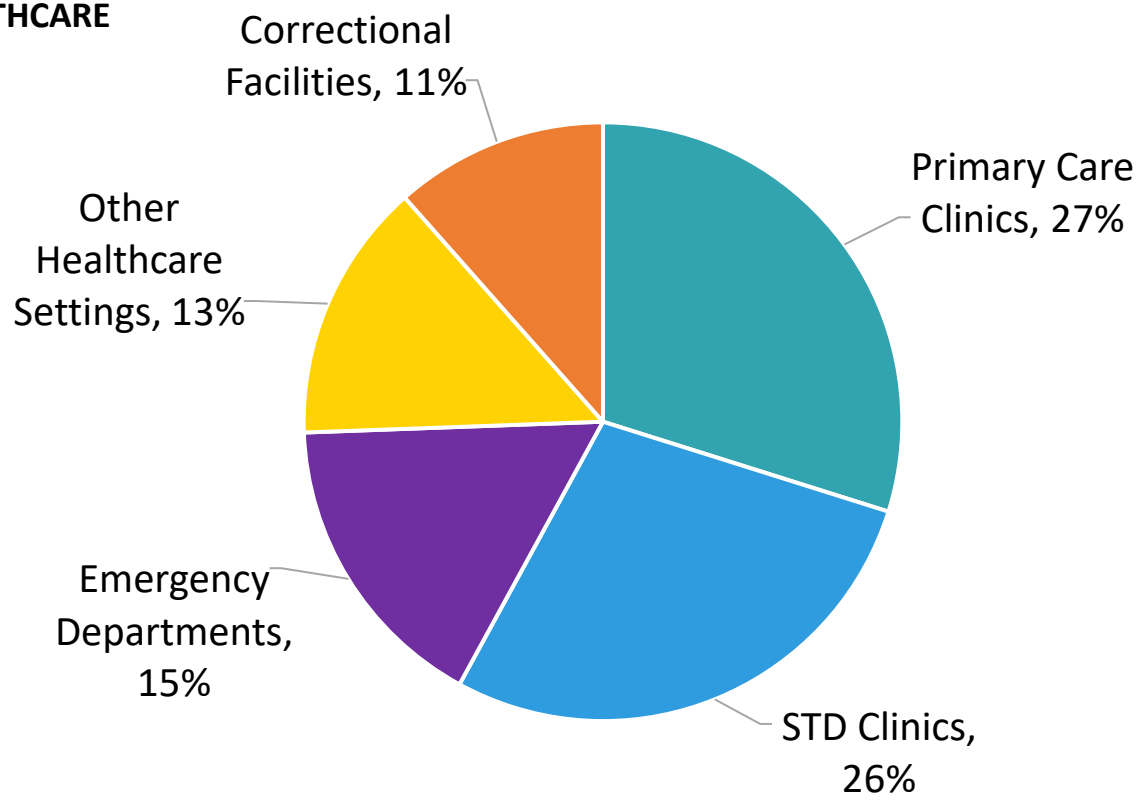
#2

HIV TESTING / SCREENING

Healthcare Setting Testing for HIV

% OF TESTING[1]

CDC FUNDED TESTING IN HEALTHCARE SETTINGS, U.S. (2013)



Seth P, et al. CDC. Identifying New Positives and Linkage to HIV Medical Care--23 Testing Site Types, United States, 2013. MMWR Morb Mortal Wkly Rep. 2015 Jun 26;64(24):663-7.

