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The effects of reduced copayments on discontinuation and adherence failure to statin medication in Australia

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ABSTRACT

This paper assesses whether the concession card, which offers discounted out-of-pocket costs for prescription medicines in Australia, affects discontinuation and adherence to statin therapy. The analysis uses data from the Australian Hypertension and Absolute Risk Study (AusHEART), which involves patients aged 55 years and over who visited a GP between April and June 2008. Socioeconomic and clinical information was collected and linked to administrative data on pharmaceutical use. Patients without a concession card were 63% more likely (hazard ratio (HR) 95% confidence interval (CI): 1.14–2.33) to discontinue and 60% (odds ratio (OR) CI: 1.04–2.44) more likely to fail to adhere to therapy compared to concessional patients. Smokers were 2.12 (HR CI: 1.39–3.22) times more likely to discontinue use and 2.23 (OR CI: 1.35–3.71) times more likely to fail to adhere compared to non-smokers. Patients who had recently initiated statin medication were also 2.28 (HR CI: 1.22–4.28) times more likely to discontinue use. In conclusion, higher copayments act as a disincentive for persistent and adherent use of statin medication.

1. Introduction

As with many developed countries, deaths from cardiovascular disease (CVD) remains Australia's leading cause of death, with 32% caused by CVD in 2010 [1]. The past two decades has witnessed the widespread use of statin medications to treat patients at elevated risk of CVD with the total volume of prescriptions dispensed through the Pharmaceutical Benefits Scheme (PBS) increasing from around 2 million in 1992 to 22 million in 2011 [2]. Statin medication has been shown to significantly improve survival and reduce the likelihood of future CVD events when used in both primary and secondary prevention [3]. Although the prescribing of statins is widespread, discontinuation is high and adherence to treatment is low [4,5,26,27], and have been shown to lead to increased hospitalization rates and medical costs [6].

A recent Australian study examined the effect of single and combination therapies involving atorvastatin on persistence, revealing high rates of discontinuation of

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treatment especially when the drug was taken with other therapies as separate tablets (as opposed to combination tablets) [7]. One factor that may account for higher persistence when using combination therapy is the lower out-of-pocket costs consumers face, as there is considerable evidence, mainly from North America that costs to the patient can impact long-term and adherent use of cardiovascular drugs [8–10].

An issue with the design of all health insurance systems is in setting levels of patient contributions through co-payments or deductibles [11]. Most countries that subsidize the cost of pharmaceuticals, including Australia, increase access to disadvantaged populations such as low-income households and those on state pensions by further reducing or eliminating co-payments for these groups [12]. Outside of North America there is little evidence whether those receiving additional benefits are *more* adherent to prescribed medications.

The Australian government subsidizes the cost of a wide range of pharmaceuticals for all Australian residents through the PBS, and promotes access to aged and disadvantaged groups through the concession card. Patients who hold a concession card (pensioners, unemployed and eligible low income households) face a significantly discounted price compared to general users (e.g. ordinary copayments in 2009 were $5.30 for concessional users, compared to $32.90 for general users). Individuals who have high pharmaceutical expenditure are also protected through a *Safety Net*, which involves reduced co-payment rates for patients that exceed a threshold level of expenditure in a calendar year (e.g. in 2009 for general users the co-payments decreased to $5.30 after they incurred $1264.90 of pharmaceutical expenditure and for concessional users there was no co-payment after $318.00 of expenditure) [13].

The aim of this study is to investigate the relative discontinuation and adherence failure rates of concessional vs. general users for patients prescribed statins. Our sample comes from the Australian Hypertension and Absolute Risk Study (AusHEART) with linked administrative data from Medicare which contains records of all pharmaceuticals purchased under the PBS. We also control for clinical and patient characteristics.

2. Methods

2.1. Study overview

The AusHEART study has been described previously [14,15]. In brief, the study recruited 322 GPs across Australia in a randomized, stratified manner. GPs were asked to provide clinical information on 15–20 consecutively presenting, consenting patients aged 55 years and over, irrespective of the reason for the consultation, who presented between April and July 2008. Patients completed a one-page questionnaire on self perceived health, risk behaviors such as smoking and socioeconomic factors. Patients were also given the option to consent to having their information linked with Medicare Australia administrative data. The study was approved by the Royal Australian College of General Practitioners National Research and Evaluation Ethics Committee.

