National Institute for Health and Care Excellence

FINAL

Reducing sexually transmitted infections (STIs)

[G] Effectiveness, cost effectiveness, acceptability and unintended consequences of pre-exposure prophylaxis (PrEP) for HIV

NICE guideline NG221

Evidence reviews underpinning recommendations 1.5.1 to 1.5.19 and research recommendations in the NICE guideline

June 2022

Final

National Institute for Health and Care Excellence

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ISBN: 978-1-4731-4612-9

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1.1 Review question

What is the effectiveness, cost effectiveness and unintended consequences of pre-exposure prophylaxis (PrEP) for HIV?

This review question underpins the quantitative element of a mixed methods review. The qualitative review question is in section 2 of this document and the mixed methods integration is in section 3.

1.1.1 Introduction

PrEP has been available through routine commissioning on the NHS since October 2020; prior to this it's availability in the UK came from the Impact trial. Current guidance from BASHH (British Association for Sexual Health and HIV) and BHIVA (British HIV association) recommend PrEP be offered to HIV-negative men who have sex with men (MSM) identified as being at high risk of HIV acquisition through condomless anal sex and HIV negative MSM and heterosexual men and women who have condomless anal and vaginal sex with partners who are HIV positive.

The aim of this review is to determine the effectiveness and cost-effectiveness of PrEP. In addition, there has been some discussion that the availability of PrEP may result in risk compensation and reduce commitment to primary prevention of STIs, with the possibility of a resultant increase in high-risk sexual behaviour and rates of STIs. This review therefore aims to also examine the unintended consequences of PrEP.

1.1.2 Summary of the protocol

Table 1: PICO inclusion criteria

Eligibility criteria	Content
Population	HIV-negative people aged 16 and older. Excluded – studies examining PrEP for conception in sero-discordant couples
Interventions	Pre-exposure prophylaxis for HIV prevention
Comparator	No pre-exposure prophylaxis
Outcomes	Primary outcomes: • HIV rates • Adverse effects • STI rates • Changes in condom use • Other unintended consequences Secondary outcomes: • Adherence

1.1.3 Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol in appendix A and in the methods chapter.

Declarations of interest were recorded according to NICE's conflicts of interest policy.

1.1.4 Clinical evidence

1.1.4.1 Included studies

A systematic search was carried out to identify systematic reviews of RCTs and RCTs for the effectiveness outcomes. Systematic reviews of RCTs, RCTs and cohort studies were searched for unintended consequences outcomes. A single literature search combined this review with the associated qualitative review (see section 2). 7,249 were found.

7,037 were excluded at title and abstract level, leaving 212 for full text screening for this effectiveness review.

Of the 212 studies identified, 2 systematic reviews were identified for effectiveness, adverse events, and unintended consequences outcomes. Both systematic reviews compared the intervention of PrEP to placebo/delayed PrEP/no PrEP. There was considerable overlap between the two included systematic reviews. A total of 8 studies that were considered relevant to the current evidence review were captured in both systematic reviews. GRADE overall quality was assessed on an outcome level and were based on the individual studies captured in the systematic literature reviews. Risk of bias was determined for the systematic reviews as a whole. Data from 2 comparative cohort studies was combined with RCT data for outcomes measuring condom use and number of sexual partners (see 1.1.6).

1.1.4.2 Excluded studies

Other systematic reviews were identified as relevant but excluded as they contained the same/fewer primary studies, were of lower quality or predated those included. No new primary studies were identified that were not included in the systematic review. Further details of excluded studies can be found in appendix L.

1.1.5 Summary of systematic reviews included in this evidence review

Study characteristics are presented in table 3:

Table 3: Included study characteristics

Author	Study design	Relevant primary studies in SR for outcome	Intervention, comparison and follow up period	Outcomes of interest for review	Population/risk category	Country	ROBIS rating
Chou et al 2019	Systematic review	12 RCTs*	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP Follow up 4 months – 4 years	HIV acquisition, adverse events, STIs, adherence	MSM / transgender women, heterosexual men and women indicating they have had anal or vaginal sex	Countries: USA, France, Canada, England, Kenya, Nigeria, Cameroon, Ghana, Uganda,	Overall risk of bias: Low Applicability: Fully applicable

					in previous 2 weeks - 12 months with either multiple partners, without a condom or on a transactional basis. People who inject drugs N=18,300	Botswana, Thailand, Peru, Ecuador, South Africa, Brazil, Tanzania, Zimbabwe	
Fonner et al 2016	Systematic review	9 RCTs and 1 cohort study*	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP Follow u 24 weeks to 5 years	Sexual behaviour (no of partners/condom use)	As above N=15,554	Countries: USA, England, Tanzania, South Africa, Kenya, Peru, Ecuador, Brazil, Uganda, Botswana, Nigeria, Cameroon, Ghana,Thailand	Overall risk of bias: Moderate Applicability: Fully applicable
*Please see appendix D and E for full evidence tables including details of primary studies.							

1.1.6 Summary of findings

Outcome	Intervention vs comparator	Sample Size	Population	Country	Effect estimate	GRADE overall quality	Interpretation of effect
Risk of HIV infection	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=18172 (11 RCTs –appendix F 1)	High risk [6] MSM, heterosexual men and women, people who inject drugs	USA, France, Canada, England, Kenya, Nigeria, Cameroon, Ghana, Uganda, Botswana, Thailand, Peru, Ecuador, South Africa, Brazil, Tanzania, Zimbabwe	RR 0.46 (0.33-0.66); ARR -2.0% (-2.8% – -1.2%)	Low[1]	56% reduced risk in HIV infection when taking PrEP compared to placebo or no PrEP.
HIV infection with ≥70% adherence*	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=7400 (7 RCTs – appendix F4)	High risk MSM, heterosexual men and women	Kenya, Uganda, USA, England, France, Canada, Botswana	RR 0.27 (0.19-0.39)	High	73% reduced risk in HIV infection when taking PrEP compared to placebo or no PrEP.
HIV infection with >40% to <70% adherence	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=5769 (3 RCTs – appendix F5)	MSM, women, people who inject drugs	Thailand, Brazil, Ecuador, Peru, South Africa, USA, Cameroon, Ghana, Nigeria	RR 0.51 (0.38-0.70)	High	49% reduced risk in HIV infection when taking PrEP compared to placebo or no PrEP.

Outcome	Intervention vs comparator	Sample Size	Population	Country	Effect estimate	GRADE overall quality	Interpretation of effect
HIV infection with Adherence ≤40%	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=5075 (2 RCTs – appendix F6)	High risk women	South Africa, Uganda, Zimbabwe, Kenya, Tanzania	RR 0.93 (0.72-1.20)	Moderate[2]	No statistically significant reduction in risk of HIV between those taking PrEP and those taking placebo/no PrEP.
HIV infection with PrEP monotherapy: tenofovir disoproxil fumarate (TDF)	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=7546 (5 RCTs – appendix F3)	High risk MSM, heterosexual men and women, people who inject drugs	Kenya, Uganda, Thailand, USA, South Africa, Zimbabwe, Cameroon, Ghana, Nigeria	RR 0.49 (0.28 – 0.84)	Low [2, 3]	Reduced risk in HIV infection in those taking PrEP TDF only compared with placebo/no PrEP. May not be clinically significant as the confidence interval crosses below the 25% minimum important difference threshold for reduced risk.
HIV infection with PrEP dual therapy: tenofovir disoproxil fumarate/emtricitabine (TDF/FTC)	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=10626 (8 RCTs – appendix F 2)	High risk MSM, heterosexual men and women	Kenya, Uganda, Thailand, Brazil, Ecuador, Peru, South Africa, USA, Uganda, Zimbabwe, England, France, Canada, Botswana, Tanzania	RR 0.44 (0.27-0.72)	Low [1]	56% reduced risk HIV infection when taking PrEP TDF/FTC compared to placebo or no PrEP.
Risk of serious adverse event****	PrEP (TDF/TDF&FTC) vs	n=18282 (12 RCTs –	High risk MSM, heterosexual men and women, people	USA, France, Canada, England,	RR 0.93 (0.77-1.12)	Low [2, 3]	No statistically significant difference in risk of serious adverse event outcomes between those taking PrEP

Outcome	Intervention vs comparator	Sample Size	Population	Country	Effect estimate	GRADE overall quality	Interpretation of effect
	placebo/delayed PrEP/No PrEP	appendix F7)	who inject drugs	Kenya, Nigeria, Cameroon, Ghana, Uganda, Botswana, Thailand, Peru, Ecuador, South Africa, Brazil, Tanzania, Zimbabwe			and those taking placebo/no PrEP.
Risk of withdrawal due to adverse event	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=10563 (4 RCTs appendix F8)	High risk MSM, heterosexual men and women	Kenya, Uganda, Thailand, Brazil, Ecuador, Peru, South Africa, USA, France, Canada, Cameroon, Ghana, Nigeria, Tanzania	RR 1.25 (0.99-1.59)	Moderate[2]	No statistically significant difference in risk of withdrawal from trials due to adverse events between those taking PrEP and those taking placebo/no PrEP.
Risk of fracture	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=15241 (8 RCTs – appendix F 11)	High risk MSM, heterosexual men and women, people who inject drugs	Kenya, Uganda, Thailand, Brazil, Ecuador, Peru, South Africa, USA, Uganda,	RR 1.23 (0.97-1.56)	Moderate[2]	No statistically significant difference in risk of fracture between those taking PrEP and those taking placebo/no PrEP

Outcome	Intervention vs comparator	Sample Size	Population	Country	Effect estimate	GRADE overall quality	Interpretation of effect
				Zimbabwe, England, France, Canada, Botswana			
Risk of renal adverse event**	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=18170 (12 RCTs – appendix F9)	High risk MSM, heterosexual men and women, people who inject drugs	USA, France, Canada, England, Kenya, Nigeria, Cameroon, Ghana, Uganda, Botswana, Thailand, Peru, Ecuador, South Africa, Brazil, Tanzania, Zimbabwe	RR 1.43 (1.18-1.75)	Moderate[2]	Increased risk of a renal adverse event in those taking PrEP compared to those taking placebo/no PrEP. May not be clinically significant as the confidence interval crosses below the 25% minimum important difference threshold for increased risk.
Risk of gastrointestinal event***	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=18300 (12 RCTs – appendix F10)	High risk MSM, heterosexual men and women, people who inject drugs	USA, France, Canada, England, Kenya, Nigeria, Cameroon, Ghana, Uganda, Botswana, Thailand, Peru, Ecuador,	RR 1.63 (1.26 – 2.11)	Moderate[3]	Increased risk of gastrointestinal events in those taking PrEP compared with those taking placebo/no PrEP

Outcome	Intervention vs comparator	Sample Size	Population	Country	Effect estimate	GRADE overall quality	Interpretation of effect
				South Africa, Brazil, Tanzania, Zimbabwe			
Risk of syphilis	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=10775 (4 RCTs)	High risk MSM, heterosexual men and women	Kenya, Uganda, Thailand, Peru, Ecuador, South Africa, Brazil, USA, Zimbabwe, England	RR 1.08 (0.98 – 1.18)	High	No statistically significant difference in risk of contracting syphilis between those taking PrEP and those taking placebo/no PrEP.
Risk of gonorrhoea	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=9296 (5 RCTs)	High risk MSM, heterosexual men and women	Thailand, Peru, Ecuador, South Africa, Brazil, USA, Uganda, Zimbabwe, England, Botswana, Kenya Tanzania	RR1.07 (0.82-1.39)	Low [2, 3]	No statistically significant difference in risk of contracting syphilis between those taking PrEP and those taking placebo/no PrEP.
Risk of chlamydia	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=9296 (5 RCTs)	High risk MSM, heterosexual men and women	Thailand, Peru, Ecuador, South Africa, Brazil, USA, Uganda, Zimbabwe, England,	RR 0.97 (0.80-1.18)	Low [2, 3]	No statistically significant difference in risk of contracting chlamydia between those taking PrEP and those taking placebo/no PrEP.

Outcome	Intervention vs comparator	Sample Size	Population	Country	Effect estimate	GRADE overall quality	Interpretation of effect
				Botswana, Kenya Tanzania			
Risk of herpes simplex virus	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=4103 (3 RCTs)	High risk MSM, heterosexual men and women	Botswana, Thailand, Peru, Ecuador, South Africa, Brazil, USA, Kenya, Uganda	RR 0.85 (0.67-1.07)	Moderate[2]	No statistically significant difference in risk of contracting herpes simplex virus between those taking PrEP and those taking placebo/no PrEP.
Risk of hepatitis C virus	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	n=896 (2 RCTs)	High risk MSM	England, France, Canada	RR 0.73 (0.25 – 2.10)	Very Low[4,5]	No statistically significant difference in risk of contracting hepatitis C virus between those taking PrEP and those taking placebo/no PrEP.
Condom use	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	N=14,063 (8 RCTs, 1 cohort study)	MSM, transgender and heterosexual men and women	Kenya, Uganda, Peru, Ecuador, South Africa, Brazil, Thailand, USA, Nigeria, Cameroon, Ghana, Botswana, Tanzania, England	Not meta-analysed	Very Low[7, 8]	Evidence from 5 placebo controlled RCTs (n= 11457), 2 RCTs comparing PrEP with delayed/no PrEP arms (n=458) and 1 cohort study comparing PrEP with no PrEP (15 n=1603) found no differences in any self-reported condom use between PrEP and placebo/delayed/no PrEP arms. 1 RCT comparing PrEP with delayed PrEP (n=545) found 21% of participants taking PrEP reported receptive anal sex without a condom with ten

Outcome	Intervention vs comparator	Sample Size	Population	Country	Effect estimate	GRADE overall quality	Interpretation of effect
							or more partners compared to 12% in the delayed PrEP arm.
Sexual Partners	PrEP (TDF/TDF&FTC) vs placebo/delayed PrEP/No PrEP	N=15,554 (8 RCTs and 1 cohort study)	MSM, transgender and heterosexual men and women, people who inject drugs	Kenya, Uganda, Thailand, Peru, Ecuador, South Africa, Brazil, United States, Botswana, England	Not meta-analysed	Low [8]	Evidence from 6 placebo-controlled trials (n= 13006) 2 studies comparing PrEP delayed/no PrEP arms, (n=945) and 1 cohort study comparing PrEP with no PrEP (n=1603) found no differences in self-reported number of sex partners between PrEP and placebo/delayed/ no PrEP arms.

1. I^2 >66.7% - rated down twice for high inconsistency
2. 95% CI crosses the MID at one end – rated down once for imprecision
3. I^2 between 33.3% and 66.7% - rated down once for inconsistency
4. More than 33.3% of studies in analysis comes from studies at moderate risk of bias – rated down once for risk of bias
5. 95% CI crosses the MID at both ends – rated down twice for imprecision
6. See appendix D for how risk is categorised in individual studies
7. Although most studies present consistent findings, 1 study has a conflicting outcome – rated down once for inconsistency.
8. Effect estimates with confidence intervals not given - rated down twice.

*Adherence measured by pill count, plasma sample and MEMS (medication event monitoring system)
**Renal abnormalities were primarily 1 or more grade-1 elevation of serum creatinine level and generally resolved following PrEP cessation or with ongoing PrEP
***Primarily nausea
****Definition not specified by review authors but includes 'any untoward medical occurrence(s) that at any dose results in death, hospitalisation or prolongation of existing hospitalisation, persistent or significant disability/incapacity or a congenital anomaly or birth defect.'[a]

[a] Definition from North Bristol NHS trust, available here: https://www.nbt.nhs.uk/research-innovation/running-your-study/safety-reporting/classification-adverse-events

1.1.7 Economic evidence

A search for relevant economic studies was undertaken, using the strategy in appendix B and applying a cost-effectiveness filter. In total, 968 records were assessed against eligibility criteria. Of these, 802 records were assessed as being ineligible based on disease, intervention and study design and 44 records were excluded based on information in the title and abstract. Two reviewers assessed all the records. The level of agreement between the two reviewers was 100%.

The full-text papers of 122 documents were retrieved and assessed. 110 were excluded, for reasons summarised in Appendix H and further detailed in Appendix K.

1.1.7.1 Included studies

Of the 12 included studies, two were assessed as fully meeting the eligibility criteria and underwent a full data extraction. The remaining ten studies partially met the inclusion criteria. A full data extraction was undertaken of one of these ten studies as it provided key information that could be used to inform the cost-effectiveness modelling. Data extraction from the remaining nine studies was limited to information that could be used to inform the decision problem. Two reviewers assessed all full-text papers. The level of agreement between the two reviewers was 100%.

The study selection process can be found in Appendix H and the economic evidence tables for the three fully extracted studies can be found in Appendix I.

1.1.7.2 Excluded studies

110 full text documents were excluded for this guideline. The documents and the reasons for their exclusion are listed in Appendix K.

1.1.8 Summary of included economic evidence

Summary of the fully extracted studies included in the economic evidence review for pre-exposure prophylaxis

Study	Limitations	Applicability	Other comments	Incremental			Uncertainty
				Costs	Effects	Cost-effectiveness	
Cambiano (2018) Cost utility model to compare the cost effectiveness of event-based PrEP among GBMSM attending GUM clinics in the UK versus no PrEP	Minor limitations	Applicable	**Study description** Cost utility model; 80-year (lifetime) time horizon; cost and benefits discounted at 3.5%; NHS perspective; 86% PrEP effectiveness assumed [a] Population size estimated to be 725,000 at start of model	**Probabilistic results** No PrEP (£ million): 20,640 (range: 11,080 to 36,320) PrEP (£ million): 19,630 (range: 11,390 to 33,690) Difference (£ million): -1,000 (range: -4,900 to 1230)	**Probabilistic results** **Cumulative mean number of HIV infections:** PrEP: 178,900 (range: 81,100 to 323,300) No PrEP: 134,600 (range: 61700 to 264,300) Difference: 44300 (range: 3,300 to 97,600) (25%) **Discounted QALYs (thousands)**	**Probabilistic results** **NMB (£ million):** 1490 (range: -1360 to 6580) **Threshold results:** The probability of a PrEP programme being cost-effective is greater than 80% at a threshold of £20,000 per QALY gained (around 75% at £13,000 per QALY gained) Costs increase for 20 years and it takes 40 years for the ICER per QALY gained	A key driver of cost-effectiveness was the uptake of PrEP (not possible to estimate with any degree of certainty) Model assumption that HIV testing will continue at the current rate (rates have rapidly increased in the UK in recent years) Introduction of PrEP may be accompanied by spread of other STIs and their consequent treatment costs Exact costs to the NHS for HIV drug treatment are confidential and not known to the authors. It is anticipated that drug costs will fall once generic PrEP is available cheaply online **Reviewer identified** Cost effectiveness of PrEP versus other risk reduction interventions (for example, active behaviour change interventions) not assessed

Study	Limitations	Applicability	Other comments	Incremental			Uncertainty
				Costs	Effects	Cost-effectiveness	
					PrEP: 18,410 (range: 18,330 to 18,450) No PrEP: 18,450 (range: 18,360 to 18,510) Gain: 40 (range: 4 to 70)	to fall below £13,000	

Abbreviations: GUM: genitourinary medicine; ICER: incremental cost-effectiveness ratio; GBMSM: gay, bisexual and other men who have sex with men: NHS: National Health Service; NMB: net monetary benefit; PrEP: pre-exposure prophylaxis; PSA: probabilistic sensitivity analysis; QALY: quality-adjusted life year; RCT: randomised control trial

a. McCormack S, Dunn DT, Desai M, Dolling DI, Gafos M, Gilson R, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open- label randomised trial. Lancet.2016;387(10013):53-60.

Study	Limitations	Applicability	Other comments	Incremental			Uncertainty
				Costs	Effects	Cost-effectiveness	
Ong (2017) Exploration of the economic implications of a first phase scale-up of a PrEP programme	Minor limitations	Applicable	Decision tree model; lifetime horizon; costs and benefits discounted at 3.5%; NHS perspective	**Costs (£ million)** 86% (64%) effectiveness assumed Year 1 PrEP cost (drug and GUM clinic): 22.5 (22.5)	**Incremental effects:** 86% (64%) effectiveness: 361 (247) QALYs saved	**ICER; €:** 86% (64%) effectiveness: Intervention was cost saving (23,000) compared with no PrEP	Results were very sensitive to assumptions about HIV incidence in the PrEP eligible group, PrEP effectiveness when scaled up, PrEP drug costs and future reductions in the cost of anti-retroviral treatment. Results from sensitivity analyses of plausible combinations of uncertain factors

Study	Limitations	Applicability	Other comments	Incremental			Uncertainty
				Costs	Effects	Cost-effectiveness	
for GBMSM GUM clinic attendees at high HIV risk versus standard of care (PROUD trial) [a]			Population of 5,000 GBMSM Effectiveness of PrEP 86% (PROUD Trial result)[a] and also considered a scenario where effectiveness was reduced to 64% to take into account increased frequency of condomless anal sex subsequent to PrEP use	HIV care costs prevented: 24.1 (16.5) PEPSE-related costs prevented: 256,000 (256,000) Incremental cost of PrEP: -1.86 (5.74)		Break even 86%: year 23 64%: year 33	did not give a high degree of certainty that the ICER per QALY gained for the comparison of PrEP versus standard of care would fall below £20,000 **Reviewer identified** PrEP is available for purchase online Cost-effectiveness of PrEP versus other risk reduction interventions (for example, active behaviour change interventions) not assessed

Abbreviations: GUM: genitourinary medicine; HIV: human immunodeficiency viruses; ICER: incremental cost-effectiveness ratio; PEPSE: post exposure prophylaxis after sexual exposure to HIV; PrEP: pre-exposure prophylaxis; QALY: quality-adjusted life year; RCT: randomised control trial

a. McCormack S, Dunn DT, Desai M, Dolling DI, Gafos M, Gilson R, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open- label randomised trial. Lancet.2016;387(10013):53-60.

Study	Limitations	Applicability	Other comments	Incremental			Uncertainty
				Costs	Effects	Cost-effectiveness	
Reitsema (2020) Assessment of the cost-effectiveness of a PrEP programme for GBMSM	Minor limitations [a]	Partly applicable [b]	**Study description** Cost effectiveness modelling: four scenarios considered: 1) standard PrEP;	**Total costs; million €:** Standard: -3.7 (-44.4 to 19.6) RC:	**Effectiveness; %: Cumulative averted HIV infections 2018-2027** Standard: 486 (12,734-6102)	**ICER; €:** Standard: 217.4 (-29,752.5 to 31,923) RC: 11,996 (-16,355 to 56,518)	Without risk compensation*, 92% of simulations were cost-effective (of which 52% were cost-saving). With risk compensation, 73% of simulations were cost-effective (of which 23% were cost-saving)

Study	Limitations	Applicability	Other comments	Incremental			Uncertainty
				Costs	Effects	Cost-effectiveness	
versus no programme			2) risk compensation*; 3) capped scenario; 4) capped scenario with risk compensation	9.2 (-23.7 to 31.4) Capped: -7.6 (-41.3 to 15.2) Capped+RC: -0.8 (-33.5 to 21.8)	RC: 3550 (1309-6131) Capped: 26916 (1200-4424) Capped+RC: 2530 (1044-4198)	Capped: -5575 (-46,281 to 29,978) Capped+RC 2967 (-48,965 to 63,577)	**Author identified limitations:** Population limited to GBMSM who present for an HIV/STI test and meet one of the criteria for PrEP Assumed no change in testing behaviour False report of CAI not considered Event-driven PrEP not considered **Reviewer identified:** Earlier modelling studies have found contradicting results because of differences in how PrEP was implemented and assumptions about the costs, efficacy, and adherence to PrEP Cost-effectiveness of PrEP versus other risk reduction interventions (for example, active behaviour change interventions) not assessed

Abbreviations: CAI=condomless anal intercourse; HIV=human immunodeficiency viruses; ICER: incremental cost-effectiveness ratio; GBMSM: gay, bisexual and other men who have sex with men; PrEP: pre-exposure prophylaxis; QALY: quality-adjusted life year; RC=risk compensation; RCT: randomised control trial; STI=sexually transmitted infection

a. There is considerable uncertainty around costs of PrEP and HIV drugs

b. Dutch population

*Risk compensation is a term for when people adjust their behaviour in response to perceived levels of risk, becoming more careful where they sense greater risk and less careful if they feel more protected. In this study, risk compensation was modelled through reduced condom use in people using PrEP

Short summary of the partially extracted studies included in the economic evidence review for pre-exposure prophylaxis

Durand-Zaleski (2018): Country: France						
Population	**Interventions**	**Evaluation details**	**Effectiveness results**	**Cost results**	**ICER**	**Comments**
High risk GBMSM	On demand PrEP with TDF-FTC versus placebo	**Evaluation type:** Economic evaluation alongside the ANRS-IPERGAY double-blind RCT **Perspective** Health care provider **Time horizon** 1 year **Discounting** Not applicable	**HIV infections/100 person-years** TDF-FTC group: 0.91 Placebo group: 6.6 Relative reduction of 86% in the incidence of HIV with TDF-FTC (95% CI: 40-98%, p=0.0019) The NNT for 1 year to prevent one HIV infection in the total IPERGAY population was 17.6 (95% CI: 10 to 42)	**Mean (SD) cost per person per year; €** TDF-FTC group: 4271 (2446) Placebo group: 0	**Cost €/infection averted/year:** 75,258 At current drug prices (€500.88/ 30 tablets) PrEP was cost saving up to 7.5 years of risk exposure At generic France prices (€179.90/ 30 tablets) PrEP was cost saving up to 13 years of risk exposure At international generic (Indian Internet) prices (€60.00/ 30 tablets) PrEP was cost saving up to 20 years of risk exposure	Uncertainty around economic results arises from uncertainty around the clinical results Note use of placebo as a comparator (zero costs but benefits in terms of counselling and testing) Analysis ignored the possibility that avoiding HIV infections in one person may benefit more than one person Providing PrEP allowed the diagnosis and treatment of other STIs which might be otherwise neglected Additional evidence on the sustained benefit of on-demand PrEP in a larger population would be useful
Abbreviations: HIV: human immunodeficiency viruses; ICER: incremental cost-effectiveness ratio; GBMSM: gay, bisexual and other men who have sex with men; NNT: number needed to treat; PrEP: pre-exposure prophylaxis: TDF-FTC: tenofovir disoproxil fumarate- emtricitabine; QALY: quality-adjusted life year; RCT: randomised control trial						

Ginsberg (2020): Country: Israel						
Population	**Interventions**	**Evaluation details**	**Effectiveness results**	**Cost results**	**ICER**	**Comments**
GBMSM (high risk [men who engage in unprotected anal intercourse] and low risk) Population size: 12,666 high risk; 14,631 low risk Assumed 80% high risk would try PrEP and 25% low risk would try PrEP and 75% of this group would cease to use condoms	A continuous PrEP programme (on demand considered as a scenario) (Protective efficacy of PrEP=86%)	**Evaluation type** CUA **Perspective** Societal **Time horizon** 10 years **Discounting** Costs: 3% Benefits: 3%	**HIV cases** With PrEP: 621 Without PrEP: 1113 Difference: -492 **DALY losses** With PrEP: 2035 Without PrEP: 3651 Difference: -1616	**Total annual cost; US$** Assuming four years background decrease in HIV incidence of 5.2% With PrEP: 2,319,199,820 Without PrEP: 755,603,201 Difference: 1,563,596,619	**ICER (US$/DALY)** 967,744 (not cost-effective)	The 'not cost effective' results (which contrasts with other published results) may be due to: • lower HIV incidence rates in Israel compared with Europe and USA • PrEP being provided to some low-risk GBMSM,and the assumption that some of these would cease using condoms High degree of uncertainty around model inputs. The authors list five reasons why their cost/DALY might be an over-estimate [a] and five why it might be an under-estimate [b] **Reviewer comment** Effect on STIs not considered

Abbreviations: ART: anti-retroviral therapy; CUA: cost utility analysis; DALY: disability adjusted life year; HIV: human immunodeficiency viruses; ICER: incremental cost-effectiveness ratio; GBMSM: gay, bisexual and other men who have sex with men; PrEP: pre-exposure prophylaxis: QALY: quality-adjusted life year; STI: sexually transmitted infection; UAI: unprotected anal intercourse

a. (1) Lower costs would be incurred in an on-demand regimen, without any evidence that efficacy would decrease; (2) the PrEP programme includes a screening programme, which has been shown to be cost-effective (or even cost saving) in high risk populations; (3) possibility that decreased condom use in non UAI who receive PrEP might be less than model baseline or sensitivity figures; (4) the source of HIV and AIDs transition times includes data from 22% females who were found to have longer transition times than males; (5) authors were unable to estimate the increased costs for non-HIV diagnosis pharmaceuticals, ambulatory, emergency room and outpatient visits that were likely to be incurred by HIV-positive persons

b. (1) No provision of possible PrEP toxicity (none reported in trials); (2) intervention might result in decreased condom use; (3) due to decreased condom use transmission will increase leading to increased treatment costs and decreased QALYs; (4) Assumed no severe adverse events – if it does exist then cost per QALY would be under-estimated; (5) effects or costs due to resistance caused by the use of PrEP were not modelled

MacFadden (2016): Country: Canada (city: Toronto)						
Population	**Interventions**	**Evaluation details**	**Effectiveness results**	**Cost results**	**ICER**	**Comments**
GBMSM Population size: 57,400	Once daily PrEP for HIV prevention PrEP efficacy: 44%	**Evaluation type** Cost utility model **Perspective** Health system **Time horizon** 20 years **Discounting** Costs: 3% Outcomes 3%	**By proportion of GBMSM (high- and low-risk) using PrEP:** **HIV cases prevented** 25%: 1970 50%: 3427 70%: 4317 100%: 4581 **HIV associated deaths** 25%: 110 50%: 182 70%: 222 100%: 236 **QALYs gained** 25%: 2,673 50%: 4,413 70%: 5,363 100%: 5,430	**Cost of implementation by proportion of GBMSM (high- and low-risk) using PrEP; $ CAD:** 25%: $1.36 billion 50%: $2.65 billion 70%: $3.80 billion 100%: $4.37 billion	**Cost per QALY gained by proportion of GBMSM (high- and low-risk) using PrEP; $ CAD:** 25%: $495,175 50%: $587,050 70%: $696,297 100%: $792,763 (not cost-effective at $100,000 CAD per QALY)	PrEP for the highest risk HIV-uninfected GBMSM was a more efficient strategy than targeting all high- and low-risk at comparable usage levels Inputs focus on Toronto and therefore results may not be generalisable to other cities PrEP on demand may be a more cost-effective strategy than a once daily strategy Cost-effectiveness ratios may be over- or under-estimated if the quality of life ratio for individuals on PrEP is not equal to one (as assumed by authors) Assumption of perfect ART adherence may overestimate the benefit of a testing-only strategy and underestimate the potential benefit of PrEP in the susceptible population (individuals with poor ART adherence could actively transmit HIV) **Reviewer comment** Effect on STIs not considered Basecase PrEP efficacy is lower than in other studies
Abbreviations: ART: anti-retroviral therapy; CAD: Canadian; HIV: human immunodeficiency viruses; ICER: incremental cost-effectiveness ratio; GBMSM: gay, bisexual and other men who have sex with men; PrEP: pre-exposure prophylaxis: QALY: quality-adjusted life year; RCT: randomised control trial; STI: sexually transmitted infection						

Nichols (2016): The Netherlands						
Population	**Interventions**	**Evaluation details**	**Effectiveness results**	**Cost results**	**ICER**	**Comments**
GBMSM in four different sexual risk groups with varying levels of sexual activity. PrEP was targeted in the analysis to the two most sexually active groups (4500 GBMSM)	PrEP with tenofovir and emtricitabine	**Evaluation type** Economic evaluation (mathematic transmission model to assess PrEP users and future partners of PrEP users) **Perspective** Payer perspective **Time horizon** 40 years **Discounting** 3%	At 40% effectiveness of PrEP and targeting PrEP to 10% of GBMSM could prevent 1400 new infections At 100% effectiveness and targeting 10% of GBMSM could prevent 2500 new infections	**Mean) cost per person per year; €** Daily PrEP: 7400 On-demand PrEP: 3850	At the current price, PrEP is expected to be cost-effective over 40 years with an effectiveness of over 70% **Cost per QALY gained; €:** **Daily PrEP** 100% effectiveness: 7800 40% effectiveness: 20,000 **On-demand PrEP** 100% effectiveness: 9100 40% effectiveness: 1400	Results have been reported in the context of a stable HIV epidemic, but PrEP was also expected to be cost-saving in the context of a declining epidemic The study has assumed that PrEP can become cost saving with reductions in price Analysis showed that at 80% effectiveness, daily PrEP can be considered cost-saving if the price is reduced by 70% and on-demand PrEP can be considered cost-saving if the price is reduced by 30-40%
Abbreviations: HIV: human immunodeficiency viruses; ICER: incremental cost-effectiveness ratio; GBMSM: gay, bisexual and other men who have sex with men; PrEP: pre-exposure prophylaxis; QALY: quality-adjusted life year						

Ouellet (2015): Country: Canada						
Population	**Interventions**	**Evaluation details**	**Effectiveness results**	**Cost results**	**ICER**	**Comments**
High risk GBMSM	On-demand PrEP	**Evaluation type:** CUA of prevention of one infection using PrEP **Perspective** Societal (lost income and productivity costs were included) **Time horizon** Lifetime **Discounting** 3 to 5%	**Lifetime LYs per person, discounted at 3%** PrEP: 25.73 HIV infection: 21.49 Incremental: 4.24 **Lifetime QALYs per person, discounted at 3%** PrEP: 25.73 HIV infection (assuming utility is 0.94 of that of a healthy individual): 20.21 Difference: 5.53	**Lifetime costs per person, discounted at 3%; $** PrEP: 621,390 HIV infection: 662,295 in least expensive ART scenario, 690,075 in most expensive ART scenario Difference: -40,905 in least expensive scenario, -68,684 in most expensive scenario	**Cost $/QALY gained:** Cost-saving (in both the least and most expensive scenarios)	Cost-effectiveness analysis is not consistent in terms of time frame, presenting the costs for one year of 'on demand' PrEP versus 35.2 years of infection Risk compensation* not factored into analysis The main limitation of the costing methodology is said to be in the estimates of indirect costs The results of this cost-effectiveness analysis should not be generalized to other populations such as IDU or serodiscordant couples for whom PrEP is recommended by the CDC/WHO, given that the rates of HIV acquisition are lower than for the GBMSM group

Abbreviations: CUA: cost-utility analysis; HIV: human immunodeficiency viruses; ICER: incremental cost-effectiveness ratio; LY: life year; GBMSM: gay, bisexual and other men who have sex with men; PrEP: pre-exposure prophylaxis: QALY: quality-adjusted life year

*Risk compensation is a term for when people adjust their behaviour in response to perceived levels of risk, becoming more careful where they sense greater risk and less careful if they feel more protected.

Reyes-Urueña (2020): Country: Spain						
Population	**Interventions**	**Evaluation details**	**Effectiveness results**	**Cost results**	**ICER**	**Comments**
GBMSM eligible for PrEP	Daily PrEP and on-demand PrEP	**Evaluation type:** CUA of prevention of one infection using PrEP **Perspective** Societal (lost income and productivity costs were included) **Time horizon** Lifetime **Discounting** 3 to 5%	**Lifetime LYs per person, discounted at 3%** PrEP (both on-demand and daily): 24.3 HIV infection: 20.8 Incremental: 3.5 **Lifetime QALYs per person, discounted at 3%** PrEP: 24.3 HIV infection (assuming utility is 0.94 of that of a healthy individual): 20.1 Difference: 4.19	**Lifetime costs per person, discounted at 3%; €** On-demand PrEP for 1st year: 246,488 Daily PrEP for 1st year: 417,241 HIV infection: 176,428 Difference: 70,060 for on-demand PrEP, 240,813 for daily PrEP	**Cost €/ QALY gained** On demand PrEP: 16,707 Daily PrEP: 57,425	Large uncertainty in the local costs associated with HIV infection Authors state the HIV costs are likely to be an under-estimate which would make the CE results less favourable than they would otherwise be The CE analysis suggests that although PrEP is cost-effective over a lifetime, it is most cost effective if targeted towards groups with high incidence rates of over 3% per year, and the beneficial ICER depends heavily on reducing the current price of PrEP and ensuring that effectiveness is maintained at very high levels
Abbreviations: CUA: cost-utility analysis; HIV: human immunodeficiency viruses; ICER: incremental cost-effectiveness ratio; LY: life year; GBMSM: gay, bisexual and other men who have sex with men; PrEP: pre-exposure prophylaxis: QALY: quality-adjusted life year						

Schneider (2014): Australia						
Population	**Interventions**	**Evaluation details**	**Effectiveness results**	**Cost results**	**ICER**	**Comments**
All GBMSM and GBMSM with sexual partners between 10 and 50	PrEP	**Evaluation type** Economic evaluation based on a HIV transmission simulation model **Perspective** Health provider perspective **Time horizon** 10 years **Discounting** 3%	The most cost-effective strategies were targeting HIV-negative men in a discordant regular partnership **HIV cases in next 10 years** Without PrEP: 2388 With PrEP in 30% of HIV-negative men in discordant regular partnerships: 2034 Difference: -354 With PrEP in 15% of HIV-negative men in discordant regular partnerships: 2221 Difference: -167 **QALYs** Without PrEP: 487,952	**Mean cost per person per year; AUS€:** 9597 **Total cost in next 10 years** Without PrEP: $817 951 923 With PrEP in 30% of HIV-negative men in discordant regular partnerships: $830,301,331 Incremental cost: $12,349,408 With PrEP in 15% of HIV-negative men in discordant regular partnerships: $822,374,587 Incremental cost: $4,422,664	**ICER (AUS$/QALY:** In 30% of HIV-negative men in discordant regular partnerships: $11,575 In 15% of HIV-negative men in discordant regular partnerships: $8399	In the scenarios analysed, providing PrEP to all GBMSM was not shown to be cost-effective. However, targeting a smaller group of GBMSM at higher risk of infection improves the cost-effectiveness of PrEP The findings in this study are dependent on several unknown assumptions. Real-world data on changed safe-sex behaviours and adherence among people taking PrEP is lacking Variations in PrEP use over time are not captured in the analysis

Schneider (2014): Australia						
Population	**Interventions**	**Evaluation details**	**Effectiveness results**	**Cost results**	**ICER**	**Comments**
			With PrEP in 30% of HIV-negative men in discordant regular partnerships: 489,019 Incremental benefit: 1067 With PrEP in 15% of HIV-negative men in discordant regular partnerships: 488,479 Incremental benefit: 527			
Abbreviations: HIV: human immunodeficiency viruses; ICER: incremental cost-effectiveness ratio; GBMSM: gay, bisexual and other men who have sex with men; PrEP: pre-exposure prophylaxis; QALY: quality-adjusted life year						
a. The authors investigated the impact of PrEP interventions by assigning a proportion of HIV-negative or undiagnosed GBMSM to be taking PrEP in a number of theoretical simulated scenarios. The scenarios investigated included prioritizing PrEP for 10%–30% of the general GBMSM population, 15%–30% of GBMSM with >10 to 50 sexual partners per 6 months, and 15% to 30% of HIV-negative GBMSM in discordant regular partnerships						

Van de Vijver (2019): Germany						
Population	**Interventions**	**Evaluation details**	**Effectiveness results**	**Cost results**	**ICER**	**Comments**
GBMSM in four sexual risk groups. PrEP was targeted to high-risk GBMSM	Generic PrEP and branded PrEP with tenofovir alafenamide fumarate (TAF)	**Evaluation type** Economic evaluation (adaptation of the Dutch mathematical transmission model) **Perspective**	Relative reduction of 85% in the risk of HIV with PrEP Generic PrEP is expected to prevent 21,000 new infections	**Mean cost per person per year; €** Generic PrEP 821	Generic PrEP is expected to result in a total population gain of 5000 QALYs per year and is expected to be	The authors highlighted that in the short term, a higher uptake of PrEP will result in higher expenses as the costs will exceed the savings from averted HIV infections. However, if a large proportion of those at high risk use PrEP, more infections will

Van de Vijver (2019): Germany						
Population	**Interventions**	**Evaluation details**	**Effectiveness results**	**Cost results**	**ICER**	**Comments**
		Healthcare payer perspective **Time horizon** 40 years **Discounting** 3%	(after 2 years scale-up and 10 years full implementation) if targeted to 30% of GBMSM at high risk of HIV	Branded PrEP-TAF 8123 Introducing PrEP at a generic price is expected to reduce the discounted costs of HIV care by €5.1 billion over 40 years	cost-saving over a 40-year time period An ICER was not reported as generic PrEP was expected to be a dominant strategy	be prevented and more costs will be saved in the long term The analysis did not consider risk compensation and did not account for the potential increase in costs from increased rates of STIs. However, it is expected that these STIs can be treated with cheap antibiotics, thus not affecting the cost-saving associated with PrEP
Abbreviations: HIV: human immunodeficiency viruses; ICER: incremental cost-effectiveness ratio; GBMSM: gay, bisexual and other men who have sex with men; PrEP: pre-exposure prophylaxis: TAF: tenofovir alafenamide fumarate; QALY: quality-adjusted life year; STI: sexually transmitted infection						

Vermeersch (2018): Belgium						
Population	**Interventions**	**Evaluation details**	**Effectiveness results**	**Cost results**	**ICER**	**Comments**
GBMSM	Outreach + TasP; Outreach + TasP + PrEP	**Evaluation type** Predictive evaluation estimating cost and benefit impact **Perspective** Healthcare payer perspective **Time horizon** 15 years	With no additional prevention, the estimated number of annual new HIV diagnoses, after an initial period of decline, was expected to increase to over 1350 new diagnoses per year by 2030	With no additional prevention, the total (pharmaceutical) budget for HIV treatment is expected to increase to over €260 million in 2030 **Expected total expenditures in 2030**:	An ICER was not calculated as no actual costs and benefits were provided	None

Vermeersch (2018): Belgium						
Population	**Interventions**	**Evaluation details**	**Effectiveness results**	**Cost results**	**ICER**	**Comments**
		Discounting Not applicable	**Expected new HIV diagnoses per year by 2030:** Outreach+TasP: 865 Outreach+TasP+PrEP: 663	Outreach+TasP: €239 million Outreach+TasP+PrEP: €227 million		
Abbreviations: HIV: human immunodeficiency viruses; ICER: incremental cost-effectiveness ratio; GBMSM: gay, bisexual and other men who have sex with men; PrEP: pre-exposure prophylaxis: TasP: treatment as prevention						
a. The model calculated the expected health benefit and budget impact of introducing two HIV prevention scenarios which included PrEP						

1.1.9 Economic model

An economic model was developed to assess the impact of unintended consequences on the cost-effectiveness of PrEP. Existing economic evaluations, not accounting for unintended consequences, were selected and the results adjusted with original estimates of the cost and QALY impacts of the unintended consequences.

A full write up of the economic modelling is provided in appendix J.

1.1.10 Health economic evidence statements

- Cambiano (2018) assessed the cost effectiveness of PrEP among gay, bisexual and other men who have sex with men (GBMSM) attending GUM clinics in the UK versus no PrEP. Findings from the analysis (with efficacy data taken from the PROUD trial) showed that the net monetary benefit was £1,490 million and results from a probabilistic sensitivity analysis showed that the probability of the PrEP programme being cost-effective at a threshold of £20,000 was 80%. Costs were shown to increase over the first 20 years, and it took 40 years for the ICER per QALY gained to fall below £13,000. The cost effectiveness of the programme increased as uptake increased; however, the authors highlighted that a key driver of cost effectiveness was the size of the PrEP programme and that it was not possible to determine this with any degree of certainty. Other areas of uncertainty were around HIV testing, the extent to which introduction of PrEP would be accompanied by spread of other STIs, the exact costs to the NHS of HIV drug treatments and the fact that PrEP is available online. The reviewers highlight that the cost effectiveness of PrEP versus active risk reduction interventions (for example, behaviour change) has not been assessed.
- Ong (2017) assessed the cost effectiveness of a first phase scale-up of a PrEP programme (daily tablet) for GBMSM GUM clinic attendees at high risk of HIV versus standard of care. Findings from this analysis showed that, assuming 86% effectiveness of PrEP (result from the PROUD trial), over a lifetime the intervention was cost saving (ICER is negative) compared with no PrEP. Assuming an effectiveness of 64% (to take into account increased frequency of condomless anal sex subsequent to PrEP use), the ICER per QALY gained was £23,000. The time to break even ranged from year 23 (86% effectiveness) to year 33 (64% effectiveness). The authors highlighted that their results were very sensitive to assumptions about HIV incidence in the PrEP eligible group, PrEP effectiveness when scaled up, PrEP drug costs and future reductions in the cost of anti-retroviral treatment and that sensitivity analyses of plausible combinations of uncertain factors did not give a high degree of certainty that the ICER per QALY gained for the comparison of PrEP versus standard of care would fall below £20,000. The authors suggested that more research is needed to explore the areas of uncertainty before embarking on a long-term PrEP-based intervention. The reviewers highlight that the cost-effectiveness of PrEP versus active risk reduction interventions (for example, behaviour change) has not been assessed.
- Reitsema (2020) assessed the cost effectiveness of a PrEP programme, delivered in clinics in the Netherlands, versus no programme. Findings from the model-based analysis showed that, in the period from 2018-2027) that the ICER estimates for all four scenarios (standard (75% uptake), risk compensation, capped (2.5% uptake), and capped with risk compensation) were less than £20,000 per QALY gained. In all four scenarios, gonorrhoea prevalence decreased after introducing PrEP. Probabilistic sensitivity analysis results showed that without risk compensation, 92% of simulations were cost-effective (of which 52% cost-saving) and that with risk compensation, 73% of simulations were cost-effective (of which 23% was cost-saving). The authors highlighted that the population was limited to GBMSM who present for an HIV/STI test and meet one of four criteria. Further, it was assumed that there would be no change in testing behaviour and the effect of false report of CAI (to gain eligibility to join the programme) was not considered. The study did

not assess the cost-effectiveness of event-driven PrEP. The reviewers highlight that earlier modelling studies have found contradicting results about the cost-effectiveness of PrEP due to differences in how PrEP was implemented and assumptions about the costs and adherence to PrEP.

- Original economic modelling undertaken for this guideline found that when both positive and negative consequences of PrEP are taken into account, the introduction of PrEP into the GBMSM population in the United Kingdom would be a more cost-effective intervention than has been previously estimated (in prior evaluations based solely on the impact on HIV). This means that if PrEP is already considered cost-effective prior to accounting for unintended consequences – a conclusion reached by Cambiano 2018, and Ong 2017 when PrEP was assumed to be 86% effective – then this decision is strengthened by accounting for the unintended consequences. If PrEP is not considered cost-effective without unintended consequences accounted for, for example in the Ong 2017 analysis with PrEP at 64% effectiveness, then the unintended consequences may change the decision if the cost-effectiveness results are close to the threshold.

2 Acceptability and factors relating to the use of pre-exposure prophylaxis (PrEP) for HIV

2.1 Review question

What is the acceptability of pre-exposure prophylaxis (PrEP) for HIV, and what other factors influence its use?

2.1.1 Introduction

Pre-exposure prophylaxis is a drug taken by HIV-negative people before sex that reduces the risk of contracting HIV. As a new approach to STI prevention it is important to consider the context and experiences of those using PrEP.

In England, prior to April 2020, PrEP was only available through the PrEP IMPACT trial (https://www.prepimpacttrial.org.uk/). From April 2020 PrEP has been made routinely available to be prescribed for those considered to be at a greater risk of getting HIV. As this is a relatively new approach to aiming to prevent HIV transmission this question is taking a wide view. Acceptability of PrEP is important to consider, but there may be other factors that may influence the use of PrEP that may be important to consider in developing recommendations in this area.

2.1.2 Summary of the protocol

Table 1 provides a summary of the review protocol. For the full review protocol see Appendix A.

Summary of the review protocol

Eligibility criteria	Content
Population	Included: HIV-negative people aged 16 and older. Excluded: Studies examining PrEP for conception in sero-discordant couples
Factors	Individual and system level factors that may influence the acceptability of and/or use of PrEP for HIV prevention.
Comparator	Not applicable
Outcomes	Individual perspectives, values, beliefs, experiences or attitudes that are considered to influence the acceptability of using PrEP and/or the use of PrEP

2.1.3 Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol in appendix A and the methods document.

Declarations of interest were recorded according to NICE's conflicts of interest policy.

2.1.4 Qualitative evidence

2.1.4.1 Included studies

7,249 references were initially identified from the literature search. 371 qualitative papers were ordered in full-text. Of these, 41 qualitative studies (reported in 45 papers) met the inclusion criteria for the qualitative review respectively as outlined in the review protocol.

12 of these papers were from the UK, 10 were from countries with comparable populations and healthcare systems (Australia, Canada, and the Netherlands) and 22 were from the USA. The populations included men who have sex with men; transgender men and women; non-binary people; cisgender women; people of black minority ethnicity; young people (16-24); and people with low socioeconomic status. It was not able to include older people.

2.1.4.2 Excluded studies

326 studies were excluded. The full list of excluded studies and reasons for exclusion are in Appendix K.

2.1.5 Summary of studies included in the qualitative evidence review

See table below for a summary of the study characteristics and Appendix D for full evidence tables.

Table 1: Study characteristics

Study	Design and analysis	Country	Setting	Sample size	Population	Objective
Auerbach, 2015	Focus Groups	USA	Community	154	Black cisgender women	To investigate PrEP's acceptability and feasibility among women at risk for HIV in the US.
Bil, 2016	Semi structured interviews with grounded theory	The Netherlands	Part of the Amsterdam Cohort Studies (ACS) conducted at the Public Health Service.	20	MSM	To explore more thoroughly the motives for wanting or not wanting to use PrEP if it becomes available, motives for daily versus intermittent PrEP use, the anticipated motives for condom use when using PrEP, and preferences for PrEP implementation (e.g., service characteristics).
Bond, 2016	Survey or questionnaire with grounded theory	USA	Online questionnaire	119	Black cisgender women	To examine the perceived advantages and disadvantages of using PrEP.
Brooks, 2019	Semi structured interviews	USA	Black and Latina transgender women (BLTW) community	19	Black and Latina transgender women	To explore the experiences of PrEP stigma among BLTW who are using PrEP in Los Angeles County.
Cahill, 2020	Focus groups	USA	Transgender community	19	Transgender women	To examine the barriers to PrEP uptake in a racially and ethnically diverse sample of TW to inform the development of culturally tailored interventions to increase PrEP uptake in TW in San Francisco at risk of acquiring HIV.
Collier, 2017	Focus groups with grounded theory	USA	Part of 'Your Body Needs You' project, a program of Planned Parenthood of New York City.	23	Black and Latina Cisgender women	To explore PrEP knowledge and attitudes, perceived facilitators and barriers to adoption, and message preferences among non-transgender Black women and Latinas in the Bronx, New York.

Study	Design and analysis	Country	Setting	Sample size	Population	Objective
D'Angelo, 2021	Semi structured interviews with socioecological model	USA	Community	33	Black women	to understand the key facilitators and barriers to PrEP use experienced and perceived by Black women in New York City.
Frankis, 2016	Semi structured interviews	Scotland, UK	Communities affected by HIV	10	MSM	To explore PrEP awareness and acceptability amongst MSM in a low prevalence region (Scotland, UK).
Gafos, 2019	Semi structured interviews	England, UK	Sexual health clinics	41	MSM and one transgender women	To explore how PrEP use impacted existing sexual risk behaviours and risk reduction strategies using qualitative data from the PROUD study.
Girard, 2019	Focus groups with biosocialities/ biopower theory	Canada	Community	86	MSM	To analyse biosocialities among gay men, in a context of a long-term epidemic.
Goparaju, 2017	Focus Groups	USA	Part of the Women's Interagency HIV Study	20	Women (3/4 of whom were Black women)	To contribute to the understanding of the social and structural barriers facing women, specifically African American and Latina women, living in the Washington D.C metropolitan region with high HIV prevalence, as they endeavour to remain HIV-negative.
Grace, 2018	Focus Groups and In depth interviews with grounded theory	Canada	Part of the PREPARATORY-5 demonstration project based in a HIV clinic	16	MSM	To inductively learn from the lived experiences of PrEP users who were part of the PREPARATORY-5 study in Toronto, Canada, and had been on PrEP for a year or longer.
Harrington, 2020	Semi structured interviews	England, UK	Community group	13	MSM	to understand how PrEP is placed within the narratives of MSM who use it.

Study	Design and analysis	Country	Setting	Sample size	Population	Objective
Hess, 2019	Semi structured interviews In depth interviews	USA	Part of the ‘‘Good to Go’’ Program for HIV testing	14	Young MSM	To identify main themes in discussion content surrounding PrEP-related decision-making
Hillis, 2021	Semi structured interviews with Interpretative Phenomenological Analysis	England, UK	Part of the IMPACT trial	20	MSM	to explore men who have sex with men (MSM) and service provider (SP) perspectives on provision and accessibility of PrEP in Northern and Central England.
Jaspal, 2016	Semi structured interviews with social representations theory	England, UK	Community	11	MSM	To provide some preliminary insights into perceptions and understandings of PrEP in this population
Klassen, 2017	Semi structured interviews	Canada	Part of the Momentum Health Study	84	MSM	1. To examine the multiple ways in which gay men in Vancouver were learning about NPTs and further asked participants to articulate what these experiences of accessing NPT knowledge had been like, allowing participants to compare multiple forms of education and articulate the relative strengths and weaknesses of various prevention sources 2. To analyze how the acceptability of NPT education could be optimized within this setting.
Klein, 2019	Semi structured interviews In depth interviews	USA	Community	30	Transgender women and two non-binary people	To assist PrEP implementation efforts by identifying strategies for best practice to increase PrEP access and uptake among transgender women and nonbinary transfeminine individuals (TGWNBI).

Study	Design and analysis	Country	Setting	Sample size	Population	Objective
Knight, 2016	Unstructured interviews	Canada	Clinical and non-clinical settings	16	Young MSM, one transgender man and one non-binary person.	To assess how socio-cultural norms may influence the implementation and scalability of future HIV PrEP interventions in Vancouver, Canada.
Martinez-Lacabe, 2019	Semi structured interviews: "oral history interviews" with biomedicalisation	England, UK	Community	15	MSM (of whom 13 were cisgender and 2 were transgender)	To explore how processes of biomedicalisation are being negotiated and confronted by gay men in England.
Mutchler, 2015	Dyadic interviews with a modified version of grounded theory	USA	Community	48	Young Black MSM and their friends	To explore YBMSM's thoughts about PrEP use in the context of the larger toolbox for HIV prevention that will be increasingly available nationally and globally.
Newman, 2018	Semi structured interviews	Canada	Community	29	MSM (of whom 26 were cisgender and 3 were transgender)	1. To explore, in depth, the experiences of GBM in considering, accessing and using (or not using) PrEP 2. To understand emerging sexual health, social and community issues among GBM in the PrEP era.
Nydegger, 2020 & 2021	Semi structured interviews and In depth interviews with syndemic theory	USA	Community	30	Black cisgender women	To qualitatively explore Black women's interest in and adoption of PrEP over time.
O'Halloran, 2019	Survey or questionnaire	UK	Online	2,389	MSM, 30 non-binary people and 6 women	To assess HIV PrEP access, and user characteristics.
Park, 2019	Semi structured interviews with grounded theory	USA	Sexual health clinic	14	Cisgender women	To characterize the pathway to PrEP uptake among women prescribed PrEP at an urban clinic that served predominantly Black and Latina women, thus reflecting

Study	Design and analysis	Country	Setting	Sample size	Population	Objective
						the current epidemic among U.S. women.
Pasipanodya, 2021	Focus Groups	USA	Community	22	Cisgender women	to better understand cisgender women's knowledge and attitudes towards PrEP and to obtain their perspectives on ways of facilitating other cisgender women's PrEP uptake and adherence.
Philpot, 2020	Survey or questionnaire	Australia	Online	1404	MSM	To use free-text data to examine the frequency of Australian GBM's PrEP-perceptions, highlighting the potential benefits and challenges to its promotion.
Poteat, 2019	Focus Groups and In depth interviews	USA	Community	32	Transgender Black and Latina women (2 of whom were young people)	To understand PrEP awareness and uptake among BLTW, and assess willingness to engage in current and future HIV prevention interventions, including oral PrEP, postexposure prophylaxis (PEP), microbicides, and vaccines.
Pyra 2021	Interviews	USA	Health centre	8	Black cisgender women	to understand and characterize the PrEP experience, particularly PrEP persistence, among Black ciswomen who have initiated PrEP.
Rael, 2018 and 2019	Focus Groups	USA	Part of Project AFFIRM, a longitudinal study of transgender identity development	18	Transgender women	2018: To shed light on NYC transgender women's perceived barriers to using PrEP and strategies to overcome them 2019: To understand transgender women's concerns and preferences on long-acting PrEP products, including injections and IMDDs.

Study	Design and analysis	Country	Setting	Sample size	Population	Objective
Reyniers, 2021	In depth interviews with grounded theory	Belgium and the Netherlands	part of BePrEP-ared and AMPrEP trials	32	MSM	To explore how early adopters of PrEP in Belgium and the Netherlands experienced and managed PrEP disclosure to others; to fully understand how social interaction and social life can influence its uptake, its use, and how PrEP is becoming part of the social and sexual culture of MSM communities, and society at large.
Rowniak, 2017	Focus groups	USA	Community	21	Transgender men	To examine the attitudes and knowledge of trans men regarding PrEP.
Santa Maria, 2019	Semi structured interviews	USA	Part of the Homeless Youth Risk and Resilience Survey	45	Homeless young people (of whom 18 were cisgender men, 22 cisgender women, and 4 transgender people whose gender was not specified)	To explore the knowledge, interest, and perceived barriers and facilitators to PrEP use among a sample of YEH in Houston, TX and Los Angeles, CA using cross-sectional survey measures and semi structured interviews.
Sevelius, 2016	Focus Groups and In depth interviews	USA	Community	30	Transgender women	To address this gap in the literature by exploring trans-specific facilitators and barriers to PrEP acceptability among a sample of urban trans women at risk for HIV acquisition.
Vaccher, 2018	Semi structured interviews	Australia	Community	24	MSM (of whom 2 were transgender)	To explore issues related to PrEP use, including the notion of safe sex, attitudes to PrEP, and management of adherence.

Study	Design and analysis	Country	Setting	Sample size	Population	Objective
Watson, 2020	Focus groups	USA	Community	37	Transgender and Gender Non-Binary people	To identify the broad PrEP-related themes raised by focus groups, and to provide an in-depth exploration of the multiple, intersecting factors identified by trans/nb individuals pertinent to increasing PrEP awareness and access.
Williamson, 2019	Focus groups	England, UK	Community	13	MSM	To use this particular location (Leicester) to understand how an ethnically and socio-economically diverse group of GMSM (both HIV+ and HIV−) felt about PrEP and to explore their views, experiences, representations and intentions.
Witzel, 2018 and 2019	Semi structured interviews with Intersectionality theory	England, UK	Community	25	Black MSM	2018: To understand the dimensions of acceptability of a potential PrEP service for BMSM aged 18–45 in London. 2019: To understand the motivations and barriers of BMSM aged 18–45 to PrEP uptake.
Wood, 2017	Semi structured interviews with grounded theory	USA	Community	25	Young transgender women	To explore factors affecting the uptake of PrEP among YTW and develop a theoretical model for PrEP uptake among YTW.
Young, 2014 and 2016	Focus Groups and In depth interviews with biomedicalization theory	Scotland, UK	Community	28	18 MSM and 10 people who were born in Africa	2014: To explore the acceptability of pre-exposure prophylaxis (PrEP) among gay, bisexual and men who have sex with men (MSM) and migrant African communities in Scotland, UK. 2016: This article examines how biomedicalisation is encountered, responded to and negotiated within

Study	Design and analysis	Country	Setting	Sample size	Population	Objective
						and in relation to new biomedical forms of HIV prevention.
Zimmermann, 2019	Unstructured interviews and Survey or questionnaire with Information-Motivation-Behavioural Skills Model and Health Belief Model	the Netherlands	Part of the AMPrEP demonstration study	374	MSM and 2 transgender people whose gender was not specified	To assess the acceptability and feasibility of offering both daily and event-driven PrEP as part of a combination prevention package.

2.1.6 Summary of themes and sub-themes

Iterative aggregation of codes generated the following key themes and sub-themes

Summary of themes and sub-themes

Major theme	Sub-themes
Knowledge of PrEP and information sources	Participants commented on how much they already knew about PrEP: Knowledge levels were high amongst MSM but lower in other demographics
	Participants expressed a desire for more information on PrEP: Many had questions and felt they should have already been told more
	Sharing knowledge within communities was valued: Knowledge often came from peers and most were keen to share information
Views and opinions on the value of PrEP	Many participants saw PrEP as a liberating experience:They valued the freedom to pursue relationships and sex without the fear of HIV
	Participants talked about PrEP as a way to take control of their health: They viewed it as a responsible and conscientious choice to use protection under their own control.
	PrEP was seen by many as being for MSM, at the expense of other demographics: Many women felt side-lined by PrEP services and trans women were often misgendered and treated as MSM
	Participants commented that using PrEP is a prosocial action: They felt that reducing the spread of HIV would benefit everyone
The level of protection offered by PrEP	The majority of participants saw PrEP as an extra layer of protection on top other methods: Most said they would use PrEP in conjunction with condoms, but some considered PrEP alone to be sufficient
	Participants held varied opinions about condoms: Many preferred sex without a condom, but often valued extra protection enough to use them.
	Many participants were concerned about contracting other STIs: They wanted to protect themselves and their partners fully. Some, however, considered all STIs other than HIV to be treatable.
Perception of the risk of contracting HIV	Participants reflected on their current risk status: Those who perceived a high risk would consider PrEP, whereas those who considered themselves low risk felt that PrEP would provide little benefit.
	Poor adherence to condoms was a prevalent concern: They were used inconsistently and use often depended on the type of sexual activity
	Participants described situations they considered to be particularly high risk for HIV transmission: Examples given included ‘chemsex’, poor mental health, and cities with high transmission rates
	Participants often assessed risk of HIV based on the person they were having sex with: For example, monogamous or casual, sero-concordant or -discordant, and whether their partner was trustworthy.

Major theme	Sub-themes
	Transgender and Cisgender women reported that they often had limited choices in sexual situations, so they did not have full control over what risks they were exposed to: These circumstances were a product of violence, abuse, transmisogyny, and survival sex work.
Social context of PrEP decisions	People with low socioeconomic status described how PrEP was not a high priority for them: Financial pressures, mental health, violence, and substance addictions had a larger impact on their wellbeing
	Social support was cited by some participants as a facilitator to PrEP use: Acceptance from friends and family made it easier to adhere to PrEP, whereas cultural barriers made it harder.
	Some participants described how marginalisation can be intersectional: Black MSM described a racial divide in the LGBT+ community and trans people felt alienated by PrEP campaigns.
Opinions on taking PrEP medication	Participants questioned whether PrEP is effective and reliable enough: There was no consensus on what constitutes acceptable enough protection
	Known and unknown side effects were a prevalent concern: Concerns were raised about short term (diarrhoea etc)and long term (kidney function etc.) side effects, and interactions with other medications.
	Participants were concerned that PrEP was a new drug and so the effects may not be fully understood yet:They didn't want to be 'treated as guinea pigs' and questioned who it had been tested on.
	Participants found the need for regular medical appointments and tests to be a barrier to using PrEP: People already undergoing medical treatment saw this as an extra burden.
	Transgender and cisgender women discussed what delivery method they would prefer to use to take PrEP: Many preferred an injectable option.
Practicalities of taking PrEP	Participants identified their thought processes when starting and stopping PrEP: Starting was often a decisive choice whereas stopping happened after an interruption or lack of motivation
	Participants described the actions they took to maintain regular adherence to taking PrEP and the barriers that made it harder adhere. Examples included having a routine, sleeping in different places, and having to conceal PrEP use.
	Participants discussed whether they preferred continuous or intermittent PrEP regimens: Preferences were mixed.
Influence of healthcare settings	Healthcare professionals' reactions to participants seeking PrEP can act as barriers or facilitators to PrEP use: Positive interactions facilitated, whereas misinformation and judgement created barriers.
	Participants discussed which parts of the health service are best placed to provide PrEP: Preferences were mixed.
	Participants from all groups suggested ways that services could be tailored to their needs: For example, greater understanding of cultural barriers, trans healthcare, and women's sexual health.

Major theme	Sub-themes
Consequences of using PrEP	Most participants speculated that risk taking behaviour might change when taking PrEP: PrEP users did not report their behaviour changing, despite this perception.
	Some MSM were more open to dating or having sex with HIV positive men while taking PrEP: They felt that being protected removed the barriers.
	Some participants worried that their PrEP use might put them at risk in other aspect of their lives: Trans women worried they would be 'outed' and some women worried about how an abuse partner would react.
Stigma surrounding PrEP use	Almost all participants mentioned the stereotype of PrEP users as promiscuous: Many wanted to avoid this stigma.
	Some participants commented that they had been mistaken for being HIV positive due to using PrEP: Needing prevention as sufficient to evoke HIV stigma.
	Some participants preferred not to disclose their PrEP use to others: They considered it to be private and feared hostile reactions.
Principles and wider implications	Some participants did not trust healthcare, pharmaceutical manufacturers, medical research or the government: This often stemmed from experiences of marginalisation that damaged trust.
	Participants objected to the medicalisation involved in HIV prevention: MSM resented the association of gay sex with disease and women objected to being made unfairly responsible for sexual health.
	Some MSM expressed discomfort with how the concept of 'safe sex' could change as a result of widespread PrEP uptake: Condoms may become less valued, making negotiating protection more complicated.
	Some MSM saw access to PrEP as a matter of LGBTQ rights: They felt that negative stereotypes and concerns were a product of homophobia.

2.1.7 Summary of the qualitative evidence

See appendix G for full GRADE-CERQual tables.

Summary of qualitative evidence

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
Knowledge of PrEP and information sources				
Participants commented on how much they already knew about PrEP. Knowledge levels were high amongst MSM: almost all had at least heard of PrEP and were aware of what it is, although there was some confusion over the differences between PrEP and PEP. Knowledge levels were lower for women. Transgender women had often heard of PrEP but had not been given any information about it, whereas many cisgender women had not heard of PrEP at all.	Auerbach 2015 Cahill 2020 Collier 2017 Klassen 2017 Knight 2016 Mutchler 2015 Nydegger 2020 Nydegger 2021 Park 2019 Pasipanodya 2021 Pyra 2021 Rowniak 2017 Santa Maria 2019 Sevelius 2016 Wood 2017	"…with regards to PrEP and PEP, sorry, I always get that mixed up" MSM "[I] was ignorant to the situation because the media don't portray PrEP. You don't go to your doctor and hear about PrEP. It's only recently, since I've been exposed to all of this." Black cisgender woman "I'm pretty sure it's being talked about like it's the holy grail over in the gayborhood. But it's not being talked about over here in Transtasia." Transgender woman	Downgraded once for minor concerns about relevance and coherence	Moderate
Participants expressed a desire for more information on PrEP. Many had questions to ask and misconceptions to clarify. Their questions were often on how to take it, what the risks are, what research has been done.	Auerbach 2015 Bond 2016 Collier 2017 D'Angelo 2021 Grace 2018 Hess 2019 Klassen 2017	"… certainly I would like to be more fully educated in terms of how the drugs work and what treatments are available. Knowledge is power, right?" MSM	Downgraded once for minor concerns about relevance	Moderate

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
Some women expressed annoyance that they had not had access to information on PrEP. They felt that they should have been told about it if they were at risk and that healthcare professionals had a responsibility to inform them.	Mutchler 2015 Newman 2018 Nydegger 2021 Pasipanodya 2021 Pyra 2021 Rowniak 2017 Santa Maria 2019 Sevelius 2016 Watson 2020 Wood 2017	It's frustrating because… We [black women] are getting it [HIV] because we're not educated about it because people are not educating us.. That's sad to me. It really is." Black cisgender woman "… If a doctor is going to be keeping himself in the dark about something – like, it's one thing to not know about it, it's another thing to know about it and not learn about it or tell your patients about it. That's just awful." Transgender woman		
Sharing knowledge within communities was valued. MSM stated that a lot of their knowledge of PrEP came from peers within the community. HIV positive men were mentioned as being advocates of PrEP for others. Participants from all groups were keen to spread awareness to others in their community and to advocate for wider PrEP use.	Auerbach 2015 Brooks 2019 Cahill 2020 Frankis 2016 Grace 2018 Harrington 2020 Hess 2019 Hillis 2021 Klassen 2017 Klein 2019 Mutchler 2015 Newman 2018 Nydegger 2021 Park 2019 Pasipanodya 2021 Pyra 2021 Rowniak 2017 Witzel 2019	"I talked to friends who had been in similar situations. I talked to some of my poz [HIV positive] friends." MSM "Oh yeah absolutely, yeah and if I took PrEP and I knew how to get PrEP I would literally advertise to as many people as I want." Black MSM	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
	Wood 2017 Young 2016			
Views and opinions on the value of PrEP				
Many participants saw prep as a liberating experience. It has allowed them to pursue relationships and sex without the fear of HIV. They described how fear and worry after unprotected sex had impacted their wellbeing and mental health, so they highly valued the reassurance PrEP provides. MSM in particular described feeling liberated from the threat of HIV and able to have sex without their actions being constrained.	Auerbach 2015 Bil 2016 Bond 2016 Gafos 2019 Grace 2018 Harrington 2020 Jaspal 2016 Martinez-Lacabe 2018 Mutchler 2015 Newman 2018 Nydegger 2021 O'Halloran 2019 Philpot 2020 Watson 2020 Wood 2017	"Frankly, it's been one of the greatest things of my life. I have absolutely loved it. I have a lot of sex, and I go to the bathhouses a lot, despite my advanced age. I can tell you, sex has never been better. For the first time in my lifetime, it's taken away the fear from having sex. Sex isn't meant to be something you're ashamed of or fearful of. It's meant to be enjoyable and PrEP has made sex enjoyable for me, which is fantastic… Sex has been liberating again thanks to PrEP." MSM "The relief from the fear of contracting HIV is enormous. I never thought I could have sex without that lingering fear." MSM	No downgrading required	High
Participants talked about PrEP as a way to take control of their health. They often described taking control in this way as being empowering. Many saw PrEP use as sign that a person is being responsible and conscientious by making a choice to take care of themselves. Cisgender women in particular valued having a prevention strategy they alone could control, regardless of their partners choices.	Bond 2016 Brooks 2019 Collier 2017 D'Angelo 2021 Gafos 2019 Goparaju 2017 Grace 2018 Jaspal 2016 Knight 2016 Martinez-Lacabe 2018 Mutchler 2015	"PrEP for me is about control. I'm on control of my own health. I'm choosing to protect myself from HIV." Black MSM "I think it is good for women to have an option they can be responsible for when their partner refuses to be responsible." Black cisgender woman "Taking PrEP is… taking care of my body, and it's knowing that I'm going to live longer, and I'm going to be around for when my family loves me and cares about me and accepts	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
	Nydegger 2021 O'Halloran 2019 Pasipanodya 2021 Philpot 2020 Pyra 2021 Sevelius 2016 Watson 2020 Williamson 2019 Witzel 2018 Witzel 2019 Wood 2017	me." Transgender woman		
PrEP was seen my many as being for MSM, at the expense of other demographics. Many women felt that they were sidelined by Prep information and services targeted towards gay men which perpetuated a myth that they were not at risk. For transgender women this also meant that they were more likely to be misgendered and treated as if they were MSM when using these services. This reflects and reinforces common transphobic tropes that suggest transgender women aren't truly women. Conversely, transgender MSM were often assumed to be heterosexual and therefore misrepresented as not	Auerbach 2015 Bond 2016 Cahill 2020 Goparaju 2017 Klein 2019 Knight 2016 Nydegger 2021 Park 2019 Pasipanodya 2021 Pyra 2021 Rael 2018 Rael 2020 Rowniak 2017 Sevelius 2016 Watson 2020	"[The health care provider] was saying, "This is what gay men take. Based on what you've explained to me, you don't seem like you have much to be worried about."." Black cisgender woman "A lot of people don't think of transwomen as women. They think of us as men who are trying to be women. And so that sort of knowledge, for me, it's this thought of PrEP as something that's for gay men. It can get kind of personal." Transgender woman "To me, this PrEP thing is a gay white man's thing, OK?" Black transgender woman	Downgraded once for moderate concerns about relevance	Moderate

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
being in a demographic that requires PrEP.				
Participants commented that using PrEP is a prosocial action. They placed value on how it protects others and could reduce the spread of HIV which would benefit everyone. MSM and transgender women claimed this was a very positive development for the LGBTQ community as a whole, as well as individual users.	Auerbach 2015 Bil 2016 Collier 2017 Grace 2018 Harrington 2020 Klassen 2017 Klein 2019 Knight 2016 Martinez-Lacabe 2018 Mutchler 2015 Philpot 2020 Reyniers 2021 Wood 2017	"I think it'll be a good thing for other trans women – trans people – trans community. It'll save lives… I think it would be a magnificent thing if everyone in the trans community was taking PrEP" Transgender woman "I feel like if they're [on PrEP], they're not only protecting themselves. It's also for the well-being of other people that they're having sex with. I don't think there's anything bad. I think it's all positive." MSM	No downgrading required	High
The level of protection offered by PrEP				
The majority of participants saw PrEP as an extra layer of protection on top other methods. They did not consider it to be a full replacement for their existing safe sex practices. Most of these said they would use PrEP in conjunction with condoms. A smaller number of MSM considered PrEP to be sufficient protection on its own, so they would swap other protection methods for PrEP if they were to use it.	Auerbach 2015 Bil 2016 Brooks 2019 Collier 2017 D'Angelo 2021 Frankis 2016 Gafos 2019 Harrington 2020 Hillis 2021 Jaspal 2016 Martinez-Lacabe 2018 Mutchler 2015 O'Halloran 2019	"it makes sense for this sort of period to take something preventative as a second backup plan. I mean, I use condoms as well, but it would be like a second option." MSM "just an added layer of security." Transgender MSM "Sex with a condom now tends to be a decision that the other guy makes… I sort of don't mind either way." MSM	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
Some MSM were ambivalent to other protection as they felt sufficiently protected by PrEP, so considered anything else to be for their partners protection: They did not feel the need to contribute to the decision.	Park 2019 Philpot 2020 Rael 2018 Rowniak 2017 Vaccher 2018 Williamson 2019 Wood 2017 Young 2014			
Participants held varied opinions about condoms. Many participants stated that they prefer sex without a condom. They described it feeling more pleasurable, more natural, and more spontaneous. Some participants avoided condoms because of this preference, while others still used them because they valued the protection more. Conversely some participants felt that condoms were the safest option available and so would prefer to use them. They commented that PrEP is not needed if condoms are used. One participant found condoms difficult to use due to a physical disability, so was glad to have a more accessible alternative.	Auerbach 2015 Bil 2016 Bond 2016 Collier 2017 Gafos 2019 Grace 2018 Harrington 2020 Hess 2019 Jaspal 2016 Knight 2016 Martinez-Lacabe 2018 Mutchler 2015 Newman 2018 Philpot 2020 Reyniers 2021 Williamson 2019 Wood 2017 Young 2016 Zimmermann 2019	“The use of a condom is really inhibiting my sexual pleasure, being passive but especially being active… it is impacting how I experience sex and how I experience my sexuality.” MSM “[using condoms] is 99% safe… it’s visible. I can see it. I can put it on.’’ Black MSM “If you just have safe sex with condoms, I think that is the best protection, and if you use them well, make sure it doesn’t break and you follow the normal guidelines or rules for safe sex, then I don’t think you need it [PrEP]”. MSM	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
Many participants were concerned about contracting other STIs. PrEP would not protect against these, so they saw PrEP as having limited value. Some also commented that PrEP would not protect their partner against contracting STIs from them. Other participants, mostly MSM, saw HIV is the biggest concern. They considered all other STIs to be treatable, therefore preventing them was not a priority. For transgender men the biggest priority was to protect against unwanted pregnancy, which would be extremely distressing for them. Condoms offered the protection they needed for this purpose and also for preventing HIV, so PrEP had fewer advantages for this group.	Auerbach 2015 Bil 2016 Brooks 2019 Cahill 2020 Gafos 2019 Hillis 2021 Knight 2016 Martinez-Lacabe 2018 Mutchler 2015 Newman 2018 Pasipanodya 2021 Philpot 2020 Rowniak 2017 Watson 2020 Young 2014	“If you said Truvada was 100% effective, I would abandon condom usage I think because as I said all of the other STIs are treatable” MSM “It’s not some magic pill that prevents you from contracting any sort of STI” MSM “The very first thing goes through my mind is getting pregnant—not anything about getting HIV… Us trans men, we have to think about the combination of HIV prevention and birth control.” Transgender man	Downgraded once for minor concerns about coherence	Moderate
Perception of the risk of contracting HIV				
Participants reflected on their current risk status. They described their interest in PrEP in terms of their circumstances and behaviour. Many participants were considered their risk status to be high enough to warrant adopting PrEP. Others considered themselves to be low risk	Bil 2016 Brooks 2019 D’Angelo 2021 Frankis 2016 Gafos 2019 Harrington 2020 Hess 2019 Hillis 2021 Jaspal 2016	“Here I am quantifying different risks at the high risk end of the spectrum, and I know there are different levels of risk in the high risk end, although I am not making the most sensible decisions I think I am at the lower end of the higher risk end, er.. sometimes anyway” MSM “It [PrEP] wouldn’t benefit me. I don’t take many risks, not much more than most guys on	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
at present, so felt that PrEP would not provide a lot of benefit to them.	Martinez-Lacabe 2018 Mutchler 2015 Newman 2018 Nydegger 2021 Pasipanodya 2021 Pyra 2021 Santa Maria 2019 Wood 2017 Young 2014 Zimmermann 2019	the scene. I suppose it's for someone high-risk." MSM		
Poor adherence to condoms was a prevalent concern. Participants described varied and inconsistent condom use in their sexual history, even amongst participants who expressed a strong preference for them. Many MSM talked of 'slip ups' and poor judgement in the heat of the moment. MSM also explained how their condom use is often dependent of the type of sexual activity they are engaging in and whether they are the active or receptive partner. They felt these factors affected how much risk they were exposed to so their	Bil 2016 Brooks 2019 Frankis 2016 Gafos 2019 Harrington 2020 Jaspal 2016 Newman 2018 Park 2019 Pasipanodya 2021	"Sometimes I do feel like, damn, why didn't I just use condoms? I should have, but of course it feels better without a condom—it's really tempting. Like yesterday, I didn't use a condom. It worries me sometimes, but, at the same time, I'm in the safe side—hopefully a safe side" Black transgender woman "In a way it sounds good I agree because I do sort of have [condom] slip ups quite a bit, like I have had unprotected sex a few times" MSM "… maybe also with me having more passive sex, so getting fucked [is higher risk]. Usually I am more active, that also has something to do with it. One of the considerations is being	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
willingness to use a condom was based on this assessment.		active, so the risk is lower. Actually you're reducing your risk, by not ejaculating and mainly being the active one." MSM		
Participants described situations they considered to be particularly high risk for HIV transmission. These included 'chem-sex' parties where groups of MSM engage in sex under the influence of illegal drugs. Women also described taking more risks when using drugs and alcohol. Episodes of poor mental health was also highlighted as contributing to risk taking sexual behaviour. Some MSM described certain geographical locations as being hubs for transmission. Cities with large LGBTQ communities such as Brighton and Manchester were mentioned. MSM claimed that they would feel less safe seeking sexual partners in these locations than in more smaller towns.	Brooks 2019 Cahill 2020 Frankis 2016 Gafos 2019 Harrington 2020 Jaspal 2016 Klassen 2017 Martinez-Lacabe 2018 Mutchler 2015 Nydegger 2020 Nydegger 2021 Pasipanodya 2021 Vaccher 2018 Williamson 2019 Zimmermann 2019	"The drug that has made the biggest difference to my sexual behaviour is mephedrone… I have noticed that for me it has a high association with bad methods of protection whereby I will do much more reckless things … I would identify that for me, as a particular drug associated with chemsex and high-risk behaviour" MSM "I went through a number of bereavements and started experiencing depression. This impacted on my sexual behaviour and I started having more unsafe sex… I started using drugs." MSM "I have actually felt that I almost needed to get away from Brighton because it seems to be a bit of a hot bed of unprotected sex, substance abuse and I know that it is a bit of a HIV hotspot" MSM	No downgrading required	High
Participants often assessed risk of HIV based on the person they were having sex with. Many MSM based this assessment on whether they had one monogamous partner or multiple casual partners. They felt that PrEP	Bil 2016 Bond 2016 D'Angelo 2021 Frankis 2016 Gafos 2019 Grace 2018	"If I have sex outside of my steady relationship then I'm having safe sex. But with my boyfriend, my steady partner, we have unsafe sex. So actually I don't really need PrEP." MSM	Downgraded once for moderate concerns about coherence	Moderate

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
was unnecessary if they were only having sex with one person they believed to be HIV negative. PrEP was welcomed by many participants as a positive way for serodiscordant couples to mitigate a known risk. MSM in serodiscordant relationships explained that the precautions they took were determined by whether their partner's viral load was detectable. Participants from all groups referred to whether they trusted their sexual partners as a risk factor. This included trust that they were truthful about their HIV status, that were adhering to medication if they were HIV positive or on PrEP if they were negative, that they were not having sex with other people or that they were having safe sex with others.	Hess 2019 Klassen 2017 Knight 2016 Martinez-Lacabe 2018 Mutchler 2015 Newman 2018 Nydegger 2021 Park 2019 Pasipanodya 2021 Philpot 2020 Rowniak 2017 Santa Maria 2019 Sevelius 2016 Williamson 2019 Young 2014 Young 2016 Zimmermann 2019	"We have unsafe sex with each other, without a condom… I know my partner well enough to know that he takes his medication and is stable [viral load]. But you never know what happens in the mean time and that is my insecurity. It [viral load] could suddenly peak and then I'm more at risk and you can miss that in the bi-annual check-up. And PrEP would provide the additional protection for that." MSM ""I'd just met him [undetectable HIV positive partner] and, you know, men will say things to get what they want, and so I didn't outright disbelieve him, but I wanted to make sure that this stranger was telling the truth."" MSM		
Transgender and Cisgender women reported that they often had limited choices in sexual situations, so they did not have full control over what risks they were exposed to. Participants who were in abusive relationships explained that they didn't have the power to negotiate	Auerbach 2015 Bond 2016 Brooks 2019 Cahill 2020 Collier 2017 D'Angelo 2021 Goparaju 2017 Klein 2019 Nydegger 2020	"When you tell people you're trans and what this and that means…they don't want you – they don't want any thing to do with us. Let alone when we find someone who wants something to do with us, we're there. It doesn't matter if it's right or wrong, it's just – we're more willing to go with the wrong person because it's harder to find someone who will accept us." Transgender woman	Downgraded twice for moderate concerns about relevance and minor concerns about coherence	Low

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
condom use with their partner, or often the power to refuse sex. They were also at risk of HIV and other STIs spread by their partners sleeping with other people. Transgender women in particular felt they were treated as low value sexual partners, so were expected to have sex under the terms that a partner wanted rather than to advocate for their own needs. They reported that partners often became violent if there was disagreement. Some women, particularly transgender women, engaged in survival sex work, so were not able to negotiate condom use, as they would lose clients or be paid less. Being dependent on income from sex work meant that they assessed the risk of contracting HIV against the more immediate consequences of poverty.	Park 2019 Pasipanodya 2021 Rael 2018 Santa Maria 2019 Sevelius 2016 Wood 2017	"'you don't know what your man is doing.'" Black cisgender woman "Not every time I have had sex have I been a willing participant. I've been sexually assaulted a few times. I mean, definitely when it happened, one of the first things I worried about was HIV. Now, at least I'm taking PrEP, if, god forbid, it [being sexually assaulted] were to happen again, at least it's one less thing for me to really worry about." Black transgender woman "Some of us, you know, we do sex work on the side, and some us, you know, we're like, part of that kind of like, marginalized community and we don't really have that much opportunity to employment. So we end up trying to make a quick buck with sex work and that's a lot of exposure, and that's a risk." Transgender woman		
Social context of PrEP decisions				
People with low socioeconomic status described how PrEP was not a high priority for them. Other pressures and life events interfered or had a bigger impact on their wellbeing. Many felt that they could not afford to take time off work to attend additional	Auerbach 2015 Cahill 2020 D'Angelo 2021 Nydegger 2020 Nydegger 2021 Pasipanodya 2021 Poteat 2019 Pyra 2021	"Not having these nagging kids around…that's how I forgot last time… I just need reminders… I got a million and one things that I got to [do]… I can get somebody to watch them [kids] real quick… I shouldn't have made the appointment when I was going to WIC [benefits office]" Black cisgender woman	Downgraded twice for moderate concerns about relevance and minor concerns about coherence	Low

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
medical appointments, or had childcare and other caring responsibilities to attend to that meant they missed appointments. Transgender men and women felt that their employment was precarious due to transphobia so they could not ask for time off without risking their job. Trans and non-binary participants discussed how financial incentives could improve access to PrEP by mitigating some socioeconomic barriers. Women in one study reported violence in their community being a greater threat to their health. Many of these women had been injured or had a loved one injured or killed recently. Some participants reported having substance addictions and mental health issues that had a larger impact on their wellbeing, as well as making it harder to prioritise accessing healthcare and harder to adhere to PrEP.	Rowniak 2017 Santa Maria 2019 Sevelius 2016 Watson 2020 Wood 2017	"HIV — it's sad to say— in the trans community is not the top concern. The top concern is housing, finding a job, becoming working women, stop working on the streets, surviving. All of that comes before HIV in the trans world," Black transgender woman "I'm dealing with PTSD, so when things are left in my hands they become very overwhelming" Transgender woman		
Social support was cited by some participants as a facilitator to PrEP use. Transgender women gave examples of family and friends supporting their choice and encouraging them to protect their health. Participants felt	Brooks 2019 D'Angelo 2021 Goparaju 2017 Nydegger 2021 Pasipanodya 2021 Pyra 2021 Reyniers 2021 Santa Maria	"It was a good thing; [my parents] recommended it [PrEP].They think it's the best for me because a girl like me should always be safe with my sex life as well, regardless of who I'm having sex with." Black transgender woman	Downgraded once for minor concerns about coherence	Moderate

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
this support motivated them to maintain regular adherence to PrEP. Conversely, cultural barriers can make it harder to access and adhere to PrEP. Black participants described how homosexuality was less accepted in some communities so talking about PrEP would be socially unacceptable. Some Black women had experienced friends trying to talk them out of taking PrEP. They also stated that they would find it more difficult to visit a clinic in their community as they would feel judged. Participants in recent studies observed that as awareness of PrEP has increased in the general population over the last few years they have felt greater support and acceptance.	2019 Vaccher 2018 Witzel 2018 Witzel 2019 Young 2014 Young 2016	"One of the girls at work . It's like, ''Have I taken my tablet this morning?'' And she'll remember . It's not just me involved in all of this. There's lots of people." MSM "If you build another [PrEP] service I'd say build it in a place that's close to a Black community. Not necessarily in the community because of that fear thing. [.. .] A lot of people would be scared and I get that, especially how homophobic the Black community can be." Black MSM		
Some participants described how marginalisation can be intersectional. This affected their experiences with PrEP and their feelings about the risk of HIV. Black MSM felt that they were often marginalised by a racial divide within the LGBTQ community. This meant that they did not access the same networks of information and support that white MSM used to access PrEP.	Hillis 2021 Klein 2019 Nydegger 2021 Witzel 2018 Witzel 2019	"If I go to the gay scene, I don't really see representation of Black or African men. That's a big reason [for not going]. In that sense as well, I feel like I don't fit in there. I feel like I'm a minority within another minority." Black MSM "It is one thing to be a gay black man on Grindr especially in the world of no fats, no fems, no Asians, no blacks for example but if you then add HIV on the top of that then you are even pushed lower down the hierarchy of who is desirable and who is not desirable."	Downgraded once for minor concerns about methodological limitations, minor concerns about relevance, minor concerns about coherence and minor concerns about adequacy.	Moderate

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
Some transgender participants felt that PrEP advertising and awareness campaigns often focus on MSM and give less consideration to transgender people. They described attempts that have been made to include transgender women in these campaigns which have failed to represent the transgender community accurately. This lack of understanding of the diversity of presentations has alienated some transgender people.		Black MSM "'A lot of the trans people that they've been using in a lot of these campaigns and stuff have been… for lack of a better term, more passable. And that's not always the reality with our community, and that's not always what our community looks like. So, you need people out there to show the diversity, and diversity of presentations… And I think it'd be great to show people at different stages of transition, and different presentations." Black transgender woman		
Opinions on taking PrEP medication				
Participants questioned whether PrEP is effective and reliable enough. Many quoted percentages they would consider acceptable risk, but there was no consensus among them. Some participants required complete certainty and viewed any risk of contracting HIV while on PrEP as too high. Others felt that any increase protection is worth having, particularly if used in combination with other methods to provide the best possible protection.	Auerbach 2015 Bil 2016 Jaspal 2016 Martinez-Lacabe 2018 Mutchler 2015 Pasipandoya 2021 Philpot 2020 Wood 2017 Young 2014 Young 2016	"What about that 1%? That one unlucky person?... You're putting yourself at risk for being that 1%. You might get that 99%, but you might not. You might be that 1% that does get it after the drug" MSM "I'll argue that while it's not 100 percent fool proof and it's not going to save you from everything, you're still going to use it… You would take it knowing it's not 100 percent because nothing's 100 percent" Cisgender woman "44% effectiveness is more than what I have now." MSM	No downgrading required	High
Known and unknown side effects were a prevalent concern.	Zimmermann 2019	"…What are the possible side effects of this pill from taking it? Does it cause liver	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
Many participants were worried about possible serious side effects that have been highlighted in clinical trials of PrEP.. Most commonly mentioned were problems with the liver, kidneys and reduction in bone density. PrEP users described the side effects they had personally experienced, including diarrhoea, insomnia, nausea, and headaches. Some participants stopped taking PrEP because they found these side effects intolerable. Many PrEP naïve participants found these side effects (particularly diarrhoea) discouraging, even if they were likely to be short term. Some participants were concerned that PrEP might interact with other medications such as antidepressants and contraceptives or other medical conditions such as diabetes. Transgender people questioned whether PrEP could interact with hormones and other medications they were taking as part of their transition. Most considered their transition to be the priority, so if PreP were to interfere it would be a deal breaker issue.	Young 2014 Williamson 2019 Watson 2020 Vaccher 2018 Sevelius 2016 Santa Maria 2019 Rowniak 2017 Rael 2020 Rael 2018 Pyra 2021 Philpot 2020 Pasipanodya 2021 Park 2019 Newman 2018 Mutchler 2015 Jaspal 2016 Hillis 2021 Hess 2019 Girard 2018 Cahill 2020 Bond 2016 Bil 2016 Auerbach 2015	disease?…high blood pressure?…stroke? I heard…that it can cause headaches, nausea, diarrhea, potential strokes. I've heard this. So I'm concerned. I mean, because I wouldn't want to consume anything in my body that's going to harm me." Transgender woman "I think it would be great if I didn't have other medical conditions that could become a problem. For example, I don't know the effects it might have with diabetes. Will it counteract the effects of how my antidepressants work?" MSM "If it stopped my hormone progress, I would be irate…That would definitely make me stop instantaneously. I'd be like [snaps fingers], I am off the pill." Transgender woman		
Participants were concerned that PrEP was a new drug and so the	Auerbach 2015 Bil 2016	"Once it's been out maybe 10 years, I might consider it then when all the effects are known.	Downgraded once for minor concerns about	Moderate

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
effects may not be fully understood yet. Some participants said they did not want to be treated as 'guinea pigs', so were reluctant to try it until it had been tested more thoroughly and established. Some women were concerned that PrEP had only been tested on men, white people or cisgender people. They felt that research needed to be conducted on the full range of people who would be eligible for PrEP. Transgender women in particular commented that their bodies had a distinct physiology from those of cisgender people, and that research often fails to address this. Some cisgender women questioned whether PrEP was suitable for children and young people as they noted that research studies only included participants over the age 18. They were concerned that this lack of evidence might preclude under 18s from accessing PrEP.	Girard 2018 Goparaju 2017 Hess 2019 Hillis 2021 Pasipanodya 2021 Rael 2018 Rael 2020 Rowniak 2017 Watson 2020	But right now it's just too new. I don't want to be one of the guinea pigs." MSM "a lot of these medications are not tested on black people, on black women. We're always at the end of that and that's because we don't participate in the researches that are coming out." Black cisgender woman "I mean, it's no disrespect, but a cis woman's body is different from a transgender woman's body. So, I mean, there's going to be different side-effects, different effects. Our bodies are going to take these medicines differently, so I want to know what did it do to this trans person." Transgender woman "What's the age range? Because I know, when I first started (sex work) - that pill sound like the best thing ever…What is considered adult? 'cause I know 13 is adult…having sex…" Cisgender woman	methodological limitations, minor concerns about relevance and minor concerns about coherence	
Participants found the need for regular medical appointments and tests to be a barrier to using PrEP. Some transgender women further explained that the frequent medical appointments required for their	Bil 2016 Bond 2016 Collier 2017 Hillis 2021 Pasipanodya 2021	"Because I'm on so much regimens now I think that squeezing in one more doctor's appointment to take care of my health, would be one more issue that I don't think I could handle… I'm constantly getting poked and prodded for hormones… I'm beginning to feel	Downgraded twice for minor concerns about relevance and moderate concerns about coherence	Low

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
transition were already burdensome and uncomfortable for them. Participants who were already using other medications and were often reluctant to add another pill to their regime.	Rael 2018 Rael 2020 Rowniak 2017 Santa Maria 2019 Sevelius 2016 Zimmermann 2019	like a damn horse at the vet's office. Look at my teeth, let me count how many years I have, put me out to pasture, and leave me alone!" Transgender woman "[I] had other daily medication, [I] did not want to burden myself too much" MSM		
Transgender and cisgender women discussed what delivery method they would prefer to use to take PrEP. Some women preferred injectable PrEP: Transgender women preferred it for the convenience and because they were accustomed to hormone injections. Cisgender women preferred it as it felt like a vaccination which they considered more discreet. Some participants had a fear of needles so would not be willing to use injectable PrEP. Several participants also expressed a strong dislike of taking pills, whereas others did not mind them.	Auerbach 2015 Cahill 2020 Collier 2017 Pyra 2021 Rael 2018 Rael 2020 Wood 2017	"It's better for the trans woman to get an injection of that…because we have to inject our hormones anyways, so that's what I'm saying. I mean, some of us use needles anyway. They show us how to do it anyway. But I think it's better for us to use needles like this also." Transgender woman "The secretive people would want the shot. They feel like I can just go in here and get this shot. No one is going to know I got it." Cisgender woman "Well it's that – ok I think that I don't like it [oral PrEP] because I don't like taking pills. It just drives me crazy." Transgender woman	Downgraded twice for minor concerns about methodological limitations and moderate concerns about relevance	Low
Practicalities of taking PrEP				
Participants identified their thought processes when starting and stopping PrEP.	Auerbach 2015 Bil 2016 Bond 2016 Newman 2018	"I finally got my ducks in a row to take it, so it felt pretty good" MSM	Downgraded twice for minor concerns about methodological limitations, minor	Low

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
When starting PrEP, many participants ruminated on the decision before committing to it. Some chose to mark the occasion of starting with a selfie to share it as news of a positive life change. Participants who stopped taking PrEP explained that they either felt they were not getting enough benefit so chose to stop, or circumstances prevented them from taking PrEP for a short time and they did not restart.	Park 2019 Young 2014	"I took a picture; I took a selfie, just like hundreds of other people have done..." Young MSM "Lost them on holiday" MSM	concerns about relevance and moderate concerns about coherence	
Participants described the actions they took to maintain regular adherence to taking PrEP and the barriers that made it harder adhere. These barriers included forgetting or not having a routine, sleeping in different places and not carrying PrEP with them, and having to hide their pills from others.	Auerbach 2015 Bil 2016 Collier 2017 D'Angelo 2021 Hillis 2021 Newman 2018 Nydegger 2020 Pasipandoya 2021 Pyra 2021 Rael 2020 Santa Maria 2019 Sevelius 2016 Vaccher 2018 Wood 2017 Young 2014 Zimmermann 2019	"I know it's just one pill a day, but when I had to start taking [another drug] and I only took it once a day, I would forget sometimes. And, it made me start to think, oh my god, what if I was on HIV meds or PrEP..." MSM "I have it with my breakfast 'cause I [also take] two fish oil capsules. So I just make sure that when I'm having those, I've got my little blue pill next to it. I'm a very routine-based kind of guy." MSM	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
Participants discussed whether they preferred continuous or intermittent PrEP regimens. People who preferred continuous PrEP liked that they could establish a habit and that they were always protected. People who preferred intermittent PrEP like that they were only medicating when they needed to and that they had fewer side effects. Other people claimed that they could not predict when they would be having sex, so intermittent was not suitable for them.	Bil 2016 Hillis 2021 Klassen 2017 Knight 2016 Vaccher 2018 Young 2014 Zimmermann 2019	"Yes, a little bit stupid. For me sex is something spontaneous and not something you plan, okay I'm having sex in three days and I'll start taking PrEP. No, I think that is nonsense." MSM "More routine and structure. It [daily PrEP scheme] is less complicated, will probably increase adherence" MSM "it feels like daily PrEP has too many constant side-effects" MSM	No downgrading required	High
Influence of healthcare settings				
Healthcare professionals' reactions to participants seeking PrEP can act as barriers or facilitators to PrEP use. Participants who had positive experiences placed a lot of value in advice from their clinicians. Participants who felt judged or uncomfortable talking to healthcare professionals found it harder to discuss PrEP. Some participants reported poor understanding and misinformation from clinicians. They cited examples	Auerbach 2015 Cahill 2020 Collier 2017 Goparaju 2017 Grace 2018 Hess 2019 Hillis 2021 Klassen 2017 Klein 2019 Martinez-Lacabe 2018 Newman 2018 Nydegger 2021 O'Halloran 2019 Park 2019	"I felt comfortable with him cause I know that he's a well-educated doctor and he specializes in these things, so I felt okay, comfortable." Black cisgender woman "Almost every healthcare professional I've disclosed to about taking PrEP assume I'm HIV Positive" MSM "you're my professional doctor and you work with trans people – and then I tell you, well, because I got a dick yeah, I fuck too, when you look at me like I'm crazy" Transgender woman	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
of clinicians not understanding the sexual practices of MSM and transgender women.	Pyra 2021 Rowniak 2017 Sevelius 2016 Vaccher 2018 Watson 2020 Witzel 2018	"It shouldn't be incumbent upon the patient to educate their doctor." Transgender man		
Participants discussed which parts of the health service are best placed to provide PrEP. Some preferred sexual health clinics for their specialist services, whereas others found GPs to be more accessible and private. Some participants described problems with obtaining PrEP through pharmacies.	Bil 2016 Goparaju 2017 Hillis 2021 Park 2019 Vaccher 2018 Young 2016	"Because I think HIV is so complicated, a General Practitioner doesn't have enough knowledge about it. I think you should rather leave it [PrEP prescription] to the specialists." MSM "I couldn't go to [the local] GUM clinic 'cause if I saw someone sittin' ootside that I ken [knew], it would look like that I had everything, d'you know what I mean? Whereas my doctor they [don't know] what I'm goin' in for an' I find it a lot safer ... So I go to my doctors I find it more secretive an' confidential." MSM "The pharmacist at one point, they didn't have it. They had to order it. They got the wrong ones. They had to reorder it, so it took a while from there. So it was like a month." Cisgender woman	Downgraded Once for minor concerns about relevance and minor concerns about coherence	Moderate
Participants from all groups suggested ways that services could be tailored to their needs.	Auerbach 2015 Cahill 2020 D'Angelo 2021 Goparaju 2017 Hillis 2021	"If you have someone from your own culture you probably think you are going to get judged more so you will be less open especially when they ask you about your sexual history and you are like 'oh my God I have to go through my	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
Black people described wanting understanding of cultural barriers and clinics that provided some distance from their communities for confidentiality reasons. Cisgender women suggested that gynaecologists and womens' sexual health clinics would their preferred option. Transgender people wanted clinicians with an understanding of wider transgender healthcare needs to be able to offer holistic support and understand their specific concerns. Participants who had a good relationship with their existing healthcare provider were keen to access PrEP from them rather than using an unknown service. MSM described feeling more comfortable accessing PrEP from services targeted at the LGBTQ community. Participants from other demographics also praised these services.	Klassen 2017 Klein 2019 Newman 2018 Park 2019 Poteat 2019 Pyra 2021 Rowniak 2017 Sevelius 2016 Witzel 2018 Watson 2020 Wood 2017	black book'… so yeah it is important to have the right type of people, type of person." Black MSM "All those doctors should be equipped with PrEP and everything else that would be a necessity to protect trans women... It should be coming from a doctor that gives them that information, who gives them that prescription, who gives them that appointment...Today you got your hormones. Next week, I'm gonna give you PrEP" Transgender woman "I don't know if they were particularly supposed to serve the LGBT community and then it opened up to others…I figure because they serve that community, they deal with people more sensitively. It's a different dynamic." Black cisgender woman		
Consequences of using PrEP				
Most participants speculated that risk taking behaviour might change when taking PrEP. Many expected they would use less protection of have more partners. Some PrEP users confirmed this was their experience but many did not find	Auerbach 2015 Bil 2016 Bond 2016 Brooks 2019 Collier 2017 Gafos 2019 Harrington 2020	"Not in the beginning but if I would use it for a long time probably it will [change my behaviour]. If I see every time that I don't have HIV, I think at one point I will start taking risks… That I would be less worried about condom use. And that would be a negative side. If I were to look at myself I can see that	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
that their sexual behaviour changed greatly. MSM commented that they expected or witnessed other people's behaviour changing when taking PrEP. They overwhelmingly commented on others' taking more risks and having more partners. They also observed that some PrEP users advertised their PrEP use on social media to indicate they were available for casual sex. Several participants had experienced sexual partners now pressuring them to have sex without a condom because one or both of them were on PrEP. Some PrEP users stated that they have declined or ended sex when a partner asked to use a condom.	Hess 2019 Hillis 2021 Jaspal 2016 Knight 2016 Mutchler 2015 Newman 2018 O'Halloran 2019 Pasipandoya 2021 Philpot 2020 Reyniers 2021 Sevelius 2016 Watson 202 Williamson 2019 Young 2014 Zimmermann 2019	happening" MSM "Since I've been on it, I really haven't had too much sex because it's just my choice right now" Black transgender woman "My thoughts are some women might stop using condoms because they feel that there is PrEP and they are not at risk for HIV as long as they have the medication." Cisgender woman "I have had personal encounters with men who get argumentative because you refuse to have unsafe sex on the notion they are using PrEP" MSM "I didn't want to have sex with condoms at all anymore, so [I started] ruling anyone out who would only use condoms" MSM		
Some MSM were more open to dating or having sex with HIV positive men while taking PrEP. They also found it easier to talk about HIV status with prospective partners, as they felt it would be less of an issue if they were protected. They suggested this might help to reduce stigma of HIV and improve the status of HIV positive men within the LGBTQ community.	Bil 2016 Gafos 2019 Grace 2018 Martinez-Lacabe 2018 Mutchler 2015 Philpot 2020	"I never want to have an HIV-positive boyfriend again, that limits me sexually, but if PrEP would be there, there wouldn't be a barrier to engage in a relationship with someone." MSM "PrEP has had a huge impact on my sense of self; I feel much more confident discussing my sexual preference for BB [bareback] now with casual sex partners as well as my & their HIV status"	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
		MSM		
Some participants worried that their PrEP use might put them at risk in other aspect of their lives. Some transgender women worried that they would be 'outed' by allowing people to find out they are trans as a result of accessing PrEP services. This can be distressing in itself and can also expose them transphobia and sometimes violence. Women with abusive partners were afraid of how their partner would react if they found out they were using PrEP. Their partner might infer that they were having sex with other people or that they didn't trust them. Some women commented that their partners may become violent if this happened.	Auerbach 2015 Brooks 2019 D'Angelo 2021 Goparaju 2017 Nydegger 2020 Reyniers 2021 Sevelius 2016	"You don't want to come out every time you get a prescription. And sometimes, being transgender in and of itself is difficult when I am constantly having to identify. Here it's safe…but out there, I just want to be stealth. Not that I'm ashamed of it, but I don't want people to know." Transgender woman "I don't want to say, ''Oh, I'm taking this.'' And they're like, ''What's that?'' ''Oh, it's an HIV pill.'' All of a sudden they just hear ''HIV'' and they just blackout or hurt me." Transgender woman "My husband is machismo and he's like, "Why are you doing this?" Just like — he was like, "For what reason? Are you cheating? Are you doing this?"" Cisgender woman	Downgraded twice for moderate concerns about relevance and moderate concerns about coherence	Low
Stigma surrounding PrEP use				
Almost all participants mentioned the stereotype of PrEP users as promiscuous. Several participants referred to the phrase 'truvada whore' as being a well-known insult amongst MSM. Some MSM expressed agreement with these views and felt the stigma was justified.	Brooks 2019 D'Angelo 2021 Goparaju 2017 Grace 2018 Hillis 2021 Jaspal 2016 Klassen 2017 Knight 2016 Mutchler 2015 Newman 2018	"I read an article that said "Truvada Whore"… It must be because this pill lets you have sex without condoms with loads of guys. I don't really want to be that guy, to be fair." MSM I don't want to be seen as a ho … I wouldn't want to be seen as a whore because I'm picking this up. Not that people who do sex work are bad, but I am talking about the	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
Many participants wanted to distance themselves from the stereotype by either refusing PrEP or by being a PrEP user who doesn't fit these expectations. Black MSM commented this this stigma was particularly problematic for them, as the LGBTQ community already held hypersexualised racial stereotypes of Black men.	O'Halloran 2019 Pasipandoya 2021 Philpot 2020 Rael 2018 Reyniers 2021 Sevelius 2016 Williamson 2019 Witzel 2018 Witzel 2019 Young 2014	stigmatized version of a whore [and] I don't want to be seen as that." Transgender woman "I find it doubly annoying because on the gay scene black guys have a certain stereotype, and I'm just, like, that's really boring" Black MSM		
Some participants commented that they had been mistaken for being HIV positive due to using PrEP. This meant that the wider stigma of HIV was applied to them. Even without the misunderstanding that PrEP is preventative rather than treatment, participants reported that just the association with HIV and needing to prevent it was enough to be stigmatised. Transgender women described a specific set of assumptions that they felt people applied to them. They reported that they were often assumed to be HIV positive regardless of PrEP use, or that they will inevitably contract HIV at some point. Some had experienced	Auerbach 2015 Bond 2016 Brooks 2019 Collier 2017 Goparaju 2017 Grace 2018 Jaspal 2016 Klassen 2017 Mutchler 2015 O'Halloran 2019 Pyra 2021 Rael 2018 Reyniers 2021 Rowniak 2017 Santa Maria 2019 Sevelius 2016 Vaccher 2018	"It would be because people would think, of the break, something is wrong with you. Just like being in this program [research study], my sister always thought I was HIV-positive." Cisgender woman "Like I told you about that incident where I was attacked, the women said, ''You fucken' HIV infected, bitch!'' Right away, that stigma and that really burned me up not only because I know I'm not, but that was the true picture of how a lot of cisgender women of color view us, as women giving people HIV." Transgender woman	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
transphobia based on the accusation that they were spreading HIV.	Witzel 2018 Young 2014 Young 2016			
Some participants preferred not to disclose their PrEP use to others. Some saw PrEP as an aspect of sexuality therefore something that should be kept private and some felt that they would face judgement and stigma if people knew. They described the actions they would take to hide their pills and the fear that someone might find them. This concern was enough to make some participants reluctant to use PrEP. Some participants who did disclose their PrEP use reported experiencing hostility or rejection from sexual partners or friends and family. They felt that PreP was not a socially acceptable choice.	Auerbach 2015 Brooks 2019 Goparaju 2017 Grace 2018 Hess 2019 Mutchler 2015 Newman 2018 Pasipanodya 2021 Rael 2018 Reyniers 2021 Sevelius 2016 Vaccher 2018 Williamson 2019 Witzel 2018 Young 2014 Young 2016	"My long-term partner doesn't know I'm taking it. So that's just something that needs to be managed. I've actually taken the pills out of the container that they come in 'cause it makes too much noise." MSM "He [a friend online] was very judgmental. His post was 'people [on PrEP] are disgusting.'" MSM "I told [my ex-boyfriend] and he was like, ''Why are you drinking that?'' …I would talk to him and I told him that I was using this. His response was like, ''You are going to be a whore. That's why you want it for.'' Transgender woman	Downgraded once for minor concerns about coherence	Moderate
Principles and wider implications				
Some participants did not trust healthcare, pharmaceutical manufacturers, medical research or the government. They were wary of PrEP as a result of this general mistrust.	Auerbach 2015 Bil 2016 Cahill 2020 D'Angelo 2021 Girard 2018 Harrington 2020	"I don't trust the scientists. One minute it's OK to just take it and then the next "oh sorry, we misjudged that" ... it's like when they didn't get the whole blood transfusions issue and loads of people wound up getting infected." MSM	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
Some MSM and transgender people referred to how the AIDS crisis was handled early on as a reason to be wary of more recent developments. they had been left with that feeling that the authorities did not care about the wellbeing of LGBTQ people. Some Black participants cited sexual health research that had abused and exploited Black communities as the basis for their mistrust, such as the Tuskegee syphilis study.	Hess 2019 Jaspal 2016 Mutchler 2015 Nydegger 2021 Poteat 2019 Pasipanodya 2021 Rowniak 2017 Santa Maria 2019 Watson 2020 Williamson 2019 Young 2014 Young 2016	"Like with this Tuskegee syphilis thing issue, we think we're getting one thing, right? Well, really they're injecting our brothers, our fathers, and husbands with syphilis. And then down the line, 25–30 years, I just don't trust the whole [thing]." Black cisgender woman "[the government's way to] round us up and like put us on an island or some—like put us in concentration camps." Black transgender man		
Participants objected to the medicalisation involved in HIV prevention. Some MSM rejected the idea of medicalising their sexuality. They resented the association of gay sex with disease, and felt that introducing a medication as a prerequisite for sex reinforced that notion. They saw PrEP as something unnatural that damages an otherwise healthy body, therefore they disagreed with the implication that they ought to take it to make them a safe sexual partner.	Bil 2016 Bond 2016 Girard 2018 Hess 2019 Jaspal 2016 Knight 2016 Martinez-Lacabe 2018 Park 2019 Philpot 2020 Poteat 2019 Sevelius 2016 Vaccher 2018 Williamson 2019 Zimmermann 2019	"If I don't have the virus why should I burden my body with [PrEP]? That would feel unnatural to me; that I would get side effects, that I have to go to the laboratory to get blood drawn because I'm taking medication while I'm not sick" MSM "Yeah, now they sell them as part of the drugs sex scene, you can buy your crystal, your G and you can buy Truvada and you buy the whole thing so that… you are covered to have bareback sex all weekend" MSM "I'm more than just possibly an HIV-positive or HIV-negative person. And so how are you	Downgraded once for minor concerns about coherence	Moderate

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
Some MSM felt more comfortable conceiving of PrEP as a recreational drug that allowed them to indulge in sex without condoms, rather than a medication required for safety. Transgender women objected to the focus placed on preventing HIV. They contrasted the emphasis of PrEP campaigns with the difficulties they faced trying to access gender affirming medication. They felt that instead of being offered the comprehensive healthcare they need, they were seen primarily as vectors for disease. Black people also felt that they were being targeted for HIV campaigns to prevent the spread of HIV as a benefit to others, while their other healthcare needs were neglected. Cisgender women commented that PrEP added to the unfair burden placed on women to accept invasive medical interventions for sexual health. They objected to their bodies being medicalised with hormonal or implanted contraceptives, and now also PrEP, while their male partners did not make an equal contribution to their shared protection.		going to make me or how are you going to really help or support me to become a woman? And that's more important than whether or not I have HIV." Black transgender woman "the only time we talk about… young Black MSM or young Black transwomen is as it relates to HIV and people know that. And I think they're burnt out. They've HIV'd out. I think they want to be more than just possible vectors of disease" Black MSM "That's too much to do. Take the pill, get tested, and still use condoms & birth control. Too much for women to have to deal with on top of everything else going on their life." Black cisgender woman		
Some MSM expressed discomfort with how the concept of 'safe sex'	Bond 2016 Collier 2017 Girard 2018	"Now that PrEP is available, and either guys are on it or not, talking about what safe sex is	Downgraded once for minor concerns about coherence	Moderate

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
could change as a result of widespread PrEP uptake. They felt that wanting to use condoms was an accepted expectation amongst MSM negotiating sex, but PrEP introduced ambiguity and confusion. They were concerned that a cultural shift in what is expected would be a change for the worse and they criticised those who advocate it. Conversely some MSM felt that PrEP had the potential to close the divide between HIV positive and negative men in the LGBTQ community by enabling both groups to take an equal share of the responsibility for reducing transmission. They felt that PrEP in combination with HIV treatments that result in undetectability could lead to a cultural change in favour of less emphasis being placed on sero-status.	Harrington 2020 Hess 2019 Knight 2016 Martinez-Lacabe 2018 Mutchler 2015 Philpot 2020 Vaccher 2018 Williamson 2019 Young 2014	has changed considerably. Before PrEP, safe sex was a fairly easy concept" MSM "It is something that will change the culture of gay sex, it will change the culture of how they behave and you know, right now it's just touching the edges but in 10 years- there'll be a complete shift, potentially if it goes mainstream. It goes, actually everyone's going around getting antibiotics every 2 weeks because they've got gonorrhoea or whatever. But that's okay because just take some antibiotics, whereas HIV we're all cool." MSM "I've always observed being positive as being part of a tribe… The sense of being in or being out… And I wonder for some PrEP using guys whether being on PrEP is the key to being into a club that they've been previously excluded from." MSM		
Some MSM saw access to PrEP as a matter of LGBTQ rights. They felt that most negative perceptions of PrEP were fundamentally homophobic. Other MSM described how stereotypes of PrEP users may reinforce these homophobic narratives. They were concerned	Grace 2018 Harrington 2020 Klassen 2017 Knight 2016 Martinez-Lacabe 2018 Pasipanodya 2021 Reyniers 2021	"The general consensus from the mainstream media. . . particularly the red-top papers is that. . . it's an expensive means of the NHS for allowing gay men to have reckless-unprotected sex without protecting themselves, that it's by all means, it's nothing like one-hundred percent successful actually it's just a means of financing peoples' promiscuousness." MSM	No downgrading required	High

Finding	Studies	Illustrative quotes	CERQual explanation	Confidence
about the implications of PrEP on how the LGBTQ community is perceived by wider society.	Vaccher 2018 Williamson 2019 Young 2016	"We now have this tool that we can use to virtually eliminate new infections in our major cities and everywhere, and those are savings for the health care system by reducing and removing HIV that would be incredible" "If somebody invented an anti-cancer drug, people would say that it is a miracle, regardless of it costing $1000 a month. Because it's an HIV treatment, there's still a stigma. Gay men just get it [HIV] because they're fooling around. That's not true at all. I think that hurts too." "I think there's a real case to be made for the equality argument, equality of access to healthy sex that straight people already have." MSM focus group		

3. Integration and discussion of the evidence

3.1 Mixed methods integration

Are the results/findings from individual syntheses supportive or contradictory?

