Cholesterol-lowering therapy and the Australian Pharmaceutical Benefits Scheme: a population study

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Abstract

Objective: The Australian Pharmaceutical Benefits Scheme (PBS) expanded the criteria for eligibility for subsidised lipid-lowering therapy (LLT) in 2006. The aim of this study was to determine the use of LLT in a representative Australian population in relation to cardiovascular disease (CVD) risk, and the effectiveness of the therapy in meeting target levels.

Design: Cross-sectional biomedical study with telephone interviews, questionnaires, clinical measurements, and PBS dispensing data.

Subjects: Representative population sample of 4060 urban adults aged ⩾18 years attending for the biomedical examination in 2001.

Results: Of the 406 who qualified for PBS-subsidised LLT at that time, only 88 (21.5%) were actually on LLT. National Heart Foundation of Australia (NHF) recommended low-density lipoprotein cholesterol (LDL-C) levels of <2.5 mmol/L were recorded in only 13% (528) of the population, and in 46.8% of those on LLT. Of those on LLT, 76% had total cholesterol <5.5 mmol/L, but over 80% had total cholesterol levels above NHF-recommended levels of 4.0 mmol/L. Of the 842 classified at the highest CVD risk, only 26% were using LLT. Those aged >60 years and on low incomes were significantly more likely to use LLT. The new PBS criteria will expand eligibility to include nearly 20% of adults.

Conclusions: The majority of people at high risk of CVD were not receiving LLT, and LLT is not being used to its full effectiveness. People with low incomes or on government benefits or pensions were not less likely to use LLT than others under the PBS scheme. Whether higher copayments for those on low incomes who do not qualify for concessional payments is a significant barrier to LLT use needs further research.

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What is known about the topic?

Many people who may benefit from lipid-lowering treatment are not receiving it. The Pharmaceutical Benefits Scheme (PBS) recently expanded eligibility for subsidised medications.

What does this paper add?

The majority of people at risk for cardiovascular events are not using lipid-lowering treatment, particularly for primary prevention. Recent changes to PBS criteria will expand eligibility for subsidised medications to 20% of adults. Those on pensions or benefits were not less likely to use medications than others. It remains speculative whether high copayments are a barrier to use by people whose incomes put them just above the threshold for concessional medications.

What are the implications for practitioners?

Practitioners should assess overall cardiovascular risk levels for patients to increase use of lipid-lowering treatment, particularly for primary prevention. Consideration needs to be given to whether financial costs are a barrier to medication use.

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DESPITE THE PROVEN efficacy of lipid-lowering therapy (LLT),[1] there still remain significant gains to be made in the frequency of prescribing of statins, and to a lesser extent fibrate therapies, to high-risk patient groups.[2] Recently the recommendations for coronary heart disease prevention have shifted from a simple focus on the level of serum cholesterol to considerations of the broader concept of cardiovascular risk.[3] Although particular target levels are recommended, in those at risk it is also argued that treatment should aim to achieve substantial absolute reductions in low-density lipoprotein cholesterol (LDL-C).[3]

In Australia, the Pharmaceutical Benefits Scheme (PBS) provides subsidised medications as part of the national universal health care system. Medications with PBS-approved indications are available for a copayment of A$4.70 for health-care card holders such as those on welfare or low incomes, or for a maximum copayment of A $31.30 per prescription for all others. LLT is available through the PBS to people who fulfil certain clinical criteria.[4] Until 2006, these included secondary prevention of cardiovascular disease (CVD), and people with elevated serum cholesterol and risk factors such as diabetes. By contrast, in 2005 the National Heart Foundation of Australia (NHF) promulgated recommendations that used assessment of overall cardiac risk as the basis for initiating cholesterol-lowering treatment and suggested substantially widened eligibility criteria for LLT beyond those available under the PBS.[5] The NHF treatment guidelines closely mirror those of the Adult Treatment Panel III of the National Cholesterol Education Program in the United States.[3,6] The PBS has recently altered the criteria for eligibility for subsidised LLT, largely to expand its use in secondary prevention of CVD and in people with a history of stroke or diabetes.[7]

