Updates on PEP and PrEP

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Intro

- **With advances in HIV prevention and care efforts in the United States, estimated new HIV infections have declined from a peak of 130,000 annually in the mid-1980s to 32,800 in 2022.**

- **Further progress in preventing new infections is critical to ending the HIV epidemic.**

CDC. HIV surveillance report: diagnoses, deaths, and prevalence of HIV in the United States and 6 territories and freely associated states, 2022. Atlanta, GA: US Department of Health and Human Services, CDC; 2024. https://stacks.cdc.gov/view/cdc/156509

- **Post-exposure Prophylaxis (PEP)**

  Taking antiretroviral (ARV) medications to reduce the likelihood of HIV acquisition after high-risk exposures.

  - **nPEP** (non-occupational) : sex / injection drug use
  - **oPEP** (occupational): needle stick injury

- **Pre-exposure Prophylaxis (PrEP)**

  Taking ARV medicine in order to prevent HIV infection in people who don't have HIV but who are at high risk of becoming infected with HIV

Post-Exposure Prophylaxis (PEP)

Definitions

- Exposure
  - A **percutaneous injury** or contact of **mucous membranes** or **non-intact skin** with blood, tissue, or other body fluids that are potentially infectious

- Infectious Fluids
  - Blood
  - CSF, Synovial, pleural, peritoneal, pericardial and amniotic fluid
  - Visibly bloody body fluids
  - Semen and genital secretions
  - Breast milk

TABLE 2. Estimated per-act probability of acquiring HIV from an infected source, by exposure act

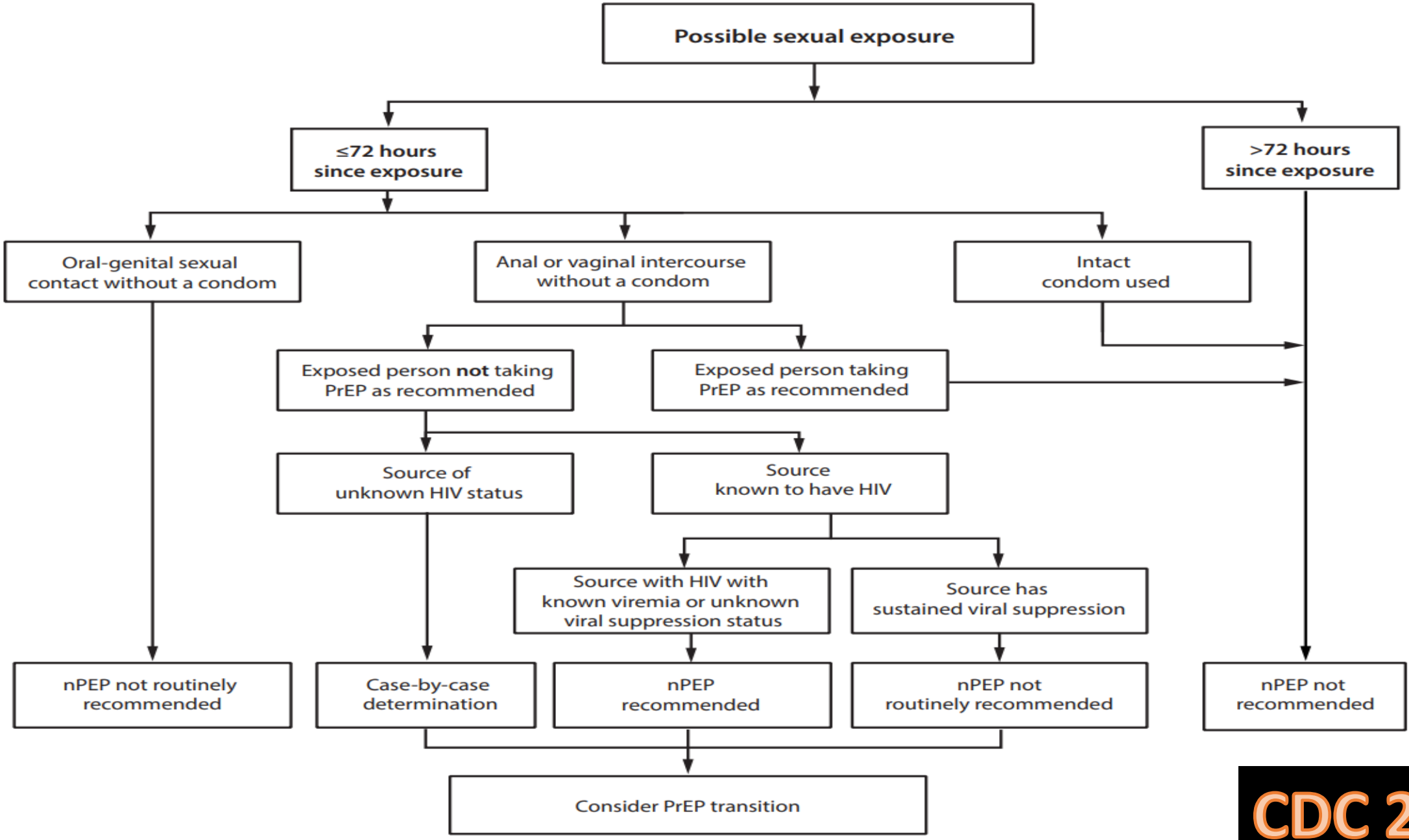
Type of exposure	Risk for HIV acquisition (per 10,000 exposures)*
Sexual	
Receptive anal intercourse	138
Insertive anal intercourse	11
Receptive penile-vaginal intercourse	8
Insertive penile-vaginal intercourse	4
Receptive oral intercourse	Low§
Insertive oral intercourse	Low§
Parenteral	
Blood transfusion	9,250
Needle sharing during injection drug use	63
Percutaneous (needle stick)	23
Other†	
Biting	Negligible
Spitting	Negligible
Sharing sex toys	Negligible

