# PEP at SFCC

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# Disclosures and disclaimers

- Nothing to disclose
- Views expressed herein are those of the presenter and do not necessarily reflect those of the San Francisco Department of Public Health

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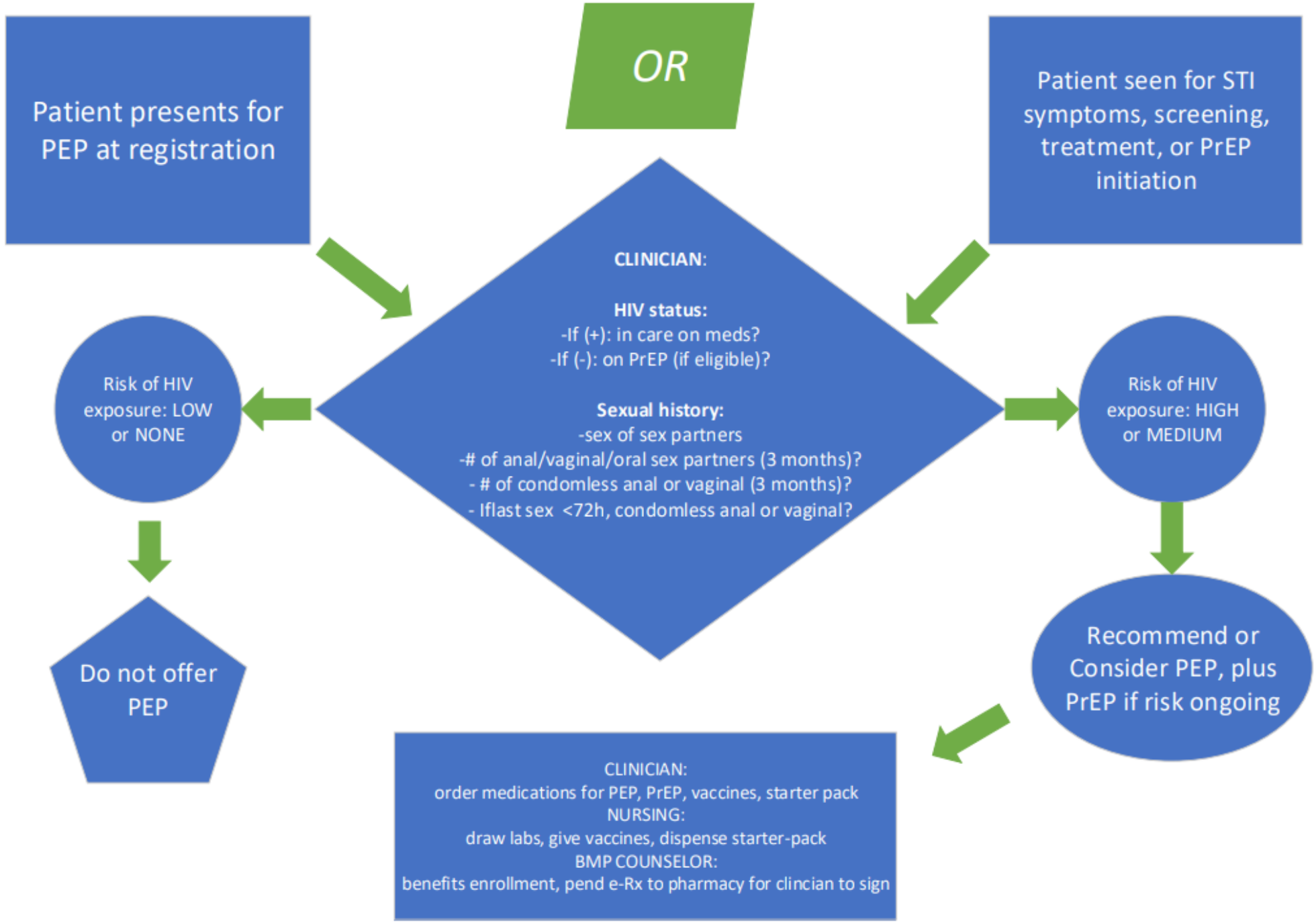
# Roadmap

