PROCESS EVALUATION OF A DATA-DRIVEN QUALITY IMPROVEMENT PROGRAM AT AUSTRALIAN PRIMARY CARE PRACTICES FOR IMPROVED MANAGEMENT OF CORONARY HEART DISEASE - A MIXED-METHODS STUDY

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STATEMENT OF ORIGINALITY

This is to certify that to the best of my knowledge; the content of this Thesis is my own work. This Thesis has not been submitted for any degree or other purposes.

I certify that the intellectual content of this Thesis is the product of my own work and that all the assistance received in preparing this Thesis and sources have been acknowledged.

Nashid Hafiz 30th April 2024

AUTHORSHIP ATTRIBUTION STATEMENT

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This is to confirm authorship attribution of all the statements above to be included in the Thesis

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As supervisor for the candidature upon which this Thesis is based, I can confirm that the authorship attribution statement above is correct.

Professor Julie Redfern 30th April 2024

THESIS ABSTRACT

Background Quality improvement (QI) strategies are increasingly being used in primary care practices in an effort to reduce the burden of coronary heart disease (CHD). These strategies involve a systematic and multi-dimensional approach, aiming to provide high-quality, efficient, and patient-centred care through review and refinement of data. This Thesis aims to comprehensively evaluate a 12-month QI intervention in a cluster randomised controlled trial, focusing on assessing primary care practices' engagement, delivery, healthcare providers' satisfaction and acceptability, and identifying barriers and enablers associated with implementing the QI intervention in the management of coronary heart disease.

Methods This Thesis presents a systematic review and mixed-methods process evaluation of the multi-featured data-driven QI intervention delivered to 27 Australian primary care practices within the QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with coronary heart disease (QUEL) study. The Thesis includes a sub-analysis of the QUEL study (Chapter Two), a systematic review and meta-analysis (Chapter Three) and a protocol of the mixed-methods process evaluation (Chapter Four). Results of the process evaluation on primary care practices' engagement with the intervention, intervention delivery and key useful features are presented in Chapter Five. Healthcare providers' satisfaction and acceptability of the intervention, explored the different factors affecting the intervention implementation presented in Chapter Six.

Results An evidence-practice gap was identified in the receipt of subsidised health services and guideline-recommended medications for the management of cardiovascular disease, where women were more likely to receive chronic disease management plans than men 46% vs 43%; adjusted odds ratio (OR): 1.22 [95% confidence interval (CI): 1.12, 1.34]. Additionally, women were also less likely to receive guideline-indicated antiplatelet medications compared to men (44% vs 51%; OR: 0.84 [95% CI: 0.76, 0.94]). However, there was no difference in the proportion of prescribed blood pressure and lipid-lowering medications (Chapter 2). The systematic review and meta-analysis showed mixed effectiveness of the QI interventions. Meta-analysis demonstrated that, compared with usual care, QI interventions significantly reduced the rate of major cardiovascular events (MACE) (OR: 0.84, 95% CI: 0.72, 0.98) and total mortality (OR: 0.88, 95% CI: 0.78, 0.99). There was no significant improvement in the prescription of guideline-recommended medications, including antiplatelets (OR: 1.24, 95% CI: 0.92, 1.67) and lipid-lowering (OR: 1.27, 95% CI: 0.95, 1.70), angiotensin-converting enzyme inhibitors or angiotensin receptor blockers (OR: 1.17, 95% CI: 0.91, 1.51), beta-blockers (OR: 1.27, 95% CI:0.94, 1.73), and smoking cessation advice (OR: 1.30, 95% CI: 0.75, 2.27) as a result of QI interventions (Chapter Three). Findings from the mixed-methods process evaluation of the QUEL study revealed varied engagement of practices with the QI intervention, with 42% of practices attending five or more of the six learning workshops. 69% of practices used Plan-Do-Study-Act cycles. Qualitative data identified learning workshops and monthly feedback reports as the key features of the intervention (Chapter Five). Finally, the QI intervention received positive satisfaction with 71% and 100% ratings of the learning workshops. Qualitative analysis found the overall intervention useful. COVID-19 and lack of time were identified as common barriers, while practice team collaboration and effective leadership emerged as major

enablers to their participation in the QI program. Additionally, 90% of the practices reported that their participation was affected by COVID-19 (Chapter Six).

Conclusion This Thesis provides valuable insights for primary care practices seeking future adoption of similar data-driven QI initiatives in improving care of CHD and other chronic diseases. Further research is needed to fully evaluate the effect of individual QI strategies in improving clinical outcomes in the management of CHD.

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DEDICATION

This Thesis is dedicated to my beloved parents, Professor A K M Hafiz and Mrs Naim Fatema. Abbu, your presence in my life has been a constant source of support and inspiration. Your unwavering dedication to serve patients and your community and your commitment to work throughout the years have never ceased to impress me. Your ability to balance your responsibilities towards both your patients and our family is nothing short of remarkable. You have consistently guided not only our immediate family but also our extended family towards success, and your support has helped countless others shape their futures. You are my ultimate role model, and because of you, I chose to pursue a career in medicine and health. Ammu, thank you for being the rock in our family. Your upbringing, guidance, and support in every aspect of my life have made me what I am today. I dedicate this Thesis to you both, and I hope that, in the future, my research can help prevent more families from losing their loved ones to this preventable but fatal disease called coronary heart disease.

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LIST OF ABBREVIATED TERMS AND ACRONYMS

ACEi	Angiotensin-Converting Enzyme Inhibitors
ACS	Acute Coronary Syndrome
AIS	Acute Ischemic Stroke
AMI	Acute Myocardial Infarction
ANZCTR	Australian New Zealand Clinical Trials Registry
ARB	Angiotensin Receptor Blocker
ASA	Acetylsalicylic Acid
ASCVD	Atherosclerotic vascular disease
BMI	Body Mass Index
BP	Blood Pressure
CABG	Coronary Artery Bypass Graft
CAD	Coronary Arterial Disease
CCB	Calcium Channel Blockers
CDMP	Chronic Disease Management Plans
CENTRAL	Cochrane Central Register of Controlled Trials
CHD	Coronary Heart Disease
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CMA	Comprehensive Meta-Analysis

COPD	Chronic Obstructive Pulmonary Disease
CQI	Continuous Quality Improvement
cRCT	Cluster-Randomised Controlled Trial
CV	Cardiovascular
CVD	Cardiovascular Disease
CVRM	Cardiovascular Risk Management,
DALY	Disability Adjusted Life Years
DBP	Diastolic Blood Pressure
DM	Diabetes Mellitus
HER	Electronic Health Record
EMBASE	Excerpta Medical database
EPOC	Effective Practice and Organisation of Care Review Group
ERP	Expert Reference Panel
GEE	Generalised Estimating Equations
GP	General Practitioner
GPMP	General Practice Management Plan
HbA1c	Glycated Haemoglobin A1c
HDL-C	High Density Lipoprotein Cholesterol
HF	Heart Failure
HIT	Health Information Technology

HR	Hazards Ratio
HREC	Health Services Research Ethics Committee
IHD	Ischemic Heart Disease
IQI	Interquartile Interval
IQR	Interquartile Range
IT	Information Technology
LDL-C	Low-Density Lipoprotein Cholesterol
LW	Learning Workshop
MACE	Major Adverse Cardiovascular Event
MBS	Medical Benefits Scheme
MEDLINE	Medical Literature Analysis and Retrieval System Online
MI	Myocardial Infarction
NA	Not Available
NCD	National Cardiac Database
NHFA	National Heart Foundation of Australia
NHMRC	National Health and Medical Research Council
NHS	National Health Service
NR	Not Reported
NSWPHSREC	New South Wales Population and Health Services Research Ethics Committee
OR	Odds Ratio

PAD	Peripheral Arterial Disease
PBS	Pharmaceutical Benefits Scheme
PCC	Primary Care Centre
PCI	Percutaneous Coronary Intervention
PDSA	Plan-Do-Study-Act
PEN CS	Pen Computer Systems
PF	Practice Facilitation
PHN	Primary Health Network
PICOS	Patient, Intervention, Comparison, Outcome and Settings
PIP-QI	Practice Incentive Program - Quality Improvement
PM	Practice Manager
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PROSPERO	International Prospective Register of Systematic Reviews
QI	Quality Improvement,
QUEL	QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with coronary heart disease
RCT	Randomised Controlled Trial
RDS	Research Data Store
ROB	Risk of Bias
RR	Relative Risk / Rate Ratio

SAS	Statistical Analysis System
SBP	Systolic blood pressure
SD	Standard Deviation
SMS	Short Message Service
SOS	Statin Outreach Support
STEMI	ST-elevation Myocardial Infarction
TC	Total Cholesterol
TCA	Team Care Arrangements
TIA	Transient Ischemic Attack
TQM	Total Quality Management
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

OUTPUTS FROM THIS THESIS

Manuscripts published in peer-reviewed journals

1. **Hafiz N,** Hyun K, Knight A, Hespe C, Chow CK, Briffa T et al. Gender comparison of receipt of government-funded health services and medication prescriptions for the management of patients with cardiovascular disease in primary care. Heart, Lung and Circ. 2021;30(10):1516-1524.
2. **Hafiz N,** Hyun K, Tu Q, Knight A, Hespe C, Chow CK et al. Data-driven quality improvement program to prevent hospitalisation and improve care of people living with coronary heart disease: Protocol for a process evaluation. Contemp Clin Trials. 2022;118:106794.

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1. **Hafiz N,** Hyun K, Tu Q, Manandi D, Usherwood T, and Redfern, J. Effectiveness of quality improvement interventions in improving cardiovascular disease related outcomes: A systematic review and meta-analysis. BMC Primary Care. 2024.

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1 **Hafiz N,** Hyun K, Tu Q, Knight A, Hespe C, Chow CK et al. Implementation of a data-driven quality improvement program in primary care for patients with coronary

heart disease: a mixed methods evaluation of acceptability, satisfaction, barriers, and enablers. Australian Journal of Primary Health. 2023.

Conference presentations - Oral

1. **Hafiz N**, Hyun K, Tu Q, Knight A, Hespe C, Chow CK, et al. Implementation of a data-driven quality improvement program in primary care for patients with coronary heart disease: a mixed-methods evaluation of acceptability, satisfaction, barriers, and enablers. Rapid fire presentation, *Australian Society of Medical Research National Scientific Conference. November, 2023.*
2. **Hafiz N**, Hyun K, Tu Q, Knight A, Hespe C, Chow CK, et al. Results from the process evaluation of a multifaceted quality improvement intervention in primary care. *NSW Cardiovascular Research Network Rising Stars Seminar Series: Digital Health and Novel Treatments, July 2023.*
3. **Hafiz N**, Hyun K, Tu Q, Knight A, Hespe C, Dhillon M, et al. Do Quality Improvement Workshops Improve Health Professionals Knowledge on Implementing Change for Patients With Coronary Heart Disease in Primary Care? *Charles Perkins Centre Early to mid-career researcher Symposium, September 2021.*

Conference Presentation - Poster

1. **Hafiz N**, Hyun K, Tu Q, Knight A, Hespe C, Chow CK, et al. Implementation of a data-driven quality improvement program in primary care for patients with coronary heart disease: a mixed-methods evaluation of acceptability, satisfaction, barriers, and enablers. *Australian Society of Medical Research National Scientific Conference. November, 2023.*

2. **Hafiz N,** Hyun K, Tu Q, Knight A, Hespe C, Chow CK et al. Process evaluation results of QUality improvement for Effectiveness of care for people Living with heart disease (QUEL), a cluster randomised controlled data-driven quality improvement trial to improve cardiovascular disease care in Australian primary care practices. Heart, Lung and Circ. 2023;32:S340-S1. *Cardiac Society of Australia and New Zealand Annual Scientific Meeting, August, 2023.*
3. **Hafiz N**, Hyun K, Hespe C, Usherwood T, Redfern J. Scope of Quality Improvement-Practice Incentive Program (QI-PIP): How Primary Care Practices Can Utilise QI-PIPs by Participating in a Quality Improvement Program (QUEL Study) Focussed on Improving Cardiovascular Disease. Heart, Lung and Circ. 2022;31:S300. *Cardiac Society of Australia and New Zealand Annual Scientific Meeting, August, 2022.*
4. **Hafiz N**, Hyun K, Tu Q, Knight A, Hespe C, Dhillon M, et al. Do Quality Improvement Workshops Improve Health Professionals Knowledge on Implementing Change for Patients With Coronary Heart Disease in Primary Care? Heart, Lung and Circ. 2021;30:S278. *Cardiac Society of Australia and New Zealand Annual Scientific Meeting, December, 2021.*
5. **Hafiz N**, Hyun K, Chow C, Briffa T, Gallagher R, Reid C, et al. 732 Gender Comparison in the use of General Practice Management Plans (GPMPs) for Patients With Cardiovascular Disease (CVD). Heart, Lung and Circ. 2020;29:S365-S6. *Cardiac Society of Australia and New Zealand Annual Scientific Meeting, August, 2020.*

AWARDS ARISING FROM THIS THESIS

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- Westmead Applied Research Centre Postgraduate Research Scholarship Award (2019 - 2023)

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7. **Charles Perkins Centre Travel grant Award, 2021**. (Value $750)
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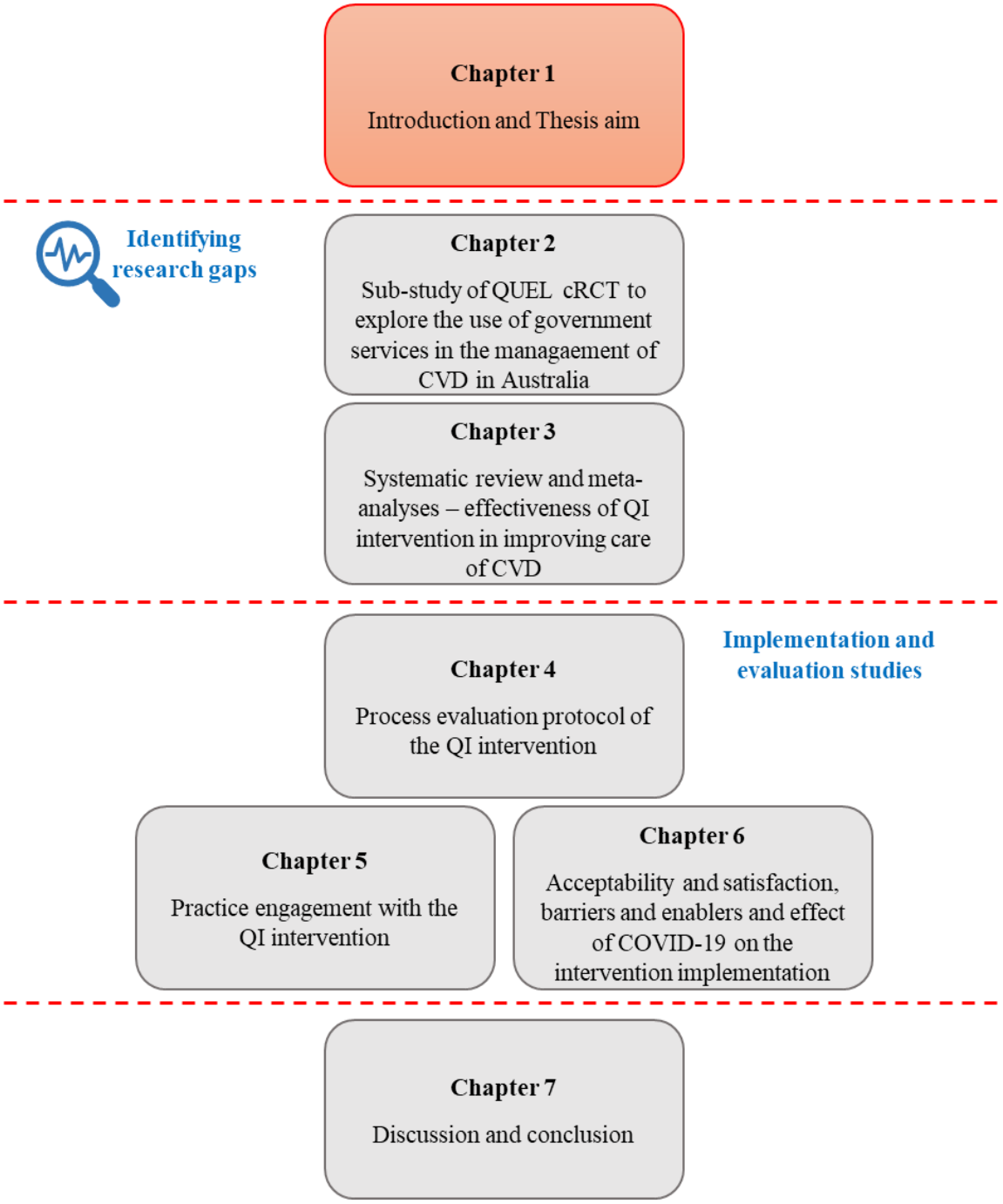
10. **University of Sydney Post Graduate Research Scheme (PRSS) award, 2020**. (Value $775)
11. **Excellence Award,** Westmead Applied Research Centre, 2019

CHAPTER ONE

Introduction and Thesis aims



CARDIOVASCULAR DISEASE AS A GLOBAL HEALTH CHALLENGE

Cardiovascular diseases (CVDs) are defined as a spectrum of disorders affecting the heart and blood vessels, including coronary heart disease (CHD), cerebrovascular disease, peripheral arterial disease, rheumatic heart disease, congenital heart disease, deep vein thrombosis, and pulmonary embolism (1). CVDs remain a significant global health challenge and continue to contribute to global deaths and disability-adjusted life years (DALYs) (2). In 2019 alone, CVD claimed approximately 18 million lives, accounting for a staggering 32% of total global deaths. Moreover, CVD significantly contributed to 330 million years of life lost and affected the quality of life for 35.6 million individuals through disability during the same period (3, 4).

In Australia, CVD is the third leading cause of disease burden, following cancer and musculoskeletal diseases (5). More than four million Australians are affected by CVD, representing approximately 17% of the entire population. Data from the Australian Institute of Health and Welfare reported that in 2021, CVD was responsible for approximately 42,700 deaths, accounting for 25% of all deaths, and 600,000 hospitalisations (5). Furthermore, in 2022, approximately 670,000 years of healthy life were lost in Australia alone (5). The major contributors to the CVD disease burden in Australia were CHD, stroke and atrial fibrillation (5).

CHD is defined as the disease of blood vessels supplying the heart muscle. It is often caused by the narrowing of an artery due to atherosclerotic plaque and usually occurs in patients in the form of heart attack (6) and angina (7). CHD is a major contributor to CVD and remains a challenge despite the gradual decline in death and disease burden since 1980 (8). Around 571,000 Australians, representing 2.9% of the adult population, were living with CHD in

2020-2021, according to the report of the Australian Institute of Health and Welfare (8). In Australia alone, CHD caused 17,300 deaths during the same year, constituting 41% of CVD-related deaths and 10% of all deaths (8). In addition, CHD was associated with 306,000 years of healthy life lost in 2022 (8). It accounts for 5.5% of Australia's total disease burden (8).

EVIDENCE-BASED SECONDARY PREVENTION STRATEGIES

Several national and international guidelines recommended therapies are currently being used for the management and prevention of CVD, including CHD, cerebrovascular disease, or peripheral vascular disease (9-14). For individuals with existing CVD, guideline recommendation for secondary prevention includes the use of guideline-indicated medications, adopting a healthy lifestyle, implementation of chronic disease management plans (CDMPs), screening for other comorbidities such as psychosocial factors including depression and anxiety, and participation in a cardiac rehabilitation program following an acute event (9, 15, 16). Recommendation for a healthy lifestyle includes smoking cessation, less alcohol consumption, adopting a well-balanced nutritional diet, engaging in at least 30 minutes of physical activity per day for five days a week and maintaining a healthy body weight (9, 13). Guideline-recommended medications for all patients include the use of antiplatelet agents, anticoagulants, angiotensin-converting enzyme inhibitors (ACEi) or angiotensin receptor blockers (ARBs), beta-blockers, statins, and short-acting nitrates (17). The guidelines also recommend managing CVD risk factors such as cholesterol level, blood pressure (BP) and diabetes (9, 13). Additionally, annual influenza and pneumococcal vaccinations are advised as part of the management for established CHD (9, 18).

Another successful secondary prevention strategy is cardiac rehabilitation, typically conducted through group-based programs where patients attend weekly exercise and

education sessions for 6-10 weeks in hospitals, community centres or clinics (19). Cardiac rehabilitation programs are cost-effective, safe, and beneficial for all patients as they provide health education, counselling, and behaviour modification, including physical activity and exercise training programs to improve heart health (9, 20). Furthermore, research has consistently demonstrated that cardiac rehabilitation not only aids in recovery from a recent cardiac event or procedure but also improves survival rates and reduces the risk of future events and hospitalisations for patients with established CHD (21).

While there are well-documented benefits, cardiac rehabilitation reach remains limited. In countries such as the Unites States of America (USA) (10% to 20%) and Australia (28.4%), despite the evidence and recommendations (22), utilisation of these programs is low (23, 24). There are several factors contributing to the underutilisation of these services, which include but are not limited to low referral rate (around 20%) (25), poor patient motivation, and distance to the location(26). Additionally, research indicates that specific groups, such as women, individuals from diverse ethnic backgrounds with cultural and language barriers and those with low socioeconomic status, face challenges in accessing these programs (23, 27). To enhance the effectiveness of secondary prevention for CVD, it is imperative that patients with established CVD receive multidisciplinary and coordinated care involving primary care providers, specialists, allied health professionals, and cardiac rehabilitation. Therefore, further research is needed to explore strategies for improving the utilisation of available secondary prevention interventions across healthcare services, particularly in primary care practices.

THE ROLE OF PRIMARY CARE IN CVD MANAGEMENT

Primary care plays a pivotal role in the successful execution of these secondary prevention strategies for the management of CVD. It serves as the first point of contact for any patients with chronic diseases, including CVD, offering comprehensive and coordinated care (28). In Australia, primary health care is provided through a multidisciplinary approach involving GPs, nurses, community health centres and allied health professionals, with support from Primary Health Networks (PHNs) (29, 30). A study found regular visits to the General practitioners (GPs) reduce the risk of emergency hospitalisation (hazard ration (HR) = 0.81, [95% confidence interval (CI): 0.67, 0.98]) and deaths (HR = 0.70, [95% CI: 0.65, 0.68]) in individuals already diagnosed with CVD (31). Therefore, a robust primary care system is needed to optimise care, provide better health outcomes, and reduce costs.

Government-funded health services

To reduce the burden of CVD and improve management, Australian primary care provides a range of services for managing CVD. These services include early detection, prescription of guideline-recommended medications, lifestyle modification counselling, provision of CDMPs and referral to various services and rehabilitation programs (19, 32, 33). Patients with established chronic diseases, including CVD, are eligible to receive CDMPs, which include preparing a General Practice Management Plan (GPMP), Team Care Arrangements (TCA) and GPMP reviews (33). GPMPs assist healthcare providers in identifying patients' healthcare needs, specifying the services offered by GPs and providing guidance for patients to self-manage their chronic conditions. TCAs are tailored for patients with complex chronic conditions requiring coordination with at least two other healthcare providers for ongoing support. GPMP reviews involve regular follow-up between GPs and patients to ensure that established goals for disease management are being met. Consequently, it enables primary

healthcare providers to coordinate multidisciplinary care for patients with chronic diseases (33).

Moreover, mental health conditions, including depression, anxiety, and other psychological factors, may have a significant impact on the management and prognosis of CVD. (34) The intricate interplay between these two conditions, often sharing underlying etiological factors, can pose unique challenges in effectively addressing modifiable risk factors for CVD (35). Therefore, the Australian government also subsidises mental health care treatments including assessments, preparation of a mental health management plans, reviews, and treatment consultations for ongoing management. These subsidised mental health services are also accessible through primary care practices for patients with symptoms or a known diagnosis of a mental health issue.

In addition, guideline-recommended CVD medications are accessible to Australian citizens at a low cost, and which can be accessed from primary care (17). Access to primary care services including CDPMs and subsidised medications are provided as part of the Australian universal health insurance scheme, known as Medicare, which ensures all Australians have access to healthcare services for free or at a reduced cost. Results from a retrospective quasi-experimental study have demonstrated that the use of government-funded health services and subsidised medications can significantly reduce the rate of CVD or diabetes-related hospitalisations ($p \leq 0.01$), re-hospitalisations ($P \leq 0.01$) and length of stay ($P \leq 0.01$) (36).

Use and impact of electronic health records in healthcare

Electronic health records (EHR) systematically collect patient information and store them securely in a digital platform. In recent years, the use of electronic health records has

revolutionised primary care (37), which provides a comprehensive, computerised, patient-oriented system that centralises individual patient information, enabling efficient and effective coordination of patient care by healthcare professionals (38). This has significantly improved how healthcare facilities operate (39, 40). According to a 2014 national physician survey of Canadian doctors, the adoption of EHRs resulted in a notable 65% of doctors reporting an improvement in patient care, with less than 5% reporting a negative impact on healthcare quality (41). Another physician survey highlighted the benefits of EHRs in reducing medication-related errors (72% to 81%, $p = 0.03$), improving the follow-up of laboratory results (62% to 87%, $p < 0.001$), and enhancing communication among physicians (72% to 93%, $p < 0.001$) (42).

Electronic health records are used in various healthcare processes, including automatic data collection, review and patient monitoring, risk assessment, patient filtering, generating aggregated reports, and sending GP reminders (39). These functions empower health professionals to identify areas of improvement and monitor progress, leading to improved efficiency in healthcare workflows and enhanced patient outcomes (38, 43). A cohort study further revealed that the use of EHRs contributed to a 22% reduction in overall cancer mortality when comparing metformin to other oral hypoglycemic medications (HR 0.78, [95% CI: 0.69, 0.88]) (44). Furthermore, diabetic patients on metformin showed a notable 39% lower mortality rates compared to those on insulin only (HR 0.61, [95% CI: 0.50, 0.73]), demonstrating the significant potential of EHRs in reducing mortality rate (44). The effectiveness of electronic patient records in improving patient care is well documented. Hence, it needs to be widely adopted in new secondary prevention strategies such as data-driven quality improvement (QI) interventions.

The potential impact of improving utilisation of secondary prevention services in primary care

There is evidence of suboptimal use of secondary prevention services provided by primary care for patients with CVD (45). A sub-analysis of a large randomised clinical trial with 905 participants revealed only half of the cohort used a CDMP (46). Additionally, another study assessing long-term adherence to guideline-recommended medications found a decrease in the proportion of use from 50-85% to 45-50% after five years (47). There is an opportunity to strengthen the implementation of more effective and innovative strategies within primary care to promote improved utilisation of these services.

Despite the positive impact of these services on reducing CVD-related hospitalisations and future events (36), studies have shown significant global and Australian variations in the use of secondary prevention strategies, particularly in the context of gender disparities. Women, in particular, were less likely to be assessed for CVD risk factors (48, 49), use guideline-recommended medications (50-52) and attend less cardiac rehabilitation programs (49). While existing studies have explored gender-based differences in care-seeking behaviours and healthcare utilisation, a gap remains in the understanding of how gender influences the utilisation of CDMPs for managing CVD.

Furthermore, beyond gender disparities, there is a significant opportunity for improvement in the provision of government-funded health services in primary care to manage chronic diseases effectively, as well as CVD (36). Therefore, further research is needed to evaluate the utilisation of secondary prevention services, mainly focusing on CDMPs in men and women. Additionally, this research should assess the overall impact of these services on improving the quality of CVD care. By addressing these issues, more equitable and effective

healthcare delivery via new and innovative strategies, like data-driven QI interventions, can be ensured for individuals with CVD.

THE EVOLUTION OF QI INITIATIVES

QI is defined as a systematic, data-driven approach to bring immediate improvement in the delivery of healthcare within a particular setting (53). Shojania and colleagues have further defined QI strategies as interventions to bridge the gap in the quality of care provided to a group of patients, aligning it more closely with the care typically delivered in routine practice (54). These strategies are innovative, multidimensional, and holistic approaches used across various healthcare settings to elevate the quality of care offered to their patients, improve outcomes, and expand health professionals' knowledge (55). A wide range of methods are employed as QI strategies throughout healthcare settings to improve the quality of care (56). Shojania and colleagues have also developed a taxonomy of QI strategies, suggesting that using particular strategies and methodologies depends on the nature of the QI initiative, Table 1 (54, 57).

Table 1: Taxonomy of QI strategies with examples of sub-strategies

QI strategy	**Examples**
Provider reminder system	• Reminders in charts for providers • Computer-based reminders for providers • Computer-based decision support
Facilitated relay of clinical data to providers	Transmission of clinical data from outpatient speciality clinic to primary care provider by means other than medical record (phone call or fax)

Audit and feedback	• Feedback on performance to individual providers • Quality indicators and reports • National/state quality report cards • Publicly released performance data • Benchmarking - provision of outcomes data from top performers for comparison with provider's data
Provider education	• Workshops and conferences • Educational outreach visits (e.g., academic detailing) • Distributed educational materials
Patient Education	• Classes • Parent and family education • Patient pamphlets • Intensive education strategies promoting self-management of chronic conditions
Patient reminder systems	Materials and devices promoting self-management
Promotion of self-management	Postcards or calls to patients
Organisational change	• Case management, disease management • Telemedicine • Total Quality Management (TQM), Continuous quality improvement (CQI) techniques

	• Multidisciplinary team • Change from paper to computer-based records • Increased staffing • Skill-mix changes
Financial incentives, regulation, and policy	**Provider directed:** • Financial incentives based on achievement of performance goals • Alternative reimbursement systems (e.g., fee-for-service, capitated payments) • Licensure requirements **Patient directed:** • Copayments for certain visit types • Health insurance premiums, user fees **Health system directed:** • Initiatives by accreditation bodies (e.g., residency work hour limit) • Changes in reimbursement schemes (e.g., Capitation, prospective payment, salaried providers)

QI strategies used in healthcare

One effective QI strategy is data and feedback reporting, which motivates health professionals to implement improvement changes within their clinical practice. A systematic review of 140 studies found that audit and feedback reporting, whether used alone or in

combination with other QI strategies, can effectively improve health professionals' practice and patient outcomes (58, 59). However, the effectiveness of this strategy was dependent on the delivery and intensity of the feedback provided (58, 59). Additionally, the use of electronic data and regular feedback reports serves as a motivating factor for practice staff and facilitates visualisation and progress monitoring (60, 61).

Continuous education for health professionals, delivered via meetings or workshops, is also an effective QI strategy. In a randomised trial, continuous training for physicians in smoking counselling led to a 2.2% increase in the proportion of patients quitting smoking (62). Similarly, another randomised trial found significant improvement in patient outcomes, including increased patient knowledge of cholesterol management ($p=0.008$) and reduced serum cholesterol level ($p=0.02$) within the intervention group, where physicians received training (63). These workshops and educational programs provide healthcare professionals with practical knowledge, problem-solving skills, and the tools necessary for effective QI efforts, including Plan-Do-Study-Act (PDSA) cycles (64-66).

Another successful QI strategy is the PDSA cycle. PDSAs are the most commonly used QI tool for measuring improvements in healthcare quality (67, 68). This iterative cycle guides health professionals through the explicit planning, implementation, reflection, and repetition of incremental improvements as they introduce systemic changes to achieve their pre-defined objectives (69). In a cluster-randomised study, qualitative findings found that implementing multiple rapid PDSA cycles led to the refinement of the initial intervention to improve outcomes and streamline practice workflows (70). Therefore, it highlights the effectiveness of PDSA as a QI strategy for identifying areas of improvement, testing changes, and achieving better results and operational efficiency.

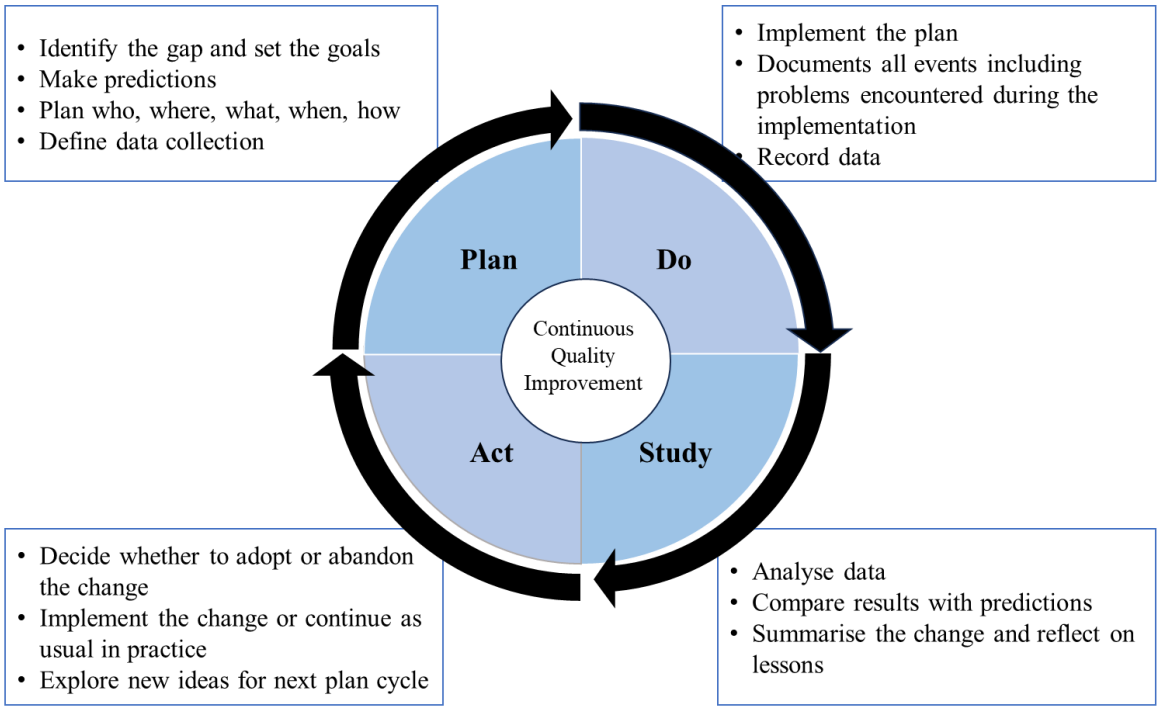


Figure 1: Plan-Do-Study-Act Cycle, adapted from (71)

Furthermore, practice accreditation and financial incentives are also often used in combination with other QI strategies to facilitate improvement in practices. Financial incentives have proven effective in encouraging health professionals to achieve quality targets within a specific time. A systematic review found that, out of seven included studies,

financial incentives had a positive impact on study outcomes in six studies, although the effectiveness varied among the outcomes (72). Another systematic review examining the impact of accreditation as a QI strategy found significant improvements in clinical outcomes and healthcare quality, particularly in managing conditions such as acute MI (73). Combining various QI strategies, such as case management, team changes, electronic patient registry or electronic health records, sharing of clinical information, and continuous QI, has also improved the quality of care. For example, a systematic review that used a combination of these strategies reported improved outcomes in several risk factors outcomes, including reduced HbA1c by 0.62%, decreased systolic BP by 4.39 mmHg and lowered LDL-C by 5.52 mg/dl to improve diabetes care (74).

In Australia, the availability of the PIP-QI and EHRs has encouraged more primary care practices to adopt various QI strategies to enhance patient care. EHRs have further streamlined the adoption of these strategies by automating data extraction processes and making patients' progress monitoring more efficient and accurate (38, 75, 76). QI initiatives in healthcare have seen the adoption of various strategies such as practice accreditation, data and feedback reporting, health professionals' education, PDSA cycles, use of electronic health records and financial incentives to enhance healthcare quality and outcomes. While there is substantial evidence supporting the effectiveness of these strategies, there are no known studies that have evaluated their impact on outcomes and associated process evaluation in the management of CVD in primary care. Further research is needed to comprehensively assess the benefits and potential limitations of these QI programs in the context of CVD management.

QUALITY IMPROVEMENT IN PRIMARY CARE TO PREVENT HOSPITALISATIONS AND IMPROVE EFFECTIVENESS AND EFFICIENCY OF PEOPLE LIVING WITH CORONARY HEART DISEASE (QUEL STUDY)

In an effort to reduce the burden of CHD and improve the quality of care while narrowing the gap between hospital and primary care, a secondary prevention alliance was formed to find and implement innovative solutions (77). As a result, the QUEL study was developed to evaluate the effectiveness of a data-driven QI program implemented in primary care practices to improve the care of CHD patients. The QUEL study aimed to determine whether the QI program:

1. Reduces the rate of unplanned CVD hospitalisations and adverse events.
2. Increases the proportion of patients who are (i) prescribed evidence-based CVD medications, (ii) achieving national targets for risk factors (cholesterol, BP, smoking), and (iii) receiving Chronic Disease Management (CDM) or review plan.

QUEL study design and participants

QUEL is a cluster randomised controlled trial (cRCT) recruiting 52 primary care practices across four Australian states, including New South Wales, Victoria, South Australia, and Queensland. Twenty-seven practices were randomised into the intervention arm, where they received the 12-month intervention and remaining 25 practices were randomised to the control group to receive usual care. The study was funded by the National Health and Medical Research Council (NHMRC) Partnership Projects (APP1140807) grant and is registered as a clinical trial in the Australian New Zealand Clinical Trials Registry (ANZCTR) (ACTRN12619001790134). The ethics approval for the study is obtained from

NSW Population and Health Services Research Ethics Committee (HREC/18/CIPHS/44) and included in Appendix A.

Primary care practices and patients were included in the study. Primary care practices were eligible to participate in the QUEL study if they managed ≥100 patients per year with prevalent CHD and used practice software compliant with the automated data collection system. Patients were included if they were ≥18 years old with a documented diagnosis of CHD in the primary care record of a participating practice and visited the participating practice at least once in the previous 12 months. Details of the study design and methods are presented in a published protocol (78).

Overview of the QI intervention in the QUEL study

The QUEL intervention consisted of multiple features, including learning workshops, submission of electronic data by the participating practices, same practices receiving feedback reports every month based on the submitted data, submission of PDSA cycles by the practices to test QI changes, and external support given to the practices by relevant PHNs. The intervention was delivered over a year between November 2019 and November 2020 in 27 primary care practices randomised in the intervention group. Details of the intervention implementation are given below:

Box 1: QUEL intervention details

Pre-work	1. Expert Reference Panel (ERP): An expert reference panel was established consisting of subject matter experts in research and collaborative QI who have applied practical improvement in the cardiovascular disease area. The QUEL intervention was designed by an ERP along with QUEL investigators and research partners,

	who also reviewed and finalised the program content to ensure the suitability of QUEL. 2. Pre-defined key performance measures as a target for improvement: Before the start of the intervention, ERP, QUEL partners and investigators worked collaboratively to identify 12 CHD measures to be used as pre-determined areas for improvement during the 12-month intervention period. 3. Setting up SharePoint account: Each practice was given access to a SharePoint web account where monthly feedback report was uploaded along with other study materials, including workshop recordings, presentations, intervention guidelines, PDSA templates, etc. The web page was also used to submit PDSA using the online template.
Length of the intervention	12 months (November 2019 to November 2020)
Orientation	The virtual orientation session provided an overview of the QUEL collaborative, introduced the 12 pre-defined key performance measures as targets for improvement, and outlined requirements and expectations and the benefits that can be expected by participating in the program.
Electronic data collection (baseline)	The intervention practices used an automated data extraction tool incorporated with their software system to access, create, and review eligible patients' data to achieve the CHD risk factor targets outlined in the QUEL study. Aggregated clinical data was collected before the first learning workshop and was presented at the first learning workshop. This data provided an important snapshot of the practices' position before making any improvements and enabled them to see the results of their work.

Learning workshop (LW)	**LW1 (full day face-to-face (F2F) event):** Introduction to QUEL collaborative, introduction to collaborative aim and change principles, Model for Improvement and PDSA cycles, the evidence behind CHD measures, understanding your CVD population, creating effective recall system, practices shared real-time experiences on how they implement activities to drive improvement and next step**. LW2: (1 hr virtual session):** How to use SharePoint to access monthly reports and submit PDSA, collaborative update on work being undertaken by the practices as Model for Improvement and PDSA cycles and aggregated reporting and benchmarking of program measures, enhancing CHD management through care planning (real-time experience shared by other intervention practices) and next step. **LW3: (1 hr virtual session)**: Collaborative update on Model for Improvement and PDSA cycles by the practices and aggregated reporting and benchmarking of program measures, real-time experience shared by other intervention practices) and next step. **LW4 and LW5 (1 hr virtual session)**: The impact of COVID-19 on the Collaborative and future plans. Collaborative update on Model for Improvement and PDSA cycles by the practices, aggregated reporting and benchmarking of program measures. Improvement in CHD (stories of achievement shared by one of the intervention practices) and next step. **LW6 (Full day virtual event):** Collaborative update on Model for Improvement and PDSA cycles by the practices and aggregated reporting and benchmarking of program measures, process mapping for heart disease - patient journey example, heart disease improvement stories (stories of achievement shared by intervention practices), sustaining change and sharing plans for sustaining change, next step, evaluation, and closure.
Activity period (in between the learning workshops)	1. Electronic data collected monthly by the study team 2. Monthly reporting and feedback graphs uploaded in SharePoint by study team

	3. Identify areas for improvement and complete PDSA cycles by the designated practice team members within the practices to implement QI changes focusing on the 12 CHD measures
Support	Five PHNs agreed to support 12 intervention practices during the intervention period. The remaining 15 practices were supported by the QUEL study team.

QUEL Study outcomes and data collection

The primary outcome is the proportion of patients with unplanned CVD hospitalisations assessed at 24 months after baseline data collection. Secondary outcomes are the proportion of patients with major adverse cardiac and cerebrovascular events, including angina, myocardial infarction (MI), stroke or CVD deaths, the proportion of patients who received guideline-recommended medications, the proportion of patients with a CDMP, and the proportion of patients achieving national targets for CVD risk factors including total cholesterol, systolic blood pressure (SBP) and smoking also assessed at 24 months.

Clinical data was collected at baseline, 12 and 24 months from the individual patients' electronic health records from all participating practices. CVD hospitalisations and cardiovascular events data were collected via state-based administrative admissions and emergency department data. Individual death data will be collected via linkage with the Australian Institute of Health and Welfare's National Death Index and medication prescriptions and health service utilisation data via linkage with Pharmaceutical Benefits Scheme (PBS) and Medical Benefits Scheme (MBS), respectively. This linked data will be collected at the end of the study.

IMPORTANCE OF PROCESS EVALUATION IN HEALTHCARE

Despite the evidence of the effectiveness of QI strategies in improving healthcare performance and patient care (79), their utilisation remains limited, as reported in one study where only 40% of the practices used QI strategies to implement changes (80). The implementation and sustainability of data-driven QI interventions and programs, particularly for managing chronic conditions like CHD, have proven to be challenging (79). Additionally, various QI interventions are used across healthcare, and studies have shown that the effectiveness of these interventions often varies across different settings (81, 82). Studies showed different formats, content, and presentation of the intervention can significantly impact its effectiveness in improving changes. For example, in one study, the intervention group consisting of GPs received feedback with individual scores and comparison of several performance measures at three time points; however, showed no improvement in their performance (83). Conversely, in another study, physicians received monthly feedback on their performance over six months, with the first three months focusing on individual management and the following three months comparing individual and group data presented as histograms (84). Therefore, it is crucial to gain a deeper understanding of the different QI interventions as it allows us to evaluate the specific details of the successes and failures associated with it to bring about changes within the healthcare settings. Further evaluation of these interventions thus helps to identify specific activities undertaken, the extent of participant exposure to these activities, and their experiences during the intervention, consequently playing a significant role in determining the ultimate outcome of the QI intervention.

Understanding these finer details is essential for improving the effectiveness of QI interventions in healthcare. Evidence suggests process evaluation is useful, particularly in QI

interventions, as it can help to describe the intervention in detail, evaluate whether it was implemented as intended and performed as planned, provide an in-depth understanding of individual features used within the QI and identify factors influencing the interventions successes or failures (85-87). Therefore, process evaluation in conjunction with complex interventions is increasing due to the multifaceted nature of these interventions (88, 89).

Evaluation of the QI intervention within QUEL

Process evaluation can be helpful in all types of QI interventions, including pilot studies, small and large-scale QI projects, and even in randomised controlled studies. The QUEL intervention includes multiple features, including data and feedback reporting, PDSA, and health professionals' education. Performing a process evaluation within the QUEL cRCT will help understand the mechanisms of impact, context and different features of the data-driven QI intervention within the QUEL study to improve CHD management in Australian primary care practices. While many studies have identified barriers and enablers to program implementation in various contexts (90, 91), few studies have explored health professionals' perspectives on the QI intervention (92). Therefore, the process evaluation within the QUEL study seeks to evaluate practices' satisfaction and acceptability of the intervention and to identify barriers and enablers, including the effect of the COVID-19 pandemic, in implementing the QI intervention for CHD management.

Evidence from previous studies further enhances the significance of performing process evaluation in QI interventions implemented in primary care. In a randomised QI study, which delivered a multi-featured intervention to 33 primary care practices, process evaluation collected feedback from 68 GPs and 83 practice assistants. The findings revealed positive feedback and satisfaction regarding the intervention from the general practitioners (GPs) and

the practice staff (83). The same study identified increased paperwork as a barrier for GPs in implementing the intervention from the process evaluation (83). Furthermore, all participants agreed that their involvement in the intervention resulted in improved workflow and brought about changes within their practice in improving the prevention of CVD (79). Another large-scale national-level QI program was evaluated to find the use of combined improvement strategies, along with the identified key factors, played a crucial role in successfully implementing the QI intervention in improving cervical cancer screening guideline adherence in 1000 primary care practices (84).

Additionally, evidence is scarce regarding the perception of practices and health professionals on using these programs, including their perceived benefits and potential reach (93). To guide scalability and future development, it is increasingly important to gain a comprehensive understanding of the individual features and processes associated with implementing such programs to improve the management of CHD and other chronic conditions (87, 88, 94). Evaluating the QUEL program will also gather rich evidence on the effectiveness of a data-driven QI strategy and, therefore, will be in a strong position to inform policymakers, PHNs and GP practices on future data-driven QI programs. A comprehensive evaluation of the QI intervention within the QUEL study will not only provide evidence surrounding the health professionals' perception and potential benefits of such programs but also will be able to provide insights to shape the future of data-driven QI initiatives in healthcare, ultimately advancing the management of CHD and other chronic conditions.

EFFECT OF COVID -19 ON HEALTHCARE SYSTEM AND PATIENTS WITH CHD

The coronavirus disease outbreak, known as COVID-19, in 2019 was declared a global emergency (95), resulting in three million global deaths and enormous personal and societal

losses (96). COVID-19 also had a greater impact on people living with chronic diseases such as heart disease, diabetes, cancer, chronic obstructive pulmonary disease (COPD) (37). Studies have found that individuals with pre-existing chronic conditions, including CHD, had an increased risk of experiencing acute events and were more likely to become severely ill from COVID-19, often leading to hospitalisations, intensive care support or death (97-99). Studies from China found that CVD, including CHD, is one of the most common comorbidities in COVID-19 patients (100, 101); around 40% of the hospitalised COVID-19 patients had co-morbidities including CHD and cerebrovascular disease (101). It was also found that the death rate in patients with CVD was 10.5%, the highest among those with co-morbidities (102).

The pandemic has also impacted the healthcare system globally (103). Healthcare facilities redesigned their services to cater towards severely ill COVID-19 patients, cancelling routine, non-urgent and elective treatments (104). In preparation to meet the surge of COVID-19, primary care also underwent radical changes and reshaped the landscape of primary care, impacting the care provided to individuals living with CHD (105). Practices cancelled many appointments and procedures, moved to telehealth or video consultations and restricted face-to-face consultations during the pandemic (106-108). One study in Australia found that face-to-face or in-person consultations in one of their states decreased by 22.1% (109), and in-person visits to cardiology clinics also reduced by more than 60% in the USA (110). Patients were required to test negative for COVID-19 prior to any in-person consultations. There was a shift in patients' overall healthcare-seeking behaviour. As a result, patients with chronic conditions failed to receive timely and effective access to primary and specialty care (111-113). Studies found CVD risk factors were not evaluated, and there was a decrease in BP measurement by 50% and cholesterol level measurements by 38% (114, 115). Cardiac

rehabilitation programs, which are an effective secondary strategy to manage CHD, were also ceased during the pandemic, leading to increased mortality (116). Given that COVID-19 has brought significant changes in the operation of primary care practices and has also impacted the care delivered to patients with CHD (105), it has become crucial to assess its effect on implementing a QI improvement program during this time.

SUMMARY

CVD, including CHD, remains one of the leading causes of death and disease burden globally. Secondary prevention strategies have become a national and international priority to reduce the burden. Primary care practices play an essential role in reducing the burden by implementing these strategies as they are the frontier of the healthcare system. However, further research is needed to better understand the use of secondary prevention services in primary care, mainly focusing on the gender disparities in receiving these services. Although the effectiveness of the relatively new, innovative, and data-driven QI solutions in primary care has been tested previously, limited research has been undertaken to evaluate such programs at a practice level. Therefore, research is required to understand different features and processes associated with implementing QI interventions and evaluate health professionals' perspectives on it. In addition, several studies have also explored factors influencing successes and failures associated with implementing these strategies in primary care. However, further research will strengthen the evidence for the future adoption of such complex strategies in improving the care of CHD.

THESIS AIMS

The overall aim of the Thesis was to investigate the primary care practices' engagement with the one-year data-driven QI intervention, understand the key features of the intervention and

investigate the acceptability, utility, barriers, enablers and the effect of COVID-19 on its implementation. Using a combination of systematic review and mixed-methods process evaluation, the specific aims of the Thesis were to:

1. Explore gender discrepancies amongst patients with CVD, in the receipt of CDMPs, mental health care and prescription of guideline-indicated medications at primary care practices for ongoing secondary prevention (sub-analysis of QUEL).
2. Understand the effectiveness of QI interventions in the management of CVD (systematic review).
3. Describe the design and methodology of a process evaluation of the one-year QI intervention delivered within the QUEL study (published protocol).
4. Describe and analyse practice engagement, attendance, time commitment, skills and capacity of the practice team members associated with the intervention; explore to what extent the intervention was delivered as intended and whether the intervention features were useful.
5. Understand the acceptability, satisfaction, uptake, utility, and feasibility of the QI intervention program; identify and describe barriers and enablers to implementation, including the impact of COVID-19 on its implementation.

