Implementing quality improvement strategies in real-world general practice - a study focused on cardiovascular disease

Charlotte Hespe
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Implementing quality improvement strategies in real-world general practice-

a study focused on cardiovascular disease.

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*MBBS Honours (SYD), DCH, FRACGP, FAICD*

Submitted in fulfilment of the requirements for the Doctor of Philosophy

School of Medicine
University of Notre Dame Australia
Sydney Campus

July 2022
Forward

These quotes stimulated my research interests and the project that came about to provide the reason for this thesis – how do we translate the theory of preventive care into the real world of Australian general practice?

"An ounce of prevention is worth a pound of cure."

- Benjamin Franklin 1736

Improvements in health care are achievable by providing targeted, evidence-based health prevention programs to reduce and mitigate modifiable risk factors known to cause costly chronic diseases. Prevention is one of the most cost-effective ways to improve population health.

"Every system is perfectly designed to get the results it gets."

- W. Edwards Deming

This quote, commonly attributed to W.Edwards Deming, is a very apt description of the Australian health system, a health system designed to treat sick patients rather than one developed to keep people healthy. The consequences are that this acute care delivery framework comes at an extraordinarily high opportunity cost for preventive care.
Origin of this thesis

My interest in quality improvement to achieve better patient health outcomes stemmed from over 25 years of working as a GP. As I am passionate about improving my patients' health and quality of life, I have remained a front-line GP but have been fortunate to also work in a range of roles in general practice management, teaching and governance.

I have observed many changes in the health care system, medical advances, and technology during this time. I have noticed that despite these significant changes, this often hasn’t translated to seismic shifts in ‘front-line’ general practice activity nor measurable differences in patient health outcomes. Over my three decades in general practice, I have also observed an increased interest in clinical practice guidelines, which aim to reduce morbidity and mortality, use health resources judiciously and standardise healthcare. Despite this, cardiovascular disease remains a significant cause of morbidity and mortality, health inequalities have persisted, and many patients are not receiving recommended care.

Healthcare and primary healthcare is a complex mesh of multiple microsystems, and implementing change in this milieu is challenging. These observations and experiences in my profession brought about my interest in the central question of this Thesis, “How do we translate cardiovascular preventive care guidelines into the real world of Australian general practice”. I was interested in exploring ways to bridge this gap.

In the mid-2000s, my general practice in Glebe (Sydney) participated in the APCC program. We noticed that by applying some basic QI principles to the systematisation of diabetes care and access, we were able to improve our patient care and advance our patient management systems within the practice. My practice was able to apply learnings from this program to other aspects of patient care, which became a turning point for my clinical practice.

My interest in QI led me to apply for funding to conduct the QPULSE study in 2014. I realised that understanding the complex phenomena of the theory-practice gap and
barriers to implementing QI in general practice could not be answered by a qualitative or quantitative approach alone; combining both methods would best capture the complexity of the clinical environment. Far beyond methodological considerations, I was motivated to have the results of this research to be able to speak to both clinical “coal face” practitioners and health system policymakers.

There is little known about the translation of QI into Australian general practice and what the barriers and facilitators are. The unique insights gained from this thesis come from drawing on the empirical data plus my experience in general practice and are embedded in the complex but fascinating world of a real-world clinical researcher. As a general practice policy advocate, I will share and discuss these insights and findings as an ‘insider’ with my GP colleagues and policymakers, so this research can assist in improving the health of our Australian community.
Candidate’s Declaration

I, Charlotte Hespe, hereby declare that the work described in this thesis is my own. I am the principal researcher of all work contained in this Thesis, including work conducted in association with my PhD supervisors and other co-authors.

This thesis does not contain written or published materials prepared by others except where acknowledged within the text and has not been submitted to any other university or institution as a part or whole requirement for any higher degree.

The research presented was conducted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007, updated 2018). This research received ethics approval from the University Of Notre Dame Australia Human Research Ethics Committee (EC00418), approval numbers 014105S and 016011S.

Signature:

Charlotte Hespe
July 2022

Supervisor’s declaration

Professor Lucie Rychetnik was my Principal Supervisor, and Professor David Peiris and Professor Mark Harris were my Associate Supervisors. The specific contributions of the co-authors of the manuscripts arising from the research undertaken for this thesis are as follows: the Candidate (CH) wrote the first and all subsequent drafts of all manuscripts, and the supervisory team, MH, DP and LR, made conceptual or editorial contributions. Further details of author contributions to each manuscript are included in the author statements within the individual manuscripts.

Mark Harris………………………………………………………….. Date……11/07/2022
Lucie Rychetnik……………………………………………………….. Date…… 11/07/2022
David Peiris…………………………………………………………….. Date….. 11/07/2022
Abstract

Introduction

General practitioners (GPs) are central to cardiovascular disease (CVD) prevention and management. However, multiple studies show they have sub-optimal assessment and management of CVD risk. The central question addressed in this thesis was: How do we translate preventive care guidelines into the real world of Australian general practice through Quality Improvement Collaboration (QIC)?

Methods

The research comprised of four studies. The first examined the experiences of stakeholders participating in a quality improvement collaboration (QIC) intervention undertaken in Australian primary care [the Australian Primary Care Collaboratives [APCC] program], and the second assessed implementation of the 2012 CVD risk management guidelines in Australian general practices. It examined electronic medical record data from 95 general practices comprising 102,225 patients. In the third and fourth studies, a QIC intervention [QPulse] focused on improving CVD risk management was implemented in 34 general practices, and its effectiveness, barriers and enablers were evaluated.

Results

There were substantial gaps in the implementation of CVD guidelines, which remained after the brief QIC intervention aimed at achieving improvements in CVD screening and management (QPulse).

The qualitative evaluation interviews of stakeholders in the APCC and QPulse interventions highlighted that the Australian primary care environment is a complex and challenging setting to implement sustainable change, and obstacles at multiple levels impact the success of QI initiatives. Leadership, practice culture, access to accurate patient data and IT/practice support systems were elements required for the long-term adoption and implementation of systematic QI. Stakeholders identified two key factors that would assist Australian general practices to make QI sustainable:
practice support by an external support organisation and financial incentives for implementing QI programs.

Discussion

Significant gains in CVD morbidity and mortality could be achieved by improving CVD management in primary care. A ‘siloed’ QI program may not be effective, as there are several barriers to sustainable change. These are cultural factors, leadership and support systems to facilitate staff to implement QI. Additionally, QI programs need to be implemented with the assistance of an external agency to support practices, and incentives are required for practices and GPs to implement and sustain change.

Conclusions

CVD management in primary care has much scope for improvement, and QI is unlikely to address this effectively unless changes at the health system and practice levels alleviate key barriers. Future progress will require concerted efforts to realign the culture of primary healthcare and the practical and financial support provided to GPs and practices so that QI is valued and implemented in day-to-day patient management and the practice workflow.
Acknowledgements

I am grateful for the financial support I received from the University of Notre Dame Australia and the Bupa Health Foundation through research grants and project funding. I also acknowledge the support received through the Research Training Program provided by the Australian Government.

Thank you to my supervisors, Professor Lucie Rychetnik, Professor David Peiris and Professor Mark Harris, for your excellent guidance. Thank you also to my UNDA work colleagues who have often played the role of "PhD mentor": Dr Katrina Giskes, Dr Craig Smith, Dr Clare Andreallo, Dr Sarah (Sally) Lord and Dr Margot Woods. The generosity you have all demonstrated in sharing your wisdom and experience, your endless encouragement and enthusiasm for my research, and the friendship and support you have offered me have been very much appreciated during my PhD journey. I am incredibly grateful to have worked with you and look forward to ongoing contact and collaboration. Thank you to the Central and Eastern Sydney Primary Health Network (CESPHN) and Improvement Foundation (IF) for supporting me in this research project and sharing your knowledge and resources. It was indeed a privilege to work with you.

Thank you also to The George Institute for providing me with the IT repository, databank repository and data analysis expertise. I want to thank Professor Anushka Patel, Associate Professor Ruth Webster and Dr Anna Campain for their assistance and collaboration in the baseline data work. I am very grateful to the CESPHN and the general practice participants for generously contributing their time and knowledge to my research. My gratitude includes the individual GP and the Primary Health Network (PHN) participants who engaged in the interviews and were forthright and open in sharing the enablers and barriers to quality improvement (QI) work in their general practice settings. I am very appreciative of their support for this work. I would like to thank CESPHN staff, Dr Michael Moore, Amanda Jones, Belinda Michie, Nathalie Hansen, Dr Brendan Goodger, Alex Dolezal and most importantly, project officer Amy Zhong for their support and hours of work required to contribute to the rollout of the QPulse project.
I would also like to acknowledge all my work colleagues for their interest and enthusiasm in my research, the team at the School of Medicine, Sydney, UNDA, my general practice colleagues at my GP practice, Glebe Family Medical Practice, in particular Drs Allison Bielawski and Naomi Ginges, and the RACGP NSW, ACT Faculty team under the leadership of Anne Davis.

This journey would not have been possible without the support of my family. Thank you to my partner in life, husband, Iain, children Caitlin, Laura and Timothy, and their partners Cameron and Lauren for all the encouragement and support you have given me during my Doctoral studies. Thank you for listening and encouraging me at those times when I was excited and proud of my work, but also at those other times when I was anxious or frustrated. It has been a longer journey than anticipated, and I'm glad to have shared it with you.
List of publications and presentations resulting from this thesis


**Presentations**
The Candidate has made several oral presentations drawing on material from the research for this Thesis, as detailed below.

**Oral presentations- international conferences**


Oral presentations- national conferences

*Implementation of CVD Quality Improvement [QI] in GP – lessons learnt.* RACGP GP21, 2021 (conference cancelled due to COVID but Abstract for oral presentation has been accepted for GP22 in Melbourne).

*Why do we continue to have significant gaps in CVD Preventive care in Australia? Lessons learnt implementing a CVD QI intervention.* Australian Primary Health Care Research Conference Australian Primary Healthcare Research Conference, 2021.

*Australian General Practice CVD screening and guideline-based treatment – Cardiovascular Disease (CVD) risk identification and management in Australian primary care. Why an implementation strategy is needed.* Australian Primary Health Care Research Conference, 2019.

*Quality improvement implementation in Australian primary care: 5 key elements for success.* Australian Primary Health Care Research Conference 2018.

*Get your pulse racing! Q Pulse- The Heart of Quality Improvement in general practice.* Australian Primary Health Care Research Conference 2015.

*Informing Quality Improvement (QI) work in the Primary care setting and Implementation of a program to support quality improvement activities through local GP organisations.* GP15, 2015.


Oral presentations- departmental

*Translating into real world general practice, implementation of quality improvement strategies – a study of evidence-based practice in cardiovascular disease: a PhD update.* University of Notre Dame Australia School of Medicine, 2020.
Poster presentations


Quality improvement implementation in primary care: 5 key elements for success. APAC Forum, 2016.

Additional publications during Candidature

During my candidature, I also contributed to the following publications on topics related to my research.


Parsonage MT, Nash E, Chalkley D, Hespe C. Patients attending an emergency department with a general practitioner referral letter who are discharged home have a longer length of stay than those without a letter. Emergency Medicine Australasia. 2019;31[3]:495-6.


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<td>APCC</td>
<td>Australian Primary Care Collaboratives</td>
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<tr>
<td>BMI</td>
<td>Body mass index</td>
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<td>BP</td>
<td>Blood pressure</td>
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<td>CVD</td>
<td>Cardiovascular disease</td>
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<td>CPG</td>
<td>Clinical practice guidelines</td>
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<td>CSI</td>
<td>Complex systems improvement</td>
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<td>GP</td>
<td>General practitioner</td>
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<td>HDL</td>
<td>High density lipoprotein</td>
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<td>IF</td>
<td>Improvement Foundation</td>
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<td>IT</td>
<td>Information Technology</td>
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<td>LDL</td>
<td>Low density lipoprotein</td>
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<td>NPHCSF</td>
<td>National Primary Health Care Strategic Framework</td>
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<td>NPT</td>
<td>Normalisation Process Theory</td>
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<td>NVDPA</td>
<td>National Vascular Disease Prevention Alliance</td>
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<tr>
<td>PDSA</td>
<td>Plan-Do-Study-Act</td>
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<tr>
<td>PHN</td>
<td>Primary Health Network</td>
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<tr>
<td>PM</td>
<td>Practice Manager</td>
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<tr>
<td>POC</td>
<td>Point of care</td>
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<tr>
<td>QI</td>
<td>Quality improvement</td>
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<tr>
<td>QIC</td>
<td>Quality improvement collaboration</td>
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<tr>
<td>RACGP</td>
<td>Royal Australian College of General Practitioners</td>
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<td>TGI</td>
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Chapter 1- Introduction and background

Cardiovascular disease (CVD) is a group of heart and blood vessel disorders, including coronary artery disease, cerebrovascular disease and peripheral vascular diseases [1]. Cardiovascular diseases, such as myocardial infarction or stroke, are acute events, however the underlying pathogenesis is due to a chronic process of vessel damage, build-up of fatty plaques and inflammation spanning decades [1, 2, 3]. Since the 1960s the mortality rates from CVD have declined, however it remains the primary cause of the death in Australia and most developed countries. A 2019 Australian Bureau of statistics report showed that Ischaemic Heart Disease was the primary cause of death in 18,244 Australians (i.e., 10.8% of all deaths during 2019) [4]. Among males, it was the leading cause of death and hospitalisation [5], being attributed to 12.2% of deaths. Among women, vascular-related conditions, such as dementia were the leading primary cause of death, accounting for 11% of deaths, closely followed by Ischaemic Heart Disease (9.2%) [4].

CVD is also a major cause of morbidity; it is estimated that 4 million Australians are affected by CVD [6, 7]. Around 1.1 million CVD-related hospitalisations (11% of total hospitalisations) occur annually in Australia [5]. Cardiovascular conditions are the second most common presentation in general practice and account for around 20% of GP presentations [8, 9]. It follows that CVD places a large social and economic burden on the Australian population; in terms of economic impacts alone it is estimated to place a $5 billion burden on the economy annually, which is the highest economic impact of any disease [10]. The bulk of these costs can be attributed to failing to recover from cardiovascular episodes, leading to loss of money through premature death or due to decreased productivity [11, 12]. This results in a diminished income for the patient as well as reduced productivity for employers, leading to overall economic losses. Furthermore, CVD results in a significantly reduced quality of life for patients through physical symptoms such as fatigue, breathlessness and discomfort, which limits physical and social activities [13, 14].

CVD is largely preventable, and it has been estimated that the combined modifiable risk factors account for around 73.8% of the burden of CVD [1, 15, 16]. This can be
attributed to select modifiable risk factors, with high blood pressure accounting for the greatest attributable burden for CVD at 31.7%, followed by physical inactivity (21.2%), high body mass (21.1%), hyperlipidaemia (16.2%), tobacco consumption (12.0%), and diet (10.1%) [17, 18]. Around two-thirds of Australians have three or more modifiable risk factors such as tobacco smoking, high blood pressure (BP) or cholesterol, physical inactivity, poor nutrition, or overweight/obesity [19, 20, 21]. Previously, guidelines focussed on reducing individual risk factors, however, more recently there has been recognition that risk factors collectively contribute to an individual's overall or ‘absolute’ risk, and that management decisions should be based on multiple risk factors [20]. In 2012, the National Vascular Disease Prevention Alliance (NVDPA) launched Australia’s first absolute risk-based management guideline bringing together several guidelines into a single cohesive approach that acknowledges the multi-risk factor approach to reducing CVD [20].

General practitioners [GPs] are uniquely placed to screen and initiate management to reduce risks of CVD, and thereby reduce morbidity and mortality from these conditions. In Australia more than 85% of the population see their GP at least once annually, and GPs conduct around 20 million consultations per year [22]. CVD screening and prevention activities in primary care are successful for reducing morbidity [23] and mortality [24] and are cost effective [25]. However, studies have shown sub-optimal assessment and management of CVD risk by GPs [26].

A 2006 study of the Bettering the Evaluation and Care of Health (BEACH) data found that patients at high risk of CVD were substantially under-treated [27]. In 2010, the AusHEART study found only 34% of patients at high CVD risk were prescribed both a BP-lowering medication and a statin [28]. In the 2011/12 National Health Survey data, Banks et al. showed that almost half (47.1%) of high-risk patients were not taking guideline-recommended medications [19]. In 2012, baseline data from the TORPEDO randomised controlled trial found that 48% of patients were appropriately screened for CVD risk [29]. Similar results were published in a more recent review of Australian data from 2015-18 that found only 47.9% of patients had evidence of CVD risk screening. Only 41% of high-risk patients were prescribed risk-reducing medications [30].
Primary health care is a complex environment, and Australian general practices are largely privatised, which further adds to the challenge of implementing system-wide change. The Australian and State and Territory governments broadly share responsibility for funding, operating, managing and regulating the entirety of the health system. General Practitioners are funded under a national universal health insurance system called Medicare. Medicare provides fee-for-service patient payments linked to each General Practitioner. On the other hand, the public hospital and hospital-based community health services (that the GPs interact with to deliver secondary and tertiary level care) are funded through activity-based funding via the State and territory governments, alongside extra payments accessed via fee for service from both Medicare and private insurance [31]. The private for-profit and not-for-profit sectors also play a role in operating private hospitals, pharmacies and allied health medical practices, as well as providing private health insurance products.

A multitude of factors acting at the national, regional, practice and GP levels can be both barriers and facilitators to implementing guidelines [32], and barriers that prevent the adoption of best practice guidelines often appear to overwhelm the ‘real world’ of primary care. To achieve significant improvements, GPs and practices could benefit from structured systems to support the implementation of QI strategies in routine primary care.

QI initiatives in primary care have the potential to improve uptake of evidence-based practices and thereby improve patient care and health outcomes. QI is a multi-dimensional concept that can be defined as having a systematic approach to making changes that will lead to better patient outcomes (health), enhanced system performance (care) and improved professional development (learning) [33]. There are several ways to intentionally implement QI initiatives, with one approach being the establishment of Quality-Improvement Collaboratives (QICs). QICs bring together groups of practitioners from different ‘organisations’ to learn about a specific aspects of health service quality, and to share experiences about making changes in their local settings. The process supports explicitly practitioners using QI tools such as Plan, Do, Study, Act (PDSA) cycles to achieve improvements [34]. There has been mixed evidence of success implementing QICs in health care [33, 35]. However, a systematic
review of 64 QIC programs in 2018 reported significant improvements in 83% of targeted clinical processes and patient outcomes [36].

In Australia, QICs gained traction after the formation of the Improvement Foundation (IF), which administered a series of QICs called the Australian Primary Care Collaboratives (APCC) since 2004 [37]. The IF was initially commissioned by the Australian federal government to assist primary care practices in five priority areas: coronary heart disease, diabetes, chronic obstructive pulmonary disease, chronic disease prevention and self-management, and health care access and redesign. APCC offered general practices financial incentives to participate in a QIC wave over 18 months. The QICs were also explicitly used to teach quality improvement methods and coaching to regional meso-level organisation support staff.

This programme (APCC) was successfully delivered for over 15 years by an independent organisation, Improvement Foundation, but was officially discontinued in general practices due to the cessation of government funding in 2014. Since then, questions have been raised about the sustainability of ongoing QIC interventions [38]. In 2015, the Federal funded meso-level Primary Health Networks (PHNs) to lead localised quality improvement initiatives [39]. There is also a small financial incentive for individual general practices to participate in QI programs via the national Quality Improvement Practice Incentive Program [38].

**Conceptual frameworks**

The research presented in this thesis occurred in a sequential manner. The work commenced with an exploration of the QIC experiences of general practices that participated in the APCC, specifically focusing on the barriers and enablers to the implementation of QIC in the Australian general practice setting. Together with baseline data on CVD risk assessment and management, this then informed the development of an abbreviated, localised QIC intervention (QPulse) focused on improving CVD risk assessment and management in general practice. The implementation of QPulse was assessed by examining changes in CVD assessment and management before and after the intervention, as well as by qualitative exploration of the barriers and enablers to implementing this CVD-tailored QIC intervention.
Normalisation Process Theory

Understanding, developing, and evaluating complex interventions is essential for improving health and healthcare. Normalisation process theory (NPT) identifies factors that promote and inhibit the routine incorporation of complex interventions into everyday practice [40]. It also explains how these interventions work, looking not only at early implementation but beyond this to the point where an intervention becomes so embedded into routine practice that it ‘disappears’ from view (i.e., is normalised). NPT was used as a framework in this research to examine and understand the uptake of QPulse.

There are four main components of NPT: coherence (or sense-making); cognitive participation (or engagement); collective action (work done to enable the intervention to happen); and reflexive monitoring (formal and informal appraisal of the benefits and costs of the intervention). These components are in dynamic relationships with each other and with the wider context of the intervention, such as organisational context, structures, social norms, group processes and conventions [41, 42].

Complex Systems Improvement Framework

Implementation barriers and enablers in QPulse were also examined using the complex systems improvement (CSI) framework [43]. This framework was selected for its relevance to the context and complexities of the Australian general practice environment. It identifies four levels of a health system that align with a successful implementation of change: environment, organisation, microsystem, and patients and their caregivers [43]. The CSI framework was used to examine implementation barriers and enablers from the microsystem (GP and general practice), and organisation (the PHN - independent organisation funded by the Federal Government to coordinate primary health care in the local region) perspectives. Patients and their caregivers were out of scope for the QPulse intervention because the QIC design did not include direct patient interaction with the tools.

The CSI framework identifies five domains for evaluating a change-making intervention in the health system. These domains include strategy, culture, structure, workforce, and technology. ‘Strategy’ addresses alignment of the improvement
intervention with the strategic intention of participants. ‘Culture’ looks at the norms, values, and beliefs of participants. ‘System’ addresses infrastructure in place to enable participants to learn new practices, spread best practices, and continuously measure performance and improve processes. ‘Workforce’ looks at how people, tasks, tools and technologies, organisational conditions, and the physical environment affect the adoption of the intervention. ‘Technology’ specifically addresses the role that information technology (IT) and electronic medical records play in adopting new processes [43].

Aims and Research Questions
The over-arching aim of this thesis is to understand how we translate cardiovascular preventive care guidelines into the real world of Australian general practice.

The aims of the research are to:

1. Identify enablers and barriers to the implementation of sustainable QI programs in the Australian general practice setting. (Chapter 4)
2. Examine the implementation of the 2012 CVD risk assessment and management guidelines in Australian general practices. (Chapters 5,6)
3. Assess whether an abbreviated QIC program (QPulse) was associated with improvements in the monitoring, prescribing practices and attainment of BP and lipid targets for CVD risk reduction, (Chapter 6) and
4. Identify and explore the factors driving implementation and examine the barriers and enables for the adoption of the QIC (QPulse) (Chapters 6,7,8).

Organisation of this thesis
This thesis is presented in the style of a ‘Thesis by Publication’. As such, it contains four manuscripts, each of which are stand-alone journal articles that have been published in the peer-reviewed medical literature.

Chapter 2 reviews the literature relating to CVD management in primary care, QICs and interventions to improve CVD risk management. A “systematised overview” methodology for conducting the literature review was adopted, noting that the medical
literature has been summarised across these broad topics and a narrative, thematic description of what is known in this area has been provided [44]. No formal quality assessment was conducted of the articles.

An overview of the Methods is provided in Chapter 3. The key issues discussed in Chapter 3 are those that are not dealt with (or only discussed in minimal detail) in the Methods sections of the four manuscripts.

The four published manuscripts are presented in Chapters 4 to 7. Each manuscript was written in the conventional publication style for the targeted journal. There is some degree of overlap and repetition in parts of their Introduction, Methods, and Discussion sections. Supplementary material accompanying published papers is included at the end of the relevant chapter.

Chapter 4 examines experiences of the APCC program from the perspectives of health agencies and multiple healthcare team members (including GPs). The research paper presents the thematic qualitative analysis of semi-structured interviews of selected participants across the breadth of the program.

Chapter 5 is a quantitative investigation of the implementation of the 2012 Australian-specific CVD guidelines in general practice, utilising electronic medical record [eMR] data from 95 Australian general practices comprising 102,225 patients.

Chapters 6 and 7 report how QPulse, a QIC intervention focused on improving CVD risk management, was implemented in 34 general practices in metropolitan Sydney. This intervention was evaluated by pre- and post-intervention data extractions that examined CVD risk management and practice processes, as well as examining the experiences of the PHN, GPs, other members of the healthcare team and practice managers with the QIC intervention, utilising both NPT and CSI frameworks.

The concluding chapter (Chapter 8) summarises the study findings across the four manuscripts. It discusses study limitations, directions for future research and the significance of the results for general practice.
Rationale for this thesis

This research contributes to several current health and policy priority areas in Australia, as detailed below. Furthermore, many of the findings can be generalised to wider issues in general practice and health services research addressing other health priority areas.

- Cardiovascular disease is a National Health Priority Area.

Despite advances in CVD prevention and management, CVD remains one of the leading causes of morbidity and mortality among Australian adults and is one of the six National Health Priority Areas [45]. Most CVD-related deaths are preventable, and a focus on combined risk assessment and management as advocated by the 2012 guidelines [20, 21] may lead to further reductions in CVD-related morbidity and mortality and the concomitant social and economic burdens of CVD.

- Effective assessment and management in primary care reduce morbidity, and mortality and is cost-effective.

Interventions in primary care have been shown to be effective and cost-efficient. The social and economic benefits of prevention have been increasingly recognised over the past few decades, and prevention is the focus of the recently launched National Preventive Health Strategy [46], which recognises that a considerable proportion of chronic disease burden can be prevented by a reduction in modifiable risk factors and improved management of existing risk factors.

- The research aligns with several priorities and objectives of the National Primary Health Care Strategic Framework (NPHCSF) [47].

A central objective of the NPHCSF is a focus on health promotion, prevention, and early detection of chronic diseases. The framework also acknowledges the roles of various healthcare team members in providing healthcare to patients. It has identified improving quality, safety, performance, and accountability as central objectives.
Chapter 2: Literature review

In Australia, primary health care is typically the first contact an individual with a non-acute and non-life-threatening health concern has with the health system. According to the Declaration of Alma-Ata in 1978, Primary health care is essential health care based on practical, scientifically sound, and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination [48]. Australian Primary health care covers health care unrelated to a hospital visit, including health promotion, prevention, early intervention, treatment of acute conditions, and management of chronic conditions [47]. Primary health care services are delivered in settings such as general practices, community health centres, allied health practices, and via communication technologies such as telehealth and video consultations. GPs, nurses, nurse practitioners, allied health professionals, midwives, pharmacists, dentists, and Aboriginal health practitioners are all considered primary health care professionals. For the purposes of this thesis, primary care has been scoped to refer to health care provided in the general practice setting. In most cases, the health care is provided by a GP or practice nurse who works within a GP practice that is supported by a practice manager, administration/reception staff and in some cases, allied health. The external organisation funded by Government to provide support for primary care service delivery in Australia is called a Primary Health Network (PHN). They are funded to coordinate primary health care in their local region, assess the needs of their community and commission health services so that people in their region can get coordinated health care where and when they need it [39].

This literature review focuses on research conducted in the general adult population aged 45-74 years (or part thereof); the age group covered by existing Australian recommendations for screening and management of CVD prevention. A “systematised overview” methodology for conducting the literature review was adopted, noting that the medical literature has been summarised across these broad topics and a narrative, thematic description of what is known in this area has been provided [44]. Studies focussing exclusively on young or elderly people [<45 or >75 years old] were not
included. Studies that only focussed on the indigenous population were excluded as this thesis focused on examining the entire high risk population-wide CVD management rather than narrowing down to the multiple specific population sub-groups.