2.2. Patient eligibility criteria

AusHEART patients were eligible if they consented to their data being linked to their Medicare records, and had evidence of statin use from PBS records within the first year following survey completion (i.e. time of GP consultation). Our statin use observation period commenced from the date the patient filled their first statin prescription following survey completion, and concluded one year after survey completion. Note that since the PBS only records information on medications that attract a subsidy, we do not have information on medications priced below relevant patient copayments. For example, the total price of Simvastatin 10 mg in 2009 was around $24 which is below the ordinary non-concessional co-payment and so do not appear in the PBS data for these patients. To ensure comparability of concessional and general patients we removed all individuals who had evidence of any use of these low-cost statins i.e. Simvastatin 5 mg/10 mg, Pravastatin 10 mg, Fluvastatin 20 mg/40 mg. We examined the effects of this exclusion in a sensitivity analysis.

2.3. Patient-provided information

We used information on self-perceived health, risk behaviors, and socioeconomic factors as stated in the patient-completed questionnaire. Patients reported their gross household income according to one of seven categories ranging from negative/nil income to $2000 or more per week. We applied Organization for Economic Cooperation and Development equivalence weights to adjust income (measured at the mean of the bounds of each income category) for household composition, where a value of 1 was assigned to the household head, 0.5 to each additional adult, and 0.3 to each child [16]. Patients were then divided into income quartiles based on calculated equivalized income. Other information from the patient-completed survey used in the analysis included age, sex, self-reported health (measured on a five-point scale, from excellent to poor), self-perceived CVD risk (measured on a six-point scale from no chance to very high chance of a CVD event in the next five years), and smoking status.

2.4. Doctor-provided information

GPs completed a questionnaire containing medical history of the patient and clinical information mainly related to the patient's CVD risk. Information reported by the GP used in this study included an estimation of the patient's absolute cardiovascular risk; the presence of chronic kidney disease (CKD), diabetes, and established CVD; height and weight of the patient to calculate body mass index; and whether the patient was initiated on statin therapy at the time of consultation. We deduced a proxy for locality type (metropolitan, regional or remote) from the GP practice's postcode using the Australian Standard Geographical Classification – Remoteness Area (ASGC-RA) correspondences [17].

2.5. Administrative data

The Medicare administrative data contained records of all pharmaceuticals purchased under the PBS and all services provided under the Medicare Benefits Scheme (MBS) from 1 March 2008 to 1 January 2010. Each PBS entry recorded the item number and description, the Anatomical Therapeutic Chemical (ATC) classification code and name, and the date of prescription and supply. PBS records divided payments for pharmaceuticals into 'net benefits' (government contributions) and patient contributions (the sum of which is the total cost of the drug). The beneficiary type of the patient was also specified for each purchase (i.e. *general* patients, *concessional* patients (those on a relevant pension or with a Commonwealth Seniors Health Card which is means tested, and/or eligible low income families), *general safety-net* patients (general patients who reached a specified annual threshold during a calendar year) and *concessional safety-net* patients (concessional patients who reached a discounted threshold during a calendar year)) [13].

Entries for statins (including statin combination therapy) were identified from fifth-level ATC codes (i.e. chemical substance) [18]. We also used Medicare records to identify patients who received treatment for cancer or mental health conditions, and the number of medication types used according to ATC level 1 classifications. We identified the presence of mental health conditions based on MBS item numbers for GP mental health-care plans, psychiatric attendances and psychological therapy services; and treatment for cancer using MBS and PBS data (including the Section 100 Highly Specialised Drugs Program) based on item numbers for chemotherapy, radiation oncology, nuclear medicine procedures, and prescriptions for Antineoplastic and immunomodulating agents.

3. Statistical analysis

3.1. Sample comparisons

The characteristics of the patients who consented to Medicare linkage were compared with those who did not using *t*-tests for continuous variables and *z* tests for binary variables. Similarly, *t*-tests/*z* tests were used to compare the characteristics of concession and non-concession users in the sample used in the analysis.

