

Two Case Studies in PEP and PrEP

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25 August 2023

Disclosures

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- Outline the management of indeterminate or reactive HIV screening tests for patients currently taking oral PrEP
- Explain the impact of subtherapeutic antiretroviral exposure on the expected time-to-positivity of HIV screening tests
- Formulate their own approach to counseling a young adult at risk for HIV about the PrEP options available to them

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 - Partner attempted to remove condom partway but “finished outside” (witnessed by Mike)
- 9/30/2018 – FwB told him one of his partners had gonorrhea. FwB denied any symptoms but encouraged Mike to get checked.

Case 1: “Mike” (November 2018) – cont’d

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- 10/8/2018 – saw same FwB, again had RAI with condom*

* had condomless oral sex (giving and receiving)

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 - Quantity not sufficient to run supplemental Ab assay
- **PCP contacted Dr. Hurt on 11/8/2018**

Polling Question #1: “Mike”

In addition to repeating the HIV Ag/Ab assay and scheduling a formal evaluation ASAP, what guidance would you give Mike’s PCP?

- A. Continue FTC/TDF
- B. Continue FTC/TDF and order HIV RNA
- C. Continue FTC/TDF and add dolutegravir
- D. Continue FTC/TDF, add dolutegravir, and order HIV RNA
- E. Stop FTC/TDF pending formal consultation

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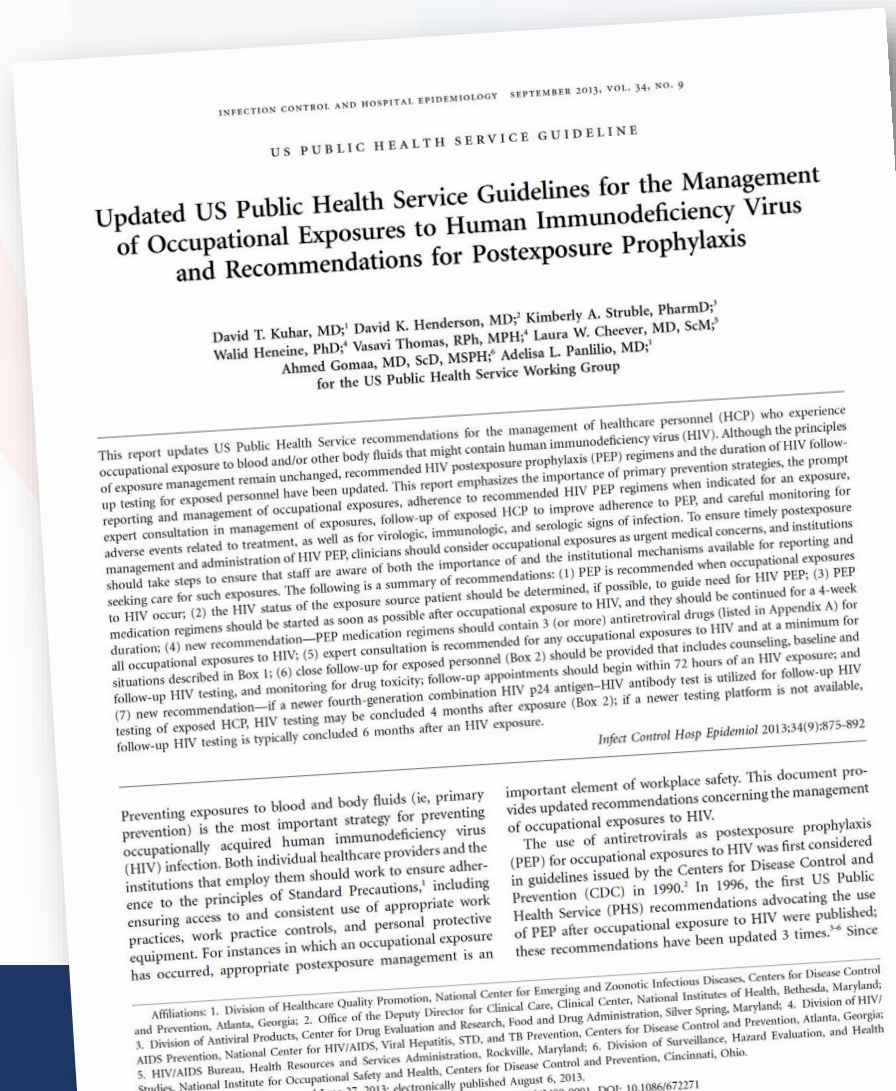
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 - Repeat HIV RNA not detected

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 - Lab-based, automated HIV Ag/Ab assay **non-reactive**
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- FTC/TDF continued until Mike filled a new prescription for a 28-day course of BIC/FTC/TAF (as PEP)

Why not FTC/TDF + (RAL or DTG)?

Occupational PEP guidance updated in 2013



Preferred regimen



**emtricitabine/
tenofovir disoproxil fumarate**
200/300 mg PO QD

AND



raltegravir
400 mg PO BID

oPEP – Kuhar DT, et al. *Infect Control Hosp Epidemiol.* 2013;34(9):875-92

FTC/TDF pill photo by Christopher Hurt; RAL/DTG pill photo from <https://www.aidsmap.com/about-hiv/av-factsheet/raltegravir>

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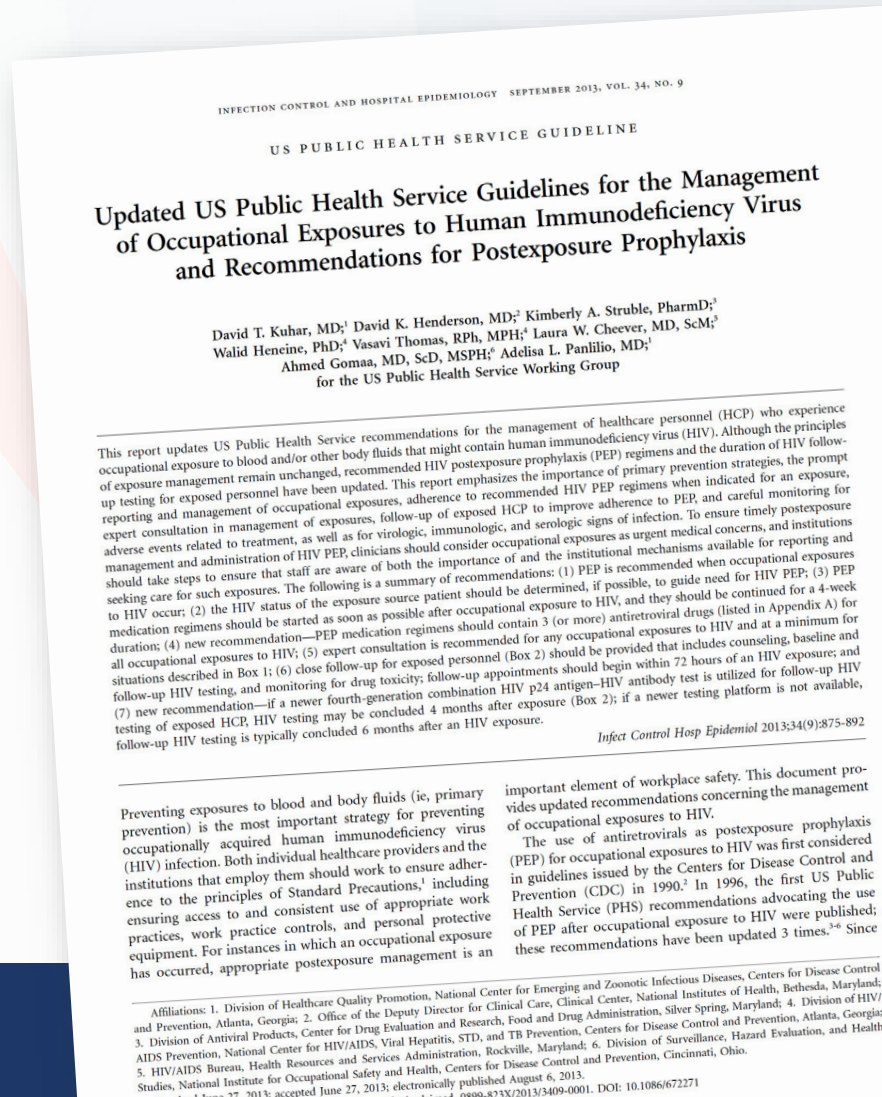
Alternative regimen



**cobicistat/
 elvitegravir/
 emtricitabine/
 tenofovir disoproxil fumarate**
 50/150/200/300 mg PO QD

Set precedent for use of a single-tablet regimen as PEP, in selected patients

oPEP – Kuhar DT, et al. *Infect Control Hosp Epidemiol.* 2013;34(9):875-92



Why not FTC/TDF + (RAL or DTG)?