Therefore, the Australian situation provides an interesting perspective for two reasons: firstly, to assess the challenge facing clinicians and policy-makers in implementing cholesterol treatment guidelines; and secondly, the information it provides on medication dispensing under a system of universal drug coverage that aims for maximum cost-effectiveness. Many previous studies on statin use have been limited by using convenience samples,[8] focusing only on secondary prevention[2] or relying exclusively on self-report of medication use.[9] The aim of this study was to determine: firstly, the use of LLT in a representative population in relation to CVD risk; secondly, who will now become eligible for subsidised LLT; and thirdly, the effectiveness of the therapy in meeting target levels in those at risk.

Methods

The North West Adelaide Health Study (NWAHS) is a representative biomedical population study of people aged 18 years or older living in the north-western suburbs of Adelaide, South Australia (population 1.2 million), and the methods have been previously described.[10] The distribution of social-demographic indicators is representative of the community profile of Adelaide.[11] Recruitment for the NWAHS of 4060 adults (1988 men, 2072 women; 69.4% of those who completed the initial interview) occurred in 2001 (Phase 1a; $n = 2523$) and 2003 (Phase1b; $n = 1537$). Households selected at random from the electronic *White pages* telephone directory were eligible for inclusion in the study. In each household, the person aged 18 years or older who was last to have a birthday was asked to participate in the telephone interview and a clinical assessment. There was no replacement for refusal, or for non-response after up to ten call-backs. The ability of these methods of selection to achieve an unbiased sample has been described previously.[12]

Information was gathered on self-reported health status (including doctor diagnosis of heart attack, angina, stroke, diabetes), risk factor prevalence, health service use, use of cholesterol/lipid-lowering medication, tobacco use and detailed demographic information. Pharmaceutical Benefits Scheme data obtained on the NWAHS cohort was also used to determine prescription of statin and fibrate therapy. Biomedical assessment of participants included measurements of height, weight and blood pressure. Obesity was defined as a body mass index > 30 kg/m^2. High blood

pressure was defined as systolic blood pressure greater than or equal to 140 mmHg and/or diastolic blood pressure greater than or equal to 90 mmHg. A fasting blood sample was drawn for lipid profiles and plasma glucose.

The NHF and the Cardiac Society of Australia and New Zealand (CSANZ) recommend the targeting of lipid-lowering therapies to high-CVD-risk individuals. The NWAHS participant CVD risk was categorised according to the 2001 Lipid Management Guidelines,[5] taking into account recommendations in the 2005 Position Statement on Lipid Management,[13] as outlined in Box 1. We also determined NWAHS participants' eligibility for PBS-subsidised lipid-lowering therapies according to the PBS guidelines[4] pertaining at the

1 Prevalence of people and use of lipid-lowering therapy (LLT) within each classification criteria for determining LLT eligibility