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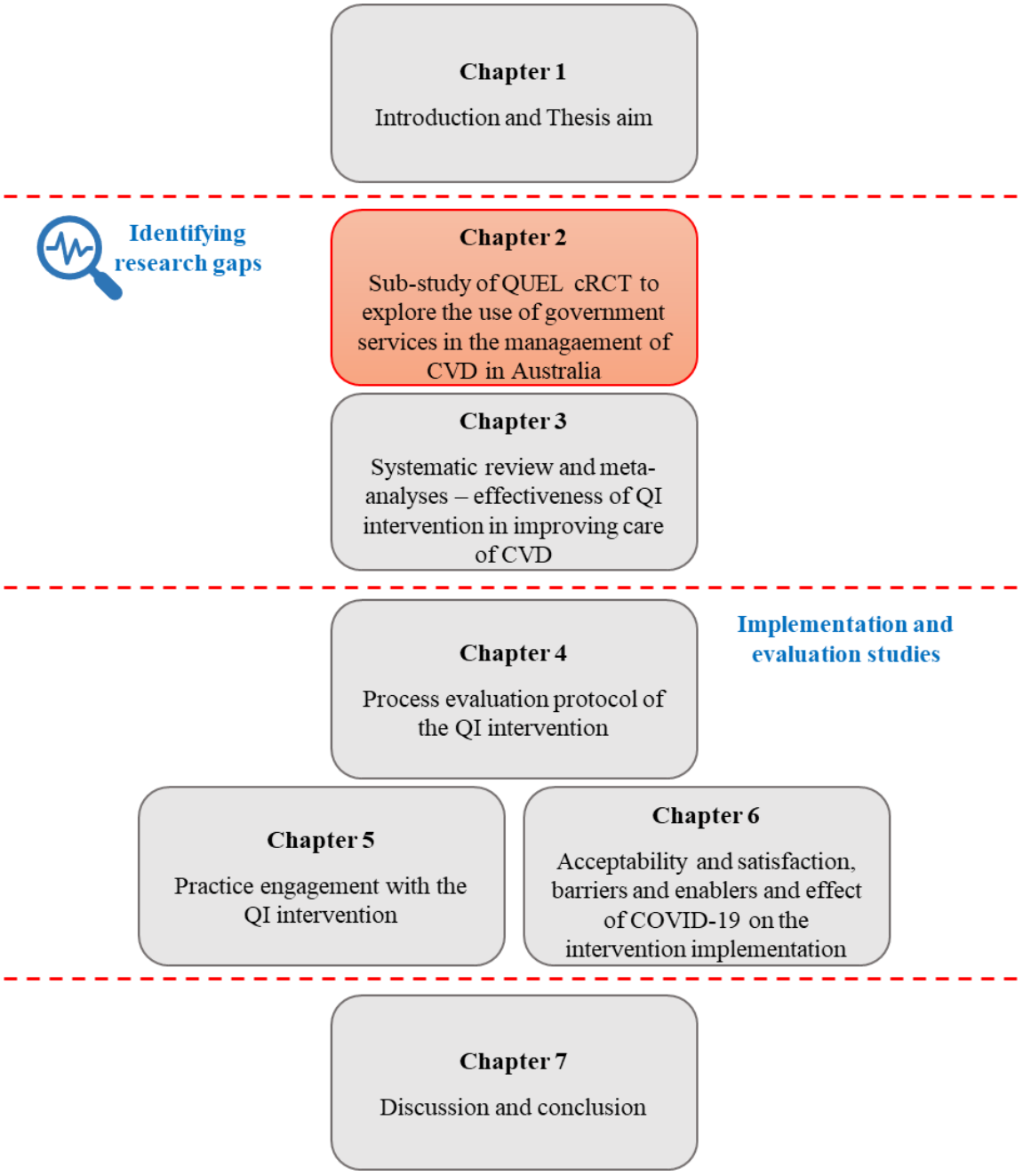
CHAPTER TWO

Gender comparison of receipt of government-funded health services and medication prescription for the management of patients with cardiovascular disease in primary care



PREFACE TO THE CHAPTER

Chapter Two describes the results of a sub-study of the QUEL study to further understand the overall utilisation of government-funded chronic disease management services and medications in primary care settings. It addresses Aim One of this Thesis. The sub-study titled "Gender comparison of receipt of government-funded health services and medication prescriptions for the management of patients with cardiovascular disease in primary care" has been published in the journal Heart, Lung and Circ. Despite the recommendations and availability of the various chronic disease management health services provided by Australian primary care, these service utilisation in patients with chronic diseases, particularly CVD were explored by a limited number of studies. The sub-study identified gaps in the overall use of government-funded chronic disease management services and medications and compared it between men and women, particularly among CVD patients. The ethics approval for this study is presented in Appendix A.

PEER-REVIEWED PUBLICATIONS AND PRESENTATIONS

Published paper

Hafiz N, Hyun K, Knight A, Hespe C, Chow CK, Briffa T et al. Gender comparison of receipt of government-funded health services and medication prescriptions for the management of patients with cardiovascular disease in primary care. Heart, Lung and Circ. 202;30(10):1516-1524.

Published abstract and conference presentation

Hafiz N, Hyun K, Knight A, Hespe C, Chow CK, Briffa T, et al. Gender comparison of receipt of government-Funded health services and medication prescriptions for the management of patients with cardiovascular disease in primary care. Heart Lung and Circ.

2021;30(10):1516-24. (*Cardiac Society of Australia and New Zealand Annual Scientific Meeting 2020, Gold Coast, Queensland, Australia*).

STATEMENT OF AUTHORSHIP

Nashid Hafiz, during her PhD candidature, developed the concept of the sub-study, performed statistical analysis, and interpreted the results, prepared the initial draft and subsequent revisions, responded to reviewers' feedback and coordinated submission and publication of the original research paper.

The individual roles of co-authors are listed below:

Task Role of co-authors	**Role of co-authors**
Refining the research question	NH, KH, JR
Data collection and analysis	NH, KH
Revision and Critical comments of manuscript	KH, JR, AK, CH, CC, TB, RG, CR, DH, NZ, MW, SJ, EA, TL, EH, TU and JR

Nashid Hafiz 30th April 2024

As supervisor for the candidature upon which this Thesis is based, I can confirm that the authorship attribution statement above is correct.

Professor Julie Redfern 30th April 2024

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ORIGINAL ARTICLE

Gender Comparison of Receipt of Government-Funded Health Services and Medication Prescriptions for the Management of Patients With Cardiovascular Disease in Primary Care

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Background Cardiovascular disease (CVD) and risk factors remains a major burden in terms of disease, disability, and death in the Australian population and mental health is considered as an important risk factor affecting cardiovascular disease. A multidisciplinary collaborative approach in primary care is required to ensure an optimal outcome for managing cardiovascular patients with mental health issues. Medicare introduced numerous primary care health services and medications that are subsidised by the Australian government in order to provide a more structured approach to reduce and manage CVD. However, the utilisation of these services nor gender comparison for CVD management in primary care has been explored. Therefore, the aim is to compare the provision of subsidised chronic disease management plans (CDMPs), mental health care and prescription of guideline-indicated medications to men and women with CVD in primary care practices for secondary prevention.

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Methods De-identified data for all active patients with CVD were extracted from 50 Australian primary care practices. Outcomes included the frequency of receipt of CDMPs, mental health care and prescription of evidence-based medications. Analyses adjusted for demography and clinical characteristics, stratified by gender, were performed using logistic regression and accounted for clustering effects by practices.

Results Data for 14,601 patients with CVD (39.4% women) were collected. The odds of receiving the CDMPs was significantly greater amongst women than men (preparation of general practice management plan [GPMP]: (46% vs 43%; adjusted OR [95% CI]: 1.22 [1.12, 1.34]). Women were more likely to have diagnosed with mental health issues (32% vs 20%, $p<0.0001$), however, the adjusted odds of men and women receiving any government-subsidised mental health care were similar. Women were less often prescribed blood pressure, lipid-lowering and antiplatelet medications. After adjustment, only an antiplatelet medication or agent was less likely to be prescribed to women than men (44% vs 51%; adjusted OR [95% CI]: 0.84 [0.76, 0.94]).

Conclusion Women were more likely to receive CDMPs but less likely to receive antiplatelet medications than men, no gender difference was observed in the receipt of mental health care. However, the receipt of the CDMPs and the mental health treatment consultations were suboptimal and better use of these existing services could improve ongoing CVD management.

Keywords Cardiovascular disease • Gender • Health services • Secondary prevention • Prevention • Primary care • Data extraction • Chronic disease • Heart disease

Introduction

Cardiovascular disease (CVD) remains one of the leading causes of death and disease burden globally for both women and men, despite the declining mortality rate in recent times [1]. Modifiable risk factors for CVD include elevated blood pressure (BP), elevated cholesterol, having diabetes, being a tobacco smoker, being overweight/obese, being inactive, poor nutrition and having a high alchohol intake [2]. Therefore, it is recommended people with CVD be prescribed and take BP, lipid-lowering and antiplatelet medications and obtain specialist care when indicated and manage their behavioural risk factors [2]. While the cause and effect of mental health issues amongst people with CVD remains a topic of debate, depression, anxiety, and other psychological factors play an important role in CVD management [2]. These two conditions have shared aetiology and managing modifiable risk factors can become challenging in the face of mental health issues [3]. Therefore, it is also recommended that patients with CVD be screened for depression (and other psychosocial factors) [2,4].

Medicare is Australia's universal health insurance scheme. The overall program involves numerous primary care health services and medications that are subsidised by the federal government in order to reduce and manage CVD [5]. The Medicare program includes the Medical Benefits Schedule (MBS) that provides a rebate for each service provided to the patients (via "Item Numbers"), which is the cost of the service recommended by the government [6]. This program has multiple components including a suite of chronic disease management plans (CDMPs) that cover (i) preparation of a general practice management plan (GPMP), (ii) Team Care Arrangements (TCA) and (iii) GPMP reviews [5]. Together, CDMPs enable general practitioners (GPs) to work with other health professionals to plan and coordinate multidisciplinary care for patients presenting to primary care with chronic disease diagnoses including but not limited to asthma, cancer, cardiovascular disease, diabetes, musculoskeletal conditions and stroke that have been present for 6 months or longer [5,7]. The government also subsidises mental health care treatments that are also available via primary care practices for patients with symptoms or known diagnosis of mental health issue. The mental health care cover aspects of care including assessment and preparation of a mental health management plan, review of the management plan and mental health treatment consultation for ongoing management/treatment [8]. Further, as part of Medicare, the Pharmaceutical Benefits Scheme (PBS) enables an Australian citizen to pay only a portion of the cost of many prescription medicines listed on the PBS [9]. This includes all the major classes of evidence-based medications for the management of CVD [9]. Importantly, there is evidence that the provision of these government-funded health services and PBS-subsidised prescribed medications have a positive impact on outcomes such as hospitalisations and length of stay [10]. However, previous research has indicated there is suboptimal utilisation of CDMPs and mental health care in terms of CVD secondary prevention [11].

Taken together, the MBS and PBS provide financial assistance to both practices and patients that support ongoing and coordinated care for patients with chronic diseases such as CVD [6]. However, there are limited studies that have explored the use of these initiatives in relation to gender equity. Previous research suggests that women and men have different behavioural patterns in seeking medical help and that women visit the primary care practices more often/regularly for both physical and mental health concerns compared to men as they have greater willingness to better manage their health and take care of themselves when sick [12]. In contrast, studies have found that women are less

likely to receive secondary preventive care such as indicated medication prescriptions, inpatient intervention and referral to cardiac rehabilitation [13]. Previous studies have shown there are gender discrepancies in the management of CVD in primary care practices which are the primary venue for CVD risk assessment and management. Although women are more likely to seek medical care [12], they are less often assessed for their CVD risk factors and receive fewer prescription indicated medications compared to men [13–15]. To help reduce the prevalence of disease and provide equitable care for all, Medicare subsidises health services [5] and evidence-based medications [6]. Therefore, this study aims to explore gender discrepancies, amongst patients with CVD, in the receipt of CDMPs, mental health care and prescription of guideline-indicated medications at primary care practices for ongoing secondary prevention.

Methods

Analysis of the baseline data collected as part of the QUEL[1] study was used for this study [16]. QUEL is a cluster randomised controlled trial involving 50 primary care practices across four Australian states, New South Wales, Victoria, South Australia and Queensland [16]. The study has ethics approval from the New South Wales Cancer Institute Population and Health Services Research Ethics Committee (HREC, HREC/18/CIPHS/44). For this sub-analysis, individual consent waiver was granted, given that data collection was based on de-identified extracts from the electronic health record system.

Practices and Participants

A total of 50 Australian primary care practices were recruited as part of cluster randomised controlled trial [16]. Inclusion criteria for participating practices were (i) manage ≥100 patients with CVD per year and (ii) using software compliant with the data extraction tool. Patients were eligible to be included in the study if they were (i) over 18 years, (ii) had a documented diagnosis of CVD and (iii) had visited the participating practice at least three times in the previous 24 months. A documented diagnosis of CVD included patients with coronary heart disease (CHD), myocardial infarction, hypertension, heart failure, stroke, peripheral vascular disease, carotid stenosis and renal artery stenosis.

Data Collection

Data extraction was performed by an external population health software system managed by Pen Computer Systems (Pen CS) [17]. The software enabled the automated extraction of de-identified patient data from participating primary care practices for the previous 12 months (December 2018–December 2019). Extracted demographic and clinical data included age, gender, Indigenous status, detailed clinical data relevant to CVD management such as BP, total cholesterol (TC), body mass index (BMI) and diabetes. BMI was analysed as per recording of the GP software. Prescribed medications for the previous 12 months were also extracted for the cohort to compare the use of guideline-indicated prescribed medication in both genders. Prescription of guideline-indicated medications for patients with established CVD was defined as having a current prescription for BP-lowering medication, lipid-lowering medication and antiplatelet medication, unless contraindicated and clinically inappropriate [2]. BP lowering medications analysed were angiotensin receptor blocker (ARBs), angiotensin converting enzyme (ACE) inhibitors, alpha-blockers, beta blockers, calcium channel blockers (CCB), diuretics [18]. In addition, MBS items claimed during the 12 months were extracted. Extraction of MBS items enabled the calculation of the receipt of both CDMPs and mental health care to compare any gender discrepancies. For the purpose of the study, mental health issue was defined as a group of disorders including psychosis, bipolar disorder, schizophrenia, major depression and other delusional disorders, commonly referred to in the literature by the umbrella term severe mental illness [4]. This definition was used to identify mental health issues within the cohort of CVD patients. The patient data was extracted directly from the primary care practices via the practice software. Anyone who had a recorded diagnosis of mental health issue in the software were included. Once extracted, the de-identified clinical dataset was securely uploaded to the University of Sydney's research data storage database in preparation for analysis.

Outcomes

The primary outcome of interest was the frequency of CDMPs utilisation in men and women with CVD. Specific descriptions and of each associated Item number are detailed in Box 1. Secondary outcomes included mental health care claims for people with documented mental health issues within the same cohort (Item numbers and components again detailed in Box 1) and frequency of prescribed medications (BP-lowering medication, lipid-lowering medication and antiplatelets).

Statistical Analysis

Categorical variables were summarised using number and percentage, and Chi-squared test was used to test for the difference between the genders. Continuous variables were summarised using the mean and standard deviation (SD) for normally distributed variables and median and interquartile interval (IQI) for skewed variables, and independent t-test and Wilcoxon rank-sum test were used to test for the difference between the two (male/female) groups, respectively. For adjusted analyses, logistic regressions were performed within the framework of generalised estimating equations (GEE) to account for clustering effects by practices. The independent variables included in the models were: gender (women vs men), age (65–74, 75–84, ≥85 vs <65 years), Indigenous status (yes vs no), current smoker (yes vs no),

[1] Quality Improvement in Primary Care to Prevent Hospitalisations and Improve Effectiveness and Efficiency of Care for People Living with Heart Disease.

Box 1. Definitions, Medicare item numbers and fees used for outcomes [5,8,19].

Chronic Disease Management Plan (CDMP) Items

1. Preparation of a General Practice Management Plan (GPMP) – MBS Item 721

Rebate (AUD$148.75) for GP to prepare a management plan for a patient who has a chronic or terminal medical condition

2. Coordination of Team Care Arrangements (TCAs) – MBS Item 723

Rebate (AUD$117.90) for GP to coordinate preparation of TCAs for a patient who has a chronic or terminal medical condition and also requires ongoing care from a multidisciplinary team (at least three care providers)

3. Review of a GPMP/Coordination of a Review of TCAs – MBS Item 732

Rebate (AUD$74.30) for GP to review a GPMP or TCA

Mental Health Care Items

1. Preparation of a GP Mental Health Treatment Plan - MBS items 2700, 2701, 2715 or 2717

Rebate (AUD$73.95, AUD$108.85, AUD$93.90, AUD$138.30 respectively) for a GP to assess and prepare a management plan for a patient who has mental illness.

2. Review of a GP Mental Health Treatment Plan - MBS item 2712

Rebate (AUD$73.95) for a GP to review patients with a GP Mental Health Treatment Plan.

3. GP Mental Health Treatment Consultation - MBS item 2713

Rebate (AUD$73.95) for a GP for the ongoing management of patients with a mental disorder including patients being managed with or without a GP Mental Health Treatment Plan.

type 2 diabetes (yes vs no), systolic BP (SBP) (120–129, 130–139, ≥140 vs <120 mmHg), TC (3.4–3.9, 4–4.8, ≥4.9 vs <3.4 mmol/L), BMI (morbid, obese, overweight, underweight vs healthy) and alcohol intake (yes vs no). When analysing the receipt of mental health items only patients diagnosed with mental health issue were included. All statistical tests were two-tailed with the significance level set at 0.05. All statistical analyses are conducted using SAS version 9.4 (SAS Institute Inc, Cary, NC, USA).

Results

Data for 14,601 patients with CVD were extracted from the 50 participating primary care practices, of whom 8,842 (61%) were male. Demographic and clinical characteristics of all female and male patients with CVD are presented in Table 1. A similar proportion of women and men visited the primary care practice at least three times in the previous 24 months (94% vs 93%). Women, compared to men, were slightly older (mean, [SD]:75 [14] vs 71 [12]), had a higher mean (SD) TC (4.6 [1.18] vs 4.0 [1.05]). However, women were less likely to have had diabetes (18% vs 23%) and fewer women than men had a BMI >24.9 kg/m2 (70% vs 81%) (Table 1). Overall, women were more likely to attend their primary care practices for brief (80% vs 76%, p<0.0001), long (68% vs 64%, p<0.0001) and extended (19% vs 16%, p<0.0001) consultations compared to men. However, women were less likely to have standard length consultations (82% vs 86%, p<0.0001) than men.

Provision of Chronic Disease Management Plans

Results for MBS item claims amongst men and women are presented in Table 2. Of the total cohort, 44% (both men and women) with CVD had a claim for "Preparation of GPMP" and women were more likely than men to have one prepared (p=0.0004). Twenty-nine per cent (29%) of the total cohort received both a GPMP and a review. Results were similar for "Coordination of Team Care Arrangement (TCA)" (p<0.0001) and "Review of a GPMP or TCA" (p=0.0086) where women were more likely to receive both these items than men. After adjusting for demographic and clinical factors, the difference in the proportion of women and men receiving CDMPs remained significant (Table 3). The odds of women receiving a GPMP were 22% greater than men. The odds of women receiving a TCA and review were 23% and 16% more than men, respectively (Table 3).

Provision of Mental Health Treatment Consultations

In total, 25% of the total CVD cohort were documented as having a mental health issue. Women were more likely to have a mental health issue diagnosis compared to men (32% women vs 20% men). Of those diagnosed with mental health issues, only 13% of the cohort received a 'Preparation of a GP Mental Health Treatment Plan' and there was no significant difference in the receipt of the preparation between women and men (p=0.3749). Similarly, there was no difference in the

Table 1 Demographic and clinical characteristics of the cohort with established CVD by gender.

Variable	Female (n=5,759)	Male (n=8,842)	Total (n=14,601)	*Missing Value*	P-value
Age, mean (SD) (yr)	74.6 (13.54)	71.2 (11.96)	72.5 (12.72)	0	<0.001
Indigenous, *N* (%)	151 (3)	189 (3)	340 (3)	2,184 (15)	0.0430
Diagnosis of diabetes, *N* (%)					
Type 1	71 (1)	92 (1)	163 (1)	0	0.2796
Type 2	1,062 (18)	2,016 (23)	3,078 (21)	0	<0.0001
Cardiovascular risk factors					
SBP (mm Hg), mean (SD)	132.8 (18.98)	131.7 (19.66)	132.1 (19.41)	633 (4)	0.0006
DBP (mm Hg), mean (SD)	74.9 (32.09)	74.8 (29.91)	74.9 (74.9)	634 (4)	0.8402
Total cholesterol (mmol), mean (SD)	4.6 (1.18)	4.0 (1.05)	4.2 (1.14)	1,292 (8)	<0.0001
HDL (mmol), mean (SD)	1.5 (0.42)	1.2 (0.33)	1.3 (0.39)	1,840 (12)	<0.0001
LDL (mmol), mean (SD)	2.4 (1.02)	2.1 (0.89)	2.2 (0.95)	1,970 (13)	<0.0001
BMI >24.9 kg/m^2, *N* (%)	3,135 (70)	5,618 (81)	8,753 (76)	3,079 (21)	<0.0001
Current smoker, *N* (%)	532 (10)	984 (12)	1,516 (11)	0	0.0012
Alcohol drinker, *N* (%)	1,676 (44)	4,050 (66)	5,726 (57)	4,588 (31)	<0.0001
HbA1c for those with diabetes, mean (SD)	7.5 (7.05)	7.6 (7.34)	7.6 (7.23)	6,269 (42)	0.4217
Mental health issue diagnosis	1,852 (32)	1,760 (20)	3,612 (25)	N/A	<0.0001
Active patients					
>3 visits in last 2 yr, *N* (%)	5,334 (93)	8,299 (94)	13,633 (93)	968 (7)	0.0013

P-values are the difference between male and female.

Abbreviations: SD, standard deviation; SBP, systolic blood pressure; DBP, diastolic blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; BMI, body mass index; HbA1c, glycosylated haemoglobin; CVD, cardiovascular disease.

receipt of 'Review of a GP mental health treatment plan' and 'mental health treatment consultations' between women and men (p=0.4182 and p=0.4524 respectively) (Table 2). Even after adjustment, no difference was observed in the receipt of all mental health treatment items between the two genders (Table 3).

Prescription of the Guideline-Recommended Cardiovascular Medications

Of the total cohort, the proportions of women and men prescribed recommended medications are presented in Table 2. When comparing individual medication groups, women were less likely to receive guideline-indicated medications compared to men (Table 2). However, after adjustment for clinical and demographic characteristics, the difference in the prescribed BP and lipid-lowering medications amongst women and men was no longer significant but the odds of women receiving antiplatelet medications were 16% less compared to men (Table 3).

Discussion

This study provides a gender comparison of the provision of government-funded CDMPs and mental health care to a large CVD cohort seeking care from Australian primary care practices. Our results show that women with CVD were more likely to receive CDMPs than men, but receipt of mental health care was similar in both men and women when attending primary care practice. Women were less likely to receive guideline-indicated antiplatelet medications compared to men, however, there was no difference in the proportion prescribed BP and lipid-lowering medications. Importantly, we found that only 44% of the cohort received a GPMP and 29% of the cohort received both GPMP and a review in the previous 12 months. We also found there was no gender difference in the receipt of mental health treatment consultations for those diagnosed with mental health issues, however it was suboptimal in both genders. The results reflect an evidence-practice gap in the management of CVD in primary care. Increased use of available CDMPs in primary care has the potential to reduce this gap and CVD burden by enabling GPs to coordinate multidisciplinary care for eligible patients along with access to several allied health care services [20]. The use of CDMPs also reminds GPs to complete annual risk factor assessment and health check-ups of eligible patients therefore creating systematic management of these patients. This cost-effective approach supported by Medicare reimbursements and financial incentives can yield better clinical outcomes of CVD in primary care [21].

A limited number of previous studies have also explored the use of health services in primary care. Our study found that a similar proportion of men and women sought health care services from their primary care despite some evidence showing women visiting their GPs more frequently than men

Table 2 Receipt of government-funded health services (MBS items) and guideline-indicated prescribed medications in the cohort with established CVD by gender in primary care.

	Female (n=5,759)	Male (n=8,842)	Total (n=14,601)	P-value
Components of Chronic Disease Management Plans				
Preparation of GPMP	2,621 (46)	3,761 (43)	6,382 (44)	0.0004
Coordination of TCA	2,281 (40)	3,217 (36)	5,498 (38)	<0.0001
Review of GPMP or TCA	2,076 (36)	3,000 (34)	5,076 (35)	0.0086
Mental Health and Psychology Items				
Preparation of a GP Mental Health Treatment Plan[a]	230/1,852 (12)	236/1,760 (13)	466/3,612 (13)	0.3749
Review of a GP Mental Health Treatment Plan[a]	87/1,852 (5)	93/1,760 (5)	180/3,612 (5)	0.4182
Mental Health Treatment Consultation[a]	197/1,852 (11)	201/1,760 (11)	398/3,612 (11)	0.4524
Guideline Recommended Prescribed Cardiovascular Medication				
BP-lowering medication	3,812 (66)	6,167 (70)	9,979 (68)	<0.0001
Lipid-lowering medication	2,989 (52)	5,528 (63)	8,517 (58)	<0.0001
Antiplatelet medication	2,508 (44)	4,495 (51)	7,003 (48)	<0.0001

Abbreviations: MBS, Medicare Benefits Scheme; GP, general practitioner; GPMP, General Practice Management Plan; TCAs, Team Care Arrangements; BP, blood pressure.
[a]Denominator: those who had mental illness listed as a condition.

Table 3 Multiple-adjusted female to male ORs and 95% CIs for the receipt of MBS items and guideline-recommended prescription medications in the cohort with established CVD.

Outcomes	Odds Ratio (95% confidence interval)	P-value
Preparation of GP Management Plan (GPMP)	1.22 (1.12, 1.34)	0.0012
Coordination of Team Care Arrangement (TCA)	1.23 (1.13, 1.34)	0.0005
Review of GPMP or TCA	1.16 (1.05, 1.28)	0.0117
Mental health treatment consultation[a]	0.91 (0.71, 1.18)	0.5268
Preparation of a GP mental health treatment plan[a]	0.95 (0.73, 1.24)	0.7035
Review of a GP Mental Health Treatment Plan[a]	0.74 (0.5, 1.1)	0.1716
Blood pressure lowering medication	0.97 (0.87, 1.08)	0.5694
Lipid lowering medication	0.93 (0.87, 1)	0.0849
Antiplatelet medication	0.84 (0.76, 0.94)	0.0176

Adjusted for age groups (4 groups), Indigenous status, current smoker, type 2 diabetes, SBP (4 groups), TC (4 groups), BMI categories and alcohol consumption.
Abbreviations: BMI, body mass index; SBP, systolic blood pressure; GP, general practitioner; TC, Team Care; TCA, Team Care Arrangements.
[a]Denominator: those who had mental illness listed as a condition.

[12]. Gender difference in care-seeking behaviour and health care utilisation has been previously explored, therefore, the present study is one of the first to look at gender differences in receipt of government-funded items for both mental health issues and CVD. Although the use of CDMPs in primary care has been explored previously in other chronic diseases, including diabetes [22], limited research explored the gender-based receipt [23,24]. Whilst our study suggests that women are more likely to receive CDMPs, including GPMP, a previous study looking at utilisation of government-funded schemes has found that gender was not a significant factor associated with the receipt of GPMP [25]. However, both studies indicate that there is an opportunity to increase the overall use of the government-funded services in relation to both genders with CVD which offers an opportunity for optimising care and closing evidence-practice gaps through quality improvement.

Currently, there are many international guidelines available for better management of chronic disease and secondary prevention that include recommendations to prescribe evidence-based medications, risk factor management, lifestyle modification, and screening for other comorbidities such as psychosocial factors and education [26,27]. Further, according to a systematic review conducted on comprehensive primary health care models, patients who received CDMPs had an improved understanding of the disease and management as well as enhanced quality of care. General practitioners also reported increased satisfaction from patients receiving care [28]. Our study results show that less than half of the cohort claimed CDMPs for management of

CVD despite the evidence-based benefits of such initiatives aimed at improving prevention of chronic diseases such as CVD, patient self-management and decreased hospital admission [10,29].

Despite the knowledge of mental health issues having a negative effect on CVD events, the available government-funded mental health care appears to be underutilised in primary care practices. There is also evidence of improved health outcome for patients with depression, diabetes, and coronary artery disease who received a more structured guideline-recommended multidisciplinary treatment in primary care [30]. Depression and anxiety can lead to unhealthy eating, smoking, alcohol consumption, and lack of physical activity [3]. Screening of mental health along with CVD and use of available mental health care plans can help with early detection and management of depression, anxiety and other mental health issues, encourage positive behaviour changes, adherence to prescribed medications, thus reducing further risk [3]. Despite recommendations, our study found that only about one in 10 people diagnosed with CVD receives MBS funded mental health consultations from primary care providers. Similarly, another study found that many patients presented to primary care practices with depression and anxiety symptoms but did not receive psychological assessment during their visit [22]. Our study results indicate the use of available mental health items are underutilised in primary care. Multiple barriers including stigma, feeling unwelcome and the existence of mental health issues often overtaking other health care needs contribute to people not seeking appropriate health care [4]. Overall, it appears there is substantial scope to increase the provision of appropriate funded CVD and mental health care by primary care practices [4].

Although the guideline-indicated medications for secondary prevention of CVD are subsidised by the government, the proportion of recommended medications prescribed to both women and men is still low. Our study results show that in general, there was no significant difference in the prescription of BP and lipid-lowering medications between male and female patients, however, women were less likely to be prescribed antiplatelet medications compared to men. Other studies found that gender difference exists in the prescription of cardiovascular medications after an event [31] but in the present cohort the women tended to be slightly older and we were unable to control for 'over-the-counter' antiplatelet medication purchases. A systematic review demonstrated a low prescription of antiplatelet, lipid-lowering and BP medications in women diagnosed with CVD or at high CVD risk compared to men [14]. Another observational study found differences in medication prescription varied largely due to age groups, where younger women were less likely and older women were more likely to be prescribed the recommended medications than their male counterparts [15].

Our study has a number of limitations. Although only 50 primary care practices were recruited for the QUEL study, there was a good representation of both urban and rural practices from four out of the eight Australian states and territories with large population density. Also, the study population was limited to regular attendees, and hence patients attending sporadically or less frequently may not be represented. CVD was defined according to the coding of the general practice software that included a wide range of conditions including all hypertension. Data were dependent on recording in general practice software and did not include unprescribed antiplatelets (e.g., aspirin purchased from supermarkets). Also, we were unable to analyse any gender-specific bleeding risk factors associated with prescription of aspirin as these data were not recorded in the GP system. Another limitation was the inability to specifically identify contraindication to all medications from the de-identified data set. Although our study population had a documented diagnosis of CVD, it was not possible to individually assess whether the use of CDMP items was specifically for CVD or other co-existing chronic conditions. However, it is ideal for patients with CVD to receive these as they help to coordinate multidisciplinary management and facilite annual health checks [5]. The quality of the recorded medical management data would vary between practices and the GPs entering data into the software. In particular, despite the evidence of their role and effectiveness, the involvement of mental health and primary care practice nurses in providing mental health assessment and intervention was not measured [32,33].

Conclusion

In our cohort of patients with CVD, more women than men received CDMPs and mental health treatment consultations in Australian primary care practices. Women were less likely to receive prescription of antiplatelet medication, but gender discrepancies were not found in the prescription of BP and lipid-lowering medications. Overall, the receipt of subsidised health services and guideline-indicated medications was suboptimal for both women and men. Increasing our understanding of the utilisation of the currently available benefits and services for people living with CVD could inform opportunities for system-level improvements that may also influence outcomes.

Conflicts of Interest

None.

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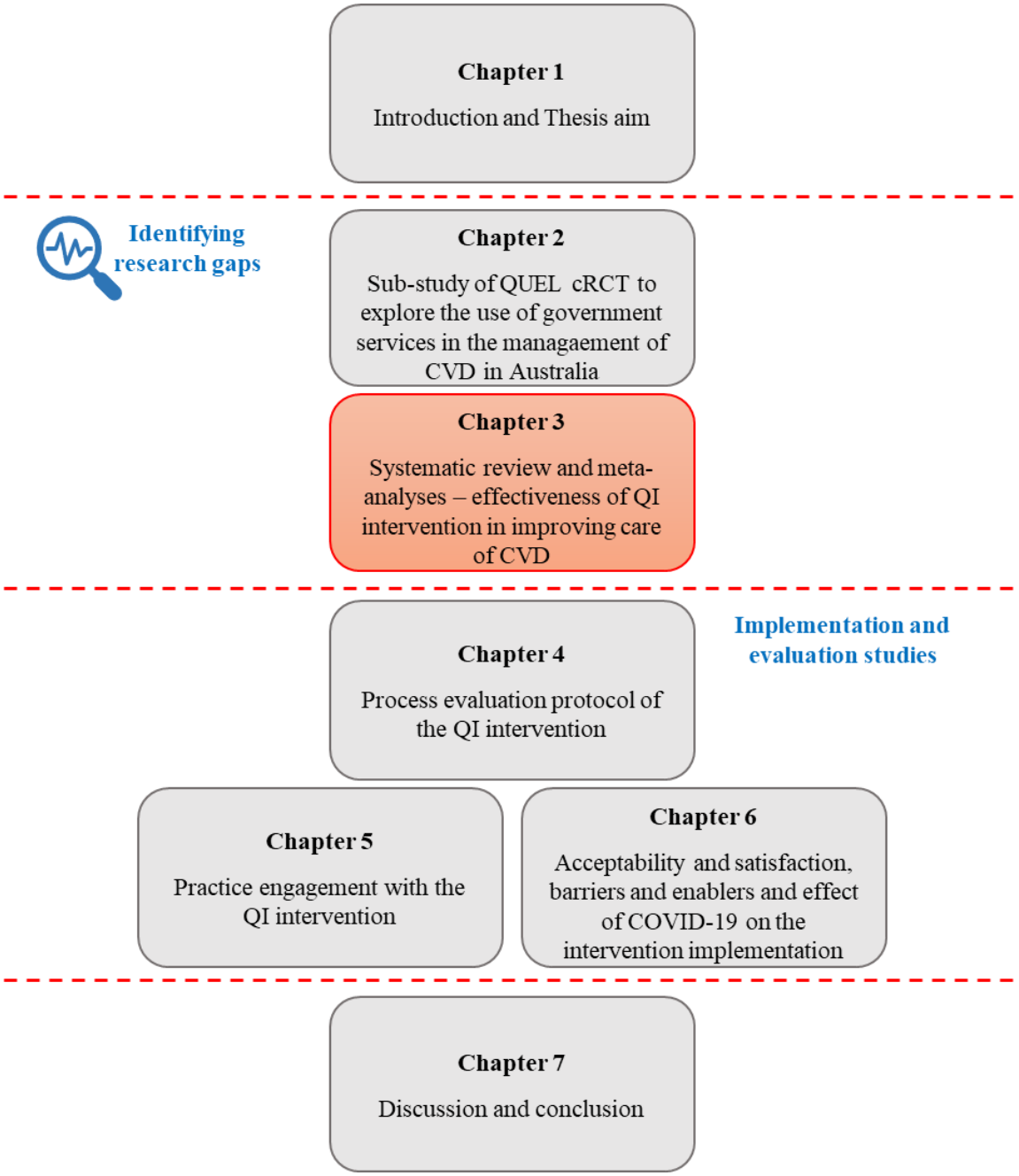
CHAPTER THREE

Effectiveness of quality improvement interventions in improving cardiovascular disease-related outcomes: A systematic review and meta-analysis



PREFACE TO THE CHAPTER

Chapter Two identified an overall underutilisation of government-funded chronic disease management plans and prescription of guideline-recommended medications in patients with CVD. It also found disparities between men and women in receiving these services and that better use of existing services could improve ongoing management of CVD. As a result, healthcare settings are implementing new, innovative and multi-dimensional quality improvement strategies to ensure improved use of these services, thereby improving the management of all patients with CVD. Chapter Three presents' findings from a systematic review with meta-analyses to understand the effectiveness of various quality improvement interventions used across all healthcare settings for improving management of CVD. This chapter addresses Aim Two of the Thesis where information will be useful in understanding what strategies are effective. This systematic review titled "Effectiveness of Quality Improvement interventions in improving cardiovascular disease-related outcomes: A systematic review and meta-analysis" has been submitted to the BMC Primary Care journal for publication. All supplementary materials used are included after references of this chapter.

PEER-REVIEWED PUBLICATIONS AND PRESENTATIONS

Manuscript submitted

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STATEMENT OF AUTHORSHIP

Nashid Hafiz, during her PhD candidature, developed the systematic review concept, developed the searched strategy, ran the literature search, determined study inclusion and exclusion, extracted, and analysed data, prepared the initial draft and subsequent revisions, responded to reviewers' feedback, and coordinated submission and publication of the original research paper.

The individual roles of co-authors are listed below:

Task Role of co-authors	**Role of co-authors**
Refining the research question	NH, KH, JR, QT
Data collection and analysis	NH, QT, KH, DM
Revision and Critical comments on manuscript	KH, QT, DM, TU and JR

Nashid Hafiz 30th April 2024

As supervisor for the candidature upon which this Thesis is based, I can confirm that the authorship attribution statement above is correct.

Professor Julie Redfern 30th April 2024

Effectiveness of Quality Improvement interventions in improving cardiovascular disease-related outcomes: A systematic review and meta-analysis.

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ABSTRACT

Objectives To systematically assess the effectiveness of quality improvement (QI) interventions in improving cardiovascular disease (CVD) related outcomes.

Design Systematic review and meta-analysis.

Data sources Medline, Embase, PsycINFO, CENTRAL, CINAHL, and Scopus (from inception to 27 June 2022).

Methods Studies were included if they were randomised trials, included people with CVD, implemented a QI intervention focused on improving CVD care, and measured at least one of the following outcomes: prescribed guideline-recommended CVD medications, risk factors, and clinical events. Databases were systematically searched for randomised and cluster-randomised controlled trials and two authors independently screened articles and extracted data from eligible studies. A random-effects model was used to estimate the pooled effects.

Results Thirteen studies were included with 430,132 people with CVD, with 73% male and a pooled mean age (standard deviation) of 67.2 (11.4). The review identified several QI strategies commonly being used, including feedback reports, decision support tools, healthcare providers' training, practice support and site visits to improve care provided to patients with CVD. Meta-analysis demonstrated that, compared with usual care, QI interventions significantly reduced the rate of major cardiovascular events (MACE) (OR: 0.84, 95% CI: 0.72, 0.98) and total mortality (OR: 0.88, 95% CI: 0.78, 0.99). There was no significant improvement in the prescription of guideline-recommended medications, including antiplatelets (OR: 1.24, 95% CI: 0.92, 1.67) and lipid-lowering (OR: 1.27, 95% CI: 0.95, 1.70), angiotensin-converting enzyme inhibitors or angiotensin receptor blockers (OR: 1.17, 95% CI: 0.91, 1.51), beta-blockers (OR: 1.27, 95% CI:0.94, 1.73), and smoking cessation advice (OR: 1.30, 95% CI: 0.75, 2.27) as a result of QI interventions.

Conclusion QI interventions have the potential to improve the management of CVD in primary care when implemented effectively. Further studies are required to fully evaluate the effectiveness of QI interventions using a variety of QI strategies in healthcare.
Systematic Review Registration: PROSPERO registration number: CRD42016047604.

Keywords: Quality improvement, primary care, cardiovascular health, secondary prevention, cardiovascular disease.

INTRODUCTION

Cardiovascular disease (CVD) remains one of the leading causes of death and disease burden globally.[1] To reduce the burden, healthcare facilities globally have been increasingly adopting new, innovative strategies targeted to improve secondary prevention of CVD. Secondary prevention strategies include but are not limited to screening, diagnosis, increased adherence to guideline-recommended medications, risk factor assessment and management, among others.[2,3] Evidence from previous research found that increased adherence to guideline-recommended medications was associated with an 8% reduction in CVD events and a 12% reduction in all-cause mortality in people with coronary arterial disease.[4] Furthermore, previous research also found that effective management of risk factors not only slows the onset of CVD but also mitigate the risk of disease progression and related events and deaths.[5,6]

Moreover, the integration of electronic health records in healthcare settings enables healthcare providers to seamlessly record, analyse and extract data to help facilitate accelerated decision-making and treatment processes.[7,8] Therefore, healthcare providers can monitor patient more efficiently and potentially improve patient outcomes with the support of electronic health records. However, the use of electronic health records faces several challenges, including,

limitations in data sharing[9], suggesting the need for improving its efficiency across all healthcare settings.[10] As healthcare continues to evolve, the performance of healthcare systems in ensuring patient safety, improving efficiency, and addressing patient needs is often suboptimal.[11] Consequently, healthcare facilities are increasingly adopting QI strategies driven by data to enhance clinical outcomes. These strategies provide a systematic and coordinated effort leading to meaningful changes that not only improve health outcomes but also enhance organisational performance.[12] Therefore, more robust evaluation of such interventions in needed to fully evaluate their effectiveness in improving care of chronic diseases, including CVD.

While several studies have already demonstrated the effect of QI interventions in improving health and service-related outcomes across various healthcare conditions[13,14], persistent limitations contribute to a lack of robustness in the results. A systematic review evaluating a variety of trial designs found that low-quality methodologies and variations in the interventions have impacted the efficacy of QI collaboratives.[15] Furthermore, when evaluating the effect of QI interventions on CVD outcomes, several studies demonstrated mixed findings.[16,17] Therefore, this systematic review and meta-analysis aimed to examine the effect of QI interventions on prescription of guideline-recommended CVD medications, risk factor management and clinical events on improving CVD management across different healthcare settings.

METHODS

The review and meta-analysis were conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis guidelines (Supplementary material 1).[18,19] The review was registered in PROSPERO (CRD42016047604).

Data sources and search strategy

Six databases were systematically searched: Medline, Embase, and PsycINFO via OvidSP, Cochrane Central Registry of Controlled Trials, CINAHL, and Scopus from inception to 27th June 2022. A combination of search terms including 'CVD', 'CVD risk factors' 'medications' and 'quality improvement' were used to search the databases. Schouten and colleagues' search process was used as reference for QI search terms and supplemented it with additional terms to encompass a broader range of QI methods.[15] The full electronic search strategy for each database is available in Supplementary material 2. Manual searches of the reference lists of all previous and relevant studies were also conducted.

Study inclusion and exclusion criteria

Studies were included that met all of the following criteria according to PICOS (Patient, Intervention, Comparison, Outcome, Settings) framework: (1) randomised controlled trials (RCTs) or cluster-randomised controlled trials (cRCTs); (2) included people with CVD; (3) implemented a quality improvement intervention focused on improving CVD care; and (4) measured at least one of the following outcomes: (i) prescribed guideline-recommended CVD medications (ii) CVD risk factors or (ii) clinical events. Studies were excluded if they were conference abstracts, reports, reviews, letters, and editorials.

Study selection

Search results were exported to Endnote X9 reference management software program. Following duplicate removal, two researchers (NH and QT) independently screened and excluded the articles by reviewing the titles and abstracts against inclusion and exclusion criteria. The remaining studies underwent full-text review and were assessed according to the

inclusion and exclusion criteria by NH and QT. References from retrieved articles were manually searched for potentially eligible papers. Any discrepancies were resolved through discussion with a third researcher (KH).

Data extraction

Data extraction was performed independently by two assessors (NH and QT) using a electronic data extraction table based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.[19] Data extraction included (i) study and participants characteristics; (ii) intervention and follow-up durations; (iii) intervention and usual care group details; (iv) outcomes; and (v) Cochrane Risk of Bias measures. Any disagreements were solved through consultation with a third researcher (KH). Data were randomly checked for accuracy by a fourth researcher to reduce errors.

Risk of Bias

Risk of bias of each included study was assessed independently by two reviewers (NH and QT) using the Cochrane risk of bias tool.[20] The assessment included the following four domains: (i) random sequence generation; (ii) allocation concealment; (iii) incomplete outcome data; and (iv) selective outcome reporting. Blinding of participants and personnel and outcome assessment was not included in the assessment due to the challenge of blinding in QI interventions.

Outcomes

The outcomes were guideline-recommended CVD medication prescriptions, risk factors management and clinical events. More specifically, guideline-recommended medications were prescription of antiplatelet therapy, lipid-lowering medications, angiotensin-converting

enzyme inhibitors (ACEi) or angiotensin receptor blockers (ARB) and beta-blockers.[2,21] The outcomes for risk factor management were proportions of adequate control of blood pressure (BP) (i.e. systolic blood pressure [SBP]: <140 mm hg or SBP/ diastolic blood pressure [DBP]: <140/<90 mm hg)[21,22]; adequate control of cholesterol (i.e. total cholesterol: <5 mmol/l or LDL-C: <2.5 mmol/l)[21,23]; and smoking cessation advice (i.e. counselling, advice or support for cessation) among smokers.[21,24] The clinical events assessed were major cardiovascular events (MACE), defined as cardiovascular deaths, strokes, reinfarctions or major bleeding,[25] and all-cause mortality.

Statistical analysis

Overall mean age and corresponding standard deviation (SD) and number and percentage of male patients were pooled where data were available. All outcomes of interest were categorical in distribution. Where three or more studies measured the same outcome, they were pooled using a random effects meta-analysis. All outcomes of interest were categorical in distribution. For meta-analysis, the majority of the studies reported the effect size as odds ratio (OR) and 95% confidence interval (CI), therefore the pooled effect size was also reported as odds ratio. Where studies reported hazard ratios or only the number of events per arm, the ORs were estimated. Consistency of the results across the included studies was assessed by forest plots and the statistical heterogeneity between studies was assessed using tau^2, the I^2 statistic and χ^2 test.

The majority of included studies presented outcomes at patient level, however, three studies presented results at the cluster level. The cluster-level outcomes were excluded from the meta-analysis but the results were described in text. Also, studies with missing information or different outcome measures were included in the systematic review through narrative

synthesis. A subgroup analysis based on the settings (hospital vs GP or outpatient clinics) was performed. Sensitivity analysis was performed excluding the studies with high risk of bias to assess the robustness of the intervention effect. Publication bias was assessed by visual inspection of funnel plots and Egger's test for each pooled outcome. Meta-analyses were performed using the Comprehensive Meta Analysis (CMA) version 4.0 software.[26]

Public and patient involvement

Public and patient involvement was not reported in any of the included studies. This research is supported, in kind, by the QUEL partnership project. Stakeholders from the QUEL partnership project, along with clinicians provided guidance in the study design, development, outcome measures and other aspects of the review.

RESULTS

Study Selection

The PRISMA flowchart for study selection is presented in Figure 1. A total of 2,661 studies were initially identified through electronic database searches and thirty-two studies through grey literature searches. After excluding duplicates, a total of 1,879 titles and abstracts were screened. After screening of titles and abstracts, a total of 285 potentially relevant articles were retained for full-text screening. After full-text assessment, 13 eligible studies were eligible for the systematic review and meta-analysis (Table S1 in Supplementary material 3).

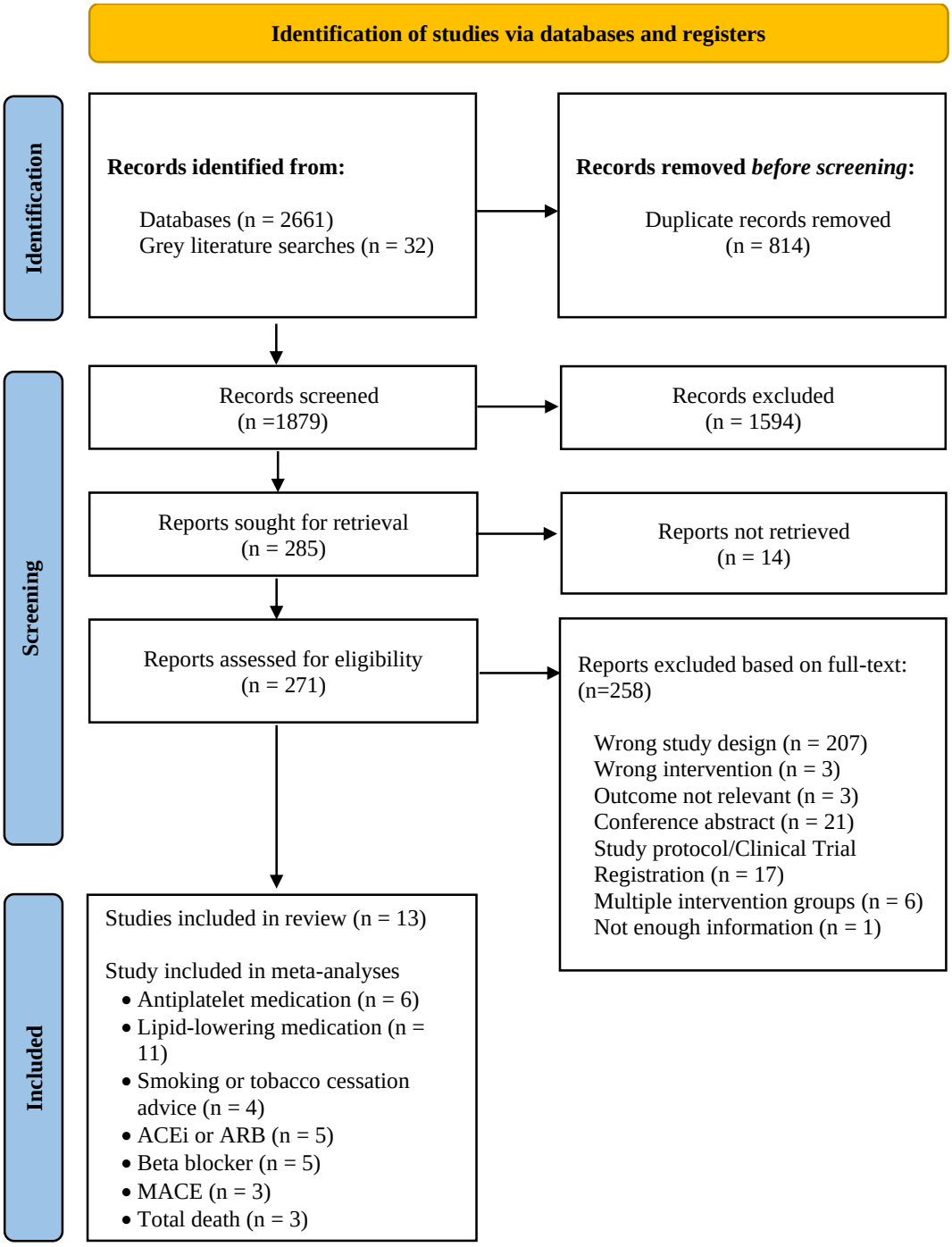


Figure 1. The PRISMA flow diagram of study selection. *ACEi* - Angiotensin-converting enzyme inhibitor, *ARB* - Angiotensin receptor blockers, *MACE* - Major adverse cardiovascular events

Study characteristics

Characteristics of the 13 included studies are summarised in Table 1. The studies were published between 2003 and 2021 and were conducted across 12 countries including United States (n=3)[27-29], European countries including United Kingdom (n=6)[30-35], China (n=2)[36,37], Brazil (n=1)[38], and India (n=1).[39] Nine studies were conducted in high-income countries[27-35], three in upper-middle-income countries[36-38], and one in lower-middle-income country.[39] Six studies were conducted in hospitals[28-30,36,37,39] and seven in GP or outpatient clinics.[27,31-35,38] One study did not report the number of patients recruited. Overall, 430,132 (26,677 from GP or outpatient clinics and 403,455 from hospitals) patients were enrolled with a pooled mean age (pooled SD) of 67.2 (11.4) and 73% of the participants were male. Nine studies were cRCTs[28-31,33,34,36-38], three were RCTs[27,32,35] and one was step-wedged cRCT.[39] Eleven studies reported outcomes at individual patient level[27,28,30,32-39] and two studies reported the outcomes at cluster level.[29,31]

The median number of participating hospitals was 48 (IQI: 39, 61). Hospital-based QI interventions targeted a wide variety of populations with CVD. The median number of participating clinics was 45 (IQI: 37, 154). Clinic-based QI interventions, in addition to the hospital-based population, included all adult patients, CVD risk factors, heart failure, Atherosclerotic Vascular Disease and peripheral arterial disease. The studies focused on improving adherence to evidence-based guidelines for secondary management of CVD, prescription of guideline-recommended CVD medications, clinical decision making, risk factor management and CVD-related performance measures.

