napwha national association of people with HIV australia

Medicare ineligible PLHIV in Australia

An analysis of new data with recommendations for systemic improvements

May 2019

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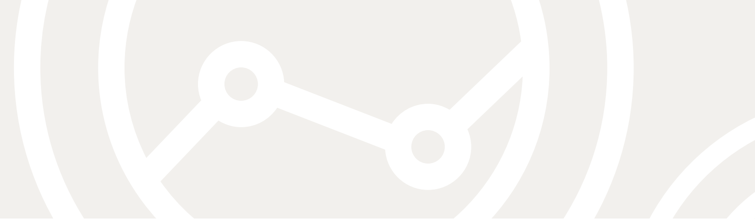

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About NAPWHA

The National Association of People with HIV Australia (NAPWHA) is Australia's peak non-government organisation representing community-based groups of people living with HIV (PLHIV). NAPWHA's membership of national networks and state-based organisations reflects the diverse make-up of the HIV-positive community and enables NAPWHA to confidently represent the positive voice in Australia. NAPWHA's vision is of a world where all people with HIV live their lives to their full potential, in good health and free from discrimination.

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Background

In 2007, a consultation between the National Association of People with HIV Australia (NAPWHA), the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM), HIV s100 prescribers nationwide and members of the Australian Health Protection Committee's Blood Borne Viruses and Sexually Transmissible Infection Standing Committee (BBVSS) estimated the number of people living with HIV (PLHIV) who are Medicare ineligible in Australia at between 250 and 300[1].

The Australian HIV Observational Database Temporary Residents Access Study (ATRAS) commenced In November 2011 and ran until 2015. ATRAS provided compassionate access to antiretroviral (ARV) treatment for up to four years to 180 HIV-positive PLHIV who were temporary residents in Australia and were ineligible for Medicare[2]. It was the first study in Australia to systematically collect visa and HIV-related information on this sub-group of Medicare ineligible PLHIV[3].

The key findings of ATRAS were:

- Providing access to the full range of PBS ARV treatments to Medicare ineligible PLHIV:
    - Increased the proportion of this cohort with an undetectable viral load from 47% at baseline to 89% after one year to 94% after two years[4] and
    - The average CD4 cell count increased from 376 cells/mm (SD 227) at baseline to 475 cells/mm (SD 198) after one year and to 534 cells/mm (SD 235) after two years[5].
- By the time the study finished in 2015, more than half the participants no longer required ARV provision through ATRAS. 75% of these had become eligible for Medicare[6].
- Mathematical modelling estimated that the subsidised provision of ART to this group would avert 81 new transmissions over a five-year period and would be broadly cost-neutral[7].

Over the course of the study, two cross-sectional surveys of HIV s100 prescribers were conducted to estimate the numbers of HIV-positive patients who were temporary residents and ineligible for Medicare. After one year it was estimated that there were 450 Medicare ineligible PLHIV in Australia[8]. After two years it was estimated that there were 464[9].

In November 2017, NAPWHA presented data to the BBVSS from the Australian pharmaceutical companies who were providing ARV access programs for Medicare ineligible PLHIV. At that date, the number enrolled in ARV access programs was estimated at 760 patients across Australia. This was based on data provided by three pharmaceutical companies only (Gilead Sciences, MSD Australia, and ViiV Healthcare Australia).

Two companies, ViiV Healthcare Australia and Gilead Sciences, were supplying the majority of these patients (n=733), and both companies stated that this represented a 100% increase in their respective program enrolments since 2016. The data did not include access to data by jurisdiction, but companies confirmed at the time that the main extent of distribution covered three states (NSW, Victoria and Queensland).

1 Petoumenos, K. (2013) The Australian HIV Observational Database Temporary Residents Access Study (ATRAS) In *One year follow-up*, The Kirby Institute, UNSW Sydney p. 5-6
2 Ibid. at p.2
3 Ibid.
4 Petoumenos, K. (2015) The Australian HIV Observational Database Temporary Residents Access Study (ATRAS) In *Two year follow-up*, The Kirby Institute, UNSW Sydney p. 2-3
5 Ibid at p.13
6 Ibid at p.3 and p.19
7 Ibid. at p.3
8 Op Cit at note 1, p.3
9 Op Cit at note 4, p.3

In September 2018, the BBVSS jurisdictional members agreed to investigate ARV provision to Medicare ineligible PLHIV in their respective jurisdictions. In collaboration with the Kirby Institute, data was provided to NAPWHA for analysis that indicated how many people were receiving ART treatments via alternative access arrangements; including personal importation, direct state-funded provision through hospitals and clinics and through pharmaceutical company compassionate access schemes.

