

APPENDIX 1

Discussion paper: Estimates of the number of people eligible for PrEP in Australia, and related cost-effectiveness.

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1 INTRODUCTION

This discussion paper lays out estimates of eligibility for HIV pre-exposure prophylaxis (PrEP) in gay men in Australia, following the Australasian Society for HIV Medicine (ASHM) Australian Commentary on the US Public Health Service Clinical Practice Guidelines on Prescribing PrEP (<http://arv.ashm.org.au/arv-guidelines/prep-resources-for-clinicians>). These guidelines are hereafter referred to as the ASHM commentary. The document also lays out cost-effectiveness estimates based on these eligibility estimates and scenarios of coverage, adherence and pace of scale up. Given the lack of precise estimates of some at-risk populations, it also provides information on the plausible ranges of these estimates.

The main purpose of this document is to provide the latest available estimates to inform the work of stakeholders working in this field, including but not limited to advocacy organisations, policy makers, funders, the pharmaceutical industry, the TGA and the PBAC.

2 ESTIMATING THE POPULATION ELIGIBLE FOR PrEP

2a Background

Following the approval by the US FDA of HIV PrEP in July 2012, the US Centres for Disease Control (CDC) published PrEP clinical practice guidelines in 2014. These guidelines recommended HIV PrEP consisting of co-formulated tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) for adults at “substantial risk” of HIV infection. Among men who have sex with men, this was loosely defined by the CDC as those with an HIV positive partner, or with a recent bacterial sexually transmitted infection (STI), or with a high number of sex partners, or with a history of inconsistent or no condom use, or with a history of commercial sex work. Initial US estimates were that this would comprise about 25% of sexually active men who have sex with men (Smith et al., 2015). A 2014 study in San Francisco based on local behavioural surveillance data estimated that 64% of HIV negative sexually active men who have sex with men in that setting would meet the CDC PrEP criteria, but that only 15% of these men were actually using PrEP (Snowden et al., 2017).

Australian researchers and clinicians first considered state-based PrEP guidelines soon after the publication of the CDC guidelines in 2014. In NSW, a multi-disciplinary group was tasked by NSW Health with developing state-based guidelines. The researchers, clinicians and community representatives on this group were concerned that the US behavioural PrEP eligibility criteria for men who have sex with men were too widely defined and did not adequately contextualise high HIV risk behaviour. Initial guidelines used data on HIV incidence from Australia’s most recent HIV risk factor cohort study, the Health in Men cohort (HIM) study conducted in Sydney, NSW (Poynten et al., 2010). Although follow-up in that study ceased in 2007, the annual number of diagnoses in MSM in NSW has remained roughly stable. In the HIM study, the HIV incidence in sexually active gay men overall was 0.78 per 100 person years, but there were easily identifiable subgroups of gay men who

had an incidence of HIV of at least 2% per year (the subgroup with the highest HIV incidence was men with a diagnosis of rectal gonorrhoea in the last 6 months, who had an HIV incidence of 7.0 per 100 person-years (Jin et al., 2010). These data were then adjusted to form clinically meaningful and easily measureable risk behaviours which could comprise a pragmatic definition of high-risk which would determine eligibility, as outlined in Table 1 below.

Table 1: Factors associated with high risk of HIV acquisition among MSM in the Health in Men (HIM) study, Australia, 2001-07, and their translation into eligibility criteria for PrEP in Australia¹.

Findings of the HIM study		PrEP eligibility criteria
High-risk factor	HIV incidence per 100 person years (95% confidence interval)	
A regular sexual partner of an HIV-positive man with whom condoms were not consistently used in the last six months	5.36 (2.78-10.25)	A regular sexual partner of an HIV-infected men (<i>not on treatment and/or detectable viral load</i>) with whom condoms were not consistently used in the last three months
At least one episode of receptive unprotected anal intercourse with any casual HIV-infected or unknown HIV status male partner during the last six months	2.31 (1.48-3.63)	At least one episode of receptive condomless anal intercourse (CLAI) with any casual HIV-infected male partner or a male partner of unknown HIV status in the last three months
Rectal gonorrhoea diagnosis in last six months	7.01 (2.26-21.74)	Rectal gonorrhoea, rectal chlamydia or <i>infectious syphilis</i> diagnosis in the last three months or at screening for PrEP
Rectal chlamydia diagnosis in last six months	3.57 (1.34-9.52)	
Methamphetamine use in last six months	1.89 (1.25-2.84)	Methamphetamine use in last three months

