# **BMJ Open** Patterns and trends of potentially inappropriate high-density lipoprotein cholesterol testing in Australian adults at high risk of cardiovascular disease from 2008 to 2014: analysis of linked individual patient data from the Australian Medicare Benefits Schedule and Pharmaceutical Benefits Scheme

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#### ABSTRACT

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Professor Federico Girosi; f.girosi@westernsydney.edu.au **Objectives** We examine the extent to which the adult Australian population on lipid-lowering medications receives the level of high-density lipoprotein cholesterol (HDL-C) testing recommended by national guidelines. **Data** We analysed records from 7 years (2008–2014) of the 10% publicly available sample of deidentified, individual level, linked Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) electronic databases of Australia.

**Methods** The PBS data were used to identify individuals on stable prescriptions of lipid-lowering treatment. The MBS data were used to estimate the annual frequency of HDL-C testing. We developed a methodology to address the issue of 'episode coning' in the MBS data, which causes an undercounting of pathology tests. We used a published figure on the proportion of unreported HDL-C tests to correct for the undercounting and estimate the probability that an HDL-C test was performed. We judged appropriateness of testing frequency by comparing the HDL-C testing rate to guidelines' recommendations of annual testing for people at high risk for cardiovascular disease.

**Results** We estimated that approximately 49% of the population on stable lipid-lowering treatment did not receive any HDL-C test in a given year. We also found that approximately 19% of the same population received two or more HDL-C tests within the year. These levels of underutilisation and overutilisation have been changing at an average rate of 2% and -4% a year, respectively, since 2009. The yearly expenditure associated with test overutilisation was approximately \$A4.3 million during the study period, while the cost averted because of test underutilisation was approximately \$A11.3 million a year.

**Conclusions** We found that approximately half of Australians on stable lipid-lowering treatment may be having fewer HDL-C testing than recommended by

# Strengths and limitations of this study

- This is the first study of potentially inappropriate high-density lipoprotein cholesterol (HDL-C) testing together with the associated expenditure in the Australian adult population.
- A strength and innovation of this study is that, in order to deal with episode coning, we are able to make use of additional information from the Australian Department of Health and Ageing about the proportion of performed HDL-C tests that is recorded in the Medicare Benefits Schedule.
- A limitation of this approach is that the adjustment we used for episode coning throughout the study was based on the only year the additional information was available (2011), and it may have shifted over time.
- Another limitation is that the estimated rates of inappropriate testing have wide lower and upper bounds due to the episode-coning rules.
- Perhaps the most important limitation is that we only examined inappropriate testing in people at high risk of cardiovascular disease (on treatment), and the relative rates of underutilisation versus overutilisation are likely to differ in lower-risk groups.

national guidelines, while nearly one-fifth are having more tests than recommended.

#### INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of non-communicable disease burden worldwide.<sup>1</sup> In Australia, CVD was ranked the second leading cause of disability-adjusted

life years (DALYs), accounting for 15% of the total burden in  $2011.^2$  Effective prevention of CVD requires early identification of high-risk individuals who might benefit from targeted intervention, to maximise potential health benefits.

High blood cholesterol is one of the major modifiable risk factors for CVD that is commonly assessed in CVD risk models or scoring systems (often called 'risk assessment tools') routinely used in general population opportunistic screening.<sup>3</sup> Prospective cohort studies show blood cholesterol levels have a dose–response effect on CVD risk.<sup>4</sup> Conversely, randomised controlled trials show that larger reductions in low-density lipoprotein cholesterol (LDL-C) have larger reductions in CVD risk; each 1 mmol/L reduction in LDL-C with statins reduces the relative risk of CVD over 4–5 years by an additional 20%.<sup>5 6</sup> Evidence on the safety and effectiveness of statins has been accompanied by increased lipid testing and statin use in high-income countries,<sup>7–12</sup> and recent lowering of risk thresholds for initiating statin treatment in the UK<sup>13</sup> and USA.<sup>14</sup>