The literature review was undertaken by using the search engines PubMed, Medline and Google Scholar, and using searches with ‘cardiovascular’ and ‘primary’ to limit the results to the context of cardiovascular disease in the primary health care setting or primary interventions.

This review focused on the following key areas:

- Development and implementation of clinical guidelines for cardiovascular disease.
- Quality improvement programmes including their development, effectiveness and challenges or efficacy within the primary health care setting [including audits and audit feedback].
- Adoption or implementation of computerised clinical-based decision-making to achieve quality improvement, and
- Implementation of research into practice, efficacy and best practice.

Additional search terms linked to quality improvement programmes, such as those listed below, were added into the search for literature to assist in capturing more detail around these more specific themes:

- Quality management
- Quality assurance
- Health care
- Quality improvement
- Context
- General practice
- GP
- Decision support
- Risk assessment
- Computerised clinical decision support systems
Clinical decision support systems
Implementation
Guidelines
Audit
Audit and feedback
Best practice
Optimisation
Challenges
Intervention

The reference lists of in-scope studies were also examined to locate additional relevant studies. Throughout reviewing search results, it was important to delineate between the effectiveness of a tool, intervention or QI programme versus their efficacy impacted by several factors during implementation within the primary health care setting. Further delineation/scoping of the literature reviewed is outlined in a narrative discussion about each theme.

**Cardiovascular disease management guidelines in Australia and their implementation in primary care**

This section provides an overview of the evolution of the Australian CVD management guidelines and existing reviews of the Australian and international literature on the current implementation of cardiovascular guidelines in primary care. The goal of disease management is to identify persons at risk for one or more chronic conditions, promote self-management by patients, and address the illnesses or conditions with maximum clinical outcome, effectiveness, and efficiency [49, 50]. For the purposes of this review, disease management is defined as a group of coherent activities designed to prevent or manage a chronic condition, through case identification, risk-factor management, and employing multiple treatment modalities, including medication and lifestyle interventions [51].

The strength and consistency of associations found in the available research suggest that modifiable risk factors such as BP, smoking status, blood lipids, glucose
metabolism, physical activity, weight status, waist circumference and dietary intake are associated with CVD [20, 21]. A review of more than 50 studies that have examined the relationship between these risk factors and CVD show that high blood pressure, smoking, hypercholesterolemia, dyslipidemia, diabetes, inactivity, overweight/obesity, high waist circumference and low fruit and vegetable intakes are associated with a higher risk of cardiovascular disease [52]. There are several proposed physiologic mechanisms whereby these factors are thought to influence CVD risk, mainly through blood vessel damage, atherosclerosis and/or inflammation [1].

This section is divided into two sub-sections. The first sub-section provides a brief overview of the CVD management guidelines- how they were developed and their recommendations. As this thesis focuses on CVD management in the Australian context, this section will only focus on Australian CVD management guidelines. The second part examines the current evidence base about how CVD management guidelines are implemented in primary care in Australia and internationally.

**Cardiovascular disease management guidelines in Australia**

Clinical practice guidelines (CPGs) are statements that include recommendations intended to optimise patient care. They are informed by a systematic review of evidence, and an assessment of the benefits and harms of alternative care options [51]. CPGs have been upheld as an essential part of quality medical practice, and interest in their development has increased over the past two decades in all areas of medicine. While CPGs were novel prior to the 1990s, the concept of CPGs is now mainstream among medical practitioners [53].

CPGs have a range of purposes, such as improving effectiveness and quality of care, decreasing variations in clinical practice, reducing health care costs and decreasing preventable mistakes and adverse events. Rising interest in CPGs by health practitioners is thought to be fuelled by increased demand for care, more expensive technologies, an ageing population, variations in service delivery among providers and geographical regions, and the intrinsic desire among healthcare professionals to offer and of patients to receive, the best care possible. Clinicians, policy makers, and
patients see guidelines as a tool for making care more consistent and efficient and for closing the gap between what clinicians do and what scientific evidence supports [54].

The Guidelines for the Management of Absolute CVD Risk were developed in 2012 by the NVDPA in response to the burden of CVD in the Australian community. The guidelines recommend strategies for the management of CVD risk in the primary prevention setting, in addition to providing guidance on the assessment of CVD risk in all adults over 45 years of age (35 years for ATSI people). The Guidelines for the Management of Absolute CVD Risk are intended for use by general practitioners, Aboriginal health workers, other primary care health professionals and physicians. They have been endorsed by the Royal Australian College of General Practitioners [20]. These Australian guidelines were not updated during the course of the entire study and are scheduled for renewal mid 2023.

Absolute risk is the numerical probability of a cardiovascular event occurring within a five-year period. It reflects a person’s overall risk of CVD and is the combined risk derived from multiple risk factors, as opposed to the traditional method that considers risk across single risk factors, such as high cholesterol or high blood pressure, in isolation. Levels of CVD risk are shown in Table 2.1. ‘High risk’ is defined as >15% risk of CVD within next 5 years [20].

Table 2.1: Cardiovascular disease risk levels and summary of management guidelines [20]
### Moderate Risk

**Calculated using FRE as 10-15% absolute risk of CVD events over 5 years**

- Appropriate, specific advice and support regarding diet and physical activity.
- Appropriate advice, support and pharmacotherapy for smoking cessation.
- Lifestyle advice given in preference to drug therapy

Not routinely recommended.

- Consider BP lowering and/or lipid lowering in addition to lifestyle advice if 3-6 months of lifestyle intervention does not reduce risk or:
  - BP persistently ≥160/100 mmHg
  - Family history of premature CVD

Specific population where the FRE underestimates risk e.g. A&TSI peoples, South Asian, Maori and Pacific Islander, Middle Eastern

- Consider withdrawal of therapy for people who make profound lifestyle changes.

TC <4.0 mmol/L; HDL-C ≥1.0 mmol/L; LDL-C <2.0 mmol/L; Non HDL-C <2.5 mmol/L; TG <2.0 mmol/L.

Adjust medication as required.

Review absolute risk every 6-12 months.

---

### Low Risk

**Calculated using FRE as <10% absolute risk of CVD events over 5 years**

- Brief, general lifestyle advice regarding diet and physical activity.
- Appropriate advice, support and pharmacotherapy for smoking cessation.

Not routinely recommended.

- Consider BP lowering therapy in addition to specific lifestyle advice if BP persistently ≥160/100 mmHg.
- Consider withdrawal of therapy for people who make profound lifestyle changes.

TC <4.0 mmol/L; HDL-C ≥1.0 mmol/L; LDL-C <2.0 mmol/L; Non HDL-C <2.5 mmol/L; TG <2.0 mmol/L.

Adjust medication as required.

Review absolute risk every 2 years.

Blood test results within 5 years can be used.

---

A&TSI: Aboriginal and Torres Strait Islander peoples; BP: blood pressure; CKD: Chronic Kidney Disease; DBP: diastolic blood pressure; FRE: Framingham Risk Equation; HDL-C: high density lipoprotein cholesterol; LDL-C: low density lipoprotein cholesterol; SBP: systolic blood pressure; TC: total cholesterol; TG: triglycerides; UACR: urinary albumin:creatinine ratio

In clinical practice, decisions regarding the management of absolute CVD risk are made according to the individual’s absolute risk level. The management goal is to reduce the patient’s level of absolute risk. This is achieved by assessing and managing several individual risk factors. The evidence shows that a moderate reduction in several risk factors is more effective in reducing overall CVD risk than a major reduction in one factor [20, 55]. The guidelines recommend monitoring patients’ response to treatment by measuring their individual risk factors and adjusting medication or lifestyle advice accordingly [20].

The guidelines identify a total of eight factors used to assess CVD risk: age, gender, smoking status, diabetes, systolic BP, total cholesterol, HDL cholesterol and presence of left ventricular hypertrophy on ECG [20]. The algorithms and charts for assessing absolute cardiovascular risk are illustrated in Figure 2.1. As shown in Table 2.1, management recommendations include lifestyle, pharmacotherapy, targets, and monitoring, are stipulated for each risk category.
Figure 2.1: Australian cardiovascular risk charts (non-diabetic patients)

Australian cardiovascular risk charts

Risk level for 5-year cardiovascular (CVD) risk

<table>
<thead>
<tr>
<th>High risk</th>
<th>Moderate risk</th>
<th>Low risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥30%</td>
<td>10-15%</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>25-29%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-24%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15-19%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

How to use the risk charts

1. Identify the chart relating to the person’s sex, diabetes status, smoking history and age. The charts should be used for all adults aged 45 years or over (and all Aboriginal and Torres Strait Islander adults aged 35 - 74 years) without known history of CVD and not already known to be at clinically determined high risk.

2. Within the chart choose the cell nearest to the person’s age, systolic blood pressure (SBP) and total cholesterol (TC):HDL ratio. For example, the lower left cell contains all non-smokers without diabetes who are 34-44 years and have a TC:HDL ratio of less than 4.5 and a SBP of less than 130 mmHg.

3. The colour of the cell that the person falls into provides their five year absolute cardiovascular risk level (see legend above for risk category). People who fall exactly on a threshold between cells are placed in the cell indicating higher risk.

*In accordance with Australian guidelines, patients with systolic blood pressure ≥150 mm Hg, or a total cholesterol of >7.5 mmol/L, should be considered at clinically determined high absolute risk of CVD.

Charts in this age bracket are for use in Aboriginal and Torres Strait Islander populations only.
Implementation of cardiovascular disease management guidelines in primary care

CPGs include statements of standard practice; providing benchmarks or standards against which individuals can audit; compare, and potentially improve their practice; or guidance regarding undertaking particular tasks [53]. Despite the efforts and rigor invested into formulating practice guidelines, their benefits are only realised if they are implemented into patient care [54, 56]. Research has demonstrated that CPGs can be effective tools in delivering evidence-based medicine to achieve better patient outcomes and safer care in managing diabetes [57], hypertension and heart failure [58]. Although potentially valuable to patient care, CPGs are often not followed by medical practitioners. These guideline-practice gaps are ubiquitous and have been shown to contribute to poorer patient outcomes and healthcare costs for a range of conditions, including asthma [59, 60], stroke prevention [61] and renal failure [62, 63].

To date, several Australian and international studies have examined guideline-practice gaps for CVD management in primary care. Overall, these have shown screening and documentation of CVD risk to be sub-optimal in primary care. Data from the Australian Bettering the Evaluation and Care of Health (BEACH) study showed that BP was not recorded for 13% of guideline-recommended patients, and up-to-date blood lipid levels were not available for more than half (53%) of patients [27]. A large study of primary care in the UK showed that only 24% of patients that were recommended for cardiovascular risk assessment had an assessment performed [64]. A study among Spanish primary care physicians reported that around 60% did not assess cardiovascular risk among patients recommended for review [65]. A large study across 12 European countries similarly showed significant disparities between CVD management guidelines and clinical practice in primary care [66].

The literature also supports that there is room for improvement in primary care for initiating therapies and achieving clinical targets when managing CVD risk. Data from the BEACH study found that patients at high risk of CVD or established CVD were substantially undertreated, with only 23% and 53%, respectively, receiving the guideline-recommended treatment of a BP-lowering medication and statin [27]. Similar findings were also documented in the AusHEART study in 2010, which found only
34% of patients at high CVD risk were prescribed both a BP-lowering medication and a statin [67]. In the 2011/12 National Health Survey data, Banks et al. showed that almost half (47.1%) of those considered to be high CVD risk were not taking any guideline-recommended medication to reduce or mitigate CVD risk [19]. A UK [64] and Canadian [68] study showed slightly higher rates of treatment, with 64% and >75% of patients at high CVD risk receiving treatment [64, 68]. The latter study also showed that the attainment of BP and blood lipid targets was low (<50%) among high-risk patients [68]. Similar findings, with poor attainment of clinical targets for BP and blood lipids, have been documented in primary care in Spain [69] and Hungary [70].

The last two decades have been characterised by increased interest in developing CPGs in primary care, including CVD guidelines. Although guidelines are associated with better patient care and outcomes, little Australian research has examined their implementation, and the research to date suggests that CVD guidelines are poorly implemented into everyday practice. Further gains in reducing the burden of CVD may be achieved by identifying and addressing the factors that lead to this gap.

**Barriers to the implementation of cardiovascular disease management guidelines**

Evidence-based CPGs are intended to assist practitioner and patient decision-making about appropriate care. However, as detailed in the preceding section, a considerable proportion of patients in Australian primary care do not receive CVD management in accordance with current scientific evidence. Translating evidence from CPGs into practice is the interface between theory and practice, and an emerging body of literature is examining the barriers to implementation of CPGs in Australian general practice.

Harris et al. [71] examined guideline-practice gaps in primary care in Australia for the management of several chronic conditions, including asthma, diabetes, hypertension, and depression, using self-reported GP data. The findings showed that practice guidelines were well-regarded by GPs and were widely disseminated and accessible to them [71]. GPs self-reported higher use of guidelines for asthma, diabetes, and hypertension than for depression management [71], and four main groups of factors
were identified as implementation barriers: guideline, organisational, practitioner and patient characteristics.

Several organisational-level factors have been identified as barriers to GPs implementing guidelines, such as time pressures during patient consultations, financial incentives, and practice systems. Time pressures are widely reported as a significant barrier to the implementation of practice guidelines. GP consultation times and modes of practice vary internationally [72]. Australian general practices operate on a fee-for-service model that rewards high patient throughput. In this model, time limitations in patient consultations are consistently reported as a barrier to patient care [66, 72, 73, 74]. Shorter consultation times are associated with less thorough history taking for risk assessment, abbreviated physical examination and reduced discussion about modification of lifestyle-related risk factors [66, 74]. The recent introduction of the Heart Health Check (Medicare item 699) has been designed to circumvent some of these barriers. However, a formal evaluation of its’ effectiveness is currently pending.

IT factors, such as the use of electronic medical records and automated systems for patient recalls and reminders for health checks, have been reported by GPs to improve their patient management [75, 76]. Automated systems to calculate individual patient risk have been identified as a facilitator of implementing CVD guidelines [77, 78]. In the study of Harris et al. [75] GPs who worked in practices with decision-support tools, automated recalls, and reminders for screening and review were more likely to practice consistent with guideline recommendations. However, a recent Australian study focussing on implementing CVD guidelines utilising automated prompts for screening and risk assessment and electronic decision support tools integrated into practice IT systems did not show significant improvements in CVD screening and management [79].

A number of other organisational factors, such as the patient care team, reporting of benchmarks to the health care team, and practice culture, have been identified as important factors for the implementation of management guidelines in primary care [75]. International studies have found that incorporating practice nurses for lifestyle modification advice has improved CVD assessment and management compared to
guideline recommendations [80]. The study of Harris et al. 2014 [71] supported this and showed that monitoring and review of patients by nursing and allied health staff in the health care team within the practice was associated with better implementation of guidelines.

Practice leadership and an organisational culture promoting implementation have been identified as critical factors in incorporating guideline recommendations into everyday clinical practice [81]. Furthermore, practices that regularly monitor the risk factor profile of their patient base and the attainment of targets and communicate these with practitioners have demonstrated better implementation [82]. Many of these factors have been identified as features of high-performing primary care practices [83, 84].

Doctor factors may also be barriers to the implementation of guidelines; these barriers may act alone or interact with other factors. In the study among Australian GPs, Harris showed that older GPs reported using guidelines somewhat less frequently than younger GPs [71]. This may be because they were already familiar with the recommendations or because they were more likely to rely on experience than guidelines. The latter has been observed in other studies of guideline implementation [85].

Studies have also shown that GPs underestimate their patients’ CVD risk [86, 87], with an Australian study showing that GPs significantly underestimated CVD risk compared to the Framingham risk assessment [28]. Another Australian study showed that GPs’ perceptions of patients’ CVD risk were more critical than the calculated absolute risk when evaluating a patient’s CVD risk [88]. This misperception of patient risk may lead to fewer GPs conducting a formal CVD risk assessment. It may contribute to infrequent/less aggressive lifestyle or medication interventions for risk reduction. Bonner et al. (2014) suggested that guided support for GPs to calculate absolute risk may overcome subjective risk estimates [88]. In addition to issues with CVD risk estimation, GPs report they lack the confidence and skills to assist patients with lifestyle changes [68, 86]. International research shows better CVD risk reduction and lifestyle modification when practice nurses or allied health were involved in patient care [89].
Patient-level factors also have a role in the implementation of CVD guidelines. Poor levels of awareness of CVD risk and a tendency of patients to also underestimate their CVD risk [87, 90] may contribute to lower engagement in lifestyle modification and medication compliance. Furthermore, socioeconomically disadvantaged patients may lack the health knowledge and skills to reduce their CVD risk [90], and financial factors may be barriers to accessing medications and support from allied health [90]. Furthermore, attaining CVD risk targets may be further challenged if the physical and social environments in which patients reside do not support behaviour change and healthy lifestyle choices [78].

In summary, a multitude of factors at the organisational, GP and patient levels may act separately and in combination as barriers to implementing CVD risk reduction guidelines. These may contribute to the evidence-practice gap in the implementation of CVD guidelines in Australian general practice. Addressing these factors may reduce this gap, improve patient care, and reduce CVD-related morbidity and mortality rates.

**Reducing the evidence-practice gap**

Taking considered action to improve healthcare is not new, and there are many well-established approaches to evaluating and making changes to healthcare services. Traditional methods have centred around four main activities: clinical audits, quantitative research, service evaluation, clinical transformation, and innovation. The approaches for each of these methods are outlined in Figure 2.2.
A systematic review [91] identified four key features of successful ‘improvement’ implementation for the management of diabetes: education and feedback to the medical providers, organisational changes to appointments and follow-up, information system changes, and patient-oriented education and support. Improving performance at the primary health care organisation level involves designing complex, multifaceted interventions.
Kraft et al. designed an improvement framework (Complex Systems Improvement (CSI)) for use in the healthcare setting to address the multi-layered complexity of the primary care environment. The CSI framework identifies four levels of a health system that align with a successful implementation of change - environment, organisation, microsystem, and patients and their caregivers [42]. The CSI framework also identifies five domains for evaluating a change-making intervention in the health system: strategy, culture, structure, workforce, and technology.

In 1995 the Boston based Institute of Healthcare Improvement developed a program called ‘Breakthrough series’ collaboratives where health organisations learned from each other and recognised experts to make improvements to clinical practice [91]. The UK National Primary Care Development Team developed this concept further and designed a series of learning workshops, Quality Improvement Collaboratives (QIC), where primary care participants learnt from experts about a specific topic for improvement, exchanged ideas, shared experiences and were then directed to systematically apply five core strategies: build a practice team, establish a system for updating a register of people with the disease or condition (such as CVD), be systematic and proactive in managing care, involve patients in delivering and developing care, and develop effective links with key local partners [92]. The core to achieving change was ensuring each practice team could identify an issue to work on, establish an overarching goal, and develop vital measurable outcomes to keep track of change. The QI approach began to be adopted and implemented in Australian healthcare in the early 2000s [93].

**Quality Improvement (QI) approach**

There are many definitions of quality improvement (QI) [33]; however, a common element is that QI is a framework used to systematically improve patient care and outcomes. QI seeks to standardise processes and structures, reduce variation, achieve predictable results, and improve outcomes, systems, and organisations [33]. The relationship between QI and traditional approaches to healthcare improvement is outlined in Figure 2.2.
In the context of healthcare, QI is defined as having a generalised systematic approach to making changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning) [33]. Transformation and change in primary care practices rely on technology, personal modification of the doctors themselves, and local support and services [94]. The multidimensional scope and principles of QI in healthcare have been summarised by Backhouse and Ogunlayi [95] and outlined in Table 2.2.

Table 2.2: The principles of Quality Improvement [95]

<table>
<thead>
<tr>
<th><strong>Primary Intent</strong></th>
<th>to bring about measurable improvement to a specific aspect of healthcare delivery, often with evidence or theory of what might work but requiring local iterative testing to find the best solution.</th>
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<tbody>
<tr>
<td><strong>Employing an iterative process of testing change ideas</strong></td>
<td>adopting a theory of change that emphasises a continuous process of planning and testing changes, studying and learning from comparing the results to a predicted outcome and adapting to hypotheses in response to results of previous tests.</td>
</tr>
<tr>
<td><strong>Consistent use of an agreed methodology</strong></td>
<td>many different QI methodologies are available: Commonly cited methodologies include the Model for Improvement, Lean, Six Sigma, and Experience-based Co-design. Systematic review shows that the choice of tools or methodologies has little impact on the success of QI, provided that the chosen methodology is followed consistently. Though there is no formal agreement on what constitutes a QI tool, it would include activities such as process mapping that can be used within a range of QI methodological approaches. NHS Scotland’s Quality Improvement Hub has a glossary of commonly used tools in QI.</td>
</tr>
<tr>
<td><strong>Empowerment of front line staff and service users</strong></td>
<td>QI work should engage staff and patients by providing them with the opportunity and skills to contribute to improvement work. Recognition of this need often manifests in drives from senior leadership or management to build QI capability in healthcare organisations, but it also requires that frontline staff and service users feel able to use these skills and take ownership of improvement work. Using data to drive improvement - to drive decision-making by measuring the impact of tests of change over time and understanding variation in processes and outcomes. Measurement for improvement typically prioritises this narrative approach over concerns about the exactness and completeness of data.</td>
</tr>
</tbody>
</table>
Scale up and spread with adaptation to context

As interventions tested using a QI approach are scaled up and the degree of belief in their efficacy increases, it is desirable that they spread outward and be adopted by others. Key to successful diffusion of improvement is the adaption of interventions to new environments, patients and staff groups. Available resources and even personal preferences of healthcare providers in surrounding areas, again using an iterative testing approach.

There are several ways to intentionally implement QI initiatives, with one approach being the establishment of a Quality Improvement Collaborative (QIC). QICs have been widely adopted as an approach to shared learning and improvement in healthcare. They bring together groups of practitioners from different ‘organisations’ to learn about specific aspects of health service quality and share experiences about making changes in their local settings. When implemented in the UK National Health Service (NHS), QICs have been shown to be an important way of engaging practitioners in QI.

A study by Lalani et al. (2018) showed that despite a challenging healthcare environment in the UK, there was motivation among individuals to participate in QI as they recognised that improvement approaches might facilitate positive change in local clinical processes and systems [96]. Collaboratives can harness this individual motivation to facilitate the spread and adoption of improvement methodology and build engagement across an organisation.

Wells et al. (2018) conducted a systematic review of the effectiveness of QICs targeting different diseases and applied them in various healthcare environments [36]. Overall, the QICs included in the study reported significant improvements in targeted clinical processes and patient outcomes. These reports are encouraging but must be interpreted cautiously since fewer than a third met established quality and reporting criteria, and publication bias is likely [36]. In primary care, a US study showed that a QIC program targeting screening and education about type 2 diabetes in high-risk women showed QICs effective in improving screening and education [97]. A large study is currently underway in Canada (COMPAS+ study) utilising a QIC approach to improve the management of a range of chronic diseases in primary care [98].
In Australian primary care, QI was adopted and implemented in 2004 by the Improvement Foundation as part of a national, federal government-funded program to improve evidence-based care, known as Australian Primary care Collaboratives (APCC). There have been no controlled evaluations of this program. However, a review of seven QIC ‘waves’ examining 743 Primary Care Health services and 150,000 patients (2004-2009) showed an improvement of 50% in mean target HbA1c levels from 25% at baseline to 38% over the 18-month review period. Similar gains occurred in lipid levels and BP measurements [99].

In another Australian study, Knight et al. reported that quality improvement strategies improved health service data on all the chosen topics: Diabetes, Cardiovascular Disease, Chronic Obstructive Pulmonary Disease, Chronic Disease patient self-management except Access (availability of patient appointments) [100]. The role of the QIC in enthusing, training, and resourcing practice teams appeared to be the key to achieving change. Knight et al. reported that a primary health organisation's local support of practice teams was instrumental in attaining practice improvements. This study also suggested that institutionalising the QIC approach from within a local primary health organisation may lead to increased engagement of primary healthcare services, resulting in an overall increase in the capacity for quality improvement [100]. Patel et al. (2014) suggested the need for increased rigorous process evaluations of QI initiatives in primary care to understand how and in what ways QI can be best incorporated into general practice [101]. Such evaluations are crucial to understanding how implementation strategies should be applied in non-trial (real-world) settings.

Tools to achieve change

Audit and feedback, electronic decision support tools

QIC encourages general practices to use a range of strategies to assist in achieving targeted goals. These include practice-generated audit and feedback and point-of-care electronic decision support (EDS) tools.
A Cochrane review found audit and feedback can achieve small-to-moderate improvements in practice across all healthcare settings. Importantly, they may gain more change when the individual participants conducted the audit [102] alongside point-of-care feedback systems. EDS systems are among the most promising interventions to improve uptake guidelines in clinical practice. In 2005, a systematic review of clinical decision support systems for improving clinical practice concluded such tools should be implemented whenever feasible and appropriate [103].

In the past decade, there have been significant improvements in the design, use, and effectiveness of point-of-care EDS systems to improve the quality of care for patients with chronic conditions. Advances in software systems, data exchange, data security, and human factors research have driven these improvements.

Studies have shown that EDS systems have high use rates and high clinician/user satisfaction rates. They have also measurably improved a range of outcomes in chronic disease management, such as glucose control, blood pressure control, and cardiovascular risk trajectories [104, 105]. When applied across a diverse range of healthcare settings, Bright et al. (2012) showed that EDS had a favourable effect on prescribing treatments, facilitating preventive care services, and ordering clinical studies [106].

When applied in primary care, a systematic review by Souza et al. (2012) showed that point-of-care computer reminders generally achieve small-to-modest improvements in provider behaviour [104]. A minority of interventions showed larger effects, but no specific reminder or contextual features were significantly associated with effect magnitude. In a meta-analysis of 162 randomised controlled trials, Roshanov et al. (2013) identified several factors that could partially explain why some EDS systems succeeded and others failed [107].

These were:
- Presenting decision support within electronic charting or order entry systems is associated with failure compared with other ways of delivering advice.
- Odds of success were greater for systems that required practitioners to provide reasons when overriding advice than for systems that did not.
- Odds of success were also better for systems that provided advice concurrently to patients and practitioners.

Finally, most systems were evaluated by their own developers and such evaluations were more likely to show benefit than those conducted by a third party [107].

Another systematic review specifically focussed on CVD risk assessment in a diverse range of health care contexts [108]. The review did not find a clear clinical benefit with the implementation of EDS in CVD risk assessment and target attainment. Some features of EDS seem more promising than others. However, the variability in EDS characteristics and heterogeneity of the health care contexts considered, limited any stronger conclusions [108].

HealthTracker, an EDS tool developed by The George Institute, was shown in a cluster randomised controlled trial (TORPEDO trial) to significantly improve the measurement and management of CVD risk in general practice. Using the tool improved general practices' ability to identify the patients at risk of CVD and introduce preventive care strategies as recommended by the current guidelines [109]. The results demonstrated a 10% absolute improvement in screening for cardiovascular disease risk [109]. Although there was no significant improvement in prescribing more medications to people at high risk [78], there was progress in increased levels of prescribing the appropriate doses of the recommended medicines. The TORPEDO trial concluded that computerised tools play a significant role in preventative treatments [109].

