Early detection and management of cardiovascular disease risk factors and chronic disease markers in community pharmacy

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MSAC application Assessment report

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The technical information in this document is used by the Medical Services Advisory Committee (MSAC) to inform its deliberations. MSAC is an independent committee established to provide advice to the Minister for Health on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform government decisions about which medical services should attract funding through the Medicare Benefits Schedule (MBS) or alternative funding programs/arrangements.

MSAC's advice does not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

This report was prepared by Sarah Tadier from Black Swan Health

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ADAR Executive Summary

It is widely accepted that delayed diagnosis of most diseases can lead to poorer health outcomes. Community screening is one way of detecting asymptomatic clinical markers and risk factors that precipitate the onset and progression of disease.

Cardiovascular disease (CVD) is one of Australia's biggest killers. It accounts for much of the health and economic burden within our healthcare system and has a highly interrelated nature with other vascular diseases such as diabetes and chronic kidney disease. The burden of CVD can be reduced through intervention at earlier points along the disease continuum including at prevention and early diagnosis. Many people at high risk of developing CVD, particularly those from the lower socioeconomic groups, are often unaware of risk factors, their own risk profile and actions to take for risk reduction. Further, due to financial barriers and limited access to bulk-billing General Practice many of these people engage with community pharmacy for health care needs.

A 2016 Australian study that implemented the Absolute CVD Risk in a broader age group suggested that around 2.6% of the population aged 18-44 years (about 230 000 people) and 60.6% of those aged 75 years or more (about 850 000 people) were at high absolute risk of a future CVD event¹.

CVD remains the underlying cause of 30% (or 43,946) of all Australian deaths (2012)ⁱⁱ and an expensive disease treated nationally, accounting for 11% of direct healthcare expenditure.

Further to this:

- 1 in 5 Australian adults (22%), about 3.7 million people, had CVD in 2011-12 based on self-reported data.
- CVD was the principle and/or the additional diagnosis in 1.1 million hospitalisations, 11% of all hospitalisations, in 2013-14.
- CVD death rates were 30% higher and hospitalisation rates twice as high for Aboriginal and Torres Strait Islander peoples compared to other Australians.
- CVD death rates were 50% higher in the lowest socioeconomic group compared with the highest group. Similarly, 20% higher for CVD hospitalisation rates.

Many people at high risk of developing CVD, particularly those from the lower socioeconomic groups, are often unaware of risk factors, their own risk profile and actions to take for risk reduction. Pharmacists are among the most readily accessible and trusted health professionals. They are well placed to implement population-based CVD screening, deliver key health promotion messages and facilitate prompt and appropriate onward referral to General Practice or Allied Health providers.

For the benefits of early intervention to be maximised, positively screened individuals need to comply with advice given and seek follow up on referrals. Much study suggests there is significant gap in health seeking behaviour here and an opportunity to influence participant actions and improve referral uptake and compliance with advice in screened individuals.

Intervention

This trial aimed to compare the effectiveness and cost-effectiveness of two community pharmacy-based approaches to cardiovascular disease (CVD) screening in a previously undiagnosed population. Specifically:

- Expand the role of Community Pharmacy in screening for people at elevated cardiovascular risk and facilitated referral for appropriate intervention.
- Adopt an easily accessible, cost-effective early intervention approach that offers effective CVD screening to facilitate increased risk identification, detection and preventative risk management in undiagnosed individuals.

• Strengthen local clinical referral pathways for timely and appropriate access to services by at risk groups and overall better health outcomes for the general population.

The intervention is the provision of a CVD risk assessment by community pharmacy, supporting people identified as being at risk of CVD to engage in early intervention activities to prevent disease onset and progression. The trial compared the clinical and cost effectiveness of a Brief Intervention CVD Risk Assessment and a Comprehensive Intervention CVD Risk Assessment delivered in community pharmacy in a previously undiagnosed population.

Participating community pharmacies were randomly allocated to either the Brief CVD Risk Assessment or the Comprehensive CVD Risk Assessment. Participants joining the trial underwent the risk assessment (Brief or Comprehensive) assigned to the pharmacy attended.

• Brief Risk Assessment: A combination of demographic information (age, gender, ethnicity, country of birth), subjective health measures (physical activity level, smoking status, nutrition, health history, lifestyle questions) and waist measurement; collected by AUSDRISK assessment tool and questionnaire.

The Brief Risk Assessment included non-invasive Point of Care assessment of blood pressure; systolic and diastolic. Opportunistic assessment of risk of cerebrovascular disease will be undertaken through non-invasive Point of Care screening of irregular heartbeat using the available technology for blood pressure measurement. The Brief Assessment was estimated to take 15-20 minutes.

• Comprehensive Risk Assessment: A combination of demographic information (age, gender), subjective health measures (smoking status, lifestyle questions); collected by questionnaire.

The Comprehensive Risk Assessment included non-invasive Point of Care assessment of blood pressure; systolic and diastolic. Opportunistic assessment of risk of cerebrovascular disease will be undertaken through non-invasive Point of Care screening of irregular heartbeat using the available technology for blood pressure measurement.

The Comprehensive Risk Assessment included biometric information; serum lipid levels, HbA1C levels measured using medical point of care devices involving fingerprick testing. Comprehensive intensity risk assessment was estimated to take 25-30 minutes.

Collected measures were used to calculate participant risk level (low, medium or high) using screening algorithms based on risk predicted equations. All participants were offered appropriate patient education including printed resources and/or lifestyle advice.

Participants assessed as being at medium or high risk were referred to their regular GP for further investigation (recommended consultation within 4 weeks or 7 days, respectively) and to community-based lifestyle modification programs in the local area.

Participants were contacted 6 months and 12 months after baseline assessment to undertake a repeat assessment. This allowed sufficient time for any demonstrated measurable effects from the intervention to be observed.

Participant screening was opportunistic, subjectively targeting pharmacy customers within the target age range, overweight or obese, or presenting as smokers.

The target population is those members of the community aged between 45 and 74 years (35 and 74 years for Aboriginal and Torres Strait Islander populations), undiagnosed with cardiovascular disease and engaged with community pharmacy.

Component	Description
Proposed Population	Adults aged 45 to 74 years (35 to 74 years for Aboriginal and Torres Strait Islander people) without known history of CVD who engage with community pharmacy.
Proposed Technology	 Integrated health check delivered by pharmacists within community pharmacy to: assess the risk of CVD screen for clinical markers using point of care testing device for indicative presence of CVD deliver key health promotion messages provide referral to local risk reduction and care management services and providers (i.e.; General Practice, lifestyle modification programs)
Main Comparator	In the absence of an exisiting community screening program, the comparator is usual care by a General Practitioner in primary clinical practice. Screening activities in General Practice are supported by MBS health assessment items, administered on the clinical judgement of the practitioner.

Table 1: Summary PICO Table

Proposal for Funding

The funding arrangement proposed for the "early detection and management of cardiovascular disease risk factors and chronic disease markers in community pharmacy" is direct financial funding (grant funding) to community pharmacy.

It is proposed each screening intervention is funded at a level of the equivalent cost of Medicare Benefits Schedule Item 699; Category Health Assessment – Fee \$76.95. The provision of CVD Risk Assessment requirements of pharmacy aligns with the clinical activity required of the hearth health check consultation and time taken by General Practice to complete the consultation (at least 20 minutes).

Comparator to the intervention

In the absence of an existing community screening program, the comparator is usual care by a General Practitioner in primary clinical practice.

Comparative safety

The use of CVD risk assessment by community pharmacy in a previously undiagnosed population results in noninferior safety compared with a previously undiagnosed population engaged with General Practice.

Comparative effectiveness

As expected, (due to non-modifiable factors included in the AUSDRISK screening tool used in the Brief CVD Risk Assessment) a greater proportion of participants were assessed as being at medium or high risk in the Brief CVD Risk Assessment arm than the Comprehensive CVD Risk Assessment arm. This was consistent at each assessment point; Baseline, 6 months and 12 months.

The use of CVD risk assessment by community pharmacy in a previously undiagnosed population results in noninferior effectiveness compared with a previously undiagnosed population engaged with General Practice.

Consumer Impact Statement

Feedback from trial participants supports community pharmacy as an acceptable location for undertaking CVD risk assessment. Participants noted the convenience and ease in engaging with community pharmacy for the intervention, confidence in community pharmacy performing the intervention and providing health information. At all points of assessment, no less than 99% of participants found it appropriate to have a CVD Risk Assessment undertaken in community pharmacy.

Outcomes

The expected clinical outcomes of the grant activity were that pharmacy-led integrated health checks to detect risk, aid diagnosis and enable early interventions:

- reduce, delay or prevent CVD and its complications in patients; and
- improve patients' quality of health care outcomes.

The trial sought to answer the following questions:

- 1) In the community pharmacy setting, is low intensity risk assessment for CVD noninferior in identification of at-risk individuals than comprehensive risk assessment?
- 2) In the community pharmacy setting, is a total CVD risk assessment a greater motivator, for populations who don't regularly seek medical advice, to seek health care and maintain improved health than a low intensity risk assessment?
- 3) Is community pharmacy-based CVD risk assessment acceptable to patients, pharmacists, and medical practitioners?
- 4) Does early intervention in CVD risk factor identification by community pharmacy offer a cost-effective opportunity to reduce burden of disease?

Question 1: In the community pharmacy setting, is low intensity risk assessment for CVD non-inferior in identification of at-risk individuals than comprehensive risk assessment?

Due to non-modifiable factors (such as gender and age) included in the AUSDRISK Tool used in the Brief CVD Risk Assessment, a considerably greater proportion of participants were assessed as being at medium or high risk in the Brief CVD Risk Assessment arm than the Comprehensive CVD Risk Assessment arm. Refer Table 5.

- At baseline assessment, 46% of participants in the Brief Intervention arm were assessed as being at high risk compared to 3% of participants in the Comprehensive Intervention Arm.
- At baseline assessment, 42% of participants in the Brief Intervention arm were assessed as being at medium risk compared to 5% of participants in the Comprehensive Intervention Arm.
- At baseline assessment, 12% of participants in the Brief Intervention arm were assessed as being at low risk compared to 92% of participants in the Comprehensive Intervention Arm.

These outcomes suggest the Brief Risk Assessment is inferior to the Comprehensive Risk Assessment.

Question 2. In the community pharmacy setting, is a total CVD risk assessment a greater motivator, for populations who don't regularly seek medical advice, to seek health care and maintain improved health than a low intensity risk assessment?

Participants self-reported that at 6 months 46% of participants who had been referred to General Practice adhered to the advice; of this, 71% attended within the suggested timeframe. At 12 months, 56% of participants who had been referred to General Practice adhered to the advice; of this, 100% attended within the suggested timeframe.

Participants self-reported that at 6 months 11% of participants who had been referred to a community-based lifestyle modification program adhered to the advice; of this, 21% attended one or more session. At 12 months, 8% of participants who had been referred to a community-based lifestyle modification program; 63% attended one or more session.

Approximately half of participants took the referral advice of the community pharmacy and sought further health care from General Practice, with a high percentage seeking health care within the advised timeframe. This demonstrates community pharmacy as a motivator to seek health care from General Practice.