¹Table adapted from draft ASHM HIV Pre-Exposure Prophylaxis: Clinical Guidelines, 2017 (See also Box 1)

At the outset, it was recognised that in defining high risk there were differences between **research-measured** risk factors such as in the HIM study data and **clinically pragmatic** measures of high risk. The most important of these differences was that while the research and behavioural surveillance measures generally related to a 6-month period, clinicians recommended that measures for clinical use should relate to a 3-month period to facilitate assessment and initiation of PrEP, and follow up with 3 monthly monitoring and drug supply. This means that exact estimates of the populations at high-risk are not possible as some form of assumption is required to make the data from Australian behavioural surveillance data fit the data required for estimation of clinically meaningful “high-risk” groups. Using a 3 month period of risk instead of the research-based 6 month period of risk would tend to lead to some over-estimation of populations at risk of PrEP.

2b Initial (2015) PrEP eligibility estimates

In 2015, the Kirby Institute undertook estimates of the number of gay men in Australia at high risk to HIV infection eligible for PrEP. These estimates were based on definitions of high HIV risk contained in the NSW PrEP guideline which were later adapted for ASHM’s clinical guidance. The initial estimates were based on the following data points and calculations.

1. The Australian Bureau of Statistics (ABS) reports the population of males aged 16 to 69 in 2015 to be 8,287,110.
2. In the population-based Second Australian Study of Health and Relationships (ASHR2, conducted in 2012-2013), the proportion of men aged 16 to 69 who identified as gay was 1.88%, equivalent to 155,798 gay men in 2015. (Men who identified as bisexual (1.3% of the sample) were not included in estimates of PrEP eligibility, because it was felt that such men would be much less likely to be prepared to present to a doctor and discuss their homosexual behaviour in a way which would be required for PrEP access. In addition, behavioural data on bisexual men, while being relatively limited, suggest that bisexual men have lower HIV risk behaviour than gay-identifying men. In EPIC-NSW, 95% of participants identify as gay compared to 4% who identify as bisexual (unpublished data), further supporting the presumption that few bisexual men will present for PrEP).
3. At the end of 2014, 20,537 MSM were living with HIV (uncertainty range 18,797 – 22,892)
4. In ASHR2, among gay-identified men aged 16 to 69, 81.9% reported same-sex sexual experiences in the last 12 months, leaving 110,779 sexually active HIV negative gay men.

Further calculations of numbers of men eligible for PrEP are based on this estimate of **110,779** sexually active HIV negative gay men aged 16-69 in Australia in 2015.

Estimates of gay men in categories who have specific risk criteria were based on behaviours and STI history reported by sexually active men in the gay community periodic surveys (GCPS). The GCPS forms the basis of Australia's behavioural surveillance for HIV risk behaviours. Surveys are conducted in gay community settings in the major cities of Australia annually or biennially, and data used in this report were from 2015 or the most recent year for those jurisdictions which do not conduct the survey annually.

As receipt of PrEP under the guidelines was conditional on the likelihood that risk behaviour would continue (and was not only in the past), it was felt that a measure of likely future behaviour was required. There was no direct research measure of this measure of future behaviour, but in the 2015 estimates Australian Gay Community Periodic Survey data on having at least 10 casual partners in the last 6 months were used in the estimates as a rough indicator of men who may be likely to have continuing risk. This is likely to have led to a degree of under-estimation of the populations at risk (some men who acquire HIV have fewer than 10 casual partners in a 3- or 6-month period).

Using this methodology, and based on the behavioural risk factors based in table 2, Kirby estimated that 12% of sexually active gay men in Australia would be eligible for PrEP (equivalent to 13293 men). This figure was used as a key input to estimate the number of high risk MSM eligible for PrEP through access studies commenced in 2016 in NSW (EPIC), Victoria (PrEPX) and Queensland (QPrEP).