	Total eligible	No. receiving LLT (no. [%])
National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand criteria[13]		
Highest risk	842	222 (26.4)
Vascular disease (CHD, and stroke); Type 2 diabetes (if after lifestyle intervention); LDL-C > 2.5 mmol/L or TG > 2.0 mmol/L; Aboriginal and Torres Strait Islander and LDL-C > 2.5 mmol/L; ⩾ 15% Framingham risk of CVD event in next 10 years; 10–15% Framingham risk of CVD event in next 10 years in presence of the metabolic syndrome		
High risk (increased absolute risk)	351	16 (4.6)
LDL-C > 4.0 mmol/L or TC > 6.0 mmol/L plus two or more other risk factors including HDL-C < 1.0 mmol/L, hypertension, overweight or obesity, smoking, impaired fasting glucose, age ⩾ 45 years		
Lower risk	45	1 (2.2)
TC > 7.0 mmol/L or LDL-C > 5.0 mmol/L or TG > 8 mmol/L		
Previous Pharmaceutical Benefits Scheme criteria[4]		
Existing coronary heart disease with TC > 4 mmol/L	138	64 (47.1)
Others at high risk with one or more of the following: diabetes, hypertension, stroke with TC > 6.5 mmol/L, or TC > 5.5 mmol/L if HDL-C < 1.0 mmol/L	201	16 (8.0)
People with HDL-C < 1.0 mmol/L and TC > 6.5 mmol/L	20	0
Men aged 35–75 years, women aged 55–75 years (post-menopausal) not eligible under above criteria with TC > 7.5mmol/L or TG > 4 mmol/L	45	6 (13.0)
Others with TC > 9 mmol/L or TG > 8 mmol/L	2	1 (50.0)
2006 Pharmaceutical Benefits Scheme criteria[7]		
Existing coronary heart disease, stroke, diabetes in Aboriginal/Torres Strait Islanders, diabetics aged ⩾ 60	352	167 (47.4)
Diabetics not otherwise included with TC > 5.5mmol/L	37	0 (0)
Aboriginal/Torres Strait Islander or hypertensive patients with TC > 6.5 mmol/L, or TC > 5.5 mmol/L if HDL-C < 1.0 mmol/L	161	11 (6.8)
People with HDL-C < 1.0 mmol/L and TC > 6.5 mmol/L	20	0 (0)
Men aged 35–75 years, women aged 55–75 years (post-menopausal) not eligible under above criteria with TC > 7.5mmol/L or TG > 4 mmol/L	44	5 (11.4)
Others not included with TC > 9 mmol/L or TG > 8 mmol/L	2	1 (50.0)

CHD = coronary heart disease. LDL-C = low-density lipoprotein cholesterol. TG = triglycerides. CVD = cardiovascular disease. TC = total cholesterol. HDL-C = high-density lipoprotein cholesterol.

time of the study, and with the recent changes to eligibility.[7] (Box 1)

Analysis

Data were analysed using SPSS for Windows, version 13.0 (SPSS Inc, Chicago, Ill, USA) and were weighted to the Australian Bureau of Statistics 1999 estimated resident population by region (west and north), age groups, gender and probability of selection in the household. This can produce minor variations in percentages in data across tables. Chi square tests identified significant differences in proportions of participants achieving target lipid levels. The Students *t* test determined significant differences in mean lipid levels, and multiple logistic regression analysis was used to determine the factors associated with lipid-lowering therapy.

Institutional ethics committee approval was obtained for the conduct of the North West Adelaide Health Study from the Ethics of Human Research Committee of the North West Adelaide Health Service. The authors had full access to the data and take responsibility for its integrity. All authors have read and agree to the manuscript as written.

Results

The demographic characteristics of the sample population have been previously described.[10] Of the total sample, lipid-lowering therapies (LLT) were used by 8.9% ($n = 362$) of study participants. LLT was significantly associated with older age (21.4% [$n = 329$] in people aged $\geqslant 50$ years v 1.3% [$n = 33$] in those less than 50 years; χ^2 $P < 0.05$). LLT use was independent of gender (9.4% [$n = 186$] in men v 8.5% [$n = 176$] in women; χ^2 $P = 0.33$). LLT was utilised by 52.0% of people with a past history of CHD or stroke (57.7% [$n = 79$] in men and 45.5% [$n = 51$] in women). There was large variation between the number of people identified by the NHF/CSANZ criteria and both the old and new PBS criteria with increased cardiovascular disease risk requiring LLT (30.5%, $n = 1238$; 10.0%, $n = 406$; 15.2%, $n = 616$, respectively) as shown in Box 1. The new PBS criteria would result in a relative expansion in eligibility for subsidised LLT of over 50%, mostly by increasing eligibility for use in secondary prevention of CHD and for those with stroke or diabetes. Of the total sample, 20.7% ($n = 842$) were classified by NHF/CSANZ criteria as being at the highest CVD risk, yet only 26.0% of this group were using lipid-lowering therapies. Of the 1238 classified by NHF/CSANZ criteria as at risk, 19.3% (239) were using LLT.

