

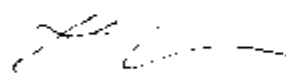
**Development and Validation of an Electronic Decision
Support Tool to improve Vascular Risk Management
in patients with Diabetes Mellitus**

By Dr Santhi Chalasani

Presented to:
Sydney School of Public Health
The University of Sydney

*A thesis submitted in partial fulfillment of requirements for the degree of
Master of Philosophy*

*I certify that the intellectual content of this thesis is the product of my own
work and that all the assistance received in preparing this thesis and sources
have been acknowledged. This thesis has not been submitted for any degree
or other purposes.*

Signature: 
Name: Santhi Chalasani

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

Supervisor Name: Anushka Patel

Signature:



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Dedication

This thesis is dedicated to my son Nathan, who during the course of my Masters was diagnosed with Autism Spectrum Disorder, and who in his short life has me taught me more about patience, compassion, resilience and faith than in all my previous years working in medicine.

*“If I can stop one heart from breaking,
I shall not live in vain;
If I can ease one life the aching,
Or cool one pain,
Or help one fainting robin
Unto his nest again,
I shall not live in vain.”*

- Emily Dickinson (Complete Poems, 1924)

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Abbreviations

ACCHS	Aboriginal Community Controlled Health Service
BMI	Body mass index
BP	Blood pressure
CDSS	Clinical decision support system
CKD	Chronic kidney disease
CVD	Cardiovascular disease
EDS	Electronic decision support tool
GEE	Generalised estimating equations
GP	General practitioner
HbA1c	Glycated haemoglobin
HDL	High density lipoprotein
HREC	Human Research Ethics Committee
LDL	Low density lipoprotein
NHANES	National Health and Nutrition Examination Survey
NVDPA	National Vascular Disease Prevention Alliance
PBS	Pharmaceutical Benefits Scheme
QI	Quality improvement
T2DM	Type 2 diabetes mellitus
TORPEDO	The Treatment of cardiovascular Risk in Primary care using Electronic Decision support study

Abstract

A growing diabetes pandemic is unfolding throughout the world. Cardiovascular disease is the major cause of mortality and morbidity in diabetes with huge associated economic burden. CVD risk factor management in patients with diabetes improves mortality and morbidity. In Australia, most opportunity for addressing CVD risk occurs within the primary health care system. Contemporary CVD risk management guidelines recommend basing the need for and intensity of prevention strategies on estimation of absolute risk. The proliferation of multiple disease specific guidelines, congested workflows, and implementation into time-pressured consultations pose critical barriers to guideline uptake into clinical practice in patients with diabetes. Clinical decision support systems are effective strategies to address these barriers. However, despite Australia's burgeoning information technology health infrastructure, few such systems exist. In The Treatment Of cardiovascular Risk in Primary care using Electronic Decision support (TORPEDO) study the investigators utilised a multifaceted electronic decision support system and quality improvement intervention (*'HealthTracker'*) to improve management of cardiovascular disease (CVD) risk. Data from TORPEDO presented in this thesis indicates that screening and treatment of cardiovascular risk factors in patients with diabetes remains suboptimal despite a number of quality incentive programs and government initiatives. As part of this thesis, the *HealthTracker* algorithm was expanded to include screening and management recommendations for patients with

diabetes. This process was completed in 4 steps: (1) review of national and international guidelines; (2) development of an algorithm encompassing 178 guideline-based recommendations in concert with an expert advisory group; (3) validation and incorporation into an existing software platform interfacing with two of the most commonly used general practice record systems; (4) user acceptance testing with further modifications. Integrated disease management software tools such as *HealthTracker* hold promise to improve treatment gaps for patients with diabetes.

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Chapter 1: Background and Overview

Candidate's contribution – Dr Chalasani reviewed the literature and wrote the Chapter in its entirety.

Diabetes mellitus is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. Type 2 diabetes mellitus (T2DM) is recognized as a pandemic disease, closely associated with population aging, obesity epidemics and 'lifestyle' changes (1). In 2015, 415 million people had a diagnosis of diabetes, and it is estimated that T2DM will affect 642 million people by 2040 (2). The economic burden of T2DM is enormous with 673 billion dollars, or 12% of global health expenditure spent on diabetes (2). T2DM is now amongst the leading causes of death in low and middle income countries worldwide.

In Australia, it is estimated that 1.7 million people have diabetes, with a total annual cost of approximately 14.6 billion dollars (3). In 2012, one in 10 Australian deaths recorded diabetes as an underlying or associated cause of death (4). T2DM is disproportionately experienced by Aboriginal and Torres Strait Islander peoples. Diabetes death rates among Aboriginal and Torres Strait Islander Australians are three times as high compared with non-Indigenous Australians (4). Diabetes is one of the major challenges facing the Australian health care system today.

Cardiovascular disease (CVD) is the major cause of mortality and morbidity in diabetes (5). There is a substantially increased risk of macrovascular events such as myocardial infarction and stroke in patients with diabetes (6). People with diabetes are up to 3 to 4 times more likely to develop CVD and six times more likely to develop atherosclerosis than people without diabetes (7). Around 75% of patients with diabetes die from CVD (7).

CVD risk factor management in patients with diabetes has been shown to improve morbidity and mortality in large studies (8, 9). A recent systematic review and meta-analysis of 40 trials among patients with T2DM, found that each 10-mmHg reduction in systolic blood pressure (BP) was associated with a lower risk of mortality, and reductions in cardiovascular events, coronary heart disease, stroke, albuminuria, and retinopathy (9). In a 2008 meta-analysis of 14 randomised trials of statin-lowering therapy in patients with diabetes, there was a 9% reduction in all-cause mortality per mmol/L reduction in low density lipoprotein (LDL) cholesterol, and a 21% proportional reduction in major vascular events per mmol/L reduction in LDL cholesterol (8). There were reductions in myocardial infarction, coronary death, and stroke amongst patients with diabetes on statin-lowering therapy (8). Uncertainty remains regarding the use of anti-platelet agents in patients with diabetes without known macrovascular disease.

Despite the proven benefits of addressing cardiovascular risk factors amongst patients with T2DM, and the recommendations of current Australian guidelines (10), large evidence practice gaps in both screening and treatment exist. Three cross-sectional studies of cardio-metabolic disease management have recently been conducted in Australian general practice and Aboriginal Community Controlled Health Service (ACCHS) settings (11) (12) (13). A key finding in these studies was that over 50% of routinely attending adults lacked sufficient recorded information to comprehensively evaluate vascular risk (11, 12). Similar evidence-practice gaps in treatment of CVD risk factors have

been noted in other Australian studies amongst patients with T2DM. A study of 3286 patients with T2DM performed more than a decade ago, found that 66% of high-risk patients were not on anti-hypertensive treatment and 77% were not on lipid-modifying treatment (14). A more recent study in 2008 of 473 patients with poor glycaemic control showed significant proportions of participants with a risk factor were not on lipid or BP-lowering therapy, and identified 74%, and 75% of patients out of target range for blood pressure and lipids, respectively (15). Existing deficiencies in attaining guideline-recommended targets for BP, lipids and glycaemic control are contributing to preventable vascular mortality and morbidity in patients with T2DM.

In Australia, most opportunity for addressing CVD risk occurs in the primary health care system. General practitioners (GP) are commonly used in Australia and are usually the initial point of contact for health concerns for many Australians. In 2012-13, GPs were the most commonly accessed health service in Australia, with 8 out of 10 (81.1%) people visiting a GP at least once in the previous 12 months (16). Additionally, Australians with a long term health condition such as T2DM, were more likely to visit the GP at least 4 or more times in a 12-month period (16). In 2009-10, diabetes accounted for 2.4% of all problems managed by GPs, making it the fourth most frequently managed chronic condition in general practice (17). However, the proliferation of multiple disease specific guidelines, congested workflows, and implementation into time-pressured consultations pose critical barriers to guideline uptake in the primary health care setting in patients with diabetes.

Clinical decision support systems (CDSS) are one effective strategy to address these barriers. In four recent systematic reviews on their effectiveness, around two-thirds of studies demonstrated improvement in practitioner performance (18-21). One systematic review identified four decision support system features associated with improved performance: incorporation in routine work flow, provision at the time and location of patient consultation, use of computer-based tools, and provision of treatment recommendations rather than just assessments (20). Australia's healthcare industry is well placed to make use of electronic decision support tools. Approximately 90% of primary health care services in Australia are now using electronic health records (22). In 2011-12, 88% of Aboriginal and Torres Strait Islander primary health-care services used electronic client records, and more than two-thirds (77%) had electronic patient information and recall systems (23).

In 2007, the Australian government introduced its National E-Health Strategy (24) promoting national co-ordination of e-health solutions and building of long term e-health capabilities. It is hoped that Australia's burgeoning information technology health infrastructure will address some of the challenges it faces: an aging population, increased burden of chronic disease, growing consumer demands for expensive and technologically advanced procedures, disparities in health outcomes between Indigenous and non-Indigenous Australians and shortage of skilled health care professionals (24). The electronic and digital platform has become increasingly central for health care delivery, and is now widely utilized for prescribing, pathology, imaging and patient referral.

Electronic decision support tools have the potential to seamlessly integrate

within the broader e-health context; both to serve as a prompt at the interface of the clinician with patient data to facilitate guideline based decision making, and to synthesize data from various portals to improve decision making.

Despite the potential of CDSS, few such systems exist in Australia.

'HealthTracker', a multifaceted electronic decision support (EDS) system was developed to improve cardiovascular risk management in Australian primary health care(25). A large-scale randomised trial of HealthTracker – the Treatment Of cardiovascular Risk in Primary care using Electronic Decision support (TORPEDO) study, demonstrated significant improvements in risk factor screening, and initiation of therapy in those at high risk who were not receiving recommended treatments at baseline (ref 24). The implications of use of such systems extend well beyond being a point-of-care clinical resource. In light of the growing burden of chronic disease in the community, even incremental improvements in treatment of cardiovascular and metabolic risk will have a profound impact on population health.

In this thesis, CVD risk management among people with Type 2 diabetes in Australian primary care is explored further. Chapter 2 provides a summary of current published knowledge of this area. Chapter 3 contributes further to this knowledge through an assessment of contemporary management of CVD risk factors in people with diabetes utilising the baseline population of the TORPEDO trial. Chapter 4 then compares the effectiveness of a quality improvement tool, *HealthTracker*, among people with and without diabetes in the TORPEDO study. Finally, Chapter 5 describes the process by which the *HealthTracker* algorithm was expanded to include specific screening and

treatment recommendations for patients with T2DM, with subsequent validation and user acceptance testing.

Chapter 2: Gaps in cardiovascular risk factor screening and treatment in patients with and without T2DM and strategies to address these – what does the existing literature show?

Candidate's contribution – Dr Chalasani reviewed the literature and wrote the Chapter in its entirety.

2.1 Current Australian guidelines

The superiority of cardiovascular risk management strategies based on a patient's absolute risk rather than individual risk factors is increasingly being recognized (26). Such strategies detect people with mild or moderate abnormalities in individual risk factors, that in combination, considerably increase overall cardiovascular risk. Absolute risk strategies maximise cost-effectiveness through identification of patients with the greatest potential to benefit from pharmacotherapy (27). Australia's first absolute risk assessment guideline was released in 2009 by the National Vascular Disease Prevention Alliance (NVDPA) and in 2012 this was augmented by a single management guideline (10). The importance of such a strategy in patients with T2DM who carry an increased cardiovascular risk is well recognised.

Primary prevention

Current Australian guidelines (10) recommend that absolute CVD risk factor assessment be performed for all adults aged 45-74 years not known to have CVD or a clinically high-risk condition (this is defined further in Chapter 3), using the Framingham Risk Equation to calculate the 5-year risk of a cardiovascular event. In Aboriginal and Torres Strait Islander patients absolute risk assessment is recommended to start from age 35. Adults who are found to be at high CVD risk are recommended treatment with both lipid and BP-lowering therapies unless contra-indicated. In patients with T2DM, targets for treatment include BP less than or equal to 130/80 mmHg, triglycerides less than 2.0 mmol/L, LDL cholesterol less than 2.0 mmol/L, and high density lipoprotein (HDL) cholesterol greater than 1.0 mmol/L (10).

Secondary prevention

Current Australian guidelines (28) recommend all adults with T2DM and known CVD receive BP-lowering therapy regardless of initial BP unless clinically inappropriate or contra-indicated. For those with pre-treatment BP values greater than 130/80 mmHg, BP should be targeted to less than or equal to 130/80 mmHg (28). Additionally, it is recommended that all adults with T2DM and prior CVD should receive the maximum tolerated dose of statin therapy irrespective of lipid levels. In Australia, target lipid levels in secondary prevention for patients with T2DM are HDL cholesterol greater than 1.0 mmol/L, LDL cholesterol less than 1.8 mmol/L, and triglycerides less than 2.3 mmol/L (28). Finally, it is recommended that all patients with T2DM and known CVD should receive long-term anti-platelet therapy unless contra-indicated (28).

2.2 What are the *screening gaps* between guideline-recommended care of cardiovascular risk factors and actual practice amongst patients with T2DM in the primary health care setting?

There is a paucity of contemporary data relating to screening gaps amongst patients with T2DM in the primary health care setting in Australia. A national cross-sectional survey of 2,618 patients in 2006, found that BP had not been recorded for 13% of the sample as recommended by Australian guidelines (12). LDL cholesterol levels were not available for 53% of patients who should have had guideline-recommended lipid screening. Similar findings were seen

amongst Aboriginal and Torres Strait Islander peoples in primary health care settings. In a study conducted between 2007 and 2008, 53% of 1165 Indigenous Australians regularly attending health care services were not adequately screened for CVD risk according to national recommendations (29). However, these studies were not limited to patients with diabetes.

Aggregated data from May 2013 to February 2014 from Wave 9 of the Primary Care Collaboratives Program indicates screening of cardiovascular risk factors amongst Australian patients with diabetes is poor (30). In February 2014, on average only 6.1 of 17 possible elements included in an annual care cycle for patients with diabetes were recorded. These elements include body mass index (BMI) assessment, HDL assessment, BP assessment, eye examination, foot examination, physical activity review, haemoglobin-A1c (HbA1c) assessment, cholesterol assessment, triglycerides assessment, urinary micro albumin test, diet review, smoking status review, medicine review, and a “Self Care Education” session. Of the modifiable risk factors: systolic BP, cholesterol, smoking, waist circumference, physical activity and alcohol intake, on average only 2.1 of 6 risk factors were recorded per eligible patient with diabetes in February 2014. However, this represented a 30% increase in recorded risk factors from May 2013 when only 1.6 out of 6 risk factors were recorded (30).

Screening gaps for patients with diabetes in Australia appear to be slightly worse than those observed internationally (31). A comparison of diabetes management in five countries found that annual HbA1c testing and lipid

assessment were performed in 70-80% of patients in the US and UK compared to 50-60% of patients in Australia and New Zealand (31). Screening gaps for albuminuria amongst patients with diabetes appear to be particularly large. In a Canadian study of data collected from 84 primary health care practices, only 55.8% of patients with diabetes received an albumin excretion test, and only 54.9% received recommended HbA1c screenings (32). Significant opportunities for primary health care providers to engage high risk patients are not being realised due to inadequate screening.