The quantitative and qualitative evidence syntheses cover very different areas and the overlap is limited. Most of the outcomes in the effectiveness review are clinical outcomes that relate to the effectiveness of PrEP in preventing HIV transmission and the risk of adverse events, including STIs. Some themes in the qualitative synthesis discuss peoples beliefs about their risks of contracting HIV and STIs while on PrEP and the practicalities relating to adherence, which are reflected in some of the outcomes in the quantitative evidence. Additionally, quantitative evidence came from a much broader range of countries than the qualitative evidence and there are difficulties with extrapolating the qualitative evidence to cover the range of locations in the quantitative evidence, for example to data from low and middle income countries.

Does the qualitative evidence explain why the intervention is/is not effective?

Participants in the studies in the qualitative evidence described strategies used to maintain adherence and the problems with that. These barriers included forgetting or not having a routine, sleeping in different places and not carrying PrEP with them, and having to hide their pills from others. The quantitative evidence reported different risks of acquiring HIV whilst on PrEP depending on levels of adherence to daily PrEP regimens, with relative risks of infection with HIV ranging from 0.27 (0.19-0.39) at >70% adherence rising to 0.93 (0.72-1.20) at <40% adherence.

Does the qualitative evidence explain differences in the direction and size of effect across the included quantitative studies?

One study in the quantitative evidence reported a 21% rate of receptive anal sex without a condom in people taking PrEP compared to 12% in the waiting list control group, however 5 other RCTs found no differences in self-reported condom use between PrEP and non-PrEP groups. 6 RCTs found no difference in self-reported number of sexual partners.

Qualitative evidence explains that MSM in particular described feeling liberated from the threat of HIV and able to have condomless sex without their actions being constrained but the majority did not consider it to be a full replacement for their existing safe sex practices. Most of these said they would use PrEP in conjunction with condoms. Many participants stated that they prefer sex without a condom. They described it feeling more pleasurable, more natural, and more spontaneous. Some participants avoided condoms because of this preference, while others still used them because they valued the protection more. Conversely some participants felt that condoms were the safest option available and so would prefer to use them. They commented that PrEP is not needed if condoms are used.

These mixed views about condom use while being on PrEP may partially explain the inability of the quantitative studies to detect differences between PrEP and non-PrEP groups for condom use.

The quantitative review was unable to differentiate between PrEP and non-PrEP for rates of STIs. The qualitative evidence clarifies that participants were aware that PrEP would not protect against these, so they saw PrEP as having limited value. Some also commented that PrEP would not protect their partner against contracting STIs from them.

Other participants, mostly MSM, saw HIV is the biggest concern. They considered all other STIs to be treatable, therefore preventing them was not a priority.

For transgender men the biggest priority was to protect against unwanted pregnancy, which would be extremely distressing for them. Condoms offered the protection they needed for this purpose and also for preventing HIV, so PrEP had fewer advantages for this group.

The ambivalence about condom use and the need for protection against STIs explains the lack of ability of the quantitative studies to detect an effect of PrEP on STI rates, because a reduction in condom use would be necessary for that to happen.

Which aspects of the quantitative evidence were/were not explored in the qualitative studies?

The qualitative evidence did not explore risks of adverse events such as fractures or renal events.

Which aspects of the qualitative evidence were/were not tested in the quantitative studies?

The quantitative evidence did not explore the social aspects of PrEP use which were the main thrust of the qualitative evidence synthesis. The qualitative evidence explored the stigma and embarrassment that can be associated with its use. The qualitative data also explored the interaction with healthcare professionals and services and the political implications of having PrEP available.

3.2 The committee's discussion and interpretation of the evidence

The qualitative and quantitative reviews are presented as a combined discussion.

3.2.1. The outcomes that matter most

Quantitative outcomes

Primary outcomes as agreed with the committee in the review protocol (appendix A) were HIV rates, adverse effects, STI rates, changes in condom use and other unintended consequences, all of which were reported across the two systematic reviews identified. The evidence found adverse events reported as:

- Serious adverse events
- Withdrawal due to adverse events
- Renal adverse events
- Gastrointestinal adverse events
- Fracture

Number of sexual partners was also included as the committee noted this fell under the 'other unintended consequences' outcome. Levels of adherence to PrEP in trials (secondary outcome) were also reported and review authors used this to demonstrate the relationship between adherence and efficacy. All primary and secondary outcomes outlined in the review protocol (Appendix A) were captured in the evidence base.

The committee agreed that in relation to the evidence presented, HIV rates were the most important outcome, followed by serious adverse events, withdrawal from PrEP, and other adverse events. While unintended consequences were also agreed as important, the

committee felt these needed to be interpreted carefully and in conjunction with the qualitative evidence around people's attitudes and behaviour changes associated to using PrEP.

Qualitative outcomes

Qualitative outcomes were perspectives, values, beliefs, experiences and attitudes relating to the acceptability or use of PrEP, which covered a range of topics. The committee focused on those that showed evidence of barriers to accessing PrEP services and views on healthcare settings which provide PrEP. Differences in outcomes between populations was highlighted in the evidence, which the committee felt was an important indication of inequalities of access between eligible groups.

Topics of particular interest were:

- Knowledge and information
- Trust in healthcare and experiences with healthcare providers
- Perceptions of stigma and marginalisation
- Access to services
- Risk perception and reduction

3.2.2 The quality of the evidence

Quantitative evidence
Two systematic reviews were included in the evidence base. One review, Chou 2019, contained 12 RCTs and the other, Fonner 2016, contained 9 RCTs and 1 cohort study. Fonner 2016 is unconventional in combining RCT and cohort evidence into meta-analysis, however as the cohort study used a non-randomised comparative design the committee considered Fonner's analysis to be acceptable.

Both reviews compared PrEP to placebo, delayed PrEP or no PrEP. The committee noted that the results indicated PrEP reduced the risk of HIV infection with statistical significance. Subgroup analysis demonstrated that this remained true as long as treatment adherence remained over 40%. The committee also identified statistically significant increases in risk of renal and gastrointestinal adverse events for those taking PrEP. Quality of the evidence was assessed using GRADE and the committee noted that:

- While the quality of evidence for HIV risk overall was assessed as low due to very high levels of inconsistency (I^2 >66.7%), this was explained by levels of adherence and was explored in subgroup analysis. Quality was assessed as high when only studies measuring >40% adherence were included in the analysis. It was noted that the only study from the UK included in the analysis measured adherence at ≥70%, increasing the committee's confidence in the quality and applicability of the effect. The committee agreed with the strength of evidence for the effectiveness of PrEP which matched their expectations and clinical knowledge of the intervention.
- Evidence for tenofovir disoproxil fumarate (TDF) monotherapy was rated as low quality by the committee due to the 95% confidence interval crossing the 0.8 minimum important difference (MID) threshold and moderate levels of inconsistency in the effect. The committee agreed that evidence for the effectiveness of TDF alone was not as high quality and the preferred treatment option as per the BASHH/BHIVA guidance is tenofovir disoproxil fumarate with emtricitabine (TDF/FTC).
- Evidence for the risk of a serious adverse event was rated as low quality by the committee due to the 95% confidence interval crossing the MID threshold of 0.8 and moderate levels of inconsistency.
- The committee noted that evidence for risk of withdrawal, fracture, and renal adverse events was rated as moderate quality, downgraded once for imprecision due to the 95% confidence interval crossing the MID threshold. Similarly, it was noted that evidence for risk of gastrointestinal event was also of moderate quality, due to

moderate levels of inconsistency. The committee agreed with the moderate rating and the direction of effect, noting that these adverse events corresponded to their pharmacological understanding of how PrEP worked.

- It was noted that while evidence for risk of Syphilis was of high quality, evidence for the risk of gonorrhoea and chlamydia was of low quality due to moderate levels of inconsistency(I^2 between 33.3% and 66.7%) and the 95% confidence interval crossing the minimum important difference threshold. The committee also noted the evidence about the risk of herpes simplex was moderate due to moderate levels of inconsistency and evidence about the risk of hepatitis C very low quality due to risk of bias and the 95% confidence intervals crossing both ends of the minimum important difference threshold.
- The committee noted that quality of the evidence for condom use and sexual partners was very low and low respectively due to confidence intervals for the data not being reported and moderate inconsistency in the condom use outcome. The committee agreed that their confidence in this outcome depended on how the findings matched to views expressed in the qualitative review.

The committee discussed the association between adherence to PrEP and its effectiveness, noting that adherence as measured through clinical trials is likely to be greater than in the real world, and that it would also vary depending on the country and population. The committee agreed that more qualitative evidence regarding specific populations would be helpful. Nevertheless, they were confident that the UK would be a setting that would be likely to have higher adherence rates in practice, and this was supported by evidence from the UK RCT. Thus they had minimal concerns about adherence rates and were confident that this would not be a barrier to making strong recommendations for the use of PrEP

The committee also commented that adherence meant different things depending on the PrEP dosing schedule being offered, i.e. 40% adherence to 4 tablets meant fewer tablets than 40% of 7 and that PrEP could be offered on a regular basis or on-demand. The dosing given across most trials appeared to be ‘regular’ at 300mg/200mg with only two reporting ‘intermittent’ dosing arms, but it was unclear how this translated into number of tablets. The committee also thought that more evidence was needed on adverse event outcomes in those taking event-based PrEP only and in younger people (taking any PrEP regime for an extended period) who have not reached peak bone density yet. The committee also noted that measuring fracture rates across the whole population eligible for PrEP may be missing an important risk in this subpopulation. Therefore, the committee decided to make a research recommendation in this area.

The committee expressed caution about using evidence for bacterial STI rates from the trials as a proxy measure for behaviour change, oni particular from those studies that were blinded. They commented that everyone selected for these trials would be in high-risk groups across both arms and that because they were blinded, knowledge of what they were taking (PrEP/placebo) had not affected their behaviour (unless people were able to identify which arm they were in as a result of treatment-related adverse events). The committee also noted that reporting of Herpes was known to be low in practice, with only 1 in 3 self-reporting, therefore this was dependent on screening. Similarly, using number of sexual partners and condom use as proxy measures for STI rates would suffer from similar limitations caused by blinding in the trials.

Qualitative evidence

The quality of the evidence was assessed using GRADE-CERQual. The majority of the themes were rated as high confidence (19 themes) or moderate confidence (12 themes). There were 8 themes rated as low confidence. The qualitative data was drawn from a large number of studies, so provided a rich and detailed account of the findings and allowed for coherent explanations of the themes to be developed. It also benefitted from including a wide variety of participants, so represented the perspectives of MSM, women, transgender people,

black people, younger age groups and people with socioeconomic status. Most participants belonged to more than one of these groups, so the thematic analysis was able to capture some of the intersectional aspects of people's experiences, which enabled a nuanced interpretation of the acceptability of PrEP. The committee felt confident that the majority of this evidence could form a firm basis for making recommendations that reflected the experiences of PrEP eligible populations.

The committee acknowledged that the evidence for women and transgender people was comprised entirely of studies from the USA, and therefore the experiences reported and the cultural context of the views expressed are likely to differ from their UK counterparts. As a result, themes which only contained these populations were inherently of lower certainty. This was reflected in the committee's discussion of this evidence; committee members noted differences from UK practice and differences from their experiences of these groups. For example, gender affirming hormones are mainly administered in pill form in the UK and as injections in the USA, therefore the finding in theme 6 that trans women are more familiar and comfortable with injectable medication does not apply to the equivalent UK population. Committee members also noted stereotypes of PrEP users cited in theme 10 that they had not encountered in the UK, such as the presumption that trans women are inevitably going to contract and spread HIV, so this may be culturally specific to the USA.

The committee commented that the perception of PrEP had changed in recent years, particularly with regard to stereotypes of PrEP users as promiscuous, so they questioned the relevance of older studies. The date range for studies in the qualitative review was 2014-2020, with the majority conducted within the last 5 years, which indicates that these views may still be prevalent.

3.2.3 Benefits and harms

Prescribing and adherence

The committee were confident in the overall combined evidence from both the quantitative and qualitative reviews and felt it was sufficient to base strong recommendations on. They agreed that this evidence made a compelling and convincing case in favour of recommending PrEP for people at high risk of HIV, in line with the criteria in the BHIVA/BASHH guidelines.

The committee were aware of the importance of PrEP adherence, as the quantitative evidence indicated that the risk of HIV infection was lower for those taking PrEP with a ≥70% adherence compared to a >40% to <70% adherence and a ≤40% adherence. Additionally, taking PrEP with a ≤40% adherence did not reduce the risk of HIV infection with statistical significance, whereas taking PrEP with a ≥70% or a >40% to <70% adherence did.

The qualitative evidence indicated a mixture of preferences for daily or event-based PrEP. Committee members confirmed that both were currently offered but event-based PrEP was less effective for people having vaginal sex due to the extra time it takes for the drug to build in vaginal tissue, and therefore is only offered to people having exclusively anal sex according to the BASHH/BHIVA guidelines. There was also some discussion about the potential for more drug resistance with dual therapy TDF/FTC over monotherapy TDF; it was confirmed however that this would not be the case as both were in the same class of drug and there was likely to be little to no increased risk. The committee agreed that PrEP should be offered in accordance with the dosing schedule in the BASHH/BHIVA guidelines, and that TDF/FTC dual therapy had the best balance of benefit over risk. The committee were aware the BASHH/BHIVA guidelines were both NICE accredited and widely used in the area, and therefore they were an appropriate source to defer to for treatment recommendations. Those guidelines recommend that TD-FTC is used for PrEP for MSM, trans women, trans men and heterosexual men and women. For heterosexual men and women only, TD alone may be considered.

The committee agreed that adherence would differ depending on setting and population, and that generic support for adherence could be found in the NICE medicine's adherence guideline, but tailored support should also be provided.

The committee commented that there are already guidelines and support available to increase adherence to medication generally, but there may be nuances in adherence for PrEP. They suggested that the barriers to uptake were a dual issue of enabling people to access clinics and encouraging them to stay in a PrEP program; the factors that put people off attending initially, such as difficulty attending appointments or having other pressures and life events that take higher priority, may also be the reasons they do not commit to regular visits. They recommended helping people to maximise adherence using the existing guidance from NICE's guideline on medicine's adherence and section 6.3 of the BHIVA/BASHH guidelines.

The possibility of offering alternative PrEP delivery methods was discussed. The committee were interested in long-acting PrEP, particularly injectable PrEP. They considered this in relation to qualitative evidence that some people, particularly women, would prefer to use long-acting PrEP and find it easier than adhering to daily pills. They concluded that there is insufficient quantitative evidence to recommend it at present, so agreed upon a research recommendation to investigate the effectiveness, cost effectiveness, accessibility and adherence to forms of PrEP other than oral delivery, particularly long-acting PrEP (such as injections), including in women.

Unintended consequences

The unintended consequence which gained the most quantitative and qualitative research attention was the possibility that people's behaviour might change when taking PrEP.. Many people in the qualitative studies predicted they might use less STI protection or have more sexual partners if they were to start using PrEP and perceived other people who use PrEP to be taking more risks. However, most current PrEP users in these studies reported that their sexual behaviour did not actually change. Accordingly, quantitative evidence did not indicate any statistically significant change in bacterial STI rates, condom use or number of sexual partners for those taking PrEP compared to those not taking PrEP

Overall, the committee were satisfied there was no convincing evidence to suggest that this happens, but that real world longitudinal data and qualitative evidence may show this so it could not be ruled out. They agreed the benefits of reducing HIV transmission by offering PrEP outweighed the risk of negative unintended consequences, but recommended that advice about sexual risk behaviour and condom use should be given when PrEP is prescribed, along with testing for STIs on a three-month basis, as per the BASHH/BHIVA guidelines. The committee also wanted to highlight the distinction between STI testing and HIV testing, and that a negative HIV test should be required before PrEP could be prescribed, again as per the BASHH/BHIVA guidelines. This is due to the significant risk of an individual developing drug resistance if they are prescribed PrEP after having been infected with HIV.

The qualitative evidence supported the quantitative findings, but also provided a more complex picture of behaviour change. There was discussion over whether PrEP should be offered to people who are likely to be consistent condom users both before and after starting PrEP. Some committee members argued that using condoms to reduce STIs is a separate need so should be encouraged and therefore the committee recommended that people taking PrEP be offered other sexual health services, including condom provision. They felt it was important to emphasise that PrEP does not protect against other STI, so also specifically recommended ensuring that PrEP candidates understood this.

The committee discussed changes in condom use in relation to condomless sex being a requirement for prescribing PrEP. Some committee members felt that restricting PrEP to people who have had recent condomless sex is counter-intuitive when people who seek PrEP are a self-selecting group who are concerned about their sexual health and also that restricting access may increase health inequalities. The committee considered whether this requirement could be removed but concluded it would be problematic as the evidence for the cost-effectiveness of PrEP is predicated on this assumption. As a result, they were unable to make a recommendation in this area and instead suggested a research recommendation to investigate further.

Committee members commented that people often aren't accurate when estimating their own risk, which was reflected in the varied ways participants described what they considered to be high risk situations in the qualitative evidence. The people who are worried about HIV may be both seeking PrEP and using other prevention which in turn lowers their risk and reduces the need for PrEP. People who are not as concerned about their sexual health are the ones who are most at risk. They stated that practitioners consider itis preferable for people to use PrEP than Post-Exposure Prophylaxis (PEP), so recommended more pro-active awareness raising for high-risk groups, using methods to target and engage with these populations.

The committee used their own knowledge to raise concerns about drug resistance as a potential harm of using PrEP unnecessarily; some questioned whether this would increase with wider availability of PrEP. A committee member explained that drug resistance is only a concern if the person becomes HIV positive, as they may become resistant to treatment. They added that PrEP failures are rare and as long as the person remains HIV negative they will not develop resistance, so this is not a concern for low risk PrEP users. No quantitative evidence regarding drug resistance was identified in the evidence review.

Other unintended consequences were highlighted in the qualitative evidence, but were mainly a product of wider social issues outside of this guideline's remit such as transphobia and domestic abuse being exacerbated by PrEP stigma. As these consequences were often also linked to socioeconomic deprivation, the committee felt there should be an explicit focus on health inequalities across the whole guideline rather than individual recommendations.

Adverse events

The committee noted the statistically significant renal and gastrointestinal adverse events reported in the quantitative evidence but agreed the HIV prevention benefits of offering PrEP still outweighed the risks of these adverse events. The committee noted that those taking PrEP should be monitored for renal health and other adverse events as per the BASHH/BHIVA guidelines and that people with significant existing renal problems should not be prescribed it. This was backed up by moderate quality evidence that PrEP increases the risk of renal adverse event in those taking PrEP compared to those taking placebo/no PrEP However, the evidence may not have been clinically significant as the confidence interval crossed below the 25% minimum important difference threshold for increased risk. Additionally, the committee were aware of alternative treatments to Truvavda PrEP for those with existing renal problems. They concluded that the recommendations should highlight the good practice points in the BHIVA/BASHH guidelines for following up and monitoring PrEP users, and specifically recommended monitoring kidney function and any other adverse health events.

There was some discussion about the effect of PrEP on bone mineral density and that while the committee were aware of other research studies in adults that shows this should recover following cessation of PrEP, there was a lack of data on this for young people who have not reached their peak bone density yet. The quantitative evidence showed that there was no statistically significant increase in risk of fracture for those taking PrEP compared to those not taking PrEP. However, the qualitative evidence indicated that people are concerned

about unknown long term health implications and the effects on young people. The committee felt these views underlined the need for further research on this topic, so decided upon a research recommendation to investigate the long-term adverse events (including the impact on bone density) of taking PrEP for an extended period after starting at a young age.

The quantitative evidence indicated a statistically significant increase in risk of gastrointestinal adverse events for those taking PrEP compared to those not taking PrEP. The qualitative evidence also outlined a range of concerns about short term side effects (such as diarrhoea) and long term risks (such as liver problems) as well as worries that PrEP may interact with other medical conditions and medications (such as diabetes or antidepressants). Trans people had specific concerns about the possibility of PrEP interfering with their medical transition. The committee acknowledged these concerns and responded that the risks were minimal, that there are very few drug interactions and specifically no interactions with gender affirming hormones. They also explained that possible long term side effects are monitored while using PrEP (for example, annual renal testing). They felt that this information should be emphasised in educational materials to reassure potential PrEP users, so recommended tailored information and education on effectiveness, adherence, side effects and monitoring risks to address individuals concerns. They also felt it was important to make a separate recommendation for trans people to reassure them that using PrEP will not affect their transition, as this was mentioned frequently and specifically in the qualitative evidence as a dealbreaker issue for this group.

No evidence review was undertaken in this guideline looking at the interaction between drugs used for gender affirmation and PrEP. However, information was sourced from the University of Liverpool HIV drug interaction checker, which was agreed to be robust based on communication with the University of Liverpool about the methodology underpinning the checker. This methodology was judged to be as rigorous as the methodology NICE would have used to address this question, and therefore the committee were comfortable to rely on this information. The document reporting the findings of the work for PrEP is available here, and the document on gender affirming hormones here.

Where PrEP is prescribed

The committee commented that PrEP was currently only being offered in sexual health clinics and that while this was the current NHS England commissioning policy, it affects the accessibility of PrEP and excludes groups who do not attend clinics. Conversely, some committee members felt that PrEP should only be prescribed by clinicians with knowledge of it and training in sexual health which would generally only occur in a sexual health clinic. It was agreed that more research would be needed into the effectiveness and cost effectiveness of providing PrEP outside of sexual health clinics and whether this would increase access by underserved groups, therefore a research recommendation was made to investigate this.

The committee agreed that commissioners should ensure health care professionals in primary care, community settings and gender identity clinics are aware of PrEP eligibility and the different population groups who might need to access it. There need to be robust pathways from the services that are seeing populations that need PrEP into the services that can provide it, these pathways need to as far as possible not rely on an individual to make the connections themselves otherwise health inequalities are likely to be exacerbated. For this reason they made a recommendation to raise awareness among healthcare professionals (particularly those in primary care, community settings and gender identity clinics) about which groups of people are eligible for PrEP.

Based on the qualitative evidence, the committee agreed that some populations may not be accessing PrEP from sexual health clinics and may feel more comfortable in other clinical settings such as gender identity clinics and GP practices. The committee also noted that sexual health clinics are mostly located in urban areas, so people who do not live in cities are

less able to access them. However they noted that PrEP services are delivered by specialists and many other healthcare professionals lack awareness of them. For this reason, recommending signposting towards specialist PrEP services, rather than prescribing directly from other settings, would be the most practical way to address this. The committee acknowledged that overall, signposting is inadequate and direct provision would be preferable since people with the most significant disadvantages were least likely to follow signposting, however they did not feel they could resolve this in the recommendations.

Knowledge and information

The qualitative evidence indicated that people want to be given more information on PrEP and that communities were enthusiastic about sharing and spreading information. The committee were keen to capitalise on this and so considered ways that peer support, sex education and awareness raising campaigns could be used. They felt that healthcare practitioners and peer support should be the focus, due to the qualitative finding that people want information to come from healthcare practitioners and that they are willing to share it with their peers. However some committee members doubted that all communities would share personal information as openly as MSM do, so suggested this shouldn't be relied upon. As a result, the committee agreed not to make a direct recommendation about this aspect. Instead they recommended expanding healthcare providers knowledge of PrEP and the population groups who are eligible for it, so providers can be better equipped to disseminate information.

Stigma

The qualitative findings contained numerous accounts of PrEP users feeling stereotyped and stigmatised, which was further evidenced by multiple references to the term 'truvada whore' being used to stigmatise PrEP use as a sign of promiscuity. The committee agreed that while there are specific stereotypes of PrEP users, the issue of stigma applies more broadly across the guideline and should be addressed with regard to all STIs. They suggested that social stigma, self stigma and professional stigma should all be considered in terms of wider STI testing.

The committee noted that trans women have the highest HIV prevalence, so there may be specific stigmatisation of this group and of other groups with low PrEP uptake. The qualitative evidence confirms and expands on this by providing examples of this stigmatisation, such as hypersexualised racial stereotypes of black men and transphobic rumours that blame trans women for the spread of HIV. Overall the committee agreed that stigma was a very complex topic and could not be adequately resolved by this guideline. They agreed however that stigma could be reduced to some extent by peer support and awareness raising to normalise PrEP use, so recommended these approaches. They further recommended that awareness raising should pay particular attention to groups with low PrEP uptake, including trans people, cisgender women, young people (aged 16-24) and people with a Black African or Caribbean family background.

Access to PrEP

The qualitative evidence outlined ways that some communities may find it harder to access PrEP services, so discussions focused on improving accessibility. The evidence highlighted groups who felt that they were not included in PrEP services and were less likely to access services where they experienced barriers relating to their identity. committee discussed ways to reduce these barriers and make services more inviting and inclusive for all groups of potential PrEP users. They suggested practical changes such as proactively expressing a sex-positive approach, providing gender neutral toilets which would facilitate non-binary individuals, and having varied clinic times which would enable people with fixed working hours and people with parental or caring commitments to access the clinic more easily. The latter issue was highlighted in the qualitative evidence from cisgender women as being a

particular barrier for them; PrEP was considered a low priority in the context of other pressures in their lives. The committee further suggested that trans people should have access to tailored assessments of their sexual health needs, to accurately assess their risk of HIV without assumptions.

The committee agreed that it is important to raise awareness of who is eligible for PrEP and to encourage these people to access PreP services. Gender identity clinics and transgender community groups were identified as settings where PrEP could be recommended and discussed with members of the trans community. The committee also raised issues about addressing intimate partner violence and sex work in the guideline. They suggested that settings where people in these situations seek help should also signpost them to PrEP services.

Community involvement

Ways to engage with communities groups were discussed. Qualitative evidence showed that when PrEP campaigns did not represent communities accurately, those communities felt alienated. For this reason the committee suggested that information materials could be co-produced with the groups they are targeting, but some were concerned that this could result in tokenism and cautioned that there are many varied groups of people under the LGBTQ 'umbrella' who do not necessarily mix or overlap, and so some may be missed. Some members also suggested 'community champions' to raise awareness and they raised the possibility of harnessing the reach of social media by working with influencers. The committee noted that NICE guidelines on community engagement were useful when considering this, and make specific recommendations on giving community groups support and information resources and on co-producing materials that target specific information gaps and causes of stigma within communities.

Training

The committee were concerned that mistrust of medicine was a wide-ranging issue which interacts with health inequality, as the qualitative evidence found many instances of mistrust stemming from experiences of racism, homophobia and transphobia and other forms of marginalisation. They commented that pathologising certain sexual practices in healthcare settings often contributes to mistrust and restricts access to PrEP. The committee discussed the qualitative evidence that healthcare professionals often lacked understanding of their patients' individual risk factors for HIV and felt this made a compelling case to address this issue. They agreed that increasing understanding of at risk groups to facilitate discussion of sexual health would help to deliver person-centred care. They stated that this was important for both general practitioners and those who work in sexual health clinics.

The committee discussed ways to incorporate additional training into existing systems, but were concerned that there may not be sufficient funding and resources available. They cautioned that healthcare professionals lacked time for additional training and that it would be unfair and unrealistic to make this their responsibility; they instead recommended that protected time should be set aside for them to access the existing training on relevant issues and this should be built in at system level.

3.2.4 Cost effectiveness and resource use

The committee agreed that, when using their preferred parameter inputs, the two cost-effectiveness analyses produced for PrEP in the UK (Cambiano 2018 and Ong 2017) both concluded it was cost-effective for preventing HIV in high-risk populations. In particular, they agreed the results using the UK specific PROUD trial estimates for the effectiveness of PrEP were the most relevant, as these would be linked more closely to expected levels of adherence in the UK, and the data from the clinical review clearly demonstrated the high levels of correlation between adherence and effectiveness of PrEP. They also agreed that,

whilst these studies were conducted in a population of gay, bisexual and other men who have sex with men, the findings should be generalisable to other populations at equivalent risk of HIV, as both the potential benefits and costs in those populations should be similar. Finally, they noted that PrEP was likely to be more cost-effective now than at the times these evaluations were conducted, due to reductions in the cost of some of the drugs used. They therefore concluded that the key questions to consider was whether any of the unintended consequences of PrEP were sufficiently large as to possibly change the conclusions of those analyses, and make PrEP less/non-cost effective.

Only 1 previous study had addressed the impact of unintended consequence on the cost-effectiveness of PrEP – Reitsema 2020 – which looked at risk compensation (changes in people's sexual behaviour once they start using PrEP). This study found that including this risk compensation reduced the cost-effectiveness of PrEP, but not sufficiently as to stop it being cost-effective (the probably of cost-effectiveness moved from 92% without risk compensation to 73% with). The committee, however, identified two key concerns with the applicability of this study. Firstly, it was conducted in the Netherlands, and the committee wanted to be able to base its decisions on the UK cost-effectiveness studies. Secondly, the model only considered negative unintended consequences from the use of PrEP, and the committee agreed there were likely to be positive unintended consequence as well. They therefore agreed it was relevant to conduct additional modelling to address these two issues.

The committee identified two main potential negative (i.e. will potentially increase the rate of STIs) unintended consequences of PrEP (changes in the number of sexual partners, and changes in the use of condoms) and two main positive unintended consequences of PrEP (increased frequency of STI testing, and increase vaccination rates due to greater contact with sexual health services). They noted the published cost-effectiveness analyses would have included the extra costs of this increased monitoring, but not the extra benefits, and these would also be important to capture. They considered whether any of other extra monitoring done with PrEP (such as liver and kidney function tests) would provide additional unintended benefits, but were not confident enough they would to justify including them in the modelling.

There was considerable uncertainty in the parameters inputs for the model, due to the lack of good data available for many of these. Throughout, the committee agreed it was appropriate to, where uncertainty was present, err on the side of assuming more negative outcomes for PrEP. This approach would mean that if PrEP could be shown to still be cost-effective, even with these negative assumptions made, it would provide considerable confidence that it would remain cost-effective, whatever the true values.

In the base-case results, two unintended consequences were ultimately included (changes in level of condom use, and increased STI testing). No evidence was found that the number of partners changes with PrEP and therefore these numbers were kept the same, and whilst there were differences estimated in the levels of vaccination against HPV and hepatitis, it was difficult to estimate the cost and QALY gains associated with these changes. In this base-case set of results, the overall balance of the unintended consequences was positive, and therefore PrEP becomes even more cost-effective than when only the impacts on HIV are considered.

The committee considered all the uncertainties in the evidence and their potential impact on the cost-effectiveness of PrEP, noting that it was found to be cost-effective in high-risk individuals when only HIV outcomes were considered. First, they noted there was no strong evidence that people would engage in more high-risk sexual behaviour when prescribed PrEP, and if it did not then PrEP would remain cost-effective. Second, they noted that even if there were changes in people' sexual behaviour, these negative consequences for STIs would likely be outweighed by the positive unintended consequences of PrEP (in the base-case this was true even if only the benefits of increased testing were considered, and not the benefits of increased vaccination rates). Third, they noted that even if the positive unintended

consequences of PrEP were ignored, the level of negative unintended consequences necessary for PrEP to stop being cost-effective were very large, and certainly well above any level which there was even suggestive evidence that they might occur. The committee were therefore convinced PrEP would remain cost-effective in these populations regardless of the true level of unintended consequences, and were confident therefore that these potential consequences did not need to result in any restrictions being made to the people eligible for PrEP. They noted that additional research was therefore better focused on the cost-effectiveness of PrEP in lower-risk populations, where a lower risk of HIV would necessarily make it less cost-effective, rather than on other non-HIV consequences of using PrEP.

The committee then discussed the potential resources impact of other recommendations made. They noted that the effectiveness and therefore cost-effectiveness of PrEP is so heavily dependent on levels of adherence that resources spent on increasing adherence are highly likely to be cost-effective (in particular, ensuring levels of adherence in practice are as similar as possible to those in the UK research studies). They noted that better data on real-world adherence in the UK would be available once the results of the UK IMPACT trial were published. The other recommendations made around prescribing PrEP were all agreed to reflect current practice (and the costs associated should already be included within the studies that found PrEP to be cost-effective) and are therefore unlikely to result in a significant resource impact.

3.2.5 Other factors the committee took into account

The committee were aware that certain groups may have unequal access to PrEP depending on their gender identity or sexual orientation, as outlined in the qualitative evidence that PrEP was often perceived as being for gay men, with other groups feeling side-lined. They commented that if PrEP is only offered in sexual health clinics, it was more likely to be given to men who have sex with men and to exclude trans and/or heterosexual women. In their experience, MSM tend to attend clinics more regularly whereas trans and/or heterosexual women were less likely to attend, even if they were to be at equivalent risk. The recommendations on service design and access to PrEP services were constructed with this issue in mind.

The committee also highlighted the potential for misinformation about PrEP among certain groups and how this could be compounded if these groups were not attending sexual health clinics where accurate information could be shared. The committee agreed it was important that knowledge of PrEP (and the identities of people who might need to access it) among health care professionals working in settings other than sexual health clinics was important, so recommended that time for training should be set aside for this.

3.3 Recommendations supported by this evidence review

This evidence review supports recommendations 1.5.1 to 1.5.19 and the research recommendations on the availability of PrEP outside of sexual health services, adverse effects of long-term PrEP use, mode of PrEP delivery, and eligibility for PrEP.

3.4 References – included studies

3.4.1 Effectiveness, adverse events, and unintended consequences

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Appendices

Appendix A Review protocols

Review protocol for Reducing STIs RQ 1.5 Effectiveness, cost effectiveness and unintended consequences of pre-exposure prophylaxis (PrEP) for HIV

ID	Field	Content
1.	Review title	Effectiveness, cost effectiveness and unintended consequences of pre-exposure prophylaxis (PrEP) for HIV
2.	Review question	What is the effectiveness, cost effectiveness and unintended consequences of pre-exposure prophylaxis (PrEP) for HIV?
3.	Objective	Pre-exposure prophylaxis is a drug taken by HIV-negative people before sex that reduces the risk of contracting HIV. The aim of this review is to determine the effectiveness and cost-effectiveness of PrEP. In addition, there are concerns that the availability of PrEP may result in risk compensation and reduce commitment to primary prevention of STIs, with the possibility of a resultant increase in high-risk sexual behaviour and rates of STIs. This review therefore aims to also examine the unintended consequences of PrEP.
4.	Searches	The following databases will be searched: • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase (OVID) • Medline (OVID) • Medline in Process (OVID) • PsycINFO (Ovid) • EmCare (OVID)

		• Web of Science (for citation searching* only, if judged to be required) *Citation searching Depending on initial database results, forward citation searching on key papers may be conducted, if judged necessary, using Web of Science (WOS). Only those references which NICE can access through its WOS subscription would be added to the search results. Duplicates would be removed in WOS before downloading. Websites Key websites will be searched for relevant reports or publications (British HIV Association, CDC, PHE, Google) Database functionality will be used, where available, to exclude: • Non-English language papers • Animal studies • Editorials, letters or commentaries • Conference abstracts or posters • Dissertations or theses • Duplicates The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion.

		The guidance Information Services team at NICE will quality assure the principal search strategy and peer review the strategies for the other databases. Any revisions or additional steps will be agreed by the review team before being implemented. Any deviations and a rationale for them will be recorded alongside the search strategies. A record will be kept of number of records found from each database and of the strategy used in each database. A record will be kept of total number of duplicates found and of total results provided to the Public Health team. No date restrictions on this search.
5.	Condition or domain being studied	HIV (human immunodeficiency virus)
6.	Population	Inclusion: HIV-negative people aged 16 and older. Excluded – studies examining PrEP for conception in sero-discordant couples
7.	Intervention/Exposure/Test	Pre Exposure Prophylaxis for HIV prevention
8.	Comparator/Reference standard/Confounding factors	No pre exposure prophylaxis
9.	Types of study to be included	Inclusion

		SRs of PrEP effectiveness studies of RCTs Effectiveness studies: • SRs of RCTs • RCTs Excluded study designs: • Cohort studies • Case control studies • Cross-sectional studies • Correlational studies • Non-randomised controlled trials • Controlled before-and-after studies • Qualitative studies For unintended consequences related to the use of PrEP; • SRs of RCTs • RCTs • Cohort studies
10.	Other exclusion criteria	Only papers published in the English language will be included

		Only full published peer-reviewed comparative effectiveness studies will be included except for unintended consequences where cohort studies are an inclusion criterion. No exclusion on country.
11.	Context	The Department of Health and Social Care in England has asked NICE to update the guideline on sexually transmitted infections and under-18 conceptions: prevention (PH3), published in 2007. Changes in policy and commissioning, financial pressures and new evidence identified through the surveillance process led to the decision to update this guideline. The updated guideline will focus solely on the reduction of sexually transmitted infections (STIs), as prevention of under-18 conceptions is covered in other guidelines. Data from Public Health England show the overall number of STI diagnoses increased by 5% between 2017 and 2018. STIs can affect personal wellbeing, mental health and relationships and can also lead to serious health problems including pelvic inflammatory disease, ectopic pregnancy or infertility. It is therefore important to address interventions to help prevent or reduce STIs.
12.	Primary outcomes (critical outcomes)	From the SRs of RCTs and RCTs • HIV rates • Adverse effects From SRs of RCTs,

		RCTs and cohort studies; Unintended consequences: • STI rates • Changes in condom use • Other unintended consequences
13.	Secondary outcomes (important outcomes)	From the SRs of RCTs and RCT's • Adherence
14.	Data extraction (selection and coding)	As this review includes a specific population and a relatively new approach to preventing HIV transmission, it is anticipated that this will not produce a large search hit rate. Priority screening will not be used in this review, but the entire database will be screened. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised template will be used to extract data from studies (this is consistent with the Developing NICE guidelines: the manual section 6.4).

15.	Methodological (quality) assessment	Risk of bias for individual studies will be assessed using the preferred checklist as described in Developing NICE guidelines: the manual As per the Cochrane review of reviews from the training handbook any systematic review that will be included for this effectiveness review will include; descriptive characteristics of the systematic review and the primary studies, risk of bias of the primary studies, and quantitative outcome data.
16.	Strategy for data synthesis	Outcome data, narratively reported study level data and any meta-analysis data will be extracted. Where there are overlapping reviews that include the same primary studies, there will be some consideration on which review is the most recent, highest quality, most relevant or most comprehensive. The selection of the most appropriate review that meets these criteria will ensure that there is not double-counting from data in overlapping reviews. Data from eligible studies will be meta-analysed (combined) if studies are judged to be similar enough in terms of population, interventions, outcomes, study design or risk of bias. It is anticipated that meta-analysed studies will be heterogeneous. Where appropriate, heterogeneity will be explored by conducting subgroup analyses and incorporated by performing random-effect analyses. If studies are found to be too heterogeneous to be pooled statistically, a narrative approach with sufficient information to make judgements about study effectiveness will be conducted.

		Tables and other forms of visual presentation may be used to summarise data where appropriate. Dichotomous data will be pooled where appropriate and the effect size will be reported using risk ratios in a standard pair-wise meta-analysis. Continuous outcomes reported on the same scale will be pooled in a standard pair-wise meta-analysis using mean difference where possible. Continuous outcomes not reported on the same scale will be pooled using a standardised mean difference in a standard pair-wise meta-analysis. The quality or certainty across all available evidence will be evaluated for each outcome using an the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/
17.	Analysis of sub-groups	Where evidence allows, sub-group analysis will be conducted, including: • Men who have sex with men (MSM) • Young people age 16 to 24 years • People from a Black African or Caribbean family background • Trans people • Older age groups • People with low socioeconomic status
18.	Type and method of review	☒ Intervention ☐ Diagnostic

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☐ Qualitative
☐ Epidemiologic
☐ Service Delivery
☐ Other (please specify)</td></tr>
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<tr><td>21.</td><td>Anticipated or actual start date</td><td>January 2020</td></tr>
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		Risk of bias (quality) assessment	☑	☐
		Data analysis	☑	☐
24.	Named contact	**5a. Named contact** Public Health Guideline Development Team **5b Named contact e-mail** PHAC@nice.org.uk **5c Named contact address** National Institute for Health and Care Excellence 10 Spring Gardens London SW1A 2BU **5d Named contact phone number** +44 (0)300 323 0148 **5e Organisational affiliation of the review** National Institute for Health and Care Excellence (NICE) and NICE Public Health Guideline Development Team.		
25.	Review team members	A multidisciplinary committee including the Public Health England Topic Advisor (PHETA) will be involved in developing the evidence review. NICE Public Health guideline development technical guideline team: • Technical lead: Robby Richey		

		• Technical analyst: Hannah Stockton • Technical analyst: Anthony Gildea • Technical analyst: Michellie Young • Health economist: Joshua Pink • Information specialist: Daniel Tuvey • Project Manager: Adam O'Keefe
26.	Funding sources/sponsor	This systematic review is being completed by Public Health guideline development, NICE.
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website
29.	Other registration details	
30.	Reference/URL for published protocol	

31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
32.	Keywords	PrEP, HIV
33.	Details of existing review of same topic by same authors	
34.	Current review status	☒ Ongoing ☐ Completed but not published ☐ Completed and published ☐ Completed, published and being updated ☐ Discontinued
35.	Additional information	
36.	Details of final publication	www.nice.org.uk

Review protocol for Reducing STIs RQ 1.6 Acceptability of pre-exposure prophylaxis (PrEP) for HIV

ID	Field	Content
1.	Review title	Acceptability and factors relating to the use of pre-exposure prophylaxis (PrEP) for HIV
2.	Review question	What is the acceptability of pre-exposure prophylaxis (PrEP) for HIV, and what other factors influence its use?'
3.	Objective	Pre-exposure prophylaxis is a drug taken by HIV-negative people before sex that reduces the risk of contracting HIV. As a new approach to STI prevention it is important to consider the context and experiences of those using PrEP.
4.	Searches	The following databases will be searched: • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase (OVID) • Medline (OVID) • Medline in Process (OVID) • PsycINFO (Ovid) • EmCare (OVID) • Web of Science (for citation searching* only, if judged to be required) *Citation searching Depending on initial database results, forward citation searching on key papers may be conducted, if judged necessary, using Web of Science (WOS). Only those references which NICE can access through its WOS subscription would be added to the search results. Duplicates would be removed in WOS before downloading. Websites

		Key websites will be searched for relevant reports or publications (British HIV Association, CDC, PHE, Google) Database functionality will be used, where available, to exclude: • Non-English language papers • Animal studies • Editorials, letters or commentaries • Conference abstracts or posters • Dissertations or theses • Duplicates The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion. The guidance Information Services team at NICE will quality assure the principal search strategy and peer review the strategies for the other databases. Any revisions or additional steps will be agreed by the review team before being implemented. Any deviations and a rationale for them will be recorded alongside the search strategies. A record will be kept of number of records found from each database and of the strategy used in each database. A record will be kept of total number of duplicates found and of total results provided to the Public Health team.
5.	Condition or domain being studied	HIV (human immunodeficiency virus)

6.	Population	Inclusion: HIV-negative people aged 16 and older. Excluded – studies examining PrEP for conception in sero-discordant couples
7.	Intervention/Exposure/Test	Individual and system level factors that may influence the acceptability of and/or use of PrEP for HIV prevention.
8.	Comparator/Reference standard/Confounding factors	Not applicable
9.	Types of study to be included	Qualitative studies such as open-ended questionnaires, structured or semi structured interviews, focus groups. Mixed methods studies with qualitative data where the qualitative evidence is relevant to the review question and can be extracted.
10.	Other exclusion criteria	Only papers published in the English language will be included. Only studies from the Organisation for Economic Cooperation and Development (OECD) countries will be included. Only full published peer-reviewed qualitative studies will be included.
11.	Context	The Department of Health and Social Care in England has asked NICE to update the guideline on sexually transmitted infections and under-18 conceptions: prevention (PH3), published in 2007. Changes in policy and commissioning, financial pressures and new evidence identified through the surveillance process led to the decision to update this guideline. The updated guideline will focus

		solely on the reduction of sexually transmitted infections (STIs), as prevention of under-18 conceptions is covered in other guidelines. Data from Public Health England show the overall number of STI diagnoses increased by 5% between 2017 and 2018. STIs can affect personal wellbeing, mental health and relationships and can also lead to serious health problems including pelvic inflammatory disease, ectopic pregnancy or infertility. It is therefore important to address interventions to help prevent or reduce STIs.
12.	Primary outcomes (critical outcomes)	Individual perspectives, values, beliefs, experiences or attitudes that are considered to influence the acceptability of using PrEP and/or the use of PrEP
14.	Data extraction (selection and coding)	As this review includes a specific population and a relatively new approach to preventing HIV transmission, it is anticipated that this will not produce a large search hit rate. Priority screening will not be used in this review, but the entire database will be screened. A random 10% sample of the studies remaining in the database when the threshold is met will be additionally screened, to check if a substantial number of relevant studies are not being correctly classified by the algorithm, with the full database being screened if concerns are identified. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above.

		A standardised template will be used to extract data from studies (this is consistent with the Developing NICE guidelines: the manual section 6.4).
15.	Methodological (quality) assessment	The CASP qualitative checklist will be used. This includes determining if the study is considered to be at low, moderate or high methodological quality.
16.	Strategy for data synthesis	The key findings from the studies will be categorised into themes relevant to the review across all studies using a thematic analysis. Supporting quotations and summaries of data will be included. GRADE CERQual will be used to assess the confidence we have in the summary findings of each of the themes. Evidence from the qualitative study designs is initially rated as high confidence and the confidence in the evidence for each theme will be downgraded from this initial point. The descriptive themes will be identified, and the third order interpretation themes and sub themes will be reviewed specifically relating to the aims of this review question. These will be further discussed with in the technical team to ensure agreement across the themes. A mixed methods synthesis including studies from question 1.5 (RQ1.5). An integration approach will be used to consider the combination of the quantitative and qualitative findings, where sufficient data has been found in this review. This will be completed sequentially; this will consider the results of the quantitative review and how the findings form the qualitative review might inform or explain this. Where evidence allows, a synthesis matrix will be produced to combine results from the two different analytical approaches. The results may be presented as a narrative summary or diagram with quantitative findings mapped onto the qualitative ones. This approach will inform the discussion of the quantitative and qualitative review.

17.	Analysis of sub-groups	Where evidence allows, sub-group thematic analysis will be conducted to include: • Men who have sex with men (MSM) • Young people age 16 to 24 years • People from a Black African or Caribbean family background • Trans people • Older age groups • People with low socioeconomic status
18.	Type and method of review	☐ Intervention ☐ Diagnostic ☐ Prognostic ☒ Qualitative ☐ Epidemiologic ☐ Service Delivery ☐ Other (please specify)
19.	Language	English
20.	Country	England
21.	Anticipated or actual start date	January 2020
22.	Anticipated completion date	September 2021

<table>
<tr><td>23.</td><td>Stage of review at time of submission</td><td>
<table>
<tr><th>Review stage</th><th>Started</th><th>Completed</th></tr>
<tr><td>Preliminary searches</td><td>☐</td><td>☑</td></tr>
<tr><td>Piloting of the study selection process</td><td>☐</td><td>☑</td></tr>
<tr><td>Formal screening of search results against eligibility criteria</td><td>☑</td><td>☐</td></tr>
<tr><td>Data extraction</td><td>☑</td><td>☐</td></tr>
<tr><td>Risk of bias (quality) assessment</td><td>☑</td><td>☐</td></tr>
<tr><td>Data analysis</td><td>☑</td><td>☐</td></tr>
</table>
</td></tr>
<tr><td>24.</td><td>Named contact</td><td>5a. Named contact
Public Health Guideline Development Team
5b Named contact e-mail
PHAC@nice.org.uk

5c Named contact address
National Institute for Health and Care Excellence
10 Spring Gardens London
SW1A 2BU

5d Named contact phone number
+44 (0)300 323 0148

5e Organisational affiliation of the review</td></tr>
</table>

		National Institute for Health and Care Excellence (NICE) and NICE Public Health Guideline Development Team.
25.	Review team members	A multidisciplinary committee including the Public Health England Topic Advisor (PHETA) will be involved in developing the evidence review. NICE Public Health guideline development technical guideline team: • Technical lead: Robby Richey • Technical analyst: Hannah Stockton • Health economist: Joshua Pink • Information specialist: Daniel Tuvey • Project Manager: Adam O'Keefe
26.	Funding sources/sponsor	This systematic review is being completed by Public Health guideline development, NICE.
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of

		Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: www.nice.org.uk
29.	Other registration details	
30.	Reference/URL for published protocol	
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
32.	Keywords	PrEP, HIV
33.	Details of existing review of same topic by same authors	
34.	Details of existing review of same topics by same authors	☒ Ongoing ☐ Completed but not published ☐ Completed and published ☐ Completed, published and being updated ☐ Discontinued
35.	Additional information	

36.	Details of final publication	www.nice.org.uk

Appendix B – Combined literature search strategies

For full literature search strategies, see the search chapter on the NICE webpage.

Database name: Medline

Database: Ovid MEDLINE(R) <1946 to April 28, 2020>

Search Strategy:

---

1 HIV Infections/ (190364)

2 Acquired Immunodeficiency Syndrome/ (76154)

3 HIV Seropositivity/ (23009)

4 HIV Seronegativity/ (3747)

5 AIDS Serodiagnosis/ (6650)

6 (HIV or (human adj immunodeficiency adj virus)).ti,ab. (294228)

7 (("Human t-lymphotropic virus type III" or HTLV-III) adj (serodiagnos* or seronegativ* or serology or seroconversion* or seropositiv*)).ti,ab. (65)

8 (AIDS not hearing).ti,ab. (129403)

9 (acquired adj immun* adj syndrome).ti,ab. (15117)

10 or/1-9 (391513)

11 Chemoprevention/ and HIV Infections/ (524)

12 ((Chemoprevent* or Chemo-prevent* or "chemo prevent*") and (HIV or antiretroviral or anti-retroviral or "anti retroviral")).ti,ab. (47)

13 ((chemoprophyla* or "chemo prophyla*" or chemo-prophyla*) and (anti-retroviral or antiretroviral or "anti retroviral" or hiv)).ti,ab. (565)

14 Pre-Exposure Prophylaxis/ (2073)

15 pre exposure prophylaxi*.ti,ab. (1826)

16 preexposure prophylaxi*.ti,ab. (669)

17 pre-exposure prophylaxi*.ti,ab. (1826)

18 prep.ti,ab. (3724)

19 iprex.ti,ab. (72)

20 or/11-19 (6008)

21 Emtricitabine, Tenofovir Disoproxil Fumarate Drug Combination/ (216)

22 Emtricitabine/ and Tenofovir/ (934)

23 truvada.ti,ab. (152)

24 (tenofovir and emtricitabine).ti,ab. (1708)

25 or/21-24 (2098)

26 (prep or preexposure or pre-exposure or "pre exposure" or prophyla* or prevent*).ti,ab. (1324314)

27 25 and 26 (722)

28 20 or 27 (6183)

29 10 and 28 (3802)

30 animals/ not humans/ (4660986)

31 29 not 30 (3734)

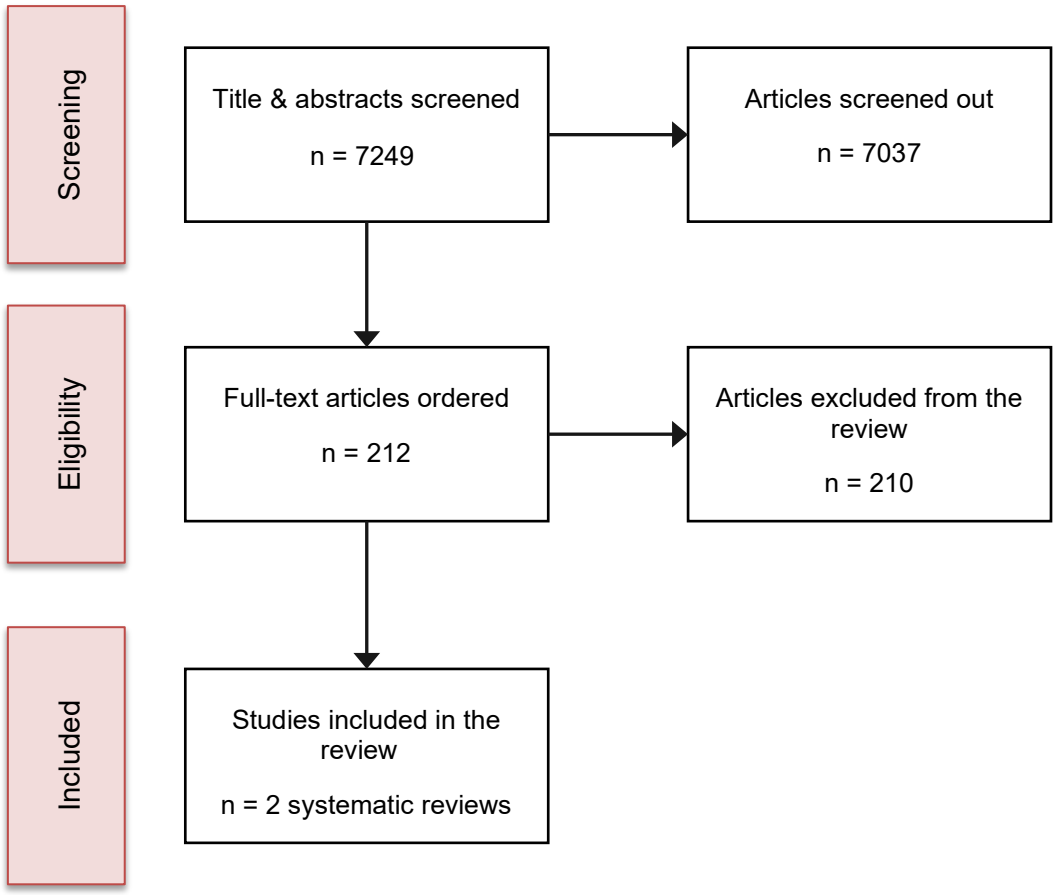
32 limit 31 to (letter or historical article or comment or editorial or news or case reports) (467)

33 31 not 32 (3267)

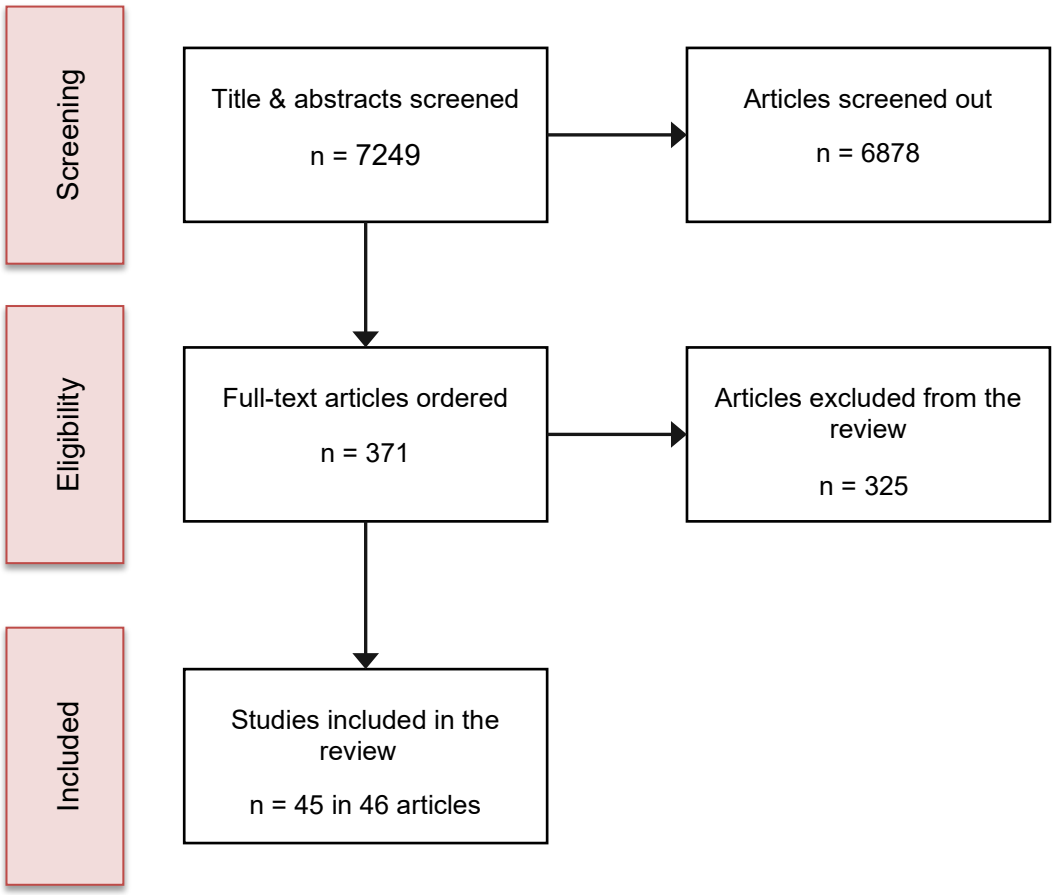
34 limit 33 to english language (3119)

Appendix C Study selection

C.1 Effectiveness evidence study selection



C.2 Qualitative evidence study selection



Appendix D Evidence tables

D.1 Effectiveness evidence

Chou 2019

Bibliographic Reference	Chou, Roger; Evans, Christopher; Hoverman, Adam; Sun, Christina; Dana, Tracy; Bougatsos, Christina; Grusing, Sara; Korthuis, P Todd; Preexposure Prophylaxis for the Prevention of HIV Infection: Evidence Report and Systematic Review for the US Preventive Services Task Force.; JAMA; 2019; vol. 321 (no. 22); 2214-2230

Study Characteristics

Study design	Systematic review
Study details	Dates searched: No historic limit - searches up to June 2018 with further surveillance in January 2019. 2005 lower limit used for diagnostic question search (irrelevant for this review) Databases searched: Ovid MEDLINE, the Cochrane Library, and EMBASE Sources of funding: Agency for Healthcare Research and Quality (AHRQ), US Department of Health and Human Services
Inclusion criteria	Study design: RCTs for effectiveness and harms; controlled observational studies for harms, diagnostic accuracy studies for risk assessment; and large observational studies for adherence (not all designs relevant for this review) Key outcomes: HIV infection, mortality, quality of life, harms Intervention: Oral combination tenofovir disoproxil fumarate/emtricitabine or tenofovir disoproxil fumarate monotherapy Population: Adolescents and adults without pre-existing HIV infection at increased risk of HIV acquisition
Exclusion criteria	Non-English language articles, persons living with HIV; children, other PrEP regimens, one PrEP regimen vs. another, outcomes not listed, including condom use, inpatient settings
Intervention(s)	PrEP single therapy / combined (Oral combination tenofovir disoproxil fumarate/emtricitabine or tenofovir disoproxil fumarate monotherapy Vs Placebo or no PrEP
Outcome(s)	Effectiveness, unintended consequences, adverse events, adherence
Number of studies included in the systematic review	14 RCTs (N = 18 837), 8 observational studies (N = 3884), and 7 studies of diagnostic accuracy (N = 32 279) were included (not all relevant to this review)

Studies from the systematic review that are relevant for use in the current review	**Bangkok Tenofovir Study, Choopanya et al 2013**, Thailand, follow up = 4 years, Intervention: A. Tenofovir disoproxil fumarate (300 mg) (n = 1204) B. Placebo (n = 1209), risk group: injection drug use in previous 12 months, patient characteristics: A vs B: Age 20-29 y: 43% vs 43%, 30-39 y: 38% vs 37%, 40-49 y: 15% vs 15%, 50-60 y: 5% vs 5% Men: 80% vs 80%, Race not reported. Funding: CDC; Bangkok Metropolitan Administration **CDC Safety Study, Grohskopf et al, 2013**, USA, follow up = 2 years, Intervention: A. Tenofovir disoproxil fumarate (300 mg) (n = 201) B. Placebo (n = 199), risk groups: MSM: Biological male engaging in anal sex with another man in the previous 12 months, patient characteristics: A vs B: Mean age: 38 vs 37 years white: 79.6% vs 66.8%, African American: 23% vs 37%, Asian/Pacific Islander: 10% vs 4%, other race: 8% vs 25%. Funding: US Department of Health and Human Services; CDC **FEM PrEP Van Damme et al 2012,** Kenya, South, Africa, Tanzania, follow up=1 year, Intervention: A. Tenofovir disoproxil fumarate/emtricitabine (300/200 mg) (n = 1062) B. Placebo (n = 1058), risk group: High-risk women: >1 vaginal sex act in previous 2 weeks or >1 sex partner in previous month, patient characteristics: A vs B: Mean age: 24 vs 24 y Race: not reported. Funding: USAID; Bill and Melinda Gates Foundation; Gilead Sciences (provided study drug) **IAVI Uganda Study, Kibengo et al 2013**, Uganda, follow up = 4 months, Intervention: A. Tenofovir disoproxil fumarate/emtricitabine (300/200 mg) (n = 24) B. Intermittent tenofovir disoproxil fumarate/emtricitabine (n = 24) C. Daily placebo (n = 12) D. Intermittent placebo (n = 12) risk group: High-risk heterosexual men and women: Unprotected vaginal sex with ART-naïve HIV-infected partner in the previous 3 months, patient characteristics: A vs B vs C vs D: Mean age: 33 vs 33 vs 33 vs 33 y Women: 50% vs 46% vs 67% vs 42% Race: not reported. Funding: IAVI; Gilead Sciences (provided study drug) **IAVI Kenya Study, Mutua et al, 2012,** Kenya, follow up = 4 months, Intervention: A. Tenofovir disoproxil fumarate/emtricitabine (300/200 mg) (n = 24) B. Intermittent tenofovir disoproxil fumarate/emtricitabine (n = 24) C. Daily placebo (n = 12) D. Intermittent placebo (n = 12), risk group: MSM and high-risk women: Current or previous STI, multiple episodes of unprotected vaginal or anal sex, or engaging in transactional sex in the previous 3 months, patient characteristics: A vs B vs C vs D: Mean age: 26 vs 26 vs 27 vs 28 y Women: 12% vs 0% vs 8% vs 8% Race: not reported, Funding: IAVI; Gilead Sciences (provided study drug) **IPERGAY, Molina et al, 2015**, France, Canada, follow up = 9 months (median), Intervention: A. On-demand tenofovir disoproxil fumarate/emtricitabine (300/200 mg) (n = 199) B. Placebo (n = 201), risk group: MSM: Unprotected anal sex with ≥2 partners in previous 6 months, patient characteristics: A vs B: Median age: 35 vs 34 y (IQR, 29-43) White: 94% vs 89% Other races: not reported. Funding: ANRS; Canadian HIV Trials Network; Fonds de Dotation Pierre Berge pour la Prevention; Bill and Melinda Gates Foundation **iPrEx Grant et al, 2010**, Brazil, Ecuador, Peru, Thailand, South Africa, United States, follow up: 1.2 years (median), Intervention: A. Tenofovir disoproxil fumarate/emtricitabine (300/200mg) (n = 1251) B. Placebo (n = 1248), risk group: MSM: Anal sex with ≥4 male partners, a diagnosis of STI, history of transactional sex activity, condomless anal sex with an HIV-infected partner or of unknown infection status in previous 6 months, patient characteristics: A vs B: Age 18-24 y: 47% vs 53%, 25-29 y: 22% vs 19%

	30-39 y: 20% vs 18%, ≥40 y: 11% vs 10%, Born male: 100% vs 100%, Black: 9% vs 8%, White: 18% vs 17%, Mixed race or other: 68% vs 70%, Asian: 5% vs 5%, Hispanic: 72% vs 73%. Funding: NIH; Bill and Melinda Gates Foundation **Partners PrEP, Baeten et al, 2012**, Kenya, Uganda, follow up = 2 years (median), Intervention: A. Tenofovir disoproxil fumarate (300 mg) + placebo tenofovirdisoproxil fumarate/emtricitabine (n = 1571) B. Tenofovir disoproxil fumarate/emtricitabine (300/200 mg) + placebo tenofovir disoproxil fumarate (n = 1565) C. Placebo tenofovir disoproxil fumarate + placebo tenofovir disoproxil fumarate/emtricitabine (n = 1570), risk group: High-risk heterosexual men and women: ART-naive HIV-infected partner, patient characteristics: A vs B vs C: Age 18-24 y: 12% vs 11% vs 11%, 25-34 y: 46% vs 44% vs 43% , 35-44 y: 30% vs 32% vs 32%, ≥45 y: 13% vs 14% vs 13% Men: 62% vs 64% vs 61% Race: not reported. Funding: Bill and Melinda Gates Foundation **PROUD McCormack et al, 2016,** England, follow up = 1 year, Intervention: A. Immediate tenofovir disoproxil fumarate/emtricitabine (245/200 mg) (n = 275) B. Tenofovir disoproxil fumarate/emtricitabine deferred for 1 y (n = 269), risk group: MSM: Anal intercourse without a condom in the previous 90 d and likely to have anal intercourse without a condom in the next 90 days, patient characteristics: A vs B Mean age: 35 vs 35 y White: 81% vs 83% Asian: 5% vs 6% Black: 4% vs 4% Other race: 10% vs 8%. Funding: Medical Research Counsel Clinical Trials Unit; Public Health England; Gilead Sciences **Study of TDF, Peterson et al, 2007**, Cameroon, Ghana, Nigeria, follow up = 6 months (mean), Intervention: A. Tenofovir disoproxil fumarate (300 mg) (n = 469), risk group: High-risk women: Mean of ≥3 coital acts per week and ≥4 sexual partners per month B. Placebo (n = 467), patient characteristics: A vs B: Mean age: 24 vs 24 y, race not reported. Funding: Bill and Melinda Gates Foundation **TDF2, Thigpen et al, 2012,** Botswana, follow up = 1 year (median), Intervention: A. Tenofovir disoproxil fumarate/emtricitabine (300/200 mg) (n = 611) B. Placebo (n = 608), risk group: High-risk heterosexual men and women: Sexually active in high-prevalence area, patient characteristics: A vs B: Age 18-20 y: 2% vs 3%, 21-29 y: 90% vs 87% , 30-39 y: 8% vs 10%, Women: 46% vs 46%, race not reported, Funding: Division of HIV/AIDS Prevention, CDC, and Division of AIDS, NIH;1 investigator reported royalties from Roche and 1 reported funding from Gilead **VOICE, Marrazzo et al, 2015**, South Africa, Uganda, Zimbabwe, follow up = 3 year (maximum), Intervention: A. Tenofovir disoproxil fumarate (300 mg) + placebo (n = 1007) B. Tenofovir disoproxil fumarate/emtricitabine (300/200 mg) + placebo (n = 1003) C. Placebo only (n = 1009), risk group, High-risk women: Sexually active in a high-prevalence area, patient characteristics, A vs B vs C: Mean age: 26 vs 25 vs 25 years, race not reported. Funding: NIH
Studies from the systematic review that are not relevant for use in the current review	• Beymer 2017 • Hoenigl 2015 • Jones 2017 • Lancki 2018 • Menza 2009 • Smith 2012 • Smith 2015 • Chan, 2016 • Grant 2014 • Landovitz 2017 • Montgomery 2016

	• Hoseck 2017 • Glidden 2016 • Liu 2016 • van Epps 2018
Additional comments	

Section	Question	Answer
Study eligibility criteria	Did the review adhere to pre-defined objectives and eligibility criteria?	Yes (Research plan linked to from document, published a priori and consulted on.)
	Were the eligibility criteria appropriate for the review question?	Yes
	Were eligibility criteria unambiguous?	Yes
	Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g. date, sample size, study quality, outcomes measured)?	Yes
	Were any restrictions in eligibility criteria based on sources of information appropriate (e.g. publication status or format, language, availability of data)?	Probably no (English language restriction)
	Concerns regarding specification of study eligibility criteria	Low (Although there was an English language restriction, studies identified were similar to SRs without restrictions. Overall concerns low.)
Identification and selection of studies	Did the search include an appropriate range of databases/electronic sources for published and unpublished reports?	Probably yes (Embase, Medline and Cochrane searched, no search for publications from conferences)
	Were methods additional to database searching used to identify relevant reports?	Yes (reference searching)
	Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible?	Probably yes
	Were restrictions based on date, publication format, or language appropriate?	Probably no (Restriction based on English language)
	Were efforts made to minimise error in selection of studies?	Yes
	Concerns regarding methods used to identify and/or select studies	Low

Section	Question	Answer
Data collection and study appraisal	Were efforts made to minimise error in data collection?	Probably no (Although two reviewers extracted independently, no standardised or piloted data extraction form is mentioned)
	Were sufficient study characteristics available for both review authors and readers to be able to interpret the results?	Yes
	Were all relevant study results collected for use in the synthesis?	Probably yes
	Was risk of bias (or methodological quality) formally assessed using appropriate criteria?	Probably yes (Cochrane RoB tool or GRADE not used but similar criteria used for assessing RoB and overall quality
	Were efforts made to minimise error in risk of bias assessment?	Yes (Two reviewers used)
	Concerns regarding methods used to collect data and appraise studies	Unclear (No information on the data abstraction forms - if these were standardised or piloted)
Synthesis and findings	Did the synthesis include all studies that it should?	Yes
	Were all pre-defined analyses reported or departures explained?	Yes (Protocol published online. QoL was a pre-defined outcome, but the reviewers found no study reported on this)
	Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?	Yes
	Was between-study variation (heterogeneity) minimal or addressed in the synthesis?	Yes (Random-effects model used and subgroup analysis)
	Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses?	Yes (sensitivity analysis conducted)
	Were biases in primary studies minimal or addressed in the synthesis?	Yes
	Concerns regarding the synthesis and findings	Low
Overall study ratings	Overall risk of bias	Low
	Applicability as a source of data	Fully applicable

Fonner, 2016

Bibliographic Reference	Fonner, Virginia A; Dalglish, Sarah L; Kennedy, Caitlin E; Baggaley, Rachel; O'Reilly, Kevin R; Koechlin, Florence M; Rodolph, Michelle; Hodges-Mameletzis, Ioannis; Grant, Robert M; Effectiveness and safety of oral HIV preexposure prophylaxis for all populations.; AIDS (London, England); 2016; vol. 30 (no. 12); 1973-83

Study Characteristics

Study design	Systematic review
Study details	Dates searched: January 1, 1990 and January April 15, 2015. Databases searched: PubMed, Cumulative Index to Nursing and Allied Health Literature, and Embase, Sources of funding: WHO/Bill & Melinda Gates Foundation
Inclusion criteria	Study designs included in SR : RCT, open label extension or demonstration project Key outcomes: (1) HIV infection, (2) any adverse event, (3) any stage 3 or 4 adverse event, (4) drug resistance (among those initiating PrEP while acutely infected and among those who seroconvert after PrEP initiation), and 5) sexual and reproductive health outcomes, including 5a) hormonal contraception effectiveness, 5b) any adverse pregnancy event, 5c) condom use, and 5d) number of sexual partners Intervention Comparing those randomised to oral PrEP versus placebo or comparing those receiving oral PrEP versus no use of PrEP (e.g. delayed use of PrEP). Date range Published in a peer-reviewed journal or presented as an abstract at a scientific conference between January 1, 1990 and January April 15, 2015. Population All people at substantial risk of HIV
Intervention(s)	PrEP single therapy / combined oral PrEP containing TDF or TDF/FTC vs Placebo or no PrEP
Outcome(s)	Effectiveness, Unintended, Consequences, Adverse events , Adherence
Number of studies included in the systematic review	18 overall including 15 RCTs and 3 observational studies (not all relevant to this review)
	FEM PrEP Van Damme et al 2012, Kenya, South, Africa, Tanzania, follow up=1 year, Intervention: A. Tenofovir disoproxil fumarate/emtricitabine (300/200 mg) (n = 1062) B. Placebo (n = 1058), risk group: High-risk women: >1 vaginal sex act in previous 2 weeks or >1 sex partner in previous month, patient characteristics: A vs B: Mean age: 24 vs 24 y Race: not reported. Funding: USAID; Bill and Melinda Gates Foundation; Gilead Sciences (provided study drug)

Studies from the systematic review that are relevant for use in the current review	**iPrEx Grant et al, 2010**, Brazil, Ecuador, Peru, Thailand, South Africa, United States, follow up: 1.2 years (median), Intervention: A. Tenofovir disoproxil fumarate/emtricitabine (300/200mg) (n = 1251) B. Placebo (n = 1248), risk group: MSM: Anal sex with ≥4 male partners, a diagnosis of STI, history of transactional sex activity, condomless anal sex with an HIV-infected partner or of unknown infection status in previous 6 months, patient characteristics: A vs B: Age 18-24 y: 47% vs 53%, 25-29 y: 22% vs 19% 30-39 y: 20% vs 18%, ≥40 y: 11% vs 10%, Born male: 100% vs 100%, Black: 9% vs 8%, White: 18% vs 17%, Mixed race or other: 68% vs 70%, Asian: 5% vs 5%, Hispanic: 72% vs 73%. Funding: NIH; Bill and Melinda Gates Foundation **Partners PrEP, Baeten et al, 2012**, Kenya, Uganda, follow up = 2 years (median), Intervention: A. Tenofovir disoproxil fumarate (300 mg) + placebo tenofovirdisoproxil fumarate/emtricitabine (n = 1571) B. Tenofovir disoproxil fumarate/emtricitabine (300/200 mg) + placebo tenofovir disoproxil fumarate (n = 1565) C. Placebo tenofovir disoproxil fumarate + placebo tenofovir disoproxil fumarate/emtricitabine (n = 1570), risk group: High-risk heterosexual men and women: ART-naive HIV-infected partner, patient characteristics: A vs B vs C: Age 18-24 y: 12% vs 11% vs 11%, 25-34 y: 46% vs 44% vs 43% , 35-44 y: 30% vs 32% vs 32%, ≥45 y: 13% vs 14% vs 13% Men: 62% vs 64% vs 61% Race: not reported. Funding: Bill and Melinda Gates Foundation **TDF2, Thigpen et al, 2012,** Botswana, follow up = 1 year (median), Intervention: A. Tenofovir disoproxil fumarate/emtricitabine (300/200 mg) (n = 611) B. Placebo (n = 608), risk group: High-risk heterosexual men and women: Sexually active in high-prevalence area, patient characteristics: A vs B: Age 18-20 y: 2% vs 3%, 21-29 y: 90% vs 87% , 30-39 y: 8% vs 10%, Women: 46% vs 46%, race not reported, Funding: Division of HIV/AIDS Prevention, CDC, and Division of AIDS, NIH;1 investigator reported royalties from Roche and 1 reported funding from Gilead **Study of TDF, Peterson et al, 2007**, Cameroon, Ghana, Nigeria, follow up = 6 months (mean), Intervention: A. Tenofovir disoproxil fumarate (300 mg) (n = 469), risk group: High-risk women: Mean of ≥3 coital acts per week and ≥4 sexual partners per month B. Placebo (n = 467), patient characteristics: A vs B: Mean age: 24 vs 24 y, race not reported. Funding: Bill and Melinda Gates Foundation **CDC Safety Study, Grohskopf et al, 2013**, USA, follow up = 2 years, Intervention: A. Tenofovir disoproxil fumarate (300 mg) (n = 201) B. Placebo (n = 199), risk groups: MSM: Biological male engaging in anal sex with another man in the previous 12 months, patient characteristics: A vs B: Mean age: 38 vs 37 years white: 79.6% vs 66.8%, African American: 23% vs 37%, Asian/Pacific Islander: 10% vs 4%, other race: 8% vs 25%. Funding: US Department of Health and Human Services; CDC **Project PrEPare, Hoseck et al 2013**, USA, follow up = 24 weeks, Intervention: Daily PrEP (FTC and FTC/TDF) to placebo and to 'no pill', risk group: Young MSM, patient characteristics: Median age: 19.97 years (range: 18–22) (n=58), Funding: National Institutes of Health through the Eunice Kennedy Shriver National Institute of Child Health and Human Development (Bill Kapogiannis, MD) with supplemental funding from the National Institutes on Drug Abuse (Nicolette Borek, PhD) and National Institute of Mental Health (Susannah Allison, PhD). **PROUD McCormack et al, 2016,** England, follow up = 1 year, Intervention: A. Immediate tenofovir disoproxil fumarate/emtricitabine (245/200 mg) (n = 275) B. Tenofovir disoproxil fumarate/emtricitabine deferred for 1 y (n = 269), risk group: MSM: Anal intercourse without a condom in the previous 90 d and likely to have anal intercourse without a condom in the next 90 days, patient characteristics: A vs B Mean age: 35 vs 35 y White: 81% vs 83%

	Asian: 5% vs 6% Black: 4% vs 4% Other race: 10% vs 8%. Funding: Medical Research Counsel Clinical Trials Unit; Public Health England; Gilead Sciences **iPrEx OLE, Grant et al 2014,** Peru, Ecuador, South Africa, Brazil, Thailand, and United States, Follow up: 72 weeks, Intervention: Daily PrEP (TDF/FTC) to no PrEP use, risk group: MSM and transgender women, patient characteristics: Age: 18–24 years (20%) 25–29 years (27%) 30–39 years (31%) 40 years (22%), Funding: US NIH, Study drug was donated by Gilead Sciences **IAVI Kenya Study, Mutua et al, 2012,** Kenya, follow up = 4 months, Intervention: A. Tenofovir disoproxil fumarate/emtricitabine (300/200 mg) (n = 24) B. Intermittent tenofovir disoproxil fumarate/emtricitabine (n = 24) C. Daily placebo (n = 12) D. Intermittent placebo (n = 12), risk group: MSM and high-risk women: Current or previous STI, multiple episodes of unprotected vaginal or anal sex, or engaging in transactional sex in the previous 3 months, patient characteristics: A vs B vs C vs D: Mean age: 26 vs 26 vs 27 vs 28 y Women: 12% vs 0% vs 8% vs 8% Race: not reported, Funding: IAVI; Gilead Sciences (provided study drug)
Additional comments	

Section	Question	Answer
Study eligibility criteria	Did the review adhere to pre-defined objectives and eligibility criteria?	Probably yes (Protocol in supplementary material but unable to determine if this was published/registered a priori). Objective clearly stated at the beginning of review)
	Were the eligibility criteria appropriate for the review question?	Yes (Population specified before inclusion criteria)
	Were eligibility criteria unambiguous?	Yes
	Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g. date, sample size, study quality, outcomes measured)?	Probably yes
	Were any restrictions in eligibility criteria based on sources of information appropriate (e.g. publication status or format, language, availability of data)?	Probably yes
	Concerns regarding specification of study eligibility criteria	Low

Section	Question	Answer
Identification and selection of studies	Did the search include an appropriate range of databases/electronic sources for published and unpublished reports?	Yes
	Were methods additional to database searching used to identify relevant reports?	Yes
	Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible?	Probably yes (Limited search term details published in supplementary material. Full strategy available on request from authors)
	Were restrictions based on date, publication format, or language appropriate?	Probably yes (No explanation of date range but likely due to known availability of PrEP)
	Were efforts made to minimise error in selection of studies?	Yes
	Concerns regarding methods used to identify and/or select studies	Low
Data collection and study appraisal	Were efforts made to minimise error in data collection?	Probably yes (Data abstraction by two reviewers independently using standardised forms. No details on if the forms were piloted however)
	Were sufficient study characteristics available for both review authors and readers to be able to interpret the results?	Probably yes (Funding for each study not provided)
	Were all relevant study results collected for use in the synthesis?	No information: (Only risk ratios on for individual studies provided in forest plot - unable to see event numbers in each arm, or how the individual studies reported their results.)
	Was risk of bias (or methodological quality) formally assessed using appropriate criteria?	Probably yes (Cochrane RoB tool used - details in supplementary data. Authors mention use of GRADE in protocol but no GRADE rating/tables found in study)
	Were efforts made to minimise error in risk of bias assessment?	No information (Not clear if RoB done by two reviewers or checked by a second)
	Concerns regarding methods used to collect data and appraise studies	Unclear
Synthesis and findings	Did the synthesis include all studies that it should?	Probably yes
	Were all pre-defined analyses reported or departures explained?	No (Protocol in supplementary material states GRADE approach will be used but this doesn't appear in the review.)

Section	Question	Answer
	Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?	Probably yes (random effects model used, but no weighting details provided)
	Was between-study variation (heterogeneity) minimal or addressed in the synthesis?	Yes (Random effects model used and subgroup analysis done)
	Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses?	Yes (Sensitivity analysis conducted)
	Were biases in primary studies minimal or addressed in the synthesis?	Yes
	Concerns regarding the synthesis and findings	Unclear
Overall study ratings	Overall risk of bias	Moderate (Moderate rating given as it is unclear if more than one reviewer assessed RoB, GRADE approach specified in protocol but not used, full search strategy not fully published and not enough data from individual studies published.)
	Applicability as a source of data	Fully applicable

Qualitative evidence

Auerbach, 2015

Bibliographic Reference	Auerbach, Judith D; Kinsky, Suzanne; Brown, Gina; Charles, Vignetta; Knowledge, attitudes, and likelihood of pre-exposure prophylaxis (PrEP) use among US women at risk of acquiring HIV.; AIDS patient care and STDs; 2015; vol. 29 (no. 2); 102-10

Study Characteristics

Study type	Focus Groups
Aim of study	to investigate PrEP's acceptability and feasibility among women at risk for HIV in the US.
Theoretical approach	None stated
Study location	USA: New York, Dallas, Atlanta, Newark, Chicago, and New Orleans.
Study setting	Community
Study dates	between July and September 2013
Sources of funding	This project was supported by funds from Gilead Sciences, Inc. (Vignetta Charles, PhD).
Data collection	The focus groups were comprised of 10 to 16 women, and were led by trained, local facilitators and conducted at the CBOs. Each session lasted about 90 min. At the beginning of each focus group session, participants completed a questionnaire with demographic information. Then the facilitator provided basic information about what PrEP (specifically oral Truvada) is, how it is administered and functions in the body, what side effects have been observed, and what clinical trial data have shown with respect to its efficacy in different populations. A fact sheet developed by the Global Campaign for Microbicides and updated by

Method and process of analysis	All focus group sessions were digitally recorded and transcribed, and transcripts were reviewed and discussed by two researchers to identify predominant themes and any demographic or site differences. The two researchers compared their thematic notes, and incorporated oral comments and notes from the project coordinator, who attended all focus group sessions. AIDS United and, subsequently, The Well Project was used for this purpose.16 Facilitators then asked a set of questions to elicit information about participants' basic awareness and understanding of PrEP, ideas about potential users of PrEP, attitudes about administration and uptake, barriers to and facilitators of use, whether PrEP might affect sexual activity, including condom use, and what kinds of PrEP methods might be desirable (or not). The focus group interview guide was informed by questionnaires used in microbicide and PrEP clinical trials (provided by colleagues in the HIV Prevention Trials Network) and a theoretically-driven interview instrument developed by Kandathil (2010)
Population and sample collection	We explicitly aimed to recruit Black/African American women, given their disproportionate risk of HIV in the US. Women were recruited by local women serving CBOs—SisterLove (Atlanta), AIDS Foundation of Chicago, Afiya Center (Dallas), Hyacinth (Newark), Women With a Vision (New Orleans), and Iris House (New York)— that had access and ability to reach the demographic of women desired for this study. Recruitment strategies included: posting flyers at apartment buildings; recruiting at an HIV testing van, homeless shelter and CBO common area; posting on Facebook; word of mouth at CBOs, homeless shelters, and substance abuse outpatient clinics; and outreach at churches. A total of 154 women participated in focus groups. Overall, 92% of participants were Black/African American; nearly one-third were 18–30 years old; 53% were single,

	divorced or separated; 52% were employed; 40% had an annual income under $10,000 and 47% had incomes of $10,000 to $40,000; and 77% were stably housed. Sixty percent of the women said they had ever had an HIV test. Only 3.5% reported having multiple sex partners.
Inclusion Criteria	Female Black
Exclusion criteria	None reported
Relevant themes	1. Knowledge of PrEP: Almost none of the participants across sites had ever heard of PrEP before the focus group session. "Because I feel like HIV is killing a lot of black people and they don't mind it happening. They're not going to tell us stuff, that there are other things to prevent it. They are just not telling us about it." 2. Sources of information and services: Primary care physician, OB-GYN; CBOs, family planning clinics, and community health centers; media; schools; and Peer-to-peer, Friend-to-friend, Outreach. ''I like that. Because we are talking about women, the best place to get information and to make a decision would be going to a woman-centered environment, so I like that.'' 3. Barriers to PrEP uptake: Lack of communication among community members; Mistrust of the medical institution; cost; side effects; stigma; newness of drug; and housing. ''I don't want to be a guinea pig. That's what I'm saying. I don't want to be a guinea pig.'' 4. Other issues and considerations: Efficacy level; adherence; Impact of PrEP on sex life and condom use; PrEP and pregnancy; PrEP and HIV testing; Delivery methods. "I will either want an injection like every month or every two months or something. But another problem is like the NuvaRing. I'm never going to do that. I'm not putting that in my vagina, but I would have this mindset like I want to protect myself, and I know I'm going to protect myself so I don't have to go through it because I don't like it."

