Supplementary Appendix A: Recommendation Strength & Rationale

1a. Recommendation Strength & Rationale for all Recommendations

Recommendation	Category	Rationale	Notes/References
HIV nPEP Indications			
1. nPEP is recommended when there has been an exposure within the last 72 hours that presents a substantial risk of HIV transmission, and the source has HIV without sustained viral suppression or their viral suppression information is not known.	**Good Practice Statement**	**Existing Recommendation**	2016 nPEP Guidelines[1]: Page 8, Summary of Guidance, Page 26, HIV Status of the Exposure Source
2. A case-by-case determination is required when there has been an exposure within the last 72 hours that presents a substantial risk of HIV transmission, but it is not known whether the source has HIV.	**Good Practice Statement**	**Existing Recommendation**	2016 nPEP Guidelines[1]: Page 9, Summary of Guidance
3. nPEP is not recommended if the exposure presents no substantial risk of HIV transmission.	**Good Practice Statement**	**Existing Recommendation**	2016 nPEP Guidelines[1]: Page 9, Summary of Guidance, Page 23, Initial Evaluation of Persons Seeking Care After Potential Nonoccupational Exposure to HIV
4. nPEP should be stopped if at any point during the course the source is determined not to have HIV.	**Good Practice Statement**	**Existing Recommendation**	2016 nPEP Guidelines[1]: Page 8, Summary of Guidance, Page 24, HIV Status of the Potentially Exposed Person
Time to Initiation of HIV nPEP			
1. Initiate nPEP as soon as possible, but no later than 72 hours after exposure.	**Good Practice Statement**	**Existing Recommendation**	2016 nPEP Guidelines[1]: Page 24, Timing and Frequency of Exposure, Page 45, Conclusion
HIV nPEP Regimens			

Recommendation	Category	Rationale	Notes/References
1. Complete a clinical assessment prior to prescribing nPEP, including assessing for medical co-morbidities, current medications, and allergies.	**Good Practice Statement**	**Standard of Care**	Informed by oPEP 2013 Guidelines and HHS Adult and Adolescent Antiretroviral Guidelines Treatment Guidelines [2,3]; clarified to reflect current standard of care as informed by subject matter experts.
2. The recommended nPEP course is 28 days.	**Good Practice Statement**	**Existing Recommendation**	2016 nPEP Guidelines[1]: Page 9, Summary of Guidance, Page 11, Possible Effectiveness of nPEP Page 30 Recommended Antiretroviral nPEP Regimens
3. The preferred regimens for adults and adolescents without relevant contraindications are:	**Recommendation**		Appendix A: GRADE Tables
a. Bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF);		**Very-low Certainty of Evidence**	Appendix A: GRADE Tables
b. Dolutegravir (DTG) plus [tenofovir alafenamide (TAF) OR tenofovir DF (TDF)] plus [emtricitabine (FTC) OR lamivudine (3TC)]		**Very-low Certainty of Evidence**	Appendix A: GRADE Tables
4. Selection of a regimen should be individualized based on comorbid conditions (e.g., renal or hepatic dysfunction), pregnancy, drug interaction potential with concurrent medications, prior exposure to ARV regimens (including long-acting injectable ARV exposure), the source's history, and regimen factors that may influence continuation of treatment (e.g., pill burden, dosing frequency, side effects, cost and access).	**Good Practice Statement**	**Standard of Care**	Informed by oPEP 2013 Guidelines and HHS Adult and Adolescent Antiretroviral Guidelines Treatment Guidelines[2,3]; clarified to reflect current standard of care as informed by subject matter experts.
Laboratory Testing and nPEP Follow-up			
1. Persons being assessed due to a known or possible exposure to HIV should be tested for HIV.	**Good Practice Statement**	**Existing Recommendation**	2016 nPEP Guidelines[1]: Table 2 (page 27); HIV Testing at the Initial Visit (page 29)

