

# 2022-23

## Pre-Budget Submission



**AMGEN**<sup>®</sup>

25 January 2021

Hon Michael Sukkar, MP  
Federal Member for Deakin  
Assistant Treasurer  
Minister for Housing  
Minister for Homelessness, Social and Community Housing

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Dear Minister,

**Re: The urgent need to act on cholesterol and reduce the impact of one of Australia's biggest killers**

On behalf of Amgen Australia, we welcome the opportunity to make a submission to inform the 2022–23 Federal Budget. This submission outlines clear, simple and actionable solutions to reduce the impact of Australia's biggest killer<sup>1</sup> – cardiovascular disease (CVD).

As a nation, we have become complacent about cholesterol, despite it being one of the most significant modifiable risk factors linked to CVD.

**We believe there are five simple solutions which make Australia's current health policies work harder to save lives and shift this cholesterol complacency.** Leveraging and expanding the existing Practice Incentive Program Quality Improvement (PIPQI) to cover secondary prevention will enable general practitioners to call in high-risk Australians to have their low-density lipoprotein cholesterol (LDL-C) level measured and treated where appropriate.

In June 2020, we learnt for the first time in 10 years, the extent of our cholesterol problem. Amgen provided funding for research that supported the development of the Baker Heart and Diabetes Institute report *CODE RED: Overturning Australia's Cholesterol Complacency* (2020) which found nearly half of high-risk Australians are not meeting the clinical guidelines goal for LDL-C – or 'bad cholesterol' – of <1.8mmol/L.<sup>2</sup> We need to do better in the clinical care and management of up to 1.15 million high-risk Australians with CVD who are vulnerable to suffering further cardiovascular events or losing their life from a further heart attack or stroke.<sup>2</sup>

We are committed to co-creating solutions that transform health systems by not only treating disease after it strikes, but also helping to **predict and prevent disease before it occurs.**

Together with the CVD community, we developed a report, *Australia's Cholesterol Heartache* (2020), that contained five simple, actionable and affordable solutions that will reduce the levels of cholesterol amongst high-risk Australians.<sup>4</sup> Together we call for action to:

1. Ensure all high-risk Australians know their LDL-C level.
2. Embed annual LDL-C tests for all high-risk Australians.
3. Standardise lipid profile reporting across Australia.
4. Update the guidelines to reflect best practice for secondary prevention of CVD.
5. Enhance the role of quality cardiac rehabilitation across Australia.

For the cost of \$197 per patient, there is the potential to avoid up to 3,221 deaths and 7,591 non-fatal CVD events in the first five years alone.<sup>4</sup>

We call on the Government to implement these solutions as part of the 2022–23 Federal Budget. The time to act on cholesterol is now. While Australia faces a number of complex health problems to solve, cholesterol needn't be one of them. We look forward to working with the Federal Government to bring these solutions to fruition.

To discuss this submission, please contact Amgen Australia's Head of Government Engagement and Industry Policy, Meriana Baxter on +61 428 276 098 or via [mbaxter@amgen.com](mailto:mbaxter@amgen.com).

Yours sincerely,



**Shannon Sullivan**  
Vice-President & Managing Director  
Australia & New Zealand

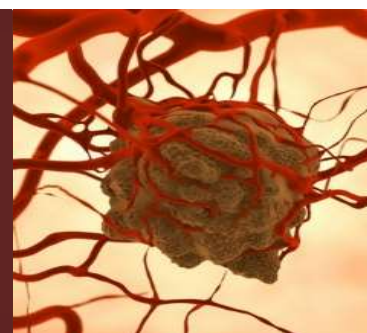
# Executive Summary

## Cardiovascular disease (CVD) is one of our nation's largest health problems.

Cardiovascular disease is our nation's biggest killer<sup>1</sup>, with one in every four deaths in Australia a result of CVD, or one Australian dying every 12 minutes.<sup>6</sup> Over four million Australians are living with CVD<sup>6</sup> including 1.15 million high-risk Australians<sup>2</sup>.