However, only a small percentage of participants took the referral advice of the community pharmacy and engaged in lifestyle modification programs.

These responses indicate greater motivation to maintain improved health at 6 months for participants in the Comprehensive Risk Assessment arm. At 12 months assessments participants in the Brief Risk Assessment arm demonstrated greater motivation to maintain improved health.

<u>Question 3: Is community pharmacy-based CVD risk assessment acceptable to patients, pharmacists, and medical practitioners?</u>

Feedback from community pharmacy indicated provision of CVD Risk assessment is acceptable. However, there is requirement for appropriate remuneration for pharmacies, due to costs associated with delivery of the assessment. Engagement with people not engaging with General Practice for their health care offers opportunity for early detection of chronic health conditions.

Feedback from trial participants supports community pharmacy as an acceptable location for undertaking CVD risk assessment. Participants noted the convenience and ease in engaging with community pharmacy for the intervention, confidence in community pharmacy performing the intervention and providing health information.

At each stage of assessment, participants in both the Brief and Comprehensive Assessment arms found it appropriate to have the risk assessment completed in a pharmacy setting. Refer Table 9.

Feedback from General Practitioners indicates support for CVD risk assessment by community pharmacy. However, the majority of General Practitioners surveyed qualified this statement by noting the appropriate referral back to General Practice for subsequent health care.

Question 4. Does early intervention in CVD risk factor identification by community pharmacy offer a cost-effective opportunity to reduce burden of disease?

The health economic analysis did not reveal statistically significant differences in quality of life between the two groups. However, the data show slight improvements in quality of life in both arms of the trial relative to the baseline point, despite showing no statistical significance.

The Comprehensive CVD Risk Assessment was of higher specificity and resulted in less participants being referred to General Practice than the Brief CVD Risk Assessment.

In Australia, the cost of heart health checks are covered by Medicare, however this requires people to present at General Practice for an assessment. CVD Risk Assessment in community pharmacy enables easy access for opportunistic testing and assessment, onward referral to General Practice for further testing and health and lifestyle advice.

In terms of financial cost impacts for the health system, the Comprehensive Risk Assessment indicates a potential for cost savings. This is applied where people are assessed and referred for diagnosis before their CVD has significant impact on their health resulting in a progressed illness or a requirement for crisis intervention through the tertiary health system.

If the program is to be implemented, future financial determinations will include the cost of conducting assessments (either as comprehensive or brief). At the time of conducting this economic evaluation, we did not have exact data on the actual time that pharmacists spent on conducting the assessments, or associated salary and wages information. It is difficult to provide an estimate on how much the future costs might be if the program is implemented.

Economic evaluation

The economic aspect of the trial will collate the time needed to provide high and low intensity screens, and through a combination of self-report and linked Medicare data (proposed), estimate the incremental downstream costs associated with the interventions relative to one another. The cost-effectiveness analysis will report a stepped economic evaluation, moving from cost per identified at risk individual to cost per QALY using the SF-36 data.

The health economic analysis did not reveal statistically significant differences in quality of life between the two groups. However, the data show slight improvements in quality of life in both arms of the trial relative to the baseline point, despite showing no statistical significance. Analysis noted significant differences in the PBS costs with the Brief Risk Assessment arm having higher costs compared to the Comprehensive Risk Assessment arm.

There were no significant differences in the MBS costs. However, the total costs (MBS + PBS + pharmacy time costs) were statistically and significantly different (p < 0.001) with the comprehensive arm having much higher intervention costs, mostly due to the relatively larger time commitment to complete assessments for this group.

Recommendations

- Overall, the trial evaluations suggest supporting the Comprehensive Risk Assessment as the preferred option for CVD screening in pharmacies.
- A community pharmacy-based CVD risk screening program for undiagnosed CVD should adopt a two-step approach, with initial risk assessment using the Framingham Risk Equation screening tool and point-of-care testing followed by referral to General Practice if CVD risk is assessed as medium or high.

- Community pharmacy undertake only baseline Comprehensive CVD Risk assessment with appropriate onward referral based on risk.
- A formal training and assessment process be implemented to ensure that pharmacists undertaking a remunerated screening service can demonstrate the requisite competencies to deliver the service at an appropriate standard.
- To be eligible to deliver CVD Risk Assessment a pharmacy must demonstrate that it has the following:
 - A separate counselling room or private counselling area;
 - One pharmacist with requisite training and competency to conduct screening; and
 - Appropriate documentation, software and suitable, regularly calibrated POC equipment and consumables.

Acronyms and abbreviations

AIHW	Australian Institute of Health and Welfare			
ARTG	Australian Register of Therapeutic Goods			
AUSDRISK	Australian Type 2 Diabetes Risk Assessment Tool			
CI	confidence interval			
CVD	Cardiovascular disease			
ESC	Evaluation Sub-Committee			
FRE	Framingham Risk Equation			
HRQoL	health-related quality of life			
HTA	health technology assessment			
ICER	incremental cost-effectiveness ratio			
MBS	Medicare Benefits Schedule			
MD	mean difference			
MSAC ESC	Medical Services Advisory Committee Evaluation Sub-			
	Committee			
NHMRC	National Health and Medical Research Council			
PBS	Pharmaceutical Benefits Scheme			
PASC	PICO Confirmation Advisory Sub-Committee of the MSAC			
QALY	quality-adjusted life year			
TGA	Therapeutic Goods Administration			

Section 1 Context

1.1 Purpose of application

This ADAR of for the 'early detection and management of cardiovascular disease (CVD) risk factors in community pharmacy' is intended for the Medical Services Advisory Committee (MSAC).

MSAC appraises medical services, health technologies and health programs for public funding through an assessment of their comparative safety, clinical effectiveness, cost-effectiveness and total cost, using the best available evidence. This includes, but is not limited to, amendments and reviews of existing services funded on the Medicare Benefits Schedule (MBS) or other non-MBS-funded programs (e.g., blood products, screening programs or prostheses referred to the Prostheses List Advisory Committee).

Black Swan Health has provided a desktop literature review of the early detection and management of cardiovascular disease risk factors in community pharmacy to inform MSAC's decision-making regarding whether the proposed health technology should be publicly funded through the Medicare Benefits Schedule. At the time of writing the draft report the economic evaluation is pending provision of Medicare Benefit Schedule and Pharmaceutical Benefits Scheme data.

The purpose of this assessment report is to synthesise the information most likely to be useful for committee members. Technical appendices provide assurance of the rigour behind the systematic review and construction of the economic and financial analyses.

The proposed use of early detection and management of cardiovascular disease risk factors in community pharmacy in Australian clinical practice was outlined in a PICO confirmation that was presented to, and accepted by, the PICO Confirmation Advisory Sub-Committee (PASC).

Strategies to address the high prevalence and mortality of non-communicable disease include risk factor reduction, diagnosing disease at an earlier stage and timely treatment. It is widely accepted that delayed diagnosis of most diseases can lead to poorer outcomes. Community screening is one way of detecting earlier diagnosis and identifying previously undetected disease risk factors. Previous studies of opportunistic pharmacy-based screening interventions have been successful in identifying a significant proportion of the population, both suffering from and at high risk of Cardiovascular Disease or Type II Diabetes Mellitus.

The aim of the 'Early detection and management of cardiovascular risk factors and chronic disease markers in community pharmacy' Program is to enhance the capacity of Community Pharmacists to identify participants who may be at risk of undiagnosed chronic disease, particularly cardiovascular disease (CVD) and provide a direct referral path for diagnosis, risk reduction, care management and education.

Black Swan Health acknowledges the Commonwealth of Australia in funding the 'Early detection and management of cardiovascular risk factors and chronic disease markers in community pharmacy' Pharmacy Trial Program through the Sixth Community Pharmacy Agreement (6CPA).

Black Swan Health acknowledges Services Australia in providing approved data for the 'Early detection and management of cardiovascular risk factors and chronic disease markers in community pharmacy' Pharmacy Trial Program through the Sixth Community Pharmacy Agreement (6CPA).

1.2 Background

MSAC has not previously considered this application for 'early detection and management of cardiovascular disease (CVD) risk factors in community pharmacy'.

1.3 Prerequisites to implementation of any funding advice

The proposed technology does not include a therapeutic good that requires TGA approval.

A key dependency that will be addressed, should the trial be approved, is approval to modify the administration of the screening tools Australian Type 2 Diabetes Risk Assessment (AUSDRISK) and Framingham Risk Equation (FRE) tools for the purposes of the program.

1.4 Population

Many people at high risk of developing CVD, particularly those from the lower socioeconomic groups, are often unaware of risk factors, their own risk profile and actions to take for risk reduction; thus, the detection of disease remains under-recognised until presentation of clinical markers, requiring GP diagnosis and secondary intervention to prompt initiation of treatment and ongoing management.

The target population for the intervention is those members of the community who may be at heightened risk of undiagnosed cardiovascular disease and visit community pharmacy.

A semi-targeted approach to patient identification was applied for trial recruitment; subjective identification of anyone over 45 years (35 years, if Aboriginal and Torres Strait Islander people), and subjectively overweight or obese. Those reporting a previous history of treatment for hypertension, diabetes, or known cardiovascular disease (stroke, myocardial infarction, or angina) or under the age of 45 were deemed ineligible for screening. Past history presumes they have previously been referred to, or treated in, their local primary health centre.

1.5 Intervention

Despite a consistent decline in cardiovascular death rates since the 1960s, cardiovascular disease (CVD) remains Australia's biggest killer, accounting primarily for almost one in three Australian deaths and 11% of health system expenditure. The overall burden attributable to CVD is far greater than simply loss of life. An estimated 4.2 million (22%) Australian adults currently live with CVD¹, with considerable inequality among disadvantaged and vulnerable population groups (including those in lower socioeconomic groups, Aboriginal and Torres Strait Islander peoples and those living in regional and remote areas).

With continuing advances in treatment and an ageing population, many people with previously fatal CVD are living longer with significant effects on their quality of life, imposing escalating social and economic burden on the health system.

Importantly, much of the burden of CVD is avoidable through preventive measures that target and identify high risk individuals and address modifiable risk factors such as smoking high cholesterol and high blood pressure. While patients with established CVD have a substantially elevated risk of subsequent cardiovascular events, 60% of cardiovascular deaths will occur in asymptomatic people who have not had a previous event². It is therefore critical to detect and manage such patients at unknown and high risk of future events.

¹ 4364.0.55.001 - National Health Survey: First Results, 2014-15

² Retrieved 21/2/17 from http://www.australiandoctor.com.au/cmspages/getfile.aspx

MSAC Assessment report – CVD Risk Assessment in Community Pharmacy

An integrated health check delivered in community pharmacy will detect and manage those at elevated risk of CVD, including onwards referral to general practice and community service providers. Many people at high risk of developing vascular and related chronic diseases, particularly those from lower socioeconomic groups, are often unaware of risk factors, their own risk profile and actions to take for risk reduction^{3 4 5}

The intervention is the provision of a CVD risk assessment by community pharmacy, supporting people identified as being at risk of CVD to engage in early intervention activities to prevent disease onset and progression.

Screening is opportunistic subjectively targeting pharmacy customers who are within the target age range, overweight or obese, or present as smokers.

The trial compared a Brief CVD Risk Assessment with a Comprehensive CVD Risk Assessment.