Continued Barriers to Screening for HIV

~40%
of ongoing transmissions acquired from persons unaware of HIV status[1]

>2/3
of patients at increased risk of HIV were not offered HIV testing during office visit[1]

MAIN BARRIERS TO HIV SCREENING INCLUDE:[2]

- Costs
- Need for venipuncture
- Delayed turn-around-time for test results
- Lack of laboratory capacity

ANTIBODY/ANTIGEN TEST REIMBURSEMENT

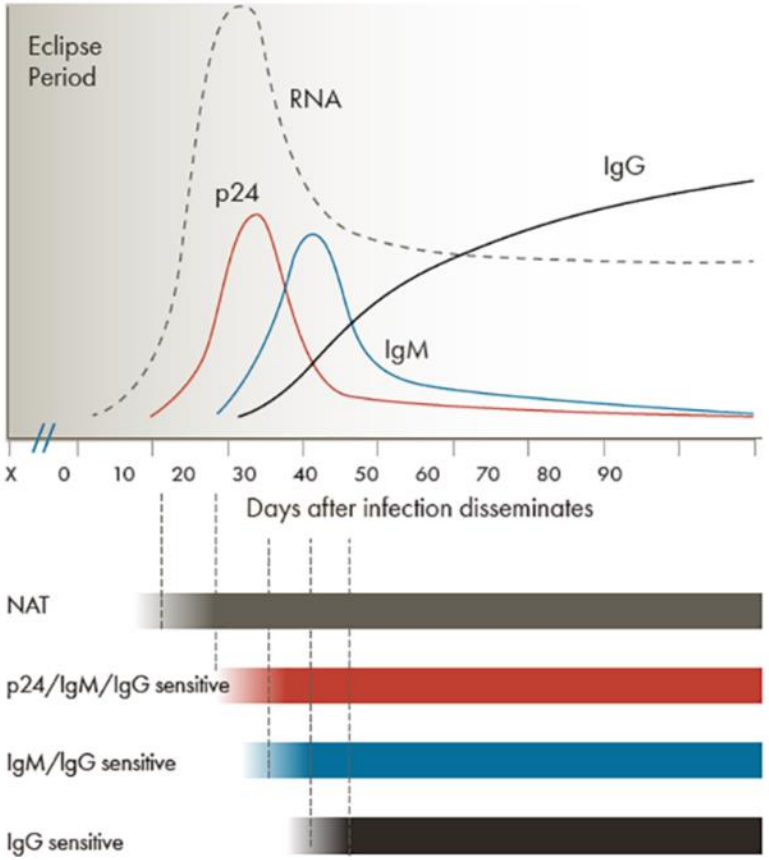
CPT® CODES:
87806 (Nonwaived), 87806QW (Waived)[1]

MEDICARE SCREENING:
G0433 (Nonwaived), G0433QW (Waived)

AHI, acute HIV infection

1. Dailey AF, et al. Vital Signs: Human Immunodeficiency Virus Testing and Diagnosis Delays — United States. MMWR Morb Mortal Wkly Rep 2017;66:1300–1306.
2. Hoenigl M, Little SJ. How can we detect HIV during the acute or primary stage of infection?. *Expert Rev Mol Diagn*. 2016;16(10):1049-1051.
3. CMS, Medicare Learning Network. MLN Matters Number: MM10055, May 12, 2017.

Antigen / Antibody Test Timing and HIV Screening



< 2 weeks

people may test negative or indeterminate post-infection[1]

p24 antigen

enhances detection during acute phase of infection to help reduce risk of missing recently infected individuals / unrecognized acute infections.[1,2]

1. CDC. Diagnostic tests. https://www.cdc.gov/hiv/clinicians/screening/diagnostic-tests.html, accessed Nov 14, 2021. Adapted, removed Western blot.
2. FDA. Testing for HIV. https://www.fda.gov/vaccines-blood-biologics/hiv-home-test-kits/testing-hiv, accessed Nov 11, 2021.

Available Types of HIV Tests

- Anti-HIV-1 Assays - Human Immunodeficiency Virus Type 1
- HIV-1 Nucleic Acid Assays - Human Immunodeficiency Virus Type 1
- HIV-Syphilis Assay
- Anti-HIV Specimen Collection Devices, Testing Services, and Home Test Kits
- Anti-HIV-2 Assays - Human Immunodeficiency Virus Type 2
- Anti-HIV-1/2 Assays - Human Immunodeficiency Virus Types 1 and 2
- **Anti-HIV-1/2 and HIV-1 Antigen Combo Assays**

FDA. Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays. https://www.fda.gov/vaccines-blood-biologics/complete-list-donor-screening-assays-infectious-agents-and-hiv-diagnostic-assays, accessed Nov 14, 2021.