As a community we have made significant steps forward in reducing the number of Australians impacted by CVD, however, the decline in deaths associated with CVD is slowing, especially amongst younger age groups.<sup>5</sup> This is concerning given the size of the disease burden, and the health, social and economic impacts. While Australia has done well to reduce the impact of CVD, our work isn't done, and we must do more.

Cardiovascular disease describes conditions affecting the heart and blood vessels and includes conditions such as heart disease, stroke, and diseases of the blood vessels.



Much of the treatment burden associated with CVD can be prevented by reducing the impact of modifiable risk factors such as cholesterol, high blood pressure and smoking status.<sup>7</sup> Out of these modifiable risk factors, elevated low-density lipoprotein cholesterol (LDL-C) – or 'bad cholesterol' – has been identified as one of the main risk factors for CVD.<sup>7</sup>

Cholesterol is a fatty substance, present in the blood, that is necessary to build the structure of cells, make hormones, and help your metabolism. Excess cholesterol – often referred to as 'bad' cholesterol or LDL-C – can cause the build-up of fatty deposits in blood vessels. This process is called atherosclerosis and underlies most diseases of the blood vessels.

Fortunately, managing LDL-C is both a straightforward and effective way to reduce the risk and burden of CVD for these Australians.<sup>4</sup> Critically, every millimole per litre (mmol/L) reduction in LDL-C reduces the potential risk of a cardiovascular event – such as a heart attack or stroke – by ~20%.<sup>8</sup>

In June 2020, for the first time in a decade, new research outlined the cholesterol levels of Australians most at risk of CVD.<sup>2</sup> These are Australians who have endured a heart attack or stroke and are at most risk of suffering a second event and potentially losing their life. One in ten heart attack survivors will experience another heart attack within one year and nearly one in five people (18%) who have experienced a stroke will have another within three months.<sup>9</sup>

Treating LDL-C is both a straightforward and effective way to reduce the risk and burden of CVD. Critically, every mmol/L reduction in LDL-C reduces the potential risk of a cardiovascular event by ~20%.<sup>2,8</sup>

The Baker Heart and Diabetes Institute report **CODE RED: Overturning Australia's Cholesterol Complacency** found 48% of high-risk Australians are not meeting their recommended target for LDL-C of <1.8 mmol/L<sup>2</sup> as outlined in Australia's clinical guidelines<sup>11</sup>. This is despite 79% of patients having been prescribed a lipid-lowering medication after they suffered a heart attack or stroke. These patients therefore remain at risk of future cardiovascular events.<sup>2</sup>

**With these statistics, we know as a nation we are not optimising the treatment of cholesterol; leaving those Australians most at risk vulnerable to a further heart attack or stroke, or death.**<sup>2</sup> Anecdotally, this problem has been exacerbated during COVID-19 with some Australians delaying testing, treatment and care.

To overcome the cholesterol complacency, **Australia's Cholesterol Heartache** report was commissioned by Amgen and developed with Australian CVD experts to outline a roadmap to better manage cholesterol amongst high-risk Australians.<sup>4</sup> **The report outlines five simple and affordable recommendations that can be delivered immediately using existing policies to improve LDL-C management.** At the centre is an ongoing cycle of 'test and treat', so each Australian at risk of a secondary CVD event has their LDL-C tested every year, and their treatment adjusted so they are treated according to the best practice clinical guidelines. Targets are evolving and international guidelines recommend a target of 1.4 mmol/L for high risk patients.<sup>4</sup> As a first step, the report recommends a target of LDL-C <1.8mmol/L as set out in the Heart Foundation and Cardiac Society of Australia and New Zealand clinical guidelines.<sup>11</sup>

This simple policy approach has the potential to save up to 3,221 Australian lives in the first five years and prevent up to 7,591 non-fatal CVD events at a cost to the Federal Government of \$197 per patient.<sup>4</sup>

