### AUSTRALIAN HIV OBSERVATIONAL DATABASE ANNUAL REPORT 2015

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# Estimating antiretroviral treatment coverage rates and viral suppression rates for homosexual men in Australia

**Background**: Gay and other men who have sex with men (GMSM) are disproportionally affected by the HIV epidemic in Australia. Below we briefly present a recent study combining data from AHOD with a community-based surveillance system to present a broader representation of the GMSM community, to determine estimates of proportions receiving antiretroviral therapy (ART) and/or with an undetectable viral load.

**Methods:** Data on men identified as GMSM, between 2010 and 2012, in AHOD were combined with data from HIV-positive men reported in the Gay Community Period Surveys (GCPS). GCPS participants recruited from a clinical setting were excluded from the analysis to reduce potential overlap. The proportion of HIV-positive GMSM receiving ART with and without an undetectable viral load for the combined sample was calculated as simple proportions. In addition, adjusted proportions including sample weighting and age standardization was calculated for the combined sample.

**Results:** During the reporting period 5251 AHOD records and 1626 GCPS responders were included in the analysis. The median age was slightly higher in the sample from AHOD than the GCPS sample. Among the AHOD patients the majority were diagnosed prior to 2000 while GCPS participants were mainly diagnosed between 2000 and 2012 (**Table 1**).

Across the three year period, the proportions of GMSM receiving ART increased in both AHOD and GCPS, though a little higher in AHOD. The adjusted proportion of GMSM receiving ART in the combined sample increased from 68% (95% CI 66-70%) in 2010 to 70% (68-72%) in 2012 (**Figure 1**). The adjusted proportion of GMSM with an undetectable viral load in the combined sample increased from 57% (55-59%) in 2010 to 62% (60-65%) in 2012. While the adjusted proportion of GMSM receiving ART with an undetectable viral load was much higher, increasing from 85% (83-87%) in 2010 to 90% (88-91%) in 2012 (**Figure 2**).

**Conclusion:** Our findings have recently been published in Sexual Health [1] and highlight the scope for further increasing ART uptake among HIV-positive GMSM, outside of the clinical setting, to receive care and achieve higher rates of ART coverage. The findings also suggest that progress is being made in increasing the proportion of HIV-infected people receiving ART in Australia.

Table 1. Patient characteristics for AHOD	and GCPS, by year of participation	

			AHOD			GCPS	
		2010	2011	2012	2010	2011	2012
Number of patients		1868	1729	1654	725	693	632
Age (years), median (IQR)		49 (43-57)	50 (43-57)	51 (44-58)	43 (37-49)	44 (37-50)	44 (38-51)
Year diagnosed, n (%)	<1990	440 (24)	401 (23)	378 (23)	134 (18)	118 (17)	107 (17)
	1990-1999	780 (42)	699 (40)	658 (40)	211 (29)	177 (26)	153 (24)
	2000-2012	576 (31)	555 (32)	543 (33)	342 (47)	361 (52)	349 (55)
	Unknown	72 (4)	74 (4)	75 (5)	38 (5)	37 (5)	23 (4)
Patient care setting, n (%)	Clinic	1481 (79)	1358 (79)	1311 (79)	146 (20)	162 (23)	116 (18)
	Hospital	387 (21)	371 (21)	343 (21)	0 (-)	0 (-)	0 (-)
	Community	0 (-)	0 (-)	0 (-)	579 (80)	531 (77)	516 (82)



Figure 1. Proportion<sup>+</sup> of HIV-positive GMSM receiving ART for AHOD, GCPS, combined and adjusted<sup>f</sup> combined sample.

Figure 2. Proportion<sup>+</sup> of HIV-positive GMSM with an undetectable viral load for the combined and adjusted<sup>f</sup> combined samples, by treatment status.



<sup>+</sup>Proportion with 95% confidence intervals.

<sup>f</sup>Adjusted sample includes sample weighting and age standardization.