Table 1: Characteristics of included studies

Author, Year	Country	Setting	Study design	Study population (N; intervention n: control n)	No of GP practices or Hospitals, N; intervention n: control n	Mean Age (SD)	Male (%)	Outcome relevant to this review
Flather, 2011	France, Italy, Poland, Spain and UK	Hospitals	cRCT	ACS patients (1403; 819:587)	38; 19:19	65.4 (10.7)	981 (69.9)	Prescription of - ACEi - Beta-blocker - Clopidogrel - Statins
Frijling, 2003	Netherlands	GP or outpatient clinics	cRCT	Risk factors and HF (5229; 2653:2567)	124; 62:62	NR	NR	Prescription of aspirin and sublingual nitrate prescriptions
Geary, 2019,	Sweden	GP or outpatient clinics	RCT	TIA or ischemic stroke (12,766; 6408:6358)	207; 104:103	73.1 (12.5)	6894 (54.0)	Prescription of - Antiplatelets - Statins
Goff, 2003	USA	GP or outpatient clinics	RCT	CHD (705; 423:282)	184; 97:87	56 (20-81)	543 (77.0)	Prescription of - ACEi. - Beta-blockers - HMG-CoA reductase inhibitors,
Huffman, 2018	India	Hospitals	Stepped-wedged cRCT	AMI Patients (22,557;10,066:11,308)	63	60.6 (12.0)	16,183 (71.7)	Prescription of - ACEi or ARB - Aspirin - Beta-blockers - Statin

								Smoking cessation advice MACE Mortality
Johnston, 2010	USA	Hospitals	cRCT	Ischemic stroke (3361; 1464:1897)	12; 6:6	73 (12.6)	1581 (47.0)	BP control <140/90 for all patient Prescription of statin
Lowrie, 2014	UK	GP or outpatient clinics	cRCT	ASCVD (4039: 2372:1667)	31; 16:15	68.3 (12.1)	2097 (51.9)	Prescription of statins
Machline-Carrion, 2019	Brazil	GP or outpatient clinics	cRCT	CAD, Ischaemic stroke or PAD (1619; 726:893)	42; 18:22	65.6 (10.6)	1029 (63.5)	Prescription of - ACEi or ARB - Antiplatelets - Beta-blockers - Statins Risk factors - BP <140/90 - LDL - C levels <70 mg/dL at 12 months Smoking cessation advice MACE Total mortality
Nouwens, 2014	Netherlands	GP or outpatient clinics	cRCT	CVD (1685; 799:886)	45; 22:23	69.1 (11.9)	1044 (61.9)	Prescription of - Aspirin or an alternative antiplatelet therapy - Statin Systolic BP <140 mmHg. LDL-C <2.5 mmol/l

								Smoking cessation advice
Qu, 2021	China	Hospitals	cRCT by provider	CABG (10,006; 5653:4353)	55; 26:29	62.7 (8.8)	7599 (75.9)	Prescription of - ACEi or ARB - Beta-blockers - Statins
Sondergaard, 2006	Denmark	GP or outpatient clinics	RCT	IHD (634; 350:284)	30; 15:15	NR	379 (59.7)	Prescription of - ASA - Lipid-lowering medications Smoking cessation advice
Wang, 2018	China	Hospital	prevention of IHD in general practice	AIS (4800; 2400:2400)	40; 20:20	NR	3043 (63.3)	Prescription of lipid-lowering medication MACE All-cause mortality
Williams, 2011	USA	Hospitals	cRCT	CABG (361,328)	458; 224:234	NR	271,357 (75.1)	Prescription of - ACEIs - ASA, - Beta-blockers - Lipid-lowering agents

ACEi - Angiotensin-converting enzyme inhibitors, ACS - Acute coronary syndrome, AIS - Acute ischemic stroke, AMI - Acute myocardial infarction, ARB - Angiotensin receptor blockers, ASA - Acetylsalicylic acid, ASCVD - Atherosclerotic vascular disease, BP - Blood pressure, CABG - Coronary artery bypass graft, CAD - Coronary arterial disease, CHD - Coronary heart disease, cRCT - cluster-randomised controlled trial, CVD - Cardiovascular disease, HF - Heart failure, IHD - Ischemic heart disease, LDL-C - Low-density lipoprotein cholesterol, MACE - Major adverse cardiovascular event, PAD - Peripheral arterial disease, RCT - Randomised controlled trial, TIA - Transient ischemic attack,

QI interventions

All 13 studies implemented complex, multicomponent QI interventions and used a combination of strategies to improve CVD management (Data supplement 3). The median duration of the intervention was 13.5 months (IQI: 12, 20.5). The most commonly used QI strategy was feedback reports provided to participating healthcare providers, which were used in 92% (n=12) of the studies.[27-29,31-39] Among the 12 studies using feedback reports; seven studies compared their performance with other sites in the intervention arm or against regional and national level data.[27,29,32,34,35,37,39] Another commonly implemented QI strategy was the use of different decision support tools by the healthcare facilities including care reminder, treatment protocols, checklists, clinical guidelines and recommendations, pocket cards, standardised admission, and discharge orders (69%, n=9).[27-29,32,35-39]

Additional QI strategies included practice support or facilitation in 46% (n=6).[28,31-34,37] QI workshops, seminars or webinars for healthcare providers was used in 38% (n=5) of the studies[28,30,36-38], use of physicians as local champions or quality coordinators in 46% (n=6)[28-30,36-38], establishment of QI teams in 38% (n=5)[28,30,36,37,39], and site visits in 30% (n=4)[31,33,35,38] of the studies. Digital platforms such as online portals and online text messaging platforms were used by 30% (n=4)[30,32,36,37] and Plan-Do-Study-Act cycles were used by 15% (n=2) of the included studies.[30,39] Two studies (15%) used regular team meetings[30,39], one study awarded certificates to GPs for six hours of accredited training[31], while another provided certificates to participating sites[34] for their participation in the QI intervention. To ensure effective implementation of interventions, six studies (46%) provided training for team members prior to the study.[28,30,31,33,36,39]

Risk of bias assessment

Figures 2 and 3 summarises the risk of bias assessment for included studies. Four out of 13 studies (31%) had an overall risk of bias judged as high.[27,32,34,35] Six studies (46%) were at low risk[28,33,36-39] and another three (31%) were judged as unclear risk of bias.[29-31] Random sequence generation and allocation concealment were described adequately in 12 (92%) and 11 (85%) studies, respectively. Eight studies (61%) were at low risk of attrition bias.[28,29,31,33,36-39] Nine studies (69%) were at low risk of selective reporting as they reported all expected outcomes in accordance with the protocol or trial registration.[27,28,30,33,34,36-39]

Publication bias

No significant publication bias was found from assessing funnel plots and Egger's regression test (Supplementary material 4).

Prescription of guideline-recommended medications

Eight studies (61.5%) measured the proportion of patients prescribed antiplatelet therapy and six studies were included in the meta-analysis. The pooled analysis showed that the QI intervention did not significantly improve the prescription of antiplatelet therapies compared to usual care (OR: 1.24, [95% CI: 0.92, 1.67]) with substantial heterogeneity ($Tau^2 = 0.087$, $I^2 = 77.38\%$, p=0.001; Figure 4.1).[30,32,34,35,38,39] Three studies had high risk of bias and a sensitivity analysis was performed on the remaining three studies.[32,34,35] The sensitivity analysis also showed non-significant improvement in the prescription of antiplatelet therapy (pooled OR: 1.46, [95% CI: 0.72, 2.95]) with substantial heterogeneity ($Tau^2 = 0.301$, $I^2 = 82.09\%$, $P = 0.004$; Figure 5.1).[30,38,39]

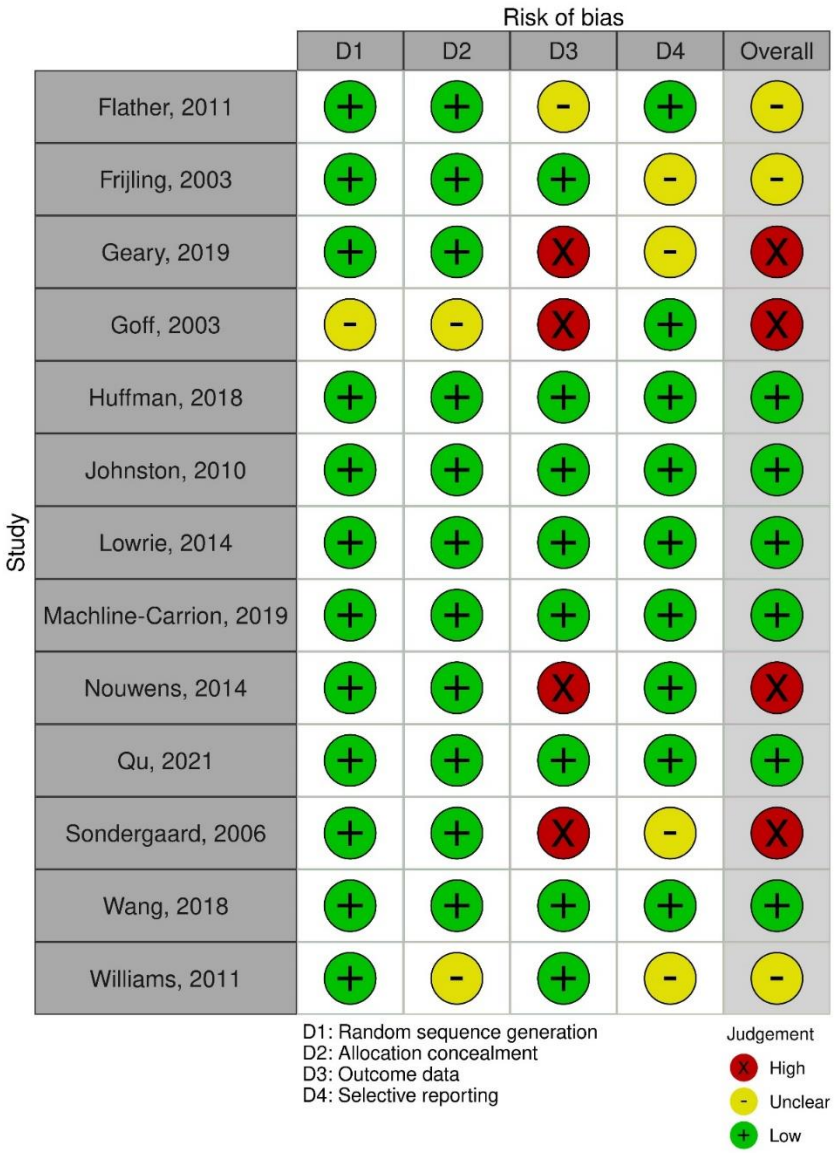


Figure 2. Risk of bias summary: risk of bias judgement on each domain by study

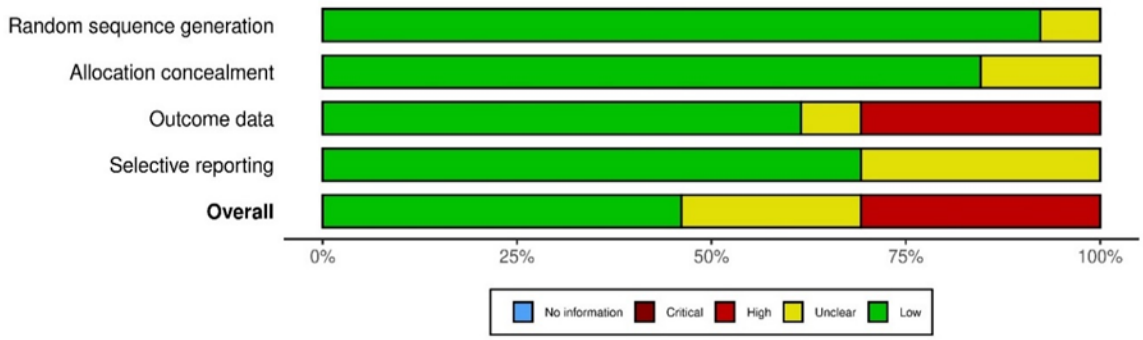


Figure 3. Risk of bias graph: judgement of risk of bias domains presented as percentages

Two studies were excluded from meta-analysis as they analysed cluster-level data. Frijling et al. measured the prescription of aspirin and sub-lingual nitrate and found similar results to the meta-analysis where the effect of the QI intervention on the outcome was not significant (OR:1.44, [95% CI: 0.86, 2.41]; Figure 5).[31] Williams et al. measured the difference between the mean change in prescription adherence score between the intervention and usual care groups was not significant (2.9% vs 4.2%, p=0.255).[29]

Twelve studies (92.3%) reported the proportion of patients prescribed lipid-lowering medications and 11 studies were included in the meta-analysis. The pooled analysis showed that the QI intervention did not improve the prescription of lipid-lowering medications compared to usual care (OR: 1.27, [95% CI: 0.95, 1.70]) with substantial heterogeneity (Tau^2 = 0.174, I^2 = 91.49%, p=0.000; Figure 4.2).[27,28,30,32-39] Four studies had high risk of bias[27,32,34,35] and therefore the sensitivity analysis was performed on the remaining seven studies. The sensitivity analysis showed significant improvement in the prescription of lipid-lowering medications (OR: 1.63, [95% CI: 1.34, 2.00]) with relatively low heterogeneity (Tau^2 = 0.019, I^2 = 28.43%, P = 0.211; Figure 5.2).[28,30,33,36-39] Results found by Williams et al. were not included in the meta-analysis as it analysed cluster-level data. Williams et al. measured the difference between the mean change in prescription adherence score between the intervention and usual care group and found that it was statistically significant (13.1% vs 15.7%; P=0.017).[29]

Six studies (46.1%) reported the prescription of ACEi/ ARB, and five of them were included in the meta-analysis. The pooled analysis showed that QI intervention did not improve the prescription of ACEi/ARB compared to usual care (OR: 1.17, [95% CI: 0.91, 1.51]) with moderate statistical heterogeneity (Tau^2 = 0.034, I^2 = 43.34%, p=0.133; Figure 4.3).[27,30,36,38,39]

One study had high risk of bias[27], therefore the sensitivity analysis was performed on the remaining four studies. However, the sensitivity analysis showed significant improvement in the prescription (OR: 1.37, [95% CI: 1.08, 1.73]) with no heterogeneity ($Tau^2 = 0.00$, $I^2 = 0.00\%$, $P = 0.869$; Figure 5.3).[30,36,38,39] Williams et al. measured the difference between the mean change in prescription adherence score between the intervention and usual care groups at cluster level, therefore the results were excluded from the meta-analysis. However, the study also reported a greater improvement in the intervention group compared to the control (13.1% versus 6.4%; P<0.001).[27]

Six studies (46.1%) reported the prescription of beta-blocker, and five of them were included in the meta-analysis. The pooled analysis showed that QI intervention did not improve the prescription of beta-blockers compared to usual care (OR: 1.27, [95% CI:0.94, 1.73]) with substantial statistical heterogeneity ($Tau^2 = 0.64$, $I^2 = 70.68\%$, p=0.009; Figure 4.4).[27,30,36,38,39] One study had high risk of bias[27], therefore the sensitivity analysis was performed on the remaining four studies. Conversely, the sensitivity analysis showed significant improvement in the prescription of beta-blocker (OR: 1.48, [95% CI: 1.31, 1.67]) with no heterogeneity ($Tau^2 = 0.00$, $I^2 = 0.00\%$, $P = 0.946$; Figure 5.4).[30,36,38,39] Williams et al. measured the difference between the mean change in prescription adherence score between the intervention and usual care groups at cluster level and could not be included in the meta-analysis. However, the study found significant improvement (12.2% versus 9.7%; P=0.032).[29]

Risk Factor Management

Three studies (23%) reported adequate control of BP. Meta-analysis was not performed for this outcome as one of the three studies used a slightly different target for adequate BP control of SBP < 140[34] and other two studies used a combined target of SBP<140 and DBP<90.[28,38]

Johnston et al. reported significant improvement in the BP control (OR: 1.27, [95% CI: 1.02, 1.57]) in intervention hospitals compared to control.[28] One study, however, showed no significant improvement in achieving adequate BP control in both groups (OR: 1.37, [95% CI: 0.87, 2.18]).[38] Another study found both the intervention and usual care group showed reduction in the proportion of patient reaching the adequate blood pressure target, but the reduction was more in the usual care group (10.7% vs 11.9%); resulting in a 1.2% between-group change, however, the change was not significant.[34]

Three studies (23%) reported the proportion of patients with adequate control of total or LDL cholesterol. Adequate cholesterol control was measured differently in the three studies, hence a meta-analysis was not performed for this outcome. Lowrie et al. measured the proportion of patients achieving a total cholesterol target of <5 mmol/l and found that patients in the intervention arm were more likely to achieve the cholesterol targets compared to the usual care (OR:1.81, [95% CI: 1.63, 2.01]).[33] The other two studies measured the proportion of patients with an LDL cholesterol level below 2.5 mmol/l. One study found a higher proportion of patients in the intervention group achieved the LDL cholesterol target compared to the usual care group (76.4% vs. 71.6%). However, the improvement was not statistically significant (OR: 1.23, [95% CI: 0.67, 2.26]).[38] The other study found slight reduction in the proportion of patient achieving cholesterol target in intervention compared to usual care group (1.1% vs 1.0%); resulting in a 2.1% between-group change, however the change was not significant.[34]

Four studies (30.7%) reported the proportion of patients receiving cessation counselling and all were included in the meta-analysis. The pooled analysis showed that there was no difference in the proportion of cessation support or counselling received between intervention

and usual care groups (OR: 1.30, [95% CI: 0.75, 2.27]) and found substantial heterogeneity between studies (Tau^2 = 0.181, I^2 = 66.22%, p=0.031; Figure 4.5).[34,35,38,39] Two studies had high risk of bias and therefore the sensitivity analysis was performed on the remaining two studies.[34,35] The sensitivity analysis showed similar results (OR: 2.93, [95% CI: 0.30, 29.77]) with substantial heterogeneity (Tau^2 = 2.431, I^2 = 87.22%, P = 0.005; Figure 5.5).[38,39]

Clinical events

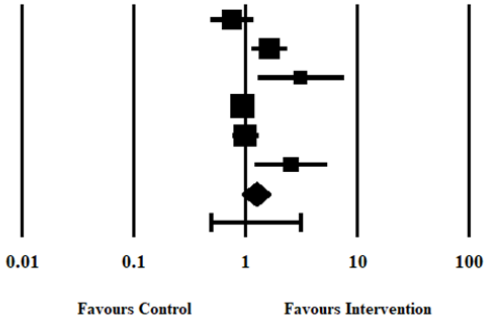
Three studies (23%) reported MACE and all three studies were included in the meta-analysis. The pooled analysis showed that QI intervention led to significant reduction in MACE compared to usual care (OR: 0.84, [95% CI: 0.71, 0.98]) with moderate heterogeneity (Tau^2 = 0.008, I^2= 40.76%, p=0.197; Figure 4.6).[37-39]

Three studies (23%) reported total mortality and all three studies were included in the meta-analysis. The pooled analysis showed significant reduction in total mortality associated with the intervention compared to usual care (OR: 0.88, [95% CI: 0.78, 0.99]) with moderate heterogeneity (Tau^2 = 0.200, I^2= 53.11%, p=0.094) (Figure 4.7).[37-39]

4.1 Antiplatelet therapy

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Flather, 2011	0.76	0.49	1.18	-1.22	0.22
Huffman, 2018	1.65	1.15	2.37	2.71	0.01
Machline-carrion, 2019	3.13	1.29	7.60	2.52	0.01
Geary, 2019	0.95	0.85	1.06	-0.91	0.36
Nouwens, 2014	1.00	0.77	1.29	-0.02	0.98
Sondegaard, 2006	2.54	1.21	5.32	2.47	0.01
Pooled	1.24	0.92	1.67	1.43	0.15
Prediction Interval	1.24	0.49	3.12		

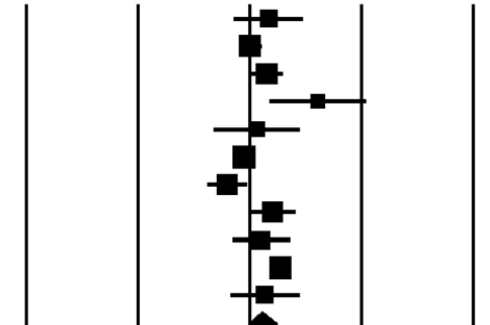
$Tau^2 = 0.087$, $Chi^2 = 22.1$, df = 5 (p=0.001), $I^2 = 77.38\%$,
Test for overall random effect: Z = 1.434, p = 0.151



4.2 Lipid-lowering medication

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Flather, 2011	1.46	0.72	2.98	1.04	0.30
Goff, 2003	1.00	0.80	1.25	0.00	1.00
Huffman, 2018	1.42	1.05	1.93	2.24	0.02
Machline-carrion, 2019	4.04	1.50	10.89	2.76	0.01
Qu, 2021	1.15	0.48	2.76	0.31	0.75
Geary, 2019	0.88	0.81	0.95	-3.14	0.00
Nouwens, 2014	0.63	0.42	0.94	-2.28	0.02
Sondegaard, 2006	1.59	1.00	2.53	1.96	0.05
Johnston, 2010	1.26	0.70	2.28	0.76	0.45
Lowrie, 2014	1.87	1.65	2.12	9.61	0.00
Wang, 2018	1.35	0.67	2.73	0.84	0.40
Pooled	1.27	0.95	1.70	1.64	0.10
Prediction Interval	1.27	0.47	3.46		

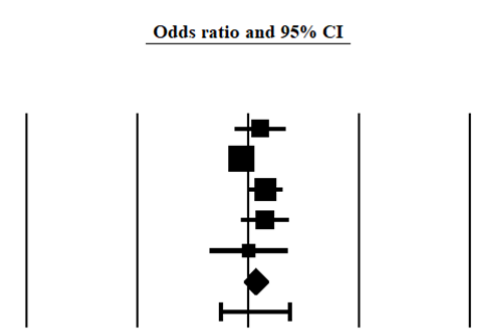
$Tau^2 = 0.174$, $Chi^2 = 117.52$, df = 10 (p=0.000), $I^2 = 91.49\%$,
Test for overall random effect: Z = 1.641, p = 0.101



4.3 ACEi or ARB

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Flather, 2011	1.29	0.76	2.18	0.95	0.34
Goff, 2003	0.88	0.68	1.13	-1.00	0.32
Huffman, 2018	1.45	1.03	2.04	2.13	0.03
Machline-carrion, 2019	1.44	0.88	2.36	1.45	0.15
Qu, 2021	1.02	0.46	2.27	0.05	0.96
Pooled	1.17	0.91	1.51	1.22	0.22
Prediction Interval	1.17	0.57	2.41		

$Tau^2 = 0.034$, $Chi^2 = 7.060$ df = 4 (p=0.133), $I^2 = 43.34\%$,
Test for overall random effect: Z = 1.221, p = 0.222



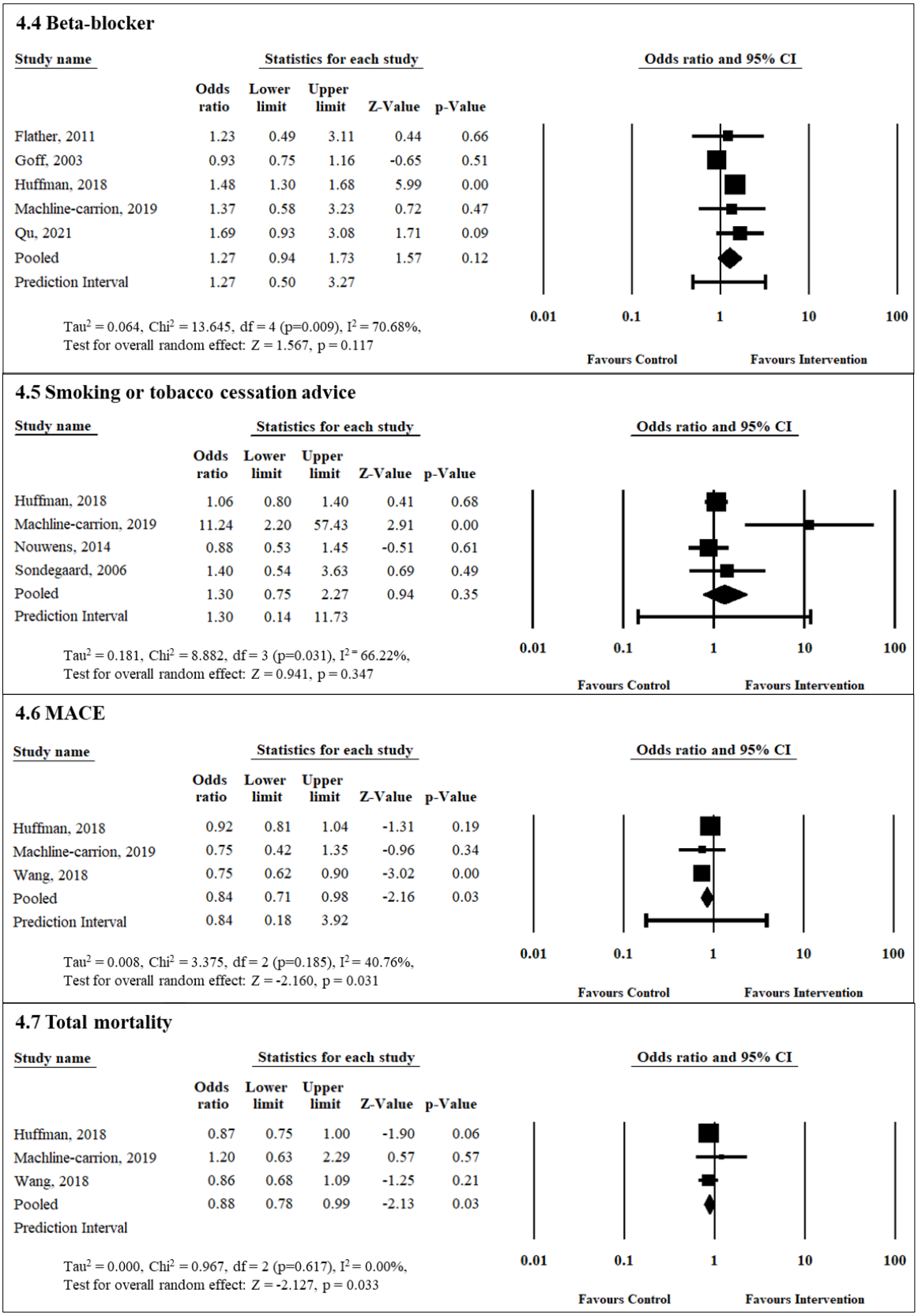
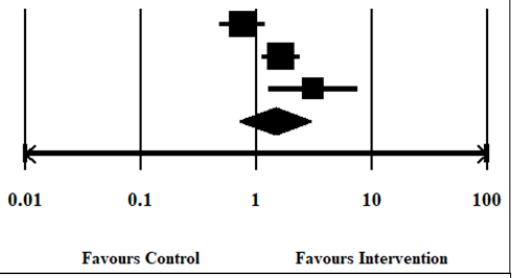


Figure 4: Meta-analysis of the effect of quality improvement intervention on medication prescription, smoking cessation advice and clinical events. *CI*: Confidence Interval, *ACEi:* Angiotensin-converting enzyme inhibitor, *ARB:* Angiotensin receptor blockers, *MACE:* Major adverse cardiovascular events

5.1 Antiplatelet therapy

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Flather, 2011	0.76	0.49	1.18	-1.22	0.22
Huffman, 2018	1.65	1.15	2.37	2.71	0.01
Machline-carrion, 2019	3.13	1.29	7.60	2.52	0.01
Pooled	1.46	0.73	2.95	1.06	0.29
Prediction Interval	1.46	0.00	6007.48		

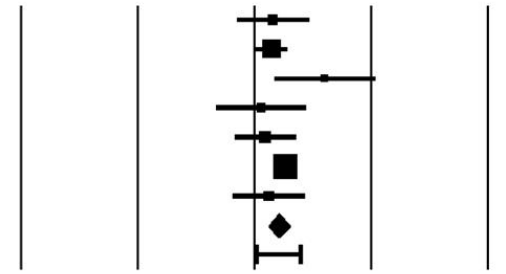
$Tau^2 = 0.301$, $Chi^2 = 11.16$, df = 2 (p=0.004), $I^2 = 82.09\%$,
Test for overall random effect: Z = 1.063, p = 0.288



5.2 Lipid-lowering medication

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Flather, 2011	1.46	0.72	2.98	1.04	0.30
Huffman, 2018	1.42	1.05	1.93	2.24	0.02
Machline-carrion, 2019	4.04	1.50	10.89	2.76	0.01
Qu, 2021	1.15	0.48	2.76	0.31	0.75
Johnston, 2010	1.26	0.70	2.28	0.76	0.45
Lowrie, 2014	1.87	1.65	2.12	9.61	0.00
Wang, 2018	1.35	0.67	2.73	0.84	0.40
Pooled	1.63	1.34	1.99	4.84	0.00
Prediction Interval	1.63	1.05	2.53		

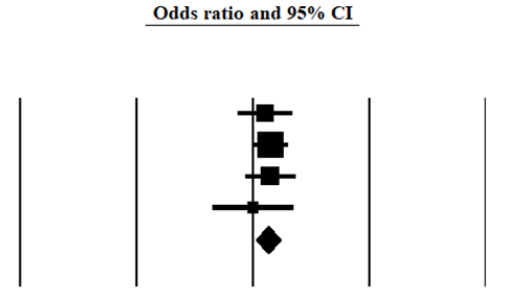
$Tau^2 = 0.019$, $Chi^2 = 8.383$, df = 6 (p=0.211), $I^2 = 28.43\%$,
Test for overall random effect: Z = 4.837, p = 0.000



5.3 ACEi or ARB

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Flather, 2011	1.29	0.76	2.18	0.95	0.34
Huffman, 2018	1.45	1.03	2.04	2.13	0.03
Machline-carrion, 2019	1.44	0.88	2.36	1.45	0.15
Qu, 2021	1.02	0.46	2.27	0.05	0.96
Pooled	1.37	1.08	1.74	2.61	0.01
Prediction Interval					

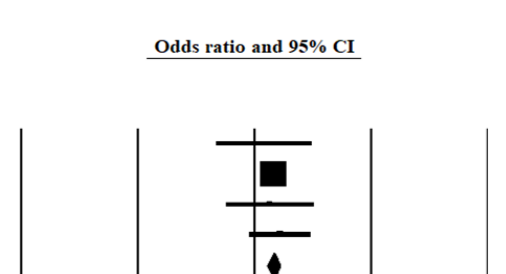
$Tau^2 = 0.00$, $Chi^2 = 0.717$, df = 3 (p=0.869), $I^2 = 0.00\%$,
Test for overall random effect: Z = 2.612, p = 0.009



5.4 Beta-blocker

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Flather, 2011	1.23	0.49	3.11	0.44	0.66
Huffman, 2018	1.48	1.30	1.68	5.99	0.00
Machline-carrion, 2019	1.37	0.58	3.23	0.72	0.47
Qu, 2021	1.69	0.93	3.08	1.71	0.09
Pooled	1.48	1.31	1.67	6.26	0.00
Prediction Interval					

$Tau^2 = 0.00$, $Chi^2 = 0.373$, df = 3 (p=0.946), $I^2 = 0.00\%$,
Test for overall random effect: Z = 6.260, p = 0.000



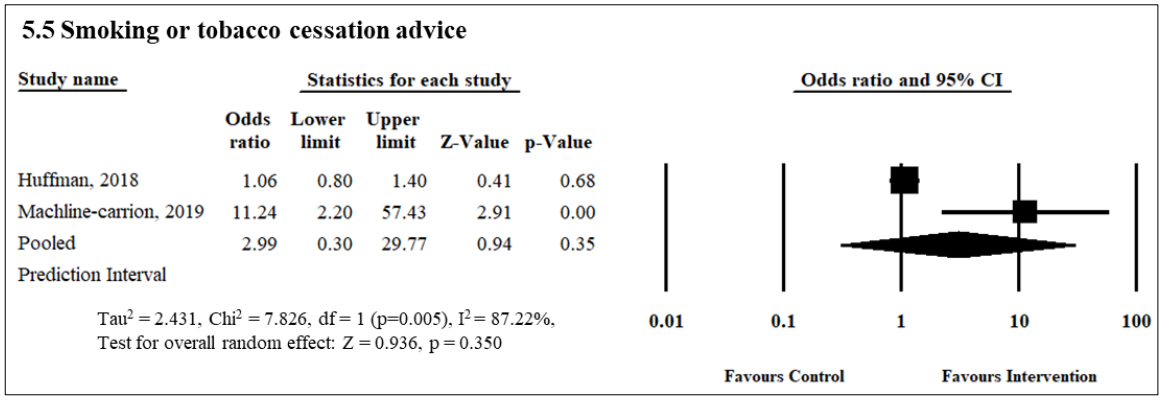


Figure. 5: Sensitivity analysis of the effect of quality improvement intervention on medication prescription and smoking cessation advice excluding high risk of bias studies. *CI*: Confidence Interval, *ACEi:* Angiotensin-converting enzyme inhibitor, *ARB:* Angiotensin receptor blockers.

Subgroup analysis

Subgroup analysis was performed to examine the effect of QI intervention in specific settings (Table 2). There were significant improvements in the prescription of ACEi or ARB and beta-blockers (p=0.000) in both hospitals[30,36,39] and GP or outpatient clinics[27,38], with a slightly stronger effect in the latter. Hospital studies showed a significant improvement in the prescription of lipid-lowering medications (p=0.008)[28,30,36,37,39], MACE (p=0.054)[37,39], and a reduction in total mortality (p=0.033).[37,39] However, no significant effects were observed in improving antiplatelet therapy (p=0.167), smoking cessation advice (p=0.513) in both hospitals[30,39] and GP or outpatient clinic settings.[32,34,35,38]

Table 2: Sub-group analysis of outcomes, based on clinical settings of the study

Outcome	Hospital		GP or outpatient clinics		P Value between groups
	No of studies	OR (95% CI),	No of studies	OR (95% CI),	
Antiplatelet therapy	2	1.13 (0.53, 2.41)	4	1.29 (0.90, 1.86)	0.167
Lipid-lowering medication	5	1.37 (1.08, 1.72)	6	1.11 (0.72, 1.72)	0.008
ACEi or ARB	3	1.35 (1.03, 1.77)	2	1.49 (1.17, 1.90)	0.000
Beta-blocker	3	1.48 (1.31, 1.68)	2	1.57 (1.15, 2.15)	0.000
Smoking cessation advice	1	1.06 (0.80, 1.39)	3	1.89 (0.59, 5.98)	0.513
MACE	2	0.84 (0.69, 1.02)	1	0.75 (0.41, 1.34),	0.054
Total mortality	2	0.86 (0.76, 0.98)	1	1.20 (0.63, 2.29)	0.033

OR - Odds ratio, CI - Confidence interval, ACEi - Angiotensin-converting enzyme inhibitor, ARB - Angiotensin receptor blockers, MACE - Major adverse cardiovascular events

DISCUSSION

Principal findings

The current meta-analyses showed no significant improvement in the prescription of guideline-recommended medications including antiplatelet therapy, lipid-lowering medications, ACEi or ARB and beta-blockers and smoking cessation advice. However, there was a significant reduction in MACE and total mortality in the meta-analysis. Adequate control of BP and cholesterol yielded mixed results as a result of the intervention. However, sensitivity analysis revealed significant improvement in prescription of lipid-lowering medications, ACEi or ARB, beta-blockers which showed non-significant improvement in the meta-analysis. Smoking cessation advice revealed similar findings in both meta-analysis and sensitivity analysis with no improvement in the outcome. Additionally, subgroup analysis found significant improvement in the prescription of ACEi or ARB and beta-blockers in both hospitals and GP or outpatient clinics. Additionally, significant improvement was seen in the prescription of lipid-lowering medications along with reduction in MACE and total mortality in hospitals and there was no significant improvement in the prescription of antiplatelet therapy and smoking cessation support in both settings.

Comparison with other studies

This systematic review and meta-analysis evaluated the effect of various QI interventions on improving CVD-related outcomes. In contrast to findings from another systematic review including both randomised and non-randomised trials, which indicated low to moderate effectiveness of hospital based QI interventions for certain clinical outcomes including discharge medications, MACE and mortality[16], the current review, which included randomised and cluster-randomised controlled trials focusing on both hospital and clinic based QI interventions, found no significant improvement in the clinical outcomes except for

reduction in MACE. Moreover, subgroup analysis found varied effectiveness of QI intervention across the outcomes. The prescription of lipid-lowering medications, MACE and total mortality showed improvement in hospitals, however there was no improvement in prescription of antiplatelet therapy and smoking cessation advice in either settings. These mixed findings also align with a large cRCT involving 60 primary care practices, demonstrating overall improvement in risk factor measurements and the prescription of guideline-recommended medications; and there was no improvement in the medications prescription in high risk cohort.[40] Previous studies explored various contextual factors, such as study settings, designs, measurement methods and effect sizes, which could have contributed to the variation in the intervention effectiveness.[17,41]

QI intervention offers an opportunity for improved healthcare efficiencies and outcomes, therefore further understanding of the effect of these interventions on clinical outcomes in other chronic conditions is also needed. Previous studies have already evaluated the effectiveness of QI interventions across various health conditions including asthma[42], diabetes[43], cancer screening[44]. One RCT evaluating a multi-component QI intervention including 1146 individuals with type 2 diabetes found the intervention was effective in reducing HbA_{1C} level, and risk factors including SBP, DBP, and LDL-C level however, there was no significant reduction in adverse events.[45] Additionally, another systematic review found QI interventions were effective in reducing healthcare service use in patients with chronic condition[14] and another found significant improvement in processes but no improvement in clinical outcomes.[15] Findings from the previous studies[14,15,45] align with the current systematic review demonstrating mixed effectiveness, further highlighting the potential effect of QI interventions in improving not only clinical outcomes but also process of care and healthcare delivery.

Strengths and limitations of this review

The systematic review has several strengths, including its comprehensive evaluation of several CVD-related outcomes across diverse studies including both RCTs and cRCTs; providing a robust understanding of the impact of QI interventions in CVD care. Additionally, use of subgroup and sensitivity analysis adds granularity to the findings and enhances the methodological rigor and strengthen the robustness of the findings. However, the review is not without any limitations. Firstly, majority of the studies were conducted in high-income countries. This contextual difference may have introduced variability and affect the generalisability of the findings in low-middle-income countries and other settings. Secondly, the selection of different study sites (hospitals and clinics) and designs may have contributed to the substantial heterogeneity of the results. Thirdly, the variability in the outcome measures and difference in their definitions used across the included studies, particularly for the adequate control of BP and cholesterol, was not included in the meta-analysis, which may have impacted the accuracy of the findings. Lastly, it was beyond the scope of the review to evaluate the effect of specific QI strategies on improving clinical outcomes and to assess the several contextual factors influencing the effectiveness of QI on clinical outcomes.

Implications and future research

QI interventions are often complex to implement[15] and have also been associated with several implementation challenges[46,47] along with limited evidence on sustainability.[48] Findings from the review suggest that several contextual factors may contribute to the variability on the findings[41], emphasising the need for further research to assess these factors for wider roll-out of such interventions. To fully evaluate the effect of QI interventions on clinical outcomes, it is important to measure the variety of QI strategies used within QI

interventions.[49] Previous studies have explored the effectiveness of individual QI strategies on improving clinical outcomes.[50-53] Since the current review did not evaluate the effectiveness of individual or combined QI strategies used within the QI interventions, future research could further elaborate on these aspects to contribute to more robust evidence. Moreover, a positive attitude, effective leadership, ongoing training, and support have been identified as important facilitators in successful QI implementation, with electronic health records offering new opportunities.[54-56] Therefore, future research is encouraged to emphasise on these factors when implementing QIs along with a comprehensive evaluation to help gain valuable insights into their implementation; this includes understanding the various features and mechanisms used within QI interventions, identifying what worked and what didn't, and assessing acceptability and feasibility to guide future implementation.[57-59]

CONCLUSION

This systematic review and meta-analysis provide a comprehensive evaluation of QI interventions targeting several CVD outcomes across a diverse range of studies. The findings revealed varying effectiveness in improving prescriptions of guideline-recommended medications, risk factor management and clinical events associated with CVD, particularly on subgroup and sensitivity analysis. Despite the robustness brought by the inclusion of randomised and cluster-randomised trials and meticulous quality assessments, certain limitations, such as contextual variations, site-specific differences, and heterogeneity in study types, should be acknowledged. The mixed results underscore the complexity of QI interventions, suggesting the need for future research to be more robust and detailed. Gaining comprehensive insights into such programs could contribute to a better understanding of the impact of QI interventions and provide valuable guidance for their successful implementation in diverse healthcare settings.

Ethics approval

Not required

Competing interests

All authors have completed the ICMJE disclosure form at http://www.icmje.org/disclosure-of-interest/and declare: no financial relationships with any organizations that might have an interest in the submitted work; and no other relationships or activities that could appear to have influenced the submitted work.

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Data availability statement

All data generated or analysed during this study are included in this published article. Search strategy for this study is available as Data Supplement 2. Data used in the study are available in Tables 1 and 2 and in Data Supplement 3 and Data Supplement 5.

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SUPPLEMENTARY MATERIALS

Supplementary material 1: PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	4-5
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	5
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	6
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	5-6
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Supplementary material 1
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	6
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	6-7
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	7-8
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	6-7
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	7
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	8

Section and Topic	Item #	Checklist item	Location where item is reported
Synthesismethods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	6, Table S1: Supplementary material 3
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	8
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	8
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	8
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	8
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	8
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	7-8
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	9, Figure 1
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	9-10, Figure 1
Study characteristics	17	Cite each included study and present its characteristics.	12-13, Table 1, Table S1, Table S2
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	15, Figures 2 and 3
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Figures 4 and 5, Table 2
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	15-19
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	15-19, Fig 4
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	15-19, Fig 4
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	15-19, Fig 5

Section and Topic	Item #	Checklist item	Location where item is reported
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	15, Figures 2 and 3, Table S3
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	NA
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	20-21
	23b	Discuss any limitations of the evidence included in the review.	21-22
	23c	Discuss any limitations of the review processes used.	23
	23d	Discuss implications of the results for practice, policy, and future research.	23-24
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	3 and 5
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	NA
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	NA
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	26
Competing interests	26	Declare any competing interests of review authors.	26
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	25

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71
For more information, visit: http://www.prisma-statement.org/

Supplementary material 2

Search methods

Database: Ovid Embase <1974 to June 27, 2022>

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1 Cardiovascular Diseases/
2 CVD.mp.
3 exp Heart Failure/
4 exp Myocardial Infarction/ or acute myocardial infarction*.mp.
5 exp Coronary Disease/
6 Coronary heart diseas*.mp.
7 ((heart or cardiac or myocardial) adj2 (failure or infrac* or diseas* or attack*)).tw.
8 exp Atrial Fibrillation/
9 Atrial fibrillation.mp.
10 exp Angina Pectoris/
11 Angina*.mp.
12 Acute Coronary Syndrome/
13 acute coronary syndrome*.mp.
14 Ischaemic Heart Disease*.mp.
15 Quality Improvement/
16 "Quality Improvement*".mp.
17 Quality Assurance, Health Care/
18 (health care adj3 quality assurance).mp.
19 Total Quality Management/
20 total quality management.mp.
21 (quality adj2 (improve* or enhanc* or program* or initative*)).mp.
22 (Collaborative Quality improvement* or collaborative model*).mp.
23 Quality Improvement collaborati*.mp.
24 Quality improvement intervention*.mp.
25 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
26 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
27 25 and 26
28 blood pressure/
29 Blood pressure*.mp.
30 hypertension/
31 Hypertention*.mp.
32 HTN.tw.
33 diabetes mellitus/
34 Diabet*.mp.
35 DM.tw.
36 smoking/
37 Smok*.mp.
38 alcohol/
39 Alcohol*.mp.
40 high density lipoprotein cholesterol/
41 HDL.tw.
42 hypercholesterolemia/
43 hypercholesterolemia.mp.
44 low density lipoprotein cholesterol/
45 low density lipoprotein cholesterol.mp.
46 LDL.tw.
47 high density lipoprotein cholesterol.mp.
48 High blood pressure.mp.
49 blood sugar*.mp.
50 blood glucose*.mp.
51 hyperglycemia/ or hyperglycemia.mp.

52 hyperlipidemia/ or hyperlipidemia.mp.
53 total cholesterol.mp.
54 body mass index.mp. or body mass index/
55 obesity/
56 obes*.mp.
57 BMI.tw.
58 (statin* or lipid lowering).tw.
59 hydroxymethylglutaryl coenzyme A reductase inhibitor/
60 Hydroxymethylglutaryl coenzyme A reductase inhibitor.mp.
61 antihypertensive agent.mp. or antihypertensive agent/
62 (blood pressure adj3 (medication* or lower*)).tw.
63 (angiotensin II receptor blocker* or ARB*).tw.
64 (angiotensin?converting enzyme inhibitor* or ACE* or ACEI* or ACEi*).tw.
65 dipeptidyl carboxypeptidase inhibitor.mp. or dipeptidyl carboxypeptidase inhibitor/
66 antiplatelet.tw.
67 antithrombocytic agent.mp. or antithrombocytic agent/
68 aspirin.tw.
69 antithrombotic*.tw.
70 nonsteroid antiinflammatory agent.mp. or nonsteroid antiinflammatory agent/
71 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70
72 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57
73 27 and 71 and 72
74 limit 73 to (adult <18 to 64 years> or aged <65+ years>)
75 cerebrovascular accident/
76 cerebrovascular accident.mp.
77 transient ischemic attack/
78 Transient Ischemic Attack.mp.
79 TIA.tw.
80 Stroke*.mp.
81 carotid stenosis.mp.
82 Cerebral Aneurysms.mp.
83 vascular malformation*.mp.
84 moyamoya disease/
85 Moyamoya Disease*.mp.
86 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85
87 Peripheral Arterial Disease*.mp.
88 peripheral vascular disease/
89 peripheral vascular disease*.mp.
90 PAD.tw.
91 PVD.tw.
92 87 or 88 or 89 or 90 or 91
93 rheumatic heart disease/
94 rheumatic heart disease*.mp.
95 93 or 94
96 Venous Thrombosis.mp.
97 venous thromboembolism/
98 Venous Thromboembolism.mp.
99 deep vein thrombosis/
100 Deep vein thrombosis.mp.
101 Pulmonary Embolism.mp.
102 96 or 97 or 98 or 99 or 100 or 101
103 25 or 86 or 92 or 95 or 102
104 26 and 71 and 72 and 103
105 limit 104 to (adult <18 to 64 years> or aged <65+ years>)

Database: Ovid MEDLINE(R) ALL <1946 to June 23, 2022>

116	1	Cardiovascular Diseases/
117	2	CVD.mp.
118	3	exp Heart Failure/
119	4	exp Myocardial Infarction/ or acute myocardial infarction*.mp.
120	5	exp Coronary Disease/
121	6	Coronary heart diseas*.mp.
122	7	((heart or cardiac or myocardial) adj2 (failure or infrac* or diseas* or attack*)).tw.
123	8	exp Atrial Fibrillation/
124	9	Atrial fibrillation.mp.
125	10	exp Angina Pectoris/
126	11	Angina*.mp.
127	12	Acute Coronary Syndrome/
128	13	acute coronary syndrome*.mp.
129	14	Ischaemic Heart Disease*.mp.
130	15	Quality Improvement/
131	16	"Quality Improvement*".mp.
132	17	Quality Assurance, Health Care/
133	18	(health care adj3 quality assurance).mp.
134	19	Total Quality Management/
135	20	total quality management.mp.
136	21	(quality adj2 (improve* or enhanc* or program* or initative*)).mp.
137	22	(Collaborative Quality improvement* or collaborative model*).mp.
138	23	Quality Improvement collaborati*.mp.
139	24	Quality improvement intervention*.mp.
140	25	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
141	26	15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
142	27	25 and 26
143	28	Blood Pressure/
144	29	blood pressure.mp.
145	30	Hypertension/
146	31	hypertension.mp.
147	32	high blood pressure.mp.
148	33	HTN.tw.
149	34	Diabetes Mellitus/
150	35	diabet*.mp.
151	36	Blood Glucose/
152	37	blood glucose*.mp.
153	38	blood sugar*.mp.
154	39	Hyperglycemia/
155	40	hyperglycemia.mp.
156	41	DM.tw.
157	42	exp Smoking/
158	43	smok*.mp.
159	44	Alcohols/
160	45	alcohol*.mp.
161	46	Hypercholesterolemia/
162	47	hypercholesterolemia.mp.
163	48	Hyperlipidemias/
164	49	hyperlipidemia.mp.
165	50	total cholesterol.mp.
166	51	Cholesterol, HDL/
167	52	high density lipoprotein cholesterol.mp.
168	53	Cholesterol, LDL/
169	54	low density lipoprotein cholesterol.mp.
170	55	HDL.tw.
171	56	LDL.tw.
172	57	body mass index.mp. or body mass index/
173	58	Obesity/
174	59	obes*.mp.

