

## **Australian HIV Observational Database (AHOD) data request**

**Requester: Industry**

**Date: April 2009**

**Purpose:**

The company is currently working on an expansion of the PBS listing for a specific antiretroviral. The results of the analysis will be used to help determine the treatment pathway of patients with HIV and the number of patients who will be eligible to receive the specific antiretroviral if PBS expansion occurs.

The following ad-hoc report is derived from the Australian HIV Observational Database (AHOD) up to 31<sup>st</sup> of March 2008. AHOD was established in 1999, and by the end of March 2008, 2667 patients had been enrolled from 27 sexual health clinics, specialist general practices or tertiary referral centres. As the majority of patients were enrolled by 2002, the cohort is currently very treatment experienced, and therefore the data need to be interpreted appropriately.

To produce the table below several assumptions were made; many are standard to all AHOD analyses.

These include:

Patients who commenced highly active antiretroviral treatment (HAART) prior to 1 January 1997 were excluded (as this relies heavily on retrospectively reported information).

Only combinations of greater than 14 day duration were counted

A regimen change was defined as having changed/dropped at least one ARV from the immediately preceding combination

These assumptions are specified throughout the document wherever relevant.

Any reporting of AHOD data need to appropriately acknowledge these assumptions.

**All data below exclude patients who commenced HAART before 1 January 1997**

**Question 1**

What proportion of the cohort is:

HAART treatment naive (defined as not yet received HAART treatment)

Treatment experienced but PI naive (defined as not having received a PI yet)

Early PI experienced (have received only one HAART regimen containing a PI)

Highly PI experienced (have received two or more regimens containing a PI)

	2001		2007	
	N	%	N	%
HAART treatment naive	231	19.9	146	14.1
Treatment experienced but PI naive	262	22.6	165	15.9
Early PI experienced	283	24.4	178	17.1
Highly PI experienced	385	33.2	549	52.9

**Assumptions made to determine the naïve population are as follows:**

HAART naïve patients are either those who: 1. never commenced ARV, and therefore to be included in the denominator for question 1 must have been enrolled in AHOD prior to 1 January 2002 (or 2008) and considered to be in active follow-up in 2001 or 2007 respectively (ie have their last visit date recorded after 1 January 2001 (or 2007)); and 2. HAART naïve patients who commenced HAART after 31 December 2001 (or 2007) had to have been enrolled into AHOD prior to 1 January 2002 (or 2008) and also considered in active follow-up in 2001 or 2007.

## Question 2

What proportion (%) received a protease inhibitor in their first HAART regimen?

- a) In patients whose **1st HAART regimen** was started before 1 January 2006
- b) In patients whose **1st HAART regimen** was started after 1 January 2006

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Year	HAART (with PI)		Total HAART
	N	%	
<=2005	679	47.7	1422
>=2006	27	24.5	110

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## Question 3

What proportion (%) received a protease inhibitor in their second HAART regimen?

- a) In patients whose **2nd HAART regimen**<sup>1</sup> was started before 1 January 2006
- b) In patients whose **2nd HAART regimen** was started after 1 January 2006

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Year	HAART (with PI)		Total HAART
	N	%	
<=2005	468	47.0	995
>=2006	50	32.3	155

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1. Second HAART regimen was defined as a new regimen where one or more of the ARVs differed to the regimen immediately prior (including dropping of an ARV).

#### Question 4

What protease inhibitor is most commonly used in patients who are previously PI naive (i.e. what is the protease inhibitor that patients use in their first PI-containing regimen)?

- a) In patients whose **1st PI regimen** was started before 1 January 2006, the protease inhibitor most commonly used in the 1st PI-containing regimen is:

PI	<=2005	
	N	%
Indinavir	293	36.22
Nelfinavir	242	29.91
<b>Total PI combinations</b>		<b>809</b>

- b) In patients whose **1st PI regimen** was started after 1 January 2006, the protease inhibitor most commonly used in the 1st PI-containing regimen is:

PI	>=2006	
	N	%
Atazanavir	24	53.3
Kaletra	16	35.6
<b>Total PI combinations</b>		<b>45</b>

### Question 5

What protease inhibitor is most commonly used in patients who have failed one prior PI (i.e. what is the protease inhibitor that patients use in their second PI-containing regimen)?