[1] De La Mata NL, Mao L, De Wit J, Smith D, Holt M, Prestage G, Wilson DP, Petoumenos K. Estimating antiretroviral treatment coverage rates and viral suppression rates for homosexual men in Australia. Sexual Health. 2015. doi: 10.1071/SH15037. [Epub ahead of print]

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North America43(1)Missing257South and Central America52(1)Median $[LQ - UQ]^4$ 20[19-40]Missing1068(26)	Africa and Middle Fast	127	(3)	>10,000	<u>/</u> 0	(2)
Norm America4.5 $(1)$ Wissing2.57South and Central America52 $(1)$ Median $[LQ - UQ]^4$ 20 $[19-40]$ Missing1068 $(26)$	North America	132	(1)	Missing	-+5 257	(-/
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	South and Central America	40 50	(±) (1)	Median $[IO - IO]^4$	257	[19-/10]
	Missing	1068	(1) (26)		20	[13-40]

### Table 1: All AHOD demographics<sup>1</sup> (Total – 4 125)

1. Age & prior AIDS defining illness at time of cohort enrolment. CD4 count & HIV viral load closest to and within 3 months of cohort enrolment date.

2. Data not available for 8 of 31 sites.

3. Year of HIV infection = mid date between date of first positive and last negative test (coded as not reported if either first positive or last negative date are missing).

4. LQ = Lower quartile UQ = Upper quartile.

5. Patients who had the most recent visit between 1 April 2014 and 31 March 2015 and have not died.

6. Most recent CD4 count & HIV viral load between 1 April 2014 and 31 March 2015.

Year	Entered study	Deaths	Lost to Follow up
1999 <sup>2</sup>	816	6	37
2000	859	25	45
2001	247	29	64
2002	164	23	63
2003	194	22	56
2004	84	19	77
2005	98	26	63
2006	120	28	58
2007	97	26	84
2008	88	22	107
2009	307	15	71
2010	239	26	100
2011	205	20	91
2012	276	16	129
2013	130	13	149
2014	161	18	66
2015 <sup>3</sup>	40	1	0
Total	4125	335	1260

### Table 2: Follow up status by calendar year<sup>1</sup>

Complete follow-up (percentage of patients)<sup>4</sup>: 67 %

### Loss to follow-up (per 100 person years): 3.93 (95% CI: 3.71-4.16 )

Mortality (per 100 person years): 1.14 (95% CI: 1.02-1.27)

1. Perth (AHOD only patients) censored 31 March 2008, Gosford censored 31 March 2013 and Dubbo censored 31 March 2006.

2. 1 July – 31 December 1999.

3. 1 January – 31 March 2015.

4. Patients who have died or any patients seen at clinic site within the last 12 months (1 April 2014 – 31 March 2015) are considered to have complete follow-up.

Figure 1: Proportion of AIDS and non-AIDS related deaths in AHOD since cohort inception by year grouping



\* 1 January 2015 to 31 March 2015.

Table 3: Total number of deaths in AHOD since cohort inception, by AIDS or non-AIDS related
death classification and year grouping

	1999- 2002	2003- 2005	2006- 2008	2009- 2011	2012- 2014	<b>2015</b> <sup>1</sup>	All years
Non-AIDS related	49	40	54	35	23	1	202
AIDS related	32	25	16	9	1	0	83
Unknown	2	2	4	7	4	0	19
Missing Coding of Death	0	0	2	10	22	0	34
Total deaths	83	67	76	61	50	1	338

1. 1 January 2015 to 31 March 2015.

Table 4: Summary	of deaths	reported in	the last 5	year p	beriod <sup>1</sup>
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Coding of Death Classification <sup>2</sup>	Number
Cancer	22
AIDS (ongoing active disease)	7
Suicide	4
Chronic viral hepatitis (progression of / complication to)	3
MI or other ischemic heart disease	3
Chronic obstructive lung disease	3
Heart or vascular	3
Other Causes	13
Unknown (autopsy inconclusive, died overseas, etc)	7
Missing information <sup>3</sup>	31

1. 1 January 2010 to 31 December 2014.

