Supplementary Materials

This is a Supplement to a complete manuscript titled: The cost-effectiveness of HIV pre-exposure prophylaxis among heterosexual men in South Africa: a cost-utility modelling analysis

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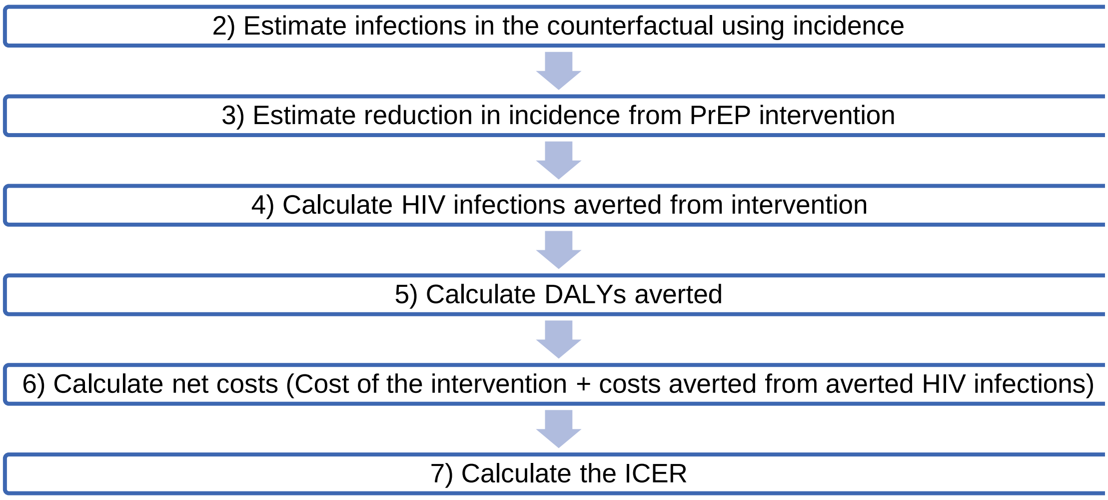
Supplement A: Graphical representation of the model

Figure 1: Static epidemiological and costing model structure. Structure outlines steps used to measure the health system costs and outcomes associated with PrEP use. Model was conducted using MS Excel.



Supplement B: Summary of all model inputs

Costs of outreach and peer training were excluded as these were specific to a programme focused on FSW, and the price of oral PrEP was revised downwards to reflect latest tender agreements (Table 1)[1]. As injectable PrEP is not yet approved for use or available for purchase, its per month central price was assumed to be equal to oral PrEP. Uncertainty in this assumption was explored by setting the lower bound as 33% cheaper than oral PrEP and the upper bound as the maximum ceiling price of oral PrEP according to the Global Fund PPM price[2]. A similar approach has been used in another modelling study [3]. Both oral and injectable PrEP was assumed to be administered per national guidelines for oral PrEP, which includes an enrolment visit, an initial one month follow up, and three-monthly monitoring and refill visits[4]. Costs associated with condom distribution were assumed not to vary under each scenario, as condoms offer protection from more than just HIV and remain an important part of the combination HIV prevention armoury.

Table 1: Comparison of cost inputs

Unit cost per visit description	**FSW PrEP Demonstration Project (Eakle et al, 2017)**	**Our model (Adjusted for inflation and excluding drugs costs which were factored in separately)**
Outreach contact	2.8	Not included
Peer Training	Unknown	Not included
VCT session (USD)	18.1	18.1
PrEP enrolment visit (USD)	34.7	29.9
PrEP monitoring visit (USD)	35.2	30.4
PrEP refill visit (USD) (Oral)	6.8	2
Early ART enrolment visit (USD)	65.5	57.2
Early ART monitoring visit (USD)	67.7	59.4
Early ART refill visit (USD)	11.6	3.3

