

BMJ Open Impact of consumer copayments for subsidised medicines on health services use and outcomes: a protocol using linked administrative data from Western Australia

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ABSTRACT

Introduction Across the world, health systems are adopting approaches to manage rising healthcare costs. One common strategy is a medication copayments scheme where consumers make a contribution (copayment) towards the cost of their dispensed medicines, with remaining costs subsidised by the health insurance service, which in Australia is the Federal Government. In Australia, copayments have tended to increase in proportion to inflation, but in January 2005, the copayment increased substantially more than inflation. Results from aggregated dispensing data showed that this increase led to a significant decrease in the use of several medicines. The aim of this study is to determine the demographic and clinical characteristics of individuals ceasing or reducing statin medication use following the January 2005 Pharmaceutical Benefit Scheme (PBS) copayment increase and the effects on their health outcomes.

Methods and analysis This whole-of-population study comprises a series of retrospective, observational investigations using linked administrative health data on a cohort of West Australians (WA) who had at least one statin dispensed between 1 May 2002 and 30 June 2010. Individual-level data on the use of pharmaceuticals, general practitioner (GP) visits, hospitalisations and death are used. This study will identify patients who were stable users of statin medication in 2004 with follow-up commencing from 2005 onwards. Subgroups determined by change in adherence levels of statin medication from 2004 to 2005 will be classified as continuation, reduction or cessation of statin therapy and explored for differences in health outcomes and health service utilisation after the 2005 copayment change.

Ethics and dissemination Ethics approvals have been obtained from the Western Australian Department of Health (#2007/33), University of Western Australia (RA/4/1/1775) and University of Notre Dame (O 14 167F). Outputs from the findings will be published in peer reviewed journals designed for a policy audience and presented at state, national and international conferences.

INTRODUCTION

The global trend of both public and private health insurance services is moving towards

Strengths and limitations of this study

- Using the whole-of-population, cross-jurisdictional, linked administrative data will allow exploration of factors that might affect a person's decision to cease or reduce their medication due to cost, providing the most detailed information to date regarding the effects from the January 2005 copayment increase.
- A major strength of this study is the use of time-series drug data linked to primary care visits, death and hospital admissions. Administrative data are objective and provide complete records.
- Limitations include that the Pharmaceutical Benefit Scheme database has month and year rather than full date of supply for each entry, and does not have dosage information. Additionally, consumer's direct account of decision making associated with change in usage is unknown.

adapting effective ways to manage the rising healthcare costs. Within Australia, the number of prescriptions and cost of medicines have been increasing over the last two decades,¹ reflected by similar increases in other western nations as populations age and disease patterns change. Patient copayments are one of many policies that the Australian Government has adopted to manage this.¹

The Australian Pharmaceutical Benefit Scheme (PBS) provides subsidised medicines for Australian residents and is subsidised by the Australian Government Department of Health.² The Repatriation Pharmaceutical Benefit Scheme (RPBS) is subsidised by the Australian Government Department of Veterans' Affairs (DVA) and covers a broader range of medications to eligible veterans.²

In 2010, an estimated 271 million prescriptions were dispensed by community pharmacies, with 75% of the prescriptions

subsidised by the PBS and the RPBS at a cost to the Australian Government of \$16.4 billion.¹ By comparison, in 2014/15, there were 302 million prescriptions dispensed of which 223 million were PBS/RPBS-subsidised medications,³ representing an 11% growth in prescription numbers over the 5 years.

