Primed for PrEP:

HIV Prevention in Primary Care

Jeremy Snyder, MD, FAAP, AAHIVS

Family Medicine Clinic Resident School

Wednesday, 10 March 2021

Disclosures

- None

Objectives

- Identify groups most at risk of HIV acquisition and articulate strategies for HIV prevention
- List key differences between pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)
- Recognize historical and laboratory information needed for initiation and maintenance of PrEP
- Describe common barriers to PrEP implementation

Respond at **PollEv.com/projectecho442**

Text **PROJECTECHO442** to **22333** once to join, then **A, B, or C**

What PGY are you?

How confident are you at prescribing PrEP?

Very Confident

Confident

Ambivalent

Not Confident

Definitely Not Confident

How confident are you at prescribing PEP?

Very Confident

Confident

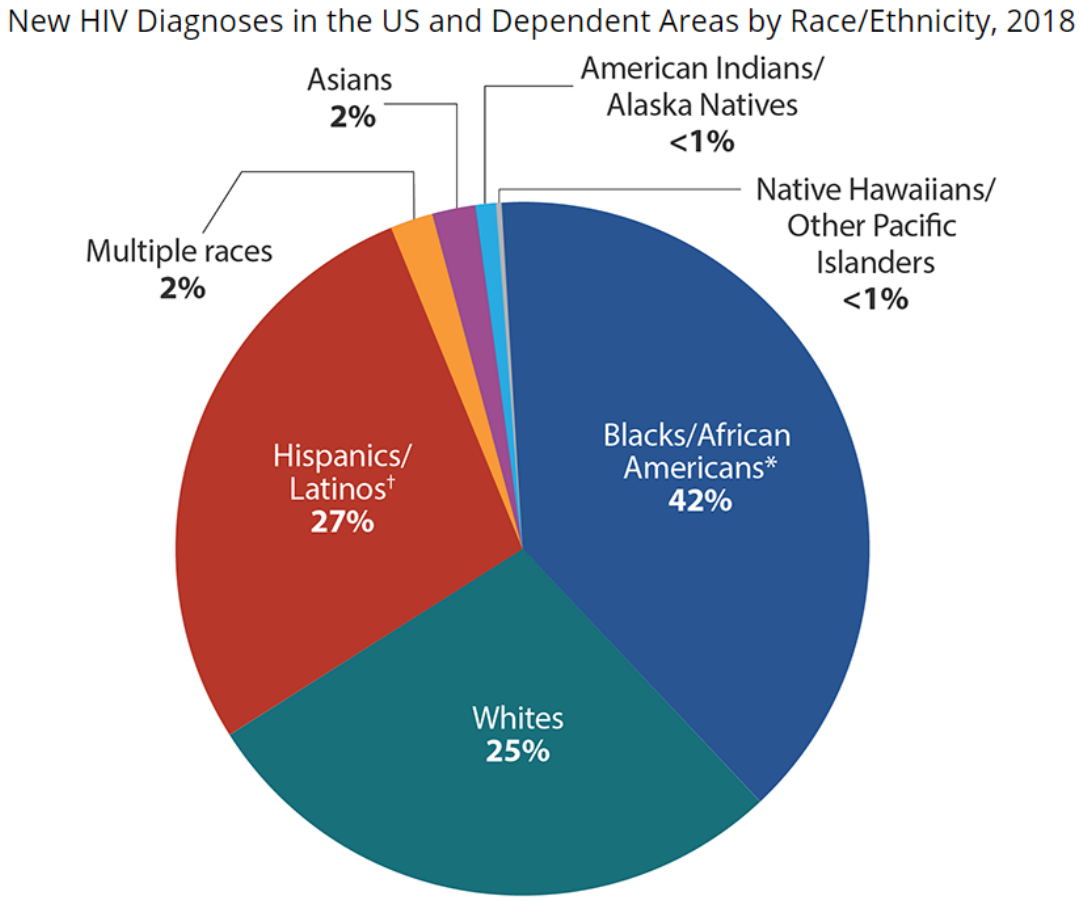
Ambivalent

Not Confident

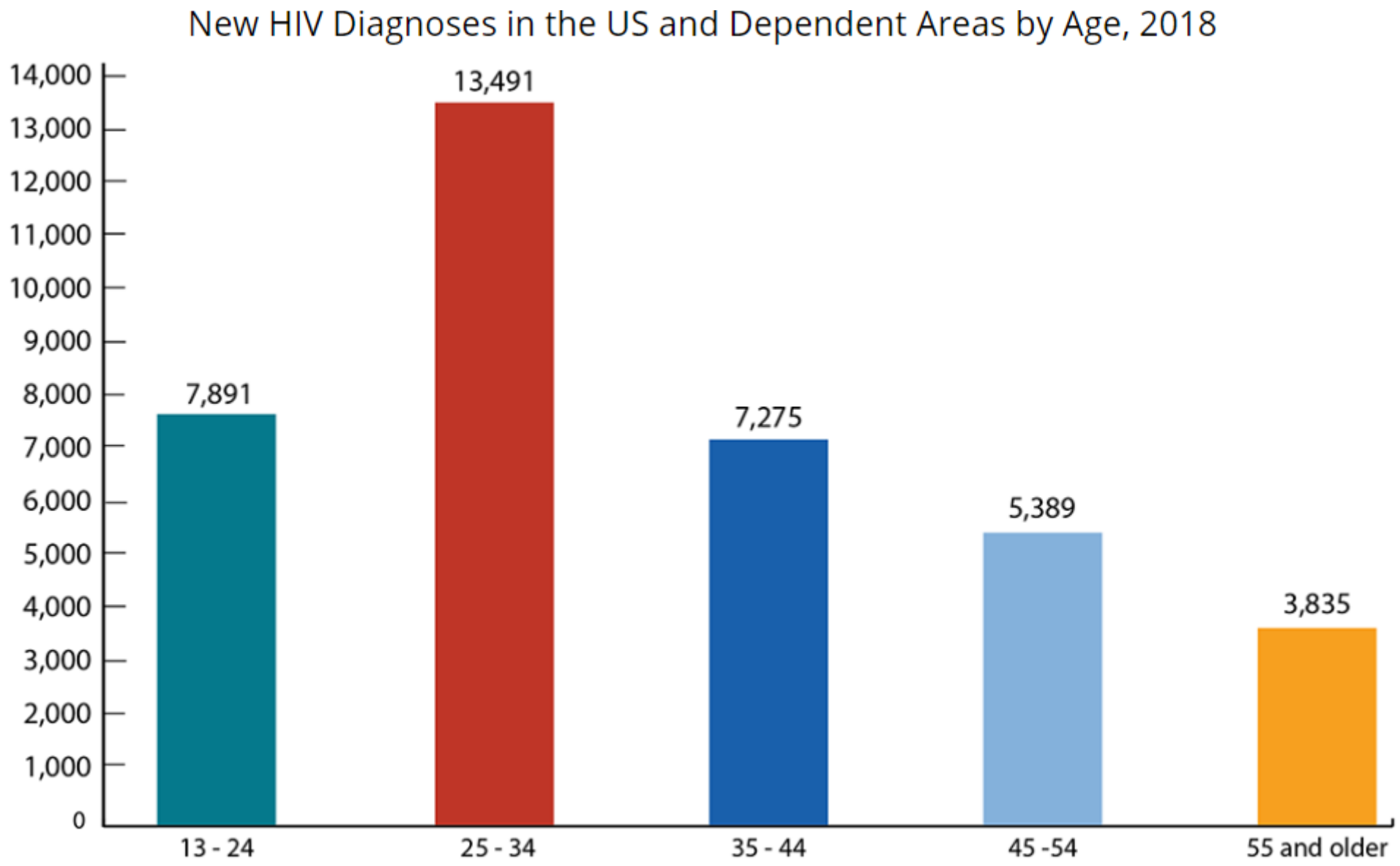
What's PEP?

We've already got HIV under control, right?

- Nearly two million new HIV infections yearly across the globe
- Nearly 1.2 million adolescents and adults in US living with HIV
- No effective vaccine to prevent transmission, and ART only provides suppression, not cure.
- In 2017, more than 38,000 people received an HIV diagnosis in the US



CDC. Diagnoses of HIV infection in the United States and dependent areas, 2018 (updated). *HIV Surveillance Report* 2020;31.