2.3 What are the *treatment gaps* between guideline-recommended care and actual practice *relating to BP* amongst patients with T2DM in the primary health care setting?

Overall, significant gaps exist in the management of BP amongst both patients with and without diabetes in Australia and internationally. In 2002, a large Australian study of 3,286 patients with T2DM in a primary health care setting found that 73.8% had BPs above the recommended target of 130/85 mmHg. Of the patients deemed to be at high cardiovascular risk, 66.2% were not on BP-lowering therapy (14). Analysis of data from studies in 2003 and 2005 of patients with T2DM found that systolic BP targets of less than or equal to 130 mmHg were not achieved in approximately half of all treated patients (33). A GP-based cohort study of CVD risk factors conducted in 1999-2005 of more than 18,000 patients with diabetes, found that 20.6% were not being treated pharmacologically according to evidence-based guidelines, and of those patients on BP-lowering therapy only 21% were meeting BP targets, with almost half of these patients only on monotherapy (34). These

treatment gaps are comparable to those seen in patients without diabetes. A national cross-sectional survey of 99 general practitioners participating in the in the Bettering the Evaluation and Care of Health (BEACH) program, found that only 59% of patients on BP-lowering therapy were meeting recommended targets, and 8% of the study population were not on BP-lowering therapy although it was indicated (12). A study of Indigenous Australians found that substantial numbers of patients determined to be at high cardiovascular risk were not prescribed BP-lowering therapy, and of those on therapy 41% did not meet guideline targets (29).

Although more recent studies demonstrate higher treatment rates, substantial numbers of patients remain untreated or undertreated, contrary to evidence-based guidelines. In a 2013 study of 272 patients with T2DM in a rural Australian primary care cohort (35), 46% of patients not receiving BP-lowering therapy had a BP above the established target of 130/80 mmHg. Additionally, of the patients receiving one, two, three, and four BP-lowering agents, 60, 49, 61, and 50% respectively were above BP targets indicating significant therapeutic inertia. Patients with more optimally controlled diabetes, and on fewer medications were more likely to be overlooked for the pharmacotherapy they required (35). Similar findings were demonstrated in a 2008 cross-sectional analysis of 473 patients with sub-optimally controlled T2DM across 59 general practices (15). 76% of patients on BP-lowering therapy were not meeting target levels for BP and 25% of patients with clinically demonstrated hypertension were not on any BP-lowering therapy (15).

Treatment gaps relating to BP in patients with diabetes in Australia are comparable to those demonstrated internationally. In a Canadian study conducted between 2005 and 2006 of 3002 outpatients with T2DM across 229 primary health care settings, 46% had BP levels above the recommended target, and of these 11% were not receiving therapy and 28% were receiving monotherapy (36). These results were somewhat more positive than those described in two studies in the United States in which recommended targets were only reached by 30% of the study population (37) (38). These treatment gaps reveal significant therapeutic inaction and may partly be due to over-dependence on monotherapy. This is of particular importance as patients with diabetes usually need three to four BP-lowering agents to achieve BP targets (39).

2.4 Are there *treatment gaps* for management of *dyslipidaemia* in patients with and without T2DM in the primary health care setting?

Gaps between guideline recommendations and practice in the management of lipids appear to be relatively high compared with gaps for BP both in Australia and internationally. In a 2002 Australian study, 76.8% of patients with T2DM at high cardiovascular risk were not on lipid modifying therapy and 87.6% of patients had total cholesterol levels greater than or equal to 4.0 mmol/L (14). In a cross-sectional analysis of Australian patients with poorly controlled diabetes, 75% were not meeting lipid targets, and 40% of patients with hypercholesterolaemia were not on lipid-lowering therapy (15). In an Australian study of patients diagnosed with T2DM between 2002 and 2005,

40% of patients were not on lipid modifying therapy 5 years post diagnosis (35). Of these patients, 58% had an LDL cholesterol greater than 2.5 mmol/L, 9% had a HDL cholesterol less than 1.0 mmol/L, and 34% had a triglyceride level greater than 1.5 mmol/L. Of the patients on a single lipid lowering agent, 33% had an LDL level above target and 46% had an elevated triglyceride level (35).

These gaps were similar amongst patients without diabetes. A population survey in rural south-eastern Australia conducted between 2004 and 2006 found that 42% of patients with established CVD or diabetes were untreated, and of the patients without CVD or diabetes who were treated, only 38% reached target LDL cholesterol levels (40). Significant proportions of patients deemed to be at high cardiovascular risk were not receiving primary prevention (40). A 2006 Australian cross-sectional study of 2618 patients found that 41% of patients were not prescribed lipid lowering therapy although it was indicated (12). Of the patients on therapy, only 62% were achieving target LDL cholesterol levels (12).

Similar gaps in lipid management amongst patients with T2DM have been demonstrated internationally. In a Canadian study of 3002 patients with T2DM in a primary health care setting, 37% of patients not achieving recommended LDL cholesterol levels were not on any lipid lowering therapy, and 43% were not prescribed statins (36). A French study of 2346 patients with T2DM found that only 38.7% of patients were meeting recommended lipid targets. Of the patients with lipid levels above target, 31.5% were not receiving any lipid

lowering drug (41). Similar findings have been noted in the US (37, 38), and demonstrate that even in those with established cardiovascular disease, prescription of lipid lowering medication amongst patients with diabetes remains low.

2.5 What are the *treatment gaps* between guideline recommended care and practice in the *glycaemic management* of patients with T2DM?

Improving blood glucose control in patients with T2DM has been shown to reduce the development or progression of microvascular complications (nephropathy, neuropathy, and retinopathy), a major source of morbidity (42-44). However, no distinct independent effect of improving blood glucose control has been demonstrated on macrovascular complications (CVD, stroke) in patients with diabetes (45, 46). Current Australian guidelines recommend a general HbA1c target of less than or equal to 7.0%, although in people with limited life expectancy, recurrent severe hypoglycaemia, hypoglycaemic unawareness, or with other co-morbidities an adjusted target may be appropriate (47).

Significant treatment gaps in optimal glycaemic management are evident in both Australia and internationally, with over 60% of patients globally not reaching recommended glycaemic targets (48). A study of 272 Australian patients with diabetes found that 13% of patients not prescribed a glucose lowering agent had an HbA1c above target (35). 30% of patients on one agent, and 75% of those on dual therapy exceeded the recommended HbA1c

target (35). In another Australian study of 3893 patients with T2DM, only 47.7% of patients had achieved the recommended target HbA1c of less than 7.0% and one quarter of patients had an HbA1c greater than 8.0% (49).

Significant therapeutic inertia has been demonstrated amongst primary care physicians when initiating glucose lowering therapy. In a study of 531 Australian patients with T2DM, the median HbA1c at initiation of oral glucose lowering therapy was 7.7%, and 9.4% for the initiation of insulin therapy (50). Australian patients with diabetes are spending a significant duration of their disease on suboptimal therapy even when intensification of therapy is indicated. This is of particular concern, given that T2DM is a chronic progressive disease and glycaemic control deteriorates over time, necessitating combination therapy. The majority of patients with diabetes will be unable to maintain an HbA1c of less than 7% (53 mmol/mol) on monotherapy alone three years after diagnosis (51).

Similar treatment gaps have been described overseas. A Canadian study of 3002 patients with T2DM, found that optimal glycaemic control was achieved in only one half of the study population (36). Furthermore, a significant number of patients failing to meet the recommended HbA1c target of less than 7.0% were prescribed only a single glucose lowering agent or were receiving no therapy (36). This is similar to the 2003/2004 assessment of the National Health and Nutrition Examination Survey (NHANES) participants in the United States (52) in which only 57% achieved an HbA1c of less than 7% (53 mmol/mol). Interestingly this study showed improving population averages

for HbA1c values in the United States (52). This is similar to population data from Wave 9 of the Australian Primary Care Collaboratives Program which demonstrates that in February 2014, close to 40% of patients on the diabetes register were achieving recommended HbA1c targets of less than or equal to 7.0%, compared to just over 30% of patients in May 2013 (30). Although treatment gaps appear to be diminishing, glycaemic management of Australian patients with diabetes remains substantially suboptimal.

2.6 Are absolute risk calculations being used to guide management decisions for patients with and without T2DM in the primary health care setting?

Despite compelling evidence that comprehensive vascular protection strategies based on absolute risk assessment yield substantive risk reduction (10), uptake into clinical practice remains suboptimal both in Australia and internationally. A cross-sectional survey of 99 general practitioners with data from 2618 patients found that absolute risk had been calculated for 74% of patients for whom it was indicated (12). Patients at high cardiovascular risk were substantially undertreated. For those at high cardiovascular risk without established CVD, only 23% had been prescribed both BP and lipid lowering therapy, and for those with established CVD only 53% had been prescribed combination therapy (12). In a review of 1165 Indigenous Australian patients seen in the primary health care setting, 53% were not adequately screened for CVD risk in accordance with current guidelines, and significant proportions

of patients at high risk were not receiving guideline-recommended combination therapy (29).

In a study of 144 Australian GPs, understanding of absolute risk versus individual risk factors was assessed. GP decision making was more consistent with management of individual risk factors rather than an absolute risk approach, with medical treatment of lower risk patients occurring especially when prescribing BP therapy (53). Data suggests that primary care physicians may use absolute risk assessments to motivate patients and promote patient compliance rather than guide decisions regarding pharmacotherapy (54).

International studies demonstrate the greatest treatment gaps in the management of combined cardiovascular risk factors compared to single risk factors alone. In a review of data from the NHANES participants, only 7.3% of adults with diabetes attained recommended combined targets of HbA1c less than 7%, BP less than 130/80 mmHg, and total cholesterol levels less than 5.18 mmol/L (38). This was similar to results from a Canadian study, in which only 21% of the study population was able to meet combined targets for BP, glycaemia, and LDL cholesterol (36). Despite strong evidence for the use of absolute cardiovascular risk to guide therapy decisions amongst patients with diabetes, its application in clinical practice remains limited.

2.7 What are the barriers to guideline implementation into clinical practice in the primary healthcare setting?

A number of factors are likely contributing to low guideline uptake into clinical practice in the primary health care setting. Firstly, the proliferation of multiple risk factor guidelines sometimes with conflicting recommendations can be confusing. Although newer guidelines are moving away from achieving specific targets and towards a classification of risk, this approach has yet to be adopted into main stream clinical practice. In the Australian setting, GPs may be restricted by Pharmaceutical Benefits Scheme (PBS) prescribing criteria which does not always correlate with current guideline recommendations (12). Additionally, CVD risk management can often only be delivered opportunistically during reviews for a separate presenting complaint. Feedback from GPs suggests that time was a major barrier to the use of absolute risk assessments in clinical practice (54). Furthermore, absolute risk assessments were being used to motivate patients rather than to guide clinical decisions (54) suggesting a need for provision of better information and education to improve GP awareness of the rationale for using absolute risk.

In a study of 1016 Australian GPs in 2009, older age of the practitioner was associated with lower use of guidelines, suggesting a reliance on experience over evidence-based guidelines (55). Other studies have suggested a lack of confidence and knowledge of newer treatment regimens as potential barriers to guideline implementation. An Australian study of 125 GPs and 2 endocrine

specialists, found that GPs were less likely to prescribe a statin, treat hypertension, or refer for lifestyle modification (56). There was significant disagreement around the prescription and modification of glucose-lowering regimens with less GPs likely to change therapy in patients being treated with a sulfonylurea. The authors hypothesized that this may be due to a reluctance to prescribe newer glucose-lowering therapies such as the glucagon-like-peptide-1 (GLP-1) analogs, dipeptidyl peptidase 4 (DPP-4) inhibitors, and sodium-glucose co-transporter 2 (SGLT2) inhibitors (56).

A hesitancy amongst GPs to abandon the traditional approach to glycaemic control may be contributing to limited uptake of guideline-driven care. Previously a more conservative, stepwise method was advocated with institution of lifestyle measures, addition of metformin therapy, and addition of subsequent agents with the maximum tolerated dose of each agent used prior to escalation of therapy. However, this approach can result in unacceptable delays in intensification of therapy with long periods of suboptimal glycaemic control. A more proactive approach with early use of combination therapy is thought to result in more optimal glycaemic control (48).

A 2007 review and synthesis of qualitative studies globally identified six themes of barriers to the uptake of guidelines into clinical practice amongst primary care physicians (57). The first and most prominent theme, occurring in all studies examined was questioning the guidelines. GPs were doubtful about the evidence-base supporting the guideline, and questioned their applicability to the individual patient. Some guidelines were perceived to be

unclear, and ambiguous in their recommendations. Guideline authorship also influenced the perceived authority of the guideline with more favorable attitudes towards guidelines developed by peers (57). GPs' experience was the second theme identified, and reported in all the studies analysed. GPs felt that guidelines often did not allow for the complexity of individual patient circumstances and needs, and were not flexible enough in accounting for patient preference (57).

Preserving the doctor-patient relationship was the third theme identified in some of the studies reviewed. GPs cited fear of endangering their connection with the patient as a reason for non-adherence with guidelines (57).

Professional responsibility, the fourth theme identified, was also cited in several studies for lack of guideline use. Fear of litigation, and missing a diagnosis were reasons for defensive practice particularly when the guideline supported limited use of a screening test. In three of the studies reviewed, GPs saw their responsibility as adapting the guidelines to suit individual patient circumstances (57). The fifth theme, practical issues, was common in all the studies. GPs cited lack of time to read and evaluate the guidelines, follow the recommendations, and negotiate with patients as major barriers to guideline uptake. Other issues included convenience, lack of resources, and lack of skills with new procedures. The sixth and final theme identified was guideline format. GPs felt that guidelines needed to be clear, concise, and simple with the option of provision of patient leaflets (57).

In addition to the factors already described, an analysis of barriers to guideline-implementation amongst Dutch GPs in 2008 found that lack of self-efficacy was a significant obstacle (58). Lack of belief amongst GPs that they would be able to successfully carry out the guideline recommendation was related to a perceived lack of skills and knowledge, and a conviction in the capability of other health care providers in implementing the guideline. Another barrier identified was a “lack of motivation to change and to overcome the inertia of previous practice due to habits and routines” (58). Interestingly, these barriers were most frequently mentioned in relation to cardiovascular risk factor management.

Lack of adherence to guideline recommendations amongst primary care physicians is related to multiple complex barriers and innovative solutions are required to improve uptake into clinical practice and improve patient outcomes.

2.8 Do electronic decision support tools overcome these barriers and what are the key determinants in making such systems successful?

Studies have suggested that better use of information technology would aid in overcoming barriers to uptake of guideline-driven care into clinical practice amongst patients with diabetes (59, 60). Diabetes is unique amongst chronic conditions in that it requires a high degree of patient engagement and self-management to achieve optimal glycaemic control. Improved compliance amongst patients with diabetes can be achieved through a focus on care

management and enhanced provider/patient communication (61). Electronic decision support (EDS) tools are well placed to enhance self-care, aid in communication, and improve patient outcomes in Australia's burgeoning information health technology infrastructure.