Of the 10.0% of participants ($n = 406$) eligible under the former PBS criteria for subsidised lipid-lowering therapies, only 21.5% ($n = 88$) were using these therapies. The prevalence of lipid-lowering therapies in people classified by the former PBS criteria as being at high risk (existing CHD and total cholesterol > 4.0 mmol/L) was 47%. However, 76% ($n = 274$) of those using LLT did not currently qualify for PBS subsidised supply. This is mostly explained by the high prevalence (66.0%, $n = 181$) of participants in this group with one or more of existing CHD, stroke, diabetes and hypertension. To be classified in these high-CVD-risk groups, prerequisite cholesterol levels applied (eg, existing CHD *and* total cholesterol > 4.0 mmol/L), and it is likely that lipid-lowering treatment in this group is efficacious and precludes their current classification in the high-risk categories. Similar findings were observed for the group classified by NHF/CSANZ criteria as not at risk, which accounted for 34% ($n = 123$) of the use of lipid-lowering therapies. Diabetes and hypertension were present in 47% of this group.

Box 2 shows the proportions of individuals meeting specified lipid target levels[5,6] in relation to CVD risk and treatment. Those in the highest risk group were more likely to have achieved target levels than in other risk categories. However, among those at risk there were substantial proportions not achieving target levels, especially of LDL-C. In people on lipid-lowering therapies, only 46.8% recorded an LDL-C < 2.5 mmol/L, with 76.4% achieving a total cholesterol < 5.5 mmol/L and 19.0% a total cholesterol < 4.0 mmol/L. Of those defined by the NHF to be at high CVD risk, only 14.1% (174/1229) met the proposed target level for LDL-C.

Mean cholesterol levels in relation to CVD risk and LLT are shown in Box 3. LLT in high-CVD-risk individuals was associated with significantly lower levels of total and LDL cholesterol. Of note is that in the primary prevention risk categories (ie, those at risk but without a history of coronary events) mean levels of cholesterol remain substantially elevated above target levels.

Factors associated with use of LLT in the multiple logistic regression models are shown in Box 4. In addition to disease-related factors, age older than 60 years and lower household income (< $40 000) or receipt of a government social security benefits were significantly associated with use of LLT. Current smokers were half as likely to be taking LLT as non-smokers.

2 Percentage (no.) of those meeting cholesterol target levels classified by cardiovascular disease risk category according to use of lipid-lowering therapy (LLT)

	TC<5.5	TC<4.0	HDL-C>1.0	LDL-C<2.5	TG<2.0
National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand criteria					
Highest (833)					
LLT (218)	77.5 (172)§	24.8 (54)§	80.3 (175)	52.4(110)§	59.4 (130)
No therapy (615)	44.3 (274)	3.1 (19)	73.7 (453)	10.9 (64)	57.4 (353)
High (351)					
LLT (16)	0.0 (0)	0.0 (0)	100.0 (16)	0.0 (0)	43.8§ (7)
No therapy (335)	0.0 (0)	0.0 (0)	87.7 (293)	0.0 (0)	70.4 (235)
Low (45)					
LLT (1)	0.0 (0)	0.0 (0)	100.0 (1)	0.0 (0)	0.0 (0)
No therapy (44)	0.0 (0)	0.0 (0)	100.0 (44)	0.0 (0)	60.5 (26)
Not at risk (2759)					
LLT (122)	86.1 (105)§	11.5 (14)	95.9 (116)	48.3 (58)§	81.1 (99)§
No therapy (2637)	74.1 (1999)	16.7 (441)	92.4 (2436)	33.2 (870)	91.5 (2414)
Previous Pharmaceutical Benefits Scheme criteria					
Yes					
LLT (87)	63.2 (55)§	1.5 (1)	76.1 (67)	35.4 (28)§	58.6 (51)§
No therapy (317)	14.5 (46)	0.0 (0)	67.2 (213)	6.0 (16)	46.4 (147)
No					
LLT (270)	81.9 (221)§	24.8 (67)§	89.6 (242)	52.4(141)§	68.1(184)§
No therapy (3313)	67.2 (2227)	13.9 (460)	91.0 (3014)	27.8 (919)	87.0 (2882)
2006 Pharmaceutical Benefits Scheme criteria					
Yes					
LLT (184)	77.8 (140)§	28.3§ (51)	79.4 (143)	60.6(103)§	66.7 (120)§
No therapy (429)	10.9 (46)	3.0 (13)	72.3 (311)	10.6 (40)	59.0 (253)
No					
LLT (177)	77.0 (137)§	9.6 (17)	93.3 (166)	37.1(66)§	74.2 (132)§
No therapy (3201)	67.6 (2163)	14.0 (447)	91.1 (2915)	28.1 (895)	89.4 (2863)