Key opportunities exist to improve clinical management by building upon data-driven strategies through improvement programs such as QIC. In 2013 a review looking at identifying factors that differentiate between effective and ineffective EDS systems also concluded that the success of a system was related to ensuring a method for instructing patients and practitioners about ‘how’ to implement the recommendations and not just ‘what’ to do [107]. EDS that assists GPs in undertaking objective CVD risk assessment and supporting management strategies, including lifestyle risk factor management, is a promising area for improving risk assessment and management in primary care.
Primary care as a clinical microsystem

Clinical microsystems are small, organised groups embedded in the larger health care system and comprise of practitioners and staff caring for a defined population of patients, such as a primary care practice. Implementation of most clinical guidelines requires review and change in how clinical microsystems operate and hence requires specific clinical pathway redesign and individual practitioner cooperation to achieve sustainable change [110].

Primary health care is complex and clinical outcomes can be adversely affected by gaps in any element of the care system. Lapses include failures in the follow-up of abnormal results or misunderstandings by clinicians and patients about how the system operates, both within the sphere of general practice and across the continuum of health care. Clinical microsystems provide a conceptual and practical framework for understanding and redesigning organisational systems to facilitate safe and effective patient care [111]. Current literature describes several ‘Success Characteristics’ of high-functioning primary care microsystems: leadership, patient focus, organisational support, staff focus, education and training, the interdependence of the health care team, community and market focus, information and information technology, process improvement and performance results [112].

High-functioning primary care practices are required to adopt innovative system redesign routinely. Four change management processes have been described in achieving redesign adoption: diffusion (passive spread), dissemination (active and planned efforts to achieve adoption of an innovation), implementation (active and planned actions to mainstream an innovation within an organisation), and sustainability (making an innovation routine until it reaches obsolescence) [113].

Paying adequate attention to the use of communication strategies where GPs can share ideas about achieving a change of practice is particularly important in the uncertainty of the primary care setting where undifferentiated presentations and low disease probability surround them. In a study examining the implications of “uncertainty” when improving healthcare systems, Leykum et al. describe the importance of clinician relationships fostering ‘sense-making’ and learning. They
suggest that actively reshaping clinician relationships may enhance the ability to improve more significantly [114].

Findings from the HEART study, which focussed on improving CVD prevention systems in primary care, showed that promoting organisational change is a complex but critical area required for producing sustained improvements in preventive care [115]. A meta-analysis conducted by Baskerville et al. showed that a practice facilitator- an individual from outside the practice that brings about organisational change- can be an effective tool in implementing change in the complex microsystem of GP practices [116].

**Conclusions**

CVD contributes to significant morbidity and mortality among the Australian population. As many risk factors for CVD are modifiable, significant reductions in CVD and its social and economic impacts can be mitigated through screening and risk factor modification. GPs are optimally placed for identifying and reducing CVD risk among the population, as they see a substantial proportion of the population and are well-equipped to implement lifestyle and medical interventions.

In 2012 Australia’s first absolute risk-based management guidelines for CVD were published. Several Australian studies have shown that although GPs have become better at identifying and managing patients at high risk of CVD, there are large gaps between guideline recommendations for screening and management of CVD and clinical practice among Australian GPs.

Clinical practice guidelines, such as the current CVD guidelines, are readily accessible to most GPs, who value guidelines for their clinical practice. However, several barriers at the organisational, practice and practitioner levels may contribute to these gaps. Addressing these may significantly reduce CVD-related morbidity and mortality in the Australian population.

Reducing evidence-practice gaps has been the focus of healthcare for many decades, but more recently, a QI approach to addressing these disparities has been
recommended. QI seeks to standardise processes and structures, reduce variation, achieve predictable results, and improve outcomes, systems, and organisations. QICs have been widely adopted as an approach to shared learning and improvement in healthcare. They bring together groups of practitioners from different ‘organisations’ to learn about specific aspects of health service quality and to share experiences about making changes in their local settings. There is a growing body of research about the effectiveness of QI and QICs in improving patient outcomes across diverse healthcare settings and a smaller body of emerging research on their effectiveness in primary care.

QIC encourages general practices to use a range of strategies to assist in achieving targeted goals. These include practice-generated audit and feedback and EDS tools. There is some mixed evidence about the effectiveness of EDS tools in healthcare. However, the small number of studies conducted in primary care have shown positive findings in improving the evidence-practice gaps for managing a range of chronic conditions. To date, there has been a lack of research examining the implementation of a QI approach for managing CVD in primary care in Australia. Furthermore, there is little known about how a QI strategy employing EDS can improve the evidence-practice gap in CVD management in primary care in Australia.
Chapter 3 Methodological background

Introduction

Each published paper in this thesis provides details of the relevant methods within the manuscripts; this section expands on those descriptions. Firstly, the rationale for combining qualitative and quantitative methodologies is provided. The chapter is then divided into three sections describing the three discrete projects that formed the basis of the four papers presented in this thesis.

Linking qualitative and quantitative research

The research in this thesis combined both qualitative and quantitative methodologies to address the research questions. The initial qualitative study examined the barriers and enablers to the implementation of QI initiatives in primary care. This was followed by a quantitative investigation that provided information on the baseline management of CVD risk in primary care, and a subsequent study about how this changed after an intervention. These findings were followed up with the qualitative part of this research that aimed to give a more in-depth understanding of managing CVD risk in primary care and how the CVD-specific QI intervention impacted the health care team and patient care.

Combining both methodologies was done for two main reasons. Firstly, and arguably most importantly, the aim was for the research results to have maximum utility to general practice in Australia and internationally. It could be reasoned that quantitative data about the baseline management of CVD by Australian GPs, and how this changed after an intervention is extremely useful in the Australian context, given the limited research to date done in this area. However, such data are limited in understanding how (and why) the intervention impacted (or not) the study's results. The findings of the mixed-methods approach may have more utility than those just formed from the quantitative results alone. The qualitative exploration provides a deeper understanding of factors contributing to CVD management in the complex primary healthcare environment. As Jick [117] wrote, qualitative methods can be considered “the glue that cements the interpretation of multi-method results”.

Secondly, using both methods may be more helpful in informing the development of further primary care interventions and research. Subsequent studies may use the research finding
in this thesis to develop interventions that overcome some of the barriers/difficulties documented in the current research. Additionally, the methodologies (used in combination) may initiate new lines of thinking and inquiry into how CVD and other chronic diseases are managed in primary care and the best ways of improving practice. There is consensus in the primary care literature that combining both methodologies provides a deeper and more credible understanding of the issue than one method can on its own. In these respects, using a combination of quantitative and qualitative methodologies was considered appropriate for addressing the research questions of this thesis as, in combination, they would add strength to the research.

3.1: The Australian Primary Care Collaboratives Program (APCC)- Paper 1 (Chapter 4)

Background

The Australian primary health care system was initially designed to deliver acute care services but has been modified over 25 years to better address preventive health and chronic disease management. Despite the modifications, large gaps are evident in the current data around preventive care measures [9, 16, 26]. QI initiatives in primary care can potentially improve uptake of evidence-based practice but have been challenging to implement and sustain [96].

In Australia, the Improvement Foundation has administered a series of QICs called the Australian Primary Care Collaboratives (APCC) since 2004 [36]. The federal government initially commissioned the Improvement Foundation to assist primary care practices in five priority areas: coronary heart disease, diabetes, chronic obstructive pulmonary disease, chronic disease prevention and self-management, and health care access and redesign. Practices participated in an APCC ‘wave’ (Figure 3.1.1), which involved looking at practice data, submitting PDSAs, undertaking QI and using practice data to monitor changes in practice.
Figure 3.1.1: Elements of an Australian Primary Care Collaboratives (APCC) program wave

Conceptual framework

A conceptual framework explains either graphically or narratively the main things to be studied and the presumed relationships among them [118]. The pertinent barriers and enablers to QI in primary care identified in previous studies were examined in interviews with key stakeholders in the APCC program. To permit the research to be undertaken within the time and resource limitations, only the factors considered the most critical barriers/enablers or those most meaningful to implementing QI in primary care were included in the analyses.

Development and piloting of interview schedule

Once the key concepts were identified from the existing literature, interview questions were formed around each concept. This included QI program governance, operational and IT support, the experience of the clinicians and the future sustainability of QI systems in practices. Questions around these concepts were structured as open-ended questions in the interview schedule to identify new or unique barriers to the Australian primary care context. The preliminary interview schedule was distributed to subject-matter experts in QI evaluation and primary care research, and further refinements were made. Furthermore, the interview schedule was piloted on four subjects, including two GPs, a practice manager and a PHN officer. Each interview lasted between 45- 60 minutes. After each interview was completed, participants in the pilot were asked if they experienced any difficulties with answering the questions, how they were worded, and the interview procedure. Their responses were noted, and the participants were asked their recommendations regarding how the interviews could be improved. They were also asked if there was anything that was missing from the interview that they considered important. The interview guide is provided in Figure 3.1.2.
Sampling and data collection

The sample size issue in qualitative studies cannot be answered on statistical grounds but on conceptual grounds [119]. An initial sample size of 15 participants representing various health care team members was proposed to provide sufficient data on each concept to reach saturation. Participants were purposely sampled from Improvement Foundation staff who had participated in the APCC program, and general practice participants who had undertaken at least one wave. The Candidate collected data through a semi-structured telephone interview. The candidates role as a GP who had personally participated in the APCC program was noted prospectively throughout the study, both before and during the interview process itself. The potential for personal biases and assumptions that may have affected the way in which the interviews were conducted and analysed was discussed with each participant and reflected upon by the candidate throughout the interview and data analysis for this study.

Data analyses

The interview data were analysed by thematic analysis using a phenomenological approach to understand participants perceptions, perspectives and understanding of the implementation of the APCC program [120]. Thematic analysis is a process of encoding data under several “themes”. A theme may describe, organise possible information, or interpret phenomena [121].

Thematic analysis was the method of choice for these data. This was primarily driven by its ability to address the research questions directly and for the results to have maximum utility.
for primary care. Thematic analysis has been advocated as an analytic method suited to applied research and for research that steps outside of academia and into the policy or practice arenas [122]. It provides both a robust analytic method and results easily understood by practitioners, policy makers, and the academic community.

A coding framework was developed for each of the themes. Each theme identified in the data was given a definition, example indicators for how the theme may arise and exclusions of factors not covered in these themes.

3.2: Methodology of the INTEGRATE study- Paper 2

Background

A fundamental challenge for improvement efforts is convincing stakeholders that a real problem needs to be addressed. Practitioners and others may argue that the problem targeted by an improvement intervention is not really a problem; it is not a problem ‘around here’; or that there are far more important problems to be addressed before this one. Trying to convince stakeholders who think they are already doing well to change is likely futile unless they can be shown that action is really needed.

Using ‘hard’ data to outline the issue is the first step in implementing QI strategies [123]. This first step of outlining the situation can facilitate stakeholder engagement in addressing a solution. Before undertaking this thesis research, little was known about how well Australian GPs followed CVD risk assessment and management guidelines. Knowledge was limited to international and smaller-scale Australian studies.

The INTEGRATE (INtegrated combination Therapy, Electronic General practice support tool, phaRmacy led intervention And combination Therapy Evaluation) study was a large study conducted across multiple states in Australia and included GP practices in both urban and rural areas. INTEGRATE was a cluster randomised controlled trial designed to reduce the evidence-practice gaps for CVD management in primary care, especially the gaps in undertreatment of high-risk patients. Baseline data collection occurred between December
2016 to July 2018. A detailed overview of the theoretical underpinnings, study design and intervention, are provided elsewhere [124].

For the purposes of the research presented in this thesis, only baseline (pre-intervention) data from the INTEGRATE study were used to inform the implementation of the 2012 CVD risk assessment and management guidelines in Australian general practices (Aim 2). Baseline data from the INTEGRATE and QPULSE studies (see subsequent section) were combined and presented in Paper 2 (Chapter 5): Implementation of cardiovascular disease preventive care guidelines in general practice: an opportunity missed, published in the Medical Journal of Australia. General Practices that participated in INTEGRATE where excluded from being included in the QPULSE project.

As only baseline data from INTEGRATE was used for the current research, this section only focuses on the sampling, data collection and measurement issues pertaining to the INTEGRATE study. Details of the intervention are not provided here but can be accessed elsewhere [124]. A brief overview of the INTEGRATE study is provided below in Figure 3.2.1.

Sampling and data collection in the INTEGRATE study

Practises using either Best Practice or Medical Director eMR software systems were considered for the trial. It is estimated that > 80% of general practices in Australia use either of these systems [125]. General Practices were recruited through established networks of the members of the study steering committee, through advertising by PHNs, and by direct approaches to the general practices. Studies were recruited in all states of Australia and both urban and rural areas.

Data for all adult patients who had visited a participating practice at least three times during the preceding two years and at least once during the past six months (Royal Australian College of General Practitioners definition of an “active/regularly attending patient”) were included. The analyses focused on those active patients recommended by guidelines for CVD risk assessment; Aboriginal and Torres Strait Islander people ≥ 35 years and all others ≥ 45 years; and those at clinically high risk of CVD regardless of age.

Baseline data were collected using the CAT 4 automated data extraction tool [126], which extracts clinical data from fixed/delimited fields of the eMR and did not extract from free text sections. A de-identified data subset from each practice eMR system was extracted,
including demographic information, selected medical history, medications, BP, blood lipids, smoking status and any medications prescribed to the patient in the past six months.

**Figure 3.2.1 Outline of the INTEGRATE trial [124]**

For the purposes of Paper 2 (Chapter 5), a combination of the baseline data from 95 practices across four states (NSW, Vic, WA and Qld) participating in either INTEGRATE or Q PULSE were used to conduct a cross-sectional audit of the electronic medical records. The deidentified baseline data supplied from practices participating in these studies utilised the same data extraction tool. This meant the data from each study were easily combined for the purposes of this audit. Definitions regarding eligible patients was uniform across both studies. Measurements for CVD risk was also uniform across both studies - complete data for assessment of CVD risk was defined as: (i) smoking status recorded, (ii) BP recorded within the previous 12 months, and (iii) total and HDL cholesterol within the previous 24 months. Sociodemographic and clinical characteristics were analysed using proportions and
standard measures of central tendency and dispersion. Associations between practice-level factors and CVD risk factor measurement/management were modelled using mixed effects logistic regression with random intercepts, clustered by practice. Model covariates included: number of GPs at the practice, presence of a practice nurse, SEIFA category, mean age of patients and proportion of female patients. Patients with missing CVD data were excluded from the model. Practice-level analyses were completed on 88 practices with complete data. Analyses were conducted with SAS software version 9.4. Statistical significance was considered as p< 0.05 (two-tailed).

3.3: Methodology of the QPULSE study- Papers 2, 3, 4

Background

The QPulse study was an intervention study conducted between April 2015- February 2017 that applied a QI approach to reducing gaps between CVD risk assessment and management guidelines and management in Australian general practices. The QPulse study addressed aims 1-4 of this thesis, specifically:

1. Identify enablers and barriers to the implementation of sustainable QI programs in Australian general practice settings;
2. Examine the implementation of the 2012 CVD risk assessment and management guidelines in Australian general practices;
3. Assess whether an abbreviated QIC program (QPulse) was associated with improvements in the monitoring, prescribing practices and attainment of BP and lipid targets for CVD risk reduction, and;
4. Identify barriers and factors driving implementation and adoption of the QIC (QPulse).

The development and evaluation of QPulse were primarily informed by the findings on the barriers and enablers of successful implementation of QI in general practices outlined in Paper 1 (Chapter 4) published in BMC Health Services Research.

We designed a mixed methods study, utilising before and after quantitative data, alongside qualitative data so that we could 1/ Objectively measure CVD risk identification before and after the intervention 2/ Subjectively interrogate the numbers to understand what happened during the intervention and better understand implementation barriers and enables. The use
of “before and after” data collection was key to knowing if the brief QIC intervention made any measurable changes. The addition of the qualitative data provided context and understanding about the “why”.

In the analyses of the qualitative interviews undertaken in QPulse, we used two different theoretical frameworks to provide a richer understanding the enablers and barriers for implementation of QI in the real world of general practice. These were Normalisation Process Theory (NPT) and the Complex Systems Improvement Framework (CSI). Using two different frameworks to analyse the interviewees responses, assisted in identifying the elements of the project that would promote and inhibit the routine incorporation of complex interventions into everyday practice (NPT) [39] as well as explore the multiple layers of the health system that align with a successful implementation of change [42]. These two frameworks built upon the previous phenomenological approach used to identify themes around understanding participants perceptions, perspectives of the implementation process. Although the CSI analysis identifies 4 levels of the health system (environment, organisation, microsystem, and patients and their caregivers), we omitted the level of the patients due to the design of the intervention within the general practice (microsystem) with no direct patient interactions.

**The QPulse intervention**

Each general practice was seen as a ‘participant’ in the QPulse study. Each practice team consisted of GPs, practice nurses, practice managers, reception staff, and allied health practitioners (if available). Participating practices provided the PHN with baseline, de-identified patient data of ‘regularly attending’ patients (defined below) and the PHN generated baseline reports for each practice.

At least one stakeholder from each practice (e.g., nurse, senior GP or PM) attended three 2-hour workshops which covered the following topics: CVD risk assessment tools, absolute risk calculators, current guidelines for preventive CVD management, including pharmacological management of high-risk patients, QI theory and the Plan Do Study Act (PDSA) methodology. Each practice team was asked to submit a monthly PDSA report to the PHN to assist them in planning and measuring change.

During the workshops, participants were also trained in the use of two quality-improvement software tools supplied to each practice: (1) a desktop ‘point of care’ tool, ‘HealthTracker’; a
software application that works in conjunction with the electronic medical record to identify high-risk patients and provides GPs with ‘real time’ personalised guideline recommendations pertaining to cardiovascular risk reduction; and (2) PenCAT Clinical Audit Tool™ a data extraction tool installed onto the computer server at each Practice. PenCAT enabled practices to download specific audit reports containing de-identified patient data on demographics, CVD disease statistics and prescribing information.

At set-up, a project officer provided in-person training at each practice and the program’s roll-out was supported by PHN staff. HealthTracker was installed on all intervention practice computers, and practice staff were trained in its use. Opening a patient file triggered the presentation of immediate, tailored, guideline-based recommendations according to individual CVD risk, including screening tests required (Figure 3.3.1), an interactive risk communication tool shown in Figure 3.3.2, and medication recommendations (Figure 3.3.3).

After the initial three training workshops, monthly webinars were organised for practices to share their progress and ideas with other practices. Each general practice was offered external support from the PHN to generate and interpret the personalised practice report, formulate the PDSAs, and submit monthly data extractions. In addition, PHN staff provided visits, phone calls, and emails providing support and advice for the intervention's implementation and provided change management strategies.

**Figure 3.3.1: Screenshots of the HealthTracker electronic decision support tool: risk factor summary and absolute risk calculation**

The Patient details in this screenshot are a mock-up for teaching purposes only
Figure 3.3.2: Screenshots of the HealthTracker electronic decision support tool: risk communication tool

The Patient details in these screenshots are a mock-up for teaching purposes only.

Figure 3.3.3: Screenshots of the HealthTracker electronic decision support tool: tailored medication recommendations

The Patient details in these screenshots are a mock-up for teaching purposes only.
Sampling and data collection for the QPulse study

Practices were recruited from the geographical catchment of CESPHN between May 2015 and November 2016 (Figure 3.3.4). CESPHN geographically aligns with two NSW state-funded tertiary healthcare regions, Sydney and South-Eastern Sydney Local Health Districts. This region has high population growth and cultural diversity. Around 1.5 million residents live in the catchment, and approximately half (46.1%) of the residents are from a non-English speaking background. There are about 700 general practices located in the region.

**Figure 3.3.4: New South Wales Primary Health Networks (PHNs)**

Several methods were employed to recruit practices, including targeting those that had participated in other QI programs, an informal invitation at professional development or local network meetings, and formal invitation via email, newsletters and a weekly fax communique to GPs and PMs. Practices were eligible if they used one of two electronic medical record software programs (i.e., Medical Director™ or Best Practice™). Baseline data were collected using the CAT 4 automated data extraction tool (PEN Computing Systems), which extracted clinical data from fixed/delimited fields of the eMR
and did not extract it from free text sections. Data extractions only included ‘active’ patients. These were defined as those who had visited a participating practice at least three times during the preceding two years and at least once during the past six months. This is consistent with the Royal Australian College of General Practitioners' (RACGP) definition of an ‘active’ patient. A de-identified data subset from each practice eMR system was extracted, including demographic information, selected medical history, medications, BP, blood lipids, smoking status and any medications prescribed to the patient in the past six months. Data extractions were collected at baseline and study close in each practice.
Chapter 4.0 – Results part 1

Paper 1: Informing implementation of quality improvement in Australian primary care

Informing implementation of quality improvement in Australian primary care

Charlotte Hespe, Lucie Rychetnik, David Peiris and Mark Harris

Abstract

Background: Quality improvement (QI) initiatives in primary care are effective at improving uptake of evidence-based guidelines, but are difficult to implement and sustain. In Australia, state-level health organisations such as Primary Health Care Organisations (PHCO) offer new opportunities to implement area-wide QI programs. This study sought to identify enablers and barriers to implementation of an existing Australian QI program and to identify strategic directions that PHCOs can use in the ongoing development of QI in this environment.

Methods: Semi-structured telephone interviews were conducted with 15 purposively selected program staff and participants from the Australian Primary Care Collaborative (APCC) QI program. Interviewees included seven people involved in design, administration and implementation of the APCC program and eight primary care providers (seven General Practitioners (GPs) and one practice nurse) who had participated in the program from 2004 to 2014. Interviewees were asked to describe their experience of the program and reflect on what enabled or impeded its implementation. Interviews were recorded, transcribed and iteratively analysed, with early analysis informing subsequent interviews. Identified themes and their implications were reviewed by a GP expert reference group.

Results: Implementation enablers and barriers were grouped into five thematic areas: (1) leadership, particularly the identification and utilization of change champions; (2) organizational culture that supports quality improvement; (3) funding incentives that support a culture of quality and innovation; (4) access to and use of accurate data; and (5) design and utilization of clinical systems that enable and support these issues. In all of these areas, the active involvement of an overarching external support organisation was considered a key ingredient to successful implementation.

Conclusion: There are substantial opportunities for PHCOs to play a pivotal role in QI implementation in Australia and internationally. In developing QI programs and policies, such organisations ought to invest their efforts in (1) identifying and mentoring local leaders; (2) fostering QI culture via development of local peer networks; (3) developing and advocating for alternative funding models to support and incentivize these activities; (4) investing in data and audit tool infrastructure; and (5) facilitating systems implementation within primary care practices.

Keywords: Quality improvement, Primary care, Implementation, Leadership, Organisational culture, Data, Primary health care organisations
appropriate care [3]. Barriers that prevent the adoption of best practice often appear to overwhelm clinicians and managers working in primary health care [4].

Quality Improvement (QI) initiatives in primary care have the potential to improve uptake of evidence-based practices, but have been difficult to implement and sustain [5]. QI is a multi-dimensional concept which, in the healthcare context, can be defined as having a systematic approach to making changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning) [6]. Batalden et al. postulate that by defining QI in this way, it allows people to have a measurable approach to the concept of improving healthcare. There are a number of ways to intentionally implement QI initiatives, and one such approach is the establishment of Quality Improvement Collaboratives (QIC). QICs actively bring together groups of practitioners from different organisations to meet and learn about a specific aspect of health service quality and to share experiences about making changes in their local settings. The process specifically supports practitioners to use QI tools such as Plan, Do, Study, Act (PDSA) cycles to achieve improvements.

There has been mixed evidence of success using QICs in health care. A systematic review of 64 QIC programs in 2018 reported significant improvements in 83% of targeted clinical processes and patient outcomes [7]. The authors noted that enthusiasm for these findings must be tempered by reflection on the limitations in design and reporting in many QICs, as well as likely publication bias. Evidence suggests that implementation processes for each QIC may be critical drivers of program success with up to 66 contextual factors identified in a 2014 study as associated with improved outcomes [8].

In Australia the Improvement Foundation (IF) has administered a series of QICs called the Australian Primary Care Collaboratives (APCC) since 2004 [9]. The program was designed in collaboration with the United Kingdom National Primary Care Development Team [10]. The IF was initially commissioned by the Australian Federal government to assist primary care practices in five priority areas: coronary heart disease, diabetes, chronic obstructive pulmonary disease, chronic disease prevention and self-management, and health care access and care redesign. APCC offered General Practices and Aboriginal health services financial incentives to participate in a QIC wave over 18 months. A wave (Fig. 1) comprised an orientation session to the principles of QI, followed by a series of learning workshops (delivered either face-to-face or online). The goal was for each primary care practice to complete requirements of one “wave” during which time Practice staff would each develop a knowledge of QI, understand the principles of measuring for improvement, the use of data in QI, the application of QI tools as well as identify ways to build a team culture and develop effective communication skills to facilitate QI. Clinical and administration staff were expected to attend workshops and submit monthly data to monitor their progress. One thousand one hundred and eighty five primary care health services (16% of all Australian General Practices) and 83% of PHCOs enrolled in the APCC program between 2004 and 2012 [11]. Practice characteristics varied enormously from solo clinician to large multi-disciplinary group practices including Aboriginal Community health centres.

Participants in the APCC program included GPs, practice nurses and practice managers. These staff were encouraged and supported to introduce small, manageable changes in specific areas during the activity periods between workshops. By 2014 over 1800 practices across Australia had participated in at least one program wave (approximately 20% of registered primary care practices in the country) [9]. A before-after evaluation of seven APCC waves involving 743 practices and 150,000 patients over the period 2004–2009 showed improvements in four of the five program areas, with the exception of health care access [5].

For over eight years IF provided QI support to practices directly, however in 2012 the funding contract changed and required them to provide support to government-funded, meso-tier primary health care organisations (PHCO) (previously called Medicare Locals and now called Primary Health Networks (PHN)) who would in turn provide direct support to practices. A review of the program by Knight et al. in 2014 suggested that further institutionalising the QIC from within a PHCO had potential to improve program utilisation, sustainability and spread [4]. The new PHN contracts in 2016 provide an opportunity to capitalise on this potential with the specific inclusion of quality improvement activity to assist in increasing and improving the efficiency and effectiveness of medical services for patients [12]. From 2019 PHNs will be required to support general practices undertake QI programs and to offer assistance in oversight and management of practice data. General Practices will be offered an incentive payment to share their data with an external organisation such as a PHN.

In this paper we report on a qualitative study that sought to identify enablers and barriers to implementation of sustainable QI programs in the primary care setting.

Methods

Participants

Participants for this study were purposively sampled from APCC program staff and practice team members who had participated in QI from around Australia, some
of whom were known to the primary researcher through the APCC program. Interviewees were sequentially selected to provide multiple perspectives, focusing on program governance, operational aspects and front-line clinician experience with varying levels of prior knowledge about Quality Improvement. Three of the interviewees were employees of a PHCO and all the clinicians had personal experience of interacting with local PHCO’s. The background and focus of the study were explained to participants prior to commencing the interviews.

Data collection
Semi-structured telephone interviews were conducted from December 2014—June 2015, ranging from 45 to 60 min in duration. Topic questions were sent via email prior to the interview (see Additional file 1). Participants were invited to reflect on their personal experience of the APCC program, and perceived enablers and barriers to completing the program and factors influencing ongoing participation. Participants were also asked to consider what level of support had been required from their local PHCO to assist practices and local regions to achieve sustainable QI practice. Interviews were recorded, professionally transcribed and supplemented with notes taken by the interviewer.