There have been a number of systematic reviews on computerised decision support systems in primary care for patients with T2DM (62, 63). A systematic review of 18 randomised controlled trials conducted between 1990 and 2011 in Europe, North America, and Asia found that trials that combined computerised decision support with reminders, feedback, and case management demonstrated improvements in both patient and process of care outcomes (62). Process of care outcomes were classified as improvements in guideline recommended screening and treatment of patients with diabetes, and patient outcomes were defined as improvements in a variety of clinical parameters such as BP and lipid levels, and glycaemic control. Use of information technology alone was associated only with improvements in process of care outcomes and not patient outcomes (62). The finding that the addition of case management, reminders, and feedback to electronic decision support improved patient outcomes, is in keeping with the Chronic Care Model (64) in which an emphasis on coordinated care strategies and a multidisciplinary approach, along with better use of registry-based information to track and trend goal achievement are key determinants of improved patient outcomes.

A systematic review and meta-analysis of 15 randomised controlled trials comparing the impact of computerised decision support systems with a non-computerised decision support control amongst patients with diabetes, found that no statistically significant differences in clinical outcomes were demonstrated (63). Clinical outcomes such as improved glycaemic control, quality of life, hospitalisations, and lipid levels, tended to favour the computerized decision support system but evidence quality was judged to be low due to high risk of bias and heterogeneity between studies (63). A review of systems to support team-based care of chronic illness, including diabetes, found that systems that were effective in improving process of care outcomes including guideline adherence, had an effective connection to an electronic health record system, computerised prompts, specialised decision support, electronic scheduling, and a personal health record (65). This is in keeping with feedback from GPs suggesting that pop up prompts and point-of-care decision support would improve uptake of guideline-driven care (66).

A systematic review of 26 studies that examined the effectiveness of patient initiated electronic support tools in diabetes, demonstrated that such systems enhance patient-provider communication, increase patient satisfaction, improve disease management and patient outcomes, and improve access to health information (67). However, more studies are needed to demonstrate the key determinants of patient based tools in improving patient outcomes. Potential factors include frequency and quality of provider feedback, tailored patient information, provider decision algorithms, visual graphing of clinical data trends, and mobile phone messaging and reminders (67). These findings

support other studies in which quality improvement tools targeting both the patient and physician seem to be more successful amongst patients with diabetes (68). Importantly, despite the usefulness of such tools, both patients and providers value the maintenance of a personalised relationship (67).

Other studies have attempted to define the essential building blocks of high-performing primary care. In a study of 23 highly regarded practices, 10 features were identified as critical for optimal delivery of patient care (69). These included 4 foundational elements: engaged leadership, data-driven improvement using computer based technology, empanelment of patients (through linking each patient to a primary care physician and care team), and team based care. Building on these elements were other factors including patient-team partnership, population management, continuity of care, prompt access to care, comprehensiveness and care coordination, and a template of the future (69). EDS tools are able to incorporate many of these elements.

In four systematic reviews on the effectiveness of CDSS, around two-thirds of studies demonstrated improvement in practitioner performance (18-21). Features associated with improved performance included: incorporation in routine work flow, provision at the time and location of patient consultation, use of computer-based tools, and provision of treatment recommendations rather than just assessments (20). In this project, these four features have been utilized in the development of a novel EDS tool to support clinicians and patients to improve guideline uptake in clinical practice in the management of diabetes.

Chapter 3: New data on the contemporary management of cardiovascular risk factor management amongst Australian patients with T2DM

Candidate's contribution: Dr Chalasani independently developed the analysis plan and wrote the first and final drafts of a manuscript that incorporates Chapters 3 and 4. This manuscript is currently under review with the MJA after a requested revision and resubmission.

3.1 Introduction

The management of chronic disease, and in particular T2DM and CVD, is a national health priority in Australia. There have been a number of targeted quality improvement programs and incentive payments to GPs aimed at improving cardiovascular risk factor management and management of T2DM in the primary health care setting. Since 1996, the National Divisions Diabetes Program (70) and the National Integrated Diabetes Program (71) have encouraged advances in the quality of diabetes care in general practice. In 1999, Australia's *National Diabetes Strategy 2000-2004* (72) was released aimed at ensuring "access to effective, efficient, evidence-based and economically viable services and programs for diabetes prevention and care for all people living in Australia". However, despite an allocation of 43.4 billion dollars over 4 years to the National Integrated Diabetes Program in the 2001-2 Commonwealth budget, progress has been slow (72). In the service incentive payment (SIP) general practices received financial incentives if their patients completed an annual cycle of care involving a detailed set of management steps including regular measurements of cardiovascular risk factors, and providing a measure of the clinical management of patients with diabetes according to national evidence-based guidelines.

The Australian Primary Care Collaboratives Program (73, 74), funded by the Australian Government Department of Health, began in 2004, and aimed to support general practices to improve clinical outcomes, and help maintain good health for those with chronic and complex health conditions such as T2DM, through promoting a culture of quality improvement in primary healthcare. The success of such strategies has been demonstrated in the UK

and USA (75). Since 2004, over 4000 health care professionals have participated in the program serving over 150,000 patients with T2DM (73).

However, whether any of these schemes have significantly impacted quality of care in patients with T2DM is unknown. Much of the data outlined in Chapter 3 predates these quality improvement programs and thus may not accurately reflect the current state of cardiovascular risk factor management amongst Australian patients with T2DM. In order to provide a snapshot of contemporary management of cardiovascular risk factor management amongst Australian patients with T2DM, data from general practices participating in a large-scale randomised trial was examined. In this Chapter, the assessment and management of CVD risk in people with and without diabetes was assessed in the TORPEDO population at baseline.

3.2 Methods

The Treatment of cardiovascular risk in primary care using Electronic Decision Support (TORPEDO) study was a parallel-arm cluster randomised controlled trial, involving 60 Australian primary healthcare services (40 mainstream general practices and 20 Aboriginal Community Controlled Health Services [ACCHS]). The purpose was to establish whether a QI intervention comprising point-of-care electronic decision support with audit and feedback tools improved CVD risk management when compared with usual care. The full methodology of the TORPEDO study is described elsewhere, but is summarised briefly below (25). The baseline data for this trial were used to assess contemporary risk factor assessment and management in those with and without diabetes.

Practice eligibility criteria

Health services were eligible to participate if there was routine and exclusive use of one of two electronic health record systems that record risk factor information, pathology test results and prescribed medications. The aid of primary healthcare organisations known as Medicare Locals was utilised to recruit general practices from the Sydney region. ACCHSs were recruited through partnership with 2 state representative bodies in NSW and Queensland. Practices were recruited between September 2011 and May 2012.

Patient eligibility criteria

The eligible population was defined as all Aboriginal and Torres Strait Islander people ≥ 35 years and all others ≥ 45 years (10) who had attended the service at least three times in the previous 24 month period *and* at least once in the previous 6-month period. The presence or absence of diabetes was determined by a recorded diagnosis of diabetes or an HbA1c $> 7\%$ at baseline. The type of diabetes was not specified.

Data Collection

At study baseline, de-identified data were extracted from each health service's clinical database for all patients who met the eligibility criteria using a validated data extraction tool (77). These extracts were securely uploaded to a study database with an encrypted identifier code attached to each patient extract.

Outcomes

We evaluated the adequacy of CVD risk assessment using the primary outcomes for TORPEDO (25), namely:

1. The proportion of eligible patients who received appropriate screening of CVD risk factors at baseline. This was defined as having recorded or updated all the essential risk factors for measurement of CVD risk (smoking status, BP in the previous 12 months, total cholesterol and high density lipoprotein (HDL) cholesterol in the previous 24 months).
2. The proportion of eligible patients at high CVD risk* at baseline, receiving recommended medication prescriptions. This was defined as: a prescription for one or more BP lowering drug and a statin for people at high-risk without CVD or a lowering of CVD risk to <15% at end of study; a prescription for one or more BP lowering drugs and a statin and an antiplatelet agent for people with established CVD; or a prescription for one or more BP lowering drugs and a statin for people with established CVD who are contraindicated an antiplatelet agent due to current oral anticoagulant use.

The Australian risk calculator, based on the 1991 Anderson Framingham equation (78) was used to calculate the estimated 5-year risk of a cardiovascular event. *High CVD risk is defined in Australian guidelines (10) as (i) a calculated 5-year CVD risk of >15% or, (ii) the presence of any of the following clinically high risk conditions: diabetes and age >60 years, diabetes and albuminuria, eGFR <45ml/min/1.73m², systolic BP>180mmHg, diastolic

BP > 110mmHg, total cholesterol >7.5 mmol/L; or (iii) the presence of CVD, defined as a recorded diagnosis of any of the following: coronary heart disease, cerebrovascular disease (ischaemic stroke and transient ischaemic attack), or peripheral vascular disease. Risk was calculated based on the most recent results available, whether or not the subjects were being treated for that risk factor.

Additional outcomes examined in these analyses included: (1) measurements of individual CVD risk factors (smoking status, BP, lipids, body mass index, estimated glomerular filtration rate, and albuminuria); and (2) BP and serum lipid levels among people at high CVD risk.

Statistical Analysis

Descriptive analyses were undertaken on the baseline data from the TORPEDO study. Data are presented as Mean (SDs), Median (IQR) or proportions, as appropriate. Baseline differences between patients with and without diabetes were tested using generalised estimating equations (GEE) with an exchangeable correlation structure to account for clustering of patients within services.

To determine the predictors of sub-optimal drug therapy at baseline, cross-sectional analyses were conducted using GEE model with logit link function including both patient level characteristics and service level data. The association between risk factors and drug therapy are expressed as

unadjusted odds ratios for binary outcomes with 95% confidence intervals and p-values.

Statistical analyses were carried out using SAS enterprise guide 5.1 (SAS institute Inc. Cary, NC).

Ethics Approval

The TORPEDO trial was approved by the University of Sydney Human Research Ethics Committee (HREC) and the NSW Aboriginal Health and Medical Research Council HREC. Signed agreements with participating sites were obtained. Individual consent waiver was granted, given data collection was based on de-identified extracts from the electronic health record system.

3.3 Results

Sample characteristics at baseline

Of the 53,164 patients in the TORPEDO study population, 8829 (19.9%) had either a recorded diagnosis of diabetes at baseline (97%) or a HbA1c greater than 7% (3%) (Table 3.1). Individuals with diabetes were on average older, more likely to be male, smokers and Indigenous compared to those without diabetes. Those with diabetes also had higher mean levels of BP and triglycerides, with lower mean levels of LDL and HDL cholesterol. Albuminuria, renal impairment and an established diagnosis of CVD were more common in those with diabetes.

Table 3.1 – Characteristics of study participants

Characteristics		All participants at baseline				
		No diabetes		Diabetes		p-value
			n		n	
Age (years), mean (sd)		60.2 (13.0)	44329	63.1 (12.47)	8829	<0.0001
Male, n (%)		18183 (41.1%)	44264	4301 (48.8%)	8821	<0.0001
Indigenous, n (%)		6467 (14.6%)	44335	2956 (33.5%)	8829	<0.0001
Current / recent smoking, n (%)		7984 (21.9%)	36498	1882 (24.1%)	7814	<0.0001
Systolic blood pressure (mmHg), mean (sd)		128.9 (16.8)	39278	133.1 (18.0)	8253	<0.0001
Total cholesterol (mmol/L), mean (sd)		5.1 (1.1)	32448	4.4 (1.1)	7716	<0.0001
HDL cholesterol (mmol/L), mean (sd)		1.5 (0.4)	28958	1.2 (0.4)	7217	<0.0001
LDL cholesterol, mean (sd)		3.1 (0.9)	28655	2.4 (1.0)	7007	<0.0001
Triglycerides (mmol/L), median (IQR)		1.2 (0.9, 1.7)	31868	1.6 (1.1, 2.3)	7630	<0.0001
HbA1c (% , mmol/mol), mean (sd)		-	-	7.8, 62 (3.9)	7556	-
Albuminuria, n (%)		745 (16.4%)	4540	1991 (38.3%)	5198	<0.0001
eGFR < 60 ml/min, n (%)		3054 (9.2%)	33285	1422 (18.6%)	7638	<0.0001
5-year CVD risk, n (%)						
	Missing	18738 (42.3%)	44335	825 (9.3%)	8829	<0.0001
	<10%	16821 (37.9%)	44335	1068 (12.1%)	8829	<0.0001
	10-15%	2046 (4.6%)	44335	356 (4.0%)	8829	0.39
	>15%	933 (2.1%)	44335	199 (2.3%)	8829	0.70
	High risk condition	1449 (3.3%)	44335	4097 (46.4%)	8829	<0.0001
	Established CVD	4348 (9.8%)	44335	2284 (25.9%)	8829	<0.0001
Coronary heart disease, n (%)		3380 (7.6%)	44335	1917 (21.7%)	8829	<0.0001
Cerebrovascular disease, n (%)		1063 (2.4%)	44335	465 (5.3%)	8829	<0.0001
Peripheral vascular disease, n (%)		299 (0.7%)	44335	198 (2.2%)	8829	<0.0001
LVH recorded, n (%)		101 (0.2%)	44335	62 (0.7%)	8829	<0.0001
Atrial fibrillation, n (%)		1343 (3.0%)	44335	511 (5.8%)	8829	<0.0001
Heart failure, n (%)		485 (1.1%)	44335	420 (4.8%)	8829	<0.0001
Appropriate CVD risk screening, n (%)		17527 (39.5%)	44335	5474 (62.0%)	8829	<0.0001
High risk patients on appropriate treatment, n (%)		2668 (39.6%)	6730	3654 (55.5%)	6580	<0.0001
High risk patients (no CVD) on appropriate treatment, n (%)		525 (22.0%)	2382	2252 (52.4%)	4296	<0.0001
High risk patients (CVD) on appropriate treatment, n (%)		2143 (49.3%)	4348	1402 (61.4%)	2284	<0.0001

Screening gaps and CVD risk at baseline

Overall, appropriate measurement of CVD risk factors among those with diabetes was greater compared to those without diabetes (62.0% vs. 39.5%; $p<0.0001$), as was appropriate treatment among those identified at high-risk (55.5% vs. 39.6%, $p<0.0001$). This was consistent after adjusting for age, sex, and Indigenous ethnicity ($p<0.001$). In the subgroup with diabetes, 86% had an HbA1c recorded, while 94% had a systolic BP recorded. Only 59% had the presence or absence of albuminuria recorded, although 87% had a documented estimated glomerular filtration rate. Total, HDL and LDL cholesterol were recorded in 87%, 82% and 79%, respectively. BMI was recorded in 81%, while smoking status was documented in 89% of patients.

Twenty-six percent of the population with diabetes had established CVD, while a further 12%, 4%, and 49% had a 5-year CVD risk that was estimated to be low ($< 10\%$), medium (10-15%), and high ($> 15\%$ or clinically high-risk condition) respectively. Only 9% had insufficient information to categorise risk.

Prescribing gaps at baseline

Prescribing gaps were substantially smaller in those with, compared to those without, diabetes (Table 3.1). Overall, 47.6% of those with diabetes but without established CVD were not prescribed recommended CVD preventive medications. The corresponding figure for patients with diabetes and established CVD was 38.6%. The use of individual drug modalities in accordance with concurrent guidelines is illustrated in Figure 3.1.