The time to act on cholesterol and overcome the slowdown in the decrease of deaths associated with CVD is now. **Australia faces a number of complex health problems to solve. Cholesterol needn't be one of them.** We know where we are falling down, and we have simple solutions that leverage existing policies and resources with the potential to significantly reduce the impact of Australia's biggest killer.<sup>1</sup>





## Women and CVD

Cardiovascular disease (CVD) is a leading cause of illness and death among Australian women. While more men than women have heart, stroke and vascular disease, the risk in women is largely under-recognised by the population.<sup>10</sup> There are aspects of cardiovascular health that are unique among women, with important sex differences in prevention, presentation of disease, diagnosis and treatment.<sup>10</sup>

Increased awareness and recognition of these differences will help women avoid under-diagnosis, under-treatment, and under-estimating the risk of dying or becoming seriously unwell due to heart, stroke and vascular disease.<sup>10</sup>

### More than half a million women have CVD

- Based on self-reported data, an estimated 510,000 (4.8%) Australian women aged 18 and over reported one or more heart, stroke or vascular diseases in 2017–18.<sup>10</sup>

### A major cause of illness and death

- Around 22,200 women had an acute coronary event (heart attack or unstable angina) in 2016, and 17,900 women had a stroke in 2015.
- There were over 200,000 hospitalisations of women with CVD in 2016.
- 22,000 women died from CVD in 2016.<sup>10</sup>

### Indigenous women are disproportionately affected

- Indigenous women were up to twice as likely as non-Indigenous women to have CVD, and to die from coronary heart disease or stroke.<sup>10</sup>

CVD and other chronic conditions are key priorities in the *National Women's Health Strategy 2020–2030*.<sup>12</sup> Increased public awareness and education, investment in research, implementing evidence-based practice, and strategies to address equity issues have been identified as areas for action to improve the heart health of Australian women.<sup>12</sup>

## Together, with the CVD community, we call on the Federal Government to implement the following solutions:

1. Ensure that all high-risk Australians know their LDL-C level.
2. Embed annual LDL-C tests for all high-risk Australians.
3. Standardise lipid profile reporting across Australia.
4. Update the guidelines to reflect best practice for secondary prevention of CVD.
5. Enhance the role of quality cardiac rehabilitation across Australia.



# The Federal Government has made important inroads in CVD; we can do more to help the Australians currently falling through the gaps.

We recognise and acknowledge the Federal Government's commitment to CVD and the important policy announcements that will reduce the impact of CVD in Australia now, and into the future, including:

- Establishing the 10-year Mission for Cardiovascular Health with funding of \$220 million through the Medical Research Future Fund.
- Introducing a Medicare Benefits Schedule (MBS) funded Heart Health Check to support GPs in assessing cardiovascular risk.
- Supporting the development of the National Strategic Action Plan for Heart Disease and Stroke with \$4 million to support the implementation of initiatives.
- Funding new medicines for the management of CVD, including targeting cholesterol on the Pharmaceutical Benefits Scheme (PBS).

Many of these initiatives have focused on the primary prevention of CVD – focusing on Australians with risk factors for CVD, but who have not yet developed CVD or had an event. Primary prevention often includes lifestyle modifications and therapeutic interventions, including exercise and diet, as well as cholesterol-lowering medication.

While investment in primary prevention remains critical, current policies leave approximately 1.15 million Australians at risk.<sup>4</sup> These high-risk Australians are living with coronary heart disease, cerebrovascular disease or peripheral vascular disease and have survived at least one cardiovascular event. These Australians are vulnerable; one in 10 heart attack survivors will experience another cardiovascular event within one year and about 20% who have experienced a stroke will have another three months.<sup>9</sup> **A secondary prevention approach, which improves health outcomes for these Australians, must be a priority to reduce the impact of CVD**

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#### Primary Prevention:

People with risk factors who have not yet developed cardiovascular disease

#### Secondary Prevention:

People with coronary heart disease, cerebrovascular disease or peripheral vascular disease