60 BMI.tw.
61 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60
62 (statin* or lipid lowering).tw.
63 Hydroxymethylglutaryl-CoA Reductase Inhibitors/
64 hydroxymethylglutaryl coenzyme A reductase inhibitor.mp.
65 antihypertensive agent.mp. or Antihypertensive Agents/
66 (blood pressure adj3 (medication* or lower*)).tw.
67 (angiotensin II receptor blocker* or ARB*).tw.
68 (angiotensin?converting enzyme inhibitor* or ACE* or ACEI* or ACEi*).tw.
69 Angiotensin-Converting Enzyme Inhibitors/ or dipeptidyl carboxypeptidase inhibitor.mp.
70 antiplatelet.tw.
71 antithrombocytic agent.mp.
72 aspirin.tw.
73 antithrombotic*.tw.
74 Anti-Inflammatory Agents, Non-Steroidal/
75 nonsteroid antiinflammatory agent.mp.
76 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75
77 27 and 61 and 76
78 limit 77 to ("all adult (19 plus years)" or "young adult (19 to 24 years)" or "adult (19 to 44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)")
79 Stroke/
80 Stroke*.mp.
81 Ischemic Attack, Transient/
82 Transient Ischemic Attack.mp.
83 Carotid Stenosis/
84 Carotid Stenosis.mp.
85 Intracranial Aneurysm/
86 Cerebral Aneurysms.mp.
87 Vascular Malformations/
88 Vascular Malformation*.mp.
89 Moyamoya Disease/
90 Moyamoya disease*.mp.
91 TIA.tw.
92 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91
93 Peripheral Arterial Disease/
94 Peripheral arterial disease*.mp.
95 Peripheral Vascular Diseases/
96 peripheral vascular disease.mp.
97 PVD.tw.
98 PAD.tw.
99 93 or 94 or 95 or 96 or 97 or 98
100 Rheumatic Heart Disease/
101 rheumatic heart disease.mp.
102 100 or 101
103 Venous Thrombosis/
104 Venous thrombosis.mp.
105 Venous Thromboembolism/
106 Venous thromboembolism.mp.
107 Deep vein thrombosis.mp.
108 Pulmonary Embolism/
109 pulmonary embolism.mp.
110 103 or 104 or 105 or 106 or 107 or 108 or 109
111 25 or 92 or 99 or 110
112 26 and 61 and 76 and 111
113 limit 112 to ("young adult (19 to 24 years)" or "adult (19 to 44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)")

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <May 2022>

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1 Cardiovascular Diseases/ (9053)
2 CVD.mp. (6473)
3 exp Heart Failure/ (10463)
4 exp Myocardial Infarction/ (11752)
5 acute myocardial infarction*.mp. (9621)
6 exp Coronary Disease/ (14752)
7 Coronary Heart diseas*.mp. (8098)
8 ((heart or cardiac or myocardial) adj2 (failure or infrac* or diseas* or attack*)).tw. (50153)
9 exp Atrial Fibrillation/ (5219)
10 Atrial fibrillation.mp. (15077)
11 exp Angina Pectoris/ (4663)
12 Angina*.mp. (14982)
13 Acute Coronary Syndrome/ (2313)
14 acute coronary syndrome*.mp. (8300)
15 Ischaemic Heart Disease*.mp. (1144)
16 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 (108049)
17 Quality Improvement/ (813)
18 Quality Improvement*.mp. (3572)
19 Quality Assurance, Health Care/ (638)
20 (health care adj3 quality assurance).mp. (642)
21 Total Quality Management/ (140)
22 total quality management.mp. (1736)
23 (quality adj2 (improve* or enhanc* or program* or initative*)).mp. (23903)
24 (Collaborative Quality improvement* or collaborative model*).mp. (113)
25 Quality Improvement collaborati*.mp. (47)
26 Quality improvement intervention*.mp. (333)
27 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 (24875)
28 Blood Pressure/ (27669)
29 blood pressure.mp. (101129)
30 Hypertension/ (18631)
31 hypertension.mp. (69164)
32 high blood pressure.mp. (2627)
33 HTN.tw. (1109)
34 Diabetes Mellitus/ (10637)
35 diabet*.mp. (109144)
36 Blood Glucose/ (17493)
37 blood glucose*.mp. (33819)
38 blood sugar*.mp. (4680)
39 Hyperglycemia/ (2053)
40 hyperglycemia.mp. (8948)
41 DM.tw. (5335)
42 exp Smoking/ (6531)
43 smok*.mp. (42198)
44 Alcohols/ (105)
45 alcohol*.mp. (35535)
46 Hypercholesterolemia/ (3599)
47 hypercholesterolemia.mp. (7890)
48 Hyperlipidemias/ (2053)
49 hyperlipidemia.mp. (5045)
50 total cholesterol.mp. (13862)
51 Cholesterol, HDL/ (3859)
52 high density lipoprotein cholesterol.mp. (8223)
53 Cholesterol, LDL/ (4955)
54 low density lipoprotein cholesterol.mp. (10194)
55 HDL.tw. (16425)

56 LDL.tw. (20630)
57 Body Mass Index/ (11064)
58 body mass index.mp. (44177)
59 BMI.tw. (46143)
60 Obesity/ (13014)
61 obes*.mp. (50665)
62 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 (366491)
63 (statin* or lipid lowering).tw. (13803)
64 Hydroxymethylglutaryl-CoA Reductase Inhibitors/ (3703)
65 hydroxymethylglutaryl coenzyme A reductase inhibitor.mp. (1965)
66 Antihypertensive Agents/ (8300)
67 antihypertensive agent.mp. (2202)
68 (blood pressure adj3 (medication* or lower*)).tw. (7063)
69 (angiotensin II receptor blocker* or ARB*).tw. (5817)
70 (angiotensin?converting enzyme inhibitor* or ACE* or ACEI* or ACEi*).tw. (42046)
71 Angiotensin-Converting Enzyme Inhibitors/ or dipeptidyl carboxypeptidase inhibitor.mp. (6129)
72 antiplatelet.tw. (6520)
73 antithrombocytic agent.mp. (705)
74 aspirin.tw. (13467)
75 antithrombotic*.tw. (2906)
76 Anti-Inflammatory Agents, Non-Steroidal/ (6635)
77 nonsteroid antiinflammatory agent.mp. (1713)
78 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 (99517)
79 16 and 27 and 62 and 78 (126)
80 Stroke/ (10334)
81 stroke.mp. (63717)
82 Cerebrovascular accident.mp. (16256)
83 Ischemic Attack, Transient/ (798)
84 Transient Ischemic Attack.mp. (2895)
85 TIA.tw. (2018)
86 Carotid Stenosis/ (687)
87 Carotid Stenosis.mp. (1326)
88 Intracranial Aneurysm/ (482)
89 Cerebral Aneurysms.mp. (151)
90 Vascular Malformations/ (37)
91 Vascular Malformations.mp. (119)
92 Moyamoya Disease/ (29)
93 Moyamoya Disease.mp. (107)
94 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 (68903)
95 Peripheral Arterial Disease/ (1211)
96 Peripheral Arterial Disease.mp. (2661)
97 Peripheral Vascular Diseases/ (915)
98 Peripheral Vascular Disease.mp. (1457)
99 PAD.tw. (4494)
100 PVD.tw. (374)
101 95 or 96 or 97 or 98 or 99 or 100 (7985)
102 Rheumatic Heart Disease/ (146)
103 Rheumatic Heart Disease.mp. (329)
104 102 or 103 (329)
105 Venous Thrombosis/ (1282)
106 Venous Thrombosis.mp. (3795)
107 Venous Thromboembolism/ (753)
108 Venous Thromboembolism.mp. (4566)
109 Deep vein thrombosis.mp. (5724)
110 Pulmonary Embolism/ (1092)
111 Pulmonary Embolism.mp. (4120)
106 or 106 or 107 or 108 or 109 or 110 or 111 (12777)
112 16 or 94 or 101 or 104 or 112 (175855)

113 27 and 62 and 78 and 113 (137)

Database: APA PsycInfo <1806 to June Week 3 2022>

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1 exp Cardiovascular Disorders/ (68022)
2 cardiovascular disease.mp. (11109)
3 Heart Failure.mp. (4540)
4 exp Myocardial Infarctions/ (3017)
5 myocardial infarction.mp. (5056)
6 Coronary disease.mp. (2826)
7 coronoary heart diseas*.mp. (1)
8 ((heart or cardiac or myocardial) adj2 (failure or infrac* or diseas* or attack*)).tw. (17077)
9 exp "Fibrillation (Heart)"/ (791)
10 atrial fibrillation.mp. (1446)
11 exp Angina Pectoris/ (304)
12 angina*.mp. (1425)
13 Acute Coronary Syndrome.mp. (664)
14 Ischaemic Heart Disease.mp. (273)
15 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 (81654)
16 Quality Improvement.mp. (6902)
17 Quality Assurance, Health Care.mp. (2829)
18 (health care adj3 quality assurance).mp. (2860)
19 Total Quality Management.mp. (1193)
20 (quality adj2 (improve* or enhanc* or program* or initative*)).mp. (28743)
21 (Collaborative Quality improvement* or collaborative model*).mp. (717)
22 Quality Improvement collaborati*.mp. (67)
23 Quality improvement intervention*.mp. (191)
24 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 (32547)
25 exp Blood Pressure/ (8180)
26 blood pressure.mp. (25300)
27 exp Hypertension/ (8030)
28 hypertension.mp. (20111)
29 high blood pressure.mp. (1614)
30 HTN.tw. (241)
31 exp Diabetes Mellitus/ (9634)
32 diabet*.mp. (36209)
33 exp Blood Sugar/ (1404)
34 blood glucose*.mp. (7039)
35 blood sugar*.mp. (2180)
36 exp Hyperglycemia/ (606)
37 hyperglycemia.mp. (1784)
38 DM.tw. (2666)
39 Smoking.mp. (64581)
40 exp Alcohols/ (18574)
41 alcohol*.mp. (156061)
42 Hypercholesterolemia.mp. (1126)
43 Hyperlipidemias.mp. (415)
44 total cholesterol.mp. (2023)
45 HDL cholesterol.mp. (800)
46 high density lipoprotein cholesterol.mp. (1006)
47 LDL cholesterol.mp. (550)
48 low density lipoprotien cholesterol.mp. (0)
49 HDL.tw. (1930)
50 LDL.tw. (1606)
51 exp Body Mass Index/ (7202)
52 body mass index.mp. (29728)
53 BMI.tw. (20167)
54 exp Obesity/ (27174)

55 obes*.mp. (49179)
56 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 (326884)
57 (statin* or lipid lowering).tw. (5941)
58 Hydroxymethylglutaryl-CoA Reductase Inhibitors.mp. (632)
59 antihypertensive agent.mp. (42)
60 (blood pressure adj3 (medication* or lower*)).tw. (1105)
61 (angiotensin II receptor blocker* or ARB*).tw. (17279)
62 (angiotensin?converting enzyme inhibitor* or ACE* or ACEI* or ACEi*).tw. (30671)
63 Angiotensin-Converting Enzyme Inhibitors.mp. (449)
64 antiplatelet.tw. (527)
65 antithrombocytic agent.mp. (0)
66 aspirin.tw. (1247)
67 antithrombotic*.tw. (309)
68 non steroidal Anti-Inflammatory Agents.mp. (20)
69 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 (56365)
70 15 and 24 and 56 and 69 (19)
71 71 limit 70 to (adulthood <18+ years> and ("300 adulthood <age 18 yrs and older>" or 320 young adulthood <age 18 to 29 yrs> or 340 thirties <age 30 to 39 yrs> or 360 middle age <age 40 to 64 yrs> or "380 aged <age 65 yrs and older>" or "390 very old <age 85 yrs and older>")) (14)
72 stroke.mp. (38560)
73 exp Cerebrovascular Accidents/ (23163)
74 cerebrovascular accidents.mp. (23278)
75 Transient Ischemic Attack.mp. (743)
76 TIA.tw. (1029)
77 Carotid Stenosis.mp. (550)
78 cerebral aneurysm.mp. (132)
79 exp Aneurysms/ (966)
80 Vascular Malformations.mp. (224)
81 Moyamoya Disease.mp. (214)
82 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 (41807)
83 Peripheral arterial disease.mp. (197)
84 peripheral vascular disease.mp. (185)
85 PAD.tw. (1676)
86 PVD.tw. (179)
87 83 or 84 or 85 or 86 (2123)
88 rheumatic heart disease.mp. (60)
89 venous thrombosis.mp. (492)
90 venous thromboembolism.mp. (302)
91 Deep vein thrombosis.mp. (203)
92 pulmonary embolism.mp. (341)
93 88 or 89 or 90 or 91 or 92 (1089)
94 15 or 82 or 87 or 88 or 93 (95218)
95 24 and 56 and 69 and 94 (19)
96 96 limit 95 to ("300 adulthood <age 18 yrs and older>" or 320 young adulthood <age 18 to 29 yrs> or 340 thirties <age 30 to 39 yrs> or 360 middle age <age 40 to 64 yrs> or "380 aged <age 65 yrs and older>" or "390 very old <age 85 yrs and older>") (14)

Database: SCOPUS, June 27, 2022

(TITLE-ABS-KEY (("Quality Improvement*" OR "Health care Quality Assurance" OR "Total Quality Management*" OR "Collaborative Quality improvement*" OR "collaborative model*" OR "Quality Improvement collaborate*" OR "Quality improvement intervention*") OR (("health care" W/3 "quality assurance") OR (quality W/2 (improve* OR enhanc* OR program* OR initative*)))))
AND

(TITLE-ABS-KEY (statin* OR "lipid lowering" OR "Hydroxymethylglutaryl-CoA Reductase Inhibitors" OR "antihypertensive agent" OR "angiotensin II receptor blocker*" OR "angiotensin?converting enzyme inhibitor*" OR "Angiotensin-Converting Enzyme Inhibitors" OR antiplatelet OR "antithrombocytic agent" OR aspirin OR antithrombotic* OR "non?steroidal Anti-Inflammatory Agents" OR (ace* OR acei* OR acei* OR arb*)))
AND
((("blood pressure" OR "Hypertension" OR "high blood pressure" OR "Diabet*" OR "Blood sugar*" OR "Blood glucose*" OR "hyperglycemia" OR "smok*" OR "alcohol*" OR "Hypercholesterolemia" OR "Hyperlipidemias" OR "total cholesterol" OR "HDL Cholesterol" OR "high density lipoprotein cholesterol" OR "LDL Cholesterol" OR "low density lipoprotein Cholesterol" OR "Body Mass Index" OR "Obes*") OR TITLE-ABS (htn OR dm OR hdl OR ldl OR bmi))) AND ((TITLE-ABS-KEY ("Acute Coronary Syndrome*" OR "Ischaemic Heart Disease*" OR cardiovascular* OR "CVD" OR "Heart Disease*" OR "Heart Failure*" OR "Myocardial Infarction*" OR "Coronary* Disease*" OR "Atrial Fibrillation*" OR angina* OR ((heart OR cardiac OR myocardial) W/2 (failure OR infrac* OR diseas* OR attack)) OR "rheumatic heart disease*") OR TITLE-ABS-KEY (stroke* OR "Transient Ischemic Attack" OR "Carotid Stenosis" OR "Cerebral Aneurysms" OR "Vascular Malformation*" OR "Moyamoya Disease*") OR TITLE-ABS-KEY ("Peripheral arterial disease*" OR "peripheral vascular disease*" OR pad OR pvd) OR TITLE-ABS-KEY ("venous thombosis" OR "Venous thromboembolism" OR "Deep vein thrombosis" OR "pulmonary embolism")))
AND
(LIMIT-TO (EXACTKEYWORD , "Aged") OR LIMIT-TO (EXACTKEYWORD , "Adult") OR LIMIT-TO (EXACTKEYWORD , "Middle Aged") OR LIMIT-TO (EXACTKEYWORD , "Aged, 80 And Over") OR LIMIT-TO (EXACTKEYWORD , "Very Elderly") OR LIMIT-TO (EXACTKEYWORD , "Age"))

Database: CINAHL Complete (EBSCOhost), 27 Jun, 2022

#	Query
S71	S28 AND S52 AND S70
S70	S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64 OR S65 OR S66 OR S67 OR S68 OR S69
S69	"blood pressure" N3 (medication* or lower*)
S68	(MH "Antiinflammatory Agents, Non-Steroidal+") OR "non steroidal Anti-Inflammatory Agents"
S67	"antithrombotic*"
S66	(MH "Aspirin") OR "aspirin"
S65	"antithrombocytic agent"
S64	TI antiplatelet OR AB antiplatelet
S63	(MH "Angiotensin-Converting Enzyme Inhibitors+")
S62	TI ACEi* OR AB ACEi*
S61	TI ACEI* OR AB ACEI*
S60	"angiotensin?converting enzyme inhibitor*"
S59	TI ACE* OR AB ACE*
S58	TI ARB OR AB ARB
S57	(MH "Angiotensin II Type I Receptor Blockers+") OR "angiotensin II receptor blocker*"
S56	(MH "Antihypertensive Agents+") OR "antihypertensive agent"
S55	"Hydroxymethylglutaryl-CoA Reductase Inhibitors"
S54	"lipid lowering agents" OR (MH "Fibrinolytic Agents+") OR (MH "Lipids and Antilipemic Agents+")
S53	(MH "Statins+") OR Statins
S52	S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR
S51	(MH "Obesity+") OR "obes*"
S50	TI BMI OR AB BMI
S49	(MH "Body Mass Index") OR "Body Mass Index"
S48	TI LDL OR AB LDL
S47	TI HDL OR AB HDL
S46	(MH "Lipoproteins, HDL+") OR "high density lipoprotein cholesterol"
S45	(MH "Lipoproteins, HDL Cholesterol") OR "HDL cholesterol"
S44	"low density lipoprotien cholesterol" OR (MH "Lipoproteins, LDL+")
S43	(MH "Lipoproteins, LDL Cholesterol") OR "LDL cholesterol"
S42	"Total Cholesterol"
S41	(MH "Hyperlipidemia+") OR "Hyperlipidemia"
S40	(MH "Hypercholesterolemia+") OR "Hypercholesterolemia"
S39	"alcohol*"
S38	(MH "Smoke+") OR "Smok*"
S37	TI DM OR AB DM
S36	(MH "Hyperglycemia+")
S35	"blood glucose*" OR (MH "Blood Glucose")
S34	"Blood Sugar*"
S33	(MH "Diabetes Mellitus, Type 1+") OR "diabet*"
S32	TI HTN OR AB HTN

540	S31	"high blood pressure"
541	S30	(MH "Hypertension+") OR "Hypertension"
542	S29	(MH "Blood Pressure+") OR "Blood Pressure"
543	S28	S11 AND S27
544	S27	S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR
545		S22 OR S23 OR S24 OR S25 OR S26
546	S26	(MH "Myocardial Ischemia+") OR "Ischaemic Heart Disease*"
547	S25	(MH "Acute Coronary Syndrome") OR "Acute Coronary Syndrome*"
548	S24	"Angina*"
549	S23	(MH "Angina Pectoris+") OR "Angina Pectoris"
550	S22	(MH "Atrial Fibrillation") OR "Atrial Fibrillation*"
551	S21	(MH "Atrial Fibrillation") OR "Atrial Fibrillation*"
552	S20	((heart or cardiac or myocardial) N2 (failure or infrac* or diseas* or attack*))
553	S19	"Coronary heart diseas*"
554	S18	(MH "Coronary Disease+") OR "Coronary Disease*"
555	S17	(MH "Myocardial Infarction+") OR "Myocardial Infarction*"
556	S16	(MH "Heart Failure+") OR "Heart Failure*"
557	S15	(MH "Heart Diseases+") OR "Heart Disease*"
558	S14	"cvd"
559	S13	"Cardiovascular*"
560	S12	(MH "Cardiovascular Diseases+") OR "Cardiovascular Disease*"
561	S11	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10
562	S10	(MH "Quality Improvement+") OR ""Quality Improvement collaborati*""
563	S9	"Quality Improvement collaborati*"
564	S8	"collaborative model*"
565	S7	(MH "Quality Improvement+") OR "Collaborative Quality improvement*"
566	S6	AB quality N2 (improve* or enhanc* or program* or initative)
567	S5	quality N2 (improve* or enhanc* or program* or initative)
568	S4	(MH "Quality Improvement+") OR "Total Quality Management*"
569	S3	"health care" N3 "quality assurance"
570	S2	"healthcare quality assurance"
571	S1	(MH "Quality Improvement+") OR "Quality Improvement*"
572		

573 Supplementary material 3

Table S1: Eligibility criteria of included studies

Author, Year	List intervention groups	Quality improvement intervention details	Intervention provided to	Intervention duration (months)	Usual care	Improvement area
Flather, 2011	Multicentre QI intervention	**1.** Set up a local QI team and nominate local champions **2.** 3 one-day QI training meetings led by experts, held approximately 5-12 weeks apart. **3.** Use of established QI tools **4.** Used PDSA cycles to overcome barriers.	Hospital staff	4	Usual care group will receive a "low intensity" QI intervention by having access to specialise data collection tool.	Measurable quality of care for ACS patients
Frijling, 2003	QI intervention with practice support	The intervention consisted of - 1. Feedback reports 2. 15 x 1 hr outreach visits per practice from trained non-physicians 3. Certificate for six hours of accredited training for each participating GP	Practice staff (GPs)	21	Usual care + feedback reports + 225 Euro per practice	Clinical decision-making for patients at high CVD risk in general practice
Geary, 2019	An audit and feedback intervention	The intervention consisted of 1. Detailed centre-specific quality reports 2. Use of pocket stroke guidelines on secondary prevention medication use and diagnosis recording	Practice staff (physicians)	18	NR	Diagnosis recording and dispensation of more secondary preventive stroke medications
Goff, 2003	QI intervention	1. A guideline recommendation summary, 2. Performance feedback, and 3. Medical chart reminders cards	Practice staff	NR	NR	Use of lipid-lowering, Beta-blockers and ACEi therapy in a network-model

						managed-care setting
Huffman, 2018	QI Intervention	1. Monthly audit and feedback reports 2. QI team meetings 3. Use of tool kit, including - PDSAs - Standardised admission and discharge order set checklist - Translated patient education materials on risk factor management, and 4. Linkage to emergency cardiovascular care and QI training for staff	Hospital staff	NR	Hospitals received QI toolkit at 1 of 5 predefined, 4-month steps over a 24-month period, after a period of usual care.	Clinical outcomes and process measures
Johnston, 2010	Implementation of a standardised stroke care order at discharge	1. Discharge order 2. Assignment of 2 local champions 3. Review of medical records by study staff 4. 2 educational sessions - one at the beginning and one 3 months post intervention.	Hospital staff (physicians, neurologist and other healthcare providers)	6	Usual care without any further contact from the study staff	Adherence to proven secondary stroke prevention practices 6 months after hospital discharge for ischemic stroke
Lowrie, 2014	multifaceted Statin Outreach Support (SOS) intervention	1. Intervention group receiving SOS 2. 3 face-to-face, 1:1 interactive educational outreach meetings in general Practices, 4 months apart, 3. NHS-employed pharmacists to deliver the intervention. 4. Pharmacist working in the practice 1 day/week for 44 weeks during the intervention period.	GPs and Nurses	12	Usual care + received a printed copy of cholesterol/statin guidelines at randomisation.	Attainment of cholesterol targets and statin prescription

Machline-Carrion, 2019	Multifaceted QI intervention	1. Case management, 2. Decision support tools 3. Distribution of educational materials to healthcare professionals and patients 4. Periodic audit and feedback reports to each cluster 5. Interactive training workshops.	Both Clinic staff and patients (patients receiving educational materials)	NR	Usual care	Prescription of evidence-based therapy
Nouwens, 2014	Practice Accreditation program - focused improvement plans during the intervention period on CVRM	1. A comprehensive audit 2. Written feedback to the practice 3. Based on the feedback, plan improvements in the practice 4. Practices performed as planned are accredited and receive certificate	Practice staff	12	Usual care group practices focused on improving any domain except on CVRM and DM	CVD risk management
Qu, 2021	smartphone-based multifaceted QI intervention using WeChat	1. Centralized training on guidelines for secondary prevention medications after CABG 2. Educational materials and up-to-date knowledge on secondary prevention medications 3. An evidence-based checklist containing information on secondary prevention medications. 4. An audit and feedback reporting mechanism on site-specific secondary prevention performance measures	Hospital staff (clinicians)	15	Usual care	Prescription of secondary prevention medications
Sondergaard, 2006	Multifaceted intervention strategy combining GP registrations,	GPs received outreach visits on their prescribing of heart disease medications and performed 2 registrations 24 months apart - 1. Feedback on GP's performance	GPs	24	Control arm practices also completed both registrations 24 months apart	Secondary prevention of IHD in GP practices

	outreach visits and feedback	2. Two guideline summaries on the prevention of IHD and motivational interviewing. 3. Information about risk reduction measures. 4. A price list of CV medications. 5. Patient handouts with relevant advice 6. Three case stories focusing on different aspects of IHD				
Wang, 2018	Multifaceted Stroke Care QI intervention	1. An evidence-based clinical pathway, 2. Written care protocols for implementation of performance measures, 3. A full-time quality coordinator, and 4. A monitoring and feedback system for performance measures.	Hospital staff	12	Usual care + stroke registry participation	Adherence to evidence-based performance measures and outcomes in patients with AIS
Williams, 2011	low-intensity continuous QI educational intervention	1. Intervention directed at a predetermined local opinion leader or quality champion at each site. 2. Sites received educational information 3. Site-specific feedback reports on the use of 4 medications every 6 months 4. Standardized care orders, care reminders, a "call to action" letter, and periodic newsletters. 5. Patients and their physicians were given a discharge "flight plan" checklist.	Mainly Hospital staff (physicians). Patients also received educational materials	24	NR	Secondary prevention adherence after CABG

ACEi - Angiotensin-converting enzyme inhibitors, ACS - Acute coronary syndrome, AIS - Acute ischemic stroke, ARB - Angiotensin receptor blockers, BP - Blood pressure, CABG - Coronary artery bypass graft, CVD - Cardiovascular disease, CV - Cardiovascular, CVRM - Cardiovascular risk management, DM - Diabetes mellitus, GP - General practitioner, HIT - Health Information technology, IHD - Ischemic heart disease, NHS - National health service, NR - Not reported, PDSA - Plan-Do-Study-Act cycles, PF - practice facilitation, QI - quality improvement.

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Table S2: Intervention details of included studies

Author, Year	Data sources	QI workshop/ webinars/seminars	Digital platform used	PDSAs	Site visits	Decision support/ Reminders/checklist/guidelines/pocket cards	Staff education material	Patient education materials	QI team	Feedback report	Practice support/ facilitation	Local champions	Others	Training
Flather, 2011	Swedish RIKS-HIA database	✓	✓	✓	⦸	⦸	⦸	⦸	✓	⦸	⦸	✓	✓ Team meetings	✓
Frijling, 2003,	Encounter forms from routine consultation	⦸	⦸	⦸	✓	⦸	✓	⦸	⦸	✓	✓	⦸	✓ Accredited training certificate	✓
Geary, 2019,	Stockholm Regional healthcare data warehouse	⦸	✓	⦸	⦸	✓ Pocket guidelines	⦸	⦸	⦸	✓	✓	⦸	⦸	⦸
Goff, 2003	Physician encounter claim database	⦸	⦸	⦸	⦸	✓ Chart reminder cards	✓ Guideline recommendation summary	⦸	⦸	✓	⦸	⦸	⦸	⦸
Huffman, 2018	Data collected via electronic software from Kerala ACS registry	⦸	⦸	✓	⦸	✓	⦸	✓	✓	✓	⦸	⦸	✓ QI team meetings	✓

Johnston, 2010	Patient medical records	✓	⦸	⦸	⦸	✓	⦸	⦸	✓	✓	✓	✓	⦸	✓
Lowrie, 2014	Electronic medical records	⦸	⦸	⦸	✓	⦸	⦸	⦸	⦸	✓	✓	⦸	⦸	✓
Machline-Carrion, 2019	Chart review, patient files, and physician prescriptions	✓	⦸	⦸	✓	✓	✓	✓	⦸	✓	⦸	✓	✓ Case management	⦸
Nouwens, 2014	Patient medical records	⦸	⦸	⦸	⦸	⦸	⦸	⦸	⦸	✓	✓	⦸	✓ Completion certificate	⦸
Qu, 2021	Web-based data submission system	✓	✓	⦸	⦸	✓ Guideline summary, Medication prescription checklist	⦸	✓	✓	✓	⦸	✓	⦸	✓
Sondergaard, 2006	APO patient registration forms	⦸	⦸	⦸	✓	✓ Guideline Summary	⦸	✓	⦸	✓	⦸	⦸	✓ 3 Case study, A price list of CVD drugs	⦸

Wang, 2018	Hospital enrolment records and registry	✓	✓	⦸	⦸	✓ Written care protocols	⦸	⦸	✓	✓	✓	✓	⦸	⦸
Williams, 2011	Society of Thoracic Surgeons National Cardiac database	⦸	⦸	⦸	⦸	✓ Standardised care order, Care reminders, letterhead, Periodic Newsletter, Flight plan checklist	✓	✓	⦸	✓	⦸	✓	⦸	⦸

HIT - Health information technology
CVD - Cardiovascular disease
PDSA - Plan-Do-Study-Act

✓= Yes,
⦸ = No,
QI - Quality improvement

Table S3: The Cochrane Collaboration of Risk of Bias

Author, Year	Random sequence generation (selection bias)		Allocation concealment (selectin bias)		Outcome data (attrition bias)		Selective reporting (reporting bias)		Overall judgement without blinding
	Judgment	Supporting evidence	Judgment	Supporting evidence	Judgment	Supporting evidence	Judgment	Supporting evidence	
Flather, 2011	Low	Centres were randomized to receive a QI training program or no QI training program using a cluster-randomized method stratified by country and presence of on-site PCI facilities	Low	The co-ordinating centre will inform centres at the beginning of the baseline phase of their randomised allocation.	Unclear	No information on attrition rate provided. Reasons for drop also not provided.	Low	Trial protocol available and referenced. Trial registration is also available. all outcomes were reported in a pre-specified way	Unclear
Frijling, 2003	Low	A random number generator was used to select permuted blocks with a block size of four	Low	the person responsible for the randomization process was blind to the practice identities.	Low	Attrition reported (low) for practices. Reasons for drop out reported. The post hoc power estimations take into account the design effect of cluster randomisation ITT analyses was performed	Unclear	Trial protocol not available	Unclear
Geary, 2019	Low	The PCCs were block-randomised according to these continuous education areas and the areas were then randomized by lottery to control or intervention	Low	The PCCs were block randomised according to these continuous education areas and the areas were then randomized by lottery to control or intervention	High	Attrition reported (high) for practices. 29% in both groups. Patient attrition not reported and reasons for exclusions for patients were also not reported. Sensitivity analysis was performed	Unclear	Trial protocol not available	High

Goff, 2003	Unclear	Random assignment of clinic practices to intervention or control conditions - Insufficient information to permit judgement	Unclear	Insufficient information to permit judgment	High	Attrition rate for practices reported with drop out reasons. However, patient attrition and reasons not reported. No information on whether missing data was imputed.	Low	Trial protocol referenced. All outcomes were reported in a pre-specified way	High
Huffman, 2018	Low	The study biostatisticians performed central computer-based randomization of hospitals.	Low	The other members of the study team and the selected sites were informed of the 12 or 13 sites that would cross over to the intervention period 2 weeks before each of the predefined steps to maintain allocation concealment	Low	Attrition rate (low) reported with reasons. Post hoc analyses was performed. All results are reported using an ITT analysis.	Low	Trial protocol referenced and registration listed. All outcomes were reported in a pre-specified way	Low
Johnston, 2010	Low	Using a random number generator, 1 hospital in each pair was randomized to receive the intervention, whereas the other was randomized to usual care.	Low	Although it was not possible to blind the study, to prevent imbalances resulting from randomizing a small number of study hospitals, we utilized a stratified, pair-matched design	Low	Attrition rate (low) as 80% were followed up and reasons for drop out was reported and all analyses were conducted using ITT.	Low	Trial registration number listed and all outcomes are reported in a pre-specified way	Low
Lowrie, 2014	Low	We then randomly allocated (using a table of random numbers) one practice from each matched pair into the SOS arm and the other practice into the usual care arm.	Low	Using a table of random numbers randomisation was performed. The allocation of practices was concealed until after allocation to SOS intervention	Low	Attrition rate (low) reported on GPs. Only one practice did not receive intervention however reason was not reported. ITT was performed. A sensitivity analysis was also carried out for primary outcome.	Low	Trial protocol referenced and registration listed. All outcomes were reported in a pre-specified way	Low

Machline-Carrion, 2019	Low	All clusters were randomized at once by a statistician using a central web-based randomization system before enrolment of the first patient	Low	All clusters were randomised at once by a statistician using a central web-based randomisation system	Low	Attrition rate (low) reported. Reasons for drop out and similar between groups All analysis followed ITT. Prespecified comparisons between groups were conducted using logistic regression with random effects corrected for the baseline performance. 2 post-hoc sensitivity analysis was done. Missing data were not imputed	Low	Trial protocol referenced and registration listed. All outcomes were reported in a pre-specified way	Low
Nouwens, 2014	Low	A computer list of random numbers was generated and used to randomly allocate practices to equally sized intervention groups or control groups by an independent statistician. This was done in a randomized block design in blocks of four practices based only on time period in order of enrolment.	Low	A computer list of random numbers was generated and used to randomly allocate practices to equally sized intervention or control group by an independent statistician.	High	The sample size calculated 35 practices to be recruited in the intervention and control group but recruited 22 and 23 instead. Reasons for drop out reported but differed in between groups. 35 practices were aimed to recruit in each group was needed to achieve statistical power, only 22 and 23 practices were recruited. (no mention of ITT or sensitivity analysis)	Low	Trial protocol referenced and registration listed. All outcomes were reported in a pre-specified way	High

Qu, 2021	Low	A web-based minimized randomization system was used to ensure balanced group assignment across regions and prescription rate of statin	Low	Web-based minimized randomization performed by an independent statistician not involved in the study was used to ensure balanced group assignment across regions and prescription rate of statin.	Low	Attrition rate for hospitals were reported (low) with reasons. A modified ITT and Sensitivity analysis was also conducted .	Low	Trial protocol referenced and registration listed. All outcomes were reported in a pre-specified way	Low
Sondergaard, 2006	Low	Allocation was done using a computer program based on a random number sequence.	Low	Allocation was done using a computer program based on a random number sequence.	High	Sample size calculated 25 GPs in each group but recruited 15 GPs in each group instead. However, attrition rate (low) of GPs reported but Reason for drop out not reported.	Unclear	Trial protocol not available	High
Wang, 2018	Low	Clusters were randomized 1:1 to a multifaceted quality improvement intervention (intervention group) or routine care plus stroke registry participation (control group) by using a randomly generated number	Low	Cluster randomisation was done by an independent statistician not otherwise involved in the study using a randomly generated number	Low	Attrition rate (low) reported but reasons for drop out not reported. ITT analysis was used for all outcomes.	Low	Trial protocol referenced and registration listed. All outcomes were reported in a pre-specified way	Low

Williams, 2011	Low	Clusters were then paired so that each pair was similar in terms of geography and CABG volume and randomized within pairs so that 1 cluster received the intervention and the other received the control assignment.	Unclear	Insufficient information to permit judgment	Low	No Loss to follow up occurred.	Unclear	Trial protocol not available	Unclear
CABG - Coronary artery bypass graft, GP - General practitioner NCD - National cardiac database, PCC - Primary care centre, PCI - Percutaneous coronary intervention, QI -Quality improvement, SOS - Statin outreach support, ITT - Intention to treat.									

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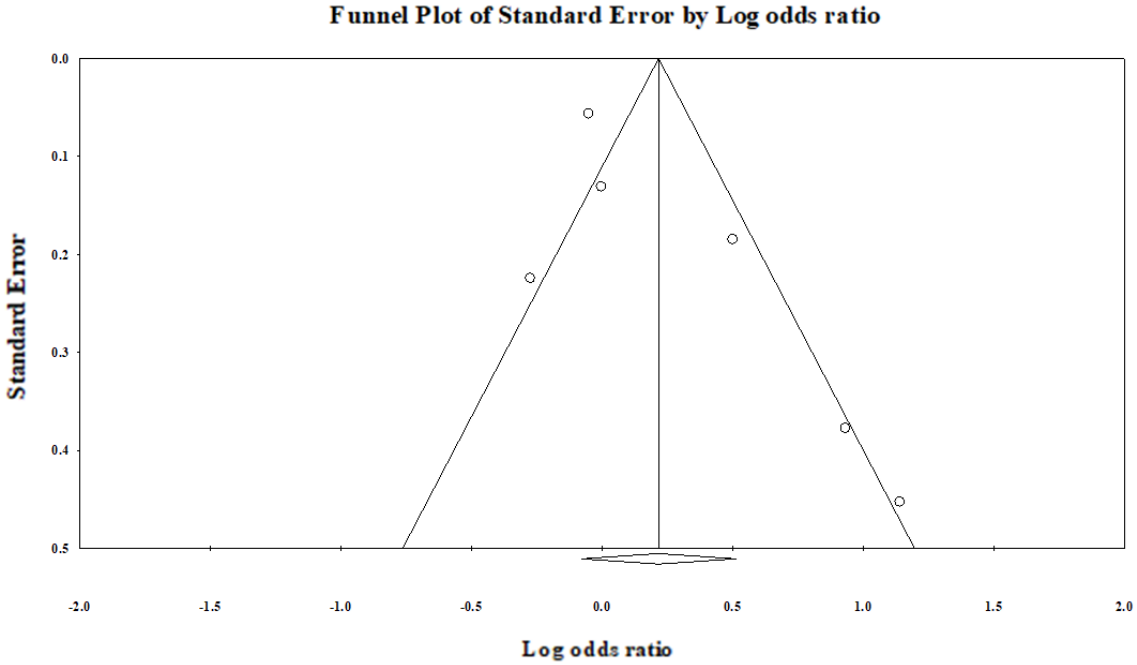
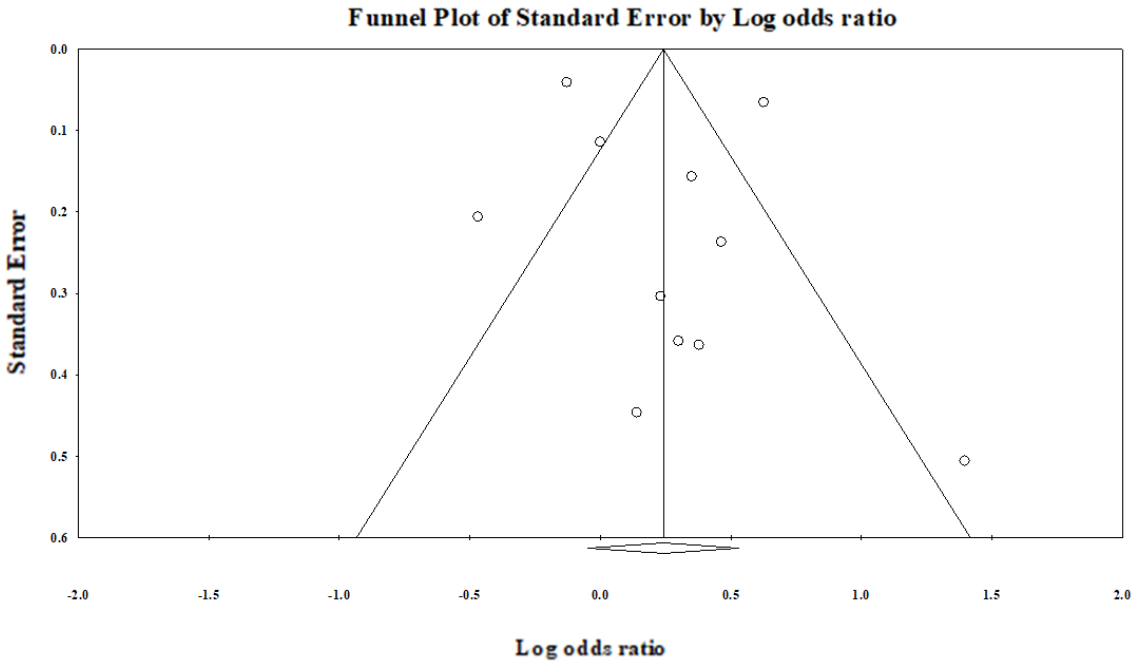
Supplementary material 4: Funnel plots and Egger's test for publication bias

Antiplatelet therapy



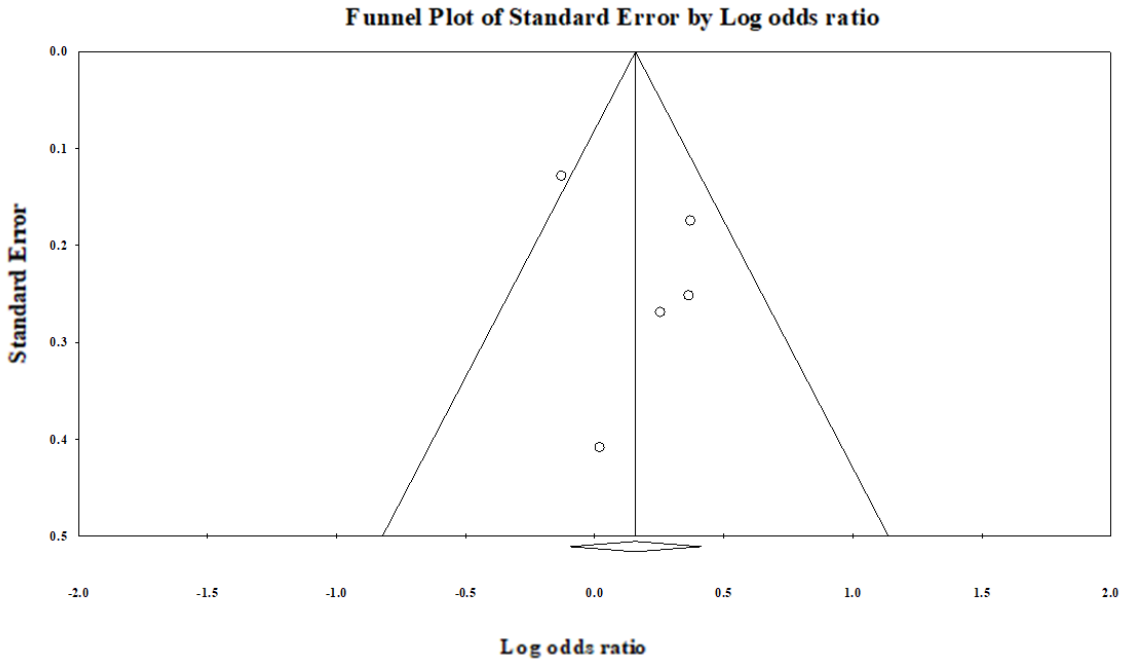
Egger's regression intercept: 2.21673, (95% CI: -0.79933, 5.23278), p-value: 0.11087

Lipid-lowering medications



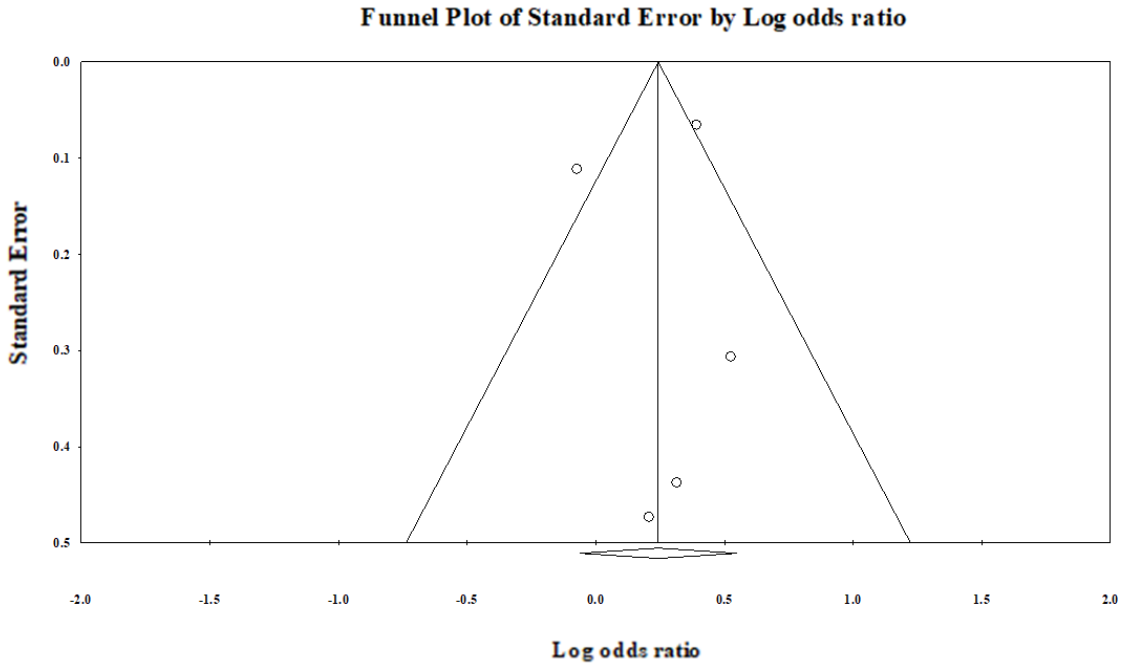
Egger regression intercept: 1.33062 (95% CI: -2.09925, 4.76049), p-value: 0.40298

ACEi or ARB



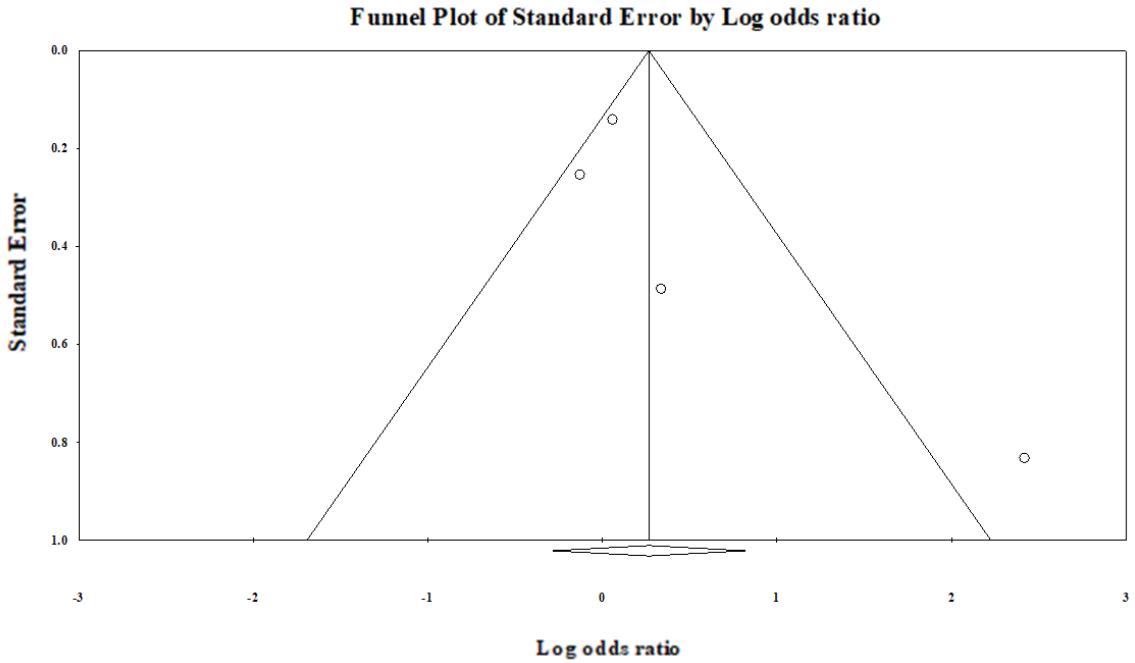
Egger's regression intercept: 1.56994 (95% CI: -3.66473, 6.80461), p-value: 0.41027

Beta-blocker



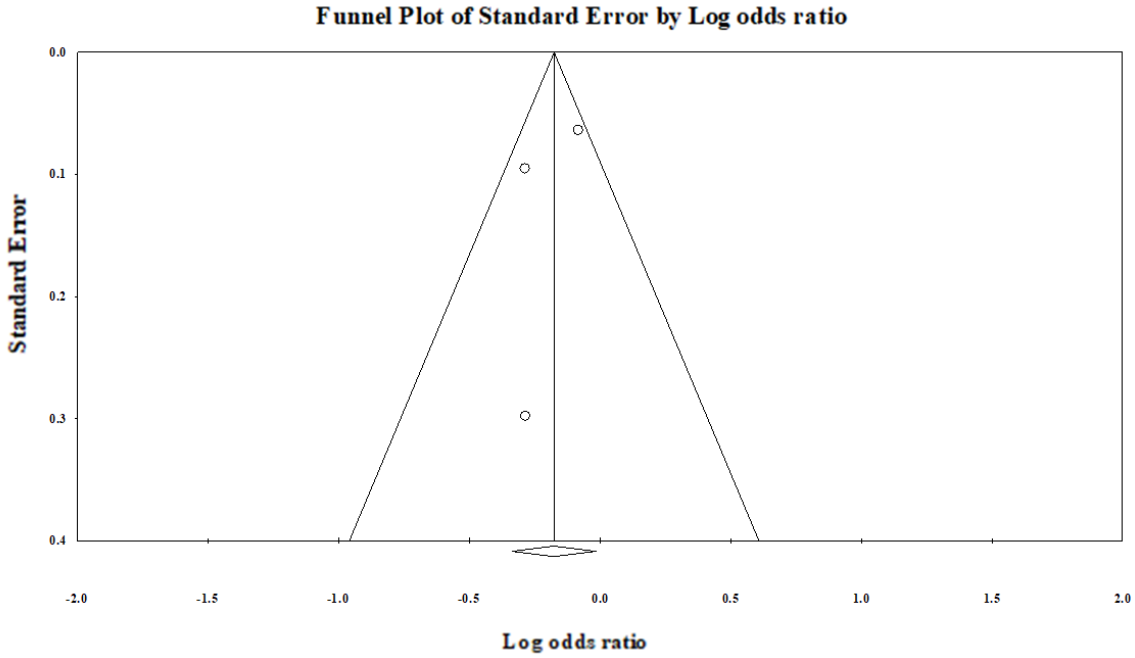
Egger's regression intercept: -0.38267 (95% CI: -5.18804, 4.42269), p-value: 0.81631

Smoking or tobacco cessation advice



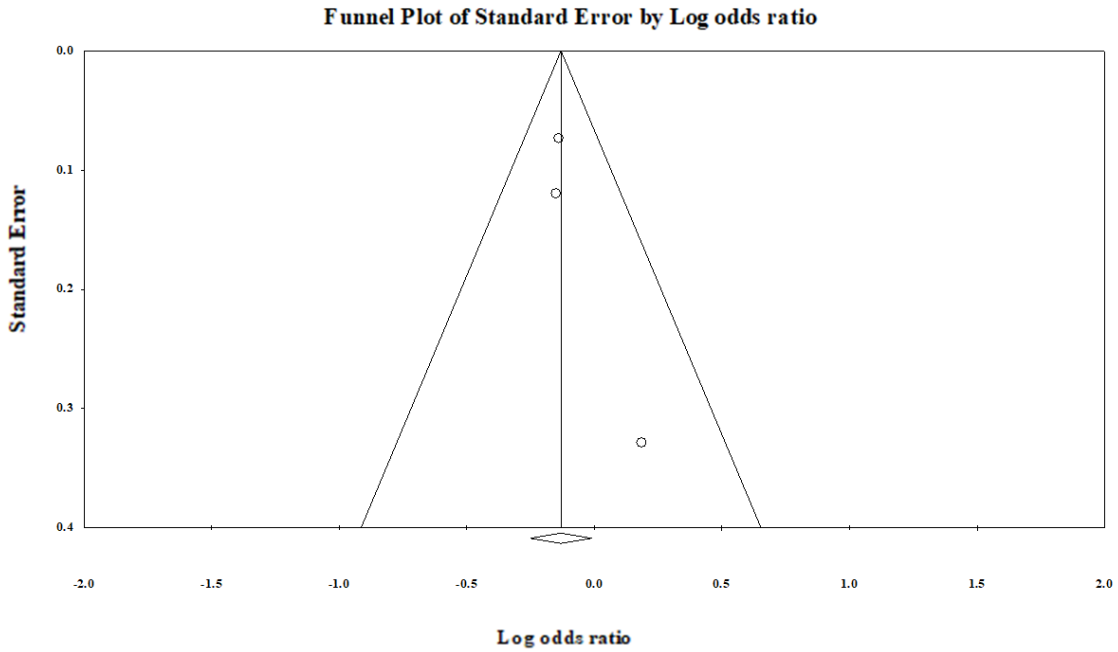
Egger's regression intercept: 2.04111 (95% CI: -3.72620, 7.80842), p-value: 0.26726