§Pearson χ^2 $P < 0.05$. TC = total cholesterol. HDL-C = high-density lipoprotein cholesterol. LDL-C = low-density lipoprotein cholesterol. TG = triglycerides.

3 Mean age and cholesterol levels in relation to level of cardiovascular disease risk and use of lipid-lowering therapy (LLT)

	LLT	Mean age (SD)	TC (SD)	HDL-C (SD)	LDL-C (SD)	TG (SD)
National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand criteria						
Highest	No (615)	59.6 (13)	5.7 (1.0)	1.2 (0.3)	3.6 (0.9)	2.1 (1.5)
	Yes (219)	66.0* (10)	4.7* (1.0)	1.2 (0.3)	2.6* (0.8)	2.0 (1.4)
High	No (335)	53.1 (16)	6.7 (0.6)	1.5 (0.4)	4.4 (0.6)	1.7 (1.0)
	Yes (16)	61.1* (15)	6.8 (1.0)	1.5 (0.3)	4.4 (1.3)	2.2 (0.9)
Low	No (44)	42.7 (13)	7.5 (0.5)	1.5 (0.4)	5.2 (0.7)	2.1 (1.3)
	Yes (1)	56.0 (15)	7.9	1.4	5.2	2.9
Not at risk	No (2637)	37.7 (15)	4.8 (0.8)	1.4 (0.3)	2.9 (0.8)	1.2 (0.7)
	Yes (122)	66.0* (13)	4.8 (0.6)	1.5* (0.4)	2.6* (0.5)	1.5* (0.7)
Previous Pharmaceutical Benefits Scheme criteria						
CHD; TC > 4.0 mmol/L	No (73)	69.7 (15)	5.5 (0.9)	1.4 (0.4)	3.3 (0.8)	1.8 (1.1)
	Yes (65)	66.8 (10)	4.8* (0.7)	1.3 (0.4)	2.7* (0.6)	1.7 (1.2)
Diabetes/stroke/hypertension; TC > 6.5 mmol/L or TC > 5.5 mmol/L if HDL < 1.0 mmol/L	No (184)	55.0 (16)	6.9 (0.8)	1.3 (0.5)	4.6 (0.7)	2.7 (2.2)
	Yes (16)	63.0* (12)	6.8 (0.3)	1.3 (0.5)	4.5 (0.8)	3.2 (1.7)
HDL < 1 mmol/L; TC > 6.5 mmol/L	No (20)	45.2 (13)	7.2 (0.6)	0.8 (0.9)	4.9 (0.6)	4.1 (2.8)
	Yes (0)	–	–	–	–	–
Male 35–75 years, Female 55–75 years; TC > 7.5 mmol/L or TG > 4 mmol/L	No (40)	52.7 (10)	6.9 (1.4)	1.2 (0.4)	4.9 (1.5)	3.8 (2.0)
	Yes (6)	60.1 (7)	6.5 (1.6)	1.0 (0.4)	4.1 (3.8)	6.5* (3.7)
Don't qualify	No (3313)	41.4 (17)	5.0 (1.0)	1.4 (0.4)	3.1 (0.9)	1.3 (0.7)
	Yes (270)	65.9* (11)	4.70*(0.9)	1.3* (0.4)	2.6* (0.8)	1.7* (0.7)
2006 Pharmaceutical Benefits Scheme criteria						
Existing CHD, stroke, diabetes in Ab/TSI, diabetes if aged ⩾ 60 years	No (185)	69.7 (11)	5.3 (1.0)	1.3 (0.4)	3.2 (0.8)	1.7 (0.9)
	Yes (167)	68.3 (9)	4.4* (0.9)	1.2* (0.3)	2.4* (0.7)	1.8 (1.4)
Diabetics not otherwise included; TC > 5.5 mmol/L	No (37)	45.4 (8)	6.5 (1.0)	1.1 (0.3)	4.1 (1.2)	3.2 (3.6)
	Yes (0)	–	–	–	–	–
Ab/TSI or hypertensive; TC > 6.5 mmol/L, or TC > 5.5 mmol/L if HDL < 1.0 mmol/L	No (150)	55.4 (16)	6.9 (0.8)	1.3 (0.5)	4.7 (0.6)	2.5 (1.7)
	Yes (11)	60.8 (13)	6.8 (0.6)	1.3 (0.5)	4.4 (0.6)	3.0 (1.4)
HDL < 1 mmol/L; TC > 6.5 mmol/L	No (20)	45.2 (14)	7.2 (0.6)	0.8 (0.1)	4.9 (0.6)	4.1 (2.8)
	Yes (0)	–	–	–	–	–
Male 35–75 years, Female 55–75; TC > 7.5 mmol/L or TG > 4 mmol/L	No (39)	52.6 (10)	6.9 (1.3)	1.2 (0.4)	4.9 (1.5)	3.7 (2.0)
	Yes (5)	60.1 (7)	6.9 (1.3)	1.1 (0.3)	4.1 (3.7)	5.3 (2.1)
Others not included; TC > 9 mmol/L or TG > 8 mmol/L	No (1)	46.0	9.0	2.0	6.0	2.2
	Yes (1)	28.0	10.0	1.5	8.3	1.4
Don't qualify	No (3262)	40.5 (16)	5.0 (1.0)	1.4 (0.3)	3.1 (0.9)	1.2 (0.7)
	Yes (178)	64.1* (12)	5.0 (0.8)	1.4 (0.3)	2.8* (0.7)	1.7* (0.7)