HIV PEP Indications

- PEP is recommended when an exposure has occurred within the past 72 hours that presents a substantial risk for HIV transmission and the source has HIV without sustained viral suppression or their viral suppression information is not known.

- A case-by-case determination is required when an exposure has occurred within the past 72 hours that presents a substantial risk for HIV transmission, but it is not known whether the source has HIV.

- PEP should be stopped if at any point during the course the source is found to not have HIV.


Possible sexual exposure
≤72 hours since exposure
>72 hours since exposure
Oral-genital sexual contact without a condom
Anal or vaginal intercourse without a condom
Intact condom used
Exposed person not taking PrEP as recommended
Exposed person taking PrEP as recommended
Source of unknown HIV status
Source known to have HIV
Source with HIV with known viremia or unknown viral suppression status
Source has sustained viral suppression
nPEP not routinely recommended
Case-by-case determination
nPEP recommended
nPEP not routinely recommended
nPEP not recommended
Consider PrEP transition

CDC 2025

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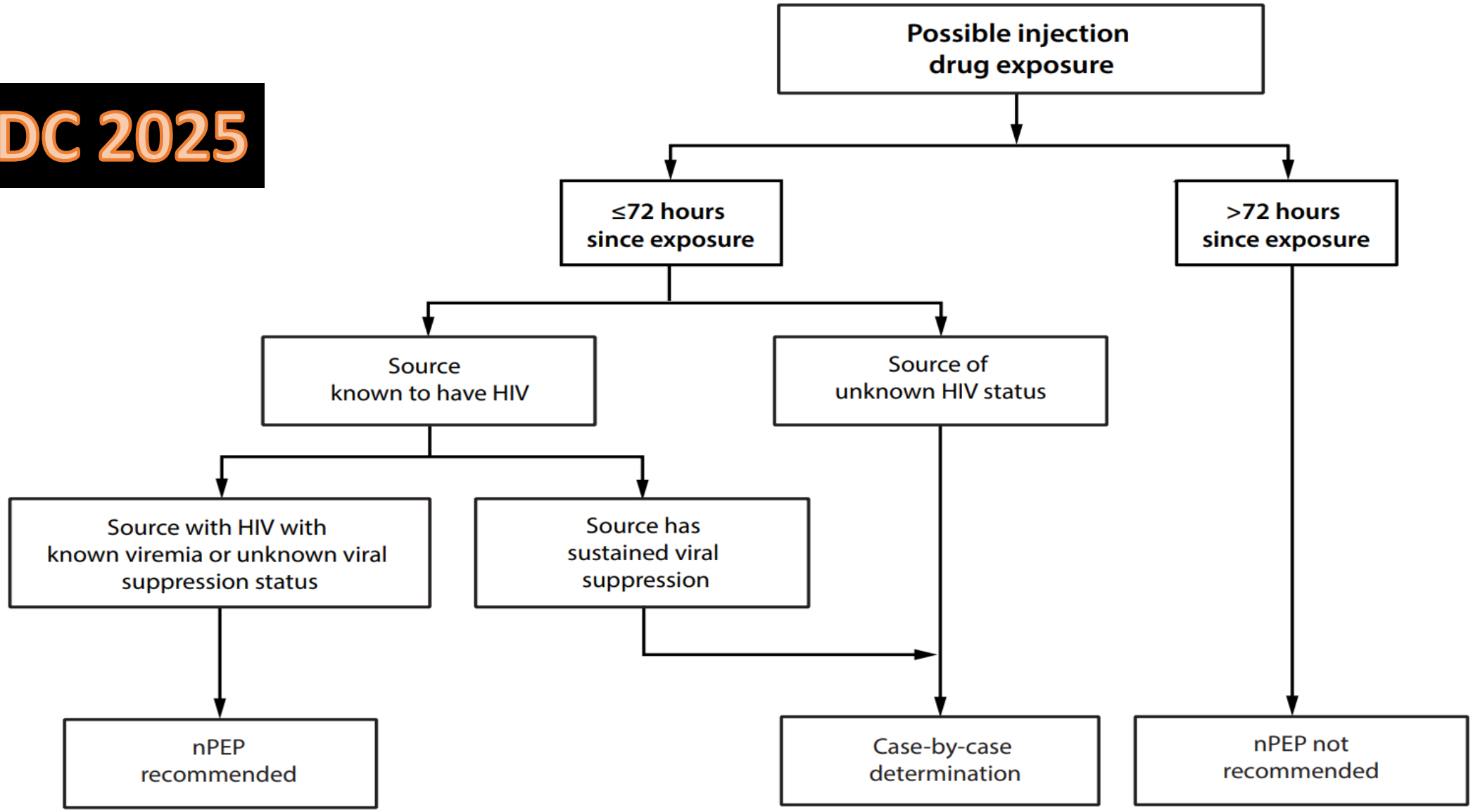
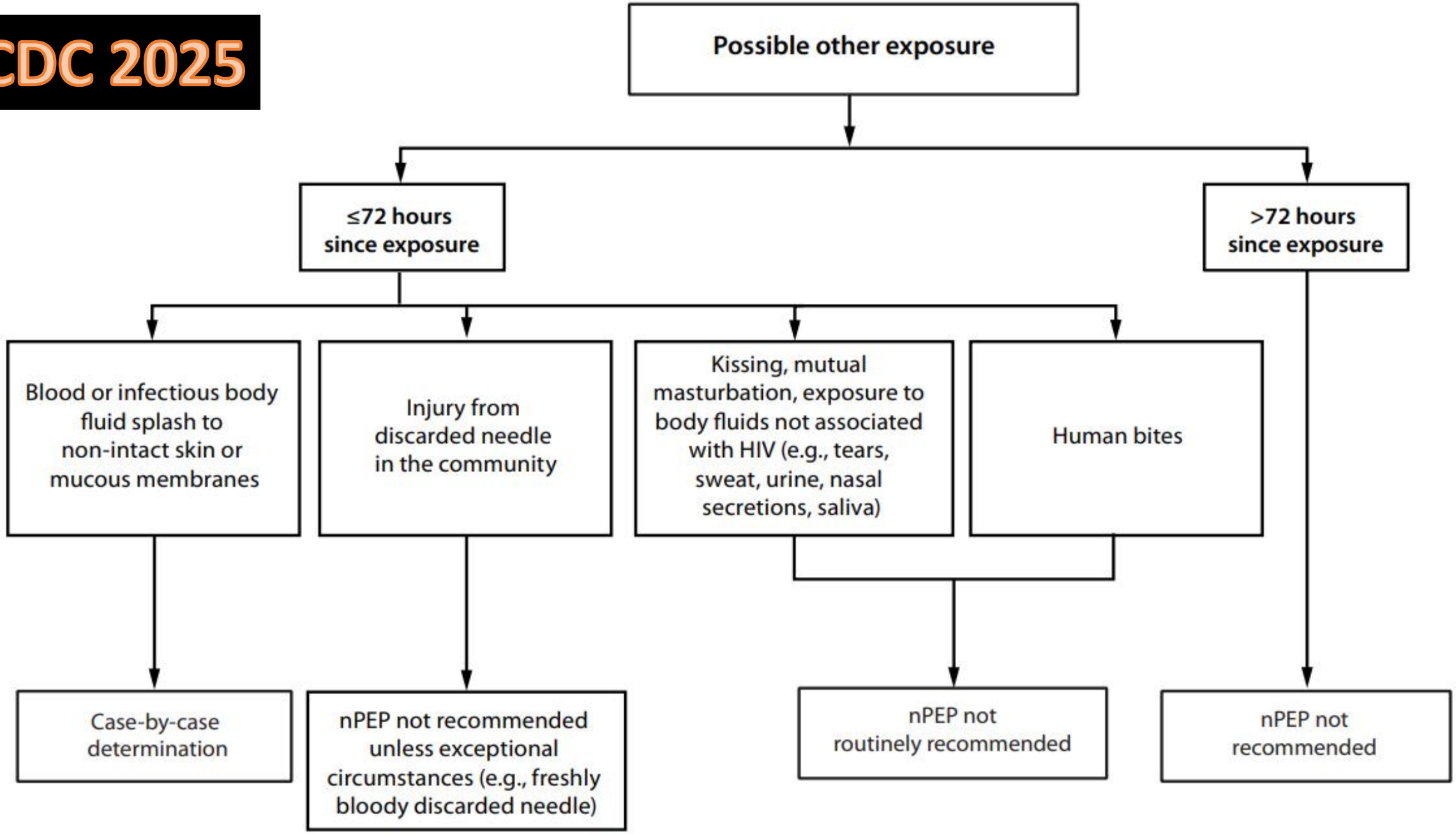