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes

Section	Question	Answer
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	No *(They specifically chose to recruit Black women, which is valuable but should have been reflected in the aims rather than just women at risk for HIV.)*
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Moderate
Overall risk of bias and relevance	Relevance	Relevant

Bil, 2016

Bibliographic Reference	Bil, Janneke P; van der Veldt, Wendy M; Prins, Maria; Stolte, Ineke G; Davidovich, Udi; Motives of Dutch men who have sex with men for daily and intermittent HIV pre-exposure prophylaxis usage and preferences for implementation: A qualitative study.; Medicine; 2016; vol. 95 (no. 39); e4910

Study Characteristics

Study type	Semi structured interviews
Aim of study	to explore more thoroughly the motives for wanting or not wanting to use PrEP if it becomes available, motives for daily versus intermittent PrEP use, the anticipated motives for condom use when using PrEP, and preferences for PrEP implementation (e.g., service characteristics).
Theoretical approach	Grounded Theory
Study location	Amsterdam, the Netherlands.
Study setting	Part of the Amsterdam Cohort Studies (ACS) conducted at the Public Health Service.
Study dates	between February and December 2013
Data collection	Semistructured interviews of approximately 60 minutes each were conducted by 1 female interviewer (JPB, PhD-student) in Dutch or English at the Public Health Service Amsterdam or at the participants' homes. Before the interviews, participants received study information, including study purpose, a short description of daily PrEP, the iPrEX study results on effectiveness and side effects,[5] CDC recommendations on PrEP follow-up check-ups,[8] and the estimated Dutch costs of PrEP (tenofovir disoproxyl fumarate/ emtricitabine: approx. €580 monthly). During one interview, the

	participant's steady partner was present. Before the start of the interview, the interviewer introduced herself, the study purpose and interview procedure were explained, and oral informed consent was obtained. Information regarding level of education, income, age, most recent HIV-test result and test location, and relationship status (having a steady partner and HIV-status of steady partner) were obtained at the start of the interview and recorded on tape. The central interview topics were: intention-to-use PrEP in the future, reasons for wanting or not wanting to use daily PrEP, and perceived benefits and barriers of using PrEP. The following topics were also addressed: motives for wanting or not wanting to use intermittent PrEP, perceived motives for using or not using condoms when using PrEP, and opinions about preferred PrEP services (location of PrEP prescription and service characteristics).
Method and process of analysis	All interviews were audiotaped and transcribed verbatim (quotes are translated) and short-field notes were made during and shortly after the interviews. Data analysis was done in accordance with the Grounded Theory approach and consisted of 3 phases.[26–28] First, JPB andWMvdV independently read and coded (open and inductive) each transcript. Labeling was concise and self-explanatory and discussed until consensus was reached. Second, after developing the provisional coding scheme, codes were combined into categories. Third, core themes were defined in which categories could be placed. Core themes consisted of at least 1 category. Categories and core themes emerged from discussions with the

	complete data analysis team. Analyses were performed using MAXQDA 11.0.6 (Verbi GmbH, Berlin).
Population and sample collection	Participants were recruited through the Amsterdam Cohort Studies (ACS). Recruitment continued until data saturation was reached. Participants had a median age of 41 years (interquartile range 38–46), 80% lived in Amsterdam, 65% were college graduates, and 45% had a high annual income level (>€33,000) according to Dutch standards.[29] Regarding steady relationships, 45% had no steady partner, 35%had an HIV-positive partner, and 15% had an HIV-negative steady partner. The HIV status of one participant's steady partner was not asked. Eight MSM expressed a high intention-to-use daily PrEP if it becomes available, 10 expressed a low intention, and 2 were in doubt about their future PrEP use.
Inclusion Criteria	Men who have sex with men HIV negative Recent condomless sex
Exclusion criteria	None reported
Relevant themes	1. 8 motives for wanting to use daily PrEP if it becomes available: Daily PrEP can protect against possible HIV infection; in combination with other protection strategies offers complete coverage against HIV infection; offers additional protection for discordant couples; reduces anxiety about HIV transmission; is easier to use than condoms; can improve quality of sex life; makes engaging in (sexual) relationships with a potential HIV-positive partner easier; provides solidarity with HIV-positive partner. "I never want to have an HIV-positive boyfriend again, that limits me sexually, but if PrEP would be there, there wouldn't

	be a barrier to engage in a relationship with someone." 2. 10 motives for not wanting to use daily PrEP in the future: Daily PrEP is not sufficiently effective as an HIV risk reduction strategy; Nonbelief in present research and data; is not needed because of a low self-perceived HIV risk; is not needed because of treatment (of HIV positives) as prevention strategy; Preference for prevention strategies other than PrEP; High costs of daily PrEP; Anticipated side effects of daily PrEP or ART resistance; Low perceived self-efficacy to adhere to daily PrEP; Monitoring procedures during daily PrEP treatment are unacceptable; Principle objections against taking daily PrEP. "If you just have safe sex with condoms, I think that is the best protection, and if you use them well, make sure it doesn't break and you follow the normal guidelines or rules for safe sex, then I don't think you need it [PrEP]" 3. 3 motives for preferring intermittent PrEP over daily PrEP: decision to start intermittent PrEP is easier compared to daily PrEP; has less side effects compared to daily PrEP; reduces financial costs compared to daily PrEP. "I still feel like I would be putting poison into my body, but it is limited and not for a long time so I would expect it to be less harmful than if you use the medication for a longer period of time." 4. 2 motives for preferring daily PrEP over intermittent PrEP: Intermittent PrEP requires unwanted planning of sex life; makes adherence to other HIV prevention strategies more difficult. "For me sex is something spontaneous and not something you plan, okay I'm having sex in three days and I'll start taking PrEP. No, I think that is nonsense." 5. 2 motives for combining PrEP with condom use: Condoms are needed to prevent other STIs; Combining the two strategies increases protection against HIV. "And if you leave out condoms, you're still at risk for other STIs. Do you want them? I don't. I just see PrEP as an additional safety measure."

	6. one motive for solely using PrEP: using PrEP solely is sufficiently effective to prevent an HIV infection. "I see it [PrEP] as something to prevent getting HIV and therefore it allows you to bareback." 7. Location of PrEP prescription: Participants preferred the following locations for PrEP prescription if it were to become available in the Netherlands: Public Health Service (i.e., STI clinic), general practitioner, and the hospital (i.e., HIV-specialist). "I do believe an STI-clinic is a location where they could prescribe PrEP, but it is important that they have insight into the [medical] background of the person and which other medication they are taking"
Additional information	

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes

Section	Question	Answer
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Highly relevant

Bond, 2016

Bibliographic Reference	Bond, Keosha T; Gunn, Alana J; Perceived Advantages and Disadvantages of Using Pre-Exposure Prophylaxis (PrEP) among Sexually Active Black Women: An Exploratory Study.; Journal of black sexuality and relationships; 2016; vol. 3 (no. 1); 1-24

Study Characteristics

Study type	Survey or questionnaire
Aim of study	to examine the perceived advantages and disadvantages of using PrEP
Theoretical approach	Grounded Theory
Study location	Online, USA
Study setting	Online questionnaire
Study dates	Not provided
Sources of funding	Not stated
Data collection	This online investigation recruited potential participants by using a social marketing campaign that involved the use of multiple venues to spread the news about this study opportunity. These included modern social networking technologies such as Facebook, Twitter, LinkedIn, and emails, as well as the posting of flyers in community settings and on website bulletin boards (e.g. Craigslist, Backpages). Social media site posts, emails, and messages included the link to the study opportunity) inviting eligible participants to complete the study survey. Those who completed the study, received emails, or saw posts about the study opportunity and were asked to forward the information to others who might be interested and eligible to participate. At the close of data collection, there were 384 potential participants who consented to the study. However, the final sample included only 119 participants. This reflected a screening of eligibility and a careful review of all the data to ensure the quality of the data. More specifically, the full data set (N=384) was reviewed for duplications (i.e. duplicate computer IP addresses), and for subjects meeting the inclusion/exclusion criteria.
Method and process of analysis	Analyses of the open-ended questions were thematic, focusing on dominant themes that emerged and were organized by the questions asked; attention was paid to the level of endorsement of a theme across the sample. For the qualitative analysis, a grounded theoretical approach was used, permitting the use of categorizing strategies to code and analyze the data (Patton, 1990; Strauss & Corbin, 1997). First, the transcripts were summarized in a “digest” that identified the major themes of the responses. Using QSR International’s NVIVO 9 qualitative software, the coding of the data was conducted in three steps. First, based on the transcripts of the responses, a list of analytic areas

	represented in the data were composed and given a code (i.e., a “closed code”) based on relevant literature pertaining to e-health using an avatar video. Second, the primary analyst (principle investigator) reread the transcripts and identified blocks of text to be given a descriptive label (i.e., either a label from the closed code list or an original one, termed an “open code”). Next, the open-coded data were organized under and integrated into the closed code list. Third, the data under each thematic code (e.g., “empowering,” “female-controlled prevention,” “fear of side effects,” “condom use,” “perceived risk”) were re-read; and, if needed, re-coded into sub-categories in order to refine the analytic categories used. As the themes of the responses emerged, special attention was paid to data that did not confirm emerging themes, noting these for exploration in future research. In addition to using these methods of analysis, we also ensured analytic rigor by engaging several peer-reviews of early analytic claims (Charmaz, 2006). For this analysis we will focus on the questions related to PrEP.
Population and sample collection	This online investigation recruited potential participants by using a social marketing campaign that involved the use of multiple venues to spread the news about this study opportunity. These included modern social networking technologies such as Facebook, Twitter, LinkedIn, and emails, as well as the posting of flyers in community settings and on website bulletin boards (e.g. Craigslist, Backpages). Social media site posts, emails, and messages included the link to the study opportunity) inviting eligible participants to complete the study survey. Those who completed the study, received emails, or saw posts about the study opportunity and were asked to forward the information to others who might be interested and eligible to participate. At the close of data collection, there were 384 potential participants who consented to the study. However, the final sample included only 119 participants. This reflected a screening of eligibility and a careful review of all the data to ensure the quality of the data. More specifically, the full data set (N=384) was reviewed for duplications (i.e. duplicate computer IP addresses), and for subjects meeting the inclusion/exclusion criteria. The sample included 119 Black women who met the inclusion criteria and completed the entire survey and video
Inclusion Criteria	Female Specific age range Over 18 Black English language Recent sex with a male partner Have read/watched study materials
Exclusion criteria	Did not watch the entire information video

Relevant themes	Perceived Advantages of Using PrEP 1. Female-Controlled: Most participants expressed that PrEP was a valuable method that would allow women to protect themselves from HIV infection without dependence on their male sex partners to use condoms. "it's a great way to help women; particularly Black women take more control of their sexual health." 2. Option for Women with Risky Sex Partners: Many women expressed that PrEP would be a viable option for women who have sex partners that would be considered risky, including men who refuse to use condoms, have co-current sex partners, cheat within exclusive relationships, or abusive to their sex partners. "I like that PrEP gives women in monogamous relationships with men who cheat some kind of peace of mind. It is also good for those who may find themselves in one night stand situations." 3. Option for Serodiscordant Couples [not relevant] 4. Empowerment: Empowerment—PrEP was viewed as an HIV prevention option that has the potential to promote empowerment and self-efficacy among Black women regarding their sexual health. "definitely an advantage for girls and women in difficult situations to have this as a choice to protect themselves. Perceived Disadvantages of Using PrEP 1. Complexity of the Choice: Several participants expressed that the side effects, the need for continuous testing (HIV, kidney, etc.), and required daily adherence was a disadvantage to using PrEP. "The process seems very involved and that is kind of discouraging" 2. Encourage Sex with Risky Partners: Participants expressed that having a medication like PrEP would encourage women to remain in relationships with men who place them at high risk for HIV infection, especially in relationships where fidelity was an issue. "women should get out of those situations with risky men instead of continually taking a drug with side effects that could harm them in the long run." 3. Burden for Women: Some participants expressed that women have too much responsibility already when it comes to sexual health in relationships, since they are responsible for hormonal birth control methods. "That's too much to do. Take the pill, get tested, and still use condoms & birth control. Too much for women to have to deal with on top of everything else going on their life." 4. Promote Unprotected Sex: Participants also expressed that PrEP may increase riskier sex behaviour because women would not feel that they need to use a condom. "I think it's a great idea. I just hope people don't decide not to use condoms just because they can get this." 5. Newness of the Drug, Medical Mistrust, and Stigma: Participants were concerned about the lack of awareness of the drug amongst the public and the effects that long-term usage of PrEP would have on the body and the monetary cost. "The stigma related to having the drug show up on my insurance and at the pharmacy level is enough to not make me want to take it"

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	No *(Generic aim, which was stated clearly.)*
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Can't tell *(Not greatly relevant to an anonymous survey)*
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Moderate *(Downgraded due to the weak statement of aims and the obvious typo in one of the headings which suggests that peer review and editing was not particularly thorough in this journal.)*
Overall risk of bias and relevance	Relevance	Relevant

Brooks, 2019

Bibliographic Reference	Brooks, Ronald A; Cabral, Alejandra; Nieto, Omar; Fehrenbacher, Anne; Landrian, Amanda; Experiences of Pre-Exposure Prophylaxis Stigma, Social Support, and Information Dissemination Among Black and Latina Transgender Women Who Are Using Pre-Exposure Prophylaxis.; Transgender health; 2019; vol. 4 (no. 1); 188-196

Study Characteristics

Study type	Semi structured interviews
Aim of study	to explore the experiences of PrEP stigma among BLTW who are using PrEP in Los Angeles County
Theoretical approach	None stated
Study location	Los Angeles County, USA
Study setting	Black and Latina transgender women (BLTW) community
Study dates	from October 2017 through November 2018
Sources of funding	This work was supported by the California Community Foundation (Grant BA-17-136260), the National Institute of Mental Health (Grant R21MH107339 and T32MH109205), and the UCLA Center for HIV Identification, Prevention, and Treatment (CHIPTS) (Grant P30MH058107).
Data collection	A purposive sample of BLTW PrEP users was recruited from October 2017 through November 2018 to complete an in-depth, semistructured qualitative interview about their experiences using PrEP. A semistructured interview guide was developed to explore experiences of stigma related to the use of PrEP among BLTW. As part of the interview, participants were asked to describe the following: (1) experiences disclosing their PrEP use to friends/peers, family, sex partners, and medical providers; (2) experiences where they did not disclose their PrEP use because they thought they would be judged or treated differently; and (3) personal feelings related to their PrEP use. Interviews were audio recorded and lasted 60–90 min
Method and process of analysis	All interviews were transcribed verbatim and checked for accuracy by two research staff members. The coding process is detailed in a previous article.24 In short, initial codes were developed from the interview guide, field notes, and multiple readings of the transcripts. Once consensus was reached on the codebook, a subset of codes was used to test for intercoder reliability. Two research team members independently coded two randomly selected transcripts and an intercoder reliability score was computed (Cohen's kappa coefficient, k = 0.87). The final codes were entered into ATLAS.ti (version 8.3.20.0) and attached to their associated quotations for all transcripts. A thematic analysis approach was then used for analyzing all qualitative data.25 Coded data extracts were sorted into potential themes and reviewed by the study team to refine each theme. Major themes were selected based on their frequency across the dataset or the depth of the discussions.

Population and sample collection	Recruitment strategies included disseminating study promotional materials at trans-specific community events and at LGBT community agencies, and through participant referrals. Several barriers to recruitment of trans women observed in the study included loss of contact with potential participants because of a lost or stolen phone, incarceration, or housing instability. An additional barrier was PrEP discontinuation among BLTW PrEP users, which occurred between the initial contact about the study and the point of enrollment. Recruitment of participants was terminated when data saturation was reached with completed interviews (i.e., no new information was being gleaned from interviews). A total of 19 BLTW participated in the study, of which 10 identified as Black/African American and 9 identified as Hispanic/ Latina. Overall, the median age was 28 (range = 21– 50). The majority identified as straight/heterosexual (68.4%), reported completing less than a college degree (57.9%), unemployed (42.1%), and having an annual household income of <$10,000 (63.2%). The majority of participants also had health insurance (84.2%) and reported being single (78.9%). The mean length of time on PrEP was 6.2 months (standard deviation = 9.9; median = 2.5; range = 0.5–44.0).
Inclusion Criteria	Trans people In a specific location Los Angeles county Female PrEP users were currently prescribed and taking Truvada for PrEP, had been using PrEP for at least 1 month, Black Recent sex with a male partner Over 18 Latina/Hispanic
Exclusion criteria	None reported
Relevant themes	1. Experiences of HIV Stigma Related to the Identity of Transgender Women: Participants shared that family members and those within the cisgender community, particularly cis women, hold the beliefs that all TW will contract HIV in their lifetime, are already HIV-positive, and are to blame for the continuing spread of HIV. "Like I told you about that incident where I was attacked, the women said, ‘‘You fucken’ HIV infected, bitch!’’ Right away, that stigma and that really burned me up not only because I know I’m not, but that was the true picture of how a

	lot of cisgender women of color view us, as women giving people HIV. " 2. Perception that BLTW PrEP users are HIV-positive: A prominent theme related to PrEP stigma was the assumption that BLTW PrEP users are HIV-positive because they are taking an HIV medication. This resulted in other trans peers discrediting the individual because of their presumed HIV-positive status. "My friends when they found out were like, ‘‘Oh, girl. you’re infected! You’re HIV-positive. Bitch, get away from me! That bitch is taking Truvada. You guys better watch out and you better get yourself tested.’’" 3. Perception that BLTW PrEP users engage in elevated sexual risk behaviours: the perception that BLTW PrEP users are more likely or willing to engage in risky sexual behaviours. This perception led some to express internalized feelings of guilt for continuing to engage in behaviours that put them at increased risk for contracting HIV. "when I tell people that I’m on it, the ones that I’ve had sex with, keeping it real, a lot of them still ask, ‘‘Well, why do I have to use a condom?’’ So I tell them, ‘‘Because you don’t know what I might have.’’ They don’t understand." 4. Negative labels ascribed to BLTW PrEP users: s the experience of being assigned a negative label or identity because of their PrEP use. This included the attachment of negative labels such as ‘‘whore’’ or ‘‘slut’’. ") [My friend] said that I was a slut. I was like, ‘‘But I’m a protected slut bitch! I’m putting up barriers."" 5. Social support after PrEP disclosure: Despite a negative reception after PrEP disclosure for some participants, others reported receiving positive social support and encouragement from friends and family, sex partners, and peers within the trans community for taking precautions to prevent HIV infection. "It was a good thing; [my parents] recommended it [PrEP]. They think it’s the best for me because a girl like me should always be safe with my sex life as well, regardless of who I’m having sex with. " 6. Dissemination of PrEP information: To help reduce HIV transmission in the trans community, some participants used their disclosure event as an opportunity to disseminate information about PrEP to other TW, particularly those who engage in sex work. "Most of the trans women that I talked to, they do the same thing I do. So therefore, they’re like, ‘‘Oh, really?’’ They wanted to try it to see if they can do it."

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes

Section	Question	Answer
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Relevant

Cahill, 2020

Bibliographic Reference	Cahill, S.R.; Keatley, J.; Wade Taylor, S.; Sevelius, J.; Elsesser, S.A.; Geffen, S.R.; Wang, T.; Mayer, K.H.; "Some of us, we don't know where we're going to be tomorrow." Contextual factors affecting PrEP use and adherence among a diverse sample of transgender women in San Francisco; AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV; 2020; vol. 32 (no. 5); 585-593

Study Characteristics

Aim of study	to examine the barriers to PrEP uptake in a racially and ethnically diverse sample of TW to inform the development of culturally tailored interventions to increase PrEP uptake in TW in San Francisco at risk of acquiring HIV
Theoretical approach	None stated
Study location	San Francisco, USA
Study setting	Transgender community
Study dates	Not provided
Sources of funding	This research was supported by an unrestricted research grant from Gilead Pharmaceuticals, Inc.
Data collection	Researchers affiliated with a Boston community health centre and at a university research and educational institution in San Francisco collaborated to conduct two (2) focus groups with diverse TW at risk of HIV acquisition in San Francisco. One focus group was conducted in English (n = 11), and another in Spanish (n = 8). Participants were asked if they had ever used PrEP. Team members developed a semi-structured interview guide (Table 1) that was translated into Spanish, then translated back into English to ensure that the original

	meaning was not altered. Qualified participants completed an informed consent in English or Spanish. Questions: Introduction; Perceptions of PrEP efficacy; Communication about PrEP with medical providers; Barriers, facilitators to taking PrEP; Cost of PrEP and sexual health counseling; PrEP and sexual decision making; Feasibility and acceptability of PrEP to MSM, transgender women; Frequency of PrEP use; Feasibility and efficacy of PrEP using rectal microbicides gel or injectable PrEP; other.
Method and process of analysis	Focus groups were audio recorded and lasted 90 min. Each participant received a $50 gift card. Audio files were transcribed verbatim and checked for errors. The Spanish audio file was transcribed verbatim, then translated into English. Two study members took written field notes, to document a rich contextual description (Phillippi & Lauderdale, 2018). The study team used a qualitative descriptive approach (Sandelowski, 2010; Sullivan-Bolyai, Boya, & Harper, 2005) to code and analyze the data. First, three team members read each transcript independently to record major insights and reflections on the data. After creating a codebook, they used a within-case and across-case approach (Ayres, Kavanaugh, & Knafl, 2003) to code transcripts and analyze emerging themes within each focus group and across focus groups. Field notes were used to improve the depth of findings and analysis (Phillippi & Lauderdale, 2018). Codes and potential themes were reviewed by the three coders,

	and emerging themes and significant statements agreed upon by the all study team members.
Population and sample collection	Affiliated study staff at both locations, including TW staff, used convenience sampling to recruit potential participants. The English language focus group participants were racially diverse (Table 2): four participants were White, three were American Indian/Alaska Native, two were Black, and two identified as multiracial. The mean age was 41, with a range from 23 to 56. Most of the Spanish language focus group participants (seven out of eight) identified as Hispanic or Latina, while one said her ethnicity was White. The mean age was 42, with a range from 27 to 64. Three of the English focus group participants were unemployed and three on disability, compared to five of the Spanish group participants who were unemployed and none on disability. A majority of the participants in both focus groups (6/11, 5/8) reported earning income of less than $12,000 per year. The English language participants reported a higher education level than the Spanish language participants. Overwhelming majorities in both focus groups had a primary care provider (PCP) and health insurance. A majority in both groups reported binge drinking at least once a month, while a small percentage in both groups reported amphetamine use.
Inclusion Criteria	Trans people Female

	HIV negative Recent condomless sex Recent sex with a male partner
Relevant themes	1. Some participant knowledge of PrEP, and some misinformation: Some participants in both focus groups demonstrated some knowledge of oral PrEP and its potential to prevent HIV transmission, but some participants in both focus groups had not heard of PrEP. “I’ve heard about a vaccine that they were talking about, and perhaps [PrEP] is what it was?” 2. Limited provider education of patients about PrEP: Several participants said that they had not learned about PrEP from providers. “I think that we are silent because the doctors haven’t really talked to us about this. We don’t have many answers and very few questions.” 3. Concerns about possible side effects: Several participants in both groups had concerns about possible side effects and safety of PrEP. "Does it cause liver disease?…high blood pressure?…stroke? I heard…that it can cause headaches, nausea, diarrhea, potential strokes. I’ve heard this. So I’m concerned. I mean, because I wouldn’t want to consume anything in my body that’s going to harm me.” 4. Issues related to hormones: Participants in the English group said that TW have competencies related to taking hormones and self-advocacy that could help support PrEP adherence, but others had concerns about how medications interact. “I can guarantee all of the girls here are on injection, I’m sure somebody here – almost all of us here are swallowing spiro everyday…so yeah, we’d be willing to swallow a pill everyday if it helped, I’m sure.” 5. Concerns about adherence under the influence of substances: Participants in both groups expressed concern that using substances could interfere with adherence to PrEP. [“What do you think interrupts taking those pills?”] “Taking them drunk.” 6. The importance of poverty as social context for TW: Participants in both groups raised concerns about poverty as a contextual factor for TW considering PrEP. “There are some people that aren’t even stable enough in their lives to know what’s going on…Some of us, we don’t know where we’re going to be tomorrow, don’t know what we’re going to be doing…some of us may not even have a stable place to live, or let alone taking PrEP.” 7. Distrust of the government and/or medical establishment, and AIDS conspiracy beliefs: Participants in both groups expressed distrust of the government and/or of the medical establishment as reasons why they might hesitate to consider taking PrEP. “I would be like a guinea pig. We don’t want another Tuskeegee, baby. No we don’t.” 8. The belief that PrEP is for gay men (and not TW):Participants in both groups expressed the feeling that PrEP is for gay men, or gay White men—i.e., People with privilege—and not for TW. “To me, this PrEP thing is a gay white man’s thing, OK? It’s for people that have stability, and maybe have money.” 9. The need for gender-affirming health care: Several participants in both focus groups reported limited provider competency regarding transgender health care. “My doctor…although he works with transgenders, he never once brought any of this up. I’ve heard about stuff like this from my gay friends, OK?”

	10. Thoughts on various modalities of PrEP: Focus group participants expressed preferences for different modalities of PrEP. "…if I were more active, I would use it [a PrEP pill]. Without fear, I would use it." 11. Discrimination compelling sex work: One unique theme emerged in the English focus group: participants spoke of the importance of addressing discrimination which forces some TW into sex work, and the criminalization of sex work. "We need to investigate and deal with the root causes of why this community is at risk…Legalize prostitution…put strictures and laws in place to protect people who are forced to work the sex trade" 12. Risk of contracting other STIs: One unique theme emerged in the Spanish focus group: the risk of contracting other sexually transmitted infections (STIs) if a person used PrEP but did not use a condom. "Better to use the condom because as they've said there are side effects, and as she said, you run the risk of being infected with other things."

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes

Section	Question	Answer
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Partially relevant *(Downgraded twice because it is a US study and because the Latina population are a major ethnical group with specific marginalization and discrimination in the US, which may not be as culturally relevant in the UK.)*

Collier, 2017

Bibliographic Reference	Collier, Kate L; Colarossi, Lisa G; Sanders, Kim; Raising Awareness of Pre-Exposure Prophylaxis (PrEP) among Women in New York City: Community and Provider Perspectives.; Journal of health communication; 2017; vol. 22 (no. 3); 183-189

Study Characteristics

Study type	Focus Groups
Aim of study	to explore PrEP knowledge and attitudes, perceived facilitators and barriers to adoption, and message preferences among nontransgender black women and Latinas in the Bronx, New York
Theoretical approach	Grounded theory
Study location	New York City, USA
Study setting	Data are from a qualitative study conducted to inform the expansion and revision of an existing social marketing campaign, Your Body Needs You. Your Body Needs You was launched in Brooklyn neighbourhoods in 2014 by Project Street Beat, a program of Planned Parenthood of New York City (PPNYC), in partnership with local social service providers. The campaign's goal is to promote sexual health among black women and Latinas in Brooklyn aged 20–44 by encouraging them to seek sexual health care such as HIV and sexually transmitted infection (STI) testing and to practice safer sex.
Study dates	2016
Sources of funding	This research was funded by the New York City Department of Health and Mental Hygiene, Bureau of HIV Prevention, through a contract with Public Health Solutions
Data collection	Group sizes ranged from 5 to 10 participants. Six groups were conducted in total, with separate groups held for staff and clients. Groups were approximately 90 minutes long and held in private conference rooms at each of the four partner organizations. The focus groups were cofacilitated by a researcher and an HIV services expert from PPNYC, and observed by another PPNYC researcher and a social marketing consultant. Staff members were not present at client focus groups at their agency nor were they informed by researchers of the identity of clients attending the groups. The facilitators followed a semistructured discussion guide that addressed a variety of HIV-related issues, with a section focused on PrEP knowledge, attitudes about PrEP, and motivational messages for social marketing. Here we report only on the data concerning PrEP. PrEP was introduced the same way in each group discussion. After giving the full name and acronym, the facilitator explained, "PrEP is for people who are HIV-negative. It is available as a once-a-day pill. If it is taken every day as prescribed, it can be more than 90% effective in preventing HIV infection." Participants were asked if they had previously heard of PrEP. The facilitators asked follow-up questions about what and how they had heard about PrEP. Standard information about PrEP was then provided. The facilitators then led the participants in a discussion

	about potential interest in PrEP use among clients or women in the community, advantages and barriers related to use, and partner responses to or influences on use. Participants were next asked to evaluate and discuss the following action messages, which were presented in random order to each group: 1. Get tested for HIV and STDs. Find out about PrEP to prevent HIV. Use condoms. 2. Get tested for HIV and STDs. Ask about PrEP to prevent HIV. Use condoms. 3. Get tested for HIV. Use condoms. Find out about PrEP for ongoing HIV protection. 4. PrEP is a pill to prevent HIV. Get tested and ask about it.
Method and process of analysis	Focus group recordings were transcribed verbatim. Two researchers analyzed the focus group transcripts using a grounded theory approach to identifying categories and themes emerging from the data (Strauss & Corbin, 1990). Transcripts were coded by hand outlining the text. No computer program was used for analysis. An initial etic analysis of the data organized the transcripts into categories derived primarily from the structure of the discussion guide that focused questions into topic areas. Transcripts were then reviewed and text identified related to each category. Thereafter, an emic analysis was conducted where we attempted to saturate categories through constantly comparing incidents that led to the development of indigenous themes within each category. Finally, a third level of analysis of identified subthemes related to the frequency of themes mentioned by staff and/or clients across groups. Researchers conducted open coding independently and simultaneously. These results were then corroborated to create a final set of categories and themes that were most dominant and repeated across multiple groups. Three groups were conducted with staff and three with clients. We note in the results which group (staff or client group 1, 2, or 3) a quote was obtained from to show the range of comments across the different groups.
Population and sample collection	Staff (n = 21) and clients (n = 23) were recruited from four organizations serving women in the Bronx. Organizations were (1) an HIV preventive services agency, (2) a homeless shelter for adult women, (3) a domestic violence organization, and (4) a judicial diversion program for nonviolent offenders, including women arrested for prostitution- and drug-related offenses. Client participants were recruited by staff members at each participating organization through verbal invitations and recruitment flyers
Inclusion Criteria	Female Specific age range 18-50 Black English language cisgender Latina/Hispanic
Exclusion criteria	transgender
Relevant themes	1. PrEP Knowledge: (1) low levels of community knowledge would decrease women's uptake, (2) lack of provider knowledge would prevent provision of information and prescriptions of PrEP to women,

	and (3) there is a desire to find out about PrEP. "People sometimes worry when it comes down to a pill, side effects and different things. So you want to be educated about it and know more. Once they know more, they will want to take it because if that's going to prevent you from getting AIDS, a lot of people are going to go for that." 2. Attitudes about PrEP: PrEP as the only woman-controlled HIV prevention method, PrEP as an option when condom use is not, and PrEP as unsuitable for young women at risk. "I've encountered gentlemen [who say] No baby, don't put that on…a lot of women let men talk them out of putting that condom on, and I don't understand that. I think the pill is great, and I think we really need it." 3. Perceived Facilitators to PrEP Uptake/Usage: PrEP would provide a good contingency plan or dealing with condom failures; participants recognized that PrEP could reduce HIV incidence in their communities; learning there are few side effects associated with PrEP would be information that would facilitate women's willingness to take it. "What if you have a condom on and it breaks, and you know you're dealing with an HIV-infected person? At least you are protected." 4. Perceived Barriers to PrEP Uptake/Usage: (1) frequency of and stigma associated with medical visits and (2) burden of pill-taking for multiple health concerns. "I'm not a pill person and my thing is, putting something in my system that's not part of who I am from birth—I have apprehension." 5. PrEP Message Preferences: the importance of referring to PrEP as a pill; references to STDs should be omitted since PrEP does not protect against STDs other than HIV; the action message should be brief—a three-line message was considered too long; both clients and staff were in favour of omitting a message related to condom use, due to both wanting to prioritize other components of the message within limited space, and finding the message tiresome or inappropriate for women. "PrEP to me sounds like a plan, like 'prepare'…it sounds like a handbook on how to prepare to prevent HIV."
Additional information	Data from staff/providers was not extracted

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes

Section	Question	Answer
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Partially relevant

D'Angelo, 2021

Bibliographic Reference	D'Angelo, Alexa B; Davis Ewart, Leah N; Koken, Juline; Bimbi, David; Brown, Justin T; Grov, Christian; Barriers and Facilitators to Pre-exposure Prophylaxis Uptake Among Black Women: A Qualitative Analysis Guided by a Socioecological Model.; The Journal of the Association of Nurses in AIDS Care : JANAC; 2021; vol. 32 (no. 4); 481-494

Study Characteristics

Study type	Semi structured interviews
Aim of study	to understand the key facilitators and barriers to PrEP use experienced and perceived by Black women in New York City.
Theoretical approach	socioecological model
Study location	New York, USA
Study setting	Community
Study dates	between February and August of 2018
Sources of funding	CUNY Interdisciplinary Research Grant
Data collection	One-on-one interviews were conducted by a Black female staff member trained in qualitative data collection. The interviews took place at a location that was safe and convenient for the participant; interview locations included the research team's offices or the participant's home. All interviews were audio recorded and transcribed verbatim. Transcripts were verified against the original recording by two staff members for quality assurance. The interviewer followed a semi-structured interview guide (Table 1), which assessed participants' knowledge, attitudes, and perceptions about PrEP use, as well as perceived barriers and facilitators to PrEP use.
Method and process of analysis	An inductive thematic approach was used to identify salient themes and subthemes relating to perceived barriers and facilitators for PrEP use (Braun & Clarke, 2006). Codes were derived inductively, starting with a thorough reading of the transcripts and identification of relevant information cited by participants. Coding followed a socioecological model as a guiding structure and conceptualized knowledge, attitudes, and perceptions about PrEP use as barriers and facilitators within the multiple levels of the model. The investigators believe saturation of core themes was reached across the interviews. To ensure credibility, we used a process of investigator triangulation, wherein the first and second authors, with the supervision of the last author, worked together to ensure that the final codebook credibly and thoughtfully reflected the data (Korstjens & Moser, 2018). An initial codebook was developed by the first author after reading all 33 transcripts, followed by coding and organizing the data in an Excel spreadsheet. Next, eight interviews were randomly selected for a second data analyst to code to establish interrater agreement. The two researchers reviewed and discussed

	any discrepancies in the coding and revised the codebook based on reflexive discussion of the data. The first author then recoded the 33 transcripts based on mutually agreed on codebook revisions. A second random sample of eight interviews were then reviewed for independent coding by the two analysts, as well as to calculate interrater agreement, defined as whether identical codes were applied to the selected text by both coders. The analysts reached an interrater agreement percentage of 89.4% in the second round of coding. To provide dependability and confirmability, our codebook development and coding files have been archived to provide an audit trail of our analytic process (Korstjens & Moser, 2018). The final codebook included 14 different codes, which were thematically organized as barriers and facilitators to PrEP.
Population and sample collection	The sample included 33 Black women living in New York City. Participants were identified via targeted sampling, wherein study staff identified areas for recruitment and collaboration with community organizations. Participants were recruited via face-to-face recruitment, including approaching women in waiting areas or as they were entering/exiting facilities, at local New York City organizations serving Black women in the identified area. The mean age of participants was 35.3 years (SD 5 12.6). All participants identified as Black, of which 64% (n 5 21) self-identified as African American, 39% (n 5 13) as Caribbean, and 21.2% (n 5 7) as Hispanic/Latina (Table 1). The race and ethnicity of participants were not mutually exclusive, reflecting the diverse identities and experiences of Black women. The majority of participants identified as cisgender women (94%, n 5 31), heterosexual (76%, n 5 25), in a romantic relationship (58%, n 5 19), employed full-time (49%, n 5 16), and had health insurance (88%, n 5 29). Additionally, 70% (n 5 23) of women reported testing for HIV within the last year, and 85% (n 5 28) reported their HIV status as negative. All participants reported no previous PrEP use
Inclusion Criteria	Trans people Female Black Recent sex with a male partner Over 18 cisgender
Exclusion criteria	None reported
Relevant themes	1. Barriers 1. Sociocultural barriers. 2. Community-level barriers 3. Interpersonal-level barriers 4. Individual-level barriers 2. Facilitators 1. Sociocultural-level facilitators 2. Community-level facilitators

	3. Interpersonal and individual levels

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Partially relevant

Frankis, 2016

Bibliographic Reference	Frankis, Jamie; Young, Ingrid; Flowers, Paul; McDaid, Lisa; Who Will Use Pre-Exposure Prophylaxis (PrEP) and Why?: Understanding PrEP Awareness and Acceptability amongst Men Who Have Sex with Men in the UK--A Mixed Methods Study.; PloS one; 2016; vol. 11 (no. 4); e0151385

Study Characteristics

Study type	Semi structured interviews
Aim of study	to explore PrEP awareness and acceptability amongst MSM in a low prevalence region (Scotland, UK)
Theoretical approach	None stated
Study location	Scotland
Study setting	communities affected by HIV
Study dates	between March and September 2013
Sources of funding	This work was supported by Glasgow Caledonian University (GCU) funds to JF and PF. the qualitative research component, was funded by the UK Medical Research Council (MRC) (MC_U130031238/MC_UU_12017/2), as part of core-funding for the Sexual Health Programme (now the Social Relationships and Health Improvement programme) at the MRC/CSO Social and Public Health Sciences Unit, University of Glasgow. IY is funded by a Chief Scientist Office (CSO) fellowship (PDF/14/02). LM is funded by the MRC (MC_UU_12017/11) and CSO (SPHSU11). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Data collection	We conducted in-depth interviews (IDIs) with communities affected by HIV in the UK (MSM and migrant African men and women) as part of a wider qualitative study exploring the acceptability of PrEP and Treatment as Prevention (TasP) in Scotland. For the purposes of this analysis, we draw on a interview data with HIV negative and/or untested MSM participants. . Exploration of the acceptability of PrEP included discussions concerning awareness, potential use, concerns and combination with existing risk management strategies. IDIs were digitally recorded, transcribed verbatim and transcripts were anonymised to ensure participant confidentiality.
Method and process of analysis	qualitative data were analysed thematically drawing on both anticipated and emergent themes. Once a full set of themes were established, anonymised transcripts were added to and coded in Nvivo 10, a qualitative data software management package. Themes were justified and consistently applied using analytical memorandum. Transparency of coding was established through use of NVivo 10. Rigour throughout the analysis was achieved through an iterative process of discussion and revision between co-authors [
Population and sample collection	The sample for this combined analysis includes 10 HIV negative/status unknown MSM aged between 19 and 52 years (median 27.5 years), resident across four urban and semi-urban Scottish regions. Participants identified as gay (n = 9) or bisexual (n = 1), white (n = 9) and British (n = 7). We did not collect information on income or education levels as part of the qualitative study.
Inclusion Criteria	Men who have sex with men In a specific location Scotland Male

	HIV negative Untested HIV status
Relevant themes	1. Understanding PrEP awareness amongst MSM in Scotland: Of the few participants who had heard of PrEP, most were likely to be HIV-positive, have friends who were, or who worked in field of sexual health. “Talking to my friend at [a sexual health charity in England]. .He started talking to me a lot about that" 2. Understanding the likelihood of PrEP use: Motivation was often identified in relation to the use or nonuse of condoms. Motivation for PrEP use was also identified in relation to sexual partners and the nature of sexual relationships. Others felt that PrEP was only a short-term solution to HIV prevention. “I perceive myself as a condom user with occasional lapses. I’d have thought that’s the sort of person who would benefit most from PrEP if it works”
Additional information	Study also looked at quantitative survey data and data from people born in Africa, which were not included in the qualitative analysis

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes

Section	Question	Answer
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Highly relevant

Gafos, 2019

Bibliographic Reference	Gafos, Mitzy; Horne, Rob; Nutland, Will; Bell, Gill; Rae, Caroline; Wayal, Sonali; Rayment, Michael; Clarke, Amanda; Schembri, Gabriel; Gilson, Richard; McOwan, Alan; Sullivan, Ann; Fox, Julie; Apea, Vanessa; Dewsnap, Claire; Dolling, David; White, Ellen; Brodnicki, Elizabeth; Wood, Gemma; Dunn, David; McCormack, Sheena; The Context of Sexual Risk Behaviour Among Men Who Have Sex with Men Seeking PrEP, and the Impact of PrEP on Sexual Behaviour.; AIDS and behavior; 2019; vol. 23 (no. 7); 1708-1720

Study Characteristics

Study type	Semi structured interviews
Aim of study	To explore how PrEP use impacted existing sexual risk behaviours and risk reduction strategies using qualitative data from the PROUD study.
Theoretical approach	None stated
Study location	England: 8 in London, 5 outside of London
Study setting	Sexual health clinics
Study dates	February 2014 to January 2016
Sources of funding	The PROUD study was supported by ad hoc funding from the Medical Research Council (MRC) Clinical Trials Unit at University College London and an innovations grant from Public Health England, and most clinics received support through the UK National Institute of Health Research Clinical Research Network. Gilead Sciences provided Truvada, distributed drug to clinics, and awarded a grant for the additional diagnostic tests including drug concentrations in plasma. MG, EW, EB, GW, D Dunn and SMc were supported by the UK Medical Research Council (MC_UU_12023/23).
Data collection	Researchers who were independent of the study clinic team conducted the IDIs. The IDIs lasted on average

	between 45 and 60 mins and participants were not compensated for their time. The IDI guide included a discussion topic on sexual risk behaviour, as well as perceptions, experiences and usage of PrEP
Method and process of analysis	The recordings were transcribed, coded and analysed using framework analysis in NVivo 10 [13]. The first author coded the interviews, each interviewer reviewed the coding of a sub-sample of their interviews, and coding discrepancies were discussed.
Inclusion Criteria	Men who have sex with men Trans people Trans women HIV negative Recent condomless sex Condomless anal sex in last 90 days
Relevant themes	1. Risk Behaviour and Management Strategies Before Using PrEP, 1. Condoms: Most participants reported using condoms inconsistently with rules about when and with whom to use them. “The use of a condom is really inhibiting my sexual pleasure" 2. Strategic Positioning: Most participants reported being versatile in their sexual positioning, depending on the type of partner they were having sex with. “I wouldn’t be passive for anyone, and this was obviously when I was compos mentis, because obviously when I was pissed or on a rare occasion, I would you know just be passive” 3. Sero-Sorting: Most participants discussed HIV status with potential partners before sex or viewed the HIV status of potential partners online if meeting via sexual networking apps. “I tend to only play bareback with undetectable guys who I know are kind of trustworthy and taking their medications" 4. Ejaculation: participants mentioned rules around ejaculation as part of their risk reduction strategies 5. Post Exposure Prophylaxis (PEP): Almost half of the participants interviewed reported using PEP. Some participants acknowledged that there were multiple occasions when they should have probably accessed PEP but did not. “One member of staff said to me at one point ‘Well you say all these things, these wonderful things, but then you end up back and doing it again’ … that’s when you think that you can’t go back”

	6. Limited Risk Reduction: not everyone applied ‘rules’ to their sexual activity and many struggled to apply the rules they had set for their own behaviour. “It depends on how you have met them and how they come across and you just go with your gut on that” 2. Contexts of Risk Taking 1. Sexualised Use of Recreational Drugs: Almost half of the participants interviewed reported engaging in chemsex and described the experience as increasing sexual desire and a fixation on sexual fulfilment, increasing sexual disinhibition, and intensifying the sexual experience. "I would identify that for me, as a particular drug associated with chemsex and high-risk behaviour” 2. Geographic Spaces: Cities like London, Brighton and Manchester, where most of the participants lived, were frequently described as being ‘risky’. "it seems to be a bit of a hot bed of unprotected sex, substance abuse and I know that it is a bit of a HIV hotspot" 3. Sexual Networking App: Applications such as Grindr, Gaydar, Scruff, BBRT and RECON, were described as fuelling both sexual contacts,identification of partners for condomless sex, and access to drugs and sex parties. “If you log onto Grindr... people talking about meth and group sessions and G and all this kind of stuff “ 4. Psychological Factors: About a quarter of participants specifically linked problematic psychological factors to their risk taking. "I went through a number of bereavements and started experiencing depression. This impacted on my sexual behaviour and I started having more unsafe sex." 3. Impact of PrEP on Sexual Behaviour 1. Fluctuating Patterns of Sexual Behaviour: Most participants described fluctuating patterns of sexual risk taking over the course of their lives. The patterns were influenced by age, stage of life, movement to a new job, home or city, changes in relationship status. "I have had all my release that I needed to and I have almost come full circle that I don’t feel that strange obsessional necessity for bareback sex like I was before” 2. Changes in Sexual Behaviour Since Using PrEP: Overall, approximately half of all participants who had used PrEP described ways in which they had changed their sexual behaviour since using PrEP. “I felt like it gave me the green card to do whatever the hell I wanted…I don’t use condoms at all any more." 3. Consistent Sexual Behaviour Before and After PrEP: The other half of the participants firmly believed that using PrEP had not altered their sexual behaviour. “I haven’t changed the way I think because I am taking this pill… having these pills doesn’t give me an excuse to be more crazy than I already am”
Additional information	Study conducted from within an RCT of PrEP

Critical appraisal - CASP qualitative checklist

Warning: There is 1 unanswered question

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	*Warning: This question has not yet been answered.*
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Highly relevant

Girard, 2019

Bibliographic Reference	Girard, Gabriel; Patten, San; LeBlanc, Marc-Andre; Adam, Barry D; Jackson, Edward; Is HIV prevention creating new biosocialities among gay men? Treatment as prevention and pre-exposure prophylaxis in Canada.; Sociology of health & illness; 2019; vol. 41 (no. 3); 484-501

Study Characteristics

Study type	Focus Groups
Aim of study	to analyse biosocialities among gay men, in a context of a long-term epidemic
Theoretical approach	biosocialities/ biopower
Study location	Vancouver, Toronto and Montreal, Canada
Study setting	'community-based research'
Study dates	2013–2014
Sources of funding	Not stated
Data collection	The Resonance Project gathered perspectives of gay men through four focus groups with gay men in each city (Vancouver, Toronto, Montreal), for a total of 12 focus groups. Focus groups were recruited purposively to engage men with potentially different relationships to new prevention technologies: men who had contact with AIDS service organisations (ASOs) and those who did not, men in serodiscordant relationships who were managing everyday HIV prevention, sexually active HIV-positive men, and men at elevated risk of HIV but who had no formal contact with ASOs. The focus group guide was developed collaboratively by the research team to cover the following topics: what biomedical information gay men are hearing and from whom; level of interest in biomedical technologies such as home testing, PrEP and Post-Exposure Prophylaxis (PEP)4 ; types of biomedical logic and reasoning that they are using; barriers to using biomedical approaches to prevention; and how biomedical knowledge of HIV informs their risk calculations. Rather than directly ask the focus group participants about their knowledge levels and how they know what they know in relation to the biomedical concepts, mock online profiles Table 2 Total number of participants in focus groups from common hook-up sites/apps, dating scenarios, and real media headlines were used to stimulate conversations to see how study participants would react, for example, to prospective partners who indicate they bareback, are undetectable, or are taking PrEP. Focus groups in Vancouver and Toronto were conducted in English; in Montreal in French

Method and process of analysis	Once cleaned of identifiers, the transcripts were loaded into NVivo10. Data analysis was conducted by a subgroup of the research team, namely the co-authors of this article. Using a process of interpretive description (Thorne, 2008), the authors repeatedly read the data to confirm, test, explore, and expand on the key concepts and patterns, emerging themes, indicative examples from the data, and connections to relevant theoretical perspectives. We analysed collectively a sample of focus groups (from different cities and focus group types), in order to establish a coding scheme. Two members of the subgroup then coded all the transcripts, allowing all co-authors to proceed to a collective reading and analysis of the entire coded data, leading to article writing. As part of a commitment to critical discourse analysis, we also analysed the use of language and metaphors to uncover interpretations of biomedical knowledge of HIV. The inductive process for thematic analysis, drawing on Boyatzis (1998), included developing a coding scheme for organising segments of similar or related texts; identifying initial themes; applying the codes from the coding scheme to the text with the intent of identifying meaningful units of text; and finally, connecting codes and developing additional themes.
Population and sample collection	The local partners – Health Initiative for Men (HIM) in Vancouver, REZO in Montreal and Gay Men's Sexual Health Alliance (GMSH) in Toronto – recruited participants for the focus groups in ways that were adapted to the local gay scene. Each city developed its own recruitment materials, based on a common template (see poster/card graphics below). Recruitment posters and ads were posted in various physical and virtual spaces, including clinics, bars, bathhouses, coffee shops, websites, social media and hook-up sites. Outreach workers and volunteers they enlisted found participants in community venues, such as social clubs, gay men's health clinics, at community meetings and events, bars, bathhouses and outside subway stations. There were also more targeted efforts for identifying potential participants for specific focus groups. Number of participants = 86 (FG1= 29, FG2=13, FG3=18, FG4=26) Vancouver = 31 (8,6,5,12) Toronto = 33 (11,5,8,9) Montreal = 22 (10, 2,5,5) Of the 86, 50 were HIV negative and 36 positive. 26 were ae 50+, 31 were 35-49, and 29 were under 35. The majority were caucasian.
Inclusion Criteria	Trans people Male Recent sex with a male partner

	cisgender
	
	Complex criteria
	
	• Focus Group 1: gay men connected to HIV organizations
	  o Attended a workshop, training or conference on HIV in the past year
	• Focus Group 2: gay men in serodiscordant relationships
	  o • HIV-negative or HIV-positive
	  o • Currently in relationship of more than 6 months
	  o • Partner's HIV status is different than theirs
	• Focus Group 3: sexually active HIV-positive gay men
	  o • Has ever received a positive HIV test result
	  o • Has had sex with >1 man in past 3 months
	• Focus Group 4: HIVnegative gay men at 'high risk'
	  o • Has never received a positive HIV test result
	  o • Has been tested for HIV more than twice in last year and/or has used recreational drugs in past 3 months
	  o • Has had sex with >1 man in past 3 months

Relevant themes	1. Mapping of social and moral risk
	  1. Risk reduction and responsibility: Some participants expressed skepticism concerning the motives for taking PrEP while others viewed PrEP as both rational and responsible. "I'm sorry but I am on PrEP myself and I am not a case of "I bareback every week." I saw a doctor and had a discussion with her and it was at my request that she prescribed it to me"
	  2. Undetectability: Areas of uncertainty: [UVL data not relevant]
	  3. Undetectability and self-identification: [UVL data not relevant]
	2. Refusal and criticism of medicalisation: other biosocialities
	  1. PrEP, a risk technology? there was a great deal of criticism and reluctance with respect to PrEP. Fears about the potential toxicity of antiretroviral treatments (ART) for uninfected people came up consistently in the concerns voiced. Some fear that PrEP raises a false sense of security, a concern rooted in generations of gay men that experienced the long-term effects of the earlier sets of anti-HIV drug treatments on the body. "The toxicity, in spite of people's longevity with HIV these days, is still there. That to me is not a desirable thing if I don't need it. We don't know what the long-term impact of that is yet, at least I don't."
	  2. Undetectability: Limits and pitfalls

Additional information	Only data from HIV negative men and data on PrEP (not TASP or UVL) was extracted

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	No *(No mention of ethics board approval or any steps taken to ensure the study would comply with the their standards if they had sought approval.)*
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research has some value
Overall risk of bias and relevance	Overall risk of bias	Moderate
Overall risk of bias and relevance	Relevance	Partially relevant *(Mostly irrelevant content, but the relevant parts are worth using.)*

Goparaju, 2017

Bibliographic Reference	Goparaju, Lakshmi; Praschan, Nathan C; Warren-Jeanpiere, Lari; Experton, Laure S; Young, Mary A; Kassaye, Seble; Stigma, Partners, Providers and Costs: Potential Barriers to PrEP Uptake among US Women.; Journal of AIDS & clinical research; 2017; vol. 8 (no. 9)

Study Characteristics

Study type	Focus Groups
Aim of study	to contribute to the understanding of the social and structural barriers facing women, specifically African American and Latina women, living in the Washington D.C metropolitan region with high HIV prevalence, as they endeavor to remain HIV-negative.
Theoretical approach	None stated
Study location	Washington DC, USA
Study setting	Study was conducted within the Women's Interagency HIV Study, a long-term, multi-center prospective study of HIV-positive and high-risk HIV-negative women
Study dates	February-May, 2014
Sources of funding	The WIHS (PI: Seble G Kassaye; U01AI34994) is funded primarily by the National Institute of Allergy and Infectious Diseases (NIAID), with additional co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Cancer Institute (NCI), the National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH).
Data collection	After ascertainment of prior knowledge of PrEP, a script based on CDC guidance documents was read to the participants describing what is PrEP, FDA's approval of PrEP and the different aspects of the comprehensive PrEP package: getting a prescription from a provider, taking the pill every day consistently along with using condoms and visiting a provider for HIV testing, blood work and prescription every three months [26,27]. This was followed by discussion to understand women's opinions and concerns about PrEP. The first author moderated all the focus group discussions. Focus groups were conducted in a private conference room at the study site; each one lasted 1.5-2 hours.
Method and process of analysis	All the focus group discussions were digitally recorded and later transcribed verbatim by two of the co-authors (LE and NP). They coded the data to facilitate inter-coder reliability and the first author reviewed the coding. NVivo 10 qualitative analysis software was used for coding and analysis. Codes were developed based on the domains of potential barriers as discussed by the women; they were further refined and agreed upon following discussions among the investigators. The study team iteratively discussed the data: after each focus group, and during and after transcribing and coding. We listened to the recordings several times and discussed emerging themes and patterns.

Population and sample collection	At the time of this study, there were 91 active HIV-negative women in the DC WIHS; letters were sent to them informing about the study and inviting their participation. An announcement was also placed in the DC WIHS newsletter. Women who volunteered were scheduled in the order in which their calls were received and based on their availability on the days when focus groups were arranged. A total of 20 HIV-negative women participated in the focus group discussions. Their ages ranged from 31 to 61 years and the median age was 50. Of the 20 participants, 16 were African American, 2 were Latina and 2 identified as “other.” The participants' socio demographic data are included in Table 1. The majority (65%) of HIV-negative participants reported having at least one male sex partner in the previous 6 months and only 31% of them used condoms. As participants in the larger WIHS study, the women undergo HIV test during their WIHS semi-annual visit; all tested HIV-negative within 6 months before the focus groups. All participants had close family members or friends that were infected with HIV.
Inclusion Criteria	Female HIV negative
Exclusion criteria	None reported
Relevant themes	1. Male partners' reactions: Perceived reactions of male partners to their female partner's use of PrEP could play an important role in women's decision making. The women thought that their partners would be upset to learn that they were taking PrEP as that would indicate mistrust of partners or infidelity on part of the women. "My husband is machismo and he's like, “Why are you doing this?” Just like — he was like, “For what reason? Are you cheating? Are you doing this?”" 2. Women's reactions to their male partners taking PrEP: Their reactions were just as varied as their perceptions of their partners' reactions to their own hypothetical use; some would get angry wondering why the men need to use it invoking issues of cheating and mistrust, while others would feel relieved that their partners were playing safe. "I'm glad he's taken it but like in the back of mind, like she's sayin' [referring to what another participant said], “What is he doing? For what — what is the purpose? Why is he--what's his reasons of doing it?” Just like he would think the same thing about me." 3. Reactions of Families and Friends: Most women reported that their families and friends would be uncomfortable with them taking PrEP because of its association with HIV. "Like if I was taking it — if I was taking it now, I wouldn't tell — I wouldn't even — my close best friend, I wouldn't even tell because once you have someone negative that you, you know, family members, friends, whatever, certain things you — you tell a little bit, certain things you — and then if you know that they gonna be judgmental…you don't do it." 4. Difficulties in patient-provider communications: Another barrier the HIV-negative women identified focused on difficulties discussing risk behaviours — theirs or their partners' — with health care providers,

	which is an important step in obtaining PrEP. "I was concerned because chlamydia was goin' around on the campus and I didn't wanna get it. And how can I protect myself and, you know, I think I might be exposed or what do I do. And the doctor looked at me like, “[makes noise indicating surprise] Really?” Like almost like, you know, made me feel like, “OK, I'm a horrible person ‘cause I'm talking about all these things.” […] So that made me shut down with wanting to talk to health care providers." 5. Impact of HIV/AIDS stigma on PrEP uptake: Perceived opinions of social networks as well as interactions with providers are influenced by HIV stigma — sometimes internalized and at other times externalized. The women indicated that they have observed HIV/AIDS stigma in their daily lives. "It would be because people would think, of the break, something is wrong with you. Just like being in this program [research study], my sister always thought I was HIV-positive." 6. PrEP guidelines and financial costs: Women indicated that they would be concerned about the PrEP guidelines issued by larger medical organizations such as CDC which may not place them in “high risk” category. "I'm thinking, what you are going to have to go through? …Who is going to be considered high-risk? You just can't go to the doctor and say, um, “Well yeah, I have been having sex” or “I'm — I've been out there using drugs and I'm out there…Can I get it?”"

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No *(Not mentioned)*
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes

Section	Question	Answer
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Relevant

Grace, 2018

Bibliographic Reference	Grace, Daniel; Jollimore, Jody; MacPherson, Paul; Strang, Matthew J P; Tan, Darrell H S; The Pre-Exposure Prophylaxis-Stigma Paradox: Learning from Canada's First Wave of PrEP Users.; AIDS patient care and STDs; 2018; vol. 32 (no. 1); 24-30

Study Characteristics

Study type	Focus Groups In depth interviews
Aim of study	to inductively learn from the lived experiences of PrEP users who were part of the PREPARATORY-5 study in Toronto, Canada, and had been on PrEP for a year or longer
Theoretical approach	Grounded theory.
Study location	Toronto, Canada.
Study setting	Study was conducted within the PREPARATORY-5 demonstration project based in a HIV clinic
Study dates	November 2014 to June 2016
Data collection	We conducted three focus group interviews (with three to five participants) and five individual interviews. Interviews were conducted by the first author and were structured to understand participants' experiences with PrEP over time, covering: (1) initial decisions to start PrEP, (2) experiences of getting PrEP access both before and after the demonstration project, (3) sex lives and sexual decision-making on PrEP, (4) challenges in relation to PrEP use, (5) decisions about continuing to use or not use PrEP; and (6) participants' policy recommendations related to PrEP use and access. Interviews were digitally audiotaped, transcribed

	verbatim, and reviewed for accuracy. Individual interviews lasted between 45 and 70 min, and focus group interviews lasted between 75 and 110 min. The same interview guide was used for both individual and focus group interviews.
Method and process of analysis	QSR NVivo 11 qualitative software was used to manage and organize the anonymized transcripts. We used a Grounded Theoretical approach to code and interpret the qualitative data.20,21 Five interview transcripts (three focus group interviews and two individual interviews) were initially reviewed and open coded by members of the research team with qualitative research experience. For focus group transcripts, this included coding for both individual participant responses and writing analytic memos to account for the dynamic exchanges between participants. Our coding strategy allowed us to inductively learn from men's narrative accounts as we systematically reviewed and open coded interview transcripts to examine the diverse experiences of our study participants. These codes were reviewed, modified, and a project code book was subsequently standardized and applied to all transcripts. Both during and after coding, short memorandums were written to capture emergent findings and inform subsequent phases of data collection and analysis.22 Variability in coding and interpretation was discussed through team meetings to resolve discrepancies.
Population and sample collection	All participants in this qualitative study were recruited from the PREPARATORY-5 demonstration project in Toronto. We interviewed 16 gay, male-identified participants, mostly gay-identified (94%) white (73%)

	men, with median age 33 years, of whom 73% had at least one postsecondary degree. Rather than stigma or
Inclusion Criteria	Men who have sex with men HIV negative Recent condomless sex Specific age range Over 18
Relevant themes	1. Positive impacts of PrEP: Rather than stigma or shame, many participants discussed being ‘‘proud’’ and ‘‘liberated’’ because of their PrEP use. "Sex isn’t meant to be something you’re ashamed of or fearful of. It’s meant to be enjoyable and PrEP has made sex enjoyable for me, which is fantastic" 1. PrEP-related stigma and the PrEP closet: for many people in their social and sexual networks PrEP use was equated with having bareback or condomless anal sex, which has led them not to tell friends and/or family about PrEP use, creating a kind of PrEP closet. "I don’t disclose that I am on PrEP to most family and most friends. That’s maybe because I am married and I have kids, so for his [husband’s] sake" 1. PrEP and HIV-related stigma: participants discussed how their PrEP use caused them to reflect on and change or challenge internalized stigma or taboos they had in relation to persons living with HIV. ".it kind of made me feel good I don’t have to ask guys what their status is and so poz guys don’t have to worry about

	disclosure or rejection and you know all that stigma stuff" 1. PrEP and structural stigma: participants described how PrEP sometimes exposed broader structural forms of stigma related to sex and gay sexuality. "participants described how PrEP sometimes exposed broader structural forms of stigma related to sex and gay sexuality"

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No *(Not mentioned)*
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Highly relevant

Harrington, 2020

Bibliographic Reference	Harrington, S.; Grundy-Bowers, M.; McKeown, E.; Get up, brush teeth, take prep: A qualitative study of the experiences of London-based MSM using prep; HIV Nursing; 2020; vol. 20 (no. 3); 62-67

Study Characteristics

Study type	Semi structured interviews
Aim of study	to understand how PrEP is placed within the narratives of MSM who use it.
Theoretical approach	None stated
Study location	London, UK
Study setting	community group
Study dates	Not provided
Sources of funding	The authors received no financial support for the research, authorship and publication of this article.
Data collection	Semi-structured telephone interviews were conducted with participants. A topic guide was developed from emergent themes found within previous qualitative research and after the first few interviews the topic guide was refined to allow for other topics that had been discussed to be included for all interviews. It covered areas such as becoming aware of PrEP, perceptions of risk and reflections on how PrEP has impacted sexual behaviour; and general questions about the PrEP user's own experiences.
Method and process of analysis	Interviews were recorded digitally and transcribed verbatim. Thematic analysis was used following the approach described by Braun and Clarke [18]. Initial codes were generated inductively to allow for an understanding of the nuances within PrEP user experiences and then higher-level codes relating to participants motivations for using PrEP were identified to create grouped themes from the emergent initial codes. All emergent themes were discussed and agreed by the research team. Analysis and data management were aided by QSR NVivo 11
Population and sample collection	A total of 13 men took part in interviews for the study. Most participants had accessed PrEP either through online pharmacies or through the ongoing Public Health England IMPACT trial. All participants reported consistent use of PrEP on the daily dosing regimen and had been using PrEP for at least 6 months. Participants' age ranged 26–56 years with a mean age of 37 years. Of these, nine identified as White British, two were Black British, one was British Indian and one did not identify his ethnicity.
Inclusion Criteria	Men who have sex with men In a specific location

	Greater London PrEP users in last 6 months English language Over 18
Exclusion criteria	None reported
Relevant themes	1. (1) PrEP and condom use; 2. (2) lessened anxiety around HIV; 3. (3) increased intimacy and pleasure; 4. (4) sense of sexual liberation; 5. (5) ease of using PrEP; 6. (6) activism as an early adopter

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable

Section	Question	Answer
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Highly relevant

Hess, 2019

Bibliographic Reference	Hess, K.M.; Crawford, J.; Eanes, A.; Felner, J.K.; Mittal, M.L.; Smith, L.R.; Hoenigl, M.; Amico, K.R.; Reasons Why Young Men Who Have Sex with Men Report Not Using HIV Pre-Exposure Prophylaxis: Perceptions of Burden, Need, and Safety; AIDS Patient Care and STDs; 2019; vol. 33 (no. 10); 449-454

Study Characteristics

Study type	Semi structured interviews In depth interviews
Aim of study	to identify main themes in discussion content surrounding PrEP-related decision-making
Theoretical approach	None stated
Study location	San Diego, USA.
Study setting	Within the ‘‘Good to Go’’ Program for HIV testing
Study dates	Not provided
Sources of funding	Primary funding source National Institutes of Health (NIH) (M.H.). Research was also supported by the National Institutes of Health Secondary funding for authors working on this project include: NIDA 3R01DA040648-02S1 and T32DA023356 (Smith)
Data collection	During the program, participants were also surveyed for risk behaviours during the previous 3 months. In addition to the SDET HIV risk assessment surveys, in-depth, in-person individual qualitative interviews were conducted based upon a semistructured interview guide with trained interviewers in private locations. Although PrEP was

	not a specific topic queried by interviewers per the interview guide, PrEP beliefs, attitudes, and reasons for not using PrEP could be brought up by participants in various parts of the interview as participants reflected on their experiences with HIV prevention. Content from each of the 15 interviews conducted were evaluate for PrEP-related content.
Method and process of analysis	Discourse that offered any PrEP content were extracted and sorted iteratively into main themes using a thematic approach 16,17 with adaptation to allow for linking codes and applying both inductive and deductive thematic analysis.18 Each transcript was coded by one primary coder with full team discussions used to iteratively refine code book and reach consensus on main codes. Main coding was double coded for a selection of transcripts to further develop coding structure and consistent application of main content codes. The coders who interpreted the main themes were blinded to the individual risk category of participants until all coding was complete. After completion of all coding, coders were unblinded to participant risk groupings and subsequently re-evaluated the data for potential differences in narratives between those at high and increasing risk per self-report of risk behaviour on the SDET measure, in comparison with those with low or decreasing risk. Relative density of codes was characterized by the total number of excerpts with a given code, number, and percent of participants who had any PrEP-related discourse of a given code.

Population and sample collection	YMSM who repeatedly engaged in the ‘‘Good to Go’’ Program for HIV testing who were not on PrEP for at least the 12 previous months were interviewed. A total of 15 participants accessing free HIV testing through the program were identified and enrolled from the San Diego Primary Infection Research Consortium (PIRC). Purposive sampling was used to identify YMSM participants (i.e., age 18–24 years). Fourteen of the 15 participants who were interviewed in the main study discussed PrEP organically at various parts in the full interview. All 14 participants who discussed PrEP were between the ages of 19 and 24 years, identified as men, and reported sex with men. Of the 14 participants, 64.3% (n = 9) identified as Hispanic, 14.3% (n = 2) identified as non-Hispanic Asian, 14.3% (n = 2) identified as non-Hispanic white, and 7.1% (n = 1) identified as non-Hispanic American Indian. In addition, of the nine individuals who identified as Hispanic, three participants identified as Hispanic other race, two identified as white, and one identified as Hispanic black.
Inclusion Criteria	Specific age range 18-24 English language Recent HIV test Non PrEP users Languages other than English Spanish
Exclusion criteria	None reported

Relevant themes	1. Burden: receiving or taking PrEP is a hassle or burden, and impacts the participant's perception and/or PrEP uptake decision. "So my insurance is still billed to my parents, and there's that, I don't know, barrier or something. It's something I'd rather not them ask me about, like ''Oh, what is this?''" 2. Low perceived need: Participants stated that they were not engaging in behaviours that they perceived put them at a high enough risk for contracting HIV to begin taking PrEP. "I haven't engaged in, you know, in unprotected sex. So technically there's no rush to get it." 3. Extreme beliefs or lack of information: Beliefs held as facts regarding damage to kidneys, bones, or other negative physical impact of PrEP and lack of PrEP uptake because of being uninformed about PrEP. "Maybe two months ago I went to go get the testing so I can be put on PrEP, but the side effects scared the crap out of me." 4. Social influence: Participants described both interpersonal and societal factors contributing to the decision not to begin taking PrEP, including the influence of conversations with others or going on in one's community. ".I've heard both sides. like, ''Don't take it because it has side effects,'' and then I've heard, ''Take it now or you'll take it later.''" 5. Current strategy preference: Discourse in which participants described believing their current protective approach to safe sex was better than starting PrEP. "But in my instance, I think it's just better to have safe sex or be in a monogamous relationship than to put that much damage on my body." 6. Discourse in reference to discussions with medical providers (potential PrEP prescribers) or service providers about PrEP: Noting decisions about PrEP not being appropriate. "Before I went to my doctor to actually get the PrEP/PEP thing, I went to, I think, another doctor at [clinic name], because my doctor was closed. So, I went to that doctor, and he said, ''Oh, you have nothing to worry about.''" 7. PrEP stigma: Comments made suggesting that people who are on PrEP engage in riskier sexual behaviors. "I think it'd be more likely to have sex without a condom if you use PrEP because you think you have that—not invincibility, but that extra shield, you know." 8. Other: Any reference to reasons not to begin using PrEP not previously captured in the themes above. "But I wish they talked about what the consequences of it. Like, if you were going to take it, what would be them? Because I only see when they talk about the benefits,"

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	No *(Implied, but not clear or explicit)*

Section	Question	Answer
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	No *("PrEP was not a specific topic queried by interviewers per the interview guide,")*
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No
Ethical Issues	Have ethical issues been taken into consideration?	No *(No statement of ethical approval)*
Data analysis	Was the data analysis sufficiently rigorous?	No *(The quotes provided are often unrelated to the theme or do not exemplify the point being made from them.)*
Findings	Is there a clear statement of findings?	No *(Several of the findings are biased and misrepresent what participants have said. For example, a quote from a participant expressing legitimate concerns about side effects is described as 'Extreme beliefs'. Furthermore, none of the findings address the negative aspects of PrEP (side effects, safety, efficacy etc.) as being barriers despite several participant quotes alluding to those concerns. This makes it a very conspicuous absence and so is indicative of a bias to not acknowledge this aspect.)*
Research value	How valuable is the research?	The research is not valuable *(The problems with the way the findings are interpreted are severe enough to cancel out any value the research may have. I'm amazed this got through peer review.)*

Section	Question	Answer
Overall risk of bias and relevance	Overall risk of bias	High
Overall risk of bias and relevance	Relevance	Relevant

Hillis, 2021

Bibliographic Reference	Hillis, Alyson; Germain, Jennifer; Hibbert, Matthew Peter; Hope, Vivian; Van Hout, Marie Claire; "Belt and braces approach; added benefit and ... extra reassurance": a multi-stakeholder examination of the challenges to effective provision of pre-exposure prophylaxis (PrEP) for HIV prevention among men who have sex with men (MSM) in Northern and Central England.; AIDS care; 2021; vol. 33 (no. 6); 736-745

Study Characteristics

Study type	Semi structured interviews
Aim of study	to explore men who have sex with men (MSM) and service provider (SP) perspectives on provision and accessibility of PrEP in Northern and Central England.
Theoretical approach	Interpretative Phenomenological Analysis
Study location	Liverpool, Manchester, Sheffield, Leeds and Birmingham, UK
Study setting	within the IMPACT trial
Study dates	between December 2018 and October 2019
Sources of funding	Sexually Transmitted Infection Research Foundation
Data collection	AH (female, research assistant), JG (female, researcher), MH (male, research assistant) and MCVH (female, lead investigator) conducted the one-to-one interviews over the phone, via Skype or in person. Interviews lasted up to 90 minutes. Referral information was provided where required, and both participants and data were anonymised. An interview guide was generated based on a scoping review of extant PrEP international literature (Hillis et al., 2020). The semi-structured interview guide was piloted within the research team and adapted throughout data collection when necessary. Open questions, with prompts, were used to explore experiences. Topics included participants' experiences of PrEP (eligibility, compliance, access, sourcing and knowledge sources); sexually transmitted infections (STIs), HIV and hepatitis testing patterns; sexual risk behaviours; barriers to access; and complexities around PrEP service provision.
Method and process of analysis	Data management and analysis were conducted in QSRNVivo v12. In using IPA, the analysis was iterative and inductive, generating codes from the data to understand the participant claims in relation to the researcher's interpretation of those claims. Preliminary coding was conducted by AH (for MSM transcriptions) and JG (for SP transcriptions). Triangulation of the codes was conducted through discussions with the research team. AH and JG catalogued the agreed codes into subordinate themes and grouped into broader superordinate themes, with constant comparison and iteration, and presented with quotes from the narratives. Findings from the triangulation process (Eet al., 2006; Foster, 1997), were presented in an individual graph

	identifying the code frequency by each group under superordinate themes (see Figures 1–3)
Population and sample collection	MSM participants were recruited from community health and support services, approached by service level staff who acted as gatekeepers. Posters at service sites and relevant social media pages were also used. At the end of interviews, interviewees were asked to refer potential participants to the study team. This was capped at two participants per MSM to avoid over representation from one particular social network. Using purposive sampling measures, the MSM sample included those intending to use, or currently on PrEP (either through the IMPACT trial or from self-sourcing). SPs included LGBT and HIV community outreach workers, nurses, clinicians and other health professionals. Recruitment and data collection ended with data saturation, when no new information was obtained from participants
Inclusion Criteria	Men who have sex with men In a specific location Liverpool, Manchester, Sheffield, Leeds and Birmingham, Male Specific age range 24-59
Exclusion criteria	None reported
Relevant themes	1. Experiences of self-sourcing PrEP 1. Reasons for self-sourcing: Cannot access PrEP through IMPACT trial and knowledge of PrEP . 2. Concerns regarding self-sourcing: o Cost of purchasing PrEP, drug efficacy and fear of taking unknown substance 2. Current patient pathway for those accessing PrEP on the IMPACT trial 1. Accessing the trial: Knowledge, referrals, availability of places, eligibility . 2. The consultation and additional elements: Regimen, setting, staff, resource capacity 3. Monitoring, testing and adherence 3. Impact of using PrEP 1. Instils confidence. 2. Reduced fear of contracting HIV 3. Betters sex life 4. Increase in STI diagnoses 5. Changes in sexual behaviour
Additional information	Data from service providers was not extracted.

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	No *(Provision of PrEP from a trial does not inform on provision generally.)*
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Moderate
Overall risk of bias and relevance	Relevance	Highly relevant

Jaspal, 2016

Bibliographic Reference	Jaspal, R.; Daramilas, C.; Perceptions of pre-exposure prophylaxis (PrEP) among HIV-negative and HIV-positive men who have sex with men (MSM); Cogent Medicine; 2016; vol. 3 (no. 1); 1256850

Study Characteristics

Study type	Semi structured interviews
Aim of study	to provide some preliminary insights into perceptions and understandings of PrEP in this population
Theoretical approach	social representations theory
Study location	East Midlands and in West London, UK
Study setting	MSM community
Study dates	Not provided
Sources of funding	The authors received no direct funding for this research.
Data collection	These data are drawn from an interview study focusing on aspects of identity and sexual health among HIV-negative and HIV-positive MSM. In this study, interviewees were asked their views regarding PrEP. Interviews were guided by a semi-structured interview schedule consisting of a series of exploratory, open-ended questions. The schedule began with questions regarding self-description and identity, followed by some questions/probes that elicited information concerning sexual behaviour and sexual risk-taking, attitudes towards PrEP and users of PrEP, and interpersonal relations with other MSM. Interviews lasted between 60 and 90 min, and were digitally recorded and transcribed verbatim.

Method and process of analysis	The data were analysed using qualitative thematic analysis. The authors transcribed the recordings and studied the transcripts. During each reading of the transcripts preliminary interpretations were noted in the left margin. These included inter alia participants' meaning-making, particular forms of language, and apparent contradictions and patterns. Initial codes aimed to capture, from the analyst's perspective, participants' attempts to make sense of the object of analysis. Then the right margin was used to collate these initial codes into potential themes, which captured the essential qualities of the accounts. The list of themes was reviewed rigorously against the data to ensure their compatibility and numerous interview extracts were listed against each corresponding theme. Finally, three superordinate themes which reflected the analysis were developed and ordered into a coherent narrative structure. In addition to the dominant themes in the interviews, the analysis identified key linguistic elements that performed the functions of anchoring and objectification
Population and sample collection	Using a snowball sampling strategy, 20 MSM were recruited. Ten individuals were White British, four were Black British, three were of South Asian heritage, and three were Latin American. Nine participants had been diagnosed with HIV, and 11 had tested HIV-negative at their last test. Participants were aged between 18 and 48 years (M = 31.6). Eight participants had university- level qualifications, eight had completed college education, and four reported having no formal qualifications. Although all of the HIV-positive interviewees had heard of PrEP before participating in this study, only six of the HIV-negative interviewees had knowledge of it which they believed to be cursory.

Inclusion Criteria	Men who have sex with men
Exclusion criteria	None reported
Relevant themes	1. Uncertainty and fear: surrounding potential (long-term) side effects, the impact of PrEP on one's own sexual behaviour. "I don't trust the scientists. One minute it's OK to just take it and then the next "oh sorry, we misjudged that"" 2. Managing relationships with others: Interviewees were acutely aware of the social stigma surrounding PrEP and feared judgement from others. "There is a bit of shame, you know, when you don't use condoms and like what you supposed to do? Tell a guy "I often wonder how people would judge me for taking PrEP. In my culture (South Asian) let's say we have a conservative culture… My parents don't even know I'm gay." 3. Stigma and categorization: Interviewees noted that PrEP was intended for individuals at high risk of HIV infection, but there was a clear social stigma appended to the category "high risk". They sought to distance themselves from this category. "I read an article that said "Truvada Whore"… It must be because this pill lets you have sex without condoms with loads of guys. I don't really want to be that guy, to be fair"
Additional information	Sample also included HIV positive men. Data from this participants is not included in the review.

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes

Section	Question	Answer
Ethical Issues	Have ethical issues been taken into consideration?	Can't tell *(No statement of ethics committee approval for the study)*
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Highly relevant

Klassen, 2017

Bibliographic Reference	Klassen, Benjamin J; Lachowsky, Nathan J; Lin, Sally Yue; Edward, Joshua B; Chown, Sarah A; Hogg, Robert S; Moore, David M; Roth, Eric A; Gay Men's Understanding and Education of New HIV Prevention Technologies in Vancouver, Canada.; Qualitative health research; 2017; vol. 27 (no. 12); 1775-1791

Study Characteristics

Study type	Semi structured interviews
Aim of study	1. to examine the multiple ways in which gay men in Vancouver were learning about NPTs and further asked participants to articulate what these experiences of accessing NPT knowledge had been like, allowing participants to compare multiple forms of education and articulate the relative strengths and weaknesses of various prevention sources 2. to analyze how the acceptability of NPT education could be optimized within this setting.
Theoretical approach	None stated
Study location	Vancouver, Canada
Study setting	The study was conducted within the Momentum Health Study, a longitudinal bio-behavioral prospective cohort study of 698 HIV-positive and HIV-negative gay men.
Study dates	Not provided
Sources of funding	This study was funded by the National Institute on Drug Abuse (R01DA031055-01A1) and the Canadian Institutes for Health Research (MOP-107544). NJL was supported by a CANFAR/CTN Postdoctoral Fellowship Award. DMM is supported by a Scholar Award from the Michael Smith Foundation for Health Research (#5209).
Data collection	the interview guide contained a series of open-ended questions regarding participants' perceptions of and experiences with various HIV prevention strategies, with a particular emphasis placed on nPEP, PrEP, viral load sorting, and condoms. The semi-structured nature of these interviews encouraged a conversational style with open-ended answers and a series of follow-up questions or prompts (Galletta & Cross, 2013). Our questions were generally aimed at discussing how participants negotiated risk and prevention within their sexual interactions. Specifically, we asked participants about their experiences of accessing and using NPTs as well as their perceptions of the strengths, weaknesses, and overall effectiveness of these prevention strategies in comparison with other forms of prevention. Additionally, participants were asked to articulate the sources through which they had learned about HIV prevention as a whole. We then asked participants about their awareness of each NPT specifically, and where this awareness came from, as well as their perceptions of the acceptability of NPTs on both a personal and community level.

Method and process of analysis	Interviews were audio recorded, transcribed verbatim, anonymized, and then subjected to an in-depth thematic analysis and coded upon completion of all interviews, thus allowing for a flexible yet comprehensive interaction with our data (Braun & Clarke, 2006). We utilized thematic analysis due to the flexibility and richness offered by this approach and closely followed the decision-making outlined by Braun and Clarke. We further sought to ensure the trustworthiness of our analysis by following Lincoln and Guba's (1985) evaluative framework for qualitative work, establishing credibility, transferability, dependability, and confirmability. Four readers engaged in the inductive, semantic, and essentialist/realist generation of a master code list based on multiple readings of the interview transcripts, with frequent discussion and comparison to ensure consistency and consensus in code application. This ensured an iterative, inductive, data-driven engagement with our interviews and supports the validity of our findings. We attempted to code for all themes present in the interviews rather than requiring a threshold number of mentions within or across interviews to be considered a code. All interviews were coded by at least two readers using track changes in Microsoft Word, and discrepancies were rectified in weekly meetings to further ensure reliability. Codes were revised and expanded as needed – and interviews thus recoded as this scheme developed – through an iterative engagement with the data before being grouped and sorted into themes and sub-themes in Microsoft Excel. Ultimately, fifty codes were generated and defined, with several of the codes pertaining to specific sources of education, which form the basis of the present analysis.
Population and sample collection	Participants were drawn from the larger Momentum Health Study, a longitudinal bio-behavioural prospective cohort study of 698 HIV-positive and HIV-negative gay men in Metro Vancouver, Canada. We purposively recruited HIV-negative study participants who reported prior NPT experience (use of PEP, PrEP, and/or viral load sorting – the selection of HIV-positive partners by HIV-negative individuals based on perceptions of low or undetectable viral load – as a proxy of TasP). Based on responses to the behavioural questionnaire in the larger cohort study, there were a total of 84 eligible participants who were not lost-to-follow-up. Of these 84, four had reported PrEP use, twelve had reported nPEP use, and the remaining only viral load sorting. For
Inclusion Criteria	Male HIV negative Specific age range Over 16 English language
Exclusion criteria	None reported
Relevant themes	1. Levels of Knowledge and the Importance of Education: participants' depth of knowledge surrounding NPTs varied immensely due to differing access to NPT knowledge that is shaped by structural systems. "I'm kind of wondering… could you like go off of it for like nine months and then go on it again, on and off sort of thing?" 2. The Internet as a Source of NPT Education: many participants emphasized the Internet and print-based media as major sources of

	NPT information. Ease of access was frequently cited as a major benefit to these education sources. "…it's all part of the secret handshake thing, right? Like, you have to sort of know somebody who knows about this Facebook group and, and join it… there's not sort of good organized sources of information on this." 3. Health Care Providers as Sources of NPT Education: Many participants stressed the expertise and trusted knowledge offered by doctors and nurses, and the ability to ask questions and interface with these experts within the health care setting, as major benefits. "…if I know of questions to ask, they're good at answering them, but they're not good at providing that information when I may not even know that I need it." 4. Community-Based Organizations as Sources of NPT Education: While participants were fairly critical of HCP education as a whole, education through queer-sensitive clinics and sexual health nurses was more positively perceived. "…growing up with computers and stuff like that, it was all kind of accessible but the resources weren't as clear. I mean, it's a lot easier to understand when you're talking to somebody about it. It's a lot different than Googling what these things mean. Then, you never know if you're getting factual information or not. So, I learnt the most through local queer sources." 5. Sexual Partners and Peers as Sources of NPT Education: Sexual partners provided another frequently cited source of NPT information for several participants, occasionally playing a crucial role in prevention education. "I talked to friends who had been in similar situations. I talked to some of my poz friends. So there were a few resources that I used in terms of learning about HIV." 6. Participants and "Peers as Educators": In addition to being on the receiving end of NPT education, many participants also identified themselves as informal educators of their peers, thus playing an active role in the educative process. "I've had guys who [said] … I don't know where is the clinic and I don't know about some of these risks and I say 'hey do you want me to go with you to the [clinic]? So you can get tested and ask?' and I have. I'm more than happy to, right? Because I know how much it put me at ease…"

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes

Section	Question	Answer
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Highly relevant

Klein, 2019

Bibliographic Reference	Klein, Augustus; Golub, Sarit A; Increasing Access to Pre-Exposure Prophylaxis Among Transgender Women and Transfeminine Nonbinary Individuals.; AIDS patient care and STDs; 2019; vol. 33 (no. 6); 262-269

Study Characteristics

Study type	Semi structured interviews In depth interviews
Aim of study	to assist PrEP implementation efforts by identifying strategies for best practice to increase PrEP access and uptake among transgender women and nonbinary transfeminine individuals (TGWNBI),
Theoretical approach	None stated
Study location	New York, USA
Study setting	Trans community
Study dates	Between April 2016 and May 2017,
Sources of funding	Not stated
Data collection	two transgenderidentified research team members conducted 30 in-depth, semi-structured interviews, each lasting between 1–1.5 h. Interviews were digitally recorded and contained a core set of questions regarding factors at the structural, interpersonal, and individual level that might influence PrEP access, adoption, adherence, and willingness to use future biomedical PrEP interventions. Participants on PrEP were asked to discuss any contributing factors that led to their PrEP use and any benefits and

	challenges experienced since initiating PrEP, including issues around access and adherence. Participants not on PrEP were asked to discuss their knowledge of and attitudes toward PrEP and any factors that contributed to their decision making around whether to take PrEP. Participants in both groups were asked to discuss factors that would be most important to facilitate broad interest and participation in PrEP.
Method and process of analysis	After interviews were transcribed and verified for accuracy, thematic coding was used, following procedures outlined by Miles and Huberman and Patton.47,48 For thematic analyses, data were indexed and coded using open and axial coding.48 Open coding procedures were used to identify emerging themes and factors associated with each research question. Following the development of the codebook, data were coded in Dedoose qualitative software. Reliability was maintained through the use of two coders. Each interview transcript was double-coded and reviewed by the authors to ensure consistency and code application. Inconsistent application of codes was discussed between the authors and coders and revised until coders maintained 90% agreement. Once the coding scheme captured the themes arising from the transcripts, the synthetic and analytic features of Dedoose were used to facilitate theory building by permitting the examination of overlap between codes to conceptualize and assess hypotheses about the co-occurrence of themes.

Population and sample collection	A total of 30 participants from the following two groups (1) TGWNBI on PrEP (n = 15) and (2) TGWNBI not on PrEP (n = 15) were recruited to participate in this study. Recruitment materials were posted at: (1) community based health centres, which provide medical and social services to transgender and nonbinary women in New York. City, (2) online via Facebook, Twitter, and transgender inclusive and specific listservs, and (3) word of mouth. A majority of participants were younger than the age of 30 (60%, n = 18), identified as a person of colour (73%, n = 22), claimed a binary gender identity (i.e., identified as female, woman, or transgender woman) (93%, n = 28), identified as heterosexual/straight (57%, n = 17), reported an income of less than $12,000 (87%, n = 26), were currently not in the workforce (90%, n = 27), and were publicly insured (87%, n = 26). PrEP users were more likely to be younger than the age of 30 (73%, n = 11) compared to non-PrEP users (47%, n = 7).
Inclusion Criteria	Trans people In a specific location New York tri-state area Recent condomless sex PrEP users Specific age range Over 18 Assigned male at birth Eligible for PrEP

Relevant themes	1. Conflation of transgender women with/as cisgender MSM: Participants expressed frustration with being categorized as cisgender MSM within HIV/STI prevention services. The practice of lumping transfeminine individuals with cisgender MSM was credited with negatively affecting patient/provider relationships, as well as health care access and utilization among this community. "I feel like those questions impose transphobic ideas in them and a lot people are not going to want to answer these kinds of questions because, if you answer it, you may be validating this transphobic thing, but if you don't answer it, you might not get the care that you need" 2. Contextual factors, HIV risk, and PrEP: Embedded in participant's narratives was the belief that systemic factors such as racism, transphobia, and sexism were driving HIV risk among transgender women, not solely individual sexual behaviour. HIV risk was seen as a negative health outcome forced upon transgender women, rather than resulting from behavioural choice or agency. "Not every time I have had sex have I been a willing participant. I've been sexually assaulted a few times. I mean, definitely when it happened, one of the first things I worried about was HIV. Now, at least I'm taking PrEP, if, god forbid, it [being sexually assaulted] were to happen again, at least it's one less thing for me to really worry about." 3. Transgender-inclusive and gender-affirming sexual health messaging and programs: Participants said that low PrEP uptake among the transfeminine community was due, in part, to a lack of transgender-inclusive and gender-affirming sexual health messaging and programming. 4. Diverse images: participants identified the need for PrEP messaging campaigns to include images representing the diverse gender identities and presentations within the TGWNBI community. "A lot of the trans people that they've been using in a lot of these campaigns and stuff have been. Quote, unquote, for lack of a better term, more passable. And that's not always the reality with our community, and that's not always what our community looks like." 5. Survival sex work and sexual violence: participants indicated that health education literature and health care provider interactions must openly address survival sex work and sexual violence. non-PrEP users who engaged in survival sex unequivocally said that they did not know if PrEP was right for them due to the language in PrEP health education pamphlets, which do not address engagement in survival/transactional sex. "if you're putting yourself at risk every day, is it a benefit to take it, will it help you? The pamphlets I see are really specific to lovers or partners, but what if that's not who you're having sex with?'" 6. Sexual health assessments: Participants discussed how current sexual risk questions, such as, ''do you have sex with men, women, or both?'' do not accurately reflect their sexual activity, the context in which they are having sex, the people they are having sex with, and whether these experiences are consensual. "Like no doctor has ever really asked me if my dick still worked or if I could top with it, unless I brought something up about it.'" 7. Active provider engagement and assistance: Active provider engagement and assistance around PrEP emerged as two interrelated factors necessary for increasing PrEP access and uptake among the

	transfeminine community. "Encouraging doctors or medical providers to specifically ask about PrEP, and maybe even ask it with some information about what PrEP is... I was just asked if I was interested in PrEP. And so, if I didn't know what it was, I would've just said no, not really knowing what I was being asked" 8. Community mobilization and activism: strategies to enhance community mobilization/activism emerged as important facilitator to increasing awareness and trust around PrEP. Participants talked about a need for role models within the community who were willing to openly discuss their PrEP use. "My friend told me about it. She used to do sex education classes for us [her friends]. She taught me about it. She was like, girl, you know, they've got that new PrEP"

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes *(Interviewers were also trans)*
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Relevant

Knight, 2016

Bibliographic Reference	Knight, Rod; Small, Will; Carson, Anna; Shoveller, Jean; Complex and Conflicting Social Norms: Implications for Implementation of Future HIV Pre-Exposure Prophylaxis (PrEP) Interventions in Vancouver, Canada.; PloS one; 2016; vol. 11 (no. 1); e0146513

Study Characteristics

Study type	Unstructured interviews
Aim of study	to assess how socio-cultural norms may influence the implementation and scalability of future HIV PrEP interventions in Vancouver, Canada.
Theoretical approach	None stated
Study location	Vancouver, Canada.
Study setting	Clinical and non-clinical settings
Study dates	Not provided
Sources of funding	This study was supported by the Canadian Institutes of Health Research (HHP-123778 and EPP- 122906) and the US National Institutes of Health (R01DA033147, R01DA028532, U01DA038886). Knight is supported by a Post-Doctoral Fellowship from CIHR and the Michael Smith Foundation for Health Research. Small is supported by a Career Scholar Award from the Michael Smith Foundation for Health Research.
Data collection	Interviews occurred at our research offices and were conducted by co-authors RK and AC, two highly experienced interviewers. Participants were asked to describe what they know about PrEP and

	were subsequently provided with additional information. Participants were then asked to provide their perspectives regarding PrEP interventions if they were to unfold on a scaled-up level in Vancouver in the future. Each interview lasted approximately one hour and was audio recorded.
Method and process of analysis	Interviews were transcribed with identifiable information removed, checked for accuracy and uploaded to QSR NVivo 10™ for data analysis. We used constant comparative techniques [21] to develop an initial set of codes that featured participants' understandings, perceptions and opinions regarding PrEP. As coding progressed, we organized our codes into 'trees' to group the open codes into more specific categories related to the objectives of this study, at which point we began to relate our data to the previous empirical and theoretical work in this area.
Population and sample collection	Participants were recruited using posters at clinical (e.g., sexual health clinics) and non-clinical settings (e.g., community centres), as well as using online strategies (Facebook Ads; Craigslist). We also recruited from the At-Risk Youth Study (ARYS), a prospective cohort of young people with a history of having used illicit drugs (other than marijuana) and being street-entrenched [20]. Of the 50 study participants, 16 identified as gay, bisexual, Two-Spirit and 24 had a history of using illicit drugs and experiences with being street-entrenched.
Inclusion Criteria	In a specific location Living in Metro, Vancouver Male Specific age range

	18-24 English language
Relevant themes	1. “One-a-day”–easy, convenient, effective: many participants likened PrEP to female birth control (“the pill”), frequently referring to the ease and convenience of being able to take a daily dose and be assured of protection. "Like, if I can go and just say, like, “Don’t wanna get HIV” and like [the doctor could say] ‘Here you go. Here’s your “one-a-day”‘." 2. ‘Bullet-proof’–exacerbating risky practices: both ‘low’ and ‘high’ risk participants articulated the assertion that PrEP could exacerbate risk practices amongst so-called ‘high-risk’ individuals. "If they know that ‘Okay, I’m on treatment. And because ‘I’m on treatment, I’m like, you know, I’m bulletproof. I could be even crazier!’ I don’t think it’s a good idea." 3. ‘High-risk lifestyles’–stigma and individualized practices: Use of PrEP was often portrayed as being problematic because it was viewed as an ‘excuse’ from adherence to other risk-reduction practices and, therefore, it was also often viewed as contributing to ‘high-risk’ lifestyles. "Instead of continuing these risky behaviours and using HIV medication, maybe people should just stop the behaviour, right?"
Additional information	Data from individuals who inject drugs were not extracted

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No *(Not mentioned)*
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes

Section	Question	Answer
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Relevant

Mabire, 2019

Bibliographic Reference	Mabire, Xavier; Puppo, Costanza; Morel, Stephane; Mora, Marion; Rojas Castro, Daniela; Chas, Julie; Cua, Eric; Pintado, Claire; Suzan-Monti, Marie; Spire, Bruno; Molina, Jean-Michel; Preau, Marie; Pleasure and PrEP: Pleasure-Seeking Plays a Role in Prevention Choices and Could Lead to PrEP Initiation.; American journal of men's health; 2019; vol. 13 (no. 1); 1557988319827396

Study Characteristics

Study type	Collective interviews
Aim of study	to examine how pleasure-seeking plays a role in prevention and in sexual QoL, and how it may lead to PrEP initiation.
Theoretical approach	None stated
Study location	France and Canada
Study setting	Study was conducted with ANRS-IPERGAY, a randomized, placebo-controlled biomedical trial.
Study dates	During 2014
Sources of funding	The author(s) received no financial support for the research, authorship, and/or publication of this article.
Data collection	CIs took place in the premises of AIDeS, an NGO that was already well known to some of the participants. The CI guide comprised four main questions: (a) What were your motivations to join and participate in the trial? (b) How have you appropriated the trial and what impact has it had on your sexual life and prevention choices? (c) How has your sexuality evolved during the trial? (d) What have you done to speak about your participation in the trial to your family and relatives?

	Confidentiality was maintained in data collection and the CBCs encouraged participants to do the same, to respect their own privacy. Anonymous personal identifiers were used for each participant. CIs were both audiorecorded and later transcribed verbatim in French. They were analysed in the original French language by French analysts. The participants' quotes presented in this article were translated into English for publication purposes. Each CI had 3–6 participants with 1–3 CBCs and lasted between 90 and 165 min.
Method and process of analysis	A thematic analysis of the integral transcription of the various CIs was performed (Braun & Clarke, 2006) using Atlas-ti, "ATLAS.ti Scientific Software" Development GmbH, version 1.0.51 (403) (Friese, 2014; Hotton et al., 2015). This tool enabled the systematic coding, comparison, and analysis of the different texts comprising the corpus. The analysis proceeded in three steps. The first involved iterative, in-depth readings of the corpus, in order to have an overview of all the themes which emerged. The second step was to place these themes into perspective using classic dimensions of sexual QoL described in the literature (Arrington, Cofrancesco, & Wu, 2004), as well as more specific studies about pleasure and intimacy concerning condom use (Gamarel & Golub, 2014; Giddens, 1992; Golub, Starks, Payton, & Parsons, 2011; Kelly & Kalichman, 1998; Randolph,

	Pinkerton, Bogart, Cecil, & Abramson, 2007; Underhill, 2015). The third step was to construct and apply the analytic grid (using the data from step 2) which consisted of 31 codes grouped into four categories: PrEP (e.g., schedule, anticipating a sexual event, side effects), psychosocial context (e.g. social sharing and stigma, community-based grounding), risk-reduction strategies (e.g. condoms, seroadaptation, vaccination for hepatitis A and B), and sexual QoL (e.g., libido, satisfaction and quality, relationship).
Population and sample collection	(n = 45) Median age was 35 [20–67] years. Educational level, living standards, and employment status were all comparable with those found for the whole ANRS-IPERGAY sample.
Inclusion Criteria	Men who have sex with men Trans people Trans women who have sex with men Male HIV negative Recent condomless sex
Exclusion criteria	None reported
Relevant themes	1. Participants' relationship with condoms: Barriers to condom use were a reduction in sexual pleasure, unpleasant sensations, stress and anxiety of correct use. "It's always a little scary to say to yourself: you have to put a condom on, because you always … well, there's always the fear of loss of performance … not easy to say,

	that." 1. Intimacy and pleasure: intimacy was an important part of sexual QoL in that it served as a condition of fulfilment for some participants "In a long-term relationship, you’re not always going to use a condom, like." 1. Achieving a better sexual QoL: When participants were asked to speak about sexual QoL in the framework of the ANRS-IPERGAY trial, a discourse emerged describing emancipation from recurrent constraints. "more serene, more fulfilled, more thoughtful, more responsible, therefore a better quality of sexual life, after having joined the trial."

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes

Section	Question	Answer
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Highly relevant

Martinez-Lacabe, 2019

Bibliographic Reference	Martinez-Lacabe, A.; The non-positive antiretroviral gay body: the biomedicalisation of gay sex in England; Culture, Health and Sexuality; 2019; vol. 21 (no. 10); 1117-1130

Study Characteristics

Study type	Semi structured interviews "oral history interviews"
Aim of study	exploring how processes of biomedicalisation are being negotiated and confronted by gay men in England
Theoretical approach	biomedicalisation
Study location	Leeds, London and Brighton, UK
Study setting	LGBTQ community
Study dates	Not provided
Sources of funding	None stated
Data collection	Semi-structured oral history interviews allowed the interviewees to talk about events that they considered relevant to their experience of using antiretroviral medication for HIV prevention in the context of other aspects of their lives. The study included a set of questions related to specific aspects of biomedicalisation theory and PrEP. These questions focused on PrEP sourcing, conceptualisations of risk and personal responsibility and access to PrEP-related information.
Method and process of analysis	Interviews were digitally recorded and transcribed. Synopses of the interviews were prepared with particular attention to testimonies that demonstrated or confronted biomedicalisation processes while taking into consideration the human factors that made PrEP, not only a biomedical intervention, but an intervention that was perceived as needed.
Population and sample collection	Recruitment took place initially through the following Facebook groups: PrEPster, PrEP Facts: Rethinking HIV prevention and sex and the LGBT Brighton and Hove Network and then through snowball sampling In-depth interviews with 13 cisgender gay men and two transgender gay men who were interviewed in Leeds (n ¼ 1), London (n ¼ 7) and Brighton (n ¼ 7) provided the primary data for analysis.
Inclusion Criteria	None reported

Exclusion criteria	None reported
Relevant themes	1. Getting pre-exposure prophylaxis: becoming active agents of biomedicalisation: All the actions described by participants in the study – getting PrEP on a grey market without medical prescription, clinic hopping, guinea pigging and enrolling in clinical trials – require a level of agency and will that distances these men from the idea of the passive medicalised gay man, while bringing them closer to the active patient model. "So, every month, I would go to a different clinic and I would say: 'Last night I had unprotected sex with someone, they came inside me, and I don't know what their status was', and they would go: 'Here is your PEP : Truvada and Raltegravir. Take one of these a day, take one of these twice a day'. 'Thank you'. I would go home, keep the Raltegravir, still have it and I would take the Truvada as PrEP" 2. Practices of freedom: condomless sex, fear control and choices: , participants in the study found PrEP practices liberating for various reasons. Several of them acknowledged that having anal sex without a condom was part of that feeling of freedom. "it gives me a sense of control that I can be with whoever I want, sleep with whoever the fuck I want. If a condom breaks, then I don't have to panic, I don't have to take post exposure and I don't have to practically have to die in my bed taking that, and its gives some more sense of freedom." 3. Zero-risk governmentalities: Participants' responses to what they considered risk were strongly shaped by the idea of acceptable risk. Non-acceptable risk was largely identified with HIV, while most participants classified other sexually transmitted diseases of lesser concern than HIV since they were perceived as treatable. "They know that if that person is taking PrEP it's pretty much guaranteed that it's never gonna happen because they're undetectable so their viral load is basically zero, you've got PrEP so, you are at virtually 100% protected against catching HIV "

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	No *(It was not a data driven design and lack detail in the methods.)*
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes

Section	Question	Answer
Data collection	Was the data collected in a way that addressed the research issue?	No *(It seems more like they were attempting to illustrate a pre-defined argument than draw inferences from the data they collected.)*
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	No
Findings	Is there a clear statement of findings?	No *(Dense prose is not very clear)*
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	High
Overall risk of bias and relevance	Relevance	Relevant *(Downgraded because while the data is relevant, the interpretation is more philosophical than analytic)*

Mutchler, 2015

Bibliographic Reference	Mutchler, Matt G; McDavitt, Bryce; Ghani, Mansur A; Nogg, Kelsey; Winder, Terrell J A; Soto, Juliana K; Getting PrEPared for HIV Prevention Navigation: Young Black Gay Men Talk About HIV Prevention in the Biomedical Era.; AIDS patient care and STDs; 2015; vol. 29 (no. 9); 490-502

Study Characteristics

Study type	Dyadic interviews
Aim of study	to explore YBMSM's thoughts about PrEP use in the context of the larger toolbox for HIV prevention that will be increasingly available nationally and globally
Theoretical approach	a modified version of grounded theory
Study location	Los Angeles, USA
Study setting	LGBT community
Study dates	2014
Sources of funding	This research was funded by the National Institute of Mental Health [
Data collection	Twenty-four pairs of friends were interviewed together in Los Angeles, CA, in 2014, with each interview lasting approximately 2 h. The dyadic interview format provided opportunities to compare and contrast the two friends' perspectives, and to facilitate active discussions between friends about how they communicate. We also conducted individual interviews with the target participant lasting about 15 min in order to identify any issues he may not feel comfortable discussing with his friend in the dyad interview and to ask about his sexual communication with other friends.