* Independent *t* test, $P < 0.05$. TC = total cholesterol. HDL-C = high-density lipoprotein cholesterol. LDL-C = low-density lipoprotein cholesterol. TG = triglycerides. BP = blood pressure. CHD = coronary heart disease. Ab/TSI = Aboriginal/Torres Strait Islander.

4 Factors associated with use of lipid-lowering therapy (multiple logistic regression analysis)

Factor	OR (95% CI)
Age ⩾ 60 years	2.8 (2.0–4.0)
Government benefit/pension	2.2 (1.6–3.2)
Income < A$40 000	1.7 (1.2–2.4)
Cardiovascular disease	5.4 (3.8–7.5)
Diabetes	2.8 (1.9–4.0)
Hypertension	1.5 (1.1–2.0)
Smoking status	
Former	1.3 (0.9–1.7)
Current	0.5 (0.3–0.8)

Discussion

The NHF/CSANZ criteria identified three times more people at risk of a CVD event who should be considered for cholesterol-lowering therapy than the PBS criteria for subsidised medication pertaining at the time of the original study, and twice as many as the newer 2006 PBS criteria. Adoption of the NHF/CSANZ criteria or similar international guidelines by the PBS would likely lead to commensurate cost increases. Similar findings regarding primary prevention with statins were reported from Norway, where implementation of European guidelines would more than double LLT use in men and the elderly.[14] The new PBS criteria potentially allow for an increase of 50% in use of LLT, mostly in secondary prevention of CHD and higher risk individuals with diabetes or hypertension. If we assume those using LLT were originally prescribed these medications according to the criteria, then 19.5% of the adult population are now eligible for PBS-subsidised LLT. The extent to which this considerable financial outlay would be offset in the longer term by savings in reduced cardiovascular morbidity is unclear. A recent study indicated that the incremental cost-effectiveness of statins was considerably less than that of aspirin and initial anti-hypertensive treatment in coronary disease prevention.[15] The author recommended that the most efficient prevention strategy would be to offer statins to those with a 30% 5-year risk of CHD and that clinical guidelines should be informed by analysis of the incremental costs and incremental benefits resulting from each additional treatment.[15]