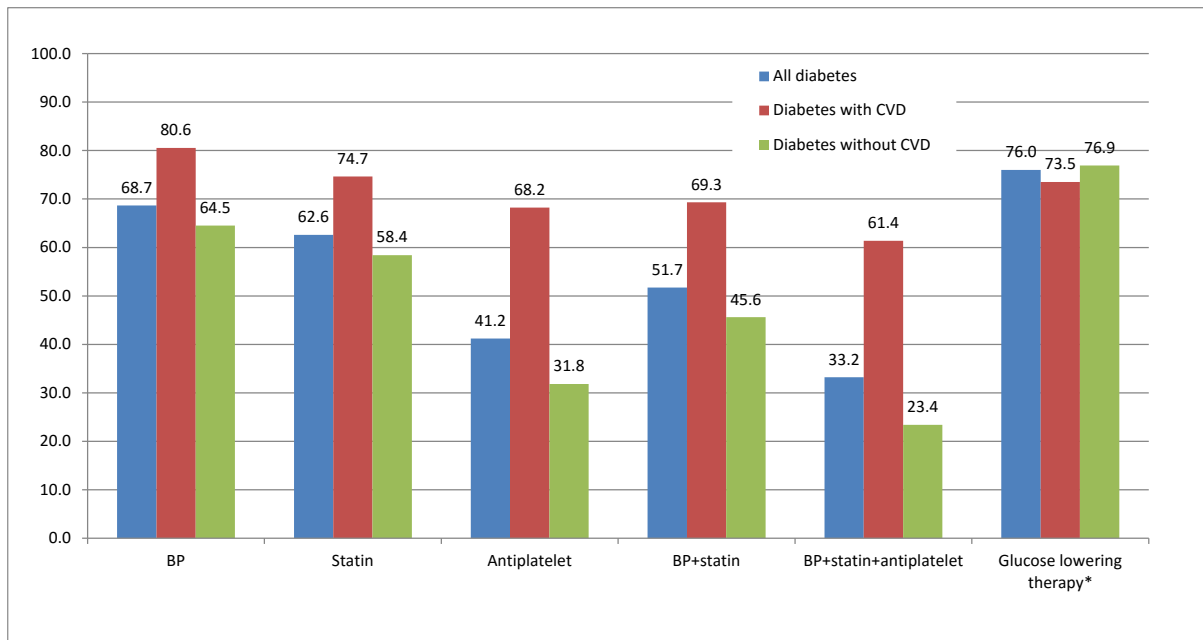


Figure 3.1 – Use of medications among patients with diabetes according to current guidelines.

*among individuals with HbA1c > 7.0% (53 mmol/mol)

Achieving risk factor target levels in those with diabetes

Overall, 57.3% of patients with diabetes had an HbA1c value above 7.0% (53 mmol/mol) and of these, approximately one-quarter were not on any glucose lowering therapy (Table 3.2). Similarly, large proportions of patients with diabetes had BP and lipid levels above recommended target levels. The gap was particularly large for LDL cholesterol, where 61.9% were above 2.0 mmol/L, with 44.3% of these individuals not receiving statin therapy.

Table 3.2 – Patients with diabetes above targets at baseline for whom treatment was indicated, stratified by treatment received

Level of HbA1c	Above specified level n (%)	Not treated with glucose lowering therapy n (%)
HbA1c > 7.0% (53 mmol/mol)	4329 (57.3%)	1038 (24.0%)
HbA1c > 8.5% (69 mmol/mol)	1822 (24.1%)	450 (24.7%)
Level of blood pressure	Above specified level n (%)	Not treated with BP lowering therapy n (%)
SBP>130 or DBP>80 mmHg	4835 (56.7%)	1354 (28.0%)
Level of LDL cholesterol	Above specified level n (%)	Not treated with lipid lowering therapy n (%)
LDL cholesterol > 2.0 mmol/L	4339 (61.9%)	1922 (44.3%)
LDL cholesterol > 2.5 mmol/L	2769 (39.5%)	1412 (51.0%)

Predictors of non-optimal drug prescription

On cross-sectional multivariable analysis at baseline, people with diabetes who were older, Indigenous, had a higher HbA1c, a higher BP level or albuminuria were more likely to be prescribed optimal combination treatment (Table 3.3). Service type was not associated with non-optimal drug prescription overall on uni- and multivariable analysis. However, patients treated in general practices were more likely to be prescribed lipid-lowering therapy. Conversely, those with higher total cholesterol levels were less likely to receive optimal combination treatment. Those who had not had a government-reimbursed health assessment or care plan were also less likely to be optimally treated.

Table 3.3 – Predictors of sub-optimal drug treatment of risk factors in patients with diabetes

Variable	Not on appropriate therapy*		Not on Glucose Lowering therapy		Not on BP Lowering therapy		Not on Lipid Lowering therapy	
	OR (95% CI)	P-value	OR (95% CI)	P-value	OR (95% CI)	P-value	OR (95% CI)	P-value
Age (5 years older)	0.93 (0.91 0.95)	<.0001	1.08 (1.05 1.11)	<.0001	0.82 (0.75 0.89)	<.0001	0.91 (0.88 0.94)	<.0001
Sex (male vs female)	0.94 (0.86 1.03)	0.2159	0.94 (0.86 1.02)	0.1508	1.03 (0.94 1.13)	0.4942	0.93 (0.85 1.02)	0.1074
Weight (1 kg higher)	1.00 (1.00 1.00)	0.1052	0.99 (0.99 1.00)	0.0175	1.00 (0.99 1.00)	0.0753	1.00 (1.00 1.00)	0.3731
HbA1c (1% higher)	0.98 (0.97 1.00)	0.0304	0.91 (0.80 1.05)	0.1862	1.01 (0.99 1.03)	0.2546	1.00 (0.98 1.03)	0.7884
Albuminuria (yes vs no)	0.72 (0.64 0.82)	<.0001	0.92 (0.82 1.04)	0.1863	0.65 (0.52 0.81)	0.0002	0.85 (0.76 0.97)	0.0126
Indigenous (yes vs no)	0.86 (0.76 0.99)	0.0298	0.77 (0.62 0.95)	0.016	1.09 (0.89 1.33)	0.3969	1.14 (0.97 1.33)	0.1092
SBP (5 mmHg increase)	0.97 (0.96 0.99)	<.0001	1.01 (1.00 1.02)	0.0469	0.92 (0.90 0.95)	<.0001	1.00 (0.99 1.01)	0.5676
Total cholesterol (1 mmol higher)	1.45 (1.35 1.55)	<.0001	1.14 (1.07 1.21)	<.0001	1.25 (1.17 1.34)	<.0001	1.38 (1.28 1.48)	<.0001
LDL cholesterol (1 mmol higher)	1.69 (1.52 1.87)	<.0001	1.24 (1.14 1.36)	<.0001	1.40 (1.28 1.53)	<.0001	1.75 (1.55 1.97)	<.0001
HDL (1 mmol higher)	1.39 (1.19 1.63)	<.0001	1.38 (1.18 1.63)	<.0001	1.11 (0.97 1.28)	0.1282	1.17 (1.01 1.35)	0.0334
Type of service								
General practice	0.91 (0.61 1.35)	0.6315	0.75 (0.39 1.44)	0.3892	0.64 (0.36 1.15)	0.1362	0.56 (0.34 0.93)	0.0241
ACCHS	1.10 (0.74 1.64)	0.6315	1.33 (0.70 2.54)	0.3892	1.56 (0.87 2.79)	0.1362	1.79 (1.08 2.98)	0.0241
Medicare Health Assessment item								
Health assessment	0.81 (0.69 0.96)	0.0124	0.96 (0.76 1.21)	0.7412	0.65 (0.55 0.77)	<.0001	0.73 (0.59 0.89)	0.0023
721 GP MP	0.78 (0.71 0.86)	<.0001	0.78 (0.68 0.89)	0.0003	0.78 (0.66 0.91)	0.0014	0.73 (0.65 0.81)	<.0001
723 Team Care Arrangement	0.80 (0.71 0.90)	0.0001	0.75 (0.65 0.87)	0.0002	0.78 (0.66 0.92)	0.0027	0.75 (0.66 0.84)	<.0001

* The Odds Ratio is estimated for the “not receiving therapy” by either per unit increase for continuous risk factors or “yes vs no” for binary factors.

3.4 Discussion

This study shows that gaps in CVD risk factor screening and treatment were lower among people with diabetes, compared to those without diabetes in a contemporary Australian primary care population. Screening gaps in people with diabetes were greatest for cholesterol and albumin: creatinine ratio tests, consistent with both international (41) and local (29) (12) data. A recent study in a French primary healthcare setting (41) reported that only half the patients with diabetes had been screened for proteinuria or albuminuria within the past 12 months. This suggests that renal function is a poorly assessed CVD risk factor in the primary health care setting.

Management gaps were striking when patients were stratified by absolute risk. Only 60% of those with established CVD, were prescribed the recommended combination of a BP lowering drug, a statin, and an antiplatelet medication. Among high-risk patients yet to experience a cardiovascular event, only half were prescribed the combination of BP lowering and statin medications. Among patients with diabetes and LDL cholesterol above 2.0 mmol/L, almost half were not receiving statin therapy. Similarly, BP targets were not met in half the diabetic population, of whom more than one-quarter had not been prescribed antihypertensive therapy. Inadequate control and intervention are consistent with international data (41) (36) (37) (38), and reflect modest improvements compared with previous Australian studies both with respect to dyslipidemia (15) (14) and hypertension (35) (14) in which 70-80% of treated patients were not at target. However, any direct comparison between different studies should be interpreted with caution.

Approximately one-half of the study population had not achieved the recommended HbA1c goal of 7% (53 mmol/mol) or lower. This is similar to the 2003/2004 assessment of the US National Health and Nutrition Examination Survey (NHANES) participants (52) in which only 57% achieved this target. Remarkably, approximately one-quarter of patients in our study with a HbA1c over 8.5% (69 mmol/mol) were not on any glucose-lowering medication. This is significantly worse than a recent Canadian study, in which only 3% of patients failing to achieve a HbA1c of less than 7% (53 mmol/mol) were not treated (36). Our findings may be explained partly by patient preference for non-pharmacological treatment, and relaxed glycaemic targets in select populations (elderly, frequent hypoglycaemia, or hypoglycaemic unawareness).

Overall our findings suggest some diminishing of treatment gaps since 2002. Earlier Australian data indicate 70-80% of treated patients for dyslipidemia and hypertension (14) (15) (34) (35) were not at target and 50-70% of treated patients were not achieving glycaemic targets (35) (49) compared to roughly 50% of treated patients not achieving lipid, blood pressure, and glycaemic targets in our study. This may reflect the effect of incentive schemes and quality of care initiatives (71) (70) (73) (74). However, any direct comparison between different studies should be interpreted with caution. Despite improvements substantial numbers of patients remain untreated or undertreated, and may be explained by the proliferation of multiple guidelines with differing perspectives, and time-pressured consultations in the context of

disparate presenting complaints. We observed that patients with diabetes with a formal care plan, a mechanism that enables coordination of management with other healthcare providers, were more likely to be optimally treated. However causal inferences cannot be made as numerous residual patient or system-level factors may confound this relationship.

The findings of better CVD risk screening and management among those with compared to those without diabetes are entirely consistent with other published data. Previous studies have similarly observed better care among patients with multi-morbidity (83, 84).

The strengths of this study include the large sample size, and the availability of source clinical data that reflects actual practice. The major limitation of this study relates to generalisability, as the services included in the study were not randomly selected. One third of services in our study were Aboriginal Health services, while the proportion of such practices in Australia is approximately 2% (85, 86). Additionally, many were teaching practices where investigation and management may be more intensive. This may account for the higher treatment rates observed amongst patients with diabetes compared to a decade ago. A further limitation was that the type of diabetes was not specified, although it is likely that the majority of patients had type 2 diabetes. Finally, the study relied on the accuracy of general practice records and did not account for clinical judgment in treatment choices.

In conclusion, although CVD risk screening and treatment was more often appropriate in people with diabetes compared to those without diabetes, gaps remain high. Development, implementation and evaluation of quality improvement initiatives to address persistent and substantial gaps remain a national priority.

Chapter 4: The effectiveness of a clinical decision support tool for improving cardiovascular disease risk management in people with type 2 diabetes

Candidate's contribution: Dr Chalasani independently developed the analysis plan and wrote the first and final drafts of a manuscript that incorporates Chapters 3 and 4. This manuscript is currently under review with the MJA after a requested revision and resubmission.

4.1 Introduction

CVD risk factor management in patients with diabetes has been unequivocally shown to improve mortality and morbidity in large studies (8, 9).

Contemporary CVD risk management guidelines recommend basing the need for and intensity of prevention strategies on estimation of absolute risk (10).

Despite the proliferation of such guidelines, Chapters 2 and 3 outline consistent findings of large gaps in the implementation of these strategies in patients both with and without diabetes.

In The Treatment Of cardiovascular Risk in Primary care using Electronic Decision support (TORPEDO) study (25), a multifaceted electronic decision support system and quality improvement intervention (*HealthTracker*) was developed in an attempt to address some of the likely barriers to the management of cardiovascular disease (CVD) risk in Australian primary care. This was the largest randomised controlled trial of a CDSS in Australia to date involving 60 health services and 40,000 people. *HealthTracker* is an intervention that utilises point-of-care decision support, clinical audit and feedback tools, and workforce training to improve the management and prevention of CVD. In the overall study population, significant improvements in risk factor screening, and initiation of therapy in those at high risk who were not receiving recommended treatments at baseline were demonstrated. The primary objective of this Chapter was to compare the effectiveness of this QI intervention aimed at improving CVD risk management between those with and without diabetes.

4.2 Methods

Some aspects of the TORPEDO study have been described in detail in Chapter 3. TORPEDO was a parallel-arm cluster randomised controlled trial, involving 60 Australian primary healthcare services (40 mainstream general practices and 20 Aboriginal Community Controlled Health Services [ACCHS]). The purpose was to establish whether a QI intervention comprising point-of-care electronic decision support with audit and feedback tools improved CVD risk management when compared with usual care. The full methodology of the TORPEDO study is described elsewhere (25), but is summarised briefly below.

Practice eligibility criteria

Health services were eligible to participate if there was routine and exclusive use of one of two electronic health record systems that record risk factor information, pathology test results and prescribed medications. The aid of primary healthcare organisations known as Medicare Locals was utilised to recruit general practices from the Sydney region. ACCHSs were recruited through partnership with 2 state representative bodies in NSW and Queensland.

Patient eligibility criteria

The eligible population was defined as all Aboriginal and Torres Strait Islander people ≥ 35 years and all others ≥ 45 years (10) who had attended the service at least three times in the previous 24 month period *and* at least once in the previous 6-month period. The presence or absence of diabetes was

determined by a recorded diagnosis of diabetes or an HbA1c > 7% at baseline. The type of diabetes was not specified.

Randomisation

Randomisation of services was in a 1:1 allocation to intervention or control stratified at 3 levels: (1) ACCHS or mainstream general practices; (2) service size (< 500 patients meeting eligibility criteria versus > 500); and (3) current participation in a national or state QI program. Permuted block randomisation was performed centrally and outcome analyses were blinded to allocation.