Lifetime health system costs associated with being HIV+ included ART and ART management for those on treatment[5] as well as annual costs of hospitalisation. Hospitalisation costs were estimated based on 2013 published South African data assessing mean inpatient costs per patient-year for those on ART and pre-ART[6]. Mean pre-ART hospital costs covering an average stay of 10.1 days for all CD4 count levels were selected and assigned to 0.08% of all HIV+ individuals as per study findings on frequency of annual hospitalisation[6]. Cost for first-line (1L) and second-line (2L) treatment were included in lifetime cost estimates for those on ART. In April 2018, South Africa adopted the new and cheaper dolutegravir (DTG)-based 1L drug which has a publicized ceiling price of USD$75 [2]. As the tender price is not yet available, the publicized ceiling price with uncertainty bounds of $\pm$25% were used. South Africa uses several regimens for 2L treatment and treatment cost ranges were estimated using data from the ART guidelines costing model[7] and the South African HIV/AIDS Society[8]. The mid-point of these two estimates was assumed to be the central cost of 2L. Time spent on each treatment line was based on the probably of patients switching lines[7]. All cost parameters were adjusted for inflation and brought to 2018 USD. Lifetime costs were applied after the first modelled year and were, per the Gates Reference Case[9], future discounted at 3% based on life expectancy and adjusted for anticipated inflation using the January 2018 inflation rate.

Discounted Lifetime Averted Costs =
*(Age-weighted discounted lifetime ART Costs * % ART Coverage) + (Lifetime hospitalisation costs for HIV+ individuals * % frequency of hospital admission)*

Lifetime cost and DALY calculations used the 2017 median age at death (52.7 years) for South African men as life expectancy. This was determined a better measure of life expectancy than current life expectancy at birth (currently 61.2 years[10]) because median age at death captures the age of death currently rather than probable age of death for the new generation[11]. Age of HIV infection was assumed for both cohorts as no literature sources were found with published average age of infection for the chosen cohorts. Similar studies also assumed age of infection[12].

A study by Johnson et al.[13] found that life expectancy of those on ART was up to 96% of normal life expectancy; therefore, the age at death for those on ART was 50 years and additional years of life when not on ART was estimated to be 10 years from age of infection, which was also modelled in similar studies[12]. A 2017 Statistics South Africa population structure by age and sex was used to determine susceptible individuals in the population[10].

Table 2: Standard errors, shape, and scale model parameters used in probabilistic sensitivity analysis. Parameters to determine the cost-effectiveness of the use of oral, injectable (inj.) or dual pre-exposure prophylaxis (PrEP) among South African (RSA) heterosexual men for one year. Where standard errors (SE) were not known, they were calculated from upper bounds using the formula: SE = (Upperbound – central value)/ 1.96
ZAR = South African Rand; USD = United States Dollars, Dist. = Distribution