	The dyad interviews focused on the content of participants' communication about sex and sexual health related to several salient topics, such as relationship issues, dating, and sexual activities; as well as on the topic we are focusing on for this analysis: their knowledge of and thoughts about PrEP, PEP, and other forms of prevention, such as condom use. We probed for how they communicated about topics found to be salient in our own preliminary research with young gay men and their friends, and other research with young men who have sex with men.30,31,36–38 Table 2 lists sample interview topics alongside sample interview items. The style of interviewing followed qualitative methods designed to provide opportunities to explore both anticipated and unanticipated themes,39–41 and to limit the influence of social desirability bias. This process involved building rapport, assuring confidentiality, sequencing interview items to begin with less personal topics, and using neutral, open ended questions followed by probes to elicit participants' descriptions of experiences with sexual communication.
Method and process of analysis	The interviews were transcribed by a professional transcription service, and reviewed by staff for accuracy. All personal identifying information was removed, and pseudonyms chosen by the participants were used in place of their actual names. Pairs of friends were asked to select pseudonyms with matching first letters (e.g., Anthony and Art). Data analyses followed a

	modified version of grounded theory incorporating analytical induction,42 in which emergent themes were reviewed alongside a close reading of salient themes in the HIV/AIDS, sexual communication, and sexual health literatures. This approach allowed us to identify themes based on participants' own views of their sexual communication, HIV prevention strategies, and their friends' influence on their behaviors. Using this method, the research team first reviewed a subsample of transcripts and developed a working codebook that included both emerging themes and themes relevant to existing theoretical frameworks and our own preliminary work. Transcripts were entered into a qualitative data analysis software program (Dedoose) for coding. The research team then conducted the first level of coding (''open coding''), including such basic codes as ''peer influence'' and ''safer sex talk.'' Team members discussed these coded data reports, reviewed remaining transcripts, and identified emergent subthemes. This strategy of investigator triangulation 43,44 facilitates analytical cooperation and exchange. The process entailed the active involvement of multiple team members, with diverse backgrounds. We prioritized team consensus over individual interpretations of the data, reaching unanimous agreement on all major themes. As subthemes were identified, they were coded and then compared with other subthemes for similarities and differences

	for categorization using a constant comparisonmethod.45 In this second level of ‘‘axial coding,’’ some of the original codes were refined or re-organized around these subthemes. For instance, ‘‘confusion about PrEP’’ was re-named as ‘‘lack of information about PrEP’’ since the data suggested that participants were not so much confused as they were lacking enough information to fully understand how PrEP works. Emerging categories were subjected to a process of member validation in which community stakeholders offered feedback to assess credibility.46 Finally, we engaged in ‘‘selective’’ or ‘‘targeted’’ coding to focus on the data relevant to our analysis. The first and second author discussed any discrepancies between coders, reconciling differences by consensus. We established inter-rater reliability for coding of key themes by using rates of agreement, with 80%as a baseline criterion for reliability. Analyses were complete once we reached theoretical saturation
Population and sample collection	A total of 48 individuals participated in the study in the Los Angeles arm, 24 target participants and 24 friends. ‘‘Friend’’ was defined as a person the participant selected based on our criteria that included: had to be friends for at least a year, had to be out to this person, and had to discuss sexual health topics with this person; we did not place any restrictions on gender or race/ethnicity of the friend. It was requested that the participant select his closest friend and that the friend was not a family member, boyfriend, or lover. Participants were recruited through purposive methods, through direct outreach at youth groups at LGBT community

	organizations, as well as targeting commonly used smartphone ‘‘dating’’ apps. Purposive sampling methods are well-suited to exploratory research that seeks to identify particular types of cases, such as friendship dyads, for in-depth investigations.34 We purposively sampled roughly equal numbers of target participants from physical venues versus apps in order to include a diverse range of participants (i.e., not all fromphysical venues or apps). Sampling numbers were predetermined based on the number of interviews typically required to achieve theoretical saturation in qualitative research, The sample consisted of 48 participants. All of the target participants (N = 24) were young gay or bisexual men who have sex with men, and were between the ages of 19 and 24. The friends (N = 24) selected by the target participantswere primarily also young black gay or bisexual men, but there was some variability in terms of demographics: friends were 71% male, 75% black, and about 80% gay or bisexual. All male friends identified as either gay or bisexual. Among all participants, 40%were in school and more than 91% had stable housing. About one-fifth of participants tested positive for HIV while 40% of male participants reported unprotected anal sex in the past 30 days. Most participants (66%) had heard of PrEP or PEP, while 39% knew someone who had used PrEP or PEP.
Inclusion Criteria	Young people

	In a specific location Living in LA Specific age range 19-24 Black Have a friend with whom they discussed sexual health, and whom they were out to
Relevant themes	Information and misinformation about biomedical HIV prevention options 1. Sources of information: Participants learned about PrEP and PEP from various sources, including prevention education programs, youth groups, health care providers, friends, or the Internet. "When we talk about [PrEP] in the group and then [Ciara and I] revisit it, it makes me better understand what's going on, so I can go and share the information with my other friends who". 2. Concerns about PrEP and PEP: Participants expressed a variety of concerns about potential problems with biomedical prevention, particularly uncertainties about efficacy. ''They're just coming out with a pill. I kind of question that. Is it really effective?.I don't even know if it's FDA approved.'' Expectations about PrEP, sexual behaviour, and stigma: 1. Concerns about being stigmatized for using PrEP or PEP: Because biomedical strategies were mainly seen as suited to sexually promiscuous or risk-prone individuals, some participants felt that using these methods would lead to being stigmatized. ''Oh, you're on PrEP, so what have you been doing? Are you always having unprotected sex?'' 2. Concerns that PrEP would be used as ''an excuse to bareback.'': Many participants were concerned that PrEP might be used to intentionally engage in more frequent condomless intercourse. "I think, especially with the kids, like the younger men than my age, they came out with this pill, and now they're just using that as an excuse to not use condoms. I don't think it's the greatest idea." 3. PrEP use as a sign of personal responsibility: a few participants felt that if someone was using PrEP, they would not be stigmatized, but instead respected because they would be caring for their own health and that of others. "I feel like if they're [on PrEP], they're not only protecting themselves. It's also for the well-being of other people that they're having sex with. I don't think there's anything bad." 4. Considering condomless intercourse as an option: although many participants thought that other people were engaged in risk compensation (using PrEP instead of condoms), almost none of them stated that they would personally be inclined to do it. "I'm not gonna sit

there and say, ‘‘Yeah, as long as they’re showing you all that [proof], go ahead and let them have sex with you, raw.""

People will talk: Gossip, disclosure, and ‘‘spreading the word’’ about PrEP and PEP:

1. Assumptions that people using PrEP and PEP are HIV positive: Many participants also expected some of their peers to assume that PrEP or PEP users were HIV-positive, or to engage in stigmatizing gossip about HIV status on this basis. ‘‘When I was taking PEP, a friend of mine started to judge me. They assumed that I had something ’cause I was taking PEP. They think that I had HIV.’’
2. Spreading the word about PrEP and PEP: Some participants were passionate advocates for PrEP and PEP, and saw conversations with peers as an opportunity to promote these new prevention options. "And I think if this is lowering my chance to catch HIV, that’s just awesome. That is how I talk about it—I try to recruit people"
3. A responsibility to tell others about PrEP and PEP: Thus, even some participants who voiced concerns about gossip or HIV stigma related to PrEP and PEP felt a responsibility to talk about it if they saw opportunities to educate their friends about these newer prevention options. "if I had a friend who I felt was somewhat at risk, or doing things that [put him or her] at risk. I would say, ‘‘Hey, I’m doing [PrEP]"

The need for HIV prevention navigation: PrEP and PEP as tools in an expanded ‘‘tool kit’’

1. New tools for prevention: Some characterized biomedical strategies as a new set of tools that was now available, among an array of options that together comprised an overall set of alternative means of reducing the risk of HIV infection. "My feeling is that [PrEP] is just another tool to use for safe sex."
2. PrEP as ‘‘peace of mind.’’: PrEP in particular was often characterized as a ‘‘back-up’’ strategy that could confer protection if for any reason other strategies failed. "If I had PrEP, I would have been a little bit more easy on the mind. I’m not saying I’m gonna sleep around, but it’s a little easier. Even as far as condoms, those aren’t always 100 [percent]."
3. A new option for serodiscordant dating: Some HIV negative participants discussed how PrEP would open up the possibility of dating someone who was HIV positive, or vice versa "I actually would go into a relationship with a person who is HIV positive, just as long as I am on top of my own health care and like if I do make that choice, then I will be on PrEP,"
4. Comparisons to the range of options for birth control: They mentioned how, like birth control, biomedical prevention provides both ‘‘before’’ and ‘‘after’’ options, comparing PrEP to ‘‘the pill’’ and PEP to ‘‘the morning after pill.’’
5. A preference for condoms: some participants said they liked the idea of PrEP but simply felt that it was not necessary as an option for them.

	"I don't feel like I need to use it, because I like the methods that I have to be protected, but it is a great idea.I like condoms, you know." 6. Preferring little or no risk: For some participants, the comparatively high rates of efficacy possible with biomedical prevention methods did not outweigh their concerns about the small possibility that infection might occur despite using PrEP or PEP. "You're putting yourself at risk for being that 1%. You might get that 99%, but you might not. You might be that 1% that does get it after the drug." 7. A range of individual values: One relatively striking aspect of the participants' responses to questions about PrEP was the diversity of individual values that was revealed regarding biomedical prevention strategies, condom use, and other methods. The topic of PrEP, in particular, seemed to touch on a range of other complex issues and personal values related to health, the medical establishment, and sexual preferences.
Additional information	Data pertaining solely to PEP was not extracted

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	No *(The inclusion criteria didn't specify MSM or LGBT. It can be inferred from their recruitment sources that these were the participants they would get but it was not specified. At least one of the friend participants was female, but throughout the analysis quotes from friend participants were given equal weighting to the initially recruited participants.)*
Data collection	Was the data collected in a way that addressed the research issue?	Yes

Section	Question	Answer
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Moderate
Overall risk of bias and relevance	Relevance	Relevant

Newman, 2018

Bibliographic Reference	Newman, Peter A; Guta, Adrian; Lacombe-Duncan, Ashley; Tepjan, Suchon; Clinical exigencies, psychosocial realities: negotiating HIV pre-exposure prophylaxis beyond the cascade among gay, bisexual and other men who have sex with men in Canada.; Journal of the International AIDS Society; 2018; vol. 21 (no. 11); e25211

Study Characteristics

Study type	Semi structured interviews
Aim of study	(1) to explore, in depth, the experiences of GBM in considering, accessing and using (or not using) PrEP; and (2) to understand emerging sexual health, social and community issues among GBM in the PrEP era.
Theoretical approach	None stated
Study location	Toronto, Canada.
Study setting	MSM community
Study dates	October 2015 to March 2016
Sources of funding	None stated
Data collection	Data were collected using a brief, self-administered sociodemographic questionnaire and in-depth semi-structured 45- to 90-minute interviews. Questionnaire items included demographics and insurance status (i.e. coverage for PrEP). Face-toface interviews explored sexual health and relationships, PrEP knowledge, access and decision-making; and additionally, for PrEP users, experiences with initiation, engagement with care, taking PrEP and long-term goals; and for PrEP non-users, anticipated comfort accessing PrEP and sexual practices. Interviews

	were conducted (by AG) at a private office at the University of Toronto or a mutually agreed upon public location.
Method and process of analysis	We used Fisher's exact tests to assess demographic differences between PrEP users and non-users. Interviews were audio-recorded, transcribed verbatim, uploaded into NVIVO (NVIVO: QSR International Pty Ltd, version 10.0, Burlington, MA, USA) and coded using thematic analysis [38,39]. Each transcript was coded independently by two investigators (AG and ALD). After reading and re-reading the transcripts for familiarization, we inductively generated initial codes through a process of open coding in which we tagged segments of text that represented underlying themes. ALD and AG met biweekly during the coding process to compare codes and discuss emerging themes. A third coder (ST) then conducted secondary coding of select transcripts. Finally, ALD, AG and PAN reviewed the themes and determined major themes that emerged from the data. Differences in coding and themes were resolved by consensus. Rigour was established through memoing (i.e. reflective note-taking), negative casefinding and creation of an audit trail (i.e. to document research activities and decisions made in the analytic process) [40,41]. Lastly, we interfaced themes with the PrEP cascade to identify correspondences, dissonances, and psychological/ affective and social phenomena that may impact on PrEP implementation.
Population and sample collection	We used purposive sampling based on participants' self-identifying as

	GBM, and as PrEP users or non-users who had thought about PrEP. Recruitment was conducted by posting flyers in community venues serving GBM and through word-of-mouth. Participants' (n = 29) mean age was 36.7 years (SD = 8.2). Most of them self-identified as gay (n = 25; 86.2%), cisgender male (n = 26; 89.7%) and white (n = 23; 79.3%). The majority had some college education or above (n = 24; 82.8%) and were employed full-time (n = 18; 62.1%). About half had insurance that covered PrEP (n = 15, 51.7%). By design, participants were equally divided between PrEP users (n = 15; 51.7%) and non-users (n = 14; 48.3%). PrEP users were significantly more likely to identify as gay versus bisexual/queer and to have insurance that covers PrEP
Inclusion Criteria	Men who have sex with men PrEP users People interested in starting PrEP
Exclusion criteria	None reported
Relevant themes	1. HIV risk behaviours: Regardless of PrEP use, participants generally described having multiple partners, using condoms inconsistently and employing a range of strategies for managing sexual risk, including condom use with particular (e.g. non-primary) partners, serosorting and seropositioning. ". . .For me, condoms sometimes either broke and made me really upset and worried. Some other times, I have to admit, I didn't like them, and so it was 50-50, it was not consistent, and it really worried me." 2. HIV risk awareness: sexual risk practices and associated HIV and STI risk awareness were construed by some GBM as a rationale for not using PrEP. ". . .Yeah, I could potentially have bareback sex, but PrEP isn't going to protect me from all the other STIs out there, and now I'm learning that some of them are much more easily transmitted than HIV. So, that's a challenging point for me." 3. PrEP information seeking: All PrEP users and some non-users reported seeking out information in scientific (e.g. academic journals) and/or community-based sources (AIDS service organization websites). "If I was considering it, I'd probably do some more serious research on it. . .." 4. PrEP access: Lack of insurance coverage for PrEP emerged as a significant concern. ". . . Well, the cost would have been such that it

	would have been inaccessible to me so I really didn't consider it on any kind of basis" 5. Linkage to PrEP care: Most participants who sought out PrEP did not report barriers in linkage to care nor discriminatory reactions from healthcare providers. "He's a gay doctor. I've talked to him about lots of stuff. I would have no problem asking him. He'd probably just, oh really, okay. What's going on?" 6. Prescribed PrEP: Participants generally described a smooth process of procuring a prescription for PrEP. "The pharmacist that I see is well-versed in PrEP. . .and the [pharmacy] deals specifically in HIV medication every day. ..." 7. Initiating PrEP: PrEP initiation was described with a range of actions, from taking PrEP immediately, to taking a PrEP selfie, to waiting. Participants also articulated a range of emotions: feeling happy, proud, overwhelmed or ambivalent. "[I did the] first pill selfie and 90-day check-in, yeah. . .I felt pretty happy." 8. Adherence to PrEP: PrEP users described various strategies for taking their medication, often borne of trial-and-error; many reported having never missed a dose, some occasional missed doses. "Sometimes the day gets away from you, and I would forget." 9. Retention/discontinuation: Those who ceased taking PrEP described weighing the risks and benefits, including financial costs during periods of low levels of sexual activity. "Yeah I told my partner, I said I really didn't want to take it for more than a year continuously. I really don't want to." 10. PrEP stigma: Participant narratives revealed acute awareness of stigma associated with PrEP use (and users) and GBM's sexuality more broadly. "The internet and the apps are opportunities to be really cruel for many people, and I have seen language used around, 'oh, silly faggot taking loads, get some self-respect', those sorts of things." 11. Impact of PrEP on sexual practices and relationships: Participant narratives invoked the broader impact of PrEP, beyond the cascade, on sexual decision-making, negotiations and relationships. "Right, because I really haven't met anybody yet that takes PrEP and hasn't asked me to do bareback sex. Usually it comes up, do we need to use condoms?"
Additional information	

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes

Section	Question	Answer
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No *(Not mentioned)*
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Relevant *(Not all themes are relevant to a UK population: Access barriers from lack of insurance were relevant to both their results and by implication their participant pool.)*

Nydegger, 2020

Bibliographic Reference	Nydegger, L.A.; Dickson-Gomez, J.; Ko, T.K.; Structural and syndemic barriers to PrEP adoption among Black women at high risk for HIV: a qualitative exploration; Culture, Health and Sexuality; 2020

Study Characteristics

Study type	Semi structured interviews In depth interviews
Aim of study	to qualitatively explore Black women's interest in and adoption of PrEP over time
Theoretical approach	syndemic theory
Study location	Milwaukee, USA
Study setting	Community
Study dates	between July 2016 and April 2017.
Sources of funding	This work was supported by the US National Institute of Mental Health under Grant P30 MH52776; the US National Institute of Mental Health under Grant under Grant T32 0MH19985; and by the Eunice Kennedy Shriver National Institute of Child Health and Human Development under Grant P2CHD042849.
Data collection	Thirty Black women (age M¼32.2, range 18 – 57) were interviewed four times over 6 months. Eligible participants completed an audio-recorded, in-depth semi-structured interview and were interviewed again one, three, and six months after baseline. We partnered with a local PrEP clinic and after the baseline interview each participant was asked if they were interested in setting up an appointment with the PrEP clinic to learn more about and

	potentially be screened for PrEP by a medical provider. Participants were contacted every two weeks in between interviews to increase retention and to check-in in the event a participant initiated PrEP. All interviews were conducted in English and LAN conducted over 90% of the interviews. The remaining interviews were conducted by a research assistant who was trained by the LAN and had prior experience conducting qualitative interviews among young gang-involved Black men and women. Interviews lasted between 30 min and 2 h, most of which (75%) were conducted in participants' homes. The remaining interviews were conducted in an interview room at LAN's office. Interview guides explored structural and SAVA syndemic factors along with PrEP interest, attitudes, adoption, and experiences. Follow-up interviews asked the same questions and how participants' lives changed across all those factors since the last interview (see online supplemental materials for details of the interview guides).
Method and process of analysis	Interviews were transcribed verbatim, and coded and analysed in MAXQDA qualitative software. LAN and JDG developed a preliminary codebook based on syndemic theory and research questions, and an initial reading of transcripts. All three authors then used didactic and iterative coding to identify family codes and sub-codes to develop the coding tree using team coding with 3 interviews. Team coding resulted in four iterations of the codebook, which was finalised once no new codes emerged and all three authors reached consensus. Examples of preliminary family codes are: intimate

	partner violence, sex exchange, drug use, sex partner, and home/house. Examples of emergent codes were: cheating, alcohol, crack, marijuana and community violence. We conducted thematic content analysis to identify primary themes to explore the feasibility and acceptability of PrEP adoption and how structural and syndemic factors acted as barriers to PrEP adoption among Black women. Analysis focused on the interrelationships among different syndemic factors (e.g. housing instability and substance use) and among syndemic factors and PrEP adoption. Pseudonyms are used throughout to protect the confidentiality of participants.
Population and sample collection	Recruitment took place in Milwaukee, WI at community events, a clinic, and through snowball sampling. Snowball sampling occurred by providing participants, if interested, with cards containing study information and contact number, and basic eligibility criteria for participants to hand out. Thirty Black women (age M¼32.2, range 18 – 57) were interviewed
Inclusion Criteria	Female Recent condomless sex Black English language Recent sex with a male partner Over 18 cisgender Having additional risk factors at least one of the following risk factors: experiencing physical, sexual, or psychological intimate partner violence in the past three

	months; engaging in sex exchange in the past three months; or engaging in problematic substance use in the past 30 days.
Relevant themes	Syndemic barriers to PrEP adoption 1. Intimate partner violence: Participants anticipated negative reactions from their partners such as thinking that the participant was HIV-positive, that the participant was accusing their partner of being promiscuous, or that the participant herself was promiscuous. "I don't know, because he seems sort of nosy, so I probably would have to put it in my purse or something, 'cause I don't think he would go through my purse." 2. Substance use: Substance use led some participants to engage in risky sexual behaviours including sex exchange. Most participants engaged in unprotected sex, often while under the influence of alcohol or drugs. "It was just the night we went out to the bar and got drunk and realised we did it without the condom. And then we just kinda continued" Structural violence as a barrier to PrEP adoption 1. Poverty, employment and housing: Several participants described poverty as both a direct and indirect barrier to adopting PrEP. Women in poverty have to go through many different processes to receive basic benefits. "Not having these nagging kids around…that's how I forgot last time… I just need reminders… I got a million and one things that I got to [do]… I can get somebody to watch them [kids] real quick…" 2. Community violence: Almost one third of participants experienced community violence during the study in which friends, family and/or significant others were severely injured or killed, or participants themselves were severely injured. "I mean like I said I missed an appointment that I had before, so I still have to reschedule, I'm trying to get on track with everything… I'm trying to wait a little bit, trying to wait…I think I just need a couple of weeks. The funeral was today, my fiancée's birthday is next Sunday so it's been a month of stressful weeks."
Additional information	Expanded upon in Nydegger 2021 with data from the same interviews. Analysed together.

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes

Section	Question	Answer
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Relevant

O'Halloran, 2019

Bibliographic Reference	O'Halloran, Charlotte; Owen, Greg; Croxford, Sara; Sims, Lee B; Gill, O Noel; Nutland, Will; Delpech, Valerie; Current experiences of accessing and using HIV pre-exposure prophylaxis (PrEP) in the United Kingdom: a cross-sectional online survey, May to July 2019.; Euro surveillance : bulletin Europeen sur les maladies transmissibles = European communicable disease bulletin; 2019; vol. 24 (no. 48)

Study Characteristics

Study type	Survey or questionnaire
Aim of study	to assess HIV PrEP access, and user characteristics
Theoretical approach	None stated
Study location	UK based online survey
Study setting	Community
Study dates	17 May to 1 July 2019
Sources of funding	Not provided
Data collection	Free text participant comments
Method and process of analysis	Qualitative data presented without analysis
Population and sample collection	2,389 participants recruited through the iWantPrEPNow mailing list, social media and Grindr completed the survey. Almost all (94%; n = 2,242) identified as exclusively gay and/ or bisexual men and the majority (85%; n = 2,041) reported white ethnicity (Table 1). Half of respondents were aged 25–39 years (50%; n = 1,202). The majority (94%; n = 2,241) were living in England, while 3%

	(n = 73) were living in Scotland, 2% (n = 41) in Wales and 1% (n = 24) in Northern Ireland. Of participants, 78% (n = 1,856) had used PrEP since January 2017 and 94% (n = 1,742) of these were current PrEP users. Of respondents, 114 reported using PrEP since January 2017, but were not current users.
Inclusion Criteria	In a specific location Living in the UK PrEP users
Relevant themes	1. Positive effect on life from PrEP comments. 'I know that I am protected whatever happens. I don't have to rely totally on condoms not failing and I don't have the weeks of anxiety wondering "what if".' 2. Feeling treated differently from using PrEP comments. 'I have been slut-shamed for using PrEP on hook-up apps. A doctor thought I had HIV because I was on PrEP.'
Additional information	The majority of the survey used closed questions with quantitative analysis, which were not extracted.

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	No *(It was only a small component of the study and not analysed.)*
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	No *(Sample population was PrEP users, but not targetting MSM. Part of the recruitment was through Grindr, a male dating app.)*
Data collection	Was the data collected in a way that addressed the research issue?	Yes

Section	Question	Answer
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Can't tell
Ethical Issues	Have ethical issues been taken into consideration?	Can't tell *(No statement of ethical approval)*
Data analysis	Was the data analysis sufficiently rigorous?	No *(No qualitative analysis)*
Findings	Is there a clear statement of findings?	No
Research value	How valuable is the research?	The research has some value
Overall risk of bias and relevance	Overall risk of bias	High
Overall risk of bias and relevance	Relevance	Highly relevant

Park, 2019

Bibliographic Reference	Park, Connie J; Taylor, Tonya N; Gutierrez, Nataly Rios; Zingman, Barry S; Blackstock, Oni J; Pathways to HIV Pre-exposure Prophylaxis Among Women Prescribed PrEP at an Urban Sexual Health Clinic.; The Journal of the Association of Nurses in AIDS Care : JANAC; 2019; vol. 30 (no. 3); 321-329

Study Characteristics

Study type	Semi structured interviews
Aim of study	to characterize the pathway to PrEP uptake among women prescribed PrEP at an urban clinic that served predominantly Black and Latina women, thus reflecting the current epidemic among U.S. women
Theoretical approach	grounded theory
Study location	New York City, USA.
Study setting	sexual health clinic The site for this study was the Oval Center, a comprehensive sexual health clinic that is part of a large integrated health care system in the Bronx,NewYork City, a region with high HIV prevalence (New York City Department of Health and Mental Hygiene, 2017). The clinic focuses on and provides a number of sexual health services, including PrEP and postexposure prophylaxis, as well as screening and treatment for sexually transmitted infections. The Oval Center is staffed by four infectious diseases specialists, a nurse practitioner, and

	two full-time PrEP patient navigators. There is broad appointment and walk-in availability. PrEP referral sources to the clinic include the health care system's HIV clinic, hospital-based HIV testing and counseling program, affiliated community-based clinics, and local community-based organizations.
Study dates	from October 2016 to May 2017
Sources of funding	National Institute of Mental Health under grant K23MH102129
Data collection	Most of the interviews were conducted by two interviewers (one of the study principal investigators and the study coordinator) in a private room at the clinic. Each interview lasted 45–60 minutes. The structured interviews explored the following: (a) how the participant first learned about PrEP, (b) motivations for initiating PrEP, (c) experiences accessing PrEP, and (d) experiences starting the PrEP regimen and continuing to take PrEP (if applicable). Sample questions included: How did you first find out/ hear about PrEP? How did you come to arrive at the Oval Center? What concerns or worries did you have at the time that made you want to use PrEP? Did you have any concerns or worries about starting PrEP? In the clinic, what were you told about PrEP and how to take it? What has your experience been like taking PrEP? What has been easy about it? and What has been hard? The following demographic variables were also collected

	to identify individual characteristics of the women: age, race, ethnicity, and level of education
Method and process of analysis	All interviews were audio-recorded and transcribed by a professional transcription service. Interview transcripts were imported into Dedoose® (a web-based qualitative research software program) to facilitate data management and analysis. Our study team was composed of four members, including a linguistic anthropologist, health services researcher, an Infectious Diseases physician, and a study coordinator with experience in qualitative research. Structural coding was used to identify responses to questions in the interview guide (MacQueen, McLellan, Kay, & Milstein, 1998). Following a review of a priori themes, we used thematic analyses to identify emerging, salient themes and relationships. The codebook was revised iteratively, and once finalized, a minimum of two team members coded each transcript. We used the constant comparative method (Strauss & Glaser, 1967) throughout to ensure that codes were applied consistently. Discrepancies in coding were resolved through consensus.
Population and sample collection	We recruited participants using the clinic's PrEP Registry, a list in the electronic medical records of all patients who were prescribed emtricitabine–tenofovir for PrEP at least once. We contacted 47 potential participants via mail or telephone; 40 participants were eligible. Of the 40 eligible participants, 14 consented to participate. We continued to recruit participants

	until we achieved theoretical saturation, which was indicated when no new concepts emerged from participant interviews. Median participant age was 40 years (interquartile range: 35–49). Most participants were either non-Latina Black (35%, n55) or Latina (50%, n57). About half of the participants had completed high school or a graduate equivalency degree (43%); about half had completed college or beyond (43%). The majority of participants learned about the Oval Center from a health care provider or community-based organization (42%) or through a friend or partner (35%). All reported having had condomless sex with at least one male partner.
Inclusion Criteria	Female HIV negative PrEP users listed in the PrEP Registry (i.e., prescribed emtricitabine– tenofovir for HIV prevention at least once at the Oval Center English language Over 18 cisgender Heterosexual
Exclusion criteria	transgender Not able to speak the language the interviews were conducted in Spanish speakers women who have sex with women

Relevant themes	Phase 1: Seeking Pre-exposure Prophylaxis 1. Self-awareness of heightened risk of HIV: The awareness of having a partner living with HIV or multiple sexual partners motivated most participants to consider PrEP. "And I believe honestly if it wasn't for the PrEP I probably would be positive. Because the, you know, when you're married to someone there are times that you are not really just focused on condoms and things of that sort." 2. Trusted pre-exposure prophylaxis referral source: Having a trusted PrEP referral source, such as a primary health care provider, partner in a relationship, or a friend living with HIV, facilitated interest in seeking PrEP. "I found out (about PrEP) because I have a friend more than 33 years…We grew up together. He's HIV-positive" 3. Misinformation and lack of information about preexposure prophylaxis: Some participants reported that they had initially dismissed the idea of taking PrEP due to misconceptions portrayed in the media or an overall lack of information about what PrEP was and how it works. "the way the media talked about it, that it was only for gay men. You didn't see the media talk about women taking it." Phase 2: Linkage to Pre-exposure Prophylaxis Care 1. Positive provider interactions and clinic experience: Positive experiences, determined by the women's perceptions that providers were knowledgeable, professional, and nonjudgmental, helped to diminish concerns prior to the visit. "They are so flexible with their schedules. So, if I can't come in on a certain date and it is 3 months past, I can call an appointment when I can come in and they will see me. That is great. That is such a relief." 2. Convenient and accessible location: All the participants in this study noted that the study clinic was easily accessible, thus facilitating access to PrEP for the community. "[A representative from the organization] called me back, and she said, "Look, I have a new name, it's not too far from you. How about this, how about we pick you up and we get you there?" … And sure enough, here she comes in the big old Boom–that's how I got here" 3. Having insurance coverage: [not relevant] Phase 3: Starting and Continuing Preexposure Prophylaxis 1. Misinformation from health care providers: Inaccurate information about PrEP or the lack of information about PrEP in general emerged as a key barrier to seeking PrEP. "(The health care provider) was saying, "This is what gay men take. Based on what you've explained to me, you don't seem like you have much to be worried about." Which I don't look at it that way. I know that it's something that can affect heterosexual people. I don't think that I'm infallible because I'm straight" 2. Concerns about safety: A barrier to initiating PrEP was concern about the safety of the medication. "They told me the first time you take the PrEP, you got diarrhea, and I got that. But now everything is okay." 3. Pharmacy challenges: About a third of the participants experienced difficulty filling and sometimes picking up their prescriptions at the pharmacy. "He gave me a packet, like a welcome packet. Like the side

	effects. It had like what the side effects are and stuff. Had big HIV on it. It didn't have my name on it, thank God." 4. Out-of-pocket health care costs. [not relevant] 5. Pre-exposure prophylaxis rumination: All participants described an ongoing consideration of the pros and cons of taking PrEP that traversed all three phases of the PrEP care continuum. We characterized this cognitive process as "PrEP rumination"—a thoughtful deliberation about PrEP over time that inadvertently delays or prevents the uptake of PrEP. "Do I really need to take it? It's a heavy hitter on the organs so I've got to go through all this testing, maybe I don't really need it. Then, my test came back negative, I was like, okay, maybe I don't need it"

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes

Section	Question	Answer
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Partially relevant *(Latina population is a less prominent social group in the UK, also multiple themes referred to insurance and financial issues as barriers which makes the overall conclusions less relevant to a UK context.)*

Pasipanodya, 2021

Bibliographic Reference	Pasipanodya, Elizabeth C; Stockman, Jamila; Phuntsog, Thupten; Morris, Sheldon; Psaros, Christina; Landovitz, Raphael; Amico, K Rivet; Moore, David J; Blumenthal, Jill; "PrEP"ing for a PrEP demonstration project: understanding PrEP knowledge and attitudes among cisgender women.; BMC women's health; 2021; vol. 21 (no. 1); 220

Study Characteristics

Study type	Focus Groups
Aim of study	to better understand cisgender women's knowledge and attitudes towards PrEP and to obtain their perspectives on ways of facilitating other cisgender women's PrEP uptake and adherence
Theoretical approach	None stated
Study location	San Diego and Los Angles, USA
Study setting	Community
Study dates	November 2015 and January 2016
Sources of funding	California HIV/AIDS Research Program and the UCLA Center for AIDS Research
Data collection	All focus groups were conducted in English, were approximately 90 min in duration, and held at clinical research sites. They were led by two facilitators in San Diego (J.K. and D.J.M.) and two facilitators in Los Angeles (R.A. and C.P.), all of whom had extensive experience in conducting qualitative research and were investigators for the planned CHRP-funded PrEP study. Additional study staff was present for administrative purposes. A light meal was provided at the beginning of each of the focus groups and all participants were compensated $35 at the end of the discussion for their time. Prior to each focus group discussion, participants completed a short form collecting data on self-reported HIV status, age, and race/ethnicity, and a facilitator provided basic information about PrEP, including its administration, mechanism of action, possible side effects, and clinical efficacy. Using a semistructured guide developed for this study, facilitators asked open-ended questions to elicit discussion about PrEP awareness and knowledge, PrEP candidacy, PrEP benefits and concerns, PrEP facilitators and barriers to uptake and adherence, and ways to increase PrEP awareness among women. For instance, in the discussion of PrEP candidates, participants were asked, "Who do you think might benefit from taking PrEP?" To obtain views on PrEP adherence, participants were asked, "What or who helps you take your medications?" and "What things could get in the way or affect a woman's ability to take PrEP?"
Method and process of analysis	All focus groups were audio-recorded and transcribed verbatim by T.P. without identifying information. Following transcription, an inductive thematic analysis approach was carried out to identify emerging themes. All transcripts were independently coded by researchers (J.B. and E.P.) using the qualitative

	analysis software MAXQDA v.12 and a coding dictionary consisting of mutually-exclusive codes and memos was constructed [12]. Initial interrater reliability of codes was low, primarily due to differences in the frequency of subtheme coding between rates, resulting in further code refinement and assignment with some subthemes merged into broader themes. Differences in coding were resolved through discussion between the two rates and re-rating content with new codes. Following further coding review, final agreement and interrater reliability was high (Cohen's kappa>0.9) [13]. The manuscript was organized in accordance with the COREQ guidelines [
Population and sample collection	Each focus group was comprised of 4 to 10 individuals, with a total of 22 participants. Participants were recruited as part of a convenience sample through local HIV testing sites, community-based organizations that support cisgender women and social media. Although focus groups focused on the views of representative prospective PrEP users (i.e., cisgender women without HIV), four women living HIV (WLHIV) participated in the focus groups in order to foster inclusivity and maintain good relations in this community-based participatory project. Of the 22 participants, 6 identified as non-Hispanic Black, 7 as non-Hispanic White, 8 as Latina, and 1 as mixed race. Participants were a median age of 44 years old (Interquartile Ratio 30–53). Four WLHIV participated in the first focus group 1; the other focus groups were entirely comprised of women who did not have HIV.
Inclusion Criteria	Female English language Over 18 cisgender
Relevant themes	1. i) PrEP awareness and suggestions of improving PrEP awareness among other women, 2. (ii) concerns and benefits of PrEP use as well as their perceptions of who might benefit the most from PrEP use, 3. (iii) perceptions of barriers and facilitators of PrEP initiation and adherence

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes

Section	Question	Answer
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	No *(Did not exclude HIV positive participants or differentiate their contributions.)*
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Moderate
Overall risk of bias and relevance	Relevance	Relevant

Philpot, 2020

Bibliographic Reference	Philpot, S.; Prestage, G.; Holt, M.; Haire, B.; Maher, L.; Hammoud, M.; Bourne, A.; Gay and Bisexual Men's Perceptions of Pre-exposure Prophylaxis (PrEP) in a Context of High Accessibility: An Australian Qualitative Study; AIDS and Behavior; 2020

Study Characteristics

Study type	Survey or questionnaire
Aim of study	to use free-text data to examine the frequency of Australian GBM's PrEP-perceptions, highlighting the potential benefits and challenges to its promotion.
Theoretical approach	None stated
Study location	Australia
Study setting	National online survey
Study dates	2017
Sources of funding	This study was funded by the Australian Research Council (ARC), ARC Grant number: DP140102483, and by a Gilead Research Fellowship. The institutes involved in this project receive funding from the Australian Government Department of Health. Two authors are funded by the award of a National Health and Medical Research Council Fellowship.
Data collection	In 2017, two questions about PrEP with open-ended responses were included in the survey for the first time: 'Would you like to tell us what you think about using PrEP?' and 'If you weren't using PrEP when you last completed the survey, and you've used PrEP since then, would you like to tell us why?' The first question was asked in both the baseline and follow-up surveys, while the second question was

	only asked in the follow-up survey. Responses to each question ranged from a few words to several sentences in length.
Method and process of analysis	The analysis process began with inductive coding of the free-text data, drawing on the framework analysis method [31]. In mid-2018, SP, BH, and AB each selected and reviewed a random sample of responses. Each author independently identified a set of themes, and then jointly developed a single thematic framework. This was 'tested' against another random sample of responses to ensure thematic distinction and consistency of coding. After further refinement, this framework was applied to all responses by the first author, where a response could be marked against one or multiple themes.
Population and sample collection	A diverse sample of men were recruited entirely online, through advertisements on a wide range of social media platforms with varying degrees of gay community engagement, including popular gay and bisexual 'dating' sites and apps, and Facebook.. In total, of 1862 HIV-negative and HIV-untested men who completed the survey in 2017, 1404 responded to the open ended PrEP questions (1388 responded to the first and 220 responded to the second). Participants who responded were older, better educated, more likely to be Anglo-Celtic, had tested more recently for HIV, were more likely to live in NSW or in capital cities, to identify as gay, and to report recent receptive condomless anal intercourse with casual male partners (CLAIC). They were also more likely to be

	using PrEP and more likely to be eligible for PrEP according to prescribing guideline
Inclusion Criteria	Men who have sex with men In a specific location Living in Australia Male Specific age range Over 16.5
Exclusion criteria	None reported
Relevant themes	1. Generic Positive: the most common set of responses were positive but non-specific. "It is a good thing for those who need it" 2. Positive Social Impact: PrEP was having, or could have, a variety of positive social impacts for the world and in particular for gay men. "It's revolutionising how I and everyone around me is having sex. It's changed the conversation and redefined the meaning of 'safe sex'." 3. Overcoming Fear and Anxiety: the capacity of PrEP to reduce anxiety about contracting HIV, suggesting psychological benefits of PrEP beyond simply preventing HIV. "It's managed to alleviate a lot of my stress during sex. Prior to PrEP I used to take risks and have major anxiety about doing so" 4. Enhancing Sexual Pleasure and Opportunity: PrEP produced a feeling of sexual liberation. "while I still believe that it's important to play as safely as possible, having the option to play in different ways with others on PrEP is sexually liberating" 5. PrEP is an Additional Line of Protection: providing additional protection and acting as an insurance policy, mitigating or removing risk in instances where condoms failed or were not used. "Perfectly fine as a second-line treatment, the first being safe(r) sex practices" 6. PrEP Makes Sex Safer, but it's not Safe: Very few men appeared to doubt that PrEP worked to prevent HIV infection, but those that did were worried that not enough research had been conducted into its effectiveness, or were concerned about future 'unknowns'. "I don't know the effects it might have with diabetes. Will it counteract the effects of how my antidepressants work" 7. Negative Social Impact: the negative social potential of PrEP, including negative social consequences on the broader gay community. "I wouldn't hook up with guys who take PrEP because it predisposes me to their skanky disposition" 8. Navigating Uncertainty: uncertainty about how they should negotiate sex and risk in the era of PrEP, a concern that was particularly the case for those who did not currently use it. "Now that PrEP is available, and either guys are on it or not, talking about what safe sex is has changed considerably. Before PrEP, safe sex was a fairly easy concept"

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	No *(Implied but not explicitly stated)*
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Can't tell *(Less relevant for an anonymous online survey)*
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Highly relevant

Poteat, 2019

Bibliographic Reference	Poteat, Tonia; Wirtz, Andrea; Malik, Mannat; Cooney, Erin; Cannon, Christopher; Hardy, W David; Arrington-Sanders, Renata; Lujan, Maren; Yamanis, Thespina; A Gap Between Willingness and Uptake: Findings From Mixed Methods Research on HIV Prevention Among Black and Latina Transgender Women.; Journal of acquired immune deficiency syndromes (1999); 2019; vol. 82 (no. 2); 131-140

Study Characteristics

Study type	Focus Groups In depth interviews
Aim of study	to understand PrEP awareness and uptake among BLTW, and assess willingness to engage in current and future HIV prevention interventions, including oral PrEP, postexposure prophylaxis (PEP), microbicides, and vaccines
Theoretical approach	none stated
Study location	Baltimore, USA
Study setting	Black and Latina transgender women (BLTW) community
Study dates	May and October 2015
Sources of funding	Supported by the Johns Hopkins University Center for AIDS Research, an NIH funded program (P30AI094189), and by services from the District of Columbia Center for AIDS Research, an NIH-funded program (AI117970), which are both supported by the following NIH CoFunding and Participating Institutes and Centers: NIAID, NCI, NICHD, NHLBI, NIDA, NIMH, NIA, FIC, NIGMS, NIDDK, and OAR
Data collection	Qualitative data collection was conducted in English only between May and October 2015 in Baltimore and included KI interviews, focus group discussions (FGDs), and in-depth interviews (IDIs). Potential KIs were recruited purposively through professional networks of the principal investigator and key community stakeholders. KI interviews (n = 12) lasted approximately 60 minutes and occurred in private office spaces or other locations of the participants' choosing. KI discussion topics included: community engagement approaches, sampling and recruitment methods, and perceptions of HIV risk and prevention among BLTW. Three FGDs of 3–8 participants each (n = 18) were held in Baltimore. A trained facilitator used a semi-structured guide to lead discussions about community norms and perceptions related to HIV and prevention interventions. In addition, input on sensitive segments of the planned survey instrument (eg, sexual behaviour questions) were solicited before survey launch. Two IDIs were conducted with adolescents. Individual interviews were

	held in response to adolescent concerns about privacy risks associated with attending FGDs. These IDIs included the same topics discussed in the FGDs with a specific focus on assessing adolescent norms
Method and process of analysis	During data analysis, we identified themes within the qualitative data that provide insight into ways stakeholders can respond to the HIV prevention needs of BLTW. All qualitative data were audiorecorded and transcribed verbatim by a professional transcription company. Atlas.ti (Version 7, Scientific Software Development GmbH) was used for management and analysis of transcripts. Data were coded using a priori codes from the semi-structured guides and emergent codes derived during the coding process. Two coders double-coded 3 transcripts and compared sideby-side to identify and reconcile inconsistences via consensus. The remaining transcripts were coded independently. Codes were then read across transcripts and grouped into emergent themes.
Population and sample collection	FGD participants were recruited via word-of mouth and flyers at transgender-serving community organizations, including organizations focused on transgender youth. 1 BLTW participants ranged in age from 19 to 82 years with an average age of 38 (median:34 years). The majority identified as Black or African American (62%), and approximately one-quarter (27%) identified as Latina/Hispanic of any race. Most participants had public health insurance, and high levels of unemployment and poverty. Sixty-nine percent had identity documents with their desired name or gender marker, and 78% were currently taking gender-affirming hormones. More than half of the participants (n = 112, 56%) tested positive for HIV and 90% of those who tested positive (n = 102) were aware of their HIV status. Eighty-nine participants tested HIV-negative, among whom 84% (n = 75) were aware of their status based on at least one HIV test in the prior 12 months. Scores for HIV knowledge (median: 5/5), HIV risk perception (median: 3/4), and transgender pride (median: 14/ 16) were high. Lifetime history of sex work (79%) and condomless anal sex in the prior 12 months (47%) were common.
Inclusion Criteria	Trans people In a specific location lived in the Baltimore, MD or Washington, DC metropolitan areas. Female Black Mixed race Assigned male at birth Over 18

	At least a years volunteering/work experience in the community >1 year of experience working or volunteering for an organization that serves the transgender community in Baltimore Latina/Hispanic
Relevant themes	1. Distrust of medical establishments: “I think people know about it (PrEP). There’s a lot of scepticism in the transgender community. About anything new that comes down the pipe just because of history, and history has been that we’ve been used for a lot of things, and the things that we’ve been used for haven’t necessarily benefitted the community" 2. Desire for holistic support: “I’m more than just possibly an HIV-positive or HIV-negative person. And so how are you going to make me or how are you going to really help or support me to become a woman? And that’s more important than whether or not I have HIV.” 3. Excessive focus on HIV/AIDS: “the only time we talk about really young Black people particularly in Baltimore young Black MSM or young Black transwomen is as it relates to HIV and people know that. And I think they’re burnt out. They’ve HIV’d out. I think they want to be more than just possible vectors of disease. 4. Need for transgender service providers: “I know they’re getting better at, but for a while it was a bunch of straight white girls working in case management, and to me I feel like that’s kind of a problem when you’re working in HIV and your clientele is going to be in Baltimore City, mostly people of colour and also gay and bisexual and same-gender-loving men and trans women. I think that you need to have individuals who are part of the community serving the community.” 5. Competing priorities: "I would also just be aware because there have been so many murders and violence. with trans women of colour in Baltimore City. It’s another thing that (is) an issue and. more of a priority than HIV."
Additional information	HIV +ve participants' data was not extracted

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	No *(The mixed methods approach with surveys, focus groups and two categories of interviews limited the*

Section	Question	Answer
		depth and consistency of data that could be obtained.)
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	No *(The themes are listed but not explained, analysed or examined.)*
Research value	How valuable is the research?	The research has some value
Overall risk of bias and relevance	Overall risk of bias	High
Overall risk of bias and relevance	Relevance	Relevant

Pyra, 2021

Bibliographic Reference	Pyra, M.; Johnson, A.K.; Devlin, S.; Uvin, A.Z.; Irby, S.; Stewart, E.; Blum, C.; Green, M.; Haider, S.; Hirschhorn, L.R.; Ridgway, J.P.; HIV Pre-exposure Prophylaxis Use and Persistence among Black Ciswomen: "Women Need to Protect Themselves, Period"; Journal of Racial and Ethnic Health Disparities; 2021

Study Characteristics

Study type	Interviews
Aim of study	to understand and characterize the PrEP experience, particularly PrEP persistence, among Black ciswomen who have initiated PrEP
Theoretical approach	None stated
Study location	Chicago, USA
Study setting	health center
Study dates	January 1, 2015 through February 1, 2019
Sources of funding	Third Coast Center for AIDS Research
Data collection	The study was primarily conducted at Howard Brown Health, a large, urban federally qualified health center (FQHC) in Chicago, IL, with a focus on sexual and gender minority health. a semi structured interview guide was developed and used to capture information on PrEP awareness in their community, perception of HIV risk, and experience starting and using PrEP. Interviews were conducted either in-person or via phone by trained research assistants; all interviews were recorded and then transcribed
Method and process of analysis	Transcripts were uploaded into Dedoose, a cloud-based mixed-methods software, for analysis. Interviews were analysed using a deductive thematic content analysis approach. A preliminary code book was created based on the interview guide and a transcript selected at random; all coders (N = 3) reviewed and revised the preliminary codes. Next, the codebook was applied by the primary coder to two transcripts, secondary coders coded a subset of excerpts selected at random and achieved reliability at >0.80. Most divergences occurred due to omission and upon review were quickly rectified to 100% agreement. Codes were then applied to all eight transcripts and were reviewed by all three coders for consensus of code application. Finally, themes were created based on clustering of code application

Population and sample collection	For the qualitative analysis, we included only active patients, from both Howard Brown Health and the University of Chicago's Infectious Disease Clinic and Sexual Wellness Clinic, and purposefully selected Black ciswomen who did and did not achieve PrEP persistence at 6 months to gather a range of experiences; patients are described in the text by their age, PrEP persistence at 6 months, and whether they were still using PrEP at the time of the interview. Sixty-one patients were included in the sampling frame. A total of 29 participants were successfully contacted to assess interest in participating in the qualitative interview. Of those who were successfully contacted, 16 agreed to participate and 8 were eligible, consented, and completed informant interviews; of note, the COVID-19 pandemic began in the middle of the study, which impacted recruitment and availability for interviews.
Inclusion Criteria	Female Black cisgender Participated in associated clinical trial Discontinued PrEP use
Exclusion criteria	Outside of location Chicago
Relevant themes	1. Introduction to PrEP 2. Provider and Clinic Interactions 3. Motivations for Using PrEP 4. Stopping PrEP 5. Community Perspectives on PrEP

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes

Section	Question	Answer
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Partially relevant

Rael, 2019

Bibliographic Reference	Rael, C.T.; Martinez, M.; Giguere, R.; Bockting, W.; MacCrate, C.; Mellman, W.; Valente, P.; Greene, G.J.; Sherman, S.G.; Footer, K.H.A.; D'Aquila, R.T.; Carballo-Dieguez, A.; Hope, T.J.; Transgender Women's Concerns and Preferences on Potential Future Long-Acting Biomedical HIV Prevention Strategies: The Case of Injections and Implanted Medication Delivery Devices (IMDDs); AIDS and Behavior; 2019

Study Characteristics

Study type	Focus Groups
Aim of study	to understand transgender women's concerns and preferences on long-acting PrEP products, including injections and IMDDs
Theoretical approach	
Data collection	Specifically, focus group discussion topics first covered oral PrEP pills, which are currently available on the market. Then, the discussion focused on potential future long-acting HIV-prevention strategies, including injections and implants for PrEP. The new PrEP methods were introduced sequentially, after description of the current use of each delivery method (including descriptions of any necessary oral lead-in procedures to detect drug allergy). After presenting this information (e.g., injections to deliver antiobiotics, IMDDs for contraception), participants were asked about their likes and dislikes concerning each delivery method, their considerations as transgender women, and foreseen barriers and facilitators to uptake and adherence to the potential new methods.
Relevant themes	1. injections and IMDDs could help to overcome challenges with adherence to daily pills: participants liked that they would not have to adhere to a daily product intake in order to have reliable protection against HIV. "I really like injections a lot because an injection is liquid. It's just a quick pain and you don't have to worry if you've taken your pill everyday." 2. transgender-specific needs must be addressed during the clinical trials process: Participants worried that the medications contained in long-acting HIV prevention strategies could interact with gender-affirming hormones. , participants felt that clinical studies should examine the effects that biomedical HIV prevention strategies have on transgender women as a distinct group with distinct needs. "I mean, it's no disrespect, but a cis woman's body is different from a transgender woman's body. So, I mean, there's going to be different side-effects, different effects. Our bodies are going to take these medicines differently, so I want to know what did it do to this trans person." 3. concerns related to injection or IMDD logistics 1. Concern about administering injections in the gluteal muscle: participants acknowledged that some transgender women have silicone (or other synthetic materials) injected or implanted in their buttocks, hips, or thighs to feminize their shape. These women would be unable to receive injections in in the area used by existing clinical trials protocols. "But the people in the community who have silicone – well overall they are going to

say, ‘I’m not able to use this. This injection method is not something I’m able to use.’ If this is on the upper hip, they’re not going to be able to inject them…”
    2. Dislike meeting with a healthcare provider to inject PrEP: transgender women are often already juggling multiple doctor’s appointments, and adding additional visits was undesirable. "we have to inject our hormones anyways, so that’s what I’m saying. I mean, some of us use needles anyway. They show us how to do it anyway. But I think it’s better for us to use needles like this also.”
    3. Dislike the oral lead-in required for injections: the 30- day oral lead in required for the injection was unpopular. “Yeah, I’m down for the injections. I’m just not down for taking the pills first and then take the injections. I’m not cool with that”
4. concerns related to injections or IMDDs presence in the body
    1. Visibility and perceptibility of IMDDs: Most participants did not want the IMDD to be perceptible, but others did. “…Once it’s not visible, it’s hard to be like, ‘Am I still protected? I know it’s in my body somewhere, but…’”
    2. Concerns about potential clinical issues associated with IMDD use: concerns about what could happen if the IMDD were bumped, potential for migration of the IMDD, scarring associated with the insertion/removal processes, skin reactions (including IMDD “rejection” or “infection”) that could occur with IMDD use, and general unpredicatible reactions (e.g., allergy) that might result from the IMDD. "I think that’s another thing that kind of bothers me is that it doesn’t look very secure…it just looks like I could go like that and it would move.”
    3. IMDD size: Overwhelmingly, participants indicated that a smaller IMDD was better. “[I’d like it to be] smaller than a matchstick. Half the size of a matchstick”
    4. Concerns about the side-effects of PrEP medications: Several transgender women feared that injectable medications would have side-effects similar or worse than those associated with the tenofovir dipivoxil and emtricitabine’s (Truvada) “start-up syndrome” (e.g., nausea, loss of appetite). “But what if the injection has side-effects worser than the pills? The injectables have never been treated, has never been tested on animals nor on humans so…”
    5. Injections and IMDDs should last for a prolonged period of time: Although they differed over exactly how long they would want the HIV prevention effects to last, all participants agreed that injection/IMDD effects should last for a prolonged period. "The benefit to this - it would mean that I wouldn’t have to think about it for a year. I would have 12 months of not having to worry about taking a pill or any other…"
5. familiarity with injections or IMDDs for other health conditions affects opinions about these products for PrEP
    1. Familiarity with injections made use of this HIV prevention strategy more acceptable: injectable PrEP felt like it was directed to transgender women in a more meaningful way, because taking injectable hormones is often a large part of the transition process. Thus, this PrEP delivery method appeared to be more congruent with transgender women’s existing preferences and behaviours. "Like, injections are fairly

	common with transwomen, but not so much with gay, lesbian, and bi. Because there's just…they usually have no need for it. Like, if they're trying to prevent HIV they use condoms or they'll use PrEP. But we have our hormones and that's one specific thing…" 2. Perceived high cost of long-acting PrEP IMDDs: [not relevant]
Additional information	Study information is the same as Rael 2018 except where otherwise stated

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No
Ethical Issues	Have ethical issues been taken into consideration?	No
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Moderate
Overall risk of bias and relevance	Relevance	Relevant

Rael, 2018

Bibliographic Reference	Rael, Christine Tagliaferri; Martinez, Michelle; Giguere, Rebecca; Bockting, Walter; MacCrate, Caitlin; Mellman, Will; Valente, Pablo; Greene, George J; Sherman, Susan; Footer, Katherine H A; D'Aquila, Richard T; Carballo-Dieguez, Alex; Barriers and Facilitators to Oral PrEP Use Among Transgender Women in New York City.; AIDS and behavior; 2018; vol. 22 (no. 11); 3627-3636

Study Characteristics

Study type	Focus Groups
Aim of study	To shed light on NYC transgender women's perceived barriers to using PrEP and strategies to overcome them
Theoretical approach	None stated
Study location	New York City, USA
Study setting	The study was conducted within Project AFFIRM, a longitudinal study of transgender identity development
Study dates	September 2016-February 2017
Sources of funding	Data collection support was provided by Project AFFIRM (R01 HD079603; Principle Investigator, Walter Bockting, Ph.D.) and a generous grant from the Mac AIDS Fund (MAF CU13-3233). The first author is supported by a training grant (T32 MH019139; Principle Investigator, Theodorus Sandfort, Ph.D.) from the National Institute of Mental Health at the HIV Center for Clinical and Behavioral Studies at the NY State Psychiatric Institute and Columbia University (P30 MH43520; Center Principle Investigator: Robert Remien, Ph.D.). Additionally, research was supported by SLAP-HIV (UM1 AI120184; Principle Investigator, Tomas Hope, Ph.D.) and the Third Coast Center for AIDS Research (P30 AI117943; Principle Investigator, Richard D'Aquila, M.D.).
Data collection	Those who fulfilled eligibility criteria and had given consent to be contacted for other studies were invited to our research offices and underwent a new consent process, before completing a brief interviewer-administered, tablet-based survey in English or Spanish. The survey included the following topics: demographics, PrEP knowledge, and access to healthcare. Immediately following the survey, participants (N=28) were asked to take a rapid oral HIV test (OrSure Advance®) to verify seronegativity. Individuals who had a negative HIV test were invited to participate in one of four focus groups, which took place at a medical center in New York City at a later date. Focus groups took approximately 90 minutes to complete and were co-led by the first author and a trained research assistant. Discussions focused on perceived barriers and facilitators to oral PrEP. Focus group discussions were divided into two parts. Part 1 focused on understanding participants' existing knowledge about oral PrEP. Specifically, focus group attendees were asked the following question: "What have you heard about PrEP or Truvada?"

	During the ensuing discussion, participants were probed about the following topics: where they had heard the information they shared about oral PrEP; how they liked oral PrEP if they had used it; what things they had heard from friends or other people in the transgender community about oral PrEP. At the beginning of Part 2, participants were given a detailed explanation of oral PrEP (e.g., dosing schedule, cost, potential side-effects, how to access PrEP), and were encouraged to ask clarifying questions until none remained. This was intended to ensure that all respondents had accurate information about this topic. Next, participants were asked what they liked and disliked about oral PrEP; respondents were encouraged to focus on specific likes and dislikes that could be unique to transgender women. Lastly, participants were asked to respond to the following question: “If you had the chance to tell the scientists who developed this product what they could do to make it better for transgender women, what would you tell them?”
Method and process of analysis	Audiotapes of focus group discussions were transcribed. Since both coders were bilingual, Spanish language transcripts were coded in Spanish. However, examples of text presented in this manuscript were translated to English by the coders. Transcripts were coded using Dedoose. Codes were identified by the first author and a research assistant, trained in qualitative methods, using a multilayered strategy. First, a list of a priori codes, or codes developed in advance by the research team (21), was generated based on topics addressed by the focus group guide. Coders also planned to analyse the text to identify in vivo codes, or experiences described by participants that characterized their perceptions of oral PrEP (22) In vivo codes were created by noting overlapping themes in the transcripts, developing code definitions that summarized these themes, and discussing code definitions to ensure consensus between coders. Themes represented by a priori and in vivo codes were intended to characterize the presumed meanings underlying the respondents’ answers (23). To ensure that themes represented data in a consistent way, the first author and the research assistant worked separately to identify codes. During the analysis phase, coders examined themes alongside the data examples they were intended to represent. Comparisons of text assigned to a priori and in vivo codes were made after the each pass through the data and inconsistencies were discussed until agreement was reached. A priori codes that were absent from or poorly represented by the text were eliminated. Coders also discussed the in vivo codes they identified and examples of quotes illustrating these themes. This was to ensure that codes were similarly assigned to text samples between the coders. Next, coders reexamined the data for an all-inclusive assessment of possible themes and met for the last time to discuss a priori and in vivo codes, ensure consensus, and verify that example quotes illustrated the intended themes.
Population and sample collection	All participants were recruited through a convenience sample of 160 diverse transgender women contained in Project AFFIRM’s database, who had previously agreed to be contacted about future research studies. To ensure a diverse sample, especially in terms of age and race/ethnicity, AFFIRM recruits transgender women into their database through a purposive, venue-based approach across a variety of settings (offline and online; e.g., bars, pride events, online social forums). Of the participants who completed quantitative surveys, nearly all (n=26; 96.3%) had heard of oral PrEP prior to participating

	in this study. However, less than one-quarter of respondents (n=6; 22.2%) had previously or currently used this product. Of the N=28 individuals who completed quantitative, 27 were eligible to participate in focus groups. Of those, 18 participated Four focus groups were completed with N=18 participants (Group 1: n=3; Group 2: n=5; Group 3: n=7; Group 4: n=3) in English (Groups 1-3) or Spanish (Group 4), depending on participants' language preference.
Inclusion Criteria	Trans people In a specific location New York City Female HIV negative Recent condomless sex Over 18
Relevant themes	Barriers 1. "It was a month and a half of misery": Participants worried about the uncomfortable side effects associated with PrEP use. Respondents were particularly concerned about stomach pain and nausea. "…it was a month and a half of misery. I spent every single day sick and miserable. I was constantly nauseous, debilitatingly nauseous at some points," 2. "I don't like taking pills…" : Many participants reported anticipated or actual difficulty taking oral PrEP pills. Three major themes emerged, including participants' aversion to the large pill size, pill fatigue, and a general dislike of all pills. "…I don't like the idea of having another pill to keep track of... I do like that it's just one pill. That's it. But I also don't like how it would be another pill to add to all the other pills I take" 3. "Yeah, there's a lot of stigma…": Some participants felt that oral PrEP use is stigmatizing and noted an explicit bias against transgender women who take PrEP. Some transgender women in our focus groups worried that they would be mistakenly identified as HIV-positive. "…I have a friend, she was a sex worker, and she had the [PrEP] pills. She told me that one of her clients, while she was in the bathroom, he was looking through her stuff. He, like, panicked almost, thinking that he had something because he thought that those pills meant that she had HIV" 4. "It's not marketed to us…": Transgender women in our groups felt that by tailoring the majority of print and other ads to gay and bisexual men, it implied that PrEP is a product mainly intended for use by this group. This was difficult, since participants felt that their female gender is central to their individual identity. Taking a product meant for use by gay and bisexual men was perceived as an affront to that identity and a significant barrier to use. "With society at large, a lot of people don't

	think of transwomen as women. They think of us as men who are trying to be women. And so that sort of knowledge, for me, it's this thought of PrEP as something that's for gay men. It can get kind of personal." 5. "You can't expect someone to be full on your PrEP wagon if you haven't…researched it…": Participants overwhelmingly felt that there was little research to support the use of oral PrEP by transgender women. Participants worried that the use of feminizing hormones and other gender affirming medications in combination with PrEP could produce unanticipated and potentially harmful, health outcomes. "Like, if you look at sexual behaviour, if you have sex with men, it's kind of looked at and researched the same with transwomen [as with MSM]. But if you look at it from a medical standpoint and you're like, 'We're on hormones and this is a whole other level of healthcare that has to be taken into account when you prescribe PrEP.' And I don't know if it's researched enough…" Facilitators 1. "I would want a smaller pill. That would make me want to take it more": Almost all participants endorsed the idea that reducing the size of oral PrEP pills would increase their willingness to take medication. Several respondents suggested that pill producers should simply manufacture a smaller tablet. 2. "…People want to try the new methods…": Participants explained that a variety of HIV prevention methods are necessary, since different people have different needs and preferences. "Up until now all we had was the pill, and that's fine for those of use who want to continue taking pills. Fine. But other people want to try new the methods that they're making that are coming to the market soon. " 3. "We need to know what this pill does to our bodies…": Because transgender women are different than gay and bisexual men, participants in our groups suggested that product developers conduct trials to evaluate the effects of PrEP on transgender women. "I'd like to know how it would - how it's going to interact with my hormones. Specifically. Specifically. Like, how is it going to interact with someone who takes hormones orally? How is it going to interact with someone who takes hormones through injections? Or patches. How - you know?"

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	No *('This paper will' rather than 'this study aims to' - The aim in inferred but not stated as something existing from the start of the project.)*
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes

Section	Question	Answer
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No *(This was not mentioned)*
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Moderate
Overall risk of bias and relevance	Relevance	Relevant

Reyniers, 2021

Bibliographic Reference	Reyniers, T.; Zimmermann, H.M.L.; Davidovich, U.; Vuylsteke, B.; Laga, M.; Hoornenborg, E.; Prins, M.; De Vries, H.J.C.; Nostlinger, C.; The social meanings of PrEP use - A mixed-method study of PrEP use disclosure in Antwerp and Amsterdam; Sociology of Health and Illness; 2021

Study Characteristics

Study type	In depth interviews
Aim of study	to explore how early adopters of PrEP in Belgium and the Netherlands experienced and managed PrEP disclosure to others. Such knowledge will be important to fully understand how social interaction and social life can influence its uptake, its use, and how PrEP is becoming part of the social and sexual culture of MSM communities, and society at large
Theoretical approach	grounded theory
Study location	Antwerp, Belgium, and Amsterdam, the Netherlands
Study setting	part of BePrEP-ared and AMPrEP trials
Study dates	between January 2016 and April 2018
Sources of funding	Agentschap voor Innovatie door Wetenschap en Technologie; Rijksinstituut voor Volksgezondheid en Milieu; ZonMw; Stichting Amsterdam Diner Foundation; AIDSfonds NL; Fonds Wetenschappelijk Onderzoek; Gilead Sciences; Janssen Pharmaceuticals; ViiV Healthcare
Data collection	Qualitative data were collected and analysed iteratively, following a grounded theory approach (Strauss & Corbin, 1998). In-depth interviews provide an ideal starting point to investigate how social meanings are derived, handled and acted upon from the standpoint of individuals (Blumer, 1969). BePrEP-ared participants were selected as part of the main Be-PrEP-ared study, based on information rich events (e.g. switching regimen or stopping with PrEP) or availability, that is before or after a follow-up visit (De Baetselier et al., 2017). We conducted in-depth interviews with AMPrEP participants who either had disclosed PrEP use to almost nobody, and participants who had disclosed to a wide range of persons, based on their answers in the AMPrEP questionnaire. During the data collection phase, the topic guide was adapted slightly, without losing consistency, to explore emerging themes in-depth, based on preliminary analyses. Two social scientists (TR and CN) conducted the Be-PrEP-ared interviews. One social scientist TR conducted the AMPrEP interviews for this study. The interviews took place in a confidential and safe place within the clinic of each study site. A comparable topic guide was used in both study sites, with one identical section on social disclosure of PrEP use. In line with symbolic interactionist theory (Blumer, 1969), we discussed with participants how they perceived PrEP use and, how it was perceived by others, which reactions they received after disclosing their PrEP use and how such disclosure differed according to social situations. All interviews were audio-recorded and transcribed verbatim.

Method and process of analysis	The data were analysed in three consecutive phases using NVIVO 12. Analyses were discussed within the research team in between each phase. A coding scheme was developed inductively while coding 15 Be-PrEP-ared interviews, with the focus on finding patterns in experiencing and managing disclosure of PrEP use. The scheme was adapted after analysing 10 additional AMPrEP interviews, in which disclosure experiences, strategies used by participants and differences according to social situations were categorised. The third phase involved re-analysing all interviews with the remaining eight Be-PrEP-ared interviews, with the purpose of developing an explanatory framework (see Figure 1). The explanatory framework is guided by symbolic interactionist principles: it provides an overview of how social meanings are derived, managed and acted upon through social interaction by focusing on social disclosure in different social situations
Population and sample collection	MSM and transgender persons at high risk of HIV infection (200 in Antwerp and 376 in Amsterdam) initiated PrEP. Participants were able to choose and switch between daily and event-driven PrEP regimens. During quarterly visits in two clinics (Antwerp and Amsterdam), study procedures included sexual health and adherence counselling, testing for HIV and other STIs, and completion of a questionnaire. We interviewed 32 participants between January 2016 and April 2018. Interviewees were comparable to the overall study sample, but were more likely to be higher educated
Inclusion Criteria	Men who have sex with men Trans people PrEP users Participated in associated clinical trial
Exclusion criteria	None reported
Relevant themes	1. Experienced reactions to PrEP use disclosure 2. Anticipated reactions to PrEP use disclosure 3. Coping with negative reactions 4. Disclosure strategies 5. Disclosure to sex partners 6. Disclosure to friends 7. Disclosure to friends

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes

Section	Question	Answer
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Highly relevant

Rowniak, 2017

Bibliographic Reference	Rowniak, Stefan; Ong-Flaherty, Chenit; Selix, Nancy; Kowell, Niko; Attitudes, Beliefs, and Barriers to PrEP Among Trans Men.; AIDS education and prevention : official publication of the International Society for AIDS Education; 2017; vol. 29 (no. 4); 302-314

Study Characteristics

Study type	Focus Groups
Aim of study	to examine the attitudes and knowledge of trans men regarding PrEP.
Theoretical approach	None stated
Study location	San Francisco, USA
Study setting	LGBTQ community
Study dates	Not provided
Sources of funding	This study was funded by the Faculty Development Funds from the School of Nursing and Health Professions at the University of San Francisco, San Francisco, California.
Data collection	The researchers recruited trans men for focus groups to discuss various aspects of PrEP and how it related to their lives and concerns. Each focus group had a facilitator who was a trans man either known by the researchers or referred to them. Each group had a different facilitator and a trans man of colour facilitated the trans men of colour group. . Each focus group lasted 11½ hours and was conducted at the Asian Pacific Islander Wellness Center, a community clinic in San Francisco that caters to a transgender population. Each facilitator had the same script to ensure that the same questions were asked of each group. A researcher who works primarily with the transgender population provided this script. The script had been used to determine attitudes and knowledge about PrEP among trans women. It was modified only to the extent that references to trans women were changed to trans men. This was possible because the questions relevant to trans women concerned medical providers' knowledge about transgender health and the specific concerns that transgender people might have. Since this tool had been demonstrated to be effective for the previous study it was believed that it would also be effective for this study. Another reason for its use was that it was hoped that a future analysis could compare the responses between trans women and trans men. There were six areas of questioning: (1) initial knowledge about PrEP, (2) where and how often the participants tested for HIV, (3) where the participants received medical care and if they would feel comfortable discussing PrEP with their medical provider, (4) concerns that the participants had regarding side effects of PrEP, (5) whether or not PrEP would influence condom use, and (6) how cost might impact the participants' feelings about PrEP. Each area of questioning had two or three questions such as "What side effects have you heard about?" and "Are there any

	specific concerns about the side effects that would influence your decision to take PrEP?" Also, each script had several prompts for each area to help clarify the questions in case there was a problem in the interpretation of what was being asked
Method and process of analysis	The data were analysed using thematic analysis (Holloway & Wheeler, 2004). Each researcher took field notes during the focus groups and an initial impression was written within 24 hours of the group. All focus groups were recorded and a transcript of the group was given to each researcher. The ATLAS.ti software program was used to store and analyse each of the transcripts. Initially extensive coding was done on a line-by-line basis with the transcripts by one of the researchers who has training and experience in Interpretive Phenomenology. Codes were collapsed into categories and proto-themes looking at the context of what was important in the lived experience of trans men. Emerging themes from the data were then determined in discussions among all the researchers. Finally, the interpretations of the data were presented to the trans male facilitators to check for validity and found to be valid.
Population and sample collection	Signs for the focus groups were placed in several locations in San Francisco that are utilized by trans men. These included the LGBT Community Center, two health clinics that see transgender patients, and a sex club that has special nights for trans men. Ads for the groups were also placed in social media websites for trans men. A total of 21 participants attended the focus groups with an age range from early twenties into the late sixties with the majority being in their late thirties. The majority of the participants were White and three identified as transgender men of colour. The first focus group consisted of six participants. All were White and ranged in age from their early 20s to late 60s. All identified as transgender and were taking testosterone. Some were one or two years into their transition and others had begun their transition decades earlier. All participants in this group spoke up, with none of the participants dominating the group. The second group, which was intended to be for trans men of colour, consisted of three participants in their 20s. Two identified as African American and one as Latino. All three identified as trans men and were self-administering testosterone. The third group consisted of 12 participants who ranged in age from late teens to late 50s. One participant identified as African American, three were Asian American, one identified as Latino, one identified as biracial and the rest were White. All participants stated that they were using testosterone and some had undergone gender-affirming surgery.
Inclusion Criteria	Trans people Male Over 18
Exclusion criteria	None reported
Relevant themes	1. THE RANGE OF INFORMATION ABOUT PREP AND SIDE EFFECTS: e. Knowledge regarding PrEP ranged from those who had read studies on the issue to those who had only heard about it from the posters used to recruit participants for the focus groups. "I've been told that it's a prevention method. And that's really about all I know about it,"

	2. THE ECONOMIC REALITIES FOR TRANS MEN: , both money and time were limiting factors for being able to commit to every 3-month appointments. Typically, these appointments are only available during weekday business hours and many were reluctant to ask for time off from work as they didn't want any excuse to be fired since they felt insecure in their current positions because of their transgender status. "A lot of people don't have any type of security." 3. FINDING A TRANS-COMPETENT PROVIDER: There was much animated talk on the subject of medical providers and if the participants would feel comfortable discussing PrEP with them. there was much variability concerning the perceived quality of care with regard to the needs of trans men. "It shouldn't be incumbent upon the patient to educate their doctor." 4. TRANS MALE SEXUALITY: participants reported difficulty in being able to discuss PrEP and sexual matters with their doctor. "If I can't talk to them about my regular health needs, how am I going to talk about my sex life?" 5. THE IMPORTANCE OF CONTRACEPTION: The majority of the participants were very concerned about pregnancy risks since they were having sex with cisgender men, yet their doctors did not engaged them in discussions about this possibility. "The very first thing goes through my mind is getting pregnant—not anything about getting HIV." 6. CONDOM USE: The majority of the participants were in agreement that condoms were a routine part of all sexual encounters with cisgender partners. "It would be a very rare circumstance where I would even consider dropping the condoms."

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes

Section	Question	Answer
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Relevant

Santa Maria, 2019

Bibliographic Reference	Santa Maria, Diane; Gallardo, Kathryn R; Narendorf, Sarah; Petering, Robin; Barman-Adhikari, Anamika; Flash, Charlene; Hsu, Hsun-Ta; Shelton, Jama; Ferguson, Kristin; Bender, Kimberly; Implications for PrEP Uptake in Young Adults Experiencing Homelessness: A Mixed Methods Study.; AIDS education and prevention : official publication of the International Society for AIDS Education; 2019; vol. 31 (no. 1); 63-81

Study Characteristics

Study type	Semi structured interviews
Aim of study	to explore the knowledge, interest, and perceived barriers and facilitators to PrEP use among a sample of YEH in Houston, TX and Los Angeles, CA using cross-sectional survey measures and semistructured interviews.
Theoretical approach	None stated
Study location	Los Angeles and Houston, USA
Study setting	The study was conducted as part of the Homeless Youth Risk and Resilience Survey
Study dates	the summer of 2016
Sources of funding	This project was partially supported by grant funding through the Greater Houston Community Foundation (Drs. Santa Maria and Narendorf), Dr. Flash's K23MH109358-0 award, and Dr. Petering's F31MH108446-01A1 award.
Data collection	After participants completed the HYRRS quantitative survey, we approached every third participant to ask if he or she would like to participate in a semistructured interview. The interview was designed to gather young adults' insights about PrEP, HIV prevention, as well as other topics such as mental health and homelessness. An interview guide was developed by the team of investigators with input from young adults in each location to assure uniformity across the sites. The interviews were conducted in a private office and lasted approximately 30–45 minutes. With permission from each participant, we digitally recorded the interviews. Prior to asking questions about PrEP, a brief description of PrEP as HIV prevention was provided. Interviewees were asked open-ended questions to explore their thoughts and opinions surrounding various PrEP and HIV prevention-related topics. The interviewers asked young adults what they thought about taking a pill each day to lower their chance of being infected with HIV. Participants were also asked about what they thought were potential advantages and disadvantages of taking PrEP and what those close to them would think if they took PrEP. Additionally, we asked young adults about their thoughts regarding their ability to take PrEP on a daily basis as prescribed.

Method and process of analysis	The Houston team had set the qualitative sample size at 30 a priori. The Los Angeles team felt saturation was achieved at 15 interviews. Audio recordings from the interviews were transcribed and coded in ATLAS-ti version 8.1.3. Thematic content analysis and peer consensus among the authors were used to establish a codebook and determine themes and exemplars (Bernard, Wutich, & Ryan, 2016). The qualitative analysis proceeded as follows. First, two authors coded two transcripts and came to consensus on the codes forming the codebook. Then one main coder completed the coding on all transcripts. Authors reviewed the coded documents and discussed the codes, exemplars, and themes throughout the process. All authors converged on the best quotes to represent the themes that emerged.
Population and sample collection	we recruited homeless or unstably housed young adults who were seeking services from shelters and drop-in centers located in Houston (n = 200) and Los Angeles (n = 220). We asked interested young adults to participate in an eligibility screener, which assessed age and housing status. Thirty YEH from Houston and 15 YEH from Los Angeles participated in the qualitative interview. Approximately 50% of participants identified as cisgender (identify as their self-reported birth sex) female, 41% identified as cisgender male, and 9% identified as transgender. Participants' average age was 20.7 years and their average age at first homelessness was 18.0 years (Table 1). Of the total sample, approximately 40% had a history of foster care, 25% had previously engaged in trade sex, and 75% of sexually-active participants had engaged in condomless sex. Young adults had been homeless for less than 6 months (44%) at this most recent incidence of homelessness or had been homeless for over one year (44%). The majority of participants in the Houston sample was Black (56.7%) and identified as heterosexual (56.7%). By contrast, the majority of participants in the Los Angeles City sample was either Black (40%) or White (40%) and identified as LBGQ (60%)
Inclusion Criteria	Specific age range 18-26 Homeless
Exclusion criteria	None reported
Relevant themes	PrEP Facilitators 1. High PrEP Acceptability: The majority of young adults across both locations were interested in taking PrEP to reduce their risk of contracting HIV. "I think it's great because like I said earlier sometimes we have to put our bodies out there just so we can get the money we need . . . Give it to me and I would use it." 2. Supportive Social Network: Overall, young adults from both Houston and Los Angeles believed individuals close to them would be

supportive of their potential decision to take PrEP. “They would agree with it. They would be like, ‘Oh, okay, I see she’s doing a good thing, she’s smart. She’s going out there she’s taking this medicine to prevent her from getting HIV.’”

3. PrEP Awareness: The majority of participants from Los Angeles were previously aware of PrEP before their participation in the study. PrEP education appeared to be widely disseminated throughout both homeless and non-homeless service outlets. "I’ve heard about it from a lot of places…I mean Pride is a prime example. It was everywhere at Pride. Um just I’ve heard it from a lot of places. I’ve heard about it here. (drop-in center staff member name omitted) has talked about it. It’s just I’ve heard about it from a lot of people"

PrEP Barriers

1. Low PrEP Awareness: While many young adults from Los Angeles were aware of PrEP, the majority of participants from Houston had never heard of PrEP prior to being introduced to it during the study. “They got for real?.... I’ve never heard about it . . .. That’s good but how do they prevent it?”
2. Medical and Medication Mistrust: Medication related barriers were the most commonly reported potential disadvantages to taking PrEP across both the Houston and Los Angeles sample. Specifically, young adults expressed their distrust in medication. Young adults also identified the potential side effects of PrEP as a major barrier to taking PrEP. "Yeah because you don’t know what the effects are, the long-term effects, because it’s brand new. This is a serious disease you can’t just put a birth control on first of all. Like this just sounds like a scam to me; sounds like a money-making scheme"
3. Other PrEP Barriers: Adherence, Cost, and Access: Young adults mentioned their homelessness circumstances would make it difficult to adhere to the daily medication requirements. Because of their life on the streets, participants reported their routines are often unpredictable. “As a homeless person . . . my stuff gets stolen, my sleep schedules are weird sometimes; I put my bag somewhere and I don’t go back to it for days.”
4. Low Perceived HIV Risk: Many young adults believed they had a low HIV risk because they did not engage intravenous drug use or risky sexual behaviours, such as having a high number of sexual partners or having sex with someone they do not know. “I don’t shoot up; I don’t sleep with people that I don’t know. Yeah I just don’t even go there.”
5. Perceived Stigma of PrEP Use: there were several young adults from the Houston sample who thought they would be stigmatized by their peers if they decided to take PrEP. Specifically, these participants felt their friends would judge them and assume they had AIDS or were HIV positive. "Probably the embarrassment. It’s like “Oh, they might feel like I got HIV.” Because when you say “at-risk” people think like “damn.” They think negative. There’s already that negative thought no matter what it is and that’s what people don’t want. "

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Relevant

Sevelius, 2016

Bibliographic Reference	Sevelius, Jae M; Keatley, JoAnne; Calma, Nikki; Arnold, Emily; 'I am not a man': Trans-specific barriers and facilitators to PrEP acceptability among transgender women.; Global public health; 2016; vol. 11 (no. 78); 1060-75

Study Characteristics

Study type	Focus Groups In depth interviews
Aim of study	to address this gap in the literature by exploring trans-specific facilitators and barriers to PrEP acceptability among a sample of urban trans women at risk for HIV acquisition
Theoretical approach	None stated
Study location	San Francisco, USA
Study setting	Trans community
Study dates	January to June 2014
Sources of funding	This work was supported by California HIV/AIDS Research Program Community Collaborative Award [CR10-SF-421].
Data collection	We conducted three focus groups and nine individual qualitative interviews with trans women (total N = 30 unique participants) focused on their knowledge of, interest in, perceptions of, and concerns about PrEP as an HIV prevention strategy. While focus groups are useful to explore community norms, individual interviews allowed participants to express personal preferences. . Interviews lasted approximately 60 minutes; focus groups ranged from 60 to 90 minutes. In-depth interviews were conducted by trained peer staff at a community-based organisation and focus groups were conducted by a trained peer facilitator. Many of the focus group members knew each other prior to participation due to tightly knit social networks among trans women in the San Francisco Bay Area. Topics included current knowledge about PrEP, appropriateness of PrEP as an HIV prevention strategy for trans women, thoughts about accessing and remaining adherent to PrEP, concerns about PrEP, efficacy of PrEP, stigma related to taking PrEP, willingness to regularly see a healthcare provider and test for HIV, and experiences and interactions with medical and pharmacy-based providers
Method and process of analysis	The in-depth interviews and focus groups were recorded and transcribed verbatim by a professional transcriptionist. Project staff also took extensive notes during focus group discussions, to capture the tone of the group, body language of the participants, and flow of the discussion and topics. All transcripts and notes were analysed using concept analysis (Walker & Avant, 2005). Concept analysis is a useful approach to analysing qualitative data collected to answer questions that are guided by a central concept and are relatively structured. For our study, we were particularly interested in learning

	about trans women's unique perspectives on PrEP acceptability, which was the organising principle guiding the endeavour. Codes or major themes in the data were derived from interview and focus group guides, with flexibility for in vivo codes to emerge during the analytic process. Example codes included 'interest in/willingness to take PrEP', 'problems with MSM focus', and 'HIV stigma'. The first and senior authors read a subset of two interview transcripts and notes to create potential codes. We then met to discuss the codes and their use in three different interview transcripts. Based on these discussions, we found some variability in our coding and identified additional emergent themes in the data, which we took into account in our next iteration of the codebook. Using the revised codebook to code one additional transcript, we then finalised the codebook. With the establishment of the codebook, each individual interview and focus group transcript was coded using Atlas.ti by the first author and senior author. The team compared coding strategies within two transcripts, identified segments where coding was discrepant, and used subsequent meetings to clarify use of the codes and create more consistency in their application across the dataset. Once the data were coded, we generated reports of segments associated with a code of interest. These reports were synthesised to facilitate discussion of the findings then elaborated upon in analytic memos. Analytic memos were written for focus group transcripts to illuminate community norms and for individual interview transcripts to compare experiences of trans women across the sample. For example, analytic memos included notes about issues such as community-level beliefs about HIV stigma as it intersects with transphobia, and comparisons of differing individual experiences with medication management.
Population and sample collection	the study team recruited adult participants from communitybased organisations and service sites in the San Francisco Bay Area and via snowball sampling. We conducted three focus groups and nine individual qualitative interviews with trans women (total N = 30 unique participants). Each focus group had seven participants, for a total of 21 focus group participants. Nine participants completed individual interviews Participants ranged in age from 21 to 51, with a mean age of 36. The majority (n = 22, 74%) self-identified as a person of colour
Inclusion Criteria	Trans people Female Assigned male at birth Over 18 Recently sexual active within 3 months

Relevant themes	1. Knowledge of and interest in PrEP: participants reported very little knowledge of PrEP. many confused PrEP with post-exposure prophylaxis. None of the participants reported having ever taken PrEP, none reported knowing of any trans woman who had taken or was taking PrEP, and none of the trans women had a medical provider ever mention or offer PrEP to them. "Like, if a doctor is going to be keeping himself in the dark about something – like, it's one thing to not know about it, it's another thing to know about it and not learn about it or tell your patients about it. That's just awful."
	2. Facilitators to PrEP acceptability
	    1. Access to a trans-competent PrEP provider: Because hormone use requires regular clinic visits, the majority of participants stated that being able to incorporate PrEP-related monitoring into these regular visits would greatly facilitate their willingness to take PrEP. "Sometimes just to find a doctor that's trans-friendly and make sure that we're on our right hormones is hard enough. I think there would be trans women who would be scared [to take PrEP] because its all about finding that right doctor. Having a good relationship with your doctor, I think, is a very good help – a very good healthy thing."
	    2. Risk perception: Engagement in sex work, either in the past or currently, was frequently mentioned by our participants and protection during sex work was a primary perceived benefit of PrEP use. "Some of us, you know, we do sex work on the side, and some us, you know, we're like, part of that kind of like, marginalized community and we don't really have that much opportunity to employment. So we end up trying to make a quick buck with sex work and that's a lot of exposure, and that's a risk."
	    3. Low power to negotiate safer sex: participants described feeling that they have less power to negotiate safer sex due to transphobia and social isolation. Several participants described feeling like trans women do not have as much say over their selection of partners and thus have riskier sex with riskier partners: "When you tell people you're trans and what this and that means … they don't want you – they don't want any thing to do with us. Let alone when we find someone who wants something to do with us, we're there. It doesn't matter if it's right or wrong, it's just – we're more willing to go with the wrong person because it's harder to find someone who will accept us."
	    4. Other facilitators: Another particularly powerful perspective came from a participant who reflected on wanting to stay healthy so she will be alive when her family comes around to accepting her. "If it's a way to maintain or take care of myself, then if I'm sexually active, then taking PrEP is just – its taking care of my body, and it's knowing that I'm going to live longer, and I'm going to be around for when my family loves me and cares about me and accepts me, and they want to be there for me, and they want to know me for me. They are trying to be open-minded to more. And God forbid, when the day comes, I don't want to be dead. I want to be known that I'm here. I love you guys, and I'm here."
	3. Barriers to PrEP acceptability

1. Marketing of PrEP is not trans-inclusive: One of the most prominent barriers was the general perception that PrEP was for gay men, and in particular, white, high socioeconomic status, gay men. "So, I feel like there's a certain sense of 'oh, we want this for ourselves' or 'we need it more.' Maybe on some level they do, but they shouldn't have a monopoly on HIV meds or HIV prevention because no one deserves to go through this"
2. Concerns about interactions with hormones and prioritisation of hormone therapy: Many wondered whether Truvada would interfere with hormone therapy, and many participants stated that if PrEP undermined the effectiveness of their hormone regimens they would immediately stop PrEP. "And if hormones do not give me that soft face while taking a pill that's supposed to stop something that condoms do pretty fine just by themselves, then I would probably try to sue … That would definitely make me stop instantaneously. I'd be like [snaps fingers], I am off the pill."
3. Managing multiple appointments and medications: Many participants noted that because they have so many other medical appointments fitting 'one more in' would be burdensome. "right now with my hormones and my other meds, I'm taking 13 pills in the morning and 7 at night. And what is that doing to my liver and my other organs? With – I take 22 pills a day. And then, on top of that, it seems like it would be more work … .it seems like it would be more of a hassle"
4. Medical mistrust due to transphobia: Focus group participants noted that many trans women generally avoid medical settings, due to prior experiences of transphobia during interactions with providers, clinic staff, and other patients in waiting rooms. "My poor provider doesn't know how to handle me, honey. I mean, my poor doctor, I think I break his brain every time I see that man … so any conversations surrounding [sex] ends up with a bit of discomfort on his part. So, I try to figure out, one, how does a man who specializes in helping transwomen not know what these things are, and two when I actually talk about my self advocacy or my self education on these types of things, why doesn't he really know how to [explore these topics with me]?"
5. HIV-related stigma, and its intersection with transphobia: . Many participants felt that HIV stigma is strong within trans communities, especially among those engaged in sex work, and that HIV status is sometimes used against those in the highly competitive and close-knit social environment of sex work. "Within the trans community, I don't think I would take it upon myself to dish my T that, hey, I'm taking PrEP as a precaution because it may come out to them as, she's covering up for the fact that she's finally contracted HIV, and now we get to read her [insult her] and terrorize her"
6. Life instability and substance use: When basic life needs such as housing and food were not secure, participants speculated that something like PrEP would not likely be treated as a priority. "Food's more important right now than something that

		might take years for it to do something to me. Unfortunately, that's the reality of the situation for some people …"

Critical appraisal - CASP qualitative checklist

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Aims of the research	Was there a clear statement of the aims of the research?	Yes
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Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Relevant

Vaccher, 2018

Bibliographic Reference	Vaccher, S.J.; Kaldor, J.M.; Callander, D.; Zablotska, I.B.; Haire, B.G.; Qualitative Insights into Adherence to HIV Pre-Exposure Prophylaxis (PrEP) among Australian Gay and Bisexual Men; AIDS Patient Care and STDs; 2018; vol. 32 (no. 12); 519-528

Study Characteristics

Study type	Semi structured interviews
Aim of study	to explore issues related to PrEP use, including the notion of safe sex, attitudes to PrEP, and management of adherence.
Theoretical approach	None stated
Study location	Sydney, Australia.
Study setting	LGBTQ community
Study dates	between October 2015 and March 2017
Sources of funding	Funding for the study was provided by UNSW Sydney and the AIDS Trust of Australia.
Data collection	Brief demographic information was collected from each participant before the interview, and participants were asked to choose personal pseudonyms for use in reporting results. The interviews were semistructured, with discussions revolving around three key themes: mechanics of PrEP access, reasons for PrEP use, and sex and HIV. Topics covered in each interview depended on how the discussion unfolded, and what was deemed relevant for the individuals and their personal situation. Interviews lasted approximately 1 h and were audiorecorded then transcribed verbatim.

Method and process of analysis	S.J.V. listened to the full audio recording of each of the interviews to understand the broader discussion and context and how this could impact on PrEP use, before focusing on the adherence section of each interview through close reading of each transcript. Notes were made about each interview and added to throughout the analysis process. Iterative coding51 was used in conjunction with thematic analysis.52 An initial coding framework was developed based on the three key interview domains, with new codes added as new concepts identified from the interviews during the coding process. Each transcript was read and coded by S.J.V. to identify key domains and relevant quotations. After the first batch of transcripts had been analysed, S.J.V. and B.G.H. met to discuss the preliminary coding and narrow down the broader topics initially included in the framework to more specific themes. All data were manually coded using Microsoft Word.
Population and sample collection	Participants were recruited from a number of sources, including advertisements on online social networking sites, and by contacting participants in PrEP implementation studies who had consented to be contacted for other research. 24 HIV-negative GBM (including 2 transgender men) who had used PrEP within the past 6 months were interviewed and included in this analysis. This included four men who had ceased taking PrEP. The age range was 18–53 years (median: 38 years). Participants reported a range

	of ways they accessed PrEP and often switched between modes of access. These included demonstration projects (n = 2) and implementation studies (n = 22), personal importation/ ordering pills online (n = 6), or by taking the antiretroviral drugs prescribed for HIV postexposure prophylaxis (PEP) on an ongoing basis (n = 2). A diverse range of lived experiences were also described, including being a homeless man with a history of mental illness, navigating the health system as a trans man, and a teenager living with his conservative family who were not aware of his PrEP use.
Inclusion Criteria	Men who have sex with men HIV negative PrEP users People whose partners are using PrEP
Relevant themes	1. How individuals adhere to PrEP 1. Establishing a routine: Establishing a routine to support pill-taking was a pivotal part of initiating PrEP for most individuals. "I have it with my breakfast 'cause I [also take] two fish oil capsules. So I just make sure that when I'm having those, I've got my little blue pill next to it . I'm a very routine-based kind of guy." 2. Identifying disruptions: Almost half of the participants interviewed personally identified difficulties in maintaining their chosen PrEP dosing schedule. "Weekends I don't have the same process for having breakfast. I generally go out . in the first couple of months, the only dosages I missed were on the weekend." 3. Creating contingency plans: Half of the participants commented that they had made contingency plans for potential or actual disruptions to their PrEP regimen. "I always have a bag with me, with a couple of tablets . you never know, you might sleep around one night" 2. Factors that aid adherence to PrEP 1. Tools: Using a phone reminder or alarm was the most common strategy used by participants to aid adherence. "I used to get a notification reminding me to take it every day. But, yeah, eventually that just got annoying." 2. Personal support: Support came from a range of sources, including siblings, friends, and colleagues. "I'm a little bit forgetful myself but my partner always remembers when I don't. So that helps."

	3. Guidance/tips: Participants were grateful for the guidance and tips they received, particularly when initiating PrEP or if they were having difficulties maintaining adherence. "There's a Facebook group that I'm part of, I think it's one of the biggest PrEP information groups. And I made a little post in there asking what people thought" 4. Risk practices: one-quarter of participants remarked that their adherence was directly affected by their perception of their HIV risk in the context of current or recent behaviours. "I can honestly say I am more vigilant and certainly acutely more aware of self-discipline in taking them [PrEP pills] if I have had a recent sexual encounter, particularly if it is I guess what you would call a higher risk." 3. Barriers to PrEP adherence 1. Health-related barriers: Health-related barriers to PrEP use included side effects and concerns about long-term toxicities. "The fact that I actually couldn't sleep started to be disturbing. I said, ''Okay. I just won't take it tonight,'' 'cause I was doing the night dose. So I didn't take the pill that night and I slept" 2. Dosing requirements: The most commonly reported adherence barrier was forgetting to take a pill every day. "It became problematic again, when I would go away [for work] . I would have to try and remember it. So a lot of the time I did forget .'cause it's just too busy." 3. Disclosure/stigma: There was a diverse range of lived experiences related to issues with disclosure or stigma that impacted on participants' ability to adhere to PrEP. "I live in a shared environment . So I was naturally apprehensive because it's a blue tablet and it's got the name written on the outside of the bottle. I was nervous that they may work out what it was." 4. Accessibility: The mechanism through which participants obtained PrEP varied not only between individuals but also over time for some individuals, which brought with it a range of difficulties. "Obtaining the medication was a problem because getting the script in the first place was the issue ."

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes

Section	Question	Answer
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Highly relevant

Watson, 2020

Bibliographic Reference	Watson, C Wei-Ming; Pasipanodya, Elizabeth; Savin, Micah J; Ellorin, Eric E; Corado, Katya C; Flynn, Risa P; Opalo, Chloe; Lampley, Elizabeth; Henry, Brook L; Blumenthal, Jill; Bolan, Robert; Morris, Sheldon; Moore, David J; Barriers and Facilitators to PrEP Initiation and Adherence Among Transgender and Gender Non-Binary Individuals in Southern California.; AIDS education and prevention : official publication of the International Society for AIDS Education; 2020; vol. 32 (no. 6); 472-485

Study Characteristics

Study type	Focus Groups
Aim of study	to identify the broad PrEP-related themes raised by focus groups, and to provide an in-depth exploration of the multiple, intersecting factors identified by trans/nb individuals pertinent to increasing PrEP awareness and access
Theoretical approach	None stated
Study location	San Diego and Los Angeles, USA
Study setting	Community
Study dates	between December 2016 and January 2017
Sources of funding	e California HIV/AIDS Research Program funded PrEP for Trans Initiative
Data collection	A semistructured format, with a series of open-ended questions, was utilized to elicit discussion about PrEP. Across the four focus groups, group discussion was guided by questions related to the following topics: (1) general medication adherence, (2) barriers and supports to current medication adherence, (3) familiarity and experience with PrEP, (4) questions and concerns about PrEP, (5) barriers to PrEP use, (6) facilitators of PrEP use and adherence, and (7) using text messages to support PrEP adherence. All focus groups were audio-recorded and transcribed without identifiable information of participants.
Method and process of analysis	All transcripts were coded using a content analysis approach to identify emerging themes across the four focus groups (Joffe & Yardley, 2004; Vaismoradi, Turunen, & Bondas, 2013). Two researchers (CWW, EP) independently coded all transcripts using MAXQDA and constructed a coding dictionary of mutually exclusive code definitions. While initial interrater reliability was suboptimal, coding differences were resolved through discussion and establishment of consensus. The final coding structure consisted of five major themes, 39 subthemes, and 423 coded statements.
Population and sample collection	Four focus groups in San Diego (n = 9; n = 9) and Los Angeles (n = 9, n = 10) were conducted with 37 trans/nb individuals 18 years or older between December 2016 and January 2017, as a part of the California HIV/AIDS Research Program-funded (CHRP) PrEP for Transgender People. Focus groups took place at the University of California, San Diego (UC San Diego)

	Antiviral Research Center (AVRC) in San Diego and the Los Angeles LGBT Center (the Center) in Los Angeles, and were conducted primarily in English. Participants who identified as transgender, gender non-binary, or gender non-conforming were recruited through local clinics, community-based organizations and advisory boards, HIV/STI testing sites, and local participant referral of trans/nb social network members. While we did not recruit for people with HIV, three individuals with HIV and three individuals with unknown HIV status participated in the focus groups. In order to maintain a highly inclusive approach to community centered research, we did not turn away any individuals recruited through peer networks who met the inclusion criterion of identifying as trans/nb. Participants included trans women, trans men, gender non-binary individuals, and individuals who did not specify their gender identity. Participants included Black, Latinx, Asian, and White individuals, and individuals who did not specify their racial/ethnic identity, the vast majority were not living with HIV, and a minority had previously used PrEP.
Inclusion Criteria	Trans people Non-binary
Exclusion criteria	None reported
Relevant themes	1. (1) perspectives on PrEP, 2. (2) trans-specific experiences in society and health care, 3. (3) sexual risk and prevention strategies, 4. (4) experiences with other medications, 5. (5) opinions about study intervention design
Additional information	3 participants with HIV were included. Their data was excluded from extraction where possible.

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes

Section	Question	Answer
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	No *(Only recruited on trans/non-binary identity: "While we did not recruit for people with HIV, three individuals with HIV and three individuals with unknown HIV status participated in the focus groups. In order to maintain a highly inclusive approach to community centered research, we did not turn away any individuals recruited through peer networks who met the inclusion criterion of identifying as trans/nb")*
Data collection	Was the data collected in a way that addressed the research issue?	No *(Did not record participants gender identities individually, despite this being the focus on the research. Cannot differentiate what views come from what perspectives.)*
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	High
Overall risk of bias and relevance	Relevance	Relevant

Williamson, 2019

Bibliographic Reference	Williamson, I.; Papaloukas, P.; Jaspal, R.; Lond, B.; 'There's this glorious pill': gay and bisexual men in the English midlands navigate risk responsibility and pre-exposure prophylaxis; Critical Public Health; 2019; vol. 29 (no. 5); 560-571

Study Characteristics

Study type	Focus Groups
Aim of study	to use this particular location (Leicester) to understand how an ethnically and socio-economically diverse group of GMSM (both HIV+ and HIV−) felt about PrEP and to explore their views, experiences, representations and intentions.
Theoretical approach	None stated
Study location	Leicester, UK
Study setting	LGBT community spaces
Study dates	2017
Sources of funding	This work was supported by the De Montfort University Internal Applied Social Sciences Fund.
Data collection	A topic guide was developed for the focus group but was used flexibly by group facilitators. Discussions were audio-recorded. Groups were facilitated by either the first or second author who are both ‘out’ gay men, with prior experience of qualitative sexual health research. Focus groups facilitate the discussion of contested issues and allow researchers to explore how arguments are promoted, challenged and defended by participants
Method and process of analysis	Data were transcribed in full and have been analysed using inductive thematic analysis. Each transcript was initially analysed as an idiographic unit by the corresponding author in the first instance and a table of themes produced for each with selected extracts. All transcripts were also read by a second member of the team and coded independently. Members of the research

	team subsequently met and refined the analysis for each group before selecting key themes across the transcripts for dissemination in the present paper.
Population and sample collection	Participants were recruited via various strategies including local LGBTQ press and social media, snowballing and flyers at Leicester Pride. In total, 18 men participated with 6 in each group. Groups One and Two were constituted of men who were HIV−. Group Three was aimed at HIV+ men but included one HIV− man who was the long-term partner of one of the other participants. Participants were UK residents aged between 24 and 48 years of age. Fifteen identified as gay and three as bisexual. They were from various occupations; several were unemployed. Using self-labels, participants described their ethnic backgrounds as ‘White-British’ (9), ‘British Indian’ (4) ‘Black-British’ (2), ‘Cypriot’ (1), ‘British Asian’ (1) and ‘British Pakistani’ (1). All HIV+ positive participants were taking Anti-Retroviral Therapy (ART). Of the 13 HIV− participants, six disclosed recent bareback sex, eight had been tested for HIV in the last 12 months, and two had used PEP. With regard to PrEP, only one participant was a regular user
Inclusion Criteria	Men who have sex with men
Exclusion criteria	None reported
Relevant themes	1. Representations of PrEP users within and beyond gay communities: PrEP was seen as a positive development for sero-discordant couples in long-term relationships. Several of the participants argued that ‘certain sorts of gay men’ would be using PrEP – and that these were typically men with ‘irresponsible’ lifestyles. "When people see the word PrEP they usually think promiscuous or safe. (.) He could be seen by different people in different ways. Oh he’s taking PrEP, presumably that means sleeping with loads and loads of different people (. . .) or it might mean that actually this person really takes care of their sexual health, therefore my sexual health as well, as a responsible person."

	2. PrEP, stigma and the interpersonal politics of HIV disclosure: men in both of the HIV− groups took a different perspective and felt that HIV+ men should disclose their serostatus to allow them to make an informed choice about whether or not, and how to have sex. "There's a culture of antitrust coming through. And how can you make a call on whose trustworthy or not? Because it isn't a call about good or bad people, it's just about people making decisions in the moment. And is having PrEP helping the situation or making it worse? I don't know. " 3. Discourses of doubt and distrust: Most of the men expressed significant concerns concerning its safety and possible side effects. Some participants believed that there could be pressure from peers and healthcare professionals to take PrEP. "Yeah side effects (. . .) I'm very suspicious about anything coming from the pharmaceutical industry. As you say, no one knows how it's going to affect you in 10 years' time. So yeah, I'm suspicious about it at the same time."
Additional information	Data from group 3 (HIV positive participants) was not extracted.

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Yes
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable

Section	Question	Answer
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Highly relevant

Witzel, 2018

Bibliographic Reference	Witzel, T Charles; Nutland, Will; Bourne, Adam; What qualities in a potential HIV pre-exposure prophylaxis service are valued by black men who have sex with men in London? A qualitative acceptability study.; International journal of STD & AIDS; 2018; vol. 29 (no. 8); 760-765

Study Characteristics

Aim of study	to understand the dimensions of acceptability of a potential PrEP service for BMSM aged 18–45 in London.
Theoretical approach	Intersectionality theory
Study location	London, UK.
Study setting	Black MSM community
Study dates	between April and August 2016
Sources of funding	This work was supported by the Wellcome Trust
Data collection	Interviews were conducted face-to-face, and participants were compensated £40. We used a topic guide exploring PrEP knowledge, sexual behaviour and risk, health service use and social contacts and peers. Interviews were audio recorded and transcribed verbatim.
Method and process of analysis	In an approach informed by framework and thematic analyses, all authors familiarised themselves with the transcripts by searching for emerging themes and collectively developed a thematic framework. CW and AB piloted and refined this framework, then applied it to all transcripts.