The Brief Risk Assessment combined demographic information (age, gender, ethnicity, country of birth), subjective health measures (physical activity level, smoking status, nutrition, health history, lifestyle questions) and waist measurement; collected by AUSDRISK assessment tool and questionnaire. The Brief Risk Assessment included non-invasive Point of Care assessment of blood pressure; systolic and diastolic. Opportunistic assessment of risk of cerebrovascular disease undertaken through non-invasive Point of Care screening of irregular heartbeat using the available technology for blood pressure measurement.

The Comprehensive Risk Assessment combined demographic information (age, gender), subjective health measures (smoking status, lifestyle questions); collected by FRE and questionnaire. The Comprehensive Risk Assessment included non-invasive Point of Care assessment of blood pressure; systolic and diastolic. Opportunistic assessment of risk of cerebrovascular disease undertaken through non-invasive Point of Care screening of irregular heartbeat using the available technology for blood pressure measurement. The Comprehensive Risk Assessment included biometric information; serum lipid levels, HbA1C levels measured using medical point of care devices.

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³ Carleton RA, Bazzarre T, Drake J, Dunn A, Fisher EB, Jr., Grundy SM, et al. Report of the Expert Panel on Awareness and Behavior Change to the Board of Directors, American Heart Association. Circulation 1996;93(9):1768-72.

⁴ Baberg HT, Jager D, Kahrmann G, de Zeeuw J, Bojara W, Lemke B, et al. [Health promotion and cardiovascular risk factors. The level of knowledge among 510 inpatients of an acute coronary care unit]. Med Klin (Munich) 2000;95(2):75-80

⁵ Davis SK, Winkleby MA, Farquhar JW. Increasing disparity in knowledge of cardiovascular disease risk factors and risk-reduction strategies by socioeconomic status: implications for policymakers. Am J Prev Med 1995;11(5):318-23

1.6 Comparator(s)

The proposed intervention of undertaking CVD Risk Assessment in Community Pharmacy enables opportunistic early, or earlier, identification of CVD risk factors in a previously undiagnosed person through engagement with a trusted and accessible health professional.

In the absence of an alternate community screening program, the comparator is standard medical management by a General Practitioner in primary clinical practice. Screening activities in General Practice are supported by MBS health assessment items, administered on the clinical judgement of the practitioner.

Community pharmacy is an appropriate and easy point of health care and advice for many people, often used in preference to General Practice. For many people pharmacy is the initial point of contact with the health system, reducing barriers to healthcare and providing health information and lifestyle advice.

Participant feedback indicates community pharmacies:

- Are trusted health professionals
- Provide accessible and immediate healthcare and/or advice
- Are local, part of the community and familiar
- Are often seen as a 'one-stop shop' for health needs; advice and medication in a single location

More recently, with changes to the economic situation in Australia and decreasing access to bulk-billing General Practice, community pharmacy has become a cost-effective alternative for many people, particularly those experiencing financial disadvantage.

1.7 Summary of the PICO criteria

The Prior tests, Population, Investigation/Index test, Comparator and Outcomes (PPICO) that were prespecified in the early detection and management of cardiovascular disease risk factors in community pharmacy PICO confirmation to guide the systematic literature review are presented in Table 2.

Table 2: PICO criteria for assessing early detection and management of cardiovascular disease risk factors in community pharmacy

Component	Description						
Population	Adults aged 45 to 74 years (35 to 74 years for Aboriginal and Torres Strait Islander people) without known history of CVD who engage with community pharmacy.						
Prior tests	Those reporting a known history of CVD or outside the target age range will be deemed ineligible for program enrolment and screening.						
Intervention	 Integrated health check delivered by pharmacists within community pharmacy to: assess the risk of CVD screen for clinical markers using point of care testing device for indicative presence of CVD deliver key health promotion messages provide referral to local risk reduction and care management services and providers (i.e., GP, lifestyle management programs) 						
Comparator	In the absence of Community Pharmacy screening program, comparator is usual care by GP in primary clinical practice. Screening activities in General Practice are supported by MBS health assessment items, administered on the clinical judgement of the practitioner.						
Outcomes	 How effective is opportunistic screening by Community Pharmacies in identifying people with, or at risk of, under-recognised conditions; specifically, cardiovascular disease. Suggested measures include: Proportion of screened individuals, identified with disease risk factors (by risk score) Percentage of screened population referred on to primary care services Participants' adherence to pharmacy advice and uptake of primary care referral Screening participants' satisfaction with pharmacy based service Service providers' satisfaction with pharmacy based service Participant awareness of CVD and its risk factors Pharmacist influence of participant health seeking behaviour Participant reported outcomes – health related quality of care Cost of program will be compared to usual costs that would have been applicable in absence of program. This includes prevented GP consultations and pathology investigations, and their resultant reduction in MBS/PBS billing. <i>Rationale</i> Delayed detection of CVD risk and clinical markers results in later symptomatic or acute presentation at General Practice or hospital requiring more advanced and costly diagnosis, treatment and management interventions						

1.8 Alignment with the PICO confirmation

This ADAR of early detection and management of cardiovascular disease risk factors in community pharmacy addresses all the PICO elements that were prespecified in the PICO confirmation submitted to PASC.

1.9 Clinical Management Algorithms

Proposed clinical management algorithm for the risk assessment of CVD in an undiagnosed population Identified as medium or high risk of CVD referred to community-based lifestyle program Opportunistic testing by community pharmacy Indentified as medium or high risk referred to GP Undiagnosed CVD Opportunistic Diagnosis of CVD screening by GPs

Figure 1: Clinical management algorithm

Currently, the management algorithm of the comparator is CVD diagnosis by General Practice through opportunistic screening. The proposed clinical management algorithm requires community pharmacists to perform opportunistic CVD risk identification screening before onward referral to General Practice for confirmed diagnosis and concurrent referral to community-based lifestyle modification programs.

1.10 Proposal for Public Funding

Should this be considered, the funding arrangement proposed for the "early detection and management of cardiovascular disease risk factors and chronic disease markers in community pharmacy" is through the use of exisiting and future public health funding

Cardiovascular disease already places a significant burden on the health budget. Through the introduction and application of early intervention strategies to identify and diagnose CVD in a previously undiagnosed population, the opportunity is presented to reduce the burden usually associated with later and subsequent intervention costs (including MBS and PBS items associated with GP consults, care coordination and pathology testing).

Recognising the delivery of the intervention impacts the ability of the community pharmacy to undertake routine business activity, there is a requirement to appropriately remunerate the participating pharmacies. Additionally, pharmacies require a private location within their premises from which to deliver the intervention.

The funding arrangement proposed for the "early detection and management of cardiovascular disease risk factors and chronic disease markers in community pharmacy" is direct financial funding (new MBS item) for activity undertaken by pharmacists.

It is proposed each screening intervention is funded at a level of the equivalent cost of Medicare Benefits Schedule Item 699; Category Health Assessment – Fee \$76.95. The provision of CVD Risk Assessment requirements of pharmacy aligns with the clinical activity required of the heart health check consultation and time taken by General Practice to complete the consultation (at least 20 minutes). Noting requirements for a General Practitioner to claim Item 699 the following alignment with Community Pharmacist activity required to complete the screening intervention:

General Practice MBS Item 699	Community Pharmacy CVD Risk Assessment Fee (Proposed)
Collection of relevant information, including taking a patient history	Completion of Risk Assessment Tool
Basic physical examination, which must include recording blood pressure and cholesterol	Biometric measurements and POCT
Initiating interventions and referrals as indicated	Completion of referral as/if required
implementing a management plan	
providing the patient with preventative health care advice and information	Provision of health information

Additional funding support is required to address establishment and ongoing costs of POCT devices and recurrent costs of equipment, reagents, quality control material and sample collection and disposal resources.

The fee per occasion of service would need to be reconsidered in the event capital expenditure cannot be considered for these devices and the required recurrent costs.

Section 2B Clinical evaluation of investigative technologies

Methods for undertaking the assessment

A non-exhaustive desktop literature review located several relevant studies reporting on the effectiveness of opportunistic disease screening and preventative intervention strategies within community pharmacy. In addition, there is one systematic review assessing the feasibility and acceptability of community-based pharmacy screening for major diseases and one systematic review assessing effectiveness of screening for diabetes and cardiovascular disease risk factors in community pharmacy.

The following search terms were used in the desktop literature review: community pharmacy; CVD; cardiovascular disease; screening; intervention.

Assessment framework

A direct evidence approach was used for evaluation of risk identification of CVD in community pharmacy.



Figure 2: Evidence approach

- Adults aged 45 to 74 years (35 to 74 years for Aboriginal and Torres Strait Islander people) without known history of Cardiovascular Disease
- B CVD Risk Factors Screening at Community Pharmacy
- O Assessment of Low, Medium or High risk of CVD
- Participants with Moderate and High risk screening assessment results referred to General Practice and community-based lifestyle program
- E Adverse events reported in association with the trial
- Medium or high risk assessment of CVD by community pharmacy in a previously undiagnosed population and onward referral to General Practice results in outcomes that are no worse than a previously undiagnosed population engaged with General Practice.
- 2 Concordance with CVD risk assessment by community pharmacy in a previously undiagnosed population and onward referral to General Practice and a previously undiagnosed population directly engaged with General Practice are unavailable.

- 3 It is inferred that similar results from both proposed test and comparator will result in the same management decisions, and noninferior health outcomes.
- 4 Harms of CVD risk assessment by community pharmacy in a previously undiagnosed population and onward referral to General Practice results in outcomes that are no worse than a previously undiagnosed population engaged with General Practice.

2B.1 Direct from Test to Health Outcomes Evidence

2B.1.1 Methods for Undertaking the Assessment

A total of 5 studies met the inclusion criteria for assessing the direct test to health outcomes evidence of CVD Risk Assessment in Community Pharmacy compared to standard medical management by a General Practitioner in primary clinical practice.

A summary of the key features of the studies providing direct from test to health outcome evidence for CVD Risk Assessment in Community Pharmacy compared to usual care is provided in Table 4.