Type	Variable Description	Dist.	Standard Error	Alpha	Beta
Epidemiology	HIV prevalence (Men, 15-24)	Beta	0.00484	91.43	1832.85
	HIV prevalence (Men, 25-49)	Beta	0.01982	77.18	319.98
	HIV incidence (Men, <25)	Beta	0.00112	18.96	3850.21
	HIV incidence (Men, 25+)	Beta	0.00061	248.57	25376.87
Costs	Inj. PrEP (ZAR, 2018)	Gamma	28.30997	0.29	52.69
	VCT session (USD, 2015)	Gamma	1.58163	130.96	0.14
	PrEP enrolment visit (USD, 2015)	Gamma	2.90816	105.71	0.28
	PrEP monitoring visit (USD, 2015)	Gamma	1.12244	733.52	0.04
	PrEP refill visit (USD, 2015)	Gamma	0.30612	42.68	0.05
	Early ART enrolment visit (USD, 2015)	Gamma	0.81632	4909.8	0.01
	Early ART monitoring visit (USD, 2015)	Gamma	2.44897	588.31	0.1
	Early ART refill visit (USD, 2015)	Gamma	0.91836	12.91	0.26
	HIV+ population annual hospital admission	Uniform	0.00510		
	Annual HIV+ hospitalisation cost to health system (USD, 2009)	Gamma	13.81122	68.85	1.66
	Annual supply 1L ART (DTG/TDF/EFV) (USD, 2017)	Uniform	9.56632		
	Annual supply 2L ART (USD, 2018)	Gamma	58.15053	63.66	7.29
	ART coverage	Beta	0.10204	13.33	8.52
HIV Prevention Products	Efficacy Oral PrEP with correct use	Uniform	0.05102		
	Efficacy Inj. PrEP with correct use	Uniform	0.10204		
	Daily Adherence to Oral PrEP	Uniform	0.05102		
	Average time on Oral PrEP over year	Uniform	0.10204		
	Average time on Inj. PrEP over year	Uniform	0.10204		
	Consistent condom user (<25)	Uniform	0.0621		
	Consistent condom user (25+)	Uniform	0.0427		
	% decrease in condom use	Uniform	-0.02551		
	Probability of correct condom use	Beta	0.01020	270.12	8.35
DALYs	DALY HIV+, symptomatic	Uniform	0.05255		
	DALY HIV+ on treatment	Uniform	0.16836		
	DALY AIDS, no treatment	Uniform	0.08214		

Table 3: Summary of additional model parameters used in static epidemiological model. Parameters to determine the cost-effectiveness of the use of oral, injectable (inj.) or dual pre-exposure prophylaxis (PrEP) among South African (RSA) heterosexual men for one year. CI = Confidence Interval

Type	Variable Description	Central Value	95% CI	Distribution	Reference
Uptake (Men 18-24)	Condom users, Inj. PrEP	0.04			[14][1]
	Condom users, Oral PrEP	0.06			
	Condom users, No PrEP	0.90			
	Non-condom users, Inj. PrEP	0.16			
	Non-condom users, Oral PrEP	0.25			
	Non-condom users, No PrEP	0.59			
Uptake (Men 25-49)	Condom users, Inj. PrEP	0.04			[14][1]
	Condom users, Oral PrEP	0.07			
	Condom users, No PrEP	0.89			
	Non-condom users, Inj. PrEP	0.15			
	Non-condom users, Oral PrEP	0.29			
	Non-condom users, No PrEP	0.56			
DALYs	DALY HIV+, no symptoms	0.051			[15]
	DALY HIV+, symptomatic	0.274	(0.184 - 0.377)	Uniform	[16]
	DALY HIV+ on treatment	0.078	(0.052 - 0.111)	Uniform	[16]
	DALY AIDS, no treatment	0.582	(0.406 - 0.743)	Uniform	[16]
	Discount rate (utilities)	0.03			[9]

Uptake predictions were generated in a discrete choice experiment (DCE) analysis, conducted by some of the study authors in 2015. The DCE, published elsewhere[14], was re-analysed to predict market shares of injectable and oral PrEP among condom users and non-users, with these predictions then weighted by self-reported condom use in the same study. Product characteristics were assumed as in the parameters table in the main text.

A nested logit model was used to analyse DCE data, which has the advantage of avoiding the independence of irrelevant alternatives (IIA) assumption required in the more widely-used multinomial logit model. We do not rescale any parameters due to the absence of revealed preference data for new products among these groups.

DCE predictions are considered to be at the upper end of what could be expected in reality, as they do not account for health system or financial constraints in decision making, for example. In this instance, the uptake predictions are higher than observed among populations for whom PrEP is already available, and also for many health interventions in South Africa. As such, they should be considered optimistic assumptions for PrEP use among heterosexual men in South Africa. Even with these optimistic assumptions, our model is still not cost-effective.

[1] Unpublished analysis, data collected in cited study

Supplement C: Protective effect of products formula and explanation

The effectiveness of any HIV prevention product is a factor of efficacy at correct use and adherence. Product effectiveness for condoms, injectable PrEP, and oral PrEP was calculated using central values and 95% confidence bounds to establish central, best case, and worse case effectiveness estimates (Table 2).