Recommendation	Category	Rationale	Notes/References
2. At the initial nPEP medical visit, a rapid (also referred to as point-of-care) or laboratory-based antigen/antibody combination (Ag/Ab) HIV test is recommended.	**Good Practice Statement**	**Existing Recommendation**	2016 nPEP Guidelines[1]: Table 2 (page 27); HIV Testing at the Initial Visit (page 29)
3. For persons with long-acting injectable PrEP ARV exposure in the last 12 months, a diagnostic HIV nucleic acid test (NAT) is recommended at the initial medical evaluation, in addition to an Ag/Ab HIV test.	**Good Practice Statement**	**Indirect Data; Existing Recommendation**	Pharmacokinetic mechanism of action[4]; 2021 PrEP Guidelines[5]: Laboratory Testing for CAB PrEP Patients (page 48)
4. Perform interim HIV testing with both a laboratory-based HIV Ag/Ab test plus a diagnostic HIV at weeks 4-6 after exposure.* *HIV testing at 4-6 weeks post nPEP initiation may be deferred for persons who started nPEP within 24 hours of a known or possible HIV exposure and who did not miss any nPEP doses.	**Good Practice Statement**	**Standard of Care**	2016 nPEP Guidelines[1]: Table 2 (page 27). Clarified to reflect current standard of care as informed by subject matter experts. See also Appendix A: GRADE Table.
5. Perform final HIV tests using lab-based HIV Ag/Ab combination immunoassay and diagnostic HIV NAT at week 12 after exposure.	**Good Practice Statement**	**Standard of Care**	2016 nPEP Guidelines[1]: Table 2 (page 27). Clarified to reflect current standard of care as informed by subject matter experts. See also Appendix A: GRADE Table.
6. Routine laboratory testing recommended for persons starting nPEP includes serum creatinine, alanine aminotransferase (ALT), and aspartate aminotransferase (AST), as well as HIV, hepatitis B virus (HBV), and pregnancy testing.	**Good Practice Statement**	**Existing Recommendation**	2016 nPEP Guidelines[1]: Table 2 (page 27); Baseline and Follow-up Testing to Assess Safety of Antiretroviral Use for nPEP (page 30)
7. Testing and treatment of hepatitis C virus (HCV) infection, other sexually transmitted infections including gonorrhea, chlamydia, and syphilis, and other medical treatment should be tailored to the clinical situation.	**Good Practice Statement**	**Existing Recommendation**	2016 nPEP Guidelines[1]: Table 2 (page 27); STI Testing (page 29); Baseline and Follow-up Testing to Assess Safety of Antiretroviral Use for nPEP (page 30)
Transitioning to PrEP after PEP			
1. An immediate transition from nPEP to PrEP, including HIV testing at the completion of the nPEP regimen with a prompt transition	**Good Practice Statement**	**Existing Recommendation**	2021 PrEP Guidelines[5]: Page 36 Nonoccupational

Recommendation	Category	Rationale	Notes/References
to a recommended PrEP regimen, may be beneficial for persons with anticipated repeat or ongoing potential HIV exposures.			Postexposure Prophylaxis. See also Appendix A: GRADE Tables.

1b. Recommendation Justification for Dolutegravir and/or Bictegravir-based ART Regimens

Component	Justification
Supporting evidence	Three open-label single arm trials, one retrospective cohort, one prospective cohort.
Level of certainty/confidence in evidence	Low to very-low: Despite concerns over small sample sizes or numbers of studies and unclear compliance with PEP, it is not anticipated that these findings will change in light of increased use of PrEP among non-occupational populations and the concomitant reduction in cases. (see Appendix A: Grade Tables)
Benefits	No difference in HIV seroconversion between dolutegravir- or bictegravir-based ART regimens; and a decreased occurrence of adverse events resulting in an increased adherence to PEP with dolutegravir- and bictegravir-based ART regimens.
Risks and harms	No increase in harms or risks with the use of dolutegravir-based ART regimens.
Resource use	Dolutegravir- or bictegravir-based ART regimens may be associated with increased financial resource use; however, this data was not retrieved from the evidence.
Benefit-Harm Assessment	Benefits outweigh harms
Value Judgements	Values include reducing patient harm, reducing pill burden, reducing side effects, and prioritizing adherence.
Intentional Vagueness	There is no prioritization of recommended regimens.

References:

1. Dominguez KL, Smith DK, Thomas V, et al. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016. 2016;
2. Kuhar DT, Henderson DK, Struble KA, et al. *Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis.* . 2013. 2013. https://stacks.cdc.gov/view/cdc/20711
3. US Department of Health Human Services. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. 2024.

4. Hodge D, Back DJ, Gibbons S, Khoo SH, Marzolini C. Pharmacokinetics and Drug-Drug Interactions of Long-Acting Intramuscular Cabotegravir and Rilpivirine. *Clin Pharmacokinet*. Jul 2021;60(7):835-853. doi:10.1007/s40262-021-01005-1
5. Centers for Disease Control and Prevention. *Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline*. 2021. 2021. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Supplementary Appendix B: GRADE Tables

Background

The guideline update systematic review literature search included the Medline, Embase, PsycINFO, Cochrane Library, CINAHL, and Scopus databases from 2015-2024. The GRADE process was applied to studies identified in the literature search that were contributory to the topics considered by the workgroup. Evidence not amenable to GRADE evaluation may have informed good practice statements. Evidence sources considered by the workgroup included: studies identified through the literature review; studies referenced in the 2016 guidelines; other relevant U.S. guidelines including those relating to oPEP, HIV treatment, perinatal HIV prophylaxis, and testing; selected international nPEP guidelines; and relevant studies identified by the workgroup or subject matter experts. References are provided throughout the guideline text to provide framework for the sources considered in the recommendation topic areas; additionally, Appendix B provides a detailed narrative review of the evidence informing specific ARV recommendations. For GRADE criteria, the Newcastle-Ottawa scale was applied to each study to assess for bias.[1] Other GRADE criteria were applied as described in the GRADE Handbook.[2]

Contents

1a. Bictegravir

Studies included:

1. Mayer KH, Gelman M, Holmes J, et al. Safety and Tolerability of Once Daily Coformulated Bictegravir, Emtricitabine, and Tenofovir Alafenamide for Postexposure Prophylaxis After Sexual Exposure. J Acquir Immune Defic Syndr. 2022 May 1;90(1):27-32. doi: 10.1097/QAI.0000000000002912.
2. Liu A, Xin R, Zhang H, et al. An open-label evaluation of safety and tolerability of coformulated bictegravir/emtricitabine/tenofovir alafenamide for post-exposure prophylaxis following potential exposure to human immunodeficiency virus-1. Chin Med J (Engl). 2022 Nov 20;135(22):2725-2729. doi: 10.1097/CM9.0000000000002494.