3.2. Discontinuation

To determine whether patients discontinued statin therapy we used the date and quantity supplied for each statin prescription to calculate the final date of statin possession during the study period (in a cumulative manner to avoid overestimation of supply due to the effects of stock-piling). If the final date of possession was before the end of our study window, the patient was considered to have discontinued therapy at this date. Note that patients who stopped taking statins and then restarted therapy sometime later (within the observation window) were not considered to have discontinued treatment, unless they stopped treatment again and did not restart before the end of the observation window.

The influence of concessional status on discontinuation was examined using a Cox proportional hazards model. During the observation period the prices of Pravastatin 20 mg and Simvastatin 20 mg decreased below the maximum patient copayment (i.e. the price of Pravastatin 20 mg decreased below $31.90 in August 2008, and the price of Simvastatin 20 mg decreased below $32.90 in January 2009). We therefore censored patients using these drugs (who did not change to a higher priced statin before the price change) at the time of the respective price changes. Since this was an older population, we also censored patients that did not have any Medicare records (neither MBS nor PBS) in the last three months of the observation period (and beyond), under the assumption that they may have died or relocated overseas.

3.3. Adherence failure

Adherence was defined using the proportion of days covered (PDC) method. The PDC is the number of days with statins on hand over a given time period [19]. The time period commenced from the date of the first statin supply during the study window and ended at the final date of statin possession (or at the end of the 12-month observation period: whichever date came first). For consistency of interpretation of results with those for discontinuation, we define a binary variable representing adherence failure. A patient was considered to fail to adhere to therapy if they possessed statins for less than 80% of days in this period [20,21]. We assessed the impact of the concession card and other factors on adherence failure using univariate and multiple logistic regression.

3.4. Model estimation

The impact of the concession card on discontinuation and adherence failure was examined in univariate, multivariate unrestricted (all control variables included) and multivariate restricted models (only significant control variables included). Control variables included age, sex, income quartile, education, marital status (married/de facto or alone), location (metropolitan or regional/remote), self-reported health, patient and GP perception of the patient's CVD risk, smoking status, and whether statins were initiated during the study consultation. Since adherence and persistence may be influenced by overall drug costs and treatment burden in general, we also included indicators for CVD, diabetes, CKD, cancer and mental health conditions, as well as the total number of medication types filled per patient according to ATC level 1 classifications (i.e. major categories). Selection for variable inclusion in the restricted models was based on forward and backward stepwise elimination (at the 5% level of significance), using robust standard errors clustered by GP practice. The Cox regression coefficients for discontinuation are presented as hazard ratios and logistic regression coefficients for adherence failure are presented as odds ratios. We also report 95% confidence intervals (CIs).

4. Results

Of the 5293 patients who participated in the AusHEART study, 3538 consented to linkage with Medicare records. Compared to the sample who did not consent to data linkage, those that consented were on average more likely to be married or in a de facto relationship (68% vs. 65%; $P = 0.0096$), have slightly higher mean systolic blood pressure (136 vs. 135; $P = 0.0452$) and more likely to be obese (36% vs. 33%; $P = 0.0321$). After excluding 691 patients who did not provide information on relevant variables used in this analysis, we identified 1315 patients who filled prescriptions for statins within 12 months of their consultation date. A further 55 people were removed as they had evidence of low-cost statin use (i.e. statins priced below the maximum patient copayment) leaving 1260 in the final sample. Characteristics of our sample are presented in Table 1, along with characteristics by beneficiary type. Of the identified statin users, 12% discontinued statin therapy during the observation window and 9% failed to adhere while on therapy. Compared to general users, those who had a concession card (80% of users) were on average older, had significantly lower incomes and had lower levels of education. The prevalence of established CVD, established chronic kidney disease, and below average self-assessed health was almost twice as high amongst concession users. This group also used more types of medications on average over the study period compared to non-concession users, according to ATC level 1 classifications.