- SFCC PEP protocol
- ~~Data on PEP at SFCC~~
- PEP questions, controversies
  - Efficacy?
  - What to use: regimens, 2 vs. 3 drug PEP
  - Screening for active hepatitis B
  - PEP-to-PrEP

# PEP at SFCC


Patient presents for PEP at registration
OR
Patient seen for STI symptoms, screening, treatment, or PrEP initiation
CLINICIAN:
HIV status:
-If (+): in care on meds?
-If (-): on PrEP (if eligible)?
Sexual history:
-sex of sex partners
-# of anal/vaginal/oral sex partners (3 months)?
- # of condomless anal or vaginal (3 months)?
- Iflast sex <72h, condomless anal or vaginal?
Risk of HIV exposure: LOW or NONE
Risk of HIV exposure: HIGH or MEDIUM
Do not offer PEP
Recommend or Consider PEP, plus PrEP if risk ongoing
CLINICIAN:
order medications for PEP, PrEP, vaccines, starter pack
NURSING:
draw labs, give vaccines, dispense starter-pack
BMP COUNSELOR:
benefits enrollment, pend e-Rx to pharmacy for clincian to sign

| Recommendation | Act (within the last 72 hours) | Risk |
|---|---|---|
| Recommend | Condomless receptive or insertive anal intercourse[1,2]<br>Sexual assault from HIV positive or unknown status partner<br>Sharing needles for injection drug use<br>Injuries with exposure to blood or other potentially infected fluids from a source known to be HIV-infected or HIV status is unknown (including needlesticks with a hollow-bore needle, human bites, accidents) | High |
| Consider | Condomless receptive or insertive vaginal intercourse[1,2,3]<br>Blood or semen splash on mucosal surface or open wound | Medium |
| Do Not Routinely Offer | Performing condomless oral sex with/without ejaculation<br>Receiving condomless oral sex<br>Sharing cookers, cotton or other drug paraphernalia<br>Oral-anal contact | Low[4] |
| Do Not Offer | Vaginal-vaginal intercourse<br>Semen or blood on intact skin<br>Kissing<br>Human bites not involving blood<br>Mutual masturbation without skin breakdown or blood exposure | None |

# Medications

Medications for PEP (30-day supply, 0 refills)

- Preferred: BIC/TAF/FTC
- Alternatives:
  - [dolutegravir 50 mg daily *or* raltegravir 400 gm BID] + TDF/FTC daily
  - TDF/FTC (if no insurance AND ineligible for governmental or industry assistance programs)
- Everyone offered a starter pack of TDF/FTC for 2-7 days while awaiting availability of meds at the pharmacy
  - Nonhuman primate models suggest relationship between early initiation and improved efficacy [REF]
- If PEP-to-PrEP: BIC/TAF/FTC #30 + TDF/FTC #60 to start on day 31
  - Alternative: dolutegravir #30 + TDF/FTC #90

# Medication coverage

- Medi-Cal (Medicaid): covers PEP and PrEP without prior authorization or TAR
- Medicare: PEP and PrEP covered for many, but not all
- Commercial plans: PEP and PrEP covered, but may need patient assistance plans for copays (BMP counselor)
- VA, Kaiser: direct patient to PEP at VA, Kaiser, with starter pack and telephone handoff to institutions' pharmacy from BMP counselor
- Uninsured: Same-day enrollment in Gilead, ViiV patient assistance programs by BMP counselor for US residents with income ≤500% FPL
- PrEPAP for CA residents: same-day enrollment by BMP counselor, no income limit
- If cash is only option: TDF/FTC ± raltegravir through GoodRx

# Baseline Labs

- NAAT for GC, CT at all sites of exposure; RPR for syphilis
- HIV: rapid fingerstick + pooled RNA (SFCC-specific algorithm)
- Serum creatinine, height, weight, HBV surface antigen ONLY if planning PEP-to-PrEP
- Costs:
  - Free to patient
  - Covered by SFDPH (general fund; HIV Prevention and STI grant funding)

# Case management by BMP counselors

At initiation:

- Patients encouraged to return for repeat HIV screening 7+ days after finishing PEP
- Provide brief client –centered risk reduction counseling

Day 2-3 after visit (text or call):