Question: Is bictegravir (plus 2 NRTIs) an effective nPEP regimen for adults, adolescents, and children?							
Outcome: HIV acquisition							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
2	Two open-label single arm trials, not designed to evaluate BIC-based PEP efficacy for HIV prevention, but no HIV seroconversions for persons using BIC-based PEP (N=164)	Very serious	No	Serious	Serious	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very low

Question: Is bictegravir (plus 2 NRTIs) a tolerable nPEP regimen for adults, adolescents, and children?							
Outcome: Regimen completion							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
2	Two open-label single arm trials	Very serious	No	No	No	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very low

	Mayer et al, 2022: Completion rate (as prescribed) 90.4%, significantly higher than historical controls Liu et al, 2022: Completion rate 96.4%						

1b. Darunavir

Studies included:

1. Fatkenheuer G, Jessen H, Stoehr A. PEPDar: A randomized prospective noninferiority study of ritonavir-boosted darunavir for HIV post-exposure prophylaxis. HIV Med. 2016 Jun;17(6):453-9.
2. Kumar T, Sampsel K, Stiell IG. Two, three, and four-drug regimens for HIV post-exposure prophylaxis in a North American sexual assault victim population. Am J Emerg Med. 2017 Dec;35(12):1798-1803.

Question: Is darunavir (plus 2 NRTIs) an effective nPEP regimen for adults, adolescents, and children?							
Outcome: HIV acquisition							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
2	1 randomized controlled trial (RCT) and 1 retrospective cohort study, neither designed to evaluate DRV/r-based PEP efficacy for HIV prevention, but no HIV acquisitions in DRV/r-based PEP groups	Serious	No	Serious	Serious	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very low

Question: Is darunavir (plus 2 NRTIs) a tolerable nPEP regimen for adults, adolescents, and children?							
Outcome: Regimen completion							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
3	Fatkenheuer G et al, 2016: DRV/r-based PEP non-inferior to standard of care (LPV/r-based PEP), early	Serious	Serious	No	No	Recommendations also informed by additional sources (see Appendix A,	Very low

	discontinuation rates 6.5% and 10% respectively in per-protocol analysis Kumar T et al, 2017: Other regimens had higher completion rates compared to DRV/r-based PEP (66.0% vs. 42.2%; p = 0.03)					Background for additional information)	

1c. Dolutegravir

Studies included:

1. Gantner P, Allavena C, Duvivier C, Cabie A, Reynes J, Makinson A, Ravaux I, Bregigeon S, Cotte L, Rey D; Dat'AIDS Study Group. Post-exposure prophylaxis completion and condom use in the context of potential sexual exposure to HIV. HIV Med. 2020 Aug;21(7):463-469.
2. Nie J, Sun F, He X, Liu J, Wang M, Li C, Gu S, Chen Z, Li Y, Chen Y. Tolerability and Adherence of Antiretroviral Regimens Containing Long-Acting Fusion Inhibitor Albuvirtide for HIV Post-Exposure Prophylaxis: A Cohort Study in China. Infect Dis Ther. 2021 Dec;10(4):2611-2623.
3. McAllister JW, Towns JM, Mcnulty A, Pierce AB, Foster R, Richardson R, Carr A. Dolutegravir with tenofovir disoproxil fumarate-emtricitabine as HIV postexposure prophylaxis in gay and bisexual men. AIDS. 2017 Jun 1;31(9):1291-1295.

Question: Is dolutegravir (plus 2 NRTIs) an effective nPEP regimen for adults, adolescents, and children?							
Outcome: HIV acquisition							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
3	1 retrospective cohort, 1 prospective cohort, and one open-label single arm trial. None designed to evaluate DTG-based PEP efficacy for HIV prevention. Gantner et al, 2020: 3 persons diagnosed with HIV (1 in PEP group stopped LPV/r-based PEP; 2 did not receive PEP) Nie et al, 2021 and McAllister et al, 2017: No HIV acquisitions	Serious	Serious	Very Serious	No	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very low

Question: Is dolutegravir (plus 2 NRTIs) a tolerable nPEP regimen for adults, adolescents, and children?							
Outcome: Regimen completion							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
3	1 retrospective cohort, 1 prospective cohort, and one open-label single arm trial. None designed to evaluate DOL-based PEP efficacy for HIV prevention. Regimen completion range 63.6%-90%	Serious	Serious	Very Serious	No	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very low

1d. Elvitegravir

Studies included:

1. Valin, N., Fonquernie, L., Daguenel, A. et al. Evaluation of tolerability with the co-formulation elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate for post-HIV exposure prophylaxis. BMC Infect Dis, 2016; 16, 718.
2. Mayer KH, Jones D, Oldenburg C, et al. Optimal HIV Postexposure Prophylaxis Regimen Completion With Single Tablet Daily Elvitegravir/Cobicistat/Tenofovir Disoproxil Fumarate/Emtricitabine Compared With More Frequent Dosing Regimens. Journal of Acquired Immune Deficiency Syndromes. 2017 Aug;75(5):535-539.
3. Inciarte A, Leal L, González E, et al; STRIBPEP Study Group. Tenofovir disoproxil fumarate/emtricitabine plus ritonavir-boosted lopinavir or cobicistat-boosted elvitegravir as a single-tablet regimen for HIV post-exposure prophylaxis. J Antimicrob Chemother. 2017 Oct 1;72(10):2857-2861.
4. Malinverni S, Gennotte AF, Schuster M, et al. Adherence to HIV post-exposure prophylaxis: A multivariate regression analysis of a 5 years prospective cohort. J Infect. 2018 Jan;76(1):78-85.
5. Gantner P, Allavena C, Duvivier C, et al. Post-exposure prophylaxis completion and condom use in the context of potential sexual exposure to HIV. HIV Med, 2020;21: 463-469.
6. Malinverni S, Bédoret F, Bartiaux M, et al. Single-tablet regimen of emtricitabine/tenofovir disoproxil fumarate plus cobicistat-boosted elvitegravir increase adherence for HIV postexposure prophylaxis in sexual assault victims. Sexually Transmitted Infections, 2021;97:329-333.

Question: Is elvitegravir (plus 2 NRTIs) an effective nPEP regimen for adults, adolescents, and children?							
Outcome: HIV acquisition							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
6	3 cohort studies, 1 case-control study, 1 open label single arm trial, 1 RCT. None designed to evaluate efficacy of EVG-based PEP for HIV prevention. Across all studies, 2253 persons reported as prescribed EVG-based PEP. • One study did not report follow-up HIV testing results.	Very serious	No	Very serious	Serious	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very low

	• Three studies reported no HIV acquisitions among persons taking EVG-based PEP who completed follow-up. • One study reported a person acquired HIV as a possible nPEP failure, but the nPEP regimen was not specified. • One study reported one HIV acquisition in a person taking EVG-based PEP who had high-risk possible HIV exposures before and after PEP use.						

Question: Is elvitegravir (plus 2 NRTIs) a tolerable nPEP regimen for adults, adolescents, and children?							
Outcome: Regimen completion							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
6	3 cohort studies, 1 case-control study, 1 open label single arm trial, 1 RCT One study did not have a comparison group; other studies compared EVG-based regimens with a variety of different PEP regimens. In comparing EVG-based regimens to other PEP regimens: • Two studies found lower PEP regimen completion rates with EVG-based PEP regimens • One study found no difference • Two studies found higher PEP regimen completion rates with EVG-based PEP regimens	Very serious	Very serious	Very serious	No	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very low

	• Completion rates for EVG-based regimens ranged from 44%-92%						

1e. Lopinavir

Studies included:

1. Chughlay MF, Njuguna C, Cohen K, Maartens G. Acute interstitial nephritis caused by lopinavir/ritonavir in a surgeon receiving antiretroviral postexposure prophylaxis. AIDS. 2015 Feb 20;29(4):503-4.
2. Alves M, Janneau-Magrino L, Legendre N, et al. Human immunodeficiency virus post-exposure prophylaxis: primum non nocere. Am J Med. 2015 Apr;128(4):e3-4.
3. Bogoch II, Siemieniuk RA, Andrews JR, et al. Changes to Initial Postexposure Prophylaxis Regimens Between the Emergency Department and Clinic. J Acquir Immune Defic Syndr. 2015 Aug 15;69(5):e182-4.
4. Inciarte A, Leal L, González E, et al; STRIBPEP Study Group. Tenofovir disoproxil fumarate/emtricitabine plus ritonavir-boosted lopinavir or cobicistat-boosted elvitegravir as a single-tablet regimen for HIV post-exposure prophylaxis. J Antimicrob Chemother. 2017 Oct 1;72(10):2857-2861.
5. Malinverni S, Bédoret F, Bartiaux M, et al. Single-tablet regimen of emtricitabine/tenofovir disoproxil fumarate plus cobicistat-boosted elvitegravir increase adherence for HIV postexposure prophylaxis in sexual assault victims. Sexually Transmitted Infections, 2021;97:329-333.
6. Gantner P, Allavena C, Duvivier C, et al. Post-exposure prophylaxis completion and condom use in the context of potential sexual exposure to HIV. HIV Med, 2020;21: 463-469.
7. Fatkenheuer G, Jessen H, Stoehr A. PEPDar: A randomized prospective noninferiority study of ritonavir-boosted darunavir for HIV post-exposure prophylaxis. HIV Med. 2016 Jun;17(6):453-9.
8. Leal L, Leon A, Torres B, et al. A randomized clinical trial comparing ritonavir-boosted lopinavir versus raltegravir each with tenofovir plus emtricitabine for post-exposure prophylaxis for HIV infection. J Antimicrob Chemother. 2016 Jul;71(7):1987-93.
9. Mulka L, Annandale D, Richardson C, et al. Raltegravir-based HIV postexposure prophylaxis (PEP) in a real-life clinical setting: fewer drug-drug interactions (DDIs) with improved adherence and tolerability. Sex Transm Infect. 2016 Mar;92(2):107.
10. Lunding S, Katzenstein TL, Kronborg G, et al. The Danish PEP Registry: Experience with the use of post-exposure prophylaxis following blood exposure to HIV from 1999-2012. Infect Dis (Lond). 2016;48(3):195-200.
11. Milinkovic A, Benn P, Arenas-Pinto A, et al. Randomized controlled trial of the tolerability and completion of maraviroc compared with Kaletra® in combination with Truvada® for HIV post-exposure prophylaxis (MiPEP Trial). J Antimicrob Chemother. 2017 Jun 1;72(6):1760-1768.
12. Mohamedi N, Mirault T, Durivage A, et al. Ergotism with acute limb ischemia, provoked by HIV protease inhibitors interaction with ergotamine, rescued by multisite transluminal balloon angioplasty. J Med Vasc. 2021 Feb;46(1):13-21.