Population and sample collection	We recruited participants through gay-specific geolocation social networking applications (apps), social media and the PROUD study mailing list through the Medical Research Council Clinical Trials Unit. Prospective participants were directed to a survey (see online supplementary material) which asked for demographic and behavioural details, their contact details and consent for contact. Men who were aged between 18 and 45, self-reported HIV-negative or untested status, described their ethnicity as black or mixed race and reported one or more instances of condomless anal intercourse (CAI) in the preceding three months were eligible to participate.
Inclusion Criteria	Male HIV negative Untested HIV status Recent condomless sex Specific age range 18-45 Black Mixed race
Relevant themes	1. Proximity and anonymity: For many, acceptability of a potential PrEP service was shaped by concerns about the degree to which accessing said service could make oneself vulnerable to HIV stigma and homophobia. "If you build another [PrEP] service I'd say build it in a place that's close to a black community. Not necessarily

	in the community because of that fear thing. [. . .] A lot of people would be scared and I get that, especially how homophobic the black community can be. " 1. Quality, efficiency and reassurance: Perceived service quality was important for BMSM. Well-maintained facilities demonstrated that a service was well run. Efficiency of services was crucial for long-term engagement. "A friend recommended [redacted] but actually the main reason I tried it [the clinic] was because I can get results a lot quicker. Also, because I could book an appointment by text" 1. Empathy, understanding and identity: Staff were consistently highlighted as the greatest determinates of service acceptability. Men valued staff who treated them with empathy and professionalism, and valued interactions when staff made efforts to develop rapport across cultures. "There have been a few occasions when I've felt like an inmate or like a dirty slag because the way they've treated me. [. . .] Have some warmth about you. You know?"

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes

Section	Question	Answer
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No *(Not mentioned, but highly relevant.)*
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Moderate *(Downgraded due to not addressing the participant-researcher relationship. The results talk about how participants' experiences of PrEP services is impacted by whether the staff are members of the same community, so it follows that the background of the researchers may also influence their participation in a similar way.)*
Overall risk of bias and relevance	Relevance	Highly relevant

Witzel, 2019

Bibliographic Reference	Witzel, T Charles; Nutland, Will; Bourne, Adam; What are the motivations and barriers to pre-exposure prophylaxis (PrEP) use among black men who have sex with men aged 18-45 in London? Results from a qualitative study.; Sexually transmitted infections; 2019; vol. 95 (no. 4); 262-266

Study Characteristics

Study type	Semi structured interviews
Aim of study	to understand the motivations and barriers of BMSM aged 18–45 to PrEP uptake. Methods
Theoretical approach	Intersectionality theory
Study location	London, UK
Study setting	Black MSM community
Study dates	between April and August 2016
Sources of funding	This work was supported by the Wellcome Trust
Data collection	All interviews were face to face in the offices of the lead author’s host institution and were conducted by one of the three authors. A semistructured topic guide explored: PrEP knowledge; sexual history and risk; social contact and peers; and health service engagement. The analysis presented in this paper relates to the first three of these topics. Interviews were recorded and transcribed verbatim.
Method and process of analysis	A thematic framework analysis was developed fusing the approaches outlined by Clarke and Braun, and Ritchie and

	Spencer.25 26 This approach involved following steps 1 through 3 in thematic analysis to develop a framework which was then used for analysis. We first read transcripts closely and extracted themes, being mindful of the intersectional effects of identity. These were arranged into groups, with meta-themes emerging above them. This framework was piloted by two authors, refined and applied to all transcripts. Each author was responsible for some analysis and met to discuss and refine the framework periodically in order to ensure accuracy. In this framework analysis, those who had not attempted or used PrEP were classified as 'PrEP naïve', and those who had used PrEP as 'PrEP experienced'. Those who had unsuccessfully attempted to access PrEP were classified as 'attempted to access'
Population and sample collection	Twenty-five BMSM were recruited through adverts on geolocation social networking applications (apps) (Growlr and Scruff), through social media (Facebook and Twitter) and through a mailing list for the PROUD study. In the final sample more (n=14) described their ethnic background as Black African compared with those of other black ethnicities. The majority were highly educated and engaged with sexual health clinics.
Inclusion Criteria	Male Recent condomless sex Specific age range 18-45 Black Mixed race

Relevant themes	1. PrEP-related knowledge, support and discussion: Discussions about sexual health and PrEP were challenging for individuals with heterogeneous social groups because of the intersection of ethnic background, family history and religion. "But just from my background, it's kind of a prudish background, but you never really talk openly about sex." 1. Participation, marginalisation and exclusion: Participating in gay male spaces, both online and offline, was often a fraught experience for BMSM, limiting exposure to health promotion initiatives, including those disseminating PrEP information. "So I'm a little bit hardened to anything else, but it can get a bit annoying. You know, being told things like: 'You're good looking for a black guy.' I'm like: 'You don't realise how racist that is!'" 1. Stereotypes, sexualisation and responsibility: Harmful beliefs and stereotypes of black men intersected with those of PrEP users, limiting feelings of PrEP candidacy and therefore PrEP acceptability. "I remember a black fella telling me it is one thing to be a gay black man on Grindr especially in the world of no fats, no fems, no Asians, no blacks for example but if you then add HIV on the top of that then you are even pushed lower down the hierarchy of who is desirable and who is not desirable."
Additional information	This is the same population was Witzel 2018.

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes

Section	Question	Answer
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Moderate
Overall risk of bias and relevance	Relevance	Highly relevant

Wood, 2017

Bibliographic Reference	Wood, Sarah M; Lee, Susan; Barg, Frances K; Castillo, Marne; Dowshen, Nadia; Young Transgender Women's Attitudes Toward HIV Pre-exposure Prophylaxis.; The Journal of adolescent health : official publication of the Society for Adolescent Medicine; 2017; vol. 60 (no. 5); 549-555

Study Characteristics

Study type	Semi structured interviews
Aim of study	to explore factors affecting the uptake of PrEP among YTW and develop a theoretical model for PrEP uptake among YTW.
Theoretical approach	Grounded theory
Study location	Not provided in the text, but presumably Philadelphia, USA.
Study setting	Trans community
Study dates	February-December, 2015
Sources of funding	Funding: This research was supported by a grant (PI: Dowshen) from the Penn Mental Health AIDS Research Center (PMHARC), an NIH-funded program (P30 MH 097488) and NIMH K23 MH102128 (Pi: Dowshen)
Data collection	Participants completed an individual, semi-structured, qualitative interview between February-December, 2015. Demographic data were obtained via computer-based Research Electronic Data Capture (REDCap).[31] The interview contained a central PrEP question stem: “What have you heard about PrEP?,” followed with additional questions regarding sources of PrEP information. For participants with no awareness of PrEP, they were told “PrEP is taking a daily pill to prevent you from getting HIV.” Participants were then asked “How do you feel about PrEP for you and other trans girls?” If participants were HIVpositive, they were asked “How do you feel about PrEP for a partner?”
Method and process of analysis	All interviews were audio-recorded, transcribed and imported into NVivo (QSR International Pty Ltd. Version 10, 2012.), a qualitative data management and analysis software. We used a grounded theory approach to identify codes that emerged from the data. The study team developed codes by independently reading each transcript line-by-line, and reaching consensus on a code list corresponding to each theme. Codes were subsequently applied to all transcripts. Four coders each independently coded two transcripts, with ≥95% inter-rater agreement before subsequent independent coding. The study team and PI met twice monthly to discuss emerging themes. All data were double-coded and coding discrepancies were resolved by consensus
Population and sample collection	Participants were recruited from a variety of clinical and community-based organizations providing social and medical services to transgender youth and backpage.com, a website used for soliciting transactional sex.

	The mean age of participants (n=25) was 21.2 years (SD 2.2, range 17–24). Participants were predominately racial and ethnic minorities, with 36% identifying as multi-racial (n=9), 28% African American (n=7), and 20% Hispanic (n=5). HIV-positive status was reported by 32% (n=8). A history of transactional sex, specifically trading sex for money or drugs, was reported by 28% (n=7). Of the sample, 60% (n=15) were recruited from sites providing clinical and social services to YTW, 20% (n=5) responded to a recruitment flyer at an unknown location, 8% (n=2) were referred by another participant, 8% (n=2) from another study recruiting YTW, 4% (n=1) from a residential substance abuse treatment facility for transgender women
Inclusion Criteria	Trans people Female HIV negative Untested HIV status Recent condomless sex Specific age range 16-24 English language Assigned male at birth
Exclusion criteria	None reported
Relevant themes	1. Variability of PrEP Awareness: Among participants, 64% (n=16) reported having prior PrEP awareness. Among those participants with prior awareness, discrepancies emerged between awareness and accuracy of PrEP knowledge, with participants citing a wide range of understanding regarding PrEP's efficacy and mechanism of prevention. "I take PrEP. I take PrEP on a daily basis … it's like Purell for HIV. It's like 99 point nine percent of it, you're good. And you just take it on a daily basis. And I'm completely okay with that, because like I said, more pills isn't a problem for me." 2. Facilitators and Barriers to PrEP Uptake: Those already taking PrEP discussed the desire to stay HIV negative as an adherence-motivator. Some individuals emphasized that while they may not benefit from PrEP, the overall benefit to the transgender community was critical. However, barriers to PrEP uptake were raised by other study participants, including cost, adherence challenges, side effects and stigma. "m. But if I do end up single, at least I know that I have some type of backup, besides just the condom. Because at the end of the day, a condom didn't break if it's not used properly…at least I have some type of assurance behind" 3. Emotional Benefits of PrEP: Participants discussed that PrEP provided a message of hope and support against what some felt was an inevitable possibility of acquiring HIV. "I think it'll be a good thing for

	other trans women – trans people – trans community. It'll save lives. It'll keep people healthy and keep them motivated and keep them moving forward with their dreams and their plans without having to worry about, oh, I didn't get tested…I think it would be a magnificent thing if everyone in the trans community was taking PrEP, but some things just aren't meant for others. But if I could fly around the world and deliver PrEP to every trans, I would do so."
Additional information	Data from HIV +ve participants was not extracted

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Low
Overall risk of bias and relevance	Relevance	Relevant

Young, 2016

Bibliographic Reference	Young, Ingrid; Flowers, Paul; McDaid, Lisa; Can a pill prevent HIV? Negotiating the biomedicalisation of HIV prevention.; Sociology of health & illness; 2016; vol. 38 (no. 3); 411-25

Study Characteristics

Study type	Focus Groups
Aim of study	This article examines how biomedicalisation is encountered, responded to and negotiated within and in relation to new biomedical forms of HIV prevention.
Theoretical approach	Biomedicalisation.
Study location	Scotland, UK.
Study setting	Communities in urban and semi-rural locations
Study dates	between August and November 2012
Sources of funding	This research was funded by the UK Medical Research Council (MRC) (MC_U130031238/ MC_UU_12017/2), as part of core-funding for the Sexual Health Programme (now the Social Relationships and Health Improvement Programme) at the MRC/CSO Social and Public Health Sciences Unit, University of Glasgow.
Data collection	Participants were first asked about their understandings and management of sexual health risks, paying particular attention to the role of sexual health technologies within these strategies. Participants were presented with a range of items, such as condoms (male and female), sachets of lubricant, a home pregnancy test, an emptied bottle of Truvada, a mock-up bottle of antibiotics, a chart of available ARVs,

	images of Oraquick In-Home HIV test and a rapid fingerprick HIV test. PrEP and TasP were then explained to participants with the help of visual aids (Young et al. 2014). Specific rates of effectiveness were not provided, but the facilitator explained the varying rates of efficacy identified in a number of clinical trials. Participants were then asked to discuss PrEP and TasP in relation to their own sexual health, including if and how they might be used.
Method and process of analysis	FGs were digitally recorded, transcribed verbatim and names and any identifying features were removed from the transcriptions. Data were analysed thematically; IY and PF independently analysed half of the transcripts by identifying emerging themes and issues and made notes in an analysis booklet through the process of reading and rereading until saturation. Notes were guided by four analytic categories: descriptive/content; interactional dynamics; microanalysis/key discourse; and general theme. The analysed transcripts were then exchanged and re-analysed, building on the original researcher’s notes. Once each transcript had been seen and analysed twice, key themes were discussed and agreed. Rigour throughout the analysis was achieved through an iterative process of discussion and revision of findings
Population and sample collection	Participants were recruited through existing community and/or support groups in order to build on established group rapport and dynamics, enabling discussions of sensitive topics. Groups were identified with the assistance of community research partner sexual health and/or LGBT organisations based in Scotland who support regular groups to discuss HIV, sexual

	health and other support needs. We held the FGs in four cities reflecting a range of urban and semi-rural Scottish locations, including its two largest cities. We conducted FGs with 33 participants who were either gay men or African men and women. We ran five FGs with twenty-two gay men, including three with HIV-positive men, and two with HIV-negative or untested men. We ran two FGs with 11 African men and women (eight women, three men), including one HIV-positive group. Participants ranged in age from 18 to 75 years across all groups.
Inclusion Criteria	Men who have sex with men Born in Africa Male Female
Relevant themes	1. Contesting the commodification of HIV prevention: Commodification and privatisation of medicine, the first tenant of biomedicalisation, shaped the responses of many participants. "They'll have to sell it to us first 'cause they've got it an' they've produced it. They'll have to sell it to us won't they? If we wanted it in the UK, they'd have to sell it to us." 1. Contesting stigma and access to knowledge: participants were highly attuned to existing forms of HIV stigma, and its implications for access to PrEP, TasP or general biomedical HIV-related information. "I couldn't go to [the local] GUM clinic 'cause if I saw someone sittin' ootside that I ken [knew], it would look like that I had everything, d'you know what I mean? Whereas my doctor they [don't know] what I'm goin' in for an' I find it a lot safer" 1. The responsibility and culpability of HIV prevention: [Theme only refers to HIV positive participants]

Additional information	Data from the HIV positive group was not extracted

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	No *(Aims could be inferred but were not explicitly stated)*
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No *(Not mentioned)*
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	No *(It's not very clear, and seems to be predetermined by the theory they're using rather than driven by the data.)*
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	High
Overall risk of bias and relevance	Relevance	Highly relevant

Young, 2014

Bibliographic Reference	Young, Ingrid; Flowers, Paul; McDaid, Lisa M; Barriers to uptake and use of pre-exposure prophylaxis (PrEP) among communities most affected by HIV in the UK: findings from a qualitative study in Scotland.; BMJ open; 2014; vol. 4 (no. 11); e005717

Study Characteristics

Study type	Focus Groups In depth interviews
Aim of study	To explore the acceptability of pre-exposure prophylaxis (PrEP) among gay, bisexual and men who have sex with men (MSM) and migrant African communities in Scotland, UK.
Theoretical approach	None specified
Study location	Scotland, UK.
Study setting	Two communities: (1) MSM (2) men and women from migrant African communities (first generation immigrants including asylum seekers, students and other migrants).
Study dates	Focus groups: August and November 2012 Interviews: March and September 2013
Sources of funding	The HIV and the Biomedical Study, IY and LMD are core funded by the UK Medical Research Council (MRC) (MC_U130031238/MC_UU_12017/2) at the MRC/Chief Scientist Office (CSO) Social and Public Health Sciences Unit, University of Glasgow. PF is funded by Glasgow Caledonian University
Data collection	FG discussion topics included existing risk management strategies in sexual health and an exploration of PrEP and TasP.

	Interviews took place in private spaces, in partner organisations or in participants' own homes, and focused the acceptability of PrEP and TasP, including awareness, potential use, concerns and combination with other and/or existing risk management strategies (such as TasP, serosorting, etc) (see box 2). PrEP was explained to participants by drawing on but not limited to the use of a visual aid (figure 1). Basic explanations of PrEP were consistent across all FG and IDI discussions (box 2, section 4a). Subsequent and more detailed descriptions of PrEP varied depending on participant questions, which were encouraged and answered. This approach was taken to identify how PrEP should be described to potential candidates. Material did not specify an exact efficacy rate due to the emerging clinical data, variability according to adherence, and to not overly complicate the explanation
Method and process of analysis	All FGs and IDIs were digitally recorded and transcribed verbatim. Transcripts were anonymised and coded in NVivo V.10. Data were analysed thematically, drawing on anticipated as well as emergent themes.19–21 Rigour throughout the analysis was achieved through an iterative process of discussion and revision between coauthors.19 20 22
Population and sample collection	Tailored flyers and posters were distributed to: workshops and support groups; community sexual health testing clinics; gay bars, saunas and

	clubs; an MSM mail-out condom programme; commercial venues (eg, African food and barber shops) and in educational settings known to have large African student populations. Community organisations also made contact with potential participants through their regular online and face-to-face outreach and support work. We conducted seven FGs: five with MSM (n=22), and two mixed sex groups with African participants (n=11). Three FGs were conducted with HIV-positive MSM (n=14) and one FG with HIV-positive Africans (n=8). Participant age ranged between 18 and 75 years and discussions took place in urban and semiurban locations across central Scotland. Participants were recruited through existing community and/or support groups with the assistance of sexual health and/or LGBT (lesbian, gay, bisexual and transgender) organisations. We then conducted 34 in-depth interviews (IDIs) with a purposive sample of MSM (n=20) and African participants (n=14). Half of the IDI participants were HIV negative or untested for HIV, and the other half had been diagnosed with HIV at the time of the interview (MSM, n=10; Africans, n=7).IDI participants were aged 19–60 years and were resident in four Scottish regions (Glasgow, Lothian, Lanarkshire and Grampian).
Inclusion Criteria	Men who have sex with men

	In a specific location Scotland Born in Africa HIV negative Untested HIV status
Relevant themes	1. interpreting effectiveness: Although participants were informed that PrEP was highly effective when taken regularly, most participants expressed concerns that it provided less than 100% protection and therefore was ‘insufficient "Its seventy-two per cent effective but then there’s still that twenty-eight per cent." 1. managing adherence: Given the evidence concerning the patterning of efficacy by adherence,2 maintaining regular adherence to medication was identified as a potential barrier to effective PrEP use. "am I [going to] take this? Am I [going to] stand tired, have a headache in a club just at the fact that I might at the end of it get a shag…" 1. PrEP candidacy and low perceptions of HIV risk: Many participants described scepticism in taking PrEP daily, especially if they were not always exposed to or at risk of HIV transmission. "Right now in my current situation as, I’m doing a monogamous relationship and everything like that, again I don’t think even in that [instance] I don’t think I would take the pills even though it would be an extra measure" 1. concerns with other risks: participants identified risk of other STIs as a concern for themselves and

	their sexual partners. "it makes people just more focused on just HIV and not other STIs. And then risk of pregnancy as well is likely to get high, provided the people are not on any other form of contraception…." 1. moral barriers: PrEP emerged as a highly contentious issue because of the perceived negative implications it had for existing risk management strategies and HIV prevention. "Are you trying to eliminate the condom?…There is no place for a condom at all when it's like this. So I think it actually encourages people to be more promisc…not promiscuous, but to be more…I don't know [if] 'ignorant' is the right word, but to be less careful"
Additional information	HIV positive participants' data was not extracted.

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No *(Not addressed)*

Section	Question	Answer
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Moderate
Overall risk of bias and relevance	Relevance	Highly relevant

Zimmermann, 2019

Bibliographic Reference	Zimmermann, H.M.L.; Eekman, S.W.; Achterbergh, R.C.A.; Schim van der Loeff, M.F.; Prins, M.; de Vries, H.J.C.; Hoornenborg, E.; Davidovich, U.; Motives for choosing, switching and stopping daily or event-driven pre-exposure prophylaxis - a qualitative analysis; Journal of the International AIDS Society; 2019; vol. 22 (no. 10); e25389

Study Characteristics

Study type	Unstructured interviews Survey or questionnaire
Aim of study	to assess the acceptability and feasibility of offering both daily and event-driven PrEP as part of a combination prevention package. (Aim for wider trial, rather than specific paper).
Theoretical approach	Information-Motivation-Behavioural Skills Model and Health Belief Model
Study location	Amsterdam, the Netherlands
Study setting	Conducted within the AMPrEP demonstration study
Study dates	between 3 August 2015 and 21 June 2017
Sources of funding	The AMPrEP project received funding as part of the H-team initiative from ZonMw (grant number: 522002003), the National Institute for Public Health and the Environment and GGD research funds. The study drug is provided by Gilead Sciences. The H-TEAM initiative is being supported by the Aidsfonds Netherlands (grant number: 2013169), Stichting Amsterdam Diner Foundation, Gilead Sciences Europe Ltd (grant number: PA-HIV-PREP-16- 0024), Gilead Sciences (protocol numbers: CO-NL-276-4222, CO-US-276- 1712), Janssen Pharmaceuticals (reference number: PHNL/JAN/0714/0005b/ 1912fde), M.A.C AIDS Fund, and ViiV Healthcare (PO numbers: 3000268822, 3000747780).
Data collection	At baseline, the motives to choose for daily or event-driven

	PrEP, and reasons not to choose for the alternative regimen were collected. A member of the AMPrEP team asked participants face-to-face to describe in their own words the two most important underlying motives for their PrEP-related choice(s). The answers were then directly fitted by the interviewer into predefined closed-end answer options (which were published in an earlier format using quantitative baseline data [29]) listed in Table 1. When none of the predefined items correctly reflected the participant's motive, the "other" option was chosen and the motive was quoted into an opentext field. Similarly, at three-monthly follow-up visits, if relevant, participants were asked the motives for switching or stopping PrEP completely. Only open-text fields were used to note these responses. The motives for stopping temporarily with daily PrEP relied on self-report using one question in the self-administered questionnaire ("What was the reason that you temporarily stopped taking PrEP?"). Participants could self-select a predefined item from the questionnaire or use the open-text field
Method and process of analysis	Qualitative data analysis was performed by three researchers from different backgrounds: health sciences (HZ and SE) and psychology (UD). Figure 1 shows the data analyses process in steps. Predefined categories and open-text fields were combined (step 1) and qualitatively analysed following an independent open-coding

	process performed by two separate coders (HZ and SE) (step 2). Next, all codes were discussed and agreed upon by all three researchers and crystallized into final categories (step 3). Last, the frequencies of the final categories were determined (step 4). All qualitative analyses were performed in MAXQDA version 12.0.
Population and sample collection	AMPrEP is a prospective, longitudinal, open-label demonstration project that aims to assess the acceptability and feasibility of offering both daily and event-driven PrEP as part of a combination prevention package. By 1 June 2016, 374 MSM and 2 TGSM had enrolled and started PrEP. Their median age was 39.5 years (interquartile range (IQR), 32 to 48). The majority were Caucasian (85.1%) and highly educated (76.1%). At start, 273 participants chose daily PrEP and 103 chose event-driven PrEP. During follow-up, 86.4% of participants had at least one visit in the past three months. Participants switched 53 times to event-driven PrEP and 56 times to daily PrEP. Daily PrEP was temporarily stopped 161 times. Twentyone participants stopped completely with PrEP.
Inclusion Criteria	Men who have sex with men Trans people HIV negative Recent condomless sex PrEP users Specific age range Over 18

	Positive for other STIs Has a partner who is HIV positive
Exclusion criteria	None reported
Relevant themes	Motives for choosing or switching PrEP 1. Perceived HIV risk: Sex is unpredictable/ frequent/risky vs. Sex is predictable/infrequent/low risk. “[I] have a lot of changing contacts, sometimes unsafe” 2. Adherence considerations: Issues with event driven vs. daily PrEP adherence. I don’t trust myself with event-driven PrEP, [I have] had PEP in between” 3. Perceived safety, efficacy and burden of the regimen: Higher perceived efficacy and safety of daily PrEP vs. toxicity and burden of daily medication. “[I am] not convinced of the effectiveness of the intermittent scheme" 4. Anticipated or experienced side effects: recurring side effects with event-driven PrEP vs. continuous side-effects with daily PrEP. “I am afraid of the (long-term) side effects of daily PrEP” 5. Freedom versus control over sexual behaviour: To maintain/gain more sexual freedom vs. To inhibit/control sexual risk episodes. “Because I can forget about HIV completely, I do not have to think about it anymore” 6. Experimenting with the regimen: Trying out event driven vs. daily regimens. “First see how body reacts on continuous intake” 7. Other: Daily PrEP provides solidarity with daily medication users vs. Event-driven PrEP is cheaper. “Would like to take the pill together with steady partner, he is HIV-positive” Motives for temporarily or completely stopping PrEP 1. Adherence and aversion issues. “Lost them on holiday” 2. Temporary reduction in risk circumstances. “I had an STI so I was not allowed to have sex” 3. Sickness or poor health conditions. “[I] needed surgery and was advised to stop briefly” 4. Side-effects and physical burden issues. “[I] had other daily medication, [I] did not want to burden myself too much” 5. Wanting to control sexual risk behaviour. “Stop [with daily PrEP] in order to have solely protected sex” 6. No more need for PrEP. “The idea that you take medication for something you can also use condoms for” 7. Unacceptable side-effects. “Participant wasn’t able to enjoy sex due to side-effects” 8. Other. “He notices that he sought more extremes due to several circumstances, PrEP was one of them” 9. Aversion against daily medication. 10. Dissatisfaction with study procedures. “The too-long questionnaires”

Critical appraisal - CASP qualitative checklist

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	No *(Aims for the wider PrEP trial were stated but not for the specific qualitative study reported.)*
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	No *(Mixture of free responses and pre-defined may have guided or constrained participants. Some of the potential complexity or depth of information may have been lost.)*
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	No
Ethical Issues	Have ethical issues been taken into consideration?	Yes
Data analysis	Was the data analysis sufficiently rigorous?	No *(The results for starting or changing regimen were thoroughly explored but the results for stopping PrEP were listed very briefly.)*
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	High
Overall risk of bias and relevance	Relevance	Highly relevant

Appendix E Summary of effectiveness evidence and GRADE overall quality – Fonner et al 2016

Outcome	Sample Size	Population	Country	Summary of effect	GRADE overall quality	Additional data from primary studies
Condom use	N=14,063 (8 RCTs, 1 cohort study)	MSM, transgender and heterosexual men and women	Kenya, Uganda, Peru, Ecuador, South Africa, Brazil, Thailand, USA, Nigeria, Cameroon, Ghana, Botswana, Tanzania, England	Evidence from 5 placebo controlled RCTs (n= 11457), 2 RCTs comparing PrEP with delayed/no PrEP arms (n=458) and 1 cohort study comparing PrEP with no PrEP (15 n=1603) found no differences in any self-reported condom use between PrEP and placebo/delayed/no PrEP arms. 1 RCT comparing PrEP with delayed PrEP (n=545) found 21% of participants taking PrEP reported receptive anal sex without a condom with ten or more partners compared to 12% in the delayed PrEP arm.	Very Low [1, 2]	-Baeten et al 2012: Reporting 'having sex without a condom with HIV-positive partners in prior month' - Baseline: 27% Follow-up (12 months): 13%, Follow-up (24 months): 9% (similar across study groups) -Grant et al 2010: Sexual practices similar in both groups at all time points (P=0.97) and percentage of those partners who used a condom increased after subjects enrolled in the study -Peterson et al 2007: At baseline, 52% self-reported condom use during last sex. At 12-month follow-up 95% self-reported condom use (for acts in past 7 days). -Thigpen 2012: Protected sex episodes with main/ most recent casual partner: Similar across groups at enrolment (p=0.66) and remained stable over time TDF-FTC: 81.4% [range, 76.6 to 86.4] Placebo: 79.2% [range, 71.6 to 87.6] -Van Damme et al 2012: sex acts without a condom (mean reduction, 0.46; P<0.001) reported by women at the last follow-up visit, as compared with 7 days before enrolment. -Grohskopf et al 2013: change in proportion of men reporting UAS from baseline to months 3–9

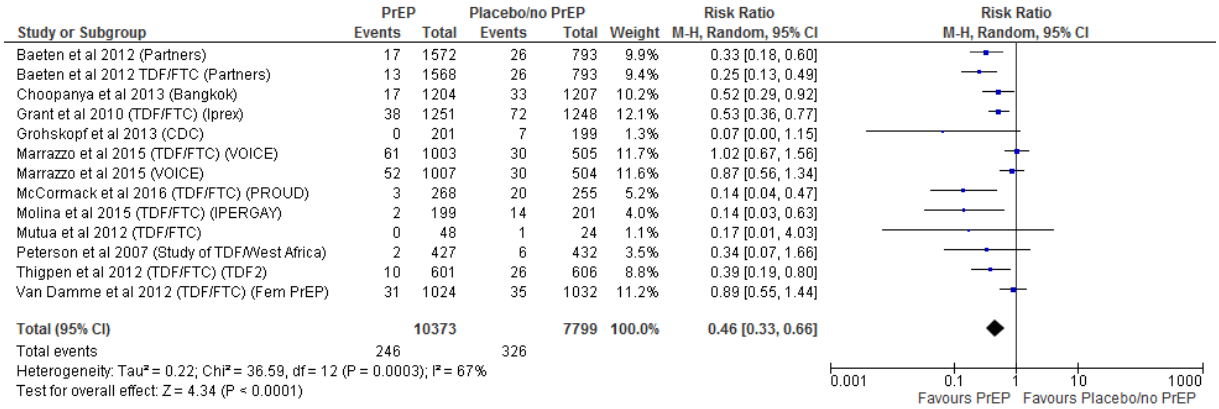
Outcome	Sample Size	Population	Country	Summary of effect	GRADE overall quality	Additional data from primary studies
						was similar between the immediate vs. delayed arms (P value for interaction = 0.15). The proportion of men reporting UAS did not change significantly after initiation of study drug in the delayed arm (P = 0.41) -Hoseck et al 2013: No significant differences among the 3 treatment groups across visits. Statistically insignificant trend from baseline to week 24 of decreasing unprotected anal sex acts across all treatment arms. McCormack et al 2016: 21% reported receptive anal sex with 10 or more men in PrEP arm compared with 12% in delayed arm (p=0·03) at 1 year. Grant et al 2014: Proportion reporting non condom receptive anal intercourse (ncRAI) decreased from 34% (377/1115) to 25% (232/926) among PrEP recipients (P =0.006) and from 27% (101/369) to 20% (61/304) among non-recipients (P=0.03); the rates of decrease in ncRAI, ncIAI (insertive), and numbers of sexual partners were comparable in the two groups (P=0.95, P=0.56, P=0.64 respectively).
Sexual Partners	N=15,554 (8 RCTs and 1 cohort study)	MSM, transgender and heterosexual men and women, people who inject drugs	Kenya, Uganda, Thailand, Peru, Ecuador, South Africa, Brazil,	Evidence from 6 placebo-controlled trials (n= 13006) 2 studies comparing PrEP delayed/no PrEP arms, (n=945) and 1 cohort study comparing PrEP with no PrEP (n=1603) found no differences in self-reported number of sex partners	Low [2]	Baeten et al 2012: Number reporting 'outside' sexual partners not statistically significant between ggroups: 29.7% TDF (vs placebo P 0.74), FTC/TDF 29.9% (vs placebo P 0.67) and placebo 29.1% Choopanya et al 2013: Sex with more than one partner decreased from 522 (22%) at enrolment to 43 (6%) at month 72 (p<0·0001 for all).

Outcome	Sample Size	Population	Country	Summary of effect	GRADE overall quality	Additional data from primary studies
			United States, Botswana, England	between PrEP and placebo/delayed/ no PrEP arms.		Grant et al 2010: Sexual practices similar in the two groups at all time points (P=0.97). Total numbers of sexual partners with whom the respondent had receptive anal intercourse decreased. Kibengo et al 2013: median number of sexual partners in the past month remained at 1 [IQR: 1-1] during the trial. Thigpen et al 2012: reported number of sexual partners declined similarly in both groups (p=0.95 between groups) Van Damme et al 2012: modest but significant reductions in the numbers of partners (mean reduction, 0.14; P<0.001 by paired-data t-test), vaginal sex acts (mean reduction, 0.58; P<0.001) reported by women at the last follow-up visit, as compared with 7 days before enrolement Grohskopf et al 2013: Overall, mean number of sex partners (per subject, in the past 3 months) decreased significantly from 7.25 at baseline to 6.02 during months 3–9 and 5.71 during months 12–24 (P < 0.001). Declines similar between immediate vs. delayed arms during months 3–9 (P value for interaction = 0.67). Mean number of partners did not differ in months 12–24 vs. months 3–9 with initiation of study drug in the delayed arm [incident rate ratio (IRR) = 0.93, P = 0.22] or continuation of drug in the immediate arm (IRR = 0.96, P = 0.56).

Outcome	Sample Size	Population	Country	Summary of effect	GRADE overall quality	Additional data from primary studies
						McCormack et al 2016: Total number varied widely at the two timepoints, but no significant difference between groups at 1 year (p=0·57). Grant et al 2014: the rates of decrease in numbers of sexual partners were comparable in the two groups (P=0.64)
1. Although most studies present consistent findings, 1 study has a conflicting outcome – rated down once. 2. Effect estimates with confidence intervals not given - rated down twice.						

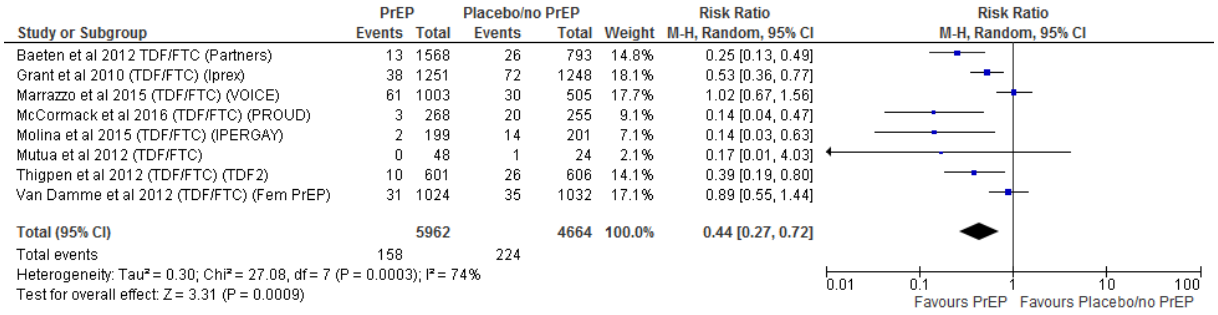
Appendix F Forest plots

Figure 1: The effect of PrEP compared to placebo or no PrEP on number of HIV infections, reproduced from Chou 2019*, (RR <1 favours PrEP, RR >1 favours placebo/no PrEP)



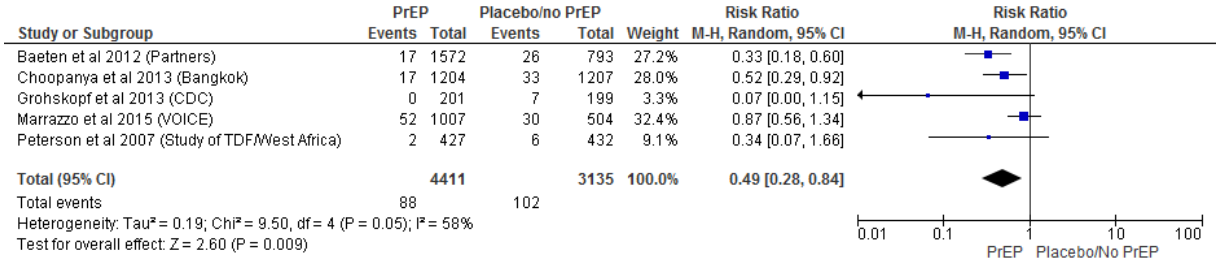
*This forest plot is reproduced directly from Chou's 2019 systematic review; the analysis was not conducted by NICE.

Figure 2: The effect of PrEP compared to placebo or no PrEP on number of HIV infections for TDF/FTC only, reproduced from Chou 2019*, (RR <1 favours PrEP, RR >1 favours placebo/no PrEP)



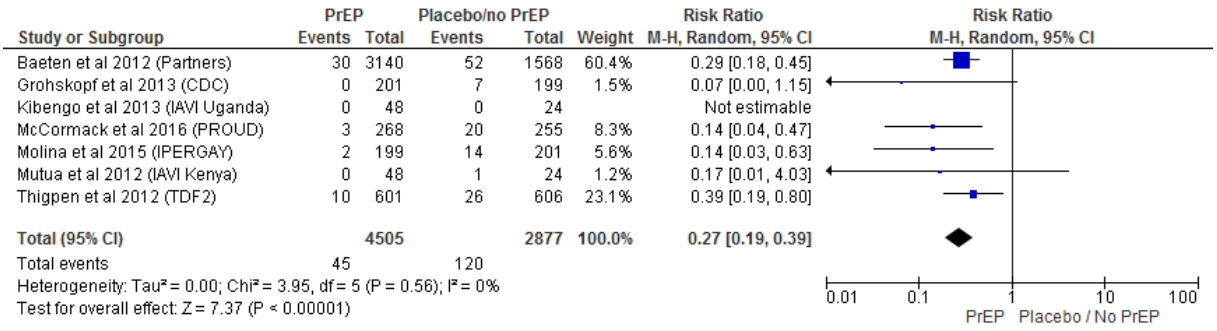
*This forest plot is reproduced directly from Chou's 2019 systematic review; the analysis was not conducted by NICE.

Figure 3: The effect of PrEP compared to placebo or no PrEP on number of HIV infections for TDF only, reproduced from Chou 2019, (RR <1 favours PrEP, RR >1 favours placebo/no PrEP)



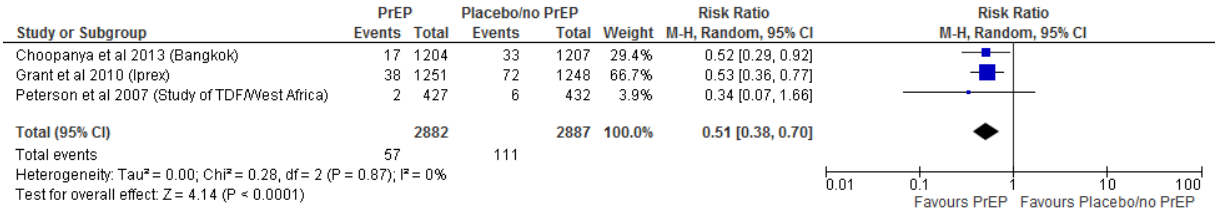
*This forest plot is reproduced directly from Chou's 2019 systematic review; the analysis was not conducted by NICE.

Figure 4: The effect of PrEP compared to placebo or no PrEP on number of HIV infections for ≥70% adherence, reproduced from Chou 2019*, (RR <1 favours PrEP, RR >1 favours placebo/no PrEP)



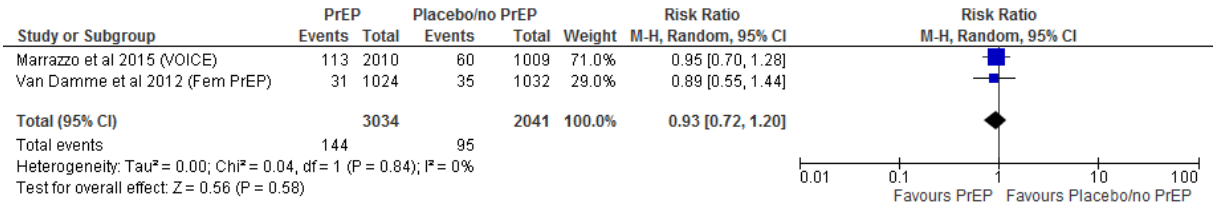
*This forest plot is reproduced directly from Chou's 2019 systematic review; the analysis was not conducted by NICE.

Figure 5: The effect of PrEP compared to placebo or no PrEP on number of HIV infections for >40% to <70% adherence, reproduced from Chou 2019*, (RR <1 favours PrEP, RR >1 favours placebo/no PrEP)



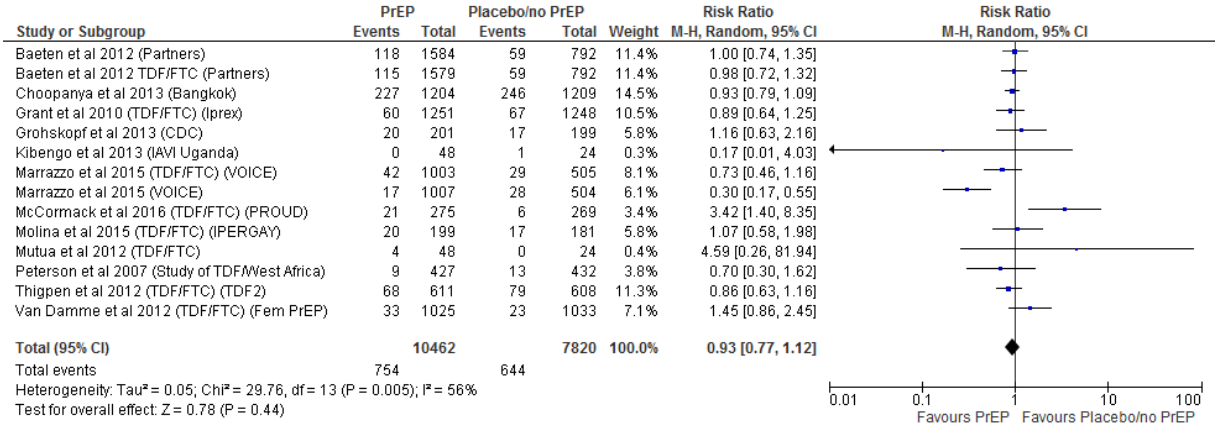
*This forest plot is reproduced directly from Chou's 2019 systematic review; the analysis was not conducted by NICE.

Figure 6: The effect of PrEP compared to placebo or no PrEP on number of HIV infections for ≤40% adherence, reproduced from Chou 2019*, (RR <1 favours PrEP, RR >1 favours placebo/no PrEP)



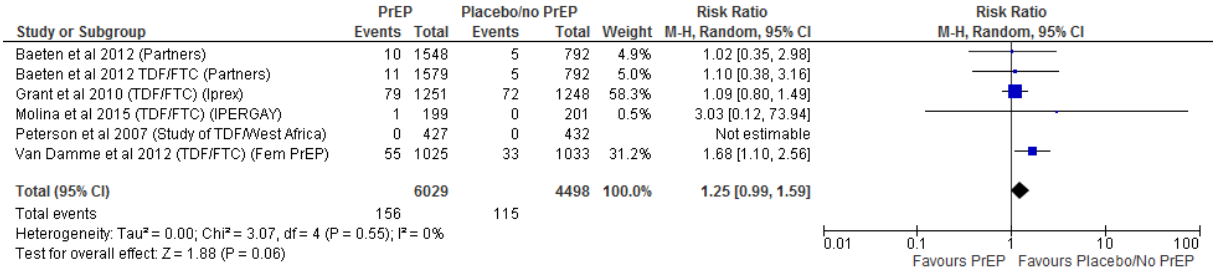
*This forest plot is reproduced directly from Chou's 2019 systematic review; the analysis was not conducted by NICE.

Figure 7: The effect of PrEP compared to placebo or no PrEP on Serious Adverse Events, reproduced from Chou 2019*, (RR <1 favours PrEP, RR >1 favours placebo/no PrEP)



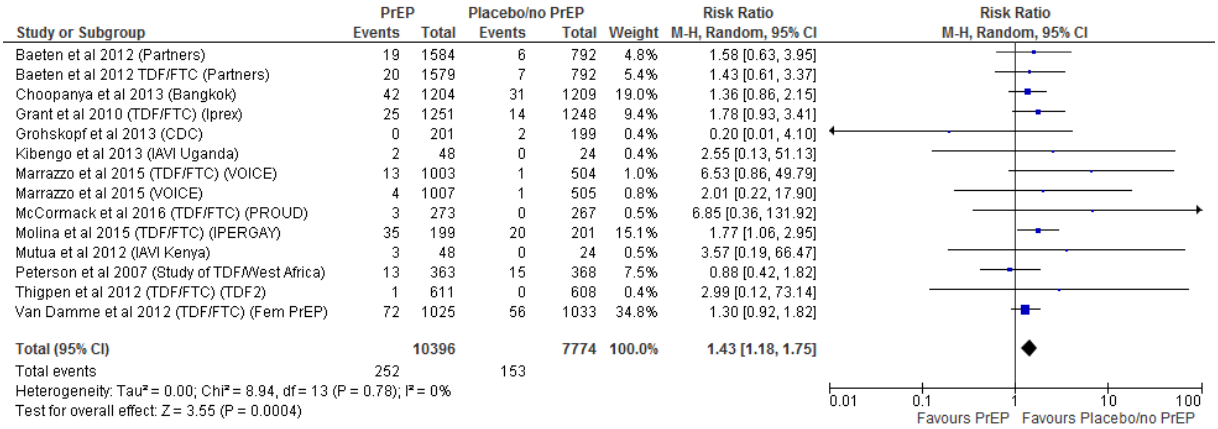
*This forest plot is reproduced directly from Chou's 2019 systematic review; the analysis was not conducted by NICE.

Figure 8: The effect of PrEP compared to placebo or no PrEP on withdrawal due to adverse events, reproduced from Chou 2019*, (RR <1 favours PrEP, RR >1 favours placebo/no PrEP)



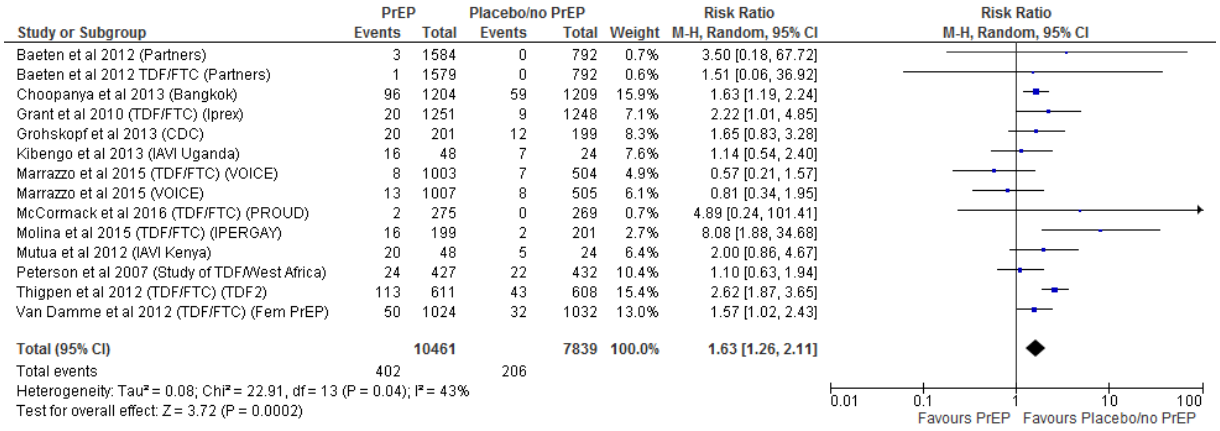
*This forest plot is reproduced directly from Chou's 2019 systematic review; the analysis was not conducted by NICE.

Figure 9: The effect of PrEP compared to placebo or no PrEP on renal adverse events, reproduced from Chou 2019*, (RR <1 favours PrEP, RR >1 favours placebo/no PrEP)



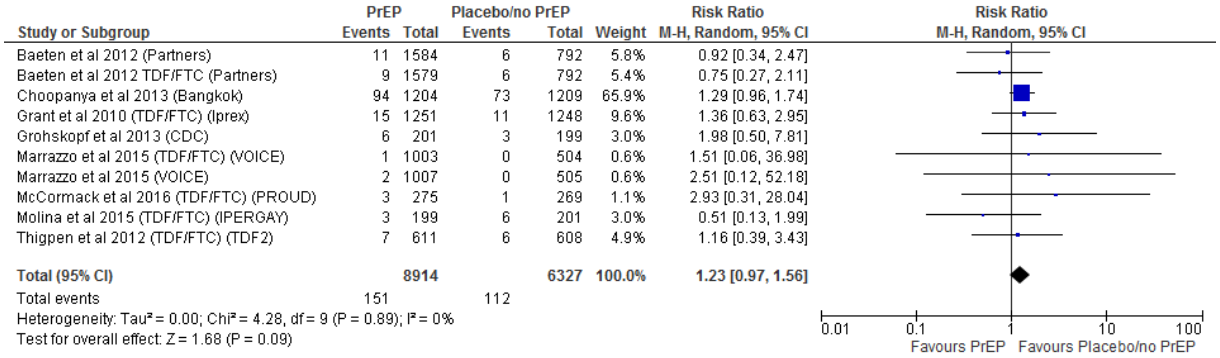
*This forest plot is reproduced directly from Chou's 2019 systematic review; the analysis was not conducted by NICE.

Figure 10: The effect of PrEP compared to placebo or no PrEP on gastrointestinal adverse events, reproduced from Chou 2019*, (RR <1 favours PrEP, RR >1 favours placebo/no PrEP)



*This forest plot is reproduced directly from Chou's 2019 systematic review; the analysis was not conducted by NICE.

Figure 11: The effect of PrEP compared to placebo or no PrEP on fracture, reproduced from Chou 2019*, (RR <1 favours PrEP, RR >1 favours placebo/no PrEP)



*This forest plot is reproduced directly from Chou's 2019 systematic review; the analysis was not conducted by NICE.

NB – Not enough data provided in systematic review (Chou et al) to reproduce forest plots for STI outcomes.

Appendix G GRADE tables and GRADE CERQual tables

G.1 GRADE tables

Chou et al 2019

Outcome	Intervention vs comparator	No of studies	Sample size	MIDs	Effect size relative risk (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Confidence
HIV infection	PrEP vs placebo/delayed PrEP/No PrEP	11 RCTs	18172	0.8-1.25	RR 0.46 (0.33-0.66)	Not Serious	Not Serious	Very Serious[1]	Not Serious	Low
HIV infection TDF only	PrEP vs placebo/delayed PrEP/No PrEP	5 RCTs	7546	0.8-1.25	RR 0.49 (0.28 – 0.84)	Not Serious	Not Serious	Serious[3]	Serious[2]	Low
HIV infection TDF/FTC	PrEP vs placebo/delayed PrEP/No PrEP	8 RCTs	10626	0.8-1.25	RR 0.44 (0.27-0.72)	Not Serious	Not Serious	Very Serious[1]	Not Serious	Low
HIV infection by ≥70% adherence	PrEP vs placebo/delayed PrEP/No PrEP	7 RCTs	7400	0.8-1.25	RR 0.27 (0.19-0.39)	Not Serious	Not Serious	Not serious	Not Serious	High
HIV infection >40% to <70% adherence	PrEP vs placebo/delayed PrEP/No PrEP	3 RCTs	5769	0.8-1.25	RR 0.51 (0.38-0.70)	Not Serious	Not Serious	Not Serious	Not Serious	High

HIV infection Adherence ≤40%	PrEP vs placebo/delayed PrEP/No PrEP	2 RCTs	5075	0.8-1.25	RR 0.93 (0.72-1.20)	Not Serious	Not Serious	Not Serious	Serious[2]	Moderate
Serious Adverse Events	PrEP vs placebo/delayed PrEP/No PrEP	12 RCTs	18282	0.8-1.25	RR 0.93 (0.77-1.12)	Not Serious	Not Serious	Serious[3]	Serious[2]	Low
Withdrawal due to adverse events	PrEP vs placebo/delayed PrEP/No PrEP	4 RCTs	10563	0.8-1.25	RR 1.25 (0.99-1.59)	Not Serious	Not Serious	Not Serious	Serious[2]	Moderate
Fracture	PrEP vs placebo/delayed PrEP/No PrEP	8 RCTs	15241	0.8-1.25	RR 1.23 (0.97-1.56)	Not Serious	Not Serious	Not Serious	Serious[2]	Moderate
Renal Adverse events	PrEP vs placebo/delayed PrEP/No PrEP	12 RCTs	18170	0.8-1.25	RR 1.43 (1.18-1.75)	Not Serious	Not Serious	Not Serious	Serious[2]	Moderate
Gastrointestinal events	PrEP vs placebo/delayed PrEP/No PrEP	12 RCTs	18300	0.8-1.25	RR 1.63 (1.26 – 2.11)	Not Serious	Not Serious	Serious[3]	Not Serious	Moderate
Syphilis	PrEP vs placebo/delayed PrEP/No PrEP	4 RCTs	10775	0.8-1.25	RR 1.08 (0.98 – 1.18)	Not Serious	Not Serious	Not Serious	Not Serious	High

Gonorrhoea	PrEP vs placebo/delayed PrEP/No PrEP	5 RCTs	9296	0.8-1.25	RR1.07 (0.82-1.39)	Not Serious	Not Serious	Serious[3]	Serious[2]	Low
Chlamydia	PrEP vs placebo/delayed PrEP/No PrEP	5 RCTs	9296	0.8-1.25	RR 0.97 (0.80-1.18)	Not Serious	Not serious	Serious[3]	Serious[2]	Low
Herpes simplex virus	PrEP vs placebo/delayed PrEP/No PrEP	3 RCTs	4103	0.8-1.25	RR 0.85 (0.67-1.07)	Not Serious	Not Serious	Not Serious	Serious[2]	Moderate
Hepatitis C virus	PrEP vs placebo/delayed PrEP/No PrEP	2 RCTs	896	0.8-1.25	RR 0.73 (0.25 – 2.10)	Serious[4]	Not Serious	Not Serious	Very serious[5]	Very Low
	1. I^2 >66.7% - rated down twice for high inconsistency 2. 95% CI crosses the MID at one end – rated down once 3. I^2 between 33.3% and 66.7% - rated down once for inconsistency 4. More than 33.3% of studies in analysis comes from studies at moderate risk of bias – rated down once 5. 95% CI crosses the MID at both ends – rated down twice									

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Outcome	Intervention vs comparator	No of studies	Sample size	Narrative summary	Risk of bias	Indirectness	Inconsistency	Imprecision	Confidence
Condom use	PrEP vs placebo/delayed	8 RCTs and 1	14,063	Evidence from 5 placebo controlled RCTs (n= 11457), 2	Not Serious	Not Serious	Serious[1]	Very serious[2]	Very Low

	PrEP/No PrEP	cohort study		RCTs comparing PrEP with delayed/no PrEP arms (n=458) and 1 cohort study comparing PrEP with no PrEP (15 n=1603) found no differences in any self-reported condom use between PrEP and placebo /delayed/no PrEP arms. 1 RCT comparing PrEP with delayed PrEP (n=545) found 21% of participants taking PrEP reported receptive anal sex without a condom with ten or more partners compared to 12% in the delayed PrEP arm.					
Sexual partners	PrEP vs placebo/delayed PrEP/No PrEP	8 RCTs and 1 cohort study	15,554	Evidence from 8 RCTs and 1 cohort study comparing PrEP with no PrEP found no differences in self-reported number of sex partners between PrEP and placebo/ delayed/ no PrEP arms.	Not Serious	Not Serious	Not Serious	Very serious[2]	Low
	1. Although most studies present consistent findings, 1 study has a conflicting outcome – rated down once. 2. Effect estimates with confidence intervals not given - rated down twice.								

GRADE CERQual tables

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
Knowledge of PrEP and information sources						
Participants commented on how much they already knew about PrEP. Knowledge levels were high amongst MSM: almost all had at least heard of PrEP and were aware of what it is, although there was some confusion over the differences between PrEP and PEP. Knowledge levels were lower for women. Transgender women had often heard of PrEP but had not been given any information about it, whereas many cisgender women had not heard of PrEP at all.	Auerbach 2015 Cahill 2020 Collier 2017 Klassen 2017 Knight 2016 Mutchler 2015 Nydegger 2020 Nydegger 2021 Park 2019 Pasipanodya 2021 Pyra 2021 Rowniak 2017 Santa Maria 2019 Sevelius 2016 Wood 2017	No concerns	Minor concerns[3]	Minor concerns[5]	No concerns	Moderate
Participants expressed a desire for more information on PrEP. Many had questions to ask and misconceptions to clarify. Their questions were often on how to take it, what the risks are, what research has been done. Some women expressed annoyance that they had not had access to information on PrEP. They felt that they should have been told about it if they were at risk and that healthcare professionals had a responsibility to inform them.	Auerbach 2015 Bond 2016 Collier 2017 D'Angelo 2021 Grace 2018 Hess 2019 Klassen 2017 Mutchler 2015 Newman 2018 Nydegger 2021 Pasipanodya 2021	No concerns	Minor concerns[3]	No concerns	No concerns	Moderate

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
	Pyra 2021 Rowniak 2017 Santa Maria 2019 Sevelius 2016 Watson 2020 Wood 2017					
Sharing knowledge within communities was valued. MSM stated that a lot of their knowledge of PrEP came from peers within the community. HIV positive men were mentioned as being advocates of PrEP for others. Participants from all groups were keen to spread awareness to others in their community and to advocate for wider PrEP use.	Auerbach 2015 Brooks 2019 Cahill 2020 Frankis 2016 Grace 2018 Harrington 2020 Hess 2019 Hillis 2021 Klassen 2017 Klein 2019 Mutchler 2015 Newman 2018 Nydegger 2021 Park 2019 Pasipanodya 2021 Pyra 2021 Rowniak 2017 Witzel 2019 Wood 2017 Young 2016	No concerns	No concerns	No concerns	No concerns	High
Views and opinions on the value of PrEP						
Many participants saw prep as a liberating experience.	Auerbach 2015 Bil 2016	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
It has allowed them to pursue relationships and sex without the fear of HIV. They described how fear and worry after unprotected sex had impacted their wellbeing and mental health, so they highly valued the reassurance PrEP provides. MSM in particular described feeling liberated from the threat of HIV and able to have sex without their actions being constrained.	Bond 2016 Gafos 2019 Grace 2018 Harrington 2020 Jaspal 2016 Martinez-Lacabe 2018 Mutchler 2015 Newman 2018 Nydegger 2021 O'Halloran 2019 Philpot 2020 Watson 2020 Wood 2017					
Participants talked about PrEP as a way to take control of their health. They often described taking control in this way as being empowering. Many saw PrEP use as sign that a person is being responsible and conscientious by making a choice to take care of themselves. Cisgender women in particular valued having a prevention strategy they alone could control, regardless of their partners choices.	Bond 2016 Brooks 2019 Collier 2017 D'Angelo 2021 Gafos 2019 Goparaju 2017 Grace 2018 Jaspal 2016 Knight 2016 Martinez-Lacabe 2018 Mutchler 2015 Nydegger 2021 O'Halloran 2019 Pasipanodya 2021 Philpot 2020	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
	Pyra 2021 Sevelius 2016 Watson 2020 Williamson 2019 Witzel 2018 Witzel 2019 Wood 2017					
PrEP was seen my many as being for MSM, at the expense of other demographics. Many women felt that they were sidelined by Prep information and services targeted towards gay men which perpetuated a myth that they were not at risk. For transgender women this also meant that they were more likely to be misgendered and treated as if they were MSM when using these services. This reflects and reinforces common transphobic tropes that suggest transgender women aren't truly women. Conversely, transgender MSM were often assumed to be heterosexual and therefore misrepresented as not being in a demographic that requires PrEP.	Auerbach 2015 Bond 2016 Cahill 2020 Goparaju 2017 Klein 2019 Knight 2016 Nydegger 2021 Park 2019 Pasipanodya 2021 Pyra 2021 Rael 2018 Rael 2020 Rowniak 2017 Sevelius 2016 Watson 2020	No concerns	Moderate concerns[4]	No concerns	No concerns	Moderate
Participants commented that using PrEP is a prosocial action. They placed value on how it protects others and could reduce the spread of HIV which would benefit everyone.	Auerbach 2015 Bil 2016 Collier 2017 Grace 2018 Harrington 2020	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
MSM and transgender women claimed this was a very positive development for the LGBTQ community as a whole, as well as individual users.	Klassen 2017 Klein 2019 Knight 2016 Martinez-Lacabe 2018 Mutchler 2015 Philpot 2020 Reyniers 2021 Wood 2017					
The level of protection offered by PrEP						
The majority of participants saw PrEP as an extra layer of protection on top other methods. They did not consider it to be a full replacement for their existing safe sex practices. Most of these said they would use PrEP in conjunction with condoms. A smaller number of MSM considered PrEP to be sufficient protection on its own, so they would swap other protection methods for PrEP if they were to use it. Some MSM were ambivalent to other protection as they felt sufficiently protected by PrEP, so considered anything else to be for their partners protection: They did not feel the need to contribute to the decision.	Auerbach 2015 Bil 2016 Brooks 2019 Collier 2017 D'Angelo 2021 Frankis 2016 Gafos 2019 Harrington 2020 Hillis 2021 Jaspal 2016 Martinez-Lacabe 2018 Mutchler 2015 O'Halloran 2019 Park 2019 Philpot 2020 Rael 2018 Rowniak 2017 Vaccher 2018 Williamson 2019	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
	Wood 2017 Young 2014					
Participants held varied opinions about condoms. Many participants stated that they prefer sex without a condom. They described it feeling more pleasurable, more natural, and more spontaneous. Some participants avoided condoms because of this preference, while others still used them because they valued the protection more. Conversely some participants felt that condoms were the safest option available and so would prefer to use them. They commented that PrEP is not needed if condoms are used. One participant found condoms difficult to use due to a physical disability, so was glad to have a more accessible alternative.	Auerbach 2015 Bil 2016 Bond 2016 Collier 2017 Gafos 2019 Grace 2018 Harrington 2020 Hess 2019 Jaspal 2016 Knight 2016 Martinez-Lacabe 2018 Mutchler 2015 Newman 2018 Philpot 2020 Reyniers 2021 Williamson 2019 Wood 2017 Young 2016 Zimmermann 2019	No concerns	No concerns	No concerns	No concerns	High
Many participants were concerned about contracting other STIs. PrEP would not protect against these, so they saw PrEP as having limited value. Some also commented that PrEP would not	Auerbach 2015 Bil 2016 Brooks 2019 Cahill 2020 Gafos 2019 Hillis 2021	No concerns	No concerns	Minor concerns[5]	No concerns	Moderate

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
protect their partner against contracting STIs from them. Other participants, mostly MSM, saw HIV is the biggest concern. They considered all other STIs to be treatable, therefore preventing them was not a priority. For transgender men the biggest priority was to protect against unwanted pregnancy, which would be extremely distressing for them. Condoms offered the protection they needed for this purpose and also for preventing HIV, so PrEP had fewer advantages for this group.	Knight 2016 Martinez-Lacabe 2018 Mutchler 2015 Newman 2018 Pasipanodya 2021 Philpot 2020 Rowniak 2017 Watson 2020 Young 2014					
Perception of the risk of contracting HIV						
Participants reflected on their current risk status. They described their interest in PrEP in terms of their circumstances and behaviour. Many participants were considered their risk status to be high enough to warrant adopting PrEP. Others considered themselves to be low risk at present, so felt that PrEP would not provide a lot of benefit to them.	Bil 2016 Brooks 2019 D'Angelo 2021 Frankis 2016 Gafos 2019 Harrington 2020 Hess 2019 Hillis 2021 Jaspal 2016 Martinez-Lacabe 2018 Mutchler 2015 Newman 2018 Nydegger 2021 Pasipanodya	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
	2021 Pyra 2021 Santa Maria 2019 Wood 2017 Young 2014 Zimmermann 2019					
Poor adherence to condoms was a prevalent concern. Participants described varied and inconsistent condom use in their sexual history, even amongst participants who expressed a strong preference for them. Many MSM talked of 'slip ups' and poor judgement in the heat of the moment. MSM also explained how their condom use is often dependent of the type of sexual activity they are engaging in and whether they are the active or receptive partner. They felt these factors affected how much risk they were exposed to so their willingness to use a condom was based on this assessment.	Bil 2016 Brooks 2019 Frankis 2016 Gafos 2019 Harrington 2020 Jaspal 2016 Newman 2018 Park 2019 Pasipanodya 2021	No concerns	No concerns	Minor concerns[5]	No concerns	High
Participants described situations they considered to be particularly high risk for HIV transmission. These included 'chem-sex' parties where groups of MSM engage in sex under the	Brooks 2019 Cahill 2020 Frankis 2016 Gafos 2019 Harrington 2020	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
influence of illegal drugs. Women also described taking more risks when using drugs and alcohol. Episodes of poor mental health was also highlighted as contributing to risk taking sexual behaviour. Some MSM described certain geographical locations as being hubs for transmission. Cities with large LGBTQ communities such as Brighton and Manchester were mentioned. MSM claimed that they would feel less safe seeking sexual partners in these locations than in more smaller towns.	Jaspal 2016 Klassen 2017 Martinez-Lacabe 2018 Mutchler 2015 Nydegger 2020 Nydegger 2021 Pasipanodya 2021 Vaccher 2018 Williamson 2019 Zimmermann 2019					
Participants often assessed risk of HIV based on the person they were having sex with. Many MSM based this assessment on whether they had one monogamous partner or multiple casual partners. They felt that PrEP was unnecessary if they were only having sex with one person they believed to be HIV negative. PrEP was welcomed by many participants as a positive way for serodiscordant couples to mitigate a known risk. MSM in serodiscordant relationships explained that the precautions they took were determined by whether their partner's viral load was detectable.	Bil 2016 Bond 2016 D'Angelo 2021 Frankis 2016 Gafos 2019 Grace 2018 Hess 2019 Klassen 2017 Knight 2016 Martinez-Lacabe 2018 Mutchler 2015 Newman 2018 Nydegger 2021 Park 2019	No concerns	No concerns	Moderate concerns[6]	No concerns	Moderate

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
Participants from all groups referred to whether they trusted their sexual partners as a risk factor. This included trust that they were truthful about their HIV status, that were adhering to medication if they were HIV positive or on PrEP if they were negative, that they were not having sex with other people or that they were having safe sex with others.	Pasipanodya 2021 Philpot 2020 Rowniak 2017 Santa Maria 2019 Sevelius 2016 Williamson 2019 Young 2014 Young 2016 Zimmermann 2019					
Transgender and Cisgender women reported that they often had limited choices in sexual situations, so they did not have full control over what risks they were exposed to. Participants who were in abusive relationships explained that they didn't have the power to negotiate condom use with their partner, or often the power to refuse sex. They were also at risk of HIV and other STIs spread by their partners sleeping with other people. Transgender women in particular felt they were treated as low value sexual partners, so were expected to have sex under the terms that a partner wanted rather than to	Auerbach 2015 Bond 2016 Brooks 2019 Cahill 2020 Collier 2017 D'Angelo 2021 Goparaju 2017 Klein 2019 Nydegger 2020 Park 2019 Pasipanodya 2021 Rael 2018 Santa Maria 2019 Sevelius 2016	No concerns	Moderate concerns[4]	Minor concerns[5]	No concerns	Low

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
advocate for their own needs. They reported that partners often became violent if there was disagreement. Some women, particularly transgender women, engaged in survival sex work, so were not able to negotiate condom use, as they would lose clients or be paid less. Being dependent on income from sex work meant that they assessed the risk of contracting HIV against the more immediate consequences of poverty.	Wood 2017					
Social context of PrEP decisions						
People with low socioeconomic status described how PrEP was not a high priority for them. Other pressures and life events interfered or had a bigger impact on their wellbeing. Many felt that they could not afford to take time off work to attend additional medical appointments, or had childcare and other caring responsibilities to attend to that meant they missed appointments. Transgender men and women felt that their employment was precarious due to transphobia so they could not ask for time off without risking their job. Trans and non-binary participants discussed how financial incentives could improve access to PrEP by mitigating some socioeconomic barriers. Women in one study reported violence in their community being a greater threat to their health. Many of these women had	Auerbach 2015 Cahill 2020 D'Angelo 2021 Nydegger 2020 Nydegger 2021 Pasipanodya 2021 Poteat 2019 Pyra 2021 Rowniak 2017 Santa Maria 2019 Sevelius 2016 Watson 2020 Wood 2017	No concerns	Moderate concerns[4]	Minor concerns[5]	No concerns	Low

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
been injured or had a loved one injured or killed recently. Some participants reported having substance addictions and mental health issues that had a larger impact on their wellbeing, as well as making it harder to prioritise accessing healthcare and harder to adhere to PrEP.						
Social support was cited by some participants as a facilitator to PrEP use. Transgender women gave examples of family and friends supporting their choice and encouraging them to protect their health. Participants felt this support motivated them to maintain regular adherence to PrEP. Conversely, cultural barriers can make it harder to access and adhere to PrEP. Black participants described how homosexuality was less accepted in some communities so talking about PrEP would be socially unacceptable. Some Black women had experienced friends trying to talk them out of taking PrEP. They also stated that they would find it more difficult to visit a clinic in their community as they would feel judged. Participants in recent studies observed that as awareness of PrEP has increased in the general population over the last few years they have felt greater support and acceptance.	Brooks 2019 D'Angelo 2021 Goparaju 2017 Nydegger 2021 Pasipanodya 2021 Pyra 2021 Reyniers 2021 Santa Maria 2019 Vaccher 2018 Witzel 2018 Witzel 2019 Young 2014 Young 2016	No concerns	No concerns	Minor concerns[5]	No concerns	Moderate

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
Some participants described how marginalisation can be intersectional. This affected their experiences with PrEP and their feelings about the risk of HIV. Black MSM felt that they were often marginalised by a racial divide within the LGBTQ community. This meant that they did not access the same networks of information and support that white MSM used to access PrEP. Some transgender participants felt that PrEP advertising and awareness campaigns often focus on MSM and give less consideration to transgender people. They described attempts that have been made to include transgender women in these campaigns which have failed to represent the transgender community accurately. This lack of understanding of the diversity of presentations has alienated some transgender people.	Hillis 2021 Klein 2019 Nydegger 2021 Witzel 2018 Witzel 2019	Minor concerns[1]	Minor concerns[3]	Minor concerns[5]	Minor concerns[7]	Moderate
Opinions on taking PrEP medication						
Participants questioned whether PrEP is effective and reliable enough. Many quoted percentages they would consider acceptable risk, but there was no consensus among them.	Auerbach 2015 Bil 2016 Jaspal 2016 Martinez-Lacabe 2018 Mutchler 2015	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
Some participants required complete certainty and viewed any risk of contracting HIV while on PrEP as too high. Others felt that any increase protection is worth having, particularly if used in combination with other methods to provide the best possible protection.	Pasipandoya 2021 Philpot 2020 Wood 2017 Young 2014 Young 2016					
Known and unknown side effects were a prevalent concern. Many participants were worried about possible serious side effects that have been highlighted in clinical trials of PrEP.. Most commonly mentioned were problems with the liver, kidneys and reduction in bone density. PrEP users described the side effects they had personally experienced, including diarrhoea, insomnia, nausea, and headaches. Some participants stopped taking PrEP because they found these side effects intolerable. Many PrEP naïve participants found these side effects (particularly diarrhoea) discouraging, even if they were likely to be short term. Some participants were concerned that PrEP might interact with other medications such as antidepressants and contraceptives or other medical conditions such as diabetes. Transgender people questioned whether PrEP could interact with hormones and other medications they were taking as part	Zimmermann 2019 Young 2014 Williamson 2019 Watson 2020 Vaccher 2018 Sevelius 2016 Santa Maria 2019 Rowniak 2017 Rael 2020 Rael 2018 Pyra 2021 Philpot 2020 Pasipanodya 2021 Park 2019 Newman 2018 Mutchler 2015 Jaspal 2016 Hillis 2021 Hess 2019 Girard 2018 Cahill 2020 Bond 2016 Bil 2016 Auerbach 2015	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
of their transition. Most considered their transition to be the priority, so if PreP were to interfere it would be a deal breaker issue.						
Participants were concerned that PrEP was a new drug and so the effects may not be fully understood yet. Some participants said they did not want to be treated as 'guinea pigs', so were reluctant to try it until it had been tested more thoroughly and established. Some women were concerned that PrEP had only been tested on men, white people or cisgender people. They felt that research needed to be conducted on the full range of people who would be eligible for PrEP. Transgender women in particular commented that their bodies had a distinct physiology from those of cisgender people, and that research often fails to address this. Some cisgender women questioned whether PrEP was suitable for children and young people as they noted that research studies only included participants over the age 18. They were concerned that this lack of evidence might preclude under 18s from accessing PrEP.	Auerbach 2015 Bil 2016 Girard 2018 Goparaju 2017 Hess 2019 Hillis 2021 Pasipanodya 2021 Rael 2018 Rael 2020 Rowniak 2017 Watson 2020	Minor concerns[1]	Minor concerns[3]	Minor concerns[5]	No concerns	Moderate
Participants found the need for regular medical appointments and tests to be a barrier to using PrEP. Some transgender women further explained that the frequent medical appointments required for their	Bil 2016 Bond 2016 Collier 2017 Hillis 2021 Pasipanodya 2021	No concerns	Minor concerns[3]	Moderate concerns[6]	No concerns	Low

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
transition were already burdensome and uncomfortable for them. Participants who were already using other medications and were often reluctant to add another pill to their regime.	Rael 2018 Rael 2020 Rowniak 2017 Santa Maria 2019 Sevelius 2016 Zimmermann 2019					
Transgender and cisgender women discussed what delivery method they would prefer to use to take PrEP. Some women preferred injectable PrEP: Transgender women preferred it for the convenience and because they were accustomed to hormone injections. Cisgender women preferred it as it felt like a vaccination which they considered more discreet. Some participants had a fear of needles so would not be willing to use injectable PrEP. Several participants also expressed a strong dislike of taking pills, whereas others did not mind them.	Auerbach 2015 Cahill 2020 Collier 2017 Pyra 2021 Rael 2018 Rael 2020 Wood 2017	Minor concerns[1]	Moderate concerns[4]	No concerns	No concerns	Low
Practicalities of taking PrEP						
Participants identified their thought processes when starting and stopping PrEP. When starting PrEP, many participants ruminated on the decision before	Auerbach 2015 Bil 2016 Bond 2016 Newman 2018 Park 2019 Young 2014	Minor concerns[1]	Minor concerns[3]	Moderate concerns[6]	No concerns	Low

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
committing to it. Some chose to mark the occasion of starting with a selfie to share it as news of a positive life change. Participants who stopped taking PrEP explained that they either felt they were not getting enough benefit so chose to stop, or circumstances prevented them from taking PrEP for a short time and they did not restart.						
Participants described the actions they took to maintain regular adherence to taking PrEP and the barriers that made it harder adhere. These barriers included forgetting or not having a routine, sleeping in different places and not carrying PrEP with them, and having to hide their pills from others.	Auerbach 2015 Bil 2016 Collier 2017 D'Angelo 2021 Hillis 2021 Newman 2018 Nydegger 2020 Pasipandoya 2021 Pyra 2021 Rael 2020 Santa Maria 2019 Sevelius 2016 Vaccher 2018 Wood 2017 Young 2014 Zimmermann 2019	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
Participants discussed whether they preferred continuous or intermittent PrEP regimens. People who preferred continuous PrEP liked that they could establish a habit and that they were always protected. People who preferred intermittent PrEP like that they were only medicating when they needed to and that they had fewer side effects. Other people claimed that they could not predict when they would be having sex, so intermittent was not suitable for them.	Bil 2016 Hillis 2021 Klassen 2017 Knight 2016 Vaccher 2018 Young 2014 Zimmermann 2019	No concerns	No concerns	No concerns	No concerns	High
Influence of healthcare settings						
Healthcare professionals' reactions to participants seeking PrEP can act as barriers or facilitators to PrEP use. Participants who had positive experiences placed a lot of value in advice from their clinicians. Participants who felt judged or uncomfortable talking to healthcare professionals found it harder to discuss PrEP. Some participants reported poor understanding and misinformation from clinicians. They cited examples of clinicians not understanding the sexual practices of MSM and transgender women.	Auerbach 2015 Cahill 2020 Collier 2017 Goparaju 2017 Grace 2018 Hess 2019 Hillis 2021 Klassen 2017 Klein 2019 Martinez-Lacabe 2018 Newman 2018 Nydegger 2021 O'Halloran 2019 Park 2019 Pyra 2021 Rowniak 2017 Sevelius 2016	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
	Vaccher 2018 Watson 2020 Witzel 2018					
Participants discussed which parts of the health service are best placed to provide PrEP. Some preferred sexual health clinics for their specialist services, whereas others found GPs to be more accessible and private. Some participants described problems with obtaining PrEP through pharmacies.	Bil 2016 Goparaju 2017 Hillis 2021 Park 2019 Vaccher 2018 Young 2016	No concerns	Minor concerns[3]	Minor concerns[5]	No concerns	Moderate
Participants from all groups suggested ways that services could be tailored to their needs. Black people described wanting understanding of cultural barriers and clinics that provided some distance from their communities for confidentiality reasons. Cisgender women suggested that gynaecologists and womens' sexual health clinics would their preferred option. Transgender people wanted clinicians with an understanding of wider transgender healthcare needs to be able to offer holistic support and understand their specific concerns. Participants who had a good relationship with their existing healthcare	Auerbach 2015 Cahill 2020 D'Angelo 2021 Goparaju 2017 Hillis 2021 Klassen 2017 Klein 2019 Newman 2018 Park 2019 Poteat 2019 Pyra 2021 Rowniak 2017 Sevelius 2016 Witzel 2018 Watson 2020 Wood 2017	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
provider were keen to access PrEP from them rather than using an unknown service. MSM described feeling more comfortable accessing PrEP from services targeted at the LGBTQ community. Participants from other demographics also praised these services.						
Consequences of using PrEP						
Most participants speculated that risk taking behaviour might change when taking PrEP. Many expected they would use less protection of have more partners. Some PrEP users confirmed this was their experience but many did not find that their sexual behaviour changed greatly. MSM commented that they expected or witnessed other people's behaviour changing when taking PrEP. They overwhelmingly commented on others' taking more risks and having more partners. They also observed that some PrEP users advertised their PrEP use on social media to indicate they were available for casual sex. Several participants had experienced sexual partners now pressuring them to have sex without a condom because one or both of them were on PrEP.	Auerbach 2015 Bil 2016 Bond 2016 Brooks 2019 Collier 2017 Gafos 2019 Harrington 2020 Hess 2019 Hillis 2021 Jaspal 2016 Knight 2016 Mutchler 2015 Newman 2018 O'Halloran 2019 Pasipandoya 2021 Philpot 2020 Reyniers 2021 Sevelius 2016 Watson 202 Williamson 2019 Young 2014 Zimmermann 2019	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
Some PrEP users stated that they have declined or ended sex when a partner asked to use a condom.						
Some MSM were more open to dating or having sex with HIV positive men while taking PrEP. They also found it easier to talk about HIV status with prospective partners, as they felt it would be less of an issue if they were protected. They suggested this might help to reduce stigma of HIV and improve the status of HIV positive men within the LGBTQ community.	Bil 2016 Gafos 2019 Grace 2018 Martinez-Lacabe 2018 Mutchler 2015 Philpot 2020	No concerns	No concerns	No concerns	No concerns	High
Some participants worried that their PrEP use might put them at risk in other aspect of their lives. Some transgender women worried that they would be 'outed' by allowing people to find out they are trans as a result of accessing PrEP services. This can be distressing in itself and can also expose them transphobia and sometimes violence. Women with abusive partners were afraid of how their partner would react if they found out they were using PrEP. Their partner might infer that they were having sex with other people or that they didn't trust them. Some women commented that their partners may become violent if this happened.	Auerbach 2015 Brooks 2019 D'Angelo 2021 Goparaju 2017 Nydegger 2020 Reyniers 2021 Sevelius 2016	No concerns	Moderate concerns[4]	Moderate concerns[6]	No concerns	Low
Stigma surrounding PrEP use						

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
Almost all participants mentioned the stereotype of PrEP users as promiscuous. Several participants referred to the phrase 'truvada whore' as being a well-known insult amongst MSM. Some MSM expressed agreement with these views and felt the stigma was justified. Many participants wanted to distance themselves from the stereotype by either refusing PrEP or by being a PrEP user who doesn't fit these expectations. Black MSM commented this this stigma was particularly problematic for them, as the LGBTQ community already held hypersexualised racial stereotypes of Black men.	Brooks 2019 D'Angelo 2021 Goparaju 2017 Grace 2018 Hillis 2021 Jaspal 2016 Klassen 2017 Knight 2016 Mutchler 2015 Newman 2018 O'Halloran 2019 Pasipandoya 2021 Philpot 2020 Rael 2018 Reyniers 2021 Sevelius 2016 Williamson 2019 Witzel 2018 Witzel 2019 Young 2014	No concerns	No concerns	No concerns	No concerns	High
Some participants commented that they had been mistaken for being HIV positive due to using PrEP. This meant that the wider stigma of HIV was applied to them. Even without the misunderstanding that PrEP is preventative rather than treatment, participants reported that just the association with HIV and	Auerbach 2015 Bond 2016 Brooks 2019 Collier 2017 Goparaju 2017 Grace 2018 Jaspal 2016	No concerns	No concerns	No concerns	No concerns	High

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
needing to prevent it was enough to be stigmatised. Transgender women described a specific set of assumptions that they felt people applied to them. They reported that they were often assumed to be HIV positive regardless of PrEP use, or that they will inevitably contract HIV at some point. Some had experienced transphobia based on the accusation that they were spreading HIV.	Klassen 2017 Mutchler 2015 O'Halloran 2019 Pyra 2021 Rael 2018 Reyniers 2021 Rowniak 2017 Santa Maria 2019 Sevelius 2016 Vaccher 2018 Witzel 2018 Young 2014 Young 2016					
Some participants preferred not to disclose their PrEP use to others. Some saw PrEP as an aspect of sexuality therefore something that should be kept private and some felt that they would face judgement and stigma if people knew. They described the actions they would take to hide their pills and the fear that someone might find them. This concern was enough to make some participants reluctant to use PrEP. Some participants who did disclose their PrEP use reported experiencing hostility or rejection from sexual partners or friends and	Auerbach 2015 Brooks 2019 Goparaju 2017 Grace 2018 Hess 2019 Mutchler 2015 Newman 2018 Pasipanodya 2021 Rael 2018 Reyniers 2021 Sevelius 2016 Vaccher 2018 Williamson 2019	No concerns	No concerns	Minor concerns[5]	No concerns	Moderate

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
family. They felt that PreP was not a socially acceptable choice.	Witzel 2018 Young 2014 Young 2016					
Principles and wider implications						
Some participants did not trust healthcare, pharmaceutical manufacturers, medical research or the government. They were wary of PrEP as a result of this general mistrust. Some MSM and transgender people referred to how the AIDS crisis was handled early on as a reason to be wary of more recent developments. they had been left with that feeling that the authorities did not care about the wellbeing of LGBTQ people. Some Black participants cited sexual health research that had abused and exploited Black communities as the basis for their mistrust, such as the Tuskegee syphilis study.	Auerbach 2015 Bil 2016 Cahill 2020 D'Angelo 2021 Girard 2018 Harrington 2020 Hess 2019 Jaspal 2016 Mutchler 2015 Nydegger 2021 Poteat 2019 Pasipanodya 2021 Rowniak 2017 Santa Maria 2019 Watson 2020 Williamson 2019 Young 2014 Young 2016	No concerns	No concerns	No concerns	No concerns	High

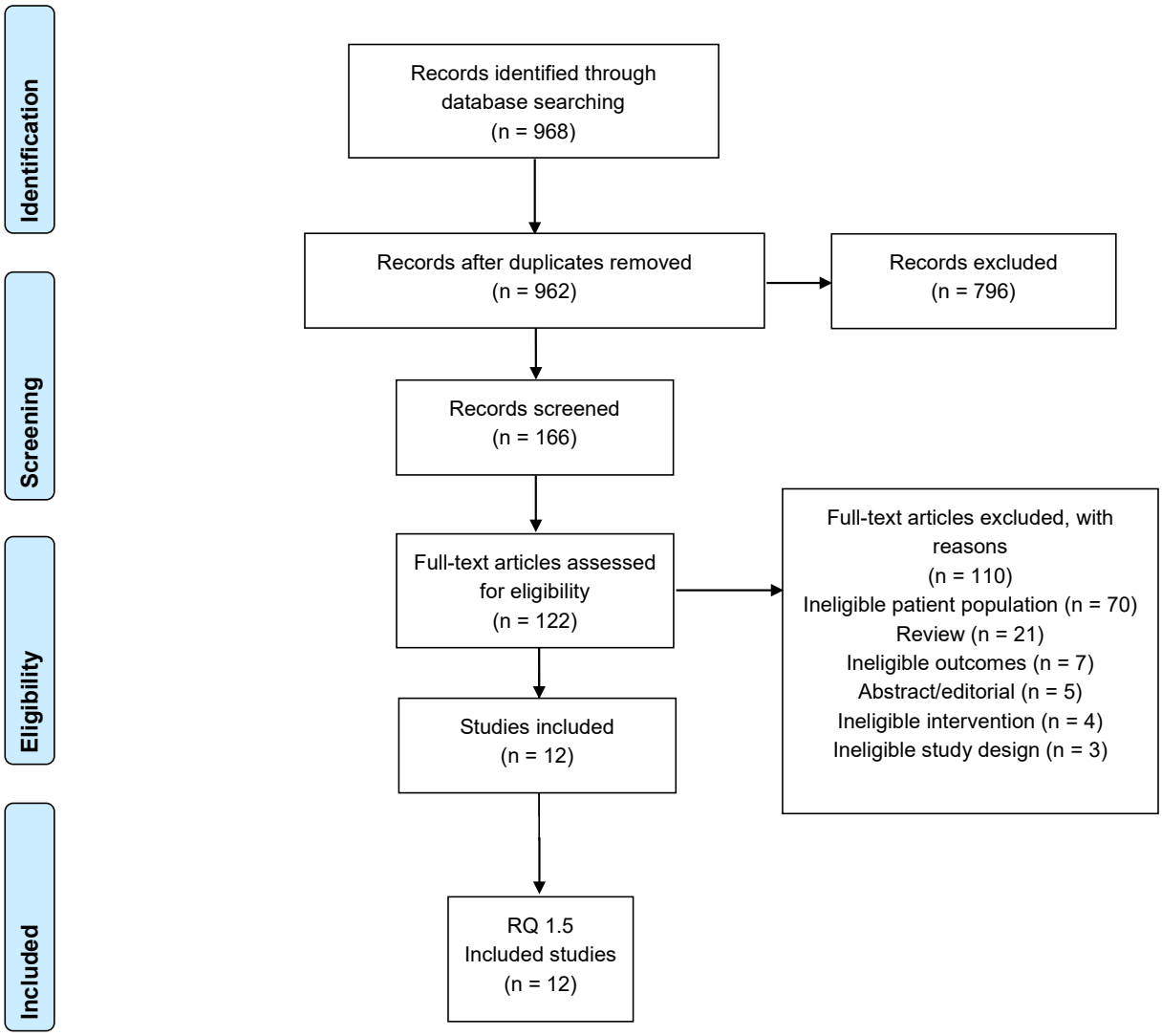
Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
Participants objected to the medicalisation involved in HIV prevention. Some MSM rejected the idea of medicalising their sexuality. They resented the association of gay sex with disease, and felt that introducing a medication as a prerequisite for sex reinforced that notion. They saw PrEP as something unnatural that damages an otherwise healthy body, therefore they disagreed with the implication that they ought to take it to make them a safe sexual partner. Some MSM felt more comfortable conceiving of PrEP as a recreational drug that allowed them to indulge in sex without condoms, rather than a medication required for safety. Transgender women objected to the focus placed on preventing HIV. They contrasted the emphasis of PrEP campaigns with the difficulties they faced trying to access gender affirming medication. They felt that instead of being offered the comprehensive healthcare they need, they were seen primarily as vectors for disease. Black people also felt that they were being targeted for HIV campaigns to prevent the spread of HIV as a benefit to others, while their other healthcare needs were neglected.	Bil 2016 Bond 2016 Girard 2018 Hess 2019 Jaspal 2016 Knight 2016 Martinez-Lacabe 2018 Park 2019 Philpot 2020 Poteat 2019 Sevelius 2016 Vaccher 2018 Williamson 2019 Zimmermann 2019	No concerns	No concerns	Minor concerns[5]	No concerns	Moderate

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
Cisgender women commented that PrEP added to the unfair burden placed on women to accept invasive medical interventions for sexual health. They objected to their bodies being medicalised with hormonal or implanted contraceptives, and now also PrEP, while their male partners did not make an equal contribution to their shared protection.						
Some MSM expressed discomfort with how the concept of 'safe sex' could change as a result of widespread PrEP uptake. They felt that wanting to use condoms was an accepted expectation amongst MSM negotiating sex, but PrEP introduced ambiguity and confusion. They were concerned that a cultural shift in what is expected would be a change for the worse and they criticised those who advocate it. Conversely some MSM felt that PrEP had the potential to close the divide between HIV positive and negative men in the LGBTQ community by enabling both groups to take an equal share of the responsibility for reducing transmission. They felt that PrEP in combination with HIV treatments that result in undetectability could lead to a cultural change in favour of less emphasis being placed on sero-status.	Bond 2016 Collier 2017 Girard 2018 Harrington 2020 Hess 2019 Knight 2016 Martinez-Lacabe 2018 Mutchler 2015 Philpot 2020 Vaccher 2018 Williamson 2019 Young 2014	No concerns	No concerns	Minor concerns[5]	No concerns	Moderate

Summary of review finding	Studies	Methodological limitations	Relevance	Coherence	Adequacy	Confidence
Some MSM saw access to PrEP as a matter of LGBTQ rights. They felt that most negative perceptions of PrEP were fundamentally homophobic. Other MSM described how stereotypes of PrEP users may reinforce these homophobic narratives. They were concerned about the implications of PrEP on how the LGBTQ community is perceived by wider society.	Grace 2018 Harrington 2020 Klassen 2017 Knight 2016 Martinez-Lacabe 2018 Pasipanodya 2021 Reyniers 2021 Vaccher 2018 Williamson 2019 Young 2016	No concerns	No concerns	No concerns	No concerns	High

1. Finding was downgraded once because it was identified mainly in studies at moderate or high risk of bias
2. Finding was downgraded twice because it was identified mainly in studies at high risk of bias
3. Finding was downgraded once because it was identified mainly in studies that were indirectly or partially relevant
4. Finding was downgraded twice because it was identified mainly in studies that were partially relevant
5. Finding was downgraded once for coherence because the theme did not emerge from all relevant studies, findings were somewhat conflicting, or there was little convincing theoretical explanation
6. Finding me was downgraded twice for coherence because the theme did not emerge from all relevant studies, findings were directly conflicting, or there was no convincing theoretical explanation
7. Finding was downgraded once for adequacy because of insufficient studies (fewer than 3) or insufficient detail
8. Finding was downgraded twice for adequacy because of both insufficient studies (fewer than 3) and insufficient detail

Appendix H Economic evidence study selection



Appendix I Economic evidence tables

Cambiano (2018)						
Study	**Method of Analysis**	**Costs**	**Outcomes**	**Results**	**Limitations**	**Comments**
Study type: Cost utility model to compare the cost effectiveness of event-based PrEP among GBMSM attending GUM clinics in the UK **Country:** UK **Population:** GBMSM if they had a negative HIV test at PrEP initiation; they had reported condomless anal sexual intercourse in the previous three months (unless the only partner they had condomless sex with was a long-term partner virologically suppressed on ART); and they had an additional documented negative HIV test in the preceding year	**Perspective:** UK NHS **Time horizon:** 80 years **Discounting:** 3.5% costs 3.5% effects **Data sources** **Costs:** BNF, eMIT, Integrated Sexual Health Tariff, a FOI request and assumptions **Effects:** PROUD trial [a] Public Health England Surveillance data; Natsal-3 survey, assumptions 86% PrEP effectiveness assumed (PROUD trial) **Utilities:** Publications [a, b]	**Mean annual cost of PrEP, £:** 4331 **Probabilistic results** **No PrEP (£ million)** 20,640 (range: 11,080 to 36,320) **PrEP (£ million)** 19,630 (range: 11,390 to 33,690) **Currency & cost year:** GB£; year NR	**Probabilistic results** **Cumulative mean number of HIV infections:** PrEP: 178,900 (range: 81,100 to 323,300) No PrEP: 134,600 (range: 61700 to 264,300) Difference: 44300 (range: 3,300 to 97,600) (25%) **Discounted QALYs (thousands)** PrEP: 18,410 (range: 18,330 to 18,450) No PrEP: 18,450 (range: 18360 to 18,510) Gain: 40 (range: 4 to 70)	**Probabilistic results** **NMB (£ million):** 1490 (range: -1360 to 6580) **PSA** The probability of a PrEP programme being cost-effective is greater than 80% at a threshold of £20,000 per QALY gained (around 75% at £13,000 per QALY gained) Costs increase for 20 years and it takes 40 years for the ICER per QALY gained to fall below £13,000 **Uncertainty:** 22 sensitivity analyses were carried out. Areas explored included costs, effectiveness, sexual practices and future changes in service provision	**Author identified:** A key driver of cost effectiveness is the uptake of PrEP (and hence the size of the PrEP programme). It is not possible to estimate this parameter with any degree of certainty In the model it was assumed that HIV testing will continue at the current rate; however, testing rates have rapidly increased in the UK in recent years Introduction of PrEP may be accompanied by spread of other STIs (including hepatitis C virus) and the consequent costs of their treatment Exact costs to the NHS for HIV drug	**Source of funding:** NIHR **Further research:** The authors did not specify any areas for future research

Cambiano (2018)						
Study	**Method of Analysis**	**Costs**	**Outcomes**	**Results**	**Limitations**	**Comments**
Population size: Hypothetical [f] **Intervention:** Event-based PrEP (i.e., two pills 2–24 hours before a sexual act, one for each consecutive day having condomless sex, for two days after the last sexual act). It was assumed that the programme was delivered at genitourinary medicine clinics and was introduced between April and June 2016 **Comparator(s):** PrEP not available [g]	Disability weights used in the model: HIV positive diagnosed with CD4>200 cells/mm (≤200 CD4 cells/mm) 0.1 (0.15) HIV-positive diagnosed with HIV with WHO4 (WHO3): 0.55 (0.22)				treatment are confidential and not known to the authors. It is anticipated that drug costs will fall once generic It is possible to buy PrEP online The HIV Synthesis Model is a simplification of reality The model estimates that around 80% of new HIV infections among GBMSM in the UK occur in men who are unaware of their HIV status **Reviewer identified:** Participants assumed to have been tested for HIV status prior to receiving PrEP and, therefore, the highest risk group (those unaware of their HIV status) are	

Cambiano (2018)						
Study	**Method of Analysis**	**Costs**	**Outcomes**	**Results**	**Limitations**	**Comments**
					not the focus of this study The validity of the assumptions used to populate the model are unclear Cost-effectiveness of PrEP versus other risk reduction interventions (for example, active behaviour change interventions) not assessed	
Overall applicability: Directly applicable **Overall quality: Minor limitations**						

Abbreviations: ART: anti-retroviral therapy; BNF: British National Formulary; CD4: a type of white blood cell; eMIT: electronic market information tool; FOI: freedom of information; GUM: genitourinary medicine; HIV: human immunodeficiency virus; ICER: incremental cost-effectiveness ratio; GBMSM: gay, bisexual and other men who have sex with men; NHS: National Health Service; NIHR: National Institute for Health Research; NMB: net monetary benefit; NR: not reported; PrEP: pre-exposure prophylaxis; PSA: probabilistic sensitivity analysis; QALY: quality-adjusted life year; STI: sexually transmitted infection; UK: United Kingdom; WHO: World Health Organisation

c. McCormack S, Dunn DT, Desai M, Dolling DI, Gafos M, Gilson R, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open- label randomised trial. Lancet.2016;387(10013):53-60
d. Miners A, Phillips A, Kreif N, Rodger A, Speakman A, Fisher M et al. Health-related quality of life of people with HIV in the era of combination antiretroviral treatment: a cross-sectional comparison with the general population. Lancet HIV. 2014 (1): e32-e40
e. Salomon JA, Vos T, Hogan DR et al. Common values in assessing health outcomes from disease and injury: disability weights measurement study for the Global Burden of Disease Study 2010. Lancet. 2012;380(9859):2129-43

f. The size of the population was estimated based on the proportion of UK GBMSM eligible for PrEP. The number eligible was estimated to be between 8400 and 12,200.
g. Both the treatment and control arms in the PROUD trial received PrEP. The treatment arm received immediate PrEP starting from the enrolment visit at the clinic and the control arm received PrEP after a deferral period of one year after the clinic visit. Therefore, the control arm did not receive any treatment within the first year of the study.

Ong (2017)						
Study	**Method of Analysis**	**Costs**	**Outcomes**	**Results**	**Limitations**	**Comments**
Study type: Decision tree model used to explore the economic implications of a first phase scale-up of a PrEP programme for GBMSM GUM clinic attendees at high HIV risk beginning in 2016 [a, b] **Country:** England, UK **Population:** GBMSM at high risk **Population size:** 5,000 (hypothetical) **Intervention:** Daily tenofovir disoproxil and emtricitabine combined tablet. Event-based dosing (i.e., PrEP given before and	**Perspective:** Health care provider **Time horizon:** Lifetime (1 year on PrEP) **Discounting:** 3.5% costs 3.5% effects **Data sources** **Costs:** PSSRU BNF Pathway analytics **Effects:** GUMCAD data (2009-2013) informed key HIV risk assumptions 86% PrEP effectiveness assumed (PROUD trial) 64% PrEP effectiveness: assumption to take into account potential increased	**Mean annual cost of PrEP; £:** 4331 **Intervention cost per person; £ million (assuming 86% effectiveness):** Year 1 PrEP cost (drug and GUM clinic): 22.5 HIV care costs prevented: 24.1 PEPSE-related costs prevented:256,000 **Intervention cost per person; £ million (assuming 64% effectiveness (with risk compensation):** Year 1 PrEP cost (drug and GUM clinic): 22.5 HIV care costs prevented: 16.5	**86% effectiveness:** 137 fewer year 1 HIV infections, 19 of these acquired HIV while at medium- or low-risk later in life, reducing total number of infections to 118 [f] **64% effectiveness:** 94 fewer year 1 HIV infections, 13 of these acquired HIV in later years [e] **QALYs per person:** 86% effectiveness: 361 QALYs saved 64% effectiveness: 247 QALYs saved	**ICER:** 86% effectiveness: Over a lifetime intervention was shown to be cost saving (ICER is negative) compared with no PrEP 64% effectiveness: ICER per QALY gained=23,500 Break even 86%: year 23 64%: year 33 **Uncertainty:** Cost effectiveness results were very sensitive to assumptions about HIV incidence in the PrEP eligible group, PrEP effectiveness when scaled up, PrEP drug costs and future reductions in the cost of ARV treatment	**Author identified:** Sensitivity analyses did not give a high degree of certainty that the ICER for PrEP would be below GB£ 20,000 per QALY gained There was doubt whether the values of model parameters (based on evidence from clinical trials) would be relevant to NHS practice Cost-effectiveness depends on those at high risk being identified, offered and accepting PrEP Unclear whether condomless anal intercourse frequency would	**Source of funding:** Public Health England **Further research:** The authors highlight a number of key areas of uncertainty that directly affect the financial considerations and sustainability of scaled up implementation of PrEP and advise that these questions should be answered before embarking on a long-term PrEP-based intervention: • When proposed high-risk eligibility criteria are implemented, who and how many will access and take up PrEP? • Will PrEP be taken up by those in whom PrEP is clinically recommended? • What will be their level of adherence? • What will be the effectiveness of regular clinical risk assessment at assuring that only those at continuing high-risk stay on PrEP to maintain cost-effectiveness and equitable access based on clinical need? **Reviewer comment:** PrEP is available online at a minimum cost of £19 per month (for a 3-month supply (https://www.iwantprepnow.co.uk/buy-

Ong (2017)						
Study	**Method of Analysis**	**Costs**	**Outcomes**	**Results**	**Limitations**	**Comments**
after sexual exposure) for an average of four tablets used per 7-day period, was explored in sensitivity analyses (PROUD trial) [c] **Comparator(s):** Standard of care risk reduction (PROUD trial)	frequency of condomless sex subsequent to PrEP use **Utilities:** Published sources Disutility between HIV infection and diagnosis [a] (and assumption): 0 Disutility associated with HIV infection (per annum) [d]: 0.11 Utility values in UK men aged over 75 years: 0.75 [e]	PEPSE-related costs prevented:256,000 **Currency & cost year:** GB£ (Euros); 2014/15			increase in those given PrEP (risk compensation), leading to more exposures and increased HIV in those with poor PrEP adherence as well as increased bacterial STIs and hepatitis C Indirect benefits not accounted for in the analysis. However, as modelled programme was small the indirect effects, if modelled, would have been small. If programme were larger, the long-term indirect effects would increase in dominance **Reviewer identified:** None	prep-now/ Accessed 26 October 2020)
Overall applicability: Directly applicable		**Overall quality: Minor limitations**				

Ong (2017)						
Study	**Method of Analysis**	**Costs**	**Outcomes**	**Results**	**Limitations**	**Comments**
Abbreviations: GUM: genitourinary medicine; HIV: human immunodeficiency virus; ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life year; STI: sexually transmitted infection						
a. McCormack S, Dunn DT, Desai M, Dolling DI, Gafos M, Gilson R, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open- label randomised trial. Lancet.2016;387(10013):53-60 b. PrEP provision to a single high-risk year was modelled at the cohort level. Individuals who remained at risk beyond the first year, formed part of a new high risk cohort in the second year (i.e., without PrEP during year one 165 people will test HIV positive, assuming 86% effectiveness, at the end of the first year 28 people will be HIV positive and 137 will be protected but still at high risk in year two. Subsequent lifetime HIV positive, without PrEP=683, with PrEP=19 c. Individuals managed via GUM clinics; for a 1-year programme, each individual had five visits to the clinic, at month 0, 1, 3, 6, and 9. The first visit included assessment of clinical need for PrEP, confirmation of HIV and STI status, and measurement of renal function. Subsequent visits were for monitoring of drug adherence, tolerability, and safety, together with quarterly checking of HIV and STI status d. Miners A, Phillips A, Kreif N, Rodger A et al. ASTRA (Antiretrovirals, Secula Transmission and Attitudes) Study. Health -related quality of life of people with HIVE in the era of combination antiretroviral treatment: a cross-sectional comparison with the general population. Lancet HIV 2014; 1(1):e32-40 e. Kind P, Hardman G, Macran S. Eq5D UK population norms. York: The University of York; 1999 (p98) f. Delayed infections reduced lifetime costs and QALYs lost						

Reitsema (2020)						
Study	**Method of Analysis**	**Costs**	**Outcomes**	**Results**	**Limitations**	**Comments**
Study type: Assessment of the cost-effectiveness of a PrEP programme for GBMSM **Country:** Netherlands **Population:** HIV-negative and met one or more of the following criteria: a) had a steady partner who was HIV-positive	**Perspective:** Healthcare payer **Time horizon:** 10 year (2018-2027) **Discounting:** 4% costs 1.5% effects (in line with Dutch guidelines for CEA) **Data sources** **Costs:** PrEP medication: Dutch website	**Cost of PrEP per 3 months; €:** 90 to 150 (range) **Total incremental costs; million €:** Standard: -3.7 (-44.4 to 19.6) RC: 9.2 (-23.7 to 31.4) Capped: -7.6 (-41.3 to 15.2) Capped+RC	**Probabilistic results** **Cumulative averted HIV infections 2018-2027** Standard: 486 (1273 to 6102) RC: 3550 (1309 to 6131) Capped: 2691 (1200 to 4424) Capped+RC 2530 (1044 to 4198)	**ICER; €:** Standard: 217.4 (-29,752.5 to 31,923) RC: 11,996 (-16,355 to 56,518) Capped: -5575 (-46,281 to 29,978) Capped+RC 2967 (-48,965 to 63,577)	**Author identified:** Population limited to GBMSM who present for an HIV/STI test and meet one of the criteria for PrEP Assumed no change in testing behaviour Effect of false report of CAI not considered (this would increase the ICER due to increase in costs but little difference in effects) Event-driven PrEP not considered **Reviewer identified:**	**Source of funding:** Grant from Aidsfonds (project 2014037) **Further research:** None suggested

Reitsema (2020)						
Study	**Method of Analysis**	**Costs**	**Outcomes**	**Results**	**Limitations**	**Comments**
with a detectable viral load; b) had a diagnosis of anogenital gonorrhoea in the preceding 6 months; c) had condomless anal intercourse with at least one casual partner in the preceding 6 months Eligibility evaluated on attendance at a healthcare clinic for HIV/STI testing **Population size:** Hypothetical [e] **Intervention:** [a] Four scenarios considered: 1) standard PrEP; 2) risk compensation; 3) capped scenario; 4) capped scenario with RC[a] Assumed men initiating PrEP would remain on PrEP for at least 12 months unless diagnosed with HIV or died	Monitoring: Dutch healthcare reference costs Monitoring and cART for HIV positive GBMSM in care: previous published study **Effects:** Publications In all scenarios it was assumed that PrEP reduces the probability of acquiring HIV in the PrEP user by 86% (PROUD trial) **Utilities:** Sources: literature and assumptions	-0.8 (-33.5 to 21.8) **Currency & cost year:** €; 2018-2027	**Gonorrhoea prevalence 2017 (%):** 0.782 (0.334 to 1.242) **Gonorrhoea prevalence 2027 (%):** Standard: 0.023 (0.000 to 0.099) RC: 0.212 (0.015 to 0.543) Capped: 0.192 (0.002 to 0.626) Capped+RC 0.560 (0.143 to 1.132) **QALYs gained:** Standard: 1482 (426 to 3570) RC: 1380 (367 to 3443) Capped: 1116 (324 to 2511) Capped+RC 901 (207 to 2205)	**Uncertainty:** Without risk compensation, 92% of simulations were cost-effective (of which 52% cost-saving). With risk compensation, 73% of simulations were cost-effective (of which 23% was cost-saving)	Earlier modelling studies have found contradicting results about the cost-effectiveness of PrEP, because of differences in how PrEP was implemented and assumptions about the costs, efficacy, and adherence to PrEP [b, c]	

Reitsema (2020)						
Study	**Method of Analysis**	**Costs**	**Outcomes**	**Results**	**Limitations**	**Comments**
Monitoring (including testing for HIV/STIs and renal function) took place every 3 months. At the 12-month check-up PrEP could continue for an additional 12 months with a probability of 75% if user still eligible. After the start of the programme, eligible GBMSM could continuously enter the programme with a probability of 75% **Comparator(s):** No PrEP						
Overall applicability: Partly applicable **Overall quality: Minor limitations**						
Abbreviations: CAI: condomless anal intercourse; cART: combination anti-retroviral therapy; CEA: cost-effectiveness analysis; HIV: human immunodeficiency viruses; ICER: incremental cost-effectiveness ratio; GBMSM: gay, bisexual and other men who have sex with men; PrEP: pre-exposure prophylaxis; QALY: quality-adjusted life year; RC: risk compensation; STI: sexually transmitted infection						
a. Risk compensation is the term used when reduced fear of HIV acquisition leads to lower condom use or more sexual partners, which could result in increased STI prevalence b. 1) Standard PrEP scenario: the number of PrEP users was uncapped and no risk compensation was assumed (75% of eligible population). 2) Risk compensation scenario: the number of PrEP users was uncapped. If at least one of the sexual partners engaging in CAI was on PrEP, the probability of CAI was increased by 75%. 3) Capped scenario: the PrEP programme size was capped at 2.5% of GBMSM. Men can go on PrEP on a first-come, first-serve basis. No risk compensation was assumed. 4) Capped scenario with risk compensation: the PrEP programme size was capped at 2.5% of GBMSM. Men can go on PrEP on a first-come, first-serve basis. If at least one of the sexual partners engaging in CAI was on PrEP, the probability of CAI was increased by 75% c. Jenness SM, Weiss KM, Goodreau SM, et al. Incidence of Gonorrhea and chlamydia following human immunodeficiency virus pre-exposure pro-phylaxis among men who have sex with men: a modelling study. Clin Infect Dis 2017; 65: 712-718						

Reitsema (2020)						
Study	**Method of Analysis**	**Costs**	**Outcomes**	**Results**	**Limitations**	**Comments**
d. Gomez GB, Borquez A, Case KK, et al. The cost and impact of scaling up preexposure prophylaxis for HIV prevention: a systematic review of cost-effectiveness modelling studies. PLoS Med 2013; 10:e1001401						
e. The size of the population was estimated based on the proportion of Dutch GBMSM eligible for PrEP. The number eligible declined from 10,573 in 2017 to 7417 in 2027.						