2. Coding of Death classification (CoDe) – [http://www.cphiv.dk/code/tabid/55/default.aspx].

3. Still awaiting forms

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Patients under active follow up <sup>1</sup>	Patients under active follow up <sup>1</sup> (n=1994) (n=1996) (n=2027) (n=2036) (n		(n=2012)	(n=2012) (n=2117)		(n=2348)	(n=2513)	(n=2498)	(n=2473)		
Treatment	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Never treatment	88 (4)	77 (4)	77 (4)	77 (4)	75 (4)	62 (3)	75 (3)	76 (3)	92 (4)	82 (3)	77 (3)
Ever treatment	n=1906	n=1919	n=1950	n=1959	n=1937	n=2055	n=2195	n=2272	n=2421	n=2416	n=2396
Currently <sup>2</sup>	1626 (82)	1641 (82)	1720 (85)	1727 (85)	1755 (87)	1891 (89)	2055 (91)	2140 (91)	2346 (93)	2368 (95)	2365 (96)
Previously, not currently	280 (14)	278 (14)	230 (11)	232 (11)	182 (9)	164 (8)	140 (6)	132 (6)	75 (3)	48 (2)	31 (1)
Number of drugs e	ver <sup>3</sup>										
≤3	625 <i>(33)</i>	563 <i>(29)</i>	500 <i>(26)</i>	469 (24)	434 <i>(22)</i>	535 <i>(26)</i>	615 <i>(28)</i>	663 <i>(29)</i>	710 <i>(29)</i>	690 <i>(29)</i>	661 <i>(28)</i>
4-6	797 <i>(42)</i>	780 (41)	760 <i>(39)</i>	772 (39)	750 <i>(39)</i>	755 <i>(37)</i>	793 <i>(36)</i>	828 (36)	915 <i>(38)</i>	948 <i>(39)</i>	953 <i>(40)</i>
7-9	358 <i>(19)</i>	419 <i>(22)</i>	493 <i>(25)</i>	500 <i>(26)</i>	505 <i>(26)</i>	486 <i>(24)</i>	489 <i>(22)</i>	483 <i>(21)</i>	489 <i>(20)</i>	475 <i>(20)</i>	472 <i>(20)</i>
10+	126 <i>(7)</i>	157 <i>(8)</i>	197 <i>(10)</i>	218 <i>(11)</i>	248 (13)	279 (14)	298 (14)	298 (13)	307 <i>(13)</i>	303 <i>(13)</i>	310 <i>(13)</i>
Number of drug cla	sses ever <sup>3,4</sup>										
1	78 (4)	68 (4)	58 <i>(3)</i>	47 <i>(3)</i>	43 <i>(2)</i>	40 <i>(2)</i>	52 <i>(2)</i>	49 <i>(2)</i>	40 <i>(2)</i>	22 (1)	15 <i>(1)</i>
2	969 <i>(55)</i>	942 <i>(53)</i>	974 <i>(54)</i>	960 <i>(53)</i>	938 <i>(52)</i>	1036 <i>(53)</i>	1099 <i>(53)</i>	1162 <i>(53)</i>	1314 <i>(55)</i>	1333 <i>(56)</i>	1282 <i>(54)</i>
3	674 <i>(38)</i>	716 <i>(40)</i>	727 (40)	723 (40)	702 <i>(39)</i>	668 <i>(34)</i>	674 <i>(32)</i>	665 <i>(31)</i>	697 <i>(29)</i>	684 <i>(29)</i>	715 <i>(30)</i>
4	31 <i>(2)</i>	46 <i>(3)</i>	54 <i>(3)</i>	65 <i>(4)</i>	102 <i>(6)</i>	147 <i>(8)</i>	212 (10)	240 (11)	267 (11)	292 <i>(12)</i>	315 <i>(13)</i>
5			3 <i>(0)</i>	15 <i>(1)</i>	30 <i>(2)</i>	47 <i>(2)</i>	54 <i>(3)</i>	59 <i>(3)</i>	62 <i>(3)</i>	67 <i>(3)</i>	68 <i>(3)</i>

#### Table 5: Trends in antiretroviral treatment<sup>1</sup>

1. Treatment status for all patients under active follow during the calendar year. Table includes prospective data only (i.e. records prior to AHOD enrolment are excluded).

2. Currently on treatment is defined as receiving treatment at some point during the calendar year.

3. Denominator is the number of patients who have ever received treatment.

4. Broad class ARV groupings are: nucleos(t)ide reverse transcriptase inhibitors; non-nucleoside reverse transcriptase inhibitors; protease inhibitors; intergrase inhibitors; entry inhibitors;

		-						-														
	20	04	20	05	20	06	20	07	20	08	20	09	201	LO	201	11	201	2	201	13	201	14
Combination <sup>2</sup>	Ν	(%)	Ν	(%)	Ν	(%)	Ν	(%)	Ν	(%)	Ν	(%)										
1 <sup>st</sup> combination	325	(18)	306	(17)	270	(15)	246	(13)	235	(13)	352	(18)	362	(17)	418	(19)	516	(22)	499	(21)	463	(19)
2 <sup>nd</sup> combination	347	(20)	315	(18)	317	(17)	337	(18)	334	(18)	332	(17)	404	(19)	420	(19)	490	(21)	515	(22)	530	(22)
3 <sup>rd</sup> combination	315	(18)	302	(17)	300	(16)	291	(16)	287	(16)	266	(14)	305	(15)	315	(15)	341	(14)	362	(15)	363	(15)
$\geq$ 4 <sup>th</sup> combination	776	(44)	857	(48)	932	(51)	951	(52)	961	(53)	992	(51)	1022	(49)	1017	(47)	1027	(43)	1015	(42)	1027	(43)

#### Table 6: Trends in combination antiretroviral treatment<sup>1</sup>

1. Includes patients who commenced their first combination ART after 1 January 1996 for at least 14 days. The denominator includes all AHOD patients that received combination antiretroviral treatment in any calendar year (i.e. HIV positive), who commenced their first combination ART after 1 January 1996 for at least 14 days. Includes prospective and retrospective data.