Question: Is lopinavir (plus 2 NRTIs) an effective nPEP regimen for adults, adolescents, and children?

Outcome: HIV acquisition							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
12	3 case reports, 4 cohort studies, 1 case-control study, and 4 open-label trials. None designed to evaluate efficacy of LPV-based PEP for HIV prevention. No reports of HIV acquisition among persons completing LPV-based PEP; two HIV acquisitions among persons who stopped LPV-based PEP early in course.	Serious	No	Very serious	Serious	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very Low

Question: Is lopinavir (plus 2 NRTIs) a tolerable nPEP regimen for adults, adolescents, and children?							
Outcome: Regimen completion							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
12	3 case reports, 4 cohort studies, 1 case-control study, and 4 open-label trials. There were case reports of LPV/r discontinuation due to serious adverse events (suspected acute interstitial nephritis, drug interaction with dihydroergotamine). Among the	Serious	Serious	Serious	Serious	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very Low

	larger randomized trials and cohort studies, estimated regimen completion rates ranged from 46%-90%.						

1f. Raltegravir

Studies included:

1. Gupta M. HIV Post Exposure Prophylaxis and Risk of Relapse in Adolescent With Bipolar Illness and Psychopharmacologic Challenges. Cureus. 2021 Mar 9;13(3):e13777.
2. Quah SP, McIntyre M, Wood A, et al. Once-daily raltegravir with tenofovir disoproxil/emtricitabine as HIV post-exposure prophylaxis following sexual exposure. HIV Med. 2021 Feb;22(2):e5-e6.
3. Gantner P, Allavena C, Duvivier C, et al. Dat'AIDS Study Group. Post-exposure prophylaxis completion and condom use in the context of potential sexual exposure to HIV. HIV Med. 2020 Aug;21(7):463-469.
4. Nolan A, Yarosh D, Shaikh S. Mitigating Risk: Post-Exposure Prophylaxis in Liver Transplant Recipients from Donors with Potential Infectious Exposure. Am J Transplant. 2017;17 (suppl 3).
5. Mayer KH, Jones D, Oldenburg C, et al. Optimal HIV Postexposure Prophylaxis Regimen Completion With Single Tablet Daily Elvitegravir/Cobicistat/Tenofovir Disoproxil Fumarate/Emtricitabine Compared With More Frequent Dosing Regimens. J Acquir Immune Defic Syndr. 2017 Aug 15;75(5):535-539.
6. Beymer MR, Weiss RE, Bolan RK, et al. Differentiating Nonoccupational Postexposure Prophylaxis Seroconverters and Non-Seroconverters in a Community-Based Clinic in Los Angeles, California. Open Forum Infect Dis. 2017 Apr 4;4(2):ofx061.
7. Mulka L, Annandale D, Richardson C, et al. Raltegravir-based HIV postexposure prophylaxis (PEP) in a real-life clinical setting: fewer drug-drug interactions (DDIs) with improved adherence and tolerability. Sex Transm Infect. 2016 Mar;92(2):107.
8. Leal L, León A, Torres B, et al; RALPEP Study Group. A randomized clinical trial comparing ritonavir-boosted lopinavir versus raltegravir each with tenofovir plus emtricitabine for post-exposure prophylaxis for HIV infection. J Antimicrob Chemother. 2016 Jul;71(7):1987-93.
9. Bogoch II, Siemieniuk RA, Andrews JR, et al. Changes to Initial Postexposure Prophylaxis Regimens Between the Emergency Department and Clinic. J Acquir Immune Defic Syndr. 2015 Aug 15;69(5):e182-4.
10. Wu Y, Zhu Q, Zhou Y, et al. Implementation of HIV non-occupational post-exposure prophylaxis for men who have sex with men in 2 cities of Southwestern China. Medicine (Baltimore). 2021 Oct 29;100(43):e27563.
11. Kumar T, Sampsel K, Stiell IG. Two, three, and four-drug regimens for HIV post-exposure prophylaxis in a North American sexual assault victim population. Am J Emerg Med. 2017 Dec;35(12):1798-1803.
12. Inciarte A, Leal L, Masfarre L, et al; Sexual Assault Victims Study Group. Post-exposure prophylaxis for HIV infection in sexual assault victims. HIV Med. 2020 Jan;21(1):43-52.
13. Thomas R, Galanakis C, Vézina S, et al. Adherence to Post-Exposure Prophylaxis (PEP) and Incidence of HIV Seroconversion in a Major North American Cohort. PLoS One. 2015 Nov 11;10(11):e0142534.
14. Ebert J, Sperhake JP, Degen O, Schröder AS. The use of HIV post-exposure prophylaxis in forensic medicine following incidents of sexual violence in Hamburg, Germany: a retrospective study. Forensic Sci Med Pathol. 2018 Sep;14(3):332-341.