The results of univariate and multivariate analysis of factors associated with discontinuation are reported in Table 2. 131 (10%) patients were censored earlier than 12 months due to either not having any Medicare records in the last three months of the observation period or beyond (13 people), or because they had evidence of the use of Pravastatin 20 mg or Simvastatin 20 mg and did not change to a higher priced statin before the associated price change (24 and 94 patients, respectively). In the restricted multivariate model, ordinary patients (i.e. those who did not have a concession card) were 1.63 (95% CI: 1.14–2.33) times more likely than concession users to discontinue use. Furthermore, at the end of the 12 month period, there was around 7% difference in discontinuation between concessional and general users (Fig. 1). Statin users whose therapy was initiated at the time of consultation were 2.28 (95% CI: 1.22–4.28) times more likely to discontinue medication compared to those who had previously commenced therapy while smokers were 2.12 (95% CI: 1.39–3.22) times more likely to discontinue compared to non-smokers. Univariate analysis and multivariate unrestricted analysis yielded similar results. There was no significant evidence that the odds of discontinuing therapy varied with CVD risk perception, comorbidities, number of medication types used, socioeconomic characteristics, or the use of combination therapies.

Table 1
Characteristics of sample used in analysis.[a]

Variable	All statin users $N = 1260$	Concession users $n = 1004$	General users $n = 257$
Personal/demographic characteristics			
Male	630 (50%)	483 (48%)	147 (57%)*
Age (years)	68 ± 8[b]	70 ± 8	62 ± 6*
Regional	481 (38%)	405 (40%)	76 (30%)*
Married or de factor	882 (70%)	683 (68%)	199 (78%)*
Socioeconomic information			
Total yearly equivalized household income ($)	23,459.25 ± 18,952.05[b]	17,804.65 ± 13,049.75	45,635.90 ± 21,997.95*
Has university degree	215 (17%)	126 (13%)	89 (35%)*
Health and risk behavior information			
Diabetes	441 (35%)	361 (36%)	80 (31%)
Established cardiovascular disease	520 (41%)	457 (46%)	63 (25%)*
Chronic kidney disease	97 (8%)	88 (9%)	9 (4%)*
Cancer	51 (4%)	42 (4%)	9 (4%)
Mental health issues	81 (6%)	67 (7%)	14 (5%)
Low-density lipoprotein (mmol/L)	2.54 ± 0.93[b]	2.51 ± 0.92	2.65 ± 0.97*
Systolic blood pressure (mmHg)	136 ± 17[b]	136 ± 17	134 ± 16*
Diastolic blood pressure (mmHg)	75.20 ± 10.13[b]	74.57 ± 10.17	77.67 ± 9.61*
Below average self-reported health	400 (32%)	352 (35%)	48 (19%)*
Current smoker	109 (9%)	83 (8%)	26 (10%)
Obese (BMI $\geq 30\,kg/m^2$)	508 (40%)	393 (39%)	111 (43%)
Statin therapy/concession information			
Initiated statin therapy at time of AusHEART data collection	50 (4%)	36 (4%)	14 (5%)
On statin combination therapy	120 (10%)	92 (9%)	28 (11%)
Number of medication types according to ATC level 1 classifications	3.34 ± 0.09	3.31 ± 0.09	4.80 ± 0.73*
Discontinued statin therapy	147 (12%)	104 (10%)	43 (17%)*
Failed to adhere to statin therapy	117 (9%)	84 (8%)	33 (13%)*
Concessional user	1004 (80%)		

[a] *t*-Tests were used to compare continuous variables and *z* tests for binary variables.
[b] Age, income, low-density lipoprotein, systolic blood pressure,diastolic blood pressure and number of medication types are presented as mean ± SD values.
* *t*-Tests/*z*-tests indicated variable means/proportions for concession and general users differed significantly at 5% level of significance.

Table 2
Hazard ratio and 95% confidence intervals for discontinuation of statin therapy (failure = discontinuation).