Analysis
The primary researcher (CH) reviewed the transcripts, conducted a thematic analysis, and prepared synthesis memos which were discussed with each of the other authors. A phenomenological approach [13] was taken to understand participants’ perceptions, perspectives and understanding of the implementation of the APCC program. An initial analysis of five transcripts was used to guide subsequent selection of interviewees by identifying areas where it was helpful to have more data regarding a particular experience (e.g. to gain an increased understanding of the barriers experienced by practice teams). The primary researcher developed descriptors of the emerging themes using a constant comparative approach with themes emerging during iterative review of the interviews. These descriptors were refined following discussion with the research team. There was evidence for data saturation by repetition of themes after 15 interviews. The resultant themes were synthesized into a conceptual model and presented for feedback at four primary care professional conferences during 2015 (see Additional file 2). Feedback from participants at these presentations (Primary care clinicians and staff from Improvement Foundation) was used to re-format the initial thematic groupings, refine the model and elaborate on the study implications. Interviewees were provided with the opportunity to review the presentation findings and ensure their views were adequately represented.

Results
Fifteen people were invited via email and all agreed to participate in the study.

Participant characteristics are listed in Table 1.

The identified QI implementation enablers and barriers were grouped into five thematic areas: Leadership, organisational culture, funding, data and clinical systems. These thematic areas are described below.

Leadership: The value of identifying and supporting change champions
Good leadership by change champions was identified as essential for all three levels of the primary care environment—individual GPs, the practice team and the PHCO itself.

Primary care teams that were most successful at adopting QI culture were able to identify the presence of a change champion, generally described as a GP leader who had the ability to enable change within their group practice and a willingness to adopt and model innovative clinical practices. Several interviewees discussed the role of the PHCOs in facilitating both practice managers and practice nurses, in addition to GPs, to be emergent leaders and change champions for QI within their work environment. These staff were often less visible compared to GPs
Table 1: Demographic details of participants

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<th>Male</th>
<th>Female</th>
<th>Rural</th>
<th>Urban</th>
<th>GP</th>
<th>Practice Nurse</th>
<th>Practice Manager</th>
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<td>3</td>
<td>6</td>
<td>3</td>
<td>7</td>
<td>1</td>
<td>1</td>
<td>9</td>
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<tr>
<td>Primary Health care organisation (PHCO)</td>
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<td>2</td>
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<td>3</td>
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<tr>
<td>APCC staff</td>
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<td>Totals</td>
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but identified as “power brokers” for facilitating system redesign and change of clinical practice.

A critical issue identified by all interviewees was the extent to which individual GPs and practice teams were willing to adopt new ideas or change current practice and the role of leadership in effecting change. Several interviewees adopted the language of Rogers’ Diffusion of Innovations Theory [14] to describe clinicians and practice teams willingness to change within the APCC program. Early adopters, early majority, late majority and laggards. GPs who were considered early adopters in the program, were identified as playing a key role in developing, shaping and adapting change ideas. Change champions often emerged during the APCC process from amongst early adopters e.g. after experiencing small changes within their own practice or whilst participating in high level peer discussions and sharing success stories at face to face meetings with colleagues.

Conversely, GPs who were more resistant to adoption of change ideas, the late majority, had the potential to block QI within a practice team. It was noted that sometimes there was greater variation in clinical practice within a team than between different practices and that this may be better addressed via the shared stories of “external” change champions and clinical leaders.

“So the majority of the practices who sit in that middle part of the change innovation bell curve (the early and late majority) seem to be more willing to start to engage by using the example of ideas shared by other practices who are early adopters or change agents.” RP1

It was also suggested by some interviewees that GPs who were most resistant to adopting changes (laggards) were “not worth pursuing” due to the increased effort required for very little tangible change in the short term.

Organisational culture: Empowering primary care practices to embody a culture of quality improvement

Organisational culture refers to the shared values and beliefs of a primary care team which governs how the people within the team behave. Organisational culture was seen as having a strong influence on the way in which Quality Improvement (QI) ideology was adopted and embraced within the primary health care setting.

The ability to consider and adapt change ideas was a key feature of practices that were described as being successful in QI methodology. Interviewees also spoke about “capacity” for QI as being a driver within the primary care arena. This capacity was influenced by GPs’ motivation to participate, their knowledge of QI and their ability to implement it within the practice setting, as well as access to staff with the skills required to do improvement work. There was strong recognition from all interviewees regarding the need for PHCOs to facilitate QI work within the practice setting. PHCOs that had pre-existing strong relationships with practice teams, and had previously provided hands-on support, practice coaching, professional education and peer to peer mentoring, were best placed to fulfill this facilitation role. Interviewees considered PHCO staff needed to play the role of coach and educator when facilitating QI work. When these roles were performed well, interviewees perceived this to result in better teamwork, more reliable data collection, and increased use of PDSA cycles, improved guideline use, development of change champions and sharing of success stories.

“Practice support has got to be the main job of the Medicare Local, and they need to become deeply knowledgeable about the how to’s...the model of support is more like that of a coach rather than a trainer.” RP1

Interviewees noted the critical need for PHCOs to establish trusted relationships with practice staff. This enabled both easier access by the PHCO staff to practices and a locally tailored approach to supporting QI initiatives that recognised the varied abilities of practice teams to engage in the program. These relationships were considered to vary greatly across the country, depending on both individual PHCOs and the staff. It was noted that government changes to the structure of PHCOs in Australia over the past five years had also resulted in changes to prioritisation of QI and their capacity to support General Practice. Interviewees noted a high level of dissatisfaction regarding the decreased prioritisation for general practice support from the former Medicare Local, and opportunities to redress this with the formation of new Primary Health Networks.
A benefit of the collaborative nature of the QI process, as experienced through the APCC, was the ability for primary care teams to share ideas and solutions for common problems, which helped to build a culture of “improvement” within practice teams. Interviewees described how participants in the QI process valued the conversations among clinical peers about clinical decision making. This included the value of working as a team member rather than working autonomously, whether that be in a group practice or as a solo clinical practitioner surrounded by non-clinical team members. Many GPs commented that they were working in systems designed to maintain individual clinician autonomy and this served as a barrier to a more systematised team-based approach.

“I think the biggest barrier really is practice culture, if the practice is really a building where a lot of independent GPs see a lot of patients, they’re not really keen to work as a team or review practice data – this isn’t really what they’re on about in terms of managing a population. So I think one of the barriers is actually philosophical.” 10 PC

For clinicians within larger practices this 'philosophical' barrier was often overcome by peers praising the value of working as a part of a team with shared responsibility for patient care and a reduced feeling of being overwhelmed by the workload, resulting in easier implementation of team-based systems.

Financial incentives: The role of funding incentives to generate change
GPs in Australia are primarily remunerated under Medicare - a public, universal insurance scheme based on a scheduled fee for face-to-face consultations and procedures. General Practices that have met accreditation standards are also able to access additional funding called “Practice Incentive Payments” (PIP) which are not directed to specific GPs and are linked to specific Government targets such as immunisation and adoption of digital systems. Over sixteen years Medicare has also introduced specific service items that encourage planned and preventative healthcare. However, there is currently no reimbursement for specific quality improvement related work. Participants all commented about the barrier of current funding mechanisms for promoting QI activities.

“I think the experience has clearly shown that GPs will do what brings in money, because we are small business people and we do need to fund what we’re doing” 13 PC

This poses challenges to engagement with QI work because “quality” may not equate to increased income, and could even lead to decreased revenue under the current funding model.

Participants commented on the role of PHCOs in assisting practices develop innovative systems for service delivery that could lead to both improved financial benefits and quality health outcomes by aligning service incentives with systematised quality care planning. They commented that this helped to address reluctance to participate in work that was perceived to be of low value from a business revenue perspective. There was general consensus that lack of financial incentives could also be partially addressed if PHCO staff provided hands on support within practices to conduct IT related work such as data extraction and analysis.

Data: The transformational value of good clinical data systems
All interviewees emphasised the crucial role that data and IT systems played in participation and successful implementation of QI by general practice teams. By “data” interviewees were referring to coded clinical information within electronic health records amenable to data extraction to generate practice and/or GP specific reports. Interviewees all identified that the quality of data and the ability to provide regular accurate reports about practice populations was key to enabling QI work. For example, if a practice used software that was compatible with the data extraction tools then they were able to easily adopt QI ideas to improve their data quality. In contrast, Practices using software that was not compatible found it too challenging to try and create their monthly data reports.

Insufficient technical support and expertise within practices around data and IT systems were identified as a significant barrier in the uptake of QI work. All interviewees talked about the frustrations experienced by practice teams over difficulties of “data cleansing”, data extraction, generation of reports, interconnectivity of IT systems and establishing uniform coding systems amongst the clinicians. Clinician interviewees emphasised the need for hands on “doing” support from PHCO staff such as assisting in data downloads and generating useful reports. APCC staff also emphasised the role of the APCCs as a mentor, imparting knowledge and training about systems and data.

All interviewees discussed the key role that PHCOs could play in assisting practice teams to understand the power of having accurate medical records and improved data quality. The APCC program required practices to generate monthly reports against specific clinical measures. Interviewees reported that on average it took practices six months to “clean up” data before they could use the reports to find possible gaps in care. It was felt that most GPs lacked training to fully appreciate the
benefits of measureable data and consequently needed support in learning how to record and utilise clinical data in meaningful ways.

“You need to engage people in constantly measuring their outcomes, understanding the gap and saying ‘how do we then bridge the gap’. Most people need leadership down that path...a clear aim and some structure to take participants on a long journey because it’s not as simple as just turning on or off a switch.” 6 PHN

“High performing” practices demonstrated structured approaches to IT and data management. They had systems for uniform data entry and coding and documented procedures for systems of care such as Diabetes annual cycle of care. PHCOs were seen as a potential conduit for sharing these systems amongst other practices.

Structured clinical systems: Improving health outcomes through organised frameworks of care
The final theme describes the need for GPs, practice teams and PHCOs to use structured systems as an overarching framework to enable implementation of QI methodology and achieve desired outcomes. Thus the work of change champions, adoption of QI culture, financial drivers and data driven improvements were considered to be enhanced by well organised clinical systems.

Interviewees commented that successful practices designed systems that were streamlined (automated if possible) and easy to adopt. Clinicians (GPs and practice nurses) would not adopt changes that took more time and were difficult to fit into their consultation routine no matter how important they may have appeared clinically.

“It’s got to make it easier to do the right thing. So, yes, benefitting patients is certainly an important part of that, but actually, if it takes me three times as long to do that same task, it’s not going to happen, so it’s got to make it easier for the clinician to do the task as well.” 8 PC

Sharing of success stories via webinars or at workshops from other practice teams facilitated the development of user friendly clinical systems.

Interviewees considered that PHCOs would be well positioned to establish local QI networks or forums where clinicians were provided with an opportunity to discuss high level evidence, current best practice and practical ways to achieve better health outcomes both at an individual and practice level through system redesign.

There was general consensus that a standout benefit of the APCC program had been the access to a network of likeminded peers that facilitated discussion around the design of systems for improving health outcomes in the primary care setting.

Interviewees noted that ensuring all team members were engaged in the adoption of changes in systems also assisted in minimising the problem of loss of ‘corporate memory’ due to staff turnover. This was particularly identified as a barrier when there had only been one or two staff members assigned to the role of overseeing QI projects and implementation. Practice teams who achieved higher success in the APCC program outcomes were noted to have developed communication systems inclusive of all team members and espoused a philosophy of teamwork and systematised care.

Discussion
The APCC program has provided a rich context for identification and analysis of enablers and barriers for QI in the Australian setting. Participants of the program provided useful insights into possible future implementation strategies.

Health systems internationally are investing in primary care meso-tier organisation to reduce fragmentation and improve system performance. Whilst there is substantial variation in the specific roles they play in the system, ranging from commissioning (Clinical Commissioning Groups in England [15]), financial accountability and provision of financial incentives (Accountable Care Organisations in United States of America [16]), direct service provision (Primary Health Organisations in New Zealand [17]), engagement in quality improvement activities is a common element and therefore the themes found in this study are likely to be relevant in an international context.

Primary Health care is a complex environment that benefits from structured systems of care to assist the adoption of best practice. The privatised model of Australian general practice acts as financial and philosophical barrier to widespread adoption of QI programs. Primary Health Networks (PHN) have an opportunity to assist in countering these barriers and implement solutions that are tailored to local health care needs.

Studies regarding the role of meso-level organisations in primary health care in UK, Canada and New Zealand suggest that such organisations can play an important role in facilitating a more integrated health system and promoting peer collaboration with resultant improvements in efficiency and quality of care [18–21]. The impact of PHCOs such as PHNs could be optimised by emphasising relationship building between the external facilitators and general practices. Trusted relationships have been demonstrated to play a key role in assisting adoption of evidence based improvements in the
healthcare environment [22, 23]. Ideally these trusted relationships will be established at both the individual and organisational level.

The five study themes identified in this study (leadership, organisational culture, funding, data and clinical systems) are closely aligned with four out of ten building blocks of high performing primary care practices described in 2014 by Bodenheimer et al. [24]. The 10 Building Blocks framework describes leadership, data driven improvement, empanelment (patient registration) and team based care as the foundation for implementation of a model for innovative thinking, improvement and primary care transformation. The challenge for the primary care setting both internationally and in Australia will be to identify and mentor local clinical leaders and change champions to facilitate the adoption of QI. The role of PHCOs in overseeing the process as well as demonstrating organisational culture in keeping with QI will be critical. This resonates with the findings of Kaplan et al. who reviewed 47 articles regarding QI in healthcare and linked success of QIC programs to high level leadership, organisational culture, data infrastructure, clinician involvement and the number of people involved in QI programs [8]. Nicholson et al. in 2013 discussed the role of meso-level primary care organisations in realising integrated health system reforms and identified ten key governance elements as key for PHCOs success, including measurement and data for quality improvement, incentives and professional education [25]. This aligns with our finding that PHCOs be tasked with a substantive facilitator role in QI implementation. In practical terms this requires PHCO staff effectively engaging and supporting individual GPs and practice teams in QI processes. Specific suggestions for such processes are outlined in Table 2.

The process of GP clinical decision making that assists the adoption of evidence based guidelines is complex. Ghabhay and le May coined the term “mindsight” to describe the GP process of internalising tacit guidelines, informed by professional reading and social interactions (opinion leaders, patients, colleagues), resulting in a socially constructed response to guidelines rather than a rigid protocol [26]. Peer networks can assist GPs in the active formulation of these “mindsight”. A PHCO-facilitated network could provide an evidence-based, social and professional platform for these interactions and establish trust between both the PHCO and individual practice teams and GPs. An example would be a group of GPs meeting to network about QI topics, once a month at a time and venue of their choice, facilitated by the PHCO.

PHCOs may also assist GPs in the philosophical adoption of system change within their workplace. For instance, the change in emphasis to systematised team based care has not been widely adopted in the Australian general practice setting and this is likely to be related to a perceived loss of individual GP clinician’s autonomy such as described by Hall in 2009 regarding professional cultures as barriers to interprofessional teamwork [27]. PHCOs can share stories of change from other local general practices that illustrate the benefits of team based care such as improved time management and decreased stress via the peer networks.

To engage individual practitioners long term, it is important to recognise the role of both practice structures and financial incentives. Under the current Australian payment model, lack of direct financial incentives for quality improvement is a significant barrier for many GPs and practice managers. This can affect practice teams’ ability to quarantine sufficient time and resources to implement QI programs. PHCOs are well-positioned to assist practice teams through provision of staff and IT tools. Long term engagement in QI programs will also require modification to the fee-for-service funding models. The Australian government is currently trialling a new model of payment for patients with chronic and complex disease where practices will receive a bundled payment to manage patients whom agree to be enrolled in a “healthcare home” [28]. This is a substantive health reform that has potential to shift primary care remuneration to a more outcomes focussed payment model, and there may be important opportunities for PHCOs to engage clinicians and practice teams in making this transition.

We note the following study limitations. Firstly the interviewees did not include those from general practices with no contact with APCC. While this sampling aligned with the study goals of eliciting lessons from participants’ experience of the APCC, their views may reflect a

<table>
<thead>
<tr>
<th>Table 2 Suggested process through which PHCOs can support QI implementation in general practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Training: Practice Coaching, CPD events, webinars, small groups</td>
</tr>
<tr>
<td>- Educate: Improvement theory, clinical microsystems, PDSA, evidence based guidelines</td>
</tr>
<tr>
<td>- Practice support: Data management / Point of care decision tools, Strong relationships with the General Practices, IT/AC accreditation support, upskill practices to be ready to adopt QI work</td>
</tr>
<tr>
<td>- Modelling: Sharing of stories and successes by early adopters / QI Networking of General Practices</td>
</tr>
<tr>
<td>- Leadership: Identification; Support leadership training across the region</td>
</tr>
<tr>
<td>- Incentivisation: Showcasing financial framework / accessing innovative funding</td>
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</tbody>
</table>
potential bias toward philosophical alignment with QI. Further study among non APCC participants may identify additional barriers to QI implementation. We also note that the first author was known to all the interviewees due to her involvement in APCC from 2008 until 2012 as a participant and clinical lead. While this allowed potential for some degree of social desirability bias, it was apparent from the interviews that the study participants felt comfortable to report and discuss both positive and negative experiences of the APCC program.

Conclusion
PHCOs such as the Australian PHN are well poised to facilitate transformation of primary care through a range of mechanisms identified in this study. However, the challenges to achieving this in the current policy environment are important to recognise and should not be minimised. In developing QI programs and policies, such organisations ought to invest their efforts in: (1) identifying and mentoring local leaders; (2) fostering QI culture through development of local peer networks; (3) developing and advocating for alternative funding models to support and incentivise these activities; (4) investing in data and audit tool infrastructure; and (5) facilitating systems implementation within primary care practices. If these opportunities are maximised the PHCOs will be well positioned to make a major contribution to improved delivery of health outcomes in the primary care arena.

Additional files

**Additional file 1** Interview Guide – questions sent to all interviewees prior to interview and used as the basis for each interview. (DOCX 13.1 kb)

**Additional file 2** Feedback regarding research findings. Presentations of the findings where feedback was sought from a wider setting. (DOCX 13.1 kb)

Abbreviations
APCC, Australian Primary Care Collaborative; GP, General Practitioner; IF, Improvement Foundation; PE, Plan, Do, Study, Act; QI, Quality Improvement; QIC, Quality Improvement Collaborative

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Funding
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Availability of data and materials
All available data can be obtained from the corresponding author. All data will be shared in a way that safeguards the confidentiality and anonymity of the respondents.

Authors contributions
CI formulated the questions for the study and conducted the interviews and qualitative analyses of transcripts. LS, DP and MH assisted in the review of the analyses and interpretation of the data. CI drafted the manuscript, and all authors revised the manuscript and approved the final version to be published.

Ethics approval and consent to participate
This study was granted research ethics approval by The University of Notre Dame Australia, Human Research Ethics Committee on 11 August 2014 (Project ID 14-1-155). Participants were recruited and consented via email and telephone invitations. All participants consented both verbally and in writing to receive consent forms.

Competing interests
The authors declare that they have no competing interests.

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References
Appendices for Chapter 4

Interview Guide

What are Qualities of practices - Predictors of success that are inherent within practices?
What is it in a wave that makes it successful – what particular inputs are provided to enhance success at the practice level?
What are the barriers to success or completion in a wave?
What do you think would achieve sustainable changes in practices?
Implementing cardiovascular disease preventive care guidelines in general practice: an opportunity missed

Charlotte M Hespe1, Anna Campain1,2, Ruth Webster3, Anushka Patel4, Lucie Rychetnik5,6, Mark F Harris5,6, David P Peiris5

Cardiovascular disease (CVD) is the leading cause of death in Australia. New treatment guidelines based on absolute CVD risk estimates were adopted in 2012. General practitioners are central to implementing these guidelines, as about 90% of people in Australia consult GPs each year, but large evidence-practice gaps in the management of people with CVD in general practice have been reported.

We therefore examined implementation of the 2012 CVD guidelines in general practice by analysing baseline electronic medical record (eMR) data from two clinical trials of computer-supported interventions for improving CVD care conducted during 2015–2018, the INTEGRATE7 and Q Pulse studies.8 Our analysis is based on data for 102 225 patients from 98 general practices in four Australian states and territories. The study was approved by the Human Research Ethics Committees of the University of Sydney (reference, 2015/66) and the University of Notre Dame (reference, 14/61O/0121).

De-identified eMR data — demographic information, medical history, prescribed medications, smoking status, blood pressure, low-density lipoprotein cholesterol (LDL-C) levels — were extracted at each practice with the CAT 4 Clinical Audit tool (PenCS). Absolute CVD risk was calculated according to current guidelines9 and patients with a documented CVD diagnosis (coronary heart disease, cerebrovascular disease, peripheral vascular disease, left ventricular hypertrophy, atrial fibrillation, or heart failure) were identified (Box 1).

Guideline-recommended treatment was defined as the prescribing of blood-pressure- and lipid-lowering medications for patients at high CVD risk, and also of antiplatelet or anticoagulant medications for patients with established CVD (Supporting Information). The proportions of patients who had attained treatment targets for blood pressure (<140/90 mmHg for patients at high CVD risk, <130/80 mmHg for people with established CVD or diabetes) and LDL-C level (<2.0 mmol/L) were calculated.

Of 102 225 patients in the two studies, 10 631 (10.4%) had established CVD and 12 983 (12.7%) clinically high risk conditions; estimated CVD risk was high for 2760 (2.7%) and low or intermediate for 46 205 people (45.2%), while the available eMR data were inadequate for estimating risk for 29 643 participants (28%).

1 Flow chart of patient risk and treatment identification

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1 The University of Notre Dame, Australia, Sydney, NSW. 2 The George Institute for Global Health, Sydney, NSW. 3 University of New South Wales, Sydney, NSW. 4 The Australian Health Prevention Partnership, Sir Charles Gairdner Hospital, Perth, WA. 5 Centre for Primary Health Care and Equity, University of New South Wales, Sydney, NSW. 6 Office of the Chief Scientist, The George Institute for Global Health, Sydney, NSW. 7 charlotte.hespe@nd.edu.au. doi: 10.5861/ijgpm.30.077.

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* Including Aboriginal and Torres Strait Islander people aged 35 years or more and non-Indigenous Australians aged 45 years or more, and people of any age with clinically high risk of CVD.

** Absolute CVD risk was defined as the proportion of people at least three times the global average during the preceding 12 months, or at least seven times during the preceding six months. 7 Australian Cardiovascular Risk Calculator (based on the Framingham Risk Equation). High CVD risk defined as either 5-year risk exceeding 15%, or presence of a clinically high-risk condition. 8 Clinically high-risk conditions: people with diabetes and over 65 years of age, diabetes and albuminuria, estimated glomerular filtration rate below 65 ml/min/1.73 m², systolic blood pressure above 160 mmHg, or diastolic blood pressure exceeding 105 mmHg.
### Research Letter

**2 Prescribing practices and attainment of blood pressure and lipid targets for patients with established cardiovascular disease or at high risk of cardiovascular disease**

<table>
<thead>
<tr>
<th>Established cardiovascular disease</th>
<th>High cardiovascular disease risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>10 631</td>
</tr>
<tr>
<td>Medications prescribed</td>
<td></td>
</tr>
<tr>
<td>No risk-lowering medications</td>
<td>2137 (20.1%)</td>
</tr>
<tr>
<td>Blood pressure-lowering medication only</td>
<td>1340 (12.6%)</td>
</tr>
<tr>
<td>Lipid-lowering medication (statin only)</td>
<td>116 (10.5%)</td>
</tr>
<tr>
<td>All guideline treatments*</td>
<td>6038 (56.9%)</td>
</tr>
<tr>
<td>Clinical targets achieved</td>
<td></td>
</tr>
<tr>
<td>Blood pressure†</td>
<td>4714 (43.7%)</td>
</tr>
<tr>
<td>Low-density lipoprotein cholesterol‡</td>
<td>5645 (53.1%)</td>
</tr>
</tbody>
</table>

* One or more blood pressure-lowering medications and a statin, for people with established cardiovascular disease, either on a statin-based or non-statin-based regimen is also recommended (Supporting Information). † High cardiovascular disease risk = 10% 20% mortality; established cardiovascular disease or diabetes ≥ 10% 20% mortality. ‡ ≥ 2 mmol/L.

Among patients with established CVD, 6038 (56.9%) had been prescribed the guideline-recommended treatments; blood pressure targets had been achieved by 4134 patients (38.7%) and LDL targets by 5645 (53.1%). Among the 15 743 patients at high CVD risk, 6486 (41.2%) were prescribed recommended treatments; 8988 (57.1%) had achieved blood pressure targets and 5734 (36.3%) LDL-C targets (Box 1, Box 2).

Our findings indicate that primary care management of patients with CVD is sub-optimal. Adopting the absolute risk assessment approach has not improved adherence to management guidelines, similar to the experience in Europe, Canada, and the United Kingdom. We may have underestimated CVD risk for patients already receiving blood-pressure- and lipid-lowering therapies. Risk estimates were based on information in eMR structured data fields; additional information recorded as free text was not considered. Rural and Aboriginal Medical Service practices were underrepresented in our practice sample.

GPs play essential roles in identifying patients at risk of CVD and managing their treatment, but ensuring their adherence to evidence-based recommendations is challenging. While risk assessment tools are important, overcoming patient, GP, and health system barriers to changes in care delivery will be critical to progress.

**Acknowledgements:** The University of Notre Dame received a Rapp Health Foundation grant for research into cardiovascular diseases and diabetes, that funded the Q Health study and is quality improvement project in GP practices in the Central and Eastern Sydney Primary Health Network. Both authors are supported by a National Health and Medical Research Council (NHMRC) Early Career Fellowship (APP1173863), Arnaud Polat by an NHMRC Principal Research Fellowship (APP1043889), and David Pate1 by a Heart Foundation Future Leaders Fellowship (191050) and NHMRC Career Development Fellowship (APP1191394).  

**Competing Interests:** George Health Enterprises, the social enterprise arm of the George Institute for Global Health, has received funding for the development of head-dose combination therapy, and has commercial relationships involving digital innovations similar to the interventions in the INTEGRATE study.

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Implementing cardiovascular disease preventive care guidelines in general practice: an opportunity missed

To the Editor: The research letter by Hespe and colleagues on cardiovascular disease prevention is itself a missed opportunity to illuminate the complexities of person-focused management of patients in general practice. While it provides a snapshot on cardiovascular disease prevention, it does not offer any exploration of the veracity or otherwise of these findings. Aggregate decontextualised and — as acknowledged — limited data ultimately fail to identify the true nature of the problem. Simply focusing on easily extractable data from computerised medical record systems, without linkage to the unique features and context of the person to whom these data belong, necessarily results in a distorted picture. Big data has the potential to inform only if it is appropriately interpreted and may be useful in process monitoring. Such data have a limited role in assessing general practitioner performance and outcomes of care.²

One must always remember that guidelines are nothing more than guides, which must be appropriately adapted to the unique circumstances of each patient. A more relevant research question would be: how appropriately or inappropriately are preventive treatments applied? This question addresses both overtreatment and undertreatment.³ As a binary question, however, it fails to ask more important contextual questions such as whether the patient can cope with the demands of the treatment, whether the treatment decision is a truly informed one, and whether it fits the needs and expectations of the patient given other health concerns. It ignores entirely the impact of a therapeutic alliance on actual health outcomes.³ Finally, the implied need for a hawkish attitude to prevention must take account of the fact that no intervention is risk-free. Our obligation clearly states primum non nocere.