Appendix J Health economic model

Introduction and Background

There have been a number of cost-effectiveness studies of PrEP for the prevention of HIV in the gay, bisexual and other men who have sex with men (GBMSM) population; these were identified in the literature review and summarised in Section 1.1.8. However, very few of these studies have taken into account any potential negative externalities as a result of the introduction of PrEP. For example, it has been speculated that PrEP use could lead to a reduced use of condoms, and/or an increase in the number of sexual partners. These changes would be damaging to population health because of the additional risk of other (non-HIV) STI transmission amongst those receiving PrEP and their sexual partners.

There is also the potential for PrEP delivery to result in positive behavioural changes. These consequences are associated with the increased sexual health monitoring that is recommended for those receiving PrEP. For example, those receiving PrEP are advised to attend regular testing for other STIs, and may be more likely to do this than people not receiving PrEP. This recommendation, if adhered to, could result in more STIs being found in the population receiving PrEP and therefore earlier treatment of these STIs, as well as increased opportunities for partner notification and reducing STI transmission within their sexual networks

Previous economic evaluations, described in Section 1.1.8, typically did not account for the unintended consequences that may be associated with PrEP delivery. The magnitude of these changes in populations eligible for PrEP in the United Kingdom, if present at all, has not been quantified, nor has their impact on the cost-effectiveness of PrEP been assessed. The aim of this economic modelling was to make use of the results of well-established economic models of PrEP in the United Kingdom and adjust them to account for unintended consequences.

Decision Problem

The decision problem to be addressed by this analysis is summarised in **Error! Reference source not found.**the table below.**Error! Reference source not found.**

Table J.1 Summary of decision problem

Perspective	NHS, PSS and local authority
Population	GBMSM in the UK
Intervention	PrEP (event-based and daily) for HIV prevention
Comparator	Standard care (no PrEP) for HIV prevention
Type of evaluation	Cost-utility analysis

Model Structure

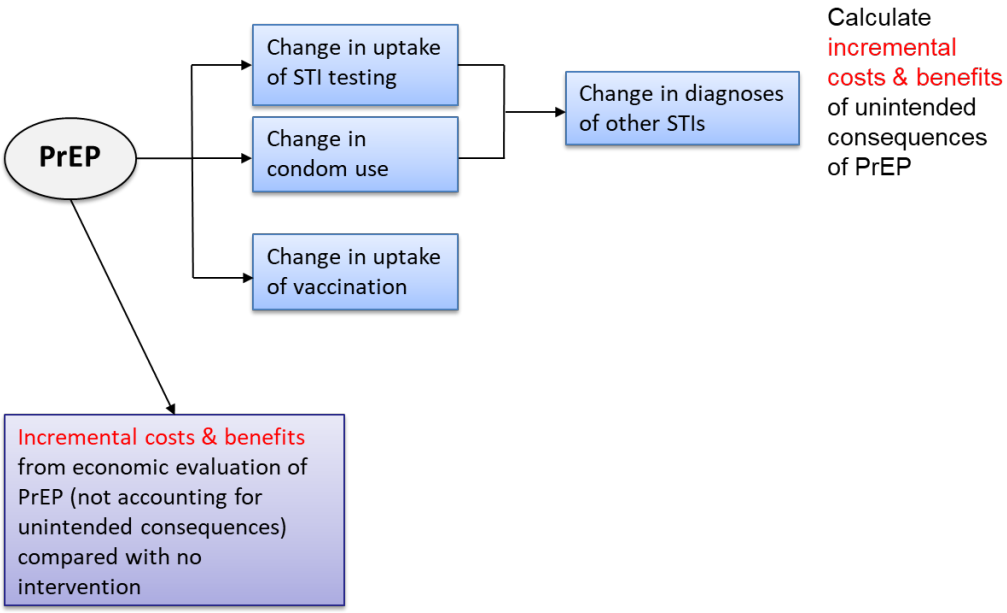
The conceptual model is presented in Figure J.1. The user is able to select from three source options of baseline cost-effectiveness results:

- Cambiano (2018)
- Ong (2017) – 64% efficacy scenario
- Ong (2017) – 86% efficacy scenario

For a summary of these economic evaluations, used as a starting point for the analysis, see the summaries of the studies in Appendix I.

The two aforementioned evaluations were selected for use in the model because of their relevance for addressing the decision problem set out in Table J.1.

Figure J.1 – Conceptual model diagram



From the selected baseline evaluation, the discounted incremental costs and QALYs of PrEP compared to standard care (no PrEP) were extracted. The results of the three economic evaluations were converted to costs and benefits per person. Subsequently all modelling of unintended consequences was also done at an individual person level.

For the change in uptake of STI testing and changes in sexual risk behaviour, the numbers of additional STIs transmitted/identified were estimated for an individual over the full duration of time for which they receive PrEP. These additional STIs were assigned costs and QALYs, which were added to the existing incremental costs and QALYs sourced from the baseline economic evaluations. The result is incremental costs and QALYs of PrEP, compared to no PrEP, with adjustments made for unintended consequences.

Whilst there is an analysis of vaccination uptake within the model, this is not linked to the cost-utility adjustment and instead is a standalone calculation. The decision to exclude the vaccination analysis from the cost-utility modelling was made in consultation with the committee, who advised that the links between PrEP use and risk of other viral STIs were multifaceted and would add considerable complexity to the modelling without much informative gain.

Inputs

This section describes the inputs used in the analysis. The inputs are categorised into general inputs (used throughout the cost-utility analysis), inputs relating to sexual risk behaviour, inputs relating to testing and inputs relating to vaccination.

General inputs

The mean length of time for which people receive PrEP was taken to be 4.5 years, sourced from Cambiano 2018. Applying discounting at 3.5% per annum, this treatment duration was adjusted to 4.25 years according to the calculations set out in Table J.2. In accounting for discounting in the treatment duration, which was used to linearly extrapolate all costs and benefits from unintended consequences within the model, it was not necessary to discount

the costs and benefits themselves, as would usually be done in more complex economic modelling.

Table J.2 – Calculating a discounted treatment duration

Year index	Discount factor	Length of time (years)	Discount factor adjusted for length of time
0	1	1	1
1	0.966	1	0.966
2	0.934	1	0.934
3	0.902	1	0.902
3.5	0.887	0.5	0.443
		Total discounted duration	4.245

In order to estimate the cost and QALY impact of the unintended consequences, a mean cost per STI and mean QALY impact of an STI are required. These inputs are used throughout the analysis and are therefore key drivers of the results.

It was decided in consultation with the committee that the analysis should focus on bacterial rather than viral STIs. The cost and QALY impacts are therefore drawn from populations infected with chlamydia, gonorrhoea and/or syphilis. These inputs are presented in Table J.3.

Table J.3 – Mean cost and QALY impact of an STI

Input	Value	Source
Mean cost per STI	£271	Huntington et al. (2018) Modelling-based evaluation of the costs, benefits and cost-effectiveness of multipathogen point-of-care tests for sexually transmitted infections in symptomatic genitourinary medicine clinic attendees. Cost inflated from 2015/2016 cost (£251) to 2019/2020 using PSSRU Unit Costs of Health and Social Care 2020 Hospital & Community Health Services Pay & Prices Index
Mean QALY impact of an STI	0.02	McKenney et al. (2017) Optimal costs of HIV pre-exposure prophylaxis for men who have sex with men.

Sexual Risk Behaviour

The analysis of sexual risk behaviour is driven by the number of condomless sex partners per year for an individual on PrEP compared to an individual not on PrEP. This is calculated using an estimate of the mean number of sexual partners, combined with an estimate of frequency of condom use with these partners.

There was no evidence to suggest that the number of sexual partners might change as a result of taking PrEP, in the iPrEx trial (Marcus 2013). In the model there is the option to put in different values for “with PrEP” and “without PrEP”, but the base case value is the same for both arms. From the iPrEx trial, it was reported that the mean number of receptive anal intercourse partners, in the three months prior to baseline, was 12. This value is representative of the full population of trial participants. Extrapolating this estimate over time poses some challenges, as the number of sexual partners in a given period is expected to be made up of both long-term/regular and “new”/non-regular partners.

The third National Survey of Sexual Attitudes and Lifestyles (Natsal-3) reported on the number of sexual partners in a one-year period and in a five-year period (Clifton 2013). This data is not specific to the GBMSM population, but the patterns over time are assumed to be

generalisable in order to guide the extrapolation (that is, the numbers of sexual partners are not assumed to be generalisable, but the ratio between the number of partners in a one-year and five-year period). In the report of this survey, the number of sexual partners in a five-year period was 2.5 times the number of sexual partners in a one-year period. To extrapolate from a three-month period to a 4.25 year period, a few alternative methods were trialled. The number of sexual partners over the 4.25 year treatment period ranged from 60 to 102, under these varying extrapolation methods.

The Natsal-3 data suggests that the incidence of new sexual partners each year, following the first year, is roughly one third of the number recorded in year one. If this pattern is assumed to hold in the GBMSM population – that is, two thirds of the 12 partners recorded at baseline were long-term partners, with the remaining four partners being "new" within this period – then extrapolation of this pattern would result in the cumulative number of sexual partners increasing by four every three months. Thus, the mean number of sexual partners for each man (either on PrEP or not), over the 4.25 year treatment period, would be 60. It was felt that this value, at the lower bound of the range of estimates, held the most face validity (for a population at high risk of STI transmission). It should be noted the precise number estimated is not critical to the results of the model, as a higher number of sexual partners will both increase the benefits of PrEP (as the risk of HIV transmission will be higher) and increase the potential harms from unintended consequences of PrEP (as the risk of other STI transmission will also be higher).

Whilst PrEP is modelled to have no effect on the number of sexual partners, the frequency of condom use is evidenced to be different when an individual is taking PrEP. This is what drives the differences in number of condomless sex partners. The model base-case inputs for condom use with and without PrEP are 79% and 88% respectively, taken from data collected in the PROUD trial (McCormack 2016). It should be noted that these inputs relate to the proportion of individuals engaging in condomless sex with 10 or more partners. In the model, these values are used to estimate the proportion of an individual's sexual partners who are condomless partners. It is unclear whether this application of the data results in an underestimation or overestimation of condom use.

Combining the number of sexual partners with the frequency of condom use, the model estimates than an average individual receiving PrEP has 12.6 condomless sex partners over the PrEP treatment period, whilst an individual not receiving PrEP has 7.2.

Applied to these estimates of number of condomless sex partners, is the risk of contracting/transmitting a bacterial STI per condomless sex partnership. The risk per sexual partnership is estimated at 17.5%, based on the calculations in Table J.4. This estimate of transmission risk per partnership should reflect a combination of both regular and non-regular sexual partnerships, and therefore is an estimate of the average risk per partnership. For this reason it was not necessary to differentiate between regular/non-regular partners when applying the risk of STI transmission.

Table J.4 – Risk of STI transmission per sexual partner

STI	Prevalence in GBMSM (PHE 2019; estimated based on proportions of positive test results)	Risk of transmission from infected partner, per event	Risk of transmitting OR contracting per event*
Chlamydia	10.3%	65% (Turner 2011)	12.02%
Gonorrhoea	12.6%	20% (assumption)	4.41%
Syphilis	2.8%	20% (assumption)	1.08%
Total risk of transmission from one partner to the other			**17.5%**

*Calculated as composite probabilities from the prevalence and risk (probability of one person in the partnership being infected × probability of the other person *not* being infected × probability of transmission × 2 [to account for the bidirectional possibility of transmission])

There are some simplifying assumptions made to enable this calculation, for example it is assumed that transmission of one these STIs within a partnership is independent of transmission of another.

Uptake of STI Testing

The aim of this part of the model is to calculate the increased number of bacterial STIs that are identified as a result of more frequent testing for individuals receiving PrEP. This is based upon the following key inputs:

1. Frequency of STI testing (with and without PrEP).
2. Percentage of tests with positive result (assumed constant regardless of PrEP).

Public health guidance is used to inform the model inputs around frequency of STI testing. The guidance for GBMSM states that annual testing for STIs is recommended (PHE 2017; based on BASHH guidance), so in the model, annual frequency of testing for those not receiving PrEP is set to one. Some people will of course test more frequently, some less, but this value is taken to be representative of an average individual in the GBMSM population.

When receiving PrEP, individuals are encouraged to test for STIs more frequently. The recommendation in the UK is that this population should be screened every three months. It is inferred that GBMSM receiving PrEP would ideally be screened for STIs four times per year (rather than the annual screening assumed for GBMSM not on PrEP). However, the expectation is that whilst this population will have more screenings than the “not on PrEP” population, four times per year is probably not representative of the average PrEP user. With this in mind, this value in the model is set to three.

The second aspect of this part of the model is a simplified estimation of total number of cases averted as a result of carrying out the additional STI tests. The percentage of bacterial STI tests with a positive result, 25%, was taken from a retrospective review of PrEP outcomes in the United States (Hevey 2018). This percentage was applied to the number of additional tests carried out as a consequence of PrEP, to provide an estimate of the number of additional cases of bacterial STIs identified by regular testing. For this part of the analysis, it was assumed that the diagnosed prevalence of bacterial STIs does not differ between PrEP users and the rest of the GBMSM population (although in practice PrEP users are likely to represent a high-risk subset, and may therefore have a higher prevalence). Whilst the sexual risk behaviour analysis suggests that there are likely to be additional STIs transmitted as a result of PrEP, it does not necessarily conclude that this impacts the population significantly enough to result in a meaningful change in the prevalence of STIs (in either the population of PrEP users or their sexual partners in the GBMSM population more generally).

The costs of administering the additional STI tests were not accounted for in this modelling, as its purpose was to adjust the original economic evaluations without double counting costs and benefits that have already been accounted for. The upfront costs of providing the recommended PrEP monitoring, including testing for other STIs, should be included within the existing economic evaluations.

Vaccination inputs

The aim of this part of the model is to capture any differences in rates of vaccination amongst men who are receiving PrEP compared with the general GBMSM population, and to estimate the number of viral infections avoided as a result. This analysis is based on the following key inputs:

1. Proportion of men completing vaccination (with and without PrEP).
2. Vaccine effectiveness rates.
3. Prevalence of viral pathogens within unvaccinated population (used as an estimate of the likelihood of contracting each infection, if unvaccinated).

The proportions of men completing vaccinations were drawn from a US study of preventative care uptake in a clinic-based cohort of GBMSM **Error! Bookmark not defined.**. Vaccination prevalence for the "no PrEP" arm was reflective of the cohort at the beginning of their use of the PrEP clinic. Vaccination prevalence for "PrEP" was reflective of the cohort after clinic follow-up. These inputs are presented in Table J.5.

Table J.5 – Proportion completing HPV, HAV and HBV vaccinations

Proportion of men completing vaccination	HPV*	HAV	HBV
No PrEP	12.0%	51.0%	71.0%
PrEP	66.6%	78.9%	83.8%

*Proportions relate to participants aged 26 or younger, not the full cohort

The effectiveness of the quadrivalent HPV vaccine (the vaccine used in the UK) was estimated to be 62% in a systematic review (Medeiros 2009); this value was adopted in the model. The HAV and HBV vaccines were respectively estimated to be 90% and 95% effective in another review (Mena 2015), and these values adopted in the modelling. The effectiveness rates were applied to the proportion receiving each vaccination to estimate the proportion with protection against each virus.

Finally, in order to quantify the impact of these increased vaccinations in terms of cases of each viral STI avoided, it was necessary to account for the likelihood of contracting each of the viruses, if unvaccinated. The prevalence of viral pathogens within an unvaccinated population was used as a proxy for this input. One study of GBMSM in Toronto presented these results for HPV and HBV: 51.7% and 49.4% respectively (Remis 2016). Another specifically studied a population of GBMSM in North-East England and found 42% of those not previously (and definitely) vaccinated to have HAV antibodies (Bhagey 2018). These three values were adopted for use in the modelling.

The costs of administering the additional vaccines were not accounted for in this modelling, as its purpose was to adjust the original economic evaluations without double counting costs and benefits that have already been accounted for. As with the additional STI testing, the upfront costs of providing preventative care should be included within the existing economic evaluations.

Base Case Results

Over the course of the treatment period, the model predicts that 0.95 additional bacterial STIs are transmitted as a result of risky behaviour, per person receiving PrEP. However, this is countered by an estimated 2.1 bacterial STIs identified by additional testing. If it can be assumed that each STI identified by additional testing is associated with a relative QALY gain – of the same magnitude as the QALY loss from each additional STI transmitted – then overall, the unintended consequences of PrEP are beneficial to population health.

This conjecture, that each additional STI identified through additional testing "offsets" one that has been transmitted, is of course challenging to validate. In the proceeding section 'Threshold Analysis', the results of the threshold analysis are described and these illustrate that even if zero STIs are identified by the increased testing, any additional STIs transmitted as a result of risky behaviour are not substantial enough to change the direction of the results.

Further to the above, the vaccination analysis predicts that per person receiving PrEP, the additional vaccinations result in 0.18 cases of HPV, 0.11 cases of HAV and 0.06 cases of HBV averted. Whilst the aversion of these primary cases would of course have knock-on benefit in the form of secondary cases avoided, only primary cases averted were modelled, to provide a conservative estimate of the benefit of the additional vaccinations given. From these results it can be inferred that:

- In order to avert one case of HPV via the increase in vaccinations, 6 people would need to be offered PrEP
- In order to avert one case of HAV via the increase in vaccinations, 10 people would need to be offered PrEP
- In order to avert one case of HBV via the increase in vaccinations, 17 people would need to be offered PrEP

Cost-utility adjustment

The absolute impact of unintended consequences on the cost-effectiveness of PrEP is the same, regardless of the economic evaluation chosen as a starting point. However, the relative impact will differ. Results are presented in Table J.6 for each choice of baseline evaluation. In Figures J.2 to J.4, the adjustment of the cost-effectiveness results is illustrated on a cost-effectiveness plane for each choice of baseline evaluation.

When using Cambiano et al. as the baseline evaluation, or Ong et al. with PrEP at 86% effectiveness, the unintended consequences do not change the cost-effectiveness decision. When using Ong et al. with PrEP at 64% effectiveness, the adjustment for unintended consequences results in PrEP becoming cost-effective (at a threshold of £20,000), when it was not in the original evaluation.

Table J.6 – Incremental costs and QALYs of PrEP, per person, adjusted for unintended consequences

	Cambiano 2018		Ong 2017 (86% efficacy)		Ong 2017 (64% efficacy)	
	Incremental costs (£)	Incremental QALYs	Incremental costs (£)	Incremental QALYs	Incremental costs (£)	Incremental QALYs
Baseline (unadjusted)	-1,393	0.06	-371	0.07	1,149	0.05
Risky behaviour	256	-0.02	256	-0.02	256	-0.02
STI testing	-576	0.04	-576	0.04	-576	0.04

	Cambiano 2018		Ong 2017 (86% efficacy)		Ong 2017 (64% efficacy)	
Overall (adjusted)	-1,712	0.08	-691	0.10	829	0.07

Figure J.2 – Impact of unintended consequences on per-person cost-effectiveness results from Cambiano 2018

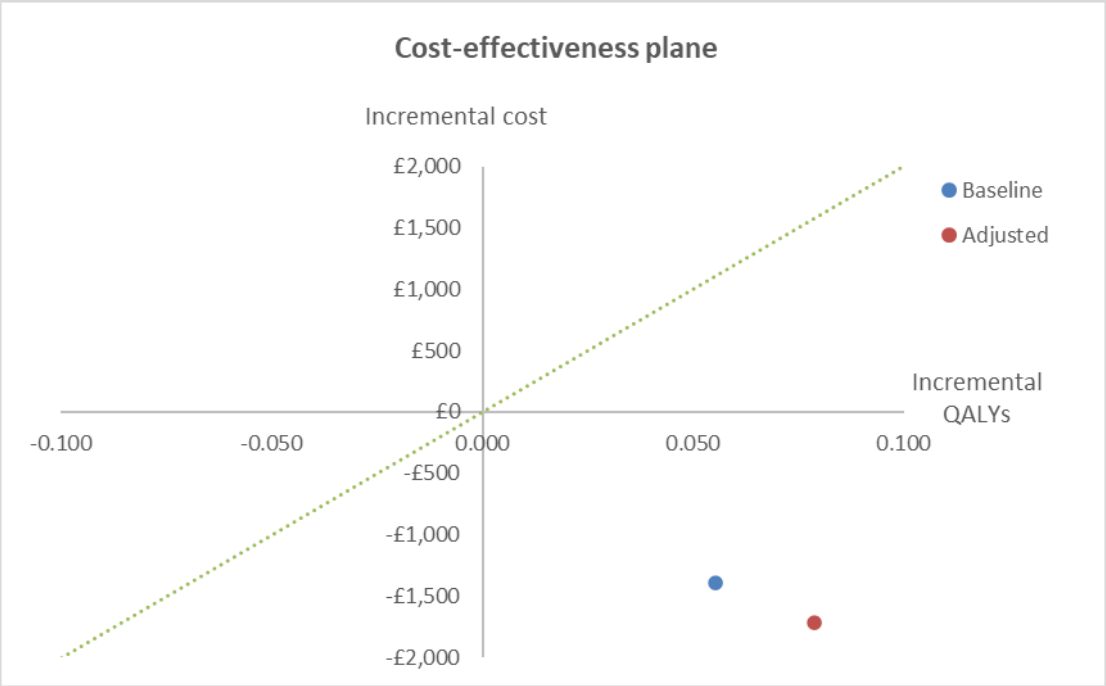


Figure I.1 – Impact of unintended consequences on per-person cost-effectiveness results from Ong 2017 (86% efficacy)

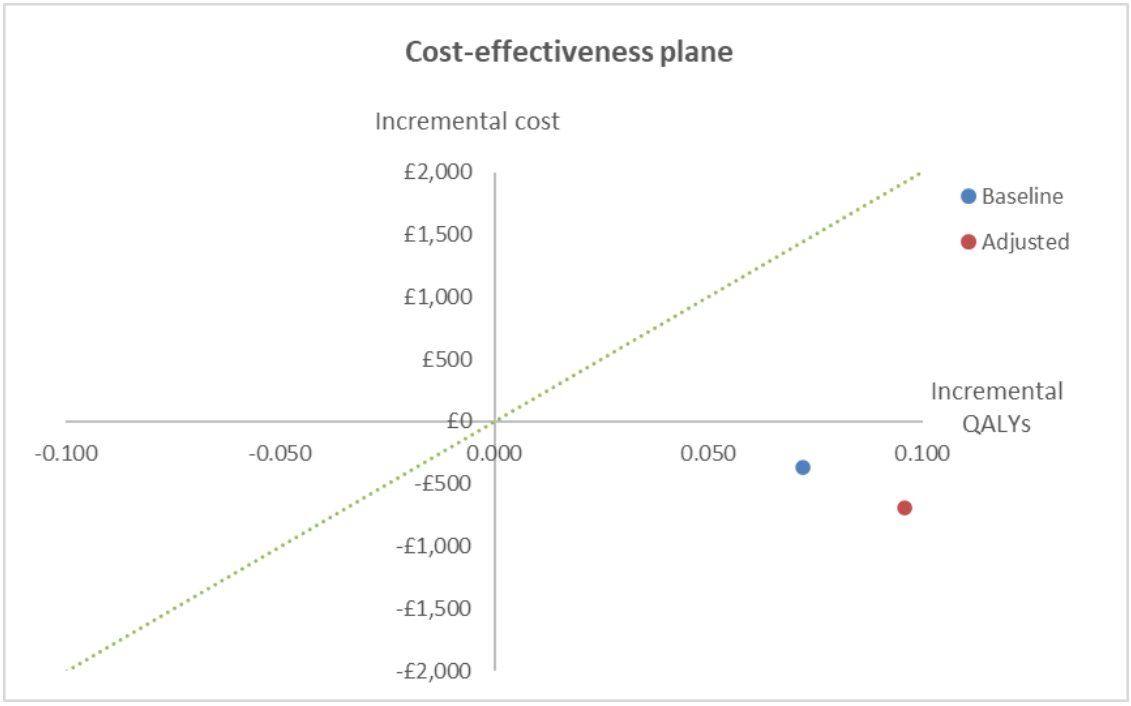
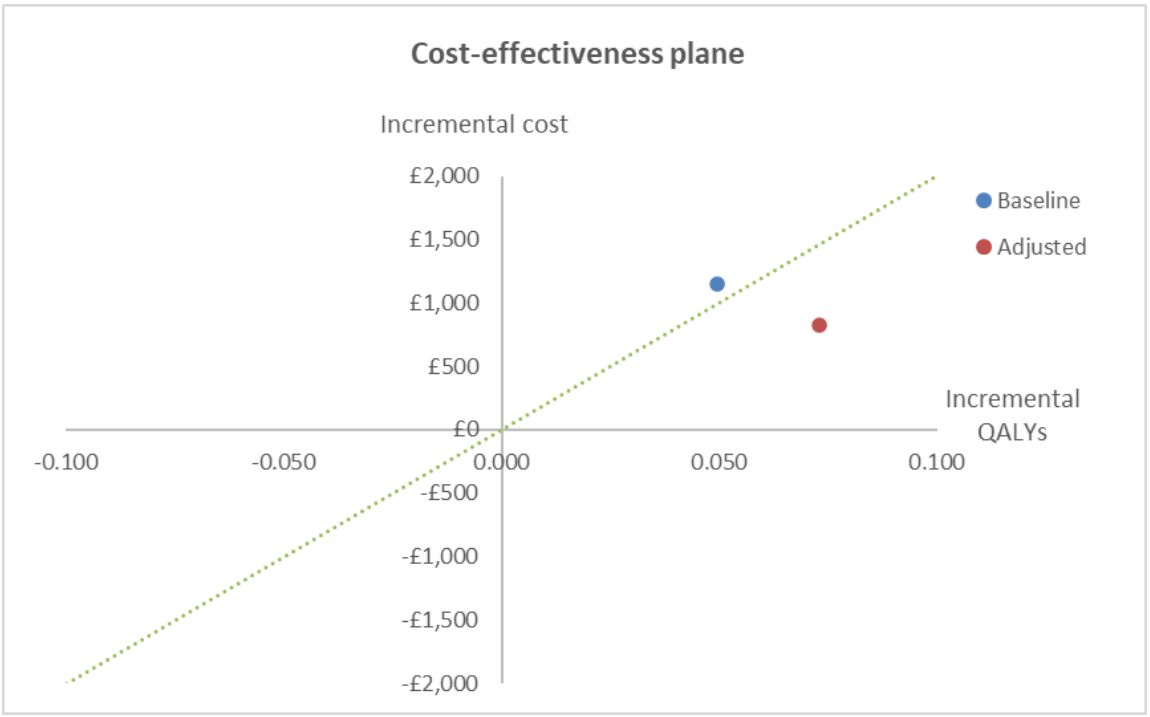


Figure I.2 – Impact of unintended consequences on per-person cost-effectiveness results from Ong 2017 (64% efficacy)



Threshold Analysis

There is considerable parameter uncertainty in the analysis. This type of uncertainty is commonly addressed in economic modelling using probabilistic or deterministic sensitivity analysis (PSA and DSA). However, these methods usually require a quantification of the level of uncertainty surrounding a parameter, for instance a confidence interval or "plausible range". If this information is not known, which was the case for many of the uncertain parameters in this analysis, then such methods may introduce further uncertainty to the conclusions of the analysis. For this reason, the approach taken to address the parameter uncertainty in the model was the use of threshold analysis.

The aim of the threshold analysis was to determine the number of additional STIs that would need to be transmitted, as a result of unintended consequences, in order to change the cost-effectiveness decision. The base case results provide an answer to the question "what impact do the unintended consequences of PrEP have on its cost effectiveness?"; the threshold analysis provides answers to the following:

How substantial (in terms of additional STIs transmitted) would the unintended consequences need to be before PrEP is no longer:

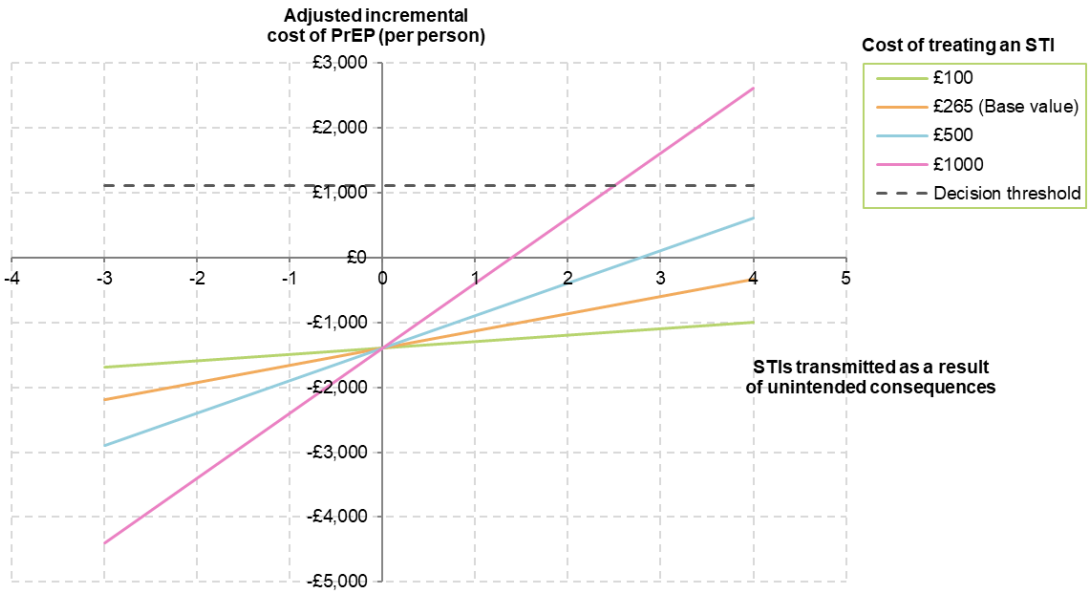
- cost-saving?
- cost-effective?

The threshold analysis, using Cambiano 2018 as a baseline evaluation, is represented graphically in Figures J.5 and J.6.

In Figure J.5, differing values of the cost of treating an STI are applied, represented by the coloured lines. The point at which a line crosses the x axis is where PrEP is a cost neutral intervention. The point at which a line crosses the dotted horizontal line is where PrEP is neutral in terms of full economic benefit (i.e. it is neither cost-effective nor cost-ineffective), assuming a cost-effectiveness threshold of £20,000 per QALY gained.

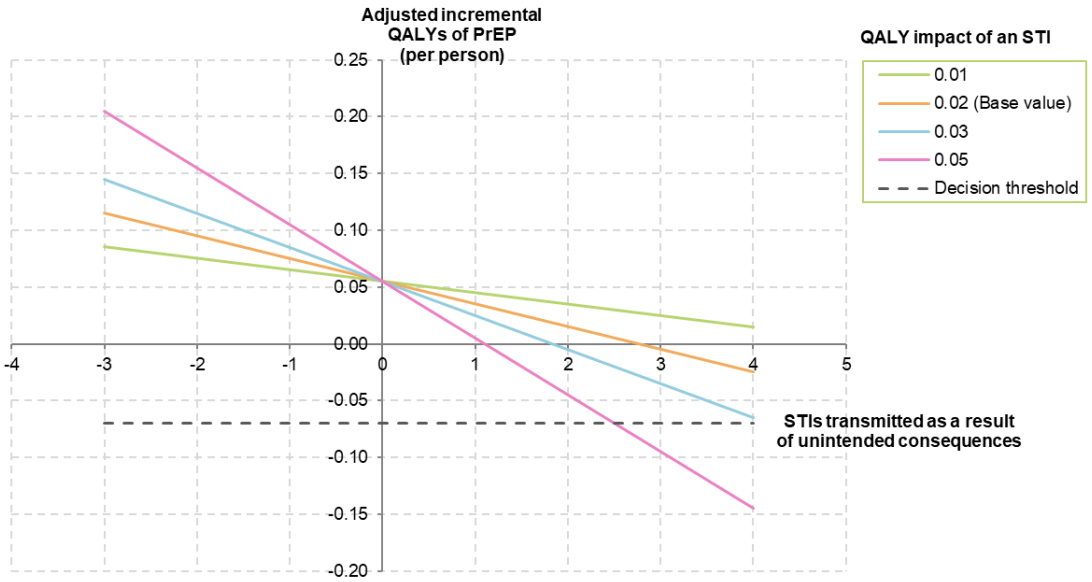
Using the base case value for the cost of treating an STI, the threshold analysis shows that approximately five additional STIs would need to be transmitted to/from an individual over the course of their PrEP treatment period before PrEP is no longer a cost-saving intervention (compared with standard care, i.e. no PrEP). A similar finding is present for QALYs, where an additional 3 STIs would need to be transmitted before PrEP was no longer clinically beneficial. This means that the negative consequences would need to significantly greater than they are estimated to be in this analysis. These consequences would need to be substantially greater still, before PrEP is determined to be cost-ineffective.

Figure J.5 – Threshold analysis: Incremental cost of PrEP plotted against the number of STIs transmitted as a result of unintended consequences



In Figure J.6, differing values of the QALY impact of an STI are applied, represented by the coloured lines. The point at which a line crosses the x axis is where PrEP is QALY neutral. The point at which a line crosses the dotted horizontal line is where PrEP is neutral in terms of full economic benefit (i.e. it is neither cost-effective nor cost-ineffective), assuming a cost-effectiveness threshold of £20,000 per QALY gained.

Figure J.6 – Threshold analysis: Incremental benefit of PrEP plotted against the number of STIs transmitted as a result of unintended consequences



Discussion

This analysis suggests that with both positive and negative consequences of PrEP taken into account, the introduction of PrEP into the GBMSM population in the United Kingdom would be a more cost-effective intervention than has been previously estimated. This results from the fact that the negative unintended consequence of potential reduced condom use is outweighed by the positive consequence of increased STI testing. This means that if PrEP is already considered cost-effective prior to accounting for unintended consequences – a conclusion reached by Cambiano 2018, and Ong 2017 when PrEP was assumed to be 86% effective – then this decision is strengthened by accounting for the unintended consequences. If PrEP is not considered cost-effective without unintended consequences accounted for, for example in the Ong 2017 analysis with PrEP at 64% effectiveness, then the unintended consequences may change the decision if the cost-effectiveness results are close to the threshold.

Many of the assumptions used in the model are difficult to validate, and the data used to populate the model is imperfect. An attempt has been made to make conservative assumptions – choosing those that would be expected to bias results *against* the cost-effectiveness of PrEP (i.e. making the unintended consequences appear more substantially negative than they are in reality) rather than biasing in favour of PrEP. Threshold analysis was utilised to add context to remaining uncertainty. The results of the threshold analysis indicate that even if the positive unintended consequences of PrEP were considered negligible, the negative consequences would need to be substantially more impactful than they are in the base case analysis before PrEP would be considered non cost-saving or cost-ineffective.

Another limitation of this analysis is that the economic evaluations on which the results are based used cost data that is now likely to be out of date. Most notably, the cost of PrEP medication itself is now materially lower than it was just a few years ago when Cambiano 2018 and Ong 2017 carried out their analysis. No adjustments to the baseline results were made to account for recent price changes. This means that the cost-effectiveness of PrEP is likely to be underestimated in the baseline results and therefore in the adjusted results too. Additionally, although evidence was found that use of Prep results in increases in vaccination rates, this was not possible to include as part of the QALY calculations, again likely resulting in an underestimate of the cost-effectiveness of PrEP.

Despite these limitations, the reported analysis can supplement existing economic evaluations to provide a more complete picture of the costs and benefits associated with PrEP introduction in the GBMSM population in the UK.

Reducing inequity in access to sexual health services

The committee expressed concerns about inequities in access to PrEP and other sexual health services. The results of this analysis of the unintended consequences demonstrate that PrEP is likely to be cost-effective in most scenarios when offered to an eligible population of GBMSM. In two out of three economic evaluations after adjustments for unintended consequences, PrEP introduction is associated with negative incremental costs and positive incremental QALYs. Therefore, there is potential for additional spending on targeted interventions which reduce inequity in HIV prevention, or sexual health more generally, from the projected cost savings of PrEP.

The results of this analysis can be explored to determine how much could be spent on inequity-reducing interventions, forming a hypothetical package of sexual health services with PrEP, whilst maintaining overall cost-effectiveness. For example, the adjusted Cambiano results produce an incremental cost of -£1,712 and incremental QALYs of 0.08, both per person. Therefore, there is room for an additional spend of up to £1,712 per person while the package (PrEP with targeted inequity-reducing interventions) remains cost saving,

or an additional spend of up to £3,312 per person while the package remains cost-effective at a £20,000 per QALY threshold. This is without considering any potential QALY gains from the inequity-reducing interventions. Whilst the interventions to reduce inequities may not improve the cost-effectiveness of PrEP (depending on the cost-effectiveness of the interventions in question), they may be considered a worthwhile use of the projected cost savings if inequities are sufficiently reduced.

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Remis et al. Prevalence of Sexually Transmitted Viral and Bacterial Infections in HIV-Positive and HIV-Negative Men Who Have Sex with Men in Toronto. PLoS One. 2016;11(7):e0158090.

Turner, et al. Costs and cost effectiveness of different strategies for chlamydia screening and partner notification: an economic and mathematical modelling study. The BMJ. 2011; 342.

Appendix K Excluded studies

K.1 Excluded effectiveness studies

Study	Reason
(2018) Effect of on demand oral PrEP with TDF/FTC on HSV-1/2 incidence among MSM. Topics in antiviral medicine conference25thconferenceonretrovirusesandopportunisticinfectionscroi2018united states26(supplement1): 467s	- Not a peer-reviewed publication *Conference abstract*
Abbas, Ume L, Hood, Gregory, Wetzel, Arthur W et al. (2011) Factors influencing the emergence and spread of HIV drug resistance arising from rollout of antiretroviral pre-exposure prophylaxis (PrEP). PloS one 6(4): e18165	- Cost-effectiveness - Non-OECD country
Abraham, Bisrat K and Gulick, Roy (2012) Next-generation oral preexposure prophylaxis: beyond tenofovir. Current opinion in HIV and AIDS 7(6): 600-6	- Review article but not a systematic review
Abuelezam, Nadia N, McCormick, Alethea W, Fussell, Thomas et al. (2016) Can the Heterosexual HIV Epidemic be Eliminated in South Africa Using Combination Prevention? A Modeling Analysis. American journal of epidemiology 184(3): 239-48	- Modelling
Adams, J., Coquilla, R., Montayre, J. et al. (2019) Knowledge of HIV pre-exposure prophylaxis among immigrant Asian gay men living in New Zealand. Journal of Primary Health Care 11(4): 351-358	- OECD remaining countries
Adamson, B., Garrison, L., Barnabas, R.V. et al. (2019) Competing biomedical HIV prevention strategies: potential cost-effectiveness of HIV vaccines and PrEP in Seattle, WA. Journal of the International AIDS Society 22(8): e25373	- Cost-effectiveness
Adamson, B.J.S., Carlson, J.J., Kublin, J.G. et al. (2017) The potential cost-effectiveness of pre-exposure prophylaxis combined with HIV vaccines in the united states. Vaccines 5(2): 13	- Cost-effectiveness
Aghaizu, Adamma, Mercey, Danielle, Copas, Andrew et al. (2013) Who would use PrEP? Factors associated with intention to use among MSM in London: a community survey. Sexually transmitted infections 89(3): 207-11	- Qualitative - closed questions
Algarin, A.B., Shrader, C.H., Bhatt, C. et al. (2019) The Pre-exposure Prophylaxis (PrEP) Continuum of Care and Correlates to Initiation Among HIV-Negative Men Recruited at Miami Gay Pride 2018. Journal of Urban Health 96(6): 835-844	- Qualitative - closed questions

Study	Reason
Allen, S.T., O'Rourke, A., White, R.H. et al. (2019) Barriers and Facilitators to PrEP Use Among People Who Inject Drugs in Rural Appalachia: A Qualitative Study. AIDS and Behavior	- Not the target population
Allende, Ruben and Acuna, Maria Paz (2017) Is pre-exposure prophylaxis effective for preventing HIV infection in men who have sex with men?. Medwave 17(9): e7117	- Study not reported in English
Amico, K Rivet, Ramirez, Catalina, Caplan, Margaret R et al. (2019) Perspectives of US women participating in a candidate PrEP study: adherence, acceptability and future use intentions. Journal of the International AIDS Society 22(3): e25247	- Qualitative - closed questions
Anderson, Sarah-Jane, Cherutich, Peter, Kilonzo, Nduku et al. (2014) Maximising the effect of combination HIV prevention through prioritisation of the people and places in greatest need: a modelling study. Lancet (London, England) 384(9939): 249-56	- Modelling
Annequin, M., Villes, V., Delabre, R.M. et al. (2020) Are PrEP services in France reaching all those exposed to HIV who want to take PrEP? MSM respondents who are eligible but not using PrEP (EMIS 2017). AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV	- Qualitative - closed questions
Anonymous (2011) CDC trial: HIV PrEP works for heterosexuals. A 63% reduction in HIV risk. AIDS alert 26(8): 85-90	- Not a relevant study design
Antoni, G, Tremblay, C, Delaugerre, C et al. (2019) On-demand pre-exposure prophylaxis with tenofovir disoproxil fumarate plus emtricitabine among men who have sex with men with less frequent sexual intercourse: a post-hoc analysis of the ANRS IPERGAY trial. The lancet. HIV	- Primary study included in systematic review
Arnold, T., Sims-Gomillia, C.E., Portz, K. et al. (2018) Preliminary investigation evaluating college students' willingness and need to take pre-exposure prophylaxis (PrEP) for HIV. HIV and AIDS Review 17(2): 98-102	- Qualitative - closed questions
Arnold, Trisha, Brinkley-Rubinstein, Lauren, Chan, Philip A et al. (2017) Social, structural, behavioral and clinical factors influencing retention in Pre-Exposure Prophylaxis (PrEP) care in Mississippi. PloS one 12(2): e0172354	- OECD remaining countries
Ascher, Simon B, Scherzer, Rebecca, Estrella, Michelle M et al. (2020) HIV preexposure prophylaxis with tenofovir disoproxil fumarate/emtricitabine and changes in kidney function and tubular health. AIDS (London, England) 34(5): 699-706	- Primary study included in systematic review
Ayala, George, Makofane, Keletso, Santos, Glenn-Milo et al. (2013) Access to Basic HIV-Related Services and PrEP Acceptability among Men Who Have sex with Men Worldwide: Barriers, Facilitators, and Implications for Combination Prevention. Journal of sexually transmitted diseases 2013: 953123	- Not a relevant study design *cross-sectional*

Study	Reason
Baeten, Jared M, Donnell, Deborah, Mugo, Nelly R et al. (2014) Single-agent tenofovir versus combination emtricitabine plus tenofovir for pre-exposure prophylaxis for HIV-1 acquisition: an update of data from a randomised, double-blind, phase 3 trial. The Lancet. Infectious diseases 14(11): 1055-1064	- Primary study included in systematic review
Baeten, Jared M, Donnell, Deborah, Ndase, Patrick et al. (2012) Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. The New England journal of medicine 367(5): 399-410	- Primary study included in systematic review
Baeten, Jared and Celum, Connie (2012) Oral antiretroviral chemoprophylaxis: current status. Current opinion in HIV and AIDS 7(6): 514-9	- Review article but not a systematic review
Bagchi, Ann D and Holzemer, William (2018) Support for PrEP Among New Jersey Health Care Workers. The Journal of the Association of Nurses in AIDS Care : JANAC 29(6): 849-857	- Population: Practitioners *- views of care workers*
Baggaley, Rebecca F; Powers, Kimberly A; Boily, Marie-Claude (2011) What do mathematical models tell us about the emergence and spread of drug-resistant HIV?. Current opinion in HIV and AIDS 6(2): 131-40	- Modelling
Barnighausen, Kate E, Matse, Sindy, Kennedy, Caitlin E et al. (2019) 'This is mine, this is for me': preexposure prophylaxis as a source of resilience among women in Eswatini. AIDS (London, England) 33suppl1: 45-s52	- Non-OECD country
Barreras, J L; Linnemayr, S L; MacCarthy, S (2019) "We have a stronger survival mode": exploring knowledge gaps and culturally sensitive messaging of PrEP among Latino men who have sex with men and Latina transgender women in Los Angeles, CA. AIDS care 31(10): 1221-1227	- OECD remaining countries
Baruch, R., Cuadra, S.M., Arellano, J. et al. (2020) Pre-exposure prophylaxis and its implications in Mexico: Notions of men who have sex with men. Sexual Health 17(1): 22-28	- OECD remaining countries
Bazzi, A.R. (2016) Antiretroviral pre-exposure prophylaxis for HIV prevention is highly effective in community settings. Evidence-Based Medicine 21(3): 99	- Not a peer-reviewed publication
Bazzi, Angela R, Biancarelli, Dea L, Childs, Ellen et al. (2018) Limited Knowledge and Mixed Interest in Pre-Exposure Prophylaxis for HIV Prevention Among People Who Inject Drugs. AIDS patient care and STDs 32(12): 529-537	- Not the target population
Bazzi, Angela R, Yotebieng, Kelly, Otticha, Sophie et al. (2019) PrEP and the syndemic of substance use, violence, and HIV among female and male sex workers: a qualitative study in Kisumu, Kenya. Journal of the International AIDS Society 22(4): e25266	- Non-OECD country

Study	Reason
Bazzi, Angela Robertson, Yotebieng, Kelly A, Agot, Kawango et al. (2018) Perspectives on biomedical HIV prevention options among women who inject drugs in Kenya. AIDS care 30(3): 343-346	- Not the target population
Bernard, C.L., Brandeau, M.L., Humphreys, K. et al. (2016) Cost-effectiveness of HIV preexposure prophylaxis for people who inject drugs in the United States. Annals of Internal Medicine 165(1): 10-19	- Cost-effectiveness
Biello, K B, Bazzi, A R, Mimiaga, M J et al. (2018) Perspectives on HIV pre-exposure prophylaxis (PrEP) utilization and related intervention needs among people who inject drugs. Harm reduction journal 15(1): 55	- Not the target population
Biello, K B, Edeza, A, Salhaney, P et al. (2019) A missing perspective: injectable pre-exposure prophylaxis for people who inject drugs. AIDS care 31(10): 1214-1220	- Not the target population
Biello, K.B., Bazzi, A.R., Mimiaga, M.J. et al. (2018) Perspectives on HIV pre-exposure prophylaxis (PrEP) utilization and related intervention needs among people who inject drugs 11 Medical and Health Sciences 1117 Public Health and Health Services 16 Studies in Human Society 1608 Sociology. Harm Reduction Journal 15(1): 55	- Duplicate reference
Biello, Katie B, Hosek, Sybil, Drucker, Morgan T et al. (2018) Preferences for Injectable PrEP Among Young U.S. Cisgender Men and Transgender Women and Men Who Have Sex with Men. Archives of sexual behavior 47(7): 2101-2107	- Qualitative - does not ask relevant questions
Biello, Katie B, Oldenburg, Catherine E, Mitty, Jennifer A et al. (2017) The "Safe Sex" Conundrum: Anticipated Stigma From Sexual Partners as a Barrier to PrEP Use Among Substance Using MSM Engaging in Transactional Sex. AIDS and behavior 21(1): 300-306	- Qualitative - closed questions
Blumenthal, Jill, Pasipanodya, Elizabeth C, Jain, Sonia et al. (2019) Comparing Self-Report Pre-Exposure Prophylaxis Adherence Questions to Pharmacologic Measures of Recent and Cumulative Pre-Exposure Prophylaxis Exposure. Frontiers in pharmacology 10: 721	- Study does not contain a relevant intervention
Bouassa, R.-S.M., Belec, L., Gubavu, C. et al. (2019) High Prevalence of Anal and Oral High-Risk Human Papillomavirus in Human Immunodeficiency Virus-Uninfected French Men Who Have Sex with Men and Use Preexposure Prophylaxis. Open Forum Infectious Diseases 6(9): ofz291	- Not a relevant study design *cross-sectional*
Bourne, Adam, Cassolato, Matteo, Thuan Wei, Clayton Koh et al. (2017) Willingness to use pre-exposure prophylaxis (PrEP) for HIV prevention among men who have sex with men (MSM) in Malaysia: findings from a qualitative study. Journal of the International AIDS Society 20(1): 21899	- Non-OECD country

Study	Reason
Braksmajer, Amy, Leblanc, Natalie M, El-Bassel, Nabila et al. (2019) Feasibility and acceptability of pre-exposure prophylaxis use among women in violent relationships. AIDS care 31(4): 475-480	- OECD remaining countries
Brinkley-Rubinstein, Lauren, Peterson, Meghan, Arnold, Trisha et al. (2018) Knowledge, interest, and anticipated barriers of pre-exposure prophylaxis uptake and adherence among gay, bisexual, and men who have sex with men who are incarcerated. PloS one 13(12): e0205593	- Not the target population
Brinkley-Rubinstein, Lauren, Peterson, Meghan, Zaller, Nickolas D et al. (2019) Best practices for identifying men who have sex with men for corrections-based pre-exposure prophylaxis provision. Health & justice 7(1): 7	- Qualitative - does not ask relevant questions
Brooks, B., Park, S.H., Guilamo-Ramos, V. et al. (2019) Sex Tourism and Pre-Exposure Prophylaxis Modality Preferences Among Men Who Have Sex With Men. Journal of Sex Research 56(45): 632-640	- Qualitative - closed questions
Brooks, R.A., Nieto, O., Landrian, A. et al. (2019) Experiences of Pre-Exposure Prophylaxis (PrEP)-Related Stigma among Black MSM PrEP Users in Los Angeles. Journal of Urban Health	- OECD remaining countries
Brooks, Ronald A, Kaplan, Rachel L, Lieber, Eli et al. (2011) Motivators, concerns, and barriers to adoption of preexposure prophylaxis for HIV prevention among gay and bisexual men in HIV-serodiscordant male relationships. AIDS care 23(9): 1136-45	- OECD remaining countries
Brooks, Ronald A, Landovitz, Raphael J, Kaplan, Rachel L et al. (2012) Sexual risk behaviors and acceptability of HIV pre-exposure prophylaxis among HIV-negative gay and bisexual men in serodiscordant relationships: a mixed methods study. AIDS patient care and STDs 26(2): 87-94	- OECD remaining countries
Brooks, Ronald A, Landovitz, Raphael J, Regan, Rotrease et al. (2015) Perceptions of and intentions to adopt HIV pre-exposure prophylaxis among black men who have sex with men in Los Angeles. International journal of STD & AIDS 26(14): 1040-8	- OECD remaining countries
Brooks, Ronald A, Landrian, Amanda, Nieto, Omar et al. (2019) Experiences of Anticipated and Enacted Pre-exposure Prophylaxis (PrEP) Stigma Among Latino MSM in Los Angeles. AIDS and behavior 23(7): 1964-1973	- OECD remaining countries
Brooks, Ronald A, Nieto, Omar, Landrian, Amanda et al. (2019) Persistent stigmatizing and negative perceptions of pre-exposure prophylaxis (PrEP) users: implications for PrEP adoption among Latino men who have sex with men. AIDS care 31(4): 427-435	- OECD remaining countries
Cahill, Sean, Taylor, S Wade, Elsesser, Steven A et al. (2017) Stigma, medical mistrust, and perceived racism may affect PrEP awareness and uptake in black compared to white gay and bisexual men in Jackson, Mississippi and Boston, Massachusetts. AIDS care 29(11): 1351-1358	- OECD remaining countries

Study	Reason
Calabrese, Sarah K, Dovidio, John F, Tekeste, Mehrit et al. (2018) HIV Pre-Exposure Prophylaxis Stigma as a Multidimensional Barrier to Uptake Among Women Who Attend Planned Parenthood. Journal of acquired immune deficiency syndromes (1999) 79(1): 46-53	- Qualitative - closed questions
Calder, Bobby J, Schieffer, Robert J, Bryndza Tfaily, Ewa et al. (2018) Qualitative Consumer Research on Acceptance of Long-Acting Pre-Exposure Prophylaxis Products Among Men Having Sex with Men and Medical Practitioners in the United States. AIDS research and human retroviruses 34(10): 849-856	- OECD remaining countries
Callander, D., Park, S.H., Schneider, J.A. et al. (2019) City of love: Group sex is associated with risks for HIV and other sexually transmissible infections among gay and bisexual men in Paris, France. Sexual Health 16(2): 192-194	- Qualitative - closed questions
Cambiano, Valentina, Miners, Alec, Dunn, David et al. (2018) Cost-effectiveness of pre-exposure prophylaxis for HIV prevention in men who have sex with men in the UK: a modelling study and health economic evaluation. The Lancet. Infectious diseases 18(1): 85-94	- Cost-effectiveness
Cambiano, Valentina; Miners, Alec; Phillips, Andrew (2016) What do we know about the cost-effectiveness of HIV preexposure prophylaxis, and is it affordable?. Current opinion in HIV and AIDS 11(1): 56-66	- Cost-effectiveness
Camlin, C.S., Koss, C.A., Getahun, M. et al. (2020) Understanding Demand for PrEP and Early Experiences of PrEP Use Among Young Adults in Rural Kenya and Uganda: A Qualitative Study. AIDS and Behavior	- Non-OECD country
Carillon, S., Gallardo, L., Linard, F. et al. (2020) Perspectives of injectable long acting antiretroviral therapies for HIV treatment or prevention: understanding potential users' ambivalences. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV	- OECD remaining countries
Carlo Hojilla, J., Marcus, J., Volk, J.E. et al. (2019) Alcohol and drug use, partner PrEP use and STI prevalence among people with HIV. Sexually Transmitted Infections	- Qualitative - closed questions
Carnevale, Caroline, Zucker, Jason, Borsa, Alexander et al. (2020) Engaging a Predominantly Latino Community in HIV Prevention: Laying the Groundwork for Pre-exposure Prophylaxis and HIV Sexual Health Programs. The Journal of the Association of Nurses in AIDS Care : JANAC 31(1): 92-97	- Review article but not a systematic review
Case, K.K.; Gomez, G.B.; Hallett, T.B. (2019) The impact, cost and cost-effectiveness of oral pre-exposure prophylaxis in sub-Saharan Africa: a scoping review of modelling contributions and way forward. Journal of the International AIDS Society 22(9): e25390	- Cost-effectiveness
Celum, Connie and Baeten, Jared M (2012) Tenofovir-based pre-exposure prophylaxis for HIV prevention: evolving evidence. Current opinion in infectious diseases 25(1): 51-7	- Review article but not a systematic review

Study	Reason
Celum, Connie, Morrow, Rhoda A, Donnell, Deborah et al. (2014) Daily oral tenofovir and emtricitabine-tenofovir preexposure prophylaxis reduces herpes simplex virus type 2 acquisition among heterosexual HIV-1-uninfected men and women: a subgroup analysis of a randomized trial. Annals of internal medicine 161(1): 11-9	- Primary study included in systematic review
Chas, J., Rojas-Castro, D., Bernaud, C. et al. (2017) Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. The Lancet HIV 4(9): e402-e410	- Not a relevant study design *No control group*
Chen, Anders and Dowdy, David W (2014) Clinical effectiveness and cost-effectiveness of HIV pre-exposure prophylaxis in men who have sex with men: risk calculators for real-world decision-making. PloS one 9(10): e108742	- Cost-effectiveness
Chi, B.H., Sinkala, M., Mbewe, F. et al. (2008) Single-dose tenofovir and emtricitabine for reduction of viral resistance to non-nucleoside reverse transcriptase inhibitory drugs in women given intrapartum nevirapine for perinatal HIV prevention: An open-label randomized trial. Obstetrical and Gynecological Survey 63(4): 206-207	- Abstract only
Chi, Benjamin H, Chintu, Namwinga, Cantrell, Ronald A et al. (2008) Addition of single-dose tenofovir and emtricitabine to intrapartum nevirapine to reduce perinatal HIV transmission. Journal of acquired immune deficiency syndromes (1999) 48(2): 220-3	- Study does not contain a relevant intervention
Chi, Benjamin H, Ellis, Giovanina M, Chintu, Namwinga et al. (2009) Intrapartum tenofovir and emtricitabine reduces low-concentration drug resistance selected by single-dose nevirapine for perinatal HIV prevention. AIDS research and human retroviruses 25(11): 1099-106	- Study does not contain a relevant intervention
Chirwa, Lovemore I, Johnson, Jeffrey A, Niska, Richard W et al. (2014) CD4(+) cell count, viral load, and drug resistance patterns among heterosexual breakthrough HIV infections in a study of oral preexposure prophylaxis. AIDS (London, England) 28(2): 223-6	- Not a relevant study design - Primary study included in systematic review
Chittamuru, Deepti, Frye, Victoria, Koblin, Beryl A et al. (2020) PrEP stigma, HIV stigma, and intention to use PrEP among women in New York City and Philadelphia. Stigma and Health 5(2): 240-246	- Qualitative - closed questions
Choopanya, Kachit, Martin, Michael, Suntharasamai, Pravan et al. (2013) Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet (London, England) 381(9883): 2083-90	- Primary study included in systematic review

Study	Reason
Closson, Elizabeth F, Mitty, Jennifer A, Malone, Jowanna et al. (2018) Exploring strategies for PrEP adherence and dosing preferences in the context of sexualized recreational drug use among MSM: a qualitative study. AIDS care 30(2): 191-198	- OECD remaining countries
Cohen, M.S.; Gamble, T.; McCauley, M. (2020) Prevention of HIV Transmission and the HPTN 052 Study. Annu. Rev. Med. 71: 347-360	- Study does not contain a relevant intervention
Collier, Dami, Iwuji, Collins, Derache, Anne et al. (2017) Virological Outcomes of Second-line Protease Inhibitor-Based Treatment for Human Immunodeficiency Virus Type 1 in a High-Prevalence Rural South African Setting: A Competing-Risks Prospective Cohort Analysis. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 64(8): 1006-1016	- Study does not contain a relevant intervention
Collins, S.P.; McMahan, V.M.; Stekler, J.D. (2016) The Impact of HIV Pre-exposure Prophylaxis (PrEP) Use on the Sexual Health of Men Who Have Sex with Men: A Qualitative Study in Seattle, WA. International Journal of Sexual Health: 1-14	- OECD remaining countries
Corneli, Amy, Perry, Brian, Agot, Kawango et al. (2015) Facilitators of adherence to the study pill in the FEM-PrEP clinical trial. PloS one 10(4): e0125458	- Non-OECD country
Cornelisse, Vincent J, Lal, Luxi, Price, Brian et al. (2019) Interest in Switching to On-Demand HIV Pre-Exposure Prophylaxis (PrEP) Among Australian Users of Daily PrEP: An Online Survey. Open forum infectious diseases 6(7): ofz287	- Qualitative - closed questions
Coutinho, Barry and Prasad, Ramakrishna (2013) Emtricitabine/tenofovir (Truvada) for HIV prophylaxis. American family physician 88(8): 535-40	- Not a peer-reviewed publication
Crawford, N.D., Josma, D., Morris, J. et al. (2020) Pharmacy-based pre-exposure prophylaxis support among pharmacists and men who have sex with men. Journal of the American Pharmacists Association	- OECD remaining countries
Crosby, R.A., Geter, A., Diclemente, R.J. et al. (2014) Acceptability of condoms, circumcision and PrEP among young black men who have sex with men: A descriptive study based on effectiveness and cost. Vaccines 2(1): 129-137	- OECD remaining countries
Dale, S.K. (2020) Using Motivational Interviewing to Increase PrEP Uptake Among Black Women at Risk for HIV: an Open Pilot Trial of MI-PrEP. Journal of Racial and Ethnic Health Disparities	- Not a relevant study design
De Man, Jeroen, Colebunders, Robert, Florence, Eric et al. (2013) What is the place of pre-exposure prophylaxis in HIV prevention?. AIDS reviews 15(2): 102-11	- Review article but not a systematic review

Study	Reason
Desai, Monica, Field, Nigel, Grant, Robert et al. (2017) Recent advances in pre-exposure prophylaxis for HIV. BMJ (Clinical research ed.) 359: j5011	- Review article but not a systematic review Although article updates included Fonner review, no new data could be found on sexual behaviour other than what is included, and newer studies cited do not match protocol criteria in that they are before and after comparisons
Deutsch, Madeline B, Glidden, David V, Sevelius, Jae et al. (2015) HIV pre-exposure prophylaxis in transgender women: a subgroup analysis of the iPrEx trial. The lancet. HIV 2(12): e512-9	- Primary study included in systematic review
Devarajan, S., Sales, J.M., Hunt, M. et al. (2020) PrEP and sexual well-being: a qualitative study on PrEP, sexuality of MSM, and patient-provider relationships. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV 32(3): 386-393	- OECD remaining countries
Dimitrov, Dobromir, Boily, Marie-Claude, Brown, Elizabeth R et al. (2013) Analytic review of modeling studies of ARV Based PrEP interventions reveals strong influence of drug-resistance assumptions on the population-level effectiveness. PloS one 8(11): e80927	- Modelling
Doblecki-Lewis, Susanne and Kolber, Michael A (2014) Preventing HIV infection: pre-exposure and postexposure prophylaxis. IUBMB life 66(7): 453-61	- Review article but not a systematic review
Donnelly, J.A., Deem, T.T., Duffy, M.A. et al. (2019) Applying national estimates of adults with indications for pre-exposure prophylaxis to populations of men who have sex with men and people who inject drugs in Colorado: Modeling study. Journal of Medical Internet Research 21(1): e11113	- Modelling

Study	Reason
Drabo, Emmanuel F, Hay, Joel W, Vardavas, Raffaele et al. (2016) A Cost-effectiveness Analysis of Preexposure Prophylaxis for the Prevention of HIV Among Los Angeles County Men Who Have Sex With Men. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 63(11): 1495-1504	- Cost-effectiveness
Dubov, Alex, Galbo, Phillip Jr, Altice, Frederick L et al. (2018) Stigma and Shame Experiences by MSM Who Take PrEP for HIV Prevention: A Qualitative Study. American journal of men's health 12(6): 1843-1854	- OECD remaining countries
Durand-Zaleski, Isabelle, Mutuon, Pierre, Charreau, Isabelle et al. (2018) Costs and benefits of on-demand HIV preexposure prophylaxis in MSM. AIDS (London, England) 32(1): 95-102	- Cost-effectiveness
Eakle, Robyn, Bourne, Adam, Mbogua, Judie et al. (2018) Exploring acceptability of oral PrEP prior to implementation among female sex workers in South Africa. Journal of the International AIDS Society 21(2)	- Non-OECD country
Eakle, Robyn, Gomez, Gabriela B, Naicker, Niven et al. (2017) HIV pre-exposure prophylaxis and early antiretroviral treatment among female sex workers in South Africa: Results from a prospective observational demonstration project. PLoS medicine 14(11): e1002444	- Not a relevant study design Case-series - no control group
Eaton, Lisa A, Matthews, Derrick D, Driffin, Daniel D et al. (2017) A Multi-US City Assessment of Awareness and Uptake of Pre-exposure Prophylaxis (PrEP) for HIV Prevention Among Black Men and Transgender Women Who Have Sex with Men. Prevention science : the official journal of the Society for Prevention Research 18(5): 505-516	- Not a relevant study design
Edeza, A., Galarraga, O., Santamaria, E.K. et al. (2019) "I Do Try To Use Condoms, But...": Knowledge and Interest in PrEP Among Male Sex Workers in Mexico City. Archives of Sexual Behavior	- OECD remaining countries
Elopre, Latesha, McDavid, Chastity, Brown, Ashley et al. (2018) Perceptions of HIV Pre-Exposure Prophylaxis Among Young, Black Men Who Have Sex with Men. AIDS patient care and STDs 32(12): 511-518	- OECD remaining countries
Escudero, Daniel J, Lurie, Mark N, Kerr, Thomas et al. (2014) HIV pre-exposure prophylaxis for people who inject drugs: a review of current results and an agenda for future research. Journal of the International AIDS Society 17: 18899	- Review article but not a systematic review
Excler, Jean-Louis, Rida, Wasima, Priddy, Frances et al. (2011) AIDS vaccines and preexposure prophylaxis: is synergy possible?. AIDS research and human retroviruses 27(6): 669-80	- Study does not contain a relevant intervention

Study	Reason
	Vaccine and PrEP
Falcao, J.R.S.P., Bradshaw, C.C., Garrett, C.C. et al. (2016) Views of HIV-negative partners in heterosexual serodiscordant relationships regarding HIV pre-exposure prophylaxis: A qualitative study. Sexual Health 13(4): 345-352	- Qualitative - does not ask relevant questions
Falcao, Joana, Ahoua, Laurence, Zerbe, Allison et al. (2017) Willingness to use short-term oral pre-exposure prophylaxis (PrEP) by migrant miners and female partners of migrant miners in Mozambique. Culture, health & sexuality 19(12): 1389-1403	- Non-OECD country
Falcao, Joana, Zerbe, Allison, Lahuerta, Maria et al. (2017) Factors Associated with Use of Short-Term Pre-Exposure Prophylaxis for HIV Among Female Partners of Migrant Miners in Mozambique. AIDS patient care and STDs 31(12): 528-534	- Non-OECD country
Felsher, Marisa, Szep, Zsofia, Krakower, Douglas et al. (2018) "I Don't Need PrEP Right Now": A Qualitative Exploration of the Barriers to PrEP Care Engagement Through the Application of the Health Belief Model. AIDS education and prevention : official publication of the International Society for AIDS Education 30(5): 369-381	- OECD remaining countries
Fernandez-Montero, Jose Vicente, Barreiro, Pablo, Del Romero, Jorge et al. (2012) Antiretroviral drugs for pre-exposure prophylaxis of HIV infection. AIDS reviews 14(1): 54-61	- Not a relevant study design
Fina, L., Phillips, A.L., Jones, A.T. et al. (2019) Early experience of implementing a national HIV pre-exposure prophylaxis service in Wales, United Kingdom 2017. Sexual Health 16(1): 56-62	- Not a relevant study design *Findings of service survey*
Flash, Charlene A, Stone, Valerie E, Mitty, Jennifer A et al. (2014) Perspectives on HIV prevention among urban black women: a potential role for HIV pre-exposure prophylaxis. AIDS patient care and STDs 28(12): 635-42	- OECD remaining countries
Fleming, Paul J, Barrington, Clare, Perez, Martha et al. (2016) HIV testing, care, and treatment experiences among the steady male partners of female sex workers living with HIV in the Dominican Republic. AIDS care 28(6): 699-704	- Non-OECD country
Fletcher, Faith E, Fisher, Celia, Buchberg, Meredith K et al. (2018) "Where Did This [PrEP] Come From?" African American Mother/Daughter Perceptions Related to Adolescent Preexposure Prophylaxis (PrEP) Utilization and Clinical Trial Participation. Journal of empirical research on human research ethics : JERHRE 13(2): 173-184	- OECD remaining countries

Study	Reason
Franks, Julie, Hirsch-Moverman, Yael, Loquere, Avelino S Jr et al. (2018) Sex, PrEP, and Stigma: Experiences with HIV Pre-exposure Prophylaxis Among New York City MSM Participating in the HPTN 067/ADAPT Study. AIDS and behavior 22(4): 1139-1149	- OECD remaining countries
Freeborn, Kellie and Portillo, Carmen J (2018) Does pre-exposure prophylaxis for HIV prevention in men who have sex with men change risk behaviour? A systematic review. Journal of clinical nursing 27(1718): 3254-3265	- Not a relevant study design SR Includes mixed-methods, qualitative designs. Same RCTs are included in more recent SR used
Fu, Rui; Owens, Douglas K; Brandeau, Margaret L (2018) Cost-effectiveness of alternative strategies for provision of HIV preexposure prophylaxis for people who inject drugs. AIDS (London, England) 32(5): 663-672	- Cost-effectiveness
Gafos, Mitzy, Brodnicki, Elizabeth, Desai, Monica et al. (2017) Acceptability of an open-label wait-listed trial design: Experiences from the PROUD PrEP study. PloS one 12(4): e0175596	- Qualitative - does not ask relevant questions
Galea, J T, Kinsler, J J, Salazar, X et al. (2011) Acceptability of pre-exposure prophylaxis as an HIV prevention strategy: barriers and facilitators to pre-exposure prophylaxis uptake among at-risk Peruvian populations. International journal of STD & AIDS 22(5): 256-62	- Non-OECD country
Galindo, Gabriel R, Walker, Ja'Nina J, Hazelton, Patrick et al. (2012) Community member perspectives from transgender women and men who have sex with men on pre-exposure prophylaxis as an HIV prevention strategy: implications for implementation. Implementation science : IS 7: 116	- OECD remaining countries
Gamarel, Kristi E and Golub, Sarit A (2020) Sexual goals and perceptions of goal congruence in individuals' PrEP adoption decisions: A mixed-methods study of gay and bisexual men who are in primary relationships. Annals of behavioral medicine : a publication of the Society of Behavioral Medicine 54(4): 237-248	- Not a relevant study design
Garcia, Jonathan, Parker, Caroline, Parker, Richard G et al. (2016) Psychosocial Implications of Homophobia and HIV Stigma in Social Support Networks: Insights for High-Impact HIV Prevention Among Black Men Who Have Sex With Men. Health education & behavior : the official publication of the Society for Public Health Education 43(2): 217-25	- OECD remaining countries
Garcia, Jonathan, Parker, Richard G, Parker, Caroline et al. (2016) The limitations of 'Black MSM' as a category: Why gender, sexuality, and desire still matter for	- Qualitative - does not ask

Study	Reason
social and biomedical HIV prevention methods. Global public health 11(78): 1026-48	relevant questions
Gatey, C., Pintado, C., Chas, J. et al. (2014) Pre-exposure prophylaxis of HIV infection. Revue du Praticien 64(8): 2083-2090	- Study not reported in English
Gibas, Kevin M, van den Berg, Polly, Powell, Victoria E et al. (2019) Drug Resistance During HIV Pre-Exposure Prophylaxis. Drugs 79(6): 609-619	Not a relevant study design adverse event outcome included in effectiveness SR
Gilbert, H.N., Wyatt, M.A., Pisarski, E.E. et al. (2019) PrEP Discontinuation and Prevention-Effective Adherence: Experiences of PrEP Users in Ugandan HIV Serodiscordant Couples. Journal of Acquired Immune Deficiency Syndromes 82(3): 265-274	- Non-OECD country
Gilkey, Melissa B, Marcus, Julia L, Garrell, Jacob M et al. (2019) Using HIV Risk Prediction Tools to Identify Candidates for Pre-Exposure Prophylaxis: Perspectives from Patients and Primary Care Providers. AIDS patient care and STDs 33(8): 372-378	- Qualitative - does not ask relevant questions
Gilmore, Hailey J, Liu, Albert, Koester, Kimberly Ann et al. (2013) Participant experiences and facilitators and barriers to pill use among men who have sex with men in the iPrEx pre-exposure prophylaxis trial in San Francisco. AIDS patient care and STDs 27(10): 560-6	- OECD remaining countries
Ginsberg, G.M. and Chemtob, D. (2020) Cost utility analysis of HIV pre exposure prophylaxis among men who have sex with men in Israel. BMC Public Health 20(1): 271	- Cost-effectiveness
Giovenco, Danielle, Kuo, Caroline, Underhill, Kristen et al. (2018) "The Time Has Arrived": Perceptions of Behavioral Adjustments in the Context of Pre-Exposure Prophylaxis Availability Among Adolescents in South Africa. AIDS education and prevention : official publication of the International Society for AIDS Education 30(6): 463-473	- Non-OECD country
Glaubius, Robert, Ding, Yajun, Penrose, Kerri J et al. (2019) Dapivirine vaginal ring for HIV prevention: modelling health outcomes, drug resistance and cost-effectiveness. Journal of the International AIDS Society 22(5): e25282	- Cost-effectiveness
Glick, J.L., Russo, R., Jivapong, B. et al. (2019) The PrEP Care Continuum Among Cisgender Women Who Sell Sex and/or Use Drugs Globally: A Systematic Review. AIDS and Behavior	Secondary outcome – analysis - through primary outcome studies

Study	Reason
Goedel, William C, Chan, Philip A, King, Maximilian R F et al. (2019) Cost-Effectiveness of a Statewide Pre-Exposure Prophylaxis Program for Gay, Bisexual, and Other Men Who Have Sex with Men. Rhode Island medical journal (2013) 102(9): 36-39	Cost-effectiveness
Golub, S.A.; Meyers, K.; Enemchukwu, C. (2020) Perspectives and Recommendations From Lesbian, Gay, Bisexual, Transgender, and Queer/Questioning Youth of Color Regarding Engagement in Biomedical HIV Prevention. Journal of Adolescent Health 66(3): 281-287	OECD remaining countries
Golub, Sarit A (2014) Tensions between the epidemiology and psychology of HIV risk: implications for pre-exposure prophylaxis. AIDS and behavior 18(9): 1686-93	Qualitative - closed questions
Golub, Sarit A, Gamarel, Kristi E, Rendina, H Jonathon et al. (2013) From efficacy to effectiveness: facilitators and barriers to PrEP acceptability and motivations for adherence among MSM and transgender women in New York City. AIDS patient care and STDs 27(4): 248-54	- Qualitative - closed questions
Gomez, Gabriela B, Borquez, Annick, Caceres, Carlos F et al. (2012) The potential impact of pre-exposure prophylaxis for HIV prevention among men who have sex with men and transwomen in Lima, Peru: a mathematical modelling study. PLoS medicine 9(10): e1001323	- Cost-effectiveness
Gomez, Gabriela B, Borquez, Annick, Case, Kelsey K et al. (2013) The cost and impact of scaling up pre-exposure prophylaxis for HIV prevention: a systematic review of cost-effectiveness modelling studies. PLoS medicine 10(3): e1001401	- Cost-effectiveness
Govender, Eliza and Abdool Karim, Quarraisha (2018) Understanding women and men's acceptability of current and new HIV prevention technologies in KwaZulu-Natal, South Africa. AIDS care 30(10): 1311-1314	- Non-OECD country
Govender, Eliza, Mansoor, Leila, MacQueen, Kate et al. (2017) Secrecy, empowerment and protection: positioning PrEP in KwaZulu-Natal, South Africa. Culture, health & sexuality 19(11): 1268-1285	- Non-OECD country
Grant, Hannah, Mukandavire, Zindoga, Eakle, Robyn et al. (2017) When are declines in condom use while using PrEP a concern? Modelling insights from a Hillbrow, South Africa case study. Journal of the International AIDS Society 20(1): 21744	- Not a relevant study design
Grant, Robert M, Anderson, Peter L, McMahan, Vanessa et al. (2014) Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. The Lancet. Infectious diseases 14(9): 820-9	- Primary study included in systematic review
Grant, Robert M, Lama, Javier R, Anderson, Peter L et al. (2010) Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. The New England journal of medicine 363(27): 2587-99	- Primary study included in systematic review

Study	Reason
Grant, Robert M, Mannheimer, Sharon, Hughes, James P et al. (2018) Daily and Nondaily Oral Preexposure Prophylaxis in Men and Transgender Women Who Have Sex With Men: The Human Immunodeficiency Virus Prevention Trials Network 067/ADAPT Study. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 66(11): 1712-1721	- Comparator in study does not match that specified in protocol
Gray, Megan E; Shenoi, Sheela V; Dillingham, Rebecca (2018) Pre-exposure Prophylaxis as HIV Prevention in High Risk Adolescents. Journal of pediatrics and pediatric medicine 2(1): 5-10	Review article but not a systematic review
Gredig, Daniel, Uggowitzer, Franziska, Hassler, Benedikt et al. (2016) Acceptability and willingness to use HIV pre-exposure prophylaxis among HIV-negative men who have sex with men in Switzerland. AIDS care 28suppl1: 44-7	- OECD remaining countries
Greenwald, Z.R., Maheu-Giroux, M., Szabo, J. et al. (2019) Cohort profile: L'Actuel Pre-Exposure Prophylaxis (PrEP) Cohort study in Montreal, Canada. BMJ Open 9(6): e028768	Not a relevant study design *No control group*
Griffin, James A, Eldridge-Smith, Elizabeth D, Yohannan, Jiby et al. (2020) Pre-exposure Prophylaxis Knowledge and Use Among Men Who Have Sex With Men in a Small Metropolitan Region of the Southeastern United States. The Journal of the Association of Nurses in AIDS Care : JANAC 31(1): 80-91	- Qualitative - closed questions
Grimm, Josh and Schwartz, Joseph (2019) "It's Like Birth Control for HIV": Communication and Stigma for Gay Men on PrEP. Journal of homosexuality 66(9): 1179-1197	Retracted paper
Grov, Christian, D'Angelo, Alexa B, Flynn, Anthony W P et al. (2018) How Do Gay and Bisexual Men Make Up for Missed PrEP Doses, and What Impact Does Missing a Dose Have on Their Subsequent Sexual Behavior?. AIDS education and prevention : official publication of the International Society for AIDS Education 30(4): 275-286	- Qualitative - does not ask relevant questions
Grov, Christian, Flynn, Anthony W P, D'Angelo, Alexa B et al. (2019) Gay and Bisexual Men's Strategies to Maintain Daily Adherence to Their HIV Pre-exposure Prophylaxis (PrEP) Medication: Results from a Qualitative Study. Prevention science : the official journal of the Society for Prevention Research 20(1): 168-177	- Qualitative - does not ask relevant questions
Grov, Christian and Kumar, Navin (2018) HIV pre-exposure prophylaxis (PrEP) is coming to Europe, but are gay men ready to accept it? Qualitative findings from Berlin, Germany. Sexuality Research & Social Policy: A Journal of the NSRC 15(3): 283-289	- OECD remaining countries
Guest, Greg, Shattuck, Dominick, Johnson, Laura et al. (2010) Acceptability of PrEP for HIV prevention among women at high risk for HIV. Journal of women's health (2002) 19(4): 791-8	- Non-OECD country

Study	Reason
Guest, Greg, Shattuck, Dominick, Johnson, Laura et al. (2008) Changes in sexual risk behavior among participants in a PrEP HIV prevention trial. Sexually transmitted diseases 35(12): 1002-8	- Primary study included in systematic review
Gupta, Sanchit; Lounsbury, David W; Patel, Viraj V (2017) Low Awareness and Use of Preexposure Prophylaxis in a Diverse Online Sample of Men Who Have Sex With Men in New York City. The Journal of the Association of Nurses in AIDS Care : JANAC 28(1): 27-33	- Qualitative - closed questions
Haberer, Jessica E, Baeten, Jared M, Campbell, James et al. (2013) Adherence to antiretroviral prophylaxis for HIV prevention: a substudy cohort within a clinical trial of serodiscordant couples in East Africa. PLoS medicine 10(9): e1001511	- Primary study included in systematic review
Hallett, Timothy B, Baeten, Jared M, Heffron, Renee et al. (2011) Optimal uses of antiretrovirals for prevention in HIV-1 serodiscordant heterosexual couples in South Africa: a modelling study. PLoS medicine 8(11): e1001123	- Cost-effectiveness
Hannaford, A., Lim, J., Moll, A.P. et al. (2020) 'PrEP should be for men only': Young heterosexual men's views on PrEP in rural South Africa. Global Public Health	- Non-OECD country
Hannaford, Alisse, Lipshie-Williams, Madeleine, Starrels, Joanna L et al. (2018) The Use of Online Posts to Identify Barriers to and Facilitators of HIV Pre-exposure Prophylaxis (PrEP) Among Men Who Have Sex with Men: A Comparison to a Systematic Review of the Peer-Reviewed Literature. AIDS and behavior 22(4): 1080-1095	- Not a relevant study design
Hanscom, Brett, Janes, Holly E, Guarino, Peter D et al. (2016) Brief Report: Preventing HIV-1 Infection in Women Using Oral Preexposure Prophylaxis: A Meta-analysis of Current Evidence. Journal of acquired immune deficiency syndromes (1999) 73(5): 606-608	- More recent systematic review included that covers the same topic
Hansson, D., Stromdahl, S., Leung, K.Y. et al. (2020) Introducing pre-exposure prophylaxis to prevent HIV acquisition among men who have sex with men in Sweden: Insights from a mathematical pair formation model. BMJ Open 10(2): e033852	- Modelling
Harper, K.N. (2016) Preexposure prophylaxis on-demand dramatically reduces HIV incidence in MSM. AIDS 30(12): n19	- Not a relevant study design
Harrison, Abigail, Colvin, Christopher J, Kuo, Caroline et al. (2015) Sustained High HIV Incidence in Young Women in Southern Africa: Social, Behavioral, and Structural Factors and Emerging Intervention Approaches. Current HIV/AIDS reports 12(2): 207-15	- Review article but not a systematic review

Study	Reason
Hartmann, Miriam, McConnell, Margaret, Bekker, Linda-Gail et al. (2018) Motivated Reasoning and HIV Risk? Views on Relationships, Trust, and Risk from Young Women in Cape Town, South Africa, and Implications for Oral PrEP. AIDS and behavior 22(11): 3468-3479	- Non-OECD country
Havens, Joshua P, Scarsi, Kimberly K, Sayles, Harlan et al. (2019) Acceptability and feasibility of a pharmacist-led HIV pre-exposure prophylaxis (PrEP) program in the Midwestern United States. Open forum infectious diseases 6(10)	- Qualitative - closed questions
Havens, P.L., Perumean-Chaney, S.E., Patki, A. et al. (2020) Changes in Bone Mass after Discontinuation of Preexposure Prophylaxis with Tenofovir Disoproxil Fumarate/Emtricitabine in Young Men Who Have Sex with Men: Extension Phase Results of Adolescent Trials Network Protocols 110 and 113. Clinical Infectious Diseases 70(4): 687-691	Adverse events covered by included SRs - this study looks at events following discontinuation of PrEP
Heffron, Renee, Ngure, Kenneth, Mugo, Nelly et al. (2012) Willingness of Kenyan HIV-1 serodiscordant couples to use antiretroviral-based HIV-1 prevention strategies. Journal of acquired immune deficiency syndromes (1999) 61(1): 116-9	- Non-OECD country
Heffron, Renee, Ngure, Kenneth, Odoyo, Josephine et al. (2017) Pre-exposure prophylaxis for HIV-negative persons with partners living with HIV: uptake, use, and effectiveness in an open-label demonstration project in East Africa. Gates open research 1: 3	Not a relevant study design No control/unexposed group
Hellinger, Fred J (2013) Assessing the cost effectiveness of pre-exposure prophylaxis for HIV prevention in the US. PharmacoEconomics 31(12): 1091-104	- Cost-effectiveness
Hermanussen, R. (2017) HIV pre-exposure prophylaxis (PrEP). Huisarts en Wetenschap 60(6): 264-267	- Study not reported in English
Hill, Andrew, Hill, Teresa, Jose, Sophie et al. (2014) Predicted savings to the UK National Health Service from switching to generic antiretrovirals, 2014-2018. Journal of the International AIDS Society 17(4suppl3): 19497	-Conference abstract
Hoenigl, M., Jain, S., Moore, D. et al. (2018) Substance use and adherence to HIV preexposure prophylaxis for men who have sex with men. Emerging Infectious Diseases 24(12): 2292-2302	- Secondary outcome - analysis through primary outcome studies

Study	Reason
Hoff, Colleen C, Chakravarty, Deepalika, Bircher, Anja E et al. (2015) Attitudes Towards PrEP and Anticipated Condom Use Among Concordant HIV-Negative and HIV-Discordant Male Couples. AIDS patient care and STDs 29(7): 408-17	- Not a relevant study design
Hojilla, J Carlo, Vlahov, David, Glidden, David V et al. (2018) Skating on thin ice: stimulant use and sub-optimal adherence to HIV pre-exposure prophylaxis. Journal of the International AIDS Society 21(3): e25103	- Not a relevant study design
Holt, M. (2014) HIV pre-exposure prophylaxis and treatment as prevention: A review of awareness and acceptability among men who have sex with men in the Asia-Pacific region and the Americas. Sexual Health 11(2): 166-170	- Review article but not a systematic review
Hoornenborg, E., Coyer, L., Achterbergh, R.C.A. et al. (2019) Sexual behaviour and incidence of HIV and sexually transmitted infections among men who have sex with men using daily and event-driven pre-exposure prophylaxis in AMPrEP: 2 year results from a demonstration study. The Lancet HIV 6(7): e447-e455	- Not a relevant study design No control group
Horn, R.; Callander, D.; Haire, B. (2020) Perceptions of sexually transmissible infection pre-exposure prophylaxis: A qualitative study of high-risk gay and bisexual men in Sydney, New South Wales. Sexual Health 17(2): 129-134	- Study does not contain a relevant intervention
Huang, Poyao, Wu, Huei-Jiuan, Strong, Carol et al. (2019) Unspeakable PrEP: A qualitative study of sexual communication, problematic integration, and uncertainty management among men who have sex with men in Taiwan. Journal of Applied Communication Research 47(6): 611-627	- Non-OECD country
Huang, X., Hou, J., Song, A. et al. (2018) Efficacy and safety of oral TDF-based pre-exposure prophylaxis for men who have sex with men: A systematic review and meta-analysis. Frontiers in Pharmacology 9(sep): 799	- More recent systematic review included that covers the same topic
Hubach, Randolph D, Currin, Joseph M, Sanders, Carissa A et al. (2017) Barriers to Access and Adoption of Pre-Exposure Prophylaxis for the Prevention of HIV Among Men Who Have Sex With Men (MSM) in a Relatively Rural State. AIDS education and prevention : official publication of the International Society for AIDS Education 29(4): 315-329	- OECD remaining countries
Hughes, Shana D, Sheon, Nicolas, Andrew, Erin V W et al. (2018) Body/Selves and Beyond: Men's Narratives of Sexual Behavior on PrEP. Medical anthropology 37(5): 387-400	- OECD remaining countries
Hugo, J M, Stall, R D, Rebe, K et al. (2016) Anti-retroviral Therapy Based HIV Prevention Among a Sample of Men Who Have Sex with Men in Cape Town, South Africa: Use of Post-exposure Prophylaxis and Knowledge on Pre-exposure Prophylaxis. AIDS and behavior 20(suppl3): 357-364	- Non-OECD country

Study	Reason
Jacobsen, Margo M and Walensky, Rochelle P (2016) Modeling and Cost-Effectiveness in HIV Prevention. Current HIV/AIDS reports 13(1): 64-75	- Cost-effectiveness
Jamieson, Lise, Gomez, Gabriela B, Rebe, Kevin et al. (2020) The impact of self-selection based on HIV risk on the cost-effectiveness of preexposure prophylaxis in South Africa. AIDS (London, England) 34(6): 883-891	- Cost-effectiveness
Janes, Holly, Corey, Lawrence, Ramjee, Gita et al. (2018) Weighing the Evidence of Efficacy of Oral PrEP for HIV Prevention in Women in Southern Africa. AIDS research and human retroviruses 34(8): 645-656	- Review article but not a systematic review
Jewell, Britta L, Cremin, Ide, Pickles, Michael et al. (2015) Estimating the cost-effectiveness of pre-exposure prophylaxis to reduce HIV-1 and HSV-2 incidence in HIV-serodiscordant couples in South Africa. PloS one 10(1): e0115511	- Cost-effectiveness
Jiang, Junjun, Yang, Xiaoyi, Ye, Li et al. (2014) Pre-exposure prophylaxis for the prevention of HIV infection in high risk populations: a meta-analysis of randomized controlled trials. PloS one 9(2): e87674	- More recent systematic review included that covers the same topic
John, Steven A, Rendina, H Jonathon, Grov, Christian et al. (2017) Home-based pre-exposure prophylaxis (PrEP) services for gay and bisexual men: An opportunity to address barriers to PrEP uptake and persistence. PloS one 12(12): e0189794	- Qualitative - closed questions
John, Steven A, Whitfield, Thomas H F, Rendina, H Jonathon et al. (2018) Will Gay and Bisexual Men Taking Oral Pre-exposure Prophylaxis (PrEP) Switch to Long-Acting Injectable PrEP Should It Become Available?. AIDS and behavior 22(4): 1184-1189	- Qualitative - closed questions
Joseph Davey, D.L., Bekker, L.-G., Gomba, Y. et al. (2019) Modelling the potential impact of providing preexposure prophylaxis in pregnant and breastfeeding women in South Africa. AIDS 33(8): 1391-1395	- Modelling
Joseph Davey, D.L., Pintye, J., Baeten, J.M. et al. (2020) Emerging evidence from a systematic review of safety of pre-exposure prophylaxis for pregnant and postpartum women: where are we now and where are we heading?. Journal of the International AIDS Society 23(1): e25426	- More recent systematic review included that covers the same topic
Joseph Davey, Dvora, Farley, Elise, Towriss, Catriona et al. (2018) Risk perception and sex behaviour in pregnancy and breastfeeding in high HIV prevalence settings: Programmatic implications for PrEP delivery. PloS one 13(5): e0197143	- Non-OECD country

Study	Reason
Juusola, Jessie L, Brandeau, Margaret L, Owens, Douglas K et al. (2012) The cost-effectiveness of preexposure prophylaxis for HIV prevention in the United States in men who have sex with men. Annals of internal medicine 156(8): 541-50	- Cost-effectiveness
Kamis, Kevin F, Marx, Grace E, Scott, Kenneth A et al. (2019) Same-Day HIV Pre-Exposure Prophylaxis (PrEP) Initiation During Drop-in Sexually Transmitted Diseases Clinic Appointments Is a Highly Acceptable, Feasible, and Safe Model that Engages Individuals at Risk for HIV into PrEP Care. Open forum infectious diseases 6(7): ofz310	- Study does not contain a relevant intervention
Kapadia, Shashi N, Wu, Chunyuan, Mayer, Kenneth H et al. (2018) No change in health-related quality of life for at-risk U.S. women and men starting HIV pre-exposure prophylaxis (PrEP): Findings from HPTN 069/ACTG A5305. PloS one 13(12): e0206577	- Modelling
Karletsos, D., Greenbaum, C.R., Kobayashi, E. et al. (2020) Willingness to use PrEP among female university students in Lesotho. PLoS ONE 15(3): e0230565	- Non-OECD country
Kasonde, Michael, Niska, Richard W, Rose, Charles et al. (2014) Bone mineral density changes among HIV-uninfected young adults in a randomised trial of pre-exposure prophylaxis with tenofovir-emtricitabine or placebo in Botswana. PloS one 9(3): e90111	- Not a relevant study design - Primary study included in systematic review
Kazemian, P., Costantini, S., Kumarasamy, N. et al. (2020) The Cost-effectiveness of Human Immunodeficiency Virus (HIV) Preexposure Prophylaxis and HIV Testing Strategies in High-risk Groups in India. Clinical Infectious Diseases 70(4): 633-642	- Cost-effectiveness
Kelesidis, Theodoros and Landovitz, Raphael J (2011) Preexposure prophylaxis for HIV prevention. Current HIV/AIDS reports 8(2): 94-103	- Review article but not a systematic review
Kelly, Christine A, Friedland, Barbara A, Morar, Neetha S et al. (2015) To tell or not to tell: male partner engagement in a Phase 3 microbicide efficacy trial in South Africa. Culture, health & sexuality 17(8): 1004-20	- Non-OECD country
Kesler, Maya A, Kaul, Rupert, Myers, Ted et al. (2016) Perceived HIV risk, actual sexual HIV risk and willingness to take pre-exposure prophylaxis among men who have sex with men in Toronto, Canada. AIDS care 28(11): 1378-85	- Not a relevant study design

Study	Reason
Kessler, Jason, Myers, Julie E, Nucifora, Kimberly A et al. (2014) Evaluating the impact of prioritization of antiretroviral pre-exposure prophylaxis in New York. AIDS (London, England) 28(18): 2683-91	- Modelling
Khan, Soheb, Funk, Connie A, Corado, Katya et al. (2017) Tenofovir Disoproxil Fumarate-Associated Fanconi Syndrome in an Human Immunodeficiency Virus (HIV)-Uninfected Man Receiving HIV Pre-Exposure Prophylaxis. Open forum infectious diseases 4(3): ofx149	- Not a relevant study design
Khanna, AS, Schneider, JA, Collier, N et al. (2019) A modeling framework to inform PrEP initiation and retention scale-up in the context of Getting to Zero Initiatives. AIDS (London, England)	- Modelling
Kibengo, Freddie M, Ruzagira, Eugene, Katende, David et al. (2013) Safety, adherence and acceptability of intermittent tenofovir/emtricitabine as HIV pre-exposure prophylaxis (PrEP) among HIV-uninfected Ugandan volunteers living in HIV-serodiscordant relationships: a randomized, clinical trial. PloS one 8(9): e74314	- Primary study included in systematic review
Kim, Sun Bean, Yoon, Myoungho, Ku, Nam Su et al. (2014) Mathematical modeling of HIV prevention measures including pre-exposure prophylaxis on HIV incidence in South Korea. PloS one 9(3): e90080	- Modelling
Kimani, Makobu, van der Elst, Elise M, Chiro, Oscar et al. (2019) PrEP interest and HIV-1 incidence among MSM and transgender women in coastal Kenya. Journal of the International AIDS Society 22(6): e25323	- Non-OECD country
Kinuthia, J., Pintye, J., Abuna, F. et al. (2020) Pre-exposure prophylaxis uptake and early continuation among pregnant and post-partum women within maternal and child health clinics in Kenya: results from an implementation programme. The Lancet HIV 7(1): e38-e48	- Not a relevant study design
Kiselinova, Maja, De Spiegelaere, Ward, Verhofstede, Chris et al. (2014) Antiretrovirals for HIV prevention: when should they be recommended?. Expert review of anti-infective therapy 12(4): 431-45	- Review article but not a systematic review
Knight, Rod, Small, Will, Thomson, Kim et al. (2016) Implementation challenges and opportunities for HIV Treatment as Prevention (TasP) among young men in Vancouver, Canada: a qualitative study. BMC public health 16: 262	- Study does not contain a relevant intervention
Koechlin, Florence M, Fonner, Virginia A, Dalglish, Sarah L et al. (2017) Values and Preferences on the Use of Oral Pre-exposure Prophylaxis (PrEP) for HIV Prevention Among Multiple Populations: A Systematic Review of the Literature. AIDS and behavior 21(5): 1325-1335	- Review article but not a systematic review
Kofman, Aaron and Adashi, Eli Y (2014) Pre-exposure prophylaxis for the primary prevention of HIV in at-risk women: empowerment and equity revisited. AIDS reviews 16(3): 134-43	- Not a relevant study design

Study	Reason
	Narrative overview
Koppenhaver, Robert T, Sorensen, Stephen W, Farnham, Paul G et al. (2011) The cost-effectiveness of pre-exposure prophylaxis in men who have sex with men in the United States: An epidemic model. JAIDS Journal of Acquired Immune Deficiency Syndromes 58(2): e51-e52	- Cost-effectiveness
Krakower, Douglas and Mayer, Kenneth H (2011) Promising prevention approaches: tenofovir gel and prophylactic use of antiretroviral medications. Current HIV/AIDS reports 8(4): 241-8	- Review article but not a systematic review
Krebs, E., Zang, X., Enns, B. et al. (2020) The impact of localized implementation: Determining the cost-effectiveness of HIV prevention and care interventions across six United States cities. AIDS 34(3): 447-458	- Cost-effectiveness
Krogstad, Emily A, Atujuna, Millicent, Montgomery, Elizabeth T et al. (2018) Perspectives of South African youth in the development of an implant for HIV prevention. Journal of the International AIDS Society 21(8): e25170	- Non-OECD country
Kruse, Leslie; Stover, Kayla; Henderson, Harold (2014) Perceptions of emtricitabine-tenofovir in HIV PrEP. HIV clinician 26(1): 1-7	- Full text paper not available
Kubicek, Katrina; Arauz-Cuadra, Cesar; Kipke, Michele D (2015) Attitudes and perceptions of biomedical HIV prevention methods: voices from young men who have sex with men. Archives of sexual behavior 44(2): 487-97	- OECD remaining countries
Kuo, C., Giovenco, D., DeAtley, T. et al. (2020) Recreational Use of HIV Antiretroviral Medication and Implications for HIV Pre-exposure Prophylaxis and Treatment. AIDS and Behavior	- Non-OECD country
Kuo, Irene, Olsen, Halli, Patrick, Rudy et al. (2016) Willingness to use HIV pre-exposure prophylaxis among community-recruited, older people who inject drugs in Washington, DC. Drug and alcohol dependence 164: 8-13	- Qualitative - closed questions
Kurtz, Steven P and Buttram, Mance E (2016) Misunderstanding of Pre-Exposure Prophylaxis Use Among Men Who Have Sex with Men: Public Health and Policy Implications. LGBT health 3(6): 461-464	- OECD remaining countries
Laborde, N.D., Kinley, P.M., Spinelli, M. et al. (2020) Understanding PrEP Persistence: Provider and Patient Perspectives. AIDS and Behavior	OECD remaining countries
Lancaster, K.E., Lungu, T., Bula, A. et al. (2019) Preferences for Pre-exposure Prophylaxis Service Delivery Among Female Sex Workers in Malawi: A Discrete Choice Experiment. AIDS and Behavior	- Non-OECD country *Qualitative*