- Ensure they have taken steps to fill prescription
- Problem-solve barriers
- Offer PrEP for when they complete PEP (if not already PEP-to-PrEP)

Day 28 after visit (call):

- If PEP-to-PrEP:  remind to start PrEP and return to clinic in 2 months for PrEP follow-up
- If not PEP-to-PrEP: inquire about plan for HIV protection, offer PrEP again (incl 2-1-1)
- Remind them of HIV test 7+ days after stopping PEP

# Questions/Controversies for PrEP programs

# What is the evidence for nPEP efficacy?

- **HIV a rare event, so enormous sample size needed to estimate efficacy, and RCT neither ethical nor practical**
- Multicenter (US, UK, France, Italy) case control study of ZDV after percutaneous occupational exposure. N=712 (33 case, 679 control):
  - Cases less likely to have taken ZDV than controls (OR 0.19, p=.003) but severely confounded as cases had more serious exposures than controls
- Non-human primate experiments of ARV vs no ARV after infection with SIV: infection less likely if:
  - ARV given sooner after exposure (<48-72h)
  - Continued longer (>3-10 days, and most studies used 28 days)
- Observational studies in humans given PEP
  - Postnatal prophylaxis (starting sooner and longer duration more protective)
  - MSM: 48 seroconversions among 1,535 MSM taking nPEP in 6 studies. 40 occurred 180+ days after nPEP (unlikely to represent nPEP failure); of the remaining 8 (5.2 infections/1000) possible failures 4 seroconverted 91+ days after nPEP.

Cardo et al, NEJM 1997; CDC, 2016 nPEP Guidelines Update;

# What is the optimal nPEP regimen?

- No comparative efficacy data
- Completion higher with more tolerable regimens (side effects, pill burden)
- 2 drug (ZDV/3TC, TDF/FTC) vs 3 drug (2NRTI + PI) were promoted for lower vs higher risk exposures in many guidelines until 2013
- Rationale for 3-drug INSTI based regimen for all nPEP: more likely to work against transmitted resistance mutations; risk of M184V if acute HIV at time of 2-drug PEP initiation; maximally suppressive; consistency
- DO NOT USE: abacavir, nevirapine
- SFCC used TDF/FTC for all nPEP until ~2014, then switched to DTG + TDF/FTC, and then to BIC/TAF/FTC for easier access, lower pill burden and confusion

Johnson et al, JAIDS 2021; CDC, 2016 nPEP Guidelines Update;

# HBV, sCr testing prior to starting nPEP

- Depending on setting, full HBV panel, sCr may be costly for patients, programs
- Risk of HBV rebound after stopping TDF and FTC/3TC given during PEP
  - Rare cases of hepatic decompensation, liver failure, and death
  - SMART study, drug conservation arm (n=54): >1 log HBV DNA rebound in 31-33% starting 1 month after stopping ART; 12 had rebound > 3 log; ALT flare (>200 U/mL) rare (2) during follow-up regardless of size of DNA rebound; no hepatic decompensation or liver-related mortality
- sCr: TFV-related Fanconi syndrome rare, usually cumulative, unlikely with 30 days of TAF or TDF
- Personal opinion: would not let unavailability of sCr, HBV sAg testing dissuade me from giving PEP for a moderate- or high-risk exposure

Dore et al  et al, AIDS 2010; CDC, 2016 nPEP Guidelines Update;

# Is PEP-to-PrEP safe?

- Concern: “masking” of HIV infection that goes undetected without an ARV-free interval for testing between PEP and PrEP, with possible dual NRTI treatment of HIV once patient is on PrEP
- Personal opinion: Risk of HIV infection if PrEP delayed after PEP outweighs this concern
  - Modern PEP highly effective, even though we can’t quantify efficacy
  - HIV a rare event
  - Many persons needing PEP are at very high ongoing risk of HIV and become infected while waiting to start PrEP
  - “masked” infections are RARE, eventually “de-mask” and can be treated with virologic suppression even with some NRTI resistance
  - At SFCC we offer and recommend PEP-to-PrEP to anyone asking for PEP who might have ongoing risk

Johnson et al, JAIDS 2021; CDC, 2016 nPEP Guidelines Update;

# Thanks!

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https://www.sfcityclinic.org/