Table 4: Product effectiveness calculation. Calculation used to estimate the real-world effectiveness of HIV prevention products based on adherence and efficacy with correct use.

Product	Product Effectiveness Calculation
Condoms	= Condom efficacy with correct use * Probability of correct condom use
Oral PrEP	= Oral efficacy PrEP with correct use * Average time on Oral PrEP over year * Daily Adherence to Oral PrEP
Inj. PrEP	= Inj. Efficacy PrEP with correct use * Average time on Inj. PrEP over year

Calculation of Protective Effect

As condoms act as a physical barrier and PrEP is pharmacological, the model assumes that protective effect of multiple products is additive. The final protective effect of PrEP product (i) under each intervention scenario (denoted i= 1…m) was determined using a formula adapted from Quaife et al.[12]. In this formula, E_0U_0 represents the base case protection from existing condom use (U_0) at current efficacy (E_0), α is the estimated proportional decrease in condom use among previous condom users who now use PrEP, and PrEP efficacy ($E_{i,c}$) and uptake ($U_{i,c}$) varies between PrEP products and among condom users (c=1) and non-condom users (c=0).

The protective effect from PrEP is calculated as the product of: protection provided to non-condom users choosing PrEP, protection to condom users choosing PrEP, and the protection to condom users who choose PrEP but discontinue using condoms. In an intervention where both PrEP formulations are used, these products would be summed. The protective effect of condoms among condom users who do not wish to uptake PrEP in the given intervention is added to the protective effect from PrEP and then the protective effect of the base case is subtracted from this total. This answer is then divided by (1 - the protective effect of the base case).

The final resulting formula is:

$$P_m^s = \frac{\sum_{i=1\ldots m}\left[U_{i,0}^s E_i^s (1 - U_0) + E_0 U_0 U_{i,1}^s E_i^s (1-\alpha) + E_0 U_0 U_{i,1}^s E_i^s \alpha\right] + \left(1 - U_{i,1}^s\right) - E_0 U_0}{1 - E_0 U_0}$$