Study	Reason
Lehman, Dara A, Baeten, Jared M, McCoy, Connor O et al. (2015) Risk of drug resistance among persons acquiring HIV within a randomized clinical trial of single- or dual-agent preexposure prophylaxis. The Journal of infectious diseases 211(8): 1211-8	- Not a relevant study design - Primary study included in systematic review
Leonardi, M; Lee, E; Tan, D H S (2011) Awareness of, usage of and willingness to use HIV pre-exposure prophylaxis among men in downtown Toronto, Canada. International journal of STD & AIDS 22(12): 738-41	- Qualitative - closed questions
Liegeon, G., Antoni, G., Senneville, E. et al. (2020) Changes in kidney function among men having sex with men starting on demand tenofovir disoproxil fumarate - emtricitabine for HIV pre-exposure prophylaxis. Journal of the International AIDS Society 23(2): e25420	- Primary study included in systematic review
Liegler, Teri, Abdel-Mohsen, Mohamed, Bentley, L Gordon et al. (2014) HIV-1 drug resistance in the iPrEx preexposure prophylaxis trial. The Journal of infectious diseases 210(8): 1217-27	- Primary study included in systematic review
Lippman, Sheri A, Koester, Kimberly A, Amico, K Rivet et al. (2015) Client and provider perspectives on new HIV prevention tools for MSM in the Americas. PloS one 10(3): e0121044	- OECD remaining countries
Liu, Albert Y, Vittinghoff, Eric, Chillag, Kata et al. (2013) Sexual risk behavior among HIV-uninfected men who have sex with men participating in a tenofovir preexposure prophylaxis randomized trial in the United States. Journal of acquired immune deficiency syndromes (1999) 64(1): 87-94	- Primary study included in systematic review
Liu, Albert Y, Vittinghoff, Eric, Sellmeyer, Deborah E et al. (2011) Bone mineral density in HIV-negative men participating in a tenofovir pre-exposure prophylaxis randomized clinical trial in San Francisco. PloS one 6(8): e23688	- Primary study included in systematic review
Liu, Albert, Cohen, Stephanie, Follansbee, Stephen et al. (2014) Early experiences implementing pre-exposure prophylaxis (PrEP) for HIV prevention in San Francisco. PLoS medicine 11(3): e1001613	- Not a relevant study design
Liu, Chunxing, Ding, Yingying, Ning, Zhen et al. (2018) Factors influencing uptake of pre-exposure prophylaxis: some qualitative insights from an intervention study of men who have sex with men in China. Sexual health 15(1): 39-45	- Non-OECD country - non-OECD
Lockard, Annie, Rosenberg, Eli S, Sullivan, Patrick S et al. (2019) Contrasting Self-Perceived Need and Guideline-Based Indication for HIV Pre-Exposure Prophylaxis Among Young, Black Men Who Have Sex with Men Offered Pre-	- OECD remaining countries

Study	Reason
Exposure Prophylaxis in Atlanta, Georgia. AIDS patient care and STDs 33(3): 112-119	
Luehring-Jones, Peter, Palfai, Tibor P, Tahaney, Kelli D et al. (2019) Pre-Exposure Prophylaxis (PrEP) Use is Associated With Health Risk Behaviors Among Moderate- and Heavy-Drinking MSM. AIDS education and prevention : official publication of the International Society for AIDS Education 31(5): 452-462	- Not a relevant study design - *cross-sectional*
Luz, Paula M, Osher, Benjamin, Grinsztejn, Beatriz et al. (2018) The cost-effectiveness of HIV pre-exposure prophylaxis in men who have sex with men and transgender women at high risk of HIV infection in Brazil. Journal of the International AIDS Society 21(3): e25096	- Cost-effectiveness
Maartens, Gary; Celum, Connie; Lewin, Sharon R (2014) HIV infection: epidemiology, pathogenesis, treatment, and prevention. Lancet (London, England) 384(9939): 258-71	Review article but not a systematic review
Macapagal, K., Kraus, A., Korpak, A.K. et al. (2019) PrEP Awareness, Uptake, Barriers, and Correlates Among Adolescents Assigned Male at Birth Who Have Sex with Males in the U.S. Archives of Sexual Behavior	- Qualitative - closed questions
Mack, Natasha, Evens, Emily M, Tolley, Elizabeth E et al. (2014) The importance of choice in the rollout of ARV-based prevention to user groups in Kenya and South Africa: a qualitative study. Journal of the International AIDS Society 17(3suppl2): 19157	- Non-OECD country
Magno, Laio, Dourado, Ines, Sutten Coats, Cassandra et al. (2019) Knowledge and willingness to use pre-exposure prophylaxis among men who have sex with men in Northeastern Brazil. Global public health 14(8): 1098-1111	- Non-OECD country
Mallayasamy, Surulivelrajan, Chaturvedula, Ayyappa, Fossler, Michael J et al. (2019) Assessment of Demographic and Socio-Behavioral Factors on Adherence to HIV Pre-Exposure Prophylaxis Using a Markov Modeling Approach. Frontiers in pharmacology 10: 785	- Modelling
Malone, Jowanna, Syvertsen, Jennifer L, Johnson, Blake E et al. (2018) Negotiating sexual safety in the era of biomedical HIV prevention: relationship dynamics among male couples using pre-exposure prophylaxis. Culture, health & sexuality 20(6): 658-672	- OECD remaining countries
Maloney, K.M., Krakower, D.S., Ziobro, D. et al. (2017) Culturally competent sexual healthcare as a prerequisite for obtaining preexposure prophylaxis: Findings from a qualitative study. LGBT Health 4(4): 310-314	- OECD remaining countries
Mansergh, Gordon; Koblin, Beryl A; Sullivan, Patrick S (2012) Challenges for HIV pre-exposure prophylaxis among men who have sex with men in the United States. PLoS medicine 9(8): e1001286	- Review article but not a systematic review

Study	Reason
Mansoor, L.E., Yende-Zuma, N., Baxter, C. et al. (2019) Integrated provision of topical pre-exposure prophylaxis in routine family planning services in South Africa: a non-inferiority randomized controlled trial. Journal of the International AIDS Society 22(9): e25381	- Study does not contain a relevant intervention - Does not include oral PrEP
Marcus, Julia L, Glidden, David V, Mayer, Kenneth H et al. (2013) No evidence of sexual risk compensation in the iPrEx trial of daily oral HIV preexposure prophylaxis. PloS one 8(12): e81997	- Primary study included in systematic review
Marrazzo, J, Rabe, L, Kelly, C et al. (2013) Herpes simplex virus (HSV) infection in the VOICE (MTN 003) study: pre-exposure prophylaxis (PrEP) for HIV with daily use of oral tenofovir, oral tenofovir-emtricitabine, or vaginal tenofovir gel. Sexually transmitted infections 89: a46	- Abstract only
Marrazzo, Jeanne M, Ramjee, Gita, Richardson, Barbra A et al. (2015) Tenofovir-based preexposure prophylaxis for HIV infection among African women. The New England journal of medicine 372(6): 509-18	- Not a relevant study design - Primary study included in systematic review
Marshall, B.D.L. and Mimiaga, M.J. (2015) Uptake and effectiveness of PrEP for transgender women. The Lancet HIV 2(12): e502-e503	- Not a relevant study design
Martin, Michael, Vanichseni, Suphak, Suntharasamai, Pravan et al. (2014) Risk behaviors and risk factors for HIV infection among participants in the Bangkok tenofovir study, an HIV pre-exposure prophylaxis trial among people who inject drugs. PloS one 9(3): e92809	- Primary study included in systematic review
Maseko, Bertha, Hill, Lauren M, Phanga, Twambilile et al. (2020) Perceptions of and interest in HIV pre-exposure prophylaxis use among adolescent girls and young women in Lilongwe, Malawi. PloS one 15(1): e0226062	- Non-OECD country
Maxwell, Steven; Gafos, Mitzy; Shahmanesh, Maryam (2019) Pre-exposure Prophylaxis Use and Medication Adherence Among Men Who Have Sex With Men: A Systematic Review of the Literature. The Journal of the Association of Nurses in AIDS Care : JANAC 30(4): e38-e61	Review article but not a systematic review
Mayeux, J.J. and Ng, Y.C. (2019) Pre-Exposure Prophylaxis in the Urgent Care Setting: A Systematic Review. Journal for Nurse Practitioners 15(8): 595-599	-Review article but not a systematic review

Study	Reason
McCormack, Sheena, Dunn, David T, Desai, Monica et al. (2016) Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. Lancet (London, England) 387(10013): 53-60	- Primary study included in systematic review
McGowan, Ian (2014) An overview of antiretroviral pre-exposure prophylaxis of HIV infection. American journal of reproductive immunology (New York, N.Y. : 1989) 71(6): 624-30	- Review article but not a systematic review
McKenney, Jennie, Chen, Anders, Hoover, Karen W et al. (2017) Optimal costs of HIV pre-exposure prophylaxis for men who have sex with men. PloS one 12(6): e0178170	- Cost-effectiveness
McNaghten, A.D., Kearns, R., Siegler, A.J. et al. (2014) Sibanye methods for prevention packages program project protocol: Pilot study of HIV prevention interventions for men who have sex with men in South Africa. Journal of Medical Internet Research 16(10): e55	- Protocol
Mehta, Sapna A, Silvera, Richard, Bernstein, Kyle et al. (2011) Awareness of post-exposure HIV prophylaxis in high-risk men who have sex with men in New York City. Sexually transmitted infections 87(4): 344-8	- Qualitative - closed questions
Merchant, R.C., Corner, D., Garza, E. et al. (2016) Preferences for HIV Pre-Exposure Prophylaxis (PrEP) Information Among Men Who Have Sex with Men (MSM) at Community Outreach Settings. Journal of Gay and Lesbian Mental Health 20(1): 21-33	- Qualitative - closed questions
Meyer-Rath, Gesine, van Rensburg, Craig, Chiu, Calvin et al. (2019) The per-patient costs of HIV services in South Africa: Systematic review and application in the South African HIV Investment Case. PloS one 14(2): e0210497	- Cost-effectiveness
Mimiaga, Matthew J, Closson, Elizabeth F, Kothary, Vishesh et al. (2014) Sexual partnerships and considerations for HIV antiretroviral pre-exposure prophylaxis utilization among high-risk substance using men who have sex with men. Archives of sexual behavior 43(1): 99-106	- OECD remaining countries
Mirembe, Brenda G, Kelly, Clifton W, Mgodi, Nyaradzo et al. (2016) Bone Mineral Density Changes Among Young, Healthy African Women Receiving Oral Tenofovir for HIV Preexposure Prophylaxis. Journal of acquired immune deficiency syndromes (1999) 71(3): 287-94	- Not a relevant study design - Primary study included in systematic review
Mitchell, Jason W, Lee, Ji-Young, Woodyatt, Cory et al. (2016) HIV-negative male couples' attitudes about pre-exposure prophylaxis (PrEP) and using PrEP with a sexual agreement. AIDS care 28(8): 994-9	- OECD remaining countries

Study	Reason
Montgomery, Elizabeth T, Atujuna, Millicent, Krogstad, Emily et al. (2019) The Invisible Product: Preferences for Sustained-Release, Long-Acting Pre-exposure Prophylaxis to HIV Among South African Youth. Journal of acquired immune deficiency syndromes (1999) 80(5): 542-550	- Non-OECD country
Montgomery, Elizabeth T, van der Straten, Ariane, Stadler, Jonathan et al. (2015) Male Partner Influence on Women's HIV Prevention Trial Participation and Use of Pre-exposure Prophylaxis: the Importance of "Understanding". AIDS and behavior 19(5): 784-93	- Non-OECD country
Moodley, Nishila; Gray, Glenda; Bertram, Melanie (2016) The Price of Prevention: Cost Effectiveness of Biomedical HIV Prevention Strategies in South Africa. Clinical research in HIV/AIDS 3(1)	- Cost-effectiveness
Moon, K.T. (2011) Reducing HIV transmission via preexposure prophylaxis with antiretroviral drugs. American Family Physician 84(10): 1169-1175	Full text paper not available Summary overview not the full paper
Moskowitz, D.A., Macapagal, K., Mongrella, M. et al. (2020) What If My Dad Finds Out!?: Assessing Adolescent Men Who Have Sex with Men's Perceptions About Parents as Barriers to PrEP Uptake. AIDS and Behavior	- OECD remaining countries
Mosley, Terrance, Khaketla, Moliehi, Armstrong, Heather L et al. (2018) Trends in Awareness and Use of HIV PrEP Among Gay, Bisexual, and Other Men who have Sex with Men in Vancouver, Canada 2012-2016. AIDS and behavior 22(11): 3550-3565	- Qualitative - closed questions
Mugo, Nelly R, Hong, Ting, Celum, Connie et al. (2014) Pregnancy incidence and outcomes among women receiving preexposure prophylaxis for HIV prevention: a randomized clinical trial. JAMA 312(4): 362-71	- Excluded outcome Conception as outcome of interest excluded
Mugwanya, Kenneth K, Donnell, Deborah, Celum, Connie et al. (2013) Sexual behaviour of heterosexual men and women receiving antiretroviral pre-exposure prophylaxis for HIV prevention: a longitudinal analysis. The Lancet. Infectious diseases 13(12): 1021-8	- Not a relevant study design No control group
Mugwanya, Kenneth K, Wyatt, Christina, Celum, Connie et al. (2015) Changes in glomerular kidney function among HIV-1-uninfected men and women receiving emtricitabine-tenofovir disoproxil fumarate preexposure prophylaxis: a randomized clinical trial. JAMA internal medicine 175(2): 246-54	- Not a relevant study design Adverse events

Study	Reason
	assessed through SRs - Primary study included in systematic review
Mugwanya, Kenneth, Baeten, Jared, Celum, Connie et al. (2016) Low Risk of Proximal Tubular Dysfunction Associated With Emtricitabine-Tenofovir Disoproxil Fumarate Preexposure Prophylaxis in Men and Women. The Journal of infectious diseases 214(7): 1050-7	- Outcome does not match protocol
Mukandavire, Zindoga; Mitchell, Kate M; Vickerman, Peter (2016) Comparing the impact of increasing condom use or HIV pre-exposure prophylaxis (PrEP) use among female sex workers. Epidemics 14: 62-70	- Modelling
Mulligan, Kathleen, Glidden, David V, Anderson, Peter L et al. (2015) Effects of Emtricitabine/Tenofovir on Bone Mineral Density in HIV-Negative Persons in a Randomized, Double-Blind, Placebo-Controlled Trial. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 61(4): 572-80	- Primary study included in systematic review
Murnane, Pamela M, Celum, Connie, Mugo, Nelly et al. (2013) Efficacy of preexposure prophylaxis for HIV-1 prevention among high-risk heterosexuals: subgroup analyses from a randomized trial. AIDS (London, England) 27(13): 2155-60	- Primary study included in systematic review
Murnane, Pamela M, Heffron, Renee, Ronald, Allan et al. (2014) Pre-exposure prophylaxis for HIV-1 prevention does not diminish the pregnancy prevention effectiveness of hormonal contraception. AIDS (London, England) 28(12): 1825-30	- Outcome does not match protocol
Mustanski, Brian, Johnson, Amy K, Garofalo, Robert et al. (2013) Perceived likelihood of using HIV pre-exposure prophylaxis medications among young men who have sex with men. AIDS and behavior 17(6): 2173-9	- Qualitative - closed questions
Mutua, Gaudensia, Sanders, Eduard, Mugo, Peter et al. (2012) Safety and adherence to intermittent pre-exposure prophylaxis (PrEP) for HIV-1 in African men who have sex with men and female sex workers. PloS one 7(4): e33103	- Primary study included in systematic review
Nadery, S and Geerlings, S E (2013) Pre-exposure prophylaxis (PrEP) in HIV-uninfected individuals with high-risk behaviour. The Netherlands journal of medicine 71(6): 295-9	- Review article but not a systematic review
Ngure, K., Ongolly, F., Dolla, A. et al. (2020) "I just believe there is a risk" understanding of undetectable equals untransmissible (U = U) among health providers and HIV-negative partners in serodiscordant relationships in Kenya. Journal of the International AIDS Society 23(3): e25466	- Non-OECD country

Study	Reason
Nichols, Brooke E, Baltussen, Rob, van Dijk, Janneke H et al. (2014) Cost-effectiveness of PrEP in HIV/AIDS control in Zambia: a stochastic league approach. Journal of acquired immune deficiency syndromes (1999) 66(2): 221-8	- Cost-effectiveness
Nichols, Brooke E, Boucher, Charles A B, van der Valk, Marc et al. (2016) Cost-effectiveness analysis of pre-exposure prophylaxis for HIV-1 prevention in the Netherlands: a mathematical modelling study. The Lancet. Infectious diseases 16(12): 1423-1429	- Cost-effectiveness
Nichols, Brooke E, Boucher, Charles A B, van Dijk, Janneke H et al. (2013) Cost-effectiveness of pre-exposure prophylaxis (PrEP) in preventing HIV-1 infections in rural Zambia: a modeling study. PloS one 8(3): e59549	- Cost-effectiveness
Nicol, M.R.; Adams, J.L.; Kashuba, A.D.M. (2013) HIV pre-exposure prophylaxis trials: The road to success. Clinical Investigation 3(3): 295-308	- Review article but not a systematic review
Nodin, N, Carballo-Dieguez, A, Ventuneac, A M et al. (2008) Knowledge and acceptability of alternative HIV prevention bio-medical products among MSM who bareback. AIDS care 20(1): 106-15	- OECD remaining countries
O'Halloran, C., Rice, B., White, E. et al. (2019) Chemsex is not a barrier to self-reported daily PrEP adherence among PROUD study participants. International Journal of Drug Policy 74: 246-254	- Adherence - secondary outcome which will be assessed from efficacy SRs
Ogunbajo, A., Leblanc, N.M., Kushwaha, S. et al. (2020) Knowledge and Acceptability of HIV pre-exposure prophylaxis (PrEP) among men who have sex with men (MSM) in Ghana. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV 32(3): 330-336	Non-OECD country
Okwundu, Charles I and Okoromah, Christy A N (2009) Antiretroviral pre-exposure prophylaxis (PrEP) for preventing HIV in high-risk individuals. The Cochrane database of systematic reviews: cd007189	- Systematic review updated
Okwundu, Charles I; Uthman, Olalekan A; Okoromah, Christy An (2012) Antiretroviral pre-exposure prophylaxis (PrEP) for preventing HIV in high-risk individuals. The Cochrane database of systematic reviews: cd007189	- More recent systematic review included that covers the same topic
Oldenburg, Catherine E, Biello, Katie B, Colby, Donn et al. (2014) Engagement with peer health educators is associated with willingness to use pre-exposure prophylaxis among male sex workers in Ho Chi Minh City, Vietnam. AIDS Patient Care and STDs 28(3): 109-112	Non-OECD country

Study	Reason
Ong, Koh Jun, Desai, Sarika, Field, Nigel et al. (2017) Economic evaluation of HIV pre-exposure prophylaxis among men-who-have-sex-with-men in England in 2016. Euro surveillance : bulletin Europeen sur les maladies transmissibles = European communicable disease bulletin 22(42)	- Cost-effectiveness
Onoya, Dorina, Hirasen, Kamban, van den Berg, Liudmyla et al. (2018) Adverse Drug Reactions Among Patients Initiating Second-Line Antiretroviral Therapy in South Africa. Drug safety 41(12): 1343-1353	- Wrong population
Oostrom, L., Rosentel, K., Motley, D. et al. (2020) Discordance in objective and self-perceived HIV risk: A potential barrier to pre-exposure prophylaxis in young gay and bisexual men. Journal of the Association of Nurses in AIDS Care 31(1): 103-109	- Not a relevant study design secondary analysis of baseline survey data
Ouellet, E., Durand, M., Guertin, J.R. et al. (2015) Cost effectiveness of 'on demand' Hiv pre-exposure prophylaxis for non-injection drug-using men who have sex with men in Canada. Canadian Journal of Infectious Diseases and Medical Microbiology 26(1): 23-29	- Cost-effectiveness
Pacifico de Carvalho, Nathalia, Mendicino, Cassia Cristina Pinto, Candido, Raissa Carolina Fonseca et al. (2019) HIV pre-exposure prophylaxis (PrEP) awareness and acceptability among trans women: a review. AIDS care 31(10): 1234-1240	- Systematic review used as source of primary studies
Paltiel, A David, Freedberg, Kenneth A, Scott, Callie A et al. (2009) HIV preexposure prophylaxis in the United States: impact on lifetime infection risk, clinical outcomes, and cost-effectiveness. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 48(6): 806-15	- Cost-effectiveness
Pantalone, D.W., Holloway, I.W., Goldblatt, A.E.A. et al. (2019) The Impact of Pre-Exposure Prophylaxis on Sexual Communication and Sexual Behavior of Urban Gay and Bisexual Men. Archives of Sexual Behavior	- OECD remaining countries
Paparini, Sara, Nutland, Will, Rhodes, Tim et al. (2018) DIY HIV prevention: Formative qualitative research with men who have sex with men who source PrEP outside of clinical trials. PloS one 13(8): e0202830	- Qualitative - does not ask relevant questions
Parker, Sharon, Chan, Philip A, Oldenburg, Catherine E et al. (2015) Patient experiences of men who have sex with men using pre-exposure prophylaxis to prevent HIV infection. AIDS Patient Care and STDs 29(12): 639-642	- OECD remaining countries
Patel, Rena C, Stanford-Moore, Gaelen, Odoyo, Josephine et al. (2016) "Since both of us are using antiretrovirals, we have been supportive to each other": facilitators and barriers of pre-exposure prophylaxis use in heterosexual HIV	- Non-OECD country

Study	Reason
serodiscordant couples in Kisumu, Kenya. Journal of the International AIDS Society 19(1): 21134	
Patel, Rupa R, Crane, John S, Lopez, Julia et al. (2018) Pre-exposure prophylaxis for HIV prevention preferences among young adult African American men who have sex with men. PloS one 13(12): e0209484	- Non-OECD country
Paxton, Lynn A (2012) Considerations regarding antiretroviral chemoprophylaxis and heterosexuals in generalized epidemic settings. Current opinion in HIV and AIDS 7(6): 557-62	- Review article but not a systematic review
Paxton, Lynn A; Hope, Tony; Jaffe, Harold W (2007) Pre-exposure prophylaxis for HIV infection: what if it works?. Lancet (London, England) 370(9581): 89-93	- Review article but not a systematic review
Pelletier, S.J., Gagnon, M.-P., Diabate, S. et al. (2019) Pre-Exposure Prophylaxis (PrEP) in men who have sex with men in bouake, cote d'Ivoire: A qualitative evaluation of acceptability. Open AIDS Journal 13(1): 49-58	- Non-OECD country
Peng, Liping, Cao, Wangnan, Gu, Jing et al. (2019) Willingness to Use and Adhere to HIV Pre-Exposure Prophylaxis (PrEP) among Men Who Have Sex with Men (MSM) in China. International journal of environmental research and public health 16(14)	- Non-OECD country
Peng, Peng, Su, Shu, Fairley, Christopher K et al. (2018) A Global Estimate of the Acceptability of Pre-exposure Prophylaxis for HIV Among Men Who have Sex with Men: A Systematic Review and Meta-analysis. AIDS and behavior 22(4): 1063-1074	- Abstract only
Penrose, Kerri J, Brumme, Chanson J, Scoulos-Hanson, Maritsa et al. (2018) Frequent cross-resistance to rilpivirine among subtype C HIV-1 from first-line antiretroviral therapy failures in South Africa. Antiviral chemistry & chemotherapy 26: 2040206618762985	- Not a relevant study design
Perez-Figueroa, Rafael E, Kapadia, Farzana, Barton, Staci C et al. (2015) Acceptability of PrEP Uptake Among Racially/Ethnically Diverse Young Men Who Have Sex With Men: The P18 Study. AIDS education and prevention : official publication of the International Society for AIDS Education 27(2): 112-25	- OECD remaining countries
Perry, Brian, Oluoch, Lennah, Agot, Kawango et al. (2014) Widow cleansing and inheritance among the Luo in Kenya: the need for additional women-centred HIV prevention options. Journal of the International AIDS Society 17: 19010	- Non-OECD country
Peterson, M., Macmadu, A., Truong, A.Q. et al. (2019) Pre-exposure prophylaxis awareness and interest among participants in a medications for addiction treatment program in a unified jail and prison setting in Rhode Island. Journal of Substance Abuse Treatment 106: 73-78	- Not the target population

Study	Reason
Peterson, Meghan, Nowotny, Kathryn, Dauria, Emily et al. (2019) Institutional distrust among gay, bisexual, and other men who have sex with men as a barrier to accessing pre-exposure prophylaxis (PrEP). AIDS care 31(3): 364-369	- Not the target population
Philbin, Morgan M, Parker, Caroline M, Parker, Richard G et al. (2018) Gendered Social Institutions and Preventive Healthcare Seeking for Black Men Who Have Sex with Men: The Promise of Biomedical HIV Prevention. Archives of sexual behavior 47(7): 2091-2100	- Qualitative - does not ask relevant questions
Philbin, Morgan M, Parker, Caroline M, Parker, Richard G et al. (2016) The Promise of Pre-Exposure Prophylaxis for Black Men Who Have Sex with Men: An Ecological Approach to Attitudes, Beliefs, and Barriers. AIDS patient care and STDs 30(6): 282-90	- OECD remaining countries
Phillips, Gregory 2nd, Raman, Anand, Felt, Dylan et al. (2019) Factors Associated with PrEP Support and Disclosure Among YMSM and Transgender Individuals Assigned Male at Birth in Chicago. AIDS and behavior 23(10): 2749-2760	- Qualitative - closed questions
Pilkington, Victoria, Hill, Andrew, Hughes, Sophie et al. (2018) How safe is TDF/FTC as PrEP? A systematic review and meta-analysis of the risk of adverse events in 13 randomised trials of PrEP. Journal of virus eradication 4(4): 215-224	- More recent systematic review included that covers the same topic
Pintye, J., Beima-Sofie, K.M., Makabong'o, P.A. et al. (2018) HIV-Uninfected Kenyan Adolescent and Young Women Share Perspectives on Using Pre-Exposure Prophylaxis during Pregnancy. AIDS Patient Care and STDs 32(12): 538-544	- Non-OECD country
Pleuhs, B., Quinn, K.G., Walsh, J.L. et al. (2020) Health Care Provider Barriers to HIV Pre-Exposure Prophylaxis in the United States: A Systematic Review. AIDS Patient Care and STDs 34(3): 111-123	- Systematic review used as source of primary studies
Poteat, Tonia, Malik, Mannat, Scheim, Ayden et al. (2017) HIV Prevention Among Transgender Populations: Knowledge Gaps and Evidence for Action. Current HIV/AIDS reports 14(4): 141-152	- Review article but not a systematic review
Prem Kumar, S G, Kumar, G Anil, Poluru, Ramesh et al. (2013) Contact with HIV prevention programmes & willingness for new interventions among truckers in India. The Indian journal of medical research 137(6): 1061-71	- Non-OECD country
Price, Joan T, Wheeler, Stephanie B, Stranix-Chibanda, Lynda et al. (2016) Cost-Effectiveness of Pre-exposure HIV Prophylaxis During Pregnancy and Breastfeeding in Sub-Saharan Africa. Journal of acquired immune deficiency syndromes (1999) 72suppl2: 145-53	- Cost-effectiveness

Study	Reason
Puppo, C., Spire, B., Morel, S. et al. (2020) How PrEP users constitute a community in the MSM population through their specific experience and management of stigmatization. The example of the French ANRS-PREVENIR study. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV	- OECD remaining countries
Qin, Y., Price, C., Rutledge, R. et al. (2020) Women's Decision-Making about PrEP for HIV Prevention in Drug Treatment Contexts. Journal of the International Association of Providers of AIDS Care 19	- Not the target population
Quaife, Matthew, Terris-Prestholt, Fern, Eakle, Robyn et al. (2018) The cost-effectiveness of multi-purpose HIV and pregnancy prevention technologies in South Africa. Journal of the International AIDS Society 21(3)	- Cost-effectiveness
Quinn, K.G., Christenson, E., Sawkin, M.T. et al. (2019) The Unanticipated Benefits of PrEP for Young Black Gay, Bisexual, and Other Men Who Have Sex with Men. AIDS and Behavior	- OECD remaining countries
Quinn, K.G., Christenson, E., Spector, A. et al. (2020) The Influence of Peers on PrEP Perceptions and Use Among Young Black Gay, Bisexual, and Other Men Who Have Sex with Men: A Qualitative Examination. Archives of Sexual Behavior	- OECD remaining countries
Quinn, Katherine, Bowleg, Lisa, Dickson-Gomez, Julia et al. (2019) "The fear of being Black plus the fear of being gay": The effects of intersectional stigma on PrEP use among young Black gay, bisexual, and other men who have sex with men. Social Science & Medicine 232: 86-93	- OECD remaining countries
Quinn, Katherine, Dickson-Gomez, Julia, Zarwell, Meagan et al. (2019) "A Gay Man and a Doctor are Just like, a Recipe for Destruction": How Racism and Homonegativity in Healthcare Settings Influence PrEP Uptake Among Young Black MSM. AIDS and behavior 23(7): 1951-1963	- OECD remaining countries
Rael, Christine Tagliaferri, Martinez, Michelle, Giguere, Rebecca et al. (2019) Knowledge About Oral PrEP Among Transgender Women in New York City. AIDS and behavior 23(10): 2779-2783	- Qualitative - closed questions
Reidy, Meghan, Gardiner, Elizabeth, Pretorius, Carel et al. (2019) Evaluating the potential impact and cost-effectiveness of dapivirine vaginal ring pre-exposure prophylaxis for HIV prevention. PloS one 14(6): e0218710	- Cost-effectiveness
Remy, Laura and Enriquez, Maithe (2019) Behavioral Interventions to Enhance PrEP Uptake Among Black Men Who Have Sex With Men: A Review. The Journal of the Association of Nurses in AIDS Care : JANAC 30(2): 151-163	- Systematic review used as source of primary studies
Restar, Arjee J, Kuhns, Lisa, Reisner, Sari L et al. (2018) Acceptability of Antiretroviral Pre-exposure Prophylaxis from a Cohort of Sexually Experienced Young Transgender Women in Two U.S. Cities. AIDS and behavior 22(11): 3649-3657	- Not a relevant study design

Study	Reason
Restar, Arjee J, Tocco, Jack Ume, Mantell, Joanne E et al. (2017) Perspectives on HIV Pre- and Post-Exposure Prophylaxes (PrEP and PEP) Among Female and Male Sex Workers in Mombasa, Kenya: Implications for Integrating Biomedical Prevention into Sexual Health Services. AIDS education and prevention : official publication of the International Society for AIDS Education 29(2): 141-153	- Non-OECD country
Reyniers, Thijs, Nostlinger, Christiana, Laga, Marie et al. (2018) Choosing Between Daily and Event-Driven Pre-exposure Prophylaxis: Results of a Belgian PrEP Demonstration Project. Journal of acquired immune deficiency syndromes (1999) 79(2): 186-194	- OECD remaining countries
Reza-Paul, Sushena, Lazarus, Lisa, Doshi, Monika et al. (2016) Prioritizing Risk in Preparation for a Demonstration Project: A Mixed Methods Feasibility Study of Oral Pre-Exposure Prophylaxis (PREP) among Female Sex Workers in South India. PloS one 11(11): e0166889	- Non-OECD country
Rice, Whitney S, Stringer, Kristi L, Sohail, Maira et al. (2019) Accessing Pre-exposure Prophylaxis (PrEP): Perceptions of Current and Potential PrEP Users in Birmingham, Alabama. AIDS and behavior 23(11): 2966-2979	- OECD remaining countries
Riddell, James 4th; Amico, K Rivet; Mayer, Kenneth H (2018) HIV Preexposure Prophylaxis: A Review. JAMA 319(12): 1261-1268	- Review article but not a systematic review
Riddler, Sharon A, Husnik, Marla, Ramjee, Gita et al. (2017) HIV disease progression among women following seroconversion during a tenofovir-based HIV prevention trial. PloS one 12(6): e0178594	- Wrong population
Rivierez, I, Quatremere, G, Spire, B et al. (2018) Lessons learned from the experiences of informal PrEP users in France: results from the ANRS-PrEPage study. AIDS care 30(sup2): 48-53	- OECD remaining countries
Roberts, D Allen, Hawes, Stephen E, Bousso Bao, Mame D et al. (2020) Trends in Reported Sexual Behavior and Y-Chromosomal DNA Detection Among Female Sex Workers in the Senegal Preexposure Prophylaxis Demonstration Project. Sexually transmitted diseases 47(5): 314-320	- Not a relevant study design *No control group*
Roberts, Sarah T, Heffron, Renee, Ngure, Kenneth et al. (2014) Preferences for daily or intermittent pre-exposure prophylaxis regimens and ability to anticipate sex among HIV uninfected members of Kenyan HIV serodiscordant couples. AIDS and behavior 18(9): 1701-11	- Non-OECD country
Rocha, Luis Miguel, Campos, Maria Jose, Brito, Joao et al. (2014) Acceptability of PrEP among HIV negative Portuguese men who have sex with men that attended 2014 Lisbon pride fair. Journal of the International AIDS Society 17(4suppl3): 19734	- Abstract only

Study	Reason
Roesch, Amanda (2019) Implementing Pre-exposure Prophylaxis for HIV Prevention at an Urban Youth Clinic. The Journal of the Association of Nurses in AIDS Care : JANAC 30(2): 232-237	- Not a relevant study design
Rogers, Brooke G, Whiteley, Laura, Haubrick, Kayla K et al. (2019) Intervention Messaging About Pre-Exposure Prophylaxis Use Among Young, Black Sexual Minority Men. AIDS patient care and STDs 33(11): 473-481	- OECD remaining countries
Rojas Castro, D., Delabre, R.M., Morel, S. et al. (2019) Community engagement in the provision of culturally competent HIV and STI prevention services: lessons from the French experience in the era of PrEP. Journal of the International AIDS Society 22(s6): e25350	- Not a relevant study design
Ross, Eric L; Cinti, Sandro K; Hutton, David W (2016) Implementation and Operational Research: A Cost-Effective, Clinically Actionable Strategy for Targeting HIV Preexposure Prophylaxis to High-Risk Men Who Have Sex With Men. Journal of acquired immune deficiency syndromes (1999) 72(3): e61-7	- Cost-effectiveness
Rubincam, Clara, Newman, Peter A, Atujuna, Millicent et al. (2018) 'Why would you promote something that is less percent safer than a condom?': Perspectives on partially effective HIV prevention technologies among key populations in South Africa. SAHARA J : journal of Social Aspects of HIV/AIDS Research Alliance 15(1): 179-186	- Non-OECD country
Rucinski, Katherine B, Mensah, Nana P, Sepkowitz, Kent A et al. (2013) Knowledge and use of pre-exposure prophylaxis among an online sample of young men who have sex with men in New York City. AIDS and behavior 17(6): 2180-4	- Qualitative - closed questions
Saberi, Parya, Gamarel, Kristi E, Neilands, Torsten B et al. (2012) Ambiguity, ambivalence, and apprehensions of taking HIV-1 pre-exposure prophylaxis among male couples in San Francisco: a mixed methods study. PloS one 7(11): e50061	- OECD remaining countries
Sagaon-Teyssier, Luis, Suzan-Monti, Marie, Demoulin, Baptiste et al. (2016) Uptake of PrEP and condom and sexual risk behavior among MSM during the ANRS IPERGAY trial. AIDS care 28suppl1: 48-55	- Primary study included in systematic review
Sales, J.M., Phillips, A.L., Tamler, I. et al. (2019) Patient recommendations for PrEP information dissemination at family planning clinics in Atlanta, Georgia. Contraception 99(4): 233-238	- OECD remaining countries
Sarkar, S., Corso, P., Ebrahim-Zadeh, S. et al. (2019) Cost-effectiveness of HIV Prevention Interventions in Sub-Saharan Africa: A Systematic Review. EClinicalMedicine 10: 10-31	- Cost-effectiveness
Saxton, Peter, Giola, Massimo, Coughlan, Edward et al. (2018) Implementing HIV pre-exposure prophylaxis (PrEP): let's not get caught with our pants down. The New Zealand medical journal 131(1481): 64-73	- Not a relevant study design

Study	Reason
	viewpoint review
Scheibe, Andrew, Grasso, Michael, Raymond, Henry Fisher et al. (2018) Modelling the UNAIDS 90-90-90 treatment cascade for gay, bisexual and other men who have sex with men in South Africa: using the findings of a data triangulation process to map a way forward. AIDS and behavior 22(3): 853-859	- Study does not contain a relevant intervention Impact of PrEP does not appear to be able to be extracted
Schnarrs, Phillip W, Gordon, Danielle, Martin-Valenzuela, Ryan et al. (2018) Perceived Social Norms About Oral PrEP Use: Differences Between African-American, Latino and White Gay, Bisexual and Other Men Who Have Sex with Men in Texas. AIDS and behavior 22(11): 3588-3602	- OECD remaining countries
Schneider, John A, Dandona, Rakhi, Pasupneti, Shravani et al. (2010) Initial commitment to pre-exposure prophylaxis and circumcision for HIV prevention amongst Indian truck drivers. PloS one 5(7): e11922	- Non-OECD country
Schneider, Karen; Gray, Richard T; Wilson, David P (2014) A cost-effectiveness analysis of HIV preexposure prophylaxis for men who have sex with men in Australia. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 58(7): 1027-34	- Cost-effectiveness
Scholl, Elizabeth (2016) Improving outpatient implementation of preexposure prophylaxis in men who have sex with men. Journal of the American Association of Nurse Practitioners 28(8): 446-52	- Review article but not a systematic review
Schwartz, J. and Grimm, J. (2017) Stigma Communication Surrounding PrEP: The Experiences of A Sample of Men Who Have Sex With Men. Health Communication: 1-7	- OECD remaining countries
Shea, Jaclyn, Bula, Agatha, Dunda, Wezzie et al. (2019) "The Drug Will Help Protect My Tomorrow": Perceptions of Integrating PrEP into HIV Prevention Behaviors Among Female Sex Workers in Lilongwe, Malawi. AIDS education and prevention : official publication of the International Society for AIDS Education 31(5): 421-432	- Non-OECD country
Shen, Mingwang, Xiao, Yanni, Rong, Libin et al. (2018) The cost-effectiveness of oral HIV pre-exposure prophylaxis and early antiretroviral therapy in the presence of drug resistance among men who have sex with men in San Francisco. BMC medicine 16(1): 58	- Cost-effectiveness
Shiri, Tinevimbo and Welte, Alex (2011) Modelling the impact of acute infection dynamics on the accumulation of HIV-1 mutations. Journal of theoretical biology 279(1): 44-54	- Modelling

Study	Reason
Shrestha, R., Altice, F.L., Didomizio, E. et al. (2020) Feasibility and acceptability of an mhealth-based approach as an hiv prevention strategy among people who use drugs on pre-exposure prophylaxis. Patient Preference and Adherence 14: 107-118	- Not the target population
Shrestha, Roman and Copenhaver, Michael (2018) Exploring the Use of Pre-exposure Prophylaxis (PrEP) for HIV Prevention Among High-Risk People Who Use Drugs in Treatment. Frontiers in public health 6: 195	- Not the target population
Shrestha, Roman, Karki, Pramila, Altice, Frederick L et al. (2017) Correlates of willingness to initiate pre-exposure prophylaxis and anticipation of practicing safer drug- and sex-related behaviors among high-risk drug users on methadone treatment. Drug and alcohol dependence 173: 107-116	- Not the target population
Sidebottom, David; Ekstrom, Anna Mia; Stromdahl, Susanne (2018) A systematic review of adherence to oral pre-exposure prophylaxis for HIV - how can we improve uptake and adherence?. BMC infectious diseases 18(1): 581	- More recent systematic review included that covers the same topic
Sithole, Bhekie (2017) HIV prevention needs for men who have sex with men in Swaziland. African journal of AIDS research : AJAR 16(4): 315-320	- Non-OECD country
Skolnik, A.A., Bokhour, B.G., Gifford, A.L. et al. (2020) Roadblocks to PrEP: What Medical Records Reveal About Access to HIV Pre-exposure Prophylaxis. Journal of General Internal Medicine 35(3): 832-838	- Not a relevant study design
Smith, Dawn K, Toledo, Lauren, Smith, Donna Jo et al. (2012) Attitudes and program preferences of African-American urban young adults about pre-exposure prophylaxis (PrEP). AIDS education and prevention : official publication of the International Society for AIDS Education 24(5): 408-21	- OECD remaining countries
Soares, Fabiane, MacCarthy, Sarah, Magno, Laio et al. (2019) Factors Associated with PrEP Refusal Among Transgender Women in Northeastern Brazil. AIDS and behavior 23(10): 2710-2718	- Non-OECD country
Solomon, Marc M, Lama, Javier R, Glidden, David V et al. (2014) Changes in renal function associated with oral emtricitabine/tenofovir disoproxil fumarate use for HIV pre-exposure prophylaxis. AIDS (London, England) 28(6): 851-9	- Primary study included in systematic review
Solomon, Marc M, Mayer, Kenneth H, Glidden, David V et al. (2014) Syphilis predicts HIV incidence among men and transgender women who have sex with men in a preexposure prophylaxis trial. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 59(7): 1020-6	- Primary study included in systematic review
Storholm, Erik D, Volk, Jonathan E, Marcus, Julia L et al. (2017) Risk Perception, Sexual Behaviors, and PrEP Adherence Among Substance-Using Men Who Have	- OECD remaining countries

Study	Reason
Sex with Men: a Qualitative Study. Prevention science : the official journal of the Society for Prevention Research 18(6): 737-747	
Stover, John (2011) HIV models to inform health policy. Current opinion in HIV and AIDS 6(2): 108-13	- Review article but not a systematic review
Straubinger, T.; Kay, K.; Bies, R. (2020) Modeling HIV pre-exposure prophylaxis. Frontiers in Pharmacology 10: 1514	- Modelling
Sun, C.J., Anderson, K.M., Bangsberg, D. et al. (2019) Access to HIV Pre-exposure Prophylaxis in Practice Settings: a Qualitative Study of Sexual and Gender Minority Adults' Perspectives. Journal of General Internal Medicine 34(4): 535-543	- OECD remaining countries
Sun, Christina J, Anderson, Kirsten M, Toevs, Kim et al. (2019) "Little Tablets of Gold": An Examination of the Psychological and Social Dimensions of PrEP Among LGBTQ Communities. AIDS education and prevention : official publication of the International Society for AIDS Education 31(1): 51-62	- OECD remaining countries
Supervie, Virginie, Garcia-Lerma, J Gerardo, Heneine, Walid et al. (2010) HIV, transmitted drug resistance, and the paradox of preexposure prophylaxis. Proceedings of the National Academy of Sciences of the United States of America 107(27): 12381-6	- Modelling
Suraratdecha, Chutima, Stuart, Robyn M, Manopaiboon, Chomnad et al. (2018) Cost and cost-effectiveness analysis of pre-exposure prophylaxis among men who have sex with men in two hospitals in Thailand. Journal of the International AIDS Society 21suppl5: e25129	- Cost-effectiveness
Tan, Darrell H S, Schnubb, Alexandre, Lawless, James et al. (2018) Acceptability and tolerability of and adherence to HIV preexposure prophylaxis among Toronto gay and bisexual men: a pilot study. CMAJ open 6(4): e611-e617	- Not a relevant study design
Tangmunkongvorakul, Arunrat, Chariyalertsak, Suwat, Amico, K Rivet et al. (2016) SEXUAL PRACTICES AMONG MEN WHO HAVE SEX WITH MEN IN CHIANG MAI, THAILAND: PART OF THE ANTIRETROVIRAL PRE-EXPOSURE PROPHYLAXIS TRIAL. The Southeast Asian journal of tropical medicine and public health 47(3): 514-27	- Non-OECD country
Terndrup, C., Streed, C.G., Tiberio, P. et al. (2019) A Cross-sectional Survey of Internal Medicine Resident Knowledge, Attitudes, Behaviors, and Experiences Regarding Pre-Exposure Prophylaxis for HIV Infection. Journal of General Internal Medicine 34(7): 1258-1278	- Population: Practitioners
Theodore, Deborah A, Zucker, Jason, Carnevale, Caroline et al. (2020) Pre-exposure Prophylaxis Use Among Predominantly African American and Hispanic Women at Risk for HIV Acquisition in New York City. The Journal of the Association of Nurses in AIDS Care : JANAC 31(1): 110-114	- Qualitative - closed questions

Study	Reason
Thigpen, Michael C, Kebaabetswe, Poloko M, Paxton, Lynn A et al. (2012) Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. The New England journal of medicine 367(5): 423-34	- Primary study included in systematic review
Thomann, Matthew, Grosso, Ashley, Zapata, Richard et al. (2018) 'WTF is PrEP?': attitudes towards pre-exposure prophylaxis among men who have sex with men and transgender women in New York City. Culture, health & sexuality 20(7): 772-786	- OECD remaining countries
Thomas, Portia D (2019) A Qualitative Exploration of Pre-Exposure Prophylaxis (PrEP) Initiation Decision-Making Among Men Who Have Sex with Men (MSM): "It Definitely was a Process". Journal of National Black Nurses' Association : JNBNA 30(2): 10-17	- OECD remaining countries
Toledo, Lauren, McLellan-Lemal, Eleanor, Henderson, Faith L et al. (2015) Knowledge, Attitudes, and Experiences of HIV Pre-Exposure Prophylaxis (PrEP) Trial Participants in Botswana. World journal of AIDS 5(2): 10-20	- Non-OECD country
Traeger, Michael W, Schroeder, Sophia E, Wright, Edwina J et al. (2018) Effects of Pre-exposure Prophylaxis for the Prevention of Human Immunodeficiency Virus Infection on Sexual Risk Behavior in Men Who Have Sex With Men: A Systematic Review and Meta-analysis. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 67(5): 676-686	- Not a relevant study design Majority of studies included have no control group making them case-series not cohort.
Tripathi, Avnish; Whiteside, Y Omar; Duffus, Wayne A (2013) Perceptions and attitudes about preexposure prophylaxis among seronegative partners and the potential of sexual disinhibition. Southern medical journal 106(10): 558-64	- Qualitative - closed questions
Tumarkin, E.; Siedner, M.J.; Bogoch, I.I. (2019) HIV pre-exposure prophylaxis (PrEP). BMJ (Online) 364: k4681	- Not a relevant study design
Underhill, Kristen, Guthrie, Kate M, Colleran, Christopher et al. (2018) Temporal Fluctuations in Behavior, Perceived HIV Risk, and Willingness to Use Pre-Exposure Prophylaxis (PrEP). Archives of sexual behavior 47(7): 2109-2121	- OECD remaining countries
Underhill, Kristen, Morrow, Kathleen M, Colleran, Christopher M et al. (2014) Access to healthcare, HIV/STI testing, and preferred pre-exposure prophylaxis providers among men who have sex with men and men who engage in street-based sex work in the US. PloS one 9(11): e112425	- Qualitative - does not ask relevant questions

Study	Reason
Underhill, Kristen, Morrow, Kathleen M, Colleran, Christopher et al. (2015) A Qualitative Study of Medical Mistrust, Perceived Discrimination, and Risk Behavior Disclosure to Clinicians by U.S. Male Sex Workers and Other Men Who Have Sex with Men: Implications for Biomedical HIV Prevention. Journal of urban health : bulletin of the New York Academy of Medicine 92(4): 667-86	- OECD remaining countries
Underhill, Kristen, Morrow, Kathleen M, Operario, Don et al. (2014) Could FDA approval of pre-exposure prophylaxis make a difference? A qualitative study of PrEP acceptability and FDA perceptions among men who have sex with men. AIDS and behavior 18(2): 241-9	- OECD remaining countries
Vaccher, Stefanie J, Gianacas, Christopher, Templeton, David J et al. (2017) Baseline Preferences for Daily, Event-Driven, or Periodic HIV Pre-Exposure Prophylaxis among Gay and Bisexual Men in the PRELUDE Demonstration Project. Frontiers in public health 5: 341	- Qualitative - closed questions
Vaitses Fontanari, A.M., Zanella, G.I., Feijo, M. et al. (2019) HIV-related care for transgender people: A systematic review of studies from around the world. Social Science and Medicine 230: 280-294	- Data not reported in an extractable format
van de Vijver, D.A.M.C., Richter, A.-K., Boucher, C.A.B. et al. (2019) Cost-effectiveness and budget effect of pre-exposure prophylaxis for HIV-1 prevention in Germany from 2018 to 2058. Eurosurveillance 24(7): 1800398	- Cost-effectiveness
van de Vijver, David A M C, Nichols, Brooke E, Abbas, Ume L et al. (2013) Preexposure prophylaxis will have a limited impact on HIV-1 drug resistance in sub-Saharan Africa: a comparison of mathematical models. AIDS (London, England) 27(18): 2943-51	- Modelling
Van Der Straten, A., Shapley-Quinn, M.K., Reddy, K. et al. (2017) Favoring "peace of Mind": A Qualitative Study of African Women's HIV Prevention Product Formulation Preferences from the MTN-020/ASPIRE Trial. AIDS Patient Care and STDs 31(7): 305-314	- Non-OECD country
van der Straten, Ariane, Stadler, Jonathan, Luecke, Ellen et al. (2014) Perspectives on use of oral and vaginal antiretrovirals for HIV prevention: the VOICE-C qualitative study in Johannesburg, South Africa. Journal of the International AIDS Society 17(3suppl2): 19146	- Non-OECD country
van der Straten, Ariane, Stadler, Jonathan, Montgomery, Elizabeth et al. (2014) Women's experiences with oral and vaginal pre-exposure prophylaxis: the VOICE-C qualitative study in Johannesburg, South Africa. PloS one 9(2): e89118	- Non-OECD country
van Vliet, M.M., Hendrickson, C., Nichols, B.E. et al. (2019) Epidemiological impact and cost-effectiveness of providing long-acting pre-exposure prophylaxis to injectable contraceptive users for HIV prevention in South Africa: a modelling study. Journal of the International AIDS Society 22(12): e25427	- Cost-effectiveness

Study	Reason
Vazquez, Laia, Moll, Anthony P, Kacin, Alexa et al. (2019) Perceptions of HIV Preexposure Prophylaxis Among Young Pregnant Women from Rural KwaZulu-Natal, South Africa. AIDS patient care and STDs 33(5): 214-219	- Non-OECD country
Velloza, J., Khoza, N., Scorgie, F. et al. (2020) The influence of HIV-related stigma on PrEP disclosure and adherence among adolescent girls and young women in HPTN 082: a qualitative study. Journal of the International AIDS Society 23(3): e25463	- Non-OECD country
Velloza, Jennifer, Bacchetti, Peter, Hendrix, Craig W et al. (2019) Short- and Long-Term Pharmacologic Measures of HIV Pre-exposure Prophylaxis Use Among High-Risk Men Who Have Sex With Men in HPTN 067/ADAPT. Journal of acquired immune deficiency syndromes (1999) 82(2): 149-158	- Secondary outcome - analysis through primary outcome studies Adherence - study included in SR
Verguet, Stephane; Stalcup, Meg; Walsh, Julia A (2013) Where to deploy pre-exposure prophylaxis (PrEP) in sub-Saharan Africa?. Sexually transmitted infections 89(8): 628-34	- Modelling
Vissers, Debby C J, Voeten, Helene A C M, Nagelkerke, Nico J D et al. (2008) The impact of pre-exposure prophylaxis (PrEP) on HIV epidemics in Africa and India: a simulation study. PloS one 3(5): e2077	- Modelling
Wade Taylor, S, Mayer, Kenneth H, Elsesser, Steven M et al. (2014) Optimizing content for pre-exposure prophylaxis (PrEP) counseling for men who have sex with men: Perspectives of PrEP users and high-risk PrEP naive men. AIDS and behavior 18(5): 871-9	- OECD remaining countries
Wand, Handan, Reddy, Tarylee, Naidoo, Sarita et al. (2018) A Simple Risk Prediction Algorithm for HIV Transmission: Results from HIV Prevention Trials in KwaZulu Natal, South Africa (2002-2012). AIDS and behavior 22(1): 325-336	- Study does not contain a relevant intervention
Wang, L.Y., Hamilton, D.T., Rosenberg, E.S. et al. (2020) Cost-Effectiveness of Pre-Exposure Prophylaxis Among Adolescent Sexual Minority Males. Journal of Adolescent Health 66(1): 100-106	- Cost-effectiveness
Wang, Zixin, Lau, Joseph T F, Fang, Yuan et al. (2018) Prevalence of actual uptake and willingness to use pre-exposure prophylaxis to prevent HIV acquisition among men who have sex with men in Hong Kong, China. PloS one 13(2): e0191671	- Non-OECD country
Wang, Zixin, Mo, Phoenix K H, Ip, Mary et al. (2020) Uptake and willingness to use PrEP among Chinese gay, bisexual and other men who have sex with men	- Non-OECD country

Study	Reason
with experience of sexualized drug use in the past year. BMC infectious diseases 20(1): 299	
Ware, Norma C, Wyatt, Monique A, Haberer, Jessica E et al. (2012) What's love got to do with it? Explaining adherence to oral antiretroviral pre-exposure prophylaxis for HIV-serodiscordant couples. Journal of acquired immune deficiency syndromes (1999) 59(5): 463-8	- Non-OECD country
Watnick, Dana, Keller, Marla J, Stein, Kimberly et al. (2018) Acceptability of a Tenofovir Disoproxil Fumarate Vaginal Ring for HIV Prevention Among Women in New York City. AIDS and behavior 22(2): 421-436	- OECD remaining countries
Watson, Ryan J, Fish, Jessica N, Allen, Aerielle et al. (2018) Sexual Identity Disclosure and Awareness of HIV Prevention Methods Among Black Men Who Have Sex With Men. Journal of sex research 55(8): 975-983	- Qualitative - closed questions
Wenzel, Suzanne L, Rhoades, Harmony, Harris, Taylor et al. (2017) Risk behavior and access to HIV/AIDS prevention services in a community sample of homeless persons entering permanent supportive housing. AIDS care 29(5): 570-574	- Qualitative - closed questions
Werner, R.N., Gaskins, M., Nast, A. et al. (2019) Correction: Incidence of sexually transmitted infections in men who have sex with men and who are at substantial risk of HIV infection - A meta-analysis of data from trials and observational studies of HIV pre-exposure prophylaxis (PLoS ONE (2018) 13(12): e0208107. DOI: 10.1371/journal.pone.0208107). PLoS ONE 14(12): e0226209	- Additional info to included study
Werner, Ricardo Niklas, Gaskins, Matthew, Nast, Alexander et al. (2018) Incidence of sexually transmitted infections in men who have sex with men and who are at substantial risk of HIV infection - A meta-analysis of data from trials and observational studies of HIV pre-exposure prophylaxis. PloS one 13(12): e0208107	-More recent systematic review included that covers the same topic
White, Ellen, Dunn, David T, Desai, Monica et al. (2019) Predictive factors for HIV infection among men who have sex with men and who are seeking PrEP: a secondary analysis of the PROUD trial. Sexually transmitted infections 95(6): 449-454	- Not a relevant study design Secondary analysis of trial included in SR of effectiveness
Williams, Brian G, Gupta, Somya, Wollmers, Matthew et al. (2017) Progress and prospects for the control of HIV and tuberculosis in South Africa: a dynamical modelling study. The Lancet. Public health 2(5): e223-e230	- Modelling
Willie, T.C., Keene, D.E., Kershaw, T.S. et al. (2020) "You Never Know What Could Happen": Women's Perspectives of Pre-Exposure Prophylaxis in the Context of Recent Intimate Partner Violence. Women's Health Issues 30(1): 41-48	- OECD remaining countries

Study	Reason
Wingood, Gina M, Dunkle, Kristin, Camp, Christina et al. (2013) Racial differences and correlates of potential adoption of preexposure prophylaxis: results of a national survey. Journal of acquired immune deficiency syndromes (1999) 63suppl1: 95-101	- Qualitative - closed questions
Wong, Chen Seong, Kumar, P Arun, Wong, Christina M et al. (2019) Acceptability of HIV Pre-exposure Prophylaxis (PrEP) and Opinions on PrEP Service Delivery Among Men Who Have Sex With Men in Singapore: A Qualitative Study. AIDS education and prevention : official publication of the International Society for AIDS Education 31(2): 152-162	- Non-OECD country
Wood, S., Dowshen, N., Bauermeister, J.A. et al. (2020) Social Support Networks Among Young Men and Transgender Women of Color Receiving HIV Pre-Exposure Prophylaxis. Journal of Adolescent Health 66(3): 268-274	- Qualitative - does not ask relevant questions
Wood, Sarah, Gross, Robert, Shea, Judy A et al. (2019) Barriers and Facilitators of PrEP Adherence for Young Men and Transgender Women of Color. AIDS and behavior 23(10): 2719-2729	- OECD remaining countries
Yang, C., Krishnan, N., Kelley, E. et al. (2020) Beyond HIV prevention: a qualitative study of patient-reported outcomes of PrEP among MSM patients in two public STD clinics in Baltimore. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV 32(2): 238-241	- OECD remaining countries
Ye, Li, Wei, Suosu, Zou, Yunfeng et al. (2014) HIV pre-exposure prophylaxis interest among female sex workers in Guangxi, China. PloS one 9(1): e86200	- Non-OECD country
Ying, Roger, Sharma, Monisha, Heffron, Renee et al. (2015) Cost-effectiveness of pre-exposure prophylaxis targeted to high-risk serodiscordant couples as a bridge to sustained ART use in Kampala, Uganda. Journal of the International AIDS Society 18(4suppl3): 20013	- Cost-effectiveness
Young, Ingrid and McDaid, Lisa (2014) How acceptable are antiretrovirals for the prevention of sexually transmitted HIV?: A review of research on the acceptability of oral pre-exposure prophylaxis and treatment as prevention. AIDS and behavior 18(2): 195-216	- Systematic review used as source of primary studies
Yu, Wenya, Wang, Lu, Han, Na et al. (2016) Pre-exposure prophylaxis of HIV: A right way to go or a long way to go?. Artificial cells, nanomedicine, and biotechnology 44(1): 201-8	- More recent systematic review included that covers the same topic
Yun, Ke, Xu, Jun-Jie, Zhang, Jing et al. (2018) Female and younger subjects have lower adherence in PrEP trials: a meta-analysis with implications for the uptake of PrEP service to prevent HIV. Sexually transmitted infections 94(3): 163-168	- Secondary outcome - analysis through primary

Study	Reason
	outcome studies
Zablotska, Iryna B (2017) Likely impact of pre-exposure prophylaxis on HIV epidemics among men who have sex with men. Sexual health 14(1): 97-105	- Review article but not a systematic review
Zaller, Nickolas D, Neher, Taylor L, Presley, Makenzie et al. (2020) Barriers to linking high-risk jail detainees to HIV pre-exposure prophylaxis. PloS one 15(4): e0231951	- Not the target population
Zhang, Lei, Peng, Peng, Wu, Yumeng et al. (2019) Modelling the Epidemiological Impact and Cost-Effectiveness of PrEP for HIV Transmission in MSM in China. AIDS and behavior 23(2): 523-533	- Cost-effectiveness
Zhao, Yuqin, Dimitrov, Dobromir T, Liu, Hao et al. (2013) Mathematical insights in evaluating state dependent effectiveness of HIV prevention interventions. Bulletin of mathematical biology 75(4): 649-75	- Modelling
Zhou, Feng, Gao, Lei, Li, Shuming et al. (2012) Willingness to accept HIV pre-exposure prophylaxis among Chinese men who have sex with men. PloS one 7(3): e32329	- Non-OECD country
Zimba, Chifundo, Maman, Suzanne, Rosenberg, Nora E et al. (2019) The landscape for HIV pre-exposure prophylaxis during pregnancy and breastfeeding in Malawi and Zambia: A qualitative study. PloS one 14(10): e0223487	- Non-OECD country

K.2 Excluded qualitative studies

Study	Reason
(2018) Effect of on demand oral PrEP with TDF/FTC on HSV-1/2 incidence among MSM. Topics in antiviral medicine conference25thconferenceonretrovirusesandopportunisticinfectionscroi2018united states26(supplement1): 467s	- Not a peer-reviewed publication - *Conference abstract*
Abbas, Ume L, Hood, Gregory, Wetzel, Arthur W et al. (2011) Factors influencing the emergence and spread of HIV drug resistance arising from rollout of antiretroviral pre-exposure prophylaxis (PrEP). PloS one 6(4): e18165	- Cost-effectiveness - Non-OECD country
Abraham, Bisrat K and Gulick, Roy (2012) Next-generation oral preexposure prophylaxis: beyond tenofovir. Current opinion in HIV and AIDS 7(6): 600-6	- Review article but not a systematic review
Abuelezam, Nadia N, McCormick, Alethea W, Fussell, Thomas et al. (2016) Can the Heterosexual HIV Epidemic be Eliminated in South Africa Using Combination	- Modelling

Study	Reason
Prevention? A Modeling Analysis. American journal of epidemiology 184(3): 239-48	
Adams, J., Coquilla, R., Montayre, J. et al. (2019) Knowledge of HIV pre-exposure prophylaxis among immigrant Asian gay men living in New Zealand. Journal of Primary Health Care 11(4): 351-358	- OECD remaining countries
Adamson, B., Garrison, L., Barnabas, R.V. et al. (2019) Competing biomedical HIV prevention strategies: potential cost-effectiveness of HIV vaccines and PrEP in Seattle, WA. Journal of the International AIDS Society 22(8): e25373	- Cost-effectiveness
Adamson, B.J.S., Carlson, J.J., Kublin, J.G. et al. (2017) The potential cost-effectiveness of pre-exposure prophylaxis combined with HIV vaccines in the united states. Vaccines 5(2): 13	- Cost-effectiveness
Aghaizu, Adamma, Mercey, Danielle, Copas, Andrew et al. (2013) Who would use PrEP? Factors associated with intention to use among MSM in London: a community survey. Sexually transmitted infections 89(3): 207-11	- Qualitative - closed questions
Algarin, A.B., Shrader, C.H., Bhatt, C. et al. (2019) The Pre-exposure Prophylaxis (PrEP) Continuum of Care and Correlates to Initiation Among HIV-Negative Men Recruited at Miami Gay Pride 2018. Journal of Urban Health 96(6): 835-844	- Qualitative - closed questions
Allen, S.T., O'Rourke, A., White, R.H. et al. (2019) Barriers and Facilitators to PrEP Use Among People Who Inject Drugs in Rural Appalachia: A Qualitative Study. AIDS and Behavior	- Does not contain a population of people on PrEP
Allende, Ruben and Acuna, Maria Paz (2017) Is pre-exposure prophylaxis effective for preventing HIV infection in men who have sex with men?. Medwave 17(9): e7117	- Study not reported in English
Amico, K Rivet, Ramirez, Catalina, Caplan, Margaret R et al. (2019) Perspectives of US women participating in a candidate PrEP study: adherence, acceptability and future use intentions. Journal of the International AIDS Society 22(3): e25247	- Qualitative - closed questions
Anderson, Sarah-Jane, Cherutich, Peter, Kilonzo, Nduku et al. (2014) Maximising the effect of combination HIV prevention through prioritisation of the people and places in greatest need: a modelling study. Lancet (London, England) 384(9939): 249-56	- Modelling
Annequin, M., Villes, V., Delabre, R.M. et al. (2020) Are PrEP services in France reaching all those exposed to HIV who want to take PrEP? MSM respondents who are eligible but not using PrEP (EMIS 2017). AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV	- Qualitative - closed questions
Anonymous (2011) CDC trial: HIV PrEP works for heterosexuals. A 63% reduction in HIV risk. AIDS alert 26(8): 85-90	- Not a relevant study design
Antoni, G, Tremblay, C, Delaugerre, C et al. (2019) On-demand pre-exposure prophylaxis with tenofovir disoproxil fumarate plus emtricitabine among men who have sex with men with less frequent sexual intercourse: a post-hoc analysis of the ANRS IPERGAY trial. The lancet. HIV	- Primary study included in systematic review

Study	Reason
Arnold, T., Sims-Gomillia, C.E., Portz, K. et al. (2018) Preliminary investigation evaluating college students' willingness and need to take pre-exposure prophylaxis (PrEP) for HIV. HIV and AIDS Review 17(2): 98-102	- Qualitative - closed questions
Arnold, Trisha, Brinkley-Rubinstein, Lauren, Chan, Philip A et al. (2017) Social, structural, behavioral and clinical factors influencing retention in Pre-Exposure Prophylaxis (PrEP) care in Mississippi. PloS one 12(2): e0172354	- OECD remaining countries
Ascher, Simon B, Scherzer, Rebecca, Estrella, Michelle M et al. (2020) HIV preexposure prophylaxis with tenofovir disoproxil fumarate/emtricitabine and changes in kidney function and tubular health. AIDS (London, England) 34(5): 699-706	- Primary study included in systematic review
Ayala, George, Makofane, Keletso, Santos, Glenn-Milo et al. (2013) Access to Basic HIV-Related Services and PrEP Acceptability among Men Who Have sex with Men Worldwide: Barriers, Facilitators, and Implications for Combination Prevention. Journal of sexually transmitted diseases 2013: 953123	- Not a relevant study design *cross-sectional*
Baeten, Jared M, Donnell, Deborah, Mugo, Nelly R et al. (2014) Single-agent tenofovir versus combination emtricitabine plus tenofovir for pre-exposure prophylaxis for HIV-1 acquisition: an update of data from a randomised, double-blind, phase 3 trial. The Lancet. Infectious diseases 14(11): 1055-1064	- Primary study included in systematic review
Baeten, Jared M, Donnell, Deborah, Ndase, Patrick et al. (2012) Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. The New England journal of medicine 367(5): 399-410	- Primary study included in systematic review
Baeten, Jared and Celum, Connie (2012) Oral antiretroviral chemoprophylaxis: current status. Current opinion in HIV and AIDS 7(6): 514-9	- Review article but not a systematic review
Bagchi, Ann D and Holzemer, William (2018) Support for PrEP Among New Jersey Health Care Workers. The Journal of the Association of Nurses in AIDS Care : JANAC 29(6): 849-857	- Population: Practitioners *- views of care workers*
Baggaley, Rebecca F; Powers, Kimberly A; Boily, Marie-Claude (2011) What do mathematical models tell us about the emergence and spread of drug-resistant HIV?. Current opinion in HIV and AIDS 6(2): 131-40	- Modelling
Barnighausen, Kate E, Matse, Sindy, Kennedy, Caitlin E et al. (2019) 'This is mine, this is for me': preexposure prophylaxis as a source of resilience among women in Eswatini. AIDS (London, England) 33suppl1: 45-s52	- Non-OECD country
Barreras, J L; Linnemayr, S L; MacCarthy, S (2019) "We have a stronger survival mode": exploring knowledge gaps and culturally sensitive messaging of PrEP among Latino men who have sex with men and Latina transgender women in Los Angeles, CA. AIDS care 31(10): 1221-1227	- OECD remaining countries
Baruch, R., Cuadra, S.M., Arellano, J. et al. (2020) Pre-exposure prophylaxis and its implications in Mexico: Notions of men who have sex with men. Sexual Health 17(1): 22-28	- OECD remaining countries

Study	Reason
Bazzi, A.R. (2016) Antiretroviral pre-exposure prophylaxis for HIV prevention is highly effective in community settings. Evidence-Based Medicine 21(3): 99	- Not a peer-reviewed publication
Bazzi, Angela R, Biancarelli, Dea L, Childs, Ellen et al. (2018) Limited Knowledge and Mixed Interest in Pre-Exposure Prophylaxis for HIV Prevention Among People Who Inject Drugs. AIDS patient care and STDs 32(12): 529-537	- Does not contain a population of people on PrEP
Bazzi, Angela R, Yotebieng, Kelly, Otticha, Sophie et al. (2019) PrEP and the syndemic of substance use, violence, and HIV among female and male sex workers: a qualitative study in Kisumu, Kenya. Journal of the International AIDS Society 22(4): e25266	- Non-OECD country
Bazzi, Angela Robertson, Yotebieng, Kelly A, Agot, Kawango et al. (2018) Perspectives on biomedical HIV prevention options among women who inject drugs in Kenya. AIDS care 30(3): 343-346	- Does not contain a population of people on PrEP
Bernard, C.L., Brandeau, M.L., Humphreys, K. et al. (2016) Cost-effectiveness of HIV preexposure prophylaxis for people who inject drugs in the United States. Annals of Internal Medicine 165(1): 10-19	- Cost-effectiveness
Biello, K B, Bazzi, A R, Mimiaga, M J et al. (2018) Perspectives on HIV pre-exposure prophylaxis (PrEP) utilization and related intervention needs among people who inject drugs. Harm reduction journal 15(1): 55	- Does not contain a population of people on PrEP
Biello, K B, Edeza, A, Salhaney, P et al. (2019) A missing perspective: injectable pre-exposure prophylaxis for people who inject drugs. AIDS care 31(10): 1214-1220	- Does not contain a population of people on PrEP
Biello, K.B., Bazzi, A.R., Mimiaga, M.J. et al. (2018) Perspectives on HIV pre-exposure prophylaxis (PrEP) utilization and related intervention needs among people who inject drugs 11 Medical and Health Sciences 1117 Public Health and Health Services 16 Studies in Human Society 1608 Sociology. Harm Reduction Journal 15(1): 55	- Duplicate reference
Biello, Katie B, Hosek, Sybil, Drucker, Morgan T et al. (2018) Preferences for Injectable PrEP Among Young U.S. Cisgender Men and Transgender Women and Men Who Have Sex with Men. Archives of sexual behavior 47(7): 2101-2107	- Qualitative - does not ask relevant questions
Biello, Katie B, Oldenburg, Catherine E, Mitty, Jennifer A et al. (2017) The "Safe Sex" Conundrum: Anticipated Stigma From Sexual Partners as a Barrier to PrEP Use Among Substance Using MSM Engaging in Transactional Sex. AIDS and behavior 21(1): 300-306	- Qualitative - closed questions
Blumenthal, Jill, Pasipanodya, Elizabeth C, Jain, Sonia et al. (2019) Comparing Self-Report Pre-Exposure Prophylaxis Adherence Questions to Pharmacologic Measures of Recent and Cumulative Pre-Exposure Prophylaxis Exposure. Frontiers in pharmacology 10: 721	- Study does not contain a relevant intervention

Study	Reason
Bouassa, R.-S.M., Belec, L., Gubavu, C. et al. (2019) High Prevalence of Anal and Oral High-Risk Human Papillomavirus in Human Immunodeficiency Virus-Uninfected French Men Who Have Sex with Men and Use Preexposure Prophylaxis. Open Forum Infectious Diseases 6(9): ofz291	- Not a relevant study design *cross-sectional*
Bourne, Adam, Cassolato, Matteo, Thuan Wei, Clayton Koh et al. (2017) Willingness to use pre-exposure prophylaxis (PrEP) for HIV prevention among men who have sex with men (MSM) in Malaysia: findings from a qualitative study. Journal of the International AIDS Society 20(1): 21899	- Non-OECD country
Braksmajer, Amy, Leblanc, Natalie M, El-Bassel, Nabila et al. (2019) Feasibility and acceptability of pre-exposure prophylaxis use among women in violent relationships. AIDS care 31(4): 475-480	- OECD remaining countries
Brinkley-Rubinstein, Lauren, Peterson, Meghan, Arnold, Trisha et al. (2018) Knowledge, interest, and anticipated barriers of pre-exposure prophylaxis uptake and adherence among gay, bisexual, and men who have sex with men who are incarcerated. PloS one 13(12): e0205593	- Does not contain a population of people on PrEP
Brinkley-Rubinstein, Lauren, Peterson, Meghan, Zaller, Nickolas D et al. (2019) Best practices for identifying men who have sex with men for corrections-based pre-exposure prophylaxis provision. Health & justice 7(1): 7	- Qualitative - does not ask relevant questions
Brooks, B., Park, S.H., Guilamo-Ramos, V. et al. (2019) Sex Tourism and Pre-Exposure Prophylaxis Modality Preferences Among Men Who Have Sex With Men. Journal of Sex Research 56(45): 632-640	- Qualitative - closed questions
Brooks, R.A., Nieto, O., Landrian, A. et al. (2019) Experiences of Pre-Exposure Prophylaxis (PrEP)-Related Stigma among Black MSM PrEP Users in Los Angeles. Journal of Urban Health	- OECD remaining countries
Brooks, Ronald A, Kaplan, Rachel L, Lieber, Eli et al. (2011) Motivators, concerns, and barriers to adoption of preexposure prophylaxis for HIV prevention among gay and bisexual men in HIV-serodiscordant male relationships. AIDS care 23(9): 1136-45	- OECD remaining countries
Brooks, Ronald A, Landovitz, Raphael J, Kaplan, Rachel L et al. (2012) Sexual risk behaviors and acceptability of HIV pre-exposure prophylaxis among HIV-negative gay and bisexual men in serodiscordant relationships: a mixed methods study. AIDS patient care and STDs 26(2): 87-94	- OECD remaining countries
Brooks, Ronald A, Landovitz, Raphael J, Regan, Rotrease et al. (2015) Perceptions of and intentions to adopt HIV pre-exposure prophylaxis among black men who have sex with men in Los Angeles. International journal of STD & AIDS 26(14): 1040-8	- OECD remaining countries
Brooks, Ronald A, Landrian, Amanda, Nieto, Omar et al. (2019) Experiences of Anticipated and Enacted Pre-exposure Prophylaxis (PrEP) Stigma Among Latino MSM in Los Angeles. AIDS and behavior 23(7): 1964-1973	- OECD remaining countries
Brooks, Ronald A, Nieto, Omar, Landrian, Amanda et al. (2019) Persistent stigmatizing and negative perceptions of pre-exposure prophylaxis (PrEP) users: implications for PrEP adoption among Latino men who have sex with men. AIDS care 31(4): 427-435	- OECD remaining countries

Study	Reason
Cahill, Sean, Taylor, S Wade, Elsesser, Steven A et al. (2017) Stigma, medical mistrust, and perceived racism may affect PrEP awareness and uptake in black compared to white gay and bisexual men in Jackson, Mississippi and Boston, Massachusetts. AIDS care 29(11): 1351-1358	- OECD remaining countries
Calabrese, Sarah K, Dovidio, John F, Tekeste, Mehrit et al. (2018) HIV Pre-Exposure Prophylaxis Stigma as a Multidimensional Barrier to Uptake Among Women Who Attend Planned Parenthood. Journal of acquired immune deficiency syndromes (1999) 79(1): 46-53	- Qualitative - closed questions
Calder, Bobby J, Schieffer, Robert J, Bryndza Tfaily, Ewa et al. (2018) Qualitative Consumer Research on Acceptance of Long-Acting Pre-Exposure Prophylaxis Products Among Men Having Sex with Men and Medical Practitioners in the United States. AIDS research and human retroviruses 34(10): 849-856	- OECD remaining countries
Callander, D., Park, S.H., Schneider, J.A. et al. (2019) City of love: Group sex is associated with risks for HIV and other sexually transmissible infections among gay and bisexual men in Paris, France. Sexual Health 16(2): 192-194	- Qualitative - closed questions
Cambiano, Valentina, Miners, Alec, Dunn, David et al. (2018) Cost-effectiveness of pre-exposure prophylaxis for HIV prevention in men who have sex with men in the UK: a modelling study and health economic evaluation. The Lancet. Infectious diseases 18(1): 85-94	- Cost-effectiveness
Cambiano, Valentina; Miners, Alec; Phillips, Andrew (2016) What do we know about the cost-effectiveness of HIV preexposure prophylaxis, and is it affordable?. Current opinion in HIV and AIDS 11(1): 56-66	- Cost-effectiveness
Camlin, C.S., Koss, C.A., Getahun, M. et al. (2020) Understanding Demand for PrEP and Early Experiences of PrEP Use Among Young Adults in Rural Kenya and Uganda: A Qualitative Study. AIDS and Behavior	- Non-OECD country
Carillon, S., Gallardo, L., Linard, F. et al. (2020) Perspectives of injectable long acting antiretroviral therapies for HIV treatment or prevention: understanding potential users' ambivalences. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV	- OECD remaining countries
Carlo Hojilla, J., Marcus, J., Volk, J.E. et al. (2019) Alcohol and drug use, partner PrEP use and STI prevalence among people with HIV. Sexually Transmitted Infections	- Qualitative - closed questions
Carnevale, Caroline, Zucker, Jason, Borsa, Alexander et al. (2020) Engaging a Predominantly Latino Community in HIV Prevention: Laying the Groundwork for Pre-exposure Prophylaxis and HIV Sexual Health Programs. The Journal of the Association of Nurses in AIDS Care : JANAC 31(1): 92-97	- Review article but not a systematic review
Case, K.K.; Gomez, G.B.; Hallett, T.B. (2019) The impact, cost and cost-effectiveness of oral pre-exposure prophylaxis in sub-Saharan Africa: a scoping review of modelling contributions and way forward. Journal of the International AIDS Society 22(9): e25390	- Cost-effectiveness
Celum, Connie and Baeten, Jared M (2012) Tenofovir-based pre-exposure prophylaxis for HIV prevention: evolving evidence. Current opinion in infectious diseases 25(1): 51-7	- Review article but not a systematic review
Celum, Connie, Morrow, Rhoda A, Donnell, Deborah et al. (2014) Daily oral tenofovir and emtricitabine-tenofovir preexposure prophylaxis reduces herpes simplex virus type 2 acquisition among heterosexual HIV-1-uninfected men and	- Primary study included in

Study	Reason
women: a subgroup analysis of a randomized trial. Annals of internal medicine 161(1): 11-9	systematic review
Chas, J., Rojas-Castro, D., Bernaud, C. et al. (2017) Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. The Lancet HIV 4(9): e402-e410	- Not a relevant study design *No control group*
Chen, Anders and Dowdy, David W (2014) Clinical effectiveness and cost-effectiveness of HIV pre-exposure prophylaxis in men who have sex with men: risk calculators for real-world decision-making. PloS one 9(10): e108742	- Cost-effectiveness
Chi, B.H., Sinkala, M., Mbewe, F. et al. (2008) Single-dose tenofovir and emtricitabine for reduction of viral resistance to non-nucleoside reverse transcriptase inhibitory drugs in women given intrapartum nevirapine for perinatal HIV prevention: An open-label randomized trial. Obstetrical and Gynecological Survey 63(4): 206-207	- Abstract only
Chi, Benjamin H, Chintu, Namwinga, Cantrell, Ronald A et al. (2008) Addition of single-dose tenofovir and emtricitabine to intrapartum nevirapine to reduce perinatal HIV transmission. Journal of acquired immune deficiency syndromes (1999) 48(2): 220-3	- Study does not contain a relevant intervention
Chi, Benjamin H, Ellis, Giovanina M, Chintu, Namwinga et al. (2009) Intrapartum tenofovir and emtricitabine reduces low-concentration drug resistance selected by single-dose nevirapine for perinatal HIV prevention. AIDS research and human retroviruses 25(11): 1099-106	- Study does not contain a relevant intervention
Chirwa, Lovemore I, Johnson, Jeffrey A, Niska, Richard W et al. (2014) CD4(+) cell count, viral load, and drug resistance patterns among heterosexual breakthrough HIV infections in a study of oral preexposure prophylaxis. AIDS (London, England) 28(2): 223-6	- Not a relevant study design - Primary study included in systematic review
Chittamuru, Deepti, Frye, Victoria, Koblin, Beryl A et al. (2020) PrEP stigma, HIV stigma, and intention to use PrEP among women in New York City and Philadelphia. Stigma and Health 5(2): 240-246	- Qualitative - closed questions
Choopanya, Kachit, Martin, Michael, Suntharasamai, Pravan et al. (2013) Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet (London, England) 381(9883): 2083-90	- Primary study included in systematic review
Closson, Elizabeth F, Mitty, Jennifer A, Malone, Jowanna et al. (2018) Exploring strategies for PrEP adherence and dosing preferences in the context of sexualized recreational drug use among MSM: a qualitative study. AIDS care 30(2): 191-198	- OECD remaining countries
Cohen, M.S.; Gamble, T.; McCauley, M. (2020) Prevention of HIV Transmission and the HPTN 052 Study. Annu. Rev. Med. 71: 347-360	- Study does not contain a relevant intervention

Study	Reason
Collier, Dami, Iwuji, Collins, Derache, Anne et al. (2017) Virological Outcomes of Second-line Protease Inhibitor-Based Treatment for Human Immunodeficiency Virus Type 1 in a High-Prevalence Rural South African Setting: A Competing-Risks Prospective Cohort Analysis. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 64(8): 1006-1016	- Study does not contain a relevant intervention
Collins, S.P.; McMahan, V.M.; Stekler, J.D. (2016) The Impact of HIV Pre-exposure Prophylaxis (PrEP) Use on the Sexual Health of Men Who Have Sex with Men: A Qualitative Study in Seattle, WA. International Journal of Sexual Health: 1-14	- OECD remaining countries
Corneli, Amy, Perry, Brian, Agot, Kawango et al. (2015) Facilitators of adherence to the study pill in the FEM-PrEP clinical trial. PloS one 10(4): e0125458	- Non-OECD country
Cornelisse, Vincent J, Lal, Luxi, Price, Brian et al. (2019) Interest in Switching to On-Demand HIV Pre-Exposure Prophylaxis (PrEP) Among Australian Users of Daily PrEP: An Online Survey. Open forum infectious diseases 6(7): ofz287	- Qualitative - closed questions
Coutinho, Barry and Prasad, Ramakrishna (2013) Emtricitabine/tenofovir (Truvada) for HIV prophylaxis. American family physician 88(8): 535-40	- Not a peer-reviewed publication
Crawford, N.D., Josma, D., Morris, J. et al. (2020) Pharmacy-based pre-exposure prophylaxis support among pharmacists and men who have sex with men. Journal of the American Pharmacists Association	- OECD remaining countries
Crosby, R.A., Geter, A., Diclemente, R.J. et al. (2014) Acceptability of condoms, circumcision and PrEP among young black men who have sex with men: A descriptive study based on effectiveness and cost. Vaccines 2(1): 129-137	- OECD remaining countries
Dale, S.K. (2020) Using Motivational Interviewing to Increase PrEP Uptake Among Black Women at Risk for HIV: an Open Pilot Trial of MI-PrEP. Journal of Racial and Ethnic Health Disparities	- Not a relevant study design
De Man, Jeroen, Colebunders, Robert, Florence, Eric et al. (2013) What is the place of pre-exposure prophylaxis in HIV prevention?. AIDS reviews 15(2): 102-11	- Review article but not a systematic review
Desai, Monica, Field, Nigel, Grant, Robert et al. (2017) Recent advances in pre-exposure prophylaxis for HIV. BMJ (Clinical research ed.) 359: j5011	- Review article but not a systematic review *Although article updates included Fonner review, no new data could be found on sexual behaviour other than what is included and newer studies*

Study	Reason
	cited do not match protocol criteria in that they are before and after comparisons
Deutsch, Madeline B, Glidden, David V, Sevelius, Jae et al. (2015) HIV pre-exposure prophylaxis in transgender women: a subgroup analysis of the iPrEx trial. The lancet. HIV 2(12): e512-9	- Primary study included in systematic review
Devarajan, S., Sales, J.M., Hunt, M. et al. (2020) PrEP and sexual well-being: a qualitative study on PrEP, sexuality of MSM, and patient-provider relationships. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV 32(3): 386-393	- OECD remaining countries
Dimitrov, Dobromir, Boily, Marie-Claude, Brown, Elizabeth R et al. (2013) Analytic review of modeling studies of ARV Based PrEP interventions reveals strong influence of drug-resistance assumptions on the population-level effectiveness. PloS one 8(11): e80927	- Modelling
Doblecki-Lewis, Susanne and Kolber, Michael A (2014) Preventing HIV infection: pre-exposure and postexposure prophylaxis. IUBMB life 66(7): 453-61	- Review article but not a systematic review
Donnelly, J.A., Deem, T.T., Duffy, M.A. et al. (2019) Applying national estimates of adults with indications for pre-exposure prophylaxis to populations of men who have sex with men and people who inject drugs in Colorado: Modeling study. Journal of Medical Internet Research 21(1): e11113	- Modelling
Drabo, Emmanuel F, Hay, Joel W, Vardavas, Raffaele et al. (2016) A Cost-effectiveness Analysis of Preexposure Prophylaxis for the Prevention of HIV Among Los Angeles County Men Who Have Sex With Men. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 63(11): 1495-1504	- Cost-effectiveness
Dubov, Alex, Galbo, Phillip Jr, Altice, Frederick L et al. (2018) Stigma and Shame Experiences by MSM Who Take PrEP for HIV Prevention: A Qualitative Study. American journal of men's health 12(6): 1843-1854	- OECD remaining countries
Durand-Zaleski, Isabelle, Mutuon, Pierre, Charreau, Isabelle et al. (2018) Costs and benefits of on-demand HIV preexposure prophylaxis in MSM. AIDS (London, England) 32(1): 95-102	- Cost-effectiveness
Eakle, Robyn, Bourne, Adam, Mbogua, Judie et al. (2018) Exploring acceptability of oral PrEP prior to implementation among female sex workers in South Africa. Journal of the International AIDS Society 21(2)	- Non-OECD country
Eakle, Robyn, Gomez, Gabriela B, Naicker, Niven et al. (2017) HIV pre-exposure prophylaxis and early antiretroviral treatment among female sex workers in South Africa: Results from a prospective observational demonstration project. PLoS medicine 14(11): e1002444	- Not a relevant study design

Study	Reason
	Case-series - no control group
Eaton, Lisa A, Matthews, Derrick D, Driffin, Daniel D et al. (2017) A Multi-US City Assessment of Awareness and Uptake of Pre-exposure Prophylaxis (PrEP) for HIV Prevention Among Black Men and Transgender Women Who Have Sex with Men. Prevention science : the official journal of the Society for Prevention Research 18(5): 505-516	- Not a relevant study design
Edeza, A., Galarraga, O., Santamaria, E.K. et al. (2019) "I Do Try To Use Condoms, But...": Knowledge and Interest in PrEP Among Male Sex Workers in Mexico City. Archives of Sexual Behavior	- OECD remaining countries
Elopre, Latesha, McDavid, Chastity, Brown, Ashley et al. (2018) Perceptions of HIV Pre-Exposure Prophylaxis Among Young, Black Men Who Have Sex with Men. AIDS patient care and STDs 32(12): 511-518	- OECD remaining countries
Escudero, Daniel J, Lurie, Mark N, Kerr, Thomas et al. (2014) HIV pre-exposure prophylaxis for people who inject drugs: a review of current results and an agenda for future research. Journal of the International AIDS Society 17: 18899	- Review article but not a systematic review
Excler, Jean-Louis, Rida, Wasima, Priddy, Frances et al. (2011) AIDS vaccines and preexposure prophylaxis: is synergy possible?. AIDS research and human retroviruses 27(6): 669-80	- Study does not contain a relevant intervention *Vaccine and PrEP*
Falcao, J.R.S.P., Bradshaw, C.C., Garrett, C.C. et al. (2016) Views of HIV-negative partners in heterosexual serodiscordant relationships regarding HIV pre-exposure prophylaxis: A qualitative study. Sexual Health 13(4): 345-352	- Qualitative - does not ask relevant questions
Falcao, Joana, Ahoua, Laurence, Zerbe, Allison et al. (2017) Willingness to use short-term oral pre-exposure prophylaxis (PrEP) by migrant miners and female partners of migrant miners in Mozambique. Culture, health & sexuality 19(12): 1389-1403	- Non-OECD country
Falcao, Joana, Zerbe, Allison, Lahuerta, Maria et al. (2017) Factors Associated with Use of Short-Term Pre-Exposure Prophylaxis for HIV Among Female Partners of Migrant Miners in Mozambique. AIDS patient care and STDs 31(12): 528-534	- Non-OECD country
Felsher, Marisa, Szep, Zsofia, Krakower, Douglas et al. (2018) "I Don't Need PrEP Right Now": A Qualitative Exploration of the Barriers to PrEP Care Engagement Through the Application of the Health Belief Model. AIDS education and prevention : official publication of the International Society for AIDS Education 30(5): 369-381	- OECD remaining countries
Fernandez-Montero, Jose Vicente, Barreiro, Pablo, Del Romero, Jorge et al. (2012) Antiretroviral drugs for pre-exposure prophylaxis of HIV infection. AIDS reviews 14(1): 54-61	- Not a relevant study design
Fina, L., Phillips, A.L., Jones, A.T. et al. (2019) Early experience of implementing a national HIV pre-exposure prophylaxis service in Wales, United Kingdom 2017. Sexual Health 16(1): 56-62	- Not a relevant study design

Study	Reason
	- findings of service survey
Flash, Charlene A, Stone, Valerie E, Mitty, Jennifer A et al. (2014) Perspectives on HIV prevention among urban black women: a potential role for HIV pre-exposure prophylaxis. AIDS patient care and STDs 28(12): 635-42	- OECD remaining countries
Fleming, Paul J, Barrington, Clare, Perez, Martha et al. (2016) HIV testing, care, and treatment experiences among the steady male partners of female sex workers living with HIV in the Dominican Republic. AIDS care 28(6): 699-704	- Non-OECD country
Fletcher, Faith E, Fisher, Celia, Buchberg, Meredith K et al. (2018) "Where Did This [PrEP] Come From?" African American Mother/Daughter Perceptions Related to Adolescent Preexposure Prophylaxis (PrEP) Utilization and Clinical Trial Participation. Journal of empirical research on human research ethics : JERHRE 13(2): 173-184	- OECD remaining countries
Franks, Julie, Hirsch-Moverman, Yael, Loquere, Avelino S Jr et al. (2018) Sex, PrEP, and Stigma: Experiences with HIV Pre-exposure Prophylaxis Among New York City MSM Participating in the HPTN 067/ADAPT Study. AIDS and behavior 22(4): 1139-1149	- OECD remaining countries
Freeborn, Kellie and Portillo, Carmen J (2018) Does pre-exposure prophylaxis for HIV prevention in men who have sex with men change risk behaviour? A systematic review. Journal of clinical nursing 27(1718): 3254-3265	- Not a relevant study design *SR Includes mixed-methods, qualitative designs. Same RCTs are included in more recent SR to be used*
Fu, Rui; Owens, Douglas K; Brandeau, Margaret L (2018) Cost-effectiveness of alternative strategies for provision of HIV preexposure prophylaxis for people who inject drugs. AIDS (London, England) 32(5): 663-672	- Cost-effectiveness
Gafos, Mitzy, Brodnicki, Elizabeth, Desai, Monica et al. (2017) Acceptability of an open-label wait-listed trial design: Experiences from the PROUD PrEP study. PloS one 12(4): e0175596	- Qualitative - does not ask relevant questions
Galea, J T, Kinsler, J J, Salazar, X et al. (2011) Acceptability of pre-exposure prophylaxis as an HIV prevention strategy: barriers and facilitators to pre-exposure prophylaxis uptake among at-risk Peruvian populations. International journal of STD & AIDS 22(5): 256-62	- Non-OECD country
Galindo, Gabriel R, Walker, Ja'Nina J, Hazelton, Patrick et al. (2012) Community member perspectives from transgender women and men who have sex with men on pre-exposure prophylaxis as an HIV prevention strategy: implications for implementation. Implementation science : IS 7: 116	- OECD remaining countries
Gamarel, Kristi E and Golub, Sarit A (2020) Sexual goals and perceptions of goal congruence in individuals' PrEP adoption decisions: A mixed-methods study of	- Not a relevant study design

Study	Reason
gay and bisexual men who are in primary relationships. Annals of behavioral medicine : a publication of the Society of Behavioral Medicine 54(4): 237-248	
Garcia, Jonathan, Parker, Caroline, Parker, Richard G et al. (2016) Psychosocial Implications of Homophobia and HIV Stigma in Social Support Networks: Insights for High-Impact HIV Prevention Among Black Men Who Have Sex With Men. Health education & behavior : the official publication of the Society for Public Health Education 43(2): 217-25	- OECD remaining countries
Garcia, Jonathan, Parker, Richard G, Parker, Caroline et al. (2016) The limitations of 'Black MSM' as a category: Why gender, sexuality, and desire still matter for social and biomedical HIV prevention methods. Global public health 11(78): 1026-48	- Qualitative - does not ask relevant questions
Gatey, C., Pintado, C., Chas, J. et al. (2014) Pre-exposure prophylaxis of HIV infection. Revue du Praticien 64(8): 2083-2090	- Study not reported in English *- French*
Gibas, Kevin M, van den Berg, Polly, Powell, Victoria E et al. (2019) Drug Resistance During HIV Pre-Exposure Prophylaxis. Drugs 79(6): 609-619	- Not a relevant study design *adverse event outcome included in effectiveness SR*
Gilbert, H.N., Wyatt, M.A., Pisarski, E.E. et al. (2019) PrEP Discontinuation and Prevention-Effective Adherence: Experiences of PrEP Users in Ugandan HIV Serodiscordant Couples. Journal of Acquired Immune Deficiency Syndromes 82(3): 265-274	- Non-OECD country
Gilkey, Melissa B, Marcus, Julia L, Garrell, Jacob M et al. (2019) Using HIV Risk Prediction Tools to Identify Candidates for Pre-Exposure Prophylaxis: Perspectives from Patients and Primary Care Providers. AIDS patient care and STDs 33(8): 372-378	- Qualitative - does not ask relevant questions
Gilmore, Hailey J, Liu, Albert, Koester, Kimberly Ann et al. (2013) Participant experiences and facilitators and barriers to pill use among men who have sex with men in the iPrEx pre-exposure prophylaxis trial in San Francisco. AIDS patient care and STDs 27(10): 560-6	- OECD remaining countries
Ginsberg, G.M. and Chemtob, D. (2020) Cost utility analysis of HIV pre exposure prophylaxis among men who have sex with men in Israel. BMC Public Health 20(1): 271	- Cost-effectiveness
Giovenco, Danielle, Kuo, Caroline, Underhill, Kristen et al. (2018) "The Time Has Arrived": Perceptions of Behavioral Adjustments in the Context of Pre-Exposure Prophylaxis Availability Among Adolescents in South Africa. AIDS education and prevention : official publication of the International Society for AIDS Education 30(6): 463-473	- Non-OECD country
Glaubius, Robert, Ding, Yajun, Penrose, Kerri J et al. (2019) Dapivirine vaginal ring for HIV prevention: modelling health outcomes, drug resistance and cost-effectiveness. Journal of the International AIDS Society 22(5): e25282	- Cost-effectiveness

Study	Reason
Glick, J.L., Russo, R., Jivapong, B. et al. (2019) The PrEP Care Continuum Among Cisgender Women Who Sell Sex and/or Use Drugs Globally: A Systematic Review. AIDS and Behavior	- Secondary outcome - analysis through primary outcome studies *Adherence*
Goedel, William C, Chan, Philip A, King, Maximilian R F et al. (2019) Cost-Effectiveness of a Statewide Pre-Exposure Prophylaxis Program for Gay, Bisexual, and Other Men Who Have Sex with Men. Rhode Island medical journal (2013) 102(9): 36-39	- Cost-effectiveness
Golub, S.A.; Meyers, K.; Enemchukwu, C. (2020) Perspectives and Recommendations From Lesbian, Gay, Bisexual, Transgender, and Queer/Questioning Youth of Color Regarding Engagement in Biomedical HIV Prevention. Journal of Adolescent Health 66(3): 281-287	- OECD remaining countries
Golub, Sarit A (2014) Tensions between the epidemiology and psychology of HIV risk: implications for pre-exposure prophylaxis. AIDS and behavior 18(9): 1686-93	- Qualitative - closed questions
Golub, Sarit A, Gamarel, Kristi E, Rendina, H Jonathon et al. (2013) From efficacy to effectiveness: facilitators and barriers to PrEP acceptability and motivations for adherence among MSM and transgender women in New York City. AIDS patient care and STDs 27(4): 248-54	- Qualitative - closed questions
Gomez, Gabriela B, Borquez, Annick, Caceres, Carlos F et al. (2012) The potential impact of pre-exposure prophylaxis for HIV prevention among men who have sex with men and transwomen in Lima, Peru: a mathematical modelling study. PLoS medicine 9(10): e1001323	- Cost-effectiveness
Gomez, Gabriela B, Borquez, Annick, Case, Kelsey K et al. (2013) The cost and impact of scaling up pre-exposure prophylaxis for HIV prevention: a systematic review of cost-effectiveness modelling studies. PLoS medicine 10(3): e1001401	- Cost-effectiveness
Govender, Eliza and Abdool Karim, Quarraisha (2018) Understanding women and men's acceptability of current and new HIV prevention technologies in KwaZulu-Natal, South Africa. AIDS care 30(10): 1311-1314	- Non-OECD country
Govender, Eliza, Mansoor, Leila, MacQueen, Kate et al. (2017) Secrecy, empowerment and protection: positioning PrEP in KwaZulu-Natal, South Africa. Culture, health & sexuality 19(11): 1268-1285	- Non-OECD country
Grant, Hannah, Mukandavire, Zindoga, Eakle, Robyn et al. (2017) When are declines in condom use while using PrEP a concern? Modelling insights from a Hillbrow, South Africa case study. Journal of the International AIDS Society 20(1): 21744	- Not a relevant study design
Grant, Robert M, Anderson, Peter L, McMahan, Vanessa et al. (2014) Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. The Lancet. Infectious diseases 14(9): 820-9	- Primary study included in systematic review
Grant, Robert M, Lama, Javier R, Anderson, Peter L et al. (2010) Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. The New England journal of medicine 363(27): 2587-99	- Primary study included in

Study	Reason
	systematic review
Grant, Robert M, Mannheimer, Sharon, Hughes, James P et al. (2018) Daily and Nondaily Oral Preexposure Prophylaxis in Men and Transgender Women Who Have Sex With Men: The Human Immunodeficiency Virus Prevention Trials Network 067/ADAPT Study. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 66(11): 1712-1721	- Comparator in study does not match that specified in protocol
Gray, Megan E; Shenoi, Sheela V; Dillingham, Rebecca (2018) Pre-exposure Prophylaxis as HIV Prevention in High Risk Adolescents. Journal of pediatrics and pediatric medicine 2(1): 5-10	- Review article but not a systematic review
Gredig, Daniel, Uggowitzer, Franziska, Hassler, Benedikt et al. (2016) Acceptability and willingness to use HIV pre-exposure prophylaxis among HIV-negative men who have sex with men in Switzerland. AIDS care 28suppl1: 44-7	- OECD remaining countries
Greenwald, Z.R., Maheu-Giroux, M., Szabo, J. et al. (2019) Cohort profile: L'Actuel Pre-Exposure Prophylaxis (PrEP) Cohort study in Montreal, Canada. BMJ Open 9(6): e028768	- Not a relevant study design *No control group*
Griffin, James A, Eldridge-Smith, Elizabeth D, Yohannan, Jiby et al. (2020) Pre-exposure Prophylaxis Knowledge and Use Among Men Who Have Sex With Men in a Small Metropolitan Region of the Southeastern United States. The Journal of the Association of Nurses in AIDS Care : JANAC 31(1): 80-91	- Qualitative - closed questions
Grimm, Josh and Schwartz, Joseph (2019) "It's Like Birth Control for HIV": Communication and Stigma for Gay Men on PrEP. Journal of homosexuality 66(9): 1179-1197	- Retracted paper
Grov, Christian, D'Angelo, Alexa B, Flynn, Anthony W P et al. (2018) How Do Gay and Bisexual Men Make Up for Missed PrEP Doses, and What Impact Does Missing a Dose Have on Their Subsequent Sexual Behavior?. AIDS education and prevention : official publication of the International Society for AIDS Education 30(4): 275-286	- Qualitative - does not ask relevant questions
Grov, Christian, Flynn, Anthony W P, D'Angelo, Alexa B et al. (2019) Gay and Bisexual Men's Strategies to Maintain Daily Adherence to Their HIV Pre-exposure Prophylaxis (PrEP) Medication: Results from a Qualitative Study. Prevention science : the official journal of the Society for Prevention Research 20(1): 168-177	- Qualitative - does not ask relevant questions
Grov, Christian and Kumar, Navin (2018) HIV pre-exposure prophylaxis (PrEP) is coming to Europe, but are gay men ready to accept it? Qualitative findings from Berlin, Germany. Sexuality Research & Social Policy: A Journal of the NSRC 15(3): 283-289	- OECD remaining countries
Guest, Greg, Shattuck, Dominick, Johnson, Laura et al. (2010) Acceptability of PrEP for HIV prevention among women at high risk for HIV. Journal of women's health (2002) 19(4): 791-8	- Non-OECD country
Guest, Greg, Shattuck, Dominick, Johnson, Laura et al. (2008) Changes in sexual risk behavior among participants in a PrEP HIV prevention trial. Sexually transmitted diseases 35(12): 1002-8	- Primary study included in systematic review