Research aiming to improve understanding of the interdependencies inherent in each and every consultation is urgently needed. The health and wellbeing outcomes of medical care are far less determined by biomedical interventions than by the contextual stressors in a person’s life.⁴ Providing general practice with the tools and resources to truly address the complexities of our patients’ needs is of utmost urgency.

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Implementing cardiovascular disease preventive care guidelines in general practice: an opportunity missed

In reply: We thank Sturmberg and Martin for their thoughtful comments on our MJA research letter, which highlight the potential for an overly reductionist approach when using big data to examine the implementation of guidelines in real-world general practice. As they note, there are many nuances and assumptions inherent in using general practitioner electronic medical record data and we agree that this does not provide a holistic account of the complex care practices that are jointly negotiated between care provider and patient.

In terms of setting performance benchmarks, we are not advocating that best practice should be defined as 100% adherence to guidelines. There are often well-considered, important reasons why GPs and patients may choose not to follow guideline recommendations. However, the gaps we measured in our study are large and this is unlikely to offer a complete explanation for what we observed.

While an individualised approach is entirely appropriate, we must also be cautious that this is not used to justify an ad hoc approach to clinical care. Audits against guideline recommendations and feedback should focus on known gaps and provide an opportunity for reflection and continuous improvement.

We agree that assessing performance in health care is complex and that traditional performance measurement may not acknowledge interdependence between different parts of the health care system and could restrict its focus to measurable outcomes rather than processes. Our study demonstrates a need to improve cardiovascular disease risk identification and management, but it should be considered as only one part of a multidimensional approach to understanding and improving performance. We support the need for a more comprehensive understanding about what occurs at multiple levels of the primary health care and hospital sectors, utilising a range of quantitative and qualitative data sources to shed more light on this multifaceted issue.

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References are available online.
Letter

Appendices for Chapter 5

A. In-scope patients were both regular patients of the practice and those recommended by current guidelines for cardiovascular disease [CVD] risk assessment. This included Aboriginal and Torres Strait Islander people ≥ 35 years and all others ≥ 45 years; and those at clinically high risk of CVD regardless of age [defined in supplementary material B]. ‘Regular attenders’ included patients who attended the practice at least three times in the previous 24 months, and at least once in the previous 6-month period.

B. CVD risk was calculated as per the Australian Risk Calculator which uses the Framingham Risk Equation, and high CVD risk defined as either: [i] 5-year risk > 15%, or [ii] presence of clinically high-risk conditions [including diabetes and age >60 years, diabetes and albuminuria, eGFR <45ml/min/1.73m², systolic BP>180mmHg, diastolic BP > 110mmHg or total cholesterol >7.5 mmol/L]. [2]

C. A complete list of the medicine active ingredients audited in the study

1. Anti-coagulant medications
   - APIXABAN
   - BIVALIRUDIN
   - DABIGATRAN
   - DALTEPARIN
   - ENOXAPARIN
   - FONDAPARINUX
   - HEPARIN
   - RIVAROXABAN
   - WARFARIN

2. Anti-platelet medications
   - ABCIXIMAB
   - ASPIRIN
   - CLOPIDOGREL
   - DIPYRIDAMOLE
   - EPTIFIBATIDE
   - PRASUGREL
   - TICAGRELO
   - TICLOPIDINE
   - TIROFIBAN

3. Antihypertensive medications
   - AMLODIPINE
ATENOLOL
BENDROFLUAZIDE
BISOPROLOL
BUMETANIDE
CANDESARTAN
CAPTOPRIL
CARVEDILOL
CHLORTHALIDONE
CLONIDINE
DIAZOXIDE
DILTIAZEM
ENALAPRIL
EPROSARTAN
FELODIPINE
FOSINOPRIL
HYDRAZINE
HYDROCHLOROTHIAZIDE
INDAPAMIDE
IRBESARTAN
LABETALOL
LERCANIDIPINE
LISINOPRIL
LOSARTAN
METHYLDOPA
METOPROLOL
MOXONIDINE
NEBIVOLOL
NIFEDIPINE
NIMODIPINE
OLMESARTAN
OXPRENOLOL
PERINDOPRIL
PHENOXYBENZAMINE
PINDOLOL
PRAZOSIN
PROPRANOLOL
QUINAPRIL
RAMIPRIL
SOTALOL
SPIRONOLACTONE
TELMISARTAN
TRANDOLAPRIL
VALSARTAN
VERAPAMIL

4. Lipid Lowering medications – Fibrate
FENOFIBRATE
GEMFIBROZIL

5. Lipid Lowering medications – Statin

ATORVASTATIN
FLUVASTATIN
PRAVASTATIN
ROSUVASTATIN
SIMVASTATIN

6. Lipid Lowering medications – Other

CHOLESTYRAMINE
COLESTIPOL
EZETIMIBE
NICOTINIC ACID
Chapter 6.0 – Results part 3

Paper 3.0: Findings and lessons learnt implementing a cardiovascular disease quality improvement program in Australian primary care: a mixed-method evaluation

Findings and lessons learnt implementing a cardiovascular disease quality improvement program in Australian primary care: a mixed method evaluation

C. M. Hespe1*, K. Giskes1,3, M. F. Harris3 and D. Pelir3

Abstract

Background: There are discrepancies between evidence-based guidelines for screening and management of cardiovascular disease (CVD) and implementation in Australian general practice. Quality-improvement (QI) initiatives aim to reduce these gaps. This study evaluated a QI program (QIPulse) that focussed on CVD assessment and management.

Methods: This mixed-methods study explored the implementation of guidelines and adoption of a QI program with a CVD risk-reduction intervention in 34 general practices. CVD screening and management were measured pre- and post-intervention. Qualitative analyses examined participants’ Plan-Do-Study-Act (PDSA) goals and in-depth interviews with practice stakeholders focussed on barriers and enablers to the program and were analysed thematically using Normalisation Process Theory (NPT).

Results: Pre- and post-intervention data were available from 15 practices (n = 19,562 and n = 20,249, respectively) and in-depth interviews from seven practices. At baseline, 45.0% of patients had their BMI measured and 15.6% had their waist circumference recorded in the past 2 years and blood pressure, lipids and smoking status were measured in 72.5, 61.5 and 65.3% of patients, respectively. Most high-risk patients (57.5%) were not prescribed risk-reducing medications. After the intervention there were no changes in the documentation and prevalence of risk factors, attainment of BP and lipid targets or prescription of CVD risk-reducing medications. However, there was variation in performance across practices with some showing isolated improvements, such as recording waist circumference (0.7-32.2% pre-intervention to 18.5-69.8% post-intervention), BMI and smoking assessment. Challenges to the program included: lack of time, need for technical support, a perceived lack of value for quality improvement work, difficulty disseminating knowledge across the practice team, tensions between the team and clinical staff and a part-time workforce.

Conclusion: The barriers associated with this QI program was considerable in Australian GP practices. Findings highlighted they were not able to effectively operationalise the intervention due to numerous factors, ranging from lack of internal capacity and leadership to competing demands and insufficient external support.

Trial registration: Australian New Zealand Clinical Trials Reference Number (ACTRN1261500108516), registered 06/02/2015.

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Background
Cardiovascular diseases (CVD) are the leading cause of death worldwide, despite major declines in morbidity and mortality over the last 40 years [1]. In 2015, CVD was responsible for 29% of deaths, and over 1.1 million hospital admissions in Australia [2, 3]. CVD burden can be reduced through risk-factor modification [4]. Around two-thirds of Australians have three or more modifiable risk factors such as tobacco smoking, high blood pressure (BP) or cholesterol, physical inactivity, poor nutrition, or overweight/obesity [1, 5]. Most international guidelines recognise that these risk factors collectively contribute to an individual’s overall or ‘absolute’ risk, and that management decisions should be based on multiple risk factors [6–7]. In 2012, the National Vascular Disease Prevention Alliance launched Australia’s first absolute risk-based management guideline bringing together several guidelines into a single cohesive approach [5].

General Practitioners (GPs) play a major role in mitigating CVD morbidity and mortality, and see over 85% of the population (approx. 20 million consultations) in Australia annually [8]. However, studies have shown sub-optimal assessment and management of CVD risk. A 2006 study of The Bettering the Evaluation and Care of Health (BEACH) data found that patients at high risk of CVD were substantially under-treated [9]. In 2010, the AusHEART study found only 34% of patients at high CVD risk were prescribed both a BP-lowering medication and a statin [10] and with 2011/12 National Health Survey data Banks et al. showed that almost half (47.1%) of high-risk patients were not taking any guideline-recommended medications [4]. In 2012, baseline data from the TORPEDO randomised controlled trial found that only 48% of patients were appropriately screened for CVD risk [11], and similar findings were documented in a more recent review of Australian data from 2015 to 18 that showed 47.9% of patients had CVD risk screening and only 41% of high-risk patients were prescribed risk-reducing medications [12].

Quality Improvement (QI) initiatives in primary care have the potential to improve uptake of evidence-based practices [13]. QI is a multi-dimensional concept, which can be defined as having a systematic approach to making changes that will lead to better patient outcomes (health), enhanced system performance (care) and improved professional development (learning) [14]. There are several ways to intentionally implement QI initiatives, with one approach being the establishment of a Quality-Improvement Collaborative (QIC). QICs bring together groups of practitioners from different ‘organisations’ to learn about a specific aspect of health service quality, and to share experiences about making changes in their local settings. There has been mixed evidence of success implementing QICs in health care [15, 16]. However, a systematic review of 64 QIC programs in 2018 reported significant improvements in 83% of targeted clinical processes and patient outcomes [17].

The current study applied a QIC approach to improving CVD management in the ‘real world’ of Australian general practice in one Primary Health Network (PHN) in Sydney, Australia. Study aims were to: (1) assess whether a brief QIC program was associated with improvements in the monitoring, prescribing practices and attainment of BP and lipid targets for CVD risk reduction; and (2) understand barriers and factors driving implementation and adoption of the QIC.

Methods
A mixed-methods sequential study design utilised data from the Q Pulse study (Central and Eastern Sydney General Practice Quality Improvement Network: building a sustainable model of QI to achieve reduced cardiovascular disease in the primary care setting) [12, 18]. The program was developed by the research team who had extensive involvement and collaboration with the PHN with a number of programs over the past decade. The QIC was designed to be overseen and coordinated by CESPHN to complement previous quality improvement programs and utilise existing relationships between PHN staff and the general practices. Prior to commencement, the study protocol was approved and registered by the Australian and New Zealand Clinical Trials Registry (https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=1261500108516). A protocol and set of QI resources were developed for the PHN to implement the program.

A Q Pulse program officer was employed by the PHN. She worked as part of the PHN QI team who oversaw the other QI projects within their footprint. All PHN staff working on Q Pulse received standardised training from the research group in the CVD risk-reduction intervention, the QIC program and the implementation processes. The QI team facilitated the workshops and oversaw the Plan Do Study Act (PDSA) activity. There were regular program updates and meetings with both PHN staff and the research group to support the program roll-out.
including discussion around recruitment and implementation. Similarly, there were regular meetings between the lead researcher and program officers to discuss issues and difficulties with the intervention and program implementation.

**General practice recruitment**

Practices were recruited from the geographical catchment of Central and Eastern Sydney Primary Health Network (Australia) between May 2015 and November 2016. Practice recruitment is outlined in Fig. 1. PHNs are federally-funded meso-tier organisations tasked with supporting the primary health care system, commissioning of services, and working collaboratively to integrate health services within their region. A number of methods were employed to recruit practices, including targeting those that had participated in other QI programs, informal invitation at professional development or local network meetings, and formal invitation via email, newsletters and/or weekly fax communiques to GPs and practice managers (PM).

Practices were eligible if they used one of two electronic medical record software programs (i.e. Medical Director™ or Best Practice™) for recording risk-factor information, pathology results and prescriptions. There was a total of 127 eligible general practices from a possible 670 in the CESPHN catchment that were approached to participate. Reasons given to the PHN team from 41 of invited non-participating practices included: not enough time, staffing limitations, competing priorities, CVD not being a practice priority area, and not wanting to participate in research.

There were three waves of recruitment between April 2015 - July 2017; 25 practices were included in Wave 1, nine in Wave 2 and nine in Wave 3. Wave 3 was subsequently cancelled due to lack of PHN staff resources, and consequently only practices from Waves 1 and 2 (n = 34) participated, with three withdrawing. Practice participation rates were lower than anticipated, and the study did not achieve the target recruitment of 80 practices prior to cessation of recruitment. Recruitment ceased after the PHN felt unable to provide resources to the program, in November 2017. Complete pre- and post-intervention data were available from 15 GP practices. In 16 practices complete data-sets were not successfully extracted using the data extraction software due to a technical problem.

![Fig. 1 Practice Recruitment to the CPulse study](image-url)
in the extraction of prescribed medications from some of the practice records, and issues in the automated delivery of the extracted data to the secure study portal (see Fig. 1). These software problems resulted in baseline data only being available for 13 of the participating practices (9 practices in wave 1, 4 practices in wave 2). Data extraction failed for both baseline and follow-up data extractions in 3 Wave 1 practices. Practices included in the study covered the geographic area of the PHN, represented practices with different billing structures (i.e., bulk- and private-billing) and included both independent- and corporate-owned practices.

The baseline patient characteristics of the 19 services with only pre-intervention data were similar to the 15 with complete (i.e., pre- and post-intervention) data (Supplementary Table 1) that have been included in this study. There were no differences in baseline patient demographic, CVD assessment and risk factor profiles between the two samples.

Quality improvement program

The QPulse program ran over 22 months (May 2015 – February 2017). Participating practices provided the PHN with baseline, de-identified patient data of ‘regularly attending’ patients (defined below). The PHN generated feedback reports at the commencement of the intervention (using baseline data) for each practice targeting the CVD guidelines.

At least one stakeholder from each practice, such as a practice nurse, senior GP or PM attended three 2-h workshops over 3 weeks. Topics covered: CVD risk assessment tools, absolute risk calculators, current guidelines for preventive CVD management including pharmacological management of high-risk patients, QI theory and specifics on how to achieve change using the Plan Do Study Act (PDSA) methodology [19]. By planning a change, trying it, observing the results, and acting on what was learned, participants were guided through a rapid feedback exercise to generate change ideas for their practice. Depending on their specific aim, practice teams were asked to choose ideas to test on a small scale and refine the change as necessary before implementing successful ideas more broadly. Each practice team was asked to submit a monthly PDSA report to the PHN to assist them in planning and measuring change.

During the workshops, participants were also trained in the use of two quality-improvement software tools supplied to each practice: (1) a desktop ‘point of care’ tool, ‘HealthTracker’; a software application that works in conjunction with the electronic medical record to identify high-risk patients and provides GPs with ‘real time’ personalised guideline recommendations pertaining to cardiovascular risk reduction; and (2) PenCAT Clinical Audit Tool™ a data extraction tool installed onto the computer server at each Practice. PenCAT enabled practices to download specific audit reports containing de-identified patient data on demographics, CVD disease statistics and prescribing information. A data extraction could be performed as frequently as practice staff desired to assist with the PDSA process and was the basis of the monthly data report sent to the PHN.

Members of each general practice were also invited to attend monthly webinars after the initial three workshops to collaboratively share their progress and ideas for change with other participating practice teams. Each practice was offered external support from the PHN to assist with provision and interpretation of the personalised practice report, formulating the PDSAs, and submitting monthly data extractions.

Target population

Eligible patients were those recommended by guidelines for CVD risk assessment [5], and who were ‘regular attenders’ at the practice. This included Aboriginal and Torres Strait Islander people ≥35 years and all others ≥45 years; and those at clinically high risk of CVD regardless of age (defined below). ‘Regular attenders’ were defined as patients who attended the practice at least three times in the previous 24 months, and at least once in the previous 6-month period.

Five-year CVD risk was calculated using the 1991 Anderson Framingham Risk equation using sex, age, systolic blood pressure, smoking status, total cholesterol, high density lipoprotein (HDL) cholesterol and diabetes status [20]. Diabetes and left ventricular hypertrophy were assumed to be absent, unless explicitly recorded as diagnoses in the patient record. As per current guidelines, high CVD risk was defined as any of the following: (i) calculated 5-year CVD risk exceeding 15% based on the FRS, (ii) presence of clinically high-risk conditions (including diabetes and age >60 years, diabetes and albuminuria, eGFR <45 ml/min/1.73m², systolic BP >180 mmHg, diastolic BP >110 mmHg or total cholesterol >7.5 mmol/L) (iii) presence of a CVD diagnosis (i.e., coronary heart disease, cerebrovascular disease, peripheral vascular disease) [5].

Outcome measures

Outcome measures were: (1) CVD risk factor assessment including BP assessment in the past year; and lipid, BMI, waist circumference and smoking status assessment in the past 2 years; (2) guideline-recommended treatment for people defined as prescription of a BP-lowering medication and a statin for people at high CVD risk and prescription of a BP-lowering medication, a statin and either an antiplatelet or an anticoagulant agent for
people with a diagnosis of existing CVD (see Appendix 1 for specific medications); and (3) meeting CVD targets, which were defined as a BP less than 140/90 mmHg for high-risk patients, and less than 130/80 mmHg for those with established CVD or diabetes and a total cholesterol <4.0 mmol/L, high-density lipoprotein (HDL) level of >1.0 mmol/L, low-density lipoprotein (LDL) level of <2.0 mmol/L.

Statistical analyses

Bivariate analyses examined the frequencies and proportions of patients by their sociodemographic, CVD risk, BP/lipid levels and prescription of risk-reducing medications. Logistic regression models examined differences between baseline and post-intervention in the key outcome variables with adjustment for gender, age and Indigenous status. Changes between baseline and post-intervention were assessed by odds ratios (95% CIs), using the baseline sample as the reference category. As the data were hierarchical (i.e. patients clustered within GP practices), all analyses were adjusted for clustering at the practice level and applying finite population correction when estimating variance. Analyses were conducted with SPSS statistics software Version 26.0.0. Statistical significance was considered as $p < 0.05$ (two-tailed).

Qualitative data analysis

The PDSAs submitted by each practice were analysed by thematic analysis. The goals addressed in the PDSAs were coded by two coders who worked independently. Coders then sorted the themes of the PDSAs into larger categories and then discussed their results, examined any discrepancies and reached consensus for a final coding classification. Following this, 19 semi-structured interviews were conducted after completion of the program with a purposive sample of people involved in QPulse implementation, including PNs, nurses and GPs, as well as program officers, IT support personnel and managers at the PHN (Table 1). The interview guide is provided in Tables 4 and 5, Appendix 2.

Interviews were digitally recorded and professionally transcribed. Transcripts were shared with the interviewees to ensure they were accurate, and that they were agreeable to the contents being used for the study. Four researchers independently read and analysed the interview transcripts; this included the principal investigator and three researchers who had not taken part in the QPulse study. Interviews were manually coded by each researcher guided by the domains in Normalisation Process Theory (NPT) [21]. The findings were iteratively reviewed and refined at two focus meetings with the principal investigator and three researchers.

NPT is a theory of implementation designed to aid interpretation of how interventions are embedded, enacted and operationalised within routine practice in healthcare settings. This approach assumes four main generative mechanisms (coherence or sense making; cognitive participation; collective action; and reflexive monitoring) which are needed to achieve change in practice. The aim of the analysis was to examine the 'real world' participant perceptions of, and responses to the multi-component Q1 program, and at which points it was considered to be sustainable or have failed [21].

This research was performed in accordance with the Declaration of Helsinki and was approved by the University of Notre Dame Australia Human Research Ethics Committee (HREC) (reference 014105S). Signed agreements with participating practices were also obtained. A consent waiver for patient-level consent was granted by the committee.

Results

Practice characteristics and engagement

Of the 15 practices with complete pre- and post-data, all attended at least one workshop, 11 attending two and six attended all three workshops. Most practices sent only one attendee to each workshop with three practices sending two attendees and one practice sending three attendees to all three workshops. The PHN recorded contact with all participating practices at least once, some requested higher levels of interaction (range 1 to 8 contacts per month) which was provided via phone or face-to-face, to help with IT and Q1 processes. The program officer recorded a median of four practice visits and 15 phone calls per practice over the duration of the program. Although 12 practices registered to attend the first two webinars, only two attended, and these were consequently discontinued after 2 months. All participating practices submitted a baseline PDSA.

Baseline patient characteristics

The mean age of patients at baseline was 63.9 years, and the majority (55.3%, $n = 10,816$) were female. 5.8% ($n = 1139$) had high absolute cardiovascular disease or high clinical risk, and 12.1% ($n = 2372$) already had a diagnosis of CVD (Table 2). A greater proportion of patients at high risk of CVD or established CVD had up-to-date BP, lipid, BMI and waist circumference measures than those with low/moderate risk. High-risk patients were more likely to be overweight/obese or current smokers than their low/moderate risk counterparts. They were also more likely to reach total cholesterol and LDL targets, however a lower proportion met BP and HDL targets. A minority (41.2%) of high-risk patients were prescribed recommended medication, whereas a
majority (69.5%) of those with established CVD were prescribed the recommended risk-reducing medications.

Post-intervention
The sociodemographic profile of patients in the post-intervention sample was similar to the baseline characteristics, as were the CVD risk factor profiles, screening and management (Table 2). Post-intervention cardiovascular risk assessment, risk profiles and CVD targets were compared with baseline in Table 3. There were no significant improvements in any of the outcomes post-intervention, however there was wide variation in practice performance. Supplementary Table 2 provides summaries of the results of four high-performing practices where marked changes in selected outcomes were observed and showed improvements in the recording of BMI in Practices 1 and 2 after the intervention. Practices 1-3 also showed large improvements in the measurement of waist circumference, whereas Practice 4 had comparatively high baseline levels of all risk factor assessment and showed no overall change in these measures post-intervention.

PDSA themes
Every practice submitted at least one PDSA with only one practice submitting monthly, as requested. Overall, the PDSAs had an emphasis on foundational goals such as improving data measurements (e.g. recording of waist circumference or smoking status) rather than focusing on changes in preventive care and guideline-based prescribing (neither lifestyle nor medication). In some cases, PDSA goals aligned with improvements in the practice recording risk factor data, as seen in one practice (Fig. 2) that focused on waist circumference measurement.

Interview analysis
The characteristics of interview participants at the PHN and practice levels are shown in Table 1. There were a range of stakeholders interviewed within various roles and levels of the organisations, with a good distribution of participants in practices are varying size and with prior QI experience. The interviews yielded rich insights into understanding the quantitative findings. Multiple barriers to implementation across all four NPT domains were described and summarised below.

Coherence (the meaning ascribed individually and collectively to a new set of practices)
Collectively, GPs and PHN staff saw the potential value of the program as very high, for example: “There are a whole lot of people at risk, and they could have better outcomes…” (GP6). Access to the education modules and the two QI tools were seen as useful in identifying
| Table 2 Pre- and post-intervention data of sociodemographic, cardiovascular risk assessment and management in CRULSE |
|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|
| **Pre-intervention**                             | **Post-intervention**                            | **Post-intervention**                            | **Post-intervention**                            |
| **Cardiovascular risk assessment**               | **Cardiovascular risk assessment**               | **Cardiovascular risk assessment**               | **Cardiovascular risk assessment**               |
| Low/moderate (n = 8171)                          | Established CVD (n = 2372)                       | Established CVD (n = 9155)                       | Established CVD (n = 2357)                       |
| **Gender**                                       | **Total sample in 13 practices (n = 19,563)**    | **Total sample in 13 practices (n = 20,249)**    |                                                |
| Male                                             | 81.2 (3124)                                     | 38.5 (3523)                                     | 53.5 (1236)                                     |
| Female                                           | 18.8 (8047)                                     | 61.5 (2630)                                     | 46.3 (6013)                                     |
| Missing                                          | 0.3 (20)                                        | 21.6 (2250)                                     | 0.2 (2)                                         |
| **Ethnicity**                                    | **Total sample in 13 practices (n = 19,563)**    | **Total sample in 13 practices (n = 20,249)**    |                                                |
| Aboriginal or Torres Strait Islander             | 0.6 (30)                                        | 0.6 (30)                                        | 0.5 (2)                                         |
| Other                                            | 99.4 (5814)                                     | 99.4 (5812)                                     | 99.5 (5813)                                     |
| **Risk factor assessment**                       | **Total sample in 13 practices (n = 19,563)**    | **Total sample in 13 practices (n = 20,249)**    |                                                |
| Blood pressure                                   | 81.9 (6640)                                     | 85.6 (7862)                                     | 85.6 (7862)                                     |
| Blood lipid                                      | 82.5 (6730)                                     | 85.0 (7781)                                     | 76.3 (3213)                                     |
| BMI                                               | 54.6 (4460)                                     | 59.0 (2954)                                     | 56.4 (7812)                                     |
| Waist circumference                              | 23.1 (719)                                      | 25.3 (2214)                                     | 19.9 (205)                                      |
| Smoking status                                   | 63.2 (5156)                                     | 70.1 (719)                                      | 65.3 (1338)                                     |
| BMI                                              | 26.9 (2187)                                     | 22.9 (2640)                                     | 27.5 (2250)                                     |
| Underweight                                      | 23.1 (8010)                                     | 21.5 (516)                                      | 23.8 (1120)                                     |
| Healthy weight                                   | 21.5 (764)                                      | 21.5 (516)                                      | 22.9 (1120)                                     |
| Overweight                                       | 10.5 (259)                                      | 10.5 (259)                                      | 11.9 (259)                                      |
| Not assessed/missing                             | 30.8 (757)                                      | 36.7 (934)                                      | 42.2 (1120)                                     |
| Waist circumference                              | 1.1 (57)                                        | 6.4 (220)                                       | 16.2 (662)                                      |
| Normal                                           | 2.1 (801)                                       | 2.1 (801)                                       | 2.1 (801)                                       |
| Abdominal                                       | 99.1 (8047)                                     | 99.1 (8047)                                     | 99.1 (8047)                                     |
| Not assessed/missing                             | 64.2 (1555)                                     | 64.2 (1555)                                     | 64.2 (1555)                                     |
| Smoking status                                   | 87.3 (5052)                                     | 85.0 (5052)                                     | 85.0 (5052)                                     |
| Never smoker                                     | 22.5 (1068)                                     | 22.5 (1068)                                     | 22.5 (1068)                                     |
| Current smoker                                   | 10.0 (815)                                      | 10.0 (815)                                      | 10.0 (815)                                      |
| Ex-smoker                                        | 31.5 (359)                                      | 31.5 (359)                                      | 31.5 (359)                                      |
| Missing                                          | 30.4 (848)                                      | 30.4 (848)                                      | 30.4 (848)                                      |
| **CVD targets achieved**                         | **Total sample in 13 practices (n = 19,563)**    | **Total sample in 13 practices (n = 20,249)**    |                                                |
| Blood pressure                                   | 79.6 (2350)                                     | 67.9 (2860)                                     | 66.4 (920)                                      |
| Total cholesterol                                | 11.4 (974)                                      | 22.7 (2212)                                     | 22.7 (2212)                                     |
| LDL cholesterol                                  | 19.9 (926)                                      | 26.0 (926)                                      | 26.0 (926)                                      |
| HDL cholesterol                                  | 92.5 (832)                                      | 73.9 (4801)                                     | 73.9 (4801)                                     |
| Prescribed BP and lipid-lowering medications     | 16.5 (1377)                                     | 23.1 (1377)                                     | 23.1 (1377)                                     |
| **Assessed in the past 12 months**               | **Assessed in the past 2 years**                | **Assessed in the past 2 years**                |                                                |
| **At risk** waists circumference >94 cm for men and >84 cm for females | **Guideline recommended treatment was defined as [1] For high risk patients the prescription of a BP-lowering medication and a statin [5] for patients with established CVD, prescription of a BP-lowering medication, a statin and either an antiplatelet or an anticoagulant agent (see Appendix I for specific medications)
Table 3 Changes in CVD risk factor assessment, CVD targets and prescribing behaviours post-intervention compared to baseline

<table>
<thead>
<tr>
<th>Risk factor assessment</th>
<th>OR (95% CI) post-intervention compared to baseline</th>
<th>Total post-intervention sample in 15 practices (n = 40,256)</th>
<th>Cardiovascular risk assessment level post-intervention</th>
<th>Established CVD (n = 4975)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Low/moderate (n = 17,365)</td>
<td>High (n = 2334)</td>
<td></td>
</tr>
<tr>
<td><strong>CVD risk factors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overweight/obesity</td>
<td>0.97 (0.94-1.00)</td>
<td>0.96 (0.91-1.01)</td>
<td>0.90 (0.85-1.00)</td>
<td>1.00 (0.90-1.11)</td>
</tr>
<tr>
<td>Waist circumference</td>
<td>1.02 (0.98-1.06)</td>
<td>0.99 (0.95-1.03)</td>
<td>0.94 (0.90-0.99)</td>
<td>1.00 (0.94-1.06)</td>
</tr>
<tr>
<td>Smoking status</td>
<td>1.09 (0.94-1.05)</td>
<td>1.07 (0.93-1.23)</td>
<td>0.99 (0.93-1.07)</td>
<td>1.00 (0.93-1.08)</td>
</tr>
<tr>
<td><strong>CVD targets achieved</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood pressure</td>
<td>1.02 (0.99-1.06)</td>
<td>1.00 (0.97-1.03)</td>
<td>1.00 (0.95-1.05)</td>
<td>1.00 (0.94-1.06)</td>
</tr>
<tr>
<td>Total cholesterol</td>
<td>0.99 (0.96-1.02)</td>
<td>0.98 (0.95-1.01)</td>
<td>0.97 (0.93-1.01)</td>
<td>1.00 (0.94-1.06)</td>
</tr>
<tr>
<td>LDL cholesterol</td>
<td>0.98 (0.95-1.02)</td>
<td>0.97 (0.94-1.01)</td>
<td>0.96 (0.92-1.00)</td>
<td>1.00 (0.94-1.06)</td>
</tr>
<tr>
<td>HDL cholesterol</td>
<td>1.00 (0.99-1.03)</td>
<td>1.00 (0.97-1.05)</td>
<td>0.99 (0.93-1.05)</td>
<td>1.00 (0.94-1.06)</td>
</tr>
<tr>
<td><strong>Prescribed CVD risk-reducing medications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescribed risk-reducing medication(s)</td>
<td>–</td>
<td>–</td>
<td>1.07 (0.97-1.19)</td>
<td>0.96 (0.91-1.02)</td>
</tr>
</tbody>
</table>

*Assessed in the past 12 months
†Assessed in the past 2 years
‡At risk waist circumference >94 cm for males and >80 cm for females

and providing preventive care guidelines to high-risk patients. Only one participant mentioned that internal leadership (‘Change Champion’) or practice support (‘QI Culture’) was needed to facilitate engagement with the program.