MACE



Egger's regression intercept: -1.32666 (95% CI: -25.56665, 22.91334), p-value: 0.61316

Total mortality



Egger's regression intercept: 1.08051 (95% CI: -6.51108, 8.67210), p-value: 0.32156

Supplementary material 5

5A: Data extracted for meta-analyses

		Continuous data		Categorical data	
Author, year	**Post-intervention follow-up**	**Intervention (n/N)**	**Control (n/N)**	**OR**	**95% Confidence interval**
Antiplatelet therapy					
Flather, 2011	Not reported	NA	NA	0.76	0.49, 1.18
Geary, 2019	36 months	NA	NA	0.95	0.85, 1.06
Huffman, 2018	30 day following cardiac event	NA	NA	1.65	1.15, 2.37
Machline-Carrion, 2019	12 months	NA	NA	3.13	1.29, 7.60
Nouwens, 2014	Not reported	787/952	593/717	0.99	NA
Sondegaard, 2006	24 months	NA	NA	2.54	1.21, 5.31
Lipid-lowering therapy					
Flather, 2011	Not reported	NA	NA	1.46	0.72, 2.99
Geary, 2019	36 months	NA	NA	0.88	0.81, 0.95
Goff, 2003	36 months	NA	NA	1.00	0.80, 1.25
Huffman, 2018	30 day following cardiac event	NA	NA	1.42	1.04, 1.92
Johnston, 2010	6 months	NA	NA	1.26	0.70, 2.30
Lowrie, 2014	Not reported	NA	NA	1.87	1.65, 2.13
Machline-Carrion, 2019	6 months	NA	NA	4.04	1.5, 10.89
Nouwens, 2014	Not reported	200/289	176/225	0.63	NA
Qu, 2021	Not reported	NA	NA	1.15	0.48, 2.76
Sondegaard, 2006	24 months	NA	NA	1.59	1.00, 2.53
Wang, 2018	12 months	NA	NA	1.35	0.67, 2.73
Smoking or tobacco cessation advice					
Huffman, 2018	30 day following cardiac event	NA	NA	1.06	0.8, 1.39

Machline-Carrion, 2019	12 months	NA	NA	11.24	2.2, 57.43
Nouwens, 2014	Not reported	69/133	65/118	0.88	NA
Sondegaard, 2006	24 months	NA	NA	1.4	0.54, 3.64
ACEi or ARB					
Flather, 2011	Not reported	NA	NA	1.29	0.76, 2.18
Goff, 2003	36 months	NA	NA	0.88	0.69, 1.14
Huffman, 2018	30 day following cardiac event	NA	NA	1.45	1.03, 2.04
Machline-Carrion, 2019	12 months	NA	NA	1.44	0.88, 2.36
Qu, 2021	Not reported	NA	NA	1.02	0.46, 2.28
Beta-blockers					
Flather, 2011	Not reported	NA	NA	1.23	0.49, 3.13
Goff, 2003	36 months	NA	NA	0.93	0.75, 1.16
Huffman, 2018	30 day following cardiac event	NA	NA	1.48	1.3, 1.68
Machline-Carrion, 2019	12 months	NA	NA	1.37	0.58, 3.22
Qu, 2021	Not reported	NA	NA	1.69	0.93, 3.09
MACE					
Huffman, 2018	30 day following cardiac event	NA	NA	0.92	0.81, 1.04
Machline-Carrion, 2019	12 months	19/705	30/844	0.75	NA
Wang, 2018	12 months	218/2400	282/2400	0.75	NA
Total mortality					
Huffman, 2018	30 day following cardiac event	NA	NA	0.87	0.75, 1.00
Machline-Carrion, 2019	12 months	19/710	19/851	1.20	NA
Wang, 2018	12 months	139/2400	160/2400	0.86	NA

OR - Odds ratio, CI - Confidence interval, MACE - Major cardiovascular events, NA - Not available

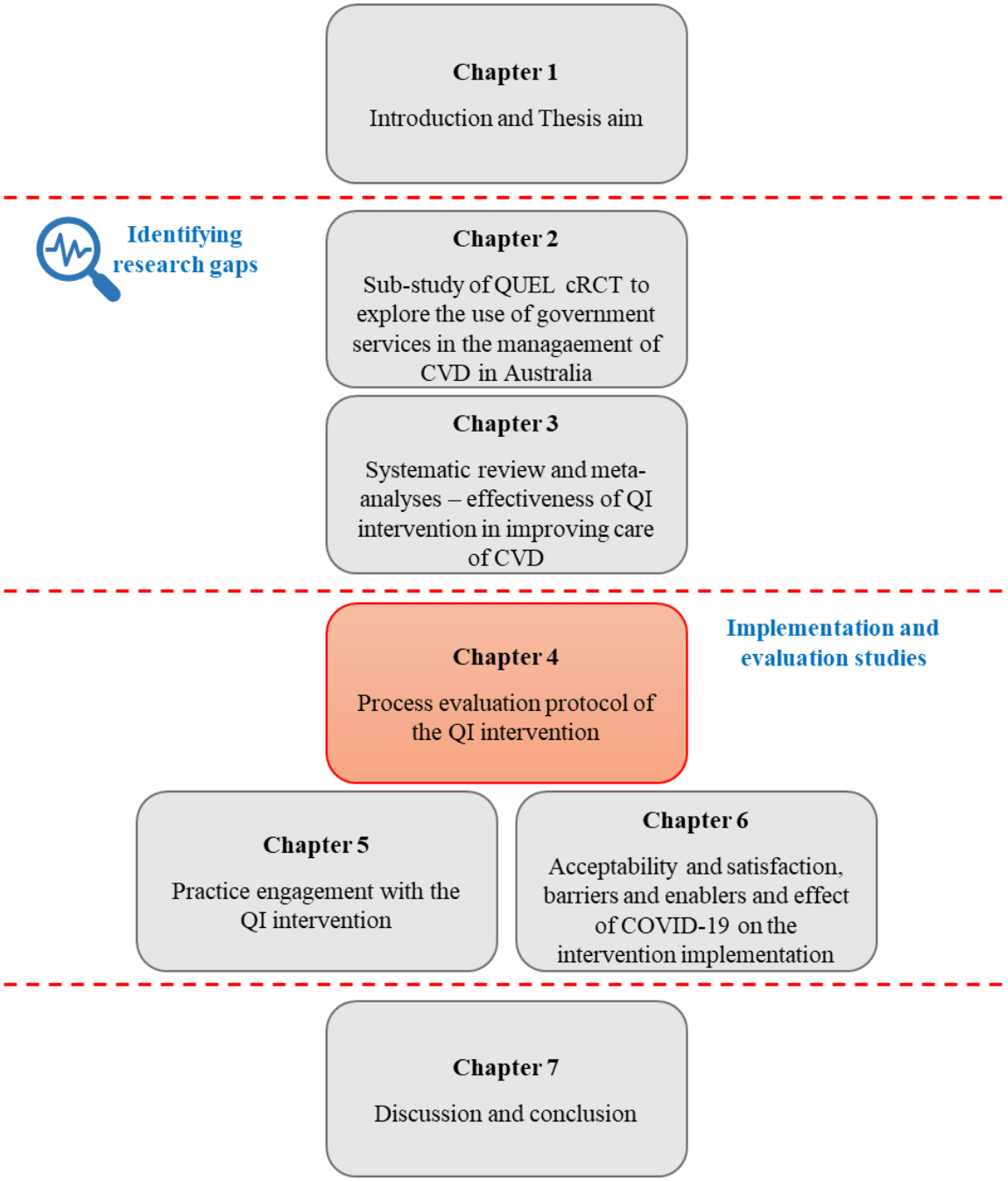
5B: Data extracted for sensitivity analyses

		Continuous data		Categorical data	
Author, year	**Post-intervention follow-up**	**Intervention (n/N)**	**Control (n/N)**	**OR**	**95% Confidence interval**
Antiplatelet therapy					
Flather, 2011	Not reported	NA	NA	0.76	0.49, 1.18
Huffman, 2018	30 day following cardiac event	NA	NA	1.65	1.15, 2.37
Machline-Carrion, 2019	12 months	NA	NA	3.13	1.29, 7.60
Lipid-lowering therapy					
Flather, 2011	Not reported	NA	NA	1.46	0.72, 2.99
Huffman, 2018	30 day following cardiac event	NA	NA	1.42	1.04, 1.92
Johnston, 2010	6 months	NA	NA	1.26	0.70, 2.30
Lowrie, 2014	Not reported	NA	NA	1.87	1.65, 2.13
Machline-Carrion, 2019	6 months	NA	NA	4.04	1.5, 10.89
Qu, 2021	Not reported	NA	NA	1.15	0.48, 2.76
Wang, 2018	12 months	NA	NA	1.35	0.67, 2.73
Smoking cessation advice					
Huffman, 2018	30 day following cardiac event	NA	NA	1.06	0.8, 1.39
Machline-Carrion, 2019	12 months	NA	NA	11.24	2.2, 57.43
ACEi or ARB					
Flather, 2011	Not reported	NA	NA	1.29	0.76, 2.18
Huffman, 2018	30 day following cardiac event	NA	NA	1.45	1.03, 2.04
Machline-Carrion, 2019	12 months	NA	NA	1.44	0.88, 2.36
Qu, 2021	Not reported	NA	NA	1.02	0.46, 2.28
Beta-blockers					
Flather, 2011	Not reported	NA	NA	1.23	0.49, 3.13

Huffman, 2018	30 day following cardiac event	NA	NA	1.48	1.3, 1.68
Machline-Carrion, 2019	12 months	NA	NA	1.37	0.58, 3.22
Qu, 2021	Not reported	NA	NA	1.69	0.93, 3.09
OR - Odds ratio, CI - Confidence interval, MACE - Major cardiovascular events, NA - Not available					

CHAPTER FOUR

Data-driven quality improvement program to prevent hospitalisation and improve care of people living with coronary heart disease: Protocol for a process evaluation



PREFACE TO THE CHAPTER

Chapter Three provided evidence that quality improvement interventions can be effective for enhancing CVD outcomes. However, implementation of such interventions is complex and challenging. To gain a deeper understanding of the process and to facilitate more effective future implementations, I designed a mixed-methods process evaluation to assess the data-driven quality improvement (QI) intervention implemented within the QUEL study. The protocol of the process evaluation is presented in Chapter Four, thereby addressing Aim Three of this Thesis. The paper is titled "Data-driven Quality Improvement Program to Prevent Hospitalisation and Improve Care of People Living with Coronary Heart Disease: Protocol for a Process Evaluation' in Contemporary Clinical Trials" and it is published in the journal, Contemporary Clinical Trials. Ethics approvals for this study are presented in Appendix A. The Participant Information Sheet and Consent Form is included in Appendix B and learning workshop evaluation and end of/post-program evaluation surveys are included in Appendix C.

PEER-REVIEWED PUBLICATIONS AND PRESENTATIONS

Published paper

Hafiz N, Hyun K, Tu Q, Knight A, Hespe C, Chow CK et al. Data-driven quality improvement program to prevent hospitalisation and improve care of people living with coronary heart disease: Protocol for a process evaluation. Contemp Clin Trials. 2022;118:106794.

STATEMENT OF AUTHORSHIP

Nashid Hafiz, during her PhD candidature, developed the original concept of the study and was responsible for designing and refining the study protocol with advice from supervisors and the cRCT co-investigators. She prepared the initial draft and subsequent revisions, responded to reviewer feedback, and coordinated submission and publication of the original research paper.

Individual roles of co-authors are listed below

Task Role of co-authors	**Role of co-authors**
Conception and design	NH, KH, JR
Refining the research question	KH, JR
Revision and Critical comments on manuscript	KH, JR, AK, CH, CC, TB, RG, CR, DH, NZ, MW, SJ, EA, TL, EH, TU and JR

Nashid Hafiz 30th April 2024

As supervisor for the candidature upon which this Thesis is based, I can confirm that the authorship attribution statement above is correct.

Professor Julie Redfern 30th April 2024

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Data-driven quality improvement program to prevent hospitalisation and improve care of people living with coronary heart disease: Protocol for a process evaluation

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Process evaluation
Mixed-method research

ABSTRACT

Background: Practice-level quality improvement initiatives using rapidly advancing technology offers a multi-dimensional approach to reduce cardiovascular disease burden. For the "QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with heart disease" (QUEL) cluster randomised controlled trial, a 12-month quality improvement intervention was designed for primary care practices to use data and implement progressive changes using "Plan, Do, Study, Act" cycles within their practices with training in a series of interactive workshops. This protocol aims to describe the systematic methods to conduct a process evaluation of the data-driven intervention within the QUEL study.

Methods: A mixed-method approach will be used to conduct the evaluation. Quantitative data collected throughout the intervention period, via surveys and intervention materials, will be used to (1) identify the key elements of the intervention and how, for whom and in what context it was effective; (2) determine if the intervention is delivered as intended; and (3) describe practice engagement, commitment and capacity associated with various intervention components. Qualitative data, collected via semi-structured interviews and open-ended questions, will be used to gather in-depth understanding of the (1) satisfaction, utility, barriers and enablers; (2) acceptability, uptake and feasibility, and (3) effect of the COVID-19 pandemic on the implementation of the intervention.

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Conclusion: Findings from the evaluation will provide new knowledge on the implementation of a complex, multi-component intervention at practice-level using their own electronic patient data to enhance secondary prevention of cardiovascular disease.
Trial registration: Australian New Zealand Clinical Trials Registry (ANZCTR) number ACTRN12619001790134.

List of abbreviations

CVD	Cardiovascular Disease
CHD	Coronary Heart Disease
PHN	Primary Health Networks
QI-PIP	Quality Improvement Practice Incentive Program
QI	Quality Improvement
QUEL	QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with coronary heart disease
cRCT	Cluster randomised controlled trial
RDS	Research Data Storage
PDSA	Plan-Do-Study-Act
GP	General Practitioner
EPOC	Effective Practice and Organisation of Care Review Group

1. Background

Cardiovascular disease (CVD) including coronary heart disease (CHD) and stroke remains the leading cause of death and disease burden worldwide despite decades of significant advances in the prevention and management of CVD [1,2]. .Globally an estimated 17.8 million people die every year from CVD constituting approximately one-third of global deaths [2,3]. The burden of CVD continues to contribute heavily towards the global economic burden due to the associated direct and indirect effects including hospitalisations, medications, post-discharge primary care management, rehabilitation services, disability, and unemployment [4]. As a result, the global cost of CVD is predicted to rise from US$863 billion in 2010 to US$1044 billion by 2030 [5,6]. With the aging population and more people surviving initial cardiac events, the prevalence of CVD is increasing along with the economic cost [7]. To reduce the risk of future cardiovascular events in those with established disease, secondary prevention strategies have become an international priority [8,9] and include the use of guideline-indicated medications, adopting a healthy lifestyle, implementation of chronic disease management plans and participation in a cardiac rehabilitation program following an acute event [8]. Primary care plays an integral role in implementing successful secondary prevention strategies as the majority of people hospitalised for CVD regularly visit their primary care practitioners and use government-funded health services at least once a year following their acute CHD diagnosis [10–13].

Funded by the federal government, primary care is the first point of contact for all Australians to access care. Under the primary care system, individuals can receive services that includes treatment of acute conditions, chronic disease management, health promotion, prevention and early intervention [14]. These services are provided via the general practices, community health centres and allied health practices with the help of Primary Health Networks (PHNs) [14,15]. The Australian government has recently launched the Quality Improvement Practice Incentive Program (QI-PIP), which encourages primary care practices to collaborate with their PHNs and undertake quality improvement activities within their practices to provide high-quality patient care for better health outcomes [16]. As a result, many primary care practices worldwide are rapidly adopting the use of quality improvement (QI) initiatives [17–19]. QI initiatives offer an innovative, multidimensional approach to healthcare and have excellent potential to improve patient outcomes in primary care [20]. Also, current technology has enabled the integration of automated data extraction leading primary care practices to consider data-driven QI programs to provide high-quality patient care [21,22]. Primary care practices have been successfully implementing QI programs in several health conditions including asthma [23], diabetes, neonatal health [24,25]. However, there is a paucity of research focused on evaluating the effectiveness of such QI interventions only at individual patient level rather than community or clinic level in CVD management [26,27]. .The "QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with heart disease" (QUEL) study aimed to determine the effectiveness of a quality improvement program for improving CVD management [28].

For the QUEL cluster randomised controlled trial (cRCT), a structured QI program is delivered within Australian primary care practices to reduce CVD hospitalisations, improve CVD risk factors and medication adherence in patients with CHD over 24 months [28]. The intervention practices are supported by the study team or their relevant PHNs to enhance efficiency in management and outcomes of CVD patients by better using their routinely collected data. The trial is ongoing involving 52 (27 intervention and 25 control) Australian primary care practices with approximately 15,000 CVD patients with 12- and 24-month follow-up with data collection scheduled for completion in mid-2022. The primary outcome is CVD hospitalisations, collected via linkage with state-based administrative data linkage centres that collect data on all hospitalisations in Australian hospitals and as such will not be adjudicated, and secondary outcomes are cardiovascular risk factors recorded electronically by the GPs in real time which will be collected routinely across all participating primary care practices using a standardised data extraction software; medication prescriptions and use collected by data linkage of the QUEL cohort with federal level Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data; and deaths collected via linkage of the same cohort with the federal level National Death Index. Specific details on the cRCT including trial aims, design, sample size, and outcome measures are described elsewhere [28].

The QUEL intervention is based on the Collaborative Framework [29] and consists of (1) a virtual orientation session, (2) electronic data collection at baseline, and thereafter monthly, from the intervention practices via a practice-level software system that enables automated data extraction [30], (3) monthly data reporting, (4) completion of Plan, Do, Study, Act (PDSA) cycles that summarise practice-level progress towards pre-determined CVD indicators for the QUEL study, (5) a series of interactive learning and benchmarking workshops (1 in-person and 5 virtual sessions due to the COVID-19 pandemic) and (6) provision of support from PHNs and the study team. The intervention is delivered over a period of 12 months.

The study team is collaborating with five PHNs to ensure optimal delivery of the collaborative intervention. PHNs are independent organisations funded by the Australian government aimed to coordinate health services for the communities in a specific region [15]. PHNs also work closely with the primary care practices and other health care professionals within the region to identify gaps and build capacity to ensure optimal service delivery [15]. There are thirty-one PHNs operating in Australia including in remote and Aboriginal Torres Strait Islanders communities to encourage use of available health resources and access health care [15]. All PHNs were invited to participate through a variety of communication channels, including a mailing list direct to PHN CEOs, University of Sydney's as well as research partners' networks. Five out of the thirty-one PHNs agreed to collaborate on the study based on their previous experience in QI collaborative and existing collaboration with the University of Sydney. For the QUEL study, each

collaborating PHN nominates a primary contact to provide liaison, leadership and coordination to the participating practices within the PHN's jurisdiction. During the intervention period, PHN representatives play a key role in ensuring successful implementation of the intervention. The role of the PHN involves, but is not limited to, supporting practices to achieve pre-defined key performance measures to optimise outcomes, participating in program activity including training and learning workshops, encouraging practice level engagement in these activities and using PDSA cycles between activity periods, sharing practice achievement and providing additional support as required.

Process evaluation is particularly important in complex intervention trials as it provides in-depth information required to evaluate the intervention's effectiveness and investigate the implementation process. It provides valuable insights into describing the various intervention components [31] and identifying factors associated with successes and challenges of the programs in various healthcare settings [32]. Use of process evaluation alongside complex interventions is increasing given because of the associated multisite, multicomponent features [33,34]. However, little research has reported the mechanisms of impact, context and what constitutes effective QI interventions aimed at improving CVD management in primary care settings.

The QUEL QI program is a complex intervention with multiple interactive components, as such, process evaluation can accurately describe the intervention implementation, exposure of the intended intervention and real-time experiences of those involved [35]. We hypothesise that evaluating the implementation of the multi-component QI intervention within the QUEL trial will help primary care practices to undertake further QI activities to improve care of CVD within their practices. The earlier protocol describes the cluster RCT itself [28], while this current protocol details the evaluation plan for the data-driven QI intervention program within the QUEL cRCT and its effects. The process evaluation aims to:

1. Explore to what extent the intervention is delivered as intended, identify key elements of the intervention associated with positive study outcomes, and how, for whom and in what context it was effective.
2. Describe and analyse practice engagement, attendance, time commitment, software capability, skills and capacity of the practice team members associated with attending learning workshops.
3. Understand acceptability, satisfaction, uptake, utility and feasibility of the QI program.
4. Identify and describe barriers and enablers of the QI program.
5. Evaluate the effect of COVID – 19 on the implementation of the QI program.

2. Methods

2.1. Study design

A mixed-methods approach will be undertaken using data from 27 intervention practices (out of 52 participating practices) from the QUEL cRCT [36,37]. For this study, data will be collected only from the intervention practices as it aims to evaluate the effect of the QI intervention program. Qualitative and quantitative data will be collected both during and at the end of the trial intervention period. Semi-structured interviews and open-ended questions will be used to collect qualitative data. Quantitative data will be collected from the intervention practices via multiple data sources throughout the intervention period.

A program logic model was developed to describe how, why and among whom the collaborative intervention works in practices within the QUEL cRCT (Fig. 1). This logic model is a visual representation of the intervention design and its intended implementation. The Cochrane Effective Practice and Organisation of Care Review Group (EPOC) checklist was used as a guidance to develop the logic model [38] to identify the key features of the intervention, check the fidelity of the implementation and assess participant's experience [31]. The model includes 5 domains of the intervention: (1) input, (2) activities, (3) outputs, (4) outcome and (5) impact specific to the data-driven QI program that will be used to describe the study objectives [39]. Inputs refer to various resources that are required to ensure program operation, activities refer to the planned actions, such as delivery of workshops, data collection that are an essential part of the implementation [39]. Resources, inputs, and activities together form the program design. Outputs include the changes in the participant's behaviour, knowledge, skills, and awareness resulting from the activities and impact describes the fundamental changes occurring in the health services over a longer period as a result of the program activities [40].

2.2. Participants

Participants in the process evaluation will include practice team members (including general practitioners, nurses and practice managers) from primary care practices allocated to the intervention arm and PHN staff who are providing direct support to the intervention practices under their jurisdiction. At least two practice team members from all 27 intervention practices who were actively involved in QI activities in their practices; such as participated in QI workshops, submitted and carried out PDSA cycles and regularly communicated and shared reports with the study team on their activities during the intervention period will be approached to complete the surveys and participate in semi-structured interviews. These participants will be able to understand sufficient English to provide written and informed consent. Practice team members from primary care practices allocated to the control group and any PHN staff not involved in the QUEL project will not be included in the process evaluation. All practice team members who are part of the intervention practices will be approached for recruitment to provide feedback and participate in interviews during and at the end of the intervention.

2.3. Data sources

Multiple data sources, collected throughout the cRCT, will be used in addition to surveys and interview data, to evaluate whether the complex intervention was delivered as planned. Combining these data sources will help to identify the key intervention elements, identify the dose, frequency and activities delivered to the intervention practices as well as describe barriers and enablers associated with the program implementation. To maintain balanced quality of information across the multiple data sources the research team will ensure a) close communications and interaction with practices and PHNs (e.g. workshops; practice visits, regular contact via email or phone calls) to promote quality of data collection; b) an experienced research officer is responsible for data collection throughout the study; c) all the practices are well informed on the study procedures before they are enrolled; d) the participating practices receive appropriate research support when required; e) routine extraction, monitor and check data for quality assurance and help practices solve issues if data is not returned. The data sources will include: 1) practice-level enrolment data, 2) attendance record, 3) SharePoint data, 4) practice correspondence record, 5) data collection record, 6) PDSA cycles, 7) learning workshop surveys, 8) end of program survey and 9) semi-structured interviews of practice team members and PHN representatives. These data sources will be used as credible evidence collected at different time point during the intervention period (Fig. 1).

2.3.1. Practice-level enrolment data

Practice-level enrolment data will be created at the time of recruitment and will be recorded in a Microsoft Excel (2016) spreadsheet. Information collected will include practice location (urban and rural), practice team members information, software compatibility, and

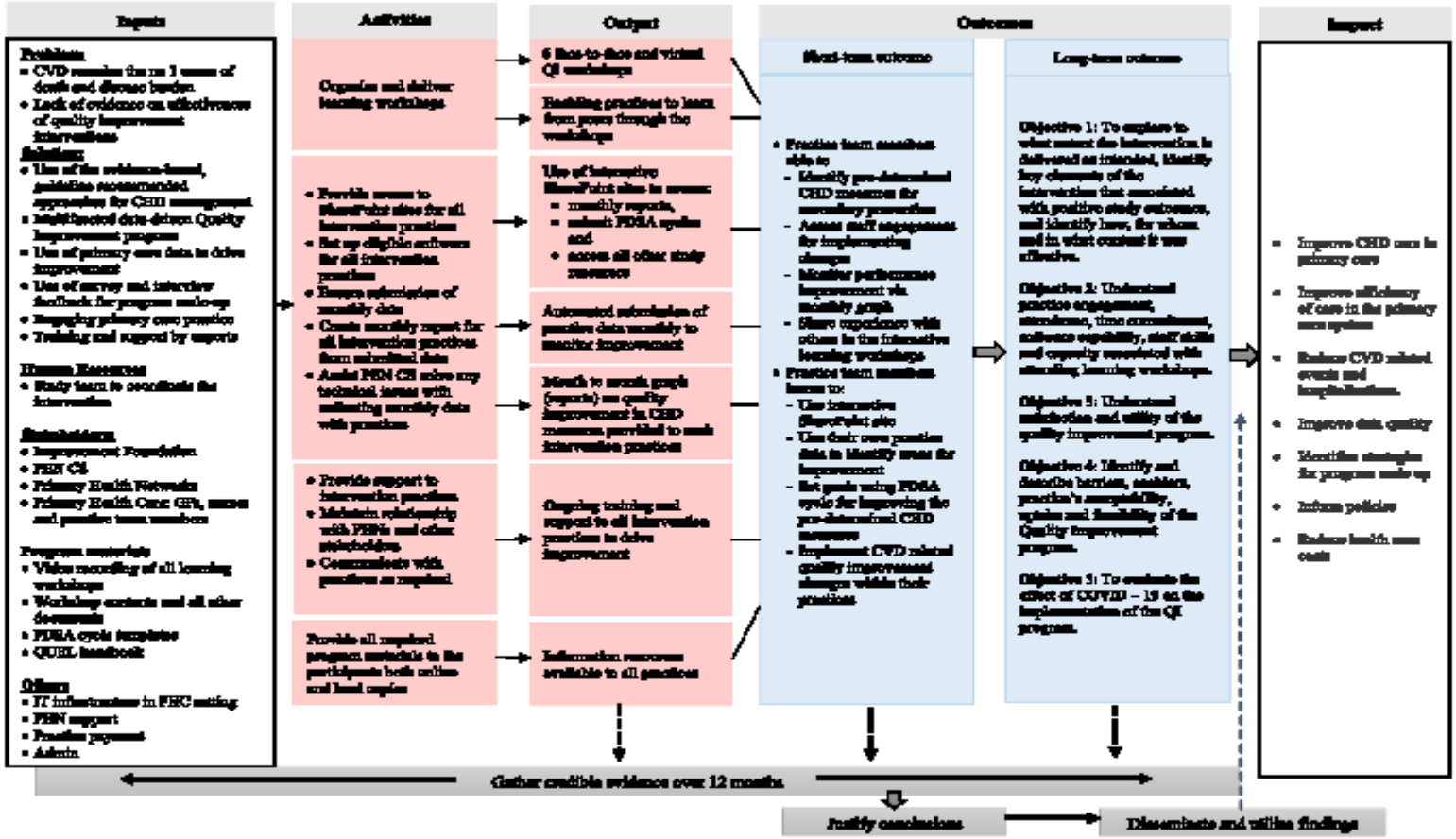

Fig. 1. Logic model for data-driven Quality Improvement (QUEL) intervention process evaluation.
CVD: Cardiovascular Disease, CHD: Coronary Heart Disease, PEN CS: Pen Computer Systems, GP: General Practitioner, PDSA: Plan, Do, Study. Act, PHC: Primary Health Care, IT; Information Technology, PHN: Primary Health Network, QI: Quality Improvement.

randomisation group. Urban and rural primary care practices were defined using the Australian department of Health's Health workforce classification guideline [41]. This spreadsheet will be used throughout the main trial period and updated regularly with current dates and version numbers. We will use these data to identify intervention practices, software eligibility and installation requirement of the eligible software, practice support, describe practice type and gather details of the practice team members involved in the delivery of the intervention.

2.3.2. Attendance records

Participation of the practice team members in any events related to the intervention including orientation and learning workshops (both face-to-face and virtual) will be recorded in another Microsoft Excel (2016) spreadsheet and updated regularly throughout the intervention period. These data will provide information on the frequency of the workshops attended by the intervention practices, the number of staff from each practice attending the orientation and workshops.

2.3.3. SharePoint data

Microsoft SharePoint [42] is an online platform where a unique account is created for individual practices in both intervention and control arms. This platform is created for the practices to submit their PDSA cycle records and track improvements via monthly graphs which are uploaded in their respective accounts by the study team. From the SharePoint data, we will identify whether each practice had access to their account and all intervention materials including workshop recordings and lectures, monthly feedback reports, frequency and number of PDSA cycles submitted by each practice.

2.3.4. Practice correspondence record

The study team will be communicating with the intervention practices during the trial period and practices will also be encouraged to directly communicate with the study team as required. These communications will be undertaken via phone call, email or in-person site visits. Any communication will be saved and used to identify the reason, mode of contact (email, site visit or phone call), time spent on the contact, person contacted and solution provided in a Microsoft Excel (2016) spreadsheet. This document will be updated throughout the study period with current dates and version numbers.

2.3.5. Data collection record

The intervention practices will submit clinical data electronically in an aggregated and de-identified form monthly via the automated data extraction software [30]. All aggregated data will be stored in the University's Research Data Storage (RDS). These data will be used to create practice level reports and will be uploaded to practices' SharePoint sites monthly as graphs for benchmarking their improvement for the predefined QUEL study performance measures. A Microsoft Excel (2016) spreadsheet will be used to record monthly data collection and reporting for each intervention practice. This spreadsheet will also be updated regularly throughout the intervention period with current dates and version numbers.

2.3.6. Plan, Do, Study, Act cycles

The PDSA cycle is a simple but powerful tool to measure improvements and increasingly used in many QI collaborative to boost quality of healthcare [43,44]. It guides users to explicitly plan, implement, reflect on, and then repeat, incremental improvements as they make system changes to achieve the aim [45]. Practices participating in the QUEL QI intervention are required to document and upload their PDSA cycles using a template. Training will be provided to the practices during the learning workshops on the process of completing PDSAs. Submitted PDSA cycles will be saved in their respective SharePoint accounts and the study team will be able to download a copy of the cycle when required. We will use all the PDSA cycles submitted by primary care practices during the intervention period to gather information on practice engagement, number of PDSAs submitted by each practice, identify key areas practices focused on improving and identify barriers and enablers to make improvement changes within the practices.

2.3.7. Learning workshop surveys

At least two practice team members (one clinical and one administrative) will be invited to participate in a series of six learning workshops that will be delivered during the intervention period. Six surveys corresponding to six workshops will be administered at the end of each workshop (paper-based for in-person workshops and online for the virtual workshops) to the workshop attendees. Each survey will contain questions that are specific to the workshop content and a set of common questions that will be asked at every workshop. The common questions include feedback on the workshop evaluation, learnings, satisfaction and suggestions for improvement collected as Likert scale and free-text response The surveys aim to evaluate practice engagement, workshop attendance, time commitment, staff skills and capacity involved in implementing QI changes in their practice. The survey will also be used to evaluate the appropriateness of content and the effectiveness in terms of practice-level implementation of QI.

2.3.8. End of program surveys

Practice team members including general practitioners, practice managers or nurses from QUEL study intervention practices who are actively involved in implementing QI changes within their practices will be invited to complete a comprehensive survey on the overall program at the end of the intervention. To ensure as many responses as possible, the survey will be sent by post, with a return address envelope, email, online or by direct contact. The survey aims to evaluate the whole intervention and examine acceptability, satisfaction, uptake, utility and feasibility among users. The survey will include fifty-five questions, of which forty questions require Likert scale responses focused on overall workshop content, design, facilitators, results and outcome; practice software usability, use of electronic data for the management of CVD patients, quality and satisfaction of care provided by the primary care team, impact of the intervention on the quality of care provided, leadership involvement and staff capacity. Six questions will require yes or no responses with possible further explanation which focuses on QI-PIP [16], SharePoint use and access. Nine questions will allow free text responses focused on sharing experience implementing changes within the practice, change in staff role, sharing feedback on different intervention components. These free text questions will also include questions and discussion points on the effect of COVID-19, which will provide detailed information to help us evaluate its effect on the intervention implementation.

2.3.9. Interviews with practice team members and PHN representatives

Practice team members participating in the QUEL study will be invited by email, telephone, or post to take part in a confidential one-on-one interview at the end of the intervention. Practices will be selected based on their performance (high, low and medium); which will be defined by the practices' interaction during the intervention period such as participation on the learning workshops, submission of PDSA cycles. We will invite practice team members from at least three practices from each high, medium and low performing tier to participate in the interviews to ensure minimum bias. The purpose of these interviews is to evaluate workforce capability, describe perceived benefits, barriers or successes to implementation, uptake, and acceptability of the program. We will also be able to explore the differences in the dose, frequency and the activities implemented by the practices which were supported by the PHNs vs the study team. The interviews will also expand on themes within the surveys to triangulate these data; explore their experiences with QI strategies, gain detailed insight into the staff involvement, changes that occurred in the staff role due to the program. Interviews will be also used to explore the capacity of the practice software and the use of electronic data extracted from the software for QI program

implementation. The semi-structured interviews will also explore how the COVID-19 affected the implementation of the intervention and will provide us with information on different approaches taken by the practices to overcome the challenges.

Interviewing the PHN representatives will enable us to describe the role of PHN in implementing QI intervention in primary care. With the interviews, we will obtain in detail PHN's perspective on the program, barriers and enablers to implementation, practice engagement, time commitment and efforts required by PHN representatives.

Semi-structured interviews are widely used in healthcare research to collect open-ended, qualitative data and to explore in-depth understanding of a specific topic [46,47]. For the evaluation, we estimate a sample of approximately 10 interviews from different suburban locations, including a variety of practice team members such as GPs, nurses and practice managers and PHN representatives reflecting diverse participant demography. However, the final number of interviews will be dependent on the thematic saturation. A trained researcher will conduct and audio record the interviews of approximately 45 min duration at the practice or health service, or via telephone, as convenient for the participants [48]. A topic-centred discussion guide will be used by the interviewer to conduct the semi-structured interviews to ensure the topics are systematically explored [48]. The researcher may take notes during the interview to document relevant information.

2.4. Data analysis

Descriptive statistical analysis will be used to analyse quantitative data. Responses and measurements from all data sources will be presented as numbers and percentages for categorical variables and mean and standard deviation or median and interquartile intervals for continuous variables. This will help to understand the level of satisfaction and perceived utility associated with program implementation and explain the extent to which the intervention is delivered as intended. The quantitative data will be compared between the following subgroups: rural vs urban and small (≤2 GPs) and large primary (>2 GPs) care practices. Chi-squared test or Fisher's exact test will be used to compare categorical variables between the subgroups and independent *t*-test or Wilcoxon rank-sum test will be used to compare continuous variables.

Qualitative data, including semi-structured interviews and free-text responses from the surveys and PDSA cycles, will undergo thematic analysis [49]. The thematic analysis will include preparing and transcribing the data, familiarising and coding, generating, reviewing and defining the themes and writing up the interpretation of the data [49,50]. Two independent researchers will thematically analyse interview transcripts. All data collected will be converted into electronic format and stored in one location. Interviews will be recorded with consent and verbatim method will be used for transcription of the interviews. Interview transcript, any free text and notes from the interviews as well as the surveys and PDSAs will be coded and managed in NVivo Software.

2.5. Data storage, retention and disposal

All data collected for the process evaluation including personal information will be securely stored in the University's RDS database. Access to the RDS will require an employee unikey and password and only a limited number of people will have access to it. All data will be stored on The University's RDS for the duration necessary to comply with regulatory requirements; thereafter database will be destroyed in accordance with University's IT recommendations. Completed surveys and interview data will be stored securely for 5 years after publications, after which time, they will be destroyed securely. No personal information will be published. At the end of this data retention period, all files will be physically destroyed.

3. Discussion

This protocol outlines the systematic methods of a process evaluation of a complex QI intervention embedded within a cRCT to improve secondary prevention of CVD in primary care. The evaluation logic model is described along with methods for understanding the impact of the intervention and the context in which the impact occurs. It will assess successes and failures related to the program implementation in addition to determining factors associated with program scale-up and adaptation for other primary care settings [32]. The EPOC framework does not provide information on describing the actual QI intervention, therefore this evaluation also includes interviewing of key participants at completion of the intervention. The study will contribute to stronger evidence around the use of QI in primary care to improve CVD outcomes as well as to literature through encouraging the development of process evaluation methodology in the design and promoting transparency in the reporting of the findings.

A strength of our study is the use of a mixed-methods approach. Mixed-methods research can strengthen data quality, improve interpretations of findings, and offer a more comprehensive understanding of the program implementation, and hence, it has become a very useful tool to evaluate complex interventions [51]. Quantitative data will provide key information on what was effective and qualitative data will provide deeper understanding of why and in what context the intervention was effective. Therefore, combination of both will provide a more holistic understanding of the complex intervention than either method alone [52]. Furthermore, this approach enables a richer perspective from a range of participants (GPs, nurses, practice managers, and PHN representatives) using various surveys and semi-structured interviews integrated within the main QUEL cRCT. Combining interview and survey data will enable in-depth knowledge on program utility, barriers, and likelihood of adoption. Findings from the process evaluation will also inform other primary care practices to implement data-driven QI programs and provide valuable insights to policymakers on wider adoption and scaling-up of such strategies.

While this process evaluation will enable evaluation of a complex QI intervention and barriers and enablers to its implementation, there are several limitations. One of the limitations is the data collected from the interviews may be subjected to recall bias as interviews will take place after the intervention. Another limitations is the cRCT is designed to be delivered in Australian primary care environment, hence it may only be relevant to health systems with similar contexts, funding, and infrastructures.

4. Conclusion

At the completion of the evaluation, we will gather rich data about collaborative implementation in terms of key features, impact, barriers and enablers and other factors including collaborative teams, staff resistance, use of experienced resources within the team to train staff specific to improving care of CVD management in primary care. Results from the evaluation will also contribute to further high-quality evidence regarding the implementation of quality improvement programs in primary care. This process evaluation will therefore help identify gaps in implementation and influence practice-level decision making in adopting data-driven quality improvement strategies and to improve CVD management.

Ethics and dissemination

The study is approved by the New South Wales Population & Health Services Research Ethics Committee (HREC/18/CIPHS/44). The ethics committee provides approval for all four participating states including New South Wales, Australian Capital Territory, Victoria, Queensland, and South Australia under the National Mutual Scheme. Participants who are participating in the process evaluation will be provided with a

Participant Information Sheet and Consent Form and written consent will be obtained from each of the participants. Written informed consent will be obtained from participants and only de-identified data will be analysed and report. Results of this process evaluation as well as the cRCT, will be communicated through peer-reviewed publications and presentations at scientific forums including national and international conferences. Published papers, reports and any barriers, enablers, and key outcome identified through the results will be shared among national stakeholder organisations, participating practices and clinical networks.

Disclaimer

The funding body and industry partners was not involved in the design of the study; and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Data statement

Not applicable.

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Authors' contributions

NH, JR and KH drafted the protocol. JR, NH, KH, AK, CH, TU helped with intervention design. JR, NH, KH and QT managed ethics and legal approvals. NH, JR, KH and QT involved in data collection and management. All authors reviewed and approved the final manuscript.

Declaration of Competing Interest

Amgen and Sanofi Australia has provided cash support to the main cRCT. MW is a consultant to Amgen, Freeline and Kyowa Kirin. Other authors has nothing to disclose.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2022.106794.

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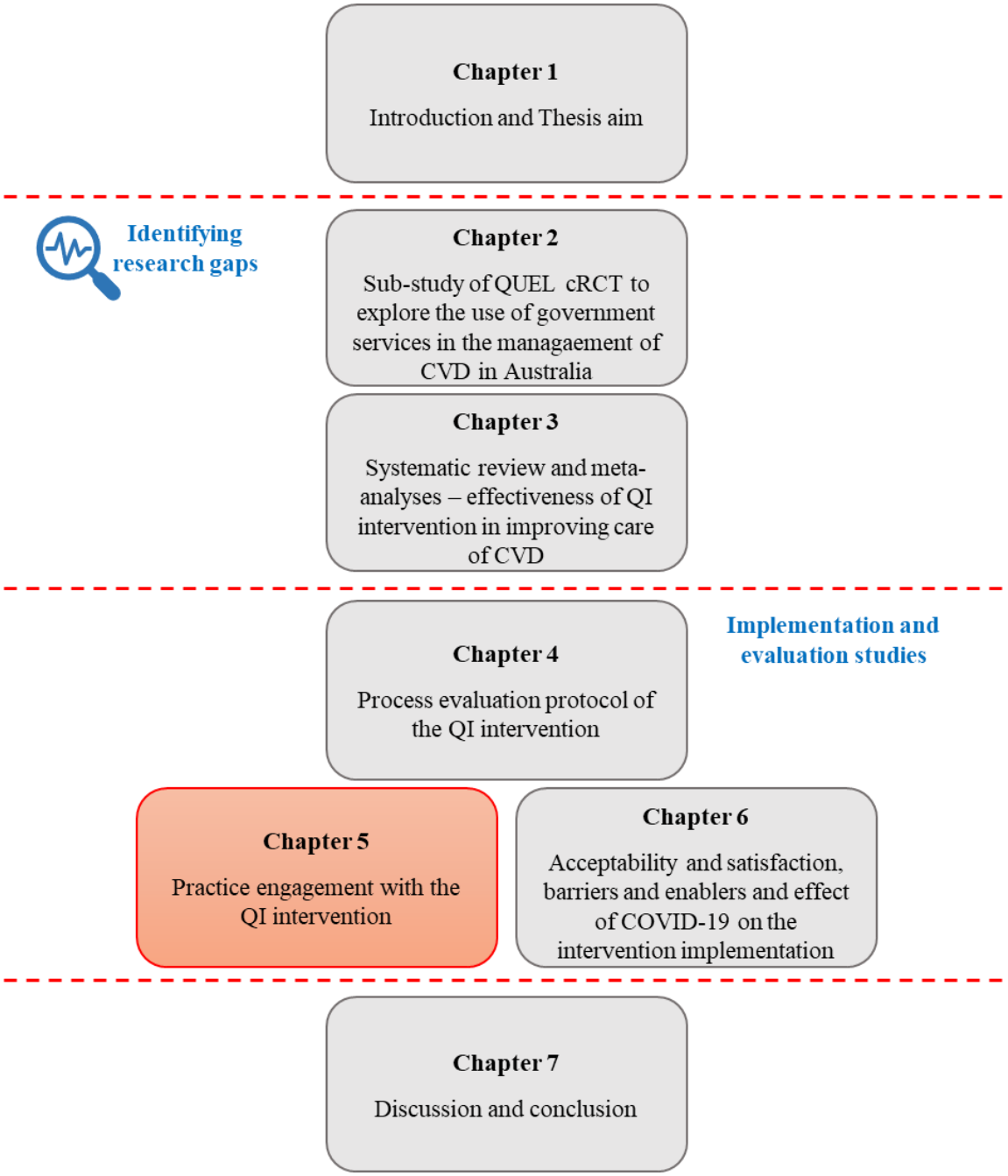
CHAPTER FIVE

Process evaluation of a data-driven quality improvement program within a cluster randomised controlled trial to improve coronary heart disease management in Australian primary care



PREFACE TO THE CHAPTER

Chapter four presented the published process evaluation protocol for the data-driven quality improvement intervention within the QUEL study. The QI intervention consisted of multiple features, spanned over 12 months, and was implemented across 27 Australian primary care practices. Chapter Five presents the findings of this process evaluation, focusing mainly on the practices' engagement with different features of the intervention. Furthermore, this Chapter assesses whether the intervention was delivered as intended and evaluates the usefulness of its features, thereby addressing Aim Four of this Thesis. The paper is titled "Process evaluation of a data-driven QI program within a cluster randomised controlled trial to improve coronary heart disease management in Australian primary care" has been accepted for publication by the PLoS One. The ethics approval for the study is included in Appendix A and the discussion guide that was used to conduct semi-structured interviews is included in Appendix D. All supplementary materials used are included after references of this chapter.

PEER-REVIEWED PUBLICATIONS AND PRESENTATIONS

Manuscript accepted for publication

Hafiz N, Hyun K, Tu Q, Knight A, Hespe C, Chow CK et al. Process evaluation of a data-driven quality improvement program within a cluster randomised controlled trial to improve coronary heart disease management in Australian primary care. PloS One Journal. (Accepted).

Published abstract and conference presentation

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cardiovascular disease care in Australian primary care practices. Heart, Lung and Circ. 2023;32:S340-S1. (*Cardiac Society of Australia and New Zealand Annual Scientific Meeting 2023, Adelaide, South Australia, Australia*).

STATEMENT OF AUTHORSHIP

Nashid Hafiz, during her PhD candidature, developed the concept of the sub-study, performed statistical analysis, and interpreted the results, prepared the initial draft and subsequent revisions, responded to reviewers' feedback, and coordinated the submission and publication of the original research paper.

Individual roles of co-authors are listed below

Task Role of co-authors	**Role of co-authors**
Refining the research question	NH, KH, JR
Data collection and analysis	NH, KH, DM
Revision and Critical comments of manuscript	KH, JR, AK, CH, CC, TB, RG, CR, DH, NZ, MW, SJ, EA, TL, EH, TU and JR

Nashid Hafiz 30th April 2024

As supervisor for the candidature upon which this Thesis is based, I can confirm that the authorship attribution statement above is correct.

Professor Julie Redfern 30th April 2024

Process evaluation of a data-driven quality improvement program within a cluster randomised controlled trial to improve coronary heart disease management in Australian primary care

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ABSTRACT

Background This study evaluates primary care practices' engagement with various features of a quality improvement (QI) intervention for patients with coronary heart disease (CHD) in four Australian states.

Methods Twenty-seven practices participated in the QI intervention from November 2019 - November 2020. A combination of surveys, semi-structured interviews and other materials within the QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with heart disease (QUEL) study were used in the process evaluation. Data were summarised using descriptive statistical and thematic analyses for 26 practices.

Results Sixty-three practice team members and Primary Health Networks staff provided feedback, and nine of the 63 participants participated in the interviews. Seventy-five percent (40/53) were either general practitioners or practice managers. Although 69% of the practices self-reported improvement in their management of heart disease, engagement with the intervention varied. Forty-two percent (11/26) of the practices attended five or more, 69% (18/26) used Plan-Do-Study-Act cycles, and the median (Interquartile intervals) visits per practice to the online SharePoint site were 170 (146, 252) visits. Qualitative data identified learning workshops and monthly feedback reports as the key features of the intervention.

Conclusion Practice engagement in a multi-featured data-driven QI intervention was common, with learning workshops and monthly feedback reports identified as the most useful features. A better understanding of these features will help influence future implementation of similar interventions.

Trial registration Australian New Zealand Clinical Trials Registry (ANZCTR) number ACTRN12619001790134.

Keywords: Cardiovascular disease; Coronary heart disease; Data; Primary care; Process evaluation; Quality improvement.

INTRODUCTION

Cardiovascular disease (CVD), including coronary heart disease (CHD), contributes to one-third of deaths annually and remains a significant contributor to disability globally.[1, 2] In Australia alone, CHD is responsible for 10% of all deaths and 41% of these are CVD-related deaths.[3] Primary care plays a crucial role in reducing the burden of CHD as it is the first point of contact for patients where their care is coordinated.[4, 5] Largely financed by the federal government's Medicare - a universal healthcare system, Australian primary care services that are available to patients with CHD include lifestyle counselling, prescription of guideline-recommended medications, chronic disease management plans (CDMPs) and participation in cardiac rehabilitation.[6, 7] In Australia, patients who had at least one follow-up with a General Practitioner (GP) or cardiologist or utilised any of the aforementioned services after an acute CHD event have been shown to lower the chance of emergency re-admission and death.[8]

The Australian government introduced the Practice Incentive Program Quality Improvement (PIP-QI) in 2019 to enhance the management and quality of care provided to people with chronic disease.[9] To receive the incentives, primary care practices are required to participate in continuous quality improvement (QI) in partnership with their local Primary Health Networks (PHN) and submit quarterly data reports to the latter. PHNs are funded by the Australian government to work closely with individual practices to coordinate health services within local communities.[10] PHNs also provide feedback to practices and support capacity to

perform QI activities to ensure optimal service delivery. However, more research is needed to understand how practices can best implement PIP-QI to improve care in CHD.

The availability of PIP-QI and advancing data collection and reporting systems have enabled practices to adopt data-driven QI programs.[11, 12] When implemented effectively, data-driven QI has demonstrated success in several health conditions, including diabetes, asthma, and chronic obstractive pulmonary disease (COPD).[13-15] However, studies have identified that implementation and sustainability of such initiatives are complex and challenging.[16] To improve the management of chronic conditions, it is increasingly important to understand the features and processes associated with implementing such programs.[17-19] The "QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with heart disease (QUEL)" study is currently being conducted in Australia. The QUEL study protocol is published elsewhere.[20] QUEL included a multifaceted 12-month intervention aimed at improving the management of CHD care in primary care practices by using data-driven QI strategies. The primary objective of this study is to comprehensively evaluate the QUEL intervention by examining practice engagement in performing QI activities, providing insight into the delivery of the intervention, and assessing the usefulness of the intervention features from healthcare providers' perspective. Specifically, it aims to (i) describe and analyse practice engagement, time commitment, skills and capacity of the practice team members associated with the intervention and (ii) explore to what extent the intervention was delivered as intended and whether the intervention features were useful. We hypothesise that higher practice engagement and perceived usefulness of intervention features are positively associated with the increased adoption of data-driven QI strategies in improving the care of patients with CHD in primary care practices.