- a) In patients whose **2nd PI regimen**<sup>1</sup> was started before 1 January 2006, the protease inhibitor most commonly used in the 2nd PI-containing regimen is

PI	<=2005	
	N	%
Indinavir	105	25.7
Nelfinavir	99	24.2
<b>Total PI combinations</b>		<b>536</b>

1. Second PI regimen is the regimen where a new PI was commenced (defined as a PI that was not used in the immediately preceding regimen)

- b) In patients whose **2nd PI regimen** was started after 1 January 2006, the protease inhibitor most commonly used in the 2nd PI-containing regimen is:

PI	>=2006	
	N	%
Atazanavir	35	68.6
Kaletra	10	19.6
<b>Total PI combinations</b>		<b>74</b>

**Note for the following questions**

As the majority of patients in the AHOD are highly treatment experienced, data are provided overall (eg demographics of patients who are naive at any time point) and split by year (<=2005, and >=2006).

Second, the AHOD population from which the following tables are derived include only patients who **commenced** HAART at some time point after 1 January 1997

**Question 6**

Please provide the demographics of those patients in the cohort who are currently HAART treatment naive (i.e. not received HAART treatment yet)<sup>1</sup>

Parameter	N	Mean	STD	No. missing	Median	LQ	UQ
<b>Age by year cat</b>							
<=2005	1422	40.1	9.9	0	38.7	32.5	46.4
>=2006	110	43.9	10.2	0	43.5	36.2	48.9
<b>Age overall</b>	1532	40.3	10.0	0	39.0	32.8	46.6
<b>Years since diagnosis</b>							
<=2005	1377	5.3	5.0	45	4.2	0.4	9.0
>=2006	98	5.0	5.4	12	2.8	0.4	8.1
<b>Years since diagnosis (overall)</b>	1475	5.3	5.0	57	4.1	0.4	9.0
<b>CD4 by year cat<sup>2</sup></b>							
<=2005	1104	350	246	0	318	178	470
>=2006	92	322	219	0	272	181	395
<b>CD4 overall</b>	1196	348	244	0	310	180	461
<b>Viral load by yearcat<sup>2</sup></b>							
<=2005	1092	205730	449848	0	58150	10000	225000
>=2006	90	93080	210929	0	34250	2340	100000
<b>Viral load overall</b>	1182	197152	437250	0	55027	9200	201333

1. Naïve status is at the time just prior to commencing HAART.

2. CD4 and viral load are within 1 year prior to commencing HAART (if more than one measure available, then the measure closest to commencing HAART was used)

### Question 7

Please provide the demographics of those patients in the cohort who are currently PI naive<sup>1</sup>

Parameter	N	Mean	STD	No. missing	Median	LQ	UQ
<b>Age by year cat</b>							
<=2005	735	40.3	9.9	0	39.0	33.0	46.6
>=2006	91	45.0	10.3	0	43.5	37.1	52.7
<b>Age overall</b>	826	40.8	10.0	0	39.3	33.6	47.1
<b>Years since diagnosis</b>							
<=2005	711	5.8	5.1	24	4.7	1.0	9.7
>=2006	79	4.8	4.8	12	3.3	0.4	7.8
<b>Years since diagnosis (overall)</b>	790	5.7	5.1	36	4.5	0.9	9.5
<b>CD4 by year cat<sup>2</sup></b>							
<=2005	659	542	321	0	493	316	705
>=2006	79	420	201	0	360	280	550
<b>CD4 overall</b>	738	529	313	0	478	310	680
<b>Viral load by year cat<sup>2</sup></b>							
<=2005	657	21881	86586	0	399	50	1800
>=2006	79	10630	27854	0	50	49	134
<b>Viral load overall</b>	736	20673	82376	0	199.5	50	1487

1. PI naive HAART status is defined at the time just prior to commencing a HAART regimen including a PI.

2. CD4 and viral load are within 1 year prior to commencing HAART with a PI (if more than one measure available, then the measure closest to commencing the HAART was used)

**Question 8**

Please provide the demographics of those patients who are currently early PI experienced (have received only one HAART regimen containing a PI)