Supplement D: Product uptake based on discrete choice experiment

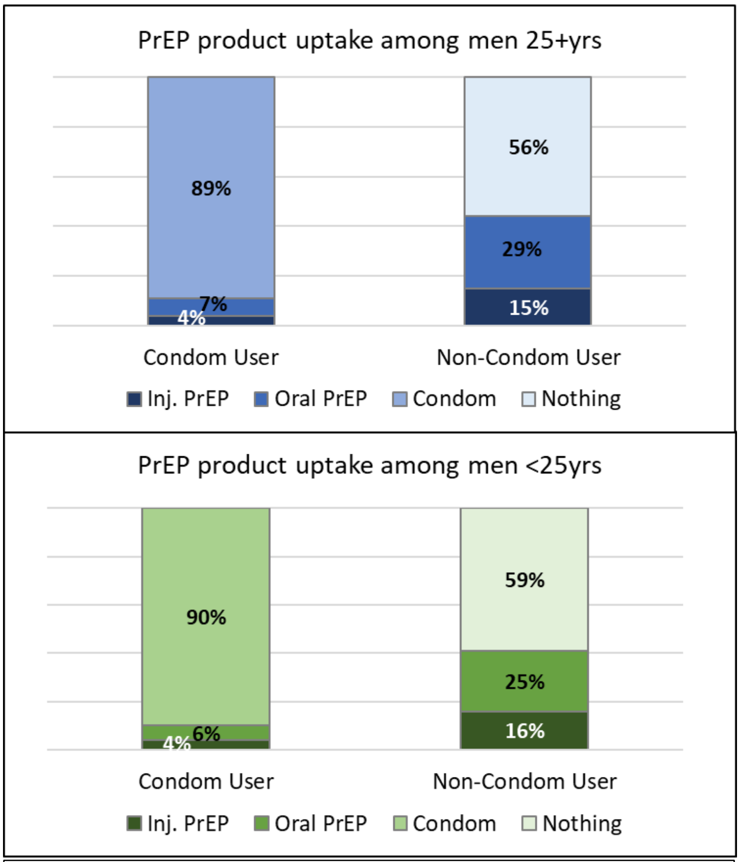


Figure 2: PrEP Uptake by Age and Condom Use. A survey of South African men using a discrete choice experiment established preferences for hypothetically available oral and injectable PrEP products relative to current practice. Responses were aggregated by age and condom use, where condom users were individuals identifying as consistent condom users.

Table 5: Scenario breakdown

Scenario	Susceptible population included in analysis	Product Introduced	Total men on PrEP in scenario	PrEP uptake among condom users assumption from DCE	PrEP uptake among non-condom users assumption from DCE	Reduction in incidence	Infections averted
Men <25, Oral PrEP only	4,608,723	Oral PrEP only	669,023	0.06	0.25	10.02%	2,269
Men <25, Inj. PrEP only		Injectable PrEP only	432,269	0.04	0.16	6.18%	1,399
Men <25, Both PrEP		Both Oral and Injectable PrEP	1,101,293	0.10	0.41	16.2%	3,668
Men 25+, Oral PrEP only	8,773,772	Oral PrEP only	1,649,940	0.07	0.29	13.24%	11,212
Men 25+, Inj. PrEP only		Injectable PrEP only	868,615	0.04	0.15	6.58%	5,574
Men 25+, Both PrEP		Both Oral and Injectable PrEP	2,518,555	0.11	0.44	19.8%	16,786

Supplement E: Calculated reduction in incidence

Table 6: Protective Effect of HIV Prevention Products. The calculated hypothetical reduction in baseline incidence given use of oral and/or injectable PrEP, known condom use, product efficacy, and product uptake in South African men from two age groups.		**Protective Effect (PE) (Reduction in baseline incidence)**		
		Worst Case (lower CI)	**Central**	**Best Case (upper CI)**
Men 18-24	Intervention with Oral PrEP only	8.7%	10.02%	21.55%
	Intervention with Inj. PrEP only	3.34%	6.18%	8.81%
	Intervention with both PrEP products	12.0%	16.2%	30.4%
Men 25-49	Intervention with Oral PrEP only	10.89%	13.24%	26.6%
	Intervention with Inj. PrEP only	3.18%	6.58%	9.47%
	Intervention with both PrEP products	14.1%	19.8%	36.1%

Importantly, on average current practice (condom use among condom users or unprotected sex) is preferred by men than any new PrEP modality (Supplement D). A greater proportion (29%) of older men opted for PrEP than younger men (25%). The highest estimated reduction in incidence across our intervention scenarios occurred when both PrEP products were introduced (-16.2% incidence in younger men and -19.8% in older men compared to counterfactual).