Since 2005, guidelines released by the Royal Australian College of General Practitioners (RACGP), also known as the 'Redbook', have consistently recommended cholesterol-lowering therapy for high-risk individuals (those with an absolute CVD risk >15% over the next 5 years),<sup>15-19</sup> and there has been a large increase in the utilisation of lipid-lowering medications by Australians.<sup>20</sup> Guidelines for blood lipid testing recommend testing every 5 years for low-risk (absolute CVD risk <10%), every 2 years for moderate-risk (absolute CVD risk 10%-15%) and every 12 months for high-risk individuals. Blood lipid testing is used by general practitioners and medical specialists for two main purposes<sup>21</sup>: (1) identifying patients at high CVD risk in order to offer lipid-lowering treatment (who may or may not also have high blood cholesterol) and (2) for monitoring response to the treatment after this has been prescribed,22 aiming recommended lipid targets.<sup>18</sup> The number of all pathology tests per person funded by the Australian government through 'Medicare' has increased by 40% in the last decade, predominately among those who had more than one test.<sup>23</sup> There is evidence suggesting that up to 20% of repeat testing is inappropriate, resulting in overutilisation of pathology tests.<sup>24</sup> This trend has led to a significant increase in Medicare expenditures.<sup>23</sup> The scale and pattern of inappropriate blood cholesterol testing in Australia has not been systematically studied.

This study examined patterns of HDL-C testing in the Australian adult population who were on a stable prescription of lipid-lowering treatment over a 7-year period, from 2008 to 2014. We limited our study to people on lipid-lowering treatment as we could assume that they were at high risk (people not on lipid-lowering treatment may or may not be low risk). The requirement that treatment was stable was to decrease the chances that lipid testing was being used for medication titration.<sup>25</sup> We chose HDL-C as a proxy for all lipid testing as unlike other tests such as total cholesterol or LDL cholesterol, it has a unique

MBS item number. The aim of this study was to systematically examine trends in inappropriate HDL-C testing (underutilisation and overutilisation) based on guidance for annual blood lipid testing in people at high risk of CVD.

#### METHODS Data sources

# This research was performed using 7 years of data (2008–2014) from the deidentified 10% sample of the Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS) released by the Australian Department of Health.<sup>26</sup> The dataset contains weights that allow accurate estimation of service use (not only at the national level, but also at the level of gender, age and geography), making the dataset representative of the Australian population. The MBS and PBS data are linkable and allow the same individual to be tracked over time, providing information for a sample of approximately 2.1 million Australians who are representative of the full population.

The PBS data contain records of pharmacy transactions for all scripts of drugs listed on the PBS schedule and dispensed to Australian resident holding a Medicare card or residents of other countries with a reciprocal healthcare agreement. In the PBS, lipid-lowering medications are identified by 46 item codes in seven major categories: atorvastatin, fluvastatin, pravastatin, rosuvastatin, simvastatin, fenofibrate and gemfibrozil. We characterised people with at least two scripts for the same item code in each calendar year as the stable target population. Prior to July 2012, records of drugs with costs below the copayment threshold (\$A36.90 in 2014) were not recorded in the data repository if they had been dispensed to non-concessional beneficiaries (as there was no associated government subsidy), causing some underestimation of prescription drug usage. We undertook sensitivity analysis to estimate the implications of this underestimation (see the Sensitivity analysis section).

The MBS administrative data allow identification of health services, diagnostic procedures and tests provided outside of the hospital setting, using a coding system with more than 6000 items. For the purpose of this research, we used the MBS to identify the episode of care that might have led to an HDL-C test.

# Study design

The target population for this study was adults who had been prescribed at least two scripts for the same lipid-lowering medication listed in the PBS schedule<sup>27</sup> in a given calendar year. We refer to this population as the 'stable target population'. This group only includes a portion of all individuals in the high CVD risk group, since not all individuals at high CVD risk are treated.<sup>28</sup> Conversely, some individuals on lipid-lowering medications may not be at high CVD risk based on the Framingham Risk Equation.<sup>29</sup> However, we chose to study this population for the following reasons:

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- ▶ It includes a large portion of the adult population.
- If cholesterol is not managed well in this group, it is unlikely that it would be managed better in others at high CVD risk.
- ► It is easily identified, for both research and health policy purposes.

Moreover, annual lipid testing for people on statins has been found likely to be beneficial to patients and to the health service.<sup>30</sup>

We used individuals' unique identifiers to link data in the PBS and MBS for each calendar year. We first identified all individuals in the PBS who were in the stable target population, and then retrieved their corresponding records in the MBS. Each MBS record (corresponding to a billed MBS item episode) contains variables including age, gender, geographical state of residence, date of service, MBS item number, benefit that was paid, service provider's scrambled identifier, service provider's state of residence and service provider's registered specialty.