**Cognitive participation (commitment to engage with the new)**

Interviewees from both PHNs and practices noted that the timing of this program (coinciding with major PHN governance and strategy change) prohibited prioritisation of support for the program by PHN Staff.

Most interviewees reported they had not fully appreciated what participation in a QI program would require of them prior to the program, "...when I took it on I didn’t realise there was more to it, so I didn’t really understand...". (GP1). For PHN participants this was illustrated at the highest executive level where management underestimated the readiness/ability of practices to be enrolled in this program, along with the need for the PHN to supply adequate resourcing to support both their staff and the participant practices. "With 40 practices enrolled, the workload sometimes got overwhelming despite team members helping me with 6 of the practices”. (PHN3). This lack of strategic planning and resourcing was amplified by the change in focus of PHN staff and a merger of three earlier meso-tier organisations into a single PHN. This affected directly on the PHN’s ability and commitment to supply practice-level support during the program.

GP engagement with the PDSSA was also extremely low. While the PDSSAs were understood by most GPs as an essential part of the QI process, they were seen as time-consuming, and "...formulative... uninteresting...”. (GP1) and "...to be honest, no, I haven’t done one since we started.” (GP9) with only a few seeing value in this aspect of the program. "It is a problem to stay on track and keep getting things done... I had a million good intentions, and then it gets too hard”. (P4)

**Collective action (how the work does not get done)**

Participants reported a lack of both ‘QI culture’ and change champions to support engagement with QIPulse. Although there was universal agreement that ‘key
Fig. 2 Plan-Do-Study-Act (PDSA) exemplar from one practice

1. Goal
   Aim to increase the rate of measurement of waist circumference

2. Measure
   Use measurement levels on PenCAT report pre- and post-intervention

3. Ideas
   Talk to other Drs to remind them they need to do waist measurements
   Check everyone has a tape measure in their rooms
   Check everyone is measuring waist in the same way and recording it in the data space

P. Plan – Discuss at this weeks practice meeting/ ensure everyone aware we are going to report back in 1 months’ time

D. Do - Practice nurse to do a weekly PenCAT report on waist circumference measurements recorded

S. Study – Report back at Doctors meeting by Nurse with results

A. Act – continue to report on a 6 monthly basis about Waist circumference measures with a goal to continuously increase our % of those measured and recorded.

Outcome: Significant improvement in numbers with waist circumference measured from 0.7% pre-intervention to 18% post-intervention.

individuals were needed to drive the program forward; this did not mean that these individuals were found, nor engaged to help with the program. "...it comes down to the culture within the practice, who is the real leader... the driver in the practice. It could be a nurse or the doctor... but crucially you really need to have somebody who is going to take the reins, or it doesn’t happen...." (PHNS).

It was clear many participants were unable to actively champion or drive the program forward due to not taking on a leadership role within their practice setting. Differing practice systems often meant each GP within the practice worked as an individual rather than part of a cohesive system of care. "It’s quite individual. That’s the way the practice is set up... your quality control is up to you... As long as it doesn’t add any extra work... because no one obviously is interested if it’s extra work" (GP2).

Communication systems between GPs, nurses and PMs were cited as a barrier to engagement. Often there was no regular practice ‘team’ meetings or systems in place to report back about QI measures and limited ability to organise tailored educational activities. Jobs were delegated to non-medical staff (e.g. the PM or nurse) who may/not have the skills or motivation to drive the program forward due to a lack of personal engagement with the goals of the program. At one practice, a manager commented that she only became involved because (the GP) "...didn’t want to do it, so she handed it to me... I actually didn’t know much
about it." (GP12). In addition, GP attendance at the educational sessions was sub-optimal and inconsistent, with many GPs delegating this to the PM or nurse. The scheduled monthly networking/seminar meetings were cancelled due to lack of attendance, despite most participants opting to join at the beginning of the program.

There was commentary that the QI program and data reports did not address key issues around improving engagement with patients: "It’s one thing to get the GPs to change what they do, it’s an entirely different thing to get patients to take in on board." (GP 6) Several GPs also discussed the problem with many competing projects and lack of time: "I think the difficulty is there’s a plan for one quality of project and then another idea comes up and then the same people are looking at implementing it, or we give the nurses something else to do, and it sort of falls off the radar." (GP 6)

Participants reported barriers to setting up a sustainable QI processes. This was highlighted by commentary about the difficulty of scheduling data extractions and generation of reports, low attendance at QI educational activities, no engagement with PDSA process, no evidence of sustained use of the IT tools. Several attributed this to both lack of dedicated time to do QI work and lack of any tangible incentives (financial or professional development). Many reported that GPs were not keen to engage with an activity that was not aligned with financial incentives and cited such incentives as a mechanism to achieve long-term engagement rather than as the first reason for engagement. However, engagement with individual “contracted” GPs was reported as requiring a financial incentive to engage them with doing any of the extra work involved in QI activities: "...from a practice perspective, it’s not going to be a priority. So really, the PHN needs to take on a lot of that responsibility on behalf of the practice if we’re going to get it up and running." (PHN)

Minor IT issues were also identified as barriers, although it was well understood by participants that IT support was readily available if asked: "I used it for a couple of weeks and found it was really useful... (when a minor IT issue arose to render the tool inactive) ...it just kind of died off, my use of it." (GP7) Finally, it was noted that the program did not adequately accommodate the roles of individual GPs (and patients) in achieving key outcomes (such as BP, lipid levels) and medication prescriptions. "It was all a bit clunky...I never saw the Manager’s data reports... and although I tried with Q Pulse,...if a doctor is not interested, they won’t do it... that’s often the way around here and I just couldn’t engage them with recording the CVD measures." (GP2)

PHN staff reported a lack of resourcing to provide individualised GP practice reports, education or face-to-face support despite observing that most practices needed significantly more support than anticipated to complete the basic requirements of the program (such as monthly data extractions, PDSAs, tidying up eMR systems). "Until you start giving monthly reports and with targeted topics and actually educating the GPs about what to do with that data, you’re just extracting data." (PHN)

Reflective monitoring (the processes through which practitioners decide whether new approaches are beneficial and lends, ultimately, to the normalisation of new practices) Normalisation of systematised QI practices was not apparent, even among the most experienced and engaged practices. This was despite many participants reporting enthusiasm for ongoing participation in QI work. "So, we’ve talked about it, but we’ve never implemented it systematically... most doctors are not taught these things, that’s the whole problem, so we’ve got to re-educate the doctors, our universities haven’t got it in the curriculum." (GP7)

Even in solo practices, GPs experienced challenges with translating the QI goals into long-term changes systematic CVD preventive care. The program was discussed as a one-off piece of work rather than something to embed into everyday routine practice. "It’s the follow through which can be difficult because you will forget. I don’t know that this is common to everyone, but... if somebody is not... pestering you and reminding you... I’ve actually forgotten how to do it - it falls off the wagon." (GP 3)

Some GPs reported adopting new ways of approaching CVD preventive care, such as utilising CVD absolute risk assessment tools or using audit data extraction tools to identify gaps in data measures such as smoking status, BMI or waist circumference. "every single patient I see I just flick onto the summary screen of HealthTracker and just see whether the percentage is something I need to worry about, and if it’s not, then I don’t pursue it." (GP 4) However, few mentioned systematic use of the tools for the whole team. Even the most engaged general practice participants noted a difficulty in systematising QI in the day-to-day running of business. "I think (the workplace of) general practice is a barrier; it’s an unpredictable, busy, chaotic job and so things happen that get in the way. And I think the other barrier is that protected time, to set up systems is an enabler and not being in place is a barrier." (GP 6)
Discussion

Engagement with the QPulse QI program was limited in most general practices. Pre-intervention data showed a sub-optimal assessment of CVD risk factors, along with low prescribing rates among high-risk patients. After the program there were no significant changes in the assessment of CVD risk factors, the achievement of BP and blood lipid targets or the prescription of risk-reducing medications. Normalisation Process theory provided a framework to analyse participants experiences of implementing the program and focused on the work required to embed and normalise QI processes in the general practice settings [22]. The qualitative data demonstrated significant real-world barriers in implementation in all four NPT domains but particularly within collective action and reflective monitoring. The framework assisted in demonstrating specific areas where future implementation strategies should be emphasised.

Overall, GPs considered the program as relevant and beneficial to patient care. Stakeholders identified that activity was mainly led by non-medical staff and focussed on improving documentation rather than clinical outcomes. There were substantial challenges for GPs for embedding the program into long-term changes in clinical practice. It is difficult to ascertain whether these were due to limitations in the design of the program or the inertia in the adoption of CVD. Furthermore, the success of many interventions in primary care [11, 23, 24] it is likely that implementation played a larger role. Primary healthcare is a complex environment that benefits from structured systems of care to aid the adoption of best practice. The privatised model of Australian general practice, which rewards clinicians for volume-based care is a financial and philosophical barrier to widespread adoption of QI programs which focus on ‘value-based’ care [18].

Lessons learned about quality improvement collaborations in Australian general practice

The challenges associated with achieving collective action for both general practices and the PHN meant participants found it difficult to move beyond ‘new’ and toward ‘normal’. Interviewees reported a ‘project-based’ approach to QI with ‘topical’ engagement and difficulty setting up systematized adoption of change due to the considerable number of competing projects. At the time of this program, there was no systematic funding or incentives for GPs and practices to improve their data collection processes, and such improvements were mainly driven by practice ‘champions’ and needed to be supported by the systems and IT infrastructure to normalise these changes. These supports were not in place and were identified as key factors limiting the program in the stakeholder interviews. In many cases, there was no clear role of a leader within practices, and when leadership developed it was often from non-medical staff. Furthermore, this QI program was unable to capture doctor-patient decision making around individual choices and adoption of CVD risk recommendations, including medications, diet and exercise.

The findings also suggest that implementing change needs to build practice capacity and culture; change needs to be supported by GPs, practice managers and reception staff, and the necessary IT systems, staffing and time allocation to QI activities need to be made available. The results showed that even after the QI program, a substantial proportion of practices (30–40%) were not meeting basic documentation and monitoring targets. These improvements have been identified as key to increasing uptake of evidence-based practice in primary care [13, 16]. This study highlights the need for concerted efforts to set up these foundations at the individual GP, practice and PHN levels to improve the uptake of QI programs.

Large-scale QI research in primary care in the US has concluded that practice support is essential to help practices, particularly those with electronic medical record data challenges, build their capacity for conducting data-driven QI [25]. Data is a fundamental step in participating in service improvements in primary care, and for performance-based payment programs [26]. A qualitative review of QI programs in Australia similarly identified the need for external support, accurate data and reporting, education and change champions in addition to financial incentives [18]. Government-funded initiatives such as heart health assessments, health assessments for 45–49-year-olds, GP management plans and home medication reviews have only had partial uptake and mixed evidence of success [8, 27, 28]. One potential driver of their mixed success is that they are still fee-for-service activities and do not support GPs to adopt quality-focused models of care [29, 30]. A recent evaluation of the Health Care Home initiative in Australia, an initiative for adopting a patient-centred model of care for those with chronic and complex health conditions, identified they key role of practice facilitators with advanced facilitation skills for implementing change in general practices [31].

While there has been increased interest in supporting QI in Australian primary care, there needs to be a
change in thinking from start-up programs to sustained initiatives. A pre-post evaluation of a national QI program, the Australian Primary Care Collaborative program from 2004 to 2014, found improvements in both CVD risk identification and management, but only had partial uptake nationally [12] and did not receive ongoing federal funding. Driving this program relied on a complex interaction of enablers such as leadership, accurate data, funding incentives, organisational culture, and primary care systems designed to support quality care [18, 23, 32]. Interim evaluation of the Health Care Home Initiative in Australia also supported allowing for sufficient time for the implementation of complex programs in primary care [29]. Scoping the focus of the program to addressing very targeted outcomes rather than implementing broader more complex QI initiatives has also been a recommendation from a large trial evaluation of the EvidenceNOW model in the US [33].

Study limitations
The current study had a number of limitations that need to be acknowledged in the context of the results. Firstly the practices were located in one PHN region and may not be representative of general practices elsewhere. For example, we have previously found higher performance for CVD risk management in Aboriginal Community Controlled Health Services compared with other general practices [10]. Secondly, although de-identified electronic medical record data extraction tools allow for a ‘whole-of-practice’ snapshot of performance, the data need to be entered in extractable fields of the record. This may result in an underestimate of management practices [34]. This mainly applies to BP and smoking status, given that electronic prescribing and pathology results are adopted in most Australian general practices. Thirdly, in assessing measurement of absolute CVD risk we looked at the recording of risk factor data but were not able to assess to what extent risk scores were calculated. Although HealthTracker, the point of care decision tool supplied to each practice, did provide this information for each patient at the time of consultation, we did not have user analytics on whether an absolute risk score was generated. Given GPs vary greatly in how they use risk scores, the gaps in risk-based management may also vary when using surrogate measures to capture the outcomes of complex GP-patient interactions [35]. Furthermore, the lower-than-anticipated practice numbers resulted in some effect sizes being non-significant.

Conclusions
There are large gaps between CVD management guidelines and practice in primary care in Australia. This QI program targeting CVD risk identification and management did not bring about overall changes in risk factor documentation, risk factor prevalence, attainment of physiological targets and prescribing for risk reduction. Overall, practitioners see the value in QI programs targeting CVD, however experience substantial challenges in implementing change if this is not supported more widely. GPs and other practice staff need support at all levels of the organisation for QI, in addition to the time, technical support and appropriate remuneration to facilitate long-term improvements in the management of CVD in general practice.

Appendix 1
Medications list
A complete list of the medicine active ingredients audited in this study

<table>
<thead>
<tr>
<th>Anti-coagulant medications</th>
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</thead>
<tbody>
<tr>
<td>APTXABAN</td>
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<tr>
<td>RIVARIXABAN</td>
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<tr>
<td>DABIGATRAN</td>
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<tr>
<td>DALTAPARIN</td>
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<tr>
<td>Enoxaparín</td>
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<tr>
<td>FONDAPARINUX</td>
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<tr>
<td>HEPARIN</td>
</tr>
<tr>
<td>RIVAROXABAN</td>
</tr>
<tr>
<td>WARRARIN</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Anti-platelet medications</th>
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</thead>
<tbody>
<tr>
<td>ABOCARBIR</td>
</tr>
<tr>
<td>ASPIRIN</td>
</tr>
<tr>
<td>CLOPIDOGREL</td>
</tr>
<tr>
<td>DPYRIDAMOLE</td>
</tr>
<tr>
<td>EPTIFIBATIDE</td>
</tr>
<tr>
<td>FRASUGREL</td>
</tr>
<tr>
<td>TICAGRELOR</td>
</tr>
<tr>
<td>TICLOPIDINE</td>
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<tr>
<td>TIBORURAN</td>
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<thead>
<tr>
<th>Antihypertensive medications</th>
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<tbody>
<tr>
<td>AMLODIPINE</td>
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<tr>
<td>ATENOLOL</td>
</tr>
</tbody>
</table>
Lipid lowering medications – other

- Cholestyramine
- Colestipol
- Ezetimibe
- Nicotinic Acid

Appendix 2
Interview questions for stakeholders from general practices and Primary Health Network

Table 4 Interview questions for stakeholders in general practices

1. Why did their practice enrol?
2. What happened in their practice during the project? What went well and what was difficult?
3. What members of the practice engaged with the project, tasks – who and why they were involved.
4. Who sets the priorities for doing tasks in the practice?
5. How did the practice work together, as a team (or not) on the project?
6. What could have been improved to assist them in participating in the project?
7. Were they continuing to do OI work?
8. Try to provide some details around the following:
   a) barriers and enablers to the implementation
   b) What worked well and what did not work well?
   c) What would they want to do differently if involved in a similar project in the future?
   d) What would they want done differently to assist in their participation in the future?
   e) Leadership in their practice
   f) Organisational Culture
   g) Funding incentives to do this work
   h) Data – access and ability to use – are they doing anything now?
   i) Clinical Systems – have they done any work on this area in their practice?
   j) External support – how has the PHN or any other organisation assisted them in any way to do this work?

Lipid lowering medications – fibrate

- Fenofibrate
- Gemfibrozil

Lipid lowering medications – statin

- Atorvastatin
- Fluvastatin
Table 5 Interview questions for stakeholders in Primary Health Networks

1. Outline their role at the PHN for Q Pulse (or similar Q projects).
2. What was their experience of the project implementation – what worked and what was challenging?
3. What was their experience of Q project implementation more generally – what worked and what was challenging?
4. Then ask some more specific questions about the following areas:
   a. Barriers and enablers to the implementation
   b. What worked well and what did not work well?
   c. What would they want to do differently if involved in a similar project in the future?
   d. What would they want to do differently to assist in their participation in the future?
   e. Leadership in the workplace
   f. Organizational Q Culture
   g. Incentives to this work from Executive level / funding body
   h. Data access and ability to use – are they doing anything now?
   i. Clinical Systems – have they done any work on this area in the PHN?
   j. External support – has any other organisation assisted the PHN in any way to do this work?

Abbreviations
BMI: Body mass index; BP: Blood pressure; CAD: Cardiovascular disease; GP: General practitioner; HDL: High-density lipoprotein; LDL: Low-density lipoprotein; PDSA: Plan-Do-Study-Act; PHN: Primary Health Network; QI: Quality improvement; QIC: Quality improvement collaboration.

Supplementary Information
The online version contains supplementary material at https://doi.org/10.1186/s12913-021-02710-6.

Additional file 1: Supplementary Table 1. Baseline characteristics of included and excluded patients. Supplementary Table 2. Pre- and post-intervention characteristics of 4 sample practices.

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Authors’ contributions
CH made substantial contributions to conception and design of the study, acquisition of funding, conducting interviews of participants, analysis and interpretation of data and drafted the manuscript. DP made a major contribution to the conception and design of the study, as well as acquisition of funding, and analysis and interpretation of the data. MH was a major contributor to conception, acquisition of the funding, design of the study, interpretation of data and drafting of the manuscript. KG was a contributor to the analysis and interpretation of the qualitative data and was involved in drafting and reviewing the manuscript. All authors read and approved the manuscript.

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Availability of data and materials
The datasets generated and/or analysed during the current study are not publicly available but data may be made available to interested parties from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This research was performed in accordance with the Declaration of Helsinki and was approved by the University of Notre Dame Australia Human Research Ethics Committee (HREC) reference 03140051. Signed agreements with participating practices were also obtained. A consent form for patient-level consent was granted by the committee.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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Paper 4: Learning from the implementation of a quality improvement intervention in Australian general practice: a qualitative analysis of participants views of a CVD preventive care project

Learning from the implementation of a quality improvement intervention in Australian general practice: a qualitative analysis of participants views of a CVD preventive care project

C.M. Hespe1*, E. Brown1 and L. Rychetnik2,3

Abstract

Background: Quality improvement collaborative projects aim to reduce gaps in clinical care provided in the health-care system. This study evaluated the experience of key participants from a Quality Improvement Program (QIPulse) that focussed on cardiovascular disease assessment and management. The study goal was to identify critical barriers and factors enabling the implementation of a quality improvement framework in Australian general practice.

Methods: This qualitative study examined in-depth semi-structured interviews with nine purposively-selected participants of the QIPulse project. Interviewees were from General Practices and the local supporting organisation, a Primary Health Network. Interviews were analysed thematically using the Complex Systems Improvement framework, focusing on five domains: strategy, culture, structure, workforce and technology.

Results: Despite reported engagement with QIPulse objectives to improve cardiovascular preventive care, implementation barriers associated with this program were considerable for all interviewees. Adoption of the quality improvement process was reliant on designated leadership, aligned practice culture, organised systems for clear communication, tailored education and utilisation of clinical audit and review processes. Rather than practice size and location, practice culture and governance alignment to quality improvement predicted successful implementation. Financial incentives for both general practice and the Primary Health Network were also identified as prerequisites for systematised quality improvement projects in the future, along with individualised support and education for each general practice. Technology was both an enabler and a barrier, and the Primary Health Network was seen as key to assisting the successful utilisation of the available tools.

Conclusions: Implementation of Quality Improvement programs remains a potential tool for achieving better health outcomes in General Practice. However, enablers such as financial incentives, individualised education and support provided via a supporting organisation, and IT tools and support are crucial if the full potential of Quality Improvement programs are to be realised in the Australian healthcare setting.

Trial registration: ACTRN12615000108516, U11111-1163-7995.

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Introduction
Cardiovascular diseases (CVD) are the single leading cause of death in Australia and most developed countries, despite significant declines in morbidity and mortality over the last 40 years [1]. In 2015, CVD was responsible for 29% of deaths and over 1.1 million hospital admissions [2, 3]. Importantly, CVD burden can be reduced through risk-factor modification [4]. Around two-thirds of Australians have three or more modifiable risk factors such as tobacco smoking, high blood pressure, high cholesterol, physical inactivity, poor nutrition, or overweight/obesity [3, 5, 6]. General Practitioners (GPs) play a significant role in mitigating CVD morbidity and mortality, seeing over 85% of the population and conducting over 20 million patient consultations annually [7]. However, previous studies have shown sub-optimal measurement and management of CVD risk in Australian and International primary care settings [8–13]. The 2021 Australian Institute of Health and Welfare data from more than 5700 Australian general practices recorded only 48.5% of patients with enough data to measure cardiac risk [14].

Quality Improvement (QI) initiatives in primary care have the potential to improve uptake of evidence-based practices [15]. QI is a multi-dimensional concept, which can be defined as having a systematic approach to making changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning) [16]. Batalden et al. postulate that defining QI in this way allows people to have a measurable approach to the concept of improving healthcare [16].

There are several ways to implement QI initiatives intentionally, and one such method is establishing a Quality Improvement Collaborative (QIC) [17]; QICs actively bring together practitioners from different organisations to meet and learn about a specific aspect of health service quality and share experiences about making changes to improve measurable outputs in their local settings. There has been mixed evidence of success implementing QICs in health care [15, 18, 19]. However, a systematic review of 64 QIC programs in 2018 reported significant improvements in 83% of targeted clinical processes and patient outcomes [20].

There have been several programs aimed at improving the adoption of guidelines using the QIC framework in the Australian healthcare setting [21, 22]. However, there is a gap in understanding the barriers or enablers for implementation.

This paper presents a qualitative analysis of interviews with participants of a QIC project, QPulse, focused on enhancing the implementation of the Australian National Vascular Disease Prevention Alliance Guidelines to manage absolute cardiovascular disease risk [23]. QPulse was a collaboration between the Central and Eastern Sydney Primary Health Network (the "PHN"), The George Institute for Global Health and Improvement Foundation Australia, funded through a Health Research Award from Bupa Health Foundation. In Australia, Primary Health Networks (PHNs) are semi-level (supporting) organisations contracted by the Australian Government to improve access to primary care services for regional patients and coordinate with local hospitals to improve the overall operational efficiency of primary care.

The overall objective of the QPulse project was to enhance the implementation of CVD risk management guidelines in general practices. The project faced significant implementation challenges, and quantitative analysis of the quality improvement outcomes failed to demonstrate any changes in risk factor documentation, risk factor prevalence, attainment of physiological targets or prescribing for risk reduction after the intervention [23, 24]. However, a detailed sub-analysis of the data did demonstrate significant variation between practices. Some high performing practices showed selected areas of improvement in patient data collection, such as recording weight and height [23]. Gaining a knowledge about individual general practice enablers and barriers is key to developing improved QI strategies for Australian general practices. This qualitative study aimed to explore the specific implementation barriers and enablers encountered by participants in the QPulse project. The overall goal was to inform future health policy and funding initiatives for QI in the General Practice setting.

Methods
Study context
The QPulse QIC project (Central and Eastern Sydney General Practice Quality Improvement Network: building a sustainable model of QI to achieve reduced cardiovascular disease in the primary care setting) was conducted in 2015–2018 [23, 24]. This mixed-methods
research project was performed in accordance with the Declaration of Helsinki and was approved by the University of Notre Dame Australia Human Research Ethics Committee (UNDA HREC) (reference 0141058). Signed agreements with participating practices and interviewees were obtained, and the committee granted a waiver for patient-level consent. The study was registered with the Australian and New Zealand Clinical Trials Registry, ACTRN12615000108516, UTN.U111-1163-7995.