Possible injection drug exposure
≤72 hours since exposure
>72 hours since exposure
Source known to have HIV
Source of unknown HIV status
Source with HIV with known viremia or unknown viral suppression status
Source has sustained viral suppression
nPEP recommended
Case-by-case determination
nPEP not recommended

CDC 2025


Possible other exposure
≤72 hours since exposure
>72 hours since exposure
Blood or infectious body fluid splash to non-intact skin or mucous membranes
Injury from discarded needle in the community
Kissing, mutual masturbation, exposure to body fluids not associated with HIV (e.g., tears, sweat, urine, nasal secretions, saliva)
Human bites
Case-by-case determination
nPEP not recommended unless exceptional circumstances (e.g., freshly bloody discarded needle)
nPEP not routinely recommended
nPEP not recommended

National Guideline

- High-risk groups
  - Intravenous drug user
  - History of incarceration
  - High risk sexual behavior
    - Sex workers
    - MSM
    - Bisexual and transsexual
  - Partners of above mentioned groups

Time to initiation and drug regimen

- Initiate PEP as soon as possible, but no later than 72 hours after exposure.
- Complete a clinical assessment before prescribing PEP, including assessing for medical comorbidities, current medications, and allergies.
- The recommended PEP course is 28 days.

Time to initiation and drug regimen *(Cont'd)*

- **The preferred regimens for adults and adolescents without contraindications:**
  - **Bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF)**
  - **Dolutegravir (DTG) plus (tenofovir alafenamide [TAF]) OR tenofovir disoproxil fumarate [TDF]) plus (emtricitabine [FTC] OR lamivudine [3TC])**

Laboratory Testing and PEP Follow-Up

- At the initial PEP medical visit, a rapid (also referred to as point-of-care), laboratory-based antigen/antibody combination (Ag/Ab) HIV test, or both, is recommended.
- Routine laboratory testing recommended for persons starting PEP includes serum creatinine, alanine aminotransferase (ALT), and aspartate aminotransferase (AST), as well as HIV, hepatitis B virus (HBV), and pregnancy testing.
- Testing and treatment of hepatitis C virus (HCV) infection, other STIs including gonorrhea, chlamydia, and syphilis, and other medical treatment should be tailored to the clinical situation.