2c Updated 2017 estimation of PrEP eligibility

To inform future PBAC submissions and further initiatives to provide PrEP in Australia, the Kirby Institute and the Centre for Social Research on Health has developed a new estimate of the number of MSM at high risk of HIV. The key change has been to modify the criteria to be more clinically pragmatic, and less restrictive using updated data sources. This has drawn on a number of inputs including the following

1. Experience from Australian clinical access studies currently providing PrEP to around 7000 individuals at high risk to HIV in NSW, Victoria and Queensland. The most advanced of these, EPIC-NSW, has thus far recruited about 900 participants more than the original estimate of 3700 and continues to recruit 50-80 new participants each week, albeit at a rate greatly reduced from the rate in early 2016 when 100-150 participants per week were enrolled. Victoria has reached its estimate of 2600 participants in the PrEPX study and the study is being expanded to allow more enrolment.
2. Experience from comparable settings who are rapidly rolling out PrEP, notably in France, and the USA (California, New York, Washington State) that in 2015-2016 roll-out of PrEP to gay men had considerably accelerated.
3. Draft updated PrEP eligibility criteria contained in clinical guidance provided by ASHM which recommended more practitioner discretion in applying the high-risk guidelines (see Box 1)
4. WHO guidelines, which recommend PrEP in populations with an HIV incidence of 3% per year or more. In fact, we chose risk groups, based on HIM study data, with an annual HIV incidence of more than approximately 2%, as there are few easily-identifiable subgroups of gay men with an incidence of more than 3%.
5. The position of PBAC in the response to Gilead's unsuccessful PBAC PrEP submission that further applications for PrEP listing on the PBS should not seek to unreasonably limit the eligible population.

In addition, new estimates of MSM living with HIV were released in the Kirby Institute 2016 annual surveillance report (ASR), and these were 7.1% lower than those in the 2015 ASR. These estimates were that an estimated 19,097 MSM were living with HIV (uncertainty limits of 16,944 – 21,341), leaving a central estimate of 136,701 HIV negative gay men.

In summary, these new eligibility estimates are substantially higher than the previous estimates, relating to the adjustments of initial calculations in the table below, the use of more updated risk estimates from the gay community periodic surveys (GCPS).

Table 2: Differences between 2015 estimates of PrEP eligibility and updated estimates

	Initial 2015 estimates of high-risk gay men eligible for PrEP (based on available 2014/15 data)	Updated estimates of high-risk gay men eligible for PrEP (based on 2015/16 data)
Population of MSM living with HIV	20,537(Kirby ASR 2015)	19,097 (Kirby ASR 2016)
Population of sexually active HIV negative MSM aged 16-69	110,779	111,953
Risk behaviour requirements (last 6 months, from gay community periodic surveys)		
Requirement for ongoing risk	For each category below, men also were required to have at least 10 casual partners in the last 6 months	No requirement: it is assumed that men who have the risk factors below are likely to have ongoing risk.
Receptive condomless anal intercourse with casual partners	Often	>= one episode (15.4%)
Methamphetamine use	Monthly or more	>= once (9.2%)
CLAI with regular partner who has detectable viral load	At least once	At least once (no change) (0.1%)
Anal STI or syphilis	Any STI	Any STI plus a rectal swab or a syphilis test (10.5%)
Results		
Number of gay men eligible for PrEP under high-risk criteria	13,293	31,347
Percent of sexually active gay men eligible for PrEP under high-risk criteria	12%	28%

Medium risk: The draft *ASHM HIV Pre-Exposure Prophylaxis Clinical Guidelines, 2017* also contain two medium risk criteria. The guidelines recommend that PrEP be considered in men reporting these behaviours. These are

1. Reporting more than one episode of anal intercourse during the last 3 months when condoms broke or slipped off during intercourse (HIV incidence in HIM of 1.3 per 100py).

2. For uncircumcised men only, having at least one episode of insertive condomless anal intercourse where the serostatus of partner is not known or is HIV-positive (HIV incidence in HIM of 1.7 per 100 person-years).

There are difficulties in estimating the proportion of the population who would fit these categories. Regarding condom breakage, data on breakage during anal intercourse in Australia are sparse. Unpublished data from the Health in Men study suggest this occurs in about 1% of HIV negative gay men in a 6 month period, but this is almost entirely in men who report one of the high-risk criteria above. Thus this criterion is unlikely to add substantially to the total pool of men requiring PrEP, unless condom breakage/slippage is over-reported.

Based on reasonable estimates of the proportion of uncircumcised men, which is much higher in younger than older adults, about 2% of gay men might fit into this category, but again, many of these men are likely to report a high-risk behaviour.

Overall, it is unlikely that more than 4% of sexually active gay men would fit into this medium-risk category.