Introduction

The Australian Government, through the Pharmaceutical Benefits Scheme (PBS) Highly Specialised Drugs (s100) program provides Medicare eligible PLHIV in Australia with fully-subsidised ARV treatment. This means that the cost of treatment is paid by the Commonwealth government. However all patients are required to make a copayment. The current patient copayment for prescriptions is $40.30 (concessional $6.50)[10]. In NSW the State government pays the copayment on behalf of the PLHIV with the effect that ARV medications are currently free in NSW. Patients who spend more than $1550.70 (concessional $390) on prescription medicines in a calendar year can access a safety net scheme which reduces the cost of further prescriptions to $6.50 per script, or free for concession card holders[11]. To be eligible to receive ARVs under this scheme, a person needs to be entitled to a Medicare card. Australian citizens and permanent residents are therefore able to access their ARVs equitably[12].

Persons ineligible for Medicare include temporary residents who are approved for non-permanent entry into Australia under various visa arrangements, including student, business, and employer-sponsored work visas. Generally, the initial visa period is for more than three months but not more than four years. Visa renewals are common among those who are awaiting decisions regarding permanent residency applications. In this context, it is notable that entry to Australia on a temporary visa often leads to permanent residency[13].

During the 2017-2018 financial year, there were 378,292 student visas, 180,459 temporary resident visas, 64,470 skilled migrant visas and 210,456 working holiday maker visas granted[14]. As HIV testing is not required prior to entry for most (although required for an application for permanent residency), the exact number of temporary residents who were HIV-positive prior to arrival is unknown[15].

Although living in Australia legally, HIV-positive temporary residents are not entitled to the same level of care as HIV-positive permanent residents[16].

Prior to the ATRAS study, Medicare ineligible PLHIV sourced ARVs from their country of origin or ordered (mostly generic) ARV online from overseas suppliers. A few paid the full unsubsidised price, a small number participated in Australian clinical trials, but many received ARVs via various compassionate access programs[17]. Most of these were ad hoc arrangements administered through clinics and hospitals and relied heavily on the good grace of the pharmaceutical industry.

Since the ATRAS study ended in 2015, through the BBVSS, various access systems have been put in place by State and Territory health departments.

The Australian Capital Territory (ACT) and Western Australia (WA) have binding legislation granting Medicare ineligible PLHIV access to treatment and care at no cost to the positive person. In practice this means that in WA the cost of ARV is met by the dispensing hospital or recouped from health insurances where possible. In the ACT at least some of this cohort is provided for through pharmaceutical company compassionate access schemes. It is unclear whether the ACT health system provides any ARV to Medicare ineligible temporary residents.

10 http://www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee
11 http://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_5_Explanatory_Notes
12 Op Cit at note 1, p 4
13 Ibid.
14 https://www.homeaffairs.gov.au/reports-and-pubs/Annualreports/2017-18/04-annual-report-2017-18-part-2.pdf at p.52
15 Op Cit at note 1, p.5
16 Ibid at p.4
17 Ibid at p.5

The Northern Territory and South Australia both have clinics which currently provide treatment for HIV at no cost to the person with HIV regardless of Medicare status (however, there is no obligation under legislation for the clinics to provide the treatment in this manner).

New South Wales has a policy directive allowing Medicare ineligible PLHIV access to ARVs at no cost when the medical practitioner decides it is necessary for adherence and to protect public health. In practice and in the majority of cases, NSW clinicians contact one of two pharmaceutical companies directly to organise access to ARVs via their compassionate access schemes. Some ARV dispensers in NSW charge the copayment regardless of the source of the ARV.

Queensland, Tasmania and Victoria do not have any formal legislation, policy or guidelines. In practice, Victoria provides Medicare ineligible PLHIV with ARVs at several main clinics who organise access through direct negotiation with two main pharmaceutical companies. In Queensland, the individual clinicians of PLHIV who are ineligible for Medicare organise treatment access on the individual's behalf either through direct relationships with pharmaceutical companies or by assisting them to personally import ARVs. In Tasmania, clinics generally utilise the pharmaceutical company compassionate access schemes as well, with a minority of people being funded through the State health budget.

This jurisdictional variation means that there is no equity of ARV access across Australia. In some jurisdictions, access to the full suite of antiretroviral treatments available on the PBS is available; while in others, access is limited to those ARVs provided by just two pharmaceutical companies. This raises issues around appropriate drug choice in complex cases where first-line treatment options are not appropriate[18].

The current system has several weaknesses. Numbers of Medicare ineligible PLHIV on temporary visas are determined by the Commonwealth Government Department of Immigration, yet it is State and Territory governments, with limited resources, that are responsible for ART provision to this group.

To date, the philanthropic commitment of the pharmaceutical industry to ensure treatment access to this group has been considerable and their ongoing commitment must be commended. However, consistently increasing numbers of Medicare ineligible PLHIV raises sustainability questions that go beyond just the supply of ARV; in particular the considerable administrative and logistical burden associated with ARV supply management. In addition, some jurisdictions that have so far provided for this cohort through their departments of health, have recently expressed a desire to access ARVs through pharmaceutical companies. This would result in another significant jump in numbers accessing pharmaceutical company compassionate access schemes.

Maintaining continuity of care would be a significant challenge if the situation arose where those currently receiving treatment through these schemes had to rapidly transition to alternative State/Territory-based treatment access arrangements . This represents a risk to Australia's HIV response.

