

Paying the price in an era of HIV treatment as prevention: a retrospective study of the cost burden of HIV treatment for people living with HIV in Victoria, Australia.

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Background: An estimated 25 700 people live with diagnosed HIV (PLWH) in Australia and ~1200 newly diagnosed cases were notified in 2012. New HIV prevention strategies focus on individual uptake of treatment; however, a potential barrier is the financial burden of antiretroviral treatment (ART). We describe HIV ART dispensed and the estimated associated costs for PLWH in Victoria. **Methods:** A retrospective cross sectional study of pharmacy data on ART dispensed between January 2012 and November 2013 from a hospital network, including Victoria's largest sexual health clinic was conducted. Estimated annual patient costs of ART were calculated by number of items dispensed per year, concession status, dispensing site and applicable co-payment. **Results:** A total of 60 225 dispensing records from 3903 individuals were included; this represented 83.8% of pharmaceutical benefits scheme-recorded ART dispensed items in Victoria over this period. The estimated annual co-payment costs for patients without a concession card and who were collecting two medications from a site was \$433.20. One- fifth of patients (21.3%) collected four or more items, equating to an estimated annual cost of at least \$866.40 without a concession card and \$141.60 with a concession card. Of those dispensed four or more items, 40.4% were concession card holders. **Conclusions:** There may be meaningful patient costs associated with accessing ART for some PLWH. New HIV treatment-based prevention strategies need to consider financial vulnerabilities and appropriately targeted initiatives to alleviate patient costs associated with ART access, ensuring they do not act as a barrier to commencement of and adherence to HIV treatment.

Introduction

There are an estimated 25 700 people living with diagnosed HIV (PLWH) in Australia and ~1200 newly diagnosed cases were notified in 2012; with the majority (~75%) of HIV diagnoses among men who have sex with men (MSM).¹ Advances in antiretroviral treatment (ART) have significantly reduced morbidity and mortality for people living with HIV (PLWH)² and recent local data suggests ART uptake continues to increase among MSM.³ There is now an established evidence base that ART-derived reductions in HIV viral load, in addition to improving individual health outcomes, can reduce HIV transmissibility, thus benefiting community HIV prevention (treatment as prevention; TasP).^{4,5} While early initiation of ART has the potential to improve individual outcomes, the notion that TasP places the prevention burden on PLWH by encouraging treatment commencement before it might be clinically indicated has attracted debate.

One aspect of this debate that is relevant is the potential financial burden TasP might place on PLWH. In Australia, the Federal Government bears the majority of the cost of prescribed medications through the publicly funded Pharmaceutical Benefits Scheme (PBS). However individuals are required to pay a contribution (co-payment) towards dispensed medications, including ART. The co-payment is charged per medication picked-up. In 2013, the co-payment for each drug dispensed was \$36.90 unless patients have a concession card (a government scheme to assist eligible individuals with living costs), which reduces the co-payment to \$6.00. Within the PBS, the Safety Net Scheme provides a ceiling (threshold) on individuals' costs in a single year (\$354.00 in 2013 for concession card holders and \$1390.60 for non-concessional patients). Once the threshold is reached, a patient can be issued a Safety Net card by a pharmacist and co-payments are waived (for concession card holders) or reduced, providing some protection to individuals from excessive prescription costs.⁶ Despite the Federal Government setting the price of co-payments, there are inconsistencies in the charging of co-payments by health services and therefore also to the financial support provided to PLWH across jurisdictions. The Northern Territory and Western Australia provide free HIV and sexual health services, including antiretroviral treatment to PLWH.^{7,8} There are also inconsistencies within jurisdictions, with co-payments for ART not being charged at a major Victorian sexual health clinic.⁹ In addition, PLWH in rural Victoria incur extra costs due to the low number of ART prescribers and dispensers. These extra costs include travel costs to receive HIV care and the postage costs of sending refill supplies of ART which are typically passed on to patients.^{6,10,11}

Despite acting as a potential barrier to treatment uptake, individual financial burden of receiving ART in settings of publicly funded care has received little attention or empirical analysis. In one Australian cross

sectional study, patients self-reported experiencing financial difficulty and delaying or ceasing HIV treatment due to associated pharmacy costs.¹² Studies outside the field of HIV show an association between increased costs and poor adherence.^{13,14} and data from lower income countries report decreased adherence to ART was associated with increased costs.¹⁵ Considering the impact of adherence to ART on treatment failure and the development of HIV drug resistance¹⁶ understanding the burden of ART costs represents a potentially critical element to the successful uptake of ART and implementation of TasP strategies. We aim to estimate patient costs associated with dispensed ART in Victoria to inform community and sector discussions on ART provision, including in the context of HIV prevention.