Question: Is raltegravir (plus 2 NRTIs) an effective nPEP regimen for adults, adolescents, and children?							
Outcome: HIV acquisition							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
14	1 RCT, 2 case-control studies, 1 case report, 10 observational cohort studies. Rare reports of HIV acquisitions among persons on RAL-based PEP (N=3101): • 3 studies did not report HIV acquisitions • 1 HIV acquisition at day 90 in a person who had completed RAL-based PEP with multiple potential HIV exposures before and after receiving PEP • 1 study with 3 HIV acquisitions in persons receiving RAL-based PEP; not significantly different than compared regimens in multivariate regression • 3 studies reported at least 1 seroconversion, however, the PEP regimen was not specified, and all but one seroconversion across all of these studies	Very serious	No	Very serious	Serious	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very low

	had continued subsequent high-risk behaviors						

Question: Is raltegravir (plus 2 NRTIs) a tolerable nPEP regimen for adults, adolescents, and children?							
Outcome: Regimen completion							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
14	1 RCT, 2 case-control studies, 1 case report, 10 observational cohort studies. Variability in completion rates across studies, with completion ranging from 32%-96.4%. Four studies reported a RAL completion rate of ≥80%. Eight studies did not have RAL-specific completion rate reported.	Very serious	Very serious	Very serious	No	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very low

1g. Tenofovir alafenamide

Studies included:

1. Mayer KH, Gelman M, Holmes J, et al. Safety and Tolerability of Once Daily Coformulated Bictegravir, Emtricitabine, and Tenofovir Alafenamide for Postexposure Prophylaxis After Sexual Exposure. J Acquir Immune Defic Syndr. 2022 May 1;90(1):27-32.
2. Liu A, Xin R, Zhang H, et al. An open-label evaluation of safety and tolerability of coformulated bictegravir/emtricitabine/tenofovir alafenamide for post-exposure prophylaxis following potential exposure to human immunodeficiency virus-1. Chin Med J (Engl). 2022 Nov 20;135(22):2725-2729.
3. Gantner P, Allavena C, Duvivier C, et al. Post-exposure prophylaxis completion and condom use in the context of potential sexual exposure to HIV. HIV Med. 2020;21(7):463-469.
4. Gantner P, Hessamfar M, Souala MF, et al. Elvitegravir-Cobicistat-Emtricitabine-Tenofovir Alafenamide Single-tablet Regimen for Human Immunodeficiency Virus Postexposure Prophylaxis. Clin Infect Dis. 2020;70(5):943-946.
5. Chauveau M, Secher S, Allavena C, et al. Tolerability and treatment completion of tenofovir alafenamide/emtricitabine/rilpivirine (TAF/FTC/RPV) as HIV postexposure prophylaxis. In: Program and abstracts of the 17th European AIDS Conference. Basel, Switzerland: 2019:257.

Question: Is TAF (plus 2 other ARVs) an effective nPEP regimen for adults, adolescents, and children?							
Outcome: HIV acquisition							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
5	Four open label, single arm trials and one cohort study; none designed to evaluate HIV prevention efficacy of TAF-containing PEP regimens. HIV acquisitions assessed in all 5 studies with no reported cases of HIV acquisition among persons on TAF-based PEP (N=479).	Very Serious	No	Serious	Serious	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very low

Question: Is TAF (plus 2 other ARVs) a tolerable nPEP regimen for adults, adolescents, and children?							
Outcome: Regimen completion							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
5	Four open label, single arm trials and one cohort study. Total on TAF-containing regimens across studies (N=479). Among 4 studies reporting completion rates of various TAF-containing regimens, the completion rates ranged from 82%-96.4%	Very Serious	No	Serious	No	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very Low

1h. Tenofovir disoproxil fumarate

Studies included:

1. Gantner P, Allavena C, Duvivier C, et al; Dat'AIDS Study Group. Post-exposure prophylaxis completion and condom use in the context of potential sexual exposure to HIV. HIV Med. 2020 Aug;21(7):463-469.
2. Jain S, Oldenburg CE, Mimiaga MJ, Mayer KH. Longitudinal trends in HIV nonoccupational postexposure prophylaxis use at a Boston community health center between 1997 and 2013. J Acquir Immune Defic Syndr. 2015 Jan 1;68(1):97-101.
3. Lunding S, Katzenstein TL, Kronborg G, et al. The Danish PEP Registry: Experience with the use of post-exposure prophylaxis following blood exposure to HIV from 1999-2012. Infect Dis (Lond). 2016;48(3):195-200.
4. Penot P, Gosset C, Verine J, Molina JM. Tenofovir disoproxil fumarate-induced Fanconi's syndrome during HIV postexposure prophylaxis. AIDS. 2016 May 15;30(8):1311-3.

Question: Is TDF (plus 2 other ARVs) an effective nPEP regimen for adults, adolescents, and children?							
Outcome: HIV acquisition							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
4	3 cohort studies and 1 case report, none designed to evaluate TDF-containing PEP regimens for HIV prevention efficacy. Among studies reporting both regimen and final HIV infection status, there were 14,305 courses of TDF-containing PEP prescribed. Among those who completed follow-up there was only 1 HIV acquisition diagnosed, and the regimen of TDF+FTC+LPV/r was stopped early in the course.	Serious	No	Very Serious	Serious	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very Low

Question: Is TDF (plus 2 other ARVs) a tolerable nPEP regimen for adults, adolescents, and children?

Outcome: Regimen completion							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
4	3 cohort studies and 1 case report. The PEP regimens and completion rates varied across studies. Among cohort studies that reported regimen completion by regimen, the range of completion was 74.5-96.4%.	Very Serious	Serious	Very Serious	Serious	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very Low

2a. nPEP Efficacy and Duration

Studies included:

1. Thomas R, Galanakis C, Vézina S, et al. Adherence to Post-Exposure Prophylaxis (PEP) and Incidence of HIV Seroconversion in a Major North American Cohort. PLoS One. 2015 Nov 11;10(11):e0142534.
2. Leal L, Leon A, Torres B, et al. A randomized clinical trial comparing ritonavir-boosted lopinavir versus raltegravir each with tenofovir plus emtricitabine for post-exposure prophylaxis for HIV infection. J Antimicrob Chemother. 2016 Jul;71(7):1987-93.
3. Beymer MR, Weiss RE, Bolan RK, et al. Differentiating Nonoccupational Postexposure Prophylaxis Seroconverters and Non-Seroconverters in a Community-Based Clinic in Los Angeles, California. Open Forum Infect Dis. 2017 Apr 4;4(2):ofx061.
4. Inciarte A, Leal L, González E, et al; STRIBPEP Study Group. Tenofovir disoproxil fumarate/emtricitabine plus ritonavir-boosted lopinavir or cobicistat-boosted elvitegravir as a single-tablet regimen for HIV post-exposure prophylaxis. J Antimicrob Chemother. 2017 Oct 1;72(10):2857-2861.
5. Milinkovic A, Benn P, Arenas-Pinto A, et al. Randomized controlled trial of the tolerability and completion of maraviroc compared with Kaletra® in combination with Truvada® for HIV post-exposure prophylaxis (MiPEP Trial). J Antimicrob Chemother. 2017 Jun 1;72(6):1760-1768.
6. Beymer MR, Kofron RM, Tseng CH, et al. Results from the post-exposure prophylaxis pilot program (P-QUAD) demonstration project in Los Angeles County. Int J STD AIDS. 2018 May;29(6):557-562.
7. Chauveau M, Billaud E, Bonnet B, et al. Tenofovir DF/emtricitabine/rilpivirine as HIV post-exposure prophylaxis: results from a multicentre prospective study. J Antimicrob Chemother. 2019 Apr 1;74(4):1021-1027.

Question: Does 1 month of PEP reduce the likelihood of HIV acquisition following possible or known recent HIV exposure?							
Outcome: HIV acquisition							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**

7	3 cohort studies, 2 randomized open label trials, 1 RCT, 1 open label, single arm trial. PEP duration was 28 days in all studies. 5745 PEP courses across all studies; 29 HIV acquisitions among persons with follow-up data. Of those 29 HIV acquisitions, 18 (62%) had reported known or possible HIV exposures after completing the PEP course. One large observational study found an incidence rate of 2.3 HIV infections/100 person-years among persons who initiated nPEP and had follow-up HIV testing, compared to an incidence rate of 6.92 HIV infections/100 person-years among persons with nPEP indications who did not access nPEP services; the same study found odds of HIV acquisition were approximately 4-fold higher among persons who reported incomplete nPEP adherence compared with persons who reported complete nPEP adherence (OR = 3.73; 95% CI, 1.2–11.56)	Very serious	No	Very serious	Serious	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very Low

2b. HIV Testing in nPEP Services

Studies included:

1. Beymer MR, Weiss RE, Bolan RK, et al. Differentiating Nonoccupational Postexposure Prophylaxis Seroconverters and Non-Seroconverters in a Community-Based Clinic in Los Angeles, California. Open Forum Infect Dis. 2017 Apr 4;4(2):ofx061.
2. Beymer MR, Kofron RM, Tseng CH, et al. Results from the post-exposure prophylaxis pilot program (P-QUAD) demonstration project in Los Angeles County. Int J STD AIDS. 2018 May;29(6):557-562.