2B.1.2 Characteristics of the evidence base

Table 3: Characteristics of evidence base

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Pharmacy diabetes care program: analysis of two screening methods for undiagnosed type 2 diabetes in Australian community pharmacy	Randomised controlled	Undiagnosed Type 2 Diabetes Mellitus	Comparison of Tick Test Only (TTO) and Sequential Screening (SS) for T2DM. Both methods used the same initial risk assessment for type 2 diabetes. Additionally, the SS method, patients with risk factors were offered a capillary blood glucose test.	Undiagnosed Type 2 Diabetes Mellitus	Rate of diagnosis in community pharmacy Referral to General Practice Cost
The effectiveness of Pharmacist Interventions on Cardiovascular Risk: The Multicentre Randomised Controlled RxEACH trial.	Randomised controlled	Participants identified as high risk for CVD randomised across two arms	Comparison of usual care or intervention, comprising a Medication Therapy Management review from their pharmacist and CVD risk assessment and education. Monthly follow-up visits for 3 months. CVD risk estimated using the greater of the Framingham, International, or United Kingdom Prospective Diabetes Study risk scores.	Participants identified as high risk for CVD	Difference in change in risk for CVD events
Diabetes and cardiovascular disease risk screening model in community pharmacies in a developing primary healthcare system: a feasibility study.	Feasibility	Purposive sample of 12 community pharmacies in three cities in the United Arab Emirates	Pharmacist screening including history, demographics, anthropometric measurements, blood pressure and point-of-care testing including HbA1c and lipids.	Adults 40 years of age and above who have not been previously diagnosed with either diabetes or CVD.	Development of UAE pharmacist-delivered screening mode. Proportion of screened participants identified as having high CVD risk. Proportion of participants identified as having elevated blood glucose Secondary outcome is participants' satisfaction with the screening.
The effectiveness of screening for diabetes and cardiovascular disease risk factors in a community pharmacy setting	Systematic review and meta data analysis		16 studies 108,414 participants		Feasibility for screening for diabetes and those at risk of cardiovascular disease. Identification of previously unknown cases of cardiovascular disease risk factors.
Screening for major diseases in community pharmacies: a systematic review	Systematic review		Screening predominantly opportunistic and screening tools included questionnaires or risk assessment forms, medical equipment for physiological measurements, or a combination of both.		The proportion of screened individuals, identified with disease risk factors or the disease, ranged from 4% to 89%. Where assessed, patient satisfaction with pharmacy-based screening was high, but individuals who screened positive often did not follow pharmacist advice to seek further medical help.

Table 4: Key features of the included evidence comparing CVD Risk Assessment in Community Pharmacy with usual care							
Trial/Study	N	Study design Bick of	Population	Intervention	Comparator	Key outcome(s)	Result used in economic model
		bias					
Diabetes and cardiovascular disease risk screening model in community pharmacies in a developing primary healthcare system: a feasibility study	12 community pharmacies 115 participants	Feasibility	Adults 40 years of age and above who have not been previously diagnosed with either diabetes or CVD.	Pharmacist screening including history, demographics, anthropometric measurements, blood pressure and point-of- care testing including HbA1c and lipids.	Usual care	Community pharmacist-delivered screening of diabetes and CVD risk is feasible in the UAE. The model offers a platform to increase screening capacity within primary care and provides an opportunity for early detection and treatment.	
Pharmacy diabetes care program: analysis of two screening methods for undiagnosed type 2 diabetes in Australian community pharmacy	30 pharmacies 1286 participants	Randomised	Undiagnosed type 2 diabetes in Australian community pharmacy	Comparison of Tick Test Only (TTO) and Sequential Screening for T2DM. Both methods used the same initial risk assessment for type 2 diabetes. Additionally, the SS method, patients with risk factors were offered a capillary blood glucose test.	Usual care	The rate of diagnosis of diabetes was significantly higher for Sequential Screening compared with the Tick Test Only (TTO) method The SS method resulted in fewer referrals to the GP and a higher uptake of referrals than the TTO method and so was the more cost- effective screening method.	
The effectiveness of Pharmacist Interventions on Cardiovascular Risk: The Multicentre Randomised Controlled RxEACH trial	56 community pharmacies 723 participants	Randomised controlled	Adults at high risk for CVD	Comparison of usual care or intervention, comprising a Medication Therapy Management review from their pharmacist and CVD risk assessment and education. Monthly follow- up visits for 3 months. CVD risk estimated using the greater of the Framingham, International, or United Kingdom Prospective Diabetes Study risk scores	Usual care	21% difference in change in risk for CVD events (p < 0.001) between the intervention and usual care groups.	

				1		
The effectiveness of	16 studies	Systematic			Results show	
screening for		review and			pharmacies are	
diabetes and	108,414	meta data			feasible sites for	
cardiovascular	participants	analysis			screening for	
disease risk factors in		-			diabetes and those	
a community					at risk of	
pharmacy setting					cardiovascular	
, , ,					disease. A significant	
					number of previously	
					unknown cases of	
					cardiovascular	
					disease risk factors	
					such as	
					hypertension	
					hypercholesterolemia	
					and diabetes are	
					identified however a	
					significant number of	
					significant number of	
					et high rick do not	
					at high hisk do hot	
					attend their	
					practitioner for follow	
					up.	
Screening for major	51 studies	Systematic	Screening		The proportion of	
diseases in		review	predominantly		screened individuals,	
community			opportunistic		identified with	
pharmacies: a			and screening		disease risk factors	
systematic review			tools included		or the disease,	
			questionnaires		ranged from 4% to	
			or risk		89%. Where	
			assessment		assessed, patient	
			forms, medical		satisfaction with	
			equipment for		pharmacy-based	
			physiological		screening was high.	
			measurements.		but individuals who	
			ora		screened positive	
			combination of		often did not follow	
			both		pharmacist advice to	
			boun.		seek further medical	
					help	
					help.	

2B.1.3 Results

Initially, participant recruitment progressed at a slower rate than predicted across the 2019 Christmas period with 185 participants recruited at the end of January 2020. The COVID-19 pandemic environment restrictions from beginning of March 2020 significantly impacted the ability of participating pharmacies to recruit to the trial.

In March 2020, at the request of the Department of Health, a new statistical plan was prepared to determine the minimum number of recruited participants required to achieve statistically sound results, in response to the low recruitment rate. Using the new statistical plan, the Department of Health approved a new recruitment minimum of 200 participants: with each pharmacy recruiting between 3 and 36 participants. The Department confirmed the new recruitment minimum allowed 80% statistical power for trial outcomes.

Safety

The Trial was a clustered randomised controlled trial that compared the effectiveness of a Brief CVD Risk Assessment to a Comprehensive CVD Risk Assessment, delivered by community pharmacy and enabling people identified as being at risk to engage in early intervention activities to prevent disease onset and progression.

CVD Risk Assessments were based on validated questionnaire tools and point of care testing. Assessments calculated participant CVD risk level as low, medium or high; with community pharmacies facilitating appropriate referral where required.

20 community pharmacies were initially recruited and randomly assigned brief intervention or comprehensive intervention assessments. Community pharmacies were located across a range of suburbs rated 1 to 5 against the Index of Economic Resources (IER) with 1 being the most disadvantaged and 5 being the most advantaged. One Community Pharmacy from each intervention arm withdrew from the trial due to inability to recruit participants.

Community pharmacies involved in the trial were randomly allocated to either the Brief CVD Risk Assessment or the Comprehensive CVD Risk Assessment. Participants joining the trial underwent the risk assessment (Brief or Comprehensive) assigned to the pharmacy attended.

Community pharmacies undertook opportunistic screening with participants aged 45 to 74 years (35 to 74 years for Aboriginal and Torres Strait Islander people) and without known history of CVD who engaged with community pharmacy. Those reporting a known history of CVD or outside the target age range were deemed ineligible for program enrolment and screening.

Collected measures were used to calculate participant risk level (low, medium or high) using screening algorithms based on risk predicted equations. All participants were offered appropriate patient education including printed resources and/or lifestyle advice. Participants assessed as being at medium or high risk were referred to General Practice for further investigation and community-based lifestyle modification programs in the local area. Participants were contacted by community pharmacies for repeat assessment at 6 and 12 months after initial assessment.

The trial was a clustered randomised controlled trial; as such the risk of bias between the two arms of the trial was assessed using Cochrane risk-of-bias tool for cluster randomised trials (RoB 2 CRT) 2021. Per RoB 2 CRT 5 domains of risk of bias were assessed: bias arising from the randomisation process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of the outcome, bias in selection of the report results.

Based on RoB 2 CRT assessment the risk of bias judgement for each domain was Low. Overall risk-of-bias judgement is Low.

No adverse events were recorded in either the brief or comprehensive intensity arms of the CVD trial.

Effectiveness

How effective is opportunistic screening by Community Pharmacies in identifying people with, or at risk of, under-recognised conditions; specifically, cardiovascular disease.

The Brief CVD Risk Assessment combined demographic information (age, gender, ethnicity, country of birth), subjective health measures (physical activity level, smoking status, nutrition, health history, lifestyle questions) and waist measurement; collected by AUSDRISK assessment tool and questionnaire. The Brief CVD Risk Assessment included non-invasive Point of Care assessment of blood pressure; systolic and diastolic. Opportunistic assessment of risk of cerebrovascular disease was undertaken through non-invasive Point of Care screening of irregular heartbeat using the available technology for blood pressure measurement.

The Comprehensive CVD Risk Assessment combined demographic information (age, gender), subjective health measures (smoking status, lifestyle questions); collected by FRE assessment tool and questionnaire. The Comprehensive CVD Risk Assessment included non-invasive Point of Care assessment of blood pressure; systolic and diastolic. Opportunistic assessment of risk of cerebrovascular disease was undertaken through non-invasive Point of Care screening of irregular heartbeat using the available technology for blood pressure measurement. The Comprehensive CVD Risk Assessment included biometric information; serum lipid levels, HbA1C levels measured using medical point of care devices that involve finger-prick testing.

Whilst 6 month and 12 month follow up of participants was undertaken by community pharmacy a small response, in both arms, resulted.

In order to determine effectiveness of opportunistic screening by Community Pharmacy in identifying people with, or at risk of, cardiovascular disease the following outcome measures are included:

- Percentage of screened individuals identified with disease risk factor (by risk category). Refer Table 5
- Percentage of screened population referred on to primary care services. Refer Table 6.
- Screening participants adherence to pharmacy advice and uptake of primary care referral. Refer Table 7 and Table 8
- Screening satisfaction with pharmacy-based services. Refer Table 9

Percentage of screened individuals identified with disease risk factor (by risk category)

88% of participants in the Brief Intervention Arm were assessed as being at high or medium risk of CVD. 12% of participants in the Brief Intervention Arm were assessed as being at low risk of CVD.

8% of participants in the Comprehensive Intervention Arm were assessed as being at high or medium risk of CVD. 92% of participants in the Comprehensive Intervention arm were assessed as being at low risk of CVD.

Due to non-modifiable factors (such as gender and age) included in the AUSDRISK Tool used in the Brief CVD Risk Assessment a considerably greater proportion of participants were assessed as being at medium or high risk in the Brief CVD Risk Assessment arm than the Comprehensive CVD Risk Assessment arm.

Table 5: Percentage of screened individuals identified with disease risk factor (by risk category) at Baseline Assessment (time 0).

Brief Intervention Arm n= 112	Baseline Assessment
Participants identified as being at high risk	46%
Participants identified as being at medium risk	42%
Participants identified as being at low risk	12%
Comprehensive Intervention Arm n= 199	Baseline Assessment
Participants identified as being at high risk	3%
Participants identified as being at medium risk	5%
Participants identified as being at low risk	92%

Percentage of screened population referred on to primary care services.

In accordance with the protocol at the Baseline Assessment participants assessed at being at high risk were referred to General Practice recommending appointment within 7 days; participants assessed as being at medium risk were referred to General Practice recommending appointment within 4 weeks.

Table 6: Percentage of screened population referred on to primary care services at Baseline Assessment

Brief Intervention Arm n= 112	Baseline Assessment
Participants referred to primary care services	88%
Comprehensive Intervention Arm n= 199	
Participants referred to primary care services	8%

At 6 month and 12 month assessments participants self-reported their adherence to advice received at Baseline Assessment, referral to General Practice and attendance within the suggested timeframe.