HDL-C tests are easily identified by the designated MBS item 66536. However, a difficulty in making population inferences for most pathology items in the MBS is a coding rule known as 'episode coning'. According to this rule, only the three most expensive pathology items in an episode of care can be claimed at the same time (with some exceptions). The rule does not apply to pathology tests requested for hospitalised patients or ordered by specialists.<sup>31</sup> The implication is that the utilisation of most pathology tests is under-reported in the MBS data. Since the schedule fee for the HDL-C test (item 66536) is lower than that for most pathology items in the MBS (approximately \$A11), it is highly likely to have been subjected to episode coning. Therefore, a mere count of MBS item 66536 will lead to a substantial underestimate of the level of HDL-C testing, and adjustment need to be applied in order to provide more realistic estimates. We describe our method of adjustment for this issue in the Statistical analyses section.

#### **Outcomes**

There are two key outcomes: one is the estimated rate (number/1000 population/year, with lower-upper bound intervals) of underutilisation of HDL-C testing, and the other one is the estimated rate (number/1000 population/ year, with lower-upper bound intervals) of overutilisation of HDL-C testing in high-risk individuals. We defined 'inappropriate' testing based on national guidelines ('Redbook').<sup>15-18</sup> The RACGP guidelines for blood lipid testing recommend every 12 months for high-risk groups. The recommendation of 12-monthly testing for those identified at high risk (who are also recommended to be started on preventative medication) implies that lipid testing in this context is being used for monitoring the adequacy of lipid-lowering treatment in these individuals. We estimated underutilisation in the high-risk group, for each of the 7 years of data, based on the following criteria: no HDL-C test in a year for adults in the stable target population (individuals with at least two scripts for a same lipid-lowering medication). For overutilisation,

we used the following criteria: two or more HDL-C tests per year for adults in the stable target population. This definition of overutilisation is consistent with our choice of the target population that includes people on stable treatment: we eliminate the need to allow multiple HDL-C tests associated with treatment initiation.

The assumption here is that we identify the population at high cardiovascular risk (at least as judged by their treating physician) with the population on a stable lipid-lowering medication.

# **Covariates**

The covariates used in the multivariate analysis were gender, age, geographical state where the individual resides and calendar year. We stratified age into six age groups: 18–34, 35–44, 45–54, 55–64, 65–74 and 75+. In the provided dataset, there were five categories for the geographical state (some states were combined): New South Wales was combined with Australia Capital Territory (NSW+ACT), Victoria was combined with Tasmania (VIC+TA), South Australia was combined with Northern Territory (SA+NT), Queensland (QLD) and Western Australia (WA).

## **Statistical analyses**

We developed a new method to provide an estimate of the number of HDL-C tests, as well as a lower and an upper bound using the MBS dataset. For the lower bound, we simply counted the number of HDL-C tests, ignoring episode coning. For the upper bound, we applied the methodology developed by Trevena *et al*<sup> $\beta^2$ </sup> to estimate the number of HDL-C tests. This methodology relied on the observation that if an episode of care contained three (or more) items and the fee associated to the test of interest was lower than the fee of the cheapest claimed item then it was possible that the test of interest was 'coned out' (meaning that it was performed but not recorded because of coning). Excluding the pathology tests requested for hospitalised patients or ordered by specialists from those episodes of care, we referred to the rest as 'potential coning' episodes, and therefore the upper bound on the number of HDL-C tests performed was simply the number of 'potential coning' episodes  $(n_{pc})$  plus the number of HDL-C test observed in the MBS  $(n_{obs})$ . Since the HDL-C test is inexpensive, the probability that it is 'coned out' in an episode of care is quite high, and therefore the difference between the lower and upper bounds is quite large.

In order to address this very large uncertainty, we make the following observation: the upper bound is unrealistic, and it implies that an enormous number of HDL-C tests are done each year. The true number of tests per population is somewhere in between the lower and upper bounds and can be estimated based on the actual number of HDL-C tests done per year which is approximately known: the Department of Health and Ageing reports that only about 35% of the number of HDL-C tests were recorded in the MBS dataset, in 2011.<sup>33</sup> This implies that the true total number of test performed,  $n_{per}$ , is given by the formula:  $n_{per} = n_{obs}/0.35$ . In turn, this allows us to estimate the probability  $p \in [0,1]$  that in each potential coning episode the HDL-C test was 'coned out'. The probability p is estimated by assuming that the true total number of tests performed  $(n_{per})$  is equal to the number of observed tests  $(n_{obs})$  plus a proportion of the potential coning episodes:

$$n_{per} = n_{obs} + p \times n_{pc}$$

Substituting  $n_{per}$  with its estimated value  $n_{obs}/0.35$  and solving for p, we obtain:

$$P = \frac{n_{obs}}{n_{pc}} \times \left(\frac{1}{0.35} - 1\right)$$

Using the records from year 2011, we estimated the value of p as 0.33.