Intervention

Full details of the intervention have been published elsewhere (87). In brief, a screening and management algorithm was developed and validated, based on a synthesis of recommendations from several guidelines (Table 5.1) (88). The algorithm incorporated CVD risk assessment, as well as recommendations for CVD, chronic kidney disease, BP and cholesterol management but did not address blood glucose management.

The Australian risk calculator, based on the 1991 Anderson Framingham equation (78) was used to calculate the estimated 5-year risk of a cardiovascular event. High CVD risk is defined in Australian guidelines (10) as (1) a calculated 5-year CVD risk of >15% or, (2) the presence of any of the following clinically high risk conditions: diabetes and age >60 years, diabetes and albuminuria, eGFR <45ml/min/1.73m², systolic BP>180mmHg, diastolic BP > 110mmHg, total cholesterol >7.5 mmol/L; or (3) the presence of CVD,

defined as a recorded diagnosis of any of the following: coronary heart disease, cerebrovascular disease (ischaemic stroke and transient ischaemic attack), or peripheral vascular disease. Risk was calculated based on the most recent results available, whether or not the subjects were being treated for that risk factor.

The algorithm interfaced directly with two commonly used clinical practice software systems in Australian primary healthcare. Data from the patient record were automatically prepopulated within the tool, with provision to the doctor of point-of-care recommendations on risk factor measurement and management. A data extraction and audit tool provided site-specific feedback performance reports. Clinical staff were trained in use of the tool and had access to a support desk and bimonthly webinars. The intervention was for a minimum of 12 months.

Data Collection

De-identified data were extracted from each health service's clinical database for all patients who met the eligibility criteria using a validated data extraction tool (77). These extracts were securely uploaded to a study database with an encrypted identifier code attached to each patient extract.

Outcomes

The primary outcomes for the randomised trial (25) were:

1. The proportion of eligible patients who received appropriate screening of CVD risk factors by the end of study. This was defined as having

recorded or updated all the essential risk factors for measurement of CVD risk (smoking status, BP in the previous 12 months, total cholesterol and high density lipoprotein (HDL) cholesterol in the previous 24 months).

2. The proportion of eligible patients at high CVD risk at baseline, receiving recommended medication prescriptions at the end of study. This was defined as: a prescription for one or more BP lowering drug and a statin for people at high-risk without CVD or a lowering of CVD risk to <15% at end of study; a prescription for one or more BP lowering drugs and a statin and an antiplatelet agent for people with established CVD; or a prescription for one or more BP lowering drugs and a statin for people with established CVD who are contraindicated an antiplatelet agent due to current oral anticoagulant use.

Additional outcomes examined in these analyses included: (1) the primary outcomes among high-risk individuals who were under-treated at baseline; (2) measurements of individual CVD risk factors (smoking status, BP, lipids, body mass index, estimated glomerular filtration rate, and albuminuria); (3) escalation of drug prescription among patients at high CVD risk (either newly prescribed or additional numbers of antiplatelet, BP-lowering and lipid-lowering agents); and (4) BP and serum lipid levels among people at high CVD risk.

Statistical Analysis

Descriptive analyses were undertaken on the baseline data from the TORPEDO study and on the cohort of participants present at baseline and

end of study. Data are presented as Mean (SDs), Median (IQR) or proportions, as appropriate. Baseline differences between patients with and without diabetes were tested using generalised estimating equations (GEE) with an exchangeable correlation structure to account for clustering of patients within services.

The intervention effects were also analyzed within the cohort from the TORPEDO study with and without diabetes using log-binomial GEE regression. The rate ratios of intervention effect were expressed for different outcomes at end of study. The effects of the intervention in the subgroup of under-treated participants at baseline were analyzed in the same model, stratified by diabetes status. An interaction term was included in all models to assess heterogeneity of effects by diabetes status.

Statistical analyses were carried out using SAS enterprise guide 5.1 (SAS institute Inc. Cary, NC).

Ethics Approval

As previously indicated, the TORPEDO trial was approved by the University of Sydney Human Research Ethics Committee (HREC) and the NSW Aboriginal Health and Medical Research Council HREC, with individual consent waiver granted.

4.3 Results

Sample characteristics at baseline

Of the 53,164 patients in the TORPEDO study population, 8829 (19.9%) had either a recorded diagnosis of diabetes at baseline (97%) or a HbA1c greater than 7% (3%) (Table 4.1). Of the 53,164 patients for which baseline data was extracted, a cohort of 38,725 patients (6,909 with diabetes) were followed up for outcome evaluation. In the cohort of patients with diabetes, there were no major differences in baseline characteristics in those in intervention and usual care practices, respectively.

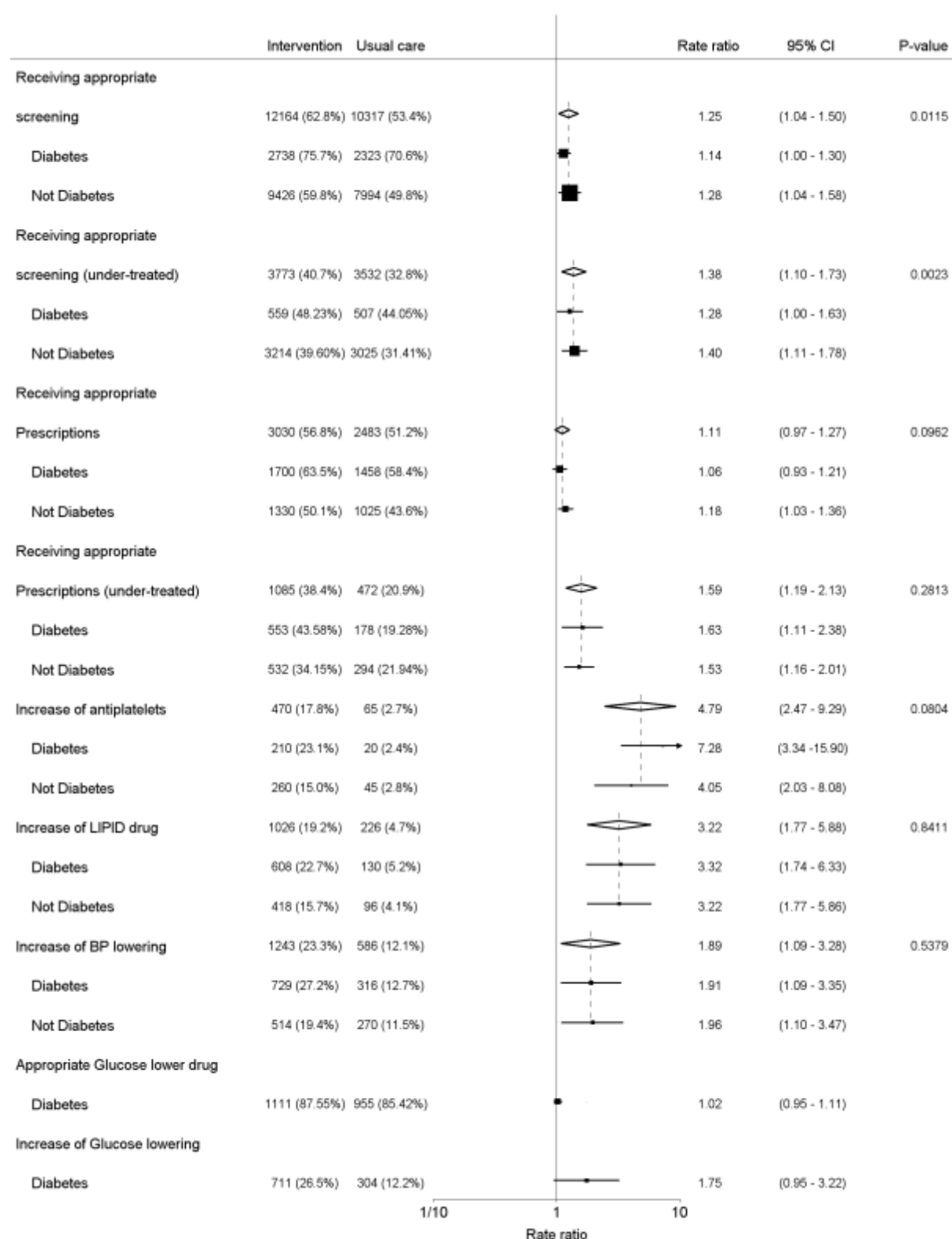
Table 4.1 – Characteristics of study participants

Characteristics	All participants at baseline					Cohort of participants with diabetes at baseline				
	No diabetes		Diabetes		p-value	Control (n=3292)		Intervention (n=3617)		p-value
		n		n			n		n	
Age (years), mean (sd)	60.2 (13.0)	44329	63.1 (12.47)	8829	<0.0001	62.9 (12.04)	3292	62.6 (12.02)	3617	0.906
Male, n (%)	18183 (41.1%)	44264	4301 (48.8%)	8821	<0.0001	1573 (47.86%)	3287	1806 (49.93%)	3617	0.2496
Indigenous, n (%)	6467 (14.6%)	44335	2956 (33.5%)	8829	<0.0001	1156 (35.12%)	3292	1196 (33.07%)	3617	0.6544
Current / recent smoking, n (%)	7984 (21.9%)	36498	1882 (24.1%)	7814	<0.0001	716 (23.87%)	3000	753 (23.39%)	3219	0.5429
Systolic blood pressure (mmHg), mean (sd)	128.9 (16.8)	39278	133.1 (18.0)	8253	<0.0001	133.2 (18.37)	3145	132.7 (17.18)	3409	0.4025
Total cholesterol (mmol/L), mean (sd)	5.1 (1.1)	32448	4.4 (1.1)	7716	<0.0001	4.3 (1.11)	2874	4.4 (1.11)	3359	0.2456
HDL cholesterol (mmol/L), mean (sd)	1.5 (0.4)	28958	1.2 (0.4)	7217	<0.0001	1.2 (0.37)	2690	1.2 (0.35)	3184	0.6076
LDL cholesterol, mean (sd)	3.1 (0.9)	28655	2.4 (1.0)	7007	<0.0001	2.3 (0.91)	2569	2.4 (1.05)	3133	0.5663
Triglycerides (mmol/L), median (IQR)	1.2 (0.9, 1.7)	31868	1.6 (1.1, 2.3)	7630	<0.0001	1.60 (1.10, 2.20)	2802	1.60 (1.20, 2.30)	3359	0.5346
HbA1c (%), mmol/mol, mean (sd)	-	-	7.8, 62 (3.9)	7556	-	7.5, 58 (1.78)	2929	8.1, 65 (4.57)	3203	0.1535
Albuminuria, n (%)	745 (16.4%)	4540	1991 (38.3%)	5198	<0.0001	734 (36.19%)	2028	885 (39.30%)	2252	0.7759
eGFR < 60 ml/min, n (%)	3054 (9.2%)	33285	1422 (18.6%)	7638	<0.0001	488 (17.11%)	2852	593 (18.08%)	3280	0.4773
5-year CVD risk, n (%)										
Missing	18738 (42.3%)	44335	825 (9.3%)	8829	<0.0001	285 (8.66%)	3292	270 (7.46%)	3617	0.3651
<10%	16821 (37.9%)	44335	1068 (12.1%)	8829	<0.0001	378 (11.48%)	3292	492 (13.60%)	3617	0.2565
10-15%	2046 (4.6%)	44335	356 (4.0%)	8829	0.39	125 (3.80%)	3292	167 (4.62%)	3617	0.3754
>15%	933 (2.1%)	44335	199 (2.3%)	8829	0.70	86 (2.61%)	3292	77 (2.13%)	3617	0.1921
High risk condition	1449 (3.3%)	44335	4097 (46.4%)	8829	<0.0001	1589 (48.27%)	3292	1703 (47.08%)	3617	0.9795
Established CVD	4348 (9.8%)	44335	2284 (25.9%)	8829	<0.0001	829 (25.18%)	3292	908 (25.10%)	3617	0.9946
Coronary heart disease, n (%)	3380 (7.6%)	44335	1917 (21.7%)	8829	<0.0001	687 (20.87%)	3292	780 (21.56%)	3617	0.5336
Cerebrovascular disease, n (%)	1063 (2.4%)	44335	465 (5.3%)	8829	<0.0001	148 (4.50%)	3292	180 (4.98%)	3617	0.6236
Peripheral vascular disease, n (%)	299 (0.7%)	44335	198 (2.2%)	8829	<0.0001	84 (2.55%)	3292	66 (1.82%)	3617	0.1276
LVH recorded, n (%)	101 (0.2%)	44335	62 (0.7%)	8829	<0.0001	32 (0.97%)	3292	17 (0.47%)	3617	0.1101
Atrial fibrillation, n (%)	1343 (3.0%)	44335	511 (5.8%)	8829	<0.0001	189 (5.74%)	3292	187 (5.17%)	3617	0.5948
Heart failure, n (%)	485 (1.1%)	44335	420 (4.8%)	8829	<0.0001	143 (4.34%)	3292	168 (4.64%)	3617	0.7948
Appropriate CVD risk screening, n (%)	17527 (39.5%)	44335	5474 (62.0%)	8829	<0.0001	2141 (65.04%)	3292	2458 (67.96%)	3617	0.6374
High risk patients on appropriate treatment, n (%)	2668 (39.6%)	6730	3654 (55.5%)	6580	<0.0001	1575 (62.90%)	2504	1412 (52.53%)	2688	0.316
High risk patients (no CVD) on appropriate treatment, n (%)	525 (22.0%)	2382	2252 (52.4%)	4296	<0.0001	990 (59.10%)	1675	883 (49.61%)	1780	0.2839
High risk patients (CVD) on appropriate treatment, n (%)	2143 (49.3%)	4348	1402 (61.4%)	2284	<0.0001	585 (70.57%)	829	529 (58.26%)	908	0.4975

Effectiveness of the QI intervention

The intervention was less effective in improving risk factor screening in patients with diabetes, both overall and among the subgroup of individuals who were under-treated at baseline (Figure 4.1). The intervention was only effective in improving appropriate medication prescriptions among under-treated high-risk individuals, and there was no heterogeneity for this outcome based on diabetes status ($p = 0.28$). Among those with diabetes the intervention was associated with intensification of existing antiplatelet, lipid lowering, and BP lowering therapy, to a similar extent to that in people without diabetes (Figure 4.1). There was no effect of the intervention on use of or intensification of glucose-lowering therapy.

Figure 4.1 – Effects of the intervention among individuals with and without diabetes



**among patients with HbA1c>7.0% (53 mmol/mol) at baseline*

4.4 Discussion

The *HealthTracker* quality improvement intervention was less effective in improving CVD risk assessment in people with diabetes, compared with those without diabetes. For CVD risk factor treatment among those under-treated at baseline, the effectiveness of *HealthTracker* did not appear to be influenced by diabetes status.

The findings of better CVD risk screening and management among those with compared to those without diabetes are entirely consistent with other published data. Previous studies have similarly observed better care among patients with multi-morbidity (83, 84). This is the likely explanation for our finding that the QI intervention was less effective in those with diabetes compared to those without diabetes, in improving CVD risk screening. Although the intervention was not effective in improving new prescriptions among high-risk individuals overall, it was associated with improved prescriptions among under-treated individuals at baseline, regardless of diabetes status. This is an important finding in light of suggestions that therapeutic inertia may be a greater contributor to lost therapeutic benefit than lack of treatment in patients with diabetes (34).