 Table 7: Screening participants adherence to pharmacy advice and uptake of primary care referral at 6 and 12 month assessments (General Practice)

Self-reported health utilisation; Brief and Comprehensive Interventions	Referred to GP	Attended (of referred)	Attended within suggested timeframe (of attended)
6 Month Assessment <i>n</i> = 125	12%	46%	71%
12 Month Assessment n=124	7%	56%	100%

 Table 8: Screening participants adherence to pharmacy advice and uptake of primary care referral at 6 and 12 month assessments (community lifestyle modification programs)

Self-reported health utilisation; Brief and Comprehensive Interventions	Referred to lifestyle modification program	Attended (of referred)
6 Month Assessment <i>n</i> = 125	11.4%	21%
12 Month Assessment n=124	8%	62.5%

Table 8a: Screening participants who were referred to Lifestyle Modification Programs and commenced another Lifestyle Modification Program on completion of the first program

	6 month Assessment	12 month Assessment
	Commenced another	Commenced another
	Lifestyle Modification	Lifestyle Modification
	Program	Program
Brief Intervention	0%	25%

Table 9: Screening satisfaction of participants with pharmacy-based services.

Brief Intervention Arm n= <i>112</i>	Did you find it appropriate to have the risk assessment completed in a pharmacy setting?
Baseline Assessment	99%
6 Month Assessment	100%
12 Month Assessment	100%
Comprehensive Intervention Arm n= <i>199</i>	Did you find it appropriate to have the risk assessment completed in a pharmacy setting?
Baseline Assessment	99%
6 Month Assessment	99%
12 Month Assessment	100%

Participants were asked what factors influenced their satisfaction with community pharmacy undertaking the CVD risk assessment.

67% of participants noted the convenience, accessibility and ease of being able to undertake the CVD risk assessment in their community pharmacy. Other key factors emerging from participant feedback were:

- Privacy and confidentiality provided; noting community pharmacy undertook assessment in a dedicated, private space
- Familiarity with the community pharmacy and staff
- Positive and pleasant environment of the community pharmacy
- Health professionals working in clinical setting
- Quick and efficient assessment
- No cost health assessment

Specific comments received from participants include:

• A good community asset

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- Appropriate (location) to collect health data
- Convenient and (pharmacy staff) follow up regularly
- Convenient, all information of patient is on hand
- Convenient, less people and less waiting time (than General Practice)

- Convenient, trust them
- Doctor's appointment is only 15 minutes, not enough time to go through everything in the session
- Easier to get in than booking an appointment with a doctor
- Excellent service
- Feels less clinical than a medical practice, more comfortable and convenient
- It's a pharmacy, they are health care professionals
- Medically trained professionals who understand patient confidentiality
- Pharmacists have requisite professional accreditation, skills and knowledge
- Pharmacy is my primary health destination
- Professionals with depth of clinical knowledge and holistic approach to care
- Relaxing, I trust the pharmacist.
- I trust them

2B.5 Conclusion

2B.5.1 Evidence Interpretation

The evidence gathered during the Trial 'early detection and management of cardiovascular disease (CVD) risk factors in community pharmacy' follows:

Assessment completed

Community pharmacies noted significant barriers to participant engagement (sic):

- There are a number of trial projects occurring in community pharmacy for a similar participant cohort.
- Participants have chosen not to engage in the project due to collection of MBS/PBS data; not understanding privacy of trial data.
- Smaller pharmacies with fewer staff do not always have the time available to undertake assessments.
- The period prior to Christmas 2019 was not ideal for participant recruitment as the focus in the pharmacy was core business rather than trial activity.
- Since March (2020), the COVID-19 social restrictions severely limited recruitment potential with the public not allowed to leave the house for non-essential engagements and a 1.5m social distance between individuals.

Black Swan Health supported community pharmacies through identification and implementation of strategies intended to boost participant recruitment and focussed on mitigating identified barriers.

A total of 311 participants were recruited to the Trial; 63% of participants were recruited to the Comprehensive CVD Risk Assessment arm and 37% recruited to the Brief CVD Risk Assessment arm.

Recognising the impact of the COVID-19 environment and restrictions within Western Australia a significant decrease in participant assessment at 6 months was experienced. Overall, a total of 141 6 month risk assessments were completed; 76% in the Comprehensive CVD Risk Assessment arm and 24% in the Brief CVD Risk Assessment arm. Overall, a total of 133 12 month risk assessments were completed; equally between Comprehensive and Brief CVD Risk Assessment arms.

- Similar proportions of participants in the Comprehensive Intervention and Brief Intervention arms completed Baseline only assessments; 38% in Comprehensive and 36% in Brief.
- Additionally, similar proportions of participants in each arm completed all three assessments, Baseline, 6 month and 12 month; 25% in Comprehensive and 26% in Brief.
- 29% of participants in the Comprehensive Intervention arm completed Baseline and 6 month assessments and did not complete the 12 month assessment.

• 34% of participants in the Brief Intervention arm completed Baseline and 12 month assessments and did not complete the 6 month assessment.

Table TV. Assessments completed		
Assessments completed	Brief	Comprehensive
Baseline only (0 months)	36%	38%
Baseline and 6 months	4%	29%
Baseline and 12 months	34%	8%
Baseline, 6 months and 12 months	26%	25%

Table 10: Assessments completed

Participant CVD Risk Rating

As expected, (due to non-modifiable factors included in the AUSDRISK screening tool used in the Brief CVD Risk Assessment) a greater proportion of participants were assessed as being at medium or high risk in the Brief CVD Risk Assessment arm than the Comprehensive CVD Risk Assessment arm. This was consistent at each assessment point; Baseline, 6 month and 12 month.

Brief	Baseline (0 month) <i>n</i> = 112	6 month <i>n</i> = 34	12 month <i>n</i> = 67
Low	13%	15%	10%
Medium	40%	32%	49%
High	46%	53%	40%
Comprehensive	Baseline (0 month) <i>n</i> = 199	6 month <i>n</i> = 107	12 month <i>n</i> = 66
Low	91%	92%	89%
Medium	5%	7%	6%
High	3%	2%	5%

Table 11: Participant CVD Risk Rating

Risk rating changes

Change in risk identification occurred in 12 instances in the Brief CVD Risk Assessment arm and 10 instances in the Comprehensive CVD Risk Assessment arm.

Whilst the Brief CVD Risk Assessment is less time-consuming and less invasive than the Comprehensive CVD Risk Assessment the Project Control Group has recognised the expected higher percentage of participants identified as being at medium or high risk of CVD in the Brief CVD Risk Assessment arm due to the non-modifiable factors assessed by the AUSDRISK tool.

Table 12: Risk rating change

Change	Brief	Comprehensive
Risk Rating Changes		
Risk increase from Baseline to 6 months	2	2
Risk increase from Baseline to 12 months	5	4
Risk increase from Baseline to 6 and 12 months	1	0
Risk increase from Baseline to 6mths, then decrease at 12 months	1	0
Risk decrease from Baseline to 6 months	0	2
Risk decrease from Baseline to 12 months	3	2
Risk decrease from Baseline to 6 and 12 months	0	0

Acceptability of community pharmacy for risk assessment

Community pharmacy was reported by trial participants as a highly acceptable and appropriate location for CVD risk assessment.

Refer Table 9. Screening satisfaction of participants with pharmacy-based services.

Participants adherence to pharmacy advice and uptake of primary care referral

Participants self-reported that at 6 months 46% of participants who had been referred to General Practice adhered to the advice; of this 71% attended within the suggested timeframe. At 12 months 56% of participants who had been referred to General Practice adhered to the advice; of this 100% attended within the suggested timeframe.

Participants self-reported that at 6 months 11% of participants who had been referred to a community-based lifestyle modification program adhered to the advice; of this 21% attended one or more session. At 12 months 8% of participants who had been referred to a community-based lifestyle modification program; 63% attended one or more session.

Refer Table 7: Screening participants adherence to pharmacy advice and uptake of primary care referral at 6 and 12 month assessments (General Practice) and Table 8: Screening participants adherence to pharmacy advice and uptake of primary care referral at 6 and 12 month assessments (community lifestyle modification programs).

Whilst not a clinical claim of the trial, it is noted the comprehensive assessment identified significantly fewer individuals at high risk of CVD. This is an expected outcome due to the use of the AUSDRISK tool as the screening intervention for the brief assessment arm noting the high risk outcome is easily achieved by gender, age and ethnicity responses in the target population.

2B.5.2 Conclusion of the Clinical Claim

The use of CVD risk assessment by community pharmacy in a previously undiagnosed population results in noninferior effectiveness compared with a previously undiagnosed population engaged with General Practice.

The use of CVD risk assessment by community pharmacy in a previously undiagnosed population results in noninferior safety compared with a previously undiagnosed population engaged with General Practice.

Overall, the trial evaluations suggest supporting the Comprehensive Risk Assessment as the preferred option for CVD screening in pharmacies due to specificity of the assessment tool supported by point of care testing. A community pharmacy-based CVS risk screening program for undiagnosed CVD should adopt a two-step approach, with initial risk assessment using the Framingham Risk Equation screening tool and point-of-care testing followed by referral to General Practice if CVD risk is assessed as medium or high.

The trial protocol did not include follow-up with general practice of outcomes of those clients identified as 'at risk'. Participant adherence to pharmacy advice and uptake of primary care referral and lifestyle modification program was only available as self-report data. Participants did not self-report receiving any diagnostic testing.

The trial protocol did not compare pharmacy-based screening with usual care (by GP in primary clinical practice). However, as 46% of participants who had been referred to General Practice at 6 months and 56% of participants who had been referred to General Practice at 12 months followed community pharmacy advice this indicates it is feasible for community pharmacy to screen for CVD and onward refer to primary health care.

Section 3A Cost-effectiveness Analysis

We present a summary of the health economic analysis assessing the cost-effectiveness of the trial. We use quality of life information collected via the SF-36 data to generate the SF-6D utility scores that are used to generate QALYs. Summary statistics are reported with comparisons between the two groups presented. Costs are also summarised for the two groups and comprising of MBS, PBS and pharmacy time related costs.

3A.1 Overview and rationale of the economic evaluation

The assessment question addressed by the economic evaluation seeks to determine if early intervention in CVD risk factor identification by community pharmacy offers a cost-effective opportunity to reduce burden of disease.

3A.2 Methods

3A.2.1 Summary table

Component	Description
Perspective	Health care system perspective
Population	Adults aged 45 to 74 years (35 to 74 years for Aboriginal and Torres Strait
	Islander people) without known history of CVD who engage with community
	pharmacy.
Prior testing	Population is those without known history of CVD
Comparator	Usual care by GP in primary clinical practice
Type(s) of analysis	Cost-effectiveness analysis
Outcomes	Determination of effectiveness of opportunistic screening by
	Community Pharmacies in identifying people with, or at risk of, under-
	recognised conditions; specifically, cardiovascular disease.
Time horizon	Data collected across 12 months at pre-defined intervals
Computational method	Trial-based economic evaluation
Generation of the base	Trial based
case	
Health states	Current health state
Cycle length	Data collection at 0, 6 and 12 months
Discount rate	5%
Software	Excel

Table	13:	Summary	/ of	the	economic	evaluatio	n
Table	10.	ounnung		uic	ccononne	cvaluatio	

3A.2.2 Structure of the economic evaluation

SF-6D and QALYs

The SF-36 is a generic health status instrument, comprising eight scalesⁱⁱⁱ. We used the SF-36 data collected as part of the trial to generate SF-6D scores that were subsequently used to compute QALYs. For the SF-6D, items of the SF-36 are converted into a six-dimensional health state classification system: physical functioning, role limitation, social functioning, pain, mental health, and vitality, with between two and six levels. This results into 18,000 different health states. The health states are then assigned preference weights derived from valuations of a sample of 249 SF-6D health states using the discrete choice experiment (DCE) in a representative sample of the Australian population value sets. We used the second version of the SF-6D algorithm for this exercise^{iv}. QALYs are then calculated using the area under the curve method^v.