Laboratory Testing and PEP Follow-Up *(Cont'd)*

- Perform interim HIV testing with both a laboratory-based HIV Ag/Ab test plus a diagnostic HIV NAT test 4–6 weeks after exposure (good practice statement, standard of care).
  - HIV testing 4–6 weeks post-PEP initiation may be deferred for persons who started PEP within 24 hours of a known or possible HIV exposure and who did not miss any PEP doses.
- Perform final HIV tests using laboratory-based HIV Ag/Ab combination immunoassay and diagnostic HIV NAT 12 weeks after exposure.

- **Health care professionals should use the most sensitive accessible HIV test if the recommended test is not available. PEP services should not be withheld if an HIV NAT is not available.**

Laboratory Testing and PEP Follow-Up *(Cont'd)*

- Any sexual exposure that presents a risk for HIV infection also might place a person at risk for acquiring other STIs.
- CDC STI Treatment Guidelines, 2021, recommend presumptive STI treatment after sexual assault because clinical follow-up often is challenging for survivors .
- Presumptive STI treatment and PEP must be tailored to the clinical situation and might include
  - empiric antimicrobial regimen effective against chlamydia, gonorrhea, and trichomonas for women and chlamydia and gonorrhea for men
  - postexposure hepatitis B vaccination with or without HBIG
  - human papillomavirus or mpox vaccination

Laboratory Testing and PEP Follow-Up *(Cont'd)*

- Certain health care professionals, in shared decision-making with a sexual assault survivor, might await STI test results rather than provide presumptive STI treatment.
- If the initial STI tests are negative and presumptive STI treatment was not provided, STI testing can be repeated 1–2 weeks after the exposure.
- For GBMSM, a single 200 mg dose of doxycycline taken within 72 hours of condomless sex (doxycycline postexposure prophylaxis, or "doxy-PEP") might be considered as part of a comprehensive approach to STI care.

Laboratory Testing and PEP Follow-Up *(Cont'd)*

- **Follow-up care** is necessary for patients prescribed PEP medications to monitor for adverse effects, follow up laboratory testing, support adherence, and optimize HIV prevention strategies (e.g., transitioning to PrEP when indicated).

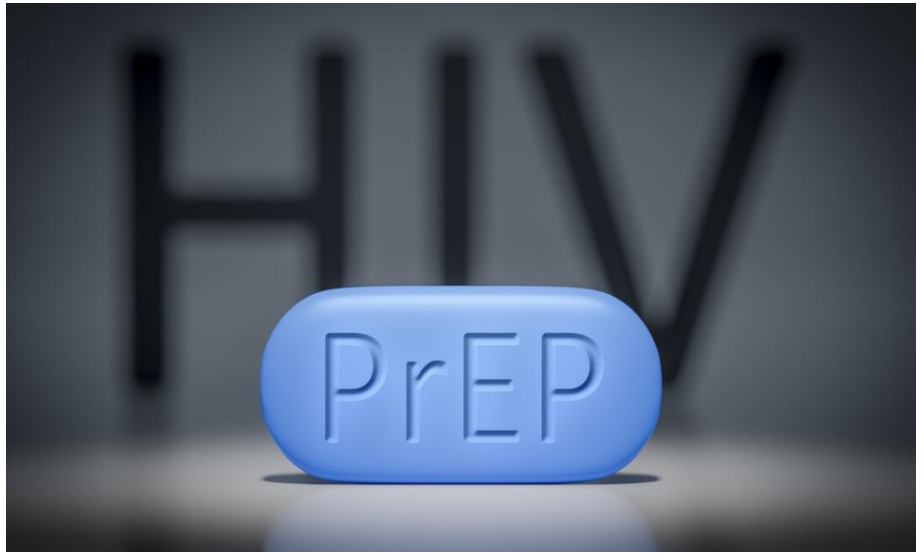
- Before the person leaves the initial PEP encounter, a **plan** for the recommended follow-up visits and testing should be in place, with appropriate referrals and resources provided.