Non-occupational PEP guidance updated in 2016

Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—
United States, 2016

from the
Centers for Disease Control and Prevention,
U.S. Department of Health and Human Services

Preferred regimen



**emtricitabine/
tenofovir disoproxil fumarate**
200/300 mg PO QD

WITH EITHER



raltegravir
400 mg PO BID



OR



dolutegravir
50 mg PO QD

nPEP – <https://stacks.cdc.gov/view/cdc/38856>

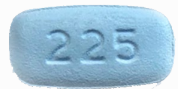
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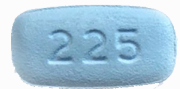
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2018



**bictegravir /
emtricitabine/
tenofovir alafenamide
fumarate**
50/200/25 mg PO QD

functionally interchangeable
with dolutegravir plus
emtricitabine / tenofovir DF

BIC/FTC/TAF is reasonable for PEP

UNC's providers aren't alone in using this

PREVENTION RESEARCH

Safety and Tolerability of Once Daily Coformulated Bictegravir, Emtricitabine, and Tenofovir Alafenamide for Postexposure Prophylaxis After Sexual Exposure

Kenneth H. Mayer, MD,^{a,b,c} Marcy Gelman, NP,^a Johnathon Holmes, NP,^a Jessica Kraft, NP,^a Kathleen Melbourne, PharmD,^d and Matthew J. Mimiaga, ScD, MPH^{a,e}

Background: Antiretroviral post-exposure prophylaxis (PEP) is recommended to prevent HIV infection after a high-risk exposure, but current regimens have presented challenges in tolerability, regimen completion, and potential drug-drug interactions. Because coformulated bictegravir, emtricitabine, and tenofovir alafenamide [BIC/FTC/tenofovir alafenamide (TAF)] is effective for HIV treatment, it was evaluated for use for PEP.

Setting: Boston community health center.

Methods: Individuals accessing PEP were enrolled in an open-label study of coformulated BIC/FTC/TAF, taken as one pill daily for 28 days. Pearson's χ^2 and Fisher's exact tests were used to assess whether BIC/FTC/TAF differed with respect to side effects and regimen completion rates compared with historical PEP regimens.

Results: Between August, 2018 and March, 2020, 52 individuals enrolled in the study. Most identified as cisgender gay (67.3%) or bisexual (11.5%) men, but 7.7% identified as cisgender heterosexual and 3.8% cisgender heterosexual women. The most common regimen side effects were nausea or vomiting (15.4%), fatigue (9.6%), and diarrhea/loose stools (7.7%), which were less common than historical controls using other PEP regimens, including those containing other integrase strand transfer inhibitors. Only 1 participant discontinued the regimen because of fatigue, and all other side effects were self-limited. Almost all participants (90.4%) completed the indicated regimen, which was a higher completion rate compared with earlier PEP regimens, and none became HIV-positive.

Conclusions: BIC/FTC/TAF coformulated as a single daily pill was found to be safe, well-tolerated, and highly acceptable when

used for PEP, and compared more favorably than historical PEP regimens used at an urban health center.

Key Words: post-exposure prophylaxis, PEP, HIV prevention, bictegravir, tenofovir alafenamide, emtricitabine

(*J Acquir Immune Defic Syndr* 2022;90:27-32)

INTRODUCTION

Although no human data are available from randomized controlled clinical trials that demonstrate the efficacy of anti-retroviral postexposure prophylaxis (PEP) in preventing HIV infection, it has become an accepted modality for individuals who sustained a recent potential exposure to HIV for close to 2 decades.¹ The empirical support for this approach has been based on numerous simian retroviral challenge studies²⁻⁴ and a on numerous human case control study of HIV-exposed health care workers, whose risk for seroconversion was decreased by more than 80% if they used postexposure azidothymidine.⁵ The demonstrated safety and efficacy of daily emtricitabine (FTC) and tenofovir-containing regimens for pre-exposure prophylaxis (PrEP) in approximately one million people has provided some additional corroborative support for the use of antiretroviral chemoprophylaxis.⁶

However, the incidence of PEP-associated adverse events related to the first approved regimens was over 60%, primarily because of the use of zidovudine and protease inhibitors.^{7,8} Although most of these adverse effects were not intolerable, experience from both occupational and nonoccupational settings found that close to 1/2 of individuals for whom PEP was recommended failed to complete their prescribed regimen.^{8,9} Drug-drug interactions with other medications created other complications.¹⁰ The demonstration of the excellent efficacy and tolerability of integrase strand transfer inhibitors as a part of a highly active antiretroviral therapy regimen has created new opportunities to create simpler and better tolerated PEP regimens. Prior studies found that raltegravir given twice a day in conjunction with once daily coformulated tenofovir disoproxil fumarate (TDF) and FTC was safe, and well-tolerated, but some participants did not complete the regimen as prescribed, often because of not adhering to the twice daily use of raltegravir.¹¹ A subsequent study of the single pill coformulation of A subsequent study of the single pill coformulation of A subsequent study of the single pill coformulation of



“...was found to be safe, well-tolerated, and highly acceptable when used for PEP, and compared more favorably than historical regimens...”

Mayer KH, et al. *J Acquir Immune Defic Syndr*. 2022 May 1;90(1):27-32

Received for publication October 26, 2021; accepted December 20, 2021. From the ^aThe Fenway Institute, Fenway Health, Boston, MA; ^bDepartment of Medicine, Beth Israel Deaconess Medical Center, Boston, MA; ^cHarvard Medical School, Boston, MA; ^dGilead Sciences, Foster City, CA; and ^eDepartment of Epidemiology, UCLA Fielding School of Public Health, Los Angeles, CA.

Presented as a poster at the Conference on Retroviruses and Opportunistic Infections, March 4-7, 2019; Seattle, WA.

Infections, March 4-7, 2019; Seattle, WA. Supported by an unrestricted research grant from Gilead Sciences and KHM has received an unrestricted research grant from Gilead Sciences and has served on their Scientific Advisory Board. The remaining authors have no conflicts of interest to disclose.

Correspondence: Kenneth H. Mayer, MD, The Fenway Institute, Fenway

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1. Politch JA, et al. AIDS. 2016 Jul 31;30(12):1899-903

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 - FwB had other partners (GC contact), so could have had acute HIV
 - Pre-ejaculatory fluid can contain HIV RNA (though it's uncommon) ¹
 - Mike had 2 doses of FTC/TDF in his system at time of sex on 10/8
 - Pharmacokinetic modeling from iPrEx suggested two doses per week reduced risk of transmission by approximately 76% ²

1. Politch JA, et al. AIDS. 2016 Jul 31;30(12):1899-903

2. Grant RM, et al. Lancet Infect Dis. 2014;14(9):820-9

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3. Petersen J, et al.. Fed Pract. 2021 May;38(5):232-237

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 - CDC: in a high-prevalence population*, one can expect 20 false positive Ag/Ab results out of 10,000 tests performed ⁴

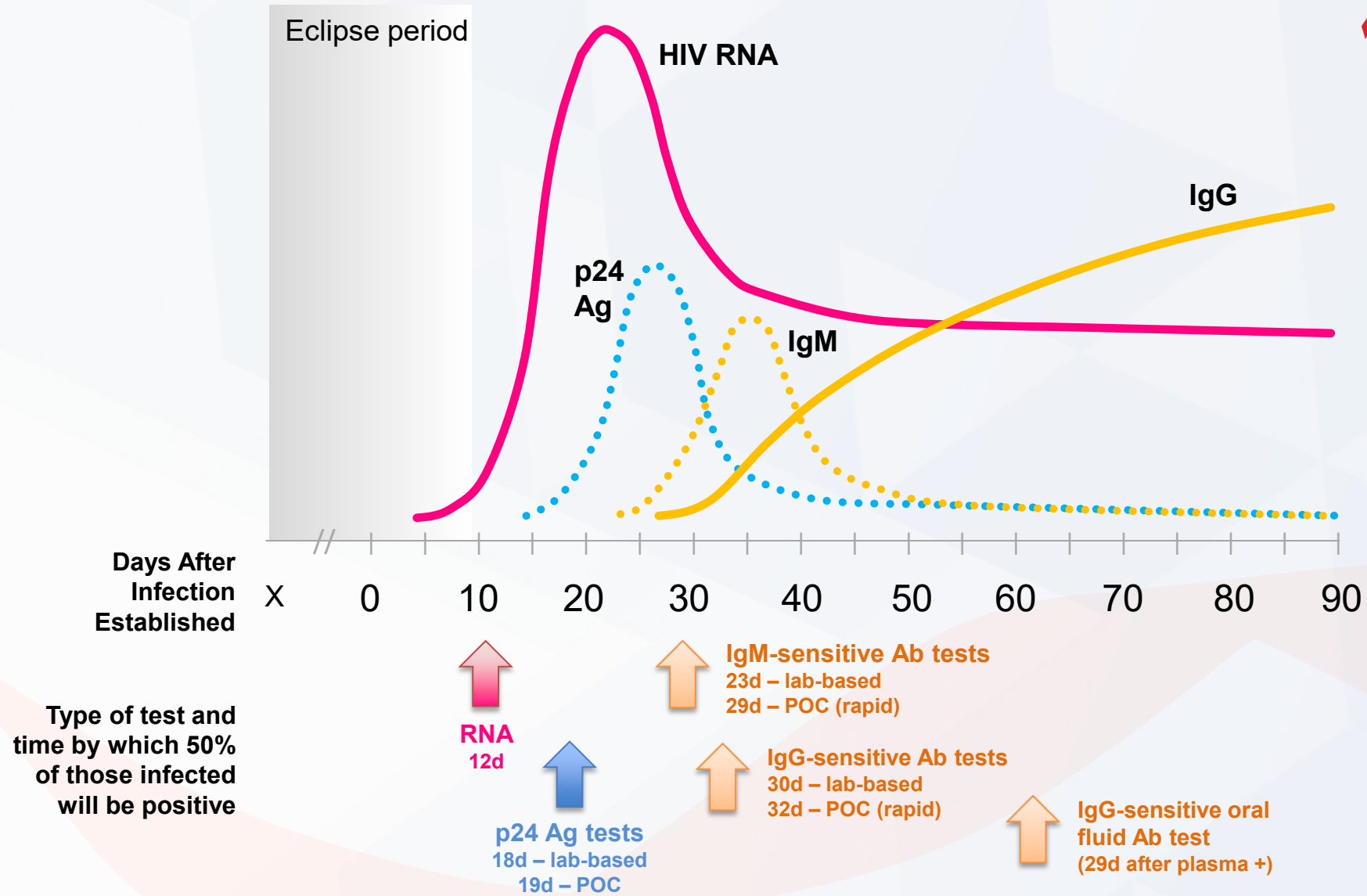
3. Petersen J, et al.. Fed Pract. 2021 May;38(5):232-237

4. <https://www.cdc.gov/hiv/pdf/testing/cdc-hiv-factsheet-false-positive-test-results.pdf>

* defined as 2% of population with HIV

How Dr. Hurt thought this through – cont'd (2)

- **Having ARVs in your blood delays HIV seroconversion**



Adapted from Branson BM, et al. Laboratory testing for the diagnosis of HIV infection: updated recommendations (2014) and updated with data from Delaney K, et al. Clin Infect Dis. 2017;64(1):53-9. PubMed PMID: 27737954.