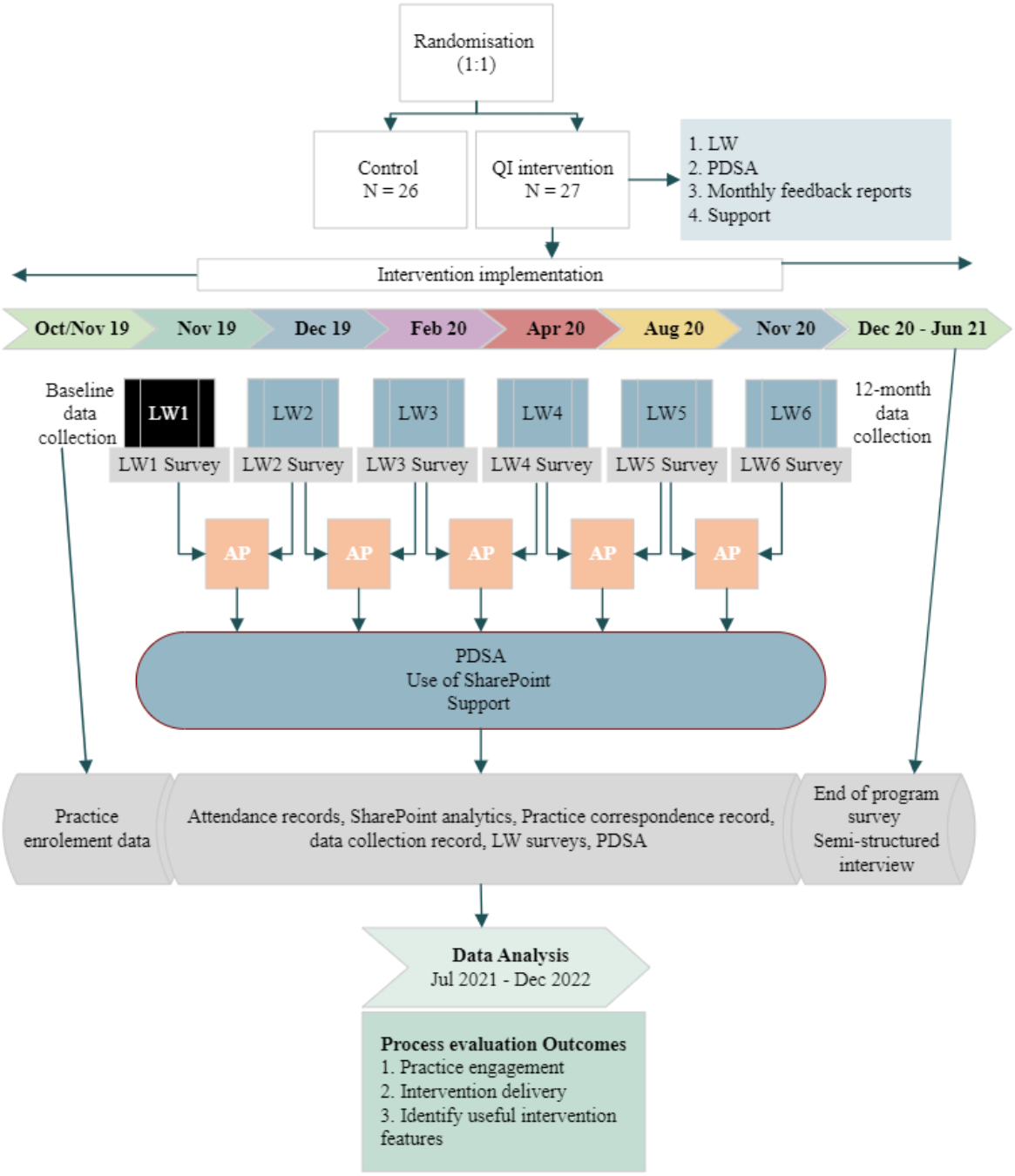
METHODS

Study design

The QUEL study is a cluster randomised trial, where primary care practices were randomised to receive the QI intervention or continued to receive usual care without access to the intervention during the study. In addition to usual care, control practices were offered an opportunity to participate in a series of virtual workshops after the completion of 24 months data collection. For this study, a process evaluation was performed on the intervention practices using a mixed-methods approach, collecting both quantitative and qualitative data from 27 urban and rural primary care practices of varying sizes within ten PHNs and across four Australian states (New South Wales, South Australia, Victoria and Queensland). The protocol for the process evaluation is published elsewhere (Appendix S1).[21] Ethics approval was obtained from the New South Wales Population and Health Services Research Ethics Committee (HREC/18/CIPHS/44). Figure 1 provides a flow diagram of the process evaluation conducted.

Participants

Participants were included if they met any of the following criteria: (i) team members from a practice randomised to receive the intervention, including general practitioners (GPs), nurses and practice managers (PM), (ii) PHN staff who provided direct support to intervention practices, and (iii) provided written informed consent.



cRCT: Cluster randomised controlled trial, LW: Learning Workshop, PDSA: Plan-Do-Study-Act, AP: Activity period
Face-to-Face, Online

Figure 1. Process evaluation flow diagram of QUEL intervention

QI intervention

The QUEL intervention was delivered between November 2019 and November 2020. It consisted of multiple features, which included attendance at six learning workshops, monthly submission of data and Plan-do-study-act (PDSA) cycles, receipt of monthly feedback reports and support from the study team or relevant PHNs. Learning workshops were delivered approximately every two months, and the practice team members undertook other QI activities (i.e., electronic data submission, continuous improvement efforts, and feedback reports) between the learning workshops.

All practices and PHN staff were given an individual SharePoint account to access study materials, including workshop recordings, presentations and the QUEL handbook as intervention guidelines. Individual monthly reports and an online template to submit PDSAs were also provided in the account. After obtaining consent, PEN Computer Systems (PenCS) used their software to extract clinical data on the pre-defined CHD measures (Table S1 in Supplementary Material) from the intervention practices automatically each month and transmitted them to the study team.[22]

After receiving electronic data, the study team reviewed and aggregated the data to create Excel reports and graphs, uploaded to the practice's individual SharePoint account as a PDF. These individual feedback graphs helped the practices to easily identify improvement areas and track their progress over time. Practices also used the PDSA cycles to test and implement changes. Each practice was required to submit monthly PDSA cycles focused on improving the pre-defined 12 performance measures for QUEL (Table S1 in Supplementary Material).

A vital component throughout the intervention was the external support provided to each practice by the study team or PHN staff. The study team and PHNs provided similar support to the practices, from ensuring practice participation in training and learning workshops, encouraging practice engagement, and helping with PDSA cycles to solving any data collection or feedback issues.

Data sources

Data from the following sources were synthesised to evaluate the QI intervention and address the study aims: 1) practice-level enrolment data, 2) attendance record, 3) SharePoint resources, 4) practice correspondence record, 5) data collection record, 6) PDSA cycles, 7) learning workshop surveys, 8) end-of-program evaluation survey and 9) semi-structured interviews of practice team members and PHN Staff. Details of the data sources are published elsewhere (Chapter Four).[21] These data were collected throughout the intervention period between November 2019 - November 2020. Additionally, the end-of-program evaluation survey and the semi-structured interviews were conducted at the intervention completion between December 2020 and June 2021. Feedback was sought from all practice team members who were involved in leading the QI activities. To ensure a balanced representation and minimise bias, team members for the semi-structured interviews were invited to participate from both rural and urban practices and from practices representing high, medium or low attendance in the learning workshops.

Data protection and confidentiality

In accordance with ethical guidelines, the authors had access to information that could identify individual participants during the data collection phase. However, all identifiable information was removed and replaced with unique identification numbers. The data was

treated with strict confidentiality and stored securely in the University's Research Storage Database. Access to the database was limited to the study team only, requiring a username and password.

Outcome measures

Practice engagement with the QUEL intervention was defined as attendance in the series of learning workshops, submission of PDSA cycles and use of SharePoint by the practices. Workshop attendance data were collected after each of the six learning workshops (delivered online and face-to-face). PDSA cycle submission was collected in SharePoint, extracted and stored on a spreadsheet. SharePoint usage data was collected as part of the end-of-program evaluation survey and using webpage analytics. Time commitment and skills of the practice team members were also collected using surveys.

The time commitment was measured as "Never (1)", "Rarely (2)", "Sometimes (3)", "Usually (4)", "Always (5)", and "Don't know (0)" using questions from the end-of-program evaluation survey. A score of ≥4/5 indicates longer time spent on QI activities. The semi-structured interviews also asked open-ended questions about the time spent by the team members on implementing these activities. The skills and capacity of a practice team member were defined as the roles, experience, and availability of practice team members leading the QI activities collected via surveys.

Data analysis

One practice withdrew following participation in the first learning workshop due to staff change and was excluded from the analysis. Data from 26 practices were analysed for the process evaluation. Descriptive statistics were used to analyse quantitative data. Responses

and measurements from all data sources are presented as numbers and percentages for categorical variables and mean and standard deviation (SD) or median and interquartile intervals (IQI) for continuous variables. Practices that did not respond to the survey were not included in the analysis. To evaluate the practice engagement, the workshop attendance, number of PDSA submissions, and SharePoint use were categorised into distinct groups for analysis. Workshop attendance was classified as low (less than three workshops attended), moderate (three to four workshops attended), and high (five or more workshops attended). PDSA submission was categorised as practices submitting less than three, three to six, and seven or more PDSA cycles. SharePoint use was grouped based on the number of visits made by the practices over the 12-month intervention period, with categories 0 to 149, 150 to 299, and 300 or more visits.

Qualitative data from semi-structured interviews, surveys and other data sources were analysed using thematic analysis.[23] Semi-structured interviews were conducted via Zoom, using an audio recorder and transcribed verbatim by NH and DM. Two researchers (NH and DM) performed thematic analysis of interview transcripts to ensure consistency in the interpretation of the themes. Both researchers individually prepared the data for transcription, coded and reviewed them before defining the themes for interpretation.[23, 24] Minor disagreements about the interpretation of some responses and the categorisation of some themes were discussed with a third researcher (KH) until a consensus was reached. Free text from surveys and PDSAs were also coded thematically. Thematic analysis was performed using QSR NVivo version 1.6.1.

RESULTS

Practice and PHN participation

Twenty-six primary care practices from four Australian states (69% of the practices from New South Wales, 15% from Victoria, 12% from South Australia and 4% from Queensland) participated in the QUEL intervention. Among these practices, six were from rural areas, and the remaining 22 were in urban areas across these four states. The practices were also of varying size, with the number of GPs varying from 1 - 18, and the median (IQI) number of GPs in these practices was 7 (3, 10). Fifty-three team members from 26 primary care practices responded to at least one of the six learning workshop surveys, the end-of-program evaluation survey or participated in a semi-structured interview. Participants responding to each learning workshop survey ranged between 13 to 26. Thirty-six participants from 20 (77%) practices responded to the end-of-program evaluation survey. Eight team members from seven practices participated in the semi-structured interviews.

Five of the ten PHNs agreed to participate in the QUEL study; lack of time and capacity to undertake the additional responsibilities attributed to the non-participation of the remaining PHNs. Ten participants from these PHNs responded to the learning workshop surveys or participated in the semi-structured interviews. PHN staff were also encouraged to attend the learning workshops to track their practices' progress in the QI intervention. Four PHNs attended three (50%), and only one attended five (80%) learning workshops. The number of PHN staff attending the learning workshops ranged from one to four who also responded to the surveys. Only one PHN staff participated in the semi-structured interview. Table 1 summarises the number of participants providing feedback for the process evaluation at the end of each learning workshop.

Table 1. Summary of participants providing feedback on learning workshop surveys.

Learning workshops	No of practices	No of participants from practices	No of PHN	No of participants from PHN	Total participants provided feedback
LW1	18	26	2	3	29
LW2	16	20	3	3	23
LW3	14	16	2	1	17
LW4	11	14	1	1	15
LW5	10	12	3	4	16
LW6	17	26	3	3	29

LW - Learning workshop, PHN - Primary Health Network

Practice engagement and attendance

Figure 2 displays the distribution of practices across different levels of workshop attendance, PDSA cycles and SharePoint use over the 12-month intervention period in frequency graphs, providing detailed insights into the use of these features.

Workshop attendance

Forty-two percent (11/26) of the intervention practices attended five to six learning workshops, another 42% (11/26) attended three to four learning workshops, and only 16% (4/26) attended two or less learning workshops.

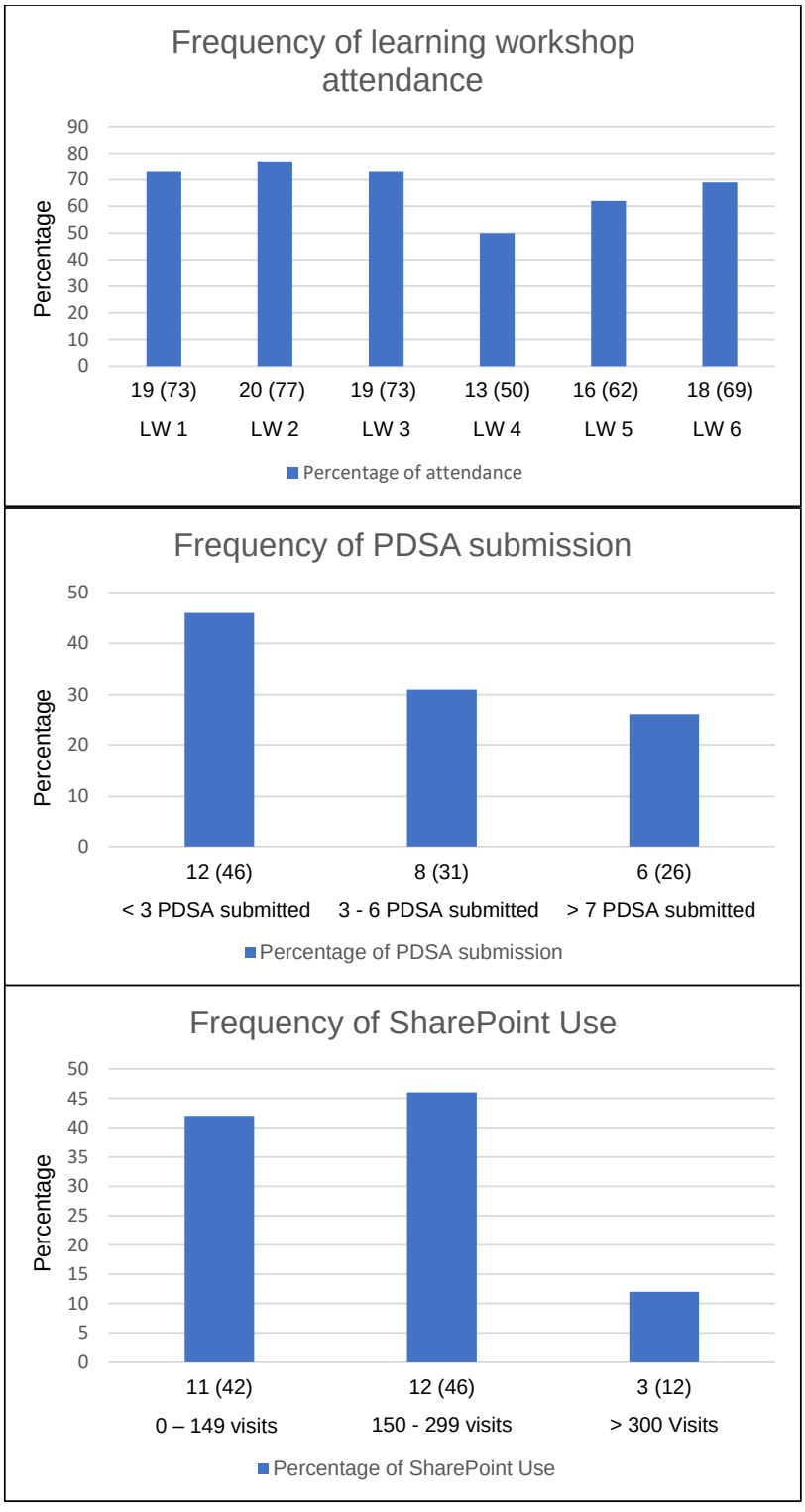


Figure 2. Frequency distribution of practices' workshop attendance, PDSA submission and SharePoint use during the 12-month intervention period; , *LW* - Learning workshop, *PDSA* - Plan-Do-Study-Act

Use of SharePoint

Seventy percent (14/20) of the practices reported using the online account via the end-of-program evaluation survey during the one-year intervention period. From the SharePoint user analytics, we found the median (IQI) number of account visits per practice was 170 (106, 252) over the site's lifetime.

Table 2 reveals cross-tabulation of workshop attendance with PDSA submissions and SharePoint use, revealing a pattern in practice engagement. PDSA submission and SharePoint use were balanced for practices that attended five or more workshops. In contrast, practices that attended less than two workshops revealed low use.

Table 2. Workshop attendance, PDSA submission and SharePoint use practice distribution.

Workshop attendance (n[a], %[b])	**PDSA submission (n)**			**SharePoint Use (n)**		
	< 3	3-6	> 7	0 - 149 Visits	150 - 299 Visits	> 300 Visits
0-2 (4,16%)	2	2	0	2	2	0
3-4 (11, 42%)	7	3	2	7	5	0
5-6 (11, 42%)	4	3	4	3	5	3

PDSA - Plan-Do-Study Act
[a]n = is the number of practices in each category,
[b]Percentage is calculated = n/N, where N is the total no of practices in the intervention (n=26)

Additionally, Table 3 provides a detailed summary of practice engagement with the intervention over the 12 months among participating practices. Overall, 11 practices that attended five or more learning workshops submitted 57 PDSAs, and the median (IQI) SharePoint use was 231 (151, 339). Another 11 practices that attended three to four workshops submitted 27 PDSAs, and the median (IQI) SharePoint use was 139 (110, 170). Four practices that attended less than three workshops submitted 13 PDSAs with a median (IQI) SharePoint use of 168.5 (92, 220).

Table 3. Detailed summary of practice engagement per practice.

Practice Code	Number of workshops attended	PDSA submission	SharePoint Use
A	6	10	475
B	6	10	393
C	5	10	284
D	6	8	268
E	4	8	154
F	3	7	278
G	2	6	122
H	5	6	441
I	2	6	236
J	6	5	231
K	5	5	225
L	4	4	80
M	3	4	185
N	4	3	139
O	5	2	231
P	3	1	257
Q	5	1	50
R	1	1	215

S	3	0	154
T	3	0	101
U	4	0	119
V	6	0	76
W	4	0	131
X	6	0	65
Y	4	0	57
Z	0	0	0

High engagement Moderate engagement Low engagement

Skills and capacity of the practice team members

As the intervention progressed, most practices designated team members to implement the QUEL QI changes within their practices. The majority of team members leading the QI activities were GPs (40%), followed by practice managers (PM) (38%) and nurses (19%). Others were research officers and admin staff (3%). More than half of the team members (58%) had five or more years of work experience. Thirty-two percent (17/53) of them were male, and the mean age (SD) of the team members was 45.7 (11.8) years. Characteristics of practice team members are described in Table 4.

Team members who held leadership roles and had clinical backgrounds were able to take on the leadership and effectively drive changes in their practices, as described by one of the participants.

> *"As the principal GP, I take on the leadership role. Whatever initiative we are undertaking as a practice, I explain to the staff, this is the reason why we are doing this, and then they will do it."* (Practice K, Female, GP)

One participant described that they were unable to sustain QI activities within their practice due to not having a clinical background.

> "*Disappointment from my point that I couldn't get it up and running because of not having the clinical background after the registrar left."* (Practice W, Female, PM)

Table 4. Characteristics of practice team members leading the QI activities in the intervention practices.

Primary care Practices	
Number of participating primary care practices, n	26
Number of total participants providing feedback, n	53
Age, mean (SD)	45.7 (11.8)
Female, n (%)	36 (68)
Health professional category, n (%)	
GP/GP registrar/ Clinical Director/ Principal GP	21 (40)
PM/ Assistant Practice Manager/ Practice Manager who is a nurse	20 (38)
Practice Nurse/ Registered Practice Nurse/ Nurse Coordinator	10 (19)
Other Admin and Research Officer	2 (3)
Years in the present position, n (%)	
< 1 year	4 (8)
1 - 3 Years	11 (21)
3 - 5 Years	6 (11)
> 5 Years	31 (58)
Not reported	1 (2)

SD - Standard Deviation, GP - General Practitioner, PM - Practice manager

Time commitment

Almost 70% (18/26) of the practices reported higher time commitment on using the electronic health system within working hours to identify CHD patients, monitor and track patients, develop care plans and record keeping. Table 5 presents a cross-tabulation of these practices on their engagement with the intervention. Additionally, two practices reported moderate level of time commitment to perform QI activities. Both practices attended five or more learning workshops, submitted 14 PDSAs, and their visits to the SharePoint site was 268 and 441 during the intervention period. 23% (6/26) of the practices that didn't report any data on time commitment showed varying levels of engagement. One practice attended five or more workshops, submitted one PDSA and visited the SharePoint site 50 times. Two practices attended three to four workshops, submitted 11 PDSAs, and their visits to the SharePoint site was 80 and 278. Three practices that attended less than three workshops, submitted 7 PDSAs, and the median (IQI) of SharePoint use was 215 (108, 226).

Table 5. Practice engagement summary based on workshop attendance and time commitment

Workshop attendance Category of attendance, (n[a], %[b])	**PDSA submission**	**SharePoint use**
0 - 2 (1, 5%)	1	No of visits[c] - 122
3 - 4 (9, 45%)	24	Median (IQI) - 139 (119, 154)
5 - 6 (8, 40%)	42	Median (IQI) - 231 (188, 311)

PDSA - Plan-Do-Study-Act, IQI - Interquartile interval

[a]n = is the number of practices in each category,

[b]Percentage is calculated = n/N, where N is the total no of practices in the intervention who reported time commitment (20)

[c]No of visits were used as only one practice in the category.

Interview data revealed that most practices had weekly or monthly team meetings to track QI progress, and one practice reported having daily update meetings. Practice team members reported setting aside 5-10 minutes during those meetings to discuss the QI targets.

> *"Our doctors have clinical meetings every Thursday and once a month, at the end of the meeting, I'd spend 5 minutes giving them an update and reminding them don't forget the QUEL project."* (Practice B, Female, PM)
>
> *"We have burst meetings where it would just be 5-10 minutes catching up on where we are at and what we need to do, and we stick to the plan. We only got three bullet points, like what is working, what's not working, and how can we achieve the level of we want to achieve for the day."* (Practice X, Female, PM)

Aside from regular meetings, practice team members set aside half an hour to half a day to perform QI activities.

> *"We would normally put in 30 minutes to an hour a week to do recalls, reminders, data cleansing, etc."* (Practice J, Female, PM)
>
> *"Especially I worked on a Thursday. Thursday afternoons are always very quiet. So that gave me the best time to do stuff. I'd say half a day a week."* (Practice B, Female, nurse)

Intervention delivered as intended, key intervention features and its usefulness

Learning workshop was identified as a key intervention feature by 60% of the practices, and one-third of the practices identified monthly feedback reporting as another important feature. Practice team members found these two features to be the most useful in facilitating QI changes within their practices. Qualitative data identified themes describing the usefulness of individual intervention features reported by the practice team members, illustrated in Box 1.

Box 1: Quotes illustrating why practices found each intervention features useful

	Themes	Quotes
Learning Workshops	(i) Opportunities to learn from other practices	"*It was one practice, a country practice, and I can't remember the name; it was a tiny, small practice with the receptionist on board with the whole thing. I was just blown away by the way that they actually had embraced this project and done it."* (Practice W, Female, PM) "*There was a lot of collaboration, such as sharing experience in these workshops, which was quite helpful. I think just hearing the way that different practices had tackled certain tasks was quite helpful*." (Practice V, Female, Nurse)
	(ii) Opportunities to share experiences with peers	"*We presented our Healthy Heart Clinic in one of the online learning workshops to other practices.*" (Practice W, Female, PM)
	(iii) Regular get together to keep practices updated and reminded them to reinforce QI	"*By having a routine training or a catch-up or a meeting with a specific focus, it brings us back to what we're aiming to do, particularly for the CHD*." (Practice X, Female, PM) "*The most important one is the workshops, I believe, important very, very important. Keep us updated all the time*." (Practice Y, Female, GP)
Monthly feedback report	(i) To identify gaps and areas of improvement	"*We actually looked at all of our reports. We worked out from the graphs which were the lowest parameters. So, using the 12 measures and using that graph was very useful. Because it actually gave us our shortfall."* (Practice W, Female, PM)

		"*It's not my opinion or someone else's opinion; it's actually data, and you can say, look, we have only got 60% of our patients that have had a blood pressure in the last 12 months, who are on antihypertensive, we need to do better than that*." (Practice V, Female, Nurse)
	(ii) To track progress with QI	"*Well, I guess the monthly reports you provided kept us on our toes in a way, I guess. We could see how we were going easily within the project, so I think that was good*." (Practice B, Female, Nurse) "*Some of the doctors were quite shocked, in terms of some of the original results received from the monthly reports, and so it's a helpful thing to be able to have everyone going towards certain goals*." (Practice V, Female, Nurse)
PDSA	(i) Helped to improve the quality of data	"*Our data has improved in small proportion in most areas of the 12 CHD measures for QUEL*." (Practice D, Female, Nurse)
	(ii) Helped to create awareness for correct coding of data	"*Clinic Drs have reported increased understanding of the need to "code" uniformly within the practice*." (Practice M, Female, GP)
	(iii) Produced successful outcome following a recall	"*We had one patient respond to an SMS for a blood test and also came in for a care plan*." (Practice J, Female, PM)
Support	Build effective relationships between	"*Your team visiting us physically, I feel pretty good, that means we are an important practice to*

	the study team and the practice	*visit, it improved the relationship between us.*" (Practice Y, Female, GP)
	Provide training and support on using data extraction tools	*"If I'm having problems with the data extraction tool, he (practice support officer) will help me fix it."* (Practice B, Female, Nurse)
PM - Practice manager, CHD - Coronary heart disease, GP - General practitioner, SMS - Short message service, QI - Quality Improvement		

Learning workshops

The first and the sixth learning workshops were initially planned as face-to-face events. Only the first learning workshop was delivered face-to-face before the impact of the COVID-19 pandemic[25], and the remaining five were all delivered virtually due to the ongoing restrictions. These workshops were scheduled approximately two months apart, but learning workshops five and six were approximately four months apart as the practices were busy with COVID-19 protocols and vaccinations.

Electronic data submission and monthly feedback reports

Although all 26 practices submitted data and received monthly feedback reports most of the time as intended, there were exceptions in some months (Table S2 in Supplementary Material). The most common reason for not submitting data and receiving monthly reports was technical errors. Common technical errors were: (i) an error in the automatic data extraction system, (ii) the automatic data extraction system was turned off, and (iii) the data extraction team not having access to technical support from the practice to run automated data collection. Once the technical issue was identified, the QUEL study team worked with relevant PHNs and the PenCS team to resolve the issue.

PDSA cycles

The practice team members also received training in the learning workshops on implementing PDSA cycles. Further support was also available for the practice team members during the activity periods by the respective PHNs and study team. We anticipated practices submitting one PDSA cycle per month, in total, 12 cycles per practice over one year. Despite the training and support, only 12% (3/26) of the practices submitted ten or more and 57% (15/26) of the practices submitted between one to nine PDSAs during the one-year intervention (Table 2), suggesting the intervention was not implemented as intended.

Support

Five PHNs that were participating in the QUEL study provided support to 12 of the 26 practices. Two of the five PHNs were located in New South Wales, which supported seven practices in that state. The other three PHNs were in South Australia, Queensland, and Victoria. The PHN in South Australia supported another three practices in that state, while the PHNs in Queensland and Victoria each supported only one practice within their respective regions. The remaining 14 practices were supported by the QUEL study team. Based on the support provided by the study team, the mean (SD) number of contacts between practices and the study team was 14 (4.3). PHNs contacted the practices independently; however, data on PHN contacts were not collected during the intervention period. Contacts were made via phone calls, emails and in person to provide support to the practices to solve any technical errors, provide monthly updates, encourage practices to perform QI and help with any other queries. This support was helpful in maintaining practices' engagement with the intervention features.

As a result of their participation in the QI intervention, practices reported the role of the practice team members changed during the one-year intervention. Around half (14/26) of the practices acknowledged an increase in the scope of their team members' roles to perform QI activities, such as data collection, coding, analysis, review, and reporting to meet QUEL targets. However, five practices reported no significant changes as QI was already a part of their role. Practice team members also performed various QI activities during the intervention year (Table S3 in Supplementary Material). Sixty-nine percent (18/26) of the practices reported an improvement in their quality of care for CHD patients due to these activities. Only one practice reported no change, and another was uncertain of any changes in their quality of care. Seventy-three percent (19/26) of practices reported participating in QUEL enhanced their capacity to be PIP-QI ready. At the end of the intervention, 42% (11/26) of practices reported they were able to claim PIP-QI.

DISCUSSION

This study elaborates on the primary care practices' engagement with the QI intervention in improving CHD care. The Intervention led to an increased scope of QI activities for the practice team members, leading to more than half of the practices (69%) self-reporting improvement in their QI activities for CHD patient care. As a result, the majority (73%) of the practices felt ready for PIP-QI, and some (42%) could claim the benefits. However, the practice engagement with the intervention was varied. Engagement with the PDSA cycles was low, with only 12% of practices submitting ten or more cycles over 12 months. However, the submission range of PDSA cycles was diverse (0-10) in all practices despite the varied attendance. Practices that attended a higher number of learning workshops submitted a higher number of PDSA cycles and showed higher engagement with the SharePoint site. However, variations were seen within each attendance category, indicating several factors contributing

to the different engagement levels. Additionally, practices reporting higher time commitment generally demonstrated higher learning workshop attendance, submitted more PDSAs, and used SharePoint more, suggesting a positive correlation between time commitment and engagement in the intervention with some variations in a small portion of the practices. Qualitative analysis identified team members in a leading role or with clinical backgrounds were able to implement QI changes more effectively within their practices and practices regularly set aside additional time during working hours to implement these changes. The study also identified learning workshops and monthly feedback reports as the two key useful intervention features to facilitate QI activities and changes.

Several QI strategies are currently being practiced in clinical settings including, the Model for Improvement, Lean, and Six Sigma.[26] The Model for Improvement, used in this intervention, is a widely used QI strategy in healthcare, which provides a systematic approach for planning, testing and implementing changes.[27] In addition, learning workshops, PDSA cycles, feedback reports, and support were also used in combination with the QI intervention to improve CHD care.[28-31]Findings from our study suggest that higher attendance in learning workshops could have positively influenced PDSA submission and SharePoint use, indicating its significance in increasing practice engagement to perform QI activities. However, associations between the intervention features and improvement in clinical outcomes have yet to be established. It is important to evaluate the effect of QI intervention on improving outcomes as research found practices receiving regular feedback reports were able to improve clinical outcomes, particularly in achieving better blood pressure control in patients with hypertension[32] and risk factor screening.[33, 34] While a systematic review revealed mixed findings on the effectiveness of PDSAs in improving clinical outcomes,[35] other studies identified several factors influencing the reduced engagement level,[36, 37] similar to our

findings. Our study also included a variety of skilled professionals, including GPs, nurses, or PMs as practice team members to lead the QI changes within their practices, which is also an important strategy for successful implementation of QI interventions.[37-39] Lastly, while some studies demonstrated the importance of using practice support within QI strategies to improve care,[40-42] the current study did not provide a deeper understanding of the level of support required for the successful implementation of such programs.

A strength of this study is the use of mixed-methods research, a commonly used method in evaluating QI studies, as it has the ability to strengthen data quality and provide a robust interpretation of the results.[36,42, 43] Further, we also combined both qualitative and quantitative data and performed triangulation of the multiple datasets providing a wide range of perspectives from multiple health professionals, consequently providing an in-depth understanding of the complex intervention features. The practices included in the evaluation were from various sizes and regions, ensuring wider representation of participants, therefore enhancing the generalisability of the findings to similar healthcare settings. The intervention features and implementation strategies described in this study can be used as a useful framework to be replicated with modifications in similar healthcare settings aiming to improve the quality of care for patients with chronic diseases.

The study, primarily focused on exploring the efficacy of the intervention rather than the effectiveness, has several limitations that may influence its potential wider roll-out into practice. The intervention period coincided with the outbreak of the global COVID-19 pandemic, potentially impacting practices, attendance in learning workshops and overall engagement.[25] Other limitations were the potential introduction of response and reporting bias arising from some practices not responding to the surveys and reliance on self-reported

data, respectively. The exclusion of non-responsive practices from the quantitative analysis and continuous data checking for errors and accuracy were used to reduce the bias. Additionally, categorical data was collected to measure health professionals' time spent on delivering the QI program, but continuous data would have offered a more accurate measure of time spent. Further, almost half of the practices were supported by their respective PHNs. However, due to the independent operations of the PHNs, we were unable to obtain comprehensive data regarding the extent of support provided by both the PHNs and the study team during the intervention period. Finally, it was beyond the scope of the process evaluation to evaluate whether the intervention was effective in improving the pre-defined CHD. These limitations may affect the generalizability of our findings and the feasibility of implementing the intervention on a larger scale.

Findings from the study suggest that external factors, such as unexpected events or occurrences, should be taken into consideration when planning broader implementation strategies. We also acknowledge that the paper could benefit from a more detailed exploration of PDSAs to understand a direct association between workshop attendance and PDSA submissions with the intervention. Highlighting a scope for future research to explore the various factors associated with PDSA engagement.[44] Adding a more robust, sophisticated, and accurate data collection and analysis method could provide more nuanced measures of the findings, therefore enhancing the feasibility of future studies. The limitation in accurately assessing the level of support required for the successful implementation can be addressed by establishing an effective collaboration and incorporating remote reporting and data collection between the research team and the PHNs.[36] Furthermore, enabling tailored support and addressing the nuanced dynamics of time commitment is important to optimise engagement with QI interventions across diverse practices. The use of these combined

strategies, along with ongoing training, designating clinicians as QI champions and increased use of data-driven technology to monitor progress, can collectively contribute towards the large-scale roll-out of future QI programs with an aim to improve care for patients with CHD across diverse healthcare settings.[45, 46]

CONCLUSION

The study highlights the varied engagement of primary care practices with the QI intervention aimed at improving the care of CHD. Learning workshops, monthly feedback reports, and PDSA cycles were found to be useful features of the intervention. Successful implementation of the intervention also depended on the additional time commitment and efforts of the practice team members, particularly GPs, nurses and practice managers, towards implementing QI changes within their practices. These findings offer valuable insights that can support other primary care practices seeking future adoption of these evolving data-driven QI initiatives, ultimately leading to improved patients' outcomes and more effective management of CHD and other chronic diseases. However, as healthcare continues to evolve in utilising data, further research is needed to evaluate the intrinsic factors influencing practices' engagement in such complex interventions and obtain a comprehensive understanding of how these strategies can be best implemented.

Ethics Statement

Ethics approval has been obtained from the New South Wales Population & Health Services Research Ethics Committee (HREC/18/CIPHS/44). No individual patient data was used for the process evaluation. Written consent was obtained from the practice team members and PHN staff before conducting semi-structured interviews. Each participating practice signed a

Health service agreement, and if a practice wished to withdraw from the study, they were free to do so at any time.

Competing interests

The funding body and industry partners were not involved in the design of the study and did not have any role during its execution, analyses, interpretation of the data, or decision to submit results. Amgen and Sanofi Australia have provided cash support to the main study. MW is a consultant to Amgen, Freeline and Kyowa Kirin. Other authors have nothing to disclose.

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Data Availability Statement

Data (interview transcripts and survey) data will not be available. Although de-identified by name and place, it may contain contextual information that would enable identification of individual participants.

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SUPPLEMENTARY MATERIALS

Table S1: The 12 CHD measures for QUEL study

1. The number of clients that are coded with a diagnosis matching the CHD definition
2. The proportion of clients with CHD where low-density lipoprotein (LDL) has been measured within the previous 12 months
3. The proportion of clients with CHD whose most recent LDL result was less than 2.0 mmol/L
4. Proportion of clients with CHD with a recorded blood pressure (BP) reading taken within the previous 12 months
5. Proportion of clients with CHD whose most recent BP reading, taken within the previous 12 months, was less than or equal to 130/80 mmHg
6. Proportion of clients with CHD whose smoking status has been recorded
7. Proportion of clients with CHD recorded as a current smoker
8. Proportion of clients with CHD who are currently prescribed an anti-platelet agent
9. Proportion of clients with CHD who are currently prescribed a statin
10. Proportion of patients with CHD who are currently prescribed an ACE inhibitor or ARB
11. The proportion of clients with CHD with MBS Items 721 or 732 claimed
12. Proportion of clients with CHD who have an influenza vaccination recorded within the previous 12 months

Table S2: Monthly data extraction submitted, and feedback report received

	No (%) of practices submitted data (N=26)	No (%) practices received monthly feedback report (N=26)	Reasons for the inability to collect data and provide monthly feedback report
Dec-19	25 (96)	25 (96)	One practice enrolled in the study in January 2020 and started submitting data from February 2020
Jan-20	25 (96)	25 (96)	One practice enrolled in the study in January 2020 and started submitting data from February 2020
Feb-20	23 (88)	23 (88)	Technical issues with PenCS data collection which were solved after the data submission due date for the month; therefore, the study team was unable to provide monthly reports to the practices
Mar-20	26 (100)	26 (100)	NA
Apr-20	26 (100)	26 (100)	NA
May-20	26 (100)	26 (100)	NA
Jun-20	26 (100)	26 (100)	NA
Jul-20	25 (96)	25 (96)	Reason not reported
Aug-20	26 (100)	26 (100)	NA
Sep-20	26 (100)	26 (100)	NA
Oct-20	26 (100)	26 (100)	NA
Nov-20	26 (100)	25 (96)	Reason not reported

Table S3: Quotes summarising Quality improvement activities performed by practices.

QI activities performed by practices	No of practices	%
Use of PenCS reports to identify areas for improvement, ensured risk factors are on target by recalling patients for regular check-ups and care plans	**18**	**69%**
"*We identified the CHD patients who require a CDMP and basically flag it to the GP for regular care planning.*" (Practice X, Female, PM) *"Printed reports through PenCS on BP, LDL & Smoking not recorded for Doctors to review & obtain this information in our system."* (Practice C, Female, PM) "*Throughout this study, we have found a lot of the errors in our PenCAT reports came from things like coding & reasons for medication."* (Practice H, Female, PM)		
Adding reminders in patient files for GPs and other practice staff to collect and update risk factors and any other missing information, including personal details	**17**	**65%**
"I would be marking the patient with QUEL so that everyone would know that this was a patient, we had to catch up on the data for and possibly do you do a care plan for just to manage them better." (Practice J, Female, PM) *"Addition of update information sheet for all patients at front desk to have up to date data regarding smoking status and alcohol as well as demographic info such as address and phone number."* (Practice B, Female, Nurse)		
Identifying CHD and CVD patients within the practices and creating a CHD/CVD register	**13**	**50%**
Regular data cleansing, auditing of inactive patients and recording of data correctly to improve data quality	**13**	**50%**
"*Inactivating patients on the register who live overseas or interstate or who have other regular GPs or those presenting for immunisation only.*" (Practice F, Female, GP) *"We chose to use Top Bar as an assistance tool to ensure the missing information was*		

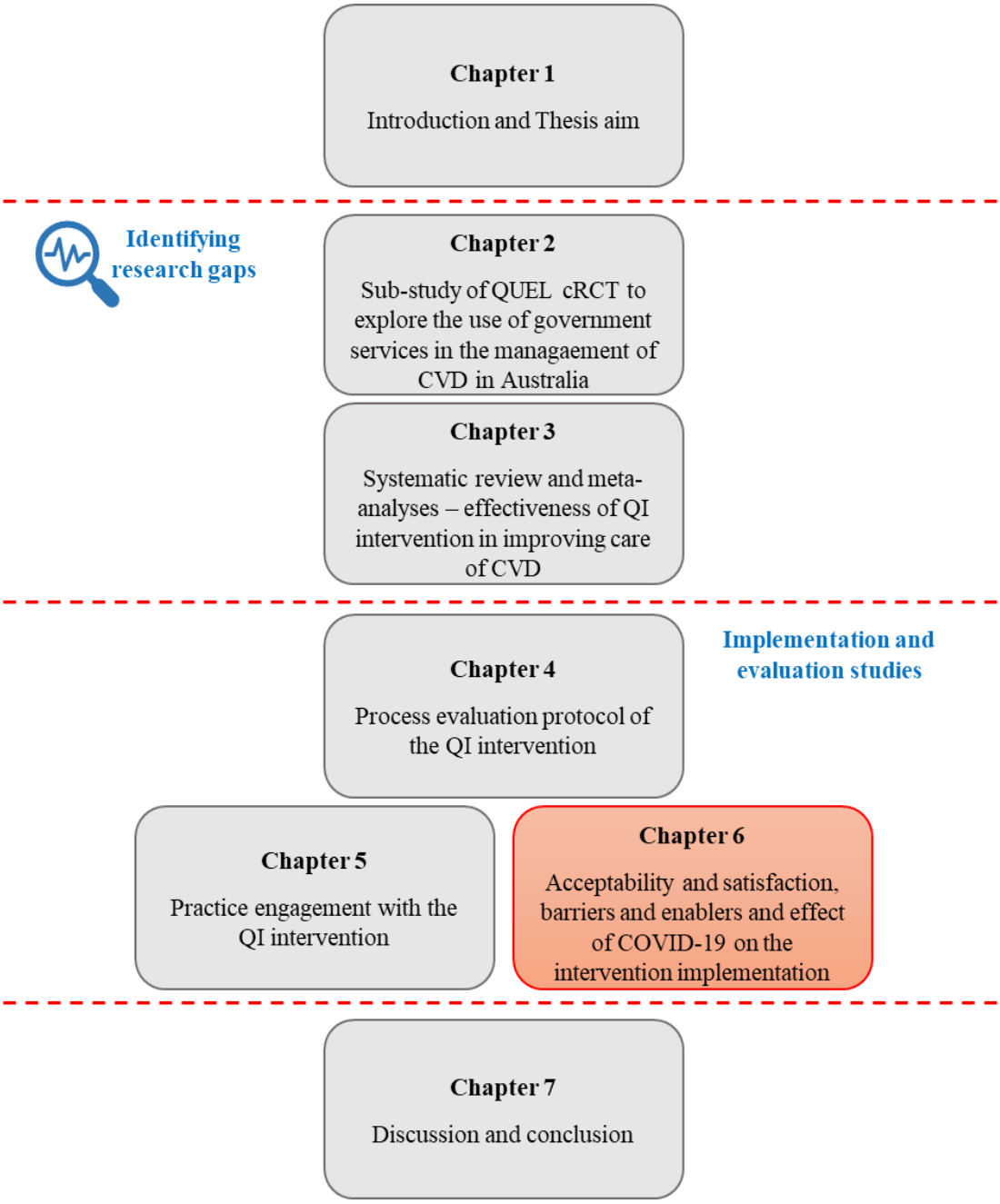
recorded properly; this is done through Top Bar Prompts." (Practice H, Female, PM) "*One of the things I did regularly was with all patients who had free text or incorrect diagnosis recorded, I would ask the doctors to change, or I would change it to make sure that it was getting captured.*" (Practice J, Female, PM)		
Team Activity - regular team meetings, allocating responsibilities to all, getting experienced staff on board.	**13**	**50%**
"We posted results on blackboards in the tearoom the progressive target results to encourage the team to implement QI." (Practice D, Female, PM) *"Hired a Nurse for two days a week to review CVD & CHD patients, check eligibility for Care Plans & Assessments, recalled patients in for an appointment with Nurse to update data and sent to doctors for pathology after seeing Nurse."* (Practice C, Female, Nurse) *"We are all working together at the practice as a team; everyone has made a concerted effort to improve our data quality, and we are particularly working on increasing our care plans for patients that meet the cohort criteria."* (Practice Q, Female, PM)		
Educate patients on heart health, smoking cessation, lifestyle modification and self-management of CHD at home	**10**	**38%**
"We have sheets set up within our database, where we would have targets for patients, particularly those who already have non-destructive cardiovascular disease. We gave those patients a handout to take home and say, look, with the risk factors you have got, this is where we'd like your target to be." (Practice V, Female, Nurse)		
Implemented new processes to improve the care of CHD patients	**7**	**27%**
"Developed a template to collect height, weight, family history, smoking, alcohol for all patients upon arrival of patients." (Practice D, Female, PM) *"We scanned 20,000 patient paper files into the computer, so we are paperless.*" (Practice C, Female, PM)		

"I lead the creation of a Cardiovascular Disease Prevention clinic called the 'Healthy Heart clinic' to regularly check CHD patients with the practice nurse and practice manager." (Practice W, Female, GP registrar)		
Review of current processes within the practices to reflect CHD QI changes	**7**	**27%**
"We created a letter for patients that encourages participation rather than another bland invite/recall letter and sent letters to eligible patients over three months." (Practice B, Female, Nurse) *"Constantly reviewing progress against our targets, changing process to achieve targets dependent upon the progress."* (Practice C, Female, GP)		
Identified CHD patients who did not have care plans, required review of care plans, had a recent event thus ensured more eligible patients received care plans	**6**	**23%**
"So, my care coordinator was tasked to ensure that whenever she sees a patient with CHD, flag it to the GP to organise a care plan if eligible." (Practice X, Female, PM)		

CHD - Coronary heart disease, CDMP - Chronic disease management plan, GP - General practitioner, PM - Practice manager, BP - Blood pressure, LDL - Low-density lipoprotein, CVD - Cardiovascular disease.

CHAPTER SIX

Implementation of a data-driven quality improvement program in primary care for patients with coronary heart disease: a mixed-methods evaluation of acceptability, satisfaction, barriers and enablers



PREFACE TO THE CHAPTER

Chapter Five found that practice engagement with the QI intervention varied. Moreover, it was found that team members in a leading role or with clinical backgrounds were able to implement QI changes more effectively within their practices. Overall, the intervention was perceived to be acceptable by the primary care practices in their efforts to enhance the quality of care provided to their patients with coronary heart disease (CHD). Chapter Six presents an evaluation of the practices' satisfaction and acceptability of this data-driven QI intervention in Australian primary care settings. It also focuses on identifying barriers and enablers, including the impact of COVID-19 pandemic on the implementation of the intervention, thereby addressing Aim Five of this Thesis. The manuscript is titled "Implementation of a data-driven quality improvement program in primary care for patients with coronary heart disease: a mixed-methods evaluation of acceptability, satisfaction, barriers and enablers" and is currently under review by the Australian Journal of Primary Health. The ethics approval for the study is included in Appendix A. All supplementary materials used are included after references of this chapter

PEER-REVIEWED PUBLICATIONS AND PRESENTATIONS

Manuscript under review

Hafiz N, Hyun K, Tu Q, Knight A, Hespe C, Chow CK et al. Implementation of a data-driven quality improvement program in primary care for patients with coronary heart disease: a mixed-methods evaluation of acceptability, satisfaction, barriers, and enablers. Australian Journal of Primary Health (under review).

Conference presentation

Hafiz N, Hyun K, Tu Q, Knight A, Hespe C, Chow CK et al. Implementation of a data-driven quality improvement program in primary care for patients with coronary heart disease: a mixed-methods evaluation of acceptability, satisfaction, barriers, and enablers. *(62nd Australian Society of Medical Research National Scientific Meeting 2023, Melbourne, Victoria, Australia).*

STATEMENT OF AUTHORSHIP

Nashid Hafiz, during her PhD candidature, developed the concept of the sub-study, performed statistical analysis, and interpreted the results, prepared the initial draft and subsequent revisions, responded to reviewers' feedback, and coordinated submission and publication of the original research paper.

Individual roles of co-authors are listed below

Task	**Role of co-authors**
Refining the research question	NH, KH, JR
Data collection and analysis	NH, KH, DM
Revision and Critical comments of manuscript	KH, JR, AK, CH, CC, TB, RG, CR, DH, NZ, MW, SJ, EA, TL, EH, TU and JR

Nashid Hafiz 30th April 2024

As supervisor for the candidature upon which this Thesis is based, I can confirm that the authorship attribution statement above is correct.

Professor Julie Redfern 30th April 2024

Implementation of a data-driven quality improvement program in primary care for patients with coronary heart disease: a mixed-methods evaluation of acceptability, satisfaction, barriers and enablers

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ABSTRACT

Background The study evaluates practices' satisfaction and acceptability of a quality improvement intervention aimed to improve care for coronary heart disease (CHD) patients in Australian primary care practices and identifies barriers and enablers, including the impact of COVID-19 on its implementation.

Methods Within the QUality improvement for Effectiveness of care for people Living with heart disease (QUEL) study, 26 Australian primary care practices, supported by five Primary Health Networks, participated in the one-year QI intervention. Data were collected via surveys and semi-structured interviews and analysed using descriptive statistics and thematic analysis.

Results Feedback was received from 63 participants, including practice team members and PHN staff, through surveys and interviews. The participants rated the individual learning workshops between 71% and 100%, indicating positive satisfaction. Qualitative analysis found the overall intervention provided structure, guidelines and data to identify improvement areas within a rigorous timeline to help the practices achieve targets. COVID-19 and lack of time were identified as common barriers, while practice team collaboration and effective leadership emerged as major enablers to their participation in the QI program. Additionally, 90% of the practices reported that their participation was affected by COVID-19, with vaccination rollout, telehealth set-up, and continuous operational review shifting their focus from QI.

Conclusion The study indicated that the use of data-driven QI programs in primary care practices has the potential to boost practice staff confidence and foster increased implementation. Barriers and enablers identified can also be used to support other practices in prioritising effective strategies for future implementation.

Trial registration Australian New Zealand Clinical Trials Registry (ANZCTR)x number ACTRN12619001790134.

Keywords Quality improvement, Coronary heart disease, Data, Primary care, Process evaluation, mixed-methods research, Qualitative research.