CDC. Diagnoses of HIV infection in the United States and dependent areas, 2018 (updated). *HIV Surveillance Report* 2020;31.

How can we reduce the risk of HIV acquisition?

- Increased testing, linkage to care
- Delayed or fewer partners
- Activities with less risk
- Increased condom use
- Empowerment, negotiation skills
- Reduce alcohol and drug use
- Reduce psychosocial barriers
- Circumcision
- STI Treatment
- HIV PEP and PrEP

**Thanks to M. Iandiorio for original slide.

PrEP versus PEP

- HIV PrEP
  - Pre-exposure prophylaxis
  - Daily regimen given **before** exposure to reduce risk of HIV acquisition
  - Start at least 7 days prior to exposure
  - Daily 2-drug regimen

- HIV PEP
  - Post-exposure prophylaxis
  - Given **AFTER** high-risk exposure to reduce risk of HIV infection
  - Start with 72 hours of exposure
  - 28-day course of daily 3-drug regimen

**Thanks to M. Iandiorio for original slide.

iPrex Study

- NEJM 2010.
  - 2499 HIV-seronegative men or transgender women who have sex with men
  - Randomized to emtricitabine and tenofovir disoproxil fumarate (FTC-TDF) or placebo
  - 100 became infected during follow-up (36 in FTC-TDF group, 64 in the placebo group)
    - 44% reduction in incidence of HIV
  - In group receiving FTC-TDF:
    - Drug detected in 22 of 43 of seronegative subjects (51%)
    - Drug detected in only 3 of 34 HIV-infected subjects

What about other groups at risk?

- Bangkok Tenofovir Study (Lancet 2013)
  - Double-blind, placebo-controlled trial enrolling volunteers who inject drugs from 17 drug-treatment programs in Bangkok, Thailand
  - 2413 participants randomized to tenofovir or placebo
    - 48.9% reduction in HIV incidence (95% CI 9·6–72·2; p=0·01); when adjusted for detectable levels of TDF, risk reduction closer to 70%
- Partners PrEP (NEJM 2012)
  - Randomized, placebo-controlled, three group trial following heterosexual, serodiscordant couples
  - 4747 couples assigned to TDF, TDF/FTC, or placebo and followed for 36 months
    - Detectable tenofovir associated with relative risk reduction 86% in TDF and 90% in TDF/FTC groups
- Partners PrEP, continued (Lancet Infectious Diseases 2014)
  - Randomized, double-blind, placebo-controlled three-group phase 3 trial for individuals in serodiscordant heterosexual relationships
    - Placebo arm terminated early and patients re-randomized to TDF or TDF/FTC
    - Detection of TDF in plasma samples associated with 85% relative risk reduction in TDF group and 93% for TDF/FTC group

Back-to-Back Results

TABLE. Results from randomized, placebo-controlled, clinical trials of the efficacy of daily oral antiretroviral preexposure prophylaxis (PrEP) for preventing human immunodeficiency virus (HIV) infection

Clinical trial	Participants	Type of medication	mITT efficacy*		Adherence-adjusted efficacy based on TDF detection in blood	
			%	(95% CI)	%	(95% CI)
Bangkok Tenofovir Study	Injecting drug users	TDF	49	(10–72)	70	(2–91)
Partners PrEP	HIV discordant couples	TDF	67	(44–81)	86	(67–94)
		TDF/FTC	75	(55–87)	90	(58–98)
TDF2	Heterosexually active men and women	TDF/FTC	62	(22–83)	84	NS
iPrEx	Men who have sex with men	TDF/FTC	42	(18–60)	92	(40–99)
Fem-PrEP	Heterosexually active women	TDF/FTC	NS	—	NA	—
VOICE	Heterosexually active women	TDF	NS	—	NA	—
		TDF/FTC	NS	—	NA	—

Abbreviations: mITT = modified intent to treat analysis, excluding persons determined to have had HIV infection at enrollment; CI = confidence interval; TDF = tenofovir disoproxil fumarate; FTC = emtricitabine; NS = not statistically significant; NA = data not available.

* % reduction in acquisition of HIV infection.

CDC. Update to interim guidance for preexposure prophylaxis (PrEP) for prevention of HIV infection: PrEP for injecting drug users. MMWR. June 14, 2013. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6223a2.htm?s_cid=mm6223a2_w. Accessed Aug 30, 2018.

Recommended Indications for PrEP

Men who have sex with men

- Adult or adolescent male weighing at least 35kg (77lbs)
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see next box)
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

- Any anal sex without condoms (receptive or insertive) in past 6 months
- A bacterial STI (syphilis, gonorrhea, or chlamydia) diagnosed or reported in past 6 months

Heterosexual women and men

- Adult or adolescent person weighing at least 35kg (77lbs)
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men (behaviorally bisexual) [also evaluate indications for PrEP use by previous box criteria]
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (PWID or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

People who inject drugs

- Adult or adolescent person weighing at least 35kg (77lbs)
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following

- Any sharing of injection or drug preparation equipment in past 6 months
- Risk of sexual acquisition (also evaluate by criteria in previous boxes)

https://www.cdc.gov/stophivtogether/library/prescribe-hiv-prevention/brochures/cdc-lsht-php-brochure-prep-faq.pdf

Population	Effectiveness Estimate	Source	Interpretation
Men who have sex with men	92%	Grant[6], 2010	**When taking PrEP,** with adherence indicated by laboratory-detected presence of drug, the risk of acquiring HIV is reduced by 92% for HIV-negative MSM. Missed doses result in lower effectiveness. Very high levels of adherence may increase effectiveness.
Heterosexual men and women	90%	Baeten[7], 2012	**When taking PrEP,** with adherence indicated by laboratory-detected presence of drug, the risk of acquiring HIV is reduced by 90% for HIV-negative heterosexual men or women. Missed doses result in lower effectiveness. Very high levels of adherence may increase effectiveness.
Persons who inject drugs (PWIDs)	70%	Choopanya[8], 2013	**When taking PrEP,** with adherence indicated by laboratory-detected presence of drug, the risk of acquiring HIV is reduced by 70% for HIV-negative PWIDs. Missed doses result in lower effectiveness. Very high levels of adherence may increase effectiveness.

https://www.cdc.gov/stophivtogether/library/prescribe-hiv-prevention/brochures/cdc-lsht-php-brochure-prep-faq.pdf

To whom should I offer PrEP?

PrEP is for people without HIV who are at risk of acquisition from sex or injection drug use. People at risk who should be assessed for PrEP include:

- Sexually active gay and bisexual men without HIV
- Sexually active heterosexual men and women without HIV
- Sexually active transgender persons without HIV
- Persons without HIV who inject drugs
- Persons who have been prescribed non-occupational post-exposure prophylaxis (PEP) and report continued risk behavior, or who have used multiple courses of PEP

https://www.cdc.gov/hiv/clinicians/prevention/prep.html

So you want to start on PrEP…

- What are key historical questions to ask?
- What labs do you order?
- Which medication do you choose?

Assessment: Initiation

- Medical History
  - Kidney disease
  - Osteoporosis / Osteopenia
  - STI history
  - Contraception / Pregnancy intent
- Allergies
- Medications
  - Drug-drug interactions
- Social History
  - History of drug use, route of use
  - Number of partners, types of sexual acts
- Vaccinations History
  - Particularly Hepatitis A and B
- Labs
  - HIV testing (Antigen/Antibody screen preferred)
  - Renal function
  - Hepatitis serologies
  - Syphilis Screening/Monitoring
  - GC/CT screening at **all** active sites
  - Pregnancy evaluation
- Psychosocial
  - Willingness/ability to adhere to treatment

IC Hx: None | GI: Male | Preferred Language:English

Diagnoses & Problems

Diagnosis (Problem) being Addressed this Visit

Add | Convert | Display: All

IMO

	Annotated Display	Code	Clinical Dx	Condition Name
	HIV exposure	Z20.6	Contact with and (suspec...	HIV exposure