The current qualitative study was conducted following the completion of the QIC component of the QPulse project. Detailed information about QPulse QIC recruitment, interviewees and data collection have been reported elsewhere [23, 24].

In brief, QPulse was a series of three QICs, each lasting six months. The QICs were designed to be overseen and delivered by the PHN into general practices using an abbreviated version of the typical 18-month duration QIC [15, 18]; comprising educational workshop followed by six monthly data audit reports alongside practice generated Plan, Study, Do, Act (PDSA) cycles [25]. The QPulse QICs used existing medical audit and decision support software [26] to assist participating General Practices in measuring and managing CVD risk factors. A timeline and Figures describing the recruitment and project rollout of the QPulse project can be seen in Figs. 1–3, Supplementary file 1.

Qualitative interviews

After the rollout of the QPulse QIC, nineteen semi-structured interviews were conducted using a purposive selection of participants involved in its implementation, including practice managers (PMS), nurses and GPs from the participating general practices, and program officers, IT support personnel and managers at the PHN. Purposive sampling was used to ensure the study achieved broad representation from participants across the full range of both general practices and the supporting organisation. Twenty-two people were approached by the first author by phone or email, inviting them to participate in a 30-min interview, face to face or via the phone (as preferred by the interviewee). Three invited GPs opted not to participate due to lack of time. All nineteen interviewees were emailed a set of questions (see Tables 5 and 6 in Supplementary file 2) to assist them in preparing for the interview on enable barriers to participating in the QPulse project. One PHN interviewee asked to respond to the questions in written format in preference to verbal responses. The oral interview was semi-structured, and interviewees were invited to elaborate on any question that they felt would be helpful to explore further. Each interview was audio-recorded and then transcribed using a transcription service. Transcriptions were shared with the interviewees to ensure they were seen as accurate and they were agreeable to the contents being used for the study.

Two GP interviewees were interviewed together at their request, but all other interviews were conducted as one-on-one sessions.

Data analysis

Our analysis drew on the Kraft et al. Complex Systems Improvement (CSI) framework [27]. This framework was selected for its relevance to the context and complexities of the Australian general practice environment. The framework identifies four health system levels that align with the successful implementation of change—environment, meso-level organisations, microsystems, and patients and their caregivers [27]. The analysis in this study primarily concentrated on three levels in the CSI framework, i.e. the environment, the meso-level organisation (PHN) and the microsystem (general practice).

The CSI framework also identifies five domains for evaluating a change-making intervention in the health system. These domains include strategy, culture, structure, workforce and technology. For the purpose of this study: "Strategy" addresses alignment of the improvement intervention with the strategic intention of interviewees. "Culture" looks at the norms, values and beliefs of interviewees. "System" addresses infrastructure in place to enable interviewees to learn new practices, spread best practices, and continuously measure performance and improve processes. "Workforce" looks at how people, tasks, tools and technologies, organisational conditions, and physical environment affect the adoption of the intervention. "Technology" specifically addresses the role that IT and electronic medical records play in the adoption of new processes. We applied the framework to examine the change intervention experience rather than describe the implementation sequence.

Four researchers independently read and analysed the interview transcripts; this comprised the principal investigator of the QPulse project (first author) and three researchers who had not participated in the design or implementation of QPulse; one is a co-author of this paper and two are noted in acknowledgments. All were approved to contribute to the analysis via the UNDA HREC process. Each researcher manually coded interviews to develop core themes and observed patterns in the data. Two co-authors (CH and EB) reviewed the identified themes and systematically analysed them against the Kraft et al. CSI framework [27].

After analysing the transcripts from all 19 interviews, the research team was confident data saturation had been achieved, with no need for further interviews.
Table 1. Interviewee characteristics of interviewees from the Primary Health Network and general practices

<table>
<thead>
<tr>
<th>Interview interviewees from PHN (n = 8)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>4</td>
</tr>
<tr>
<td>Project Officer</td>
<td>2</td>
</tr>
<tr>
<td>Team Manager</td>
<td>2</td>
</tr>
<tr>
<td>Executive Officer</td>
<td>1</td>
</tr>
<tr>
<td>IT Support Officer</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interview interviewees from general practices (n = 12)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>9</td>
</tr>
<tr>
<td>Practice nurse</td>
<td>1</td>
</tr>
<tr>
<td>Practice manager</td>
<td>1</td>
</tr>
<tr>
<td>General Practitioner</td>
<td>10</td>
</tr>
</tbody>
</table>

Practice size (number of regular patients)

| <2000 | 1 |
| 2001–4000 | 1 |
| 4001–6000 | 3 |
| 6001–8000 | 3 |
| 8001–10,000 | 2 |
| 10,001–20,000 | 1 |
| >20,000 | 1 |
| Previous Qi experience | 6 |

Results

Nineteen participants were interviewed after providing the research team with written and verbal consent to participate in the qualitative study. Individual and practice demographics for each interviewee are provided in Table 1 and 2.

Qualitative data analysis: complex system improvement framework

The CSI framework was used to identify insights and issues that affected the QPulse intervention environment, and the experience of implementation for the general practices and PHN (health system levels) examined across the five domains.

A summary of the key findings of our analysis aligned to the Complex System Improvement Framework is presented in Table 3. Incentives were identified as a key enabler across all five domains and these findings are summarised in Table 4.

Goals and strategies (incentives, priorities, opportunities for change) for improved adoption of CVD risk prevention guidelines

All interviewees in the study aligned with the QPulse goal of decreasing CVD related mortality and morbidity,

Table 2. Practice demographics of general practice interviewees

<table>
<thead>
<tr>
<th>Wave</th>
<th>Gender</th>
<th>Role</th>
<th>Practice size</th>
<th># downloads</th>
<th>Billing</th>
<th># GPs in practice</th>
<th>Practice Nurse</th>
<th>Allied Health On site</th>
<th>PM / Admin support</th>
<th>Prior Qi</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>GP</td>
<td>Small</td>
<td>16</td>
<td>Mixed billing</td>
<td>6</td>
<td>1 x PN</td>
<td>Y</td>
<td>PM + Admin support</td>
<td>Y</td>
</tr>
<tr>
<td>1</td>
<td>F</td>
<td>GP</td>
<td>Small</td>
<td>16</td>
<td>Bulk Billing</td>
<td>7</td>
<td>2 x PN</td>
<td>Y</td>
<td>Corporate</td>
<td>N</td>
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<tr>
<td>1</td>
<td>F</td>
<td>GP</td>
<td>Moderate</td>
<td>16</td>
<td>Mixed Billing</td>
<td>1</td>
<td>1 x PN</td>
<td>Y</td>
<td>PM + Admin support</td>
<td>N</td>
</tr>
<tr>
<td>1</td>
<td>M</td>
<td>GP</td>
<td>Moderate</td>
<td>17</td>
<td>Bulk Billing</td>
<td>2</td>
<td>0.5 x PN</td>
<td>Y</td>
<td>PM + Admin support</td>
<td>N</td>
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<tr>
<td>1</td>
<td>F</td>
<td>GP</td>
<td>Small</td>
<td>18</td>
<td>Bulk Billing</td>
<td>2</td>
<td>No</td>
<td>Y</td>
<td>No PM + Admin support</td>
<td>N</td>
</tr>
<tr>
<td>1</td>
<td>F</td>
<td>GP</td>
<td>Large</td>
<td>24</td>
<td>Mixed Billing</td>
<td>16</td>
<td>2 x PN</td>
<td>Y</td>
<td>PM + Admin support</td>
<td>Y</td>
</tr>
<tr>
<td>1</td>
<td>M</td>
<td>GP</td>
<td>Large</td>
<td>14</td>
<td>Mixed Billing</td>
<td>4</td>
<td>1 x PN</td>
<td>Y</td>
<td>PM + Admin support</td>
<td>Y</td>
</tr>
<tr>
<td>1</td>
<td>M</td>
<td>GP</td>
<td>Large</td>
<td>15</td>
<td>Mixed Billing</td>
<td>5</td>
<td>1 x PN</td>
<td>N</td>
<td>PM + Admin support</td>
<td>N</td>
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<tr>
<td>1</td>
<td>F</td>
<td>GP</td>
<td>Small</td>
<td>14</td>
<td>Mixed Billing</td>
<td>4</td>
<td>1 x PN</td>
<td>N</td>
<td>PM + Admin support</td>
<td>Y</td>
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<tr>
<td>2</td>
<td>F</td>
<td>GP</td>
<td>Large</td>
<td>13</td>
<td>Mixed Billing</td>
<td>1.5</td>
<td>1 x PN</td>
<td>N</td>
<td>PM + Admin support</td>
<td>Y</td>
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<tr>
<td>2</td>
<td>F</td>
<td>PN</td>
<td>Large</td>
<td>13</td>
<td>Mixed Billing</td>
<td>1.5</td>
<td>1 x PN</td>
<td>N</td>
<td>PM + Admin support</td>
<td>Y</td>
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<tr>
<td>1</td>
<td>F</td>
<td>PM</td>
<td>Large</td>
<td>25</td>
<td>Mixed Billing</td>
<td>16</td>
<td>1 x PN</td>
<td>Y</td>
<td>PM + Admin support</td>
<td>Y</td>
</tr>
<tr>
<td>Goals and strategies (Incentives, priorities, opportunities for change)</td>
<td>Culture (values, beliefs, norms)</td>
<td>Structure of learning (Infrastructure to support continuous learning and improvement)</td>
<td>People, workflow and care processes (role optimisation, processes of care, standard workflows)</td>
<td>Technology (information services, electronic health records)</td>
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<tr>
<td><strong>Patients and caregivers</strong></td>
<td>Support GPs in improved CVD prevention and care</td>
<td>Highly variable, a key determinant of success</td>
<td>GPs have ongoing structured CPD with emphasis on evidence-based care, support from the college</td>
<td>Increased workload for GP practices would have appreciated more support, e.g., from PHN</td>
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<tr>
<td></td>
<td>Engage GPs in Quality Improvement data collection and scrutiny</td>
<td>Encouraged GPs personally motivated to improve their practice</td>
<td>GPs supported by PHN staff during implementation</td>
<td>Healthtrack often needed trouble-shooting (PHN generally prompt with this). Practice members sometimes experienced problems due to knowledge deficits. Moral incentive required to encourage the sustainable use of the tool by GP or PHN</td>
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<tr>
<td></td>
<td>Patients voice was not captured in this study: no ability to record their role in adopting preventive care strategy.</td>
<td>Patient satisfaction</td>
<td>PHN stated Healthtrack to be educational and engaging for patients, but this was reported from the perspective of the GP and PHN</td>
<td>Patient-centred workflow processes lacking and should be included in the next stage of the design</td>
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<tr>
<td></td>
<td><strong>Microsystems (small units where care is delivered)</strong></td>
<td>GP practice widely in nature (free, internal support, team culture/bid/bid, business models, etc.); opportunities for change are affected by this on an individual level. Solo and large practices are seen to struggle more with the adoption of systematised QI practices</td>
<td>Practices required hands-on support – and would have appreciated more proactive support from PHN (staff, e.g., regularly scheduled visits, facilitated networking, more in-depth teaching about QI and clinical topics requiring improvement, structured learning using practice data)</td>
<td>Some practices were agile concerning role optimisation and adoption of new processes. Successful implementation required effectively engaging PHN and PAs as well as the GP. Change leadership by a GP, PHN or PM was key to success</td>
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<tr>
<td><strong>(The General Practices)</strong></td>
<td>GP practice culture and leadership key to implementation</td>
<td>The culture was noted to be very variable. Level of engaged leadership variable. Practice culture/ circumstances dictate or limit possibilities for change. In systems, individual GP priorities appeared to override the ability to introduce changes in practice and systems</td>
<td>Software used varied between practices, sometimes incompatible. They were seen as time-consuming. It quickly became a barrier due to the time required. PHN was generally competent in resolving practice-level IT problems but was often left out of the loop</td>
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<tr>
<td>Meso-level Organisations (Supporting Microsystems)</td>
<td>Clear guidelines, readily accessible, need for improvement universally agreed</td>
<td>The identity and nature of PHN were in flux at the time of the study. The need for established and trusted relationships between PHN and GP was identified as key to ongoing success</td>
<td>Seen as the role of the PHN by practices PHN did not visualise its role consistently throughout this project due to a lack of prioritisation and resourcing by senior management for the work. Strategic leadership by executives aligned to QI was fundamental. Personnel selection and support at PHN may have been non-optimal</td>
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<tr>
<td><strong>i.e. PHN, RACGP</strong></td>
<td></td>
<td></td>
<td></td>
<td>IT support by PHN key to implementation – PHN offered excellent IT support in most cases, but GPs did not always utilise the service</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Environment (policy, payment, regulation)</td>
<td>Goals and strategies (incentives, priorities, opportunities for change)</td>
<td>Culture (values, beliefs, norms)</td>
<td>Structure of learning (infrastructure to support continuous learning and improvement)</td>
<td>People, workflow and care processes (role optimisation, processes of care, standard workflows)</td>
<td>Technology (information services, electronic health records)</td>
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</tr>
<tr>
<td>Clear guidance from the Department of Health to prioritise this work and part of the new PHN contract. Minimal reimbursement available to assist practices or PHN to fund the work adequately.</td>
<td>“Quality Improvement” is part of Australian Primary Health Care policy. Document but not incentivised for individual GPs not adequately funded within the entire primary care health system.</td>
<td>Adversely affected through changes in ML to PHN. They are not funded. GPs have to do mandatory COP to maintain Australian Medical registration. RACGP has mandated 1 QI activity every three years for each GP to maintain specialty status and registration.</td>
<td>QI Practice Incentive Payment is available for accredited General Practices but not yet linked to any tangible programs related to improvements in services.</td>
<td>No current funding is available for practices to support the adoption of any specific technology. PHN contracted to provide “generic” QI support to general practice by the Federal Health department but no actual funding stream to implement.</td>
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<td></td>
</tr>
</tbody>
</table>
| **Goals and strategies** | **Microsystems**  
- General Practices | **Meso-level organisations**  
- PHN | **Environment**  
- Government Policy and funding (State and National)  
- Professional |
|-------------------------|------------------|-------------------|------------------|
| Funding incentives to support targeted Quality Improvement projects within general practice that include Preventive care | Clear guidelines from the Department of Health regarding support for QI project  
Provide funding in contracts to deliver these strategies  
Target improvement projects with universally agreed goals as well as locally identified projects | Align Health Policy Strategies with funding into primary care  
Reform Primary care funding policy |
| **Culture** | Funding incentives to create Quality Improvement ‘cultural buy-in’ for all styles of General Practices  
Participation - enable adequate resourcing  
= Practice Administration  
= Individual Practitioner | Enable provision of flexible support for general practice to assist in the establishment of systematised QI in all general practices - solvigroup/corporate | Align Health Policy Strategies with funding into primary care  
Reform Primary care funding policy |
| **Structure of Learning** | Professional Incentives for attendance and active participation in practice-based QI/CPOD activities  
- Professional points / Registration  
- Financially linked to income/practice payments  
- Access to clinical / IT services | Contracted to provide individualised support to the general practice to systematised QI education programs and clinical pathways and processes | Professional bodies to set Quality Improvement benchmarks and KPI as part of the registration and accreditation requirements |
| **People, workflow and processes** | Funding Incentives to provide Team-based solutions for systems of patient care  
- Provision of QI/CPOD  
- Ensure CPOD programs link directly with QI programs and overall QI systems change  
Provide financial incentives to Practices who participate in QI programs/data collection  
Provide reminders and support for data reports and PDSA related systems change | Provide IT support for new technology | Reform Primary care funding |
| **Technology** | Funding Incentives to encourage practices to adopt technology to assist with QI programs | Practice incentive payments to align with Technology requirements |  |
and saw this as a priority for QI work in their community. However, they reported difficulty in adopting QI process into regular work systems due to lack of any other tangible incentive.

It was reported that GP interviewees signed up for the QIPulse study because they were personally interested in improved preventive care and individual patient health outcomes.

"It was an opportunity to become more proactive rather than reactive, ... it's too much reactive care in general practice, I think, even though we're obviously aiming to be preventative, often in the day to day running of a practice, they don't happen." GP9

Still, doing this work as part of usual business proved difficult for most. The lack of financial incentives meant that it was ultimately not given sufficient priority by the GP practice staff or the PHN. In particular, QI was seen as time-consuming and low priority to systematise into existing business models.

"QI projects currently happen outside of consulting and in general practice the only way that you can have money coming in is to be seeing patients and providing services....I think funding incentives for QI projects would be good because then you can then allocate some time." GP6

**Culture (values, beliefs, norms)**

The overriding organisational QI culture was reported as key to implementation of QI activities for both the general practice and the PHN. QI culture being defined in this context as an environment where the organisational team hold a shared understanding and belief in the value of doing QI activities designed to evaluate and/or improve healthcare delivery and outcomes [28].

There were significant cultural differences noted between the participating practices. While initial interest in and enrolment into the project was driven mainly by an individual GP or Practice Manager, having a practice culture which aligned with a supporting QI activities was reported as an essential factor for successful implementation of QI, rather than the size or location of the practice.

One GP interviewee described a practice culture characterised by clearly defined leadership, collaboration with all the staff (primarily via regular meetings and discussion around identified areas of improvement) and commitment to try new initiatives.

"It really comes down to the culture within the practice, who is the real leader, who is the driver in the practice... with QI, for it to be really successful, you need all of practice engagement, but you really need to have somebody who is going to take the reins on that." (PHN1)

The general practice interviewees highlighted that the most critical determinant for whether or not they could implement and sustain the QI work was the culture created by their significant leaders. Identified influential leaders were usually a GP (owner or designated "lead") but also noted to be the Practice Manager or Practice Nurse.

Interviewees reporting a pre-existing QI culture also noted increased practice engagement during this project. Practices with no prior experience of QI reported difficulty engaging GPs in the QI process. In particular, corporate style practices did not appear to have systems to enable the adoption of QI to improve patient outcomes by contracted GPs. This style of practice was also noted to lack a practice culture designed to engage the entire team with each of the identified changes to achieve an improvement. On the other hand, practice teams who had previously embraced QI were more enthusiastic about being involved. They utilised established clinical audit and review systems to identify what needed to be done, by whom and how to check whether it achieved the desired outcome. Some interviewees reported recruiting staff aligned with QI culture and had a policy of ensuring the entire team received regular updates about QI projects. Conversely, in practices that described a lack of commitment to defined leadership or QI project uptake was less enthusiastic and difficult to disseminate to the GPs working in the practice. One interviewee from a larger corporate style practice who was personally motivated by an interest in CVD noted that implementing practice-wide change was only possible with the cooperation of the owner, practice manager, nurse and secretaries. They reported that this had not been evident in their practice during QIPulse. They noted that it was challenging to engage the GPs to do anything that might involve extra work. This corporate style of practice enabled GPs to work as individuals with no culture around promoting clinical governance and accountability around the quality of care delivered to their patients.

Several interviewees who discussed the clinical benefits of working within a group of GPs aligned with QI contrasted with a solo GP who noted interactions in her team tended to revolve around practice management rather than clinical issues. Peer support for QI in clinical management for the solo GP was gained through external activities such as PHN organised professional
development. This practice reported difficulty in achieving sustainable implementation of QI processes, despite having authority and clinical leadership in adopting change. The constant demands upon the GPs’ time from acute issues precluded what were perceived as optional, less essential activities.

At its most pragmatic, a lack of consensus or accountability regarding clinical input from peers meant that introducing QI was seen as too time-consuming from the clinician viewpoint—particularly given the lack of visible or measurable benefits over the longer term.

"Unless I can see an immediate necessity for it, I’d rather not do it... (GPS)"

A PHN interviewee also noted that their meso-level organisation needed to have a cultural shift from seeing QI as an optional add-on and instead identifying it as a core process that integrates into all projects, alongside building relationships with the general practices in their footprint.

"QI should be embedded in everything we do..." (PHN4)

Structure of learning (infrastructure to support continuous learning and improvement)

Overall, most GP interviewees did not report having a structured approach to continuous learning and quality improvement within practices. Many GP interviewees described a lack of clinical leadership within their Practice team, operating as a group of siloed independent GPs with no structured approach to education or support by their employer. Most Practices held some face-to-face meetings as an entire Practice; however, the purpose and intention of the sessions varied from practice to practice depending on the owner’s preference. Corporate practice interviewees noted regular huddle meetings sponsored by Pharma with no relationship to their individual or collective learning needs. Several interviewees said they would have appreciated shorter, practice-level presentations from the PHN, particularly after the QI workshop, to assist with how to implement what had been presented.

However, some interviewees noted the difficulty in getting GPs together to meet as this was unpaid time and so not seen as a priority for contracted GPs. Specifically, there was no time available during practice hours for scheduling meetings around QI topics. PHN interviewees also noted the difficulty in gaining access to general practices to talk to GPs—they reported being heavily reliant on communication via the non-GP staff such as the practice managers and nurses. Education was seen as an individual responsibility for the GPs rather than as part of the Practice responsibility.

The PHN interviewees also noted the lack of resources to provide educational support, despite acknowledgement by the PHN senior executive that the provision of face-to-face support was key to engagement and implementation of programs with GPs and practices.

"Support from an individual at the PHN was essential and a main driver of the project" (PHN1)

Another barrier noted by interviewees to the adequate provision of PHN services to practices was the regular turnover of key project staff. This led to the need to retrain and upskill new project staff, loss of corporate memory, and inadequate capacity to fully undertake the required scope of GP support programs. In most cases, the priorities of each general practice were reported as influenced by the lead GP, but with implementation usually handed over to PM or PN. All interviewees felt that a lack of tailored practice support hampered the implementation of the QPulse project activities. Positive adoption of QI and change in systems were reported as more likely where key practice staff had an inherent interest and capabilities in clinical data management and computer software skills.

While interviewees reported initially completing the PDSAs [29] as requested, these were reported as negative experiences. The PDSAs were described as tedious, time-consuming or repetitive—with no one adopting this methodology as a systematised way to assist in QI activity, despite acknowledging their value in targeting change. The PHN interviewees also reported very little engagement with the PDSA process.

"Getting practices to submit PDSAs was very difficult...I think that GPs think it is too time-consuming...If we can come up with a less time-consuming version, I think they would be more willing to complete it." (PHN3)

Some interviewees did note positive changes within their practice following the implementation of previous structured QI programs, including increased coding of diagnosis and the ability to track improvements over time with reports that included all of their data and charted improvements. The opportunity to engage with the data was limited, with only intermittent reporting amongst the participating practices due to the IT and scheduling problems associated with the software. PHN interviewees also noted that data extractions without the follow-up provision of monthly reports and targeted education provided little long term value for the practices.

When asked about attending education, training and networking sessions designed to upskill general
practice staff to do QI work, most GPs reported that they favoured face-to-face engagement. However, this was also reported as a significant barrier to participation as there were never mutually convenient times or places for everyone to attend. For QPulse, this was reflected in the poor attendance rates by participating practices at scheduled training and support sessions despite prior agreement to attend.

"The CPD workshops were good at engaging members but it was very hard to get them there" (PHN4)

People, workflow and care processes (role optimisation, processes of care, standard workflows)
Although it was confirmed in the interviews that all interviewees had engaged with baseline requirements of the QPulse project (measurement of baseline data, initial goal setting, setting up (at least one) PDSA cycle and then reviewing goals). It was also evident that only two practices had implemented practice workflows to achieve a sustainable QI process. Most GP interviewees reported that they saw it as just another extra thing to do, rather than an opportunity to improve their data or health outcomes.

"QPulse was lighter touch than we would have liked, like this was supposed to be much more engaging program than what it ended up being." (PHN4).

Two interviewees from the most engaged practices also discussed the difficulty of achieving sustainable QI. They cited both lack of tangible incentives (for practice management and GP employees) and dedicated time to do this work. PHN interviewees identified the need to provide long-term assistance in this work rather than brief interventions rolled out with no system or solutions to achieve sustainability.

They noted that most individual GPs are not interested in practice management and workflow systems and instead are focused on getting through their daily acute clinical care workload. The need to align appropriate resourcing by the PHN to enable role optimisation for the frontline PHN project officers was highlighted as key to the implementation of QI by PHN and GP interviewees. All interviewees noted the lack of resources allocated to QI work by the PHN.

Lack of clarity around the roles and responsibilities of PHN staff was highlighted by PHN interviewees as another barrier to QI implementation. One interviewee observed that a lack of clear guidance by team leaders about the QPulse project had resulted in a lack of motivation and uncertainty in terms of what each staff member should be setting out to achieve and the outcomes they were accountable for delivering.

"QPulse became a mini-project, carried out by a lone project officer separated from the 'core business' of the PHN" (PHN3).

PHN interviewees identified specific enablers included strategic use of flexible funding streams (to fund QI work). Key barriers were the high staff turnover, lack of engagement and skills in QI work by crucial staff (particularly frontline project officers), full time versus part-time roles (continuity of functions) and client managing competing priorities with minimal time allocation to assisting with "add on" QI projects.

In addition, it was noted that at the start of QPulse, three meso-level GP organisations (formerly known as Medicare Locals) were merged to form one PHN increasing the number of practices that fell within the remit of individual PHN project officers. This appeared to exacerbate their difficulty in meeting project and practice expectations. For QPulse, one project officer was responsible for overseeing 40 practices in a role funded at three days per week.

PHN interviewees also noted that QI support needed to be better tailored to individual practice needs and priorities rather than directed by the preferences of specific PHN projects.

"Lack of funding for the PHN to adequately resource QPulse together with lack of financial incentives for practices to engage was seen as the major barrier to getting things happening" (PHN2).

The PHN interviewees discussed the importance of prioritising engagement with people in the practice who are responsible for the oversight of systems of care.

Several mentioned that a provision of more regular updates and visits from the PHN might have helped maintain the prominence of this work amongst all the other competing priorities of the busy GP practice.

"without the reminders from the PHN...it doesn't happen" (GP1).

Significantly, GP interviewees noted the additional workload arising from QI was not sustainable in the long term without some tangible incentive for interviewees - both for the individual GP and the practice team. Incentives might be both financial and aligned with accreditation and registration. The particular challenges of sustained engagement when the practice operated as a group of independent contractors was also noted, especially with a lack of obvious financial incentives.

Technology (Information services, electronic health records)
The use of technology tools to aid QI, such as Healthtracker, the clinical decision support tool, was reported as
crucial in successful implementation but was also a cause of failure and disengagement, often needing additional time investment in troubleshooting. There were varying levels of IT ability and IT difficulties experienced within the GP practices and by PHN staff. Barriers ranged from poor IT connectivity, incomplete data entry, challenges with using the software tools, and achieving sustained usage, specifically for QPulse, adopting the new technology (Healthtracker) during clinical patient encounters.

From a practice perspective, most interviewees saw the PHN as an essential resource, particularly concerning the installation and troubleshooting of the Healthtracker software.

The importance of good relationships with the PHN was made clear by several interviewees, both as a supportive IT support resource (e.g., installation of PenCAT and troubleshooting problems with Healthtracker) and as a source of reminders to do the monthly data extractions and data review. GPs appreciated the assistance provided by the PHN at the point of software installation, noting that this ensured the program was useable by the general practice participants.

"Healthtracker needed GPs sure it... wasn’t a white elephant... that no one could use" (GP2).

Many GP interviewees stated that learning to use new technology was a barrier; yet also noted the decision support tool, Healthtracker, was user friendly and appealing to both GPs and patients. However, Healthtracker did not always run as intended in some practices, with several interviewees reporting that they had experienced problems, although these were usually readily solved by the PHN contacts. It was evident that none of the GP interviewees achieved sustainable adoption of Healthtracker despite acknowledging its value-add during consultations.