HIV Assays by Test Category

ANTIGEN / ANTIBODY NAT

Test Category [a]	HIV Screening Tests	Run Time	Instrument	Report Ag and Ab separately	Detects IgG	Detects IgM	Uses whole blood (WB) specimens	Uses oral fluid (OF) specimens	Uses dried blood spot specimens	Least complex[b] CLIA category	External quality control not required in each run
Nucleic acid laboratory test	Aptima HIV-1 RNA Qualitative Assay[c]	>3 hours	semi-automated							high	
Ag/Ab laboratory test	ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay	<1 hour	automated		✓	✓				moderate	✓
	ARCHITECT HIV Ag/Ab Combo Assay	<30 mins	automated		✓	✓				moderate	✓
	BioPlex 2200 HIV Ag-Ab	45 mins	automated	✓	✓	✓				moderate	✓
	Elecsys HIV combi PT	27 mins	automated		✓	✓				moderate	✓
	GS HIV Combo Ag/Ab EIA	>3 hours	semi-automated		✓	✓				high	
	VITROS HIV Combo Test	48 mins	automated		✓	✓				moderate	✓
Ag/Ab rapid test	Determine HIV-1/2 Ag/Ab Combo	20 mins	single-use	✓	✓	✓	✓			waived	✓

For the most current list of available HIV assays, please visit:
https://www.fda.gov/vaccines-blood-biologics/complete-list-donor-screening-assays-infectious-agents-and-hiv-diagnostic-assays

CDC. https://www.cdc.gov/hiv/pdf/testing/hiv-tests-advantages-disadvantages_1.pdf?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fhiv%2Feffective-interventions%2Flibrary%2Fredirects%2Fmarketing-materials%2Fredirect3m.html

HIV Assays by Test Category (continued)

ANTIBODY

Test Category [a]	HIV Screening Tests	Run Time	Instrument	Report Ag and Ab separately	Detects IgG	Detects IgM	Uses whole blood (WB) specimens	Uses oral fluid (OF) specimens	Uses dried blood spot specimens	Least complex[b] CLIA category	External quality control not required in each run
Ab laboratory test	ADVIA Centaur HIV 1/O/2 Enhanced (EHIV) Assay	< 1 hour	automated		✓	✓				moderate	
	Avioq HIV-1 Microelisa System	>3 hours	semi-automated		✓	✓		✓	✓	high	
	GS HIV-1/2 Plus O	>3 hours	semi-automated		✓	✓				high	
	VITROS Anti-HIV 1+2	< 1 hour	automated		✓	✓				high	✓
Ab rapid test	DPP HIV-1/2 Assay	10 mins WB/ 25 mins OF	single-use		✓		✓	✓		waived	✓
	HIV 1/2 STAT-PAK	15 mins	single-use		✓		✓			waived	✓
	INSTI HIV-1/HIV-2 Antibody Test	<2 mins	single-use		✓	✓	✓			waived	✓
	OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	20 mins	single-use		✓	✓	✓	✓		waived	✓
	Reveal G4 Rapid HIV-1 Antibody Test	<2 mins	single-use		✓		✓			moderate	✓
	SURE CHECK HIV 1/2 Assay	15 mins	single-use		✓		✓			waived	✓
	Uni-Gold Recombigen HIV-1/2	10 mins	single-use		✓	✓	✓			waived	✓

For the most current list of available HIV assays, please visit:
https://www.fda.gov/vaccines-blood-biologics/complete-list-donor-screening-assays-infectious-agents-and-hiv-diagnostic-assays

CDC. https://www.cdc.gov/hiv/pdf/testing/hiv-tests-advantages-disadvantages_1.pdf?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fhiv%2Feffective-interventions%2Flibrary%2Fredirects%2Fmarketing-materials%2Fredirect3m.html

What Advantages Do POC HIV Tests Have Over Laboratory-based Assays?