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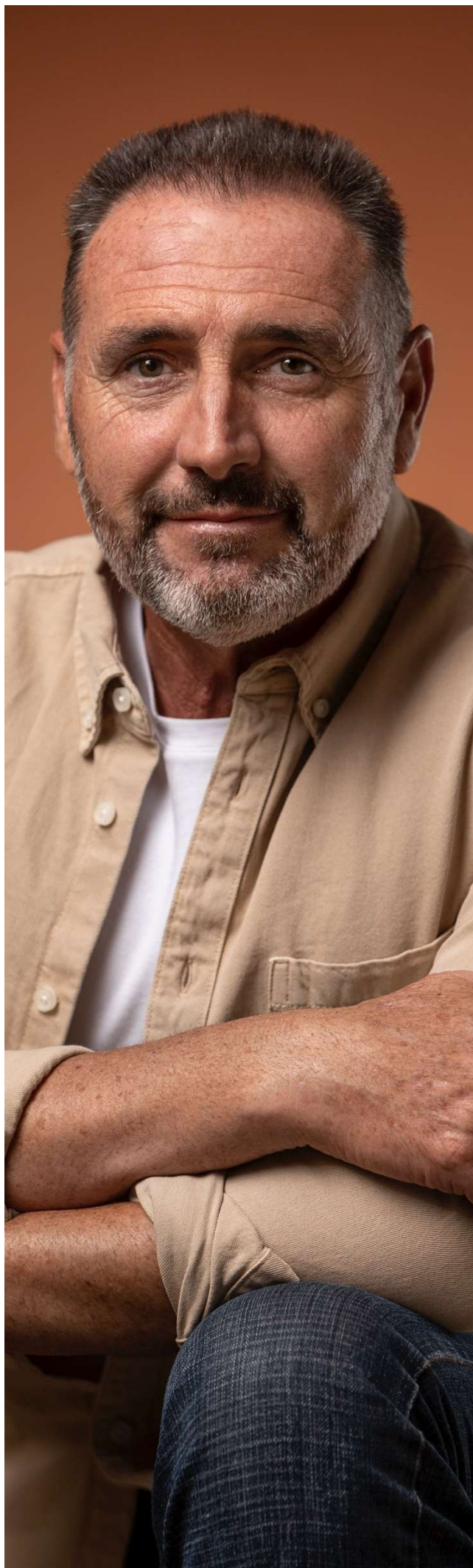


# CODE RED outlines the work that must be done

Launched in June 2020, the CODE RED report explores Australia's management of cholesterol in high-risk patients in primary care. It examines Medicines Insight data of more than 107,000 high-risk patients with prior CVD who had seen a GP in the 10 years from 2010.

The report found Australia is suffering from complacency towards cholesterol with results that showed:

- While 79% of secondary prevention patients were prescribed a lipid-lowering therapy, critically 48% failed to meet the recommended clinical targets for LDL-C, exposing them to risk of further cardiovascular events.
- 56% of women who have had a cardiovascular event are not having their LDL-C optimally managed. This compares to 42% men.
- Over the past decade, the number of Australians not reaching the treatment targets for LDL-C has remained steady (56% in 2010 compared to 52% in 2019). In any year, LDL-C was higher for women than men.<sup>2</sup>