There is evidence that QI interventions that target the patient as well as the physician may be more successful in patients with diabetes (68). Successful elements of collaborative care programs to improve chronic disease management include the use of evidence-based guidelines, systematic screening and monitoring of risk factors, timetabled recall visits, new or

adjusted roles for team members, information support for the clinician, enhanced patient self-management, a means of effective communication between all members of the care team, and audit information for the practice (89). New policy proposals such as the 'Health Care Homes' (90) and a renewed focus on initiatives such as 'My Health Record' in Australia incorporate some of these elements.

As discussed in Chapter 3, the strengths of this study include the large sample size, and the availability of source clinical data that reflects actual practice. From the perspective of relevance of the QI intervention, services recruited were reasonably representative of Australian general practice in use of information technology (22). Approximately 90% of services in Australia are using electronic health records (22). The ACCHSs involved represented urban, rural and remote areas, and demonstrated service characteristics that were similar to that sector at large (23). In 2011-12, 88% of Aboriginal and Torres Strait Islander primary health-care services used electronic client records (23). A further limitation was that the type of diabetes was not specified, although it is likely that the majority of patients had type 2 diabetes. Additionally, our study relied on the accuracy of general practice records and did not account for clinical judgment in treatment choices. Finally, our study ran for a 12-month period which may have limited the intervention effect observed.

In conclusion, while the QI intervention evaluated here was moderately effective for conventional CVD risk factors, broader strategies will be needed

to achieve Australia's goals in line with the global target of a 25% reduction in premature mortality from CVD and diabetes by 2025 (93). Importantly, it is not unexpected that *HealthTracker* was not associated with any improvements in the use of glucose lowering therapy among those not achieving target, given that the decision support algorithm did not include blood glucose management. Chapter 5 of this thesis focuses on the expansion of the *HealthTracker* algorithm to include specific screening and treatment recommendations for the management of other cardio-metabolic conditions including T2DM, atrial fibrillation, and chronic kidney disease. The remainder of this thesis describes the development, validation and user acceptance testing of the expanded *HealthTracker* algorithm.

Chapter 5: Development and Validation of an Expanded Electronic Decision Support Tool

Candidate's contribution – Dr Chalasani reviewed the literature, was responsible for the algorithm development (validation performed independently, as is required), and wrote the Chapter in its entirety.

5.1 Summary

In brief, the development and validation of the updated *HealthTracker* proceeded in 4 steps:

1. A review of national and international guidelines was conducted.
2. An algorithm encompassing 178 guideline-based recommendations was then developed in consultation with an expert advisory group.
3. The algorithm was validated and incorporated into an existing software platform that interfaces with the most commonly used GP record systems
4. Following user acceptance testing with two general practices further modifications were made.

5.2 Stage 1: Systematic review of guidelines and algorithm development and validation

A content advisory group with experts in the fields of CVD, chronic kidney disease (CKD), T2DM, and atrial fibrillation was formed to provide clinical advice on algorithm development. This group has close ties with the peak professional bodies responsible for the development and updating of Australian guidelines and was able to provide expert knowledge associated with these guidelines.

A systematic review and synthesis of recommendations from relevant national and international guidelines was conducted (Table 5.1). Levels of supporting evidence were identified and inconsistencies were highlighted between

different guidelines. Where evidence was inconclusive, recommendations were developed in consultation with the content advisory group. From this review the *HealthTracker* algorithm was updated with new and expanded recommendations. The risk management outputs of the tool were defined by the consolidation of the guidelines described in Table 5.1. The threshold, and treatment targets amongst patients with diabetes for BP, lipid, and glycaemic management are summarised in Table 5.2.

Table 5.1: Guidelines reviewed for development of the modified HealthTracker algorithm

Professional Organisation	Guideline
International Diabetes Federation	Global Guideline for Type 2 Diabetes 2012
	Managing Older People with Type 2 Diabetes Global Guideline 2013
American Diabetes Association/European Association for the Study of Diabetes	Position Statement: Management of Hyperglycemia in Type 2 Diabetes: A Patient-Centred Approach 2012
National Vascular Disease Prevention Alliance	Guidelines for the Assessment of Absolute Cardiovascular Disease Risk 2012
	Guidelines for the Management of Absolute Cardiovascular Disease Risk 2012
National Aboriginal Community Controlled Health Organisation/ Royal Australian College of General Practitioners	National guide to a preventive health assessment for Aboriginal and Torres Strait Islander People 2012
Royal Australian College of General Practitioners	Guidelines for preventive activities in general practice 8 th Edition 2012
Kidney Health Australia	Chronic Kidney Disease Management in General Practice 2015
Australasian Proteinuria Consensus Working Group	Chronic kidney disease and measurement of albuminuria or proteinuria: a position statement 2012
Royal Australian College of General Practitioners /Diabetes Australia	Diabetes Management in General Practice 2014/2015
Diabetes Australia Consortium	NHMRC Evidence Based Guidelines for Case Detection and Diagnosis of Type 2 Diabetes 2009
	NHMRC Evidence Based Guidelines for Diagnosis, Prevention and Management of Chronic Kidney Disease in Type 2 Diabetes 2009
	NHMRC Evidence Based Guideline for Blood Glucose Control in Type 2 Diabetes 2009
	NHMRC Evidence Based Guideline for the Primary Prevention of Type 2 Diabetes 2009
	NHMRC Guidelines for the Management of Diabetic Retinopathy 2008
	NHMRC Evidence Based Guideline for Patient Education in Type 2 Diabetes 2009
Baker IDI Heart and Diabetes Institute/The George Institute for Global Health	NHMRC National Evidence-Based Guideline: Prevention, Identification and Management of Foot Complications in Diabetes 2011
Baker IDI Heart and Diabetes Institute	National Evidence-Based Guideline on Secondary Prevention of Cardiovascular Disease in Type 2 Diabetes 2016
National Heart Foundation	Reducing Risk in Heart Disease 2012
American College of Cardiology/American Heart Association	Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults 2013
American College of Cardiology/American Heart Association/Heart Rhythm Society	Guideline for the Management of Patients With Atrial Fibrillation: Executive Summary 2014
National Stroke Foundation	Clinical Guidelines for Stroke Management 2010

Table 5.2: Indications and treatment targets amongst patients with diabetes for BP, lipid and glycaemic management

1. Diagnosis of diabetes mellitus is defined by one of the following: • HbA1c $\geq$ 6.5% or • Fasting plasma glucose $\geq$ 7.0 mmol/L or • Two-hour plasma glucose $\geq$ 11.1 mmol/L following a 75 g oral glucose load
2. Blood pressure medication • Indications for commencing treatment If BP > 130/80 mmHg For all patients with diabetes and CVD regardless of BP value For all patients with diabetes and high CVD risk regardless of BP value • Target treatment levels Primary prevention: BP $\leq$ 130/80 mmHg Secondary prevention: BP $\leq$ 130/80 mmHg
3. Lipid lowering therapy • Indications for therapy Diabetes and LDL cholesterol $\geq$ 2.0 mmol/L, or triglycerides $\geq$ 2.0 mmol/L All adults with diabetes and high CVD risk All adults with diabetes and CVD should receive the maximum tolerated dose of statin therapy • Target treatment levels Primary prevention: LDL cholesterol < 2.0 mmol/L, triglycerides < 2.0 mmol/L, HDL cholesterol > 1.0 mmol/L Secondary prevention: LDL cholesterol < 1.8 mmol/L, triglycerides < 2.0 mmol/L, HDL cholesterol > 1.0 mmol/L
4. Anti-platelet therapy • For all patients with diabetes and known CVD
5. Glucose lowering therapy • Indications for therapy If glycated haemoglobin (HbA1c) > 7%; HbA1c must be checked at least twice yearly in all patients with diabetes • Target treatment levels Glycated haemoglobin (HbA1c) $\leq$ 7% Fasting blood glucose levels: 6-8 mmol/L 2 hour post prandial blood glucose levels: 6-10 mmol/L

The expanded algorithm was then coded into a Java-based prototype by a software developer in close collaboration with the research team. A two-stage validation process was undertaken to check that this coding was correct. A researcher independently programmed the algorithm into a statistical software package (SAS Enterprise guide V6.1). A large general practice dataset of 1565 patients was imported into both this statistical software program and the prototype and outputs were compared. For each calculated variable, agreement was assessed using kappa statistics for categorical variables and Bland-Altman plots were constructed to assess correlation for continuous variables. In an iterative process, cases of disagreement were examined for coding or logic errors, fixed and then re-tested until all calculated variables achieved perfect agreement. Content issues were reviewed by the advisory group where necessary and resolved.

5.3 Stage 2: User interface development and integration with GP desktop systems

The prototype application was incorporated into Pen Computer System's TopBar™ platform enabling it to be pre-populated with data from GP systems. This platform currently interfaces with Medical Director™ and Best Practice™ software platforms and is accessible via a desktop application that is visible above the open patient record. User acceptance testing was performed with four General Practices. Following user feedback, further changes were implemented.

In total, 178 recommendations for assessment and management of CVD risk, atrial fibrillation management, diabetes management and complications monitoring, and CKD screening and management were developed and programmed into the software application. With regards to diabetes, 27 recommendations related to screening, treatment, and treatment targets; 2 recommendations related to hypoglycaemia recognition and management; 5 recommendations related to regular eye assessment and retinopathy; 6 recommendations related to foot care; 3 recommendations concerned neuropathy; and 10 recommendations related to general lifestyle advice, diet, and physical activity.

These recommendations are accessible from a total of seven screens accessible via a dashboard when the application is opened.

- 1. Summary screen:** The summary screen provides a snapshot of the patient's cardiovascular profile, the status of individual risk factors, past medical and family history of vascular related conditions, and current medications (Figure 5.1). Colour-coded prompts and pop-up text are used to alert the health professional to particular actions.



Figure 5.1: Summary screen demonstrating patient risk-communication interface

- CVD risk:** A 'risk dial' provides a visual tool for communication of CVD risk with the patient and allows the health professional to conduct 'what if scenarios' demonstrating the effect of alteration of individual risk factors on overall CVD risk (Figure 5.2).

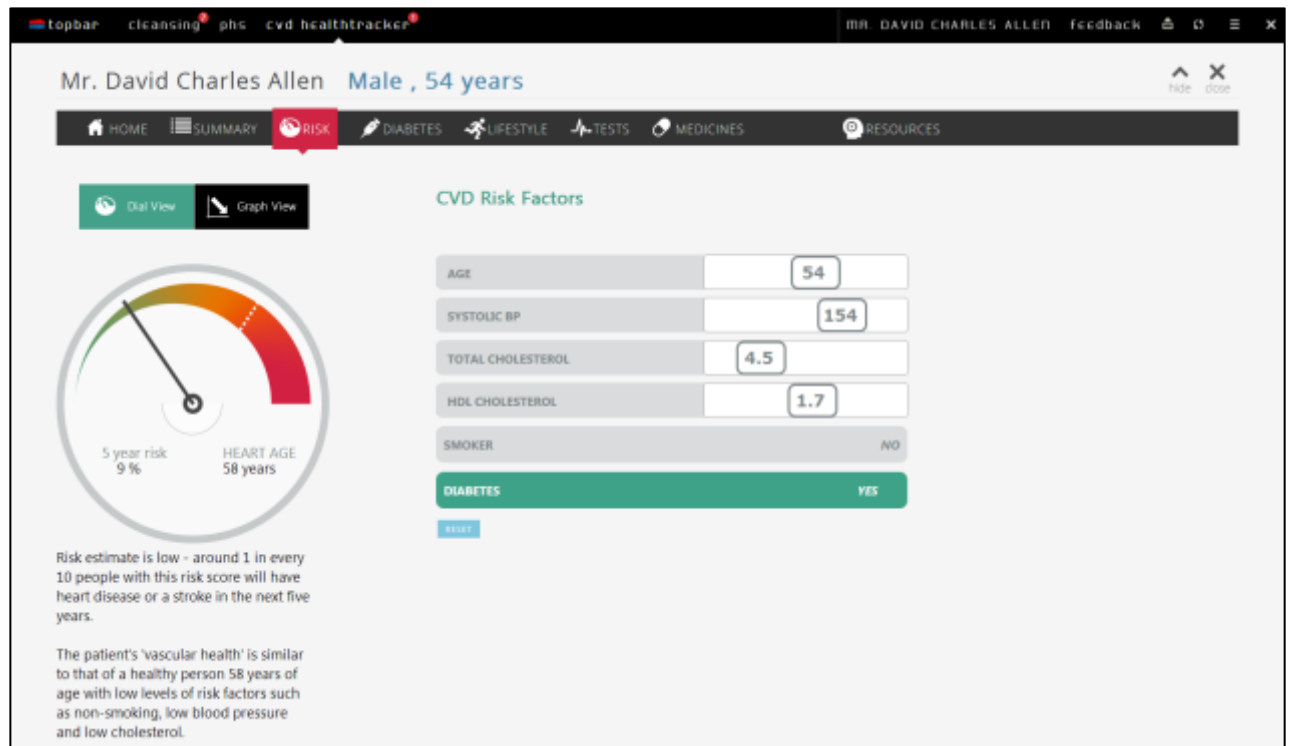


Figure 5.2: Sample display of cardiovascular disease risk assessment and interactive dial

3. Diabetes risk assessment and management: Screening

recommendations for patients not known to have diabetes are provided. This is replaced with a management screen for those with a recorded diagnosis of diabetes, which includes information on HbA1c targets, general management principles, review of glucose-lowering therapy and awareness of hypoglycaemia symptoms, and complications monitoring for retinopathy, peripheral vascular disease and neuropathy (Figure 5.3).