Heterosexual people and injecting drug users: The draft ASHM HIV Pre Exposure Prophylaxis Clinical Guidelines, 2017 recommend PrEP in heterosexual people and injecting drug users only in very limited circumstances. These are likely to involve very small numbers and we have not made formal estimates of eligibility under these criteria.

Box 1: Risk criteria for MSM to identify their eligibility for PrEP, from DRAFT 2017 Australasian Society for HIV Medicine HIV Pre-exposure Prophylaxis Clinical Guidelines.

A. High risk – recommend prescribing daily PrEP if the patient acknowledges		
Having had any of the following in the last 3 months <ul style="list-style-type: none"> • At least one episode of condomless anal intercourse with a regular HIV + partner (not on treatment and/or detectable viral load) • At least one episode of receptive CLAI with any casual HIV + male partner or a male partner of unknown status • Rectal gonorrhoea, rectal chlamydia or infectious syphilis diagnosis (during the last 3 months or at screening for PrEP) • Methamphetamine use which may lead to an increased risk of HIV acquisition 	AND	Being likely to have in the next 3 months (indicating sustained risk) <ul style="list-style-type: none"> • Multiple events of condomless anal intercourse (CLAI) • With or without sharing intravenous drug equipment
B. Medium risk – consider prescribing daily PrEP, based on case by case approach if discussion reveals		
Having had any of the following in the last 3 months <ul style="list-style-type: none"> • More than one episode of anal intercourse when proper condom use was not achieved (e.g. condom slipped off or broke) where the serostatus of partner was not known, or was HIV + and not on treatment or with a detectable viral load • (if patient uncircumcised) more than one episode of insertive CLAI where the serostatus of partner was not known, or was HIV + and not on treatment or with a detectable viral load 	AND	Being likely to have in the next 3 months (indicating sustained risk) <ul style="list-style-type: none"> • Multiple events of condomless anal intercourse (CLAI) • With or without sharing intravenous drug equipment
Case by case approach If, based on a complete sexual and drug-using history, and the personal circumstances of the patient, the doctor is of the opinion that they are likely be at high-risk of HIV, then PrEP prescription may be considered despite the absence of the high- or medium risk factors above.		

3. COST-EFFECTIVENESS ANALYSES

3a. Possible proportions of gay men receiving PrEP

A range of scenarios are possible with respect to use of PrEP at the population level. As the likely numbers of recipients who receive PrEP on the basis of heterosexual behaviour or IDU is believed to be small, we have confined these analyses to gay identifying men. We do not believe high levels of uptake are likely in bisexual men (1.3% of adult males aged 16-69), for reasons outlined above, and as supported by the fact that only 4% of participants in EPIC NSW enrolled in 2016 identified as bisexual. The following categories were developed. Although further categories could be added, we believe this gives us a reasonable range based on current calculations of those at risk.

Table 3: PrEP usage scenarios for cost-effectiveness analysis.

PrEP usage scenarios	Percentage of high risk gay men who receive PrEP (approximately 28% of gay men)	Percentage of medium risk gay men who receive PrEP (approximately 4% of gay men)	Percentage of all other gay men who receive PrEP. (approximately 68% of gay men)	Scenario name
Use only in high-risk gay men, lowest uptake	30%	0%	0%	Scenario30-0-0
Use only in high-risk gay men, medium levels of uptake	60%	0%	0%	Scenario60-0-0
Use only in high-risk gay men, highest plausible uptake	90%	0%	0%	Scenario90-0-0
High uptake in high risk, low uptake in medium risk	90%	20%	0%	Scenario90-20-0
High uptake in high risk, medium-high uptake in medium risk	90%	60%	0%	Scenario90-60-0
High uptake in high risk, some uptake in both medium and low uptake	90%	20%	10%	Scenario90-20-10
High uptake in high risk, higher uptake in medium and low risk	90%	60%	30%	Scenario90-60-30
90% of gay men use PrEP, regardless of risk	90%	90%	90%	Scenario90-90-90

3b. Cost-effectiveness

The detailed methods used to determine cost-effectiveness of PrEP as a public health intervention are detailed in the Appendix. The following is a brief summary. All monetary values are given in Australian dollars.