2. Combinations include 3 or more antiretroviral drugs, does not include mono/dual therapy. Regimens with interruptions of less than 7 days were considered as continuous treatment.

### Figure 2: Trends in combination antiretroviral treatment (as above)



	Table 7:	Immunological	and viro	logical	trends1
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	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Viral load (copies/ml)											
Total N (with measure)	2195	2254	2275	2330	2384	2319	2275	2387	2406	2366	2216
Off Treatment <sup>2</sup>											
No. with a viral load count <sup>4</sup>	449	489	431	416	369	314	254	229	168	124	94
Median	21410	19050	14300	13593	12023	10305	8505	4700	4988	2851	556
IQR	4030-68900	4130-63500	3450-48050	3161-42137	2400-40900	1950-37150	447-34150	329-40000	67-32652	39-22900	20-24711
On Treatment <sup>3</sup>											
No. with a viral load count <sup>4</sup>	1746	1765	1844	1914	2015	2005	2021	2158	2238	2242	2122
Median	50	50	50	49	49	49	49	40	34	20	20
IQR	50-400	49-399	49-70	42-50	40-50	40-50	40-50	30-49	19-49	19-40	19-40
CD4 count (cells/µl)											
Total N (with measure)	2217	2269	2269	2336	2381	2350	2324	2449	2470	2453	2290
Off Treatment <sup>2</sup>											
No. with a CD4 count <sup>5</sup>	468	505	441	424	381	325	268	236	179	134	100
Median	490	490	506	500	490	505	493	504	550	599	641
IQR	372-650	370-640	379-651	400-632	388-651	396-660	395-640	392-669	446-730	451-742	469-810
On Treatment <sup>3</sup>											
No. with a CD4 count <sup>5</sup>	1749	1764	1828	1912	2000	2025	2056	2213	2291	2319	2190
Median	484	486	500	520	528	540	552	573	584	610	636
IQR	312-684	323-690	340-710	360-717	371-740	380-733	397-735	420-766	427-772	440-792	463-825

1. Includes retrospective and prospective data. Off treatment if never on a regimen of duration greater than 14 days for given calendar year. Viral load taken as median value during given calendar year. Undetectable assay level taken as ≤50 copies/ml.

2. Patients who have not received treatment during the calendar year.

3. Patients who have received any treatment during the calendar year.

4. Includes patients with a viral load measured during the relevant calendar year.

5. Includes patients with a CD4 count measured during the relevant calendar year.

### Table 8: CD4 cell count at antiretroviral therapy initiation by calendar year<sup>1</sup>

	1996 to 1997	1998 to 1999	2000 to 2001	2002 to 2003	2004 to 2005	2006 to 2007	2008 to 2009	2010 to 2011	2012 to 2013	2014 to 2015 <sup>4</sup>
Number	of participa	nts initiati	ng ART <sup>1</sup>							
N=	780	371	171	159	139	166	206	195	106	30
CD4 cell d	count (copi	es/μl) <sup>2,3</sup>								
Mean	323	346	286	310	325	270	280	347	396	367
Median	300	309	234	260	260	240	273	337	379	400
IQR	160-450	165-470	110-400	132-420	190-372	153-353	170-360	247-444	290-484	220-470

1. First ART defined as a combination of 3 or more antiretroviral agents and a duration of ART>14 days. Includes retrospective and prospective data. ATRAS sub study participants were excluded from analysis.

2. CD4 cell count selected from the observation closest to ART start date within a timeframe window of 12 months prior to ART start date and 1 month post ART start date.

3. A patient was excluded from the analysis if an undetectable viral load was recorded prior to initiating ART or was missing a viral load measurement prior to initiating ART.