INTRODUCTION

Use of data-driven quality improvement programs is increasing globally due to the availability of electronic health records generating widespread, routinely collected data.[1] QI is a continuous, systematic approach that implements small-scale changes across various healthcare settings with an aim to improve performance, achieve better health outcomes and increase knowledge of health professionals.[2] QI programs are often multifaceted and include educating teams of health professionals, using QI tools such as Plan-do-study-act (PDSA) cycles and data to identify areas for improvement to achieve targets.[3]

Primary care practices have been implementing QI programs in managing several health conditions, including chronic obstructive pulmonary disease (COPD), diabetes Aboriginal health, and coronary heart disease (CHD).[4] CHD continues to be a significant global health concern, responsible for 17,300 deaths in Australia alone in the year 2021.[5] Primary care plays a pivotal role in secondary prevention of CHD by supporting patients to identify and manage risk factors and promote medication prescription and adherence according to international and national guidelines.[6] However, the COVID-19 pandemic has changed the way practices operate worldwide and also affected the care provided to those living with CHD.[7]

Previous research has demonstrated QI programs to be effective[4,8], yet there is little evidence regarding practices' and health professionals' perception of using such programs to understand their perceived benefits and potential reach.[9] To inform scalability, future development and implementation, it is crucial to evaluate such programs and obtain comprehensive information. Several studies have already identified barriers and enablers to program implementation in various settings[10,11]; however, only a limited number of studies were found to evaluate the satisfaction and acceptability of a QI program focused on improving CHD.[12] Therefore, the aim of this study was to (*1) understand acceptability, satisfaction, uptake, utility, and feasibility, (2) identify and describe barriers and enablers* and (3) *evaluate the effect of COVID-19 on the implementation of a QI program* delivered within the QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with heart disease (QUEL) study.[13]

METHODS

Study design

A mixed-methods process evaluation was conducted to evaluate the one-year data-driven QI intervention program nested within the QUEL study. [13] Twenty-six Australian primary care practices randomised into the intervention arm of the study participated in the evaluation. [14] These intervention practices were within the jurisdictions of ten primary health networks (PHNs). Five PHNs agreed to participate by providing support to their relevant practices. Therefore, these five PHNs were also included in the process evaluation. Ethics approval was obtained from the New South Wales Population & Health Services Research Ethics Committee (HREC/18/CIPHS/44).

Participants

Participants were included if they were: (i) practice team members from all intervention practices, including general practitioners (GP), nurses or practice managers (PM), (ii) PHN staff providing external support to the intervention practices in their region and (iii) provided written informed consent.

Data-driven QI intervention

The multifaceted QUEL intervention consisted of learning workshops, practices submitting monthly electronic data and implementing PDSA cycles, practices receiving monthly feedback reports based on the submitted data and external support[10]. The intervention was delivered between November 2019 and November 2020. Six learning workshops were delivered over the 12 months, and the practices carried out the QI activities supported by the study team or their PHNs in between the learning workshops. An individual SharePoint account was established for each intervention practice, which was used as a platform to share the monthly feedback reports and study resources. Practices also submitted the PDSAs via their individual accounts. The intervention practices used an automated data extraction tool incorporated with their software system to access, create, and review eligible patients' data for achieving the CHD risk factor targets outlined in the QUEL study (Table S1 in Supplementary Material). By reviewing the aggregated data, practices were able to identify gaps and implement changes to improve the CHD risk factor targets such as cholesterol, smoking, blood pressure and chronic disease management plans. Additionally, the automated aggregated data enabled practices to monitor changes in the targets over the intervention period.

Data sources

For this study, the following three data sources were used:

1. *Learning workshop surveys*: Six surveys corresponding to six workshops were sent to practice team members who attended the workshops. The first learning workshop was delivered face-to-face, and attendees completed a paper survey, while the remaining five workshops were delivered online and, therefore, completed online.

2. *End-of-program evaluation survey*: At the end of the program, practice team members actively involved in implementing QI changes within their practices were invited to complete a comprehensive survey assessing the overall intervention program. The surveys were sent via online link, email and by post, with a return address envelope.

3. *Semi-structured interviews*: Individual interviews with a sub-group of practice team members and PHN staff were conducted at the completion of the 12-month intervention. Practices were selected based on their attendance in learning workshops and submission of PDSA cycles (high, medium, and low) during the intervention. Interviews were conducted either face-to-face or via telephone/video conference. The interviews lasted 45-60 minutes, were recorded and transcribed verbatim for analysis.

Outcome measures

Satisfaction

Practices' satisfaction was assessed via the individual learning workshop surveys by asking practice team members, "overall, how would you rate this workshop" using a 5- and 10-point Likert scale and in the end-of-program evaluation survey, by asking, "I will be able to use what I learned in this workshop" and "the workshops were a good way to learn" using a 6-point Likert scale. The individual responses of the team members were averaged for the questions to create a practice-level rating, as the team members were asked to report on the experiences of their respective practices.

Workshop content, design, and facilitators

Satisfaction with the overall workshop content, design and facilitators was assessed via the end-of-program evaluation survey by asking participants to respond to individual domains using a 6-point Likert scale. Three questions were asked about the content, seven about the design, and two about the facilitators. The responses were again averaged to create a practice-level score.

Program acceptability and utility

Acceptability of the program was assessed via the end-of-program evaluation survey by asking practice team members, "would you be interested in participating in a similar program in future?" requiring a 'Yes' and 'No' responses, which was further explored by the semi-structured interviews.

Barriers and enablers

Barriers and enablers were assessed via synthesis of all three data sources. Learning workshop surveys prompted participants to provide free text responses to the questions “outline any challenges you are facing towards achieving your target to improve care of patients with CHD” and "outline any success you have achieved towards meeting your target to improve care of patients with CHD”. At the completion of the intervention, the end-of-program evaluation survey asked participants for free text responses regarding “what did you find least useful from the program over the past year?” and “what did you find most useful from the program over the past year?”. Semi-structured interviews again further explored the barriers and enablers to program implementation.

Effect of COVID-19

The effect of COVID-19 was measured via the end-of-program evaluation survey, where practice team members were asked, “did COVID-19 impact your participation in the QI program?” which required a ‘yes’ or ‘no’ response. Additionally, participants were asked to provide free-text responses to the question 'can you give some examples of how' to further evaluate their responses. The semi-structured interviews also identified themes to further understand the effect of COVID-19 on the intervention implementation.

Data Analysis

Descriptive statistical analysis was used to analyse quantitative data obtained from the surveys. Responses and measurements were presented as numbers and percentages for categorical variables, mean and standard deviation or median and interquartile range for continuous variables. For Likert-scale responses, a score of ≥8/10 or ≥4/5 was taken to indicate positive satisfaction, acceptability, and utility of the intervention program.

Thematic analysis was used to analyse qualitative data collected from semi-structured interviews and free-text responses from the surveys. The data were thematically analysed using NVivo. Two independent researchers (NH and DM) conducted a thematic analysis to identify key themes and any disagreement was solved by discussing it with a third researcher until a consensus was reached. Data from all sources were triangulated to gain a comprehensive understanding of the study aims and increase credibility of the findings.[15] (Carter *et al.* 2014).

RESULTS

Participating practices and staff

Twenty-six primary care practices from four Australian states from both rural and urban areas (69% of the practices from New South Wales, 15% from Victoria, 12% from South Australia and 4% from Queensland) participated in the QUEL intervention. The median (IQI) number of GPs in participating practices were 7 (3, 10), ranging between one to 18. Fifty-three practice team members and 10 PHN staff participated in the process evaluation (Table 1).

Participants' satisfaction with different features of the QI intervention program

Across the six learning workshops surveys, number of participants from practices responded varied (Table 2). From each practice, one to three team members completed the surveys.

Table 1: Characteristics of practices and participants

Primary care Practices	
Number of participating primary care practices, n	26
Number of total participants providing feedback, n	53
Age, mean	45.67 (11.8)
Female, n (%)	36 (68)
Urban vs Rural practices, n (%)	21 (81%) vs 5 (19%)
No of GPs, median (IQI)	7 (3,10)
Range of GPs (Min-Max)	1 - 18
Health professional category, n (%)	
GP/GP registrar/ Clinical Director/ Principal GP	21 (40)
PM/ Assistant Practice Manager/ PM who is a nurse	20 (38)
Practice Nurse/ Registered Practice Nurse/ Nurse Coordinator	10 (19)
Other Admin and Research Officer	2 (3)
Years in the present position, n (%)	
< 1 year	4 (8)
1 - 3 Years	11 (21)
3-5 Years	6 (11)
> 5 Years	31 (58)
Not reported	1 (2)
Primary Health Networks (PHN)	
Number of participating PHN, n	5
Number of PHN staff providing feedback, n	10

Age, mean	51.16 (9.74)
Female % (n)	7 (70)
PHN staff Category, % (n)	
Practice support Officer	5 (50)
Practice Facilitator	1 (10)
Primary care & QI manager	1 (10)
Program coordinator - general practice quality improvement	1 (10)
Manager regional services	1 (10)
Program support officer	1 (10)
Years in the present position, % (n)	
1 - 3 Years	3 (30)
3-5 Years	3 (30)
> 5 Years	2 (20)
Not reported	2 (20)

GP - General practitioner, PHN: Primary health network, PM - Practice manager

1. Learning workshops

The average overall rating of learning workshops was 87% (10.82), with individual workshop ratings ranging from 71% (10/14) to 100% (11/11). (Table 2) Participants reported satisfaction with the overall content, design, and instructors for each workshop (Table 2). The qualitative data further elucidated participants' perceptions of the workshop numbers, timing, duration, mode of delivery, and content.

Table 2: Satisfaction of learning workshops

Learning workshop Survey	No of practices provided feedback	No of practice team members provided feedback	Proportion of practices scoring 8,9,10[a]
Learning workshop rating			
LW1	18	26	17/18 (94%)
LW2	16	20	14/16 (88%)
LW3	14	16	10/14 (71%)
LW4	11	14	11/11 (100%)
LW5	10	11	9/10 (90%)
LW6	17	25	13/17 (76%)
End-of-program evaluation survey	**No of practices provided feedback, n = 20**	**No of practice team members provided feedback = 36**	**Proportion of practices scoring four or 5[a]**
Overall content			
I was well informed about the objectives of the workshops			18/20 (90%)
Workshops lived up to my expectations			15/20 (75%)
The content was relevant to my job			15/20 (75%)
Overall design			
The objectives were clear to me			17/20 (85%)
The activities stimulated my learning			16/20 (80%)
The activities gave me sufficient practice and feedback			14/20 (70%)
The difficulty level was appropriate			12/20 (60%)

The pace of the workshops was appropriate	14/20 (70%)
The duration of the workshops was appropriate	15/20 (75%)
The quantity of the information presented at the workshops was appropriate	15/20 (75%)
Instructor	
The instructors were well prepared	17/20 (85%)
The instructors were helpful	14/20 (70%)
Overall Satisfaction	
I will be able to use what I learned in this workshop	17/20 (85%)
The workshops were a good way for me to learn this content	14/20 (70%)

LW - Learning Workshop
[a]Practices scoring ≥8/10 or ≥4/5 indicating positive satisfaction of the learning workshop

Workshop number: Participants felt that the number of workshops delivered during the 12 months was appropriate.

> *"We would not have wanted them every month, and every six months would not have been enough either. It was keeping us connected with what was happening. I think one or two would not have been satisfactory."* (Female, nurse)

Mode of delivery: Learning workshops one and six were initially planned as face-to-face. However, due to COVID-19 restrictions, only learning workshop one was delivered face-to-face, and the remaining five were all delivered via Zoom. Participants reported satisfaction with the online workshops.

"I think this Zoom meeting was an overall success, and the team did a great job in facilitating it. It is always great to listen and learn from others." (Female, nurse)

Participants also suggested they prefer these workshops delivered in person to encourage increased interaction with the other practices.

"If you were to use learning workshops as an exercise of being in touch with other practices and sharing ideas, then maybe face-to-face might work better." (Female, GP)

Workshop duration: Learning workshops one and six were full-day events, and the remaining four were one-hour webinars. Participants thought the one-hour duration for the webinars was appropriate.

"I think an hour is max because, sitting on Zoom, you don't want to sit more than that. When we're all busy, I think it needs to be precise and to the point." (Female, nurse)

Workshop timing: The one-hour webinars were delivered during lunchtime and repeated the following evening to ensure maximum practice engagement. Participants thought the availability of lunch and evening options was appropriate as it provided them with the flexibility to attend the workshops outside of working hours.

"Definitely the way to go, because working in general practice it so it's go go go from the time they open the front door till they close at night. So doing things outside of working hours or at lunchtime is often the only way that you're going to get them there." (Male, practice support officer, PHN)

"I prefer evening because after a busy day, we get down, we can spend more time with focus the hard part in having a morning webinar is it's hard to focus." (Female, PM)

Workshop design and delivery: Participants were satisfied with the workshop design and how it was delivered.

"Keep presenting with the same format. Great workshop." (Female, PM)

Learning workshops consisted of interactive small group breakout sessions. Participants were also satisfied with these sessions.

"I think the breakout groups are a great way of giving everyone a chance to contribute when you have a large group." (Female, program coordinator, PHN)

During the workshops, team members from different intervention practices were invited to share different QI strategies adopted in their practices to improve patient care. Participants found listening to those practices enabled them to gain insights from their real-time experiences.

"This was a great workshop. The sharing of ideas, barriers and lessons learnt is invaluable in informing effective QI strategies. Loved the opportunities for open discussion." (Female, program coordinator, PHN)

"I remember a few talks on how a GP and a nurse getting together and speaking about what they did it in their practice, how they made improvements, and how they had conversations with patients. I think that was quite meaningful because it's an experience from which you can get insight from." (Female, PM)

However, some participants reported that a few strategies shared by others were not relevant to all practices.

"Some individual practice ideas that were shared were not necessarily relevant to our practice." (Female, GP)

"Lots of talk about other clinics - not entirely same with our experience." (Female, practice care coordinator)

2. Electronic data submission and monthly feedback report

Throughout the intervention, practices received monthly feedback reports via their individual SharePoint accounts to help them identify gaps in care and keep them on track with the improvement targets. Participants were satisfied with receiving the feedback reports reflected in the following quotes.

"You send those reports, they were really useful because I always looked at them and go okay this one look good, but that does not and try to focus on improving those things." (Female, nurse)

"I liked the feedback with the data reports coming back and really appreciated them on SharePoint." (Female, PM)

3. PDSA

As part of the intervention, practices were required to submit PDSAs via a template provided in their SharePoint account. Participants were satisfied with submitting PDSAs via the online portal.

"Submitting PDSAs online is better. Then you don't have all these bits of paper everywhere. It's all nice and tidy, and you can't lose it." (Male, practice support officer, PHN)

Moreover, participants appreciated the opportunity to review other practices' PDSAs, which helped them to identify implementation strategies.

"I really liked looking at people's PDSAs. I like to see small and accomplishable things in a short time and the methodology of how people went about it." (Female, PM)

However, some participants said they would prefer to avoid working with PDSAs in future QI projects.

"In fact, our practice is currently working on a QI program with the PHN, and I said to the practice manager I'm happy to be involved, but I don't want to be doing PDSAs." (Female, nurse)

4. Support

Practices were externally supported by the study team or their PHNs to help implement PDSAs, ensure attendance in learning workshops and engagement with other intervention features. Participants were satisfied with the support received, as reflected in the following quotes.

"Whenever we had a problem, I would email him (study coordinator), and then he would respond back to me within about 10 minutes usually. I feel we got great support." (Male, practice support Officer, PHN)

"We really appreciate what he (PHN practice support officer) has done for us. Every time he visits, he would be mainly spending time with the practice staff to do with either data cleansing, quality improvement." (Female, GP)

However, some participants identified challenges with communication and indicated an opportunity for improving the support provided.

"I think that the person of contact changed over time, so that was probably a bit confusing, and maybe there was a bit of lack of communication until another person of contact introduced himself." (Female, PM)

"I think that the support is good in terms of IT, providing information; we cannot ask for more from that, but it could get better." (Female, PM)

Overall program acceptability, feasibility, and utilisation of the program

Qualitative data revealed that the intervention was well received by the practice team members.

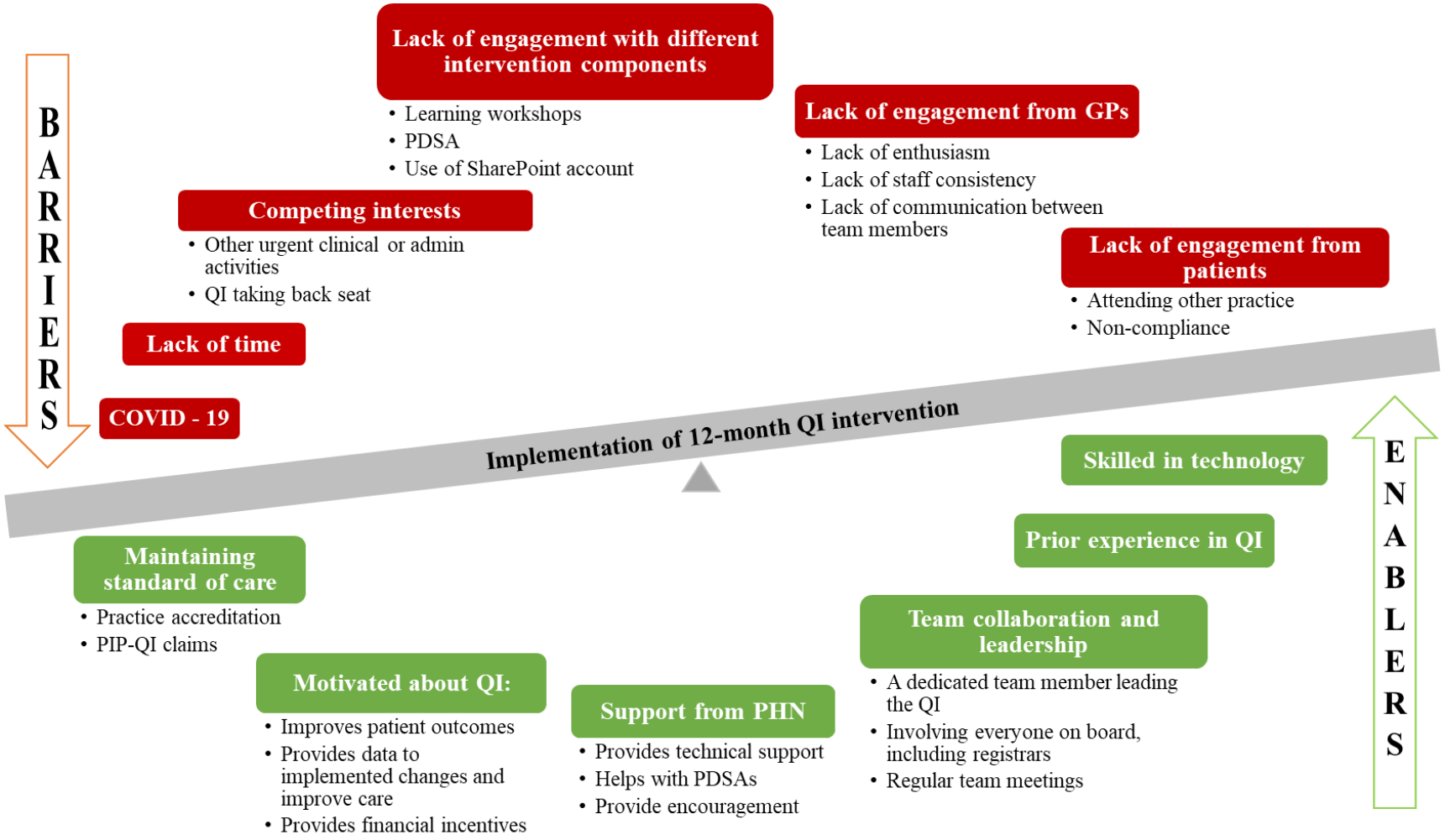
"I really enjoyed it. Just the different parameters we were looking at are all important in keeping people out of hospital for cardiovascular disease. There were just so many learning opportunities and so many ways we can make improvements, so it was quite practical." (Female, PM)

Participants also reported that participating in this kind of intervention provided a structure to facilitate them reaching their improvement targets in a timely manner.

"A program like this gives you a little bit of structure, some guidelines, graphs, and data to work with. No matter what topic you want to use, it is really helpful. So, I'd be happy to engage in that." (Female, PM)

"I think it (QI programs) gives you rigorous timelines and forces you to work towards your goals within the timelines." (Female, nurse)

These findings were further reinforced by the surveys demonstrating team members from 90% (18/20) of the practices expressed interest in participating in a similar program in the future. However, some participants reported there were *"currently too many issues to manage"* (Male, GP); therefore, they were unsure of their future participation.



GP: General practitioner, PHN: Primary Health Network, QI: Quality improvement, PIP-QI: Practice incentive program – Quality Improvement

Figure 1: Themes identified as barriers and enablers to intervention implementation

Barriers and enablers to implementation

Qualitative data has identified several barriers and enablers associated with the practices' engagement with the intervention (Figure 1). COVID-19 and lack of time have been identified as the most common barriers to intervention implementation. Other themes identified were lack of engagement from GPs and patients along with competing interests in the practices such as other more urgent clinical or admin activities; therefore, QI taking a back seat due to those tasks as barriers. Qualitative data further identified several themes to explore practices' lack of engagement with individual intervention features, including practices suffering from workshop fatigues and difficulty in getting practices to engage in the QUEL online workshops due to the number of other webinars offered concurrently. Also, many participants thought of PDSAs as tedious, difficult to document and formulate and often found them intimidating, resulting in limited use of PDSAs. There were also technical challenges associated with using the SharePoint online account, such as forgetting login details or having no prior user experience. Box 1 provides participants' quotes illustrating the barriers identified to intervention implementation.

We identified six themes enabling practices' participation in the intervention. These included (i) practice team collaboration and effective leadership within the team, (ii) maintaining practices' standard of care via participating in continuous QI program for accreditation, which involves an external assessment of practices' performance to ensure they meet required safety and quality standards and Practice incentive programs-Quality Improvement (PIP-QI) claims, which is a government-funded initiative offering financial incentives to the practices for implementing evidence-based improvements in specific clinical areas. (iii) practices having previous experience in QI, practice team members having technological skills to use data to create and review reports, perform data cleansings, etc, (v) practices motivated about

QI as participating in QI helps to improve patient outcomes, provides data to implement changes and improve care and provides financial incentives (vi) support from PHNs. Themes arising from qualitative data associated with intervention enablers are presented in Box 2.

Effect of COVID-19

Most participants reported that COVID-19 affected all aspects of their primary care services, with 90% (18/20) of the practices reporting that COVID-19 impacted their participation in the intervention. Qualitative data provided insight into its effect on the intervention implementation and overall care provided by the practices (Box 3).

Some participants reported that their practice would have done things differently during the QI intervention without COVID-19.

> *"In terms of the patients, I probably would have done more recalls and got them in more often."* (Female, nurse)
>
> *"I think we would have been more focused on QI and on the face-to-face interactions."* (Female, PM)
>
> *"I could have invited you (the study team) to participate in our clinical meetings. It would have given you a chance to present the study to all our six GPs for maximum engagement. That would have made a lot of difference."* (Female, GP)

Overall, most participants thought the intervention would have been easier to implement without COVID-19.

Box 1: Barriers to intervention implementation

Barriers	Themes	Quotes
COVID-19	*Practices overwhelmed with COVID-19*	‘Progress has been limited because of COVID & Victorian lockdown.” (Male, GP) “I think we would have been more productive if it was not for COVID.” (Male, PM)
Lack of time	*Limited time affecting participation in all aspects of the intervention*	“It's just the commitment to that time (to attend workshops and perform QI activities) and getting somewhere. Even in good times, we are all very time poor in GP world, whether you are a practice manager, whether you are a GP or whatever.” (Female, PM) “It was actually a matter of trying to put our thoughts into action (PDSAs), just because we were very time poor.” (Female, Nurse) “It’s because the practice is busy; we do not have time to regularly to log in (accessing the online portal to check monthly feedback report).” (Female, GP)
Lack of engagement from GPs	*Lack of enthusiasm from GPs*	“Greatest difficulty was getting the doctors to comply and don't have the enthusiasm in my practice to implement things I would like to.” (Female, Nurse) “Other doctors are reluctant or resistant to participate” (Male, GP)

	Lack of consistency and regular staff turnover	"To get a GP from this practice to actually bite into something like this, it's extremely hard. None of them works full time. They are not here every day." (Female, PM) "Recent holiday period and resignation of one of our practice nurses has affected our participation." (Female, GP)
	Lack of team involvement and communication between team members	"We have six GPs here, only I signed the agreement. What about the other GPs? Fortunately, I am the principal GP who educates others. If only I am involved, I can't guarantee other GPs will do the same things like me. It is going to affect the whole practice data." (Female, GP) "It was just dumped on me. Others (team members) put their hands up to be leaders in a lot of QI things that the PHN wants and informs me this is the next thing we're doing. No one asked me." (Female, Nurse)
Lack of engagement from patients	*Patients attending other practices*	"One of the challenges that we encountered is patients attending different practices, but they are still on our data." (Female, PM)
	Patient non-compliance	"We can be recalling patients, and they don't necessarily appreciate, so long as they get their script or they think that they're being cared for, they don't necessarily appreciate the extra fiddle-faddle." (Female, Nurse) "So, the big challenge we experience in our clinic is the non-compliance patients. For example, a patient

		was hospitalised for heart failure and diabetes at a very young age, and he needs to do Warfarin INR monitoring. It's hard when he's not doing his blood tests to measure INR." (Female, PM)
Competing interests	*QI taking back seat*	"If there is pressure on the practice, the big example now would be COVID. Sometimes they have to cut something, and one of the first things to get cut is a QI initiative, or they might withdraw some of the time and resources from it." (Male, Practice Support Officer, PHN)
	Other more urgent clinical and admin activities	"GPs now tend to be inundated with a whole lot of additional stuff. So, the small tick boxes, which are very important for their heart health, tend to be overlooked because there's much bigger things happening in our lives." (Female, PM) "The practice currently has some non-clinical demands on management and admin staff, meaning that they are having to prioritise workload." (Female, GP)
Lack of engagement with intervention components	*Learning workshops*	**Workshop fatigue** "Practices are being invited to all sorts of events now, which have all been transferred online, regularly, and a lot of them are after hours. So, practices are suffering from webinar/workshop fatigue, and you have to deal with that when you're running something like this (QI program)." (Male, Practice Support Officer, PHN) **Competing against other online webinars**

		"You are competing with a lot of other people who are trying to take out those hours with other training and online events." (Male, Practice Support Officer, PHN)
	PDSA	**Finds PDSA tedious** "It's mandatory for our accreditation, and you do so many incidental things as a PDSA for it. To go back and then document it all as PDSAs, I find it tedious." (Female, PM) "But my biggest hassle is I am just sick to the back teeth of doing PDSAs; I always have a bit of problem writing them." (Female, Nurse) **Difficult to document and formulate new PDSAs** "I don't know whether it's just myself with my training or how I do things; I just say, what's the endpoint or the outcome we want to achieve, and that's how we do it. But breaking them down into little steps than having to put things into writing and then pre do it as a PDSA, I find it very difficult to do." (Female, GP) **Finds PDSA intimidating** "A lot of practices, what I call are PDSA-phobic. With COVID and PSDA-phobia a combination of those two probably just made it a bit too much for some of them." (Male, Practice Support Officer, PHN) "PDSA cycle, that is my pet peeve." (Female, GP)

	Use of the online portal	**Forgetting login and password** "I know the online portal; it's really common now to have those platforms to look into. But the trouble was I kept forgetting my password and had to keep ringing X to help with the login details. So, that's more a user error." (Female, PM) **Access to the online portal** "Getting on to the site was a bit clunky with the login." (Female, PM) **No previous experience** "I think the challenge for my care coordinator was she didn't know how to use the online portal. So, I had to teach her how to use it. I was fortunate that I've worked with it previously. So I'm familiar with it, but I've realised not everyone's familiar with it." (Female, PM)
GP - General practitioner, PM - Practice manager, QI - Quality improvement, PHN - Primary health network, INR - International normalised ratio, PDSA - Plan-Do-Study-Act.		

Box 2: Enablers to program implementation

Enabler	Themes	Quotes
Team collaboration and leadership	*Having a motivated team*	"It came as a relief for them (the GPs) when we said that we have a very supportive nursing and administrative team, so you don't have to do your own record management or recalling. Our team is small, but everyone knows what they need to do, and they work as a synchronised team." (Female, PM) "So when we are involved in those sorts of (QI) programs, all our team gets included. Because that's the only way to improve things generally across the board." (Female, Nurse)
	A dedicated team member leading the QI activities	"You also need someone who has been given dedicated time to work on it (QI). That was probably the key to 'X' practice's success because half of the nurse's job description is QI." (Male, Practice Support Officer, PHN) "So I probably take the role of the leader. Whatever initiative that we are undertaking, I explain to the staff, this is the reason why we are doing it, and then they will do it." (Female, GP)

	Involving everyone on board, including registrars	"Also, we have a lot of registrars. Because they were involved and learning, which I think played a part in some of those results (Improved data)." (Female, Nurse)
	Having regular team meetings to discuss progress	"For me, that's a chance (team meetings) for me to catch up with my team and see how I can support them in terms of training. I ask them what is it that they wanted to achieve and how can we support them with the training they needed to achieve that." (Female, PM) "When we have our clinical meetings, we update the team as to where we're at, what we're looking at, and then I grab the individual doctors when they were around these meetings and inform them on the progress." (Female, Nurse)
Maintaining practices and standard of care	*Participating in continuous QI for practice accreditation and PIP-QI claims*	"Yeah, do a lot of it (QI). It's a part of our accreditation process that we have to participate in QI. It is also very much part of the funding that practices have at the moment because of the PIP-QI." (Female, PM) "I definitely have participated in several, if not plenty of QI programs. Both in research or as part of accreditation and because we wanted to improve the service within the clinic." (Female, PM)

Experience in quality improvement	*Prior involvement in QI*	"They were already a high-performing practice with previous experience, so it was so hard for them to do just that little bit better. But they managed to do it." (Male, Practice Support Officer, PHN) "That was the easiest part because we are constantly using data reporting tools to run and constantly following up on people. When we ran the report, there were some patients who were incorrectly coded, so we started fixing that quite quickly. I think that is because it's something we are constantly doing in our practice. But I recognise there are probably some practices who hadn't done it (QI) before and may have found that daunting or harder." (Female, Nurse)
Skilled in technology	*Having Technical skills to use data reporting tools*	"I guess we're pretty skilled in using the data reporting tool; I think that was probably an advantage." (Female, Nurse) "If you are inexperienced with it (data reporting tools), it can seem quite daunting; even sometimes navigating through the tools or those sorts of things if you're not familiar with it can be a little bit of a challenge as you get used to it." (Female, Nurse)
	Improves patient outcome	"It's all about how you can look after your patients in different ways and move forward technology-wise, specialist wise and create good referral pathways. So

Motivated about Quality improvement		no, for us, it (the QI program) was not so much part of the everyday thing at all. It was actually set up as something extra but became something worthwhile that the patients enjoyed." (Female, PM) "We believe that QI is really important, and it drives better outcomes for patients. And I think when it comes to quality improvement, it has to have a meaning at the end. Why are we cleaning up the data, why are we putting people on cholesterol medications. We are doing this because we're trying to keep them (patients) out of hospital." (Female, PM)
	Provides data to implement changes and improve care	"I think it's always helpful to participate in QI because it forces you to think. It gives you current data and information. It's just helpful to keep things moving." (Female, Nurse)
	Participating in QI provides financial incentives	"I suppose the financial incentive is definitely a bonus, especially in general practice these days. So not only are we doing something that's for the improvement of the practice, but if you get rewarded financially, even though it's not a huge amount, that helps a little bit." (Female, GP)
Support from PHN	*Provides technical support in using data reporting tools*	"My role ranges from helping practices with their PIP-QI projects and also training them up on data reporting tools and how to document QI Projects." (Male, Practice Support Officer, PHN)

	Helps to generate new ideas for PDSA	"It was really just getting together to exchange ideas, do a bit of brainstorming and also to give them a bit of encouragement to keep going." (Male, Practice Support Officer, PHN)
	Encourages the practices to implement QI changes	"Oh he (practice support officer) is the most supportive practice person we have, and he often drops in. He will always do something. I think, once I said to him come and talk to the doctors" (Female, Nurse
GP - General practitioner, PM - Practice manager, QI - Quality improvement, PHN- Primary health network.		

Box 3: Effect of COVID-19

Effect of COVID-19	Themes	Quotes
Practices overwhelmed	*Reduced capacity of practices to do QI*	"COVID-19 changed our priorities of how we allocated our resources." (Male, PM) "Workload of COVID was extensive affecting other tasks." (Male, GP)
	COVID -19 vaccination taking priority	"Because of the COVID-19 vaccination rollout, a lot of these (QI) have to step aside, and important projects have to take the bench so that it will give way to initial rollout." (Female, PM) "It (COVID-19) definitely changed the focus of GP practices. It was as if we were in survival mode, all of our energy was into vaccine planning or automating systems, keeping the practice safe, it took so much so much resource, and that was our only focus." (Female, PM)
	Continuous review of practice operation	"For a while, managing anything other than our day-to-day work was almost impossible due to constantly changing environments." (Female, GP) "Whole focus of the practice was shifted entirely to a day-to-day basis of what and how are we doing things today? What are the latest guidelines? What are the latest figures?" (Female, PM)

	Setting up telehealth	"Introducing telehealth, introducing telephone consults. Telehealth for us was a massive change" (Female, PM) "It forced us to change the way we deliver our service via telehealth." (Female, PM)
	Patients not attending the practices	"Because of COVID, patients hadn't come in, so there were a number of patients who haven't had their BP checked and things like that for a while." (Female, Nurse) "Patients were asked to use telehealth, thus dropping the ability to measure BP and similar biometrics." (Male, Research manager)
Patients overwhelmed	*Not focused on own health*	"COVID is affecting us as some patients don't want to come in the surgery or they aren't interested in their own health & wellbeing." (Female, PM)
	Rising mental health issues	"We've found over the last two years that people actually coming in with quite acute mental health problems with COVID." (Female, PM)
Doctors overwhelmed	*Overworked and stressed*	"I think the doctors were feeling very stretched, and we had to trade very carefully with some of that." (Female, Nurse)
GP - General practitioner, PM - Practice manager, QI - Quality improvement, PHN- Primary health network. BP- Blood pressure		

Box 4: Recommendation for improvement

Recommendations	Themes	Quotes
Overall program	*Including the whole practice in the study*	"For example, in our practice, we already have all the GPs attend lunch time meeting. In future if there is a study available if you guys (study team) can join us via zoom that kind of allows all our GPs to know about it and also can help more GPs to increase research interests." (Female, GP)
	Working with a good PHN	"Maybe that's something you can think about in future like definitely work with a good PHN, not ones that bit hands off, you got to have people that are really dedicated." (Female, PM)
	Training on data extraction tools and data cleansing	"I'd like to know how to reproduce graph(s) and save in the (online portal) to compare after PDSA completion and extract CHD measures from the data extraction tool." (Female, PM) "Making sure people know how to use the data extraction tools, I think that can be a bit of a roadblock." (Female, PM) "I was kind of surprised with the study that there wasn't any kind of data cleansing exercise beforehand just to improve the quality of the data. It would be beneficial, with a study like this to go through some sort of standardized data cleansing

		procedure.” (Male, practice support officer, PHN)
Learning workshops	*More face-to-face interactions during the program*	“I work better if participating in person.” (Female, GP)
	Better workshop content and shorter duration	“If you can pack it better, make it shorter, let's say four to six every 3 months is ok depending on how much information you want to educate and pass to the GPs.” (Female, GP) “Some topics discussed were a little basic for our group but we understand diversity in the group. Perhaps there could be two streams for one session. Advanced and introductory and then move to group collaborations so we all learn from each other.” (Male, Research officer)
Monthly reports	*Receiving monthly feedback reports via email or in-person*	“If someone actually shows it to me then I would be more inclined to look at it. But, if I was asked to actually go and look at that myself then I probably wouldn't be bothered.” (Female, GP) “In future you leave that option (online portal) and also monthly send us the data as well via email.” (Female, GP)
PDSAs	*Simplification of PDSAs*	“If we could come up a different way of doing a PDSA cycle that would be good.” (Female, GP)

	Sharing of More PDSAs	"I would like to see more examples of how PDSA cycles are written." (Female, Nurse)
Support	*Regular communication with the practices*	"I think sometimes if you've got somebody who's going to hold you accountable for a different timeline, like to phone you up and say okay what's your plan for your PDSA, when are you hoping to get it done by and then have a phone call how's that going, it's really useful." (Female, Nurse) "Probably just more regular communication. And if we're slacking off, have those face-to-face or zoom meetings and just go hey, this is our data at the moment what are you thinking about." (Female, PM)
	Regular reminders	"Having some more reminders such as 'you haven't done it for this month' or follow up on the one we did last month and just keep adding to that would have been good." (Female, PM) "It'd be very useful for someone to come out and say, 'what's going on. Look at this report, what do you think is happening?' Just as a reminder that you're not focusing on this (Quality improvement program) as much." (Female, PM)
GP - General practitioner, PM - Practice manager, QI - Quality improvement, PHN- Primary health network.		

Recommendations for future improvements

Several recommendations were made by the participants for better implementation of future QI programs. (Box 4) Participants felt such programs should include everyone in the practice for increased research interest. Some participants also recommended working with a good PHN to maximise effectiveness, as well as including training on using data reporting tools and data cleansing. Participants also made several recommendations to increase practice engagement with the different intervention features for better implementation of future QI initiatives (Box 4).

DISCUSSION

Overall, the data-driven QI intervention aimed at improving care for CHD patients received positive satisfaction from the practice team members and PHN staff. Participants provided positive feedback about several features of the intervention program; however, the use of PDSA cycles and overall support during the program received mixed feedback. From qualitative analysis, the overall intervention program was well accepted, perceived as useful to identify gaps and motivated practices to drive improvement within a specific timeframe. Through thematic analysis, several barriers and enablers were identified to impact practices' ability to implement the intervention effectively. COVID-19 and time constraints were identified as common barriers, and team collaboration and effective leadership were identified as the most common enablers.

QI programs are often complex and have multiple features[2]; process evaluation can help gain detailed insights to understand the practice team members' real-time experience with using these features.[16] Our process evaluation results have identified some of the features of the QI program were better accepted than others. PDSAs were found to be the least

liked feature despite being the most commonly used tool in QI programs.[17,18] Our findings also align with previous research that suggests that health professionals found PDSAs difficult to use in practice and were not able to apply them as intended. [17] Another important feature of the program is the provision of support during its implementation[10]; however, limited research has evaluated its usefulness. [9] Our study found the support received during the intervention program helped the practices to build relationships and feel motivated, although some participants felt the support could have been better.

This study identified several barriers for practice team members in embedding the data-driven QI into their routine practices. GPs and practice team members were found less engaged throughout the program, mainly due to tackling COVID-19 and the constant changes within their practices. Similar to our findings, previous studies have found that QI is more effective in a stable clinical environment.[19] In addition, the lack of communication between the team members also contributed to non-engagement from the GPs.[11] Most often, practices are required to prioritise their clinical and routine administrative tasks regularly; therefore, QI tends to take the back seat.[20] Findings from our study are consistent with previous research[10, 11] and indicate the need to address these barriers and re-evaluate for better engagement in future data-driven QI programs.

Only a limited number of enablers have been identified by previous studies. One study found that the involvement of the multidisciplinary team and effective leadership are important enablers in driving QI within their practices.[21] Similar to our study, another study reported that regular communication from the local PHNs helped build an effective relationship with the practices[12], which in turn motivated the practices to implement QI programs and kept them on track. [22] Furthermore, a systematic review found that practices

participating in accreditation programs and PIP-QI have achieved better clinical outcomes and improved processes of care for patients with CVD and diabetes, amongst others, therefore enabling practices to undertake further QI activities.[23]

The use of electronic health records and recent advancements in technology have enabled data to be used in various healthcare processes such as automated data collection, filtering of eligible patients, aggregated reporting, GP reminders, etc. These have significantly increased healthcare facilities' participation in QI programs. Previous studies have shown healthcare facilities that used electronic health records to automatically collect data, review their patients, create reports and track improvement against performance measures have demonstrated improved patient outcomes.[24] Similarly, in our QI study, we used electronic health records to filter and collect data to identify patients with gaps in care and provided GPs with reminders to improve care.[25] The effectiveness of electronic patient records in improving patient care is well documented. Therefore, it should be frequently used in QI programs implemented across all healthcare settings.

This study has several strengths. It is a relatively large national study, including small and large-sized primary care practices from both urban and rural areas covering different geographical regions; as a result, representing a wide range of Australian primary care practices. Another strength is the use of a mixed-method approach by combining both qualitative and quantitative data, which was further enhanced by triangulation of multiple datasets to obtain a comprehensive understanding of the satisfaction, acceptability, utility, barriers and enablers to implementing the QI program.[16] While this mixed-methods evaluation provides significant insights into the complex QI program, the study is not without limitations. Firstly, the program was delivered during the COVID-19 outbreak and

lockdowns, restricting the evaluation to online. Conducting semi-structured interviews via videoconference may have also limited team members' participation in the evaluation. Second, participants for the semi-structured interviews were not randomised, leading to selection bias. Third, the responses of the practice team members were averaged to reflect practice-level responses, which may also introduce potential bias in the results. Finally, the retrospective nature of the evaluation may lead to recall bias and subject to confounding.

CONCLUSION

The mixed-methods process evaluation found that the data-driven QI program received positive satisfaction and was well accepted in implementing changes to improve CHD care. The study identified several barriers, including lack of time, limited GP engagement, COVID-19 and other competing priorities within the practices. Conversely, a collaborative team under a dedicated leader to drive QI changes, availability of PIP-QI and participation in practice accreditation programs were identified as enablers for successful program implementation. However, further research is needed to determine if the implementation of data-driven QI improves clinical outcomes for CHD patients.

Ethics Statement

Ethics approval has been obtained from the New South Wales Population & Health Services Research Ethics Committee (HREC/18/CIPHS/44). No individual patient data was used for the process evaluation. Written consent was obtained from the practice team members and PHN staff before conducting semi-structured interviews. Each participating practice signed a Health service agreement, and if a practice wished to withdraw from the study, they were free to do so at any time.

Competing interests

The funding body and industry partners were not involved in the design of the study and did not have any role during its execution, analyses, interpretation of the data, or decision to submit results. Amgen and Sanofi Australia have provided cash support to the main study. MW is a consultant to Amgen, Freeline and Kyowa Kirin. Other authors have nothing to disclose.

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Data Availability Statement

Data (interview transcripts and survey) data will not be available. Although de-identified by name and place, it may contain contextual information that would enable identification of individual participants.

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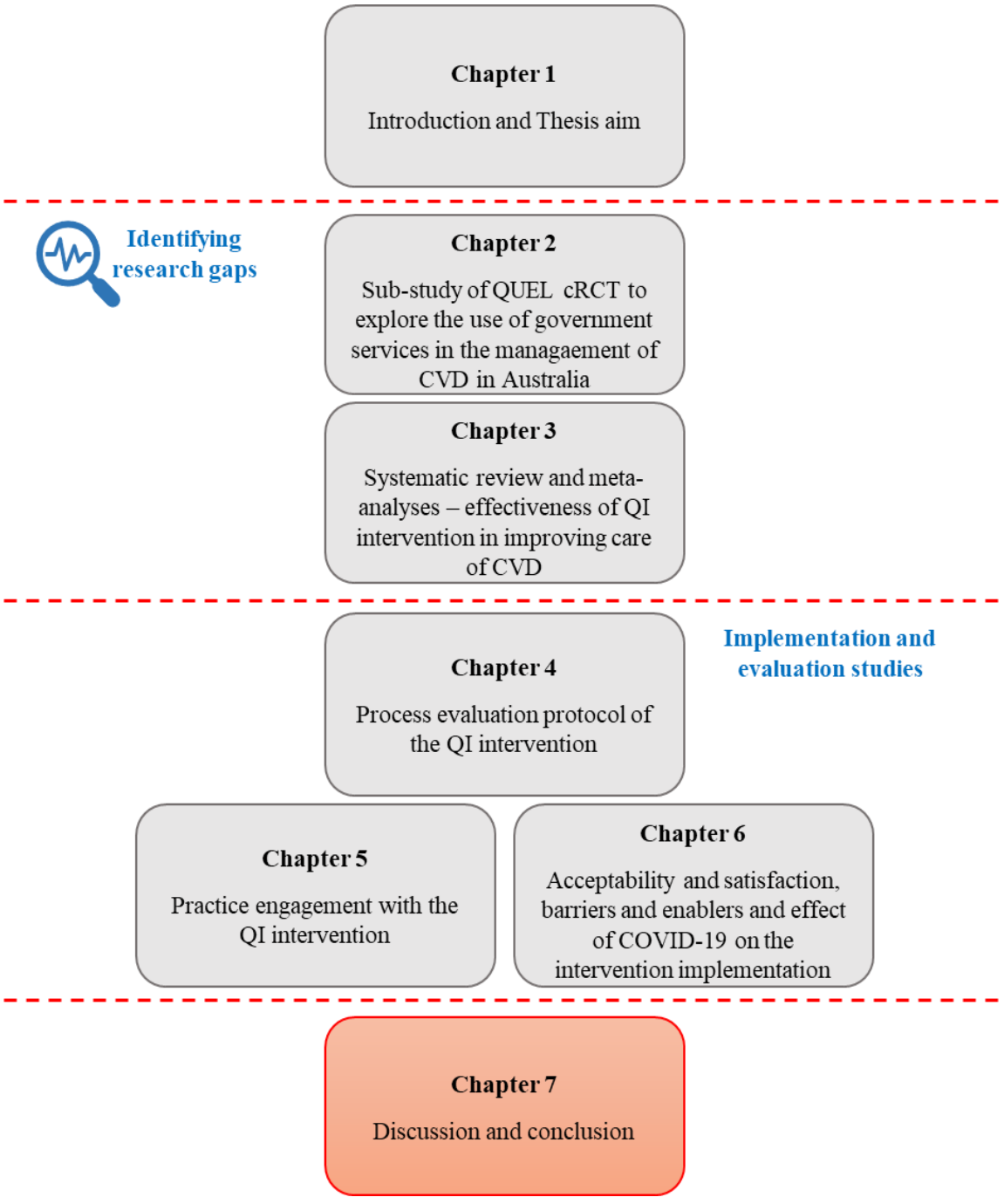
SUPPLEMENTARY MATERIALS

Table S1: The 12 CHD measures for QUEL study

1. The number of clients that are coded with a diagnosis matching the CHD definition
2. The proportion of clients with CHD where low-density lipoprotein (LDL) has been measured within the previous 12 months
3. The proportion of clients with CHD whose most recent LDL result was less than 2.0 mmol/L
4. Proportion of clients with CHD with a recorded blood pressure (BP) reading taken within the previous 12 months
5. Proportion of clients with CHD whose most recent BP reading, taken within the previous 12 months, was less than or equal to 130/80 mmHg
6. Proportion of clients with CHD whose smoking status has been recorded
7. Proportion of clients with CHD recorded as a current smoker
8. Proportion of clients with CHD who are currently prescribed an anti-platelet agent
9. Proportion of clients with CHD who are currently prescribed a statin
10. Proportion of patients with CHD who are currently prescribed an ACE inhibitor or ARB
11. The proportion of clients with CHD with MBS Items 721 or 732 claimed
12. Proportion of clients with CHD who have an influenza vaccination recorded within the previous 12 months

CHAPTER SEVEN

Discussion and conclusion



This Thesis systematically evaluated a QI intervention from needs assessment and conceptualisation (Chapters Two, Three and Four) to primary care practices' engagement with the intervention (Chapter Five) and the perceptions of practice team members regarding the uptake, use, and satisfaction with the intervention (Chapter Six). This chapter summarises the key findings, highlights important clinical implications, discusses strengths and limitations, and suggests direction for future research.

MAIN FINDINGS

Overall, this Thesis found that QI interventions are well-received and beneficial for primary care practices aiming to improve care of people with CHD. In Chapter Two, an evidence-practice gap in the management of CVD within Australian primary care practices was identified, revealing disparities in the utilisation of government-funded services (Aim One). These gaps included underutilisation of government-funded health services, including CDMPs and guideline-recommended medications, was persistently reported in an RCT involving 732 patients (1) and also in the subgroup analysis of large RCTs such as TORPEDO, which involved 6123 (2) and CONNECT, which involved 905 CVD patients (3). In addition to underutilisation, gender disparities were also observed in this Chapter, reflecting results from a large observational study involving 10,745 patients with ACS (4). Increased use of these services has the potential to improve health outcomes in both genders and reduce CVD burden by enabling coordinated multidisciplinary care for eligible patients through primary care and allied health care services (5). Although the Thesis primarily focused on evaluating the QI intervention's process, it also identified gaps in primary healthcare, including suboptimal prescription of medication and the use of CDMP and mental health plans, which are worse in women, as identified in Chapter 2. Therefore, addressing

these gaps through QI interventions that can be easily accepted and implemented in primary care is essential for improving patient outcomes and reducing the burden of CVD.

Healthcare providers are shifting towards adopting systematic, robust, technology-driven approaches to improve secondary prevention of chronic diseases, including CHD. Previous studies by Dorr et al. (6) and Grossglauser et al. (7) have already emphasised the use of data-driven solutions to improve healthcare delivery. However, a systematic review of 21 RCTs and cRCTs, evaluating the effectiveness of a data-driven QI intervention in the management of chronic kidney disease, found it was effective in improving LDL cholesterol levels and prescription of ARBs, but not in reducing mortality, CVD events, and improving BP control (8). The varied effectiveness is also seen in another systematic review (9), reinforced by varied findings from the systematic review and meta-analysis in Chapter Three of the Thesis (Aim Two), suggesting the complexity associated with implementing QIs and possible contextual factors influencing the variation in the effectiveness (10).

To address this variability in the effectiveness, Chapter Four, therefore, described a process evaluation plan using a mixed-methods approach to comprehensively evaluate a data-driven QI intervention used within the QUEL cRCT. The mixed-methods process evaluation, as demonstrated in previous studies, is instrumental in informing intervention implementation, identifying factors influencing participation, and exploring contextual characteristics influencing study outcomes across various healthcare settings and health conditions (11-14). This approach enabled us to collect both qualitative and quantitative data, providing a holistic understanding of the intervention, similar to another study that gained valuable insights from health professionals on a digital health intervention (14). The data sources used in this evaluation collected credible evidence at different time points during the one-year

intervention period to assess practices' engagement with the intervention and intervention delivery, understand practices' satisfaction and acceptability of the program, identify barriers and enablers and evaluate the effect of COVID-19 on the program implementation (Aim Three).

Although several studies have evaluated the effectiveness of QI interventions in improving clinical outcomes (15-17), limited research was found exploring participants' engagement with various features of the QI intervention. Therefore, findings from the Thesis in Chapter Five contribute valuable insights by revealing varying levels of practices' engagement with different features used during the one-year intervention period (Aim Four). These detailed findings signify the dynamic nature of practice involvement and emphasise the need for tailored approaches, as evidenced by findings from another study that increased healthcare providers' engagement with the QI intervention by employing tailored strategies (18). Moreover, a systematic review involving 140 RCTs demonstrated effectiveness of feedback reports in improving health professionals' compliance with recommended clinical practices although it did not explore their impact on clinical outcomes (19). Another systematic review indicated that continuous education was found effective in improving care (20). Findings from Chapter Five are consistent with these reviews, identifying learning workshops or health professionals' education and feedback reports as the most useful of the multiple intervention features as reported by the practice team members (Aim Four). Furthermore, a separate systematic review highlighted the effectiveness of using a nurse as a QI champion, emphasising their role in fostering and implementing QI changes to drive positive outcomes (21). Similarly, this chapter also emphasised using team members with clinical backgrounds to lead QI activities. Thereby facilitating effective implementation of QI changes in the

practices. Overall, the intervention was implemented as intended, except for the use of PDSAs (Aim Four).