(i) Brief summary of methods

- We developed a HIV transmission mathematical model and determined what impact PrEP would have on reducing HIV among Australian gay men in a range of usage scenarios (Table 3) and willingness to pay thresholds, and initially assumed the following: 1) PrEP unit cost is \$10,249; 2) scale up occurred over a 3-year period; 3) high adherence (90%) resulting in very high efficacy (99%) and 4) no reduction in condom use.
- We assumed the current estimated PrEP unit cost is \$10,249 based on the 2015 dispensed price for maximum quantity (DPMQ) of tenofovir with emtricitabine on the Pharmaceutical Benefits Scheme website (see Tables A1-A3 in the Appendix). We assessed lower unit costs needed for PrEP to be cost-effective.
- We assumed three years for scale up to reach the usage coverage levels based on the clinical capacity and experience of rolling out PrEP programs in jurisdictions during 2016, and assessed the impact of scaling up in shorter periods.
- A high level of 90% adherence was assumed based on emerging evidence from Australian demonstration projects, including measures based on biological assays in the PRELUDE study which were presented at the ASHM conference in 2016 (Zablotska, 2016). We also assessed the impact of PrEP if there were lower levels of adherence (70%, 50% and 30%) and assumed efficacy at these lower levels based on the Anderson et al study [18] which estimated an HIV-1 risk reduction of 99% for seven doses per week, 96% for four doses per week, and 76% for two doses per week.
- We estimated the unit cost required for the PrEP intervention to become cost-effective at \$30,000, \$60,000 and \$90,000 willingness-to-pay thresholds (Table 4) as well as the total cost (Table 5). Willingness-to-pay thresholds are a subjective value determining whether a program is 'cost effective' or if it is 'cost effective' to switch from one program to another and reflects the maximum amount the health sector is willing to pay to procure a good or avoid something undesirable. These three thresholds were selected to encompass a broad range of potential outcomes as the Pharmaceutical Benefits Advisory Committee (PBAC) does not use a specific cost-effectiveness threshold for inclusion onto the PBS.
- Based on data from the Gay Periodic Survey, at baseline we assumed 47% and 42% of high-risk gay men taking PrEP used condoms with casual and regular partners respectively, and assessed the impact if condom use decreased by 10%, 30% and 50% (for those taking PrEP and overall).

(ii) Projected impact of PrEP on reductions in new HIV infections

The HIV model showed that PrEP interventions are projected to have a large impact on new HIV infections over 2016-2030 particularly if a high coverage is reached in the high-risk gay men, who make up 28.2%, or 31,700 (range: 25,400-38,100) of HIV-negative gay men (Table A7 and Figure A8 in the Appendix). Expanding PrEP to medium-risk gay men reduces new infections minimally due to the relatively small population size of medium risk men, as defined in the ASHM guidelines. Expanding PrEP to low-risk gay men does result in some additional new infections averted but this is small relative to the population size (67.8% of all HIV-negative gay men).

(iii) Cost-effectiveness considering different PrEP usage scenarios

Table 4 shows the PrEP unit cost needed for difference usage scenarios to be cost-effective and willingness to pay thresholds and Table 5 shows the total costs of these scenarios to the health system.

Considering the middle \$60,000 threshold, the current estimated PrEP unit cost (of \$10,249) would need to fall by 35-52% for the scenarios in which PrEP is used only by high-risk gay men to be cost-effective, this would result in an incremental cost per annum of \$7,186,000-\$17,107,000 considering 9,450-28,350 gay men will receive it (in 2016).

For the **Scenario90-0-0** (where coverage is restricted to 90% of high-risk men only) the unit cost would need to be \$4,960 (incremental cost per annum of \$17,107,000), ranging from \$3,750 to \$6,170 for the lower and upper thresholds, respectively.

For the scenario **(90-20-10)** where PrEP is provided to 90% of high-risk men, 20% of medium risk men and 10% of low-risk men, PrEP unit cost would have to fall to \$3,730, or total incremental costs per year of \$18,422,000.

In a scenario where PrEP coverage further expands to medium-risk men (Scenario**90-60-0**) the unit cost needs to be \$4,500, and when it expands to medium and low risk gay men (Scenario**90-60-30**), the unit cost would need to be \$2,570 to be cost effective, or total incremental costs per year of \$19,647,000.

Finally in a scenario where 90% of all gay men (high, medium and low) received PrEP (Scenario**90-90-90**), the PrEP unit cost would have to fall to below \$1,600 per year (or total incremental costs per year of \$24,153,000 for all men) at the \$60,000 willingness-to-pay threshold.