4. Includes data reported from 1 January 2015 to 31 March 2015.

### Figure 3: Empirical CD4 cell count distribution (boxplot) at antiretroviral therapy initiation by year of ART initation<sup>1-3</sup> (median CD4 indicated by horizontal grey bar)



1. First ART defined as a combination of 3 or more antiretroviral agents and a duration of ART>14 days. Includes retrospective and prospective data. ATRAS sub study participants excluded from analysis.

2. CD4 cell count selected from the observation closest to ART start date within a timeframe window of 12 months prior to ART start date and 7 days post ART start date.

3. A patient was excluded from the analysis if an undetectable viral load was recorded prior to initiating ART or was missing a viral load measurement prior to initiating ART.



## Figure 4: Proportion of patients with an undetectable viral load, by treatment status (off /on treatment) and year according to assay sensitivity<sup>1</sup>

- 1. Off treatment if never on a regimen of duration greater than 14 days for given calendar year. Viral load taken as median value during regimen of longest duration for given calendar year.
- In the "off-treatment" group (n=94 in 2014), there are patients where their viral load time series is strongly indicative of the patient receiving therapy, defined as 2 or more recent records where pVL <50 copies/ml. <u>Data validation is ongoing</u> with sites.



Figure 5: CD4 cell counts (cells/µl) in patients receiving treatment by calendar year<sup>1-3</sup>

1. Includes patients with a prospective CD4 measure during the relevant calendar year.

2. For patients on treatment, analysis based on the initial treatment intent, not on treatment administered (ITT), i.e. no adjustments are made for off-treatment following ART initiation.

3. Patients off treatment include those who have enrolled and have not initiated combination antiretroviral therapy.

### Table 9: Top ten treatment combinations among the AHOD cohort<sup>1</sup>: January-December 2014

In 2014, there were a total of 419 unique antiretroviral treatment (ART) combinations among the 2344 AHOD patients on combination ART. A total of 2745 combination regimens were recorded among these patients throughout 2014. The top ten most common ART combinations are described below.

ART combinations	Number of regimens recorded during 2014
emtricitabine+tenofovir+efavirenz	466
emtricitabine+tenofovir+nevirapine	199
emtricitabine+tenofovir+atazanavir+ritonavir	191
abacavir+lamivudine+nevirapine	178
emtricitabine+tenofovir+raltegravir	176
emtricitabine+tenofovir+rilpivirine	134
abacavir+lamivudine+efavirenz	71
emtricitabine+tenofovir+elvitegravir+cobicistat	52
abacavir+lamivudine+atazanavir+ritonavir	49
emtricitabine+tenofovir+dolutegravir	45

1. Includes retrospective and prospective data. Combinations include 3 or more antiretroviral drugs. Fixed dose combinations are separated into individual component antiretroviral drugs.





1. Includes retrospective and prospective data. Combinations include 3 or more antiretroviral drugs. Fixed dose combinations are separated into individual component antiretroviral drugs.

2. Proportion defined as frequency of ART line divided by total number of ART regimens recorded. For example, 2014 Rank 1 proportion calculated by 466/2745=16.98%. Thickness of line over time is proportional to calculated percentage.