Quantity of target depends on the specimen

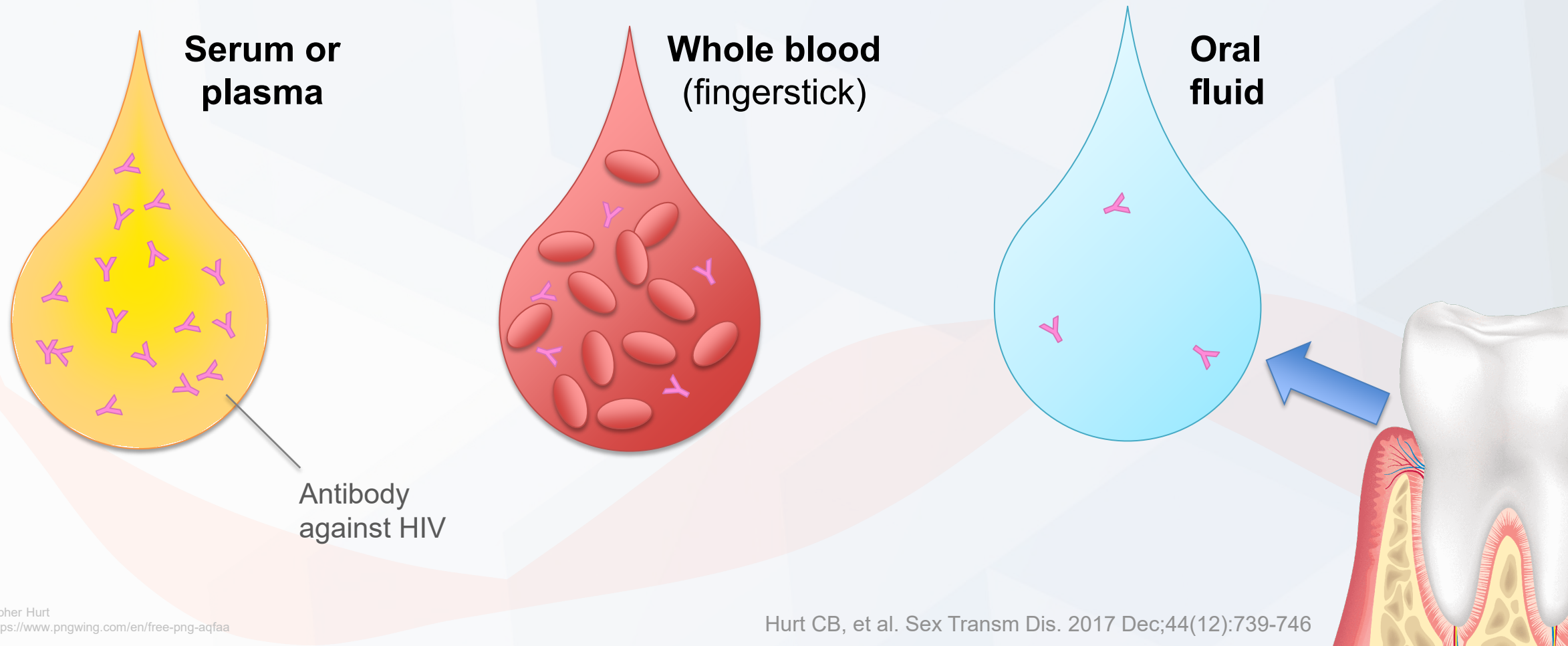


Illustration by Christopher Hurt
Tooth image from: <https://www.pngwing.com/en/free-png-aqfaa>

Hurt CB, et al. Sex Transm Dis. 2017 Dec;44(12):739-746

Window period depends on the test and time

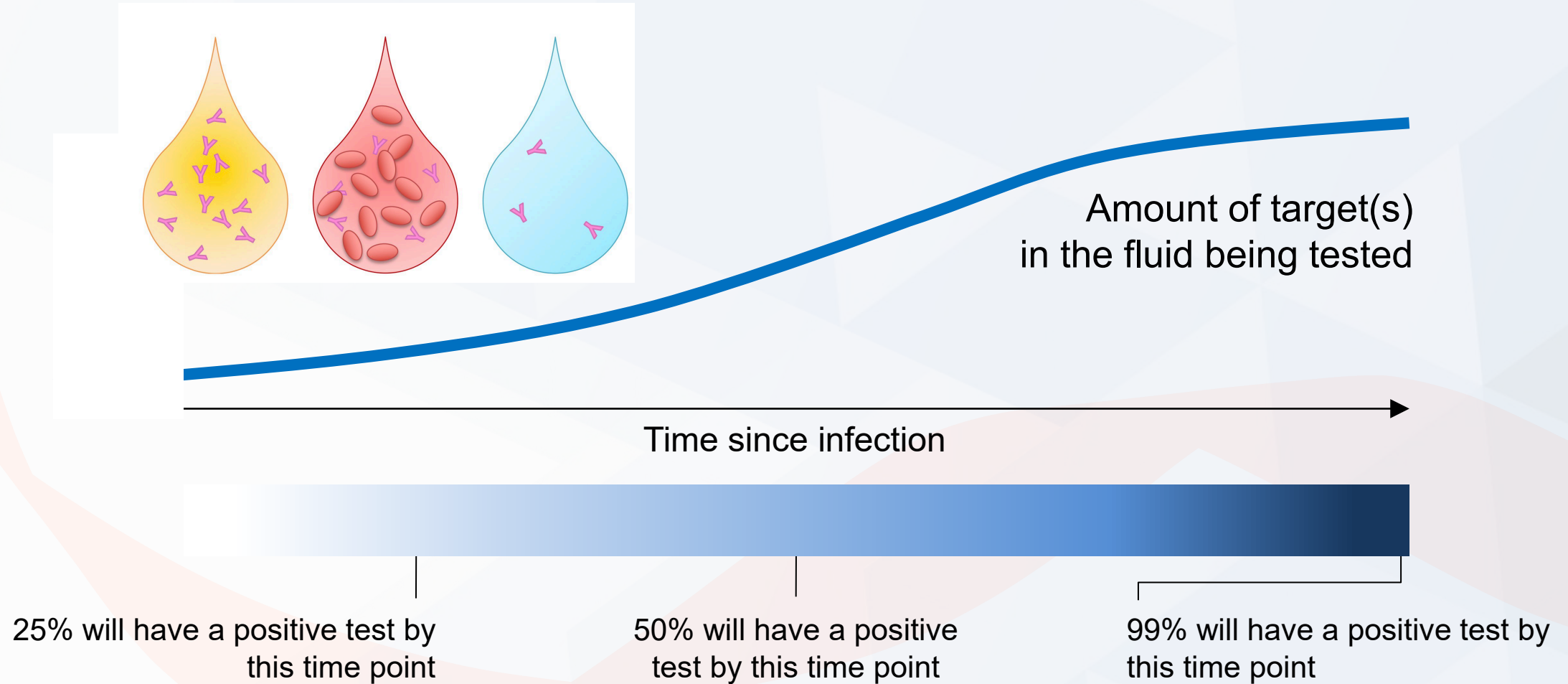


Illustration by Christopher Hurt

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 - HPTN 083 (CAB vs FTC/TDF): there were 39 infections among those randomized to FTC/TDF and 4 randomized to CAB-LA ⁷
 - 31-day delay in detection on FTC/TDF
 - 98-day delay in detection on CAB-LA

5. Donnell D, et al. AIDS. 2017;31(14):2007-16

6. Sivay MV, et al. JAIDS 2017;75(3):271-9

7. Marzinke MA, et al. J Infect Dis. 2021;224(9):1581-92

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RNA levels will be lower than expected, also – but because viral load detection involves nucleic acid amplification, early detection is still reliable.

Managing “ambiguous” test results

CDC outlined an approach in 2018



Open Forum Infectious Diseases

MAJOR ARTICLE



A Strategy for PrEP Clinicians to Manage Ambiguous HIV Test Results During Follow-up Visits

Dawn K. Smith¹, William M. Switzer, Philip Peters, Kevin P. Delaney, Timothy C. Granade, Silvina Masciotra, Luke Shouse, and John T. Brooks
 Division of HIV/AIDS Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia

Prompt determination of HIV infection status is critical during follow-up visits for patients taking pre-exposure prophylaxis (PrEP) medication. Those who are uninfected can then continue safely taking PrEP, and those few who have acquired HIV infection can initiate an effective treatment regimen. However, a few recent cases have been reported of ambiguous HIV test results using common testing algorithms in PrEP patients. We review published reports of such cases and testing options that can be used to clarify true HIV status in these situations. In addition, we review the benefits and risks of 3 antiretroviral management options in these patients: (1) continue PrEP while conducting additional HIV tests, (2) initiate antiretroviral therapy for presumptive HIV infection while conducting confirmatory tests, or (3) discontinue PrEP to reassess HIV status after a brief antiretroviral-free interval. A clinical consultation resource is also provided.