Problems

Add | Convert | No Chronic Problems

Display: All

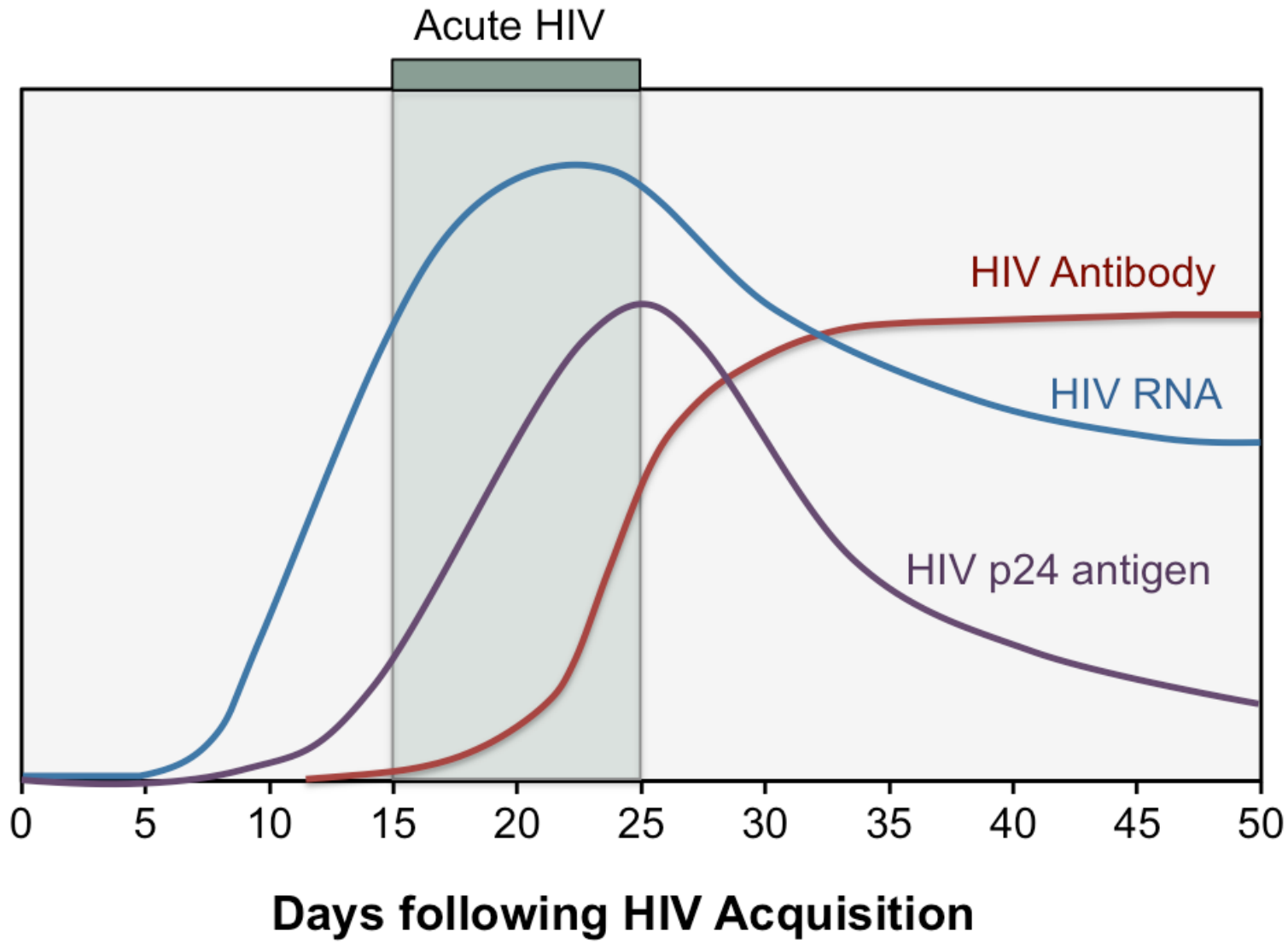
IMO

Annotated Display	Name of Problem	Code	Condition Name

Search: HIV | Contains | Advanced Options | Type: Prescriptions & Orders

Folder: | Search within: All

- NF AccessPak for HIV PEP Expanded with Kaletra oral kit
- NF AccessPak for HIV PEP Expanded with Viracept oral kit
- Adult HIV Inpatient Initiation of care labs
- Adult HIV Perinatal Prophylaxis
- Adult ICU Shivering
- Pref1 Claritin Hives Relief 10 mg oral tablet
- HIV-1 Integrase Inhibitor Resistance (SO)
- HIV-1 Qualitative, NAAT (SO)
- HIV 1/HCV/HBV NAT (Ultrio) (SO)
- HIV Drug Resistance Mutation
- HIV Gart
- HIV Pheno (SO)
- HIV Phenosense (SO)
- HIV Screen
- HIV Trofile Co-Receptor Tropism (SO)
- HIV Viral Load RT PCR
- HIV West Blot (SO)
- HIV1 NGS DNA Sequencing (SO)
- HIVARC (SO)
- HIVGen
- HIVINT (SO)
- HIVNAT (SO)
- HIVPHN (SO)
- HIVRNA (HIVTAQ)
- HIVRUS (HIVTAQ)
- HIVScr
- HIVTAQ
- HIVTro (SO)
- HIVWB (SO)
- Neonatal HIV Perinatal Prophylaxis
- Ref Link for Nurse - Shivering
- US HIV RNA (HIVTAQ)
- Western Blot (HIV Confirm) (SO)
- Pref1 ZyrTEC Hives 1 mg/mL oral syrup



HIV National Curriculum: https://www.hiv.uw.edu/custom/screening-diagnosis/3/2

Assessment: Maintenance

- Follow up visits at least every 3 months
- Repeat labs at follow up
  - HIV screen (Ag/Ab preferred)
  - Bacterial STI testing (GC/CT swabs at all active sites, syphilis screening/monitoring)
  - Renal function at first three months, then every six months thereafter
  - Hepatitis C antibody yearly (more frequently if MSM or otherwise high risk)
  - Pregnancy test (and assessment of pregnancy intent)