Table 10. Current use of mulvicual antifetroviral treatments
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	20	004	20	05	20	006	20	007	20	008	20	009	20	010	20	)11	20	)12	20	13	20	)14
	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%
Nucleoside analogu	le rever	se trans	criptase i	nhibito	rs (RTI)																	
Abacavir	546	(24)	531	(24)	483	(21)	402	(17)	386	(16)	285	(12)	269	(11)	248	(10)	216	(8)	194	(8)	199	(8)
Combivir <sup>2</sup>	451	(20)	452	(20)	399	(18)	311	(14)	256	(11)	222	(9)	205	(8)	168	(7)	139	(5)	108	(4)	87	(4)
Didanosine	363	(16)	283	(13)	205	(9)	135	(6)	94	(4)	62	(3)	52	(2)	33	(1)	27	(1)	19	(1)	17	(1)
Emtricitabine	1	(0)	39	(2)	100	(4)	85	(4)	127	(5)	159	(7)	199	(8)	221	(9)	223	(9)	240	(9)	185	(8)
Kivexa <sup>3</sup>	8	(0)	72	(3)	265	(12)	369	(16)	410	(17)	405	(17)	381	(15)	410	(16)	428	(16)	420	(16)	421	(17)
Lamivudine	988	(44)	1004	(45)	945	(42)	660	(29)	566	(24)	432	(18)	396	(16)	365	(14)	328	(13)	291	(11)	289	(12)
Stavudine	299	(13)	198	(9)	139	(6)	83	(4)	65	(3)	48	(2)	36	(1)	22	(1)	20	(1)	12	(0)	10	(0)
Tenofovir	623	(28)	743	(33)	772	(34)	532	(23)	496	(21)	471	(20)	471	(19)	444	(18)	407	(16)	387	(15)	304	(12)
Trizivir <sup>4</sup>	160	(7)	154	(7)	129	(6)	91	(4)	71	(3)	58	(2)	46	(2)	41	(2)	27	(1)	20	(1)	17	(1)
Truvada⁵	10	(0)	17	(1)	369	(16)	544	(24)	713	(30)	903	(38)	945	(38)	798	(32)	866	(33)	870	(34)	812	(33)
Zalcitabine	8	(0)	7	(0)	5	(0)	3	(0)	3	(0)	2	(0)	2	(0)	1	(0)	1	(0)	1	(0)	1	(0)
Zidovudine	247	(11)	209	(9)	167	(7)	126	(5)	102	(4)	63	(3)	51	(2)	39	(2)	35	(1)	33	(1)	26	(1)
Non-nucleoside ana	alogue F	RTI																				
Delavirdine	17	(1)	13	(1)	11	(0)	9	(0)	3	(0)	2	(0)	2	(0)	-		-		-		-	
Efavirenz	482	(22)	472	(21)	503	(22)	546	(24)	561	(24)	569	(24)	527	(21)	338	(13)	343	(13)	292	(11)	226	(9)
Nevirapine	680	(30)	653	(29)	633	(28)	646	(28)	670	(28)	659	(28)	631	(26)	601	(24)	598	(23)	545	(21)	495	(20)
Etravirine	-		-		2	(0)	24	(1)	53	(2)	84	(4)	103	(4)	109	(4)	116	(4)	119	(5)	120	(5)
Rilpivirine	-		-		-		-		-		2	(0)	2	(0)	5	(0)	17	(1)	33	(1)	37	(2)

1. All treatment records of >2 weeks of treatment in any calendar year were included in this analysis. The denominator includes all patients that could have been on antiretroviral therapy (i.e. HIV positive) in any calendar year. The proportion of patients on each drug in any calendar year does not add up to 100% across all ART drug groups in each calendar year as patients on more than one ARV during a calendar year period will be counted in all of the relevant ART groups. Includes retrospective and prospective data.

**2**. Comibivir – Lamivudine & Zidovudine.

**3.** Kivexa – abacavir & lamivudine. **4.** Trizivir - abacavir & lamivudine & zidovudine. **5.** Truvada – tenofovir & emtricitabine.

	20	004	20	05	20	06	20	07	20	08	20	09	20	010	20	11	20	12	20	)13	20	14
	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%
Protease Inhibito	r																					
Amprenavir	52	(2)	45	(2)	30	(1)	28	(1)	27	(1)	27	(1)	25	(1)	21	(1)	19	(1)	16	(1)	12	(0)
Atazanavir	264	(12)	388	(17)	444	(20)	484	(21)	536	(23)	548	(23)	567	(23)	559	(22)	550	(21)	505	(20)	444	(18)
Darunavir	8	(0)	14	(1)	42	(2)	74	(3)	120	(5)	165	(7)	199	(8)	229	(9)	264	(10)	273	(11)	283	(12)
Fosamprenavir	2	(0)	31	(1)	36	(2)	32	(1)	30	(1)	24	(1)	17	(1)	15	(1)	13	(1)	11	(0)	10	(0)
Indinavir	124	(6)	70	(3)	46	(2)	31	(1)	20	(1)	10	(0)	6	(0)	4	(0)	4	(0)	4	(0)	1	(0)
Kaletra <sup>6</sup>	451	(20)	445	(20)	412	(18)	388	(17)	362	(15)	337	(14)	326	(13)	286	(11)	246	(9)	201	(8)	163	(7)
Nelfinavir	105	(5)	72	(3)	47	(2)	35	(2)	9	(0)	8	(0)	7	(0)	6	(0)	6	(0)	5	(0)	4	(0)
Ritonavir	520	(23)	597	(27)	667	(29)	689	(30)	735	(31)	736	(31)	778	(32)	791	(31)	817	(31)	769	(30)	710	(29)
Saquinavir	140	(6)	127	(6)	109	(5)	90	(4)	70	(3)	44	(2)	35	(1)	32	(1)	27	(1)	23	(1)	18	(1)
Entry Inhibitor																						
Enfurvitide	55	(2)	63	(3)	69	(3)	62	(3)	45	(2)	28	(1)	17	(1)	9	(0)	7	(0)	6	(0)	4	(0)
Maraviroc	-		8	(0)	7	(0)	8	(0)	15	(1)	22	(1)	29	(1)	32	(1)	41	(2)	48	(2)	49	(2)
Integrase Inhibito	ors																					
Raltegravir	2	(0)	3	(0)	10	(0)	64	(3)	180	(8)	303	(13)	444	(18)	505	(20)	590	(23)	627	(25)	622	(26)
Dolutegravir	-		-		-		-		-		-		-		1	(0)	8	(0)	9	(0)	146	(6)
Elvitegravir	-		-		-		-		-		1	(0)	1	(0)	1	(0)	4	(0)	18	(1)	18	(1)
Class Combinatio	ns																					
Atripla <sup>7</sup>	1	(0)	1	(0)	2	(0)	4	(0)	5	(0)	15	(1)	282	(11)	382	(15)	413	(16)	439	(17)	389	(16)
Eviplera <sup>8</sup>	-		-		-		-		-		-		-		3	(0)	56	(2)	109	(4)	124	(5)
Stribild <sup>9</sup>	-		-		-		-		-		-		-		-		2	(0)	3	(0)	55	(2)