	Univariate analysis	Multivariate analysis: unrestricted model	Multivariate analysis: restricted model
Male	1.09 (0.76–1.55)	1.03 (0.69–1.55)	
Female	1.00	1.00	
Age	1.00 (0.97–1.02)	1.02 (0.99–1.05)	
Location			
City	1.00	1.00	
Regional/Remote	0.95 (0.68–1.34)	0.97 (0.69–1.37)	
Married/de facto			
Yes	0.98 (0.67–1.42)	1.10 (0.73–1.65)	
No	1.00	1.00	
Income quartile			
1st (lowest)	1.00	1.00	
2nd	0.82 (0.51–1.30)	0.80 (0.49–1.31)	
3rd	1.37 (0.89–2.12)	1.28 (0.82–2.02)	
4th (highest)	1.15 (0.74–1.77)	0.94 (0.56–1.59)	
Has university degree			
Yes	0.87 (0.54–1.40)	0.76 (0.44–1.30)	
No	1.00	1.00	
CVD			
Yes	0.89 (0.63–1.27)	0.94 (0.63–1.41)	
No	1.00	1.00	
Diabetes			
Yes	0.83 (0.58–1.21)	0.84 (0.57–1.24)	
No	1.00	1.00	
Kidney disease			
Yes	1.43 (0.83–2.48)	1.56 (0.87–2.79)	
No	1.00	1.00	
Cancer			
Yes	0.89 (0.36–2.24)	0.95 (0.38–2.37)	
No	1.00	1.00	
Mental health conditions			
Yes	0.92 (0.39–2.18)	0.88 (0.37–2.09)	
No	1.00	1.00	
Self-reported health			
Excellent, Very good, Good (combined)	1.00	1.00	
Below average (Fair and Poor combined)	0.99 (0.70–1.41)	1.04 (0.69–1.56)	
Number of ATC level 1 medications	0.94 (0.87–1.02)	1.00 (0.90–1.10)	
Patient perception of their CVD risk			
Low	1.00	1.00	
Moderate	0.84 (0.59–1.20)	0.83 (0.57–1.19)	
High	1.13 (0.59–2.18)	1.15 (0.55–2.40)	
GP perception of patient's CVD risk			
Low	0.86 (0.48–1.54)	0.73 (0.40–1.33)	
Moderate	1.01 (0.54–1.92)	0.89 (0.48–1.67)	
High	1.16 (0.66–2.06)	0.99 (0.54–1.80)	
No response	1.00	1.00	
Current smoker			
Yes	2.19 (1.44–3.34)***	2.28 (1.44–3.61)***	2.12 (1.39–3.22)***
No	1.00	1.00	
Obese			
Yes	0.80 (0.58–1.10)	0.84 (0.59–1.18)	
No	1.00	1.00	
Statin therapy initiated at time of AusHEART survey			
Yes	2.46 (1.33–4.52)***	2.00 (1.01–3.96)**	2.28 (1.22–4.28)**
No	1.00	1.00	
On statin combination therapy			
Yes	0.75 (0.42–1.36)	0.73 (0.40–1.33)	
No	1.00	1.00	
Concession user			
Yes	1.00	1.00	1.00
No	1.69 (1.19–2.40)***	1.98 (1.15–3.41)**	1.63 (1.14–2.33)***

$n = 1252$.
95% confidence intervals are displayed in brackets.
Standard errors are clustered by GP.
Note: 131 patients were censored earlier than 12 month due to either not having any Medicare records in the last three months of the observation period or beyond (13 people), or because price of the statin they were prescribed dropped below non-concessional co-payment (118 patients). Selection for variable inclusion in the restricted model was based on forward and backward stepwise elimination (at the 5% level of significance), which give identical results.
** $P < 0.05$.
*** $P < 0.01$.

Table 3
Logistic regression odds ratios and 95% confidence intervals for adherence failure to Statin therapy.