Keywords. PrEP; pre-exposure prophylaxis; HIV testing; seroconversion.

Utilization of daily oral antiretroviral pre-exposure prophylaxis (PrEP) in the United States to reduce HIV transmission has increased markedly over the past 5 years, with more than 120 000 persons estimated to have initiated PrEP from 2012 into early 2017 [1, 2]. With quarterly HIV screening of more than 100 000 patients, there will be some number of false-positive and false-negative test results occurring among them. Existing HIV testing recommendations and algorithms for PrEP patients [3] are intended to resolve inconclusive test results. However, the presence of antiretrovirals used as PrEP at the time of infection may alter the dynamics of viremia and a patient's immune response in ways that can affect how these algorithms perform. Recent cases of indeterminate or otherwise unclear (ambiguous) HIV test results, despite use of common testing algorithms, have been reported in persons who acquired HIV infection while adherent to daily doses of tenofovir disoproxil fumarate (TDF) coformulated with emtricitabine (FTC) taken as PrEP [4–7]. An additional 2 cases of unambiguous HIV test results in men who have sex with men who acquired HIV infection while adherent to daily PrEP [8] or TDF for treatment of hepatitis B infection [9] have been reported (Table 1). Accurate and quick resolution of ambiguous test results enables timely and proper clinical management to minimize potential harm, such as antiretroviral drug (ARV) resistance and psychological stress. We

suggest strategies to clarify ambiguous test results among persons taking PrEP, as well as options for antiretroviral management, until the patient's HIV status is confirmed.

POTENTIAL SCOPE OF THE PROBLEM

Frequency of HIV Infection Among Persons Taking PrEP

Acquiring HIV infection by persons taking PrEP is uncommon. In 32 international open-label demonstration projects, Mera et al. reported 67 infections during 27061 cumulative person-years of FTC/TDF exposure for a seroconversion rate of 0.95/100 person-years of use (95% CI, 0.74, 1.21) [10]. Marcus et al. reported no seroconversions during 5104 person-years of PrEP in an observational cohort in northern California [11]. Thus, the expected frequency of new infections when patients are taking PrEP as prescribed is expected to be low, but the absolute number of new infections may increase as PrEP is more widely used.

Frequency of False-Positive HIV Test Results Among Persons Taking PrEP

In the context of PrEP, the probability of someone who is not infected testing falsely positive is low; however, with more testing, the number of false-positive tests observed will increase. Rigorous licensing and manufacturing requirements help ensure that false-positive HIV test results are rare. For example, in the iPrEx PrEP trial, there were 8 reactive test results resolved as false-positive among 50 260 tests of 2499 study participants [12]. In the US PrEP Demonstration Project, there were 6 reactive rapid point of care (POC) HIV test results and 3 reactive antigen/antibody (Ag/Ab) laboratory tests resolved as false-positive among 2680 and 2673 tests, respectively [13]. In both studies, a negative HIV RNA test was used to resolve HIV status as uninfected.

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 Correspondence: D. K. Smith, MD, MS, MPH, Division of HIV/AIDS Prevention, NCHHSTP, Centers for Disease Control and Prevention, 1600 Clifton Road, MS E-45, Atlanta, GA 30329 (dsmith1@cdc.gov).

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Acquiring HIV infection by persons taking PrEP is uncommon. In 32 international open-label demonstration projects, Mera et al. reported 67 infections during ≥7061 cumulative person-years of FTC/TDF exposure for a seroconversion rate of 0.95/100 person-years of use (95% CI, 0.74, 1.21) [10]. Marcus et al. reported no seroconversions during 5104 person-years of PrEP in an observational cohort in northern California [11]. Thus, the expected frequency of new infections when patients are taking PrEP as prescribed is expected to be low, but the absolute number of new infections may increase as PrEP is more widely used.

Frequency of False-Positive HIV Test Results Among Persons Taking PrEP

In the context of PrEP, the probability of someone who is not infected testing falsely positive is low; however, with more testing, the number of false-positive tests observed will increase. Rigorous licensing and manufacturing requirements help ensure that false-positive HIV test results are rare. For example, in the iPrEx PrEP trial, there were 8 reactive test results resolved as false-positive among 50 260 tests of 2499 study participants [12]. In the US PrEP Demonstration Project, there were 6 reactive rapid point of care (POC) HIV test results and 3 reactive antigen/antibody (Ag/Ab) laboratory tests resolved as false-positive among 2680 and 2673 tests, respectively [13]. In both studies, a negative HIV RNA test was used to resolve HIV status as uninfected.

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Managing “ambiguous” test results

CDC outlined an approach in 2018



Open Forum Infectious Diseases

MAJOR ARTICLE



A Strategy for PrEP Clinicians to Manage Ambiguous HIV Test Results During Follow-up Visits

Dawn K. Smith¹, William M. Switzer, Philip Peters, Kevin P. Delaney, Timothy C. Granade, Silvana Masciotra, Luke Shouse, and John T. Brooks

Division of HIV/AIDS Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia

Prompt determination of HIV infection status is critical during follow-up visits for patients taking pre-exposure prophylaxis (PrEP) medication. Those who are uninfected can then continue safely taking PrEP, and those few who have acquired HIV infection can initiate an effective treatment regimen. However, a few recent cases have been reported of ambiguous HIV test results using common testing algorithms in PrEP patients. We review published reports of such cases and testing options that can be used to clarify true HIV status in these situations. In addition, we review the benefits and risks of 3 antiretroviral management options in these patients: (1) continue PrEP while conducting additional HIV tests, (2) initiate antiretroviral therapy for presumptive HIV infection while conducting confirmatory tests, or (3) discontinue PrEP to reassess HIV status after a brief antiretroviral-free interval. A clinical consultation resource is also provided.

Keywords. PrEP; pre-exposure prophylaxis; HIV testing; seroconversion.

Utilization of daily oral antiretroviral pre-exposure prophylaxis (PrEP) in the United States to reduce HIV transmission has increased markedly over the past 5 years, with more than 120 000 persons estimated to have initiated PrEP from 2012 into early 2017 [1, 2]. With quarterly HIV screening of more than 100 000 patients, there will be some number of false-positive and false-negative test results occurring among them. Existing HIV testing recommendations and algorithms for PrEP patients [3] are intended to resolve inconclusive test results. However, the presence of antiretrovirals used as PrEP at the time of infection may alter the dynamics of viremia and a patient's immune response in ways that can affect how these algorithms perform. Recent cases of indeterminate or otherwise unclear (ambiguous) HIV test results, despite use of common testing algorithms, have been reported in persons who acquired HIV infection while adherent to daily doses of tenofovir disoproxil fumarate (TDF) coformulated with emtricitabine (FTC) taken as PrEP [4–7]. An additional 2 cases of unambiguous HIV test results in men who have sex with men who acquired HIV infection while adherent to daily PrEP [8] or TDF for treatment of hepatitis B infection [9] have been reported (Table 1). Accurate and quick resolution of ambiguous test results enables timely and proper clinical management to minimize potential harm, such as antiretroviral drug (ARV) resistance and psychological stress. We

suggest strategies to clarify ambiguous test results among persons taking PrEP, as well as options for antiretroviral management, until the patient's HIV status is confirmed.

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1. Continue FTC/TDF as PrEP while additional HIV testing is performed
2. Add another agent while additional testing is conducted (i.e., convert to PEP)

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1. Continue FTC/TDF as PrEP while additional HIV testing is performed
2. Add another agent while additional testing is conducted (i.e., convert to PEP)
3. Discontinue PrEP and monitor with lab testing to confirm or refute infection

Smith DK, et al. Open Forum Infect Dis. 2018;5(8):ofy180

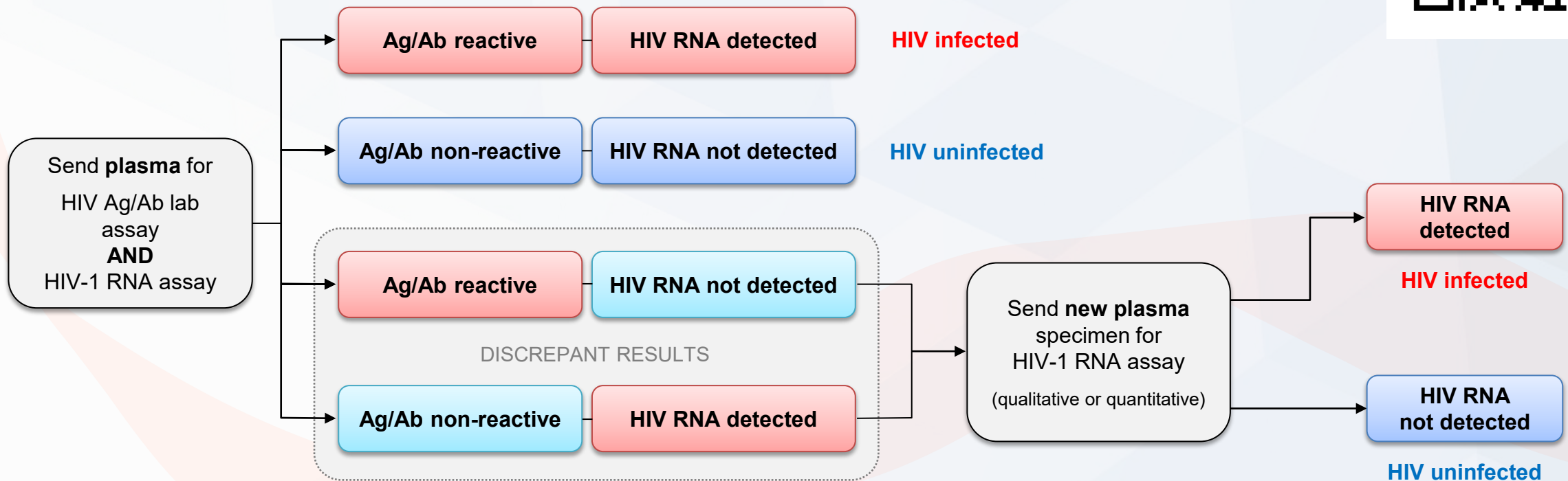
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HIV testing in 2021 PrEP guidelines