PrEP is more cost-effective if it is prioritized to men at highest risk of HIV. When coverage is expanded to medium-risk men (Scenario**90-60-0**) the unit cost needed to be cost effective only drops moderately by a further 9.3%, compared to Scenario**90-0-0**, however when coverage is expanded to low-risk risk men (Scenario**90-60-30**), the unit price needs to drop considerably, by a further 44.6% to be cost effective, compared to Scenario**90-0-0**.

Table 4: PrEP unit cost required per year to be cost effective at three different willingness-to-pay threshold, for all the usage scenarios. Ranges available in Table A8 of the appendix.

Percent of gay men receiving PrEP, by HIV risk			Willingness to pay threshold		
High-risk	Medium-risk	Low-risk	30k per QALY	60k per QALY	90k per QALY
30%	0	0	\$4,910	\$6,560	\$8,200
60%	0	0	\$4,290	\$5,680	\$7,080
90%	0	0	\$3,750	\$4,960	\$6,170
90%	20	0	\$3,640	\$4,810	\$5,980
90%	60	0	\$3,410	\$4,500	\$5,590
90%	20	10	\$2,820	\$3,730	\$4,640
90%	60	30	\$1,940	\$2,570	\$3,200
90%	90	90	\$1,190	\$1,560	\$1,940

Table 5: Total costs to health system.

Percent of gay men receiving PrEP, by HIV risk			Unit cost to be cost-effective at 60k per QALY	Average annual incremental cost 2016-2030 (nearest \$1000)
High-risk	Medium-risk	Low-risk		
30%	0	0	\$6,560	\$7,186,000
60%	0	0	\$5,680	\$12,956,000
90%	0	0	\$4,960	\$17,107,000
90%	20	0	\$4,810	\$17,260,000
90%	60	0	\$4,500	\$17,351,000
90%	20	10	\$3,730	\$18,422,000
90%	60	30	\$2,570	\$19,647,000
90%	90	90	\$1,560	\$24,153,000

(iv) Variation in cost-effectiveness estimates considering scenarios of unit cost, adherence, usage patterns, speed of scale up and condom use

- a. Unit cost:** If we assumed the agreed generic price of PrEP is \$1000 per unit (around 10% of the current PBS cost), then all the PrEP scenarios would be cost-effective, and the Scenario90-0-0 would be cost-saving (see Appendix Figure A11).
- b. Adherence:** Reducing adherence to moderate levels only slightly reduces the epidemiological impact of the PrEP intervention. This is because PrEP efficacy does not reduce substantially until the number of pills taken per week falls below three with efficacy remaining at 75% even if only two pills are taken per week (assumed efficacy for 7, 5, 3, 1 pills per week is 99%, 97%, 90%, 77%, 45% respectively; Figure A7 in the Appendix). Given efficacy is maintained despite a lower adherence, this has the effect of greatly increasing the cost-effectiveness of PrEP (as the PrEP costs are lower as men require fewer pills per year) (Figure A12 and Table A9 in the Appendix). If a lower adherence reflected men were taking PrEP on 'demand' then such a scenario would be even more cost-effective (as long as PrEP was taken at the appropriate time, so that high levels of efficacy are maintained).
- c. Scale up duration:** Taking less than three years to reach the intervention coverage increases the impact and cost-effectiveness of PrEP interventions. This highlights the importance of scaling up PrEP programs as fast as possible to maximize the benefit (Figure A15 and Table A11 in the Appendix).
- d. Condom use:** If the presence of a PrEP program reduces the level of condom use in gay men taking PrEP, then we project only a small increase in new infections overall (compared to the no risk compensation scenario) and a corresponding small reduction in cost-effectiveness. This is because at high adherence PrEP is highly effective at preventing HIV transmission and essentially replaces the need for condoms with respect to reduction in HIV transmission risk. However, such a scenario would likely lead to an increase in other sexually transmitted infections (not costed here). However, an initial increase in new HIV infections could occur before PrEP is completely rolled-out (Figure A13 in the Appendix). If there is a reduction condom use across all gay men, even in those not taking PrEP—potentially due to a general belief of lower risk—then the effect of PrEP will be reduced slightly but will not counteract the overall benefits of PrEP (Figure A14 and Table A10 in the Appendix).