Cost Data

Cost data was based on the MBS and PBS data requested for the 2019-2021 period. As this data span multiple years, we adjusted the costs to reflect 2021 average health price inflation (Australian Bureau of Statistics, 2022). The costs in this report reflect cumulative averages.

Another component of the cost data related to the cost associated with the intervention itself. The community pharmacist spent an estimated 15-20 minutes to conduct each low intensity risk assessment with 25-30 minutes spent on comprehensive intensity risk assessments. In order to calculate the intervention-related costs in terms of the pharmacist's time, we used the community pharmacist's median hourly rate of pay in 2019-2020 which was estimated to be \$38.00 (Professional Pharmacists Australia, 2021). This community pharmacy median hourly rate was multiplied by the average time to complete one screening assessment in either arm of the trial (i.e., 15-20 minutes in the brief arm and 25-30 minutes in the comprehensive arm) and multiplied by the total number of assessments in either arm of the trial.

3A.2.3 Model population and setting

The setting of the economic evaluation is the Australian health care setting, with the modelled population being adults aged 45 to 74 years (35 to 74 years for Aboriginal and Torres Strait Islander people) without known history of CVD who engage with community pharmacy.

3A.3 Results

3A.3.1 Base-case analysis

Descriptive Characteristics

Table 14 provides a summary of the basic demographic characteristics, quality of life scores (SF-6D version 2), and risk classification at baseline.

Overall, 68.69% of study participants were female, 67.27% in the brief intervention arm and 69.52% in the comprehensive intervention arm. Most participants were Australian born (58.92%), 3.37% were Aboriginal and Torres Strait Islander people, 40.74% were aged 45-54 years, 39.73% were aged 55-64 years and 19.53% were aged 64 years and older. The average health utility score for the overall sample was 0.71 with an interquartile range of (0.65-0.80).

Pearson's chi-square test (or Fisher's exact test where appropriate) for categorical variables and independent samples t-test for continuous variables found no significant differences between the brief intervention arm and the comprehensive intervention arm on any demographic variables and quality of life tested at baseline. However, statistically significant differences were observed in terms of risk classification.

	Total	Brief arm	Comprehensive arm	p- value
Variables	N=297	N=110	N=187	
Health utility score (SF-6D ver. 2)	0.71 (0.65- 0.80)	0.72 (0.64- 0.80)	0.70 (0.65-0.79)	0.44
Female	204 (68.69%)	74 (67.27%)	130 (69.52%)	0.69
Aboriginal and Torres Strait Islander people	10 (3.37%)	5 (4.55%)	5 (2.67%)	0.39
Australian born	175 (58.92%)	62 (56.36%)	113 (60.43%)	0.49
Age group				
45-54 years	121 (40.74%)	50 (45.45%)	71 (37.97%)	0.20
55-64 years	118 (39.73%)	43 (39.09%)	75 (40.11%)	0.86
64 years or over	58 (19.53%)	17 (15.45%)	41 (21.93%)	0.17
Risk classification				
Low risk	185 (62.29%)	14 (12.73%)	171 (91.44%)	<0.001
Medium risk	55 (18.52%)	43 (39.09%)	12 (6.42%)	<0.001
High risk	57 (19.19%)	53 (48.18%)	4 (2.14%)	<0.001

Data are presented as median (IQR) for continuous measures, and n (%) for categorical measures. Notes: Data are presented as median (IQR) for continuous variables, and n (%) for categorical variables. Pearson's chi-squared test (p-value) or (Fisher's exact test (p-value) (where appropriate) is reported for categorical measures and independent samples t-test is reported for continuous variables).

Figure 3 shows a summary of the SF-6D scores for the brief and comprehensive intervention arms at baseline. The data indicates that at baseline, the distribution of quality of life as measured by the SF-6D score was almost the same.



Figure 3: Distribution of the SF-6D scores for the brief and comprehensive intervention arms at baseline.

Table 15 provides a summary of the quality-of-life scores (SF-6D version 2), risk categories, and referral data for participants in the brief intervention arm and who had complete nonmissing data. Quality of life scores as measured by the SF-6D in the brief intervention arm showed some improvements over time especially when comparing the 6-month and 12month data relative to the baseline. The median SF-6D score in the brief arm at baseline was 0.72 (the mean was 0.69) with an interquartile range (IQR) of (0.64-0.80), 0.76 at 6months and 0.75 at the 12-month time point. The Friedman test was used to compare differences in SF-6D health utility scores over time. The results indicate no statistically significant differences in health utility scores over time (p-value = 0.53).

	Total	Baseline	6 Month	12 Month	p- value
	N=209	N=110	N=34	N=65	
SF-6D preference-based measured of health (version 2)	0.73 (0.65- 0.80)	0.72 (0.64- 0.80)	0.76 (0.63- 0.80)	0.75 (0.67- 0.81)	0.53
riskcat==Low risk	24 (11.48%)	14 (12.73%)	4 (11.76%)	6 (9.23%)	0.78
riskcat==Medium risk	86 (41.15%)	43 (39.09%)	12 (35.29%)	31 (47.69%)	0.40
riskcat==High risk	99 (47.37%)	53 (48.18%)	18 (52.94%)	28 (43.08%)	0.63
Referred to a GP	11 (33.33%)		6 (37.50%)	5 (29.41%)	0.62
=1 if referred to GP and attended	6 (50.00%)		2 (33.33%)	4 (66.67%)	0.25
Referred to GP and attended within timeframe	5 (71.43%)		1 (50.00%)	4 (80.00%)	0.43

Table 15: Outcomes for participants in the brief intervention arm with non-missing data

Notes: Data are presented as median (IQR) for continuous variables, and n (%) for categorical variables.

Table 15 also shows a summary of the proportion of participants who were screened and classified as either low, medium, or high risk in the brief arm. The results indicate that 12.73% in the brief arm were categorised as low risk at baseline, 39.09% had medium risk and 48.18% had high risk of cardiovascular disease. At 6-months, 52.94% were high risk, 35.29% were medium risk while at 12-months 43.08% were classified as high risk.

However, there were significant differences in the proportion of individuals identified under each risk category over time. At the 6 months point, 37.5% of the participants had been referred to a GP, 33% had attended the GP consultation and 50% had done so within the recommended timeframe. There were no significant differences observed over time in the brief arm on the fraction of people referred to a GP, referred and attended and attendance within the required timeframe.

Table 16 (following) provides a summary of the quality-of-life scores, risk classifications, and referral information for participants in the comprehensive intervention arm and who had complete non-missing data.

The median SF-6D score at baseline in the comprehensive arm was 0.70 and slightly lower than that in the brief arm (0.72). There was an improvement in the SF-6D score at 6 months point relative to baseline 0.72 and slightly lower that that in the brief arm at the same time point (0.76). We did not observe any improvement in the SF-6D score between the 6-month and the 12-month time point data in the comprehensive arm. Also, the SF-6D scores did not show statistically significant differences over time as indicated by Friedman's p-value of 0.48. There were no significant differences in the fraction of people classified as either low, medium, or high risk over time. However, comparing the brief and comprehensive arms indicates significant differences in the fraction of individuals classified as either low, medium or high risk. For example, at the 6 months point, 52.94% were classified as high risk in the brief arm compared to 1.92%.

However, caution should be taken when interpreting or comparing these numbers since the numbers in the comprehensive arm are very low. Similarly, the numbers reported on referrals to GP were also very small and hence less likely to give robust conclusions.

Table 16: Outcomes for participants in the comprehensive intervention arm with non-missing data.

	Total	Baseline	6 Month	12 Month	p- value
	N=394	N=187	N=104	N=103	
SF-6D preference-based measured of health (version 2)	0.72 (0.65- 0.79)	0.70 (0.65- 0.79)	0.72 (0.65- 0.78)	0.72 (0.67- 0.80)	0.48
riskcat==Low risk	359 (91.58%)	171 (91.44%)	95 (91.35%)	93 (92.08%)	0.98
riskcat==Medium risk	26 (6.63%)	12 (6.42%)	7 (6.73%)	7 (6.93%)	0.99
riskcat==High risk	7 (1.79%)	4 (2.14%)	2 (1.92%)	1 (0.99%)	0.78
referred to a GP	13 (6.53%)		9 (9.09%)	4 (4.00%)	0.15
=1 if referred to GP and attended	7 (53.85%)		5 (55.56%)	2 (50.00%)	0.85
Referred to GP and attended within timeframe	6 (75.00%)		4 (80.00%)	2 (66.67%)	0.67

Notes: Data are presented as median (IQR) for continuous variables, and n (%) for categorical variables.

Intervention costs per patient

Table 17 provides a summary of the expenses in terms the pharmacist's time incurred to provide the intervention. Since the actual time commitment for each assessment was not recorded, we assumed as per the study protocol that a single assessment in the brief arm will require 15-20 minutes and 25-30 minutes for the comprehensive intervention arm. We have also assumed that the pharmacist spent 20 minutes on each assessment in the brief arm and 30 minutes in each comprehensive assessment arm.

Applying the median annual hourly wage as described earlier, we costed all assessments completed at baseline, 6-months and 12-months incorporating these assumptions. The total costs of assessments in the brief intervention arm were \$2,698 and \$7,923 in the comprehensive arm with an incremental difference of \$5,225. This difference is statistically significant (p-value < 0.001).

	Brief inte	rvention a	rm	Comprehensive intervention			
	Hourly rate (\$)	Time (15-20 min)	Assessmen ts (N)	Total (\$)	Time (25-30 mins)	Assessmen ts (N)	Total (\$)
Baseline 6-months	38 38	20 20	112 34	1,418. 67 430.67	30 30	199 108	3,781 2,052
12-months Total intervention cost	38	20	67	848.67 2,698	30	110	2,090 7,923

Table 17: Summary of the expenses incurred by the pharmacist in conducting the assessments

The costs relating to healthcare services used by study participants and as covered by the MBS and PBS were used. As the data spans the years 2019-2021, we used the average health price inflation index (ABS 2022) to adjust the costs for inflation and such that the data reflected 2021 prices.

For each study participant, we summed health service costs over the respective period. Thus, costs reflect average total costs for the period 2019-2021 for which the data was requested for. Observed means and standard deviation of healthcare costs are summarised in Table 18 and stratified by the intervention arms. The average MBS costs for the brief arm were \$2634.50 compared to \$2608.29 resulting in an incremental cost of \$26.21. The incremental cost difference suggests that average MBS costs were slightly higher for the brief intervention compared to the comprehensive intervention. However, this cost difference was not statistically significant. For PBS costs, the average for the brief arm was \$642.37 compared to \$172.26 for the comprehensive arm and with a cost difference of \$470.11. This cost difference was statistically significant.