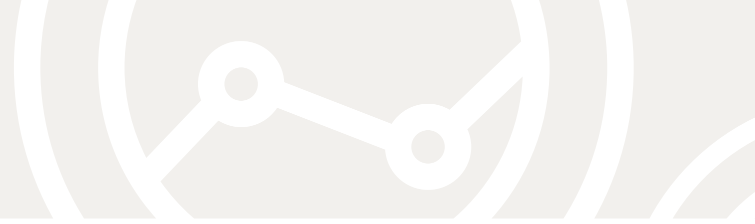
The current system places significant burden on the prescribing clinician. Considerable clinic time is spent arranging access via individual relationships with pharmaceutical companies. And most significantly, they are unable to choose from the full range of ARVs available to their patients who are eligible for Medicare. There are concerns that direct relationships between doctors and pharmaceutical companies are influencing prescribing patterns; particularly where ease of ARV availability varies.

As the current system cannot be widely promoted to the cohort it exists to serve, it is likely that campaigns that encourage regular testing, early diagnosis and immediate treatment are less effective for those within Medicare ineligible communities. This hinders the ability of the Australian HIV response to end new transmissions; and is arguably a contributing factor to the high proportions of late diagnoses in some overseas born populations[19].

Late diagnosis often manifests as an emergency presentation to a public hospital with one or more of the opportunistic infections or tumors associated with Acquired Immune Deficiency Syndrome (AIDS) and leads to further serious health complications. As most Medicare

18 http://arv.ashm.org.au/virologic-failure/

19 Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia: annual surveillance report 2018. Sydney: Kirby Institute, UNSW Sydney; 2018. p. 41



ineligible PLHIV transition to Medicare eligibility within two to three years[20], avoidable sub-optimal health outcomes will become more complex, more difficult, and more expensive to treat once Medicare eligibility is obtained.

Accessing ARVs from overseas poses serious issues for prescribing clinicians. Cost influences the individual's choice of drug. Many ARVs currently considered optimal are not available in generic form, while some are not available in countries to which PLHIV may have to return. Ordering from overseas often results in treatment interruptions due to late ordering or stock supply issues leading to additional frequent unscheduled treatment visits[21].

This report attempts to draw together several years' worth of data from the main pharmaceutical industry suppliers of compassionate access ARVs in Australia and combines this with, for the first time, data from the State and Territory jurisdictions to produce the most accurate estimate to-date of the number of Medicare ineligible PLHIV in Australia.

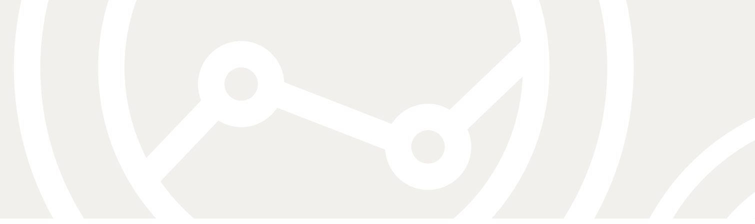
We now estimate that, as of October 2018, there were a **total of 763** Medicare ineligible PLHIV accessing HIV treatment and care through all access mechanisms in Australia. Of these, between 623 and 660 were accessing ARV treatment and care through pharmaceutical company compassionate access systems. This total (n=763) represents approximately 2.8% of all people with HIV in Australia[22].

Eliminating HIV transmission in Australia as well as minimising the personal and social impacts of HIV infection is a key focus of the current 8th National HIV Strategy[23]. The strategy outlines a goal of virtually eliminating new HIV transmissions in Australia by 2022. This includes a series of targets: increasing to 95% the proportion of PLHIV in Australia who are diagnosed, to 95% the proportion of diagnosed PLHIV on treatment, and to 95% the proportion of PLHIV on treatment who achieve an undetectable viral load. Achieving these targets necessarily involves the provision of ARVs to all people in Australia with HIV, including those who are ineligible for Medicare[24].

In Australia, as in other developed countries, most HIV-positive people on effective ARVs are able to achieve and maintain an undetectable viral load. HIV is no longer a terminal illness but rather a chronic condition, both treatable and manageable[25]. People with HIV now have vastly improved long-term clinical outcomes[26], AIDS-related conditions are far less common and death rates from AIDS have reduced so significantly that they are no longer recorded. Further, we now have evidence that shows that maintenance of an undetectable viral load makes the transmission of HIV through sexual contact effectively impossible[27]. Achieving universal ART coverage therefore has significant public health implications[28]. In particular, significantly reducing, and in many cases effectively eliminating, the risk of HIV transmission completely. Further, the recent listing of Pre-Exposure Prophylaxis on the PBS means that HIV negative people also have a treatment intervention that prevents HIV transmission. HIV testing has also become more commonplace and accessible in Australia. Over the last few years, numerous community-based rapid HIV testing sites have sprung up and a home-test for HIV has been approved by the TGA.