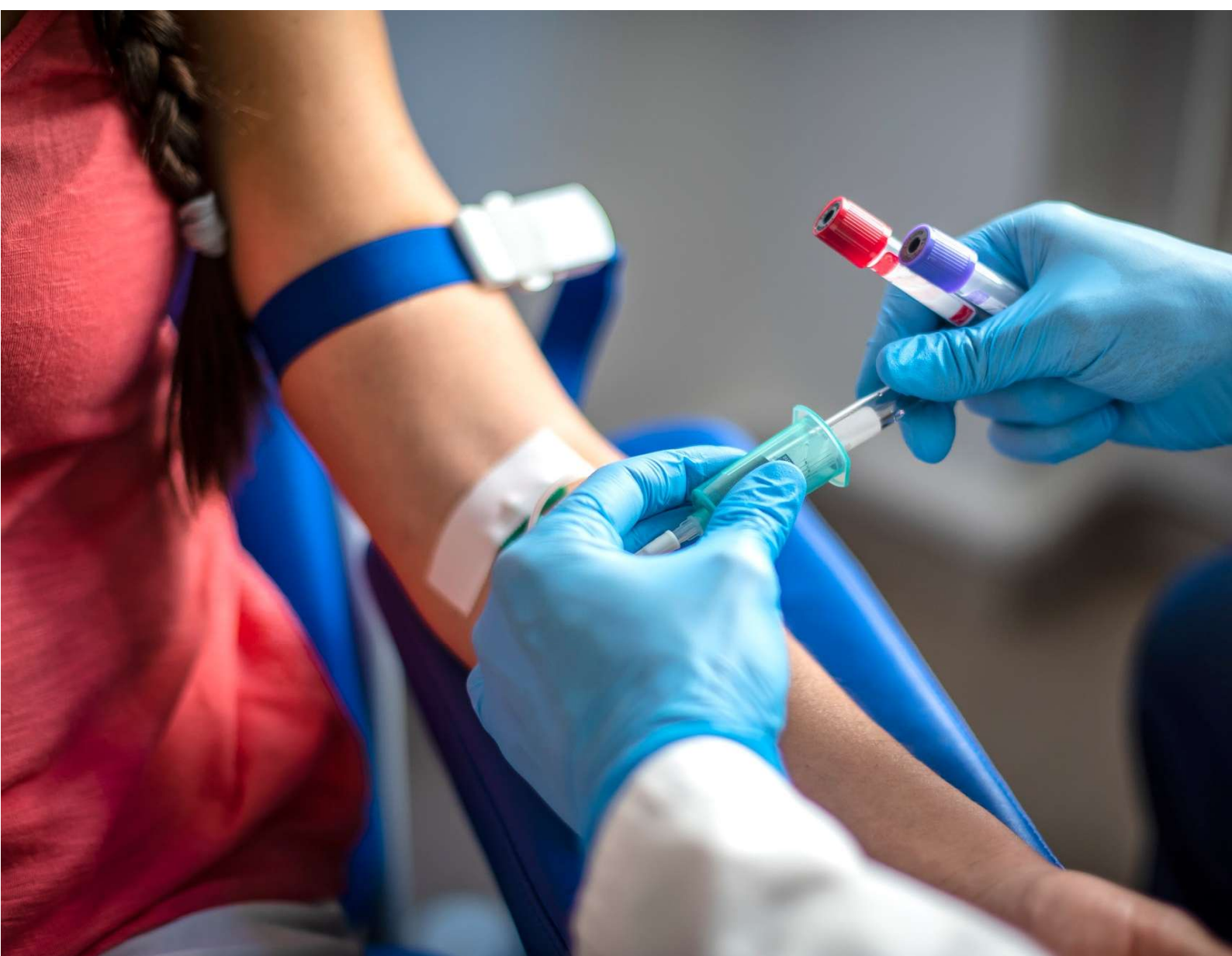
# We can, and must, improve the management of cholesterol in Australia

To better address the challenge of LDL-C amongst high-risk Australians, Amgen commissioned evohealth to work with the CVD community to develop solutions to help improve the management of cholesterol to reduce the burden of CVD.

The result is five simple, achievable, and cost-effective solutions that align with existing Federal Government policies to form a comprehensive approach to improving the management of lipids in Australia.

The report was written to clearly outline the actions needed to improve cholesterol management in Australia, optimising the use of existing policies and programs.