Supplement F: DALYs averted by all PrEP interventions

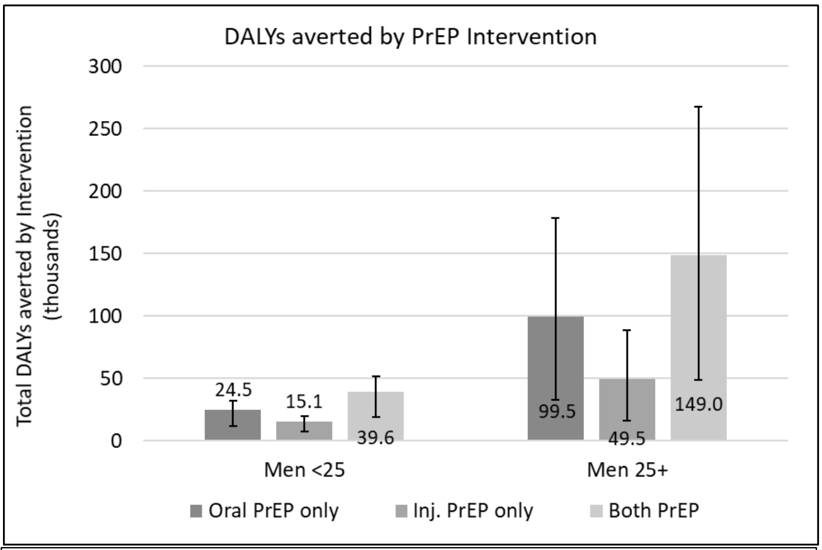


Figure 3: DALYs averted by PrEP intervention. Results following a one-year cost-utility analysis of the use of oral, injectable, or dual PrEP for two age cohorts in South Africa (men 18-24 and men 25-49). Error bars indicate variance in results using 95% confidence intervals for incidence.

Supplement G: Deterministic Sensitivity Analysis

Threshold analysis on Incidence

Table 7: Minimum Incidence for Cost-Effectiveness at $1,175/ DALY Averted at current ART coverage levels		
Population	**Scenario**	**Min. incidence**
Men <25	Oral PrEP only	1,47%
	Inj. PrEP only	1,70%
	Both PrEP interventions	1,56%
Men 25+	Oral PrEP only	1,81%
	Inj. PrEP only	2,12%
	Both PrEP interventions	1,91%

Table 8: Inputs resulting in the most percent variation in the ICER in one-way sensitivity analysis.			
Scenario	**Model Input**	**Variation in ICER from lower bound**	**Variation in ICER from upper bound**
Men <25, OP only	Daily Adherence to Oral PreP	22%	-16%
	Efficacy Oral PreP with correct adherence	24%	-17%
	Average time on Oral PreP over year	12%	-31%
	ART Coverage estimate	-14%	71%
	HIV incidence (<25)	123%	-27%
Men <25, IP only	Cost: Inj PrEP	-2%	23%
	Average time on Inj PrEP over year	12%	-31%
	ART Coverage estimate	-15%	73%
	Efficacy Inj PrEP with correct adherence	75%	-32%
	HIV incidence (<25)	120%	-26%
Men <25, Both	Efficacy Oral PrEP with correct adherence	14%	-11%
	Average time on Oral PrEP over year	7%	-21%
	Efficacy Inj PrEP with correct adherence	21%	-15%
	ART Coverage estimate	-14%	72%
	HIV incidence (<25)	122%	-26%
Men 25+, OP only	Efficacy Oral PrEP with correct adherence	23%	-17%
	Average time on Oral PrEP over year	11%	-31%
	Age at infection (older)	-15%	29%
	ART Coverage estimate	-10%	43%
	HIV incidence (25+)	161%	-50%
Men25+, IP only	Average time on Inj PrEP over year	11%	-31%
	Age at infection (older)	-14%	28%
	ART Coverage estimate	-11%	47%
	Efficacy Inj PrEP with correct adherence	68%	-32%
	HIV incidence (25+)	152%	-47%
Men 25+ both	Average time on Oral PrEP over year	7%	-22%
	Efficacy Inj PrEP with correct adherence	17%	-13%
	Age at infection (older)	-15%	28%
	ART Coverage estimate	-10%	45%
	HIV incidence (25+)	158%	-49%

Supplement H: Two-way sensitivity analysis

A two-way sensitivity analysis on ART coverage and HIV incidence found that ICERs fall below the willingness to pay threshold for older men when ART coverage is low (lower bound) and incidence high (upper bound) (Tab. 2). Also, under conditions of medium (61%) to high ART coverage (81%) and high HIV incidence (>1.7%), PrEP for heterosexual men could be cost-saving, all else held constant. Furthermore, a threshold analysis found that the minimum incidence for all scenarios to be cost-effective at a threshold of $1,175/DALY averted was <2.2% (Supplement G). The minimum incidence required for cost-effectiveness was lower for younger men.