Despite a reduction in new HIV diagnosis in Australia in 2017, not all populations are benefiting equally from these new scientific advances in HIV prevention, diagnosis, treatment and care. Late diagnoses and undiagnosed HIV are still significantly more prevalent in certain populations of those born overseas[29]. Recent data from NSW, while showing a decline in new HIV transmission rates overall among Men Who Have Sex with Men (MSM), showed no decrease in new transmissions in overseas born MSM[30]. These data underline an urgent need to do better in the provision of equitable access to treatment and care for marginalised and hard to reach populations of people with HIV such as those ineligible for Medicare.

20 ATRAS
21 Op Cit at note 1 at p.5
22 Kirby surveillance figure for 2017 is 27545 PLHIV in Aus; Op Cit at note 16, p. 49
23 http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1/$File/HIV-Eight-Nat-Strategy-2018-22.pdf
24 Op Cit at note 1 at p.7
25 Ibid at p.6
26 Ibid
27 https://www.preventionaccess.org/consensus
28 Op Cit at note 1 at p.7-
29 Op Cit at note 16 at p.44-47
30 NSW HIV Strategy 2016-2020, Quarter 4 and Annual 2018 Data Report. Available at: https://www.health.nsw.gov.au/endinghiv/Publications/q4-2018-and-annual-hiv-data-report.pdf



Latest Data

This report is based on new data provided by two pharmaceutical companies, Gilead Sciences and ViiV Healthcare, and supported by estimates from State and Territory jurisdictions up to March 2019. The data provided has been collected from the individual companies for drug supply over varying periods of time, including the actual number of "active" (any patient who has had drug orders placed with the company within the previous six months) PLHIV patients being supplied access to ARVs at no cost to themselves at March 2019.

Due to variation across company data records, there is incomplete or non-matched data categories available, which means not all information can be compared for analysis.

Nevertheless, this data is the most complete and current data available for the purpose of monitoring access to ARVs through pharmaceutical company supply for those PLHIV in Australia who are not eligible for Medicare and the PBS for their health care.

NAPWHA and the Kirby Institute provide this data to support change on a national level as the limitations of the current arrangements through pharmaceutical company access are problematic.

These limitations include:

- The treatment options to PLHIV are largely limited to ARV combinations available by just two pharmaceutical companies.
- A lack of information on prescribing patterns and patient demographics prevents any meaningful analysis of cases across the country.
- Absence of regular, standardised comparative data from other ARV supply sources (Public Health arrangements across jurisdictions, private importation supply) limits the understanding of population size and trends across time.
- Lack of standardised and consistent data across pharmaceutical companies' compassionate access schemes.

Most recent estimates of PLHIV receiving ARVs through pharmaceutical access programs – reported by Gilead Sciences and ViiV Healthcare

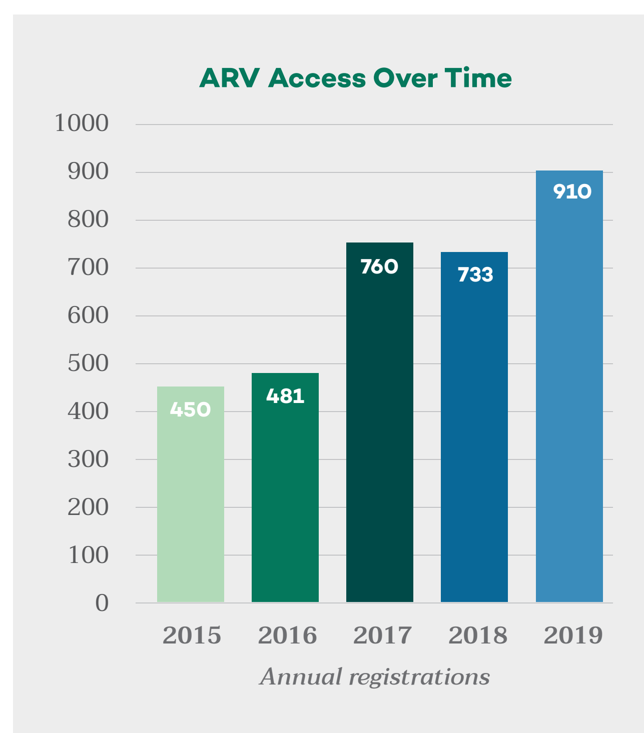
In March 2019, the registered number of PLHIV receiving ARVs through two Australian companies (Gilead Sciences and ViiV Healthcare) was 910 patients in total.

The largest proportion of patients being supplied ARVs by the companies were based in NSW and representing over half of the population registered (N=491, 54%). Twenty-nine percent were from Victoria, 11% from QLD, less than 2% for WA and NT, and less than 1% from the ACT, TAS and SA. (**Table 1**).

Table 1 Total numbers of PLHIV receiving ARVs in Australia through Gilead and ViiV supply as reported in March 2019

	Number	Proportion
NSW	491	54
VIC	268	29
QLD	99	11
WA	14	2
NT	17	2
ACT	8	1
SA	4	0
TAS	9	1
TOTAL	**910**	**100**

Figure 1 PLHIV accessing ARVs through Industry Access Programs 2015 to 2019*



* 2015 and 2016 estimates come from ATRAS data. Data up to 2017 include reports provided by MSD. 2018 and 2019 include Gilead and ViiV reports only.

