

APPENDIX 4 (AS SUPPLIED BY THE AUTHORS) – SUMMARY OF FINDINGS TABLES

Table D1. PrEP Regimens^{ab}

Regimen	Population	PrEP	Control (Placebo or no PrEP)	Effect size (95% confidence interval) ^c	Quality of evidence	Comments	Number of participants (studies)
Outcome: HIV infection							
TDF/FTC daily	MSM & TGW	39/1487	84/1477	RR=0.31 (0.08, 1.21)	High	Includes only 339 TGW	2964 (3)
		1.8/100 PY	2.6/100 PY	HR=0.51 (0.21,1.01)	Low	Includes only 140 TGW	1225 (1)
	MSM ^d	0.26/100 PY	NA	NA	Low	All four infections occurred in persons not taking, not adherent to or just after starting PrEP	1985 (4)
	Heterosexual women	124/3671	165/3554	RR=0.63 (0.39, 1.00)	High		7225 (6) ^e
	Heterosexual men	13/2757	58/2253	RR=0.18 (0.10, 0.34)	High		5010 (4) ^e
	Heterosexual men & women	0.2/100 PY	5.2/100 PY	RR=0.04 (0.01,0.19)	Low	Control value is a simulated counterfactual result	1013 (1)
TDF/FTC on- demand	MSM	2/199	14/201	RR=0.14 (0.02, 0.60)	High	Control value is placebo	400 (1)
		0.19/100 PY	6.60/100 PY	RR=0.03 (0.00,0.19)	Low	Control value is placebo arm of randomized phase of the trial	361 (1)
TDF	MSM	0/101	7/299	RR=0.20 (0.01, 3.40)	High		400 (1)
	Heterosexual women	77/2847	97/2669	RR=0.53 (0.21, 1.37)	High		5516 (4) ^e
	Heterosexual men	25/2359	48/1918	RR=0.42 (0.26, 0.68)	High		4277 (2) ^e
	PWID	17/1204	33/1207	RR=0.51 (0.28, 0.90)	High		2411 (1)

Regimen	Population	PrEP	Control (Placebo or no PrEP)	Effect size (95% confidence interval) ^c	Quality of evidence	Comments	Number of participants (studies)
	PWID	0.21/100 PY	NA	NA	Low		573 (1)
Outcome: Any adverse event							
TDF/FTC daily	All populations	3634/5537 (65.6%)	3590/5525 (65.0%)	RR=1.01 (0.99,1.03)	High		11062 (8)
TDF/FTC on-demand	MSM	186/199 (93.5%)	181/201 (90.0%)	RR=1.58 (0.76,3.27)	High		400 (1)
TDF daily	All populations	2785/4222 (66.0%)	2800/4234 (66.1%)	RR=0.98 (0.86,1.13)	High		8456 (4)
Outcome: Resistance to PrEP medication(s) among those acquiring HIV infection							
TDF/FTC daily	All populations	13/219	2/242	RR=7.18 (1.64, 31.47)	High		461 (17)
TDF/FTC on-demand	MSM	0/3	0/14	Not estimable	High		17 (2)
TDF daily	All populations	1/121	0/157	RR=3.89 (0.16,94.54)	High		278 (7)

^a FTC=emtricitabine, HR=hazard ratio, MSM=men who have sex with men, NA=not applicable, P-Y=person-years, RR=risk ratio, TDF=tenofovir disoproxil fumarate.

^b Data are from fourteen randomized controlled trials¹⁻¹⁴ and nine cohort studies¹⁵⁻²³.

^c When only one study was available, the presented value represents the effect size reported in the original study. When multiple randomized studies were available, presented values were estimated through meta-analysis using random-effects models, with weighting of studies according to the inverse variance method.

^d Includes two studies^{18,19} that enrolled small numbers of non-MSM.

^e Number of participants listed here is an overestimate since data from the placebo arm of the Partners PrEP study was used as the comparator for the Partners Continuation study also.

Table D2. Recommended nPEP Regimens^{ab}

Regimen	N (%) with this regimen	N (%) with comparator: TDF/FTC/LPV/r	Risk Ratio (95% confidence interval)	Quality of evidence	Comments	Number of participants (studies)
Outcome: Completion of regimen as prescribed						
TDF/FTC/RAL	75/122 (64.1%)	63/121 (52.1%)	1.18 (0.95, 1.47)	High	Main reasons for non-completion were missing 2 nd daily dose for RAL, side effects for LPV/r	243 (1 study)
	121/205 (59.0%)	274/474 (57.8%) ^b	1.02 (0.89, 1.17)	Low	-	679 (6 studies)
TDF/FTC/DTG	90/100 (90%)	274/474 (57.8%) ^b	1.56 (1.41, 1.72)	Low	-	574 (4 studies)
TDF/FTC/DRV/r	145/155 (94%)	135/150 (90.0%) ^c	1.04 (0.97, 1.11)	High	21% were occupational PEP	305 (1 study)
Outcome: Adverse events leading to PEP discontinuation or regimen change						
TDF/FTC/RAL	2/122 (1.6%)	4/121 (3.3%)	0.50 (0.09, 2.66)	High	-	243 (1 study)
	8/424 (1.9%)	101/2511 (4.0%) ^b	0.47 (0.23, 0.96)	Low	-	2935 (8 studies)
TDF/FTC/DTG	1/100 (1.0%)	101/2511 (4.0%) ^b	0.25 (0.04, 1.76)	Low	-	2611 (5 studies)
TDF/FTC/DRV/r	1/155 (0.6%)	5/150 (3.3%) ^c	0.19 (0.02, 1.64)	High	21% were occupational PEP	305 (1 study)
Outcome: HIV infection at 3-month follow-up						
TDF/FTC/RAL	1/55 (1.8%)	0/38 (0%)	2.09 (0.09, 49.96)	Moderate ^d	All observed infections occurred in patients with ongoing exposures, except in 1 patient on TDF/FTC/LPV/r	93 (1 study)
	1/404 (0.2%)	7/2399 (2.9%) ^b	0.85 (0.10, 6.88)	Very low ^d		2803 (8 studies)
TDF/FTC/DTG	0/77 (0%)	7/2399 (2.9%) ^b	2.05 (0.12, 35.60)	Very low ^d		2476 (5 studies)
TDF/FTC/DRV/r	0/155 (0%)	0/150 (0%)	Not estimable	High	21% were occupational PEP	305 (1 study)

^a DRV/r=darunavir + ritonavir, DTG=dolutegravir, FTC=emtricitabine, LPV/r=lopinavir/ritonavir, RAL=raltegravir, TDF=tenofovir disoproxil fumarate.

^b Data are from two randomized trials^{24,25} and seven cohort studies²⁶⁻³².

^c Estimate pooled from three observational studies³⁰⁻³² and TDF/FTC/LPV/r arm from one randomized trial³³.

^d Denominator includes six patients receiving zidovudine/lamivudine + LPV/r and one patient receiving abacavir/lamivudine + LPV/r.

^e Quality of evidence downgraded for confounding (ongoing exposures in patients who seroconverted) and inconsistency.

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Canadian Guidelines on HIV PrEP and nPEP – APPENDIX 4

Appendix to: Tan DHS, Hull MW, Yoong D, et al. Canadian guideline on HIV pre-exposure prophylaxis and nonoccupational postexposure prophylaxis. *CMAJ* 2017. doi: 10.1503/cmaj.170494. Copyright © 2017 Joule Inc. or its licensors

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