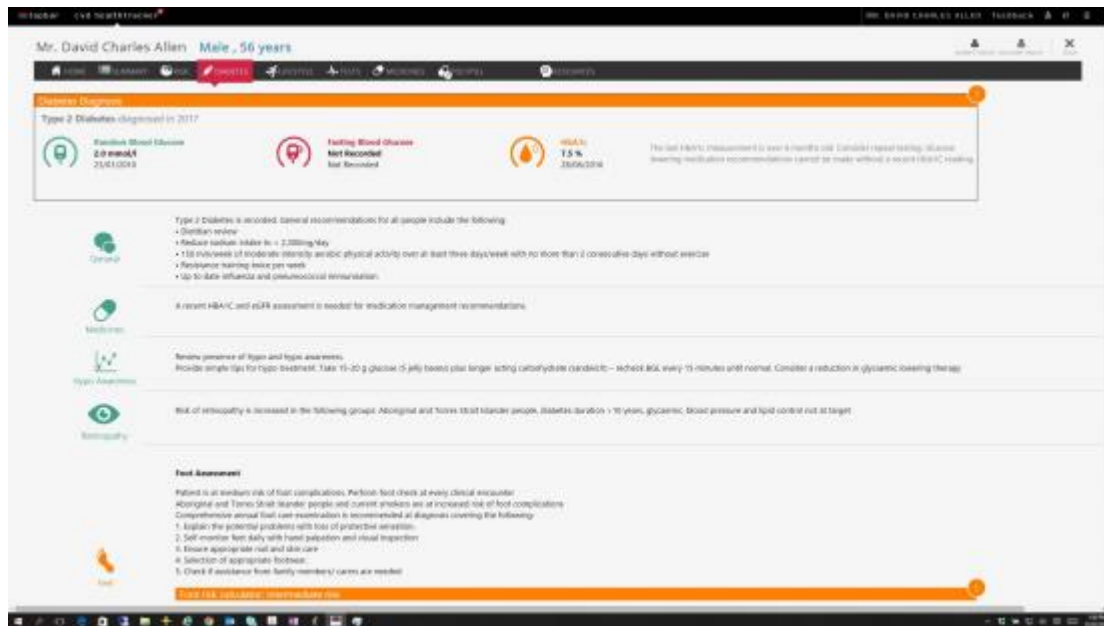


Figure 5.3: Sample display of diabetes risk assessment and management with colour-coded prompts

- 4. Lifestyle management:** General dietary and physical activity recommendations plus specific recommendations tailored to certain patient populations such as Aboriginal and Torres Strait Islander people and older Australians are provided.
- 5. Tests:** Screening and monitoring investigations for HbA1c, lipids, kidney function, and office-based clinical parameters such as blood pressure are provided. Missing, out-of-date and not-at-target values are highlighted using colour-coded traffic light alerts (Figure 5.4).

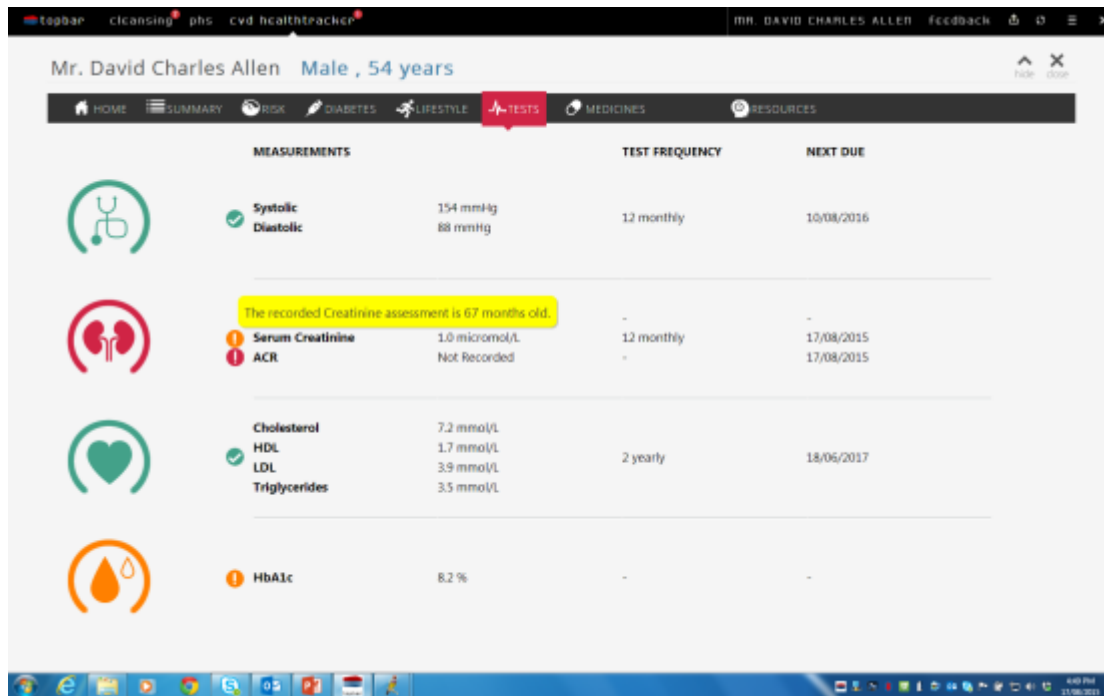


Figure 5.4: Sample display of tests function with colour-coded prompt

6. Medication management: Suggestions for glucose-lowering, lipid-lowering, blood pressure-lowering, anti-platelet and anti-coagulant therapy are provided based on the available patient information (Figure 5.5). Information on eligibility for Pharmaceutical Benefits Scheme subsidies is also included. In all instances recommendations are worded in a non-directive manner and emphasize that management decisions should account for the clinician's broader understanding of the specific patient's circumstances.

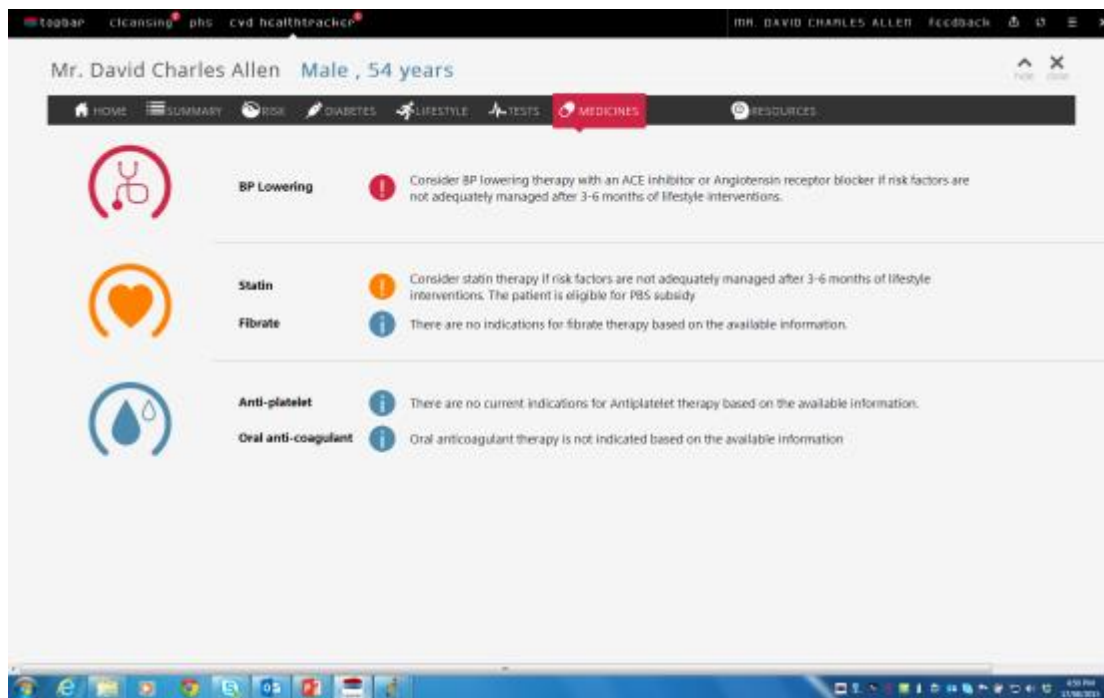


Figure 5.5: Sample display of medications summary with colour-coded prompts

- 7. Reports and resources:** Printable health professional and patient summary reports are provided in Portable Document Format. In the resources section a curated list of fact sheets from trusted professional organizations are provided for specific patient populations and health conditions. Hyperlinks to the guidelines used in the algorithm are also provided for health professionals.

This chapter described the successful development and validation of an EDS tool to enhance guideline-driven care in patients with diabetes and other chronic health conditions. The following chapter will go on to describe the implementation of the tool in primary health care settings and qualitative analysis of GP feedback.

Chapter 6: User Acceptance Testing

Candidate's contribution – Dr Chalasani personally conducted the field research described and wrote the Chapter in its entirety.

6.1 Introduction

The success of new information systems is determined by user acceptance. Although such systems are designed to improve practitioner performance, these potential improvements are lost when the system is rejected by users. There have been a number of conceptual models (94) applied to health information technology systems and most of these address the structural level (employment of technology, design, and efficacy), clinical level (workflow assimilation), and physician level (perception of usability and perceived usefulness). Qualitative analysis was carried out using in-depth semi-structured interviews and an online survey to elucidate feedback regarding each of these levels.

6.2 Methods

Practices in Victoria with a Pen Computer Systems license were emailed an invitation to participate in user acceptance testing. Practices participating in a QI project in the Central and Eastern Primary Health Network in Sydney were also invited to participate (95). User acceptance testing was conducted in four general practices in Victoria and New South Wales. An independent manager visited each of the practice sites and installed the modified tool. Practice managers, clinical nurse consultants, and general practitioners were trained in use of the tool and offered training support via telephone. All license costs and technical support was provided free to the testing sites. The tool was tested for a minimum of 4 weeks at each site.

Process Evaluation

Qualitative analysis using a structured questionnaire and semi-structured telephone interview was carried out. The structured questionnaire contained 5 domains including: (1) background of the practitioner, (2) practice characteristics, (3) use of information technology, (4) access to medical information, and (5) use of the electronic decision support tool itself. The structured questionnaire was adapted from a previous study with permission (88). A copy of the structured questionnaire has been included as Appendix 1.

The semi-structured telephone interview covered 3 domains including: (1) a general overview of the electronic decision support tool, (2) patient perspectives on utility of the tool, and (3) implementation of the electronic decision support tool (EDS) in general practice. A copy of the semi-structured interview questions has been included as Appendix 2.

6.3 Results

GP characteristics

All of the GPs participating in the feasibility study were educated in Australia and spoke English at home. The age range was between 40 and more than 60 years. The majority worked full-time and were not actively involved in research. All of the GPs indicated that they utilised the Internet professionally at least several times per day. Overall, GPs were satisfied with the computer systems in use at their practice.

Practice characteristics

All of the practices involved were accredited and either offered selective bulk-billing or no bulk-billing services (Table 6.1). In general, GPs felt that their practices were innovative, actively engaged in attempts to improve quality of care, actively involved in evaluating system changes, and active in updating procedures and systems to prevent errors from occurring. The primary practice software system used was Best Practice in half the practices and Medical Director in the remaining practices. All of the GPs indicated that their practices utilised the following features: electronic medication prescribing, electronic pathology ordering, electronic downloads of pathology results, electronically generated patient recalls, electronic on-line billing, and scanning of paper documents such as specialist letters into practice software (Table 6.1). Roughly half of the GPs indicated that while electronic care plans and disease registers were available through practice software, these were not features that they regularly used.

Table 6.1: Baseline service characteristics

	Practices (n=4)
Access to bulk-billing services	
- No bulk-billing	2/4 (50%)
- Selective bulk-billing	2/4 (50%)
Accredited	4/4 (100%)
Medical software used	
- Best Practice	2/4 (50%)
- Medical Director	2/4 (50%)
Use of information technology	
- Electronic medication prescribing	4/4 (100%)
- Electronic pathology ordering	4/4 (100%)
- Electronic downloads of pathology results	4/4 (100%)
- Electronically generated patient recalls	4/4 (100%)
- Electronic on-line billing	4/4 (100%)
- Scanning of paper documents into practice software	4/4 (100%)

Use of information technology and access to medical information

The majority of GPs felt that technical limitations such as slow response time of computers, and poor technical support, along with medical software limitations were the major barriers to successful implementation of computer systems within their practices. Staff training and privacy or security concerns were not felt to be barriers to effective uptake of computer systems within the practice. All of the GPs felt that the impact of computer systems on patient safety and practice of evidence based medicine was positive. Some GPs felt that the influence of computer systems on patient-doctor communication had been negative. Roughly half the GPs felt that computer systems had made no impact on patient privacy or practice cost effectiveness.

GPs commonly indicated the most influential source of medical information in their practice to be evidence based medicine guides such as Up to Date, and clinical guidelines from professional organisations. The least influential source of medical information was pharmaceutical company representatives. All GPs felt the most influential clinical guideline used in their clinical practice was The Pharmaceutical Benefits Scheme criteria.

General overview of the EDS tool

Overall, GPs felt that the EDS tool impacted positively on the quality of care that they were able to deliver to their patients. All of the GPs interviewed felt that the EDS tool was effective in improving practice according to national guidelines for cardiovascular risk factor management. The majority of GPs

indicated that the EDS tool was easy to understand and navigate. All of the GPs indicated that the screening and monitoring, treatment, and treatment target recommendations were appropriate.

All of the GPs indicated that based on the recommendations of the EDS tool, clinical records were updated. The most frequently updated clinical records were smoking status, diabetes status, waist circumference, and past history of CVD. All of the GPs indicated that they changed treatment plans based on the recommendations of the EDS tool. The most commonly changed treatment plans pertained to lipid lowering and anti-platelet therapies.

Patient perspectives on utility of the EDS tool

All of the GPs felt that the EDS tool was constructive in supporting communication with their patients. The tool was perceived to be useful as a source of authoritative advice to support GP recommendations. The patient information sheets were seen to be a helpful practical component of the EDS tool, synthesizing key messages that would otherwise have taken some time to explain. In particular, the risk dial was considered beneficial in strengthening discussions with patients about lipid and BP management.

Implementation of the EDS tool into general practice

GPs generally considered the user interface to be clear, logical and readily accessible. Importantly the speed of the primary electronic health record system was not compromised when the application was in use – a factor

which GPs highlighted to be a major barrier to use of third party applications in the past. GPs felt that the EDS tool integrated well with system software and were able to rapidly navigate to areas of interest. In particular, colour-coded traffic light alerts highlighting missing, out of date, and not at target values were found to be useful.

Suggested improvements included resource links that could be emailed directly to the patient, more accessible print application tabs, and improvements in the workflow for re-populating the application with data that was newly entered during the course of the consultation (e.g. blood pressure and weight recordings).

6.4 Discussion

The principal results from user acceptability testing include:

- (1) The algorithm underpinning the EDS tool appeared to have face validity when implemented amongst GPs
- (2) The EDS tool effectively integrated with existing electronic health record systems commonly used in Australia
- (3) Acceptable usability amongst Australian GPs

Although uptake and general satisfaction was encouraging, several limitations need to be acknowledged. The major limitation of the user acceptability testing undertaken was the small number of general practices participating. The characteristics of the GPs participating indicate that all had been educated within Australia and English was the primary spoken language at

home. Additionally, all of the GPs involved indicated that they commonly used computer based resources to aid in clinical practice. This may limit the generalisability of the usability findings as GPs who are less familiar with information technology, and for whom English was not their primary language may have found the EDS tool more difficult to navigate. Additionally, the perspectives of patients, and other health professionals such as clinical care nurses and practice managers were not assessed. However, the EDS tool was developed with GPs as the primary target user.

The testing undertaken did not attempt to assess the clinical effectiveness of the tool and as such cannot make any conclusions regarding the impact of the EDS tool on patient outcomes. The focus was to assess usability factors, detect enhancements needed, and further modify the tool. The findings support the systematic review evidence that EDS tools need to be incorporated into routine workflow, provided at the point of consultation (20), and thus aid rather than contribute to the burden of workload faced by time-pressured GPs.

Chapter 7: Conclusions

Candidate's contribution – Dr Chalasani wrote this Chapter in its entirety.