Table 9: Two-way sensitivity analysis of HIV incidence and ART coverage. Two parameters from a one-year cost-utility analysis of the use of oral, injectable, or dual PrEP (both oral and injectable) were varied to estimate uncertainty in the ICER and determine cost-effectiveness at a threshold of $1,175/ DALYs averted. 1% higher incidence above the upper bound was explored as an outlier

Not cost-effective | Cost-effective

ICER ($/DALY Averted) for Men <25		Incidence assumption for Men <25			
Oral PrEP Only		**Lower bound (0.27%)**	**Base Case (0.49%)**	**Upper bound (0.71%)**	**1.7%**
Variance in ART Coverage	Lower bound(48%)	8 531	4 455	2 905	894
	Base Case (61%)	10 107	5 194	3 325	902
	Upper bound(81%)	14 379	7 196	4 465	922
Inj. PrEP Only					
Variance in Coverage	Lower bound	9 973	5 250	3 453	1 123
	Base Case	11 846	6 152	3 986	1 178
	Upper bound	16 922	8 597	5 432	1 326
Both PrEP Interventions					
Variance in Coverage	Lower bound	9 081	4 758	3 114	982
	Base Case	10 770	5 559	3 577	1 007
	Upper bound	15 349	7 731	4 834	1 076
ICER ($/DALY Averted) for Men 25+		**Incidence assumption for Men 25+**			
Oral PrEP Only		**Low 95% CI (0.85%)**	**Base Case (0.97%)**	**High 95% CI (1.09%)**	**2.09%**
Variance in Coverage	Lower bound(48%)	3 024	2 585	2 242	916
	Base Case (61%)	3 390	2 873	2 470	911
	Upper bound(81%)	4 298	3 589	3 036	897
Inj. PrEP Only					
Variance in Coverage	Lower bound	3 632	3 117	2 716	1 163
	Base Case	4 104	3 499	3 027	1 201
	Upper bound	5 278	4 447	3 800	1 296
Both PrEP Interventions					
Variance in Coverage	Lower bound	3 226	2 761	2 399	998
	Base Case	3 627	3 081	2 655	1 007
	Upper bound	4 623	3 874	3 290	1 030

Supplement I: Budget Impact Analysis

Older men receiving oral PrEP had the lowest calculated ICER; therefore, we conducted a crude 5-year budget impact estimate of this programme given 2019 national funding commitments to HIV prevention and treatment programmes.

We estimate that making oral PrEP available to older heterosexual men will cost the government approximately $2.1billion (R29 billion) over 5 years. Annual cost estimates are expected to equal approximately 8% of the currently allocated R66.4 billion annual HIV budget. We note in our discussion that providing PrEP to heterosexual men may require a distribution method outside of government clinics. Until this is assessed, we cannot estimate the cost of alternative distribution channels and its budget impact.

Supplement J: Comparison using 2012 HRSC prevalence and incidence figures [17]

Table 10: An comparison of calculated ICERs generated by the model using prevalence and incidence estimates from the 2012 and the 2017 HSRC surveys

Intervention Scenario	Cost per DALY Averted (2012)	Cost per DALY Averted (2017)
Men <25, Oral PrEP only	$4,536	$5,194
Men <25, Inj PrEP only	$5,389	$6,152
Men <25, Both PrEP	$4,861	$5,559
Men 25+, Oral PrEP only	$1,965	$2,873
Men 25+, Inj PrEP only	$2,435	$3,499
Men 25+, Both PrEP	$2,121	$3,081