For patients who have taken any oral ARVs in prior 3m
OR received an injection of CAB-LA in prior 12m

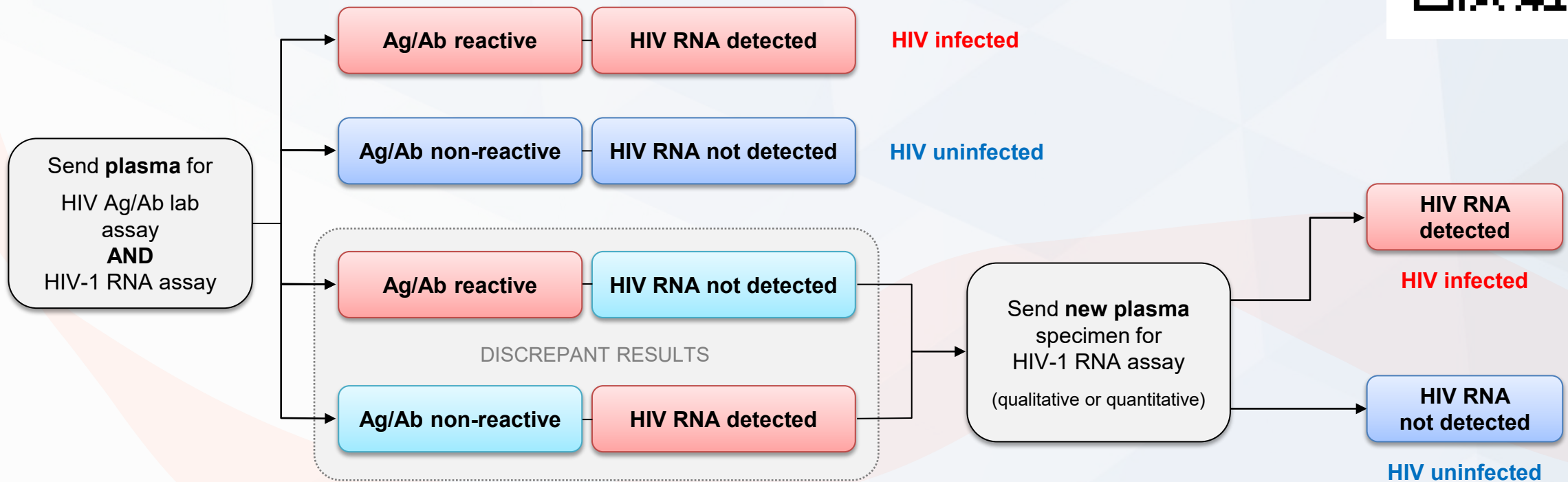


Adapted from Figure 4b from USPHS 2021 PrEP Guideline Update

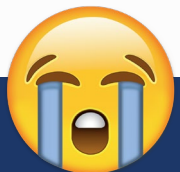
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For patients who have taken any oral ARVs in prior 3m
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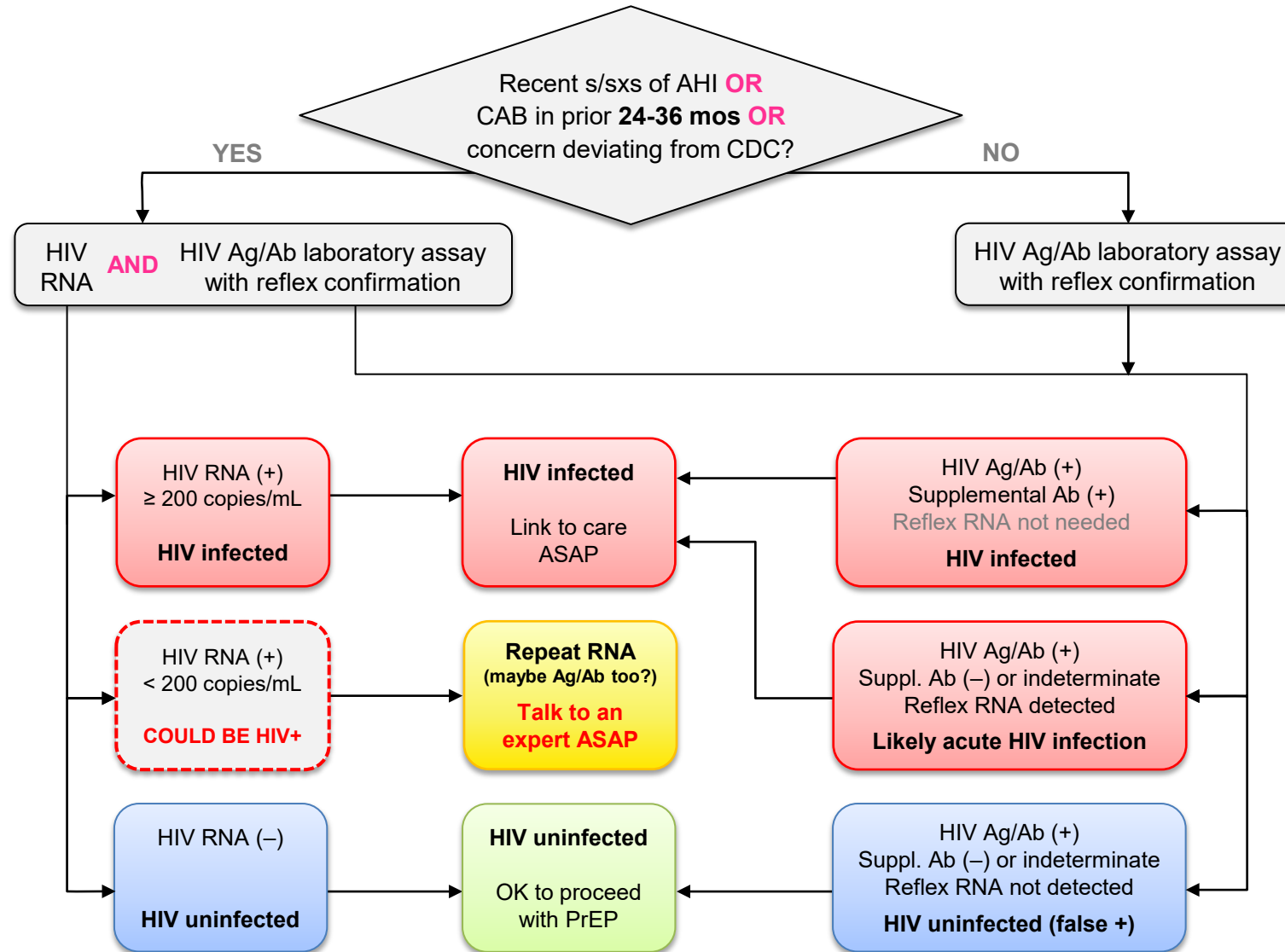


Adapted from Figure 4b from USPHS 2021 PrEP Guideline Update



← Dr. Hurt (and many colleagues) when the new guidelines came out

Suggested approach for HIV testing on PrEP



No useful role for rapid / point-of-care tests for on-PrEP monitoring

Polling Question #2

What's your current practice for patients on “maintenance” PrEP with oral FTC/TDF or oral FTC/TAF?

- A. HIV Ag/Ab every 3 months
- B. HIV Ag/Ab every 6-12 months
- C. HIV Ag/Ab and HIV RNA every 3 months
- D. HIV Ag/Ab and HIV RNA every 6-12 months
- E. HIV RNA every 3 months

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Case 1: “Mike” – false positive!

- Dr. Hurt coordinated with the UNC CFAR’s clinical lab to perform HIV DNA testing on a sample of Mike’s blood (not detected).

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Case 1: “Mike” – false positive!

- Dr. Hurt coordinated with the UNC CFAR’s clinical lab to perform HIV DNA testing on a sample of Mike’s blood (not detected).
- BIC/FTC/TAF was continued for 28 days and then stopped.
- HIV RNA testing was repeated every 8 weeks for 6 months.

Case 1: “Mike” – false positive!

- Dr. Hurt coordinated with the UNC CFAR’s clinical lab to perform HIV DNA testing on a sample of Mike’s blood (not detected).
- BIC/FTC/TAF was continued for 28 days and then stopped.
- HIV RNA testing was repeated every 8 weeks for 6 months.
- Mike restarted FTC/TDF as PrEP in mid-2019.
- Mike remains HIV-free as of most recent follow-up in June 2023.

Case 2: “Thomas” (June 2021)

- 18 years old, without any significant past medical history

Case 2: “Thomas” (June 2021)

- 18 years old, without any significant past medical history
- Came out to his mom, who’s a provider at UNC
- Mom contacted Dr. Hurt to get Thomas on PrEP

Case 2: “Thomas” (June 2021) – cont’d

- Honor Roll student heading off to college in the NE that fall

Case 2: “Thomas” (June 2021) – cont’d

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Case 2: “Thomas” (June 2021) – cont’d

- Honor Roll student heading off to college in the NE that fall
- Thomas takes no medications currently
- In the 6 months prior to visit, has had 2 cis male partners for oral sex and RAI (for which he “always” uses condoms)
- Free of any symptoms concerning for acute HIV infection
- Lab-based, automated HIV Ag/Ab was **non-reactive**
- HIV RNA was **not detected** (trust but verify...)
- *Visit was prior to FDA approval of cabotegravir for PrEP*

Polling Question #3: “Thomas”

What would you recommend for Thomas?