Study	Reason
Gupta, Sanchit; Lounsbury, David W; Patel, Viraj V (2017) Low Awareness and Use of Preexposure Prophylaxis in a Diverse Online Sample of Men Who Have Sex With Men in New York City. The Journal of the Association of Nurses in AIDS Care : JANAC 28(1): 27-33	- Qualitative - closed questions
Haberer, Jessica E, Baeten, Jared M, Campbell, James et al. (2013) Adherence to antiretroviral prophylaxis for HIV prevention: a substudy cohort within a clinical trial of serodiscordant couples in East Africa. PLoS medicine 10(9): e1001511	- Primary study included in systematic review
Hallett, Timothy B, Baeten, Jared M, Heffron, Renee et al. (2011) Optimal uses of antiretrovirals for prevention in HIV-1 serodiscordant heterosexual couples in South Africa: a modelling study. PLoS medicine 8(11): e1001123	- Cost-effectiveness
Hannaford, A., Lim, J., Moll, A.P. et al. (2020) 'PrEP should be for men only': Young heterosexual men's views on PrEP in rural South Africa. Global Public Health	- Non-OECD country
Hannaford, Alisse, Lipshie-Williams, Madeleine, Starrels, Joanna L et al. (2018) The Use of Online Posts to Identify Barriers to and Facilitators of HIV Pre-exposure Prophylaxis (PrEP) Among Men Who Have Sex with Men: A Comparison to a Systematic Review of the Peer-Reviewed Literature. AIDS and behavior 22(4): 1080-1095	- Not a relevant study design
Hanscom, Brett, Janes, Holly E, Guarino, Peter D et al. (2016) Brief Report: Preventing HIV-1 Infection in Women Using Oral Preexposure Prophylaxis: A Meta-analysis of Current Evidence. Journal of acquired immune deficiency syndromes (1999) 73(5): 606-608	- More recent systematic review included that covers the same topic
Hansson, D., Stromdahl, S., Leung, K.Y. et al. (2020) Introducing pre-exposure prophylaxis to prevent HIV acquisition among men who have sex with men in Sweden: Insights from a mathematical pair formation model. BMJ Open 10(2): e033852	- Modelling
Harper, K.N. (2016) Preexposure prophylaxis on-demand dramatically reduces HIV incidence in MSM. AIDS 30(12): n19	- Not a relevant study design
Harrison, Abigail, Colvin, Christopher J, Kuo, Caroline et al. (2015) Sustained High HIV Incidence in Young Women in Southern Africa: Social, Behavioral, and Structural Factors and Emerging Intervention Approaches. Current HIV/AIDS reports 12(2): 207-15	- Review article but not a systematic review
Hartmann, Miriam, McConnell, Margaret, Bekker, Linda-Gail et al. (2018) Motivated Reasoning and HIV Risk? Views on Relationships, Trust, and Risk from Young Women in Cape Town, South Africa, and Implications for Oral PrEP. AIDS and behavior 22(11): 3468-3479	- Non-OECD country
Havens, Joshua P, Scarsi, Kimberly K, Sayles, Harlan et al. (2019) Acceptability and feasibility of a pharmacist-led HIV pre-exposure prophylaxis (PrEP) program in the Midwestern United States. Open forum infectious diseases 6(10)	- Qualitative - closed questions
Havens, P.L., Perumean-Chaney, S.E., Patki, A. et al. (2020) Changes in Bone Mass after Discontinuation of Preexposure Prophylaxis with Tenofovir Disoproxil Fumarate/Emtricitabine in Young Men Who Have Sex with Men: Extension Phase	- Outcome does not match protocol

Study	Reason
Results of Adolescent Trials Network Protocols 110 and 113. Clinical Infectious Diseases 70(4): 687-691	*Adverse events covered by included SRs - this study looks at events following discontinuation of PrEP*
Heffron, Renee, Ngure, Kenneth, Mugo, Nelly et al. (2012) Willingness of Kenyan HIV-1 serodiscordant couples to use antiretroviral-based HIV-1 prevention strategies. Journal of acquired immune deficiency syndromes (1999) 61(1): 116-9	- Non-OECD country
Heffron, Renee, Ngure, Kenneth, Odoyo, Josephine et al. (2017) Pre-exposure prophylaxis for HIV-negative persons with partners living with HIV: uptake, use, and effectiveness in an open-label demonstration project in East Africa. Gates open research 1: 3	- Not a relevant study design *No control/unexposed group*
Hellinger, Fred J (2013) Assessing the cost effectiveness of pre-exposure prophylaxis for HIV prevention in the US. PharmacoEconomics 31(12): 1091-104	- Cost-effectiveness
Hermanussen, R. (2017) HIV pre-exposure prophylaxis (PrEP). Huisarts en Wetenschap 60(6): 264-267	- Study not reported in English
Hill, Andrew, Hill, Teresa, Jose, Sophie et al. (2014) Predicted savings to the UK National Health Service from switching to generic antiretrovirals, 2014-2018. Journal of the International AIDS Society 17(4suppl3): 19497	- Conference abstract
Hoenigl, M., Jain, S., Moore, D. et al. (2018) Substance use and adherence to HIV preexposure prophylaxis for men who have sex with men. Emerging Infectious Diseases 24(12): 2292-2302	- Secondary outcome - analysis through primary outcome studies
Hoff, Colleen C, Chakravarty, Deepalika, Bircher, Anja E et al. (2015) Attitudes Towards PrEP and Anticipated Condom Use Among Concordant HIV-Negative and HIV-Discordant Male Couples. AIDS patient care and STDs 29(7): 408-17	- Not a relevant study design
Hojilla, J Carlo, Vlahov, David, Glidden, David V et al. (2018) Skating on thin ice: stimulant use and sub-optimal adherence to HIV pre-exposure prophylaxis. Journal of the International AIDS Society 21(3): e25103	- Not a relevant study design
Holt, M. (2014) HIV pre-exposure prophylaxis and treatment as prevention: A review of awareness and acceptability among men who have sex with men in the Asia-Pacific region and the Americas. Sexual Health 11(2): 166-170	- Review article but not a systematic review
Hoornenborg, E., Coyer, L., Achterbergh, R.C.A. et al. (2019) Sexual behaviour and incidence of HIV and sexually transmitted infections among men who have	- Not a relevant study design

Study	Reason
sex with men using daily and event-driven pre-exposure prophylaxis in AMPrEP: 2 year results from a demonstration study. The Lancet HIV 6(7): e447-e455	*No control group*
Horn, R.; Callander, D.; Haire, B. (2020) Perceptions of sexually transmissible infection pre-exposure prophylaxis: A qualitative study of high-risk gay and bisexual men in Sydney, New South Wales. Sexual Health 17(2): 129-134	- Study does not contain a relevant intervention
Huang, Poyao, Wu, Huei-Jiuan, Strong, Carol et al. (2019) Unspeakable PrEP: A qualitative study of sexual communication, problematic integration, and uncertainty management among men who have sex with men in Taiwan. Journal of Applied Communication Research 47(6): 611-627	- Non-OECD country
Huang, X., Hou, J., Song, A. et al. (2018) Efficacy and safety of oral TDF-based pre-exposure prophylaxis for men who have sex with men: A systematic review and meta-analysis. Frontiers in Pharmacology 9(sep): 799	- More recent systematic review included that covers the same topic
Hubach, Randolph D, Currin, Joseph M, Sanders, Carissa A et al. (2017) Barriers to Access and Adoption of Pre-Exposure Prophylaxis for the Prevention of HIV Among Men Who Have Sex With Men (MSM) in a Relatively Rural State. AIDS education and prevention : official publication of the International Society for AIDS Education 29(4): 315-329	- OECD remaining countries
Hughes, Shana D, Sheon, Nicolas, Andrew, Erin V W et al. (2018) Body/Selves and Beyond: Men's Narratives of Sexual Behavior on PrEP. Medical anthropology 37(5): 387-400	- OECD remaining countries
Hugo, J M, Stall, R D, Rebe, K et al. (2016) Anti-retroviral Therapy Based HIV Prevention Among a Sample of Men Who Have Sex with Men in Cape Town, South Africa: Use of Post-exposure Prophylaxis and Knowledge on Pre-exposure Prophylaxis. AIDS and behavior 20(suppl3): 357-364	- Non-OECD country
Jacobsen, Margo M and Walensky, Rochelle P (2016) Modeling and Cost-Effectiveness in HIV Prevention. Current HIV/AIDS reports 13(1): 64-75	- Cost-effectiveness
Jamieson, Lise, Gomez, Gabriela B, Rebe, Kevin et al. (2020) The impact of self-selection based on HIV risk on the cost-effectiveness of preexposure prophylaxis in South Africa. AIDS (London, England) 34(6): 883-891	- Cost-effectiveness
Janes, Holly, Corey, Lawrence, Ramjee, Gita et al. (2018) Weighing the Evidence of Efficacy of Oral PrEP for HIV Prevention in Women in Southern Africa. AIDS research and human retroviruses 34(8): 645-656	- Review article but not a systematic review
Jewell, Britta L, Cremin, Ide, Pickles, Michael et al. (2015) Estimating the cost-effectiveness of pre-exposure prophylaxis to reduce HIV-1 and HSV-2 incidence in HIV-serodiscordant couples in South Africa. PloS one 10(1): e0115511	- Cost-effectiveness
Jiang, Junjun, Yang, Xiaoyi, Ye, Li et al. (2014) Pre-exposure prophylaxis for the prevention of HIV infection in high risk populations: a meta-analysis of randomized controlled trials. PloS one 9(2): e87674	- More recent systematic review included that covers the same topic

Study	Reason
John, Steven A, Rendina, H Jonathon, Grov, Christian et al. (2017) Home-based pre-exposure prophylaxis (PrEP) services for gay and bisexual men: An opportunity to address barriers to PrEP uptake and persistence. PloS one 12(12): e0189794	- Qualitative - closed questions
John, Steven A, Whitfield, Thomas H F, Rendina, H Jonathon et al. (2018) Will Gay and Bisexual Men Taking Oral Pre-exposure Prophylaxis (PrEP) Switch to Long-Acting Injectable PrEP Should It Become Available?. AIDS and behavior 22(4): 1184-1189	- Qualitative - closed questions
Joseph Davey, D.L., Bekker, L.-G., Gomba, Y. et al. (2019) Modelling the potential impact of providing preexposure prophylaxis in pregnant and breastfeeding women in South Africa. AIDS 33(8): 1391-1395	- Modelling
Joseph Davey, D.L., Pintye, J., Baeten, J.M. et al. (2020) Emerging evidence from a systematic review of safety of pre-exposure prophylaxis for pregnant and postpartum women: where are we now and where are we heading?. Journal of the International AIDS Society 23(1): e25426	- More recent systematic review included that covers the same topic
Joseph Davey, Dvora, Farley, Elise, Towriss, Catriona et al. (2018) Risk perception and sex behaviour in pregnancy and breastfeeding in high HIV prevalence settings: Programmatic implications for PrEP delivery. PloS one 13(5): e0197143	- Non-OECD country
Juusola, Jessie L, Brandeau, Margaret L, Owens, Douglas K et al. (2012) The cost-effectiveness of preexposure prophylaxis for HIV prevention in the United States in men who have sex with men. Annals of internal medicine 156(8): 541-50	- Cost-effectiveness
Kamis, Kevin F, Marx, Grace E, Scott, Kenneth A et al. (2019) Same-Day HIV Pre-Exposure Prophylaxis (PrEP) Initiation During Drop-in Sexually Transmitted Diseases Clinic Appointments Is a Highly Acceptable, Feasible, and Safe Model that Engages Individuals at Risk for HIV into PrEP Care. Open forum infectious diseases 6(7): ofz310	- Study does not contain a relevant intervention
Kapadia, Shashi N, Wu, Chunyuan, Mayer, Kenneth H et al. (2018) No change in health-related quality of life for at-risk U.S. women and men starting HIV pre-exposure prophylaxis (PrEP): Findings from HPTN 069/ACTG A5305. PloS one 13(12): e0206577	- Modelling
Karletsos, D., Greenbaum, C.R., Kobayashi, E. et al. (2020) Willingness to use PrEP among female university students in Lesotho. PLoS ONE 15(3): e0230565	- Non-OECD country
Kasonde, Michael, Niska, Richard W, Rose, Charles et al. (2014) Bone mineral density changes among HIV-uninfected young adults in a randomised trial of pre-exposure prophylaxis with tenofovir-emtricitabine or placebo in Botswana. PloS one 9(3): e90111	- Not a relevant study design - Primary study included in systematic review
Kazemian, P., Costantini, S., Kumarasamy, N. et al. (2020) The Cost-effectiveness of Human Immunodeficiency Virus (HIV) Preexposure Prophylaxis and HIV Testing Strategies in High-risk Groups in India. Clinical Infectious Diseases 70(4): 633-642	- Cost-effectiveness

Study	Reason
Kelesidis, Theodoros and Landovitz, Raphael J (2011) Preexposure prophylaxis for HIV prevention. Current HIV/AIDS reports 8(2): 94-103	- Review article but not a systematic review
Kelly, Christine A, Friedland, Barbara A, Morar, Neetha S et al. (2015) To tell or not to tell: male partner engagement in a Phase 3 microbicide efficacy trial in South Africa. Culture, health & sexuality 17(8): 1004-20	- Non-OECD country
Kesler, Maya A, Kaul, Rupert, Myers, Ted et al. (2016) Perceived HIV risk, actual sexual HIV risk and willingness to take pre-exposure prophylaxis among men who have sex with men in Toronto, Canada. AIDS care 28(11): 1378-85	- Not a relevant study design
Kessler, Jason, Myers, Julie E, Nucifora, Kimberly A et al. (2014) Evaluating the impact of prioritization of antiretroviral pre-exposure prophylaxis in New York. AIDS (London, England) 28(18): 2683-91	- Modelling
Khan, Soheb, Funk, Connie A, Corado, Katya et al. (2017) Tenofovir Disoproxil Fumarate-Associated Fanconi Syndrome in an Human Immunodeficiency Virus (HIV)-Uninfected Man Receiving HIV Pre-Exposure Prophylaxis. Open forum infectious diseases 4(3): ofx149	- Not a relevant study design
Khanna, AS, Schneider, JA, Collier, N et al. (2019) A modeling framework to inform PrEP initiation and retention scale-up in the context of Getting to Zero Initiatives. AIDS (London, England)	- Modelling
Kibengo, Freddie M, Ruzagira, Eugene, Katende, David et al. (2013) Safety, adherence and acceptability of intermittent tenofovir/emtricitabine as HIV pre-exposure prophylaxis (PrEP) among HIV-uninfected Ugandan volunteers living in HIV-serodiscordant relationships: a randomized, clinical trial. PloS one 8(9): e74314	- Primary study included in systematic review
Kim, Sun Bean, Yoon, Myoungho, Ku, Nam Su et al. (2014) Mathematical modeling of HIV prevention measures including pre-exposure prophylaxis on HIV incidence in South Korea. PloS one 9(3): e90080	- Modelling
Kimani, Makobu, van der Elst, Elise M, Chiro, Oscar et al. (2019) PrEP interest and HIV-1 incidence among MSM and transgender women in coastal Kenya. Journal of the International AIDS Society 22(6): e25323	- Non-OECD country
Kinuthia, J., Pintye, J., Abuna, F. et al. (2020) Pre-exposure prophylaxis uptake and early continuation among pregnant and post-partum women within maternal and child health clinics in Kenya: results from an implementation programme. The Lancet HIV 7(1): e38-e48	- Not a relevant study design
Kiselinova, Maja, De Spiegelaere, Ward, Verhofstede, Chris et al. (2014) Antiretrovirals for HIV prevention: when should they be recommended?. Expert review of anti-infective therapy 12(4): 431-45	- Review article but not a systematic review
Knight, Rod, Small, Will, Thomson, Kim et al. (2016) Implementation challenges and opportunities for HIV Treatment as Prevention (TasP) among young men in Vancouver, Canada: a qualitative study. BMC public health 16: 262	- Study does not contain a relevant intervention
Koechlin, Florence M, Fonner, Virginia A, Dalglish, Sarah L et al. (2017) Values and Preferences on the Use of Oral Pre-exposure Prophylaxis (PrEP) for HIV Prevention Among Multiple Populations: A Systematic Review of the Literature. AIDS and behavior 21(5): 1325-1335	- Review article but not a systematic review

Study	Reason
Kofman, Aaron and Adashi, Eli Y (2014) Pre-exposure prophylaxis for the primary prevention of HIV in at-risk women: empowerment and equity revisited. AIDS reviews 16(3): 134-43	- Not a relevant study design *- Narrative overview*
Koppenhaver, Robert T, Sorensen, Stephen W, Farnham, Paul G et al. (2011) The cost-effectiveness of pre-exposure prophylaxis in men who have sex with men in the United States: An epidemic model. JAIDS Journal of Acquired Immune Deficiency Syndromes 58(2): e51-e52	- Cost-effectiveness
Krakower, Douglas and Mayer, Kenneth H (2011) Promising prevention approaches: tenofovir gel and prophylactic use of antiretroviral medications. Current HIV/AIDS reports 8(4): 241-8	- Review article but not a systematic review
Krebs, E., Zang, X., Enns, B. et al. (2020) The impact of localized implementation: Determining the cost-effectiveness of HIV prevention and care interventions across six United States cities. AIDS 34(3): 447-458	- Cost-effectiveness
Krogstad, Emily A, Atujuna, Millicent, Montgomery, Elizabeth T et al. (2018) Perspectives of South African youth in the development of an implant for HIV prevention. Journal of the International AIDS Society 21(8): e25170	- Non-OECD country
Kruse, Leslie; Stover, Kayla; Henderson, Harold (2014) Perceptions of emtricitabine-tenofovir in HIV PrEP. HIV clinician 26(1): 1-7	- Full text paper not available
Kubicek, Katrina; Arauz-Cuadra, Cesar; Kipke, Michele D (2015) Attitudes and perceptions of biomedical HIV prevention methods: voices from young men who have sex with men. Archives of sexual behavior 44(2): 487-97	- OECD remaining countries
Kuo, C., Giovenco, D., DeAtley, T. et al. (2020) Recreational Use of HIV Antiretroviral Medication and Implications for HIV Pre-exposure Prophylaxis and Treatment. AIDS and Behavior	- Non-OECD country
Kuo, Irene, Olsen, Halli, Patrick, Rudy et al. (2016) Willingness to use HIV pre-exposure prophylaxis among community-recruited, older people who inject drugs in Washington, DC. Drug and alcohol dependence 164: 8-13	- Qualitative - closed questions
Kurtz, Steven P and Buttram, Mance E (2016) Misunderstanding of Pre-Exposure Prophylaxis Use Among Men Who Have Sex with Men: Public Health and Policy Implications. LGBT health 3(6): 461-464	- OECD remaining countries
Laborde, N.D., Kinley, P.M., Spinelli, M. et al. (2020) Understanding PrEP Persistence: Provider and Patient Perspectives. AIDS and Behavior	- OECD remaining countries
Lancaster, K.E., Lungu, T., Bula, A. et al. (2019) Preferences for Pre-exposure Prophylaxis Service Delivery Among Female Sex Workers in Malawi: A Discrete Choice Experiment. AIDS and Behavior	- Non-OECD country *- Qualitative*
Lehman, Dara A, Baeten, Jared M, McCoy, Connor O et al. (2015) Risk of drug resistance among persons acquiring HIV within a randomized clinical trial of single- or dual-agent preexposure prophylaxis. The Journal of infectious diseases 211(8): 1211-8	- Not a relevant study design - Primary study

Study	Reason
	included in systematic review
Leonardi, M; Lee, E; Tan, D H S (2011) Awareness of, usage of and willingness to use HIV pre-exposure prophylaxis among men in downtown Toronto, Canada. International journal of STD & AIDS 22(12): 738-41	- Qualitative - closed questions
Liegeon, G., Antoni, G., Senneville, E. et al. (2020) Changes in kidney function among men having sex with men starting on demand tenofovir disoproxil fumarate - emtricitabine for HIV pre-exposure prophylaxis. Journal of the International AIDS Society 23(2): e25420	- Primary study included in systematic review
Liegler, Teri, Abdel-Mohsen, Mohamed, Bentley, L Gordon et al. (2014) HIV-1 drug resistance in the iPrEx preexposure prophylaxis trial. The Journal of infectious diseases 210(8): 1217-27	- Primary study included in systematic review
Lippman, Sheri A, Koester, Kimberly A, Amico, K Rivet et al. (2015) Client and provider perspectives on new HIV prevention tools for MSM in the Americas. PloS one 10(3): e0121044	- OECD remaining countries
Liu, Albert Y, Vittinghoff, Eric, Chillag, Kata et al. (2013) Sexual risk behavior among HIV-uninfected men who have sex with men participating in a tenofovir preexposure prophylaxis randomized trial in the United States. Journal of acquired immune deficiency syndromes (1999) 64(1): 87-94	- Primary study included in systematic review
Liu, Albert Y, Vittinghoff, Eric, Sellmeyer, Deborah E et al. (2011) Bone mineral density in HIV-negative men participating in a tenofovir pre-exposure prophylaxis randomized clinical trial in San Francisco. PloS one 6(8): e23688	- Primary study included in systematic review
Liu, Albert, Cohen, Stephanie, Follansbee, Stephen et al. (2014) Early experiences implementing pre-exposure prophylaxis (PrEP) for HIV prevention in San Francisco. PLoS medicine 11(3): e1001613	- Not a relevant study design
Liu, Chunxing, Ding, Yingying, Ning, Zhen et al. (2018) Factors influencing uptake of pre-exposure prophylaxis: some qualitative insights from an intervention study of men who have sex with men in China. Sexual health 15(1): 39-45	- Non-OECD country *- non-OECD*
Lockard, Annie, Rosenberg, Eli S, Sullivan, Patrick S et al. (2019) Contrasting Self-Perceived Need and Guideline-Based Indication for HIV Pre-Exposure Prophylaxis Among Young, Black Men Who Have Sex with Men Offered Pre-Exposure Prophylaxis in Atlanta, Georgia. AIDS patient care and STDs 33(3): 112-119	- OECD remaining countries
Luehring-Jones, Peter, Palfai, Tibor P, Tahaney, Kelli D et al. (2019) Pre-Exposure Prophylaxis (PrEP) Use is Associated With Health Risk Behaviors Among Moderate- and Heavy-Drinking MSM. AIDS education and prevention : official publication of the International Society for AIDS Education 31(5): 452-462	- Not a relevant study design *cross-sectional*
Luz, Paula M, Osher, Benjamin, Grinsztejn, Beatriz et al. (2018) The cost-effectiveness of HIV pre-exposure prophylaxis in men who have sex with men and	- Cost-effectiveness

Study	Reason
transgender women at high risk of HIV infection in Brazil. Journal of the International AIDS Society 21(3): e25096	
Maartens, Gary; Celum, Connie; Lewin, Sharon R (2014) HIV infection: epidemiology, pathogenesis, treatment, and prevention. Lancet (London, England) 384(9939): 258-71	- Review article but not a systematic review
Macapagal, K., Kraus, A., Korpak, A.K. et al. (2019) PrEP Awareness, Uptake, Barriers, and Correlates Among Adolescents Assigned Male at Birth Who Have Sex with Males in the U.S. Archives of Sexual Behavior	- Qualitative - closed questions
Mack, Natasha, Evens, Emily M, Tolley, Elizabeth E et al. (2014) The importance of choice in the rollout of ARV-based prevention to user groups in Kenya and South Africa: a qualitative study. Journal of the International AIDS Society 17(3suppl2): 19157	- Non-OECD country
Magno, Laio, Dourado, Ines, Sutten Coats, Cassandra et al. (2019) Knowledge and willingness to use pre-exposure prophylaxis among men who have sex with men in Northeastern Brazil. Global public health 14(8): 1098-1111	- Non-OECD country
Mallayasamy, Surulivelrajan, Chaturvedula, Ayyappa, Fossler, Michael J et al. (2019) Assessment of Demographic and Socio-Behavioral Factors on Adherence to HIV Pre-Exposure Prophylaxis Using a Markov Modeling Approach. Frontiers in pharmacology 10: 785	- Modelling
Malone, Jowanna, Syvertsen, Jennifer L, Johnson, Blake E et al. (2018) Negotiating sexual safety in the era of biomedical HIV prevention: relationship dynamics among male couples using pre-exposure prophylaxis. Culture, health & sexuality 20(6): 658-672	- OECD remaining countries
Maloney, K.M., Krakower, D.S., Ziobro, D. et al. (2017) Culturally competent sexual healthcare as a prerequisite for obtaining preexposure prophylaxis: Findings from a qualitative study. LGBT Health 4(4): 310-314	- OECD remaining countries
Mansergh, Gordon; Koblin, Beryl A; Sullivan, Patrick S (2012) Challenges for HIV pre-exposure prophylaxis among men who have sex with men in the United States. PLoS medicine 9(8): e1001286	- Review article but not a systematic review
Mansoor, L.E., Yende-Zuma, N., Baxter, C. et al. (2019) Integrated provision of topical pre-exposure prophylaxis in routine family planning services in South Africa: a non-inferiority randomized controlled trial. Journal of the International AIDS Society 22(9): e25381	- Study does not contain a relevant intervention *Does not include oral PrEP*
Marcus, Julia L, Glidden, David V, Mayer, Kenneth H et al. (2013) No evidence of sexual risk compensation in the iPrEx trial of daily oral HIV preexposure prophylaxis. PloS one 8(12): e81997	- Primary study included in systematic review
Marrazzo, J, Rabe, L, Kelly, C et al. (2013) Herpes simplex virus (HSV) infection in the VOICE (MTN 003) study: pre-exposure prophylaxis (PrEP) for HIV with daily use of oral tenofovir, oral tenofovir-emtricitabine, or vaginal tenofovir gel. Sexually transmitted infections 89: a46	- Abstract only

Study	Reason
Marrazzo, Jeanne M, Ramjee, Gita, Richardson, Barbra A et al. (2015) Tenofovir-based preexposure prophylaxis for HIV infection among African women. The New England journal of medicine 372(6): 509-18	- Not a relevant study design - Primary study included in systematic review
Marshall, B.D.L. and Mimiaga, M.J. (2015) Uptake and effectiveness of PrEP for transgender women. The Lancet HIV 2(12): e502-e503	- Not a relevant study design
Martin, Michael, Vanichseni, Suphak, Suntharasamai, Pravan et al. (2014) Risk behaviors and risk factors for HIV infection among participants in the Bangkok tenofovir study, an HIV pre-exposure prophylaxis trial among people who inject drugs. PloS one 9(3): e92809	- Primary study included in systematic review
Maseko, Bertha, Hill, Lauren M, Phanga, Twambilile et al. (2020) Perceptions of and interest in HIV pre-exposure prophylaxis use among adolescent girls and young women in Lilongwe, Malawi. PloS one 15(1): e0226062	- Non-OECD country
Maxwell, Steven; Gafos, Mitzy; Shahmanesh, Maryam (2019) Pre-exposure Prophylaxis Use and Medication Adherence Among Men Who Have Sex With Men: A Systematic Review of the Literature. The Journal of the Association of Nurses in AIDS Care : JANAC 30(4): e38-e61	- Review article but not a systematic review *Not restricted by RCT*
Mayeux, J.J. and Ng, Y.C. (2019) Pre-Exposure Prophylaxis in the Urgent Care Setting: A Systematic Review. Journal for Nurse Practitioners 15(8): 595-599	- Review article but not a systematic review
McCormack, Sheena, Dunn, David T, Desai, Monica et al. (2016) Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. Lancet (London, England) 387(10013): 53-60	- Primary study included in systematic review
McGowan, Ian (2014) An overview of antiretroviral pre-exposure prophylaxis of HIV infection. American journal of reproductive immunology (New York, N.Y. : 1989) 71(6): 624-30	- Review article but not a systematic review
McKenney, Jennie, Chen, Anders, Hoover, Karen W et al. (2017) Optimal costs of HIV pre-exposure prophylaxis for men who have sex with men. PloS one 12(6): e0178170	- Cost-effectiveness
McNaghten, A.D., Kearns, R., Siegler, A.J. et al. (2014) Sibanye methods for prevention packages program project protocol: Pilot study of HIV prevention interventions for men who have sex with men in South Africa. Journal of Medical Internet Research 16(10): e55	- Protocol

Study	Reason
Mehta, Sapna A, Silvera, Richard, Bernstein, Kyle et al. (2011) Awareness of post-exposure HIV prophylaxis in high-risk men who have sex with men in New York City. Sexually transmitted infections 87(4): 344-8	- Qualitative - closed questions
Merchant, R.C., Corner, D., Garza, E. et al. (2016) Preferences for HIV Pre-Exposure Prophylaxis (PrEP) Information Among Men Who Have Sex with Men (MSM) at Community Outreach Settings. Journal of Gay and Lesbian Mental Health 20(1): 21-33	- Qualitative - closed questions
Meyer-Rath, Gesine, van Rensburg, Craig, Chiu, Calvin et al. (2019) The per-patient costs of HIV services in South Africa: Systematic review and application in the South African HIV Investment Case. PloS one 14(2): e0210497	- Cost-effectiveness
Mimiaga, Matthew J, Closson, Elizabeth F, Kothary, Vishesh et al. (2014) Sexual partnerships and considerations for HIV antiretroviral pre-exposure prophylaxis utilization among high-risk substance using men who have sex with men. Archives of sexual behavior 43(1): 99-106	- OECD remaining countries
Mirembe, Brenda G, Kelly, Clifton W, Mgodi, Nyaradzo et al. (2016) Bone Mineral Density Changes Among Young, Healthy African Women Receiving Oral Tenofovir for HIV Preexposure Prophylaxis. Journal of acquired immune deficiency syndromes (1999) 71(3): 287-94	- Not a relevant study design - Primary study included in systematic review
Mitchell, Jason W, Lee, Ji-Young, Woodyatt, Cory et al. (2016) HIV-negative male couples' attitudes about pre-exposure prophylaxis (PrEP) and using PrEP with a sexual agreement. AIDS care 28(8): 994-9	- OECD remaining countries
Montgomery, Elizabeth T, Atujuna, Millicent, Krogstad, Emily et al. (2019) The Invisible Product: Preferences for Sustained-Release, Long-Acting Pre-exposure Prophylaxis to HIV Among South African Youth. Journal of acquired immune deficiency syndromes (1999) 80(5): 542-550	- Non-OECD country
Montgomery, Elizabeth T, van der Straten, Ariane, Stadler, Jonathan et al. (2015) Male Partner Influence on Women's HIV Prevention Trial Participation and Use of Pre-exposure Prophylaxis: the Importance of "Understanding". AIDS and behavior 19(5): 784-93	- Non-OECD country
Moodley, Nishila; Gray, Glenda; Bertram, Melanie (2016) The Price of Prevention: Cost Effectiveness of Biomedical HIV Prevention Strategies in South Africa. Clinical research in HIV/AIDS 3(1)	- Cost-effectiveness
Moon, K.T. (2011) Reducing HIV transmission via preexposure prophylaxis with antiretroviral drugs. American Family Physician 84(10): 1169-1175	- Full text paper not available *Summary overview not the full paper*
Moskowitz, D.A., Macapagal, K., Mongrella, M. et al. (2020) What If My Dad Finds Out!?: Assessing Adolescent Men Who Have Sex with Men's Perceptions About Parents as Barriers to PrEP Uptake. AIDS and Behavior	- OECD remaining countries

Study	Reason
Mosley, Terrance, Khaketla, Moliehi, Armstrong, Heather L et al. (2018) Trends in Awareness and Use of HIV PrEP Among Gay, Bisexual, and Other Men who have Sex with Men in Vancouver, Canada 2012-2016. AIDS and behavior 22(11): 3550-3565	- Qualitative - closed questions
Mugo, Nelly R, Hong, Ting, Celum, Connie et al. (2014) Pregnancy incidence and outcomes among women receiving preexposure prophylaxis for HIV prevention: a randomized clinical trial. JAMA 312(4): 362-71	- Excluded population *Conception as outcome of interest excluded*
Mugwanya, Kenneth K, Donnell, Deborah, Celum, Connie et al. (2013) Sexual behaviour of heterosexual men and women receiving antiretroviral pre-exposure prophylaxis for HIV prevention: a longitudinal analysis. The Lancet. Infectious diseases 13(12): 1021-8	- Not a relevant study design *No control group*
Mugwanya, Kenneth K, Wyatt, Christina, Celum, Connie et al. (2015) Changes in glomerular kidney function among HIV-1-uninfected men and women receiving emtricitabine-tenofovir disoproxil fumarate preexposure prophylaxis: a randomized clinical trial. JAMA internal medicine 175(2): 246-54	- Not a relevant study design *adverse events assessed through SRs* - Primary study included in systematic review
Mugwanya, Kenneth, Baeten, Jared, Celum, Connie et al. (2016) Low Risk of Proximal Tubular Dysfunction Associated With Emtricitabine-Tenofovir Disoproxil Fumarate Preexposure Prophylaxis in Men and Women. The Journal of infectious diseases 214(7): 1050-7	- Outcome does not match protocol
Mukandavire, Zindoga; Mitchell, Kate M; Vickerman, Peter (2016) Comparing the impact of increasing condom use or HIV pre-exposure prophylaxis (PrEP) use among female sex workers. Epidemics 14: 62-70	- Modelling
Mulligan, Kathleen, Glidden, David V, Anderson, Peter L et al. (2015) Effects of Emtricitabine/Tenofovir on Bone Mineral Density in HIV-Negative Persons in a Randomized, Double-Blind, Placebo-Controlled Trial. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 61(4): 572-80	- Primary study included in systematic review
Murnane, Pamela M, Celum, Connie, Mugo, Nelly et al. (2013) Efficacy of preexposure prophylaxis for HIV-1 prevention among high-risk heterosexuals: subgroup analyses from a randomized trial. AIDS (London, England) 27(13): 2155-60	- Primary study included in systematic review
Murnane, Pamela M, Heffron, Renee, Ronald, Allan et al. (2014) Pre-exposure prophylaxis for HIV-1 prevention does not diminish the pregnancy prevention effectiveness of hormonal contraception. AIDS (London, England) 28(12): 1825-30	- Outcome does not match protocol

Study	Reason
Mustanski, Brian, Johnson, Amy K, Garofalo, Robert et al. (2013) Perceived likelihood of using HIV pre-exposure prophylaxis medications among young men who have sex with men. AIDS and behavior 17(6): 2173-9	- Qualitative - closed questions
Mutua, Gaudensia, Sanders, Eduard, Mugo, Peter et al. (2012) Safety and adherence to intermittent pre-exposure prophylaxis (PrEP) for HIV-1 in African men who have sex with men and female sex workers. PloS one 7(4): e33103	- Primary study included in systematic review
Nadery, S and Geerlings, S E (2013) Pre-exposure prophylaxis (PrEP) in HIV-uninfected individuals with high-risk behaviour. The Netherlands journal of medicine 71(6): 295-9	- Review article but not a systematic review
Ngure, K., Ongolly, F., Dolla, A. et al. (2020) "I just believe there is a risk" understanding of undetectable equals untransmissible (U = U) among health providers and HIV-negative partners in serodiscordant relationships in Kenya. Journal of the International AIDS Society 23(3): e25466	- Non-OECD country
Nichols, Brooke E, Baltussen, Rob, van Dijk, Janneke H et al. (2014) Cost-effectiveness of PrEP in HIV/AIDS control in Zambia: a stochastic league approach. Journal of acquired immune deficiency syndromes (1999) 66(2): 221-8	- Cost-effectiveness
Nichols, Brooke E, Boucher, Charles A B, van der Valk, Marc et al. (2016) Cost-effectiveness analysis of pre-exposure prophylaxis for HIV-1 prevention in the Netherlands: a mathematical modelling study. The Lancet. Infectious diseases 16(12): 1423-1429	- Cost-effectiveness
Nichols, Brooke E, Boucher, Charles A B, van Dijk, Janneke H et al. (2013) Cost-effectiveness of pre-exposure prophylaxis (PrEP) in preventing HIV-1 infections in rural Zambia: a modeling study. PloS one 8(3): e59549	- Cost-effectiveness
Nicol, M.R.; Adams, J.L.; Kashuba, A.D.M. (2013) HIV pre-exposure prophylaxis trials: The road to success. Clinical Investigation 3(3): 295-308	- Review article but not a systematic review
Nodin, N, Carballo-Dieguez, A, Ventuneac, A M et al. (2008) Knowledge and acceptability of alternative HIV prevention bio-medical products among MSM who bareback. AIDS care 20(1): 106-15	- OECD remaining countries
O'Halloran, C., Rice, B., White, E. et al. (2019) Chemsex is not a barrier to self-reported daily PrEP adherence among PROUD study participants. International Journal of Drug Policy 74: 246-254	- Outcome does not match protocol *Adherence - secondary outcome which will be assessed from efficacy SRs*
Ogunbajo, A., Leblanc, N.M., Kushwaha, S. et al. (2020) Knowledge and Acceptability of HIV pre-exposure prophylaxis (PrEP) among men who have sex with men (MSM) in Ghana. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV 32(3): 330-336	- Non-OECD country

Study	Reason
Okwundu, Charles I and Okoromah, Christy A N (2009) Antiretroviral pre-exposure prophylaxis (PrEP) for preventing HIV in high-risk individuals. The Cochrane database of systematic reviews: cd007189	- Systematic review updated
Okwundu, Charles I; Uthman, Olalekan A; Okoromah, Christy An (2012) Antiretroviral pre-exposure prophylaxis (PrEP) for preventing HIV in high-risk individuals. The Cochrane database of systematic reviews: cd007189	- More recent systematic review included that covers the same topic
Oldenburg, Catherine E, Biello, Katie B, Colby, Donn et al. (2014) Engagement with peer health educators is associated with willingness to use pre-exposure prophylaxis among male sex workers in Ho Chi Minh City, Vietnam. AIDS Patient Care and STDs 28(3): 109-112	- Non-OECD country
Ong, Koh Jun, Desai, Sarika, Field, Nigel et al. (2017) Economic evaluation of HIV pre-exposure prophylaxis among men-who-have-sex-with-men in England in 2016. Euro surveillance : bulletin Europeen sur les maladies transmissibles = European communicable disease bulletin 22(42)	- Cost-effectiveness
Onoya, Dorina, Hirasen, Kamban, van den Berg, Liudmyla et al. (2018) Adverse Drug Reactions Among Patients Initiating Second-Line Antiretroviral Therapy in South Africa. Drug safety 41(12): 1343-1353	- Wrong population
Oostrom, L., Rosentel, K., Motley, D. et al. (2020) Discordance in objective and self-perceived HIV risk: A potential barrier to pre-exposure prophylaxis in young gay and bisexual men. Journal of the Association of Nurses in AIDS Care 31(1): 103-109	- Not a relevant study design *- seondary analysis of baseline survey data*
Ouellet, E., Durand, M., Guertin, J.R. et al. (2015) Cost effectiveness of 'on demand' Hiv pre-exposure prophylaxis for non-injection drug-using men who have sex with men in Canada. Canadian Journal of Infectious Diseases and Medical Microbiology 26(1): 23-29	- Cost-effectiveness
Pacifico de Carvalho, Nathalia, Mendicino, Cassia Cristina Pinto, Candido, Raissa Carolina Fonseca et al. (2019) HIV pre-exposure prophylaxis (PrEP) awareness and acceptability among trans women: a review. AIDS care 31(10): 1234-1240	- Systematic review used as source of primary studies
Paltiel, A David, Freedberg, Kenneth A, Scott, Callie A et al. (2009) HIV preexposure prophylaxis in the United States: impact on lifetime infection risk, clinical outcomes, and cost-effectiveness. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 48(6): 806-15	- Cost-effectiveness
Pantalone, D.W., Holloway, I.W., Goldblatt, A.E.A. et al. (2019) The Impact of Pre-Exposure Prophylaxis on Sexual Communication and Sexual Behavior of Urban Gay and Bisexual Men. Archives of Sexual Behavior	- OECD remaining countries
Paparini, Sara, Nutland, Will, Rhodes, Tim et al. (2018) DIY HIV prevention: Formative qualitative research with men who have sex with men who source PrEP outside of clinical trials. PloS one 13(8): e0202830	- Qualitative - does not ask relevant questions

Study	Reason
Parker, Sharon, Chan, Philip A, Oldenburg, Catherine E et al. (2015) Patient experiences of men who have sex with men using pre-exposure prophylaxis to prevent HIV infection. AIDS Patient Care and STDs 29(12): 639-642	- OECD remaining countries
Patel, Rena C, Stanford-Moore, Gaelen, Odoyo, Josephine et al. (2016) "Since both of us are using antiretrovirals, we have been supportive to each other": facilitators and barriers of pre-exposure prophylaxis use in heterosexual HIV serodiscordant couples in Kisumu, Kenya. Journal of the International AIDS Society 19(1): 21134	- Non-OECD country
Patel, Rupa R, Crane, John S, Lopez, Julia et al. (2018) Pre-exposure prophylaxis for HIV prevention preferences among young adult African American men who have sex with men. PloS one 13(12): e0209484	- Non-OECD country
Paxton, Lynn A (2012) Considerations regarding antiretroviral chemoprophylaxis and heterosexuals in generalized epidemic settings. Current opinion in HIV and AIDS 7(6): 557-62	- Review article but not a systematic review
Paxton, Lynn A; Hope, Tony; Jaffe, Harold W (2007) Pre-exposure prophylaxis for HIV infection: what if it works?. Lancet (London, England) 370(9581): 89-93	- Review article but not a systematic review
Pelletier, S.J., Gagnon, M.-P., Diabate, S. et al. (2019) Pre-Exposure Prophylaxis (PrEP) in men who have sex with men in bouake, cote d'Ivoire: A qualitative evaluation of acceptability. Open AIDS Journal 13(1): 49-58	- Non-OECD country
Peng, Liping, Cao, Wangnan, Gu, Jing et al. (2019) Willingness to Use and Adhere to HIV Pre-Exposure Prophylaxis (PrEP) among Men Who Have Sex with Men (MSM) in China. International journal of environmental research and public health 16(14)	- Non-OECD country
Peng, Peng, Su, Shu, Fairley, Christopher K et al. (2018) A Global Estimate of the Acceptability of Pre-exposure Prophylaxis for HIV Among Men Who have Sex with Men: A Systematic Review and Meta-analysis. AIDS and behavior 22(4): 1063-1074	- Abstract only
Penrose, Kerri J, Brumme, Chanson J, Scoulos-Hanson, Maritsa et al. (2018) Frequent cross-resistance to rilpivirine among subtype C HIV-1 from first-line antiretroviral therapy failures in South Africa. Antiviral chemistry & chemotherapy 26: 2040206618762985	- Not a relevant study design
Perez-Figueroa, Rafael E, Kapadia, Farzana, Barton, Staci C et al. (2015) Acceptability of PrEP Uptake Among Racially/Ethnically Diverse Young Men Who Have Sex With Men: The P18 Study. AIDS education and prevention : official publication of the International Society for AIDS Education 27(2): 112-25	- OECD remaining countries
Perry, Brian, Oluoch, Lennah, Agot, Kawango et al. (2014) Widow cleansing and inheritance among the Luo in Kenya: the need for additional women-centred HIV prevention options. Journal of the International AIDS Society 17: 19010	- Non-OECD country
Peterson, M., Macmadu, A., Truong, A.Q. et al. (2019) Pre-exposure prophylaxis awareness and interest among participants in a medications for addiction treatment program in a unified jail and prison setting in Rhode Island. Journal of Substance Abuse Treatment 106: 73-78	- Does not contain a population of people on PrEP

Study	Reason
Peterson, Meghan, Nowotny, Kathryn, Dauria, Emily et al. (2019) Institutional distrust among gay, bisexual, and other men who have sex with men as a barrier to accessing pre-exposure prophylaxis (PrEP). AIDS care 31(3): 364-369	- Does not contain a population of people on PrEP
Philbin, Morgan M, Parker, Caroline M, Parker, Richard G et al. (2018) Gendered Social Institutions and Preventive Healthcare Seeking for Black Men Who Have Sex with Men: The Promise of Biomedical HIV Prevention. Archives of sexual behavior 47(7): 2091-2100	- Qualitative - does not ask relevant questions
Philbin, Morgan M, Parker, Caroline M, Parker, Richard G et al. (2016) The Promise of Pre-Exposure Prophylaxis for Black Men Who Have Sex with Men: An Ecological Approach to Attitudes, Beliefs, and Barriers. AIDS patient care and STDs 30(6): 282-90	- OECD remaining countries
Phillips, Gregory 2nd, Raman, Anand, Felt, Dylan et al. (2019) Factors Associated with PrEP Support and Disclosure Among YMSM and Transgender Individuals Assigned Male at Birth in Chicago. AIDS and behavior 23(10): 2749-2760	- Qualitative - closed questions
Pilkington, Victoria, Hill, Andrew, Hughes, Sophie et al. (2018) How safe is TDF/FTC as PrEP? A systematic review and meta-analysis of the risk of adverse events in 13 randomised trials of PrEP. Journal of virus eradication 4(4): 215-224	- More recent systematic review included that covers the same topic
Pintye, J., Beima-Sofie, K.M., Makabong'o, P.A. et al. (2018) HIV-Uninfected Kenyan Adolescent and Young Women Share Perspectives on Using Pre-Exposure Prophylaxis during Pregnancy. AIDS Patient Care and STDs 32(12): 538-544	- Non-OECD country
Pleuhs, B., Quinn, K.G., Walsh, J.L. et al. (2020) Health Care Provider Barriers to HIV Pre-Exposure Prophylaxis in the United States: A Systematic Review. AIDS Patient Care and STDs 34(3): 111-123	- Systematic review used as source of primary studies
Poteat, Tonia, Malik, Mannat, Scheim, Ayden et al. (2017) HIV Prevention Among Transgender Populations: Knowledge Gaps and Evidence for Action. Current HIV/AIDS reports 14(4): 141-152	- Review article but not a systematic review
Prem Kumar, S G, Kumar, G Anil, Poluru, Ramesh et al. (2013) Contact with HIV prevention programmes & willingness for new interventions among truckers in India. The Indian journal of medical research 137(6): 1061-71	- Non-OECD country
Price, Joan T, Wheeler, Stephanie B, Stranix-Chibanda, Lynda et al. (2016) Cost-Effectiveness of Pre-exposure HIV Prophylaxis During Pregnancy and Breastfeeding in Sub-Saharan Africa. Journal of acquired immune deficiency syndromes (1999) 72suppl2: 145-53	- Cost-effectiveness
Puppo, C., Spire, B., Morel, S. et al. (2020) How PrEP users constitute a community in the MSM population through their specific experience and management of stigmatization. The example of the French ANRS-PREVENIR study. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV	- OECD remaining countries

Study	Reason
Qin, Y., Price, C., Rutledge, R. et al. (2020) Women's Decision-Making about PrEP for HIV Prevention in Drug Treatment Contexts. Journal of the International Association of Providers of AIDS Care 19	- Does not contain a population of people on PrEP
Quaife, Matthew, Terris-Prestholt, Fern, Eakle, Robyn et al. (2018) The cost-effectiveness of multi-purpose HIV and pregnancy prevention technologies in South Africa. Journal of the International AIDS Society 21(3)	- Cost-effectiveness
Quinn, K.G., Christenson, E., Sawkin, M.T. et al. (2019) The Unanticipated Benefits of PrEP for Young Black Gay, Bisexual, and Other Men Who Have Sex with Men. AIDS and Behavior	- OECD remaining countries
Quinn, K.G., Christenson, E., Spector, A. et al. (2020) The Influence of Peers on PrEP Perceptions and Use Among Young Black Gay, Bisexual, and Other Men Who Have Sex with Men: A Qualitative Examination. Archives of Sexual Behavior	- OECD remaining countries
Quinn, Katherine, Bowleg, Lisa, Dickson-Gomez, Julia et al. (2019) "The fear of being Black plus the fear of being gay": The effects of intersectional stigma on PrEP use among young Black gay, bisexual, and other men who have sex with men. Social Science & Medicine 232: 86-93	- OECD remaining countries
Quinn, Katherine, Dickson-Gomez, Julia, Zarwell, Meagan et al. (2019) "A Gay Man and a Doctor are Just like, a Recipe for Destruction": How Racism and Homonegativity in Healthcare Settings Influence PrEP Uptake Among Young Black MSM. AIDS and behavior 23(7): 1951-1963	- OECD remaining countries
Rael, Christine Tagliaferri, Martinez, Michelle, Giguere, Rebecca et al. (2019) Knowledge About Oral PrEP Among Transgender Women in New York City. AIDS and behavior 23(10): 2779-2783	- Qualitative - closed questions
Reidy, Meghan, Gardiner, Elizabeth, Pretorius, Carel et al. (2019) Evaluating the potential impact and cost-effectiveness of dapivirine vaginal ring pre-exposure prophylaxis for HIV prevention. PloS one 14(6): e0218710	- Cost-effectiveness
Remy, Laura and Enriquez, Maithe (2019) Behavioral Interventions to Enhance PrEP Uptake Among Black Men Who Have Sex With Men: A Review. The Journal of the Association of Nurses in AIDS Care : JANAC 30(2): 151-163	- Systematic review used as source of primary studies
Restar, Arjee J, Kuhns, Lisa, Reisner, Sari L et al. (2018) Acceptability of Antiretroviral Pre-exposure Prophylaxis from a Cohort of Sexually Experienced Young Transgender Women in Two U.S. Cities. AIDS and behavior 22(11): 3649-3657	- Not a relevant study design
Restar, Arjee J, Tocco, Jack Ume, Mantell, Joanne E et al. (2017) Perspectives on HIV Pre- and Post-Exposure Prophylaxes (PrEP and PEP) Among Female and Male Sex Workers in Mombasa, Kenya: Implications for Integrating Biomedical Prevention into Sexual Health Services. AIDS education and prevention : official publication of the International Society for AIDS Education 29(2): 141-153	- Non-OECD country
Reyniers, Thijs, Nostlinger, Christiana, Laga, Marie et al. (2018) Choosing Between Daily and Event-Driven Pre-exposure Prophylaxis: Results of a Belgian PrEP Demonstration Project. Journal of acquired immune deficiency syndromes (1999) 79(2): 186-194	- OECD remaining countries

Study	Reason
Reza-Paul, Sushena, Lazarus, Lisa, Doshi, Monika et al. (2016) Prioritizing Risk in Preparation for a Demonstration Project: A Mixed Methods Feasibility Study of Oral Pre-Exposure Prophylaxis (PREP) among Female Sex Workers in South India. PloS one 11(11): e0166889	- Non-OECD country
Rice, Whitney S, Stringer, Kristi L, Sohail, Maira et al. (2019) Accessing Pre-exposure Prophylaxis (PrEP): Perceptions of Current and Potential PrEP Users in Birmingham, Alabama. AIDS and behavior 23(11): 2966-2979	- OECD remaining countries
Riddell, James 4th; Amico, K Rivet; Mayer, Kenneth H (2018) HIV Preexposure Prophylaxis: A Review. JAMA 319(12): 1261-1268	- Review article but not a systematic review
Riddler, Sharon A, Husnik, Marla, Ramjee, Gita et al. (2017) HIV disease progression among women following seroconversion during a tenofovir-based HIV prevention trial. PloS one 12(6): e0178594	- Wrong population
Rivierez, I, Quatremere, G, Spire, B et al. (2018) Lessons learned from the experiences of informal PrEP users in France: results from the ANRS-PrEPage study. AIDS care 30(sup2): 48-53	- OECD remaining countries
Roberts, D Allen, Hawes, Stephen E, Bousso Bao, Mame D et al. (2020) Trends in Reported Sexual Behavior and Y-Chromosomal DNA Detection Among Female Sex Workers in the Senegal Preexposure Prophylaxis Demonstration Project. Sexually transmitted diseases 47(5): 314-320	- Not a relevant study design *No control group*
Roberts, Sarah T, Heffron, Renee, Ngure, Kenneth et al. (2014) Preferences for daily or intermittent pre-exposure prophylaxis regimens and ability to anticipate sex among HIV uninfected members of Kenyan HIV serodiscordant couples. AIDS and behavior 18(9): 1701-11	- Non-OECD country
Rocha, Luis Miguel, Campos, Maria Jose, Brito, Joao et al. (2014) Acceptability of PrEP among HIV negative Portuguese men who have sex with men that attended 2014 Lisbon pride fair. Journal of the International AIDS Society 17(4suppl3): 19734	- Abstract only
Roesch, Amanda (2019) Implementing Pre-exposure Prophylaxis for HIV Prevention at an Urban Youth Clinic. The Journal of the Association of Nurses in AIDS Care : JANAC 30(2): 232-237	- Not a relevant study design
Rogers, Brooke G, Whiteley, Laura, Haubrick, Kayla K et al. (2019) Intervention Messaging About Pre-Exposure Prophylaxis Use Among Young, Black Sexual Minority Men. AIDS patient care and STDs 33(11): 473-481	- OECD remaining countries
Rojas Castro, D., Delabre, R.M., Morel, S. et al. (2019) Community engagement in the provision of culturally competent HIV and STI prevention services: lessons from the French experience in the era of PrEP. Journal of the International AIDS Society 22(s6): e25350	- Not a relevant study design
Ross, Eric L; Cinti, Sandro K; Hutton, David W (2016) Implementation and Operational Research: A Cost-Effective, Clinically Actionable Strategy for Targeting HIV Preexposure Prophylaxis to High-Risk Men Who Have Sex With Men. Journal of acquired immune deficiency syndromes (1999) 72(3): e61-7	- Cost-effectiveness

Study	Reason
Rubincam, Clara, Newman, Peter A, Atujuna, Millicent et al. (2018) 'Why would you promote something that is less percent safer than a condom?': Perspectives on partially effective HIV prevention technologies among key populations in South Africa. SAHARA J : journal of Social Aspects of HIV/AIDS Research Alliance 15(1): 179-186	- Non-OECD country
Rucinski, Katherine B, Mensah, Nana P, Sepkowitz, Kent A et al. (2013) Knowledge and use of pre-exposure prophylaxis among an online sample of young men who have sex with men in New York City. AIDS and behavior 17(6): 2180-4	- Qualitative - closed questions
Saberi, Parya, Gamarel, Kristi E, Neilands, Torsten B et al. (2012) Ambiguity, ambivalence, and apprehensions of taking HIV-1 pre-exposure prophylaxis among male couples in San Francisco: a mixed methods study. PloS one 7(11): e50061	- OECD remaining countries
Sagaon-Teyssier, Luis, Suzan-Monti, Marie, Demoulin, Baptiste et al. (2016) Uptake of PrEP and condom and sexual risk behavior among MSM during the ANRS IPERGAY trial. AIDS care 28suppl1: 48-55	- Primary study included in systematic review
Sales, J.M., Phillips, A.L., Tamler, I. et al. (2019) Patient recommendations for PrEP information dissemination at family planning clinics in Atlanta, Georgia. Contraception 99(4): 233-238	- OECD remaining countries
Sarkar, S., Corso, P., Ebrahim-Zadeh, S. et al. (2019) Cost-effectiveness of HIV Prevention Interventions in Sub-Saharan Africa: A Systematic Review. EClinicalMedicine 10: 10-31	- Cost-effectiveness
Saxton, Peter, Giola, Massimo, Coughlan, Edward et al. (2018) Implementing HIV pre-exposure prophylaxis (PrEP): let's not get caught with our pants down. The New Zealand medical journal 131(1481): 64-73	- Not a relevant study design *- viewpoint review*
Scheibe, Andrew, Grasso, Michael, Raymond, Henry Fisher et al. (2018) Modelling the UNAIDS 90-90-90 treatment cascade for gay, bisexual and other men who have sex with men in South Africa: using the findings of a data triangulation process to map a way forward. AIDS and behavior 22(3): 853-859	- Study does not contain a relevant intervention *Impact of PrEP does not appear to be able to be extracted*
Schnarrs, Phillip W, Gordon, Danielle, Martin-Valenzuela, Ryan et al. (2018) Perceived Social Norms About Oral PrEP Use: Differences Between African-American, Latino and White Gay, Bisexual and Other Men Who Have Sex with Men in Texas. AIDS and behavior 22(11): 3588-3602	- OECD remaining countries
Schneider, John A, Dandona, Rakhi, Pasupneti, Shravani et al. (2010) Initial commitment to pre-exposure prophylaxis and circumcision for HIV prevention amongst Indian truck drivers. PloS one 5(7): e11922	- Non-OECD country
Schneider, Karen; Gray, Richard T; Wilson, David P (2014) A cost-effectiveness analysis of HIV preexposure prophylaxis for men who have sex with men in Australia. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 58(7): 1027-34	- Cost-effectiveness

Study	Reason
Scholl, Elizabeth (2016) Improving outpatient implementation of preexposure prophylaxis in men who have sex with men. Journal of the American Association of Nurse Practitioners 28(8): 446-52	- Review article but not a systematic review
Schwartz, J. and Grimm, J. (2017) Stigma Communication Surrounding PrEP: The Experiences of A Sample of Men Who Have Sex With Men. Health Communication: 1-7	- OECD remaining countries
Shea, Jaclyn, Bula, Agatha, Dunda, Wezzie et al. (2019) "The Drug Will Help Protect My Tomorrow": Perceptions of Integrating PrEP into HIV Prevention Behaviors Among Female Sex Workers in Lilongwe, Malawi. AIDS education and prevention : official publication of the International Society for AIDS Education 31(5): 421-432	- Non-OECD country
Shen, Mingwang, Xiao, Yanni, Rong, Libin et al. (2018) The cost-effectiveness of oral HIV pre-exposure prophylaxis and early antiretroviral therapy in the presence of drug resistance among men who have sex with men in San Francisco. BMC medicine 16(1): 58	- Cost-effectiveness
Shiri, Tinevimbo and Welte, Alex (2011) Modelling the impact of acute infection dynamics on the accumulation of HIV-1 mutations. Journal of theoretical biology 279(1): 44-54	- Modelling
Shrestha, R., Altice, F.L., Didomizio, E. et al. (2020) Feasibility and acceptability of an mhealth-based approach as an hiv prevention strategy among people who use drugs on pre-exposure prophylaxis. Patient Preference and Adherence 14: 107-118	- Does not contain a population of people on PrEP
Shrestha, Roman and Copenhaver, Michael (2018) Exploring the Use of Pre-exposure Prophylaxis (PrEP) for HIV Prevention Among High-Risk People Who Use Drugs in Treatment. Frontiers in public health 6: 195	- Does not contain a population of people on PrEP
Shrestha, Roman, Karki, Pramila, Altice, Frederick L et al. (2017) Correlates of willingness to initiate pre-exposure prophylaxis and anticipation of practicing safer drug- and sex-related behaviors among high-risk drug users on methadone treatment. Drug and alcohol dependence 173: 107-116	- Does not contain a population of people on PrEP
Sidebottom, David; Ekstrom, Anna Mia; Stromdahl, Susanne (2018) A systematic review of adherence to oral pre-exposure prophylaxis for HIV - how can we improve uptake and adherence?. BMC infectious diseases 18(1): 581	- More recent systematic review included that covers the same topic
Sithole, Bhekie (2017) HIV prevention needs for men who have sex with men in Swaziland. African journal of AIDS research : AJAR 16(4): 315-320	- Non-OECD country
Skolnik, A.A., Bokhour, B.G., Gifford, A.L. et al. (2020) Roadblocks to PrEP: What Medical Records Reveal About Access to HIV Pre-exposure Prophylaxis. Journal of General Internal Medicine 35(3): 832-838	- Not a relevant study design

Study	Reason
Smith, Dawn K, Toledo, Lauren, Smith, Donna Jo et al. (2012) Attitudes and program preferences of African-American urban young adults about pre-exposure prophylaxis (PrEP). AIDS education and prevention : official publication of the International Society for AIDS Education 24(5): 408-21	- OECD remaining countries
Soares, Fabiane, MacCarthy, Sarah, Magno, Laio et al. (2019) Factors Associated with PrEP Refusal Among Transgender Women in Northeastern Brazil. AIDS and behavior 23(10): 2710-2718	- Non-OECD country
Solomon, Marc M, Lama, Javier R, Glidden, David V et al. (2014) Changes in renal function associated with oral emtricitabine/tenofovir disoproxil fumarate use for HIV pre-exposure prophylaxis. AIDS (London, England) 28(6): 851-9	- Primary study included in systematic review
Solomon, Marc M, Mayer, Kenneth H, Glidden, David V et al. (2014) Syphilis predicts HIV incidence among men and transgender women who have sex with men in a preexposure prophylaxis trial. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 59(7): 1020-6	- Primary study included in systematic review
Storholm, Erik D, Volk, Jonathan E, Marcus, Julia L et al. (2017) Risk Perception, Sexual Behaviors, and PrEP Adherence Among Substance-Using Men Who Have Sex with Men: a Qualitative Study. Prevention science : the official journal of the Society for Prevention Research 18(6): 737-747	- OECD remaining countries
Stover, John (2011) HIV models to inform health policy. Current opinion in HIV and AIDS 6(2): 108-13	- Review article but not a systematic review
Straubinger, T.; Kay, K.; Bies, R. (2020) Modeling HIV pre-exposure prophylaxis. Frontiers in Pharmacology 10: 1514	- Modelling
Sun, C.J., Anderson, K.M., Bangsberg, D. et al. (2019) Access to HIV Pre-exposure Prophylaxis in Practice Settings: a Qualitative Study of Sexual and Gender Minority Adults' Perspectives. Journal of General Internal Medicine 34(4): 535-543	- OECD remaining countries
Sun, Christina J, Anderson, Kirsten M, Toevs, Kim et al. (2019) "Little Tablets of Gold": An Examination of the Psychological and Social Dimensions of PrEP Among LGBTQ Communities. AIDS education and prevention : official publication of the International Society for AIDS Education 31(1): 51-62	- OECD remaining countries
Supervie, Virginie, Garcia-Lerma, J Gerardo, Heneine, Walid et al. (2010) HIV, transmitted drug resistance, and the paradox of preexposure prophylaxis. Proceedings of the National Academy of Sciences of the United States of America 107(27): 12381-6	- Modelling
Suraratdecha, Chutima, Stuart, Robyn M, Manopaiboon, Chomnad et al. (2018) Cost and cost-effectiveness analysis of pre-exposure prophylaxis among men who have sex with men in two hospitals in Thailand. Journal of the International AIDS Society 21suppl5: e25129	- Cost-effectiveness
Tan, Darrell H S, Schnubb, Alexandre, Lawless, James et al. (2018) Acceptability and tolerability of and adherence to HIV preexposure prophylaxis among Toronto gay and bisexual men: a pilot study. CMAJ open 6(4): e611-e617	- Not a relevant study design

Study	Reason
Tangmunkongvorakul, Arunrat, Chariyalertsak, Suwat, Amico, K Rivet et al. (2016) SEXUAL PRACTICES AMONG MEN WHO HAVE SEX WITH MEN IN CHIANG MAI, THAILAND: PART OF THE ANTIRETROVIRAL PRE-EXPOSURE PROPHYLAXIS TRIAL. The Southeast Asian journal of tropical medicine and public health 47(3): 514-27	- Non-OECD country
Terndrup, C., Streed, C.G., Tiberio, P. et al. (2019) A Cross-sectional Survey of Internal Medicine Resident Knowledge, Attitudes, Behaviors, and Experiences Regarding Pre-Exposure Prophylaxis for HIV Infection. Journal of General Internal Medicine 34(7): 1258-1278	- Population: Practitioners
Theodore, Deborah A, Zucker, Jason, Carnevale, Caroline et al. (2020) Pre-exposure Prophylaxis Use Among Predominantly African American and Hispanic Women at Risk for HIV Acquisition in New York City. The Journal of the Association of Nurses in AIDS Care : JANAC 31(1): 110-114	- Qualitative - closed questions
Thigpen, Michael C, Kebaabetswe, Poloko M, Paxton, Lynn A et al. (2012) Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. The New England journal of medicine 367(5): 423-34	- Primary study included in systematic review
Thomann, Matthew, Grosso, Ashley, Zapata, Richard et al. (2018) 'WTF is PrEP?': attitudes towards pre-exposure prophylaxis among men who have sex with men and transgender women in New York City. Culture, health & sexuality 20(7): 772-786	- OECD remaining countries
Thomas, Portia D (2019) A Qualitative Exploration of Pre-Exposure Prophylaxis (PrEP) Initiation Decision-Making Among Men Who Have Sex with Men (MSM): "It Definitely was a Process". Journal of National Black Nurses' Association : JNBNA 30(2): 10-17	- OECD remaining countries
Toledo, Lauren, McLellan-Lemal, Eleanor, Henderson, Faith L et al. (2015) Knowledge, Attitudes, and Experiences of HIV Pre-Exposure Prophylaxis (PrEP) Trial Participants in Botswana. World journal of AIDS 5(2): 10-20	- Non-OECD country
Traeger, Michael W, Schroeder, Sophia E, Wright, Edwina J et al. (2018) Effects of Pre-exposure Prophylaxis for the Prevention of Human Immunodeficiency Virus Infection on Sexual Risk Behavior in Men Who Have Sex With Men: A Systematic Review and Meta-analysis. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 67(5): 676-686	- Not a relevant study design *Majority of studies included have no comparator making them case-series not cohort*
Tripathi, Avnish; Whiteside, Y Omar; Duffus, Wayne A (2013) Perceptions and attitudes about preexposure prophylaxis among seronegative partners and the potential of sexual disinhibition. Southern medical journal 106(10): 558-64	- Qualitative - closed questions
Tumarkin, E.; Siedner, M.J.; Bogoch, I.I. (2019) HIV pre-exposure prophylaxis (PrEP). BMJ (Online) 364: k4681	- Not a relevant study design

Study	Reason
Underhill, Kristen, Guthrie, Kate M, Colleran, Christopher et al. (2018) Temporal Fluctuations in Behavior, Perceived HIV Risk, and Willingness to Use Pre-Exposure Prophylaxis (PrEP). Archives of sexual behavior 47(7): 2109-2121	- OECD remaining countries
Underhill, Kristen, Morrow, Kathleen M, Colleran, Christopher M et al. (2014) Access to healthcare, HIV/STI testing, and preferred pre-exposure prophylaxis providers among men who have sex with men and men who engage in street-based sex work in the US. PloS one 9(11): e112425	- Qualitative - does not ask relevant questions
Underhill, Kristen, Morrow, Kathleen M, Colleran, Christopher et al. (2015) A Qualitative Study of Medical Mistrust, Perceived Discrimination, and Risk Behavior Disclosure to Clinicians by U.S. Male Sex Workers and Other Men Who Have Sex with Men: Implications for Biomedical HIV Prevention. Journal of urban health : bulletin of the New York Academy of Medicine 92(4): 667-86	- OECD remaining countries
Underhill, Kristen, Morrow, Kathleen M, Operario, Don et al. (2014) Could FDA approval of pre-exposure prophylaxis make a difference? A qualitative study of PrEP acceptability and FDA perceptions among men who have sex with men. AIDS and behavior 18(2): 241-9	- OECD remaining countries
Vaccher, Stefanie J, Gianacas, Christopher, Templeton, David J et al. (2017) Baseline Preferences for Daily, Event-Driven, or Periodic HIV Pre-Exposure Prophylaxis among Gay and Bisexual Men in the PRELUDE Demonstration Project. Frontiers in public health 5: 341	- Qualitative - closed questions
Vaitses Fontanari, A.M., Zanella, G.I., Feijo, M. et al. (2019) HIV-related care for transgender people: A systematic review of studies from around the world. Social Science and Medicine 230: 280-294	- Data not reported in an extractable format
van de Vijver, D.A.M.C., Richter, A.-K., Boucher, C.A.B. et al. (2019) Cost-effectiveness and budget effect of pre-exposure prophylaxis for HIV-1 prevention in Germany from 2018 to 2058. Eurosurveillance 24(7): 1800398	- Cost-effectiveness
van de Vijver, David A M C, Nichols, Brooke E, Abbas, Ume L et al. (2013) Preexposure prophylaxis will have a limited impact on HIV-1 drug resistance in sub-Saharan Africa: a comparison of mathematical models. AIDS (London, England) 27(18): 2943-51	- Modelling
Van Der Straten, A., Shapley-Quinn, M.K., Reddy, K. et al. (2017) Favoring "peace of Mind": A Qualitative Study of African Women's HIV Prevention Product Formulation Preferences from the MTN-020/ASPIRE Trial. AIDS Patient Care and STDs 31(7): 305-314	- Non-OECD country
van der Straten, Ariane, Stadler, Jonathan, Luecke, Ellen et al. (2014) Perspectives on use of oral and vaginal antiretrovirals for HIV prevention: the VOICE-C qualitative study in Johannesburg, South Africa. Journal of the International AIDS Society 17(3suppl2): 19146	- Non-OECD country
van der Straten, Ariane, Stadler, Jonathan, Montgomery, Elizabeth et al. (2014) Women's experiences with oral and vaginal pre-exposure prophylaxis: the VOICE-C qualitative study in Johannesburg, South Africa. PloS one 9(2): e89118	- Non-OECD country
van Vliet, M.M., Hendrickson, C., Nichols, B.E. et al. (2019) Epidemiological impact and cost-effectiveness of providing long-acting pre-exposure prophylaxis to injectable contraceptive users for HIV prevention in South Africa: a modelling study. Journal of the International AIDS Society 22(12): e25427	- Cost-effectiveness

Study	Reason
Vazquez, Laia, Moll, Anthony P, Kacin, Alexa et al. (2019) Perceptions of HIV Preexposure Prophylaxis Among Young Pregnant Women from Rural KwaZulu-Natal, South Africa. AIDS patient care and STDs 33(5): 214-219	- Non-OECD country
Velloza, J., Khoza, N., Scorgie, F. et al. (2020) The influence of HIV-related stigma on PrEP disclosure and adherence among adolescent girls and young women in HPTN 082: a qualitative study. Journal of the International AIDS Society 23(3): e25463	- Non-OECD country
Velloza, Jennifer, Bacchetti, Peter, Hendrix, Craig W et al. (2019) Short- and Long-Term Pharmacologic Measures of HIV Pre-exposure Prophylaxis Use Among High-Risk Men Who Have Sex With Men in HPTN 067/ADAPT. Journal of acquired immune deficiency syndromes (1999) 82(2): 149-158	- Secondary outcome - analysis through primary outcome studies *Adherence - study included in SR*
Verguet, Stephane; Stalcup, Meg; Walsh, Julia A (2013) Where to deploy pre-exposure prophylaxis (PrEP) in sub-Saharan Africa?. Sexually transmitted infections 89(8): 628-34	- Modelling
Vissers, Debby C J, Voeten, Helene A C M, Nagelkerke, Nico J D et al. (2008) The impact of pre-exposure prophylaxis (PrEP) on HIV epidemics in Africa and India: a simulation study. PloS one 3(5): e2077	- Modelling
Wade Taylor, S, Mayer, Kenneth H, Elsesser, Steven M et al. (2014) Optimizing content for pre-exposure prophylaxis (PrEP) counseling for men who have sex with men: Perspectives of PrEP users and high-risk PrEP naive men. AIDS and behavior 18(5): 871-9	- OECD remaining countries
Wand, Handan, Reddy, Tarylee, Naidoo, Sarita et al. (2018) A Simple Risk Prediction Algorithm for HIV Transmission: Results from HIV Prevention Trials in KwaZulu Natal, South Africa (2002-2012). AIDS and behavior 22(1): 325-336	- Study does not contain a relevant intervention
Wang, L.Y., Hamilton, D.T., Rosenberg, E.S. et al. (2020) Cost-Effectiveness of Pre-Exposure Prophylaxis Among Adolescent Sexual Minority Males. Journal of Adolescent Health 66(1): 100-106	- Cost-effectiveness
Wang, Zixin, Lau, Joseph T F, Fang, Yuan et al. (2018) Prevalence of actual uptake and willingness to use pre-exposure prophylaxis to prevent HIV acquisition among men who have sex with men in Hong Kong, China. PloS one 13(2): e0191671	- Non-OECD country
Wang, Zixin, Mo, Phoenix K H, Ip, Mary et al. (2020) Uptake and willingness to use PrEP among Chinese gay, bisexual and other men who have sex with men with experience of sexualized drug use in the past year. BMC infectious diseases 20(1): 299	- Non-OECD country
Ware, Norma C, Wyatt, Monique A, Haberer, Jessica E et al. (2012) What's love got to do with it? Explaining adherence to oral antiretroviral pre-exposure prophylaxis for HIV-serodiscordant couples. Journal of acquired immune deficiency syndromes (1999) 59(5): 463-8	- Non-OECD country

Study	Reason
Watnick, Dana, Keller, Marla J, Stein, Kimberly et al. (2018) Acceptability of a Tenofovir Disoproxil Fumarate Vaginal Ring for HIV Prevention Among Women in New York City. AIDS and behavior 22(2): 421-436	- OECD remaining countries
Watson, Ryan J, Fish, Jessica N, Allen, Aerielle et al. (2018) Sexual Identity Disclosure and Awareness of HIV Prevention Methods Among Black Men Who Have Sex With Men. Journal of sex research 55(8): 975-983	- Qualitative - closed questions
Wenzel, Suzanne L, Rhoades, Harmony, Harris, Taylor et al. (2017) Risk behavior and access to HIV/AIDS prevention services in a community sample of homeless persons entering permanent supportive housing. AIDS care 29(5): 570-574	- Qualitative - closed questions
Werner, R.N., Gaskins, M., Nast, A. et al. (2019) Correction: Incidence of sexually transmitted infections in men who have sex with men and who are at substantial risk of HIV infection - A meta-analysis of data from trials and observational studies of HIV pre-exposure prophylaxis (PLoS ONE (2018) 13(12): e0208107. DOI: 10.1371/journal.pone.0208107). PLoS ONE 14(12): e0226209	- Additional info to included study
Werner, Ricardo Niklas, Gaskins, Matthew, Nast, Alexander et al. (2018) Incidence of sexually transmitted infections in men who have sex with men and who are at substantial risk of HIV infection - A meta-analysis of data from trials and observational studies of HIV pre-exposure prophylaxis. PloS one 13(12): e0208107	- More recent systematic review included that covers the same topic
White, Ellen, Dunn, David T, Desai, Monica et al. (2019) Predictive factors for HIV infection among men who have sex with men and who are seeking PrEP: a secondary analysis of the PROUD trial. Sexually transmitted infections 95(6): 449-454	- Not a relevant study design *secondary analysis of trial included in SR of effectiveness*
Williams, Brian G, Gupta, Somya, Wollmers, Matthew et al. (2017) Progress and prospects for the control of HIV and tuberculosis in South Africa: a dynamical modelling study. The Lancet. Public health 2(5): e223-e230	- Modelling
Willie, T.C., Keene, D.E., Kershaw, T.S. et al. (2020) "You Never Know What Could Happen": Women's Perspectives of Pre-Exposure Prophylaxis in the Context of Recent Intimate Partner Violence. Women's Health Issues 30(1): 41-48	- OECD remaining countries
Wingood, Gina M, Dunkle, Kristin, Camp, Christina et al. (2013) Racial differences and correlates of potential adoption of preexposure prophylaxis: results of a national survey. Journal of acquired immune deficiency syndromes (1999) 63suppl1: 95-101	- Qualitative - closed questions
Wong, Chen Seong, Kumar, P Arun, Wong, Christina M et al. (2019) Acceptability of HIV Pre-exposure Prophylaxis (PrEP) and Opinions on PrEP Service Delivery Among Men Who Have Sex With Men in Singapore: A Qualitative Study. AIDS education and prevention : official publication of the International Society for AIDS Education 31(2): 152-162	- Non-OECD country
Wood, S., Dowshen, N., Bauermeister, J.A. et al. (2020) Social Support Networks Among Young Men and Transgender Women of Color Receiving HIV Pre-Exposure Prophylaxis. Journal of Adolescent Health 66(3): 268-274	- Qualitative - does not ask relevant questions

Study	Reason
Wood, Sarah, Gross, Robert, Shea, Judy A et al. (2019) Barriers and Facilitators of PrEP Adherence for Young Men and Transgender Women of Color. AIDS and behavior 23(10): 2719-2729	- OECD remaining countries
Yang, C., Krishnan, N., Kelley, E. et al. (2020) Beyond HIV prevention: a qualitative study of patient-reported outcomes of PrEP among MSM patients in two public STD clinics in Baltimore. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV 32(2): 238-241	- OECD remaining countries
Ye, Li, Wei, Suosu, Zou, Yunfeng et al. (2014) HIV pre-exposure prophylaxis interest among female sex workers in Guangxi, China. PloS one 9(1): e86200	- Non-OECD country
Ying, Roger, Sharma, Monisha, Heffron, Renee et al. (2015) Cost-effectiveness of pre-exposure prophylaxis targeted to high-risk serodiscordant couples as a bridge to sustained ART use in Kampala, Uganda. Journal of the International AIDS Society 18(4suppl3): 20013	- Cost-effectiveness
Young, Ingrid and McDaid, Lisa (2014) How acceptable are antiretrovirals for the prevention of sexually transmitted HIV?: A review of research on the acceptability of oral pre-exposure prophylaxis and treatment as prevention. AIDS and behavior 18(2): 195-216	- Systematic review used as source of primary studies
Yu, Wenya, Wang, Lu, Han, Na et al. (2016) Pre-exposure prophylaxis of HIV: A right way to go or a long way to go?. Artificial cells, nanomedicine, and biotechnology 44(1): 201-8	- More recent systematic review included that covers the same topic
Yun, Ke, Xu, Jun-Jie, Zhang, Jing et al. (2018) Female and younger subjects have lower adherence in PrEP trials: a meta-analysis with implications for the uptake of PrEP service to prevent HIV. Sexually transmitted infections 94(3): 163-168	- Secondary outcome - analysis through primary outcome studies
Zablotska, Iryna B (2017) Likely impact of pre-exposure prophylaxis on HIV epidemics among men who have sex with men. Sexual health 14(1): 97-105	- Review article but not a systematic review
Zaller, Nickolas D, Neher, Taylor L, Presley, Makenzie et al. (2020) Barriers to linking high-risk jail detainees to HIV pre-exposure prophylaxis. PloS one 15(4): e0231951	- Does not contain a population of people on PrEP
Zhang, Lei, Peng, Peng, Wu, Yumeng et al. (2019) Modelling the Epidemiological Impact and Cost-Effectiveness of PrEP for HIV Transmission in MSM in China. AIDS and behavior 23(2): 523-533	- Cost-effectiveness
Zhao, Yuqin, Dimitrov, Dobromir T, Liu, Hao et al. (2013) Mathematical insights in evaluating state dependent effectiveness of HIV prevention interventions. Bulletin of mathematical biology 75(4): 649-75	- Modelling

Study	Reason
Zhou, Feng, Gao, Lei, Li, Shuming et al. (2012) Willingness to accept HIV pre-exposure prophylaxis among Chinese men who have sex with men. PloS one 7(3): e32329	- Non-OECD country
Zimba, Chifundo, Maman, Suzanne, Rosenberg, Nora E et al. (2019) The landscape for HIV pre-exposure prophylaxis during pregnancy and breastfeeding in Malawi and Zambia: A qualitative study. PloS one 14(10): e0223487	- Non-OECD country

K.3 Excluded economic studies

Reference	Reason for exclusion
Abbas UL. Uptake of biomedical interventions for prevention of sexually transmitted HIV. Current Opinion in HIV and AIDS. 2011;6(2):114-18.	Systematic review
Adams JL, Shelley K, Nicol MR. Review of Real-World Implementation Data on Emtricitabine-Tenofovir Disoproxil Fumarate as HIV Pre-exposure Prophylaxis in the United States. Pharmacotherapy. 2019;39(4):486-500.	Systematic review
Adamson B, Garrison L, Barnabas RV, Carlson JJ, Kublin J, Dimitrov D. Competing biomedical HIV prevention strategies: potential cost-effectiveness of HIV vaccines and PrEP in Seattle, WA. Journal of the International AIDS Society. 2019;22(8):e25373.	Wrong patient population
Adamson BJS, Carlson JJ, Kublin JG, Garrison LP. The potential cost-effectiveness of pre-exposure prophylaxis combined with HIV vaccines in the united states. Vaccines. 2017;5(2):13.	Wrong patient population
Akudibillah G, Pandey A, Medlock J. Maximizing the benefits of ART and PrEP in resource-limited settings. Epidemiology and infection. 2017;145(5):942-56.	Wrong patient population
Alistar SS, Grant PM, Bendavid E. Comparative effectiveness and cost-effectiveness of antiretroviral therapy and pre-exposure prophylaxis for HIV prevention in South Africa. BMC medicine. 2014;12:46.	Wrong patient population
Alistar SS, Owens DK, Brandeau ML. Effectiveness and cost effectiveness of oral pre-exposure prophylaxis in a portfolio of prevention programs for injection drug users in mixed HIV epidemics. PloS one. 2014;9(1):e86584.	Wrong patient population
Alsallaq RA, Buttolph J, Cleland CM, Hallett T, Inwani I, Agot K*, et al.* The potential impact and cost of focusing HIV prevention on young women and men: A modeling analysis in western Kenya. PloS one. 2017;12(4):e0175447.	Wrong patient population
Anonymous. Prevention. Using PrEP cost-effective in high-risk MSM groups. AIDS policy & law. 2012;27(7):1.	Wrong outcomes
Begnel ER, Escudero J, Mugambi M, Mugwanya K, Kinuthia J, Beima-Sofie K*, et al.* High pre-exposure prophylaxis awareness and willingness to pay for pre-exposure prophylaxis among young adults in Western Kenya: results from a population-based survey. International Journal of STD and AIDS. 2020;31(5):454-59.	Wrong patient population
Blaizot S, Maman D, Riche B, Mukui I, Kirubi B, Ecochard R*, et al.* Potential impact of multiple interventions on HIV incidence in a hyperendemic region in Western Kenya: a modelling study. BMC infectious diseases. 2016;16:189.	Wrong patient population
Boily M-C, Shubber Z. Modelling in concentrated epidemics: informing epidemic trajectories and assessing prevention approaches. Current opinion in HIV and AIDS. 2014;9(2):134-49.	Systematic review
Borquez A, Guanira JV, Revill P, Caballero P, Silva-Santisteban A, Kelly S*, et al.* The impact and cost-effectiveness of combined HIV prevention scenarios among transgender women sex-workers in Lima, Peru: a mathematical modelling study. The Lancet Public Health. 2019;4(3):e127-e36.	Wrong patient population
Cambiano V, Miners A, Dunn D, McCormack S, Gill N, Nardone A*, et al.* O1 Is pre-exposure prophylaxis for hiv prevention cost-effective in men who have sex with men who engage in condomless sex in the uk? Sexually Transmitted Infections 2015;91:A1-A1.	Abstract
Cambiano V, Miners A, Phillips A. What do we know about the cost-effectiveness of HIV preexposure prophylaxis, and is it affordable? Current opinion in HIV and AIDS. 2016;11(1):56-66.	Systematic review
Cambiano V, Phillips AN. Modelling the impact of treatment with individual antiretrovirals. Current Opinion in HIV and AIDS. 2011;6(2):124-30.	Systematic review
Campbell JD, Herbst JH, Koppenhaver RT, Smith DK. Antiretroviral prophylaxis for sexual and injection drug use acquisition of HIV. American journal of preventive medicine. 2013;44(1suppl2):63-9.	Systematic review

Reference	Reason for exclusion
Cao W, Sun S, Peng L, Gu J, Hao C, Li J*, et al.* Low willingness to pay for pre-exposure prophylaxis (PrEP) among men who have sex with men (MSM) in China. BMC public health. 2020;20(1):337.	Wrong patient population
Case KK, Gomez GB, Hallett TB. The impact, cost and cost-effectiveness of oral pre-exposure prophylaxis in sub-Saharan Africa: a scoping review of modelling contributions and way forward. Journal of the International AIDS Society. 2019;22(9):e25390.	Systematic review
Chan SS, Chappel AR, Maddox KEJ, Hoover KW, Huang Y-LA, Zhu W*, et al.* Pre-exposure prophylaxis for preventing acquisition of HIV: A cross-sectional study of patients, prescribers, uptake, and spending in the United States, 2015-2016. PLoS medicine. 2020;17(4):e1003072.	Wrong outcomes
Chen A, Dowdy DW. Clinical effectiveness and cost-effectiveness of HIV pre-exposure prophylaxis in men who have sex with men: risk calculators for real-world decision-making. PloS one. 2014;9(10):e108742.	Wrong patient population
Cremin I, Alsallaq R, Dybul M, Piot P, Garnett G, Hallett TB. The new role of antiretrovirals in combination HIV prevention: a mathematical modelling analysis. AIDS (London, England). 2013;27(3):447-58.	Wrong patient population
Cremin I, Hallett TB. Estimating the range of potential epidemiological impact of pre-exposure prophylaxis: run-away success or run-away failure? AIDS (London, England). 2015;29(6):733-8.	Wrong patient population
Cremin I, McKinnon L, Kimani J, Cherutich P, Gakii G, Muriuki F*, et al.* PrEP for key populations in combination HIV prevention in Nairobi: a mathematical modelling study. The lancet. HIV. 2017;4(5):e214-e22.	Wrong patient population
Cremin I, Morales F, Jewell BL, O'Reilly KR, Hallett TB. Seasonal PrEP for partners of migrant miners in southern Mozambique: a highly focused PrEP intervention. Journal of the International AIDS Society. 2015;18(4suppl3):19946.	Wrong patient population
Desai K, Sansom SL, Ackers ML, Stewart SR, Hall HI, Hu DJ*, et al.* Modeling the impact of HIV chemoprophylaxis strategies among men who have sex with men in the United States: HIV infections prevented and cost-effectiveness. AIDS (London, England). 2008;22(14):1829-39.	Wrong patient population
Drabo EF, Hay JW, Vardavas R, Wagner ZR, Sood N. A Cost-effectiveness Analysis of Preexposure Prophylaxis for the Prevention of HIV Among Los Angeles County Men Who Have Sex With Men. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America. 2016;63(11):1495-504.	Wrong patient population
Eakle R, Gomez GB, Naicker N, Bothma R, Mbogua J, Cabrera Escobar MA*, et al.* HIV pre-exposure prophylaxis and early antiretroviral treatment among female sex workers in South Africa: Results from a prospective observational demonstration project. PLoS medicine. 2017;14(11):e1002444.	Wrong patient population
Glaubius R, Ding Y, Penrose KJ, Hood G, Engquist E, Mellors JW*, et al.* Dapivirine vaginal ring for HIV prevention: modelling health outcomes, drug resistance and cost-effectiveness. Journal of the International AIDS Society. 2019;22(5):e25282.	Wrong patient population
Glaubius RL, Hood G, Penrose KJ, Parikh UM, Mellors JW, Bendavid E*, et al.* Cost-effectiveness of Injectable Preexposure Prophylaxis for HIV Prevention in South Africa. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America. 2016;63(4):539-47.	Wrong patient population
Goedel WC, Chan PA, King MRF, Prosperi MCF, Marshall BDL, Galarraga O. Cost-Effectiveness of a Statewide Pre-Exposure Prophylaxis Program for Gay, Bisexual, and Other Men Who Have Sex with Men. Rhode Island medical journal (2013). 2019;102(9):36-39.	Wrong patient population
Goedel WC, Mimiaga MJ, King MRF, Safren SA, Mayer KH, Chan PA*, et al.* Potential Impact of Targeted HIV Pre-Exposure Prophylaxis Uptake Among Male Sex Workers. Scientific reports. 2020;10(1):5650.	Wrong patient population
Golub SA, Myers JE. Next-Wave HIV Pre-Exposure Prophylaxis Implementation for Gay and Bisexual Men. AIDS patient care and STDs. 2019;33(6):253-61.	Systematic review
Gomez GB, Borquez A, Caceres CF, Segura ER, Grant RM, Garnett GP*, et al.* The potential impact of pre-exposure prophylaxis for HIV prevention among men who have sex with men and transwomen in Lima, Peru: a mathematical modelling study. PLoS medicine. 2012;9(10):e1001323.	Wrong patient population
Gomez GB, Borquez A, Case KK, Wheelock A, Vassall A, Hankins C. The cost and impact of scaling up pre-exposure prophylaxis for HIV prevention: a systematic review of cost-effectiveness modelling studies. PLoS medicine. 2013;10(3):e1001401.	Systematic review
Hallett TB, Baeten JM, Heffron R, Barnabas R, de Bruyn G, Cremin I*, et al.* Optimal uses of antiretrovirals for prevention in HIV-1 serodiscordant heterosexual couples in South Africa: a modelling study. PLoS medicine. 2011;8(11):e1001123.	Wrong patient population
Hellinger FJ. Assessing the cost effectiveness of pre-exposure prophylaxis for HIV prevention in the US. PharmacoEconomics. 2013;31(12):1091-104.	Editorial

Reference	Reason for exclusion
Hill A, Hill T, Jose S, Pozniak A. Predicted savings to the UK National Health Service from switching to generic antiretrovirals, 2014-2018. Journal of the International AIDS Society. 2014;17(4suppl3):19497.	Abstract
Hoornenborg E, Krakower DS, Prins M, Mayer KH. Pre-exposure prophylaxis for MSM and transgender persons in early adopting countries. AIDS (London, England). 2017;31(16):2179-91.	Systematic review
Hu Q-H, Meyers K, Xu J-J, Chu Z-X, Zhang J, Ding H-B*, et al.* Efficacy and cost-effectiveness of early antiretroviral therapy and partners' pre-exposure prophylaxis among men who have sex with men in Shenyang, China: a prospective cohort and costing study. BMC infectious diseases. 2019;19(1):663.	Wrong patient population
Irungu EM, Sharma M, Maronga C, Mugo N, Ngure K, Celum C*, et al.* The Incremental Cost of Delivering PrEP as a Bridge to ART for HIV Serodiscordant Couples in Public HIV Care Clinics in Kenya. AIDS Research and Treatment. 2019;2019:4170615.	Wrong patient population
Jacobsen MM, Walensky RP. Modeling and Cost-Effectiveness in HIV Prevention. Current HIV/AIDS reports. 2016;13(1):64-75.	Systematic review
Jamieson L, Gomez GB, Rebe K, Brown B, Subedar H, Jenkins S*, et al.* The impact of self-selection based on HIV risk on the cost-effectiveness of preexposure prophylaxis in South Africa. AIDS (London, England). 2020;34(6):883-91.	Wrong patient population
Jewell BL, Cremin I, Pickles M, Celum C, Baeten JM, Delany-Moretlwe S*, et al.* Estimating the cost-effectiveness of pre-exposure prophylaxis to reduce HIV-1 and HSV-2 incidence in HIV-serodiscordant couples in South Africa. PloS one. 2015;10(1):e0115511.	Wrong patient population
Juusola JL, Brandeau ML. HIV Treatment and Prevention: A Simple Model to Determine Optimal Investment. Medical decision making : an international journal of the Society for Medical Decision Making. 2016;36(3):391-409.	Wrong patient population
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Mitchell KM, Dimitrov D, Hughes JP, Xia F, Donnell D, Amico KR*, et al.* In what circumstances could nondaily preexposure prophylaxis for HIV substantially reduce program costs? AIDS (London, England). 2018;32(6):809-18.	Systematic review
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Nakagawa F, Miners A, Smith CJ, Simmons R, Lodwick RK, Cambiano V*, et al.* Projected lifetime healthcare costs associated with HIV infection. PLoS ONE. 2015;10(4):e0125018.	Wrong intervention
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Revill P, Dwyer E. Pre-exposure prophylaxis is cost-effective for HIV in the UK. The Lancet Infectious Diseases. 2018;18(1):10-11.	Abstract
Roberts DA, Barnabas RV, Abuna F, Lagat H, Kinuthia J, Pintye J*, et al.* The role of costing in the introduction and scale-up of HIV pre-exposure prophylaxis: evidence from integrating PrEP into routine maternal and child health and family planning clinics in western Kenya. Journal of the International AIDS Society. 2019;22(s4):e25296.	Wrong patient population
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Schackman BR, Fleishman JA, Su AE, Berkowitz BK, Moore RD, Walensky RP*, et al.* The lifetime medical cost savings from preventing HIV in the United States. Medical care. 2015;53(4):293-301.	Wrong intervention
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Thavorn K, Kugathasan H, Tan DHS, Moqueet N, Baral SD, Skidmore B*, et al.* Economic evaluation of HIV pre-exposure prophylaxis strategies: protocol for a methodological systematic review and quantitative synthesis. Systematic reviews. 2018;7(1):47.	Systematic review
Tseng CW, Dudley RA, Chen R, Walensky RP. Medicare Part D and Cost-Sharing for Antiretroviral Therapy and Preexposure Prophylaxis. JAMA Network Open. 2020	Wrong outcomes
Tung EL, Thomas A, Eichner A, Shalit P. Implementation of a community pharmacy-based pre-exposure prophylaxis service: A novel model for pre-exposure prophylaxis care. Sexual Health. 2018;15(6):556-61.	Wrong study design
Uyei J, Fiellin DA, Buchelli M, Rodriguez-Santana R, Braithwaite RS. Effects of naloxone distribution alone or in combination with addiction treatment with or without pre-exposure prophylaxis for HIV prevention in people who inject drugs: a cost-effectiveness modelling study. The Lancet. Public health. 2017;2(3):e133-e40.	Wrong patient population

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Verguet S, Stalcup M, Walsh JA. Where to deploy pre-exposure prophylaxis (PrEP) in sub-Saharan Africa? Sexually transmitted infections. 2013;89(8):628-34.	Wrong patient population
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Walensky RP, Jacobsen MM, Bekker L-G, Parker RA, Wood R, Resch SC*, et al.* Potential Clinical and Economic Value of Long-Acting Preexposure Prophylaxis for South African Women at High-Risk for HIV Infection. The Journal of infectious diseases. 2016;213(10):1523-31.	Wrong patient population
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Wang LY, Hamilton DT, Rosenberg ES, Aslam MV, Sullivan PS, Katz DA*, et al.* Cost-Effectiveness of Pre-Exposure Prophylaxis Among Adolescent Sexual Minority Males. Journal of Adolescent Health. 2020;66(1):100-06.	Wrong patient population
Wang Z, Lau JTF, Fang Y, Ip M, Gross DL. Prevalence of actual uptake and willingness to use pre-exposure prophylaxis to prevent HIV acquisition among men who have sex with men in Hong Kong, China. PloS one. 2018;13(2):e0191671.	Wrong patient population
Wong NS, Kwan TH, Tsang OTY, Lee MP, Yam WC, Lam W*, et al.* Pre-exposure prophylaxis (PrEP) for MSM in low HIV incidence places: should high risk individuals be targeted? Scientific reports. 2018;8(1):11641.	Wrong patient population
Yazdanpanah Y, Goldie SJ, Paltiel AD, Losina E, Coudeville L, Weinstein MC*, et al.* Prevention of human immunodeficiency virus-related opportunistic infections in France: a cost-effectiveness analysis. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America. 2003;36(1):86-96.	Wrong intervention
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Zhang L, Peng P, Wu Y, Ma X, Soe NN, Huang X*, et al.* Modelling the Epidemiological Impact and Cost-Effectiveness of PrEP for HIV Transmission in MSM in China. AIDS and behavior. 2019;23(2):523-33.	Wrong patient population

Appendix L Research recommendations – full details

L.1 Availability of PrEP

What is the effectiveness and cost effectiveness of providing PrEP outside sexual health services and does this reach eligible population groups different to those who do access sexual health services?

L.1.1 Why this is important

In addition to making existing services more accessible, the committee were interested in the possibility of offering PrEP in other settings. However, they agreed that more evidence was needed on the effectiveness of doing this before they could recommend specific actions Rationale for research recommendation.

Importance to 'patients' or the population	Currently people can only access PrEP through sexual health services, which may not be accessible to all people because of the stigma that can be associated with using sexual health services.
Relevance to NICE guidance	Data on whether PrEP could be effectively prescribed and monitored outside of sexual health services would enable future committees to make a clear recommendation about whether this should happen or not.
Relevance to the NHS	Being able to prescribe PrEP outside of sexual health services would distribute the burden of providing this and may mean that people who would not access PrEP via a sexual health service may be able to use it. This intervention should have minimal impact on resources, although increased uptake of PrEP will have an impact.
National priorities	Medium
Current evidence base	None
Equality considerations	People from some faith and cultural groups may have more difficulty accessing sexual health services.

L.1.2 Modified PICO table

Population	Adults age 16 or over who meet the eligibility criteria for PrEP in the UK.
Intervention	PrEP offered, provided and monitored in non-sexual health services
Comparator	Sexual health service PrEP
Outcome	Uptake of PrEP Cost-effectiveness of PrEP provision Compliance with monitoring Quality of life Adverse or unintended consequences
Study design	RCT
Timeframe	Long term
Additional information	None

L.2 Adverse effects of long-term PrEP use

What are the long-term adverse events (including the impact on bone density) of taking PrEP for an extended period after starting at a young age?

L.2.1 Why this is important

The evidence suggested some adverse effects associated with PrEP use (such as kidney or gastrointestinal symptoms). The committee agreed that monitoring the renal health of those taking PrEP was important. Although the committee were aware of evidence that shows bone-mineral density will rebound after stopping PrEP, there was a lack of data on this for young people who have not yet reached their peak bone density.

L.2.2 Rationale for research recommendation

Importance to 'patients' or the population	Little is known about the long-term risks associated with taking PrEP
Relevance to NICE guidance	NICE guidelines encourage the use of PrEP even though there is no long term data about adverse outcomes, especially for young people who potentially will be taking it for many years.
Relevance to the NHS	Adverse outcomes in the longer term associated with PrEP would change the way that it is prescribed. Better safety data would encourage greater provision. This should have minimal impact on resources, although increased uptake of PrEP will have an impact.
National priorities	Moderate
Current evidence base	No long-term data
Equality considerations	None known

L.2.3 Modified PICO table

Population	Young people taking PrEP
Intervention	PrEP
Comparator	People not taking PrEP
Outcome	Safety and adverse event outcomes
Study design	Cohort study
Timeframe	Long term
Additional information	None

L.3 Mode of PrEP delivery

What is the effectiveness, cost effectiveness, accessibility and adherence to forms of PrEP other than oral delivery, particularly long-acting PrEP (such as injections), including in women?

L.3.1 Why this is important

The committee were interested in the potential adherence benefits of offering long-acting PrEP by injection, and noted that some people may prefer it to taking tablets. However, they thought there was insufficient evidence to recommend it and that research was needed to establish whether it is as effective as PrEP tablets.

L.3.2 Rationale for research recommendation

Importance to 'patients' or the population	Some people have difficulties with adherence to daily PrEP because they may find it difficult to establish a daily routine for taking it, for example because they are hiding their PrEP use. Long acting PrEP given by injection would mean they did not need to take daily tablets.
Relevance to NICE guidance	The committee was unable to recommend injectable PrEP because they diod not see any data about it, in spite of qualitative evidence suggesting that some people would prefer it.
Relevance to the NHS	Injectable PrEP would offer an alternative to tablets for those who find compliance with the regime difficult. It may also be safer for people who would be at risk of stigma or violence if their PrEP use were discovered. This intervention should have minimal impact on resources, although increased uptake of PrEP will have an impact.
National priorities	Medium
Current evidence base	No quantitative evidence
Equality considerations	Injectable PrEP was highlighted by black cisgender women as a preference because it meant they would not have to hide their PrEP use. This is also relevant to some cultural and faith groups.

L.3.3 Modified PICO table

Population	People over 16 eligible for PrEP in the UK, including trans people and cisgender women as subgroups of interest
Intervention	Injectable PrEP
Comparator	Tablet PrEP
Outcome	Uptake of PrEP by eligible people Quality of life Adherence Rates of HIV acquisition Adverse events Accessibility
Study design	Mixed methods: RCT with qualitative component
Timeframe	Long term
Additional information	None

L.4 Eligibility for PrEP

What is the cost effectiveness of providing PrEP to people who do not report recent condomless sex?

L.4.1 Why this is important

The committee noted the eligibility criteria for PrEP currently restricted it to people who reported recent condomless sex. They were interested in whether providing PrEP to people who do not report recent condomless sex but report an intention to have condomless sex in the future would also be cost effective.

L.4.2 Rationale for research recommendation

Importance to 'patients' or the population	Currently only people who report recent condomless sex are eligible for PrEP in the UK. People who intend to try condomless sex are not able to access PrEP
Relevance to NICE guidance	The committee was restricted in its recommendations by the legal status of PrEP in the UK.
Relevance to the NHS	Increases in the number of people eligible for PrEP would have a potentially large resource impact on the NHS, but could potentially reduce rates of HIV acquisition and therefore may be cost-effective.
National priorities	Medium
Current evidence base	No evidence
Equality considerations	None known

L.4.3 Modified PICO table

Population	People over 16 who intend to have condomless sex in the future
Intervention	PrEP provision
Comparator	Standard of care (PrEP only provided after condomless sex in line with current UK guidelines)
Outcome	Rates of HIV acquisition Cost-effectiveness and utility measures Quality of life Adverse outcomes and unintended consequences
Study design	Cost-effectiveness modelling analysis
Timeframe	Long term
Additional information	None