Under the PBS and RPBS, consumers pay a part cost towards their medicines dependent on their financial status: general or concessional. Once a family reaches a certain expenditure threshold from their cumulative PBS copayments in a calendar year, they are issued a Safety-Net card providing additional financial support through further subsidies on medication.⁴

Copayments increase on the 1st of January each year generally in line with the Consumer Price Index.² The largest individual increase in copayments in recent times was in January 2005, when a 21% increase in consumer co-payments occurred for PBS medications for both general patients (from \$23.70 in 2004 to \$28.60 in 2005 per item dispensed) and concessional patients (\$3.80–\$4.60 per item dispensed).⁴

Sharp increases in the copayment threshold are of potential concern from a patient and population health perspective. National and international evidence suggest that rising costs of medication can result in patients ceasing or reducing their medication often without clinical consultation.^{5–7}

Previous research using aggregated data has demonstrated that following the PBS copayment increase in January 2005, there was a significant decrease in dispensing of between 3% and 11% for 12 out of the 17 medicine classes examined.⁵ The largest reductions observed during this period were seen for concessional patients rather than general patients. Essential medicines used to manage serious but asymptomatic conditions, including lipid-lowering therapy, were among the most affected in terms of reduced dispensing after the copayment increase with dispensing decreasing by 5%.⁸ In a separate study based on patient self-report, the same authors found that the population groups most likely to reduce their medications due to cost were young adults, low-income earners, the chronically ill, those with high out-of-pocket costs, Aboriginal and Torres Strait Islanders and patients who did not feel involved in decisions about their treatment.⁹ Many of these groups are also generally known to have poorer health outcomes.¹⁰ Therefore, additional costs may have a more pronounced effect on the health outcomes for these groups. A 2013 study, in Australia, demonstrated that the likelihood of facing substantial financial burden becomes significantly higher for each additional chronic disease experienced due to extra out-of-pocket healthcare costs.¹¹ Additionally, self-report surveys provide estimates that 12% of Australians did not get medication dispensed at the pharmacy or skipped doses of prescribed medication due to cost.¹² The relationship between financial stress and failure to purchase necessary medical services or medicines was also emphasised in a study where it demonstrated that a

quarter of those under financial stress forgo medical care and refilling their prescriptions.¹³

International research has shown that ceasing a medication due to cost can have implications on health outcomes and increase health service utilisation.^{14 15} Additionally, it has been demonstrated that improved adherence to essential medicines can lead to savings in other health expenditure.^{16 17}

What is currently unknown in Australia is the flow-on effect from increased copayments to subsequent health services utilisation including frequency of general practitioner (GP) consultations and adverse health outcomes including unplanned hospitalisation or death. For example, it is unknown for any individuals who discontinued or reduced their medication if they were under more or less clinical supervision before, during and after this time. While copayments may reduce some of the cost burden to the Government, this may have unintended negative effects if higher costs are incurred elsewhere in the healthcare system through the increased need for secondary healthcare and premature morbidity.^{7 15 18}

The main aim of this study will explore the effect of an increase in patient contributions (consumer copayments) for PBS-subsidised medicines in 2005 on health service utilisation and health outcomes, among people using prescribed statins as lipid-lowering therapy. This group was selected because research has shown that statin users were affected by increasing costs.^{5 8 19} Statins are used for asymptomatic conditions, but the consequences of discontinuing statins are potentially serious. Use of statins for primary prevention reduces all-cause mortality and cardiovascular (CV) events among people with low-CV or high-CV risk,²⁰ while use as secondary prevention significantly reduces the risk of a further CV event.^{20 21} Due to the known positive benefits of statin medication, the prescribing rate is high across Australia.²² However, a change in copayments that leads to reduced use may result in poorer outcomes or poorer compliance. Poor compliance has been attributed to many factors including the dosing frequency, financial burden, lack of concessional card, low income, less CV morbidity at commencement of therapy, frequency of GP visits, depression, dementia and age.^{23–27}

The aim of this study will be achieved through the following five objectives:

Objective 1: To determine whether consumers who ceased or reduced statin medication use have different demographic and clinical characteristics across 2000 to 2004 compared with those who continued to take their medication after the January 2005 PBS copayment increase.

Objective 2: To compare hospitalisation rates from 2006 to 2010 between consumers who ceased, reduced or continued statin medication after the January 2005 PBS copayment increase.