Question: Does HIV NAT increase the number of HIV infections diagnosed during nPEP services, compared to ag/ab tests?							
Outcome: HIV acquisition							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
2	2 cohort studies (1 subset of the other), not designed to evaluate HIV NAT performance in the setting of nPEP services. In the overall cohort, 17 HIV acquisitions diagnosed; 3 of the 17 HIV infections were HIV NAT positive, HIV rapid ab test negative at 12 week follow-up.	Serious	No	Very serious	No	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very Low

2c. nPEP to PrEP

Studies included:

1. Johnson KA, Hessol NA, Kohn R et al. HIV Seroconversion in the Era of Pharmacologic Prevention: A Case-Control Study at a San Francisco STD Clinic. J Acquir Immune Defic Syndr. 2019 Oct 1;82(2):159-165.
2. Beymer MR, Weiss RE, Bolan RK, et al. Differentiating Nonoccupational Postexposure Prophylaxis Seroconverters and Non-Seroconverters in a Community-Based Clinic in Los Angeles, California. Open Forum Infect Dis. 2017 Apr 4;4(2):ofx061.
3. O'Byrne P, MacPherson P, Orser L. Nurse-Led HIV PEP Program Used by Men at High Risk for HIV Seroconversion. J Assoc Nurses AIDS Care. 2018 Jul-Aug;29(4):550-559.
4. Kowalska JD, Pietraszkiewicz E, Firlag-Burkacka E, Horban A. When effective post-exposure prophylaxis of HIV infection fails – data from clinical practice. HIV AIDS Rev 2017; 16: 54-57.
5. Hovaguimian F, Günthard HF, Hauser C, et al. Data linkage to evaluate the long-term risk of HIV infection in individuals seeking post-exposure prophylaxis. Nat Commun. 2021 Feb 22;12(1):1219.
6. Thomas R, Galanakis C, Vézina S, et al. Adherence to Post-Exposure Prophylaxis (PEP) and Incidence of HIV Seroconversion in a Major North American Cohort. PLoS One. 2015 Nov 11;10(11):e0142534.
7. Quah SP, McIntyre M, Wood A, et al. Once-daily raltegravir with tenofovir disoproxil/emtricitabine as HIV post-exposure prophylaxis following sexual exposure. HIV Med. 2021 Feb;22(2):e5-e6.

Question: Do persons completing nPEP have a substantial risk of HIV acquisition if not transitioning to HIV PrEP?							
Outcome: HIV acquisition							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
7	1 case-control study, 6 cohort studies Heterogeneous group of studies with varying designs, testing, and outcomes. Studies that reported exposure assessment in persons who acquired HIV during/after PEP services report a	Serious	Serious	Serious	Serious	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very Low

	high proportion of persons with known or possible HIV exposures after completion of the PEP course.						

2d. Two- versus Three- ARV nPEP Regimens

Studies included:

1. Kumar T, Sampsel K, Stiell IG. Two, three, and four-drug regimens for HIV post-exposure prophylaxis in a North American sexual assault victim population. Am J Emerg Med. 2017 Dec;35(12):1798-1803.
2. Pierce AB, El-Hayek C, McCarthy D, et al. Comparing non-occupational post-exposure prophylaxis drug regimens for HIV: insights from a linked HIV surveillance system. Sex Health. 2017 Apr;14(2):179-187.

Question: Are 2- and 3-drug nPEP regimens equally effective for HIV prevention?							
Outcome: HIV acquisition							
Number of Studies	**Findings**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Certainty**
2	2 cohort studies One study included only 16 persons who were prescribed a 2-drug PEP regimen (total n prescribed PEP=188). No HIV acquisitions documented among persons completing follow-up. One study of MSM reporting receptive anal intercourse with a source of unknown HIV serostatus; 10 HIV diagnoses made < 12 months after completing PEP; eight (0.5%) received two drugs and two (0.9%) received three drugs (P = 0.38).	Serious	No	Serious	Very Serious	Recommendations also informed by additional sources (see Appendix A, Background for additional information)	Very Low

GRADE References:

1. Wells GA, Shea B, O'Connell D, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of non-randomised studies in meta-analyses. https://www.ohri.ca/programs/clinical_epidemiology/oxford.asp. Updated 2021. Accessed December 12, 2023.

2. Grading of Recommendations, Assessment, Development and Evaluation Working Group. GRADE Handbook. https://gdt.gradepro.org/app/handbook/handbook.html#h.svwngs6pm0f2. Updated October 2013. Accessed September 21, 2023.

Supplementary Appendix C: 2024 nPEP Guideline Update Authors, Contributors, and Conflicts of Interest

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