Software incompatibility was also cited as a significant barrier, with no on-call IT support to troubleshoot a solution. Ongoing and often unresolved difficulties encountered included software crashing with updates, lack of automation with data extractions and reminders, inability to access or use the PenCAT tools, and problems setting up and training all practice team members.

Some interviewees also noted that access to the PenCAT Data extraction tool could be difficult. It was only available on one computer terminal within a practice providing a barrier for easy implementation of the QI process.

One GP interviewee expressed her disappointment when there were problems with data extractions and exports, resulting in a disruption in ongoing data reports.

"we put all those figures in for 12 months... I thought"

we’d be reviewing all our data to see if we were better but they stopped our access..." (GP4)

Most GP interviewees found that regularly submitting data to the PHN was beneficial for setting up a pattern of QI work.

"certainly having that done is very important to see how we’re going" (GP2)

Still, they found the ongoing time requirements challenging without any financial incentive to compensate for this task's administrative burden in the too-hard basket.

The QPulse project did not examine patient barriers to medication utilisation nor the adoption of recommended lifestyle measures as these data fields were not extractable from the GP medical records.

"patients were very keen to be involved – but they wouldn’t realise the risk and TopBar (Healthtracker) was a great way of visually explaining this to them" (PN1)

However, GP interviewees discussed improved conversations with patients when using the Healthtracker point of care tool, which they stated achieved better engagement in discussions regarding preventive care strategies.

Discussion

The QPulse interviewees provided an opportunity to understand the why and what happened of the project’s failure to quantitatively demonstrate changes in the measured data outcomes as previously reported [23].

What is the daily experience of real-world general practice that prevents the adoption of routine CVD preventive care? QPulse interviewees understood improving CVD preventive care provided them with an opportunity to decrease mortality rates linked to CVD in Australia. Yet, they were unable to demonstrate any tangible change in the recorded risk measures or prescription of CVD preventive care [23]. A 2021 AIHW report looking at data from >5700 Australian general practices showed disappointingly similar results, with only 48.5% of patient records showing cardiac risk measures [14]. This figure has not shifted over the last 15 years [8, 24, 30] despite the introduction in 2019 of a Government-funded Heart Health check by GPs [31]. This study, together with the AIHW data, demonstrate a need to change health policy strategic approaches, such as implementing incentives alongside quality improvement projects to address barriers revealed by this analysis.

There are differences between the implementation of change exemplified by the original Kraft et al. article and those found in this study. QPulse relied on general practices opting into the project, whereas Kraft et al. focused...
on a mandatory, all-practice, system-wide implementation. The critical role of the supporting organisation in the QPulse project was complicated by the PHN being a new and evolving entity rather than an established organisation with a clear strategy for supporting and implementing QI projects.

Both general practice and PHNs are reliant on their external environment to provide the incentive required to enable work outside of the current fee-for-service model of primary healthcare.

Our analysis identified incentives as critical enablers across all five domains for improvement strategies in both general practice (microsystem) and the PHN (meso-level organisation), which included both dedicated funding for QI directly into general practice, such as the financial incentives introduced into Sweden in 2016 [32] and mandatory continuing professional development that incorporates quality improvement, to encourage changing clinical practice aimed at improving patient outcomes [33].

The analysis also identified a range of themes across the five domains of the CSI framework that align with current national and international research on implementing quality care initiatives within primary care settings [34–38]. The themes identified from this study include the crucial need for leadership both at the practice and PHN, and the provision of tailored education and support for each practice setting. The need for better communication systems and trust amongst all staff and project officers is essential, including the need to address many GPS’ lack of readiness for change.

Implementing change also requires a paradigm shift from individual practitioner care toward team-based care alongside a longer-term commitment to achieving sustainability rather than rolling out a series of independent projects, as found in other healthcare settings [38, 39]. Other resonant themes were the need for better IT systems and support, such as integrated electronic health records, decision support tools and data reports, and funding models designed to support sustainable changes in general practice systems [38–40]. In QPulse, the culture of each general practice was crucial to implementing the Q1 program. Each practice had distinct and unique characteristics affected by previous QI experience, practice ownership and their underlying philosophy regarding patient-centred, team-based models of care versus physician autonomy. It was also evident that even the Q1 culturally engaged practices needed financial support to normalise QI work to sustain a constantly growing portfolio of QI projects. There is evidence of the flow-on effect of the fee-for-service funding model, which provides a perverse disincentive for most GPS to participate in non-face-to-face care, such as QI activity [40]. This will need to be addressed, via funding reformation, if implementation and sustainability of QI programs are to be improved.

Overall implementation of the QPulse project was adversely affected by the timing of its rollout. Specifically, the initial rollout coincided with a significant change in contract, funding and structure of the meso-level organisation. As a result, QPulse was sidelined into being a siloed QI project rather than becoming part of a strategic QI program for both the general practices and PHN staff. This affected the implementation for all participants in the study. The current study also had specific limitations in that it was conducted in one urban PHN with a limited number of general practices located in this footprint and thus cannot reflect barriers specific to rural or regional areas.

Conclusions
A strategic, evidence-based approach should be taken for future funding of primary care QI programs. The need for incentives prioritising the adoption of QI, such as funding for both infrastructure and time, has been identified as crucial in the current Australian healthcare system.

Implementation strategies should flexibly address and support the required incentives to address the identified range of issues specific to general practice setting: culture and readiness for change, practice-based education programs, leadership training and accessible IT support. PHNs need to be contracted to deliver these programs. Staff can only do this if the organisation has contractual obligations and funding to enable this level of support proactively.

Abbreviations

Supplementary Information
The online version contains supplementary material available at https://doi.org/10.1186/s12975-022-01629-0.

Additional files 1: Figure 1. QPulse timeline. Figure 2. QPulse Practice Recruitment Flowchart. Figure 3. Interview questions for QIC Intervention.

Additional files 2: Table 4. Interview questions for stakeholders in general practices. Table 5. Interview questions for stakeholders in Primary Health Network.

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gouga/Quality-Improvement-Academy/quality-improvement-tools/'
model-for-improvement-and-pdca-cycles.'


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Chapter 8.0: General discussion

Introduction

Each of the published manuscripts in Chapters 4 – 7 includes a discussion of the findings in relation to the literature, and interpretation of factors that may contribute to the findings, their limitations, and the implications of the results for understanding how we translate preventive care guidelines into the real world of Australian general practice. This closing chapter takes a macro view of how the findings of the four manuscripts (in combination) address the research aims and add to the literature on implementing preventive care guidelines in Australian general practices. Recommendations for future research are also discussed.

Substantive discussion

Aim 1: What are the enablers and barriers to the implementation of sustainable QI programs in Australian general practice settings? and Aim 4: Identify and explore the factors driving implementation and examine the barriers and enables for the adoption of the QIC (QPulse)

Chapters 4, 6 and 7 identified current barriers and enablers to the implementation of sustainable QI programs in Australian general practice. In the discussion below, I draw on my findings to consider the important enablers and barriers to the implementation of sustainable QI programs in Australian general practice.

The results highlighted that the Australian primary care environment is complex and is a challenging setting in which to implement change. Although general practitioners and other healthcare team members valued improved patient outcomes, the qualitative findings from the QI interventions (APCC and QPulse) highlighted several common barriers. Each of these factors was seen to be enablers of sustainable QI when present or available to a general practice; however, all were also seen as barriers to successful implementation if they were not present or available. Paper 4, which analysed QPulse participants’ feedback, highlighted that implementation of QI varied considerably between the individual practices, with key enablers emerging as incentivisation and QI organisational culture within each practice setting.
Notably, stakeholders identified a lack of importance/salience given to quality care and improvement as a major barrier to implementing QI. In the real-world setting, implementing QI simply was not seen as a priority in service delivery and, therefore, not given precedence by practice staff. Organisational culture refers to a team's shared values and beliefs that govern how the people within the team behave [127]. Implementing QI change in general practice also requires a paradigm shift from the individual practitioner delivering care toward team-based care, alongside a longer-term commitment to achieving sustainability [128, 129]. The general practice setting will need a more tailored, long-term approach to QI rather than rolling out a series of independent projects, which has been found to be effective in some other healthcare settings [130]. Implementation research looking at achieving sustained improvements has also demonstrated the need for tailored approaches across each context [113].

Furthermore, in both the APCC and QPulse, stakeholders identified that implementing QI required leadership within the organisation, clearly delineating who was responsible for implementing or driving the change. Clearly defined leadership by ‘change champions’ was identified as essential at three levels: among the broader GP community, internally within the general practice team and at the meso-level primary care organisation (PHN) itself. ‘Change champions’ were defined as the QI implementation champions who volunteered or were selected to help facilitate change [131].

In addition to these factors, having organisational systems for clear communication among practice staff and user-friendly IT systems for tracking practice data were also considered necessary pre-requisites for QI. Stakeholders emphasised the crucial role that data and IT systems played in the participation and successful implementation of QI by general practice teams [132]. By ‘data’, stakeholders referred to coded clinical information within electronic health records to generate practice or GP-specific reports. Quality data and providing regular, accurate reports about practice populations were key to enabling QI work. The crucial importance of data for QI has also been found in other Australian [133] and international studies [134].
Stakeholders also reported that practices and workflows of staff and GPs were prioritised around time. Because funding is based on a fee-for-service model, clinicians and practice staff will generally not adopt changes that take more time, are challenging to fit into their workflow or are ‘unbillable’ aspects of patient care. There is no Medicare reimbursement for specific QI-related work for Australian GPs. In August 2019, the Federal Department of Health introduced a new Quality Improvement Practice Incentive Payment for accredited general practices [45]. This payment requires the general practice to participate in a QI project and provide a regular download of de-identified patient data to their local PHN [135]. However, no data-related targets or improvements were aligned to the payment, meaning it was a reporting payment rather than a QI payment.

These specific barriers and facilitators identified in the current research resonate with the findings of Kaplan et al., who reviewed 47 articles regarding QI in healthcare. They linked the success of QIC programs to high-level leadership, organisational culture, data infrastructure, clinician involvement and the number of years involved in QI programs [136]. Nicholson et al. in 2013 discussed the role of meso-level primary health care organisations (PHCO) in realising integrated health system reforms and identified ten key governance elements to PHCOs success: joint planning; integrated information communication technology; change management; shared clinical priorities; incentives; population focus; measurement – using data as a quality improvement tool; continuing professional development supporting joint working; patient/community engagement; and, innovation [137]. In Australia, the Federal Department of Health oversees the implementation of meso-level Primary Health Care Organisations (31 PHNs). There are two publicly available goals for these organisations to achieve. The first is to improve the efficiency and effectiveness of health services for people, particularly those at risk of poor health outcomes. The second is improving the coordination of health services and increasing access and quality support for people. Despite providing a publicly available, comprehensive performance framework that each PHN needs to report against, two of Nicolson et al.’s key governance elements, change management and incentives, were absent from the listed PHN review criteria [38, 138]. The importance of incentives and change management (as seen through the lens of change champions) in the results of Chapters 6 and 7 suggests policy writers should target this potential gap in future PHN performance reviews.
Aim 2: To what extent, how and why, are the 2012 CVD risk assessment and management guidelines implemented in Australian general practices? and Aim 3: Was an abbreviated QIC program [QPulse] associated with improvements in the monitoring, prescribing practices and attainment of BP and lipid targets for CVD risk reduction?

The quantitative data analyses documented in Chapters 5 and 6 (papers 2 and 3) showed significant gaps between CVD management guidelines and practice. The results showed that only half of the patients with established CVD or at high risk of CVD were prescribed the recommended risk-reducing medications. Most high-risk patients did not meet blood pressure and lipid targets, and more than half of the patients did not have their BMI or waist circumference measured. There were no changes in the prevalence of risk factors or attainment of targets after implementing a brief QIC intervention aimed at improving CVD screening and management (QPulse). However, there was variation noted across practices, with some demonstrating isolated improvements in the documentation of some CVD risk factors. These quantitative results showed there is much scope for GPs to improve CVD risk assessment and management. However, a brief QI intervention in general practices was not associated with improving CVD risk assessment and management.

Although these findings are startling, similar research in Australia and internationally has demonstrated similar gaps in CVD management in general practice [26, 66, 67]. The qualitative interviews with QPulse participants offered insights into a range of factors that may have contributed to no changes in CVD management after the intervention, as detailed in Chapter 7.

As highlighted in Chapters 4, 6 and 7, all stakeholders in general practice acknowledged their opportune position to reduce the evidence-practice gaps in CVD; however, there was consensus that the broader environment and health system around general practice prevented the attainment of this goal. In both the APCC and QPulse evaluations, there was no mention that the motivations or skills of practitioners, practice staff or the PHN were barriers to QI. All parties were genuinely motivated to improve patients’ health and felt they had the necessary skills to do so. These results concord with similar Australian and international studies that also suggest the main barriers to improvements in patient care are
not at the healthcare-worker level [127, 139, 140] but rather lie in the broader environment of the health service and the health care system [127, 141].

Another explanation for the persistence of the evidence-practice gap in CVD management seen in Chapter 5 is how guidelines are interpreted in the ‘real world’ general practice setting. Practitioners’ knowledge of guidelines and their ‘rationalised’ clinical decision-making processes may be barriers to the uptake of newer changes in guidelines [142]. Guidelines are constantly updated, and GPs may not be knowledgeable about more recent changes with a lag period between the release and uptake of guidelines in practice [143]. This may have played a role in the current study as the guidelines were updated in 2012, and data collection for QPulse took place between 2014-2016. GPs often base their clinical decisions on a complex range of factors in addition to guidelines. They may incorporate patient choices into decision-making about their management, which is advocated in patient-centred care [144].

Additionally, the less often discussed role of ‘mindlines’ in clinical decision-making should be considered whilst trying to make sense of the persistent evidence-practice gaps. The term ‘mindlines’ was coined by Gabbay and le May in 2004 [145]. Mindlines are described as guidelines in the head, in which evidence from a wide range of sources has been melded with tacit knowledge through experience and continual learning to become internalised as a clinician’s personal guide to implementing evidence-based guidelines [145, 146]. The observed differences in implementation of the QI process by the enrolled general practices, seen through both the quantitative and qualitative data in Chapters 5-7, suggest further research into the role of mindlines could be undertaken. In particular, the sources that inform and influence GPs in the melding of mindlines, and how this affects the systems of care within each general practice to assist in better implementation of systems to deliver improved preventive care.

The results of Chapters 5 and 6 highlight there are also many complexities in marrying the extracted medical record data with guideline recommendations to benchmark the provision of CVD prevention in primary care. Assessing ‘performance’ in health care is complex; a frequent but unintended consequence of health service research is that performance
assessment is often scoped or simplified due to time/resource or data access constraints. Furthermore, the way GPs and patients negotiate CVD risk management in their consultations was not captured in the current research or any other known data to this scale in Australia or internationally. Research providing these insights would undoubtedly provide valuable understanding into the evidence-practice gap. In addition to this, the current study did not consider patient compliance with recommendations/therapy, and in QPulse, there was a short time frame (6 months) between the intervention and measurement of clinical outcomes (e.g., BP, lipids), which is a limitation for examining changes in physiological outcomes.

Implications for practice: How do we translate preventive care guidelines into the real world of Australian general practice?

Interventions that take all shapes and forms may be futile if the system within which they are embedded does not support them and if they do not address the fundamental barriers and enablers. As Einstein famously said - "Insanity is doing the same thing over and over and expecting different results."

The combined findings of the APCC, QPulse study and literature suggest that for QI initiatives to be successfully implemented into practice and for QI to persist in Australian general practices, changes are required at the health system, practice, and practitioner levels. More specifically, this research identified that the following factors were required for implementing enduring QI in Australian general practices:

- Leadership within general practices that is supportive of QI and change management
- Creating and sustaining a QI culture within general practices.
- Developing accurate patient datasets that enable regular auditing and review.
- Implementing IT systems that assist GPs in optimisation of individual patient care.
- Designing practice systems that support QI.
- Providing financial incentives to GPs and practices for implementing QI, and
- Provision of external support for QI systems via a meso-level organisation such as the PHN.
A culture that recognises and internalises the principles of QI in Australian primary care needs to be fostered if such initiatives are to endure and promote continuous improvement, rather than ongoing stasis. Education and training in QI need to be introduced into both the GP training pathway and continuing professional development, as well as in the training of practice staff, such as practice nurses, practice managers and reception staff. Practice IT and management systems should incorporate QI into the workflow of GP practices so that participation in QI enhances patient care rather than placing a burden on it. Staff in meso-level support organisations, such as the PHN, will also need the skills and knowledge to implement QI in practices and to facilitate practices to integrate QI into their day-to-day operations. Internationally, countries, such as Denmark, Canada and Scotland, have adopted a genuinely localised approach to QI via a system called “Quality Circles” or “GP Clusters” [147, 148]. These are small local groups of GPs, with a specific goal to deliver improved quality care to their patients. The Scottish model is compulsory for all GPs across the country. A recent qualitative review about the effectiveness of the Scottish model at supporting QI identified some similar barriers to implementation of QI as documented in this thesis. Specifically, the study identified the need for external support of these initiatives. Although GPs reported the groups as being friendly and well organised, they were not seen as productive. Support for cluster activity (data, health intelligence, analysis, quality improvement methods, advice, leadership, and evaluation) was reported as being suboptimal [148].

**Primary care funding**

Primary care funding is the biggest barrier, as well as the potential enabler, to the adoption of guideline recommendations in Australia. Australian general practice funding occurs under a fee-for-service model linked to individual clinicians, encouraging short consultations and episodic care. There is a smaller variable funding stream called Practice Incentive Payments (PIPs) for accredited practices aligned to government-driven agendas [45, 149]. GPs, therefore, currently face a disincentive to providing high ‘quality’ care versus high ‘volume’ care. Indeed, many GPs have stated that it is impossible to provide high-quality care under the current funding model due to the decreased pay schedule per hour generated for a longer time and increased complexity of care [150].
Furthermore, there are no incentives for the practice or the patient to use a single general practice (or specific clinician) to provide care preferentially. Therefore, the current funding arrangements promote episodic short-term care rather than long-term care required for high-quality chronic disease management and prevention [133, 151]. The current funding model could be described as promoting ‘fast medicine,’ with increasingly adverse effects on health outcomes similar to the ‘fast food’ epidemic - increasing rates of preventable diseases such as CVD, diabetes, renal impairment, depression, and obesity.

Qualitative analysis of the APCC and QPulse participants highlighted the need to reform the current funding model to prioritise QI. In April 2019, specific Medicare item numbers became available to GPs that focussed on CVD preventive care such as the heart health check (items 177, 699) [45, 149] along with a broader scope of CVD risk factors incorporated in routine data collected by PHNs [152]. However, the measurable gaps in patient care persist when reviewing recent GP data [45, 149]. This may be because these interventions have not addressed the fundamental barriers and enablers of change. Although Medicare has specifically itemised heart health checks for GPs, they are not financially incentivised above the standard Medicare rate for a longer Level C consultation (item 36). Additionally, while there has been increased inclusion for CVD risk factors on the QI data sets collected by PHNs, this has not been coupled with QI targets for missing data or the attainment of specified clinical targets.

**Sustaining change**

The most benefits from interventions come when they are integrated consistently into standard patient care, become part of the operation or workflow of patient care, and become the basis of the practice systems [163, 154]. While numerous studies have addressed the efficacy and effectiveness of health interventions, less research addresses successfully implementing and sustaining interventions [155]. Despite several useful frameworks for improving the implementation of interventions into general practice, there continues to be a gap in research informing dissemination and sustainability activities [156].

The NPT and CSI framework analyses of the implementation of the QPulse project enabled a deeper and more nuanced understanding of barriers and enablers to sustainable QI. The results from the NPT analyses (Chapter 6) showed that widespread deficiencies in factors
identified as ‘enablers’ in the APCC program (Chapter 4) were cited as barriers to the successful implementation and normalisation of QI in the QPulse intervention. NPT identifies, characterises and explains key mechanisms that promote and inhibit the implementation, embedding and integration of new health interventions viewed through four lenses – coherence, cognitive participation, collective action and reflection. When reviewed from the collective action or reflexive monitoring lens, the positive coherence and initial commitment to improving CVD management expressed by each practice did not subsequently align with their ability to implement the intervention.

The evaluation using the CSI framework (Chapter 7) identified the key lack of incentivisation to systematise QI affecting all five domains of this framework – goals and strategy, culture, structure of learning, people and processes and the technology. This was seen across the three levels of health system level examined by this project - micro-level [general practice], meso-level (the PHN) and the broader health system levels.

In 2014 Bodenheimer et al. [83] described the following four ‘foundational’ building blocks that were present in all the US general practices identified as delivering sustainable, high-performing care:

a. Engaged leadership
b. Data-driven improvement
c. Empanelment [patient registration]
d. Team-based care.

The Australian primary health care system does not currently adequately incentivise nor reward the provision of these ‘foundational’ building blocks. This is an essential context to the findings of the barriers, enablers and intervention effects reported in this thesis. The current funding model (as discussed above in primary care funding) provides marginal incentivisation for data-driven improvement. A Practice Incentive Payment is provided to practices for the provision of de-identified patient data regarding 10 ‘baseline indicators’ (such as the number of patients with smoking status recorded) and for ‘team-based’ care through team care arrangements (TCA) for patients with chronic conditions [157, 158]. It is worth noting that this payment is not incentivising general practice ‘team-based’ care. The TCA incentivises patient referrals and access to Medicare funding for five allied health visits
per year rather than improved communication and collaboration by the ‘team.’ At the time of writing this thesis, general practices have not been required to ‘improve’ any of the measures aligned to the practice incentive payments [159].

Implications of this research for policy

Improved cardiovascular assessment management has the potential to reduce the burden of CVD among the population, and GPs are optimally located in the health care system to implement CVD preventive care. However, interventions are unlikely to be effective unless changes at the health system and practice levels alleviate the barriers to change. This will require concerted efforts and commitment from the government to realign the culture of primary healthcare and the practical and financial support provided to GPs and practices so that change is valued and implemented in day-to-day patient management and the practice workflow.

A recent literature review in 2022, looking at the role of QICs in general practice, concludes that re-funding collaboratives could build quality improvement capacity in the primary care system and that QICs can meet the improvement needs of general practice and their teams [160]. General practice participants in collaboratives reported positive effects from effective peer interaction, high-quality local support, and real engagement with data during the QIC programs [37]. The potential for economic benefits to the healthcare system as a whole needs to be recognised. There is a noticeable gap in research examining the economic benefits of funding Australian General Practice QIC for the health system as a whole. The APCC program was closed down in 2015 with high cost cited as the reason for cessation by the Australian Government funders. This was despite improvements in measurable outcomes seen throughout the 10 years of the program [37]. A systematic review published in 2020 looked at studies reporting on costs and cost-effectiveness of QICs when used to implement clinical guidelines in healthcare. The cost savings to the healthcare setting identified in these studies outweighed the costs of the collaborative itself [161].

Well-designed and implemented QI interventions have the potential to achieve sustained change and need to be part of planned funding reforms in Australian primary care. Primary care funding needs to be reformed to include innovative models of care with the following suggestions that align with four income streams into general practice.
- Remuneration for improvement activity, such as evidence of individual GP and practice participation in QIC programs.
- Reward quality of care rather than volume of care. Payments that are aligned to improving or sustaining preventive care activities such as measuring CVD risk and prescribing evidence-based medications.
- Incentivise patient empanelment (enrolment or registration with one General Practice). Seeing the same GP for most of an individual's care (continuity of care) is linked to better uptake of preventive care and lower mortality [162]. Introducing targeted funding that supports regular and continuous care by one General practice or GP, such as Voluntary Patient enrolment as proposed by the recently released Australian Primary care 10-year plan [163].
- Incentivise improvements in patient outcomes. Introduce payments aligned to decreased preventable hospitalisations, improved patient-related outcome measures (PROMs) or patient-related evaluation measures (PREMs) [164].

Meso-level support organisations, such as the PHNs, need to be contracted to re-orient their role to better support improvements in primary care in the following ways:

- Provide leadership for QI activity.
- Promote a culture of improvement in practices.
- Train GPs and practice staff in QI, and
- Provide hands-on implementation and support for QI to all stakeholders in primary care.

Professional and training organisations, such as Australian medical schools and general practice colleges (RACGP and Australian College of Rural Remote Medicine), must prioritise the dissemination and education of systems to support QI. The following three opportunities exist in this context:

- Embed a culture of improvement across all professional activities.
- Include QI in their curriculum, and
- Include QI activities in CPD.
Limitations and implications for further research

Several limitations and implications of this research's findings need to be considered for the development and planning of further research examining the implementation of clinical guidelines in Australian general practices.

The generalisability of the findings may be limited to specific geographical areas. The QPulse study was undertaken in the CESPHN footprint and may not be generalisable beyond central and eastern Sydney. Participation bias may have also affected the generalisability of results across all Australian general practices, and there was a short time frame (6 months) to measure physiological changes. Recruitment of participants to the qualitative interview of both the APCC and QPulse were from practices that participated in these QI initiatives; therefore, the participants may have been biased toward practices that supported QI.

Future studies examining the implementation of clinical practice guidelines could examine a range of health priority areas. Practices from across the wide diversity of Australian urban and rural settings should be studied, and interviews with non-participatory practices to get a more comprehensive representation of barriers and enablers as well as examining the experience of patients of participating practices. The intervention effect of the QI interventions may have been examined better using an RCT or cohort study design to minimise composition and contextual sources of bias. A longer follow-up period than six months after the intervention would also enable a more realistic assessment of the findings, as many of the physiological outcomes may take more than six months to become apparent.

The QPulse intervention design did not include any direct patient interaction or feedback around the usefulness of the POC decision making tools nor their engagement with intensification of CVD preventive care activities such as exercise, dietary recommendations or the addition of more medications. Measurement of several 'interim measures' that may precede changes in physiological outcomes, such as changes in diet, and physical activity-which were not included in the current data extractions, may also inform on whether the QI interventions were effective in engagement with the associated desired lifestyle changes. The addition of the patient voice in collaboration with the clinician is crucial in understanding the full impact of clinical recommendations, adoption and adherence of evidence-based guidelines by both GPs and patients. Further research that includes patients as stakeholders in the process evaluations of interventions may further capture the complex negotiation
process. Prioritising management goal setting between GPs and their patients may also shed more light on the role of QI in the primary care setting.

This research also highlighted the complexity of the healthcare environment and the multiple factors that impact the provision of healthcare and patient outcomes. The true complexity of this system cannot be captured by traditional qualitative or quantitative research methods alone. These results advocate a more profound understanding by employing a broader systems-based analysis of the Australian primary health care system. A systems-mapping process could explore how the elements within the Australian primary care system identified here interact and influence each other and the possible leverage points to support practice change in alignment with clinical practice guidelines.

Finally, the candidate’s role as a General Practitioner within the footprint of the study may have affected how participants responded during interviews. The potential for personal biases and assumptions that may have affected how the interviews were conducted and analysed was discussed with each participant and reflected upon by the candidate with each interviewee. Data analysis for this study was conducted by a numerous independent researchers to assist in moderating bias of interpretation of the emergent themes.

**Conclusions**

CVD management in primary care has a lot of scope for improvement. QI is unlikely to address this effectively unless changes at the health system and practice levels alleviate the barriers to QI. This will require concerted efforts to realign the culture of primary healthcare and the practical and financial support provided to GPs and practices so that QI is valued and implemented in day-to-day patient management and within the practice workflow.
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