Objective 3: To measure the risk of death from 2006 to 2010 (all-cause or coronary heart disease) between consumers who ceased, reduced or continued statin

medication after the January 2005 PBS copayment increase.

Objective 4: To investigate whether regularity and frequency of health service use in the 12 months prior to January 2005 PBS copayment increase affected the rate at which consumers ceased, reduced or continued statin medication.

Objective 5: To examine whether consumers who ceased or reduced statin medication after the January 2005 copayment increase concurrently ceased or reduced other medications in 2005 compared with 2004.

METHODS

Study design and population

This retrospective observational study uses whole-of-population administrative data in Western Australia (WA). The initial data extract for the total statin cohort was identified from PBS data and included individuals who had at least one statin medication dispensed in the period between 1 May 2002 and 30 June 2010. Statins were identified by any of their primary anatomical therapeutic chemical (ATC) codes (C10AA01, C10AA03, C10AA04, C10AA05, C10AA06 and C10AA07).

The WA population was chosen due to the long-standing data linkage system in this State. Comparisons of national census data and health statistics have indicated that WA was the most representative population of Australia's eight jurisdictions.²⁸ Hence, findings from this study are expected to be applicable to the Australian population.

Data sources

The study will use linked datasets extracted from multiple State and Commonwealth population-based administrative data collections (figure 1). PBS and Medicare Benefits Scheme (MBS) data were obtained from the Australian Government Department of Human Services.

The other two datasets were extracted from the WA Hospital Morbidity Data Collection (HMDC) and WA Mortality Register. The HMDC and mortality register are two core datasets of the WA Data Linkage System.²⁹ The study cohort was identified from the PBS data, and PBS records were linked to matching MBS, HMDC and death records.

PBS data contain records for each pharmaceutical product that is subsidised by the Australian Government and supplied by PBS-approved pharmacies. The data include item name and strength, PBS item code, ATC classification code, month and year of supply, quantity dispensed, repeat number, beneficiary status (concessional or general), patient gender, age and Accessibility Remoteness Index of Australia (ARIA+) code³⁰ based on patient postcode and an index of relative socioeconomic disadvantage (Socio-Economic Indexes for Areas) based on patient postcode.³¹

The MBS data contain information related to health services used outside the hospital setting including GP consultation, diagnostic services and laboratory tests. These services are subsidised by the Australian Government and the data include information on service type, date of service and patient age.

The HMDC is a statutory data collection that is compiled from all inpatient admissions supplied by all hospitals (public and private) in WA. The data supplied provide information on admitted patient care including demographics, length of stay, diagnoses (principal discharge diagnosis and up to 20 secondary discharge diagnoses), procedures (primary and up to 10 secondary) and external cause codes for injury and poisoning. For the period of this study, the diagnoses and procedures were recorded using the International Statistical Classification of Diseases and related health problems Tenth revision, Australian Modification (ICD-10-AM).³²