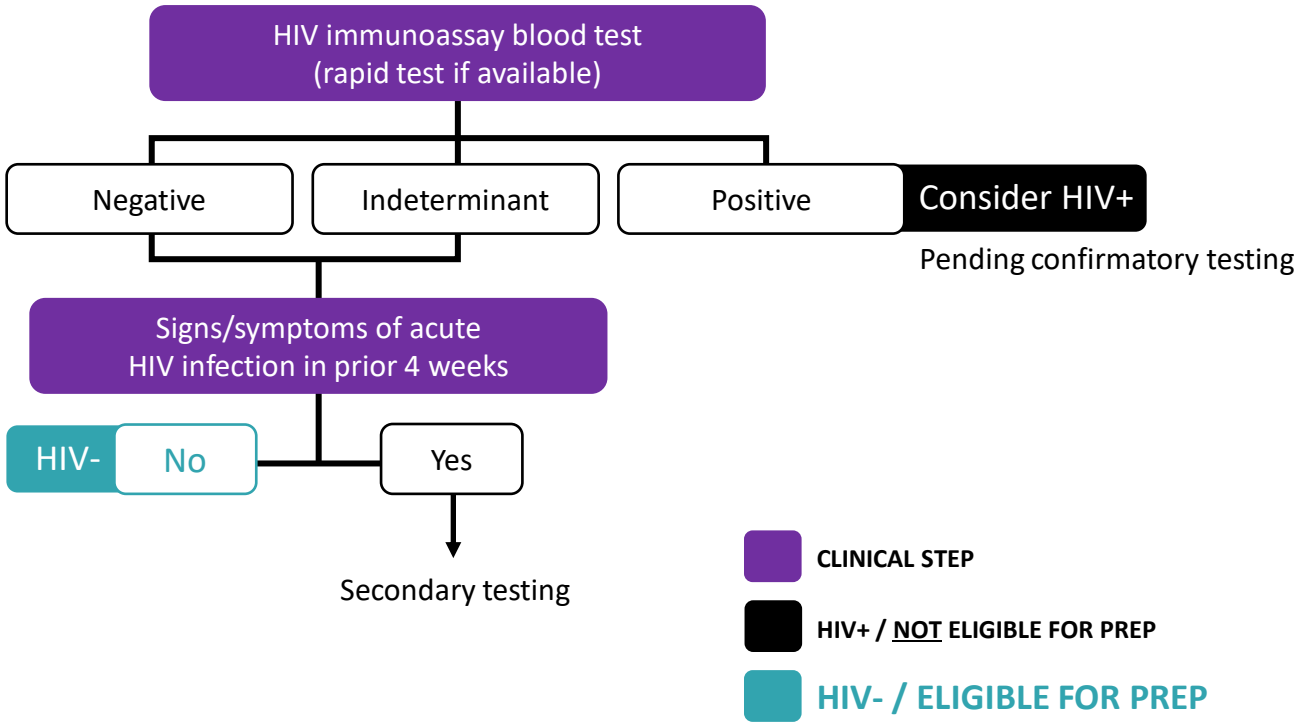
- Ease of use[1]
- Fingerstick whole blood or oral fluid[1], although oral fluid is less sensitive[2]
- Eliminate venipuncture, samples handling, processing, or storage of blood[1]
- Permit a self-contained encounter[1]
- Greatly increase likelihood patient receives result[1]
- Provide alternative test when automated platform is not available[1]

> *Absence of easy to use, rapid tests that reliably detect AHI may represent the greatest limitation,* ***as loss to follow up remains a major concern in these settings.***[3]

1. Hurt CB, Nelson JAE, Hightow-Weidman LB, Miller WC. Selecting an HIV Test: A Narrative Review for Clinicians and Researchers. *Sex Transm Dis*. 2017;44(12):739-746.
2. CDC. US Public Health Service: PrEP for the prevention of HIV infection in the U.S. —2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018.
3. Hoenigl M, Little SJ. How can we detect HIV during the acute or primary stage of infection?. *Expert Rev Mol Diagn*. 2016;16(10):1049-1051.