Trends over time

Data summaries provided by Gilead and ViiV show an increase in access program registrations through both companies, despite what appears to be a slowing down in 2018. (**Figure 1)**

Discontinuations over time advised by companies have suggested a number of patients have either returned to country of origin or transitioned to Medicare eligibility within Australia (although the reporting of discontinuations is often incomplete). "Active" status of PLHIV is determined as any patient who has had drug orders placed with the company within the previous six months, so it should be noted that a number of PLHIV may still be in Australia, but may be not be seeking specific ARV drugs for other reasons.

It should also be noted that neither company shares data, so duplication of patients across two access programs may also be occurring. In this scenario, only the HIV s100 prescriber could confirm if this is the case. However, data from the Australian HIV Observational Database (AHOD) estimate a 10% – 15% potential overlap (co-use) of ViiV and Gilead ARVs in the most recent AHOD reporting period (March 2018) .

GILEAD report – updated March 2019

The current access program run by Gilead (**Table 2**), represents 39% of the ARVs supplied to Medicare ineligible PLHIV in Australia.

Since 2016, the overall number of patients accessing their program was 684. The current number increased from 241 patients in July 2018 to 360 patients in March 2019 (an increase of approximately 50%). Correspondence from Gilead to NAPWHA also indicated that since August 2018 only 4 patients were reported to Gilead to have become Medicare eligible.

Table 2 Gilead Access Supply in Australia for PLHIV not eligible for PBS supply of ARVs (2016 – 2019)

	OVERALL Program (2016 – 2019)	Current numbers @ July 2018	Current numbers @ March 2019
TOTAL	**684**	**241**	**360**
NSW	353	130	175
VIC	202	71	110
QLD	89	31	49
WA	15	0	13
NT	15	7	6
ACT	3	-	3
SA	1	-	1
TAS	6	2	3

ViiV Report – updated March 2019

The current access program run by ViiV **(Table 3)** represents 61% of the ARVs supplied to Medicare ineligible PLHIV in Australia.

Since 2011, the overall number of patients accessing their program was 878. In July 2018, a total of 492 patients were deemed active (having received supply in the last 6 months) and this number rose to 550 in March 2019 - an overall increase of approximately 12%.

Table 3 ViiV Access Supply in Australia for PLHIV not eligible for PBS supply of ARVs (2011 – 2019)

	OVERALL Program (2011 – 2019)	Current numbers @ July 2018	Current numbers @ March 2019
TOTAL	**878**	**492**	**550**
NSW	-	284	316
VIC	-	144	158
QLD	-	43	50
WA	-	1	1
NT	-	9	11
ACT	-	6	5
SA	-	1	3
TAS	-	4	6

Most recent estimates of PLHIV receiving ARVs through pharmaceutical access programs and other arrangements – reported by State and Territory

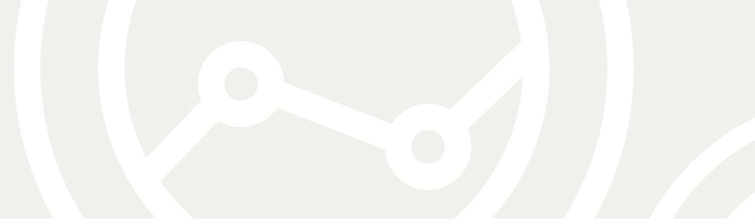
During October and November 2018, NAPWHA communicated with all eight States and Territories seeking information on the number of Medicare ineligible PLHIV and of those, how many were accessing ARVs through pharmaceutical access programs or through alternatively state-funded programs. **Table 4** below is a breakdown of the figures reported by each of the jurisdictions.

Table 4: Data of estimated Medicare ineligible PLHIV reported by state and by access program (as at Oct-Nov 2018)

Jurisdiction	Total estimated HIV positive Medicare ineligible	Number provided ART via pharmaceutical access programs	Proportion of patients Medicare ineligible (n=763)
NSW	368	357	48%
VIC	226*	226	30%
QLD	43	32	4%
NT	14	14	2%
ACT	--	--	--
TAS	10	8	1%
SA	30	0	0%
WA	72	1	0%
TOTAL	**763**	**638**	84%

* Number accessing ART through other sources not reported by VIC Health

Of the estimated 763 Medicare ineligible PLHIV in November 2018 as reported by the jurisdictions, 84% were receiving ARV via the pharmaceutical access program. In only two jurisdictions, WA and SA, was ARV supplied almost without exception through a state-funded scheme (N=100), whilst the remaining less than 20 patients accessed ARV from overseas. However, updated data from Gilead in March 2019 which report an increase in WA numbers from 0 in 2018 to 13 in 2019, suggests that more patients in WA are accessing ARV via the pharmaceutical access program.