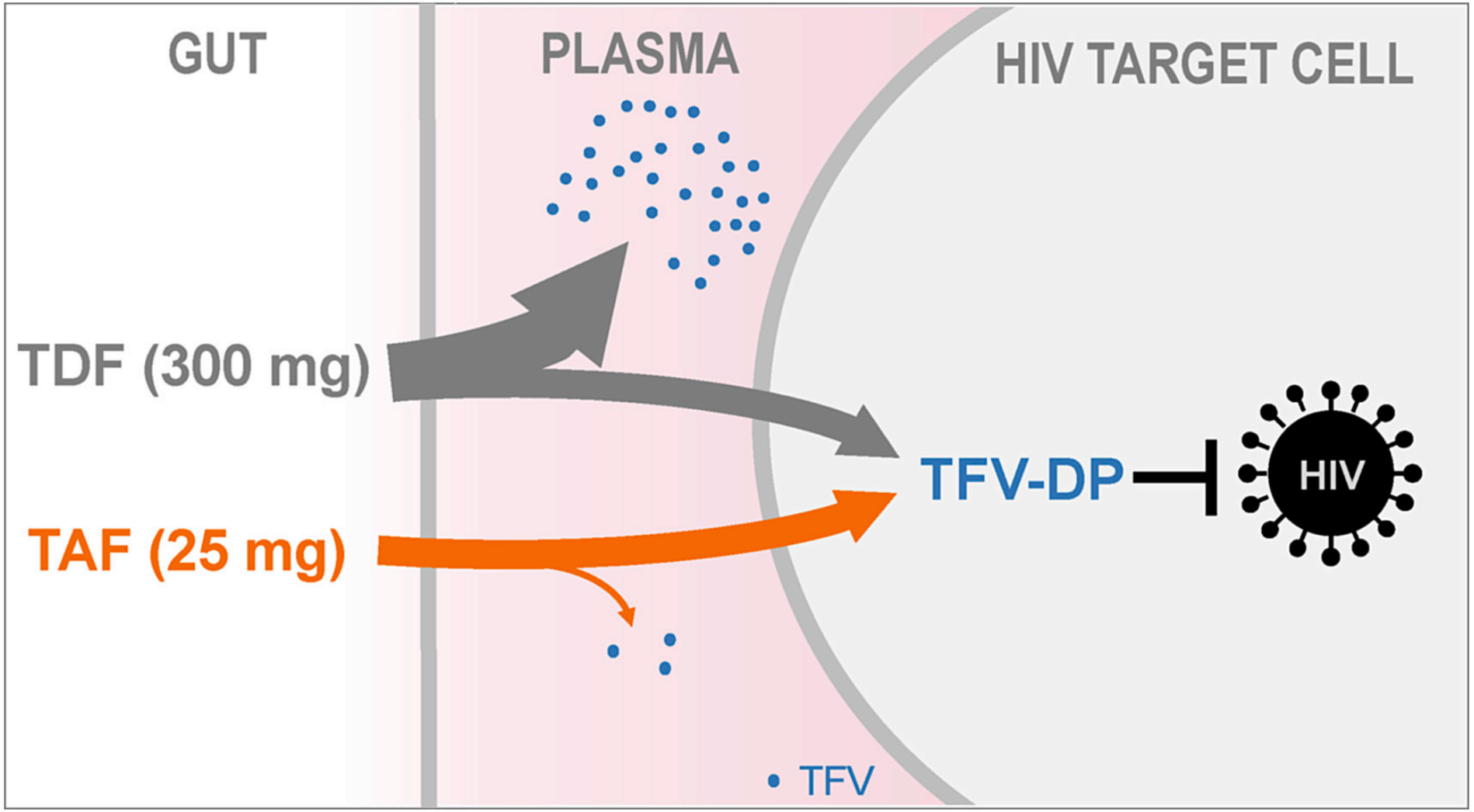
Medications

TDF/FTC (Truvada®)

- Approved for HIV treatment in 8/2004
- Approved for HIV prevention in 7/2012
  - MSM, transwomen, heterosexuals, PWID
- Approved for CrCl ≥60 ml/min
- Side effects
  - Decreased bone mineral density
  - Decreased GFR

TAF/FTC (Descovy®)

- Approved for HIV treatment in 4/2016
- Approved for HIV prevention in 10/2019
  - MSM and transwomen ONLY
- Approved for CrCl ≥ 30 ml/min
- Side effects
  - Weight gain
  - Increase in LDL cholesterol



Ray et al., Antiviral Research 2016.

Which medication should I prescribe for PrEP?

TDF/FTC (Truvada)

EFFECTIVENESS
- ✓ for multiple populations

SAFETY
- Small ↓ in eGFR and BMD

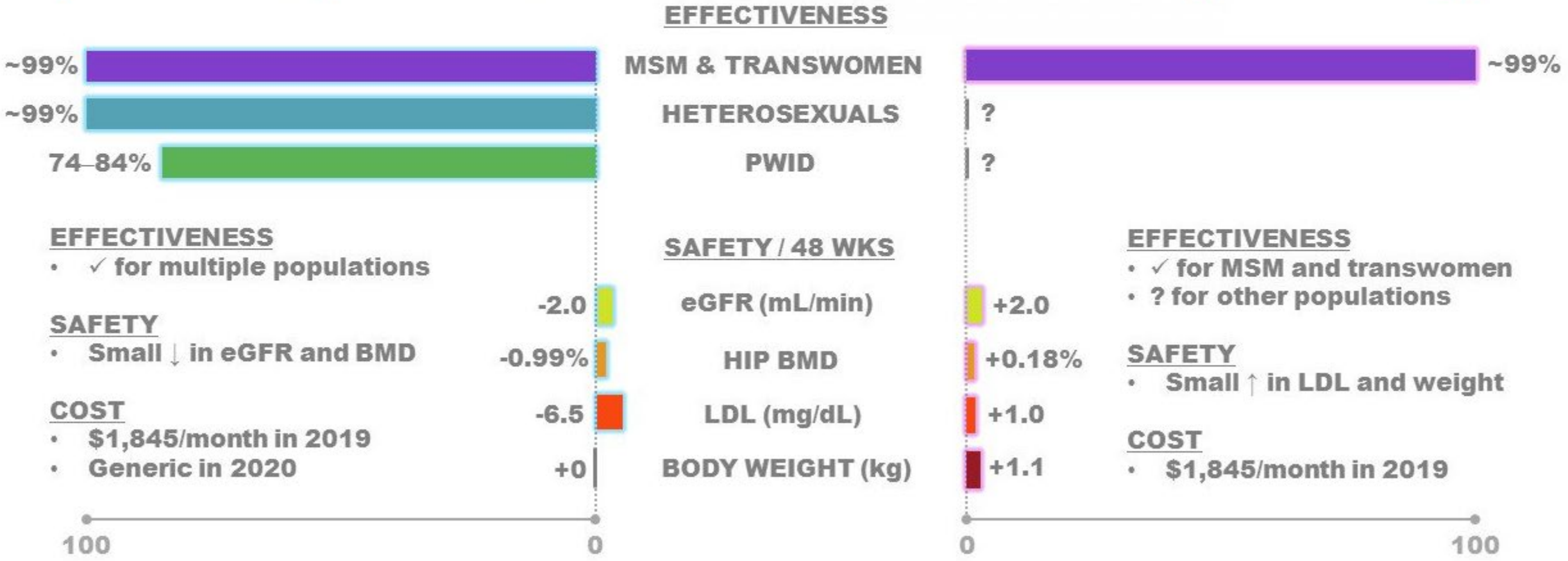
COST
- $1,845/month in 2019
- Generic in 2020

TAF/FTC (Descovy)

EFFECTIVENESS
- ✓ for MSM and transwomen
- ? for other populations

SAFETY
- Small ↑ in LDL and weight

COST
- $1,845/month in 2019



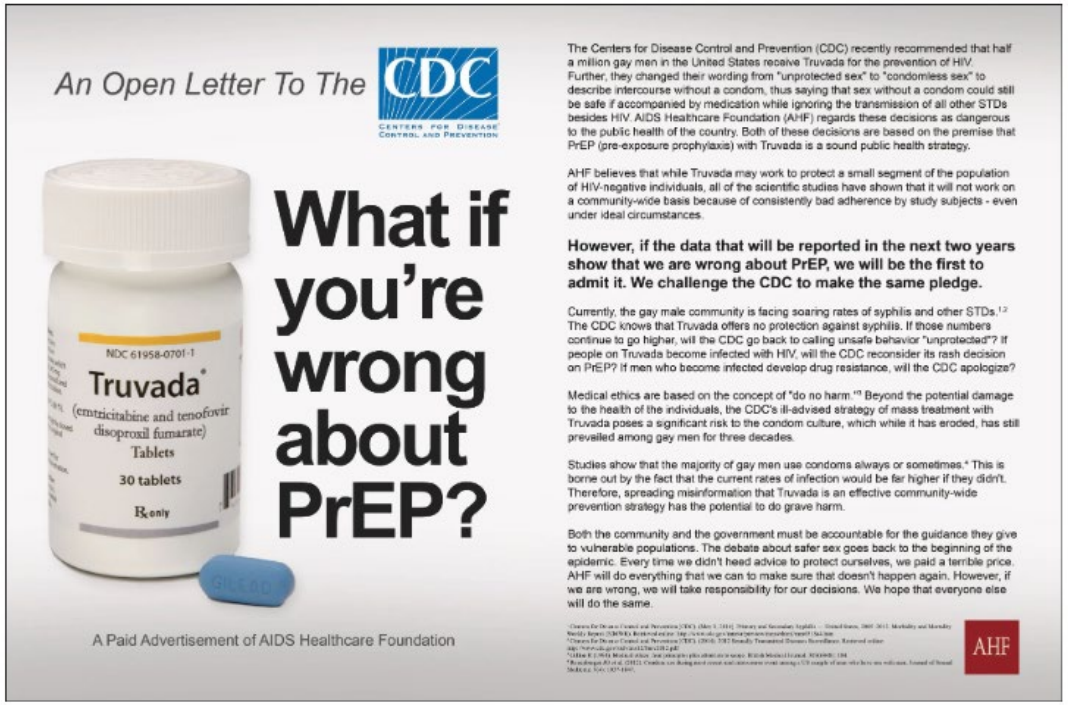
Sources: fda.gov/media/129607/download; fda.gov/media/129609/download; cdc.gov/hiv/risk/estimates/preventionstrategies.html Created by: @JuliaLMarcus

Medications coming soon?

- Long-acting injectables – Late 2021?
- Slow release implants
- Intravaginal rings
- Antibody infusions

It's so easy…why aren't more PCPs doing it?

- Barriers to prescription
  - "There are too many potentially detrimental side effects…"
  - "Taking this medication could lead to increased HIV resistance…"
  - "Truvada is a party drug that will only lead to more sex and more STIs…"



Too many side effects?