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APPENDIX 2 – Modelled HIV incidence with varying PrEP access – by Epidemiologist Nick Scott, the Burnet Institute, Victoria

Table 6: HIV Notifications in Australia 2010–2015 and projections under various scenarios.

Percentages are relative to the number of HIV notifications in 2010 (1043).

Year	HIV notifications	Maintain status-quo	95-95-95 by 2020	95-95-95 by 2020 + PrEP (75% eligible)	95-95-95 by 2020 + PrEP scale-up (to 80% eligible by 2020)	95-95-95 by 2020 + PrEP (85% eligible)	95-95-95 by 2020 + PrEP (90% eligible)
2010	1043 (100%)						
2011	1050 (101%)						
2012	1065 (102%)						
2013	1030 (99%)						
2014	1082 (104%)						
2015	1025 (98%)	1025 (98%)	1025 (98%)	1025 (98%)	1025 (98%)	1025 (98%)	1025 (98%)
2016		1025 (98%)	939 (90%)	784 (75%)	774 (74%)	764 (73%)	754 (72%)
2017		1064 (102%)	881 (84%)	708 (68%)	697 (67%)	685 (66%)	674 (65%)
2018		1105 (106%)	814 (78%)	628 (60%)	616 (59%)	604 (58%)	592 (57%)
2019		1147 (110%)	738 (71%)	547 (52%)	534 (51%)	522 (50%)	509 (49%)
2020		1191 (114%)	654 (63%)	464 (44%)	452 (43%)	439 (42%)	427 (41%)

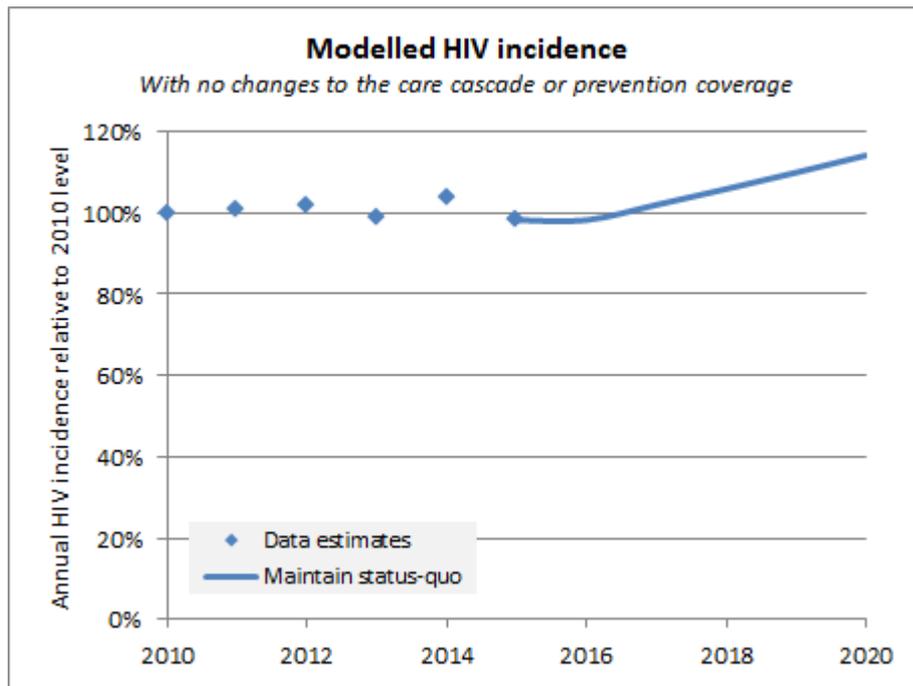


Figure A1: Baseline HIV incidence projection for Australia. Status-quo scenario assumes no PrEP scale-up and that no improvements are made to the percentage of people with HIV who are diagnosed or on treatment.