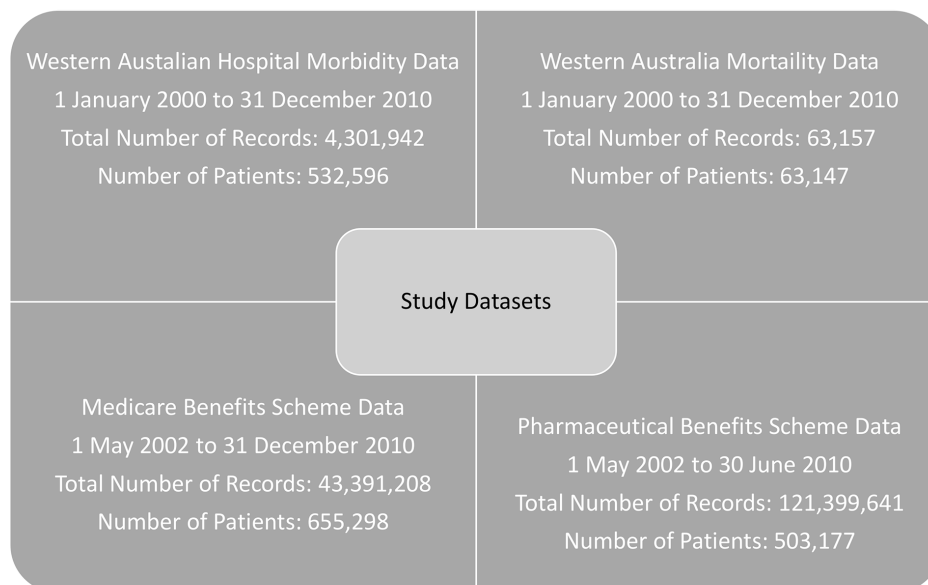


Figure 1 Study dataset sources from State (Western Australia) and Australian Government administrative health data.

Table 1 Statin medications above and below the general copayment

Description	Name and strength
Statin medications above the general beneficiary copayment	Atorvastatin 10/20/40/80 mg; fluvastatin 40 mg; pravastatin 10/20/40/80 mg; simvastatin 10/40/80 mg
Statin medications below the general beneficiary copayment as of 1 December 2005	Fluvastatin 20 mg; simvastatin 5 mg

Note: All statin medications were above the concessional copayment.

The WA Mortality Register includes records for each registered death in WA and includes information on date of death, cause of death (primary and contributing) and patient's gender, postcode and age at death.

Limitations of PBS and MBS data

There are some limitations with the PBS and MBS data. Specifically, PBS data prior to 1 July 2012 were not collected for medications below the patient copayment or dispensed privately. In relation to statin medications, there were two item codes (of 14 items) below the general copayment threshold during the study period (see table 1), but none below the concessional copayment threshold. For this reason, results will be stratified to look at concessional and general beneficiaries separately. PBS data do not include the prescribed dose nor the frequency, so the dose per day is unknown. Additionally, some patients may have ceased taking a statin medication because they switched to another lipid-lowering medication that is not a statin medication, these patients will be excluded. This represented, in 2004, 3% of overall lipid-lowering use dispensing.³³

While MBS data capture all health services provided outside the public hospital setting, they do exclude services provided to public inpatients, DVA card holders, patients treated at Aboriginal Medical Services and diagnostic information including reason for consultation and pathology test results.³⁴

Study cohort

The study cohort was identified from the total statin cohort and included patients who were stable statin users as of December 2004. As month not day of supply was provided, a stable user was defined as a patient who had at least 60 days' supply in the last 3 months of 2004 (the average prescription refill rate for statin medication is every 35 days) (see box 1). Patient's aged <18 years in 2004, died in 2004 or 2005 or who had an excessive supply of statin medication during 2004 were excluded from the study (see box 1). Excessive supply was defined as >1.5 years of supply of statin medications during 2004 (<0.5% of total cohort) (see box 1). Sensitivity subanalysis will be conducted on the definition. All stable users will be further classified as a 'new user' if they have no dispensing of a statin medication in 2002 or 2003 otherwise they be classified as an 'existing user'. In 2004 in WA, there were 2 213 959 dispensing records for a statin medication for 262 330 patients.

After defining the study cohort, adherence will be calculated for the years 2004 and 2005 using the portion of days covered (PDC) method calculated from the start of 2004 or when they commence a statin medication in 2004.²³ The level of adherence will be compared between 2004 and 2005 to evaluate change in usage. Three groups will be identified within the study cohort to identify changes in the dispensing of statins (table 2): (i) those 'continuing' statin medications (<20% change) (ii) those who 'reduce' the amount of statin medication (greater than 20% change); and (iii) those who 'cease' taking statin medications. Sensitivity Analysis will be conducted around changes in reduction of PDC levels. Cessation of statin medications in 2005 will be defined as no dispensing of a statin medication for a period of 6 months in 2005. This takes into consideration the stockpiling phenomenon that happens at the end of each year, in this case 2004. This phenomenon occurs when consumers reach the safety net spending threshold for PBS medicines and are entitled to free medicines or a reduced copayment for the remainder of the calendar year.³⁵ This can result in consumers filling additional prescriptions towards the end of the year before they return to their usual copayment the following January. Hence, excess medication will be carried forward to ensure PDC is not under estimated. Time of discontinuation will be calculated as the time of last dispensing plus 3 months.