	Univariate analysis	Multivariate analysis: unrestricted model	Multivariate analysis: restricted model
Male	0.95 (0.66–1.36)	0.99 (0.66–1.47)	
Female	1.00	1.00	
Age	0.98 (0.96–1.01)	1.00 (0.97–1.03)	
Location			
City	1.00	1.00	
Regional/Remote	1.01 (0.69–1.50)	1.03 (0.70–1.51)	
Married/de facto			
Yes	0.88 (0.58–1.34)	0.82 (0.52–1.30)	
No	1.00	1.00	
Income quartile			
1st (lowest)	1.00	1.00	
2nd	1.07 (0.66–1.73)	1.11 (0.65–1.90)	
3rd	1.07 (0.63–1.83)	0.97 (0.56–1.68)	
4th (highest)	1.28 (0.77–2.14)	1.30 (0.70–2.41)	
Has university degree			
Yes	0.69 (0.41–1.18)*	0.56 (0.31–1.01)*	
No	1.00	1.00	
CVD			
Yes	0.84 (0.57–1.25)	0.93 (0.61–1.42)	
No	1.00	1.00	
Diabetes			
Yes	0.88 (0.58–1.34)	0.87 (0.56–1.36)	
No	1.00	1.00	
Kidney disease			
Yes	0.87 (0.41–1.83)	1.02 (0.47–2.20)	
No	1.00	1.00	
Cancer			
Yes	0.83 (0.30–2.28)	0.91 (0.32–2.52)	
No	1.00	1.00	
Mental health conditions			
Yes	1.78 (0.88–3.58)	1.64 (0.82–3.28)	
No	1.00	1.00	
Self-reported health			
Excellent, Very good, Good (combined)	1.00	1.00	
Below average (Fair and Poor combined)	0.91 (0.59–1.41)	0.89 (0.55–1.42)	
Number of ATC level 1 medications	0.96 (0.88–1.04)	1.02 (0.91–1.14)	
Patient perception of their CVD risk			
Low	1.00	1.00	
Moderate	1.15 (0.72–1.83)	1.08 (0.66–1.76)	
High	0.95 (0.42–2.13)	0.91 (0.39–2.14)	
GP perception of patient's CVD risk			
Low	0.73 (0.38–1.43)	0.65 (0.34–1.28)	
Moderate	0.77 (0.36–1.65)	0.70 (0.32–1.54)	
High	0.82 (0.42–1.60)	0.74 (0.36–1.50)	
No response	1.00	1.00	
Current smoker			
Yes	2.27 (1.37–3.74)***	2.16 (1.27–3.67)***	2.23 (1.35–3.71)***
No	1.00	1.00	
Obese			
Yes	1.32 (0.90–1.95)	1.39 (0.92–2.11)	
No	1.00	1.00	
Statin therapy initiated at time of AusHEART survey			
Yes	1.63 (0.77–3.46)	1.39 (0.63–3.06)	
No	1.00	1.00	
On statin combination therapy			
Yes	0.88 (0.42–1.85)	0.83 (0.39–1.80)	
No	1.00	1.00	
Concession user			
Yes	1.00	1.00	1.00
No	1.62 (1.07–2.45)**	1.78 (0.91–3.49)*	1.60 (1.04–2.44)**

$N = 1260$.
95% confidence intervals are displayed in brackets.
Standard errors are clustered by GP.
Note that estimating adherence using a continuous rather than binary measure found a similar result. Selection for variable inclusion in the restricted model was based on forward and backward stepwise elimination (at the 5% level of significance), which give identical results.
* $P < 0.1$.
** $P < 0.05$.
*** $P < 0.01$.

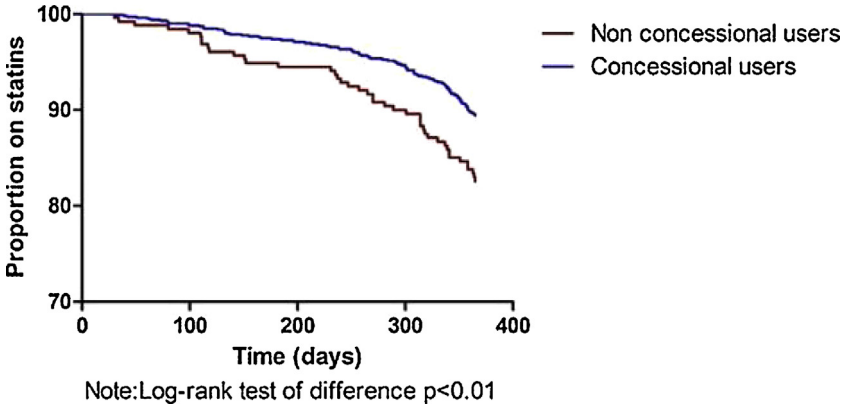

Fig. 1. Persistence in use of statins after GP consultation. *Note*: 131 patients were censored earlier than 12 month due to either not having any Medicare records in the last three months of the observation period or beyond (13 people), or because price of the statin they were prescribed dropped below non-concessional co-payment (118 patients).