- A. Start taking a daily multivitamin to build an adherence habit and return in 1 month.
- B. Daily oral PrEP with FTC/TDF
- C. On-demand (“2-1-1”) PrEP with FTC/TDF
- D. Daily oral PrEP with FTC/TAF
- E. On-demand (“2-1-1”) PrEP with FTC/TAF


Polling Question #3: “Thomas”

What would you recommend for Thomas?

- A. Start taking a daily multivitamin to build an adherence habit and return in 1 month.
- B. Daily oral PrEP with FTC/TDF
- C. On-demand (“2-1-1”) PrEP with FTC/TDF
- D. Daily oral PrEP with FTC/TAF
- E. On-demand (“2-1-1”) PrEP with FTC/TAF


How Dr. Hurt discussed this with “Thomas”

Track Record



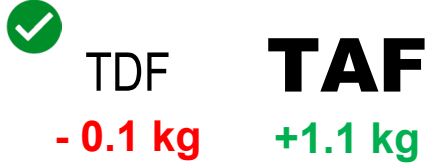
✓ TDF TAF

Pill size



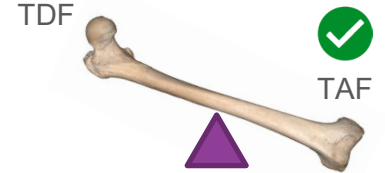
701 225 ✓

Weight change



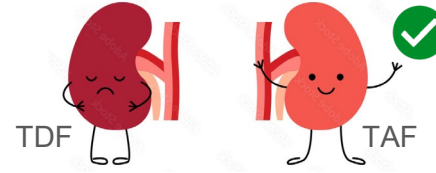
✓ TDF TAF
- 0.1 kg +1.1 kg

Bone health



TDF TAF ✓

Kidney health



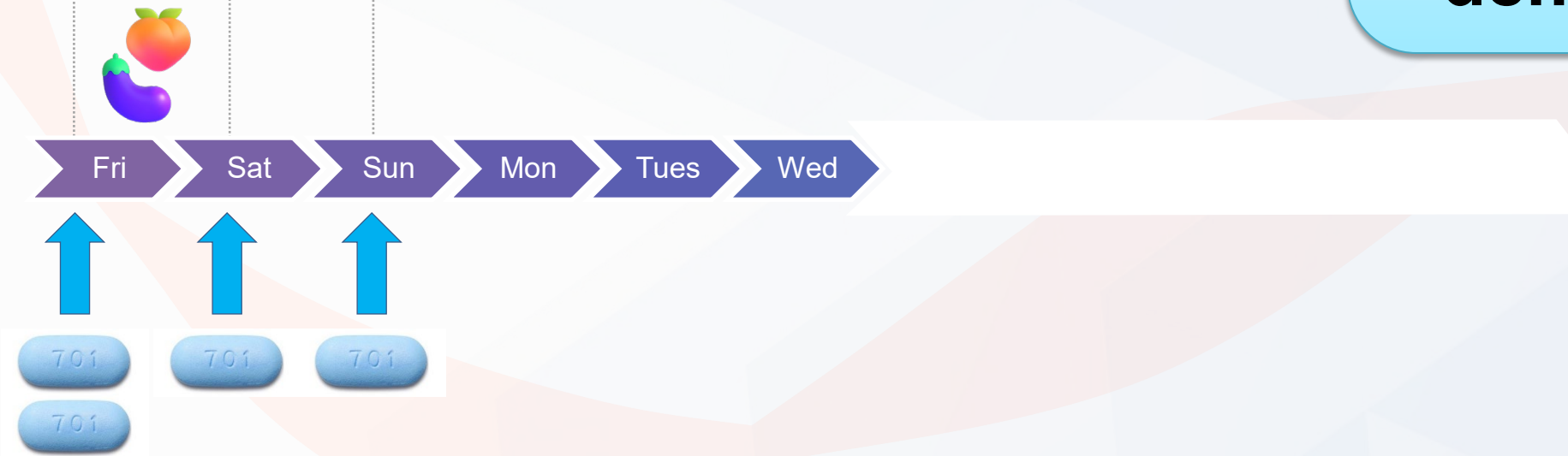
TDF TAF ✓

FOR WEIGHT CHANGE AND BMD CHANGE DATA, SEE SUPPLEMENTARY MATERIAL from → Mayer KH, et al. Lancet. 2020 Jul 25;396(10246):239-254. PMID: 32711800

“2-1-1” sounds easier than it actually is

- Two FTC/TDF tablets 2-24h before sex
 - One FTC/TDF tablet 24h after first two tablets
 - One FTC/TDF tablet 48h after first two tablets

**Only FTC/TDF
has been
studied for on-
demand use!**

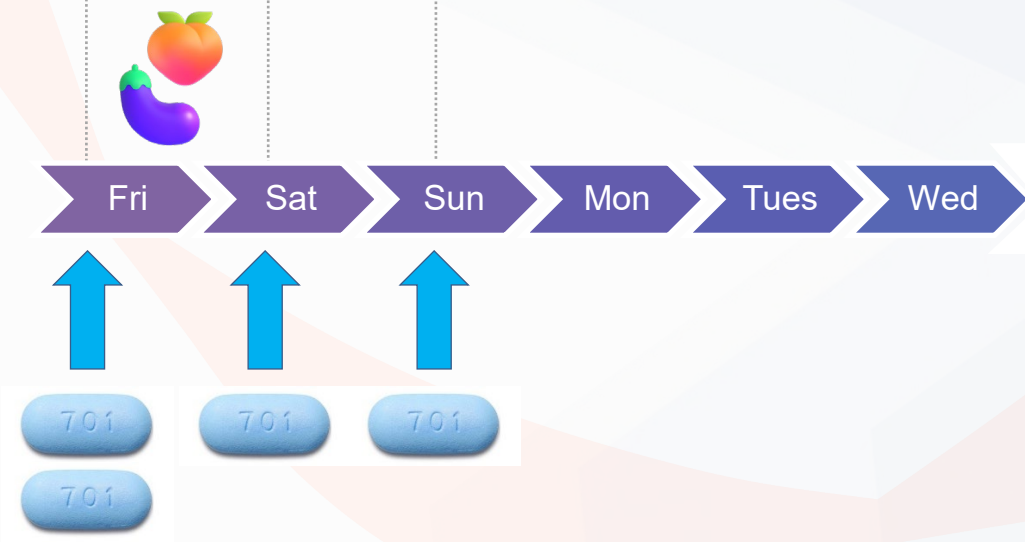


IPERGAY
Molina JM, et al. N Engl J Med. 2015;373:2237-2246.
Molina JM, et al. Lancet HIV. 2017;4:e402-e410.
Antoni G, et al. Lancet HIV. 2020 Feb;7(2):e113-e120

ANRS Prévenir
Molina JM, et al. CROI 2021. Abstract 148.
<http://www.croiwebcasts.org/p/2021croi/croi/148>
https://www.natap.org/2021/CROI/croi_55.htm

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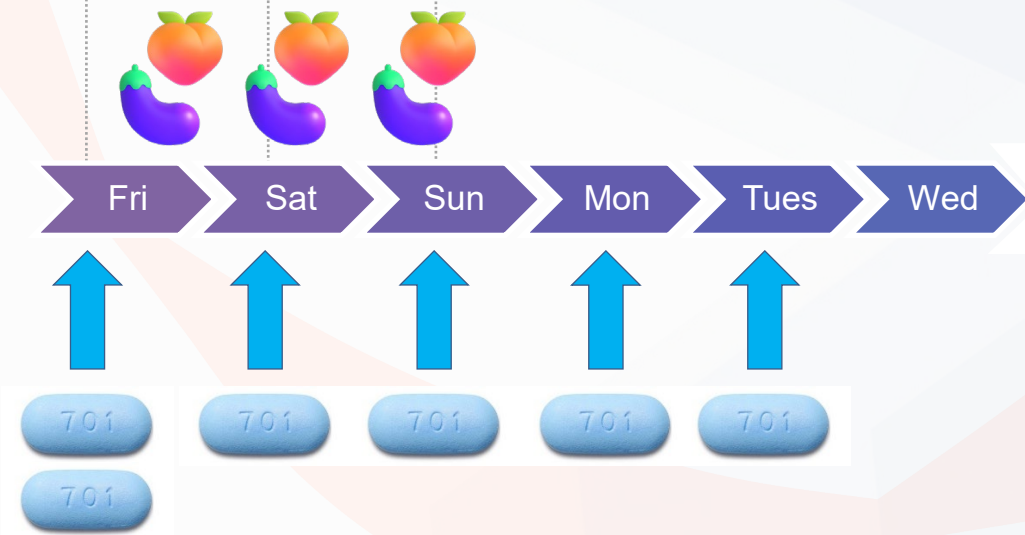
**Dosing continues until the
day after the day after
the last “sex day”**

Adapted from → Saberi, P., Scott, H.M. *J Gen Intern Med* 35, 1285–1288 (2020)