	Total	Brief arm	Comprehensive arm	Incremental costs (brief- comprehensive)	p- value
	N=311	N=112	N=199	. ,	
Average MBS costs	2538.85 (2520.83)	2557.27 (2533.32)	2531.83 (2525.20)	25.44	0.95
Average MBS costs (inflation adjusted)	2615.52 (2596.95)	2634.50 (2609.82)	2608.29 (2601.46)	26.21	0.95
Average PBS costs	293.18 (912.04)	623.54 (1217.13)	167.21 (731.56)	456.33	0.002
Average PBS costs (inflation adjusted)	302.03 (939.58)	642.37 (1253.88)	172.26 (753.65)	470.11	0.002
Pharmacy time costs	10,621.00	2,698.00	7,923.00	5,225.00	<0.001
Total costs (unadjusted for inflation)	9312.71 (3657.92)	5878.81 (3003.19)	10622.04 (2977.46)	4,743.23	<0.001

Table 18: Healthcare costs (MBS/PBS) of study participants

Notes: Mean and standard deviations in parentheses. Costs were inflated to reflect the 2021 average health prices (ABS 2022).

Figure 4 shows a distribution of the total costs (i.e., MBS, PBS, plus program costs) for both intervention groups.

The results indicate a somewhat skewed distribution of the costs with a right skew observed in the comprehensive intervention arm suggesting the existence of a few outliers with higher costs. Figure 5 shows that approximately 25% of the people in the brief arm had total costs in the region of \$2500-\$4000.

Similarly, the graph also shows that an estimated 65% of the people had a combined PBS, MBS and Program cost in the region of \$9000-\$10000. Since each bar in the histogram does not represent a single number in terms of costs but rather a range, we are unable to provide a single cost for each bar.

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Figure 4: Distribution of costs (MBS and PBS) for the brief and intervention arm inflated to 2021 dollars.

Figure 5 shows a summary of the distribution of PBS and MBS costs combined for both arms of the trial. The distribution of costs is almost identical to the one exhibited in Figure 4 above with the only difference being that the absolute dollar values are higher in Figure 5 than they are in Figure 4 only because of the inclusion of program costs in Figure 5.



Figure 5: Distribution of total costs (MBS+PBS) for the brief and intervention arms.

Quality Adjusted Life Years (QALYs)

Table 19 provides a summary of the Quality adjusted life years data calculated using the SF-6D scores and following the standard methodology in the economic evaluation literature^{vi}.

Overall, the results show no significant differences between the two groups regarding QALYs gained at the 12-month time point. However, the point estimates of QALYs were marginally higher for the brief intervention arm compared to the comprehensive arm. For example, the QALYs gained after 12 months were 0.72 in the brief arm compared to 0.69 in the comprehensive arm (p-value = 0.39). However, we wish to point out that the data on quality of life was not always complete for all study participants and had several gaps (or was missing) for several participants.

	Total	Brief (1)	Comprehensive (2)	Incremental QALYs (1)- (2)	p- value
	N=311	N=112	N=199		
QALYs (at 6 month)	0.35 (0.06)	0.36 (0.07)	0.35 (0.06)	0.01	0.29
QALYs (12 months)	0.34 (0.08)	0.35 (0.08)	0.34 (0.09)	0.01	0.52
QALYs (overall)	0.70 (0.14)	0.72 (0.13)	0.69 (0.14)	0.03	0.39
QALYs (baseline and 12 months)	0.71 (0.14)	0.74 (0.13)	0.70 (0.15)	0.04	0.11

Table 19: Quality Adjusted Life Years (QALYs) for the brief and comprehensive intervention arms

A comparison of the QALYS for the two assessment arms at 12 months revealed that the comprehensive assessment arm did not yield improvements in the QALYS compared to the brief assessment arm, as shown by the negative difference in the QALYS. However, the difference was not statistically significant. In light of this finding, we concluded that implementation of the comprehensive assessments did not yield any inferior outcome compared to the brief arm. As such, we did not conduct a full economic evaluation.

Furthermore, the data for QALYS was not available for all the study participants with only 96 out of 311 participants having non-missing data on the QALYS.

Additionally, the statistically insignificant difference in QALYs suggests that the intervention is not in any way superior in terms of QALY gains. Despite this statistically insignificant difference, the incremental QALYs as shown in Table 19 are negative suggesting that the comprehensive assessment arm is somewhat dominated by the brief assessment arm. Table 18 also reveals that the comprehensive assessment arm is slightly costly. Thus, we have a scenario where the intervention is costly but non-inferior in terms of QALY gains. As a result of this descriptive observation, we did not conduct a full cost utility analysis in this instance. In this instance, calculating the metric showing the cost per QALY (i.e., the incremental cost effectiveness ratio) is somewhat not useful (see for example, Wordsworth et al., 2016⁶). The ICER is only applicable in the instance when the comprehensive assessment arm (which is not the case here).

⁶ Wordsworth S, Buchanan J, Towse A, 2016. Chapter 5 - Health Economic Perspectives of Genomics, In: Kumar D, Chadwick R (Eds), Genomics and Society. Academic Press, Oxford; 2016. pp. 83-117.

Sensitivity Analysis

The analysis conducted in this report was primarily descriptive. The descriptive assessment revealed no statistically significant differences in QALYs between the comprehensive and brief assessment arms (see Table 19). Thus, given the noted differences in QALYs between the two groups, we did not conduct a full cost utility analysis.

For quantifying the pharmacist's time in conducting the assessments in the low and comprehensive intensity arms, we have assumed following:

- Low-intensity arm: 20 minutes
- Comprehensive arm: 30 minutes

We have also assumed a \$38 median wage per hour for the community pharmacist.

For sensitivity analysis, we considered a one-way sensitivity analysis in which we changed one parameter at a time e.g., time spent by the pharmacist on completing the assessment for each person in each arm. Table 20 provides the results when we assume the minimum time of 15 and 20 minutes spent on low intensity and comprehensive assessments. Doing so gives a minimum total cost of completing 213 low-intensity assessments of \$2,024 and \$5,282 for completing 417 comprehensive assessments. There is a cost difference of \$3,259 and this is a statistically significant difference. Changing the wage rate per hour for the community pharmacist's time will have the effect of increasing the costs in both arms but will not change any conclusions.

				Compreh	ensive interve	ention	
	Brief inter	vention ar	m		arm		
	Hourly rate (\$)	Time (15-20 min)	Assessmen ts (N)	Total (\$)	Time (25-30 mins)	Assessmen ts (N)	Total (\$)
Baseline	38	15	112	1,064	20	199	2,521
6-months	38	15	34	323	20	108	1,368
12-months Total intervention	38	15	67	636.5 0	20	110	1,393
cost				2,024			5,282

Table 20: One-way sensitivity analysis: Summary of the expenses incurred by the pharmacist in conducting the assessments.

As we did not conduct a full cost-utility analysis for this project given the reasons outlined earlier, we are unable to conduct any typical and comprehensive sensitivity analysis as the types usually conducted in cost-utility analysis studies e.g., probabilistic sensitivity analysis. Also, we have reported the QALYs data alongside their standard errors (in Table 19) and alongside their 95% confidence intervals (95% CI) in Table 21.

Table 21: Quality Adjusted Life Years (QALYs) [95% CI) for the brief and comprehensive intervention arms

	Total	Brief (1)	Comprehensive (2)	Incremental QALYs (1)- (2)
	N=311	N=112	N=199	
QALYs (at 6 month)	0.35 [0.34-0.37]	0.36 [0.34-0.39]	0.35 [0.33-0.37]	-0.01
QALYs (12 months)	0.34 [0.33-0.36]	0.35 [0.32-0.38]	0.34 [0.32-0.36]	-0.01
QALYs (overall)	0.70 [0.67-0.73]	0.72 [0.67-0.77]	0.69 [0.66-0.72]	-0.03
QALYs (baseline and 12 months)	0.71 [0.67-0.73]	0.74 [0.67-0.78]	0.70 [0.65-0.73]	-0.04

Table 21 gives the average QALYs for the two arms of the study alongside their 95% confidence intervals. 95% confidence intervals around point estimates are typically used as measures of uncertainty in economic evaluations (Briggs 1999⁷).

Future costs if implemented

If the program is implemented in other areas, sources of costs will include the cost of conducting assessments (either as comprehensive or brief). As these costs are calculated using information on the annual salaries or wages of pharmacists involved in conducting the assessments, applicable hourly wages for these health professionals will be used to calculate the cost of assessments. At the time of conducting this economic evaluation, we did not have exact data on the actual time that pharmacists spent on conducting the assessments. This data was not captured and made available for use in the economic evaluation.

3A.4 Conclusions

The health economic analysis did not reveal statistically significant differences in quality of life between the two groups. However, the data show slight improvements in quality of life in both arms of the trial relative to the baseline point, despite showing no statistical significance.

We did note significant differences in the PBS costs with the brief arm having higher costs compared to the comprehensive arm. There were no significant differences in the MBS costs. However, the total costs (MBS + PBS + pharmacy time costs) were statistically and significantly different (p < 0.001) with the comprehensive arm having much higher intervention costs mostly due to the relatively larger time commitment to complete assessments for this group.

The trial evidenced a low rate of re-presentation for 6 and 12 month follow up screening by participants in both the Brief and Comprehensive Risk Assessment arms; 26% and 25% respectively.

Risk rating between 0, 6 and 12 months for participants in the Comprehensive arm did not show considerable change across the life of the trial. Risk rating between 0, 6 and 12 months for participants in the Brief arm showed some change at 6 months, however the small number of participants, 30% of the baseline cohort, attending at 6 months may influence this change.

The trial recognises community pharmacy offers access to the target population, who are not engaging with General Practice, to receive Cardiovascular Disease Risk Screening. The trial further recognises where a participant is identified as being at risk of CVD, moderate or high, and referred to General Practice, further diagnostic testing and/or treatment is likely to be undertaken. The trial did not seek participant data from General Practice to inform ongoing intervention costs. MBS and PBS data informs ongoing intervention and treatment costs.

⁷ Briggs, A. (1999). Handling uncertainty in economic evaluation. BMJ, 319(7202), 120.

Section 4 Use of the health technology in practice

4.1 Justification of the selection of approach and data sources

The economic evaluation considered the time needed to provide high and low intensity screens, and through a combination of self-report and linked Medicare and PBS data, estimated the incremental downstream costs associated with the interventions relative to one another.