Table 10 continued: Current use of individual antiretroviral treatments<sup>1</sup>

All treatment records of ≥2 weeks of treatment in any calendar year were included in this analysis. The denominator includes all patients that could have been on antiretroviral treatment (i.e. HIV positive) in any calendar year. The proportion of patients on each drug in any calendar year does not add up to 100% across all ARV drug groups in each calendar year as patients on more than one ART during a calendar year period will be counted in all of the relevant ART groups. Includes retrospective and prospective data.
 Atripla – tenofovir & emtricitabine & efavirenz.
 Eviplera - tenofovir & emtricitabine & rilipivirine.
 Stribild - tenofovir & emtricitabine & elvitegravir & cobicistat.

#### MONITORING DISPENSED ANTIRETROVIRALS VIA THE S100 PROGRAM

Table 11 reports the number of people dispensed antiretroviral (ARV) treatment through the Australian Government's Highly Specialised (HSD) (s100) program. Data up to and including 2013 were based on data reported in the Public Health Dispensed National Patient report. The number of patients who were dispensed antiretroviral drugs per state per financial year quarter were analysed together with data on ARV use from the AHOD sample.

For the time period 2009 – 2013, to estimate the number of patients receiving ART, we combined data on the proportion of patients receiving certain mutually exclusive ARVs in AHOD with data from the s100 program on the total number of people receiving the same ARVs. For example, lamivudine and emtricitabine are a common component of combination ART regimens in Australia, but should not be prescribed in combination. We calculated the proportion of all treated patients in AHOD who received lamivudine or emtricitabine as part of an ART regimen by year and state. We also estimated the total number of patients dispensed lamivudine or emtricitabine for HIV infection each year through the s100 program by calculating the average number of patients prescribed each drug from the corresponding four financial year quarters. An estimate of the total number of people receiving any ART was then obtained by dividing the total number of patients receiving lamivudine or emtricitabine through the s100 program by the proportion of treated patients in AHOD receiving the same ARV drugs.

<u>Note:</u> Prior to 2009, the HSD Report provided prescribed patient numbers by each antiretroviral agent. However after noting some inconsistencies with their methodology, they have since ceased providing these numbers. For years 2009-2010, instead we (The Kirby Institute) evaluated patient numbers by using a combination of total packs dispensed and an average "packs-per-patient" adjustment ratio. The packs-per-patient adjustment figure was calculated from 2008 data, where total packs dispensed and patient numbers were available. However, due to the relatively recent diversification of pack sizes, newer dosing schedules and the introduction of antiretroviral agents that were absent in 2008, we are uncertain as to how our packs-per-patient adjustment ratio has changed over time. Therefore we caution our estimates for 2011- 2013 data for Table 11.

In 2014 we report the number of people receiving ART based on a 10% sample of the Pharmaceutical Benefits Scheme (PBS) data, including s100 drugs. Data on dispensed prescriptions for a PBS 10% sample is updated every quarter and supplied to a number of approved users or clients including Prospection which provides a dashboard interface (PharmDash) for querying the PBS 10% sample [1, 2]. The 10% sample of the PBS is a randomised patient level, de-identified PBS script claims data set from 2006-present. Currently the data set has 170 million script claims and 3 million patients. It includes all PBS listed drugs with HIV indications. The presented figures are annual totals of unique patients in December 2014. This represents total number of patients obtaining at least one prescription for the indicated drug anytime during 2014. This methodology is preferable due to increased accuracy of the source data and the removal of assumptions and extrapolations previously required. This may also explain the considerable increase in estimated number of patients receiving ART from 2013 to 2014.