QI interventions often receive positive satisfaction from the team members as evidenced by previous studies and the findings from Chapter Six in the current Thesis, indicating wider adoption of such interventions (22). Additionally, findings revealed positive feedback about several features of the intervention program, except for the use of PDSA cycles and overall support received throughout the intervention period (Aim Five). Despite the mixed findings, evidence from a systematic review suggests that QI interventions are practical in identifying gaps and effective in driving improvement, not only for CHD but also for other conditions (Aim Five) (23).

Several studies have explored the barriers and enablers associated with implementing QI interventions. The research within the Thesis not only adds credibility to the existing evidence (24-27) but also further identifies barriers and enablers influencing practices' engagement with the individual QI intervention features, as described in Chapter Six (Aim Five). In addition to COVID-19, common barriers identified in the Thesis align with the findings from previous research, which included lack of time (26, 28), lack of collaboration from team members (25), and competing priorities within the practices (29, 30). Additional barriers were complexity of implementing the PDSAs as reported in another systematic review (31), workshop fatigue affecting attendance and engagement in learning workshops, and technical difficulties like forgetting login details or having no prior user experience in the use of the QUEL SharePoint account, were also found to impact practices' engagement with individual intervention features. Team collaboration and effective leadership were identified as common enablers in this Thesis Chapter, aligning with findings from other studies (24,

25). Additionally, maintaining practices' standards through participation in accreditation program and PIP-QI, prior QI experience, technical skills to implement data-driven QI activities (25, 26, 32), motivation, including financial incentives (27) and continuous professional development (33), and lastly, support from PHNs (34) were identified as factors facilitating practices' participation in the QI intervention. These findings are reinforced by the evidence from previous research, further emphasising on the importance of these factors in promoting successful implementation of QI interventions. By leveraging insights gained from this Thesis to understand QI interventions, there is a significant opportunity to bridge the gap between research and clinical practice, ultimately impacting clinical outcomes. Consequently, it is imperative that future QI studies will need to incorporate findings from this Thesis, along with evaluating clinical outcomes, to comprehensively address gaps in healthcare and drive substantive improvements in patient care.

Moreover, healthcare services in Australia were severely affected during the COVID-19 outbreak, with a 22% reduction in face-to-face consultations in primary care and a 14% decrease in admissions to public hospitals (35). Building on this context, Chapter Six further evaluated the effect of COVID-19 on the intervention implementation and found that most practices' participation was impacted by the COVID-19 pandemic (Aim Five). Practices faced overwhelming challenges, including reduced capacity, the demands of vaccination rollout, continuous operational review, and a rapid transition to telehealth, as evidenced by findings from a systematic review (31). Furthermore, doctors were also stressed and overworked, consequently, affecting all aspects of the primary care services, including participation in the QI intervention. This finding is similar to the findings from the systematic review, indicating that the pandemic has led to reduced access and quality of care provided by primary care worldwide (31). Overall, the data-driven QI intervention program received

positive satisfaction and was well accepted in implementing changes to improve CHD care in primary care practices and can be easily scalable.

CLINICAL IMPLICATIONS AND FUTURE RESEARCH

The Thesis identified the gaps in CVD care provided in the Australian primary care practices and explored the scope of QI interventions in Chapters Two and Three. Described a robust process evaluation to obtain comprehensive overview of an innovative, multi-dimensional, technology-driven solution aimed at improving the care of patients with CVD through primary care in Chapter Four. Provided valuable insights in the intervention delivery, participants' engagement and important factors influencing their engagement with the intervention in Chapter Five. Explored health professionals' perspectives on acceptability and satisfaction associated with the intervention in Chapter Six. Due to the limited evidence available regarding the acceptability of QI interventions among health professionals (36), this Thesis will be one of the first to evaluate health professionals' perspectives on individual features of a data-driven QI intervention aimed at improving care for CHD.

The systematic review and meta-analysis in this Thesis evaluated the effect of QI interventions on improving CVD-related outcomes in Chapter Three. Additionally, the Thesis also evaluated practice engagement with different intervention features used within the QI intervention. However, the Thesis did not evaluate the effectiveness of individual or combined QI strategies in improving clinical outcomes related to CVD care. While previous studies have examined the effectiveness of individual QI strategies (19, 37, 38), a gap remains in understanding whether combining these strategies provides better results compared to using them individually, and vice versa (19). These findings emphasise the

variety of QI strategies used in healthcare and advocate for large-scale trials to assess their potential impact on patient outcomes, whether employed individually or in combination.

The findings from this Thesis can help guide the integration of well-accepted features from the data-driven QI intervention into health policy frameworks, encouraging wider adoption of such programs across the primary healthcare system. PHNs can play an important role in supporting practices to increase their use of EHRs, offering guidance, training, and resources. Additionally, practice staff, including GPs, can contribute to better patient outcomes and enhanced quality of care by actively engaging in QI activities and embracing evidence-based practices.

Leveraging user-friendly QI tools and effective leadership to improve engagement

Previous studies have found that the use of PDSA is effective in implementing small, incremental, and measurable changes, helping practices become aware of the risks and benefits before implementing the change more widely (39). Despite the evidence and widespread use of PDSA as a QI tool (31, 40), studies have found low PDSA engagement in primary care practices (41), similar to the findings from this Thesis in Chapter Five. The lack of engagement with PDSAs underscores the need for policymakers to promote a robust framework that emphasises continuous training and support for QI tools to help make PDSAs more practical for health professionals, potentially increasing their adoption and engagement, as evidenced by another study (42). Consequently, this can lead to increased engagement with not only with PDSAs but also with other complex QI tools in future QI studies.

Moreover, while the role of clinical leaders has been proven crucial in successful implementation of QI (21, 34), the QI intervention evaluated in this Thesis did not include

designation of a QI leader or champion as an intervention feature to drive QI changes within their practices. However, some GPs and nurses from the participating practices automatically assumed leadership roles during the intervention period, while others suggested employing a clinician as a QI leader would have facilitated their participation, indicating the importance of designating clinicians as leaders or champions to improve engagement in future QI studies. Such leaders can foster a culture of QI within their practices by supporting continuous learning among practice staff, encouraging team participation in QI activities, and ensuring the delivery of guideline-recommended quality healthcare to their patients. It is important for future QI interventions to prioritise training and support for QI tools, as well as designate clinicians as leaders or champions, to improve engagement within the practices. Additionally, PHNs can provide resources and guidance for overcoming obstacles in the adoption of QI tools to ensure success of QI interventions. Understanding the challenges associated with PDSA cycles and supporting the designation of QI leaders within practices are crucial for effective policy formulation and future implementation.

Expanding use of EHR

One key factor enabling the success of QI efforts in healthcare is the integration of technology, particularly EHRs, in patient care. EHRs have demonstrated a positive impact on various aspects of patient care, such as reducing heart failure readmissions, improving discharge quality, and enhancing adherence to guidelines and medication prescriptions (31). They enable healthcare providers to set alerts and reminders, identify critical laboratory values, and ultimately enhance patient safety (32-34). Despite their benefits, challenges such as lack of training, education, technical support, and time constraints have influenced the usability of EHRs in healthcare (19, 35, 37, 38). To optimize the use of EHR systems and contribute to better data quality and reporting, policymakers can create a supportive

environment for EHR adoption, offering incentives, technical support and resources. PHNs can support GPs in integrating data analytic tools into primary care practices and provide necessary training. GPs can enhance patient care by fully engaging with EHRs, focusing on accurate data collection, secure data storage, and efficient data sharing to support informed, data-driven decision-making, ultimately improving delivery of patient care (43-45).

An efficient EHR system allows practices to implement data-driven decision-making in patient care. Alongside maintaining up-to-date EHR systems, increased adoption of high-quality data analytics tools can be beneficial to the practices for tracking and assessing performance metrics, patient outcomes, and adherence to evidence-based guidelines (46). This Thesis, based on a cluster randomized controlled trial, utilized a data analytics tool to extract practice-level clinical data and generate regular feedback reports. While the impact on clinical outcomes related to CHD performance measures was beyond the Thesis's scope, further research is crucial to evaluating the effect of QI interventions on improving patients' clinical outcomes.

Optimising CVD care through utilisation of data

The increased use of EHRs has encouraged healthcare providers to improve CVD care, underscoring the importance of robust data governance policies, standardised data collection methods, secure data storage and transfer platforms, and measures to ensure patient data confidentiality. It is important for policymakers to prioritise investments in data infrastructure and technical training. PHNs can support GPs to build and maintain accurate databases and help practices establish proactive recall and reminder systems to ensure patients receive systematic care. GPs can effectively use these systems to identify high-risk patients, monitor their progress, and improve adherence to evidence-based guidelines, and foster a culture of

continuous improvement. While programs like QIPIP are already in place to encourage QI, policies should further support and encourage the adoption of more comprehensive QI strategies within primary care settings.

Several studies, including those by Curtis et al. and Tu et al. also emphasised the positive impact of using data to improve quality of care and patient outcomes (47, 48). By using and analysing the data effectively, healthcare providers can accurately identify high risk patients (49), closely monitor patient progress (50), improve process of care by prescribing guideline-recommended medications to all eligible patients (51), and facilitate clinical decisions (52), consequently improving the quality of care.

This Thesis describes healthcare providers' observed benefits in receiving data as evidence to identify the need for improvements, learn from peers, and track and monitor progress used in improving care for CVD in Chapter Five (Aim Four). These findings are crucial, suggesting potential clinical implications for a positive effect on patient health outcomes through implementation of different data-driven QI strategies. Including (i) building and maintaining accurate and up-to-date databases (iii) establishing appropriate care pathways, using evidence-based guidelines, (iv) developing and implementing a proactive recall and reminder system to ensure patients receive systematic and proactive care and (iv) regular data cleansing and quality checks (v) including a robust data collection system and (vi) establishing a small multidisciplinary team to facilitate the QI work; therefore creating a systematic and efficient approach to deliver quality health care. However, previous research has identified several challenges in using data to improve care including data governance, storage and transfer, standardisation, inaccuracies lack of technical skills, security and confidentiality of personal information (53, 54). Future research should focus on addressing

these challenges to explore the full potential of data to provide high-quality patient care in improving management of CVD.

Adoption of QI strategies in primary care practices as routine care

The increased adoption of QI in primary care practices as routine practice is a pivotal step in translating the findings of the Thesis into real-world healthcare settings. The findings underscore the significant benefits of different QI strategies, encouraging increased implementation of QI activities to bring positive changes, potentially improving patient outcomes, patient safety, and cost-efficiency (55-57). To bridge the gap between research and practical application, it is imperative that healthcare providers and institutions recognize the clinical implications of these findings and take proactive steps to integrate QI strategies into their daily routines. This involves embracing evidence-based guidelines, creating systematic and coordinated patient care, fostering a culture of continuous learning and adaptation, using data and analytic tools and ensuring that QI becomes an intrinsic part of the healthcare delivery process (41). Recognising and addressing the barriers to effective QI implementation is essential, along with providing necessary infrastructure and support. Policies play a vital role in facilitating the integration of QI into routine care delivery, ultimately improving the quality of patient care.

The future of QI interventions in primary care and across all healthcare settings will revolve around the effective integration of health technology, data-driven decision-making, patient, and healthcare provider engagement amongst many others. QI is a multifaceted process; therefore, all healthcare providers and their organisations are required to stay proactive in addressing these future implications to ensure the delivery of high-quality, patient-centred

care. Policies need to promote the integration of evidence-based guidelines, incentivize QI strategy adoption, and facilitate the establishment of multidisciplinary teams in primary care settings. Key implications for primary care practices and healthcare providers include ongoing training to enhance technical skills, systematic approaches to data management, and the fostering of a culture of continuous improvement. Additionally, Primary Healthcare Nurses (PHNs) should advocate for policies that prioritise QI initiatives and foster a culture of continuous improvement. Through collaborative efforts and strategic initiatives, primary care practices can lead the way in incorporating QI in their routine care to provide more accessible healthcare services for all thus reducing the burden on healthcare systems.

STRENGTHS

One of the main strengths of this research is the implementation of a unique QI strategy within the Australian primary care setting. The processes and results explored in Chapters Four, Five, and Six provide an in-depth understanding of the design, development, implementation, delivery, and uptake of the unique intervention tailored to the needs of the local practices. The study was conducted at a national level and included practices with diverse characteristics. The participants were representatives of practices from varying sizes and geographical areas (both urban and rural) across four Australian states to ensure generalisability, making the Thesis findings relevant across all healthcare settings. Furthermore, the in-depth examination of practice team members including GPs, practice managers, nurses and PHN representatives' experiences of the intervention provides valuable insight into how the intervention worked in the real environment. Moreover, the research identified and documented usefulness of the intervention features. These findings shed light on the potential for various QI strategies to shape the delivery of care, improve patient outcomes and enhance overall system performance in the continuously evolving healthcare.

The Thesis also enhances the understanding of the barriers and enablers involved in the implementation of data-driven QI interventions, strengthening the evidence for addressing these factors in future iterations of similar interventions to enhance their success and effectiveness.

Another strength of the study is the use of mixed-methods research. It is the recommended approach for evaluating processes within randomised trials (58) as it improves external validity, strengthens the quality of the data and offers an in-depth analysis and comprehensive understanding of the study results (59, 60). Further, we also combined both qualitative and quantitative data and performed triangulation of the multiple datasets providing a wide range of perspectives from multiple health professionals, consequently providing in-depth understanding of the complex intervention features (61). For example, in this Thesis, quantitative data explored the practices' engagement with the intervention to identify which intervention features received low engagement and qualitative data further delved into healthcare providers' perspectives on the reasons for non-engagement with these features. Combining these also provides a complete understanding of the satisfaction, acceptability, utility, barriers and enablers to implementation of the QI program (62).

LIMITATIONS

The Thesis has several limitations. First, the intervention was delivered during the outbreak of the global COVID-19 pandemic, which could have impacted practices attendance in learning workshops and overall engagement with the intervention (63). Second, the sample size of only 27 primary care practices may limit the generalizability of the findings, despite the efforts to include both rural and urban practices from across four Australian states. Third, the findings may be relevant to health systems similar to Australia, as the Thesis evaluated

practices' engagement and obtained healthcare providers perspective on the intervention within Australian primary care environment. Fourth, the Thesis acknowledges the possible introduction of selection bias due to nature of the participant selection for the interviews. Moreover, the Thesis also acknowledges the retrospective nature of the data collection and analysis, and reliability of self-reported data may have introduced recall bias and subjected to confounding. Fifth, multiple practice team members from the study provided feedback via the survey and semi-structured interviews, which were consolidated to obtain practice's view of the results. This may has led to reporting bias. Additionally, participation of only one staff member from the PHNs in the semi-structured interviews may have limited the breadth of PHN's perspectives on the intervention. Sixth, some of the outcomes were measured using categorical data which may not provide an accurate representation of the results. Seventh, the Thesis was unable to collect complete data on the support received by the practices during the intervention, as almost half of the practices were supported by their respective PHNs which were operated independently. Therefore, we were unable to assess their contribution to the QI intervention. Finally, it was beyond the scope of the Thesis to evaluate the effectiveness of the QI intervention on improving clinical outcomes, as it explored the implementation and efficacy of the intervention.

CONCLUSION

Despite the significant efforts to reduce CHD related deaths (64), it still remains the leading cause of death and disease burden in Australia (65) and globally (66). This Thesis aimed to evaluate the engagement of primary care practices with a one-year, multi-featured, data-driven QI intervention within a cRCT. It focused on its key features, acceptability, satisfaction, utility, barriers, enablers, and the impact of COVID-19 on its implementation. This Thesis also emphasises the importance of effective leadership and team collaboration to

improve engagement with such interventions. Additionally, it highlights the significance of continuous training and support in utilizing technology, such as EHRs and data extraction tools, to facilitate successful data-driven QI changes in practices. Overall, this Thesis found that QI interventions are acceptable, helpful and motivating strategies for primary care practices to provide a systematic and efficient approach to deliver quality health care. These findings can help support other practices and healthcare organisations to implement effective QI strategies for successful future implementations. However, further research is needed to explore how this strategy can be integrated into routine care along with large multi-centre clinical trials with full cost effectiveness analyses. This approach will facilitate the translation of findings into practice, ensuring sustainability and continued improvement in CVD care.

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APPENDICES

Appendix A

Ethics approval of the QUEL Study:

NSW Population and Health Services Research Ethics Committee (NSWPHSREC)

NSW GOVERNMENT | Cancer Institute

Working together to lessen the impact of cancer

1 November 2018

Associate Professor Julie Redfern
julie.redfern@sydney.edu.au
University of Sydney

Dear Associate Professor Redfern,

NSW Population & Health Services Research Ethics Committee

AU RED Reference: HREC/18/CIPHS/44

Cancer Institute NSW Reference: 2018HRE0907

Project Title: QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with heart disease (QUEL)

Thank you for your correspondence dated 23 October 2018 responding to a request for further information/clarification of the above referenced study, submitted to the NSW Population & Health Services Research Ethics Committee. The Committee has reviewed your response and has agreed that the aforementioned application meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*. This approval is for a maximum of five years from the date of this letter, after which time a renewal application will be required if the protocol has not been completed.

The Committee granted a waiver of the usual requirement of consent for the use of re-identifiable information held by NSW agencies, in line with the State Privacy Commissioner's Guidelines for Research and the Health Records and Information Privacy Act 2002 (NSW) and the Guidelines approved under Section 95 & 95A of the Privacy Act 1988.

The documents reviewed and approved include:

- Email of Response, dated 23 October 2018
- Cover Letter dated 3 September 2018
- Human Research Ethics Application, v1.3.1, submission code AU/1/2F88312, dated 7 September 2018
- Combined Protocol version 1, dated 23 October 2018
- Data Flowchart
- NSW APDC Variable List
- NSW EDDC Variable List
- NSW APDC & EDDC Data Custodian Sign Off Form, dated 24 August 2018
- ACT APC Variable List
- ACT EDDC Variable List
- QUEL Clinical Data Variable List
- CHeReL Technical Feasibility Letter, dated 7 September 2018
- NSW Privacy Form
- Peer Review Report

Cancer Institute NSW
ABN 48 538 442 594

Level 9, 8 Central Avenue, Australian Technology Park, Eveleigh NSW 2015
PO Box 41, Alexandria, NSW 1435
t: +61 (0)2 8374 5600 f: +61 (0)2 8374 3600 e: information@cancerinstitute.org.au
www.cancerinstitute.org.au

- Julie Redfern CV
- Clara Chow CV
- Christopher Reid CV
- Nick Zwar CV
- Tim Usherwood CV
- Tom Briffa CV
- Robyn Gallagher CV
- Karice Hyun CV
- ACT Waiver of Consent Request
- QUEL Quality Improvement Workshop Participant information and consent form v1.0, dated 31 August 2018
- QUEL Quality Improvement Workshop Evaluation Survey v1.0, dated 31 August 2018
- QUEL Post-Program Final Evaluation Survey v1.0, dated 31 August 2018

Approval is now valid for the following site for unit record data:

- The University of Sydney

The NSW Population & Health Services Research Ethics Committee has been accredited by the NSW Ministry of Health to provide single ethical and scientific review of research proposals conducted within the NSW public health system.

The Committee is a joint initiative of the Cancer Institute NSW and NSW Ministry of Health. The Committee has been constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* and relevant legislation and guidelines.

Please note that ethical approval is valid for **5 years**, conditional on the following:

- Principal investigators will immediately report anything which might warrant a review of ethical approval of the research, including unforeseen events that might affect continued ethical acceptability.
- Proposed amendments to the research proposal or conduct of the research which may affect the ethical acceptability of the research are to be provided to the NSW Population & Health Services Research Ethics Committee for review.
- The NSW Population & Health Services Research Ethics Committee will be notified giving reasons, if the research is discontinued before the expected date of completion.
- The Principal Investigator will provide a progress report to the NSW Population & Health Services Research Ethics Committee annually and at the completion of the study.

Your first progress report will be due **on 01/11/2019** and the duration of approval is until **01/11/2023,** after which time a new submission to the Ethics Committee will be required.

You are reminded that this letter constitutes *'ethical approval'* only. This research project must not commence at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. It is your responsibility to forward a copy of this letter together with any approved documents as enumerated above, to all site investigators for submission to

the site's Research Governance Officer. Where relevant, copies will also need to be provided to the CHeReL and the data custodian.

For further information about the NSW Population & Health Services Research Ethics Committee, please refer to our website https://www.cancerinstitute.org.au/Data-research/Research-ethics-committee.

Should you have any queries about the ethical review of your research proposal, please contact ethics at CINSW-Ethics@health.nsw.gov.au.

Yours sincerely,

[redacted]

Professor David Roder
Chairperson
NSW Population & Health Services Research Ethics Committee

Appendix B

Participant Information Sheet and Consent Form

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with heart disease (QUEL)

Chief Investigator: Prof Julie Redfern
The University of Sydney

Invitation

You are invited to participate in a quality improvement workshop program evaluation as part of the QUEL study to determine if implementation of a practice-level quality improvement strategy can boost the quality of CHD management delivered in primary care and reduces hospitalisations and health outcomes in a cost-effective way. The evaluation requires completion of an online (hardcopy also possible based on your preference) evaluation survey to provide feedback about the heart disease QI program your practice has recently completed.

Before you decide whether or not you wish to participate in this evaluation, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and ask the research team about anything you don't understand or want to more about.

What is the purpose of the study?

The purpose of the program was to test the implementation of a data-driven structured quality improvement program in primary care practices and whether it improves management of chronic heart disease at practice level and reduces hospitalisations and health outcomes in a cost-effective way. The strategy is based on supporting primary practices to make better and more proactive use of their existing practice data.

Who will be invited to enter the study?

You are invited to participate in this evaluation because you are staff member within a practice (Doctor, Nurse, Administrator) participating in the QUEL study.

Do you have a choice?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage. If you do decide to take part, you will be given this Participant Information sheet to read and keep as a reference. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the researchers conducting this study, or your relationship with your employers.

What will happen in the study?

If you agree to participate in this evaluation to provide feedback about your experience, you are asked to sign the Participant Consent Form.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with heart disease (QUEL)

QUEL is a 'cluster randomised controlled trial'; approximately 50 general practices were recruited in the study. All practices were randomly allocated to control and intervention groups. Practices allocated to control group continued to function as usual and practices allocated to intervention group were asked to take part in 6 quality improvement workshops over 14 months.

As part of the workshops, data were collected from the participating practices (intervention arm) using PENCAT (an automated data extraction tool) with an encrypted identifier code attached to patient data. This data will be collected at three times; at baseline, 12 months and finally at 24 months. The Improvement Foundation used these data to design the workshops and ideally at least 2 staff from each practice participated in the workshops. During the workshops, participants were divided into smaller groups to discuss and perform group activities.

Prior to completion of each workshop, you were provided with a workshop evaluation form. Practice staff who participated in at least 1 quality improvement workshop will be asked to provide feedback and complete surveys. This was not be personal health information but more qualitative data about barriers and enablers to quality improvement implementation, practice level changes and suggestions for workshop improvement. These outcomes will inform downstream implementation and capacity needed to deliver the program. No patient level information will be collected for this aspect of the study.

Are there any benefits?
It is anticipated that participation in the workshops will contribute to improved management of chronic disease management at practice level and enhance the enhance understanding and skills of the practice staff in the practical application of quality improvement and change management, resulting in reduced risk factors for future cardiovascular events and even hospitalisation. There will be no monetary benefits of participation to you although your practice may implement improved systems and data-driven Quality Improvement.

Confidentiality / Privacy
The researchers will need to collect very basic personal data about you, which may be sensitive, e.g. age, gender and professional background (no names). Any personal information will be kept private and confidential. It will be stored securely and only authorised people, will have access to it. The study records will be kept in the University of Sydney secured storage network for at least 5 years from publication and may be destroyed at any time thereafter.

What are the possible risks and disadvantages of taking part?
The likelihood of risk to you is near negligible. Some of the items in the questionnaires may elicit some feelings of discomfort or anxiety. If this does occur, you are encouraged to speak to one of the research team and you can choose to discontinue your participation at any time if you wish to.

Compensation
If you suffer any distress or injuries as a result of this project, you should contact the research team as soon as possible, who will assist you in arranging appropriate treatment and support.

Will taking part in this study cost me anything, and will I be paid?
Participation in this study will not cost you anything and you will not be paid for taking part in the study.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with heart disease (QUEL)

What will happen at the conclusion of the study?
At the conclusion of this project we expect to have (i) determined the impact of a practice-level quality improvement program on health outcomes and cost, (ii) implemented a scalable program that will close evidence-practice gaps in CHD management, (iii) collected and analysed rigorous quantitative and qualitative data about program implementation, (iv) assessed strategies and capacity within practices and PHNs that maximise outcomes and efficiency, (v) enhanced research capacity amongst PHNs and practices and (vi) developed a set of prioritised recommendations to inform government/stakeholder decision-making regarding the potential of a QI PIP that supports nationwide integration into service delivery in primary care.

What happens with the results?
It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. In any such publication or presentation, information will only be reported at an aggregated level, thus ensuring confidentiality.

Complaints
This study has been approved by the NSW Population & Health Services Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the committee.

Who is organising and funding the research:
The research has been initiated by Prof Julie Redfern. University of Sydney is the study sponsor and it is funded by NHMRCH. The quality improvement workshop is the intervention delivered by the Improvement Foundation, one of the 15 partners of the QUEL study. Other partners include government, primary health networks (PHNs), clinical groups and consumers and as a group they see this evidence generation as fundamental to informing service delivery.

Contact details
If you would like to know more at any stage, or if you have any problems while on the study please do not hesitate to contact:

Mr Tony Tu: giang.tu@sydney.edu.au or 0481 131 656 (QUEL research team)

Ms Cati Smith: Cati.Smith@improve.org.au or 0481 103 963 (Improvement Foundation)

Thank you for taking the time to consider this study. If you wish to take part in it, please sign the attached consent form. This information sheet is for you to keep.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: QUality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people Living with heart disease (QUEL)

CONSENT FORM – QUEL Quality Improvement Workshop

THE UNIVERSITY OF SYDNEY

Principal Investigator: Julie Redfern
University of Sydney

1. I understand that the researcher will conduct this study in a manner conforming to ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.
2. I acknowledge that I have read, or have had read to me, the Participant Information Sheet relating to this study. I acknowledge that I understand the Participant Information Sheet. I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by the QUEL study researcher and I, being over the age of 18, acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.
3. I acknowledge that I have been given time to consider the information and to seek other advice.
4. I acknowledge that refusal to take part in this study will not affect the usual treatment of my condition.
5. I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.
6. I acknowledge that this research has been approved by the Human Research Ethics Committee.
7. I acknowledge that any regulatory authorities may have access to my medical records relevant to this study to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.
8. I understand that at the end of the study there will be a focus group discussion which will be audiotaped. Participation to the focus group is optional.
9. I agree to be contacted about potential participation in a focus group over the coming year:
   - ☐ Yes
   - ☐ No
10. I understand that I will be given a signed copy of this document to keep

_____	_____	_____
Signature of participant	Please PRINT name	Date
_____	_____	_____
Signature of witness	Please PRINT name	Date

Appendix C

- Learning workshop one survey
- Learning workshop two, three, four and five survey
- Learning workshop six survey
- End-of-program evaluation survey

QUEL Heart Disease Collaborative

Learning Workshop 1

EVALUATION FORM

Date

To help us improve future events we would be grateful if you would complete this evaluation form and place in the Evaluation Box at the end of the day.

Training Location:

Participant Initials: _____ **Age:** _____ **Gender:** _____

Name of organisation: _____

Job title: _____

Years in present position: <1 1-3 3-5 5+ (please circle your response)

How did you hear about the collaborative: _____

Please rate the presentations / session you attended:

1.0 Introduction to the Collaborative aim and change principles	Strongly Disagree									Strongly Agree
My knowledge of the topic was increased by attending this presentation?	0	1	2	3	4	5	6	7	8	9	10
The presentation was well organised?	0	1	2	3	4	5	6	7	8	9	10
The presenter spoke clearly?	0	1	2	3	4	5	6	7	8	9	10
I would recommend this presentation to others?	0	1	2	3	4	5	6	7	8	9	10

2.0 Model for Improvement	Strongly Disagree									Strongly Agree
My knowledge of the topic was increased by attending this presentation?	0	1	2	3	4	5	6	7	8	9	10
The presentation was well organised?	0	1	2	3	4	5	6	7	8	9	10
The presenter spoke clearly?	0	1	2	3	4	5	6	7	8	9	10
I would recommend this presentation to others?	0	1	2	3	4	5	6	7	8	9	10

Please rate the presentations / session you attended:

3.0 Breakout Sessions	Strongly Disagree										Strongly Agree
A1 & B1 – Creating improvement teams											
My knowledge of the topic was increased by attending this presentation?	0	1	2	3	4	5	6	7	8	9	10
The session was well organised?	0	1	2	3	4	5	6	7	8	9	10
I would recommend this presentation to others?	0	1	2	3	4	5	6	7	8	9	10
A2 & B2 – System thinking using recalls and protocols											
My knowledge of the topic was increased by attending this presentation?	0	1	2	3	4	5	6	7	8	9	10
The session was well organised?	0	1	2	3	4	5	6	7	8	9	10
I would recommend this presentation to others?	0	1	2	3	4	5	6	7	8	9	10

4.0 Team Time	Strongly Disagree										Strongly Agree
My knowledge of the topic was increased by attending this presentation?	0	1	2	3	4	5	6	7	8	9	10
The session was well organised?	0	1	2	3	4	5	6	7	8	9	10

5.0 Evidence behind the CHD measures	**Strongly Disagree**										**Strongly Agree**
My knowledge of the topic was increased by attending this presentation?	0	1	2	3	4	5	6	7	8	9	10
The presentation was well organised?	0	1	2	3	4	5	6	7	8	9	10
The presenter spoke clearly?	0	1	2	3	4	5	6	7	8	9	10
I would recommend this presentation to others?	0	1	2	3	4	5	6	7	8	9	10

6.0 Understanding your population	Strongly Disagree										Strongly Agree
My knowledge of the topic was increased by attending this presentation?	0	1	2	3	4	5	6	7	8	9	10
The presentation was well organised?	0	1	2	3	4	5	6	7	8	9	10
The presenter spoke clearly?	0	1	2	3	4	5	6	7	8	9	10
I would recommend this presentation to others?	0	1	2	3	4	5	6	7	8	9	10

Please let us know how you found the overall event:

7.0 Overall Evaluation of the workshop:	
7.1	Today, the topic/topics impressed me or interested me most was … (please explain why)
7.2	Today what facilitated my learning was
7.3	The topics or issues that were not clear to me today were …
7.4	I would like the following topics to be discussed in this or future workshops …
7.5	My recommendations for next workshops are …

8.0 Please let us know how you found today's event		Poor										Outstanding
8.1	Overall importance of topic	0	1	2	3	4	5	6	7	8	9	10
8.2	Relevance of topic to my work	0	1	2	3	4	5	6	7	8	9	10
8.3	Quality of presentation	0	1	2	3	4	5	6	7	8	9	10
8.4	Organization of content	0	1	2	3	4	5	6	7	8	9	10
8.5	Training objectives met	0	1	2	3	4	5	6	7	8	9	10
8.6	All things considered, how would you rate this workshop?	0	1	2	3	4	5	6	7	8	9	10

9.0 Please let us know how you found the organisation of today's event		Poor										Outstanding
9.1	Event Organisation	0	1	2	3	4	5	6	7	8	9	10
9.2	Accommodation (if applicable)	0	1	2	3	4	5	6	7	8	9	10
9.3	Venue	0	1	2	3	4	5	6	7	8	9	10
9.4	Catering	0	1	2	3	4	5	6	7	8	9	10

10.0 Please rate how well the activity's stated learning objectives were met:		Not at all met	Partially met	Completely met
10.1	**Objective 1:** I am able to list and discuss the Collaborative aim and change principles	1	2	3
10.2	**Objective 2:** I can describe the Model for Improvement including PDSA cycles	1	2	3
10.3	**Objective 3**: I am able to create a list of change ideas to test in my practices	1	2	3
10.4	**Objective 4:** I can discuss the Collaborative measures used	1	2	3
		Not at all met	**Partially met**	**Completely met**
10.5	Rate the degree to which your learning needs were met	1	2	3
10.6	Rate to what degree is this workshop relevant to your practice	1	2	3

12.0 Any other comments?
(Including suggestions on how the learning workshop could be improved?)

Thank you for your time in completing this evaluation

QUEL Heart Disease Collaborative

Learning workshop 2 3 4 5

EVALUATION FORM

Date of the workshop:

To help us improve future events we would be grateful if you would complete this evaluation form and place in the Evaluation Box at the end of the day.

Training Location: Webinar

Participant Initials: _____ **Age:** _____ **Gender:** _____

Name of organisation: _____

Job title: _____

Years in present position: <1 1-3 3-5 5+ (please circle your response)

How many people were in attendance with you today, excluding yourself _____

Please rate the presentations / session you attended:

1.0 Overall importance of topic. (1- Very Poor to 5 Outstanding)		Very poor ↓		↓		outstanding ↓
1.1	Overall importance of topic	1	2	3	4	5
1.2	Relevance of topic to my work	1	2	3	4	5
1.3	Quality of presentation	1	2	3	4	5
1.4	Organisation of content.	1	2	3	4	5
1.5	Overall, how would you rate this workshop	1	2	3	4	5

2.0 Please rate how well the activity's stated learning objectives were met	**Not at all met**	**Partially met**	**Completely met**
Objective 1: I am able to Identify ideas to test within the practice.	1	2	3
Objective 2: I have an increased understanding of how to undertake care planning for patients with Chronic Heart Disease	1	2	3
Objective 3: I can describe next steps/requirements for the next activity period.	1	2	3

3.0 Outline any Quality Improvement initiative(s) your practice has taken since the first face to face Learning Workshop in November

4.0 Have you submitted your PDSA Cycle?		**Yes**	**No**
4.1	If you answered 'Yes' to Question 4.0, how many have you submitted		
4.2	If you answered 'No' to Question 4.0, when do you plan on submitting a MFI/PDSA cycle?		
5.0 Outline any success you have achieved towards meeting your MFI/PDSA cycle targeted to improve care of patients with Chronic Heart Disease?			
6.0 Outline any challenges you are facing towards achieving your MFI/PDSA cycle targeted to improve care of patients with Chronic Heart Disease?			
7.0 Any other comments (including what topics would you like discussed at future workshops and my recommendations for next workshop are):			

Thank you for your time in completing this evaluation

QUEL Heart Disease Collaborative
Learning workshop 6
EVALUATION FORM

Date:

To help us improve future events we would be grateful if you would complete this evaluation form and place in the Evaluation Box at the end of the day.

Training Location: Webinar

Participant Initials: _____ **Age:** _____ **Gender:** _____

Name of organisation: _____

Job title: _____

Years in present position: <1 1-3 3-5 5+ (please circle your response)

Please let us know how you found the overall event:

1.0 Welcome and Update on the QUEL Collaborative Research		Strongly disagree ↓ ↓ ↓ Strongly agree
1.1	My knowledge of the topic was increased by attending this presentation.	0 1 2 3 4 5 6 7 8 9 10
1.2	The presentation was well organised.	0 1 2 3 4 5 6 7 8 9 10
1.3	The presenters spoke clearly.	0 1 2 3 4 5 6 7 8 9 10
1.4	I would recommend this presentation to others.	0 1 2 3 4 5 6 7 8 9 10
2.0 Process Mapping for Heart Disease		Strongly disagree ↓ ↓ ↓ Strongly agree
2.1	My knowledge of the topic was increased by attending this presentation	0 1 2 3 4 5 6 7 8 9 10
2.2	The presentation was well organised	0 1 2 3 4 5 6 7 8 9 10
2.3	The presenters spoke clearly	0 1 2 3 4 5 6 7 8 9 10
2.4	I would recommend this presentation to others	0 1 2 3 4 5 6 7 8 9 10

		Strongly disagree										Strongly agree
3.0 Heart Disease Improvement Stories - Part 1												
3.1	My knowledge of the topic was increased by attending this presentation	0	1	2	3	4	5	6	7	8	9	10
3.2	The presentation was well organised	0	1	2	3	4	5	6	7	8	9	10
3.3	I would recommend this presentation to others	0	1	2	3	4	5	6	7	8	9	10
4.0 Heart Disease Improvement Stories - Part 2		Strongly disagree										Strongly agree
4.1	My knowledge of the topic was increased by attending this presentation	0	1	2	3	4	5	6	7	8	9	10
4.2	The presentation was well organised	0	1	2	3	4	5	6	7	8	9	10
4.3	I would recommend this presentation to others	0	1	2	3	4	5	6	7	8	9	10
5.0 Sustaining Change and Sharing Plans for sustaining change		Strongly disagree										Strongly agree
5.1	My knowledge of the topic was increased by attending this presentation	0	1	2	3	4	5	6	7	8	9	10
5.2	The presentation was well organised	0	1	2	3	4	5	6	7	8	9	10
5.3	I would recommend this presentation to others	0	1	2	3	4	5	6	7	8	9	10

6.0 Overall Evaluation of the workshop	
6.1	**Today, the topic/topics impressed me or interested me most was/were ... (please explain why)**
6.2	**Today what facilitated my learning was**
6.3	**The topics or issues that were not clear to me today were**
6.4	**My recommendations for future workshops are**

7.0 Please let us know how you found today's event		Strongly disagree										Strongly agree
7.1	Overall importance of the topic	0	1	2	3	4	5	6	7	8	9	10
7.2	Relevance of the topic to my work	0	1	2	3	4	5	6	7	8	9	10
7.3	Quality of presentations	0	1	2	3	4	5	6	7	8	9	10
7.4	Organization of content	0	1	2	3	4	5	6	7	8	9	10
7.5	Training objectives met	0	1	2	3	4	5	6	7	8	9	10
7.6	All things considered, how would you rate this learning workshop?	0	1	2	3	4	5	6	7	8	9	10

8.0 Please rate how well the activity's stated learning objectives were met:		Not at all met	Partially met	Completely met
8.1	**Objective 1:** I can discuss tools to support service redesign, including patient journey mapping	1	2	3
8.2	**Objective 2:** I am confident I can create a list of change ideas to test in my health service	1	2	3
3.3	**Objective 3**: I can describe strategies for sustaining change	1	2	3
		Not at all met	**Partially met**	**Completely met**
9.0	Rate the degree to which your learning needs were met	1	2	3
10.0	Rate to what degree is this workshop relevant to your practice	1	2	3

11.0 Any other comments?
(Including suggestions on how the learning workshop could be improved?)

Thank you for your time in completing this evaluation

QUEL Post-Program evaluation survey

Participant Initials: _____ **Age:** _____ **Gender:** _____

Name of Practice: _____

Job title: _____ **Date:** _____

Years in present position: <1 1-3 3-5 5+ (please circle your response)

INSTRUCTIONS

Please circle your response to the items. Rate aspects of the workshop on a 1 to 6 scale:

Choose N/A if the item is not appropriate or not applicable to this workshop. Your feedback is sincerely appreciated.

Thank you

OVERALL WORKSHOP CONTENT (Circle your response to each item.)	**Strongly Agree**	**Agree**	**Neutral**	**Strongly disagree**	**Disagree**	**N/A**
1. I was well informed about the objectives of the workshops	1	2	3	4	5	6
2. Workshops lived up to my expectations	1	2	3	4	5	6
3. The content was relevant to my job	1	2	3	4	5	6
4. I would recommend the program to others	1	2	3	4	5	6
OVERALL WORKSHOP DESIGN	**Strongly Agree**	**Agree**	**Neutral**	**Strongly disagree**	**Disagree**	**N/A**
5.The workshop objectives were clear to me	1	2	3	4	5	6
6. The workshop activities stimulated my learning	1	2	3	4	5	6
7. The activities in the workshops gave me sufficient practice and feedback	1	2	3	4	5	6
8. The difficulty level of the workshops was appropriate	1	2	3	4	5	6
9. The pace of the workshops was appropriate	1	2	3	4	5	6
10. The duration of the workshops was appropriate	1	2	3	4	5	6
11. The quantity of the information presented at the workshops was appropriate	1	2	3	4	5	6
OVERALL WORKSHOP FACILITATOR:	**Strongly Agree**	**Agree**	**Neutral**	**Strongly disagree**	**Disagree**	**N/A**
12. The instructors were well prepared	1	2	3	4	5	6
13. The instructors were helpful	1	2	3	4	5	6

OVERALL WORKSHOP RESULTS	Strongly Agree	Agree	Neutral	Strongly disagree	Disagree	N/A
14. I will be able to use what I learned in this workshop	1	2	3	4	5	6
15. The workshops were a good way for me to learn this content	1	2	3	4	5	6

WORKSHOP OUTCOME	Not at all	A little	Some	Quite a bit	A lot
16. Overall, how satisfied are you with your progress as a result of the workshops over the past year	1	2	3	4	5
17. How much has the workshops contributed to improve quality of your practice over the past year	1	2	3	4	5
18. To what extent you are able to utilise the learning from the workshops over the past year	1	2	3	4	5
19. How confident are you in implementing changes in your practice based on the learning from the workshops	1	2	3	4	5

20. What new initiatives (up to three) have you taken in your practice as a result of the workshops over the past year?

1._____

2._____

3._____

21. What changes have you made in your practice as a result of the workshops over the past year?

1._____

2._____

3._____

22. What did you find most useful from all the quality improvement workshops over the past year?

_____

_____

_____

23. What did you find least useful from all the quality improvement workshops over the past year?

_____

_____

_____

24. What other improvements would you recommend in these workshops:

_____

_____

25. How easy or difficult is it for you to us the practice management system to do the following for your patients?	Very easy	Somewhat easy	Somewhat difficult	Very difficult	Not applicable
a. Review basic pathology results	1	2	3	4	5
b. Update medication list and drug allergies for patients	1	2	3	4	5
c. Review information from hospital discharge summary	1	2	3	4	5

circle one	Never	Rarely	Sometimes	Usually	Always	Don't know
26. How often does your Primary Care Team ask for patient input when making a plan for their care	1	2	3	4	5	6
27. How often does your Primary Care Team use electronic data to identify patients with CVD	1	2	3	4	5	6
28. How often does your Primary Care Team use electronic data to monitor and track patient health indicators and outcomes	1	2	3	4	5	6
29. How often does your Primary Care Team use electronic systems to support the documentation of patient needs	1	2	3	4	5	6
30. How often does your Primary Care Team use electronic systems to develop care plans	1	2	3	4	5	6
31. How often does your Primary Care Team use electronic systems to determine Clinical outcomes	1	2	3	4	5	6

	Poor	Fair	Good	Very Good	Excellent
32. In general, how would you rate the coordination of care provided by your primary care practice/ service?	1	2	3	4	5
33. In general, how would you rate the quality of care provided to patients by your primary care practice/ service?	1	2	3	4	5

Please indicate your level of agreement with the following statements about your job:

	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Don't know
34. We have clearly defined quality improvement goals	1	2	3	4	5	6
35. Our practice leaders visibly demonstrate a commitment to quality improvement	1	2	3	4	5	6
36. Our practice leaders strongly support practice change efforts	1	2	3	4	5	6
37. In what ways has your role in the practice changed as a result of the quality improvement initiative?	**Disagree**	**Somewhat disagree**	**Neither agree nor disagree**	**Somewhat agree**	**Agree**	**Don't know**
a. The depth of my job has increased (e.g. through extending my skills)	1	2	3	4	5	6
b. The breadth of my job has expanded (e.g. wider range of tasks, and/ or working with more organisations)	1	2	3	4	5	6
c. I now delegate more responsibility to others	1	2	3	4	5	6
d. I now have more responsibilities delegated to me	1	2	3	4	5	6

e. Can you briefly describe how/if your role has changed as a result of the CVD QI program?

_____

_____

_____

	Got better	Stayed the same	Got worse	Not sure
38. Since the Quality Improvement program commenced, has the quality of care in received by patients at your practice/ service	1	2	3	4

39. Does your practice have software capacity to implement the QI program? O **Yes** O **No**

If not, explain:

_____

_____

_____

40. Did the workshops enhance capacity for your practice to be ready for the introduction of a QI-PiP? O **Yes** O **No**

41. Would you be interested in participating in a similar workshop in future? O **Yes** O **No**

Comment:

_____

_____

42. Have you claimed QI-PIP as a part of this study? ○ Yes ○ No

If yes,

a. How many times have you claimed QI-PIP since December 2019? _____

	Strongly Agree	Agree	Neutral	Strongly disagree	Disagree
b. Did the availability of QI-PIP influence your practice's engagement/participation in quality improvement?	1	2	3	4	5

c. Any comments on the experience of using QI-PIP?

43. Have you used the QUEL SharePoint site during the past 14 months? ○ Yes ○ No

a. If yes, how often did you use the SharePoint and what did you use it for?

_____

_____

	Strongly Agree	Agree	Neutral	Strongly disagree	Disagree
b. Did the availability of the SharePoint influence your practice's engagement/ participation in quality improvement?	1	2	3	4	5

c. Any comments on the experience of using the SharePoint?

44. Did COVID-19 impact on your participation in the CVD QI program? ○ Yes ○ No

If yes, can you give some example/s of how?

_____

_____

_____

45. Do you have any other comments or feedback:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Thank you for completing the QUEL Post-Program Evaluation Survey

Appendix D

Discussion guide for QUEL health professional's interview

1. Explore to what extent the intervention is delivered as intended, identify key elements of the intervention associated with positive study outcomes, and how, for whom and in what context it was effective.
2. Describe and analyse practice engagement, attendance, time commitment, software capability, skills and capacity of the practice team members associated with attending learning workshops.
3. Understand acceptability, satisfaction, uptake, and feasibility of the QI program.
4. Identify and describe barriers and enablers of the QI program.
5. Evaluate the effect of COVID-19 on the implementation of the QI program.

We implemented QUEL study intervention from December 2019 to December 2020. During which, practices submitted monthly data via PenCS (which was automatic) and participated in six learning workshops. Practices were also required to submit PDSA cycles regularly using a template provided in their SharePoint account. The study team provided a monthly report based on their submitted data to monitor improvement in the 12 CHD measures within the QUEL study. Practices were able to look at those reports to track their improvements over months.

1. What experience have you or your practices had with quality improvement programs?
    - Previously participated in QI; can you provide an example?
    - How was it different from QUEL?
2. How is your experience of taking part in this study?

3. Learning workshops - Practices were asked to participate in 6 learning workshops initially; the first and last workshops were supposed to be face-to-face, five out of the six learning workshops were delivered online.
    - Thoughts on the number of workshops - Too many/too little or enough.
    - What influenced or did not influence their participation in the learning workshops, including attendance for both practices and PHN?
    - Workshops were repeated twice once in the afternoon and again in the evening) What are your thoughts on the timing? What would you change?
    - Duration (1 hour) and method of delivery (Online)
    - Time commitment to attend the workshop
    - Did the workshop provide enough support/training to guide the QI activities in your practices?
    - We discussed some case studies in the webinars. Anything from the workshop you remember or an example that you can think of which you thought was memorable?
4. In between workshops:
    - How was the support between webinars - Is there any example of support you can remember?
    - Was the support sufficient?
    - What sort of support would you recommend for better implementation in future (research team, PHN, within practice)?
5. SharePoint: for part of the program, we provided each practice with a SharePoint account, which enabled them to access all learning workshop recordings and slides from the presentations, QUEL handbook and a platform to submit PDSA cycles with a template. Could you tell me about your overall experience with SharePoint?

- Access to SharePoint
- Were you easily able to log in to your account and navigate? Any challenges (give examples) accessing project materials, including workshop recordings, monthly reports and Submitting PDSA cycle?

6. Between the learning workshops practices were required to submit PDSA cycles on the 12 CHD measures for the QUEL study every month.
   - how easy or difficult was it to complete every month?
   - Any challenges while creating a PDSA cycle?
   - Can you give us an example of successful PDSA implementations?
   - Based on the PDSA cycle, is there any change idea you incorporated as a regular agenda in your practice for CHD patients? If so, how long did it take to implement?
   - What is your preferred method of PDSA submission - online or paper?
7. Data - An initial aim of the CVD program was to improve the quality of data entry as it related to CVD performance indicators
   - How was your practice data at the start of the program?
   - What activities did you implement to improve it?
   - What are the remaining challenges?
8. A second aspect of the program was aiming to improve 12 measures (share the 12 measures), including increasing proportions of patients meeting targets for blood pressure and Cholesterol
   - Anything you did to implement quality improvement strategies that aimed to improve these targets, can you give us an example?
   - Did you review your data and use it as you progressed?
   - Any challenges in achieving the targets?

9. Involving your team to make changes in your practice

FOR PHN:

- How many practices did you support?
- How did you support those practices?
- Did any practice require additional support, training or health resources to implement the study?
- How often did you visit the practices - was it additional or part of your regular scope of work?
- Roughly how much time did you spend talking about QUEL on those visits?
- How many members from the practices were involved in implementing the changes?
- What are your thoughts on the capacity of your team to deliver the intervention?
- How much time was spent on implementing QUEL during your team meeting?
- Did you have to make any changes to your staff to accommodate QUEL activities? If so, how much?

FOR PRACTICE TEAM MEMBERS

- How many team members were involved?
- How did you train and support your team to implement the QUEL study within your practice?
- How much time did you spend on training team members?
- Do you think your team member needed additional training or resources?
- What are your thoughts on the capacity of your team to deliver the intervention?

- Did you have to make any changes to your staff to accommodate QUEL activities? If so, how much?
- How much time was your team able to spend on the collaborative per week/per fortnight/per month?
- If not - why not?

10. What are your thoughts on the challenges or disadvantages of collaborative quality improvement programs
    - Staff capacity
    - Time commitment
    - Creating/Submitting of PDSA cycles
    - Implementing any improvement ideas in the practice
    - Any part of the intervention you did not find useful - Why?
11. What were the advantages of the QUEL program?
    - Do you think they benefit things like practice efficiency and patient care, and if so, how?
    - Which part of the intervention you found most useful and why?
12. Going forward, how would the practices use the learnings from the program to improve CVD care?
    - Which part of the program would you continue to implement and why (sustainability)?
    - If you are not planning to use - why not?
13. Did participating in the program help the practice with QI PIP?
    - Help you prepare for PIP-QI
    - Were you able to claim PIP-QI as a result of the collaborative in the past year?
    - If yes - How many times

- If no - will you?

14. How did COVID-19 affect your participation in the Collaborative?
15. Do you think your practice would have done anything different, if there was no pandemic?
16. What do you think are the pros and cons of participating in research?
17. Do you have anything else to add that I forgot to ask?