An economic model, based on a discrete event simulation (DES) model, was developed to enable a quantitative assessment of the costs and benefits of the recommended policy interventions by modelling the impact of improved lipid treatment adherence and escalation of the intensity of lipid-lowering therapy.<sup>4</sup>



Solution	Issue	Summary	Benefit	Cost
<b>1. Ensure all Australians know their LDL-C levels</b>	<p>Australia does not currently have a national approach for determining the level of LDL-C for high-risk Australians.</p> <p>Improving the management of elevated LDL-C in high-risk patients presents a simple, achievable and cost-effective means of addressing the disease burden of CVD events, particularly in the high-risk patient cohort.</p>	<p>Leverage and expand the existing Practice Incentive Program Quality Improvement (PIPQI) to cover secondary prevention. This will enable general practitioners to ensure all high-risk Australians are called in to have their LDL-C level measured and treated where appropriate.</p>	<p>Embed the annual 'test and treat' cycle into clinical practice to ensure patients receive optimum treatment.</p> <p>The economic model developed for <i>Australia's Cholesterol Heartache</i> suggested that over five years solutions 1 and 2 combined will potentially avoid up to:</p> <ul style="list-style-type: none"> <li>• 3,221 deaths.</li> <li>• 7,591 non-fatal CVD events.</li> </ul>	<p>Over five years, the cost will be:</p> <ul style="list-style-type: none"> <li>• \$197 per patient.</li> <li>• \$226 million*.</li> </ul> <p>Importantly, the economic model developed for Australia's Cholesterol Heartache suggested the cost of not implementing Solutions 1 and 2 in terms of healthcare costs are in excess of \$102 million over 5 years. These healthcare costs can be saved and reallocated to other high priority areas of healthcare for Australians.</p>
<b>2. Embed annual LDL-C tests for all high-risk Australians</b>	<p>There is a need to encourage proactive, rather than reactive, testing and management of cholesterol.</p>	<p>Using the baseline established through Solution One, embed an annual 'test and treat' cycle for all high-risk Australians. Ensure that these patients have their LDL-C measured annually and are treated as per best practice guidelines.</p>		
<b>3. Standardise lipid profile reporting</b>	<p>When a physician requests a cholesterol test, the LDL-C component of cholesterol is not automatically calculated and reported. Further, there are no standardised nationally consistent clinical support flags against each of the tests. This makes it difficult to ensure clinicians have the information to effectively manage their patients.</p>	<p>Co-ordinate the national rollout of the work undertaken by the Australasian Association of Clinical Biochemists to harmonise lipid reporting across Australia.<sup>†</sup></p>	<p>Ensure LDL-C and clinical support flags are reported on all appropriate diagnostic reports to ensure clinical visibility of a patient's cholesterol risk. This will enable increased referral to specialised care for lipid management, where appropriate to improve health outcomes.</p>	<p>This solution can be actioned within current government resourcing.</p>

\*Awareness campaign to be an additional cost.

<sup>†</sup>Australasian Association of Clinical Biochemists. Harmonised Lipid Reporting – Recommendations from the Harmonisation Workshop 2018 accessed at [www.aacb.asn.au/documents/item/5185](http://www.aacb.asn.au/documents/item/5185)