Parameter	N	Mean	STD	No. missing	Median	LQ	UQ
<b>Age by year cat</b>							
<=2005	1113	41.1	10.1	0	39.7	33.5	47.4
>=2006	139	44.4	9.8	0	43.6	37.2	50.3
<b>Age overall</b>	1252	41.5	10.1	0	40.2	34.0	47.6
<b>Years since diagnosis</b>							
<=2005	1089	6.2	5.2	24	5.5	1.3	10.2
>=2006	130	8.5	6.3	9	7.2	3.4	13.6
<b>Years since diagnosis (overall)</b>	1219	6.4	5.4	33	5.6	1.4	10.4
<b>CD4 by year cat<sup>1</sup></b>							
<=2005	971	542	311	0	500	310	735
>=2006	128	589	285	0	540	395	718
<b>CD4 overall</b>	1099	547	308	0	505	321	735
<b>Viral load by year cat<sup>1</sup></b>							
<=2005	954	16835	73666	0	398	50	1100
>=2006	129	1418	9565	0	49	40	50
<b>Viral load overall</b>	1083	14998	69394	0	130	50	800

1. Only CD4 and viral load measures during the PI containing HAART are included (if more than one measure available, then the measure closest to the stop date of that regimen (or last follow-up visit) was used)



**Question 9**

Please provide the demographics of those patients who are highly PI experienced (have received two or more regimens containing a PI)

Two tables are provided, the first where two PIs have been used, and the second with 3 PIs

**Table 9a:** Demographics when patients have received two PI containing regimens)

Parameter	N	Mean	STD	No. missing	Median	LQ	UQ
<b>Age by year cat</b>							
<=2005	802	42.5	9.9	0	41.3	35.2	49.1
>=2006	121	48.1	10.8	0	45.6	40.7	55.4
<b>Age overall</b>	923	43.3	10.2	0	41.8	35.9	50.0
<b>Years since diagnosis</b>							
<=2005	790	7.7	5.2	12	6.9	3.1	11.7
>=2006	119	10.8	6.3	2	9.5	5.8	15.9
<b>Years since diagnosis (overall)</b>	909	8.1	5.5	14	7.3	3.5	12.1
<b>CD4 by year cat<sup>1</sup></b>							
<=2005	704	539	330	0	490	297	720
>=2006	109	583	329	0	510	380	730
<b>CD4 overall</b>	813	545	330	0	500	312	720
<b>Viral load by year cat<sup>1</sup></b>							
<=2005	700	17498	84480	0	87.5	50	1050
>=2006	110	2781	19034	0	49	40	50
<b>Viral load overall</b>	810	15500	78999	0	50	49	550

1. Only CD4 and viral load measures during the PI containing HAART are included (if more than one measure available, then the measure closest to the stop date of that regimen (or last follow-up visit) was used)

**Table 9b:** Demographics when patients have received at least 3 PI containing regimens)

Parameter	N	Mean	STD	No. missing	Median	LQ	UQ
<b>Age by year cat</b>							
<=2005	524	43.9	9.9	0	42.6	36.6	50.2
>=2006	114	49.4	10.4	0	47.3	42.1	54.6
<b>Age overall</b>	638	44.9	10.2	0	43.5	37.6	51.7
<b>Years since diagnosis</b>							
<=2005	520	8.9	5.2	4	8.5	4.6	12.9
>=2006	112	11.7	5.4	2	10.3	7.6	15.4
<b>Years since diagnosis (overall)</b>	632	9.4	5.3	6	9.0	5.1	13.6
<b>CD4 by year cat<sup>1</sup></b>							
<=2005	466	522	306	0	482	290	702
>=2006	107	624	336	0	600	379	809
<b>CD4 overall</b>	573	541	314	0	500	310	730
<b>Viral load by year cat<sup>1</sup></b>							
<=2005	463	17318	72266	0	50	49	910
>=2006	108	2145	13010	0	49	40	50
<b>Viral load overall</b>	571	14448	65574	0	50	49	400

1. Only CD4 and viral load measures during the PI containing HAART are included (if more than one measure available, then the measure closest to the stop date of that regimen (or last follow-up visit) was used)