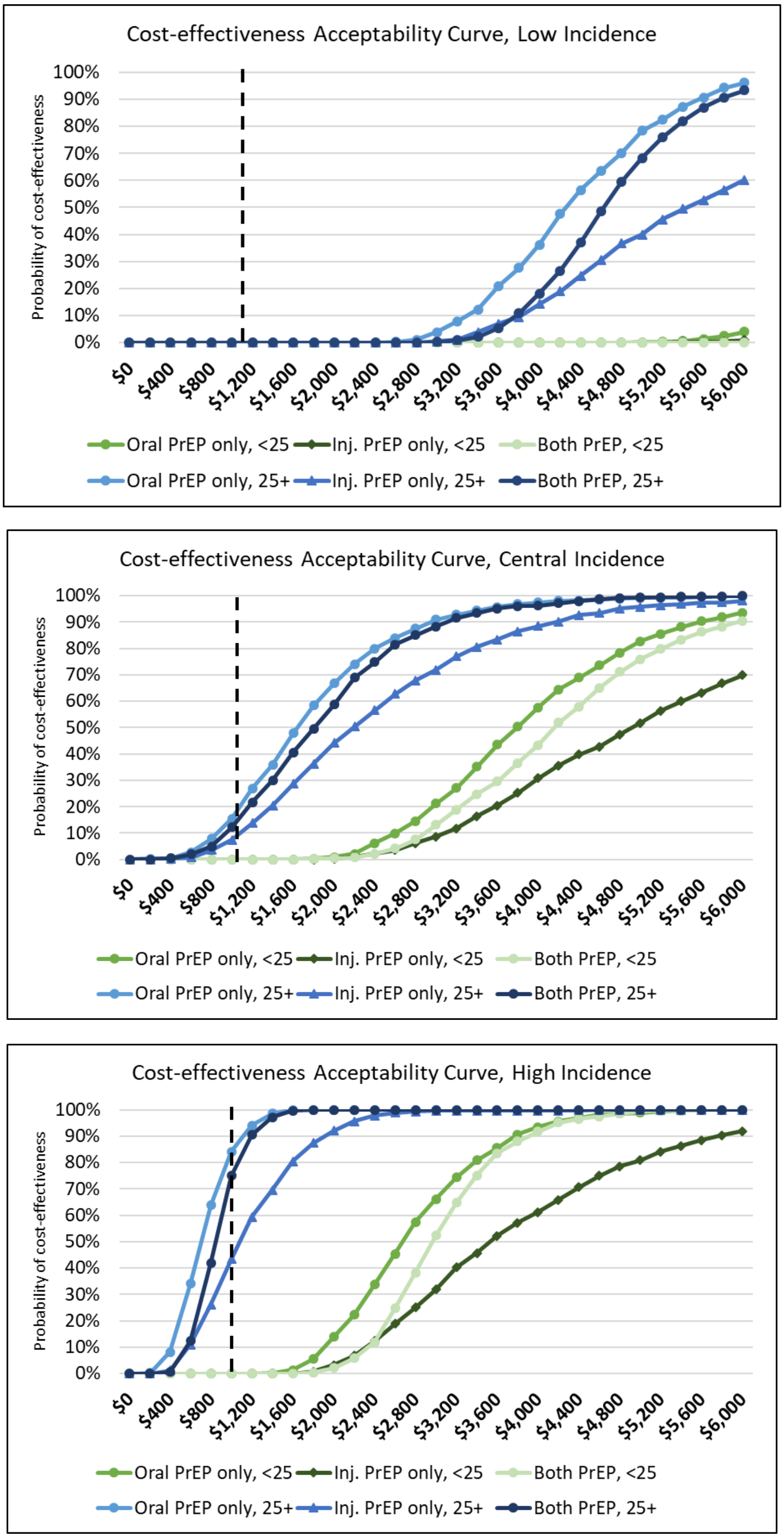


Fig. 4: Cost-effectiveness Acceptability Curves based on 2012 prevalence and incidence. The cost-effectiveness of PrEP availability under three intervention scenarios (oral, injectable, or dual PrEP (both oral and injectable)) for two cohorts (South African men 18-24 and men 25-49 years) at varying incidence was assessed through a Monte Carlo simulation. – – = Willingness to pay (WTP) – US$1,175/ DALY averted

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