Overall estimates of number of Medicare ineligible PLHIV accessing ARV through the pharmaceutical access program

Based on the March 2019 data reported by Gilead and ViiV, a total of 910 PLHIV were accessing ARV via pharmaceutical access programs. Of these, we estimate 10-15% would be accessing ARV from both companies (according to AHOD estimates of overlap in Gilead and ViiV in individual regimens). This translates to between 773 and 819 unique individuals accessing ARV via the pharmaceutical programs as of March 2019 as reported by GIlead and ViiV.

It is difficult to confirm these numbers through pharmaceutical company reporting, as the latest information is from two companies only, although they may make up more than 95% of the current ARV market. Anecdotally, we know that some ARV is provided compassionately by other pharmaceutical companies.

Data reported back from the jurisdictions in October-November 2018 suggested that of the total 763 PLHIV who are Medicare ineligible, 638 were reported to be receiving ARV via the pharmaceutical access program. For the same period, data by Gilead and ViiV report 733 individuals receiving ARV from either company. After accounting for a 10-15% overlap in patients, the estimated number of unique individuals receiving ARVs from these companies is somewhere between 623 and 660.

The concordance between the jurisdictional data (n=638) on PLHIV receiving ARV via pharmaceutical access programs and the data reported by ViiV and Gilead (between 623 and 660) during the similar reporting period is reassuring.

These estimates from both the jurisdictions and from Gilead and ViiV are to date the best estimates of the number of individuals receiving ARV via the pharmaceutical access program (between 623 and 660 during October and November 2018) and a total of 763 of PLHIV who are medicare ineligible (and accessing treatment) during the same period.

However, we have seen a 20% increase in numbers accessing ARV from Gilead and ViiV access programs between October 2018 and March 2019 (N=910). It is unclear what this increase reflects or whether it in fact translates to a increased estimate of the current (2019) numbers of individuals accessing ARV via pharmaceutical companies.

The number of PLHIV who are Medicare ineligible however remains only as accurate or as complete as the information reported to the jurisdictions – and can only ever be an estimate of the number of Medicare ineligible patients who are seeking access to ARV. The undiagnosed or untreated Medicare ineligible population remains hidden.

Data limitations and what information is needed in the future

Since the end of the ATRAS study, the only data available to NAPWHA has been through incomplete surveys of HIV s100 prescriber sites across some jurisdictions, or through limited reports from some pharmaceutical companies. Final numbers have not been able to be confirmed across all companies that list ARV drugs on the PBS in Australia. The latest data is now only reported through two companies, and has been provided in different formats across different time periods. This is a significant limitation for assessing overall trends across time and by region.

The reporting by the jurisdictions has helped to better estimate the number of Medicare ineligible PLHIV who are accessing ARV via pharmaceutical access programs compared to other state-funded programs. States were asked to provide estimates for the number of Medicare ineligible PLHIV accessing ARV via pharmaceutical access programs, via overseas/personal import, via clinical trials or other state-funded programs. Whilst all states and territories (except the ACT) could report numbers receiving ARV via pharmaceutical companies, there was variation in ability to report numbers by the other categorisations. Also, reporting is compiled from different sources within each jurisdiction, with no standard mechanisms. Not all clinics are required to provide Medicare eligibility status or treatments information on their HIV positive patients to their jurisdictional health departments.

In the past nine months we have seen a considerable increase (20%) in the proportion of patients receiving ARV via the ViiV and Gilead programs (12% and 50% respectively). It is unclear what this increase may be attributed to. It may be due to more PLHIV who are Medicare ineligible being 'moved' over to the pharmaceutical access programs. Alternatively, Medicare ineligible PLHIV could be presenting to services more often because of a combination of testing or awareness of treatment access via such programs or perhaps there is a delay in reporting tof the individuals no longer requiring ARV through these programs.

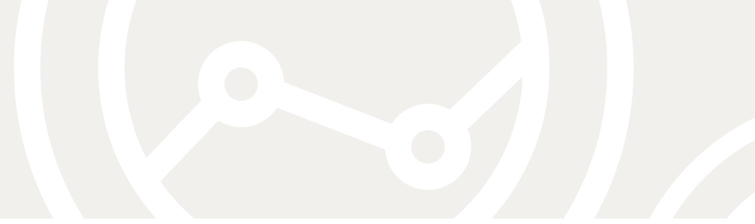
The significantly higher increase in the proportion of patients receiving compassionate ARV access through one company in particular highlights a need to better understand the relationship between the ease or difficulty of organising treatment access and prescribing patterns.

Although we perhaps have the best estimate to-date of the number of Medicare ineligible PLHIV accessing ARV via compassionate access programs, considerable data limitations remain.

We continue to lack information on prescribing patterns and patient demographics. This prevents any meaningful analysis of cases across the country. Absence of accurate comparative data from other ARV supply sources, namely public health arrangements and private importation supply, limits our understanding of population size and trends across time. There also continues to be a lack of standardised and consistent data across pharmaceutical companies' compassionate access schemes.