The study period will vary for each objective ranging from 1 January 2000 to 31 December 2010.

Box 1 Entry criteria into the study defined as stable statin user as of December 2004 inclusion and exclusion criteria

Inclusion criteria 'stable user'

- ▶ ≥1 supply of a statin medication between 1 January and 31 December 2004; and 60 days' supply in the last 3 months of 2004 or >150 days of supply in the last 6 months of 2004.

Exclusion criteria

- ▶ Age <18 years in 2004.
- ▶ Died in 2004 or 2005.
- ▶ >550 days' supply of a statin medication in 2004.

New user

- ▶ If no dispensing of a statin medication in 2002 or 2003.

Table 2 Groups of statin users to be identified in the study cohort

Type of statin user	Definition
Continuing	Maintained the same or greater level of adherence from 2004 to 2005 ($\leq 20\%$ change)
Reduced	Level of adherence decreases from 2004 to 2005 ($> 20\%$ change)
Ceased	No dispensing of a statin medication for a period of 6 months in 2005

Other explanatory factors to consider

Patient age, gender, ‘new’ statin user (initiated statin therapy in 2004), PBS beneficiary status (general or concessional) and other PBS-subsidised prescription medication use will be ascertained from the PBS dataset. This will include a number of additional medications to measure the extent of comorbidity, however it is more related to the study as exploring the impact of cost. Social disadvantage ascertained from the PBS data will be classified by applying an area-based measure of disadvantage (the Index of Relative Socioeconomic Disadvantage³¹) to each record based on the residential postcode. This will be divided into quintiles, with one representing most disadvantaged and five representing least disadvantaged. Level of remoteness (ARIA+) will be identified from the residential postcode in the PBS data and categorised as major cities, inner regional, outer regional, remote, very remote and unknown.³⁰ To determine primary or secondary prevention status, previous myocardial infarction (MI, ICD-10-AM I21), or stroke (ICD-10-AM I60-I64) with look-back to 2000 will be ascertained from any of the diagnosis fields in the HMDC data.³²

Change in PDC covered across 2004 and 2005 will be considered both as a categorical and a continuous variable at time zero for the follow-up of outcomes. In order to address immortal time bias and to reduce the likelihood of over estimating hospitalisation and death, the follow-up period will commence from 2006 onwards. In addition, hospitalisation and death in the months after 2005 arguably would not be due to statin discontinuation.

Statistical analysis

Objective 1: For this objective, the three outcome variables will refer to type of statin user dichotomized as continuing, reduced and ceased as defined in table 2. The study period is defined as 2000 to 2005. Crude differences in characteristics between the three groups of the study cohort will be initially compared using *t*-tests and χ^2 tests. Univariate and multivariate logistic regression models will then be developed and run to determine the association between patient clinical and demographic characteristics at baseline and statin use based on PBS-dispensed records. Unadjusted and adjusted ORs and 95% CIs will be calculated for each individual characteristic and for the three outcome variables. Bonferroni correction will be applied to account for multiple testing. Additionally, stratification by beneficiary status will be conducted

Objective 2: The primary analysis here will report the hazard ratios for hospitalisation for any causes or for MI or stroke from 2006 to 2010. The study period is defined

as 2000 to 2010. Cause-specific diagnoses will be identified from the principal discharge diagnosis field in the HDMC dataset by using ICD codes (MI: I21, Stroke: I60–I64).³² Multivariate Cox proportional hazards regression modelling will be used to determine the difference in hazard rates between the three statin user groups: continuing, reduced and ceased. Any individual’s hospitalisation due to a cardiac event prior to 2005 will be treated as a fixed effect in the Cox model. Subsequent analysis will be performed to assess the effects of other predictors due to differences in the baseline demographics and clinical characteristics of the two cohorts that are also associated with hospitalisation using multivariate Cox regression modelling.