Methods

Non-identifiable, retrospective data from January 2012 to November 2013 on all ART items dispensed by Alfred Health pharmacy were used. The Alfred Health pharmacy manages dispensing at the following Alfred sites: Alfred Hospital, Caulfield General Medical Centre and Melbourne Sexual Health Centre (MSHC). Data were extracted from the pharmacy management system and items verified by a pharmacist as being used for HIV ART. One dispensing episode is medication/s collected by one individual, on one date. Analyses are presented per item (given co-payments are charged per item), rather than individual or treatment grouping. An ART item is one medication, including combination medications (>one antiretroviral in one formulation) that similarly attract one co-payment.

The total number of records extracted was 73 032. Participants were uniquely identified and their ART dispensing episodes linked over time by their Medicare number, a unique number allocated to individuals by the universal public health system. Dispensing episodes that could not be uniquely linked to an individual were excluded (0.6%). Items dispensed for the purpose of non-occupational post exposure prophylaxis (0.6%), as part of clinical trial (1.5%), or which were provided under a compassionate access scheme (0.2%) were excluded. Records that were not HIV antiretrovirals and inadvertently extracted (e.g. azithromycin, ceftriaxone) were also excluded (14.5%). Concession status was assigned to records with a valid concession number. Analyses were stratified by Alfred sites (where a co-payment is charged) and the MSHC (where no co-payment is charged). A sub analysis of dispensing and patient costs, limited to 2013 and Alfred sites was conducted because the recording of concession card status was most complete for 2013 at Alfred sites. This sub-analysis was conducted to examine patient eligibility and utilisation of the PBS Safety Net scheme, and compared cumulative patient costs to 2013 Safety Net thresholds (\$1390.60 for non-concession and \$354.00 for concession card holders). The study was approved by Alfred Health Ethics Committee (Project 221/12).

RESULTS

A total of 60 225 ART items were dispensed to 3903 individuals by Alfred Health from January 2012 to November 2013 (Table 1). Of patients attending Alfred sites, 29.0% received a two-item regimen (Table 2) equating to an estimated annual cost in 2013 of \$70.80 (concessional) or \$433.20 (no concession card). More than one-fifth of patients (21.3%) at Alfred sites collected four or more items and accrued an estimated annual cost of at least \$141.60 (concessional) or \$866.40 (no concession card). The numbers of items dispensed in an episode were generally consistent between the Alfred sites and MSHC (Table 2). Patients were most commonly (33.6%) dispensed two items and approximately one in five patients (21.3%) were dispensed four or more items per dispensing episode. Concession card holders were more often dispensed a higher number of items per dispensing episode; of those dispensed four or more items per dispensing episode, 40.4% were concession card holders (Table 2). Two thirds of items (67.1%) were dispensed at MSHC (Table 1). This data represented 83.8% of all PBS-reported antiretrovirals dispensed in Victoria for the same period.¹⁷

In 2013 at Alfred sites, there were 3713 episodes of ART dispensing to 1080 patients. The majority of patients (56.6%) did not hold a concession card. The median cumulative patient cost at the last dispensing episode was \$216.60 (IQR = \$121.07 - \$392.63) for non-concession card holders ($n=611$) and \$59.00 (IQR = \$30.80 - \$106.20) for concession card holders ($n=469$). By November 2013, 12 (1.8%) non-concession card holders and 45 (9.5%) concession card holders had a cumulative cost above the threshold. Of the 45 concession card holders eligible for a Safety Net card (thus eligible for no further co-payments), only six patients (13.3%) had a Safety Net card recorded, equating to 109 episodes of dispensing (332 items).