- iPrex
  - Serum creatinine levels elevated at more than one consecutive test in 5 subjects in the TDF/FTC group (<1%) and resolved after discontinuation of study drug
  - Nausea and unintentional weight loss only statistically significant side effects compared to placebo group

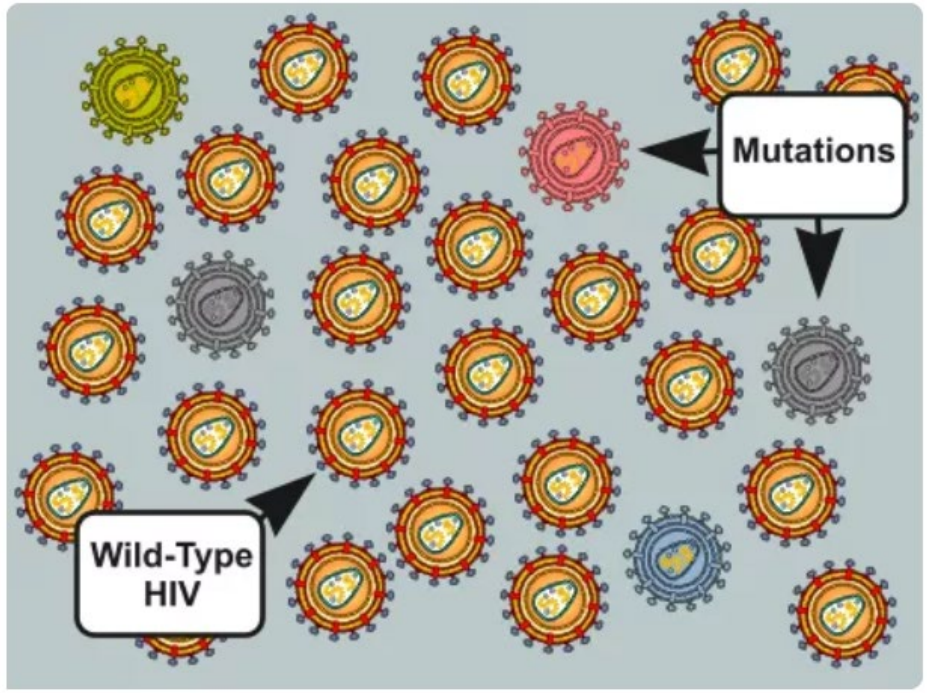
Table 2. Adverse Events.*

Adverse Event	FTC–TDF (N=1251)		Placebo (N=1248)		P Value†
	no. of patients (%)	*no. of events*	*no. of patients (%)*	*no. of events*	
Any adverse event	867 (69)	2630	877 (70)	2611	0.50
Any serious adverse event	60 (5)	76	67 (5)	87	0.57
Any grade 3 or 4 event	151 (12)	248	164 (13)	285	0.51
Grade 3 event	110 (9)	197	117 (9)	225	0.65
Grade 4 event	41 (3)	51	47 (4)	60	0.57
Elevated creatinine level	25 (2)	28	14 (1)	15	0.08
Headache	56 (4)	66	41 (3)	55	0.10
Depression	43 (3)	46	62 (5)	63	0.07
Nausea	20 (2)	22	9 (<1)	10	0.04
Unintentional weight loss (≥5%)	27 (2)	34	14 (1)	19	0.04
Diarrhea	46 (4)	49	56 (4)	61	0.36
Bone fracture	15 (1)	16	11 (<1)	12	0.41
Death	1 (<1)‡	1	4 (<1)	4	0.18
Discontinuation of study drug					
Permanently	25 (2)	26	27 (2)	33	0.82
Permanently or temporarily	79 (6)	99	72 (6)	92	0.49

* A listing of all laboratory abnormalities and clinical adverse events of grade 2 or higher that were reported in 25 or more subjects (1%) is provided in Tables S9 and S10 in the Supplementary Appendix. FTC–TDF denotes emtricitabine and tenofovir disoproxil fumarate.
† P values were calculated by the log-rank test.
‡ This death was due to a motorcycle accident.

What about resistance?

- In Partners PrEP:
  - Of the 8 subjects retrospectively found to be HIV-1 infected at initial randomization, 2 developed HIV-1 with resistance to study medications
  - Of the 52 subjects who acquired HIV-1 after randomization, 48 had resistance data, but no resistance to study drugs were detected



Picture from: https://www.verywellhealth.com/things-should-know-hiv-drug-resistance-48633

Does PrEP lead to more STIs?

- PROUD (2016) showed no evidence of increase in other STIs
- Other studies suggest that there may be some risk compensation
- Those on PrEP actually receive *more* STI screening on a regular basis

More on PEP…

- WHO Guidelines
  - PEP initiated as soon as possible after exposure, ideally within 72 hours
  - Exposures that may warrant PEP include:
    - Bodily fluids (blood, blood-stained saliva, breast milk, genital secretions, CSF, synovial)
    - Mucous membrane (sexual exposure, splashes to eye/nose/oral cavity)
    - Parenteral exposures
  - Labs needed:
    - HIV screen
    - Hepatitis serologies
    - STI screening
    - Kidney function
  - Three-drug regimen for 28 days
    - TDF/FTC + raltegravir
    - TDF/FTC + dolutegravir

Key Resources

- HIV ECHO
  - Occurs every Tuesday afternoon, 12-1p
  - First Tuesday of every month on PrEP

- Clinician Consultation Center
  - Phone or email consults from PrEP experts
    - http://www.nccc.ucsf.edu

- Truman Health Services Connect-2-Care Line
    - 505-206-7048

Summary

- PrEP is a program consisting of both routine STI testing AND medications to prevent HIV transmission
- Medications used for PrEP have few side effects and are well tolerated
- Regular follow up for people receiving PrEP should occur every 3 months
  - No one should receive a prescription with 11 refills…
- Screen for STIs routinely in those at high risk and discuss PrEP with those who might benefit
- Consider PrEP for PWID, particularly those with STI history or who engage in sex with substance use

Resources

Cardo DM, Culver DH, Ciesielski CA, et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. Centers for Disease Control and Prevention Needlestick Surveillance Group. *N Engl J Med*. 1997;337(21):1485-1490. doi:10.1056/NEJM199711203372101

Cohen MS, Shaw GM, McMichael AJ, Haynes BF. Acute HIV-1 infection. *New Eng J Med*. 2011; 364:1943-54.

Ford N, Mayer KH; World Health Organization Postexposure Prophylaxis Guideline Development Group. World Health Organization Guidelines on Postexposure Prophylaxis for HIV: Recommendations for a Public Health Approach. *Clin Infect Dis*. 2015;60 Suppl 3:S161-S164. doi:10.1093/cid/civ068

Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med*. 2010;363(27):2587-2599. doi:10.1056/NEJMoa1011205

Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV. aidsinfo.gov. https://aidsinfo.nih.gov/guidelines/brief-html/4/adult-and-adolescent-opportunistic-infection/0. Published October 16, 2019. Accessed October 16, 2019.

HIV Nexus Clinician Resources. cdc.gov. https://www.cdc.gov/hiv/clinicians/prevention/prep.html. Last reviewed November 26, 2019. Accessed December 4, 2019.

Marcus JL, Katz KA, Krakower DS, Calabrese SK. Risk compensation and clinical decision making—the case of HIV preexposure prophylaxis. *New Eng J Med*. 2019: 510-512.

Peters PJ, Pontones P, Hoover KW, et al. HIV Infection Linked to Injection Use of Oxymorphone in Indiana, 2014-2015. *N Engl J Med*. 2016;375(3):229-239. doi:10.1056/NEJMoa1515195

Prescribe PrEP. cdc.gov. https://www.cdc.gov/stophivtogether/library/prescribe-hiv-prevention/brochures/cdc-lsht-php-brochure-prep-faq.pdf. Reviewed September 26, 2019. Accessed October 16, 2019.

Ray AS, Fordyce MW, Hitchcock MJM. Tenofovir alafenamide: a novel prodrug of tenofovir for the treatment of human immunodeficiency virus. *Antiviral Research*. 2016: 125:63-70.

Screening and diagnosis. National HIV Curriculum. https://www.hiv.uw.edu/custom/screening-diagnosis/3/2. Published April 16, 2019. Accessed October 16, 2019.