Solution	Issue	Summary	Benefit	Cost
<p><b>4. Update guidelines to reflect best practice</b></p>	<p>No updated clinical guidelines for secondary prevention currently exist in Australia to guide and support clinicians in treating high cholesterol.</p>	<p>Update the clinical guidelines for the secondary prevention of CVD to reflect the latest global evidence.</p>	<ul style="list-style-type: none"> <li>• Improved patient outcomes by ensuring all clinicians have access to updated guidelines that provide best practice care.</li> <li>• A standardised approach to lipid management in secondary prevention.</li> <li>• Reinforces the importance of LDL-C management in secondary prevention of CVD.</li> </ul>	<p>This solution can be actioned within current government resourcing.</p>
<p><b>5. Enhance the role of quality comprehensive cardiac rehabilitation (CR)</b></p>	<p>Patients who participate in CR have fewer hospital admissions, better medication adherence and an overall improved survival rate. Unfortunately, participation in Australia is poor with just one in three patients referred for CR at discharge. Additionally, there is no standardised approach, monitoring or clear measurement of the quality of care offered.</p>	<p>Implement the recommendations proposed by the Australian Cardiovascular Health and Rehabilitation Association to standardise the approach to quality comprehensive CR across Australia.</p>	<ul style="list-style-type: none"> <li>• Consistent delivery of care for Australians recovering from an event.</li> <li>• Improved transition and continuity of care from tertiary to primary setting.</li> <li>• Enhanced access for some patient cohorts, including regional and rural Australia.</li> <li>• The impact of CR has been shown to improve up to: <ul style="list-style-type: none"> <li>– 65% improvement in medication adherence.</li> <li>– 26% reduction in mortality.</li> <li>– 18% reduction in hospital readmissions.*</li> </ul> </li> </ul>	<p>This solution can be actioned within current government resourcing.</p>

\*Australian Cardiac Rehabilitation Association. Why cardiac rehabilitation really matters. 2016.

# Our work must begin now

Australia has become complacent about cholesterol, and as a result, we are failing the clinical care and management of up to 1.15 million high-risk Australians with CVD<sup>4</sup>, who are vulnerable to suffering a further event or losing their life<sup>2</sup>.

For the cost of \$197 per patient, we have the potential to avoid up to 3,221 deaths and 7,591 non-fatal CVD events in the first five years alone by implementing these five simple and affordable solutions that will make Australia's current health policies work harder and improve health outcomes.<sup>4</sup>

The policy response isn't complicated or costly, but it will strengthen Australia's secondary prevention of CVD, and in doing so, potentially save lives.<sup>4</sup>

We look forward to working with the Federal Government to bring these solutions to fruition.



# About Amgen Australia

Amgen has a long heritage of serving patients in Australia.

Established in 1991, Amgen Australia works to further the company's global efforts to transform the promise of science and biotechnology into therapies that restore health and save lives. Hundreds of thousands of Australians use an Amgen product. In 2020, our clinical trials involved 704 Australian patients, participating in 49 clinical trials and more than 30 investigator-sponsored studies, at more than 60 leading Australian hospitals.

Five years ago, Amgen first stepped into the CVD space in Australia. As a biotechnology company, we believe we have a responsibility to do more than simply bring new medicines forward but to stimulate and contribute to the broader policy conversation that improves patient outcomes.

CVD remains one of Australia's most significant health problems. Through our work, we are committed to supporting the generation of new independent data that shows where Australia stands on cholesterol management. This information highlights the barriers that patients face, and together with policy solutions developed in partnership with the CVD community, will improve health outcomes and save lives.

For more information, please visit: <https://www.amgen.com.au>

**For further information or any additional queries relating to this submission, please contact:  
Meriana Baxter, Head of Government Engagement & Industry Policy.**

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# Appendix A:

## Overview of our work

Amgen has provided independent financial support to the development of two key cholesterol reports:

**CODE RED: Overturning Australia's Cholesterol Complacency:** The Baker Heart and Diabetes Institute generated the first new data in 10 years, highlighting "the extent of the cholesterol problem observed in patients receiving medical care from a general practice" in Australia<sup>2</sup>. The report launched in June 2020.

**Australia's Cholesterol Heartache:** A simple roadmap for urgent action on cholesterol management: evohealth collaborated with the Australian CVD community to create simple, tangible evidence-based policy reforms to address current gaps in care and improve CVD management.<sup>4</sup> The report launched in November 2020.

The project advisory committee consisted of the following members:

- Professor Gemma Figtree, University of Sydney and Interventional Cardiologist Royal North Shore Hospital.
- Professor Robyn Gallagher, Australian Cardiovascular Health and Rehabilitation Association.
- Professor Alun Jackson, Australian Centre for Heart Health.
- Professor Tom Marwick, Baker Heart and Diabetes Institute.
- Professor Rosemary Calder, Mitchell Institute. Victoria University.
- Associate Professor Peter Psaltis, Australian Atherosclerosis Society.
- Dr Louise Sukkar, George Institute for Global Health.
- Mr Shoukat Khan, Heart Support Australia.
- Mr Bill Stavreski, Heart Foundation of Australia.