Initial HIV Testing Algorithm Prior to Initiating PrEP

FRONT LINE TESTING



CDC. US Public Health Service: PrEP for the prevention of HIV infection in the U.S. —2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018. Adapted: Partial algorithm of initial testing, only.

Example Patient: Brian

Follow-Up

One week later, Brian returns to the office to discuss his results:

- HIV (4th gen blood draw) - negative
- STI tests - negative
- Hepatitis B S Ab - positive/ immune
- Hepatitis C Ab - negative
- Basic Metabolic Panel - normal

Not an actual patient image. Image licensed by Abbott.

Patient Example Brian (continued)

Discuss why he is a candidate for PrEP

- ✓ Does not consistently use condoms with male partners
- ✓ Not in a monogamous relationship
- ✓ Does not know HIV status of regular partner and only assumes he is negative
- ✓ Treated for STI in prior ~6 months

Not an actual patient image. Image licensed by Abbott.

Providing Risk Reduction Counseling and Introducing PrEP

- Open discussion of current sexual practices and ways to reduce HIV infection risk
  - Condoms, 70-80% protective[1]
  - Include discussion of patient's sexual partners and awareness of their HIV status
  - Encourage rapid testing at sites for sexual partners
- Inform patients of risks of HIV if engaging in sexual practices without appropriate protection
- Introduce patients to the benefits of PrEP as a safeguard against HIV infection

> *"Addressing these themes in behavioral interventions in the context of prescribing PrEP may result in the optimal "packaging" public health programs that implement PrEP for high-risk MSM.[2]"*

1. USPSTF. Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213.
2. Taylor SW, et al. Optimizing content for pre-exposure prophylaxis (PrEP) counseling for men who have sex with men: Perspectives of PrEP users and high-risk PrEP naïve men. *AIDS Behav*. 2014;18(5):871-879.

WHO IS AT GREATEST RISK OF NOT HAVING ACCESS TO PREP?

Age, Sex and Demographic Factors Associated with Each Step of the PrEP Continuum

Characteristic	PrEP status, hazard ratio (95% CI)	
	Prescription	Initiation
Age, y		
18-25	1 [Reference]	1 [Reference]
26-35	1.33 (1.26-1.41)	1.04 (0.98-1.10)
36-45	1.41 (1.33-1.50)	1.10 (1.03-1.17)
>45	1.21 (1.14-1.29)	1.09 (1.02-1.16)
Race and ethnicity		
White	1 [Reference]	1 [Reference]
Latinx	0.88 (0.84-0.93)	0.90 (0.86-0.95)
Asian	0.96 (0.91-1.02)	1.06 (1.00-1.12)
African American	0.74 (0.69-0.81)	0.87 (0.80-0.95)
Other or unknown[a]	0.91 (0.84-0.97)	1.03 (0.95-1.11)
Women	0.56 (0.50-0.62)	0.71 (0.64-0.80)
Neighborhood Deprivation Index, quintile		
First (highest SES)	1 [Reference]	1 [Reference]
Second	0.90 (0.85-0.95)	1.01 (0.95-1.07)
Third	0.85 (0.80-0.90)	0.96 (0.91-1.02)
Fourth	0.86 (0.81-0.91)	0.97 (0.91-1.03)
Fifth (lowest SES)	0.72 (0.68-0.76)	0.93 (0.87-0.99)

SES, socioeconomic status.