Discussion

This study examined retrospective pharmacy data on ART dispensed to individuals by a major hospital pharmacy network in Victoria from January 2012 to November 2013. We estimated that the most common scenario (two ART medications, six pick-ups, and a higher co-payment) would equate to an annual patient cost of \$433.20, with ART dispensing costs overall ranging from \$35.40 to at least \$866.40 depending on concession status and number of items dispensed. Despite Australia's publicly funded universal health care system, the estimated out-of-pocket annual cost of ART may be substantial for some PLWH, and the financial cost may act as a disincentive for PLWH commencing and adhering to treatment, particularly those on low incomes and collecting multiple items.

The financial barrier to medications and risk of poor adherence may be greater for particular sub-populations. Those with a concession card in this study were more often dispensed a higher number of ART items and therefore experienced higher costs. Additionally, only a small proportion of concession card holders received financial relief through the Safety Net mechanism. Importantly, this demonstrates how concession card holders who have lower incomes may actually accrue higher ART-related medication costs as they generally received increased numbers of ART items. In addition, the increased numbers of ART items represents increased complexity of the treatment regimen, which has been associated with more longstanding HIV and worse clinical outcomes.¹⁸

This study supports previous findings showing some Australians are experiencing a significant financial burden from the cost of medications.^{19,20} Medication costs has been shown to cause economic hardship and impact health seeking behaviours, disproportionately among those with low income, chronic disease and multimorbidity^{13, 21} Importantly, there is evidence that among those with chronic disease, cost may adversely affect adherence to medication.¹⁴ To the best of our knowledge, only one study in Australia has examined the financial burden of ART specifically and the impact on treatment adherence. In this study, almost one-fifth of patients with HIV at a New South Wales hospital reported finding it 'difficult' or 'very difficult' to meet HIV medication costs and this was associated with interrupting treatment.¹²

Our findings are of particular concern in the context of both HIV care and prevention, given the direct link between treatment adherence and poor clinical outcomes. Reductions in adherence and altered patterns of adherence, such as 48-h treatment interruptions, can lead to the development of HIV drug resistance and treatment failure.^{16, 22, 23} In addition, treatment initiation and medication costs may be a barrier to contemporary strategies for HIV prevention. International findings derived from epidemic modelling,²⁴ ecological analyses²⁵ and randomised controlled trials²⁶ have provided strong support for the prevention benefit of early HIV treatment, and this evidence has led to recent changes in Australian policy to consider earlier initiation of ART.²⁷ Such changes mean PLWH are being offered ART earlier to reduce the potential for onward HIV transmission; possibly leading to significant healthcare costs, over a longer period of time. To maximise the individual and community benefits of ART, treatment must be affordable for a lifetime to minimise the risk of interruption. Affordability of HIV care may also be affected by the most recent Australian Federal budget (2014-15) that outlined significant changes to the patient contributions to their health care,²⁸ with subsequent public debate regarding the implications, particularly for those vulnerable to high costs.²⁹

The cost burden associated with HIV treatment is likely to disproportionately affect older PLWH and those with longer-term established HIV infection. Because of co-morbidities associated with ageing and long-term infection, these PLWH are more likely to be eligible concession card holders but are also likely to experience the additional financial burden of having more drugs dispensed per dispensing episode, including other non HIV-related medications, which were not included in our cost estimates. Current provisions (PBS Safety Net Scheme) may not be protecting those who are paying out-of-pockets costs; our estimates of the cumulative patient ART costs in 2013 at Alfred sites were below the Safety Net thresholds, and the majority of patients eligible for a Safety Net card did not receive one. This supports other literature expressing concern that individuals are either not aware of the Safety Net Scheme or application requirements for a Safety Net card and the requirement to keep a record of their prescription medications were too onerous.^{31, 32}

The methods used in this study did have some limitations. First, the relative affordability of medications was not assessable in the absence of individual patient income and living costs. Second, including non-ART medications was beyond the scope of this study; therefore, results only reflect ART costs and true overall medication costs are likely to be higher for a proportion of participants. Finally, some caution is advised when interpreting the results as Alfred Health data is collected primarily for operational purposes. However, this study represents the most comprehensive assessment of ART dispensing costs in Australia and the only to estimate patient costs associated with ART provision.