Table 3 presents the results of the logistic regression models for adherence failure. In the restricted model, patients who did not have a concession card were 1.60 (95% CI: 1.04–2.44) times more likely to fail to adhere to statin therapy compared to concession users and smokers were 2.23 (95% CI: 1.35–3.71) times more likely to fail to adhere compared to non-smokers. No other variables were found to significantly affect adherence failure in multivariate or univariate models, with the exception of education which was weakly significant in the unrestricted multivariate model (people who had a university degree were 56% [95% CI: 0.31–1.01] more likely to fail to adhere to therapy when all other variables were controlled for).

A sensitivity analyses involving all identified statin users (i.e. inclusive of those who were removed due to evidence of low-cost statin use), found no changes to overall significance of results and the maximum change in the size of any coefficient was less than 5%.

5. Discussion

This study has examined how the concession card impacted on discontinuation and adherence failure to statin medication which is commonly used in primary and secondary prevention of CVD. PBS concession card users had a significantly higher degree of continuation and adherence to statin therapy compared to general users, even after controlling for income, education and a range of clinical factors. These findings suggest that the higher out-of-pocket costs associated with not having a concession card impacted on the frequency and continuation of dispensing of prescriptions for these cardiovascular drugs and may lead to higher levels of morbidity and mortality among these patients. We also found that smokers were significantly less likely to continue and adhere to statin therapy, which may reflect their time preferences for health and/or attitudes toward risk.

The findings of this study are consistent with a previous study using aggregate PBS data before and after the rise in PBS co-payments in 2005 [22] which showed that dispensing volumes significantly decreased in 12 of the 17 medicine categories including statin medications. The overall cost and out-of-pocket payments for pharmaceuticals such as statins are relatively high in Australia [12,23], so most non-concessional patients faced co-payments of more than $30 per month for these drugs during the study period. The impact of a recent proposal to further increase co-payments for general users by $5 would likely have a negative impact on adherence [24].

In regard to policy implications, reducing high levels of co-payments are likely to improve continuation and adherence and hence health outcomes across the population. However, the recent reductions in the price of most statins following patent expiry should improve adherence among non-concessional users as the cost of many of these drugs is now below the level of co-payment examined in this study (e.g. Simvastatin 40 mg is now only $12). It may also be worth educating smokers on the benefits of treatments and the risks associated with adherence failure and discontinuation of therapy.

An advantage of the AusHEART study is that it collected socioeconomic and clinical information that was linked to administrative data on pharmaceutical drug use. This allowed the tracking of prescriptions during the follow-up, obviating the need to obtain this information through less reliable means such as self-report.

Our study has several limitations which should be considered. Firstly, our study examines patients aged 55 years and over who attended a GP and consented to linkage with Medicare records. We experimented with weighting the regressions by a factor of GP consultations per patient however this made no difference to our conclusions. Secondly, most patients in our sample (96%) commenced statin therapy prior to our observation period and so we could not include information on lipid levels or estimated CVD risk at the time of the GP consultation as reverse causality (i.e. lipid levels of patients already on statins are therapeutically lowered) would likely confound the results. Thirdly, our persistence levels are likely to be much higher than if we were able to observe patients from when they first commenced therapy, as many studies find that patients discontinue use shortly after commencing therapy for the first time, [28,29] which was confirmed by our analysis. Moreover, adherence rates have also been shown to be higher for

patients that continue with therapy [25,30]. It may be that out-of-pocket costs are even more important in this early period. Fourthly, we do not know whether statins were actually consumed, or when they were consumed; we only know when prescriptions were filled. Finally, some patients may have ceased taking statins because they switched to other lipid lowering medications. We have not been able to investigate this matter due to issues with double-counting in the case that alternative medicines are used in conjunction with statins (but as different pills), or if they are used for purposes other than lowering cholesterol.

In conclusion, we have shown that higher copayments act as a disincentive for persistent and adherent use of statin medication. Reducing out-of-pocket costs may not only increase affordability, but also lead to reduced levels of morbidity and mortality through improved rates of adherence and continuation of therapy.

Competing interests

The AusHEART study was conducted as a collaborative project between the George Institute for Global Health and Servier Australia. Emma Heeley and Philip Clarke have received travel grants from Servier. John Chalmers has received research grants and lecture fees from Servier.

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