We applied this finding to the individual level: since patients differed in the number of potential coning episodes in each year, and since the probability p applies to each coning episode, some patients were more likely to receive an HDL-C test than others. Therefore, for an individual *i* with  $n_{pc}^i$  potential coning episodes, the number of HDL-C tests (in addition to the observed ones) has a binomial distribution over  $n_{pc}^i$  trials with probability of success equal to p. If  $n_{obs}^i$  is the number of observed HDL-C tests for individual *i* in a year, the probability distribution for the total number *k* of HDL-C tests in that year for individual *i*,  $P\left(k; n_{pc}^i, n_{obs}^i\right)$ , is obtained by shifting the binomial distribution by  $n_{obs}^i$ :



The formula above allows us to estimate for each individual *i* both the probability of receiving no HDL-C test,  $P_i^{under}$ , and the probability of receiving two or more HDL-C tests,  $P_i^{over}$ , as:

$$\begin{split} P_i^{under} &= P\left(k=0; \, n_{pc}^i, \, n_{obs}^i\right) \\ P_i^{over} &= \sum_{k\geq 2} P\left(k; \, n_{pc}^i, \, n_{obs}^i\right) \end{split}$$

We performed three types of analyses:

- 1. We aggregated the probabilities  $P_i^{under}$  and  $P_i^{over}$  over the entire target population and estimated the proportions of individuals who either underuse or overuse HDL-C tests.
- 2. Since the cost of an HDL-C test is known, we also computed the total cost averted, that is the additional amount that should have been spent on HDL-C tests, but was not, because of underutilisation. For the overutilisation cases, we also compute the theoretical total savings that would accrue if all overutilisation was prevented.
- 3. In order to understand what factors are associated with apparent inappropriate testing, we performed two sets of logistic regression on the variables we have constructed to define the probability of underutilisation and overutilisation. In each of the regressions, we controlled for age, gender, state of residence, calendar year, and the interaction between age and year.

#### RESULTS

Figure 1 sets the stage for the rest of the analysis and shows the estimated number of HDL-C tests with the lower and upper bounds, and the number of lipid-lowering scripts



**Figure 1** The estimated number of high-density lipoprotein cholesterol (HDL-C) tests (bottom graph, scale on the left side) and lipid-lowering scripts per 1000 people (top graph, scale on the right side) from 2008 to 2014. The bars in the bottom graph show the lower and upper bounds of the estimate.

Table 1 Descriptive analysis of HDL-C testing and lipid-lowering scripts in the stable target population in 2014					
		Estimated HDL-C tests		Lipid-lowering	g scripts
Demographics	Population size	Total	Per 1000 population	Total	Per 1000 population
Total	2 395 340	1 628 477	680	22 726 283	9488
Gender					
Female	1 155 602	772 323	668	11 060 756	9571
Male	1 239 738	856 154	691	11 665 527	9410
Age group					
18–34	8 600	6 475	753	55 578	6463
35–44	46 563	34 488	741	327 483	7033
45–54	192 809	128 795	668	1 515 479	7860
55–64	491 589	325 797	663	4 225 698	8596
65–74	756 266	523 975	693	7 335 472	9700
≥75	899 513	608 947	677	9 266 572	10 302
States					
NSW+ACT	859 266	601 207	700	8 148 928	9484
VIC+TA	655 626	458 551	699	6 230 681	9503
SA+NT	209 346	122 986	587	2 025 266	9674
QLD	447 170	310 464	694	4 218 660	9434
WA	223 932	135 269	604	2 102 747	9390

ACT, Australia Capital Territory; HDL-C, high-density lipoprotein cholesterol; NSW, New South Wales; NT, Northern Territory; QLD, Queensland; SA, South Australia; TA, Tasmania; VIC, Victoria; WA, Western Australia.

in Australian adults from 2008 to 2014. The number of HDL-C tests increased from 248 tests per 1000 people in 2008 to 313 tests per 1000 people in 2014. In the same period, the number of lipid-lowering scripts increased from 1149 scripts in 1000 people in 2008 to 1313 scripts in 1000 people in 2014. These curves show that the number of HDL-C tests increased by 26%, while the number of lipid-lowering scripts increased by 14% over the study period. The prevalence of HDL-C test is comparable with the figures of Exeter *et al* for New Zealand, that were estimated in the range of 247 to 351 per 1000 people in the period 2006–2010.<sup>10</sup>