This study provides a crucial first step in understanding the extent of the financial burden of ART on PLWH. The data presented are highly representative, as Alfred Health dispenses >80% of ART in Victoria; in no other jurisdiction in Australia is such a large proportion of HIV dispensing data held in a single database.¹⁶ Our findings support previous suggestions of targeted strategies to assist those particularly vulnerable to high medication costs such as subsidies, income support or a non-means tested concession card and the need for specific recording of individuals' medication costs in order to assess cost burdens and affordability.^{21, 33} Furthermore, we have highlighted the inconsistencies across jurisdictions and within Victoria in relation to the financial support provided to PLWH for their HIV treatment. Patients requiring more items are paying disproportionately more to treat HIV, further suggesting the need for a broader policy review of equitable access to ART. While future research is needed with sufficient individual-level data to determine financial burden relative to income, our data further contribute to the debate on co-payments, barriers to ART and the uptake of TasP in Australia. Medication co-payments have the potential to undermine the health and community benefits of ART, and diminish the benefit of prevention strategies, including TasP.

Conflicts of interest

AL Wilkinson is supported by a NHMRC public health scholarship. YS Cheah is an Australian Youth Ambassador, funded by AustralianAID. M Stoové is supported by the NHMRC Centre for Research Excellence in Injecting Drug Use. This work was commissioned by Living Positive Victoria and Victorian AIDS Council/Gay Men's Health Centre.

Acknowledgements

The authors would like to thank Mr Luke Hannath and Ms Alison Duncan for coordinating data extraction and clarification on data fields. The authors gratefully acknowledge the contribution of the Victorian Operational Infrastructure Support Program to this work, received by the Burnet Institute.

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Table 1. Description of dispensing records overall, and by sites, from January 2012 to November 2013

| Variable | All sites | Alfred sites | Melbourne Sexual Health Centre |
|--|-----------|--------------|--------------------------------|
| | n | n | n |
| Dispensing records (No. of items) | 60,225 | 19,805 | 40,420 |
| No. of individuals | 3,903 | 1,160 | 2,743 |
| Median dispensing episodes per person, per calendar year [Interquartile range; IQR] | 7 [6, 8] | 8 [7, 11] | 6 [6, 7] |
| Financial quarters (No. of items) | | | |
| Q1 | 15,713 | 5,261 | 10,452 |
| Q2 | 15,886 | 5,145 | 10,741 |
| Q3 | 15,852 | 5,212 | 10,640 |
| Q4 ^A | 12,774 | 4,187 | 8,587 |

Table 2. Number of items dispensed, per dispensing episode, by concession status and site, from January 2012 to November 2013

| | All sites (n=23,469) | | | | Alfred sites (n=7900) | | Melbourne Sexual Health Centre (n=15569) | |
|---------------------|-------------------------|------|--------------------------|---|--------------------------|------|---|------|
| | All items | | 2013 items (n=11,065) | 2013 items to concession card holders (n=3,519) | n | % | n | % |
| Number ^A | n | % | n | % | n | % | n | % |
| 1 | 5,843 | 24.9 | 2,867 | 22.4 | 2,364 | 29.9 | 3,479 | 22.3 |
| 2 | 7,877 | 33.6 | 3,741 | 29.6 | 2,291 | 29.0 | 5,586 | 35.9 |
| 3 ^B | 4,744 | 20.2 | 2,095 | 38.9 | 1,494 | 18.9 | 3,250 | 20.9 |
| ≥4 ^B | 5,005 | 21.3 | 2,362 | 40.4 | 1,751 | 22.2 | 3,254 | 20.9 |

^ANumber of items (medications, single or combination formulations) given out when a patient has a transaction (dispensing episode) with a pharmacist.

^B Of those episodes with three items (n=4,744), 8.2% of items were Ritonavir, and of those episodes with four or more items (n=5,005), 18.9% of items were Ritonavir, which is not prescribed for its antiviral activity but its capacity to increase the blood levels of other active antiretrovirals.