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## References

1. Australian Bureau of Statistics Available at: <https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/latest-release#australia-s-leading-causes-of-death-2020> [Jan 2022]
2. Carrington MJ, Cao T, Haregu T, Gao, L, Moodie M, Yiallourou SR & Marwick T. CODE RED: Overturning Australia's cholesterol complacency. 2020. Baker Heart & Diabetes Institute. [https://www.baker.edu.au/-/media/documents/impact/baker-institute\\_code-red-report.pdf?la=en](https://www.baker.edu.au/-/media/documents/impact/baker-institute_code-red-report.pdf?la=en) [Nov 2021]
3. ABS. National Health Survey: First Results, 2017-18. In: Statistics. ABo, editor. Canberra 2019. <https://www.abs.gov.au/statistics/health/health-conditions-and-risks/national-health-survey-first-results/2017-18> [Nov 2021]
4. evohealth. 2020. Australia's Cholesterol Heartache: a simple roadmap for urgent action on cholesterol management. <https://www.abs.gov.au/statistics/health/health-conditions-and-risks/national-health-survey-first-results/2017-18> [Nov 2021]
5. AIHW. Trends in Cardiovascular Deaths. Accessed at <http://www.aihw.gov.au/getmedia/2ba74f7f-d812-4539-a006-ca39b34d8120/aihw-21213.pdf> [Nov 2020]
6. Heart Foundation. Key Statistics: Cardiovascular Disease. Accessed at <http://www.heartfoundation.org.au/activities-finding-or-opinion/key-stats-cardiovascular-disease> [Nov 2020]
7. Heart Foundation. Key statistics: risk factors for heart disease. Accessed at <http://www.heartfoundation.org.au/activities-finding-or-opinion/key-statistics-risk-factors-for-heart-disease> [Nov 2020]
8. Baigent C, Blackwell L, Emberson J, Holland LE, Reith C, Bhalra N, et al. Efficacy and safety of more intensive lowering of LDL cholesterol: a meta-analysis of data from 170,000 participants in 26 randomised trials. *Lancet* 2010;376(9753):1670-81.
9. No second chances. Controlling risk of cardiovascular disease. Baker Heart and Diabetes Institute 2019 [https://www.baker.edu.au/-/media/documents/impact/baker-institute\\_no-second-chances.pdf](https://www.baker.edu.au/-/media/documents/impact/baker-institute_no-second-chances.pdf) [Nov 2021]
10. AIHW, 2019 Cardiovascular disease in women. Available at: <https://www.aihw.gov.au/getmedia/25915222-41b7-4697-b877-8a8d7daaa836/aihw-cdk-15.pdf.aspx?inline=true> [Nov 2021]
11. National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand. Reducing risk in heart disease: an expert guide to clinical practice for secondary prevention of coronary heart disease. Melbourne: National Heart Foundation of Australia, 2012. [https://www.csanz.edu.au/wp-content/uploads/2014/12/2012\\_HF\\_CSANZ\\_Reducing\\_Risk\\_in\\_Heart\\_Disease.pdf](https://www.csanz.edu.au/wp-content/uploads/2014/12/2012_HF_CSANZ_Reducing_Risk_in_Heart_Disease.pdf)
12. National Women's Health Strategy 2020-2030. Department of Health, April 2019 <https://www.health.gov.au/resources/publications/national-womens-health-strategy-2020-2030> [Nov 2021]
13. Australian Government Department of Health - Cardiovascular Health Mission. Available at <https://www.health.gov.au/initiatives-and-programs/cardiovascular-health-mission> [Nov 2021]

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