Data	Source and value	Justification
Pharmacy median	Professional	The Pharmacists employment remuneration report
hourly wage (\$AUD)	Pharmacists	contains up to date wage information for
	Australia – report	community pharmacists in Australia and is a
	(Professional	respectable source for getting such information.
	Pharmacists	
	Australia, 2021) -	
	\$38.00 / hour	
SF-6D version 2	B. Mulhern, Norman,	The SF-6Dv2 is the updated version of the SF-6D
health utility scores	& Brazier, 2021; B. J.	with improved consistency and dimension
	Mulhern, Bansback,	descriptors and representative of the Australian
	Norman, & Brazier,	population value sets.
	2020	
MBS & PBS	MBS / PBS	Used to quantify health resource usage costs.
Health care	Within-trial data	Used to determine referrals and adherence to
utilisation – self	collection	pharmacist's advice.
report		Required to map the SF36 to SF-6Dv2 and used to
SF36	Within-trial collection	calculate health utility scores and Quality Adjusted
		Life Years (QALYs)
Assessments	Within-trial collection	
		Used to quantify CVD risk into low, medium and
		high

Table 22: Data sources and parameter values applied in the utilisation and financial estimates

4.2 Estimation of use and financial impact of the proposed health technology

As a major cause of death and disability in Australia, CVD places a huge burden on the economy as well as the healthcare system, costing \$11.8 billion a year and being responsible for 11 per cent of all hospitalisations.⁸

An estimated 1.2 million Australians aged 18 and over (6.2% of the adult population) had 1 or more conditions related to heart, stroke or vascular disease, based on self-reported data from the ABS 2017-18 National Health Survey⁹. In 2019 CVD was the underlying cause of 42,300 death (25% of all deaths).⁷

In Australia, the cost of heart health checks are covered by Medicare, however this requires people to present at General Practice for an assessment. CVD Risk Assessment in community pharmacy enables easy access for opportunistic testing and assessment, onward referral to General Practice for further testing and health and lifestyle advice.

The proportion of people attending General Practice per age group¹⁰, relevant to the target age cohort for the trial in 2018 was:

- 45 54years: 85.7% attended General Practice; i.e. 14.3% did not attend
- 55 64years: 88.8% attended General Practice; i.e. 11.2% did not attend
- 64 75years: 94.7% attended General Practice; i.e. 5.3% did not attend

In 2021¹¹:

- 1,589,685 Australians were aged 45 54 years
- 1,465,393 Australians were aged 55 64 years
- 1,187,180 Australians were age 65 74 years

The CVD Risk Assessment in a population that does not engage with General Practice within a 12 month period may be applied to:

- 227,325 Australians aged 45 54 years
- 164.124 Australians aged 55 64 years
- 62,920 Australians aged 65 74 years

Whilst this does not speak the risk of CVD within the population it may indicate an estimated use of the CVD Risk Assessment in people not engaging with General Practice.

As noted in 3A.3 if the program is to be implemented, financial determinations will include the cost of conducting assessments (either as comprehensive or brief). At the time of conducting this economic evaluation, we did not have exact data on the actual time that pharmacists spent on conducting the assessments, or associated salary and wages information. It is difficult to provide an estimate on how much the future costs might look if the program is implemented.

⁸ Australian Bureau of Statistics 2020, Causes of death 2019, cat. No. 3303.0,

⁹ <u>Heart, stroke and vascular disease</u>—Australian facts, Total heart, stroke and vascular disease - Australian Institute of <u>Health and Welfare (aihw.gov.au)</u>

¹⁰ <u>Australia: proportion of visits to a general practitioner by age | Statista</u>

¹¹ <u>Five year age groups | Australia | Community profile (id.com.au)</u>

4.3 Estimation of changes in use and financial impact of other health technologies

As the trial compared the costs of the Brief CVD Risk Assessment and Comprehensive CVD Risk Assessment, an estimation of change in use and financial impact of other health technologies was not considered.

The Comprehensive CVD Risk Assessment was higher specificity and resulted in less participants being referred to General Practice than the Brief CVD Risk Assessment. As the Protocol required referral to General Practice for medium and high risk participants there is a resultant financial impact as General Practice is expected to undertake further investigative activity.

4.4 Net financial impact

We did note significant differences in the PBS costs with the Brief CVD Risk Assessment arm having higher costs compared to the Comprehensive CVD Risk Assessment arm. There were no significant differences in the MBS costs.

However, the total costs (MBS + PBS + pharmacy time costs) were statistically and significantly different (p < 0.001) with the comprehensive arm having much higher intervention costs mostly due to the relatively larger time commitment to complete assessments for this group.

As the Protocol required referral to General Practice for medium and high risk participants there is a resultant financial impact as General Practice is expected to undertake further investigative activity. This investigative activity was not measured as part of the trial.

4.5 Net financial impact to other health budgets

In terms of financial cost impacts for the health system, the Comprehensive Risk assessment indicates a potential for cost savings. This is applied where people are assessed and referred for diagnosis before their CVD has significant impact on their health resulting in a progressed illness or a requirement for crisis intervention through the tertiary health system.

Appendix A Systematic review methods

Method of assessment and research questions



Figure 6: Assessment framework for evaluation of risk identification of CVD in community pharmacy

Development of a research protocol

Prior to the start of the systematic review, a research protocol was developed, based on the PICO confirmation ratified by the PICO Advisory Sub-Committee of MSAC. The research protocol was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) with the registration number ACTRN12619000405112P.

PICO criteria

Table 23: PICO criteria for assessing early detection and management of cardiovascular disease risk factors in community pharmacy

Component	Description
Population	Adults aged 45 to 74 years (35 to 74 years for Aboriginal and Torres Strait Islander people)
	without known history of CVD who engage with community pharmacy.
Prior tests	Those reporting a known history of CVD or outside the target age range will be deemed
	ineligible for program enrolment and screening.
Intervention	Integrated health check delivered by pharmacists within community pharmacy to:
	assess the risk of CVD
	 screen for clinical markers using point of care testing device for indicative
	presence of CVD
	deliver key health promotion messages
	 provide referral to local risk reduction and care management services and
	providers (i.e., GP, lifestyle management programs)
Comparator	In the absence of Community Pharmacy screening program, comparator is usual care by
	GP in primary clinical practice.
	Screening activities in General Practice are supported by MBS health assessment items,
0.1	administered on the clinical judgement of the practitioner.
Outcomes	How effective is opportunistic screening by Community Pharmacies in identifying people
	with, or at risk of, under-recognised conditions; specifically, cardiovascular disease.
	Suggested measures include:
	Proportion of screened individuals, identified with disease risk factors (by risk
	Score)
	Percentage of screened population referred on to primary care services
	Participants adherence to pharmacy advice and uptake of primary care referral
	Screening participants satisfaction with pharmacy based service
	Service providers' satisfaction with pharmacy based service
	Participant awareness of CVD and its risk factors
	Pharmacist influence of participant health seeking behaviour
	 Participant reported outcomes – health related quality of care
	Cost Effectiveness
	<u>Cost of program will be compared to usual costs that would have been applicable in</u>
	cost of program. This includes prevented CP consultations and pathology
	investigations and their resultant reduction in MBS/PBS billing
	Rationale
	Delayed detection of CVD risk and clinical markers results in later symptomatic or acute
	presentation at General Practice or hospital requiring more advanced and costly diagnosis
	treatment and management interventions.

Literature sources and search strategies

A non-exhaustive desktop literature review was conducted January 2022 to identify relevant studies and systematic reviews published during the period 2007 to 2020. Searches were conducted of the databases and sources described in Table 24.

The search located several relevant studies reporting on the effectiveness of opportunistic disease screening and preventative intervention strategies within community pharmacy. In addition, there is one systematic review assessing the feasibility and acceptability of community-based pharmacy screening for major diseases and one systematic review assessing effectiveness of screening for diabetes and cardiovascular disease risk factors in community pharmacy.

The following search terms were used in the desktop literature review; community pharmacy; CVD, cardiovascular disease; screening; intervention.

Table 24: Literature sources and search strategies

	5501063	Study					Posult used in economic model
Trial/Study	N	design Risk of bias	Population	Intervention	Comparator	Key outcome(s)	rkesuit usea in economic model
Diabetes and cardiovascular disease risk screening model in community pharmacies in a developing primary healthcare system: a feasibility study	12 community pharmacies 115 participants	Feasibility	Adults 40 years of age and above who have not been previously diagnosed with either diabetes or CVD.	Pharmacist screening including history, demographics, anthropometric measurements, blood pressure and point-of- care testing including HbA1c and lipids.	Usual care	Community pharmacist-delivered screening of diabetes and CVD risk is feasible in the UAE. The model offers a platform to increase screening capacity within primary care and provides an opportunity for early detection and treatment.	
Pharmacy diabetes care program: analysis of two screening methods for undiagnosed type 2 diabetes in Australian community pharmacy	30 pharmacies 1286 participants	Randomised	Undiagnosed type 2 diabetes in Australian community pharmacy	Comparison of Tick Test Only (TTO) and Sequential Screening for T2DM. Both methods used the same initial risk assessment for type 2 diabetes. Additionally, the SS method, patients with risk factors were offered a capillary blood glucose test.	Usual care	The rate of diagnosis of diabetes was significantly higher for Sequential Screening compared with the Tick Test Only (TTO) method The SS method resulted in fewer referrals to the GP and a higher uptake of referrals than the TTO method and so was the more cost-effective screening method.	
The effectiveness of Pharmacist Interventions on Cardiovascular Risk: The Multicentre Randomised Controlled RxEACH trial	56 community pharmacies 723 participants	Randomised controlled	Adults at high risk for CVD	Comparison of usual care or intervention, comprising a Medication Therapy Management review from their pharmacist and CVD risk assessment and education. Monthly follow-up visits for 3 months. CVD risk estimated using the greater of the Framingham, International, or United Kingdom Prospective Diabetes Study risk scores	Usual care	21% difference in change in risk for CVD events (p < 0.001) between the intervention and usual care groups.	
The effectiveness of screening for diabetes and cardiovascular disease risk factors in a community pharmacy setting	16 studies 108,414 participants	Systematic review and meta data analysis				Results show pharmacies are feasible sites for screening for diabetes and those at risk of cardiovascular disease. A significant number of previously unknown cases of cardiovascular disease risk factors such as hypertension, hypercholesterolemia and diabetes are identified, however a significant number of referred participants at high risk do not attend their practitioner for follow up.	

[
Screening for major	51 studies	Systematic	Screening	The proportion of
diseases in community		review	predominantly	screened individuals,
pharmacies: a systematic			opportunistic and	identified with disease
review			screening tools	risk factors or the
			included	disease, ranged from
			questionnaires or risk	4% to 89%. Where
			assessment forms,	assessed, patient
			medical equipment for	r satisfaction with
			physiological	pharmacy-based
			measurements, or a	screening was high,
			combination of both.	but individuals who
				screened positive
				often did not follow
				pharmacist advice to
				seek further medical
				help.

References

ⁱ Banks E et al, Absolute risk of cardiovascular disease events, and blood pressure- and lipid-lowering therapy in Australia. MJA 204 (8):320e1-320e8

ⁱⁱ Australian Institute of Health and Welfare (2015). Cardiovascular disease Retrieved from <u>http://www.aihw.gov.au</u>

ⁱⁱⁱ Brazier, Roberts, & Deverill, 2002

^{iv} B. Mulhern, Norman, & Brazier, 2021; B. J. Mulhern, Bansback, Norman, & Brazier, 2020

^v Glick, Doshi, Sonnad, & Polsky, 2014; Richardson & Manca, 2004

vi Drummond, Sculpher, Claxton, Stoddart, & Torrance, 2015; B. J. Mulhern et al., 2020