Hojilla JC, Hurley LB, Marcus JL, et al. Characterization of HIV Preexposure Prophylaxis Use Behaviors and HIV Incidence Among US Adults in an Integrated Health Care System. JAMA Netw Open.2021;4(8):e2122692. doi:10.1001/jamanetworkopen.2021.22692

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>45	1.21 (1.14-1.29)	1.09 (1.02-1.16)
Race and ethnicity		
White	1 [Reference]	1 [Reference]
Latinx	0.88 (0.84-0.93)	0.90 (0.86-0.95)
Asian	0.96 (0.91-1.02)	1.06 (1.00-1.12)
African American	0.74 (0.69-0.81)	0.87 (0.80-0.95)
Other or unknown[a]	0.91 (0.84-0.97)	1.03 (0.95-1.11)
Women	0.56 (0.50-0.62)	0.71 (0.64-0.80)
Neighborhood Deprivation Index, quintile		
First (highest SES)	1 [Reference]	1 [Reference]
Second	0.90 (0.85-0.95)	1.01 (0.95-1.07)
Third	0.85 (0.80-0.90)	0.96 (0.91-1.02)
Fourth	0.86 (0.81-0.91)	0.97 (0.91-1.03)
Fifth (lowest SES)	0.72 (0.68-0.76)	0.93 (0.87-0.99)

- **Fewer prescriptions** in:
  - Young adults
  - Certain minorities
  - Women
  - Individuals in lower socioeconomic status

SES, socioeconomic status.

Hojilla JC, Hurley LB, Marcus JL, et al. Characterization of HIV Preexposure Prophylaxis Use Behaviors and HIV Incidence Among US Adults in an Integrated Health Care System. JAMA Netw Open.2021;4(8):e2122692. doi:10.1001/jamanetworkopen.2021.22692

PRESCRIBING AND RESOURCES FOR PREP

PrEP Prescribing – current options

- **TDF/FTC: TRUVADA® (2012) *OR GENERIC EQUIVALENT (2020)***
- **TAF/FTC: DESCOVY® (2018)**
  - Safer for patients at risk of kidney disease, eCrCl ≥ 30 ml/min
  - Only approved for men and transgender women
  - Recommended in patients with bone disease

Both well-tolerated, occasional nausea/diarrhea (self-resolving)[1]

PrEP

- **SINGLE TABLET, 1/DAY[1]**
- **COST: $1800/MONTH (VS LIFETIME COST OF ONE HIV INFECTION)**
  - Covered by most insurances
  - Patient Assistance Programs (PAPs)[2,3]
    - https://www.pleaseprepme.org/payment
    - https://www.nastad.org/prep-access/state-prep-assistance-programs

FTC/TDF, emtricitabine/tenofovir disoproxil fumarate; FTC/TAF, emtricitabine/tenofovir alafenamide

1. TRC, Prescriber's Letter, November 2019 ~ Resource #351107
2. Please Prep Me.org. Resources for Covering the Costs of PrEP and PEP. https://www.pleaseprepme.org/payment.
3. NASTAD. State PrEP Assistance Programs. https://www.nastad.org/prep-access/state-prep-assistance-programs

Monitoring Patients on PrEP

At least every **3** months

- Assess medication access, adherence and side effects
- Assess HIV risk behaviors
- **Repeat HIV testing**
- Repeat 3-site STI testing
- 3-month PrEP Rx (FTC/TDF)

CKD, chronic kidney disease

CDC. US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018.