Recommended data to be consistently reported:

- ALL Pharmaceutical companies need to regularly report the number of 'active patients' receiving ARV via their access programs with a standardised definition of 'active patient', standardised reporting periods and standardised data fields.
- ALL States and Territories need to monitor all their Medicare ineligible PLHIV and whether they are receiving ARV via pharmaceutical access programs, state-funded programs or personal importation
- Additional standardised demographic information including age, gender, country of origin and visa status is required (from both companies and jurisdictions) to compare across states and programs which will enable the best estimates of access and need. Adequate data protections must be in place to ensure the safety of vulnerable populations of PLHIV.



- Commencement and cessation times need to be recorded in order to better understand the length of time individuals are accessing ARV via the various programs, and the reasons for termination

Clearly, these statistics would be better maintained centrally on a national level via a standardised form maintained by a federal body or national research centre.

It is important to monitor Medicare ineligible PLHIV in order to accurately estimate the overall number of PLHIV on ARV in Australia. This estimate is used for surveillance and monitoring purposes in the Australian HIV diagnosis and care cascade[31]. This cascade tool is used to assess whether people are receiving adequate care and treatment on a population level. Maximising the level of HIV treatment is important for reducing HIV transmission. The negative public health implications of having an unmonitored cohort of HIV positive individuals in Australia that experience significant barriers to accessing appropriate care and treatment are considerable.

General points

Data reported by NSW Health showed 97% of Medicare ineligible PLHIV in NSW are receiving their treatment via pharmaceutical company compassionate access programs (Table 4).

From the most recent estimates provided by ViiV Healthcare and Gilead Sciences more than 60% of pharmaceutical company compassionate access in NSW is provided via just two clinics; Sydney Sexual Health and the Albion Centre.

Data reported from the Victorian Department of Health and Human Services showed that 91% of Medicare ineligible people accessing ARV through pharmaceutical company compassionate access programs in Victoria did so via just one clinic; Melbourne Sexual Health.

The pharmaceutical company compassionate access provided through these three sites (Sydney Sexual Health, Melbourne Sexual Health and the Albion Centre) represents 55% of the total number of Medicare ineligible PLHIV connected to care in Australia (n=763).

31 Op Cit at note 16 at p.57

According to jurisdictional data 91% of pharmaceutical compassionate ARV supply is delivered to PLHIV living in NSW and Victoria (Table 4).

78% of all Medicare ineligible PLHIV are accessing care in NSW and Victoria (Table 4).

If NSW and Victoria were providing ARV supply solely through public health arrangements it would represent 594 patients for ongoing ARV treatment access costs, through the respective state-based public health systems (Table 4).

In the absence of ongoing pharmaceutical supply of ARVs to PLHIV who are not able to access the PBS, there would be a significant issue for predominantly public health clinics and hospitals across Australia, and especially within NSW and Victoria. In this circumstance maintaining continuity of care may prove challenging.

The role of the Commonwealth Government

The number of people in Australia on temporary visas is determined by the Commonwealth government. Yet, it is the State and Territory governments that are currently responsible for managing the public health risk associated with untreated PLHIV who are Medicare ineligible. The Commonwealth government has the power to manage the public health risk posed by communicable diseases and indeed does so in the case of tuberculosis, for example.

The Commonwealth government also regulates the conditions associated with the grant of a temporary visa. For example, the Commonwealth requires all international students to obtain Overseas Student Health Cover (OSHC) as a requirement of their visa[32]. However, coverage for HIV medicines is limited. OSHC policies currently limit pharmaceuticals benefits for out-patients at $50 per pharmaceutical item, with a maximum benefit of $300 per calendar year per single membership[33].

32 http://www.health.gov.au/internet/main/publishing.nsf/content/overseas+student+health+cover+faq-1

33 http://www.health.gov.au/internet/main/publishing.nsf/Content/6E337D28A15BB2CBCA257BF000206297/$File/Deed%20for%20the%20Provision%20of%20Overseas%20Student%20Health%20Cover.pdf

Appropriate regulation would ensure that 1) approved Health Cover insurance is required for, and affordably available to, all Medicare ineligible temporary residents in Australia and 2) HIV treatment and care is included in all approved Heath Covers. This would remove barriers to treatment access for this group as well as reducing the long-standing problem of insurance discrimination against HIV positive people.

NAPWHA supports HIV screening before arrival in Australia to ensure appropriate connection to clinical and peer based services. It must be noted that HIV screening prior to arrival in order to prevent HIV positive immigration is not a public health solution. Medicare ineligible temporary residents who seroconvert after arrival in Australia would continue to face the same systemic barriers to appropriate treatment and care.

Finally, an endorsement from the Commonwealth Government Australian Health Protection Principal Committee (AHPPC) would help to guide policy formulation and implementation across jurisdictions to optimise health outcomes and protect public health. Such an endorsement would state the principle that access to ARVs is a public health issue and that all people with HIV in Australia, regardless of Medicare status, should receive equitable and affordable access to all HIV testing services and the most appropriate HIV treatment and care.