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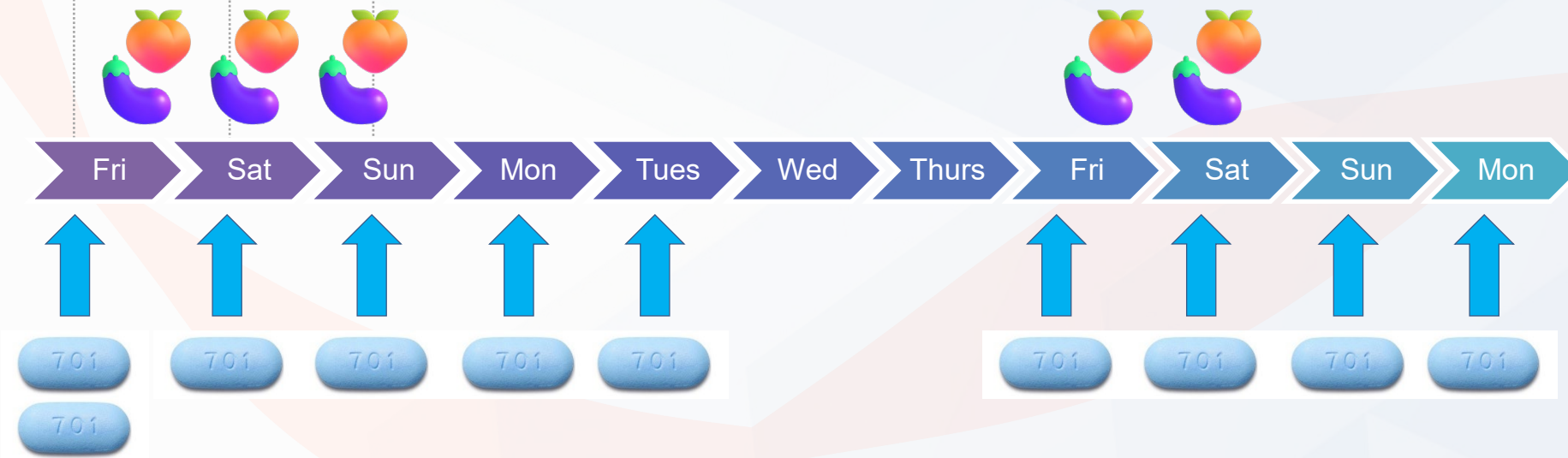


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If less than 7 days elapse between end of one dosing period and next sex, take ONE tablet to restart

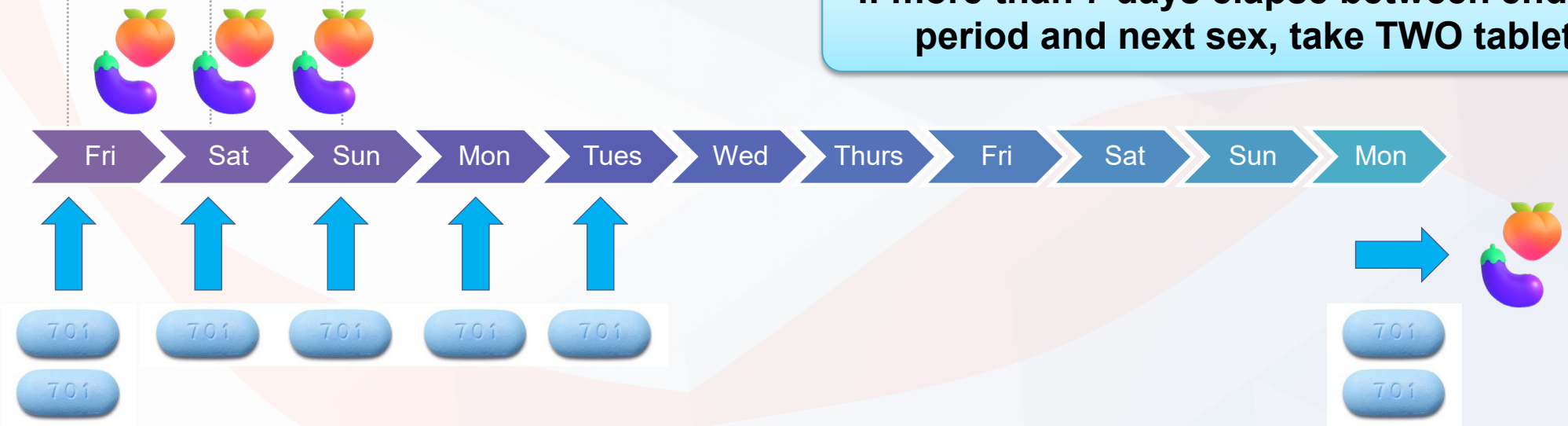
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- Two FTC/TDF tablets 2-24h before sex
 - One FTC/TDF tablet 24h after first two tablets
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If more than 7 days elapse between end of one dosing period and next sex, take TWO tablets to restart



Adapted from → Saberi, P., Scott, H.M. *J Gen Intern Med* 35, 1285–1288 (2020)

Polling Question #4

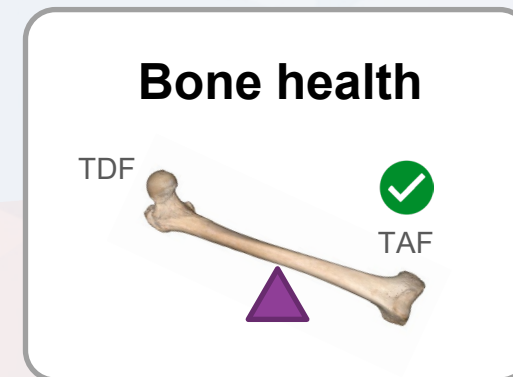
On average, by what age is peak bone mineral density achieved in an otherwise healthy person?

- A. 15-17
- B. 18-20
- C. 21-25
- D. 26-30

Polling Question #4

On average, by what age is peak bone mineral density achieved in an otherwise healthy person?

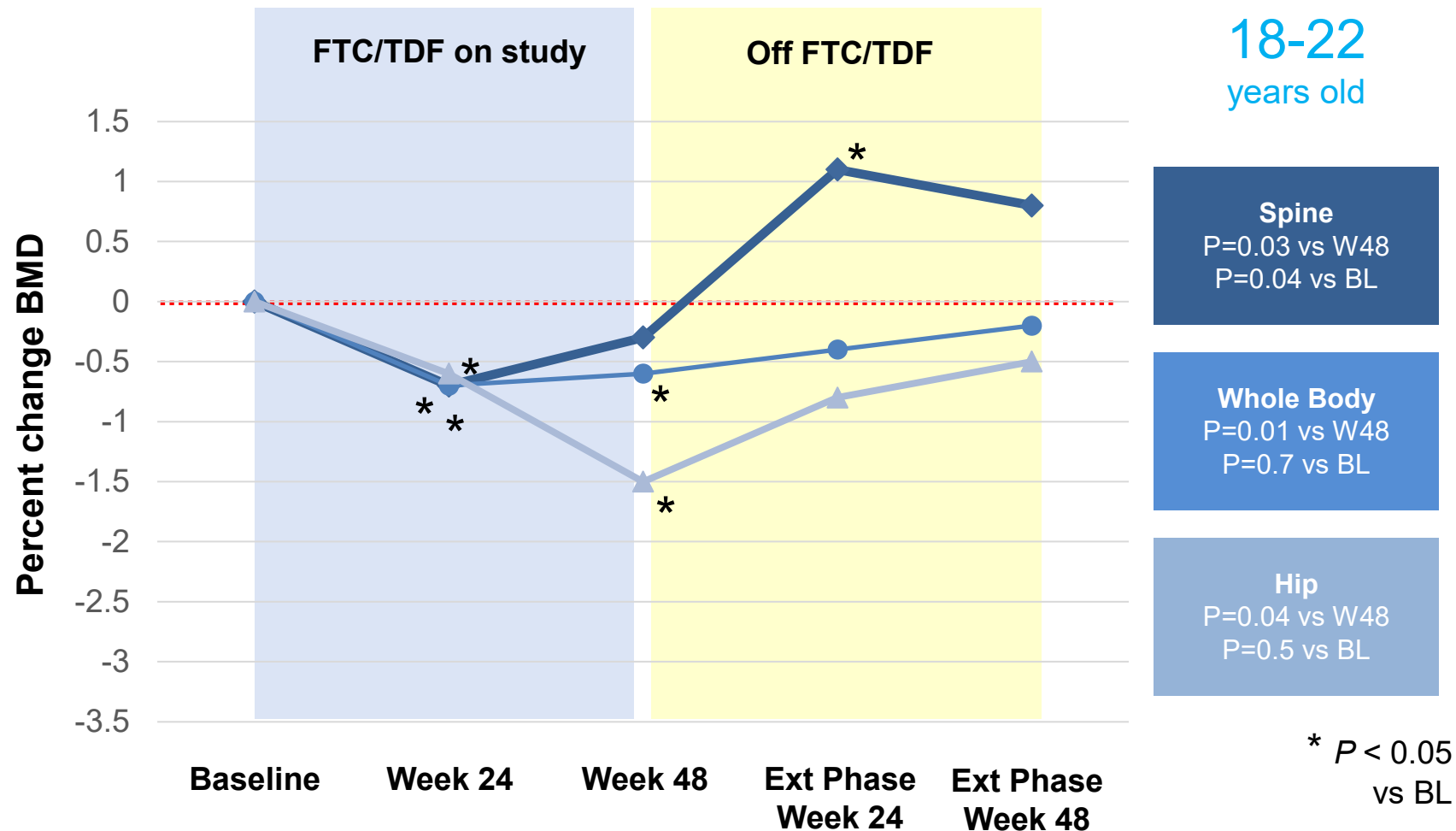
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- B. 18-20
- C. 21-25
- D. 26-30