TABLE 3. Recommended schedule of laboratory evaluations of source and persons exposed to HIV who are evaluated for HIV nonoccupational postexposure prophylaxis — CDC recommendations, United States, 2025

	Source	Exposed			
	Baseline	Baseline	4–6 weeks after exposure	12 weeks after exposure	6 months after exposure
Test*	**All persons evaluated for nPEP**				
Rapid (point-of-care) or laboratory-based HIV Ag/Ab test†	X	X	X§	X	—
HIV diagnostic NAT¶	X**	X**	X§	X	—
HBV serology, including HBsAg, HBsAb, and HBcAb	X	X††	—	—	If HBV nonimmune at baseline
HCV antibody testing	—	X§§	—	—	If follow-up testing recommended¶¶
HCV RNA NAT	X***	—	If follow-up testing recommended†††	—	—
Syphilis serology§§§	X	X	X¶¶¶	X¶¶¶	—
Gonorrhea NAAT****	X****	X****	—	—	—
Chlamydia NAAT****	X****	X****	—	—	—
Pregnancy test††††	—	X	X	—	—
	All persons prescribed nPEP				
Serum creatinine		X	Only if abnormalities at baseline	—	
Alanine transaminase and aspartate aminotransferase		X	Only if abnormalities at baseline or symptomatic	—	

CDC 2025

Pre-Exposure Prophylaxis (PrEP)



- PrEP refers to the use of antiretroviral medication to reduce the risk of acquiring HIV, especially among individuals who are at high risk of HIV.

- Research suggests that if used correctly and consistently, it can reduce the risk of HIV by over **90%** among those who are sexually exposed and by around **70%** among those who inject drugs.

Who are eligible

	Sexually-Active Adults and Adolescents[1]	Persons Who Inject Drug[2]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[3] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥30 ml/min[4] • No contraindicated medications	

PrEP Medications

- Daily TDF/FTC (2012)
- Daily TAF/FTC (2019)
- Monthly vaginal Dapivirine ring (2020)
- long-acting injectable Cabotegravir (2021)
- Long-acting injectable Lenacapavir (2025)

Follow up on oral PrEP

Test	Screening/Baseline Visit	Q 3 months	Q 6 months	Q 12 months	When stopping PrEP
HIV Test	X*	X			X*
eCrCl	X		If age ≥50 or eCrCL <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥90 ml/min at PrEP initiation	X
Syphilis	X	MSM /TGW	X		MSM/TGW
Gonorrhea	X	MSM /TGW	X		MSM /TGW
Chlamydia	X	MSM /TGW	X		MSM /TGW
Lipid panel (F/TAF)	X			X	
Hep B serology	X				
Hep C serology	MSM, TGW, and PWID only			MSM,TGW, and PWID only	

Cabotegravir

- 600 mg of Cabotegravir injected into gluteal muscle every 2 months
- Follow up

Test	Initiation Visit	1 month visit	Q2 months	Q4 months	Q6 months	Q12 months	When Stopping CAB
HIV*	X	X	X	X	X	X	X
Syphilis	X			MSM^/TGW~ only	Heterosexually active women and men only	X	MSM/TGW only
Gonorrhea	X			MSM/TGW only	Heterosexually active women and men only	X	MSM/TGW only
Chlamydia	X			MSM/TGW only	MSM/TGW only	Heterosexually active women and men only	MSM/TGW only

* HIV-1 RNA assay
X all PrEP patients
^ men who have sex with men
~ persons assigned male sex at birth whose gender identification is female