In table 1, we shift our attention to the stable target population in 2014 and present the population size, the number of estimated HDL-C tests and the number of lipid-lowering scripts for different subgroups defined by gender, age and region. The total number of estimated HDL-C tests was 680 tests per 1000 population, with slightly larger number of tests in males than females. The number of lipid-lowering scripts was 9488 per 1000 population, with very small difference between males and females. Individuals aged 55-64 years had the lowest HDL-C testing rate (663 per 1000 population), while individuals aged 18-34 years had the lowest number of scripts (6463 per 1000 population). From the residential area viewpoint, NSW+ACT had the highest rate of HDL-C testing (700 per 1000 population), while SA+NT had the highest rate of lipid-lowering scripts (9674 per 1000 population).

Table 1 shows raw, unadjusted estimates. To gain a better understanding of the patterns of HDL-C tests and lipid-lowering medications, we also performed a multivariate analysis on the same data. We used a negative binomial model with gender, age and region as covariates and report the results in table 2. Males were slightly more likely to use HDL-C tests (OR=1.03). Younger individuals were also more likely to use HDL-C tests compared with individuals aged 75 or more, with the highest OR in the youngest group (OR=1.23). In addition, individuals living in NSW+ACT were significantly more likely to use HDL-C tests compared with most states. From the lipid-lowering medication point of view, there is a clear and significant pattern of increasing utilisation with age. No sizeable pattern was observed across geographies.

Figure 2 shows the estimated proportion, with lower and upper bounds, of individuals in the stable target population who did not have an HDL-C test in a 12-month period (underutilisation rate, blue colour). It also shows the estimated proportion of individuals in the stable target population who received two or more HDL-C tests in 12-month periods (overutilisation rate, red colour). For completeness, we also show in figure 2 the estimated proportion of individuals in the stable target population who received one HDL-C test in 12-month periods (correct utilisation, green colour). Approximately 49% (range: 45.8%– 51.0%) of the stable target population were not tested for HDL-C consistently from 2008 to 2014. In contrast, approximately 19% (range: 16.9%–20.8%) of the target

Table 2	Multivariate analysis of HDL-C testing and lipid-
lowering	scripts in the stable target population in 2014

	Estimated HDL-C tests		Lipid-lowering scripts	
Demographics	OR	(95% CI)	OR	(95% CI)
Gender				
Female	1	Reference	1	Reference
Male	1.03	1.02 to 1.04***	1.00	1.00 to 1.00
Age group				
18–34	1.23	1.13 to 1.32***	0.63	0.61 to 0.65***
35–44	1.15	1.11 to 1.19***	0.68	0.67 to 0.69***
45–54	1.03	1.01 to 1.05***	0.76	0.75 to 0.77***
55–64	1.00	0.99 to 1.02	0.83	0.83 to 0.84***
65–74	1.02	1.00 to 1.03**	0.94	0.94 to 0.94***
≥75	1	Reference	1	Reference
States				
NSW+ACT	1	Reference	1	Reference
VIC+TA	1.00	0.99 to 1.02	1.00	1.00 to 1.00
SA+NT	0.88	0.87 to 0.90***	1.02	1.01 to 1.02***
QLD	0.99	0.98 to 1.01	1.00	0.99 to 1.00
WA	0.89	0.88 to 0.91***	0.99	0.99 to 1.00

\*\*p<0.01; \*\*\*p<0.001.

ACT, Australia Capital Territory; HDL-C, high-density lipoprotein cholesterol; NSW, New South Wales; NT, Northern Territory; QLD, Queensland; SA, South Australia; TA, Tasmania; VIC, Victoria; WA, Western Australia.

population had more than the recommended number of HDL-C tests per annum, whereas approximately 32.9% (range: 32.1%–33.4%) of high-risk individuals had the recommended number of HDL-C tests per annum. A simple trend analysis shows no significant linear trend for any of the utilisation curves for the period between 2008 and 2014, with p-values for the trend over 0.2. However,

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an analysis of the most recent years suggests that there is an upward trend for underutilisation and downward trend for overutilisation. Given the very limited lengths of the time series, it does not seem appropriate to draw any definite conclusion and take the presence of these trends as suggestive.