Our current method for baseline testing and monitoring PrEP is:

a) In-house rapid antibody test
b) In-house rapid antigen/antibody test (4th gen)
c) Send out antigen/antibody test
d) a & c
e) b & c
f) Other

FOR CLINICAL/
HIV CARE SITES

POLL QUESTION

#3

Monitoring Patients on PrEP

At least every 3 months

- Assess medication access, adherence and side effects
- Assess HIV risk behaviors
- **Repeat HIV testing**
- Repeat 3-site STI testing
- 3-month PrEP Rx (FTC/TDF)

At least every 6 months

- **Monitor serum creatinine**
  - Concerns for other risk of CKD (e.g., hypertension, diabetes) consider monitoring every 3 months
  - PrEP safely continued if eCrCl ≥60 ml/min
  - Consider change to FTC/TAF if eCrCl ≤60 ml/min but ≥30 ml/min

Monitoring

CKD, chronic kidney disease

CDC. US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018.

Monitoring Patients on PrEP

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  - Concerns for other risk of CKD (e.g., hypertension, diabetes) consider monitoring every 3 months
  - PrEP safely continued if eCrCl ≥60 ml/min
  - Consider change to FTC/TAF if eCrCl ≤60 ml/min but ≥30 ml/min

At least every 12 months

- **Evaluate need to continue PrEP as component of HIV prevention**
  - Some patients may elect to stop due to lifestyle/partner change
  - Encourage follow-up for resumption of PrEP if change in sexual behaviors or illicit drug use

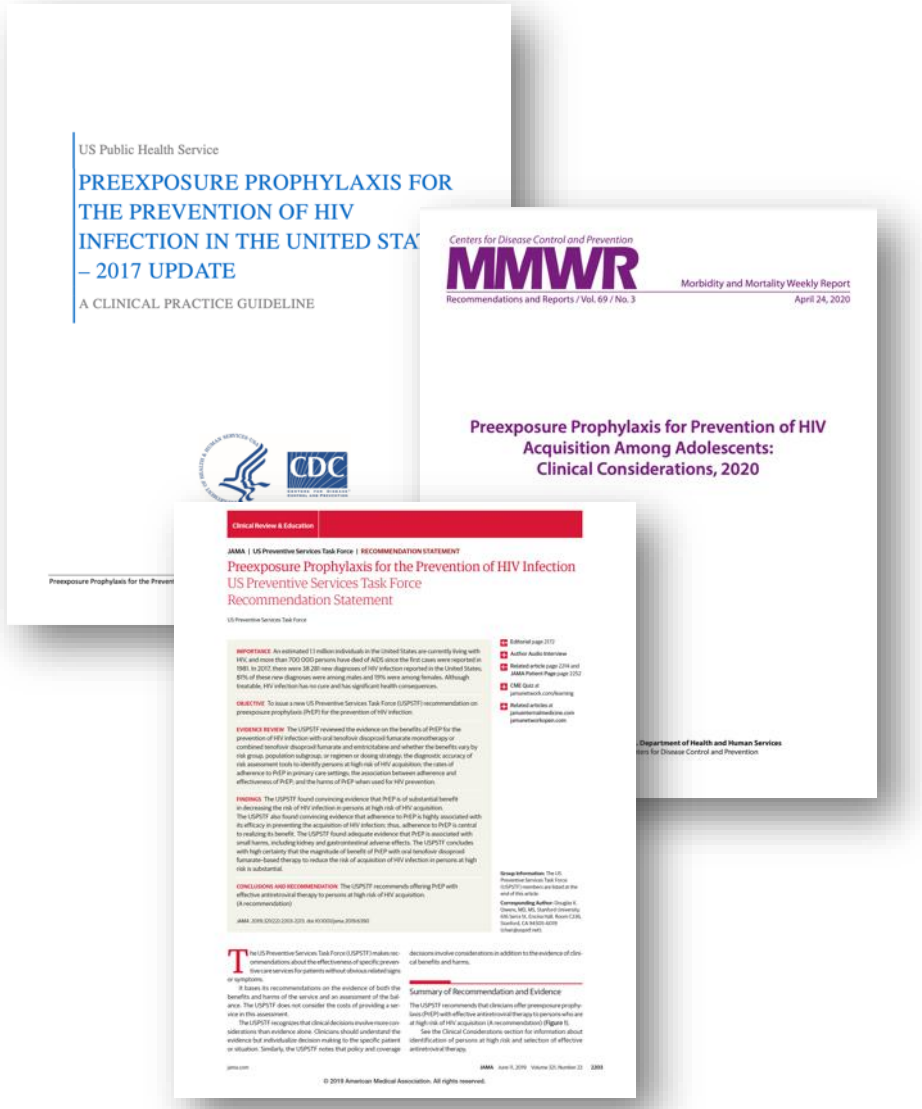
Monitoring

CKD, chronic kidney disease

CDC. US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018.