Spiller MW, Broz D, Wejnert C, et al. HIV infection and HIV-associated behaviors among persons who inject drugs--20 cities, United States, 2012. *MMWR Morb Mortal Wkly Rep*. 2015;64(10):270-275.

Questions?

Scan for link to Dropbox folder with access to PDFs of papers and slides from today's discussion.

Built-In Bio Break

After this didactic, how confident are you at prescribing PrEP?

- Very Confident
- Confident
- Ambivalent
- Not Confident
- (Still) Definitely Not Confident

After this didactic, how confident are you at prescribing PEP?

- Very Confident
- Confident
- Ambivalent
- Not Confident
- I still don't know what's PEP...

Case #1

- David Ross is a 24 yo cisgender male with history of asthma and alcohol use, presenting to establish care.
- At the beginning of the visit, he asks about PrEP.
- What do you want to know?

Case #1 continued…

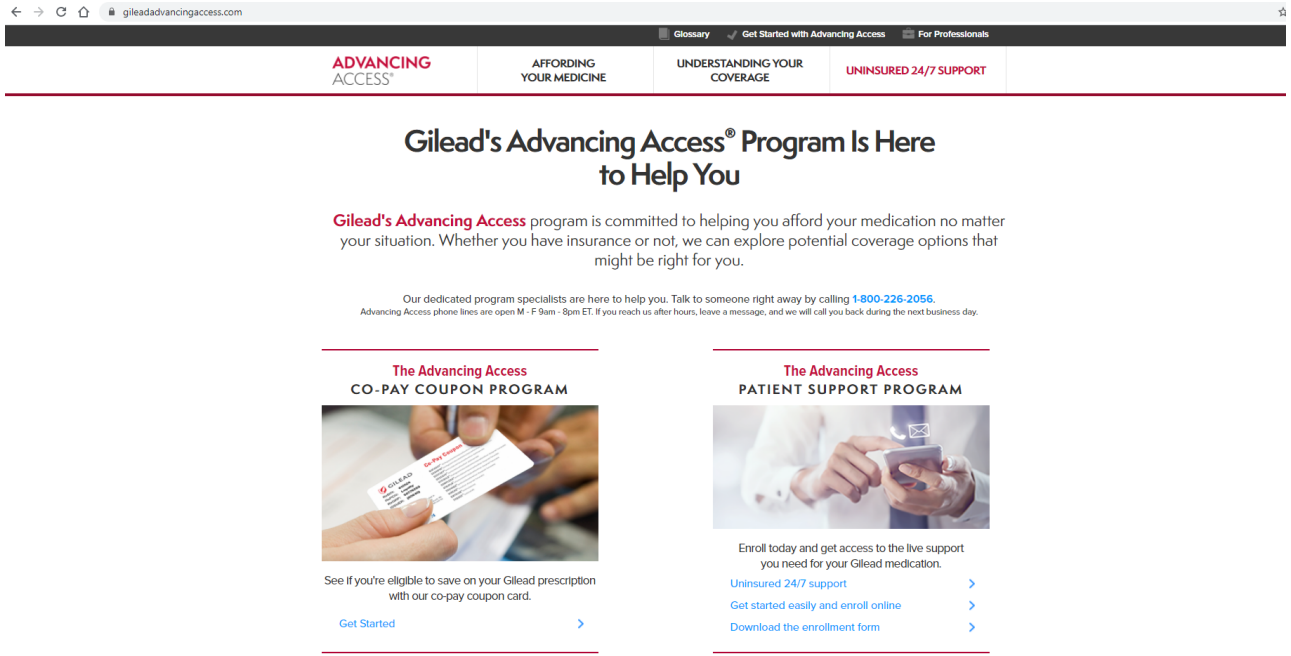
- No personal or familial history of renal, liver or bone disease, no meds or allergies
- Sexual debut at 18 with cisgender men and women
  - In the last 6 months, 15 male partners – he is anal insertive and receptive partner, also oral sex (giving/receiving)
  - Rarely uses condoms
- Two cases of gonorrhea in the last six months
- What do you do next?

Case #1 continued…

- Labs
  - HIV screen
  - TPAB
  - GC/CT 3 site testing
  - Hepatitis serologies
  - Chem 7
- Medications
  - Truvada (TDF/FTC)
  - Descovy (TAF/FTC)
    - When?

Case #1 continued…

- David calls back the next day, stating that he went to pick up his medications, but he had a $50 copay.
- What options are available to help with copays?
  - Gilead Advancing Access Program (gileadadvancingaccess.com)
  - Teva Copay Assistance (tevahivgenerics.com/Truvada-generic)



Practice Pearls

- Use dot phrases to remember key points of history and counseling to discuss
- Use appropriate ICD Codes
  - Z20.6 “Contact with HIV”
  - Z11.3 “Routine screening for STI”

Subjective/HPI

Selected Visit

Tahoma | 9

Subjective: The patient is seen today for NPV for an HIV risk assessment, discussion of risk reduction and evaluation for initiation of HIV PrEP. They were made aware of HIV PrEP services by a partner. The patient reports a potential risk of HIV transmission by multiple unprotected sexual exposures including MSM partners. They have been screened for HIV in the past. The last HIV screen was done today and was nonreactive.

Sexual history was reviewed. The patient's initial sexual debut was _ and was consensual. They denied a history of prior sexual abuse or coercion. The patient's sexual partners are cis-gender men and sexual activities have included insertive anal intercourse. Pt does not have a regular partner. for monogamous relationship. Partners HIV status is unknown. They use condoms never. The patient does not report other potentially high risk sexual practices, including sexual activitiy with a partner with known HIV or IDU. The patient denied a history of prior STI. Patient denied a prior history of syphilis. Patient reports last encounter for condomless intercourse was _.

The patient denied current symptoms of an STI including dysuria, penile discharge, genital ulcer or sore, genital warts, anal discharge, anal pain, pharyngeal discharge, sore throat, rash. The patient denied current symptoms consistent with acute retroviral syndrome (rash, fever, myalgias, sore throat).

The patient's substance use history was reviewed. See social history findings. Patient disclosed a history of IDU or needle sharing for any reason. Patient disclosed unprofessional tattoos or piercings. The patient denied a history of or ongoing occupational or recreational exposure to blood.

Past Medical History:
-- Denied a history of liver, kidney, bone problems, history of blood/blood product/organ transplantation
-- Reports receiving all routine childhood vaccines
-- Denied a family history of liver, idney, or bone problems.

PrEP Information:
1. HIV Exposure Risk: MSM
   --- HIRI-MSM Risk Score: _ (_date)
2. Baseline labs: *pending*
3. PMH: *as above*
4. PCP: _
5. Insurance: _
6. Pharmacy: _

Assessment/Plan

Selected Visit

Tahoma | 9

Ongoing risk of HIV acquisition. The patient was educated on the risks of HIV transmission and transmission of other STI and viral hepatitis. HIV risk reduction was discussed, including barrier protection, monogamous relationships, routine screening and early treatment of STIs, less risky sexual acts, HIV PEP, and HIV PrEP. U=U with PWH on stable ART also discussed.

The risks and benefits of HIV PrEP were discussed with the patient including that HIV PrEP does not prevent STIs nor pregnancy and should not be used in those with HIV infection. In addition, HIV PrEP requires daily dosing and close clinic and laboratory monitoring at least every 3 months. Also discussed alternate dosing, while not FDA-approved, is evidence informed when sexual interactions are infrequent and predicted. We discussed TAF/FTC versus TDF/FTC.

The patient voiced understanding of the information presented, as documented above, and is interested in starting medications today. If there are any abnormal laboratory findings, the patient will be contacted by clinic staff. Also informed that if any STI symptoms occur in between visits, they can call for an ACV with clinic provider.

-- Truvada 1 pill PO daily, Disp #30, Refill 2
-- Labs today, including HIV screen, TPAB, STI, Chem 7, HCV Ab
-- RTC in 12 weeks

Save

Calculate the HIRI-MSM Score

Answer these questions to calculate a HIRI-MSM score:

How old are you today?

○ Under 18 ○ 18-28 ○ 29-40 ○ 41-48 ○ 49 +

In the last 6 months, how many men have you had sex with?

○ Over 10 ○ 6-10 ○ 0-5

In the past 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?