Figure 3 shows, in blue colour, the estimated yearly cost averted by HDL-C test underutilisation, that is the cost that Medicare would have incurred if the underutilising individuals had received the recommended level of testing. This amount oscillates over time around an average of \$A11.3 million per year. The figure also shows, in red colour, the amount that the government could save by effectively preventing overutilisation which is approximately \$A4.3 million per year.

The descriptive analysis of underutilisation and overutilisation in 2014, considering gender, age and state of residence as covariates, is reported in table 3, where we show the distribution of underutilisation and overutilisation by gender, age and region. Table 3 shows that males contribute somewhat more than females to both underutilisation and overutilisation populations. The table also shows that people aged  $\geq$ 75 years constitute the largest percentage of both underutilisation (37.73%) and overutilisation (36.75%) (this is likely to be because they represent the highest proportion of people who were prescribed a lipid-lowering medication, as shown in table 1). In addition, the table shows that most underutilisation and overutilisation are found in NSW+ACT, while the least proportions are found in SA+NT.

We performed a multivariate analysis to gain insight in which factors are associated with underutilisation and overutilisation. The covariates entering the logit were: gender, age, region and year. We controlled for changing composition of the population by including pairwise interactions between year and gender, age and



**Figure 2** Underutilisation, correct-utilisation and overutilisation rates of high-density lipoprotein cholesterol test in the stable target population from year 2008 to 2014.



**Figure 3** Costs that were averted because of underutilisation and total potential savings that could have been theoretically realised if all overutilisation were prevented. All the cost figures were converted to 2014 \$A using the Australian Bureau of Statistics all groups Consumer Price Index.<sup>42</sup>

region. The results are reported in table 4, where for clarity we have omitted the coefficients for all interactions. Table 4 provides a number of insights on predictors

Table 3Descriptive analysis of underutilisation andoverutilisation of HDL-C testing in the stable targetpopulation in 2014					
	Underutilisation		Overutilisation		
Demographics	%	(95% CI)	%	(95% CI)	
Gender					
Female	48.78	48.5 to 49.06	46.82	46.33 to 47.31	
Male	51.22	50.94 to 51.5	53.18	52.69 to 53.67	
Age group					
18–34	0.35	0.32 to 0.38	0.41	0.35 to 0.48	
35–44	1.86	1.79 to 1.94	2.24	2.1 to 2.39	
45–54	8.15	8 to 8.31	8.05	7.79 to 8.32	
55–64	20.83	20.6 to 21.06	20.1	19.71 to 20.50	
65–74	31.08	30.82 to 31.34	32.45	31.99 to 32.91	
≥75	37.73	37.46 to 38	36.75	36.28 to 37.22	
States					
NSW+ACT	35.54	35.27 to 35.81	37.32	36.85 to 37.80	
VIC+TA	26.82	26.57 to 27.07	28.57	28.13 to 29.02	
SA+NT	9.39	9.23 to 9.56	6.96	6.71 to 7.21	
QLD	18.43	18.21 to 18.65	19.53	19.14 to 19.92	
WA	9.82	9.65 to 9.99	7.62	7.36 to 7.88	

ACT, Australia Capital Territory; HDL-C, high-density lipoprotein cholesterol; NSW, New South Wales; NT, Northern Territory; QLD, Queensland; SA, South Australia; TA, Tasmania; VIC, Victoria; WA, Western Australia. of underutilisation and overutilisation of HDL-C tests among the stable target population.

Males were less likely to underutilise HDL-C tests, although not to a large extent (OR=0.97), and individuals aged  $\geq$ 75 were more likely to underutilise than individuals in all other age groups, except for those aged 18–34. The latter group exhibits a much higher likelihood of underutilisation than those aged 75 or more. Moreover, there was a significant geographical variation in underutilisation: VIC+TA is the only region which is less likely to underutilise than NSW+ACT.

For overutilisation, males are more likely to overutilise HDL-C tests than females (OR=1.06), and younger people, aged 35–54 years, are more likely to overutilise than those aged 75 years or older. To a lesser extent, this is also true for those aged 55–74 years. Also, there is a significant variation of overutilisation across states. WA is much less likely to overutilise than NSW+ACT, followed by QLD, while VIC+TA is slightly more likely to overutilise.

The coefficients of the year variables show that there is temporal variation in both underutilisation and overutilisation which is not explained by demographic and regional changes.