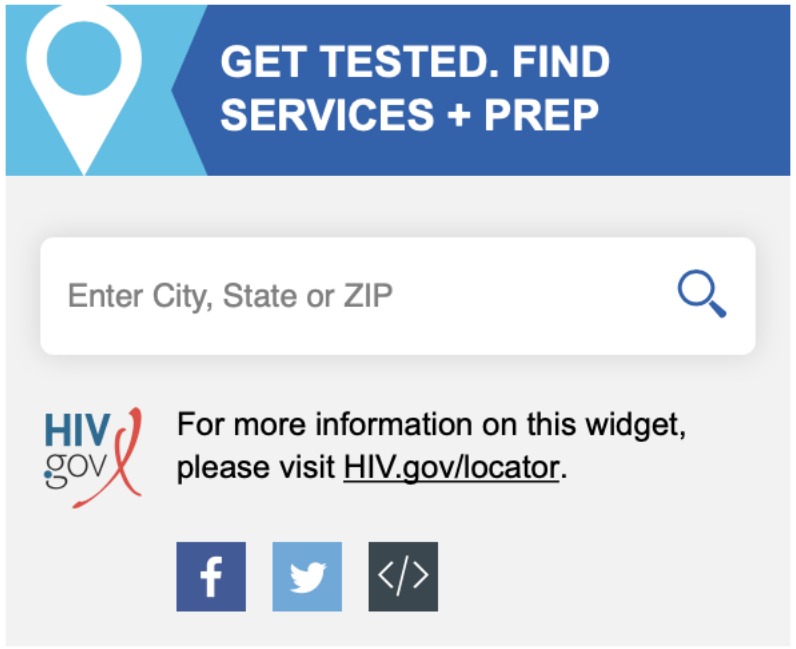
Resources / Recommendations

- Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update: a Clinical Practice Guideline[1]
- Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement (2019)[2]
- Preexposure Prophylaxis for Prevention of HIV Acquisition Among Adolescents: Clinical Considerations, 2020[3]



1. CDC. US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.%20March%202018. March 2018.
2. USPSTF. Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213.
3. Tanner MR, Miele P, Carter W, et al. Preexposure Prophylaxis for Prevention of HIV Acquisition Among Adolescents: Clinical Considerations, 2020. MMWR Recomm Rep 2020;69(No. RR-3):1–12.

Finding HIV Testing Sites and PrEP Providers



https://www.cdc.gov/hiv/

https://www.hiv.gov/locator/

https://gettested.cdc.gov/

https://locator.aids.gov/

https://preplocator.org/

https://www.greaterthan.org/get-prep/

https://www.stdcheck.com/

https://www.healthysexuals.com/

https://samedaystdtesting.com/

https://www.healthlabs.com/

Conclusions

- Daily PrEP use is safe and highly effective in preventing HIV infection in patients at risk
- Baseline and periodic follow-up testing is required, including regular HIV screening using 4^{th} generation assays
- Rapid, point of care testing may help overcome challenges in patient follow-up
- PrEP remains significantly underutilized in the U.S. - cost and medication access should not be a barrier to PrEP eligible patients
- Initiating and prescribing PrEP to a wide range of patients is well within scope and expertise of primary care physicians and advanced practice professionals
- Additional PrEP therapies with other delivery formats are pending FDA approval (e.g., long-acting injectable, vaginal ring, long-acting oral therapies)