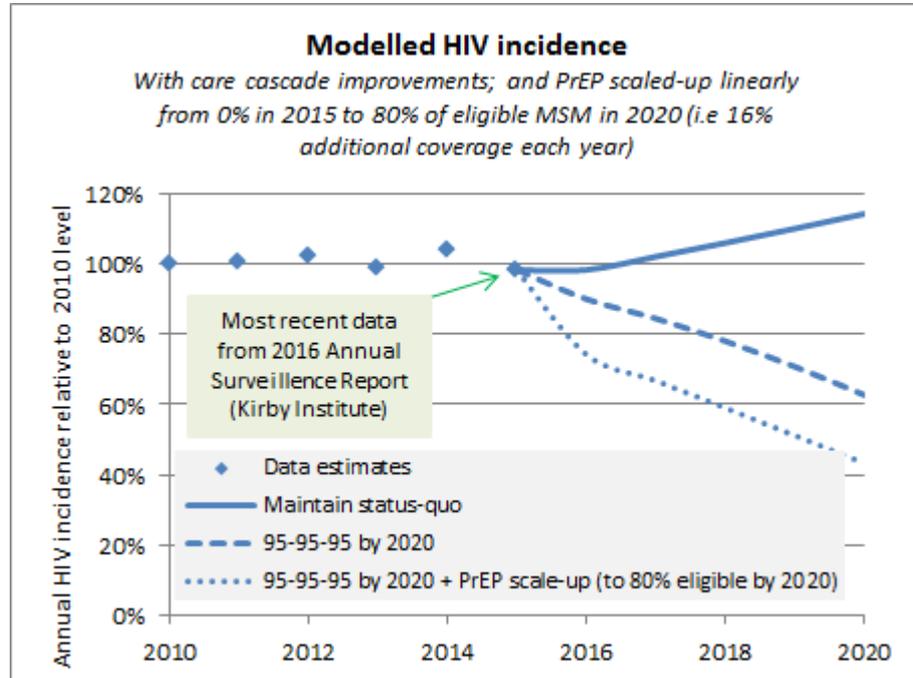


Figure A2: Projected HIV incidence with 95-95-95 target by 2020 (dashed blue line), and 95-95-95 target + 80% of eligible men who have sex with men on PrEP by 2020 (dotted blue line). This is based on the assumption that by 2020, 95% of all people living with HIV will know their HIV status, 95% of all people diagnosed with HIV will receive sustained antiretroviral therapy, and 95% of all people receiving antiretroviral therapy will have viral suppression, which means that they cannot

transmit HIV through sexual contact (the “95-95-95 target”). The status-quo scenario (solid blue line) is the same as Figure A1.

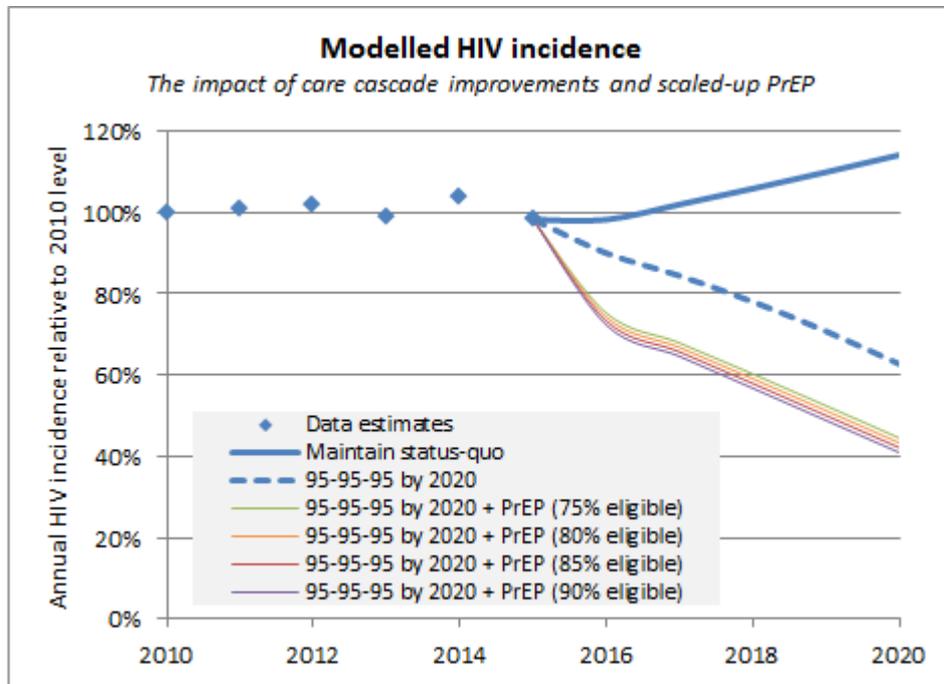


Figure A3: Effect based on different levels of scale-up of PrEP, ranging from 75–90%. The status-quo (solid blue line) and 95-95-95 by 2020 (dashed blue line) scenarios are the same as Figure A1 and A2 respectively.