#### Sensitivity analysis

Our definition of overutilisation is a strict interpretation of the guidelines and does not leave space for additional HDL-C tests in 1 year, often associated with initiation of treatment. This is justified because we focus on the stable target population, who had initiated treatment already. However, we also tested a more conservative definition of overutilisation that allows two HDL-C tests a year as Table 4Multivariate analysis of underutilisation andoverutilisation of HDL-C testing in the stable targetpopulation in 2008–2014

Understiliestien			Overntiliestion		
	Underutilisation		Overutilisation		
Demographics	OR	(95% CI)	OR	(95% CI)	
Gender					
Female	1	Reference	1	Reference	
Male	0.97	0.95 to 0.99***	1.06	1.04 to 1.09***	
Age group					
18–34	1.21	0.96 to 1.54	1.06	0.77 to 1.43	
35–44	0.76	0.68 to 0.84***	1.49	1.32 to 1.68***	
45–54	0.84	0.8 to 0.87***	1.24	1.17 to 1.31***	
55–64	0.88	0.86 to 0.91***	1.15	1.11 to 1.19***	
65–74	0.88	0.86 to 0.89***	1.16	1.13 to 1.19***	
≥75	1	Reference	1	Reference	
States					
NSW+ACT	1	Reference	1	Reference	
VIC+TA	0.87	0.85 to 0.89***	1.1	1.07 to 1.14***	
SA+NT	0.97	0.94 to 1.00	1	0.97 to 1.05	
QLD	1.08	1.05 to 1.11***	0.91	0.88 to 0.94***	
WA	1.07	1.04 to 1.11***	0.85	0.81 to 0.88***	
Year					
2008	1	Reference	1	Reference	
2009	0.81	0.79 to 0.83***	1.29	1.25 to 1.33***	
2010	0.85	0.83 to 0.87***	1.19	1.15 to 1.23***	
2011	0.87	0.85 to 0.90***	1.15	1.11 to 1.19***	
2012	0.86	0.84 to 0.88***	1.17	1.13 to 1.21***	
2013	0.88	0.86 to 0.91***	1.13	1.09 to 1.17***	
2014	0.95	0.93 to 0.98***	1.05	1.01 to 1.09**	

The OR were computed using logistic regression. \*\*p<0.01; \*\*\*p<0.001.

ACT, Australia Capital Territory; HDL-C, high-density lipoprotein cholesterol; NSW, New South Wales; NT, Northern Territory; QLD, Queensland; SA, South Australia; TA, Tasmania; VIC, Victoria; WA, Western Australia.

normal. We found that the results are sensitive to this definition and that the overutilisation rate decreases by a factor of three (approximately 6%).

We also considered the hypothesis that people who moved across states within a calendar year might have different utilisation patterns. We found that moving was marginally significantly associated with underutilisation (p=0.004), but not with overutilisation (p=0.085). However, this effect was small and affected only 0.5% of the study population.

A final issue considered was the effect of the change in the PBS data that took place in 2012. Prior to July 2012, scripts for drugs costing below the copayment threshold, dispensed to general patients, were not recorded. This means that prior to July 2012, the study population is missing the general beneficiaries using lipid-lowering medications below copayment. In order to estimate the missing population size, we analysed data for the year 2013. In this year, only 26% of the lipid-lowering scripts were dispensed to general beneficiaries. Out of this 26%, only 32% were under copayment. Therefore, if the data collection rules existing prior to year 2012 applied to year 2013, we would have missed only 8% ( $0.26 \times 0.32 = 0.083$ ) of the population. This implies that the composition of the target population is unlikely to have changed significantly before and after 2012.

#### DISCUSSION

The main finding of this work is that a considerable proportion of individuals on lipid-lowering treatment do not receive at least one HDL-C test a year (approximately half). Since people on lipid-lowering treatment are usually prescribed these drugs because their physician judges them to be at high cardiovascular risk, this study suggests that a large fraction of this group may not be undertaking HDL-C testing, or indeed other lipid testing at the frequency recommended by clinical guidelines. While the lower and upper bounds for our estimates show a wide interval, the implications of the findings about underutilisation are robust: even the rates provided by the highly improbable lower bound, which are around 20%, are sufficiently high to merit further investigation. In addition, support for the validity of our estimates comes from the closeness between the overall rates of HDL-C tests (figure 1) and the estimates obtained by Exeter et  $al^{10}$  in New Zealand, where testing data are not subject to episode coning and are considerably more accurate.