○ 0 times ○ 1 and more times

In the past 6 months, how many of your sex partners were HIV-positive?

○ 0 partners ○ 1 partner ○ More than 1 partner

In the past 6 months, how many times did you have insertive anal sex (you were the top) without a condom with a man who was HIV-positive?

○ 0-4 times ○ 5 or more times

In the last 6 months, have you used metamphetamines such as crystal or speed?

○ Yes ○ No

Calculate Now

Case 2

- Kris is a 58 yo cisgender male with hypertension, hyperlipidemia, and diabetes presenting for evaluation of pre-exposure prophylaxis.

Case #2 continued…

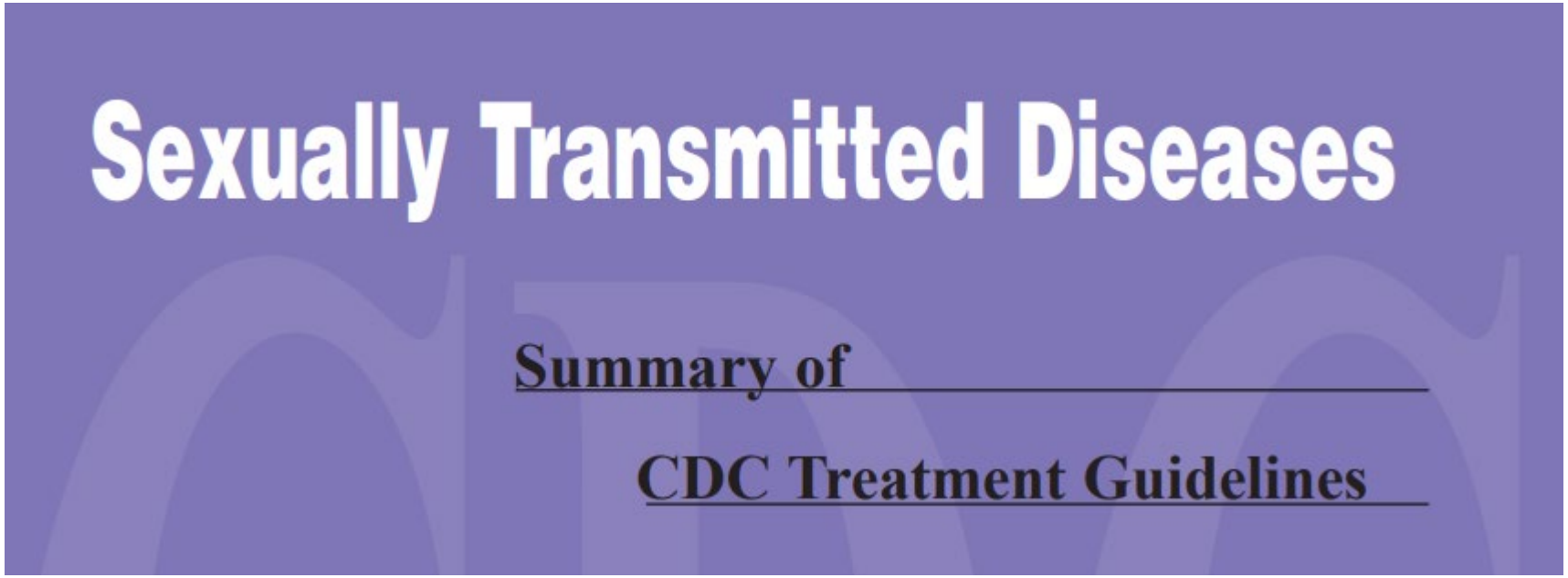
- Familial history of renal failure (mother, DM)
- No other known personal or familial history of liver or bone disease
- On metformin, losartan, amlodipine
- Sexual debut at 13 with cisgender men
  - In the last 6 months, 3 male partners – he is anal insertive partner, also oral sex (giving/receiving)
  - Rarely uses condoms
- One case of chlamydia in the last six months; believes he was also diagnosed with syphilis previously
- What do you do next?

Case #2 Continued…

- Vitals
  - T 36.5
  - BP 152/98
  - HR 95
  - Ht 165 cm
  - Wt 90 kg
- Labs
  - Serum creatinine 1.3 mg/dL
  - TPAB reactive, RPR 1:8
  - GC/CT positive for rectal chlamydia
  - Hep B s Ag nonreactive, Hep B s Ab reactive, Hep B c Ab reactive
  - Hep C Ab nonreactive
  - HIV screen negative

Practice Pearls

- Be sure to swab ALL SITES where patients are sexually active
- Be familiar with STI recommendations for STI treatment
  - GC now treated with ceftriaxone 500 mg IM
  - If CT not completely excluded, doxycycline 100 mg BID x 7 days recommended



BOX. CDC recommended regimens for uncomplicated gonococcal infections, 2020

Regimen for uncomplicated gonococcal infections of the cervix, urethra, or rectum:

Ceftriaxone 500 mg IM as a single dose for persons weighing <150 kg (300 lb)

- For persons weighing ≥150 kg (300 lb), 1 g of IM ceftriaxone should be administered.
- If chlamydial infection has not been excluded, providers should treat for chlamydia with doxycycline 100 mg orally twice daily for 7 days. During pregnancy, azithromycin 1 g as a single dose is recommended to treat chlamydia.

Alternative regimens for uncomplicated gonococcal infections of the cervix, urethra, or rectum if ceftriaxone is not available:

Gentamicin 240 mg IM as a single dose plus azithromycin 2 g orally as a single dose OR

Cefixime 800 mg orally as a single dose. If treating with cefixime, and chlamydial infection has not been excluded, providers should treat for chlamydia with doxycycline 100 mg orally twice daily for 7 days. During pregnancy, azithromycin 1 g as a single dose is recommended to treat chlamydia.

Recommended regimen for uncomplicated gonococcal infections of the pharynx:

Ceftriaxone 500 mg IM as a single dose for persons weighing <150 kg (300 lb)

- For persons weighing ≥150 kg (300 lb), 1 g of IM ceftriaxone should be administered.
- If chlamydia coinfection is identified when pharyngeal gonorrhea testing is performed, providers should treat for chlamydia with doxycycline 100 mg orally twice a day for 7 days. During pregnancy, azithromycin 1 g as a single dose is recommended to treat chlamydia.
- No reliable alternative treatments are available for pharyngeal gonorrhea. For persons with a history of a beta-lactam allergy, a thorough assessment of the reaction is recommended.*
- For persons with an anaphylactic or other severe reaction (e.g., Stevens Johnson syndrome) to ceftriaxone, consult an infectious disease specialist for an alternative treatment recommendation.

Abbreviation: IM = intramuscular.

* CDC. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2015;64(No. RR-3). https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm.

Case #2 Continued…

- Syphilis
  - Contact DOH, find out that last RPR was 1:2 three months ago
  - Treat with IM PCN 2.4 million units x 1

- Chlamydia
  - Treat with doxycycline 100 mg BID x 7 days
  - Instruct him to avoid sex until roughly 7 days after completing treatment and have partners tested/treated

- Hep B core positivity
  - Discuss possibility of HBV reactivation after PrEP discontinuation