Chevalley T, Rizzoli R. Best Pract Res Clin Endocrinol Metab. 2022 Mar;36(2):101616
Gordon RJ, Misra M, Mitchell DM. Endotext.org (via NLM) – <https://www.ncbi.nlm.nih.gov/books/NBK593436/>

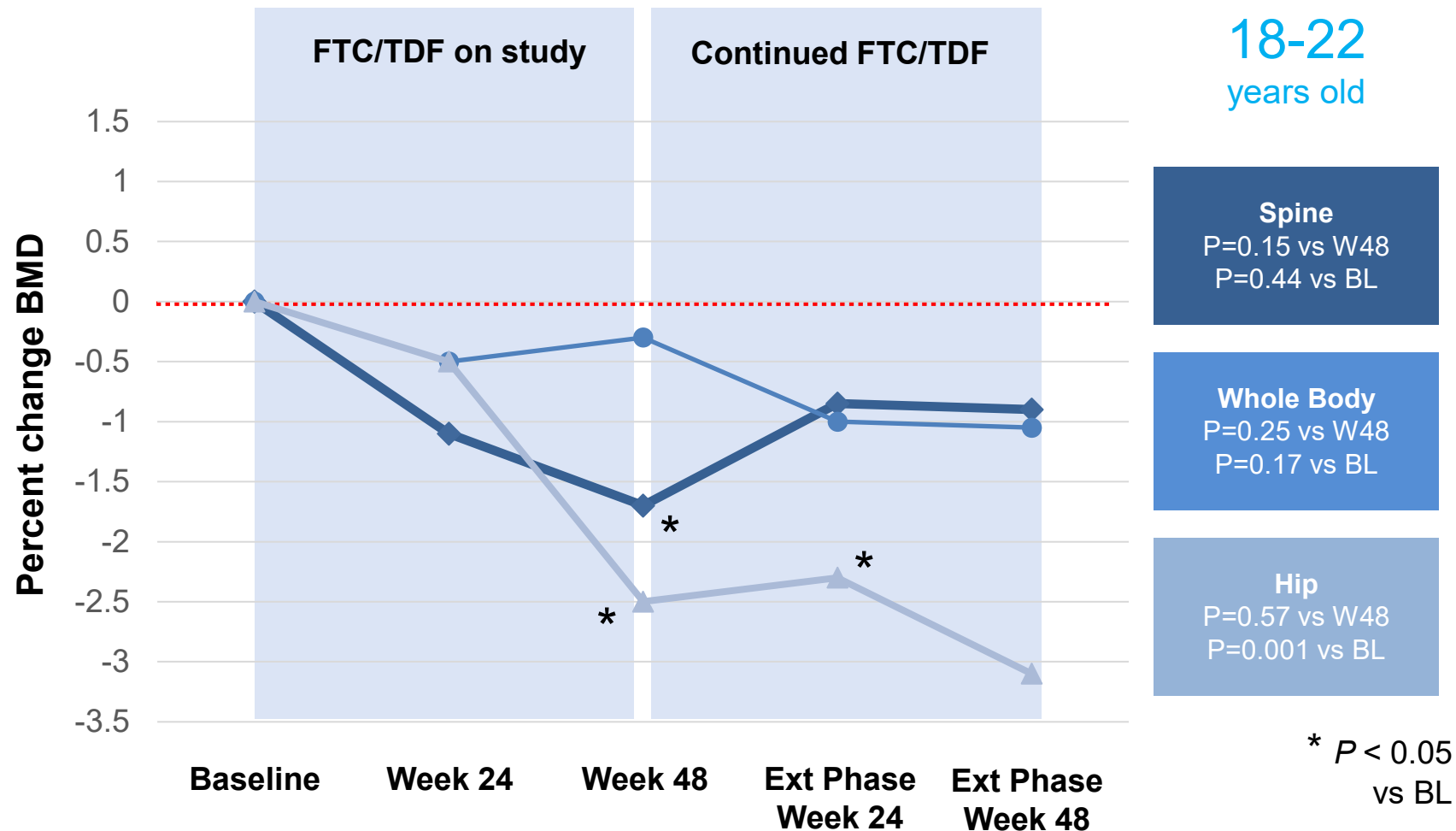
Adolescent & YA bone health on FTC/TDF

Project PrEPare (ATN 110), 72 who stopped FTC/TDF



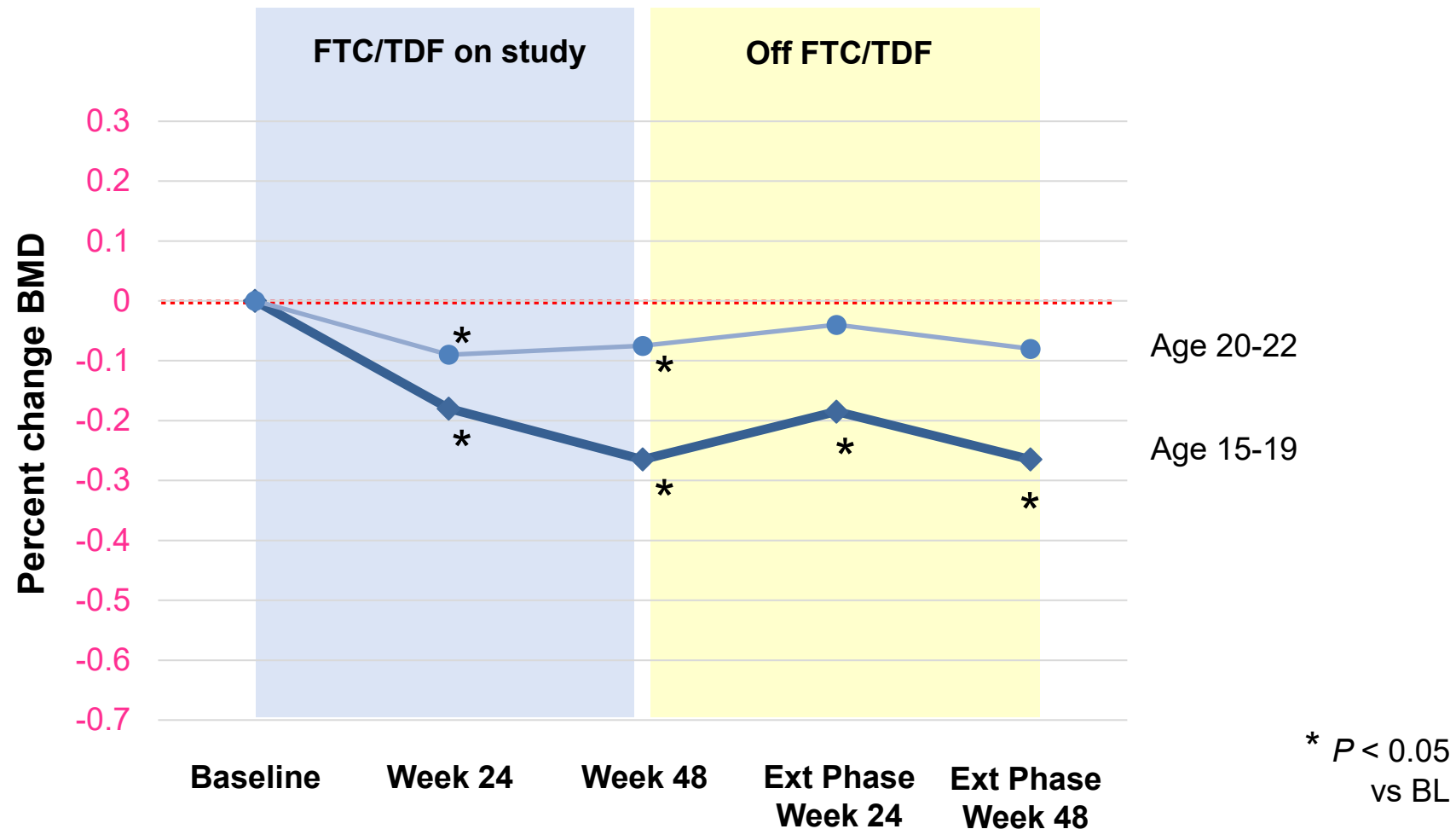
Adolescent & YA bone health on FTC/TDF

Project PrEPare (ATN 110), 15 who continued FTC/TDF



Adolescent & YA bone health on FTC/TDF

Projects PrEPare (ATN 110) and PrEPare 2 (ATN 113)



Is there an “antidote” for this?

Is there an “antidote” for this?



+
-



Vitamin D₃ (or D₂)
4,000 IU daily

Calcium (carbonate)
1,000 mg daily

ACTG 5280: 4000 IU D3 + 1000 mg CaCO₃ attenuated bone turnover by 50% among 165 PwH starting EFV/FTC/TDF – Overton ET, et al. Ann Intern Med. 2015 Jun 16;162(12):815-24
CCTG 595: adding 4000 IU D3 after 24 weeks of FTC/TDF PrEP reduced markers of turnover among YA MSM & TGW – Nanayakkara DD, et al. AIDS Res Hum Retroviruses. 2019 Jul;35(7):608-614

Case 2: “Thomas” – FTC/TDF FTW^(for the win)

- Thomas was not OK with potential weight gain on FTC/TAF.

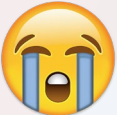
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- He felt like daily dosing would be easier to manage than on-demand and wasn't sure how sexually active he'd be at college.
- He was OK with taking vitamin D₃ but didn't want to take calcium.
- He transferred his PrEP care to campus and just finished his first year in college... *they grow up so fast!* 



<https://www.wikiart.org/en/keith-haring/stop-aids-1989>

Thank you!

Questions?

Christopher Hurt, MD, FIDSA
churt@med.unc.edu