Vascular disease risk factor assessment and management amongst patients with and without diabetes in the Australian primary health care setting is suboptimal. Although there appear to be some diminishing of treatment gaps following the implementation of government incentives, large numbers of patients remain untreated or undertreated. Development and implementation of quality improvement initiatives are necessary to improve guideline uptake into clinical practice amongst patients with diabetes.

In this project the development of a point-of-care decision support software tool for management of cardiometabolic disease risks, which is integrated with the most commonly used GP record systems in Australia is described. The underlying algorithm was validated utilising a large patient dataset, and user acceptance tested in general practices. This is the first GP application that comprehensively incorporates management of several vascular and metabolic conditions in the Australian primary health care setting. Guideline proliferation and regular updates make it challenging for health professionals to implement best practice recommendations. Given the growing burden of chronic disease, modest but scalable improvements in provision of recommended management of cardiovascular and metabolic disease risk could have a profound impact on improving population health outcomes and lowering downstream costs associated with avoidable hospitalization.

The implications of use of decision support systems extend beyond being a point-of-care clinical resource. Australia has consistently had amongst the highest rates of GP electronic health record usage in the world (96). The

opportunities to build on this through provision of additional software tools and incentives to use them are great (97). New policy proposals such as the 'Health Care Homes' will require increased leverage of electronic health information to improve management for patients with chronic and complex conditions (90, 98). Primary Health Networks are poised to play a substantial role in implementing these initiatives and the development of effective performance monitoring systems will be integral. A major challenge, however, is in translating these initiatives into tangible improvements in health care provision. Decision support tools could therefore play an important enabling role linking everyday clinical practice with the broader primary health care reform context; both as a prompt to support clinician and patient decision-making and to synthesise data for quality improvement monitoring at the practice and system levels.

Although in this project the primary focus has been on the health professional, there is a clear need to better engage patients as well. Despite increased consumer demand for and acceptance of the use of information technology to improve health care, there remain few examples of patient-focused applications that are integrated with GP information systems. This is particularly important for the over 65-year-old population who are rapidly catching up in terms of internet and smartphone adoption and are at highest risk of chronic and complex health conditions. The Australian government's renewed focus on the 'My Health Record' initiative is an important mechanism to enable patient access to their electronic health information, however a major limitation to its uptake (aside from its complex registration process) has

been the lack of rich, patient-focused content. Decision support tools could therefore not only better engage patients during a GP consultation but also allow for secure export of this information to portals such as 'My Health Record' for access outside of the clinical encounter.

The work presented in this thesis is preliminary in nature and, on its own, is not sufficient to shed light on how these tools would be used in practice. Nor can it make any inference on the impact of such tools on patient outcomes. It is therefore critical that robust evaluations be conducted to assess their impact. Two major trials are currently underway to help address this: (1) a large cluster randomized controlled trial (RCT) of an intervention comprising HealthTracker decision support, fixed dose combination polypills and a pharmacy-based medication adherence program for people at high CVD risk; and (2) an RCT of a consumer portal that extracts HealthTracker-related information from the GP record for patients to access via desktop computer or mobile device (95). It is expected that trials of these nature will mature the evidence base on effective quality improvement strategies and identify the barriers and enablers to their implementation.

Decision support tools could play a critical enabling role in implementing health care reform and improving the efficiency, safety and ultimately the sustainability of the Australian health care system.

Major implications of this project:

1. Guideline-indicated vascular risk factor assessment and management in patients with diabetes in the Australian primary health care setting remains suboptimal.
2. Computerised clinical decision support systems are scalable strategies to improve implementation of existing evidence into routine primary healthcare. The data presented in this thesis suggests these tools are particularly useful in under-treated individuals regardless of diabetes status.
3. In order to maximize their uptake important usability factors need to be considered to support their use by time-pressured GPs, as demonstrated by the limited user acceptance testing undertaken in this study.
4. Robust implementation studies are needed to assess their impact on health system performance.

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Appendix 1 – Health Tracker Online Questionnaire

We are collecting this information to evaluate HealthTracker and develop it further. Your assistance is appreciated.

Section 1: Your Background

1. What is your age?
 - a. 20 to 29
 - b. 30 to 39
 - c. 40 to 49
 - d. 50 to 59
 - e. 60 or over
2. What is your gender?
 - a. Female
 - b. Male
3. What is the primary language you speak at home?
4. Which country were you born in?
5. What is your occupation?
 - a. General Practitioner
 - b. Nurse
 - c. Allied Health
 - d. Other (please specify):
6. From which university did you obtain your degree?
7. How many sessions per week do you work at this practice?
8. How many sessions per week do you work elsewhere?
9.
 - A. How often do you participate in research?
 - a. Never
 - b. Sometimes
 - c. Often
 - d. Very Often
 - B. How often do you conduct your own research?
 - a. Never
 - b. Sometimes
 - c. Often
 - d. Very Often

Section 2: Practice Characteristics

10. How many of each category of the following staff are employed in this practice? (if none then please write '0'):
- a. Doctors
 - b. Nurses
 - c. Aboriginal health Workers
 - d. Practice Managers
 - e. Other administrative staff
 - f. Allied Health professionals
11. Which of the following best describes access to bulk-billing at your practice? (please choose one)
- a. Exclusively bulk-billing
 - b. Selective bulk-billing (e.g. children, seniors, concession card holders)
 - c. No bulk-billing
12. Is your practice accredited?
- a. Yes
 - b. No
13. Please indicate your agreement or disagreement with the following statements about your practice.
- a. I consider this practice to be innovative.
 - i. Strongly Disagree
 - ii. Disagree
 - iii. Neutral
 - iv. Agree
 - v. Strongly Agree
 - b. We are actively doing things to improve quality of care.
 - i. Strongly Disagree
 - ii. Disagree
 - iii. Neutral
 - iv. Agree
 - v. Strongly Agree
 - c. After we make changes to improve quality, we evaluate their effectiveness.
 - i. Strongly Disagree
 - ii. Disagree
 - iii. Neutral
 - iv. Agree
 - v. Strongly Agree
 - d. We have quality problems in our practice.
 - i. Strongly Disagree
 - ii. Disagree
 - iii. Neutral
 - iv. Agree
 - v. Strongly Agree

- e. Our procedures and systems are good at preventing errors from occurring.
 - i. Strongly Disagree
 - ii. Disagree
 - iii. Neutral
 - iv. Agree
 - v. Strongly Agree

Section 3: Use of Information Technology

- 14. How often do you use the internet for personal and/or professional use, including email from home, work or another location?
 - a. Several times a day
 - b. Daily
 - c. Weekly
 - d. Monthly
 - e. Less than monthly or not at all

- 15. Which practice software system do you currently use at your practice?
 - a. Medical Director
 - b. MedTech
 - c. Best Practice
 - d. Practix
 - e. Other (please specify):

- 16. Overall how satisfied are you with the computer system at your practice?
 - a. Very Unsatisfied
 - b. Unsatisfied
 - c. Neutral
 - d. Satisfied
 - e. Very Satisfied

- 17. Please indicate which of the following features you use in your practice.
 - a. Electronic medication prescribing
 - i. Not available at this practice
 - ii. Available but I do not use it
 - iii. I use *some* of the time
 - iv. I use *most* or *all* of the time
 - b. Electronic pathology ordering
 - i. Not available at this practice
 - ii. Available but I do not use it
 - iii. I use *some* of the time
 - iv. I use *most* or *all* of the time
 - c. Electronic downloads of pathology results
 - i. Not available at this practice
 - ii. Available but I do not use it
 - iii. I use *some* of the time
 - iv. I use *most* or *all* of the time
 - d. Electronic care plans

- i. Not available at this practice
 - ii. Available but I do not use it
 - iii. I use *some* of the time
 - iv. I use *most* or *all* of the time
- e. Electronic disease registers (e.g. diabetes)
 - i. Not available at this practice
 - ii. Available but I do not use it
 - iii. I use *some* of the time
 - iv. I use *most* or *all* of the time
- f. Electronically generated recalls (eg. immunisations, pap smears)
 - i. Not available at this practice
 - ii. Available but I do not use it
 - iii. I use *some* of the time
 - iv. I use *most* or *all* of the time
- g. Electronic on-line billing
 - i. Not available at this practice
 - ii. Available but I do not use it
 - iii. I use *some* of the time
 - iv. I use *most* or *all* of the time
- h. Scanning of paper documents into practice software (eg. specialist letters)
 - i. Not available at this practice
 - ii. Available but I do not use it
 - iii. I use *some* of the time
 - iv. I use *most* or *all* of the time

18. How much of a barrier is each of the following to successful implementation of computer systems at your practice?

- a. Staff training
 - i. Not a barrier
 - ii. Minor barrier
 - iii. Major barrier
- b. Privacy/security concerns
 - i. Not a barrier
 - ii. Minor barrier
 - iii. Major barrier
- c. Medical software limitations
 - i. Not a barrier
 - ii. Minor barrier
 - iii. Major barrier
- d. Technical limitations (e.g. slow response time of computers, poor technical support)
 - i. Not a barrier
 - ii. Minor barrier
 - iii. Major barrier

19. Please indicate how positive the impact of computer systems has been for each of the areas below.

- a. The practice of evidence based medicine

- i. Very negative
 - ii. Somewhat negative
 - iii. No effect
 - iv. Somewhat positive
 - v. Very positive
- b. Patient-doctor communication
 - i. Very negative
 - ii. Somewhat negative
 - iii. No effect
 - iv. Somewhat positive
 - v. Very positive
- c. Patient privacy
 - i. Very negative
 - ii. Somewhat negative
 - iii. No effect
 - iv. Somewhat positive
 - v. Very positive
- d. Practice cost-effectiveness
 - i. Very negative
 - ii. Somewhat negative
 - iii. No effect
 - iv. Somewhat positive
 - v. Very positive
- e. Overall patient safety (e.g. reduction in medication errors)
 - i. Very negative
 - ii. Somewhat negative
 - iii. No effect
 - iv. Somewhat positive
 - v. Very positive

Section 4: Access to medical information

20. Please indicate how influential the following sources of medical information are in your practice.

- a. Observation and discussion with GP colleagues
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential
- b. Correspondence with specialists
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential
- c. Pharmaceutical company representatives
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential
- d. Drug product information within clinical software (e.g. MIMS)
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential

- e. Continuing Medical Education (CME) events
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential
- f. Conferences
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential
- g. Australian Medicines Handbook
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential
- h. Medical newspapers (e.g. Medical Observer/Australian Doctor)
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential
- i. Australian Family Physician
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential
- j. Peer-reviewed journals
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential
- k. Evidence Based Medicine guides (e.g. Up to Date)
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential
- l. Personal internet searches (e.g. Google, PubMed etc)
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential
- m. Clinical guidelines from professional organisations
 - i. Not influential
 - ii. Somewhat influential
 - iii. Very influential

21. Please indicate how influential the following clinical guidelines are on your clinical practice.

- a. National Heart Foundation “Hypertension Management Guide for Doctors”
 - i. I am not aware of this guideline
 - ii. Not influential
 - iii. Somewhat influential
 - iv. Very influential
- b. National Heart Foundation and Cardiac Society of Australia and New Zealand “Position Statement on Lipid Management”
 - i. I am not aware of this guideline
 - ii. Not influential
 - iii. Somewhat influential

- iv. Very influential
- c. National Heart Foundation “Reducing Risk in Heart Disease”
 - i. I am not aware of this guideline
 - ii. Not influential
 - iii. Somewhat influential
 - iv. Very influential
- d. The RACGP “Red Book” – “Guidelines for Preventive activities in General Practice”
 - i. I am not aware of this guideline
 - ii. Not influential
 - iii. Somewhat influential
 - iv. Very influential
- e. Diabetes Australia and RACGP “Diabetes Management in General Practice”
 - i. I am not aware of this guideline
 - ii. Not influential
 - iii. Somewhat influential
 - iv. Very influential
- f. Kidney Health Australia “Chronic Kidney Disease Management in General Practice”
 - i. I am not aware of this guideline
 - ii. Not influential
 - iii. Somewhat influential
 - iv. Very influential
- g. Therapeutic Guidelines – Cardiovascular
 - i. I am not aware of this guideline
 - ii. Not influential
 - iii. Somewhat influential
 - iv. Very influential
- h. The Pharmaceutical Benefits Scheme criteria for lipid lowering therapies
 - i. I am not aware of this guideline
 - ii. Not influential
 - iii. Somewhat influential
 - iv. Very influential

Section 5: HealthTracker

22. Please indicate whether you agree or disagree with the statement below:

- a. The HealthTracker screen was easy to understand and navigate
 - i. Strongly disagree
 - ii. Disagree
 - iii. Neutral
 - iv. Agree
 - v. Strongly agree
 - vi. Don't know or not applicable
- b. The screening/monitoring recommendations were appropriate
 - i. Strongly disagree
 - ii. Disagree

- iii. Neutral
 - iv. Agree
 - v. Strongly agree
 - vi. Don't know or not applicable
- c. The treatment recommendations were appropriate
 - i. Strongly disagree
 - ii. Disagree
 - iii. Neutral
 - iv. Agree
 - v. Strongly agree
 - vi. Don't know or not applicable
- d. The treatment target recommendations were appropriate
 - i. Strongly disagree
 - ii. Disagree
 - iii. Neutral
 - iv. Agree
 - v. Strongly agree
 - vi. Don't know or not applicable

23. Did you update your clinical records based on the recommendations of HealthTracker?

- a. Yes
- b. Sometimes
- c. No

24. If yes, which of the following did you add or update most often?

- a. Family history of cardiovascular disease
- b. Past history of cardiovascular disease
- c. Smoking status
- d. Genetic dyslipidaemia/Familial Hypercholesterolaemia
- e. Diabetes status
- f. Other cardiovascular disease related information (please specify):

25. Did you change the treatment plans for your patients based on the recommendations from HealthTracker?

- a. Yes
- b. Sometimes
- c. No

26. If yes, which of the following did you add or change most often?

- a. Blood pressure lowering therapy
- b. Lipid lowering therapy
- c. Blood glucose lowering therapy
- d. Anti-platelet therapy (aspirin, clopidogrel, dipyridamol etc)
- e. Lifestyle modification advice (either Smoking, Nutritional, Alcohol, or Physical Activity advice)
- f. Other treatments (please specify):

27. What did you most like/find useful about HealthTracker?

28. What did you least like/find unhelpful about HealthTracker?

Thank you for your participation!

Appendix 2: Electronic Decision Support Feasibility Study

Interview Guide

Part 1: General overview of the EDS tool

1. Overall, what do you think was the impact of the EDS tool on the quality of care you were able to provide for your patients?
2. How effective was the EDS tool in assisting you to practice according to national guidelines for cardiovascular risk management?
3. Did you change your clinical practice based on the recommendations of the EDS tool?

Part 2: Patient perspectives on the utility of the EDS tool

1. How useful was the EDS tool in supporting communication with your patients?
2. Did patients find the interactive user interface features such as the risk dial and diabetes information pages useful?

Part 3: Implementation of the EDS tool in general practice

1. What do you see as the potential benefits of the EDS tool?
2. What barriers do you see to the implementation of the EDS tool into your clinical practice?
3. How do you think the EDS tool could be improved?
4. Would you personally consider using it long-term in your practice?
5. Are there any other issues not covered that you would like to discuss?