Objective 3: The primary analysis for this objective will report on the risk of death for the two groups by all cause of death and coronary heart disease. The study period is defined as 2006 to 2010. Cause of death will be determined by ICD codes from the coded cause of death field in mortality data (coronary heart disease: I20–I25).³² Differences in the risk of death between patients who continue statins and those who reduce or cease their statins will be compared using the log-rank test (unadjusted Kaplan-Meier risk) and by Cox proportional hazards regression to calculate the HR.

Objective 4: The primary analysis will report on the frequency and periodicity of GP visits and specialist visits for the study cohort from MBS data. The study period is 2004. Commencing from the date of entry into the study cohort, we will measure the annual intensity (ie, incidence rate) of service contact for each person to determine if more or less clinical supervision affects an individual’s decision to continue, reduce or cease medication. Previous published work has developed and trialled a periodicity score and to estimate regularity of service provision and these methods will be used in our study.^{36–39} Subsequent analysis will be performed to assess the effects of differences in the baseline demographic and clinical characteristics of the cohorts using multivariate regression modelling.

Objective 5: The primary analysis will describe the type and frequency of additional medications that were ceased or reduced after January 2005 for those who had reduced or ceased their statin therapy, and identify medications other than statins more likely to be ceased or reduced. The study period is defined as 2004 to 2005. Generalised estimating equation modelling will be performed to identify subgroups at greater risk of ceasing other medication(s) by their demographic and clinical baseline characteristics.

ETHICS AND DISSEMINATION

Ethics approval was obtained from the human research ethics committees (HREC) of The Western Australian Department of Health (#2007/33), The University of Western Australia (RA/4/1/1775) and The University of Notre Dame (014167F). A waiver of consent was approved by the HREC committees to provide linked de-identified data to the researchers in order to conduct this study.

The large amount of data available will result in several publications and will be presented at state, national and international conferences. The results from the study will ensure that all stakeholder groups including Government, policy makers, consumers, the pharmaceutical industry, pharmacy and medical groups will be informed about the outcome to guide future policy.

DISCUSSION

This research will provide the first individual-level evidence of the effect of the PBS consumer copayments on health outcomes and the broader healthcare system in Australia. It proves timely in relation to the Government's proposal to introduce higher and potentially more consumer copayments, including an emergency department copayment across the health system.⁴⁰ The results of this study may be pivotal in informing policy development that will support sustainable pharmaceutical budgets, as well as potentially minimising harm to consumers that may arise from reducing or ceasing medications due to cost.

A recent paper demonstrated that patients without a concessional card were 63% more likely to discontinue statin therapy and 60% more likely to fail to adhere to statin therapy compared with those with a concessional card over a 1-year period when controlling for factors such as income, education and a range of clinical factors.²⁴ A study by Warren, *et al*²⁷ looked at adherence in long-term use of statin medication and showed that adherence levels to statin therapy were high for concessional beneficiaries (80.1%) and lower in general beneficiaries (56.7%). Both studies demonstrated a higher adherence to statin medication for concessional beneficiaries, highlighting the importance to explore these two groups at the time of medication copayment increase and the effect it had on adherence, health outcomes and health service utilisation. Literature worldwide has demonstrated that statin medication use and adherence is price sensitive.^{5-7 23} However, there is a gap in understanding whether this places patients at risk of adverse outcome or shifts costs to other health services such as hospitalisation.

Identifying whether there are differences between consumers who continue their medication, those who reduce their medication and those who cease their medication will be important in informing policy. The findings will have implications on future decision making of increasing a copayment and the consequences for vulnerable populations and long-term outcomes, including

people with low income or living in rural and remote areas.

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Competing interests None declared.

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