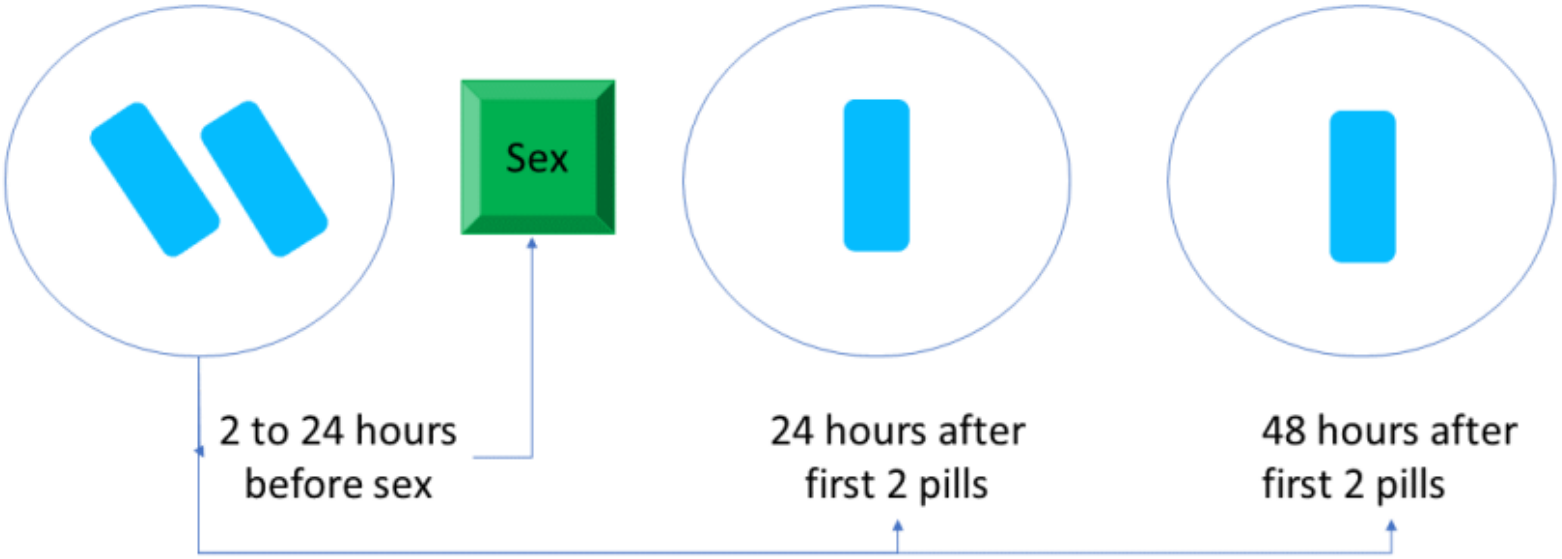
Lenacaprevir

Initiation	
Day 1	927 mg by subcutaneous injection (2 x 1.5 mL injections) and 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Continuation	
927 mg by subcutaneous injection (2 x 1.5 mL injections) every 6-months (26 weeks) from the date of the last injection +/-2 weeks.	

Nondaily Oral Prep Regimens For MSM

- **Some clinicians may choose to prescribe F/TDF off-label using "2-1-1" dosing for adult MSM who request non-daily dosing and who**
  - **have sex infrequently (e.g., less often than once a week)**

    and
  - **can anticipate sex (or delay sex) to permit the doses at least 2 hours prior to sex**



PrEP vs. PEP

When you take steps to protect yourself against a disease, like HIV, it's called prophylaxis. PrEP and PEP are for protecting people who are HIV negative.

PrEP		PEP
PrEP stands for pre-exposure prophylaxis.	**What's it called?**	PEP stands for post-exposure prophylaxis.
Before HIV exposure. PrEP is taken before sex, drug use, or other HIV exposure.	**When is it taken?**	**After HIV exposure.** In emergency situations, PEP is started within 72 hours after possible exposure, and taken for a month thereafter.
PrEP is for people who don't have HIV and: • are at risk of getting HIV from sex • are at risk of getting HIV from injection drug use	**Who's it for?**	PEP is for people who don't have HIV but may have been exposed: • during sex • during a sexual assault • at work through a needlestick or other injury • by sharing injection drug equipment
Consistent use of PrEP can reduce the risk of getting HIV from sex by about 99% and from injection drug use by at least 74%.	**How effective is it?**	PEP can prevent HIV when taken correctly, but it is not always effective. Start PEP as soon as possible to give it the best chance of working.
Ask your health care provider about a prescription for PrEP, or use PrEPlocator.org to find a health care provider in your area who can prescribe PrEP.	**How do you get it?**	Within 72 hours after potential exposure to HIV, get a PEP prescription from your health care provider, urgent care, or an emergency room.

For more information, visit HIVinfo.NIH.gov.

HIVinfo.NIH.gov

Thank You

World AIDS Day 2025

Ending Stigma Through Awareness & Education