Consistent with the previous reports, we found that a significant proportion of participants at high risk were not receiving LLT.[2] Only around half of people with a history of CHD were using LLT. Across the three different eligibility criteria the proportion of eligible people using statins was low, in the region of 19% to 30%. However, those at most risk were more likely to be treated, given that users were significantly more likely to have existing CVD, diabetes, hypertension and be elderly, according to multivariate analyses. This suggests that doctors are using some form of risk assessment in management decisions. Consistent with this is that only a small proportion (about 5%) of those not eligible are treated (although this is a relatively high proportion of total treated because of the larger numbers of non-eligible people). A tendency for general practitioners to focus risk factor measurement on patients with a known history of CHD has been previously reported,[16] a problem that may relate to physician's perceptions of risk in intermediate-risk individuals.[17] It is clear that, for primary prevention, statins are not being used to their full effectiveness, and/or patients without a history of coronary events have reduced adherence to treatment.

Treatment results in only a marginal change in mean levels of indicators although it results in significant increases in proportions reaching target levels. Importantly, users of LLT were significantly more likely to have met target cholesterol levels compared with people not on therapy. However, a majority on LLT did not achieve target LDL-C levels (< 2.5 mmol/L), and while over 76% had total cholesterol < 5.5 mmol/l, over 80% had total cholesterol levels above 4.0 mmol/L. This demonstrates that when statin therapy has been initiated there remains considerable scope to maximise the intensity of treatment to achieve greater reductions in cholesterol. This is particularly the case in people without known CHD, in

whom group mean levels and proportions not achieving target levels were considerably greater than for secondary prevention groups. Compared with secondary prevention, primary prevention achieves a fourfold larger reduction in CHD deaths.[18] Although at a population level most of the contribution from cholesterol lowering has came from dietary changes across the population, if statins are to be used then aiming for the largest reductions possible should be the goal. Total cholesterol levels of 6.8 mmol/L or more in people with known diabetes, hypertension or stroke is clearly failure in this regard.

The Australian PBS aims to achieve maximum cost-effectiveness with public funding and promote equity in the use of pharmaceuticals. Older people with limited incomes or on government benefits or pensions were more likely than others to be using LLT. This suggests that the PBS has been successful in providing access to medications to those on benefits, and this partly overcomes some of the disparities in treatment by socio-economic status seen elsewhere.[9,19] However, given the generally low level of statin use, the question arises as to whether the relatively high general copayments (currently $31.30) may act as a significant disincentive, especially where patients have multiple medicines or for the "working poor" (those who are just above the income cut-off for a concessional payment).

Our study is limited by lack of knowledge of actual medication use. In patients prescribed lipid-lowering therapies, adherence to therapy is a major problem,[20] and this has been shown to be associated with cardiovascular morbidity.[21] We obtained self-report data on actual use of lipid-lowering therapies, but this does not give us an accurate measure of adherence. Similarly, our PBS prescribing data tell us which participants have had medication dispensed before their clinic attendance. It is possible that failure to meet target levels reflects poor adherence,[20] and that providing patients with comprehensive knowledge about statins improves adherence and facilitates lipid target-level achievement.[22] We were also unable to assess the use of complementary LLTs, for example fish oils,[23] and assess any effect such therapies may have had on cholesterol levels.

Use of LLT for both primary and secondary prevention of CHD remains suboptimal among those who will benefit. Under the PBS it is unlikely that cost to individuals on low incomes or government benefits is the major barrier to LLT use. Whether copayment costs are a major barrier to use in the broader population is an unanswered question. Further efforts are required to maximise use of LLT in those at highest risk, possibly including use of financial incentives and education programs. Expanded use of clinical risk assessment tools that measure CVD risk, such as the Framingham risk criteria, may be one way of achieving better use of LLT for those at high and intermediate risk.

Competing interests

Robert Adams and Richard Ruffin have received honoraria for speaker fees and travel grants to attend meetings from GlaxoSmithKline to the value of less than $10 000 over the past 5 years.

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