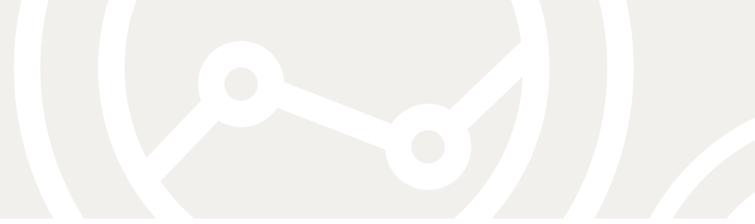
Testing, treatment, care and access for PLHIV ineligible for Medicare

The provision of care for PLHIV who are ineligible for Medicare is broader than just the provision of ARV. Clinical management, testing and regular monitoring are all required to achieve optimal health outcomes and to maximise the potential for maintaining an undetectable viral load; for individual health and as a public health response.

These elements of patient care should remain with the jurisdictions as the majority of PLHIV ineligible for Medicare already access services through publicly run clinics. This approach is also advantageous in addressing the need identified above for regular, standardised data collection.

The Medicare ineligible status of many temporary residents means that they do not access medical services with the same frequency as the permanently resident population of Australia. This is in part because of the considerable associated unsubsidised costs. Fear of disclosure or discrimination may also make people reluctant to access their health insurance or present to services. In the case of international students, many of whom depend on financial support from families back home, medical costs associated with HIV testing, treatment and care may act as a form of disclosure; not just in relation to HIV status but also sexuality. It may be the case that awareness among temporary residents of services available for HIV testing, treatment and monitoring is low.

Home HIV testing is likely to be an attractive option for this cohort, given the perceived and actual barriers to accessing health services they experience. Without the widespread understanding that HIV testing and treatment services are available to Medicare ineligible PLHIV, this group will be significantly less likely to present for confirmatory testing and appropriate treatment.



Summary

The current system does not work for PLHIV, clinicians, industry partners or State/Territory governments and is in urgent need of review. Medicare ineligible PLHIV should have the same access to HIV treatment and care as other PLHIV in Australia, without additional barriers.

A solution is required that allows clinicians to prescribe to all PLHIV in Australia from the entire suite of ARV available on the PBS without the additional burden of direct negotiation with pharmaceutical companies. This solution would facilitate community-based organisations to promote the availability of HIV treatment and care to Medicare ineligible PLHIV.

An unmonitored cohort of HIV positive individuals who are experiencing significant barriers to appropriate care and treatment presents considerable public health implications. Improved, regular and standardised data collection from the State and Territory jurisdictions and pharmaceutical companies is urgently required to better understand this population of PLHIV and their doctors' prescribing patterns. For this to happen, Commonwealth leadership and coordination is required.

The commitment of the pharmaceutical companies that facilitate compassionate access to ARV for this population has long been a crucial piece of Australia's HIV response. Maintaining this commitment into future will be vital to achieving the virtual elimination of HIV transmission in Australia by 2022.

However, the lack of a formal system through which Medicare ineligible PLHIV can access equitable treatment and care has meant that the negative consequences of alternative, informal and work-around systems have been visited on these most vulnerable PLHIV. People in this situation are amongst the least able to assert their right to appropriate care and treatment. Thus, it is an important principle that the appropriate philanthropic commitments from industry be negotiated directly between the Commonwealth government and the pharmaceutical industry itself. Cost-sharing arrangements between stakeholders would ensure that Medicare ineligible PLHIV would have the same access as Medicare eligible PLHIV and would not experience treatment interruptions, uncertain ARV access or delayed treatment commencement.

Leadership from the Commonwealth government is needed to assist pharmaceutical companies to coordinate and align their positions on compassionate access to ARV for Medicare ineligible PLHIV. Formalising predictable and consistent philanthropic financial contributions from industry (in accordance with market share) can provide certainty and enable appropriate business planning. Provision by the Commonwealth government to the full range of HIV treatment and care to this finite cohort of temporary residents with HIV could then take place with appropriate contributions from those profiting the most from ARV sales. This would remove the problematic interface between clinicians and pharmaceutical companies and provide them the same unbiased treatment options enjoyed by permanent residents.

Recommendations

- That the AHPPC endorse the principle that access to ARVs is a public health issue and that all people with HIV in Australia, regardless of Medicare status, should receive equitable and affordable access to all HIV testing services and the most appropriate HIV treatment and care.
- That all Medicare ineligible PLHIV currently residing in Australia be given equitable access to all PBS listed ARV treatments in the same way as the permanently resident Australian population.
- That improved, regular and standardised data be collected from the State and Territory jurisdictions and pharmaceutical companies (and be held centrally) to better understand the cohort of Medicare ineligible PLHIV in Australia and their doctors' prescribing patterns.
- That the grant of all temporary resident visas to Australia require health insurance that covers all HIV treatment and care.
- That the Commonwealth government negotiate with pharmaceutical companies to secure proportionate contributions towards the provision of ARV to this finite group.

napwha national association of people with HIV australia

Medicare ineligible PLHIV in Australia

An analysis of new data with recommendations for systemic improvements