There are several possible explanations for this finding. One points to lack in continuity of care and to the fact that often people see multiple practitioners at once. If there is no designated 'medical home' for the patient, it is not clear who bears the responsibility for managing cardiovascular risk. In this scenario, it is not surprising that many individuals may miss their annual lipid tests. Another contributing factor may be the lack of continuity in medical records. Under the current fragmented medical records infrastructure, it is possible that practitioners are not aware that some of their patients are on lipid-lowering medications and therefore do not take the recommended action in ordering lipid tests. Another possibility is that medical practitioners choose not to follow the guidelines' recommendations as although there is evidence that annual testing may be the most cost-effective option,<sup>30</sup> less frequent testing may also be a clinically reasonable choice.<sup>34</sup> On the other hand, patients may choose to not undertake the testing (even when this is recommended by their doctor). There is also likely to be individuals on lipid lowering treatment who are not at high risk of CVD, and for whom annual lipid testing is not recommended (more individuals in the youngest age group, who had the highest odds of underutilisation, may be in this category).

While the cause of the high underutilisation rate is uncertain, the number of affected people is large and warrants further investigation. The additional cost associated with reducing the underutilisation rate is approximately \$A11.3 million per year, which although a relatively small proportion of the total health budget, should nevertheless be justified by evidence that annual testing in this group will improve health outcomes. In particular, the clinical utility of annual testing in individuals who are not high risk according to previous explicit thresholds (>15% 5-year risk<sup>35</sup> or >20% 10-year risk<sup>13</sup>), but who are treated as high risk with prescription of lipid-lowering treatment, needs to be determined.

A lack in continuity of medical records may be one explanation for the other main finding of this paper: a relatively small proportion of people at high risk of CVD overutilising HDL-C testing. If an HDL-C test has been performed but its record is not available to a practitioner, the practitioner has no alternative other than to reorder the test. However, the overutilisation rate is rather low, approximately 19%, and even if it could be reduced to 0, it would only save approximately \$A4.3 million per year. Furthermore, our sensitivity analysis showed that these rates would drop by a factor three if we use a more conservative definition of overutilisation. Combining this observation with the fact that overutilisation rates might have a downward secular trend (figure 2) suggests that overutilisation of HDL-C test in people at high risk of CVD should not be a public health priority. It is important to note that our study did not examine overutilisation or underutilisation rates of lipid testing in people who are not at high risk of CVD, who represent by far the majority of the general population.<sup>36</sup> Because less frequent lipid testing is recommended for these lower-risk groups, rates of overutilisation are likely to be higher and underutilisation lower than what we found for high-risk individuals in the current study.

Some of the divergence in the suggested underutilisation and overutilisation trends in high-risk individuals may be attributable to public healthcare policy. There has been much activity in the area of monitoring and attempting to reduce the increasing overutilisation rates worldwide.<sup>24 34 37-40</sup> Similarly, the benefit paid per pathology and diagnostic tests declined by 1.1% annually in real terms driven by funding agreements between the Australian Government and the relevant industries designed to cap growth in spending on these tests.<sup>41</sup>

This is the first study that estimates the level of potentially inappropriate HDL-C testing in the Australian adult population, as well as the corresponding financial implications. A strength of this study is that we were able to use additional information from the Australian Department of Health and Ageing to improve the accuracy of the estimates. The data for the study come from a random 10% sample of the Australian population, and therefore is quite large. In addition, the dataset contains weights that allow to generalise the findings to the whole Australian population at high risk of CVD, achieving a good level of external validity in the Australian context. These findings may not necessarily generalise to other countries because they may originate from characteristics which are unique to the Australian healthcare system, such as lack of continuity in medical records. The study has some limitations. For example, the key modelling parameter from the Department of Health and Ageing, regarding the proportion of performed HDL-C tests that is recorded in the MBS, was available only for year 2011, and it might have shifted slightly over time. Also, the estimates of the underutilisation and overutilisation rates have wide lower and upper bounds because they correspond to extreme scenarios in which coning episodes either never have HDL-C test or always have an HDL-C test.

In summary, the apparent high rates of underutilisation lipid testing in Australians at high risk of CVD warrants further investigation. Research to define inappropriate lipid testing in people who are not at high risk (most of the general population) is also needed.

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**Data sharing statement** The MBS/PBS data used for this study were made publicly available from the Department of Health. Information about the dataset is available at https://researchdata.ands.org.au/linkable-de-identified-schedule-pbs/673945 At the time of writing, the website above contains the following statement: 'This data is temporarily unavailable. The Department of Health is currently working on the dataset and hope to have it restored and available again as soon as possible'. The dataset is not available from the Dryad repository, and researchers interested using the dataset should contact the Department of Health directly.

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