<u>http://www.pbs.gov.au/info/industry/useful-resources/sources/</u>, 22 September 2015.
 <u>http://www.prospection.com.au/</u>, 22 September 2015.

### Table 11: Number of people dispensed antiretroviral treatment through the HighlySpecialised Drugs (s100) program by year and antiretroviral agent

			Year of pre	escription <sup>1, 2</sup>	2	
Antiretroviral agent	2009	2010	2011	2012	2013	2014 <sup>3</sup>
Nucleoside analogue reverse transcriptase inhibitors						
Abacavir	544	492	473	425	400	460
Didanosine	229	163	117	84	60	130
Emtricitabine	131	211	146	157	60	90
Lamivudine	921	822	718	609	540	650
Stavudine	104	77	48	36	20	≤60
Zidovudine	156	128	98	70	60	70
Lamivudine & Zidovudine	846	719	602	461	400	420
Abacavir & Lamivudine	2243	2220	2179	2041	2500	3460
Abacavir. Lamivudine & Zidovudine	240	163	133	103	100	100
Tenofovir	1294	1586	1967	2039	2480	760
Tenofovir & Emtricitabine	5246	4772	4510	4404	4340	6150
Non-nucleoside analogue reverse transcriptase inhib	itors					
Delavirdine	7	6	-	-	-	-
Efavirenz	2996	2003	973	738	700	830
Nevirapine	2791	2809	2728	2376	2260	2770
Etravirine	155	403	456	454	520	580
Rilpivirine	-	-	-	18	40	140
Protease inhibitors						
Atazanavir	2609	2879	2906	2582	2380	2790
Darunavir	685	887	1058	1131	1140	1800
Fosamprenavir	219	181	148	111	80	120
Indinavir	52	31	21	18	20	≤60
Lopinavir & ritonavir	1871	1734	1581	1341	960	1030
Ritonavir	2850	3181	3098	2652	3180	4010
Saguinavir	148	121	95	72	40	≤60
Tipranavir	27	20	15	11	<5	≤60
Entry inhibitors						
Enfuvirtide	60	37	22	13	20	-
Maraviroc	-	55	118	122	160	310
Integrase inhibitor						
Raltegravir	821	1250	1848	2250	2740	3900
Dolutegravir	-	-	-	-	-	1910
0						
Combination Class Agents						
Tenofovir, Emtricitabine & Efavirenz	-	2013	2873	2786	3100	3710
Tenofovir, Emtricitabine & Rilpivirine	-	-	-	217	1040	2250
Tenofovir, Emtricitabine, Elvitegravir & Cobicistat	-	-	-	-	-	880
_						
Total patients <sup>4</sup>	10,900	12,400	12,700	12,800	13,700	17,480
5						
Total cost <sup>2</sup> (\$'000s)	156.810	181.508	200.165	210.005	229.000	230,930

1. For 2009 to 2013 the number of people dispensed each antiretroviral drug during a calendar year was estimated by calculating the average of the total number of people dispensed each drug during the corresponding financial year quarters. Number of person years for July - December 2009 to December 2012 estimated from the HSD Program Public Hospital Dispensed National Pack Number Report because of changes to \$100 data collection methodology. Number of person years for 2013 and 2014 estimated from the PBS item reports on services and benefits.

2. Dashes (-) indicate that data were not available.

3. PharmDash [http://www.prospection.com.au/, 22 September 2015]

4. Total patients calculated as (Lamivudine + Combivir (Lamivudine & Zidovudine)+Trizivir (Abacavir, Lamivudine & Zidovudine)+Kivexa (Abacavir & Lamivudine)+Emtricitabine + Truvada(Tenofovir & Emtricitabine) + Atripla(Tenofovir & Emtricitabine & Efavirenz) + Exiplera(Tenofovir & Emtricitabine & Rilpivirine))/the proportion of patients in the Australian HIV Observational Database receiving any of the previously mentioned drugs in each year. Estimates of total patients are rounded to nearest 100 patients.
5. Public Hospital Expenditure.

### Sources: PharmDash, Highly Specialised Drugs (S100) Program




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All data in this report are provisional and subject to future revision