Case #2 Continued…

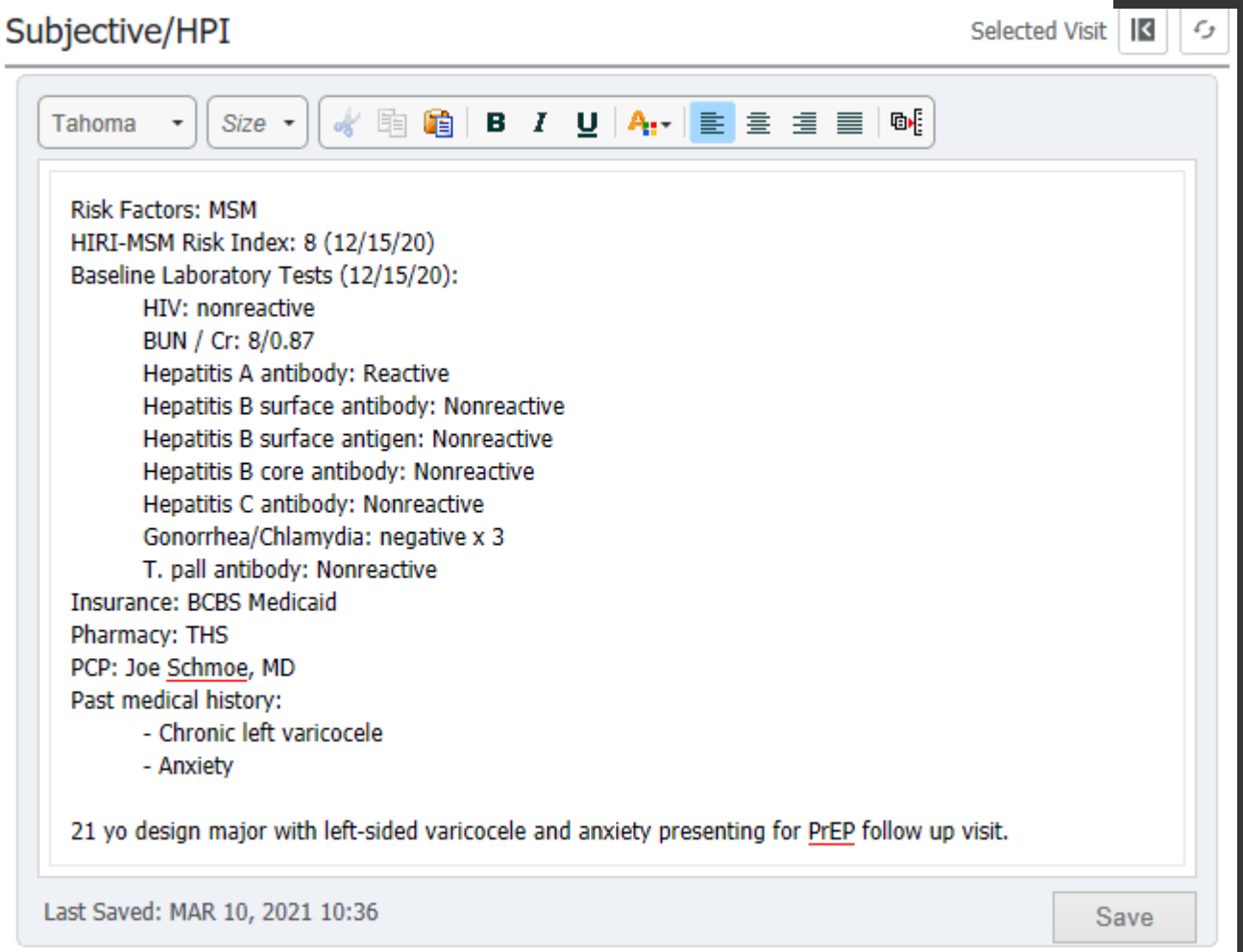
- Kris returns for 3 month check up
  - What labs do you obtain?
- Labs
  - HIV screen nonreactive
  - TPAB reactive, RPR 1:2
  - GC/CT x 3 nonreactive
  - Serum creatinine 1.6 mg/dL
- Next steps?

Practice Pearls

- In patients whose serum creatinine clearance declines below 60 mL/min/1.73 m2, or in those who function declines 20% but remains above 60, discontinue TDF/FTC and consider transition to TAF/FTC.
- If evidence of Fanconi syndrome (e.g. hyperphosphaturia, renal glucosuria, hypouricemia, aminoaciduria), do not use TAF/FTC.
- Evaluate for other causes of renal dysfunction.

Practice Pearls

- Be able to access the baseline labs at ease so that you can see if serum creatinine is increasing



Case #3

- Sam is a 48 yo cisgender woman with history of hypothyroidism, osteopenia, CKD stage 2, alcohol use disorder in remission, presenting for evaluation of PrEP.
- What do you want to know?

Case #3 Continued…

- Unknown cause of CKD, avoids NSAIDs but not on other medications
- Vitamin D for osteopenia, last DEXA 6 months ago
- Recently began having oral and vaginal intercourse with new partners of unknown status; occasional drugs with sex
- Currently condoms with all sexual encounters

Case #3 Continued…

- Vitals
  - T 36.8
  - HR 45
  - BP 120/60
  - Wt 55 kg
  - Ht 167 cm

- Labs
  - HIV screen nonreactive
  - Hep B s Ab, Hep B s Ag, Hep B c Ab nonreactive
  - TPAB nonreactive
  - GC/CT x 3 negative
  - Serum creatinine 1.31

Case #3 Continued

- Creatinine clearance 49 mL/min
- Recommendations?

Case 4

- Alex, a 45 yo transgender woman, presents to clinic requesting evaluation. She stated that she had sex with a new partner recently. She stated that she is unaware of her partner's status and is concerned for HIV.
- What do you do?
- What questions do you ask?

Case 4 Continued…

- Her partner was a cis-gendered male; Alex was the anal receptive partner.
- Intercourse was roughly 48 hours ago.
- She has a history of hypertension, chronic back pain.
- She transitioned 5 years ago. She had a vaginoplasty 2 years ago. She has no known history of kidney, liver or bone problems.
- Medications:
  - Lisinopril 40 mg daily
- Next steps?

Case 4 Continued…

- Labs
  - Rapid HIV test negative
  - Hep B s Ag negative, Hep B s Ab positive, Hep B c Ab negative
  - TPAB nonreactive
  - GC/CT negative x 3
  - Serum creatinine 1.4
- Medications
  - Truvada (TDF/FTC) + Dolutegravir x 28 days
- Practice Pearl: If patient uninsured, can use copay cards to help offset costs for PEP:
  - Truvada: Gilead Advancing Access Program
  - Dolutegravir: ViivConnect Savings Card (us.tivicay.com/patient-savings/)
  - Raltegravir: Merck Program (activatethecard.com/7967/)

Case 4 Continued…

- Alex returns on day 28. She has completed the course of PEP with no missed doses. She has had no fevers, chills, lymphadenopathy.
- She is interested in transitioning to PrEP.
- What do you want to know?
- What do you do now?

Case 4 Continued…

- Alex is interested in cis-gender male partners
- She anticipates both anal receptive and vaginal receptive partner.
- Vitals:
  - T: 37.5
  - H: 75
  - BP: 141/92
  - Ht: 72 in.
  - Wt: 180 lb.
- Labs:
  - HIV screen: negative
  - Serum creatinine: 1.45
    - Next steps?

Class 4 Continued…

- Creatinine clearance: 54 mL/min (for NBW)
  - What medication do you use?
  - What other recommendations do you give?

Case #5

- John is a 48 yo cisgender male with history of hypothyroidism, hypertension, bipolar disorder.
- In a monogamous relationship with male partner for 5 years, recently broke up. Reports two male sexual partners in the last 6 months.
- Last sexual encounter 4 weeks ago.
- Diagnosed with syphilis 4 months ago.
- Fevers, chills two weeks ago, resolved. Sore throat and myalgias for the last week. No discharge or rashes noted.

Case #5 Continued…

- Vitals:
  - T 36.5
  - HR 98
  - BP 114/82
  - Wt 74.3 kg
  - Ht 173 cm

- Labs:
  - Serum creatinine 0.78
  - TPAB reactive, RPR 1:2
  - Hep B s Ag nonreactive, Hep B s Ab nonreactive, Hep B c Ab nonreactive
  - Hep C Ab nonreactive
  - HIV screen indeterminate

  - What do you do next?

Case #5 Continued…

- HIV VL >10,000,000

Key Resources

- HIV ECHO
  - Occurs every Tuesday afternoon, 12-1p
  - First Tuesday of every month on PrEP

- Clinician Consultation Center
  - Phone or email consults from PrEP experts
    - http://www.nccc.ucsf.edu

- Truman Health Services Connect-2-Care Line
  - 505-206-7048
  - jwsnyder@unmmg.org

After this session, how confident are you at prescribing PrEP?

Very Confident

Confident

Ambivalent

Not Confident

(Still) Definitely Not Confident

After this session, how confident are you at prescribing PEP?

Very Confident

Confident

Ambivalent

Not Confident

I still don't know what's PEP...

Questions for you…

- What barriers do you foresee to providing PrEP and PEP to your patients, both during residency and after?
- Do you have patients who would benefit from PrEP? How would you approach them about this?
- If you have questions about PrEP/PEP, do you have the support that you need to have your questions answered?

Other questions?

Jeremy Snyder

jwsnyder@unmmg.org

505-925-7501 / TigerConnect